Pain in community-dwelling people with dementia: a mixed methods study

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Abstract

Introduction

Dementia and pain are common in older adults. Clinical features of dementia such as communication difficulties may complicate the identification, assessment, and management of pain. This thesis therefore aimed to investigate pain identification, assessment, and management for community-dwelling people with dementia.

Methods

A systematic review was conducted to describe and synthesise existing evidence on pain assessment and pain treatment for community-dwelling people with dementia. The review then informed on a convergent mixed methods strategy; using quantitative and qualitative methods. Quantitative methods utilised the Clinical Practice Research Datalink (a UK wide database of primary care health records) to examine the incidence and prevalence of musculoskeletal consultations and analgesic prescriptions for people with dementia. Qualitative semi-structured interviews were conducted with people with dementia (*n*=8), family caregivers (*n*=9), general practitioners (*n*=9), and old age psychiatrists (*n*=5) to explore their perspectives of pain identification, assessment, and management for community-dwelling people with dementia.

Results

The systematic review identified 32 studies and highlighted a dearth of high quality evidence in community settings.

With regards to pain identification and assessment, quantitative findings show that people with dementia had consistently lower incidence and prevalence of musculoskeletal consultations than older adults. Qualitative findings highlighted the unique challenges of pain identification and assessment; including the complexity of untangling the self-reported pain, and the importance of observing behavioural, psychological, and physical changes. Participants also reflected upon the importance of familiarity and the use of pain assessment tools to identify and assess pain.

Quantitative findings exploring pain management show that people with dementia had consistently lower prevalence of analgesic prescription compared to older adults, with the

discrepancy between people with and without dementia increasing over time. Qualitative findings revealed many potential explanations for this discrepancy, with concerns relating to side effects, illness burden, and treatment burden. Alternatively, many participants supported the use of non-drug strategies to manage pain. Regardless of the pain management strategy, family caregivers were often responsible to manage pain in the community.

Conclusion

This thesis provides a novel and in-depth investigation of pain identification, assessment, and management for community-dwelling people with dementia by integrating quantitative and qualitative data. Implications for practice, policy, and future research are described.

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List of abbreviations

ACE-R The Addenbrooke's Cognitive Examination Revised.

AD Alzheimer’s disease

AGS American Geriatric Society

AR Attributable Rate

BNF British National Formulary

BPSD Behavioural and Psychological Symptoms of Dementia

CAS Colour Analogue Scale

CI Confidence Interval

CLR Conditional Logistic Regression

CPRD Clinical Practice Research Datalink

CVD Cardiovascular Disease

EHR Electronic Health Records

FTD Frontotemporal Dementia

GP General Practitioner

HR Hazard Ratio

HRA Health Research Authority

IMD Indices of Multiple Deprivation

IPT Iowa Pain Thermometer

IRR Incidence Rate Ratio

MCI Mild Cognitive Impairment

MMSE Mini Mental State Examination Score

NHS National Health Service

NICE National Institute for Health and Care Excellence

NRS Numerical Rating Scale

OR Odds Ratio

PPIE Patient and Public Involvement and Engagement

PR Prevalence Ratio

RCT Randomised Controlled Trial

RUG Research User Group

SD Standard Deviation

UK United Kingdom

VDS Verbal Descriptor Scale

VRS Verbal Rating Scale

WHO World Health Organisation

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1 Chapter One: Introduction

1.1 Dementia

The word ‘dementia’ describes a syndrome or common set of symptoms that may include memory loss and difficulties with thinking, problem-solving or language (Harwood & McCulloch, 2017). It is an ‘umbrella’ term that encompasses over 200 neurodegenerative conditions, usually of a chronic or progressive nature (Brooker & Lillyman, 2013).

The most common type of dementia is Alzheimer’s disease (AD) which accounts for approximately one half of all people diagnosed, followed by vascular dementia, and dementia with Lewy bodies (Livingston et al., 2017). Importantly, mixed dementia with features of more than one cause is also common (Livingston et al., 2017).

1.1.1 Dementia: a paradigm shift

The conceptualisation of dementia was often based upon biomedical models of disease and illness due to the neurological changes associated with dementia (Kitwood, 1997). The biomedical model or the ‘standard paradigm’ (as named by Kitwood, 1997) assumes a linear causal relationship between neuropathology and dementia. The neurological understanding of dementia led to a focus upon ‘*treatments*’ and a ‘*cure*’ for the dementia *patient*. In more recent years, however, the biomedical model has been criticised for having an oversimplified view of dementia. A focus upon neuropathology in isolation has neglected the highly individual, subjective and variable nature of dementia. Additionally, the standard paradigm has failed to provide insights into care for people with dementia. Ultimately, the biomedical model has fed into the deterministic view that dementia is the ‘death that leaves the body behind’ (Kitwood, 1997, p. 37).

In relatively recent years, there has been a shift away from the ‘standard paradigm’ to an Enriched Model of dementia (Brooker, 2007). Dementia has been reconceptualised as a subjective and individual experience greatly influenced by a number of factors, including neurological impairment, but also physical health, personality, and the social environment. The conceptual lens of dementia has widened to consider the unique identity of the person with dementia; often referred to as ‘personhood’. Kitwood (1997) defined personhood as ‘a

position or social relationship that is bestowed on one human being by 'others', in the context of relationship and social being. It implies recognition, respect and trust' (p. 8). Person-centred care is important to support personhood for people with dementia in the face of cognitive decline. Person-centred care encompasses four key elements, known as the VIPS framework (Brooker, 2004):

- Valuing people with dementia and people who care for them (V)
- Treating people with dementia as individuals (I)
- Looking at the world from the perspective of the person with dementia (P)
- A positive social environment in which the person living with dementia can experience relative wellbeing (S)

The concepts of 'personhood' and person-centred care have placed the person with dementia at 'centre stage'; shifting the focus from the person with *dementia* to the *person* with dementia.

1.1.2 Dementia as a holistic concept

In this thesis, I use the term dementia in a broad and descriptive way, acknowledging the 'whole person' (rather than just the brain) with a clinically identified condition. By using 'dementia' as a holistic concept, the 'whole person' and all dementia conditions can be observed in their entirety.

1.2 Symptoms of dementia

1.2.1 Cognitive symptoms

Cognitive symptoms such memory loss and difficulties with thinking, problem-solving, orientation or language are clinical hallmark features of dementia (Herr, Bjoro & Decker, 2006a). Cognitive symptoms are a primary disease characteristic associated with dementia, however such symptoms are not clinical features of dementia independently, and may present in a variety of disease profiles.

1.2.2 Activities of Daily Living

One of the most common symptoms of dementia is the difficulty, or inability to complete activities of daily living, such as organising finances, medication management, washing, and eating (Giebel, Sutcliffe & Challis, 2015).

1.2.3 Behavioural and Psychological Symptoms

Behavioural and psychological symptoms of dementia (BPSD; or otherwise known as neuropsychiatric symptoms, Cummings, 1994; Cerejeira, Lagarto & Mukaetova-Ladinska, 2012) are defined as 'signs and symptoms of disturbed perception, thought content, mood, or behavior that frequently occur in patients with dementia' (Finkel et al., 1996, p. 498). In other words, BPSD is an umbrella term that encompasses many non-cognitive symptoms associated with dementia, such as aggression, 'wandering', sexual disinhibition, agitation, and psychological symptoms such as anxiety, depression, and delusions (Jennings et al., 2018a), often categorised into three main syndromes: agitation, psychosis, and mood disorders (Cohen-Mansfield & Libin, 2004). The aetiology of BPSD is complex and poorly understood. It is often unclear if behavioural or psychological symptoms can be directly attributed as a symptom of dementia, or if behavioural and psychological symptoms are an expression of an alternative underlying cause (Flo, Gulla & Husebo, 2014). The perspective that BPSD may be an expression of an unmet need is discussed in Section 1.14. Epidemiological evidence suggests that the point prevalence of BPSD ranges from 60% to 80%, with a cumulative risk that 90% of people with dementia experience one or more clinically significant behavioural and psychological symptom throughout the course of their condition (Norton, Allen, Snow, Hardin & Burgio, 2010; Steinberg et al., 2008; LoGiudice, 2002; Kales, Gitlin & Lyketsos, 2015). BPSD often becomes more severe as dementia progresses (Kazui et al., 2016), increasing the rate of nursing home admission, longer hospital stays, and decreased quality of life for the person with dementia (Lichtner et al., 2014; Kales et al., 2015; Forester & Vahia, 2019; Ballard, Corbett, Chitramohan & Aarsland, 2009). In addition, a breadth of literature highlights the negative impact of BPSD upon family caregivers and care providers; including increased distress (Feast, Orrell, Russell,

Charlesworth & Moniz-Cook, 2016), increased burden (Rosdinom, Zarina, Zanariah, Marhani & Suzaily, 2013), and decreased quality of life (Feast et al., 2016).

1.3 Preventable, modifiable yet incurable

Pharmacological treatments are available to slow the disease progression for certain dementia conditions (e.g. cholinesterase inhibitors including donepezil, rivastigmine and galantamine). Dementia as a condition has been typically considered as neither preventable nor treatable, however, a recent Lancet commission by Livingston et al. (2017) identified a number of preventable or modifiable risk factors for dementia. The research identified that an increase in childhood education and exercise, maintaining social engagements, reducing or stopping smoking, and management of hearing loss, depression, diabetes, hypertension, and obesity could all contribute to the prevention or delay of dementia (Livingston et al., 2017). These preventable or modifiable risk factors have the potential to prevent one-third of dementia cases (Livingston et al., 2017). Despite necessary progression in our understanding about preventable and modifiable risk factors, age remains the largest risk factor for dementia, which is not modifiable nor preventable.

1.4 Epidemiology of dementia

1.4.1 Incidence of dementia

Dementia is often perceived as the greatest global challenge for health and social care in the 21st century (Livingston et al., 2017). The incidence of dementia increases with age, from 3.1 per 1000 person-years at age 60 to 64, to 175 per 1000 person-years at age 95+ (World Health Organisation [WHO], 2015). In accordance with these findings, previous studies suggest a higher incidence of dementia in female populations due to longer life expectancy increasing the likelihood that females reach the typical age of dementia onset (Mielke, Vemuri & Rocca, 2014; Hebert, Scherr, McCann, Beckett & Evans, 2001). Recent evidence, however, suggests that the incidence of dementia is beginning to fall in high-income countries (Prince et al., 2014; 2016; Livingston et al., 2017). The lowering incidence in these settings seems to be associated with the preventable and modifiable factors outlined

previously (see Section 1.3), such as higher education standards, activity levels, and improved cardiovascular health (Grasset et al., 2016; Livingston et al., 2017).

1.4.2 Prevalence of dementia

Despite the incidence of dementia lowering in high-income countries, the world's population is ageing. Dementia is not an inevitable part of ageing; however, ageing is the largest risk factor for dementia. This means that the prevalence of dementia continues to increase, irrespective of the lowering dementia incidence in high-income countries (Livingston et al., 2017; Prince et al., 2016). Approximately 47 million people were living with dementia worldwide in 2015, with 850,000 people living with dementia in the United Kingdom (UK), equating to 1.3% of the entire UK population. The prevalence of dementia in the UK rises to 7.1% for people over the age of 65 (Prince et al., 2014). Based on the current estimated prevalence rate, the amount of people with dementia in the UK will rise to over one million by 2025, and over two million by 2051 (Prince et al., 2014).

1.5 Progression of dementia symptoms

Symptoms of dementia are typically persistent and progressive. This means that, generally speaking, cognitive ability gradually and progressively deteriorates over time with the condition (Duong, Patel & Chang, 2017). Many cognitive screening instruments have been developed to assess the severity of cognitive impairment for people with dementia (Ismail, Rajji & Shulman, 2009), including The Mini Mental State Examination (MMSE; Folstein, Folstein & McHigh, 1975), Montreal Cognitive Assessment Scale (MoCA; Nasreddine et al., 2005), Mini-Cog, the General Practitioner Assessment of Cognition (GPCOG), and the Memory Impairment Screen (MIS). Importantly, each of these tools in isolation are not diagnostic tools for dementia (Tombaugh & McIntyre, 1992).

The MMSE remains the best known and most commonly used brief cognitive screening tool to determine an overall measure of cognitive impairment in healthcare and research settings (Ismail et al., 2009; Arevalo-Rodriguez et al., 2015). Therefore, an MMSE score is frequently used in the following chapters to depict the severity of cognitive impairment for people with dementia. The MMSE has a maximum score of 30 (Tombaugh & McIntyre, 1992). Research

evidence has developed a range of standard 'cut-points' to classify and conceptualise the severity of cognitive impairment (a score of 24 to 30 means no cognitive impairment; 18 to 23 means mild cognitive impairment; and 0 to 17 denoting severe cognitive impairment; Tombaugh & McIntyre, 1992). Although there are limitations to classifying people with dementia as 'mild', 'moderate' or 'severe' based upon a cognitive screening test (e.g. buying into neurological determinism; Kitwood, 1997), classification based on severity of the condition can be useful for clinical and research purposes.

1.6 Cost of dementia

Dementia is recognised as a 'public health priority' (WHO, 2017) and has received extensive research interest worldwide. Despite research, there is currently no cure (see Section 1.3), therefore dementia continues to have a significant economic impact (Annear, Tierney, Vickers & Palmer, 2016). The overall annual economic impact of dementia in the UK is approximately £25 billion (Prince et al., 2014; Wittenberg et al., 2019), including social care, health care costs, and contributed work from unpaid caregivers. The average cost of dementia is estimated at £32,250 per person per year (Prince et al., 2014), with the cost of dementia in England rising from mild, to moderate, to severe dementia (£24,400, £27,450, and £46,050, respectively; Wittenberg et al., 2019). The Alzheimer's Society Dementia UK report found that supporting people with dementia to continue living in the community (thus reducing the rate of preventable hospital admissions and early care home admission) would reduce the economic cost of dementia upon society (Prince et al., 2014).

1.7 Dementia in the community

Community-dwelling is defined as people with dementia living in private residences or non-nursing home settings (Hunt et al., 2015). Community-dwelling people with dementia may live in their own home alone, with family members, in an assisted living facility, retirement community, or residential home. Two-thirds of people with dementia live in the community (Prince et al., 2014; Knapp et al., 2007; Jones et al., 2009; Magaziner et al., 2000). Of this population, two-thirds live with a family caregiver (often a spouse; Banerjee, 2009), with one-third living alone (Lakey, Chandaria, Quince, Kane, & Saunders, 2012). An estimated

670,000 people act as primary caregivers for people with dementia in the UK, estimated to save the state £8 billion per year (Lakey et al., 2012). In addition to the importance of family caregivers, general practitioners (GPs) play an important role as the first point of contact for ongoing care and support (Jennings, Linehan & Foley, 2018b; Lakey et al., 2012), especially for people living in the community whom (unlike nursing home residents) may not have regular contact with qualified healthcare professionals. Remaining in the community is important to people with dementia (Alzheimer's Society, 2011; Lakey et al., 2012). Research and care that continues to support people with dementia to live independently in their own homes is essential to avoid preventable or early nursing home admission (Alzheimer's Society, 2011).

1.8 The concept of pain

Pain is a complex and multi-factorial symptom derived from sensory stimuli or neurologic injury and modified by individual memory, expectations, and emotions (Corbett et al., 2014; American Geriatric Society [AGS] Panel, 2002). The task force on taxonomy of the International Association for the Study of Pain (IASP) defined pain as:

> *an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*
>
> Merskey and Bogduk, 1994, p. 210

The accompanying notes for this definition highlight the subjectivity of pain and that 'the inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment' (Merskey & Bogduk, 1994, p. 210). However, researchers have continued to criticise the definition, as the definition is often presented without the accompanying notes (Kaasalainen, 2007). The definition in isolation fails to illuminate the subjectivity of pain and places too much emphasis upon the 'description' of pain, when many populations may be unable to verbally describe their subjective experience. An alternative definition of pain is:

> *whatever the experiencing person says it is, existing whenever the experiencing person says it does*
>
> McCaffery, 1968 p. 95

This definition acknowledges the subjectivity of pain, however alike to other definitions does not consider the pain experienced by people with dementia that may have difficulty verbally communicating their pain experience. To acknowledge the limitations of previous definitions of pain, a recent definition describes pain as:

> *an unpleasant subjective experience that can be communicated to others either through self-report when possible or through a set of pain-related behaviours*
>
> Kaasalainen, 2007, p. 7

This definition provides a basis to understand the subjective pain experienced by people with dementia who may not have the ability to verbally communicate, or self-report their pain, illuminating the importance of non-verbal means of pain communication.

1.9 Theories of pain

Many theoretical frameworks have been proposed to understand the physiological basis of pain (Moayedi & David, 2013). For many years our understanding of pain was based upon René Descartes' description of the pain system. Descartes described pain as a biomedical concept; the experience of pain is produced by a direct, straight-through transmission system from injured tissues in the body to a pain centre in the brain (Melzack, 1996). The first theory to move away from the biomedical model was the Gate Control Theory (Melzack & Wall, 1965). This theory proposed that a mechanism or 'gate' in the spinal cord inhibits or facilitates the transmission of pain. Importantly, this theory illuminated the modulation of inputs in the spinal dorsal horn and the dynamic role of the brain in pain processes. When nociceptive information reaches a threshold it 'opens the gate' and activates pathways that lead to the experience of pain. Since the development of the Gate Control Theory, many limitations have been noted, including the inability to identify a 'gate', and the limits of the theory to explain painful conditions such as phantom limb pain for people with paraplegia

who do not have a connection between the brain and the spinal gate, yet continue to experience pain (Melzack 1996). Despite limitations, the Gate Control Theory had a major influence on the direction of pain research (Sufka & Price, 2002). Importantly, the Gate Control Theory moved away from the traditional biomedical perspective that had dominated our understanding of pain, viewing pain as a perception rather than a sensation, and acknowledging individuals' active rather than passive influence on pain experience. In recent years, research has identified the importance of biopsychosocial factors in pain; with pain for people with dementia being conceptualised as an interaction between predisposing, lifelong, and current biological, psychological, and social factors (Gagliese, Gauthier, Narain & Freedman, 2018).

1.10 Persistent and acute pain

The terms *persistent* and *chronic* pain are often used interchangeably. Recent guidance, however, recommends the use of *persistent* pain due to patients' and healthcare professionals' negative connotations towards *chronic* pain (AGS Panel, 2009). The term *chronic pain* is associated with negative images and stereotypes that may alter perspectives towards treatment options (AGS Panel, 2009). In accordance with this guidance, this thesis uses the term persistent pain from this point forwards.

There remains no universally accepted definition for persistent pain (Reid, Eccleston & Pillemer, 2015), with researchers and healthcare professionals debating the most appropriate duration of time to classify pain as being persistent in nature. Definitions classify pain as persistent if it lasts longer than 3 months, 6 months, or more (AGS Panel, 2009; Schofield, 2018). Other researchers have argued that the time frame is only one element of persistent pain, and definitions need to take into account the physical, psychological, social and spiritual dimensions of pain (Ong, Dunn & Croft, 2006).

Alternatively, acute pain is typically associated with trauma or injury (Schofield, 2018). Older adults frequently undergo medical or surgical treatments that result in acute pain (Ardey et al., 2003).

1.11 Nociceptive pain and neuropathic pain

Nociceptive pain describes pain in a normally functioning somatosensory nervous system (Merskey & Bogduk, 1994). Nociceptive pain is commonly derived from the stimulation of pain receptors caused by actual tissue damage or potentially tissue-damaging stimuli (Nicholson, 2006). Alternatively, neuropathic pain syndromes develop after a lesion or disease affecting the somatosensory nervous system (Finnerup et al., 2016; Treede et al., 2008). Neuropathic pain can arise from a variety of conditions that affect the peripheral and/or central nervous system (Nicholson, 2006). Painful neuropathic conditions include diabetic neuropathy, herpes zoster (shingles), and post-stroke central or thalamic pain. People experiencing neuropathic pain may describe their symptoms as spontaneous electrical attack-like pain, pins and needles, or a loss a function (Finnerup et al., 2016; Baron et al., 2017). Nociceptive and neuropathic pain often co-exist, meaning that the presence of one type of pain does not mean the absence of the other type of pain.

1.12 Epidemiology of pain

1.12.1 Incidence of pain

The incidence of pain for older adults is yet to be widely investigated (Shi, Hooten, Roberts, & Warner, 2010), with a gap in the evidence examining the incidence of pain for people with dementia. The minimal evidence suggests that the annual incidence of pain for older adults ranged from 3.3% to 16% (Elliott, Smith, Hannaford, Smith & Chambers, 2002; Thomas, Mottram, Peat, Wilkie & Croft, 2007; Jordan, Thomas, Peat, Wilkie & Croft, 2008; Magni et al., 1993). Research investigating the incidence of pain found that 4.7 older adults per 100-person years reported pain (Shi et al., 2010).

1.12.2 Prevalence of pain

Age is a risk factor for pain, with prevalence estimates suggesting that half of older adults living in the community experience pain (AGS Panel, 2002; Corbett et al., 2012; Donald & Foy, 2004; Jakobsson Klevsgård, Westergren, & Hallberg, 2003; Herr, 2002; Patel, Guralnik, Dansie & Turk, 2014; Zarit, Griffiths & Berg, 2004). The prevalence of pain increases to

approximately 80% in nursing home settings (Hadjistavropoulos, Fitzgerald, & Marchildon, 2010).

In addition to pain, age is also a common risk factor for dementia (Reid et al., 2015; Malec & Shega, 2015). This means that as people get older, their risk of dementia and pain increases. Many older adults with dementia are therefore likely to concurrently have a painful condition (Frampton, 2003). Cross-sectional studies suggest that the point prevalence rate of pain for people with dementia living in the community ranges from 16.7% to 87.5% (Jensen-Dahm et al., 2012; Krulewitch et al., 2000; Gilmartin et al., 2015; Barry, Parsons, Passmore, & Hughes, 2016; Shega, Hougham, Stocking, Cox-Hayley & Sachs, 2004; Mäntyselkä, Hartikainen, Louhivuori-Laako, & Sulkava, 2004). The prevalence of pain for people with dementia living in nursing homes is similar to community estimates and ranges from 17% to 83% (Ferrell, Ferrell & Rivera, 1995; McClean & Higginbotham, 2002; Lin, Lum, Mehr & Kane, 2006; Parmelee, Smithy & Katz, 1993; Fisher et al., 2002; Sengupta, Bercovitz, & Harris-kojetin, 2010; Barry, Parsons, Passmore, & Hughes, 2015; Kooten et al., 2017; Chen et al., 2010). Studies estimating the prevalence of pain for people with dementia used a variety of pain assessment methods; including but not limited to self-report, staff report (observation or documentation in medical records), family caregiver report, or a combination of methods. The variety of methods used to estimate the prevalence of pain, in addition to the heterogeneous settings and sample characteristics are likely to contribute to the wide prevalence estimates (Chen, Lin & Watson, 2010; Bjorkman et al., 2008). A critique of the methods used to assess pain are discussed in Section 2.3.

Musculoskeletal conditions, such as osteoarthritis, lower back pain, and pain from healed bones and fractures are the most common cause of persistent pain for people with dementia (and older adults generally) (Schofield, 2018; Herr, Coyne, McCaffery, Manworren & Merkel, 2011). The annual prevalence of musculoskeletal consultation within primary care ranged from 33% to 41% for people aged over 65 years old in the UK (Jordan et al., 2010), making musculoskeletal pain one of the most common reasons for people to access healthcare

services (Briggs et al., 2016), and the leading cause of disability worldwide (Blyth & Noguchi, 2017).

1.13 Neurodegeneration and pain

A number of experimental studies have investigated if the neurodegenerative changes associated with dementia implicate the experience of pain. This exploration is based upon the idea that the neurodegenerative changes may affect pain processing pathways (depending upon the type, extent, and location of the lesions). A systematic review and meta-analysis conducted by Stubbs et al. (2016) examined if the sensory aspect of pain was altered for people with dementia. Thirteen studies were identified, including 256 people with dementia and 260 healthy controls. Results of the meta-analysis found no significant difference in pain threshold, pain tolerance, pain intensity ratings, or heart rate response to pain. In fact, the review by Stubbs et al. identified that people with dementia had significantly raised facial expression scores in response to pain compared with healthy controls. This finding is in accordance with other studies that suggest a potential amplified experience of pain for people with dementia (De Tommaso et al., 2016; De Tommaso, Kunz, & Valeriani, 2017; Kunz, Mylius, Scharmann, Schepelman & Lautenbacher, 2009; Lautenbacher & Kunz, 2017). Aside from the sensory component of pain, research investigating the affective and cognitive components of pain suggest subtle changes in the pain experience for people with dementia compared to people without dementia, however evidence is limited (Gagliese et al., 2018).

At present, many experimental studies continue to use self-report as an indication of tolerance and threshold, despite the unsuitability of this method for some people with dementia (see Section 2.3.1). Additionally, most experimental evidence to date include only a small sample of people with dementia, many of which have mild-to-moderate cognitive impairment and therefore may not be representative of the full range of condition severity. Furthermore, as pain processing may be implicated by neurodegenerative changes in the brain (in which the anatomical location is different depending upon the subtype of dementia) each dementia subtype may affect the pain experience differently (Álvaro González et al.,

2015; De Tommaso et al., 2017), however at present, such experimental evidence is largely limited to people with AD (Defrin et al., 2015).

On the basis of the current experimental findings, there is 'no convincing evidence to suggest that the brain deterioration that occurs with dementia leads to clinically significant reductions in pain intensity' (Hadjistavropoulos, Fitzgerald & Marchildon, 2010, p. 105). In fact, recent research suggests that pain perception may be enhanced for people with dementia (De Tommaso et al., 2017; Stubbs et al., 2016).

1.14 Pain as an unmet need

Earlier in this chapter, BPSD was introduced as a symptom of dementia (alongside cognitive symptoms, and difficulties performing activities of daily living; see Section 1.2.3). The neurological cause of dementia meant that the understanding of behavioural and psychological changes were largely based upon biomedical models of disease and illness (see Section 1.1.1; Kitwood, 1997). Therefore, behavioural and psychological changes were conceptualised and researched as direct 'symptoms' of dementia.

Contrary to the biomedical model, the unmet needs model (Algase et al., 1996; Cohen-Mansfield, 2000) provides an alternate view of behavioural and psychological changes for people with dementia. This model postulates that so-called 'challenging behaviour' is a response to the individual social and/or physical needs of the person with dementia. In other words, 'challenging' or 'problematic' behaviours are attempts for the person with dementia to communicate distress when unmet needs arise (Kovach, Noonan, Schlidt & Wells, 2005, p.135). This position is aligned to a person-centred framework of care in which all 'behaviour has meaning' (Brooker, 2007, p. 16) and that 'problem behaviours' should be seen primarily as attempts to communicate. Common unmet needs that may lead to 'challenging behaviour' include pain, boredom, fatigue, a noisy environment, or uncomfortable room temperature (Algase et al., 1996; Cohen-Mansfield, 2000; Kovach et al., 2005). The unmet needs model therefore shifts the reference from the person with *dementia*; in which 'challenging behaviour' is attributed to neuropathological changes associated with dementia (biomedical approach), to the *person* with dementia; exploring the individual needs, social environment, and

perspective of the person with dementia to understand why their behaviour may have become 'challenging'. This shift allows focus upon the *person* rather than the *illness* (Kitwood, 1997).

One of the most popular unmet needs models is the need-driven, dementia-compromised behavior model (Kovach et al., 2005). This model highlights the cascading nature of unmet needs when the behavioural or psychological symptom is misinterpreted as a symptom of dementia (Kovach et al., 2005). A good example of this cascading effect is the presence of pain. Pain results in a need for pain relief (e.g. analgesic medication), which may result in agitation and 'wandering' if the person with dementia struggles to verbally express their pain. If the need for pain relief remains unmet, the primary BPSD (in this case, 'wandering') may continue or worsen, with the potential for negative outcomes (e.g. falling). The cascading impact continues, with the fall resulting in secondary BPSD (e.g. physical aggression, increased agitation).

A review of the literature investigated the link between pain and BPSD, concluding that there is an association between unmet pain and BPSD in people with dementia (Flo, Gulla & Husebo, 2014). A number of studies have examined analgesic medication and the effects on BPSD (Blytt, Bjorvatn, Husebo & Flo, 2017; Husebo, Ballard, Sandvik, Nilsen & Aarsland, 2011b; Husebo, Ballard, Fritze, Sandvik & Aarsland, 2014a; Manfredi et al., 2003; Cipher, Clifford, & Roper, 2007; Chibnall, Tait, Harman & Luebbert, 2005; Habiger, Flo, Achterberg & Husebo, 2016; Husebo, Ballard, Cohen-Mansfield, Seifert & Aarsland, 2014b), with the logic that if the unmet need was indeed pain, the initiation of analgesic medication (thus 'meeting' the need) would reduce BPSD. Two systematic reviews (Husebo, Ballard & Aarsland, 2011a; Pieper et al., 2013) and a perspective review (Tampi, Hassell, Pallavi & Tampi, 2017) concluded from the available evidence that analgesic medication appears to reduce BPSD. Whilst these findings show a promising link between BPSD and pain, the actual testing of this link to assess the benefit in the reduction of BPSD by the administration of analgesia has been restricted to pilot randomised control trials conducted solely within formal nursing home settings, with small sample sizes, and short duration follow up times (Bjorvatn, Husebo, &

Flo, 2017; 2018; Blytt, Husebo, Flo, & Bjorvatn, 2018). The findings of these trials however do show a beneficial effect, again reinforcing the link between pain and BPSD.

Despite evidence of the link between BPSD and pain (and BPSD and other drivers) and the wider 'unmet' needs hypothesis, the current method often used to manage BPSD is the administration of anti-psychotics (Banerjee, 2009). Such treatment approaches target BPSD as a direct symptom of dementia (in line with a biomedical approach) rather than investigating the underlying cause of the presentation. Estimates suggest that only 20% of people with dementia prescribed anti-psychotics for BPSD derived some benefit from the treatment (Banerjee, 2009). Additionally, anti-psychotics increase the risk of cerebrovascular adverse events and avoidable mortality (Kales et al., 2012; Forester & Vahia, 2019; Banerjee, 2009). Given the inefficacy and risks associated with anti-psychotic medication for BPSD, several UK policies and guidance documents have called for the reduction of inappropriate antipsychotic prescription for people with dementia (Department of Health, 2015; Napp Pharmaceuticals, 2014; Banerjee, 2009). Instead it is proposed that the underlying driver of the behavioural change should be investigated first (e.g. pain) in order to target appropriate treatments (Livingston et al., 2017). By identifying the cause of BPSD, effective treatments have the potential to manage BPSD, in turn reducing avoidable admissions to hospitals and nursing homes, allowing the person with dementia to continue living in the community (Department of Health, 2015).

1.15 Impact of pain

Pain has a detrimental impact for older adults with and without dementia (Reid et al., 2015). Pain is associated with an occurrence of falls (Stubbs et al., 2014; Crowe et al., 2017a), frailty (Saraiva et al., 2018), changes in mood (e.g. depression and anxiety) (AGS Panel, 2002), increased emergency department visits (Hunt et al., 2018), delirium (Feast et al., 2018), loss of ability to perform activities of daily living (Shega et al., 2010a), decreased quality of life (Rostad et al., 2017) and mortality (Rajkumar et al., 2017). In addition to these various negative implications of pain, research also suggests unique implications for people with dementia, with pain exacerbating cognitive impairment (Cook, Niven & Downs, 1999;

Buffum, Sands, Miaskowski, Brod & Washburn, 2004), and behavioural and psychological symptoms (Flo, Gulla & Husebo, 2014; see Section 1.14). The negative effects of pain extend beyond the person with dementia to disrupt family and social relationships, with a significant economic burden on society (Reid et al., 2015).

1.16 The structure of the thesis

This thesis is organised into ten chapters. The following chapter, Chapter Two, provides an overview of the literature into pain identification, assessment, and treatment for people with dementia, drawing upon the large body of evidence based from nursing homes. In Chapter Three, a systematic review was conducted to examine pain assessment and pain treatment for people with dementia who reside in the community. The literature review (Chapter Two) and the systematic review (Chapter Three) were conducted with a differing purpose. The literature review takes a more flexible and broad stance (due to the availability of pre-existing evidence) to allow key debates in the literature to be examined (Greenhalgh, Thorne & Malterud, 2018). The systematic review of Chapter Three builds upon the findings of the literature review but narrowing the focus to findings reported on people with dementia living in the community. Chapter Four provides a brief overview of the rationale, aim and research objectives of this thesis, reflecting on the gaps in evidence identified from the literature review (Chapter Two) and the systematic review (Chapter Three).

Chapter Five provides an overview of the convergent mixed methods approach for this thesis; including the theoretical underpinning of critical realism. The quantitative and qualitative methods chosen to encapsulate the mixed methods design are described in Chapter Six. A descriptive overview of the populations (quantitative) and people (qualitative) is given in Chapter Seven to provide a contextual foundation prior to the findings.

The findings are presented in Chapters Eight and Nine. Each findings chapter is based upon a conceptually distinct area. Chapter Eight draws upon quantitative and qualitative findings to investigate pain identification and pain assessment for community-dwelling people with dementia. Chapter Nine also draws upon quantitative and qualitative findings to investigate the management of pain for community-dwelling people with dementia.

The final chapter of this thesis, Chapter Ten, will summarise the thesis overall by providing an integrated summary of the quantitative and qualitative findings for each research objective, while reflecting upon findings from the existing literature. The thesis concludes by highlighting the implications of the research and suggestions for future research.

1.17 The style of the thesis

Traditionally, a formal, third person style is used to report scientific results. The third person allows scientific research to remain 'objective' rather than personal, moving the emphasis to the arguments made by the author, rather than the author themselves (Gillett, Hammond & Martala, 2013). The use of the third person may, however, 'silence' the author (Gilgun, 2005), minimising the extent that the researcher influenced, interpreted, and made decisions about the direction and the conclusions of the research (Webb, 1992). In accordance with my theoretical approach (see Section 5.3.2), I have decided to take a balanced approach between third and first person. The use of both styles acknowledges my presence as part of the research, whilst keeping the focus on the research.

1.18 Conclusion

This chapter provided an introduction to the key tenants of this thesis; dementia and pain. Chapter Two (literature review) and Chapter Three (systematic review) build upon this chapter by critically reviewing the literature on pain identification, assessment, and management for people with dementia.

2 Chapter Two: Literature review

2.1 Introduction

This chapter provides a critical review of the literature to examine the current understanding of pain identification, assessment, and management for people with dementia. This review builds upon the previous chapter that provided an overview to dementia and pain (see Chapter One). This chapter begins by describing the aim and approach to the literature review. Following this, the key issues, debates, and concepts relating to pain identification, assessment and management for people with dementia are described sequentially.

2.2 Aim of the literature review

In the previous chapter, the prevalence of pain was found to be high for people with dementia (see Section 1.12.2). Most pain in people with dementia is due to musculoskeletal problems, and is most often persistent in nature (Pautex et al., 2005; Rubey, 2005; Scherder & Plooij, 2012; Corbett et al., 2012; Jørgensen, Thorleifsson, Selbæk, Benth & Helvik, 2018). As stated previously, pain has many negative implications for older adults with and without dementia (see Section 1.15).

Research on pain for people with dementia has, to date, focused largely on formal settings, particularly nursing home (Tan et al., 2015; Chow et al., 2016), hospital (Closs et al., 2016), and palliative settings (Burns & McIlfatrick, 2015a). Pain in acute settings is often related to acute injury (e.g. long bone fractures; Arendts & Fry, 2006; Fry, Arendts, Chenoweth & MacGregor, 2015). Pain in palliative settings is complex, with a mix of acute and persistent pain within an end of life setting. Both of these settings therefore have numerous contextual differences that may not represent the broader population of people with dementia (Platt, 2010; Coyne, Mulvenon & Paice, 2018). Therefore, in order to give a contextual foundation for this thesis, this literature review will draw largely upon the evidence from nursing home settings; with the systematic review (see Chapter Three) narrowing the focus to community-dwelling people with dementia in order to generate novel research questions.

Whilst this literature review was not a systematic review (in terms of the analytical approach), the search was conducted systematically using an iterative process. Searches were

conducted in a variety of electronic databases (EBSCO [including: CINAHL, Medline, PsycINFO, AgeLine], Web of Science, and PubMed) to identify relevant abstracts and full-text articles. Firstly, a general search was conducted ((‘pain’ or ‘discomfort’) and (‘dementia’ or ‘cognitive impairment’)) to identify the breadth of core literature related to the topic of interest. Importantly, key researchers in the field were identified and their publications searched, along with the reference screening of published literature reviews and systematic reviews. The iterative nature of the literature review meant that additional searches were conducted before, during, and after the findings.

This literature review will provide an overview of the evidence related to i) pain identification, and assessment, and ii) management of pain for people with dementia. A number of reviews and studies have identified barriers to optimal pain identification, assessment, and management for people with dementia in a variety of settings (McAuliffe, Nay, O’Donnell & Fetherstonhaugh, 2008; Zwakhalen et al., 2018; Geddis-Regan, Stewart & Wassall, 2018; Rantala, Kankkunen, Kvist & Hartikainen, 2014). An overview of the barriers is provided in Table 2.1. Although each barrier is categorised into two conceptual domains i) pain identification and assessment and ii) management of pain, it is acknowledged that these barriers may cross each domain. Many of these barriers have been integrated and discussed throughout this chapter.

Table 2.1. Barriers to adequate pain identification, assessment and management for people with dementia

Domain	**Barrier**
Pain identification and assessment	• Lack of objectivity[a] • Lack of information or 'evidence'[a, b] • Communication difficulties[a, d] • Lack of education, knowledge and expertise[a] • Lack of recognition, misdiagnosis, or late diagnosis[b, e] • Lack of time[a, b] • Lack of interest and awareness[a] • Lack of available assessment tools[a, b, d] • Stoical attitudes[b, e]
Management of pain	• Difficulties in pain assessment[c, d] • Reluctance to prescribe and take analgesic medication[c, e] • Lack of familiarity[d] • Physiological changes associated with ageing (e.g. side effects, comorbidities)[d, e]

[a]Zwakhalen et al. (2018); [b]McAuliffe et al. (2008); [c]Rantala et al. (2014); [d]Geddis-Regan, Stewart and Wassall (2018); [e]Veal et al. (2018)

2.3 Pain identification and assessment

People with dementia experience the same pain as older adults without dementia (see Section 1.13). It is important that pain is systematically and adequately assessed to ensure appropriate management (Pink, O'Brien, Robinson & Longson, 2018). This is all the more true for some people with dementia, where assessment can be problematic due to the symptoms of dementia (AGS Panel, 2002; Herr et al., 2011). Symptoms of dementia such as impaired reasoning, planning, memory, and communication may cause difficulty when recalling, and reporting physical conditions and pain (Kovach, Logan, Simpson & Reynolds, 2010). Therefore, many guidance documents and clinical protocols have been developed to guide the systematic identification and assessment of pain for older adults (Hadjistavropoulos et al., 2007; Hadjistavropoulos, Fitzgerald & Marchildon, 2010), including people with dementia (Herr et al., 2011; Snow & Shuster, 2006). These guidelines, however, often do not critically examine the evidence that underpins their recommendations (Corbett et al., 2016). Recently, Schofield (2018) published UK national guidelines on the assessment of pain for older people (updated from the Royal College of Physicians, British Geriatrics Society and British Pain Society guidance published in 2007). Unlike previous guidelines, Schofield adopts a more critical and systematic approach to the current evidence, including a section dedicated to pain assessment for people with dementia. As part of the guidelines, Schofield (2018) acknowledges the need for a multifaceted approach to pain identification and assessment, in line with NICE (2018) guidelines, and as reported in research, protocols, and USA guidelines for non-verbal older adults (Herr et al., 2011; Pasero & McCaffery, 2011; Hadjistavropoulos et al., 2007; Snow & Shuster, 2006). Each element of the multifaceted approach to pain identification and assessment is displayed in Table 2.2.

Table 2.2. A multifaceted approach to pain identification and assessment (adapted from Herr et al., 2011)

Pain identification and assessment method	**Specific consideration for people with dementia**
Obtain self-report	Self-report of pain is often possible in mild-to-moderate cognitive impairment, but ability to self-report decreases as dementia progresses
Search for potential causes of pain	Consider common chronic pain aetiologies. Musculoskeletal and neurologic disorders are the most common causes of pain in older adults
Observe patient behaviour	Observe facial expressions, verbalisations/vocalisations, body movements, changes in interactions, changes in activity patterns or routines, and mental status
Informant reporting	In long-term care settings, the certified nursing assistant is a key health care provider shown to be effective in recognising the presence of pain. Family are helpful if visit regularly
Attempt an analgesic trial	Estimate the intensity of pain based on information obtained from prior assessment steps and select appropriate analgesic

Despite recommendations, research continues to suggest that pain identification and assessment for people with dementia remains inadequate (Chen & Lin, 2016; Corbett et al., 2012). The diagnosis of dementia may 'overshadow' other potentially painful comorbid conditions (Tolman & Dening, 2018). Research has found that the vast majority of nursing home managers (Barry, Parsons, Passmore & Hughes, 2012), nurses (Burns & McIlfatrick, 2015b), and GPs (Jennings et al., 2018b) agree that the presence of dementia can make pain assessment difficult (91.7%, 91%, 98%, respectively). The difficulty of pain identification and assessment for people with dementia means that healthcare professionals are

concerned that pain remains inadequately identified and assessed (Kaasalainen et al., 2007). This is illuminated by a systematic review and meta-analysis that found a lower identification of pain for people with dementia (using self-report and nurse observation) than older adults without dementia (OR 0.36, 95% CI 0.28 to 0.45), despite both groups having a similar prevalence of painful conditions (e.g. musculoskeletal conditions, fractures and cancer) (Tan et al., 2015). Similarly, recent research by Nakashima, Young and Hsu (2019) found that people with dementia in nursing home settings had significantly fewer pain assessments than people without dementia (74.3% vs 92.5%, $p<0.001$), negatively impacting the identification of pain. In an alternative nursing home study, people with dementia were less likely to have pain identified on their most recent pain assessment than people without dementia (Veal, Williams, Bereznicki, Cummings & Winzenberg, 2019). Such findings highlight the potential inadequacy of pain identification and assessment for people with dementia, which seems to incrementally lower with increasing cognitive impairment (Reynolds, Hanson, DeVellis, Henderson & Steinhauser, 2008).

In accordance with these findings, a recent cross-sectional study by Jørgensen et al. (2018) examined the number of physical diagnoses recorded in the medical records of nursing home residents with (n=2470) and without dementia (n=513) at two time-points (2004/2005 and 2010/2011). This study found that people with dementia had fewer physical diagnoses in their medical records than people without dementia (including potentially painful musculoskeletal conditions, 22.4% vs. 29.8%, respectively). Additionally, the number of recorded physical diagnoses lowered in line with increased severity of dementia. Such findings may suggest that people without dementia may live in nursing homes due to their physical morbidities (thus explaining the higher prevalence) whereas people with dementia may live in nursing homes due to their cognitive impairment. Alternatively, these findings may also infer that less attention is paid to the physical symptoms of people with dementia, especially as their severity of dementia increases and the symptoms associated with dementia (e.g. BPSD) become ‘clinically dominant’. Longitudinal research (rather than cross-sectional) in community settings would overcome the distinct reasons that a person with and

without dementia may live in a nursing home (physical vs. cognitive morbidity), therefore providing greater confidence and direction when interpreting these findings.

In contrast to this evidence, Hoffman et al. (2014) found that people with and without dementia had a similar prevalence rate of pain diagnosis (74.4% vs. 72.5%, respectively; p=0.11), indicating potentially adequate pain identification. This study, however, only examined pain diagnoses during the first year following dementia diagnosis. Therefore, this study did not examine pain-related diagnoses over time, and cannot provide insight into pain identification and assessment throughout the expected course of dementia progression.

The following sections will provide an overview of the evidence into a variety of pain identification and assessment methods, as outlined by Herr et al. (2011; see Table 2.2). Throughout each section, the challenges and barriers specific to people with dementia are highlighted.

2.3.1 Self-report

The subjectivity of pain renders verbal self-report methods as the 'gold standard' assessment for typical populations (Horgas, Elliott & Marsiske, 2009; Schofield, 2018). Self-report allows the person to describe the location, intensity, type, frequency, and duration of the pain experienced (Kang & Demiris, 2018). The symptoms associated with dementia (i.e. communication difficulties, problems with abstract reasoning, decline in executive functioning; see Section 1.2) may impede the person with dementia's ability to provide a verbal self-report that reflects their pain experience (Brennan & Soohoo, 2019), including the efficacy of pain treatments and potential side effects. Qualitative research has repeatedly illuminated reduced or altered verbal communication as a barrier to self-report for people with dementia (Geddis-Regan, Stewart & Wassall, 2018). Whilst self-report can be problematic, guidance suggests that self-report remains the most reliable and accurate pain assessment method for people with dementia, and therefore should be attempted, irrespective of the degree of cognitive impairment (Herr et al., 2006b; Schofield, 2018). In accordance, research

utilising focus groups of nursing home staff, and family caregivers perceived self-report as the 'most meaningful assessment route' for people with dementia (Corbett et al., 2016).

The current UK guidelines for pain assessment for older adults suggest that there are a number of valid and reliable self-report measures suitable for use with people with mild-to-moderate dementia, including Numerical Rating Scales and Verbal Descriptor Scales (Schofield, 2018).

- Numerical Rating Scales (NRS); respondents pick a number (usually starting from zero indicating no pain), with higher numbers indicating increased pain intensity.
- Verbal Rating/Descriptor Scale (VRS/VDS); respondents select a word descriptor that represents pain of progressive intensity (e.g. mild pain to excruciating pain).

In accordance with these recommendations, many studies have found that the majority of people with mild-to-moderate dementia can provide a self-report of their pain experience (Ware, Epps, Herr & Packard, 2006; Kaasalainen & Crook, 2004; Chibnall & Tait, 2001; Chen & Lin, 2015). A review completed by Stolee et al. (2005) found that completion rates for self-report pain assessment tools varied from 20% to 100% depending upon the severity of cognitive impairment. This finding has been supported in a number of studies, which also found that as the severity of dementia increases, the percentage of people with dementia able to self-report pain or use a self-report measure reduces (Closs, Barr, Briggs, Cash & Seers, 2004; Kunz, Scharmann, Hemmeter, Schepelmann & Lautenbacher 2007; 2009; Lukas, Niederecker, Günther & Nikolaus, 2013a).

Recommendations stress the potential need for individualised adaptations (e.g. simplified language, large fonts, involvement of a speech therapist), especially for people with moderate-to-severe cognitive impairment (AGS Panel, 2002; Schofield, 2018). Research suggests that simple dichotomous questions that require a concrete yes or no response such as 'are you currently experiencing pain?' may be useful for people with dementia (Hadjistavropoulos, Fitzgerald & Marchildon, 2010). When endorsing this method of pain assessment, Fisher, Burgio, Thorn and Hardin (2006) found that 81% of people with

dementia living in a nursing home had the ability to respond 'yes' or 'no' to a dichotomous question. Simple, dichotomous questions are therefore often used, with qualitative observation and interview studies showing that nurses used simple and direct questioning to assess their patient's pain irrespective of their cognitive ability (Manias, 2012; Karlsson, Ernsth-Bravell, Ek & Bergh, 2014).

Many studies investigating self-report pain assessment tools focus upon the percentage response or completion rate of people with dementia (Ware et al., 2006; Closs et al., 2004). However, many studies do not investigate the person with dementia's comprehension of the self-report tool. Scherder and Bouma (2000) examined comprehension and understanding of the Faces Pain Scale by asking nursing home residents with and without dementia to choose which face indicated 'most pain' and 'least pain'. This research found that even 25% of older adults without dementia, and 50% and 80% of older adults with early and mid-stage dementia, respectively misinterpreted the scale. These findings highlight the importance of considering the comprehension of self-report instruments, in addition to relying upon the completion rate for people with dementia.

To further question the extent that self-reported pain reflects the pain experience, older adults, including people with dementia, may have a stoical attitude towards pain. Stoicism is defined as 'illness behaviour characterised by silent endurance and lack of emotion' (Moore, Grime, Campbell & Richardson, 2012, p.159), often colloquially described as a 'stiff upper lip' in the UK. Research suggests that a stoical attitude may stem from the acceptance of pain as a perceived inevitability in older age that cannot be alleviated (AGS Panel, 2009; McAuliffe et al., 2008; Barry, Parsons, Passmore & Hughes, 2013; Zwakhalen, Hamers, Peijnenburg & Berger, 2007; Makris et al., 2015; Crowe, Gillon, Jordan & McCall, 2017b). Additionally, a stoical attitude towards pain may be due to the perception that pain is a lower priority problem compared with other comorbidities (Makris et al., 2015). The stoical attitudes, beliefs and expectations held by older adults and healthcare professionals may impede care seeking, and accurate pain identification and assessment (Makris et al., 2015; AGS Panel, 2002; 2009). This is demonstrated in qualitative research including family

members of people with cognitive impairment living in nursing homes (Mentes, Teer & Cadogan, 2004) and older adults, family caregivers, and healthcare professionals (Martin, Williams, Hadjistavropoulos, Hadjistavropoulos & MacLean, 2005). In these qualitative studies, stoicism was perceived as a barrier to pain identification and assessment, with people with dementia denying or minimising their pain experience.

In contrast to the stoical attitude, a minority of family members perceived their relative's pain report as 'dramatic' as a means to get attention (Mentes et al., 2004). This finding again highlights the challenge of pain assessments for people with dementia, and in particular highlights the perceptions and interpretations of pain presence by others. In contrast, other studies have shown that nurses emphasise the importance of trusting the person with dementia's self-report of pain (Karlsson et al., 2014). Multiple pain assessment methods may be used to support or refute self-report, and to determine if complaints or denials of pain can be taken 'literally' (Dowding et al., 2016). This multidimensional approach may help clarify if the self-report of pain reflects the pain experience (Gilmore-Bykovskyi & Bowers, 2013).

Although guidance emphasises the importance of attempting to obtain a self-report for people with dementia (irrespective of cognitive ability), people with severe cognitive impairment may be unable to self-report pain, even with adaptation and full assistance (Schofield, 2018; Wynne, Ling & Remsburg, 2000; Closs et al., 2004; Barry et al., 2015). Therefore, although self-report is the preferential pain assessment method for people with dementia (Ngu et al., 2015; Pautex et al., 2005), self-report in isolation may not be appropriate nor sufficient to measure pain for people with dementia (Hadjistavropoulos et al., 2007; Kaasalainen & Crook, 2004). Certainly, there are drawbacks to a reliance on self-report alone, and research has suggested that healthcare professionals often rely upon self-report to assess pain; inferring that a lack of self-report equates to no pain (McAuliffe et al., 2009; Reynolds et al., 2008). A reliance upon self-report may contribute to the under-detection of pain for people with dementia (Stubbs et al., 2016), especially so for people with advanced cognitive impairment. This reiterates the need for a multifaceted approach to pain identification and assessment, in which self-report is always attempted, but other pain

assessment techniques are used to build a complete picture of the pain experience (Cohen-Mansfield, 2008; Herr et al., 2011; Schofield, 2018).

2.3.2 Search for causes of pain

The multifaceted approach to pain identification and assessment for people with dementia recommends the search for painful conditions (Herr et al., 2011; see Table 2.2). This 'search' may include an investigation into the patient's medical and medication history, complemented by a physical examination (Hadjistavropoulos et al., 2007; Schofield, 2018). Searches for the potential source of physiological pain may identify a treatable cause to relieve pain. Importantly, guidelines emphasise that pain can exist even if physical examination is normal (Schofield, 2018).

In recent questionnaire studies, the majority of GPs (91.7%) (Jennings et al., 2018b) and nursing home nurses (100%) (Burns & McIlfatrick, 2015b) agreed that physiological indicators of pain (e.g. heart rate, blood pressure, temperature) were an important aspect of pain assessment for people with dementia. Though worthy of note, the study by Burns and McIlfatrick report a low sample response rate of 33% (32/96) indicating potential under-representation of the wider population of nurses, and it is not known whether an affirmative answer translated to actual practice. Interview studies with nursing assistants in nursing home settings show that regular physical examination of the person during daily care tasks was important to identify physiological changes that might be indicative of pain (Karlsson, Bravell, Ek & Bergh, 2012; De Witt Jansen et al., 2017a). Despite the potential usefulness of examination, Chang et al. (2009) illuminated the difficulty of physical examination for people with dementia due to their understanding of, and potential 'lack of co-operation' with the examination. This then highlights not only the potential for dementia (and linked severity) to affect self-report but also to affect physiological examination.

2.3.3 Observation of changes in presentation

Behavioural indicators, facial expressions, and changes in normal functioning may indicate that the person with dementia is experiencing pain (Schofield, 2018). Such indications of pain are especially important when the person with dementia can no longer verbally self-report

their experience. The AGS Panel (2002; 2009) identified six behavioural domains that are indicative of pain. The six domains are outlined in Table 2.3, and should be observed during activity if possible, as pain for people with dementia is often musculoskeletal in nature and initiated in response to motor activity (see Section 1.12.2). Despite the high profile of the AGS panel behavioural domains, the methodological development of the behavioural categories has been poorly documented.

Table 2.3. Pain related behaviours for people with dementia (adapted from AGS Panel, 2002).

Behaviour domain	Example behaviour
Facial expressions	Slight frown, sad, frightened face
	Grimacing, wrinkled forehead, closed or tightened eyes
	Any distorted expression
	Rapid blinking
Verbalisations, vocalisations	Sighing, moaning, groaning
	Grunting, chanting, calling out
	Noisy breathing
	Asking for help
	Verbally abusive
Body movements	Rigid, tense body posture, guarding
	Fidgeting
	Increased pacing, rocking
	Restricted movement
	Gait or mobility changes
Changes in interpersonal interactions	Aggressive, combative, resisting care
	Decreased social interactions
	Socially inappropriate, disruptive
	Withdrawn
Changes in activity patterns or routines	Refusing food, appetite change
	Increase in rest periods
	Sleep, rest pattern changes
	Sudden cessation of common routines
	Increased wandering
Mental status changes	Crying or tears
	Increased confusion
	Irritability or distress

A recent systematic review by Strand et al. (2019) investigated the scientific basis for claiming that pain behaviours (such as facial expressions, vocalisations, and body movements) indicate an underlying pain experience for people with dementia. A total of 17 quantitative, and 8 qualitative studies provided strong evidence that restlessness (agitation), rubbing, guarding, rigidity, and physical aggression were valid indicators of pain. Despite being strong indicators of pain, such pain behaviours are not necessarily pain-specific and may be indicative of other experiences. In a questionnaire study, Barry et al. (2012) found that 'nearly all' (percentage unknown) nursing home managers recognised the importance of delirium, confusion, or a marked change in the residents' behaviour as a possible indication of pain. However, only 96 nursing home nurses responded to this survey (response rate of 39%). The small sample limits generalisability to the wider nursing home nurse population, and also limited the statistical analysis beyond descriptive statistics. Qualitative studies offer support to these findings, with a recent meta-review showing that behavioural and psychological cues (e.g. irritability, vocalisation, grimacing, guarding, rubbing the affected area, physical withdrawal from touch) were important to identify and 'build a picture' of pain for the person with dementia (Geddis-Regan et al., 2018).

Facial expressions are a key behavioural domain indicative of pain experience for people with dementia (see Table 2.3; AGS Panel, 2002; Sheu, Versloot, Nader, Kerr & Craig, 2011). Facial reactions are a reflexive response to pain, and therefore become increasingly important to identify pain for people with dementia, especially as the ability to provide a self-report diminishes (Lints-Martindale, Hadjistavropoulos, Barber & Gibson, 2007; Browne, Hadjistavropoulos, Prkachin, Ashraf & Taati, 2019; Oosterman, Zwakhalen, Sampson & Kunz, 2016). Two studies examined which facial expressions were perceived by nurses (and 'non-professional' observers) to be indicative of pain (Lautenbacher, Sampson, Pähl & Kunz, 2016; Lautenbacher, Walz & Kunz, 2018). Both studies asked participants to observe people with dementia and to rate their pain using facial descriptors. Facial expressions that participants attributed to pain were 'frowning', 'opened mouth', 'narrowed eyes', 'looking tense', and 'looking frightened'. However, identification of pain using facial descriptors was

only weakly correlated with the self-report of pain from the person with dementia (Lautenbacher et al., 2018) and ratings did not differ between nurses and 'non-professional' age-matched observers (Lautenbacher, Niewelt & Kunz, 2013). This finding may highlight the difficulty of using facial expressions to identify and assess pain in isolation. Despite these findings, qualitative evidence found that nursing assistants often used facial expressions (focusing upon the eyes and mouth) to identify pain and to examine the efficacy of pain relief for people with dementia in nursing home settings (Mentes et al., 2004).

2.3.3.1 Observational tools to assess change

The association between pain and a changed presentation, along with the need to assess pain for people with dementia without relying upon self-report has led to a proliferation of behavioural observation tools (Lichtner et al., 2014; AGS Panel, 2002). Recent UK pain assessment guidelines identified 16 behavioural pain assessment tools for people with dementia (Schofield, 2018). The most frequently reviewed behavioural observation tools to identify and assess pain are listed below (Lichtner et al., 2014):

- Abbey Pain Scale
- Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN)
- Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)
- Pain Assessment in Dementing Elderly (PADE)
- Checklist of Nonverbal Pain Indicator (CNPI)
- Pain Assessment in Advanced Dementia (PAINAD)

Many guidance documents recommend the Abbey Pain Scale to assess pain for people with advanced dementia (The Napp Pharmaceuticals, 2014; Social Care Institute for Excellence, 2015), including the guidelines by the Royal College of Physicians, British Pain Society and British Geriatric Society in 2007. However, when these guidelines were updated in 2018, the Pain in Advanced Dementia (PAINAD) and Doloplus-2 were recommended, due to the lack of recent validation of the Abbey Pain Scale (Schofield, 2018).

A number of reviews have examined behavioural observation tools for people with dementia (Van Herk, Van Dijk, Baar, Tibboel & De Wit, 2007; Zwakhalen, Hamers, Abu-Saad, & Berger, 2006; Schofield et al., 2005; Stolee et al., 2005; Herr et al., 2006a; Smith, 2005; Park, Castellanos-Brown & Belcher, 2010; Ng, Brammer & Creedy, 2012; Thuathail & Welford, 2011). When compiling the evidence as a meta-review, tools with the 'most promise' were the DS-DAT, Doloplus 2, Mahoney Pain Scale, PACSLAC, PAINAD, Abbey Pain Scale, and ECPA (Lichtner et al., 2014; Closs et al., 2016). However, the meta-review emphasised that the psychometric evidence of each tool was limited, with no one behavioural observation tool being more reliable or valid than the others (Lichtner et al., 2014).

The proliferation of behavioural observation tools has led to the creation of a number of meta-tools, such as The Pain Assessment in Impaired Cognition scale (PAIC15) developed in Europe (Kunz et al., 2019), and the Pain Intensity Measure for Persons with Dementia (PIMD) developed in America (Ersek et al., 2018). These meta-tools used a Delphi-like consensus exercise and psychometric evaluation to identify and compile items from pre-existing behavioural observation tools for people with dementia. Initial testing seems promising, however, further psychometric testing and investigation of clinical utility in a variety of settings and countries remains essential.

Despite UK guidelines advising the use of behavioural observation tools to assess pain in people with dementia (NICE, 2018; Schofield, 2018), and many tools being available, only 10% of GPs reported any knowledge of their existence (Jennings et al., 2018b). Unlike other studies of this kind (e.g. Barry et al., 2012), the response rate of GPs was modest (49%), yet remained underpowered. Qualitative studies have explored the perspective of nurses and physicians regarding the use of behavioural observation tools for people with dementia. De Witt Jansen and colleagues (2018) interviewed 23 physicians and 24 nurses providing end-of-life care to people with advanced dementia in primary care, hospital, secondary care, and nursing homes settings. All participants recognised that their place of work mandated the use of behavioural observation for people with advanced dementia, however only 34% used a behavioural observation tool (often the Abbey Pain Scale) if self-report could not be obtained.

Similarly, interviews with nurses and formal caregivers in nursing home settings (Tordoff, Wei & Smith, 2017) and hospital settings (Lichtner, Dowding & Closs, 2015) discussed that behavioural observation tools were rarely used in their practice. Reasons for the lack of use may include the difficulty and subjectivity of interpreting pain behaviours, a lack of training, interest, and time to implement behavioural observation assessments in practice (Zwakhalen et al., 2018), and the opinion that behavioural observation tools 'add no value' (De Witt Jansen et al., 2018; McMahon, De Witt Jansen & Kernohan, 2019).

Several intervention studies have investigated if systematic and regular use of behavioural observation pain tools improved pharmacological treatment initiation for people with dementia (Fry, Chenoweth & Arendts, 2018; Liu & Lai, 2017; Zwakhalen, van't Hof & Hamers, 2012). Despite systematic and regular use of behavioural observation tools, the initiation of pharmacological treatment for people with dementia did not improve. These findings indicate that even when a behavioural observation tool was systematically used to assess pain for people with dementia, there remains potential barriers to pharmacological treatment initiation. In these studies, the treatment protocol included an option to manage pain using non-pharmacological treatments. Non-pharmacological treatments were identified as the most common treatment approach following a positive pain score (Fry et al., 2018; Zwakhalen et al., 2012), with the use of non-pharmacological treatments being significantly higher in the intervention nursing homes (using the pain protocol) compared to control nursing homes (usual pain management strategies). This might reflect nurses' and nurse assistants' preference towards non-pharmacological options for people with dementia (Kovach, Griffie, Muchka, Noonan & Weissman, 2000; Mentes et al., 2004; Liu, 2014). Each of these findings highlight a dissonance between policy, protocol, or guidance and the challenge of translating research into practice to improve pain assessment and the management of pain for people with dementia (Cohen-Mansfield, 2012).

Aside from their inclusion in behavioural observation tools, facial expressions have also received attention in their own right driven by the development of facial recognition technology, such as the Facial Action Coding System (FACS) (Oosterman et al., 2016), and

more recently, mobile applications such as PainChek™ (Atee, Hoti & Hughes, 2018). Facial recognition technology is a promising avenue for pain assessment for people with dementia who cannot verbally communicate, however more work is essential before such technologies can be implemented in everyday practice.

2.3.3.2 Misattributing changes in presentation

Despite the well-known link between pain and behavioural and psychological changes (see Section 1.14), such changes may also be indicative of many alternative unmet needs (e.g. hunger, fatigue, constipation, isolation, or urinary infection; Kovach et al., 2005). GPs participating in semi-structured interviews reflected upon the difficulty of assessing for the driver of behavioural and psychological symptoms (Jennings et al., 2017), with care home staff suggesting that behavioural changes may disguise the identification of pain for people with dementia (Veal et al., 2018). In support of these findings, caregivers of people with dementia and nurses discussed the challenge of determining if behavioural and psychological symptoms are driven by pain or if behavioural and psychological symptoms are driven by an alternate reason (Martin et al., 2005; Gilmore-Bykovskyi & Bowers, 2013). The ambiguity of pain-related behaviours contributes to uncertainty regarding the presence or absence of pain (Gilmore-Bykovskyi & Bowers, 2013; Zwakhalen et al., 2018). The challenge of determining the driver may contribute to the misattribution of pain behaviours; the idea that behavioural signs of pain are being incorrectly attributed to a psychological or psychiatric problem (McAuliffe et al., 2008). If behavioural changes are not recognised as an expression of an unmet need for pain relief, pain may remain inadequately identified, assessed, and suboptimally treated.

In the alternate direction, behavioural observation tools may lead to behavioural changes being incorrectly attributed to pain. Research suggests that behaviours and facial expressions included in behavioural observation tools are not unique behavioural indicators of pain (Liu, Briggs & Closs, 2011), with research suggesting that others are not indicative of pain experience (e.g. ‘seeming disinterested’, ‘empty gaze’ from the Doloplus 2) (Lautenbacher et al., 2018). This increases the sensitivity of behavioural observation tools,

and thus may detect distress not caused by pain (Jordan, Regnard, O'Brien & Hughes, 2012; Feast et al., 2018). For example, a person with dementia with a urinary tract infection may show behaviours that are misinterpreted as pain behaviours. This misinterpretation may lead to inappropriate analgesic prescription when alternative treatments are more appropriate (i.e. an antibiotic prescription). Furthermore, many items included within behavioural observation tools require a degree of observer interpretation, heightening the subjectivity of the assessment and increasing variability (Lautenbacher & Kunz, 2017). Consequently, although behavioural observation tools may aid pain identification for people with dementia, a reliance upon behavioural observation tools in isolation may lead to false positives and false negatives (Lukas, Barber, Johnson & Gibson, 2013b); a high score on an observational pain tool is not diagnostic of pain. This may in turn impede accurate pain prevalence estimates (potentially leading to inflated prevalence, as false positives appear more likely), and ultimately leading to erroneous pain treatment.

2.3.4 Informant assessment of pain

Another key component to the multifaceted pain assessment, as outlined by Herr et al. (2011), is the informant assessment of pain (see Table 2.2). Informant assessments involve a person familiar with the person with dementia providing their perspective on the pain experienced by the person with dementia. The informant may include informal (family, friends, neighbours) or formal (nursing home staff) caregivers, depending upon the residential setting of the person with dementia. Informal and/or formal caregivers that are familiar with the person with dementia may provide in-depth insights into subtle individual pain behaviours, detecting and interpreting pain-related changes, and a knowledge of pain history (Geddis-Regan et al., 2018). Qualitative research has identified that familiarity with the person with dementia allows for the identification of unusual or 'out of character' behaviour that may go unnoticed, especially when the baseline, or 'usual behaviour' of the person with dementia is unknown (Kovach et al., 2000; Liu, 2014; Mentes et al., 2004). The insights of informal and formal caregivers (who know the person with dementia well) are

particularly beneficial when the person with dementia is no longer able to verbally articulate their pain (Corbett et al., 2016; Geddis-Regan et al., 2018).

Knowing the person well aids the identification and assessment of pain for people with dementia (Geddis-Regan et al., 2018). Therefore, continuity of care is beneficial for healthcare professionals to identify and assess pain for people with dementia. Continuity of care encompasses *relationship continuity* – 'a continuous therapeutic relationship with a clinician' and *management continuity* – 'continuity and consistency of clinical management, including providing and sharing information and care planning, and any necessary co-ordination of care required by the patient' (Freeman & Hughes, 2010, p. 4). Continuity of care has been described as an essential feature of general practice in England (Freeman & Hughes, 2010), however, recent developments in primary care (e.g. increasing specialisation, changing professional work patterns) mean that relationship continuity with a GP is becoming more difficult to achieve. For example, the availability of appointments and staff could impede patients' attempts to see the same GP – patients may sacrifice relationship continuity to get a quicker appointment. Research has found that poor continuity (and thus familiarity) with the person with dementia may make pain identification and assessment more challenging (Geddis-Regan et al., 2018). In circumstances where the healthcare professional is unfamiliar of the person with dementia, they may rely upon the perception and interpretation of the person that knows the person with dementia well, in addition to medical records, as a surrogate familiarity (Scherder & van Manen, 2005; Monroe, Parish & Mion 2015; Jennings et al., 2018b). Aside from pain identification and assessment, familiarity with the person with dementia is important to gauge the effectiveness of pain-related treatment and to facilitate optimum medication management (Barry et al., 2019).

2.3.4.1 Informant rating of pain

Dementia-specific informant rating scales have been developed, including the Pain Assessment for the Dementing Elderly (PADE; Villanueva, Smith, Erickson, Lee & Singer, 2003) and the Pain Assessment Instrument in Noncommunicative Elderly (PAINE; Cohen-

Mansfield, 2006). In an intervention study conducted by Cohen-Mansfield and Lipson (2008), self-report, informant report (using the PADE and PAINE), and behavioural observation tools were used to assess pain for people with advanced dementia at each 'step' of a stepped analgesic trial. This study found that nursing staff informant ratings were the most sensitive method to identify pain, and to detect the effects of analgesic medication (reduction of pain) for people with dementia compared to self-report and behavioural observation tools. This study emphasised the importance of using multiple assessment methods, including informant reports, to assess and monitor a person with dementia's response to pain treatment.

Although informant specific pain assessment tools have been developed, such as PADE and PAINE, many studies have examined informant ratings of pain using common self-report tools described previously (see Section 2.3.1). When examining nursing home staff (informant) ratings of pain compared to self-reported pain ratings, many studies reported a degree of congruence between the two pain scores (Hemmingsson et al., 2017; Cohen-Mansfield, 2005; Ersek, Polissar & Neradilek, 2011). However, the congruence between informant and independent measures of pain (e.g. self-report, Minimum Data Set) seemed to be negatively affected by the presence and severity of cognitive impairment (Ruben, van Osch & Blanch-Hartigan, 2015; Hemmingsson et al., 2017; Cohen-Mansfield, 2002; Scherder & van Manen, 2005; Fisher et al., 2002).

All of these previous studies have focused on informant ratings of pain by nursing home staff with regular contact with people with dementia. However, the dynamic and relationship between the person with dementia and their family caregivers may influence the informant report of pain. Research by Santos and Castanho (2014) investigated family caregiver's informant pain ratings using the Colour Analogue Scale (CAS) for their relative with dementia (residence unknown). They found that family caregivers rated the pain experienced by the person with dementia as significantly lower than the self-report of the person with dementia (mean CAS score: 1.2 vs. 4.7, respectively). Additionally, differences have been reported between family caregivers of people with dementia and family caregivers of people who do not have dementia; results have shown a lower report of pain from informant ratings for

people with dementia compared to people without dementia (mean CAS score: 1.2 vs. 6.2, respectively). Similarly, Cohen-Mansfield (2002) found that relatives were less likely to provide a pain rating for the person with dementia (i.e. respond 'don't know') if they have more severe cognitive impairment, or longer duration living in a nursing home. These findings provide support to previous research, indicating that cognitive impairment may increase the difficulty for informants to provide an informant report of pain. Family caregivers' informant reports of pain for community-dwelling people with dementia is explored in the systematic review (see Section 3.5.3.2).

Each of these studies reported above commented upon the accuracy of informant reports of pain by determining the 'congruence' or 'agreement' between the self-report and informant report of pain. However, the self-report of the person with dementia may not reflect their pain experience for the many reasons outlined in section 2.3.1. Therefore, it is unknown if the informant truly 'under-estimated' pain, or whether this reflects an over-estimation of the self-report (or vice versa). Furthermore, the accuracy of informant ratings of pain could only be investigated for people with dementia who could self-report their own pain (as used as the comparison). Therefore, and importantly, these findings do not provide insight into the utility of informant reports for people with advanced dementia unable to self-report their pain.

To overcome these challenges, Eritz and Hadjistavropoulos (2011) compared self-reported (where possible), informant reported, and behavioural observation of pain (using the PACSLAC). This study found that the informant reports provided by family caregivers were able to distinguish between painful and non-painful states, and correlated well with self-reported pain. This study also found a link to familiarity, the behavioural observation score of pain only predicted the informant report of pain successfully if the family caregiver spent more than 10 hours per week with the person with dementia (compared to family caregivers that spend less than 10 hours per week). These findings suggest that the informant report of pain is moderated in part by familiarity and regular contact with the person with dementia to provide an informant rating of pain that is informed by behavioural cues (see Section 2.3.4).

2.3.5 Response to analgesic medication

The final aspect of the multidimensional pain identification and assessment for people with dementia is an analgesic trial (see Table 2.2; Herr et al., 2011). This would typically involve the examination of pain before and after the administration of analgesics (Hadjistavropoulos, Fitzgerald & Marchildon, 2010). This technique of pain assessment works on the premise that a reduction in pain assessment score or pain-related behaviour following the initiation of an analgesic trial is likely to reflect improved pain control (Hadjistavropoulos et al., 2007; De Witt Jansen et al., 2017b). In other words, the unmet need for pain relief now being met. Qualitative research found that nurses often approach pain management in a 'trial and error' manner; employing various pharmacological and non-pharmacological treatments while observing pain-related behaviours of the person with dementia as a means of pain assessment (Gilmore-Bykovskyi & Bowers, 2013; Monroe et al., 2015; Geddis-Regan et al., 2018; Dowding et al., 2016).

In the previous chapter, randomised controlled trials (RCT) found that analgesic medication reduced behavioural indicators thought to be related to pain in people with dementia (Husebo et al., 2011a; Pieper et al., 2013; Tampi et al., 2017; see Section 1.2.3). However, many of these studies attributed lowering BPSD as an indication of lowering pain or addressing pain, rather than directly assessing pain pre-and-post administration. To build upon these findings, research has examined the effect of analgesic medication upon pain assessment scores. A systematic review and meta-analysis investigated the efficacy of analgesic treatments to reduce pain scores for nursing home residents with persistent pain (Knopp-Sihota, Patel & Estabrooks, 2016). Four studies were included in the meta-analysis (two RCTs; Corsinovi et al., 2009; Kovach et al., 2006, and two cluster RCTs; Sandvik et al., 2014; Husebo et al., 2011b). Only one study was not focused upon people with dementia (Corsinovi et al., 2009) and so the evidence is useful for inclusion. The meta-analysis found that pain scores had shown statistically significant improvements at all-time points in the respective studies, with a reported clinically useful moderate to large treatment effect. To date however, there has been limited studies investigating the effectiveness of analgesics for people with dementia,

despite it being an area requiring urgent attention (Knopp-Sihota, Patel & Estabrooks, 2016; Achterberg et al., 2013).

The systematic review and meta-analysis outlined directly above only included RCTs (Knopp-Sihota, Patel & Estabrooks, 2016). A randomised crossover trial examined if regular, scheduled administration of paracetamol (intervention phase) improved discomfort for people with dementia more than as-required administration of paracetamol (Buffum et al., 2004). This study found that there was no difference in discomfort score for people with dementia when taking scheduled versus as-required administration of paracetamol, despite only seven (out of 39) people taking the as-required paracetamol during the month long study period. Importantly, neither administration method of paracetamol reduced discomfort scores for people with dementia. These findings are discordant with the meta-analysis that found that analgesic medication reduced pain scores (Knopp-Sihota, Patel & Estabrooks, 2016). The discordance between these findings may be explained by the inefficacy of paracetamol to treat the pain experienced by participants. The RCTs included in the meta-analysis used a stepped analgesic treatment, meaning that the analgesic treatment in the intervention phase could escalate to opioid medications if required (Husebo et al., 2011a; Sandvik et al., 2014). However, in the study by Buffum et al. analgesic treatment was limited to paracetamol, which may not have been sufficient to reduce discomfort or demonstrate a detectable effect for people with dementia experiencing pain. These findings demonstrate the importance of individualised pain assessment and matched analgesic treatment, rather than a blanket administration of paracetamol.

2.3.6 Key findings

Each method of pain identification and assessment had its own challenges; meaning that no single method was deemed sufficient in isolation for people with dementia in the absence of self-report. Guidelines therefore recommend an individualised, multifaceted approach to pain identification and assessment, with each method comprising of a wider, comprehensive assessment (Herr et al., 2011; Pasero & McCaffery, 2011; Hadjistavropoulos et al., 2007; Horgas & Miller, 2008). Despite recommendations, the majority of research continues to

suggest that pain identification and assessment for people with dementia remains inadequate due to the complexity of the process (Chen & Lin, 2016; Corbett et al., 2012; Monroe et al., 2015), especially with increasing cognitive impairment. These findings are essential as pain identification and assessment is a precursor for optimal pain management (Godfrey, 2005).

2.4 Management of pain

The British Geriatric Society and British Pain Society collaborated to create the current UK pain management guidelines for older adults, including people with dementia (Abdulla et al., 2013). The UK guidelines, along with the current American guidelines (AGS Panel, 2009) recommend a dual approach to manage pain; using a combination of non-pharmacological and pharmacological strategies (analgesic medications). Despite recommendations, research in nursing home settings has found that a dual approach for pain was only used for 10% of people with dementia (Liu & Leung, 2016). This finding highlights a discordance between the guidance recommending dual approaches for pain treatment and the employment of approaches in practice. Alternatively, clinical pain management protocols developed for people with dementia (such as the Serial Trial Intervention; Kovach et al., 2000; Snow & Shuster, 2006) advise that non-pharmacological approaches should be attempted prior to the use of analgesic medications. In agreement with these recommendations, family caregivers of people with dementia living in care homes perceived non-pharmacological strategies as an important first step of pain management (Corbett et al., 2016). The following sections follow this guidance, by providing a sequential overview of non-pharmacological approaches, followed by pharmacological treatments for pain.

2.4.1 Non-pharmacological management

Non-pharmacological or ‘non-drug’ interventions are broadly defined as an intervention not involving drugs or medications (McDermott et al., 2018). Non-pharmacological interventions for pain may range from simple measures to improve comfort (e.g. changing sitting position, distraction techniques) to psychosocial interventions which involve physical, cognitive, or

social activities that aim to improve wellbeing and functioning (Moniz-Cook, Vernooij-Dassen, Woods, Orrell & INTERDEM Network, 2011; Pu, Moyle, Jones & Todorovic, 2019).

A review of the evidence was conducted by Abdulla et al. (2013) to inform the UK guidance on the management of pain for older adults. This review (and other reviews focused upon older adults; Park & Hughes, 2012) identified that a number of non-pharmacological strategies are effective for persistent pain (e.g. acupuncture, transcutaneous electrical nerve stimulation (TENS), and massage). However, these guidelines (as with almost all guidelines; Corbett et al., 2016) were for older adults rather than specific to people with dementia. Despite the recommendations, such non-pharmacological strategies may not be available, especially as part of the National Health Service (NHS, 2018).

Pieper et al. (2013) conducted a comprehensive overview of the current evidence regarding the effectiveness of pain interventions targeting behaviour, and behavioural interventions targeting pain for people with dementia. The review concluded that rocking chair therapy, music therapy, Reiki (a biofield therapy; direct or indirect pressure is applied to affect the energy fields; Koithan, 2009), reflexology, person-centred showering or bathing (e.g. providing choices, towels for warmth, product recommendations from family caregivers; Sloane et al., 2004), and cognitive behavioural therapy can be effective in reducing pain and discomfort for people with dementia. However, the conclusions of this review are based upon a small number of studies, many of which had small sample sizes, which limit generalisability. To illustrate, the conclusion that Reiki improved pain and discomfort was based upon one case-series study including six people with dementia (Meland, 2009); questioning the reliability of this evidence.

In line with these findings, a recent systematic review and meta-analysis investigated the effectiveness of psychosocial interventions on pain in people with dementia (Pu et al., 2018). Inclusion was restricted to RCTs, with eight low to moderate quality studies identified. Six studies focused on sensory stimulation – reflexology, massage, ear acupressure, music therapy, and person-centred showering or bathing – whereas two studies reported physical activity interventions, including Tai Chi and passive movement therapy. The meta-analysis

indicated that psychosocial interventions were beneficial for pain when assessed using a behavioural observation pain assessment. Conversely, there was no significant result found for self-reported pain. Although this systematic review provides preliminary evidence for the effectiveness of psychosocial interventions for people with dementia, alike to previous reviews (Pieper et al., 2013) there remains relatively limited high quality evidence. Most evidence to date is based on small samples meaning that the certainty of evidence is currently low. The uncertainty of evidence was illuminated as a sensitivity analysis found that the effectiveness of psychosocial interventions on pain no longer reached statistical significance when high-risk studies were omitted from the meta-analysis (Pu et al., 2018).

Since the completion of the systematic reviews discussed above, Maltais et al. (2018) conducted a 24-week cluster RCT, in which people with dementia living in a nursing home were assigned to a moderate intensity exercise program (intervention), or a social interaction group (control). The intervention group exercised twice per week, for 60 minutes (n=44). The social interaction group did not involve physical activity (n=47). Pain was assessed using the Algoplus scale (a behavioural observation rating scale), at baseline and post-intervention. Findings suggest no difference in pain score between the exercise intervention and control group at post-intervention. There may be many reasons that no difference was evident between the intervention and control group. Participants had a relatively low pain score at baseline; leaving the intervention little scope to further decrease the pain score (floor effects). Additionally, although the social interaction group was intended to act as a control group, the activities involved (e.g. music meditation, drawing alone or in groups) may have improved the perception of pain experience for people with dementia, contributing to the lack of difference between the intervention and control group.

In a recent qualitative meta-synthesis, non-drug pain management strategies were supported for people with dementia, largely due to their reluctance to use analgesic medications (Geddis-Regan et al., 2018). Non-pharmacological treatments may therefore play a role to reduce pharmacological burden (e.g. polypharmacy; defined as taking more than five prescription and over-the-counter medications at one time; Skinner, 2015). Questionnaire

studies suggest that the majority of nursing home managers (Barry et al., 2012), community pharmacists (Barry et al., 2013), and GPs (Jennings et al., 2018b) agree that non-pharmacological methods are useful in the management of pain in people with dementia (51%, 59.9%, and 82.1%, respectively). In accordance, interviews with nurses (Kovach et al., 2000), clinical nursing assistants, and family caregivers of people with dementia living in nursing homes (Mentes et al., 2004) found that they perceived a variety of non-pharmacological approaches as effective for pain, including massage, one-to-one interaction, repositioning, lying down in a quiet room, relaxation, physical therapy, exercise and distraction techniques. In contrast to the generally positive opinion towards non-drug pain treatment, qualitative research with care assistants in a care home described non-drug treatments as 'time consuming' and 'ineffective' (Petyaeva et al., 2017). Studies have also noted that dementia (depending upon the severity) may impede the ability to self-manage pain using non-drug strategies (Bunn et al., 2016). This may mean that family or formal caregivers are relied upon to engage in non-pharmacological strategies to manage pain for the person with dementia.

2.4.2 Pharmacological treatment

The most common strategy to manage pain is to use analgesic medications (defined as drugs classified within the Anatomical Therapeutic Chemical (ATC) groups N02 or M01A), however, this is also the area of greatest risk (AGS Panel, 2009). The following sections will first discuss the physiological changes associated with ageing that increase the risk of analgesic treatment (see Section 2.4.2.1), and the stepwise treatment of analgesic medication (see Section 2.4.2.2). The literature review will then discuss analgesic medication use for people with dementia living in formal settings.

2.4.2.1 Physiological changes associated with ageing

Older adults have a higher risk of side effects due to the effects of ageing on the pharmacokinetics and pharmacodynamics of medications (McLachlan et al., 2011; Abdulla et al., 2013; AGS Panel, 2009). Older adults are more heterogeneous concerning morbidity and physiology, leading to less predictable responses to medications (McLachlan et al., 2011).

Research suggests that people with dementia may have unique physiological changes, above and beyond ageing alone, increasing their risk of side effects (Reeve, Trenaman, Rockwood & Hilmer, 2017), with healthcare professionals perceiving dementia as an additional risk factor for analgesic treatment (Jennings et al., 2018b). People with dementia are often excluded from medication trials meaning that safe and effective analgesic dosage regimes are often unknown (Erdal, Ballard, Vahia & Husebo, 2019). The specific side effects associated with each therapeutic classification of analgesic medication are discussed later in this chapter.

As the population ages, the proportion of people with dementia and comorbidity increases (Bunn et al., 2016). In the UK, people with dementia have, on average, 4.6 comorbidities in addition to dementia, many of which require pharmacological treatment (Guthrie et al., 2012; Piccirillo et al., 2008). Comorbid conditions or their associated pharmacological treatments may contraindicate the use of analgesic medications. The amount of medications being taken by the person with dementia (due to their comorbidities) was perceived as a barrier to taking additional medications (Mentes et al., 2004; Kaasalainen et al., 2007). Research suggests that older adults accept pain because it is tolerable and not life threatening, with other 'more important' medications taking priority (Sale, Gignac & Hawker, 2006; Makris et al., 2015). This aligns with the perception of pain as a 'lower priority' condition, as described in section 2.3.1.

Physiological changes associated with ageing (including side effects and comorbidities), along with the additional challenge of cognitive impairment means that pain management is perceived as complex and restricted for people with dementia (Corbett et al., 2016; Griffioen, Husebø, Achterberg, Willems & Husebo, 2017a). Despite the challenge, in qualitative research, healthcare professionals emphasised the importance of balancing the benefits of pain relief against the potential negatives (e.g. side effects) when prescribing analgesics to people with dementia (Kaasalainen et al., 2007), in line with NICE (2018) guidelines.

2.4.2.2 Stepwise treatment

In 1986, the WHO developed a model for the slow introduction, and titration of analgesic medication (Ventafridda & Stjernsward, 1996). The model was developed to guide analgesic treatments for people with cancer (WHO, 1996). This model was named the 'WHO analgesic pain stepladder' (see Figure 2.1). The principle of this model included the slow incremental increase of analgesic medication, starting at simple non-opioid analgesics, with a progression to weak opioids, and then strong opioids guided by the patient's pain experience. Although originally developed for cancer pain, the model has been widely adopted for persistent pain. In recent years, however, the use of the WHO analgesic pain stepladder for persistent pain has been criticised, as total alleviation from pain is often unrealistic (AGS Panel, 2009; Ballantyne, Kalso & Stannard, 2016). Therefore, escalation of analgesic medicating in line with pain intensity may lead to inappropriate prescribing for persistent pain (NICE, 2017).

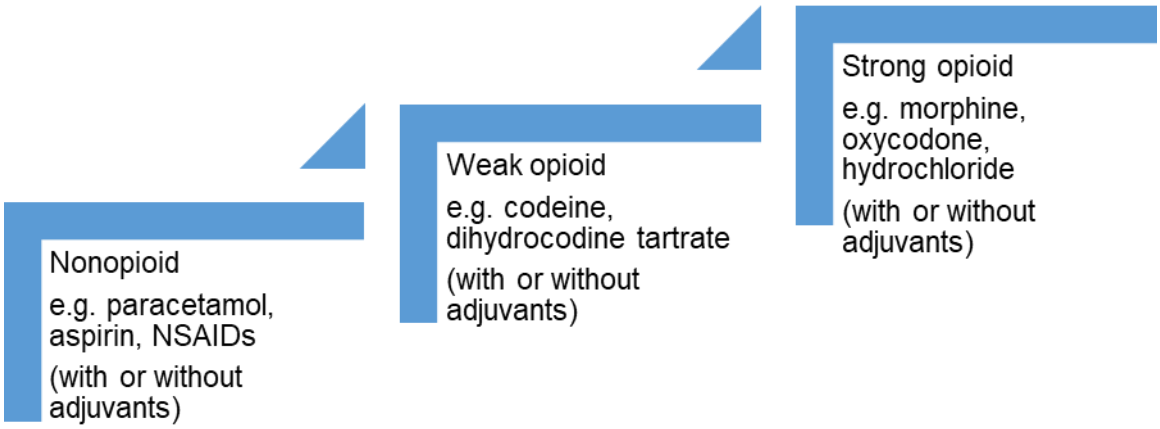


Figure 2.1. World Health Organisation (WHO) Analgesic Stepladder

In line with the WHO analgesic pain stepladder, current management guidelines for persistent pain for older adults recommend the slow upwards titration of analgesic medication with frequent reassessment to adjust dosage and to determine optimum pain relief with minimal side effects (AGS Panel, 2009; Abdulla et al., 2013; NICE, 2018). This is especially recommended for older adults due to the physiological changes associated with ageing altering the efficacy, sensitivity, and toxicity of analgesic medication (see Section 2.4.2.1; AGS Panel, 2009).

The preference towards a stepped approach to analgesic treatment is observed in many studies, with the majority of nursing home managers (Barry et al., 2012) and community pharmacists (Barry et al., 2013) included in a questionnaire study agreeing that analgesic medications should follow a stepped approach. Interviews (Kovach et al., 2000) and focus groups (Kaasalainen et al., 2007) with nurses, and interviews with physicians (Kaasalainen et al., 2007) found a preference towards the systematic escalation of analgesic medications, describing their approach using the phrase: 'start low and go slow'. However, nurses participating in the interview study by Kovach et al. had received 'extensive education in pain management' one year before the interviews. Nurses included in this study may have an increased knowledge and understanding of pain management for people with dementia that may not be transferable to the wider nurse population. Despite the perceived positives of the 'start low and go slow' approach to pain management, Hanlon, Backonja, Weiner and Argoff, (2009) highlighted that this risk management strategy is often misinterpreted as 'start low and *stay* low' leading to potentially inadequate pain relief as an attempt to minimise risk.

2.4.2.3 Analgesic medications

This section of the literature review provides an overview of analgesic use and prescription as a whole - irrespective of the type or strength of the analgesic. A systematic review conducted by La Frenais and colleagues (2017), along with evidence published since the completion of the review (Hemmingsson et al., 2017) found that the prevalence of analgesic prescription incrementally increased in nursing and residential home settings from 1995 to 2015, many of which included a significant dementia population. Only one study in this systematic review examined the temporal trend of analgesic prescription, stratifying the sample into people with and without dementia living in nursing homes (Sandvik, Selbaek, Kirkevold, Husebo & Aarsland, 2016). People with dementia were prescribed less analgesic medication compared to older adults without dementia in 2000, 2004, and 2009 (p=0.002; p=0.008; p=0.002, respectively). However, there was no difference in analgesic prescription between older adults with and without dementia in the later year of 2011. These findings may indicate that in recent years, the prevalence of analgesic prescription in nursing home

settings has increased for people with dementia, in line with people without dementia. This study used a series of cross-sectional time points to investigate the temporal pattern of analgesic prescription. This method meant that the samples obtained at each time point were not the same, and in fact differed significantly concerning a number of demographic characteristics. The difference between samples may influence analgesic prescription, thus hinder the comparability of findings over time.

When comparing the prevalence of analgesic prescription in nursing home settings, a systematic review and meta-analysis found that the overall prevalence of analgesic use in people with and without dementia ranged from 20.2% to 61.2% and 38.8% to 79.6%, respectively (Tan et al., 2015). Meta-analysis revealed that people with dementia had a significantly lower analgesic prevalence compared to people without dementia (OR 0.58, 95% CI 0.41 to 0.82, p=0.002) (Tan et al., 2015). In line with these findings, Hoffmann, van den Bussche, Wiese, Glaeske and Kaduszkiewicz (2014) found that people with dementia were prescribed significantly less analgesics than age and sex matched older adults during the first year following dementia diagnosis (adjusted OR 0.78, 95% CI 0.68 to 0.88). In the Hoffman et al. study, paracetamol was not included as it was only available over-the-counter. Paracetamol is often the first-line treatment for musculoskeletal pain, and the preferred treatment for pain relief due to the good safety profile of the drug (see Section 2.4.2.4). The lack of inclusion of paracetamol may therefore influence the interpretation of these findings. Regardless, these findings question if people with dementia are inadequately treated for their pain.

The potential under treatment of pain for people with dementia is reiterated as other studies identified that 34.2% to 38.4% of people with dementia in nursing homes did not receive an analgesic medication despite experiencing pain (Griffioen, Husebo, Flo, Caljouw & Achterberg, 2017b; de Souto Barreto, Lapeyre-Mestre, Vellas & Rolland, 2013). This percentage was higher than people without dementia, in which only 23% experiencing pain were not prescribed an analgesic medication (de Souto Barreto et al., 2013). In line with these findings, Hunnicutt, Ulbricht, Tjia and Lapane (2017) examined pain and

pharmacological pain treatments for 1,387,405 long-stay nursing home residents in the United States. This study found that people with severe cognitive impairment had an increased prevalence of untreated and undertreated pain compared to people with no/mild cognitive impairment. These findings appear to show that cognitive impairment (because of dementia) may be a potential barrier to adequate pain treatment. This evidence is in accordance with older studies also concluding that people with dementia are under treated for their pain (Horgas & Tsai, 1998).

However, in discordance with the findings above, recent evidence indicates that people with and without dementia in nursing home settings were prescribed a similar amount of analgesic medication (Tan et al., 2016; Nakashima et al., 2019). However, Nakashima et al. found that people with dementia received fewer as-required analgesic medications than people without dementia. This discordance may again reflect that analgesic prescription for people with dementia has increased in nursing home settings, in line with people without dementia, but highlights that people with dementia may be suboptimally treated for their pain due to the lower administration of as-required analgesic medication.

It is important to acknowledge that many of the studies investigating the prevalence of analgesic prescription are cross-sectional (Tan et al., 2015; Tan et al., 2016), or have a limited follow up period (i.e. one year; Hoffmann et al., 2014). These current approaches do not allow for the investigation of analgesic prescriptions throughout the course of dementia progression, and do not report on the prevalence of analgesic prescription stratified by different levels of cognitive impairment. Therefore, these studies do not examine increasing cognitive impairment and the potential effects this has on analgesic prescription.

That said, a small number of studies have investigated analgesic prescription for people with dementia with varying severities of cognitive impairment. Studies have found that the prevalence of analgesic prescription incrementally lowered with increasing cognitive impairment (Neumann-Podczaska et al., 2016; Cornali, Franzoni, Gatti & Trabucchi, 2006; Bauer et al., 2016), with people with dementia that could no longer verbally communicate receiving even fewer analgesic medications (Bauer et al., 2016). Such findings show that the

symptoms associated with increased severity of cognitive impairment (such as lowered communicative ability) may not only act as a barrier to pain identification and assessment, but also limit the person with dementia's ability to express their unmet need for pain relief (Corbett et al., 2016). It is important to consider that the stratification of participants (often by MMSE score) in each of these studies led to small samples within each stratum. For example, in the study by Cornali et al. (2006) only 17 participants contributed to the MMSE 0 to 12 strata. The small samples reduce confidence in the findings.

2.4.2.4 Paracetamol

Paracetamol is a simple non-opioid analgesic medication. Recommendations unequivocally highlight paracetamol as the first-line treatment for many painful conditions due to the 'good safety profile' with minimal side effects and contraindications for older adults (AGS Panel, 2009; Abdulla et al., 2013; McLachlan et al., 2011; Zhang et al., 2008; Jordan et al., 2003; NICE, 2015; Erdal et al., 2019; Girard, Sourdet, Cantet, de Souto Barreto & Rolland, 2019). However, recent studies have called the safety of paracetamol into question. A systematic review and meta-analysis of observational data found that paracetamol was associated with an increased number of cardiovascular and gastrointestinal adverse events, renal impairment, and mortality (Roberts et al., 2016). In recent years, NICE guidelines have also questioned the effectiveness of paracetamol to treat the pain caused by osteoarthritis (Wise, 2014; NICE, 2014) and low back pain (NICE, 2016; Saragiotto et al., 2016). Despite concerns, paracetamol remains the most commonly prescribed analgesic for nursing home residents with and without dementia (McLachlan et al., 2011; La Frenais et al., 2017; Hemmingsson et al., 2017; Rajkumar et al., 2017).

The prevalence of paracetamol use ranges from 45.2% to 71.0% for people with dementia in nursing home settings (Tan et al., 2015; Tan et al., 2016), with an increasing temporal trend of paracetamol from 1995 to 2015 for nursing home residents, many of which had dementia (La Frenais et al., 2017). When comparing paracetamol for nursing home residents with and without dementia, a systematic review found that people with dementia were more likely to use paracetamol than people without dementia (Tan et al., 2015). This finding has also been

identified for people with and without dementia living in a variety of settings (including nursing and residential homes, and in their own homes; Lövheim, Karlsson & Gustafson, 2008). Additional studies since the completion of the systematic review (Tan et al., 2015) indicate no significant difference between the prevalence of paracetamol use for people with and without dementia (Tan et al., 2016; Bauer et al., 2016). Although these findings indicate that a similar, if not greater proportion of people with dementia use paracetamol in nursing home settings, many epidemiological studies were unable to capture over-the-counter medications (Tan et al., 2015). This requires consideration as paracetamol is commonly obtained over-the-counter (Hoffmann et al., 2014; Mentes et al., 2004). Therefore, it is important to remain mindful that these prevalence estimates may minimise the true extent of paracetamol use for people with and without dementia.

Studies also investigated the prevalence of paracetamol use in nursing home residents, stratified by MMSE score (Bauer et al., 2016; Cornali et al., 2006). Both studies found that the prevalence of paracetamol remained stable, or increased in line with increasing cognitive impairment. These findings may reflect attempts to provide adequate pain relief for people with dementia using an analgesic with a good safety profile.

In a qualitative study using semi-structured interviews to generate data, nurses perceived paracetamol as the analgesic of choice for mild-to-moderate pain, reflecting upon the low side effect profile for older adults (Kovach et al., 2000). The preference towards paracetamol for these reasons may explain the similar prevalence estimates for people with and without dementia. However, a questionnaire study with GPs (Jennings et al., 2018b), community pharmacists (Barry et al., 2013), and nursing home managers (Barry et al., 2012) found that many respondents neither agreed nor disagreed that ‘paracetamol is the best analgesic to use in people with dementia who are experiencing chronic pain’ (27.3%, 46.2%, 29.2%, respectively). These findings suggest that despite the preference towards paracetamol, many healthcare professionals are not convinced that paracetamol is *always* the best analgesic of choice. This may reflect the recent debates regarding the efficacy and safety of long-term

paracetamol use for persistent pain (Roberts et al., 2016; NICE, 2016; Saragiotto et al., 2016).

2.4.2.5 Non-steroidal anti-inflammatory drugs

Non-steroidal anti-inflammatory drugs (NSAIDs) are valuable agents in the treatment of painful musculoskeletal conditions, due to their analgesic and anti-inflammatory properties. NSAIDs include ibuprofen, naproxen, and diclofenac. Older adults are at higher risk of NSAID related side effects (e.g. gastrointestinal, renal, and cardiovascular side effects) than adults of working age, with numerous absolute and relative contraindications to consider (AGS Panel, 2009). Recommendations suggest that NSAIDs should be considered rarely for older adults, and only if alternative therapies (i.e. non-pharmacological approaches and paracetamol) have failed to relieve pain (AGS Panel, 2009; Abdulla et al., 2013; McLachlan et al., 2011). Qualitative research with nursing assistants highlighted their concern relating to NSAID side effects for people with dementia, including possible bleeding problems and stomach upset (Kovach et al., 2000).

A systematic review of cross-sectional studies (Tan et al., 2015), and cross-sectional studies conducted since the completion of the review (Tan et al., 2016; Bauer et al., 2016) have found that the prevalence of oral NSAID use ranges from 2.0% to 25.1% for people with dementia in nursing homes. When examining the temporal pattern of NSAID prescription, the prevalence lowered over time for nursing home residents (a large percentage of which had dementia), with a reduction from 6.8% in 2000 to 3.2% in 2011 (Sandvik et al., 2016), and 4.7% in 2007 to 3.6% in 2013 (Hemmingsson et al., 2017). In nursing home and assisted living settings, the prevalence lowered from 13.0% in 2003 to 2.6% in 2011 (Pitkala et al., 2015). These findings reflect the repeated national guidelines advising that NSAID use is reduced due to the complications associated with NSAIDs, especially for older adults (NICE, 2015; AGS Panel, 2009; Abdulla et al., 2013; McLachlan et al., 2011; Cavalieri, 2007; MHRA, 2015; Bedson et al., 2013).

In nursing home settings, people with dementia had a lower prevalence of oral NSAID prescription than people without dementia (2% vs. 3.9% de Souto Barreto et al., 2013; 2.4%

vs. 4.7% Tan et al., 2016). However, in multivariable analysis, following statistical adjustment, Haasum, Fastbom, Fratiglioni, Kareholt and Johnell (2011) found no difference between NSAID use for people with and without dementia in nursing home settings (adjusted OR 0.41, 95% CI 0.15 to 1.11).

Studies also investigated the prevalence of NSAID use, stratified by MMSE score (Bauer et al., 2016; Neumann-Podczaska et al., 2016). Both studies found that the prevalence of NSAID prescription lowered with increasing cognitive impairment. Additionally, Bauer et al. found that when further stratifying people with cognitive impairment based upon their ability to verbally communicate (verbal and non-verbal), 28.9% of the cognitively impaired but verbal group, and 18.4% of the cognitively impaired but non-verbal group used NSAIDs. These studies suggest that NSAID use lowered in line with increased cognitive impairment, with the suggestion that limited verbal communication may act as a potential barrier to NSAID use.

2.4.2.6 Opioids

Opioid narcotic drugs are typically advocated for the effective treatment of acute pain (i.e. following injury or surgery), at the end of life, and for cancer-related pain. Opioids sit at the top of the WHO analgesic stepladder (see Figure 2.1). Opioids include Morphine, Fentanyl, and Oxycodone. In recent years, opioids have been recommended for persistent non-cancer pain if the pain is causing functional impairment or reducing quality of life (Abdulla et al., 2013). In persistent pain, it is recommended that opioids should be prescribed to older adults on a trial basis with clearly defined therapeutic goals (AGS Panel, 2009). This is despite research highlighting the limited efficacy of opioids to treat persistent pain (NICE, 2017; Noble et al., 2010). In addition to the limited efficacy, the potential harms of opioids for older adults have been well documented (AGS Panel, 2002; Abdulla et al., 2013; McLachlan et al., 2011). Opioids are associated with addiction, dependence, self-poisoning, confusion, gastrointestinal problems, daytime sedation, delirium, constipation, and falls for older adults (McLachlan et al., 2011; Tannenbaum, Paquette, Hilmer, Holroyd-Leduc & Carnahan, 2012; Clegg & Young, 2010). The potential side effects associated with opioids means that patients

should be regularly monitored to explore therapeutic goals, side effects, and safe and responsible medication use (AGS Panel, 2009).

The prevalence of opioid use for people with dementia ranges from 13.8% to 30.1% (Tan et al., 2015; Tan et al., 2016). A systematic review identified 10 studies investigating the temporal pattern of opioid prescriptions for older adults (including people with dementia) in nursing home settings (La Frenais et al., 2017). This review found an increasing trend of opioid use from 1995 to 2015 (La Frenais et al., 2017). Since the completion of this review, studies continue to identify an increase prevalence of opioid use over time (from 2007 to 2013) (Hemmingsson et al., 2017) for nursing home residents, a large percentage of which have dementia. A number of reasons may contribute to this increase:

1. The epidemiological investigation of opioid use throughout this period (1995 to 2015) has found an increasing trend of prescriptions generally; often referred to as the 'opioid epidemic' (Manchikanti et al., 2012; Basler, 2017).
2. Studies that found NSAID use to be steadily decreasing over time also found an increase of opioid use over time (Sandvik et al., 2016; Hemmingsson et al., 2017; Pitkala et al., 2015). Such findings suggest that healthcare professionals may be increasingly cautious of NSAIDs (and their side effects; see Section 2.4.2.1), and may prescribe opioids as an alternative.
3. The introduction of transdermal analgesic patches (e.g. buprenorphine and fentanyl) may have contributed to the use of strong opioids for people with dementia. The reasons healthcare professionals may use transdermal patches for people with dementia is multifaceted, including the perception that they are associated with a lower risk of side effects (such as constipation), and ease of administration and adherence, especially for people with dementia. Despite their use, research has highlighted that transdermal patches are not well tolerated by people with dementia (Erdal et al., 2018).

A recent systematic review examined opioid prescription rates for people with and without dementia, irrespective of residential setting (Griffioen et al., 2017a). In total, 21 studies (out

of the total 24 identified, 87.5%) found that people with dementia use equal or less opioids than people without dementia. This review therefore concluded that people with dementia often have a lower use of opioids than people without dementia. None of the studies included in this review used a pain rating scale validated for people with dementia, therefore, it cannot be determined if the lower prevalence of opioid use truly reflects pain 'under treatment'.

A number of qualitative studies support these findings, with a recent meta-review suggesting that the side effects associated with opioids caused concern when treating the pain experienced by people with dementia (Geddis-Regan et al., 2018). The fear and concern of causing harm increased healthcare professionals' reluctance to prescribe opioids to older adults (Spitz et al., 2011), with dementia being perceived as an additional complexity or 'risk factor' (Chang et al., 2009; Manias, 2012). Additionally, interviews with nursing home staff indicated a resistance (from family members, nurses, and care workers) for opioids to be used even when they are prescribed to the person with dementia (Peisah, Weaver, Wong & Strukovski, 2014). Resistance towards opioid medications remained even when alternative treatments (e.g. paracetamol) were not effective (Martin et al., 2005). These findings reflect the 'negative social stigma' towards opioid medications for people with dementia due to their potential harm (AGS Panel, 2009).

2.4.3 Key findings

This section of the literature review provided a critical summary of the evidence examining pain management for people with dementia, with a focus largely upon nursing home settings. Overall, the evidence concerning the management of pain for people with dementia has shown that there is limited high quality evidence investigating non-pharmacological approaches. Qualitative evidence, however, suggests that non-drug treatments are often viewed positively for people with dementia. Concerning pharmacological treatment, the temporal trend of analgesic use increased over time, however people with dementia continued to receive/use less analgesic medication than people without dementia. An increasing temporal trend was also evident for paracetamol use, with evidence suggesting that people with dementia used similar, if not more paracetamol than people without

dementia. This finding reflects the preference towards paracetamol due to its 'good safety profile' for older adults. Conversely, NSAID use lowered over time, with people with dementia having a lower prevalence of NSAID use compared to people without dementia. These findings reflect the repeated national guidelines to reduce NSAID prescribing, and the perceived caution surrounding NSAIDs due to their side effects for older adults. Finally, there was a general increasing temporal trend of opioid use in nursing homes, in line with the increasing prescription of opioids worldwide. Irrespective of this increasing trend, people with dementia used less opioids than people without dementia, highlighting the potential caution surrounding the side effects associated with opioids.

2.5 Additional barriers to pain management

The barriers to adequate pain identification, assessment, and management were outlined at the start of this chapter, in Table 2.1. Many of these barriers have been integrated and discussed throughout this chapter due to their close association with particular pain identification/assessment or management strategies. Barriers discussed so far include communication difficulties (see Section 2.3.1), lack of recognition or misdiagnosis of pain (see Section 2.3.3.2), stoical attitudes (see Section 2.3.1), lack of familiarity (or *relationship continuity*) (see Section 2.3.4), and the physiological changes associated with ageing (see Section 2.4.2.1). The following sections will provide an overview of additional barriers to pain identification, assessment, and management for people with dementia that could not be integrated during the review, including time pressures (see Section 2.5.1) and training, guidance, expertise and support (see Section 2.5.2).

2.5.1 Time pressures

Time is precious in healthcare settings, with a traditional 10-minute consultation model in UK general practice (The Royal College of General Practitioners, 2019). An in-depth assessment of pain using a multidimensional approach is often timely, especially with people with dementia where additional time and flexibility may be required to conduct an assessment (Chang et al., 2009). In a European survey, including healthcare professionals working in hospital settings, care home, and primary care settings, many respondents viewed

insufficient time as a key barrier to adequate pain identification and assessment for people with dementia (Zwakhalen et al., 2018).

2.5.2 Training, guidance, expertise, and support

The majority of nursing home managers (63.5%) had not received any recent training on pain in people with dementia (Barry et al., 2012), with the vast majority of community pharmacists also not receiving training in dementia (95.6%) or pain (93.4%) (Barry et al., 2013). In a questionnaire study across 13 care homes, the majority of nurses (66%) were unaware of any formal education programs exploring pain management for people with dementia that were adequate for their needs (Neville, McCarthy, Laurent, Creedy & Walker, 2006). In a cross European survey of healthcare professionals, respondents reported a lack of guidance, training, expertise, and awareness to adequately assess pain (Zwakhalen et al., 2018). In accordance with these survey/questionnaire studies, qualitative interviews with nurses in nursing home settings found that discomfort for people with dementia was not taught to them during their nursing training, with many conceptualising pain assessment as a 'guessing game' (Kovach et al., 2000; Dobbs, Baker, Carrion, Vongxaiburana & Hyer, 2014). Each of these findings highlight the gap in training, guidance and expertise for healthcare professionals; potentially contributing to the inadequate pain identification and assessment for people with dementia.

Not only is training, guidance, and support essential for healthcare professionals to adequately identify and assess pain for people with dementia, but also for family caregivers. In a study by Maidment, Aston, Moutela, Fox and Hilton (2017) people with dementia and their family caregivers expressed their need for support to manage the person with dementia's medications, especially as many family caregivers had their own comorbidities and medications to manage. Unlike all other qualitative studies discussed in this literature review, this research allowed people with dementia to contribute their perspective as part of a dyadic interview. However, this study focused upon 'medication management' generally, and therefore did not uncover their unique perspectives and experiences of pain management.

2.6 Conclusion

This literature review provided an overview of pain identification, assessment, and management for people with dementia, with a particular focus primarily on nursing home settings as currently this is where the majority of research has been based. Overall, pain identification and assessment seems inadequate for people with dementia within nursing home settings. Evidence also suggests that, on a whole, people with dementia seem to receive suboptimal pain treatment, with limited research investigating non-drug strategies for people with dementia. The following chapter continues to build upon the findings of this literature review; narrowing the focus to pain assessment and treatment for community-dwelling people with dementia.

3 Chapter Three: Systematic Review

3.1 Introduction

The previous chapter provided an overview of the large body of published literature examining pain identification, assessment and treatment for people with dementia living in nursing home settings. This research often found that people with dementia are suboptimally assessed and treated for their pain when compared to people without dementia.

Despite evidence that people with dementia may be underserved in terms of pain (assessment, treatment) compared to people without dementia, randomised controlled trials (RCTs) in nursing home settings provide evidence that a stepped analgesic treatment can lead to a reduction in a range of behavioural and psychological symptoms (see Section 1.2.3). Whilst evidence shows the benefits of assessment and treatment of pain for people with dementia, the focus of such research has been largely restricted to nursing home, hospital, and palliative settings, despite upwards of 60% of people with dementia living in the community in the UK (Prince et al., 2014). To date, a number of reviews (Corbett et al., 2012; Schofield et al., 2005; Stolee et al., 2005; Herr et al., 2006a; Smith, 2005; Park, Castellanos-Brown & Belcher, 2010; Ng et al., 2012; While & Jocelyn, 2009) and a meta-review (Lichtner et al., 2014; Closs et al., 2016) have examined pain assessment and/or pain treatment for people with dementia. However, previous reviews have not taken account of the residential setting of the person with dementia, and the influence this may have on findings. Many of the reviews almost exclusively focus on people with dementia that can no longer verbally communicate their pain (Herr et al., 2006a; Smith; Park et al., 2010), or assessed observational pain tools specifically (Ng et al., 2012; Closs et al., 2016).

Despite the abundance of systematic reviews, there has yet been a review to investigate pain assessment and pain treatment for people with dementia living in community settings. This highlights a significant knowledge gap in understanding the needs of community-dwelling people with dementia. People with dementia living in the community have greater diversity in the capacity to self-report their pain; differences may exist in informant reports

from family caregivers compared to formal caregivers who may have professional training in pain assessment. Finally, access to healthcare professionals may be different for people with dementia living in the community compared to people living in nursing home settings. This chapter builds upon the existing knowledge of pain assessment and pain treatment for people with dementia gained from the literature review, but narrowing the focus to people living in the community. An adapted version of this chapter has recently been published (Bullock et al., 2019).

3.2 An overview of systematic reviews

Systematic reviews summarise large bodies of evidence endorsing systematic strategies to limit bias, critically appraise, and to synthesise evidence to answer a specific research question (Cook, Mulrow & Haynes, 1997). Systematic reviews allow researchers, clinicians, consumers, and policy makers to keep up to date with the current evidence in their field without the need to allocate the time and resources to find, appraise, and interpret a large amount of primary research evidence (Higgins & Green, 2011). As a result, systematic reviews have become increasingly important in healthcare research (Moher, Liberati, Tetzlaff & Altman, 2010) to inform and influence healthcare management and policy making (Lavis, Posada, Haines & Osei, 2004).

3.2.1 Strengths and limitations of systematic reviews

By using replicable and transparent methods, an objective appraisal of the evidence means that potential biases can be minimised (Egger, Davey-Smith & Altman, 2001). Systematic strategies can identify, tabulate, and integrate evidence objectively, meaning that potential conflicts and disagreements between individual research papers are resolved (Egger et al., 2001). Systematic reviews have the potential to identify gaps in the literature and methodological flaws to develop future research and intervention. When collating evidence for a systematic review and thus making the research evidence more accessible for a larger audience, the likelihood of unnecessary replication of research is minimised.

Despite the strengths of systematic reviews, it is also important to acknowledge the potential limitations associated with their conduct and interpretation. Systematic reviews often answer a relatively narrow question, with a primary focus on the extraction, tabulation and summation of empirical data. The narrow focus may limit the inclusion of relevant and informative evidence (Greenhalgh et al., 2018). To overcome this limitation, a narrative literature review was also conducted to provide a broader summary of the relevant literature with interpretation and critique (see Chapter Two). Furthermore, a critical phase of a systematic review is to conduct a 'comprehensive search strategy with the ability to identify all studies applicable for the review' (Higgins & Green, 2011), however this may be time consuming due to the high sensitivity of the screening strategies. The quality of the systematic review itself can be compromised by the inclusion of low quality papers leading to inaccurate conclusions. In addition, prior knowledge of the research field may influence alterations to the inclusion and exclusion criteria during the protocol development stages of the systematic review, leading to increased bias.

3.3 Aim of the systematic review

This review aims to provide a broad overview of the current literature examining pain assessment and pain treatment for community-dwelling people with dementia. Specific objectives of the systematic review were to:

- Synthesise the evidence on the use of pain assessment tools and methods, and assess their utility for community-dwelling people with dementia
- Synthesise the evidence on the use of pain treatments and evidence of efficacy for community-dwelling people with dementia

3.4 Methods

3.4.1 Search strategy

I created a comprehensive search strategy with oversight from my supervisory team (PC, JB) and members of the systematic review team (JJ) within the School of Primary, Community and Social Care.

The search strategy was initially created and piloted using MEDLINE Ovid. Search terms were obtained from existing search strategies from systematic reviews in the field (see Section 3.1), with additional terms added as appropriate. The search strategy contained five filters, each of which included subject headings (e.g. MeSH headings), title and abstract in-text terms (see Table 3.1).

The search strategy was created to be highly sensitive. In this context, sensitivity refers to a 'search's ability to correctly identify relevant articles' (Higgins & Green, 2011). By using a highly sensitive and comprehensive search strategy in a number of medical and psychological databases with overlapping content, precision may be reduced. In this context, precision is defined as the amount 'of relevant articles identified by a search strategy' (Higgins & Green, 2011). A highly sensitive, yet low precision search strategy increased the amount of time taken to remove irrelevant and duplicate texts, however minimised the likelihood of missing potentially relevant articles (Montori, Wilczynski, Morgan & Haynes, 2005).

Table 3.1. Example of MEDLINE Ovid Search Filters and Terms

Search Filter	Example* of search terms
Dementia	exp Dementia/ dement*.ti,ab. (cognitive* adj3 impair*).ti,ab. Alzheimer*.ti,ab. lewy* bod*.ti,ab. pick* disease.ti,ab. creutzfeldt.ti,ab. huntington*.ti,ab. binswanger*.ti,ab. Wernicke Korsakoff.ti,ab.
	AND
Community	exp Primary Health Care/ exp General Practitioners/ exp Community Health Services/ communit*.ti,ab. community?dwelling.ti,ab. domestic.ti,ab. (home adj3 dwelling).ti,ab. general practi*.ti,ab. family practi*.ti,ab. family doctor.ti,ab. GP.ti,ab. GPs.ti,ab. doctor*.ti,ab. outpatient*.ti,ab.
	AND
Pain	exp Pain/ discomfort.ti,ab. nociception.ti,ab. pain*.ti,ab.
	AND
Pain assessment	(pain adj3 tool).ti,ab. (rating adj3 pain).ti,ab. (scale* adj3 pain).ti,ab. (measur* adj3 pain).ti,ab. (assess* adj3 pain).ti,ab. (pain adj3 behavio?r).ti,ab. (observat* adj3 pain).ti,ab. (identif* adj3 pain).ti,ab.
	OR
Pharmacological	exp Analgesics/ analgesi*.ti,ab. drug*.ti,ab. ('drug*' adj3 'trial').ti,ab. medication*.ti,ab. prescription*.ti,ab. pharmacolog*.ti,ab. ('pain' adj3 'manag*').ti,ab. assess*.ti,ab. treat*.ti,ab. opioid*.ti,ab. paracetamol.ti,ab. acetaminophen.ti,ab. tylenol.ti,ab. panadol.ti,ab. NSAIDS.ti,ab.
	OR
Non-pharmacological	exp Exercise/ exp Cognitive Therapy/ therap*.ti,ab. non?pharmacol*.ti,ab. physiotherap*.ti,ab. rehabilitation.ti,ab. aromatherap*.ti,ab. art therap*.ti,ab. acoustic stimulation.ti,ab. (colo?r adj3 therap*).ti,ab. music.ti,ab. (play adj3 therap*).ti,ab. movement.ti,ab. role play.ti,ab. tai chi.ti,ab.

*Full MEDLINE search strategy available in Appendix 1.

After the search strategy was piloted in MEDLINE, a mapping exercise was conducted to determine the most appropriate MeSH headings for each database. In addition, wildcard (a symbol that is added towards the end of a word; e.g. therap* would search for therapy or therapies) and truncation symbols (a symbol that replaces or represents a single character; e.g. colo?r would search for colour and color) were adapted depending upon the interface. After adaptation of the search strategy, eight databases were searched; MEDLINE, EMBASE, AMED (Allied & Complementary Medicine Database), AgeLine, CINAHL, PsycINFO, Web of Science Core Collection, and The Cochrane Library.

3.4.2 Additional searches

In addition to database searches, I conducted further supplementary searches. The reference lists of the eligible papers, relevant commentaries, literature reviews, and systematic reviews were hand screened. Finally, a citation search of all included papers were tracked to ascertain subsequent potential publications, as well as searching the publications of researchers publishing in the area of dementia and pain. These additional searches reduced the chance of missing potentially relevant papers.

3.4.3 Criteria for considering studies for this review

3.4.3.1 Inclusion

All full text peer-reviewed scientific journal articles were eligible for inclusion, irrespective of study design or publication date. Studies were eligible if they were published in English or other languages translatable via colleagues at the School of Primary, Community and Social Care.

Study population

- Study participants must have a diagnosis of dementia. The term ‘cognitive impairment’ or a cognitive assessment score (e.g. MMSE) was not deemed as a sufficient indication of dementia in isolation (see Section 1.5; Neumann-Podczaska et al., 2016).

- People with dementia must live in private residences or non-nursing home settings (Hunt et al., 2015). This includes living in their own home alone, with family members, in an assisted living facility, retirement community, or residential home (Prince et al., 2014; Hunt et al., 2015; see Section 1.7).
    - If a study included people with dementia living in a variety of settings, the findings specific to people with dementia living in the community were extracted independently where possible.

Issue of interest

- Studies examining pain assessment; including self-report, informant report, and behavioural observation pain tools and methods (Cohen-Mansfield & Lipson, 2008)
- Studies examining pharmacological and non-pharmacological treatments for pain
- Studies evaluating the effectiveness of pharmacological or non-pharmacological treatments for pain by using a pain-specific assessment tool

Comparison group

The presence, absence, or type of comparison group depends upon the study design. Examples of comparison groups may include:

- Older adults without a diagnosis of dementia residing in the community
- Older adults with dementia residing in an alternative setting (e.g. nursing homes).

3.4.3.2 Exclusion

- Studies solely focused on malignant pain. Cancer pain is distinctly different from persistent pain (Shega, Hougham, Stocking, Cox-Hayley & Sachs, 2006), and therefore beyond the realm of the present review.

3.4.4 Screening of texts

All identified texts were exported into RefWorks, where exact and close duplicates were checked for accuracy and removed. All remaining texts were exported into an excel

document to complete title and abstract screening, and to record whether the article was eligible or ineligible for the review, the reason for exclusion, and to provide comments.

- I completed title screening to remove obviously irrelevant references
- I completed abstract screening, with 20% of the abstracts blind screened independently by PC with good interrater agreement (>95%)

After abstract screening, the references eligible for full text screening were retrieved where possible. I contacted the author to request access if full text articles could not be obtained. Full text articles were managed in Mendeley Reference Manager Software. This software had the ability to attach PDF documents, make in text notes, and write comments. To accompany the Mendeley Reference Manager Software, an excel document was used to record whether the article was eligible or ineligible for the review, reason for exclusion, and to provide comments. I completed full text screening, with 20% of the full text articles blind screened independently by PC with good interrater agreement (>95%).

If at any point throughout the screening process discrepancies, disagreement, or uncertainty arose regarding the eligibility of references, a third independent reviewer (JB) was employed to aid consensus prior to a final decision.

3.4.5 Data extraction

I completed data extraction, which was checked for consistency and accuracy by two independent reviewers (PC and JB). Data were extracted onto a standardised data extraction form. The extracted data included bibliographic information (author, date, journal, country of origin), participant characteristics (sample size, the type and stage of dementia), and information regarding the pain assessment and pain treatments (e.g. the pain assessment tool used, the prevalence of analgesics). If further information or clarification was required, I contacted the author of the paper.

3.4.6 Quality appraisal

Quality assessment is an integral element of the systematic review process to determine each paper's susceptibility to bias. To assess the quality of papers in this review, the National Institute of Health (NIH) toolkit was used (National Heart, Lung, and Blood Institute, 2014). The NIH tools were developed by researchers from the Agency for Healthcare Research and Quality Evidence-Based Practice Centres, the Cochrane Collaboration, and the National Health Service Centre for Reviews and Dissemination, as well as methodologists and experts in the field. Guidance documents were created to provide detailed descriptions, and applications of each assessment item to assist reviewers to focus on the concepts, questions, and domains that are integral for the critical appraisal and evaluation of internal validity.

The NIH toolkit was chosen for numerous reasons. Firstly, despite the exploratory nature of this review, no eligible qualitative studies were identified that included participants with dementia living in the community. Therefore, all eligible studies were quantitative in nature, including case-control, observational cohort, cross-sectional, controlled intervention, pre-post studies with no control group, and ABAB within subject designs. At the time of conducting the review, there was no obvious 'gold standard' tool to assess the quality or risk of bias for ABAB within subjects study designs. However, in consultation with the systematic review team in the School of Primary, Community, and Social Care, the Before-After (Pre-Post) Studies with No Control Group tool by the NIH was determined as the most appropriate tool. Therefore, the NIH provided a suitable tool to quality appraise each of these study designs. Secondly, the NIH quality assessment tools have been used in other health related systematic reviews (Ofori-Asenso et al., 2017; Ismail et al., 2017; Hatzis, Dawe & Harnett, 2017), and are highly regarded, and appropriate to quality assess observational and intervention designs (Sanderson, Tatt & Higgins, 2007). Finally, by using each tool within the NIH toolkit there was a degree of convergence and commonality across all tools. For example, each tool focused my attention to identify potential flaws in study method, implementation, confounding, study power, and other sources of bias (e.g. patient selection, performance, attrition, and detection).

Each tool in the NIH toolkit consists of 11 to 14 items (dependent on design type), each evaluated as 'yes', 'no', or 'not applicable/cannot decide' as guided by NIH guidance documents. Each item was used to guide the overall quality rating of 'good,' 'fair,' or 'poor'. The overall rating of the study was considered during the analysis process, with more confidence and weight being given to studies with a good and fair quality rating.

I completed the quality assessment of included studies, with a 20% sample blind checked by PC, again, with good interrater agreement (>95%). Discrepancies were resolved in discussion with a third reviewer (JB).

3.4.7 Analysis approach

The results of a systematic review can be summarised statistically, in the form of a meta-analysis, or descriptively, as a narrative synthesis. Due to heterogeneity; of the sample populations, settings, study designs, follow up periods, interventions, and reported outcomes, as well as a lack of statistical information to perform a meta-analysis, a narrative approach was adopted. Such an approach involves the 'synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings' (Popay et al., 2006, p. 5). As Popay and colleagues continue to discuss, narrative synthesis approaches for systematic reviews are sometimes wrongly viewed as a 'second best' approach. The positives of conducting a narrative synthesis are often overlooked, with the ability to produce a convincing story based upon quality assessed evidence to bridge the gaps between research, policy, and practice. To conduct the narrative synthesis, the guidance document by Popay et al. (2006) was followed.

Each study was assigned to the overarching theme or 'cluster' of 'pain assessment' and/or 'pain treatment' (Popay et al., 2006). Studies were further clustered thematically to form sub-domains. Sub-domains for pain assessment were self-report, informant report, and behavioural observation. Sub-domains for pain treatment were pharmacological (further clustered by analgesic potency; paracetamol, NSAID, and opioid) and non-pharmacological treatments. Studies were tabulated based on their domain and sub-domain. This allowed for

the initial comparison within and across study findings. To deepen the analysis, idea webbing was used to identify the key relationships, connections, commonalities, groupings, and differences between the studies in each domain and sub-domain. Tabulation and idea webbing exercises allowed for the identification of patterns across the data to draw informative conclusions relevant to current research, policy, and practice, whilst taking into account the quality rating of each study (Popay et al., 2016).

3.5 Results

3.5.1 Identification of studies

Searches were conducted from inception to October 2018. Searches identified 6741 unique records. One potentially eligible paper could not be obtained in full text despite contacting the authors (Park, Chun & Gang, 2015). Three additional papers were found through supplementary searching (Brummel-Smith et al., 2002; Schmader et al., 1998; Jensen-Dahm, Gasse, Astrup, Mortensen & Waldemar, 2015). One hundred and twenty-nine papers were screened at full-text stage. A number of studies failed to provide clear definitions regarding the residency of the participants and therefore the authors were contacted. One author responded to confirm that participants lived in the community (Benedetti et al., 2006). This process resulted in 32 studies included within the review (see Figure 3.1).

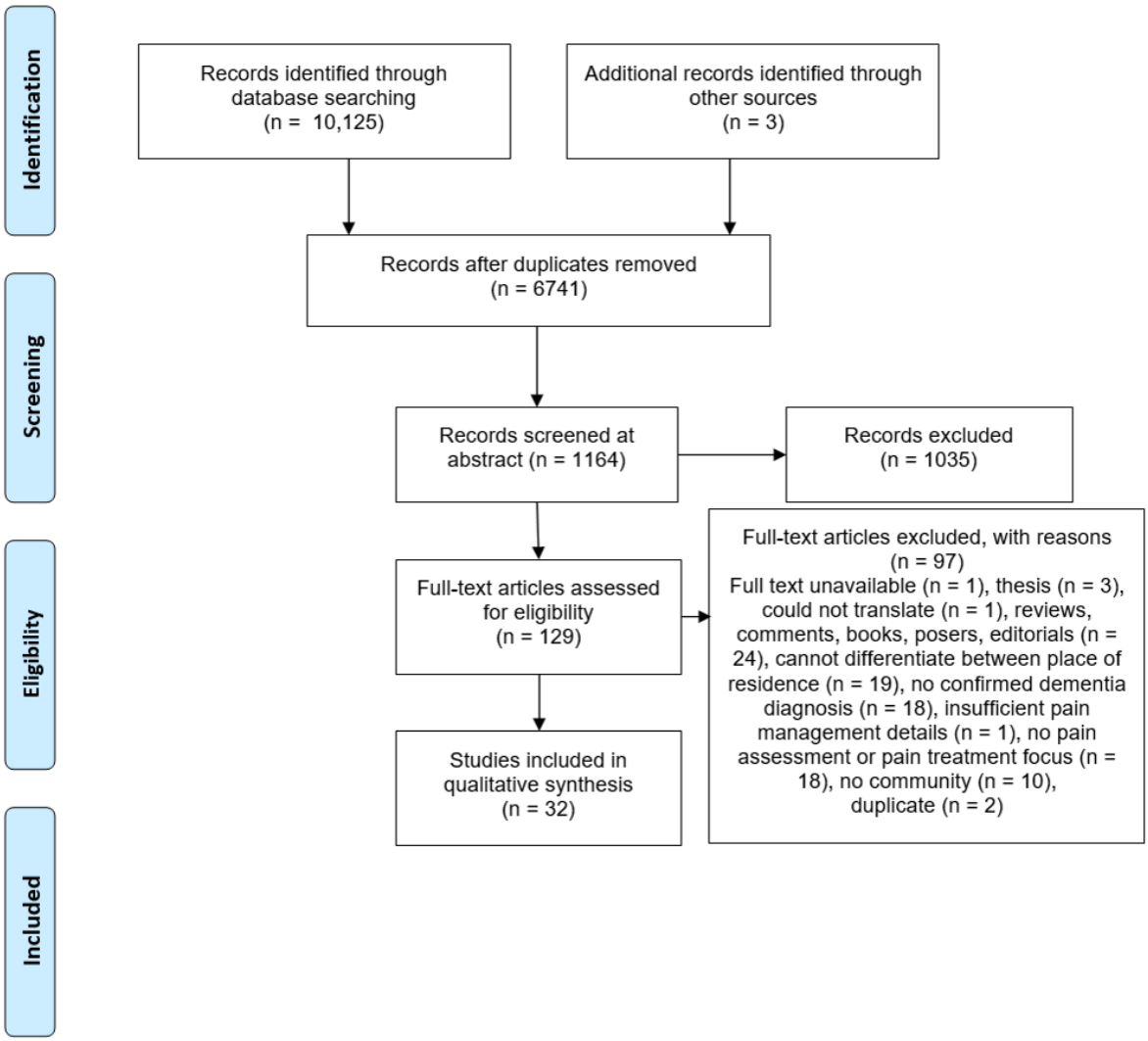


Figure 3.1. PRISMA Flow diagram

Upon full text screening it became apparent that a number of studies used the same sample but reported different outcomes. Three studies used the same sample identified from the Palliative Excellence in Alzheimer Care Efforts (PEACE) project (Shega, Hougham, Stocking, Cox-Hayley & Sachs, 2005; Shega et al., 2004; Shega et al., 2006). Two of these studies examined informant ratings using the VDS (Shega et al., 2005; Shega et al., 2004), while the other examined pharmacological pain treatment use (Shega et al., 2006). Additionally, three studies used the same Kuopio 75+ cohort to examine analgesic prescriptions for people with dementia (Hartikainen, Mäntyselkä, Louhivuori-Laako, Enlund & Sulkava, 2005a; Hartikainen, Mäntyselkä, Louhivuori-Laako & Sulkava, 2005b; Mäntyselkä, Hartikainen,

Louhivuori-Laako, & Sulkava, 2004), however one study excluded two participants in their analysis (Mäntyselkä et al., 2004).

Most of the studies in this review focused on dementia as a whole, without specifying the subtype diagnosis, with a minority of studies only recruiting participants with Alzheimer's disease (AD), and Dementia with Lewy Bodies (DLB). No other subtypes of dementia were investigated independently, and no studies stratified their findings dependant on dementia subtype. Out of the 32 studies included in the review, 12 restricted recruitment to participants with mild-to-moderate, or 'newly diagnosed' dementia.

Few studies included a matched control group of people without dementia (Hamina et al., 2016; 2017; 2018; Hunt et al., 2015; Benedetti et al., 2006; Bell et al., 2011). Other studies used a non-matched comparator group of older adults without dementia living in the community (Brummell-Smith et al., 2002; Hartikainen et al., 2005a; 2005b; Mäntyselkä et al., 2004; Haasum et al., 2011; Schmader et al., 1998; Jensen-Dahm et al., 2015; Haasum et al., 2011). Two studies also included people with dementia living in nursing homes as comparator groups (Haasum et al., 2011; Jensen-Dahm et al., 2015).

Of the included studies, 11 reported findings on pain assessment tools or methods, whereas 27 reported findings that examined treatments for pain. Fifteen studies were conducted in North America, eight in Finland, two in Denmark, two in the United Kingdom, and one each in Canada, Sweden, France, Japan, and Italy.

3.5.2 Quality assessment

Using the NIH toolkit, four studies (12%) were assessed as good quality, 21 (66%) as fair quality, and seven (22%) as poor quality.

Cross-sectional and cohort study designs were assessed using the NIH Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies. Many questions in the tool received a high percentage of 'no' responses largely because of the cross-sectional design. For example, only seven (22%) studies investigated the exposure prior to the outcome. A 'no'

response did not necessarily lead to a poor quality rating, but rather indicated areas of potential biases that may influence the relationship between the exposure and outcome associated with cross-sectional designs. Intervention studies were quality assessed using the NIH Quality Assessment Tools for Controlled Intervention Studies, or Pre-Post Studies with No Control Group depending upon the presence of a comparator group. One study was a cohort design with a nested case-control study and was therefore quality assessed using both the Observational Cohort and Cross-Sectional tool, and the Case-Control tool (Gallini et al., 2013). The quality rating of each study is provided in the summary tables (see Table 3.2, Table 3.3, and Table 3.4). An in-depth investigation of quality assessment is provided in Appendix 2.

3.5.3 Pain assessment tools and methods

Eleven studies examined pain assessment tools and methods for community-dwelling people with dementia. Four studies examined self-report pain tools, seven studies examined informant ratings of pain, and one study examined a behavioural observation tool (see Table 3.2).

Only one study provided an overview of the frequency of pain assessment for community-dwelling people with dementia in primary care (Li et al., 2015), with pain assessment documented in 98% of patients' medical records. Of the pain assessments documented in this study, 94% used the Numerical Rating Scale (NRS), Visual Descriptor Scale (VDS), or Faces Pain Scale (FPS), whereas only 2% of medical records reported the use of modified or dementia-specific pain scales. However, people with dementia in this study had mild-to-moderate dementia, and therefore modification may not be required.

3.5.3.1 Self-report

Four studies (one good quality; Snow et al., 2009, one fair quality; Breland et al., 2015, and two poor quality; Brummel-Smith et al., 2002; Krulewitch et al., 2000) examined self-report for people with dementia. Two poor quality studies examined the FPS, Visual Analogue Scale (VAS), and Pain Intensity Scale (PIS) (Brummel-Smith et al., 2002; Krulewitch et al.,

2000), whereas two studies examined the Philadelphia Geriatric PIS (Snow et al., 2009; Breland et al., 2015). The completion rates of the FPS, VAS and PIS were between 53-67% for people with largely moderate-to-severe dementia (MMSE of 15.6, ± 5.9 SD; MMSE of 15.7, ± 5.9 SD). Two studies found that the Philadelphia Geriatric PIS was sensitive to identify painful conditions and predictive of negative psychosocial events at 4 months follow up (Breland et al., 2015; Snow et al., 2009).

3.5.3.2 Informant pain ratings

In total, seven studies (four fair quality; Barry et al., 2016; Jensen-Dahm et al., 2012; Orgeta, Orrell, Edwards, Hounsome & Woods, 2015; Shega et al., 2004, and 3 poor quality; Krulewitch et al., 2000; Hunt et al., 2015; Kunik et al., 2017) investigated informant ratings of pain compared to self-reported pain. Tools included the VDS, EQ5D, the Philadelphia Geriatric PIS, FPS, VAS, and PIS. Five of these studies compared the percentage of self-reported and informant reported pain for community-dwelling people with dementia, finding that family caregivers reported pain presence in the person with dementia more than the person with dementia (see Figure 3.2). Three studies investigated the congruence between people with dementia and their family caregiver's rating of pain, with interrater reliability ranging from 0.25 to 0.34 (Krulewitch et al., 2000; Jensen-Dahm et al., 2012; Orgeta et al., 2015), with two fair quality studies finding an average agreement of 58.6% (range 58.2% to 59%; Orgeta et al., 2015; Shega et al., 2004). In accordance with these findings, Kunik et al. (2017) found that family caregivers reported a higher mean pain score than the person with dementia.

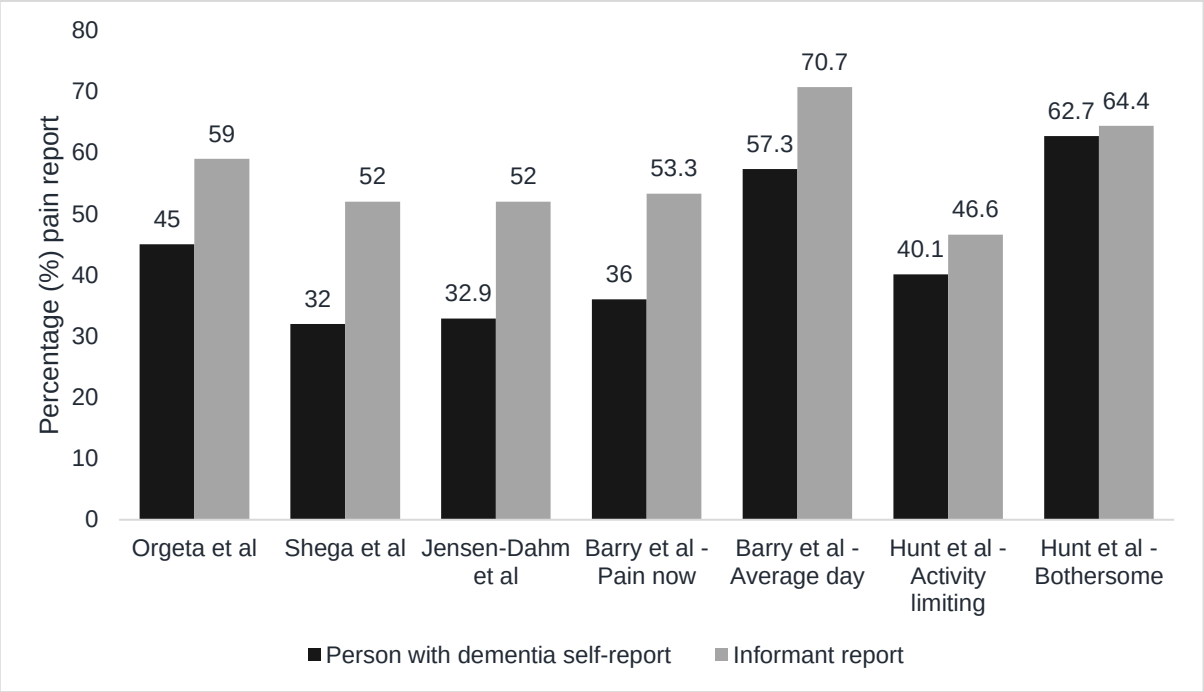


Figure 3.2. Bar chart to illustrate the percentage of pain self-reported by people with dementia compared to informant reported by a family caregiver

3.5.3.3 Observation of pain behaviours

One poor quality study investigated the Hospice Approach Discomfort Scale, a behavioural observation pain tool (Snow et al., 2009). Behavioural observation tools aim to identify pain using non-verbal cues (e.g. behaviour, facial expression, body language) (see Section 2.3.3.1). Such tools are often psychometrically tested by comparing their score of pain to other means of pain assessment (e.g. self-reported pain; Zwakhalen et al., 2006). This study reported poor correlations between the Hospice Approach Discomfort Scale and self-reported pain scales (FPS, VAS, and PIS); however, the authors of this study did not provide statistical evidence to support the findings and therefore estimations of concordance could not be reported.

Table 3.2. Summary of pain assessment studies

Author	**Orgeta et al (2015)**	**Shega et al (2004; 2005)**	**Jensen-Dahm et al(2012)**	**Breland et al(2015)**	**Snow et al(2009)**
Sub-theme	Informant rating	Informant rating	Informant rating	Self-report	Self-report
Design	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cohort
Origin	UK	USA	Denmark	USA	USA
Diagnosis	Dementia	Dementia	AD or DLB	Dementia	Dementia
n (reference/control)	488¶|	115¶|	321¶	136	171¶
Quality	Fair	Fair	Fair	Fair	Good
Pain assessment tool	EQ5D	VDS	EQ5D	PGC PIS	PGC PIS
Completion rate %	-	-	-	-	-
PWD (caregivers) % [*p*]	45 (59) [*p*<.001]	32 (52)	32.9 (52)	-	-
Informant agreement	58.2% Kappa = 0.25	59% congruent 40% over report 13% under report	Kappa = 0.34 (X^2 = 71.7, df= 4; *p*<.001)	-	-
Predictive validity	-	-	-	Pain diagnosis in previous year (β=.20, t_{132}=2.17, *p*<.05)	Increased depression (z=2.70) agitation (z= 2.33) decreased pleasant events (z=-2.38)

Table 3.2. cont. Summary of pain assessment studies

Author	**Barry et al[2016]**	**Li et al[2015]**	**Brummel-Smith et al[2002]**	**Krulewitch et al[2000]**	**Hunt et al[2015]**	**Kunik et al[2017]**
Sub-theme	Informant rating	Self-report	Self-report	Self-report Informant rating Behavioural observation	Informant rating	Informant rating
Design	Cross-sectional	Cross-sectional	Cohort	Cross-sectional	Cross-sectional	Cross-sectional - Intervention baseline
Origin	UK	USA	USA	USA	USA	USA
Diagnosis	Dementia	Dementia	Dementia	Dementia	Dementia	Dementia
n (reference/control)	75	203	154 (255)	156¶	802 (802)	203¶
Quality	Fair	Fair	Poor	Poor	Poor	Poor
Pain assessment tool	VDS	PGC PIS	FPS, VAS, PIS	FPS, VAS, PIS, HADS	VDS	PGC PIS
Use of tool %	-	94% self-report 2% modified tool	-	-	-	-
Completion rate %	-	-	32.5	PIS, 62; FPS, 53; VAS, 53 33 unable to complete FPS, VAS, or PIS	-	-
PWD (caregivers) % [*p*]	Pain now - 36 (53.3) [*p*=.033]	-	-	-	Activity limit 40.1 (46.6) [*p*= .03]	-

Table 3.2. cont. Summary of pain assessment studies

	Average day – 57.3 (70.7) [*p*=.089]				Bothersome 62.7 (64.4) [*p*=.59]	
Informant agreement				kappa = .32 HADS: NR		Mean Pain Score: Worst pain: 2.93 (3.15) Overall pain: 2.04 (2.24)
Predictive validity	-	-	-	-	-	

¶ dyadic paired participants (e.g. person with dementia and their family caregiver).

Abbreviations: CI, confidence interval; FPS, Faces Pain Scale; HADS, Hospice Approach Discomfort Scale; IPT, Iowa Pain Thermometer; NR, not reported; NRS, numerical rating scale; OR, odds ratio; PGC, Philadelphia Geriatric Centre; PIS, Pain Intensity Scale; PWD, people with dementia; VAS, Visual Analogue Scale; VDS, Visual Descriptor Scale.

3.5.4 Treatments for pain

Twenty-two papers (three good quality; Gilmartin et al., 2015; Hamina et al., 2017; Hamina et al., 2018, 16 fair quality; Haasum et al., 2011; Li et al., 2015; Barry et al., 2016; Jensen-Dahm et al.,, 2012; Hartikainen et al., 2005a; Mäntyselkä et al., 2004; Schmader et al., 1998; Jensen-Dahm et al., 2015; Hamina et al., 2016; Bell et al., 2011; Thakur et al., 2016; Breland et al., 2015; Shega et al., 2006; Regier & Gitlin, 2018; Grace, Allen, Ivey, Knapp & Burgio, 2018; Gallini et al., 2013, and three poor quality; Brummel-Smith et al., 2002; Hunt et al., 2015; Nakanishi et al., 2018) provided an overview of the pain treatments used by people with dementia (see Table 3.3).

3.5.4.1 An overview of analgesic use

Two papers investigated the use of analgesics for community-dwelling people with dementia over time, irrespective of their analgesic potency (Gilmartin et al., 2015; Hamina et al., 2016). Hamina et al. examined analgesic use during the first 180 days after index date (dementia diagnosis, or equivalent for matched controls), stratified by the year of index date (from 2005 to 2011). People with and without dementia in 2011 were 2.3 times more likely to be prescribed analgesic medication during the first 180 days after index date than in 2005. Alternatively, Gilmartin et al. found that analgesic use remained largely consistent from the first year following dementia diagnosis to five years after dementia diagnosis. These fair and good quality studies may suggest changes with prescribing practices over time (cohort effect), irrespective of dementia severity.

Eleven papers reported that 24.7% to 63% of people with dementia used analgesic medication (Haasum et al., 2011; Li et al., 2015; Brummel-Smith, 2002; Barry et al., 2016; Hartikainen et al., 2005a; Mäntyselkä et al., 2004; Hamina et al., 2016; Breland et al., 2015; Regier & Gitlin, 2018; Nakanishi et al., 2018; Gallini et al., 2013). Four papers found that the percentage of people with dementia reporting pain that did not use analgesic medication ranged from 30.3% to 68% (Jensen-Dahm et al., 2012; Hunt et al., 2015; Thakur et al., 2016; Shega et al., 2006).

When exploring the prevalence of analgesic use by community-dwelling people with dementia compared to a comparator group, four papers (all of which are fair quality) found a mixed trend. Research found that community-dwelling people with dementia had a lower (Mäntyselkä et al., 2004), similar (Hamina et al., 2016), or higher (Haasum et al., 2011) prevalence of analgesic medication compared to community-dwelling older adults without dementia. Furthermore, Schmader et al. (1998) found that community-dwelling people with dementia had a lower odds of analgesic prescription than community-dwelling older adults with mild cognitive impairment (adjusted OR 0.54, 95% CI 0.39 to 0.75). Although Haasum et al. found that community-dwelling people with dementia had a greater prevalence of analgesic prescription than community-dwelling people without dementia; they also found that people with dementia living in nursing homes had a higher prevalence of analgesic use than community-dwelling people with dementia, however this finding was non-significant (52.7% vs. 36%, respectively, adjusted OR 1.72, 95% CI 0.96 to 3.10).

3.5.4.2 Categories of analgesics prescribed

3.5.4.2.1 Paracetamol

Good quality longitudinal research suggests that the use of paracetamol increased from the first year after dementia diagnosis to five-year follow up (Gilmartin et al., 2015). Despite being good quality, the sample size of this study became small throughout follow up due to attrition, potentially leading to imprecise estimates in the latter years of follow up.

Paracetamol was used by 14% to 32% of people with dementia (Haasum et al., 2011; Brummel-Smith et al., 2002; Barry et al., 2016; Hamina et al., 2016). The amount of paracetamol used by community-dwelling people with dementia (with the exception of Hamina et al., 2016) included over-the-counter and prescribed paracetamol. Evidence suggests that the prevalence of paracetamol use was higher for people with dementia compared to people without dementia (Haasum et al., 2011; Hamina et al., 2016). However, Haasum et al. found that people with dementia in nursing home settings used more

paracetamol than people with dementia in community settings (45.2% vs. 24.4%, respectively, adjusted OR 2.52, 95% CI 1.35 to 4.73).

3.5.4.2.2 Nonsteroidal anti-inflammatory drugs (NSAIDs)

NSAID use decreased from the first year after dementia diagnosis to five years after diagnosis (Gilmartin et al., 2015). Additionally, the amount of NSAIDs prescribed during the first 180 days after index date (dementia diagnosis or equivalent for matched controls) also decreased each year from 2005 to 2011 (Hamina et al., 2016) suggesting a change in the practice of prescribing NSAID medication over time.

Across all studies, the prevalence of NSAID use ranged from 5.9% to 21% (Haasum et al., 2011; Brummel-Smith et al., 2002; Barry et al., 2016; Hamina et al., 2016). Two studies found lower rates of NSAID use and prescription for people with dementia compared to people without dementia (Haasum et al., 2011; Hamina et al., 2016). Haasum et al. also found that people with dementia in nursing homes had a lower prevalence of NSAID prescription than community-dwelling people with dementia, however this was not significant (3.8% vs. 5.9%, respectively; OR 0.32, 95% CI 0.07 to 1.42)

3.5.4.2.3 Opioids

The use of opioids for community-dwelling people with dementia was relatively consistent from the first year after dementia diagnosis to five years after dementia diagnosis (Gilmartin et al., 2015). However, the amount of opioids prescribed during the first 180 days of index date (dementia diagnosis or equivalent for matched controls) increased each year from 2005 to 2011, with participants in 2011 being 3.7 times more likely to be prescribed an opioid than in 2005 (Hamina et al., 2016).

The prevalence of opioid use for community-dwelling people with dementia ranged from 3.6% to 27.5% (Haasum et al., 2011; Brummel-Smith et al., 2002; Barry et al., 2016; Hamina et al., 2016; 2017; 2018; Hartikainen et al., 2005a; Jensen-Dahm et al., 2015; Bell et al., 2011). Three studies (two fair quality; Hamina et al., 2016; Bell et al., 2011, and one good quality; Hamina et al., 2017) show that the amount of community-dwelling people with

dementia prescribed opioids was less than age, sex, and region of residence matched controls without dementia. However, two studies (both of fair quality; Haasum et al., 2011; Jensen-Dahm et al., 2015) found that more people with dementia used (Haasum et al., 2011) or were prescribed (Jensen-Dahm et al., 2015) opioid medication compared to people without dementia (see Figure 3.3).

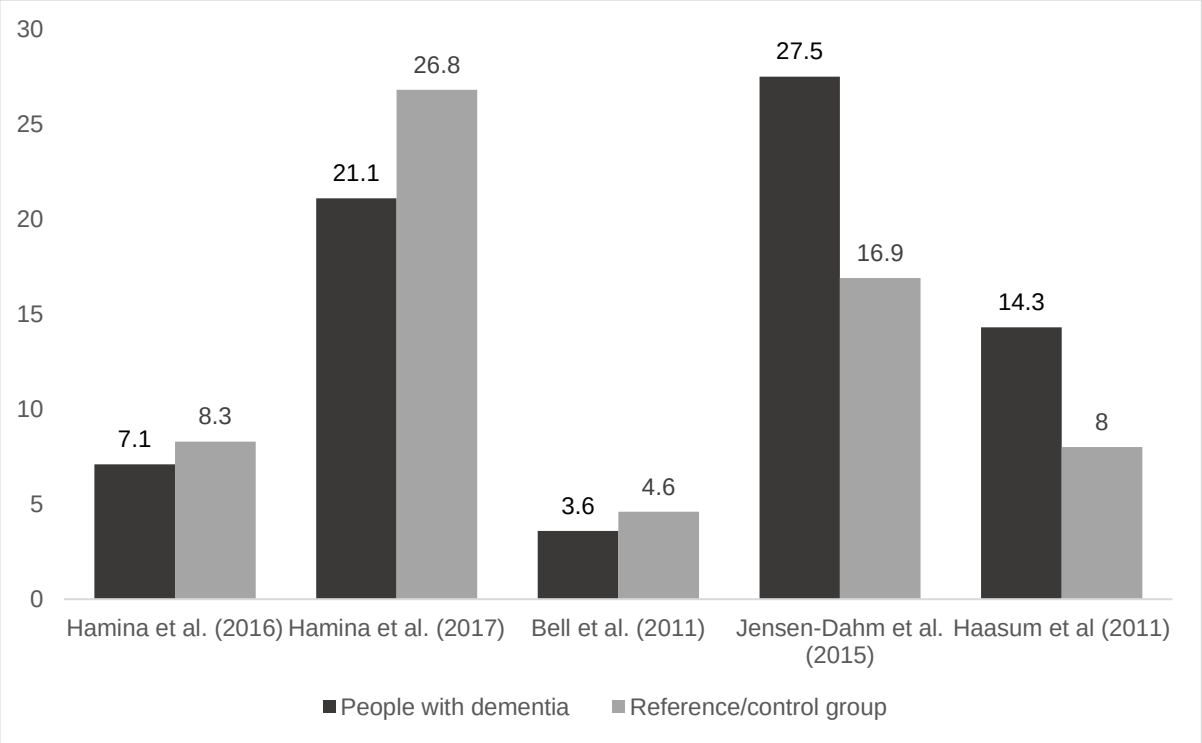


Figure 3.3. Prevalence of opioid use

Following statistical adjustment, mixed findings remained. People with dementia had higher odds (Jensen et al., 2015; adjusted OR 1.27, 95% CI 1.22 to 1.31), similar odds (Hamina et al., 2016; adjusted OR 1.02, 95% CI 1.00 to 1.02), and lower odds (Bell et al., 2011; adjusted OR 0.76, 95% CI 0.76 to 0.83) of opioid prescription than people without dementia. Haasum et al. (2011) found that people with dementia in nursing home settings had a higher odds of opioid use than people with dementia in community settings (adjusted OR 2.84, 95% CI 1.33 to 6.07).

Weak opioids

When opioids were stratified based upon their strength (defined by the WHO analgesic pain stepladder), between 2.7% to 16.8% of people with dementia were prescribed weak opioids (Li et al., 2015; Jensen-Dahm et al., 2015; Hamina et al., 2016; Bell et al., 2011). The six month (Hamina et al., 2016) and annual crude prevalence (Bell et al., 2011) of weak opioid use was lower among community-dwelling people with dementia compared to older adults without dementia. This finding was also evident when annual prevalence estimates were adjusted (Jensen-Dahm et al., 2015).

Strong opioids

The proportion of people with dementia prescribed strong opioids ranged from 0.95% to 17.4% (Li et al., 2015; Jensen-Dahm et al., 2015; Hamina et al., 2016; Bell et al., 2011). Hamina et al. (2016) found that the prevalence of strong opioid prescription was higher for community-dwelling people with dementia compared to matched older adults without dementia during the 180 days after index date (dementia diagnosis or equivalent for controls) (1.3% vs. 1.1%, respectively). In accordance with these findings, the annual prevalence of strong opioid prescription was higher among community-dwelling people with dementia compared to matched older adults without dementia (0.95% vs. 0.76%, respectively, adjusted OR 1.26, 95% CI 1.05 to 1.51; Bell et al., 2011), and a comparator group of older adults without dementia (17.4% vs. 7.1%, respectively, adjusted OR 1.79, 95% CI 1.72 to 1.86; Jensen-Dahm et al., 2015).

3.5.4.3 Non-pharmacological treatments used

One fair quality study provided an overview of the non-pharmacological treatments used for community-dwelling people with dementia (Li et al., 2015). This study examined the quality of pain care for community-dwelling people with dementia using medical notes from primary care, geriatric, nursing, and mental health/psychiatric outpatient clinics. This study concluded that with the exception of exercise (45.8%), all other non-pharmacological treatments (physical therapy, pain education, and community resources) were underused (19.2%, 29.6%, 17.2%, respectively). Although this paper concluded that non-pharmacological

treatments were underused for people with dementia, this may be implicated by poor recording of such treatments in medical records.

Table 3.3. Summary of pain treatment studies

Author	**Hartikainen et al[2005a;2005b]**	**Mäntyselkä et al[2004]**	**Schmader et al[1998]**	**Jensen-Dahm et al[2012]**	**Jensen-Dahm et al[2015]**	**Haasum et al[2011]**
Design	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional
Origin	Finland	Finland	USA	AD or DLB	Denmark	Sweden
Diagnosis	Dementia	Dementia	Dementia	Dementia	Dementia	Dementia
n (reference)†	77 (446)	75 (446)	100 (420)	321¶	35,455 (870,645)	119 (2199†, 186‡)
Quality	Fair	Fair	Fair	Fair	Fair	Fair
Analgesic use % (control %)	63	33.3 (47.3)	-	51.5†† 8.3 received >1	-	36 (24.3†, 52.7‡)
Analgesic use, PWD vs. control [OR (95% CI)]	-	-	0.54 (0.39 to 0.75) (reference group cognitive impairment)	-	-	Nursing home vs. community 1.72 (0.96 to 3.10)§
Paracetamol use % (control %)	58 (paracetamol and NSAID)	-	-	-	-	24.4 (15.4†, 45.2‡)

Table 3.3. Summary of pain treatment studies

Paracetamol use vs. control [OR (95% CI)]	-	-	-	-	-	Nursing home vs. community 2.52 (1.35 to 4.73)§
NSAID use % (control %)	58 (paracetamol and NSAID)	-	-	-	-	5.9 (12†, 3.8‡)
NSAID use vs. control [OR (95% CI)]		-	-	-	-	0.32 (0.07 to 1.42)§
Opioid use % (control %)	13	-	-	-	27.5 (16.9); Weak 14.9 (12.4); Strong 17.4 (7.1)	14.3 (8†, 30.1‡)
Opioid use vs. control [OR (95% CI)]	-	-	-	-	All 1.27 (1.22 to 1.31); buprenorphine 2.57 (2.41 to 2.74)	Nursing home vs. community 2.84 (1.33 to 6.07)§
Non-pharm (%)	-	-	-	-	-	-

Table 3.3 cont. Summary of pain treatment studies

Author	**Brummel-Smith et al[2002]**	**Gallini et al[2013]**	**Gilmartin et al[2015]**	**Hamina et al[2017]**	**Hamina et al[2016]**	**Barry et al[2016]**
Design	Cohort	Cohort, nested case-control	Cohort	Cohort	Cohort	Cross-sectional
Origin	USA	France	Finland	Finland	Finland	Northern Ireland
Diagnosis	Dementia	AD	AD	AD	AD	Dementia
n (reference)†	154 (255)	595	236¶	62,074 (62,074)	67,215 (67,215)	75¶
Quality	Poor	Fair	Good	Good	Fair	Fair
Analgesic use % (control %)	49 received >1	26 13 persistent	13.6, 10.6, 13.7, 16.8, 15.3§§	-	34.9 (33.5)	40 20 taking ≥2
Analgesic use, PWD vs. control [OR (95% CI)]	-	-	-	-	2011 vs. 2005 [2.34 (2.24 to 2.45)] AD vs. no AD [1.02 (1.00 to 1.04)]	-
Paracetamol use % (control %)	14	67.5¶¶	5.5, 5.6, 5.4, 13.0, 11.1§§	-	25 (19.1)	32

Table 3.3 cont. Summary of pain treatment studies

Paracetamol use vs. control [OR]	-	-	-	-	-	-
NSAID use % (control %)	21	31.2¶¶	8.1, 4.0, 7.7, 3.1, 4.1§§	-	13.3 (17.4)	8
NSAID use vs. control [OR (95% CI)]	-	-	-	-	2011 vs. 2005 [0.73 (0.69 to 0.77)] AD vs. no AD [0.71 (0.69 to 0.73)]	-
Opioid use % (control %)	13	36.2¶¶	1.3, 1.5, 3.0, 2.3, 1.4§§	All 21.1 (26.8); Long term 7.2 (8.7)	All 7.1 (8.3); Weak 5 (6.9); Strong 1.3 (1.1)	16
Opioid use vs. control [OR (95% CI)]	-	-	-	-	2011 vs. 2005 [3.78 (3.44 to 4.15)] AD vs. no AD [0.79 (0.75 to 0.82)]	-
Non-pharm (%)	-	-	-	-	-	-

Table 3.3 cont. Summary of pain treatment studies

Author	**Bell et al[2011]**	**Hunt et al[2015]**	**Thakur et al[2016]**	**Breland et al[2015]**	**Li et al[2015]**	**Shega et al[2006]**
Design	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional	Cross-sectional
Origin	Finland	USA	USA	USA	USA	USA
Diagnosis (subtype)	AD	Dementia	Dementia	Dementia	Dementia	Dementia
n (reference)†	28,089 (28,089)	802 (802)	202	136	203	115¶
Quality	Fair	Poor	Fair	Fair	Fair	Fair
Proportion taking analgesic % (control %)	-	69.7††	56††	49	59.7	32†† 15‡‡
Analgesic - pwd vs. control [OR (95% CI)]	-	-	-	-	-	-
Paracetamol % (control %)	-	-	-	40 (non-narcotics)	32.5 (paracetamol/NSAID)	19†† 8‡‡
Paracetamol use vs. control [OR (95% CI)]	-	-	-	-	-	-
NSAID % (control %)	-	-	-	40 (non-narcotics)	32.5 (paracetamol/NSAID)	8†† 8‡‡

Table 3.3 cont. Summary of pain treatment studies

NSAID use vs. control [OR (95% CI)]	-	-	-	-		-
Opioid % (control %)	All 3.56 (4.62); Weak 2.68 (3.83); Strong 0.95 (0.76)	-	-	9	Weak 16.8 Strong 1.5	4†† 0‡‡
Opioid vs. control [OR (95% CI)]	All 0.77 (0.71 to 0.84); Weak 0.70 (0.64 to 0.77); Strong 1.26 (1.05 to 1.51)	-	-	-	-	-
Non-pharm (%)	-	-	-	-	Exercise 45.8	-

Table 3.3 cont. Summary of pain treatment studies

Author	**Regier & Gitlin[2018]**	**Nakanishi et al[2018]**	**Hamina et al[2018]**	**Grace et al[2018]**
Design	Cross-sectional	Cross-sectional (baseline)	Cohort	Cross-sectional
Origin	USA	Japan	Finland	USA
Diagnosis (subtype)	Dementia	Dementia	AD	Dementia
n (reference)	596¶	219	24,747 total n 3327 opioid initiators (3325 non-opioid initiators)	543¶
Quality	Fair	Poor	Good	Fair
Proportion taking analgesic % (control %)	40.1	24.7	-	22 Caucasian 30 African American 17 Latino
Analgesic - pwd vs. control [OR (95% CI)]	-	-	-	-
Paracetamol % (control %)	-	-	58.9 (21.5) (non-opioid initiators)	-
Paracetamol use vs. control [OR (95% CI)]	-	-	-	-
NSAID % (control %)	-	-	16.4 (3.6) (non-opioid initiators)	-
NSAID use vs. control [OR (95% CI)]	-	-	-	-
Opioid % (control %)	-	-	13.44 (total n)	-

Table 3.3 cont. Summary of pain treatment studies

Opioid vs. control [OR (95% CI)]	-	-	-	-
Non-pharm (%)	-	-	-	-

AD, Alzheimer's disease; CI, confidence interval; NSAID, Non-Steroid Inflammatory Drugs; OR, Odds Ratio; PWD, people with dementia, USA, United States of America; DLB Dementia with Lewy Bodies

The control/reference group is community-dwelling people without dementia unless noted otherwise. However, for Haasum et al. (2011) community-dwelling people without dementia (†) is labelled regardless for clarification between the multiple reference groups.

† people without dementia living in the community; ‡ people with dementia living in a nursing home; § comparison of nursing home dwelling people with dementia to community-dwelling people with dementia as the reference population.; ¶ dyadic paired participants (e.g. person with dementia and their caregiver); †† analgesic medication in a sample of people with dementia reporting pain; ‡‡ analgesic medication in a sample of people with dementia reporting no pain; §§ baseline, year 1, year 2, year 3, year 4, and year 5; ¶¶ percentage of each analgesic in a sample of people with dementia prescribed analgesic medication

3.5.5 The effectiveness of treatments for pain

Five papers investigated the effectiveness of pain treatments for community-dwelling people with dementia (one fair quality; Benedetti et al., 2006 and four poor quality; Kunik et al., 2017; Nakanishi et al., 2018; Elliott & Horgas, 2009; Park, 2010). Each study measured the effectiveness of the intervention using pain assessment scores. Two papers investigated pharmacological interventions (Benedetti et al., 2006; Elliott & Horgas, 2009), with three investigating a non-pharmacological intervention for pain (Kunik et al., 2017; Nakanishi et al., 2018; Park, 2010).

Concerning pharmacological treatments, Elliot and Horgas (2009) investigated the effectiveness of scheduled paracetamol in reducing pain behaviours (e.g. rubbing, grimacing, and sighing) for people with dementia with musculoskeletal pain. This study found that observed pain behaviours were lower in treatment phases than during baseline phases, indicating that scheduled paracetamol may be effective to relieve pain for people with dementia. Alternatively, Benedetti et al. (2006) conducted an experimental study to investigate the analgesic placebo mechanism for people with dementia. This study examined pain scores for people with and without dementia during the expected or unexpected application of a topical analgesic during the insertion of a needle. This study concluded that the placebo effect that is typically evident when an 'expected' analgesic is applied (openly discussed with the participant) was reduced for people with dementia, in line with their loss of frontal executive functions (as assessed using the Frontal Assessment Battery). This finding highlights the potential loss of placebo mechanism for people with dementia, which may make analgesic treatment less effective to relieve their pain. This study was fair quality; however further research is essential to validate these conclusions.

In regard to the effectiveness of non-pharmacological treatments, one study investigated a music intervention (Park, 2010) by asking family caregivers to assess the person with dementia's pain 30 minutes before, during, and after listening to their favourite music. Many comparisons indicated non-significant findings (see Table 3.4) however, pain was

significantly lower after listening to music than before listening to music. Two studies investigated the effectiveness of psychosocial interventions (Kunik et al., 2017; Nakanishi et al., 2018). Both interventions included an element of pain education and training targeted towards formal (Nakanishi et al., 2018) and informal family caregivers (Kunik et al., 2017) of community-dwelling people with dementia. Both interventions found that the person with dementia's pain reduced from baseline to post-intervention. However, in regard to other outcomes the efficacy was mixed. All of the studies had a small sample size, and poor quality ratings (see Table 3.4), limiting reliable conclusions.

Table 3.4. Studies evaluating the utility and effectiveness of treatments for pain

Author	**Elliott & Horgas[2009]**	**Benedetti et al[2006]**	**Park[2010]**	**Nakanishi et al[2018]**	**Kunik et al[2017]**
Design	Before-after ABAB within subjects	Non-RCT	Before-after ABAB within subjects	Before-after	RCT
Sub-theme	Pharmacological	Pharmacological	Non-pharmacological	Non-pharmacological	Non-pharmacological
Origin	USA	Italy	USA	Japan	USA
Quality	Poor	Fair	Poor	Poor	Poor
Diagnosis (subtype)	Dementia	AD	Dementia	Dementia	Dementia
n (reference/ control)	3	38 (16)	15	219	101¶ (102¶)
Pain assessment	Coded pain behaviours	NRS	M-PADE	Abbey Pain Scale	PGC PIS
Intervention	Paracetamol 1.3g every 8hrs during treatment phases	Open-hidden application of 1% lidocaine during insertion of needle	Preferred music initiated 30 minutes prior to peak agitation time	2-day training course, a web-based tool for ongoing monitoring and assessment for challenging behaviour, and multi-agency discussion meetings for formal caregivers.	6 to 8 weekly sessions of 45-minute home visits targeted to informal caregivers. Improving: caregivers pain recognition, communication, making daily activities pleasant
Follow up	24 day follow up.	1 year	8 week A = Baseline = 3, 4, 7, 8. B = Week 1, 2, 5, 6.	6 months	3, 6, 12 months

Table 3.4. Studies evaluating the utility and effectiveness of treatments for pain

Results (A = baseline, B = Intervention)	Ppt 1: 32.1 (A1), 18.6 (B1), 27.5 (A2), 17.5 (B2) Ppt 2: 33 (A1), 22.5 (B2), 31.1 (A2), 20.1 (B2) Ppt 3: 57.8 (A1), 30 (B1), 53.3 (A2), 29.8 (B2).	The effects of the open treatment lowered in AD after 1 year (t(27) = -5.151, *p*<.001).	Pain during vs. before (*p*=.06) Pain during vs. after (*p*=.86). Intervention weeks vs. baseline (*p*=.22). Pain after vs. before (t=2.21; df=28; *p*<.05)	Decreased pain after the intervention compared to before (t(218)=2.63, *p*=.009). No difference in analgesics after the intervention compared to before ($X^2(1)=2.00$, *p*=0.5).	Decreased pain over time for treatment group (PWD overall pain: F(3, 412) = 4.59, *p*=.004). No difference between groups.

¶ dyadic paired participants (e.g. person with dementia and their caregiver).

USA United States of America, NRS numerical rating scale, AD Alzheimer's Disease, PGC Philadelphia Geriatric Centre, PIS Pain Intensity Scale, PWD person with dementia, M-PADE Pain Assessment in Dementing Elderly, RCT randomised control trial, ppt participant

3.6 Discussion

This review provides an overview of the current evidence on pain assessment and pain treatment for community-dwelling people with dementia. These two areas are discussed in turn, contextualised by contrasting with comparative population groups, and considering implications for practice, research and policy.

3.6.1 Pain assessment

The first aim of this review was to synthesise evidence that examined pain assessment tools and methods for community-dwelling people with dementia. A large proportion of people with dementia with moderate-to-severe cognitive impairment were unable to complete a self-report pain instrument. This finding reflects research in formal care settings that show the majority of people with mild-to-moderate dementia were able to complete a self-report of their pain (Ware et al., 2006; Kaasalainen & Crook, 2004; Chibnall & Tait, 2001; Chen & Lin, 2015), however, the ability to complete a self-report pain tool decreased as the severity of dementia increased (Closs et al., 2004; Kunz et al., 2007; 2009; Lukas et al., 2013a; see Section 2.3.1). Recommendations encourage the use of self-report measures for people with dementia (irrespective of their degree of cognitive ability); however, adaptation (e.g. simplified language and large fonts) may be required, especially for people with moderate-to-severe cognitive impairment (Schofield, 2018). Despite recommendations highlighting the importance of attempting self-report for people with dementia irrespective of the severity of cognitive impairment, it is important to acknowledge that people with very severe cognitive impairment may be unable to self-report pain, even with adaptation and full assistance (Wynne, Ling, & Remsburg, 2000; Closs et al., 2004). Therefore, the findings from this review would reiterate previous recommendations that discourage a reliance on self-report methods in isolation, especially for people with moderate-to-severe dementia (Hadjistavropoulos et al., 2014).

This review found a degree of congruence between the person with dementia's self-report and their family caregiver's informant rating of pain, however, family caregivers reported pain

more commonly. In nursing home settings, congruence between the informant and the person with dementia's rating of pain has also been identified (Hemmingsson et al., 2017; Cohen-Mansfield, 2005; Ersek, Polissar & Neradilek, 2011; Scherder & van Manen, 2005; Chen, Lin, & Watson, 2010). However, in some cases, nurses and nursing assistants underestimated the pain experienced by the person with dementia (Chen et al., 2010) indicating potential differences dependant on the environment of care and the relationship of the informant. To illustrate, a recent systematic review and meta-analysis (not specific to dementia) found that healthcare professionals (e.g. nurses and physicians) underestimated pain, whereas informal caregivers over-estimated pain (Ruben et al., 2018). Informant 'over and under' estimations of pain are likely to have negative implications for pain treatment for people with dementia (Neumann-Podczaska et al., 2016; Rantala et al., 2014). Studies investigating informant ratings of pain included in this review used self-report instruments (such as the VDS and EQ5D) to compare informant and self-reports of pain. Tools created specifically informant use (e.g. Pain Assessment for the Dementing Elderly; PADE; Villanueva et al., 2003, and Pain Assessment in Noncommunicative Elderly Persons; PAIN; Cohen-Mansfield, 2006) are yet to be tested, or validated for community-dwelling people with dementia.

This review identified only one, low quality study examining a behavioural observation pain assessment tool, suggesting a poor correlation with self-report methods. Previous reviews have evaluated behavioural observation pain tools for people with dementia residing in formal care settings (Herr et al., 2006a; Hadjistavropoulos et al., 2007; Van Herk et al., 2007). These reviews suggest that behavioural observation pain tools hold promise to identify pain for people with dementia, with UK guidance recommending the PAINAD and Doloplus-2 (Schofield, 2018). However, a meta-review of systematic reviews found that there was no single behavioural observation tool that was deemed more reliable or valid than the others, with the need for further psychometric development and testing (Lichtner et al., 2014). Behavioural observation tools may be suitable for community-dwelling people with dementia, with preliminary evidence suggesting that lay persons and care home nurses can

use behavioural observation tools to identify pain (Ammaturo, Hadjistavropoulos & Williams, 2016). The current lack of testing and development in this setting, however, as illuminated by this review hinders the ability to provide definitive conclusions.

3.6.2 Treatment of pain

The second aim of this review was to synthesise the evidence examining pain treatments for community-dwelling people with dementia.

This review found mixed evidence when comparing the analgesic medications used by community-dwelling people with and without dementia. This mixed evidence may be explained by the varying healthcare organisation and funding models across each region (USA, Finland, and Sweden). In nursing home settings, the abundance of research means that a clear picture is evident. A meta-analysis found that people with dementia had a significantly lower analgesic prevalence compared to people without dementia (Tan et al., 2015).

This review identified that 30.3% to 68.0% of people with dementia reporting pain did not use analgesic medication. This finding is comparable to nursing home settings, where 34.2% to 38.4% of people with dementia did not receive an analgesic medication despite experiencing pain (Griffioen et al., 2017b; de Souto Barreto et al., 2013).

When analgesic medications were stratified into therapeutic classifications, more community-dwelling people with dementia used paracetamol compared to people without dementia. Similar findings are evident in nursing home settings (Tan et al., 2015; Haasum et al., 2011), and population settings (including nursing home and community-dwelling; Lövheim et al., 2008). The higher use of paracetamol for people with dementia is consistent with recommendations suggesting paracetamol as a first-line analgesic treatment (Schofield, 2018), and the notable preference towards paracetamol due to its good safety profile (Kovach et al., 2000). Additionally, the recent focus of pain in people with dementia may have contributed to increased paracetamol use, as an attempt to provide adequate treatment for this vulnerable population.

This review found that NSAID prescribing is lower for people with dementia compared to people without dementia, and that NSAID use decreased over time for people with dementia. In accordance with these findings, in nursing home settings fewer people with dementia use NSAIDs than people without dementia (de Souto Barreto et al., 2013; Tan et al., 2016; Bauer et al., 2016). These findings potentially reflect guidelines advising that NSAIDs should only be prescribed with caution for older adults, and only if alternative therapies have failed (NICE, 2015; Abdulla et al., 2013; McLachlan et al., 2011; Cavalieri, 2007; MHRA, 2015; Bedson et al., 2013). The reluctance to use NSAIDs for older adults are due to the numerous absolute and relative contraindications (AGS Panel, 2009; Cavalieri, 2007; MHRA, 2015; see Section 2.4.2.5). Cognitive impairment and certain vascular-based types of dementia may be perceived as an additional risk factor for NSAID treatment and may contribute to caution in prescription. The reduction of NSAID prescriptions may have contributed to the increased use of paracetamol as a compensatory treatment (Haasum et al., 2011).

This review identified three studies (Hamina et al., 2016; 2017; Bell et al., 2011) that found less community-dwelling people with dementia were prescribed opioids, however, two studies (Haasum et al., 2011; Jensen-Dahm et al., 2015) found that more community-dwelling people with dementia used opioid medication compared to people without dementia. Differences between the studies may contribute to the unclear findings; opioid prescriptions were identified at the time of the research interview (Haasum et al., 2011), during a six-month period of dementia diagnosis (Hamina et al., 2016), or a one-year period (during 2005) (Bell et al., 2011). A much larger percentage of opioid prescriptions were evident when the length of investigation increased to a five-year period (Hamina et al., 2017). A recent systematic review investigating opioid use for people with dementia (irrespective of residential status) found that people with dementia used less opioids than people without dementia (Griffioen et al., 2017a). High quality research to further explore opioid use for community-dwelling people with dementia is essential to determine if the findings align to those found in other residential settings.

Aside from pharmacological treatments for pain, this review also wished to synthesise the evidence investigating the use of non-pharmacological treatments of pain for community-dwelling people with dementia. The findings of this review highlighted a dearth of evidence investigating non-pharmacological treatments in this population, with the limited research suggesting that they are underused. This is despite healthcare professionals perceiving non-pharmacological treatments as useful to relieve pain (Barry et al., 2012; Barry et al., 2013).

Finally, this review aimed to evaluate the effectiveness of pharmacological and non-pharmacological treatments; however, evidence was limited and low quality. A pilot study found that scheduled paracetamol treatment reduced pain scores for people with dementia (Elliot & Horgas, 2009). Such findings are comparable to larger trials conducted in nursing home settings (Knopp-Sihota et al., 2016; see Section 2.3.5). Additionally, experimental evidence suggests people with dementia may require more analgesia to reach the appropriate level of pain relief, questioning the current efficacy of analgesic treatment for people with dementia (Benedetti et al., 2006), however more research is required to confirm this finding. This review identified only poor quality papers investigating the efficacy of non-pharmacological treatments (including music and psychosocial interventions) for pain in community-dwelling people with dementia, with these studies highlighting mixed efficacy. Other systematic reviews report that non-pharmacological treatments (e.g. music therapy, Reiki, reflexology, person-centred showering or bathing) can be effective to reduce pain for people with dementia (Pu et al., 2018; Pieper et al., 2013). However alike to community settings, evidence from nursing home settings is also relatively limited, with small samples and low quality evidence (see Section 2.4.1).

3.6.3 Strengths and limitations

This review has notable strengths. It is the first to provide a broad overview of the evidence on pain assessment and treatment for pain for community-dwelling people with dementia. The search strategy developed in collaboration with experienced information specialists was comprehensive, and was conducted in a multitude of relevant databases to reflect the many

disciplines associated with both dementia and pain management (such as nursing, psychology, and physiotherapy). In addition to database searches, extensive supplementary searches were also completed. Despite extensive efforts, this review acknowledges the possibility that potentially eligible papers were not found, and thus not included in this review. For example, studies may have examined pain assessment and/or treatment for community-dwelling older adults, however a proportion of the sample have dementia (despite dementia not being their primary focus).

Despite best efforts to identify research conducted for people with dementia living in the community, many studies were not explicit regarding the residence of participants. In some cases, the necessary information was requested, but was not obtained (see Section 3.4.3.1) and therefore potentially eligible texts may have been excluded. Additionally, some studies provided information on pain assessment or pain treatment for people with cognitive impairment, using standardised instruments such as the MMSE. However, these studies did not provide sufficient information to confirm that participants had a diagnosis of dementia. Despite being ineligible for this review, the papers investigating pain assessment (Taylor & Herr, 2003; Taylor, Harris, Epps & Herr, 2005) and pain treatment (Maxwell et al., 2008; Hanlon et al., 1996; Pokela et al., 2010; Westerbotn, Hillerås, Fastbom & Agüero-Torres, 2008) for community-dwelling people with cognitive impairment reflect the findings and conclusions of this review.

As for all systematic reviews, there is the potential for publication bias or commonly coined 'file drawer problem' (Rosenthal, 1979, p. 638); the idea that a much larger proportion of significant findings are published than non-significant findings. Publication bias may mean that published studies do not reflect reality, thus implicating the conclusions of a systematic review. For this review, a mix of findings are evident; it is therefore anticipated that the likelihood for publication bias is low.

Finally, the conclusions of this review need to be contextualised within the limited research to date; 12 studies actively recruited participants with mild-to-moderate, or 'newly diagnosed'

dementia, with many more recruiting an insufficient number of participants with severe dementia. Therefore, the extent of evidence on people with advanced dementia is limited and further investigation is essential in this population.

3.6.4 Clinical implications

Due to the minimal high quality research to date, this review was unable to provide definitive recommendations regarding a pain assessment tool to use with community-dwelling people with dementia. Alternatively, healthcare professionals should adopt a multidimensional approach using 'a hierarchy of pain assessment techniques' including self-report assessments, pain history information, physical examinations, informant ratings, and observation of pain behaviours, in line with previous recommendations (Herr et al., 2011, p. 231). Reliance on one method alone may lead to suboptimal assessment and treatment.

In terms pain treatment, side effects, comorbidities, and polypharmacy are common in older adults, with the added complexity of cognitive impairment associated with dementia. Due to these complexities, care is particularly needed when new analgesics are initiated to balance the risks (e.g. side effects) against the need for pain relief. Additionally, regular and structured medication reviews are needed to assess the use, efficacy, and side effects of analgesic prescriptions in the community. In conjunction with pharmacological strategies, prescribing healthcare professionals should consider the use of non-pharmacological strategies to minimise pharmacological burden. Such measures are essential to improve pain treatment for people with dementia, which as identified in this review (and the literature review), remains suboptimal in many areas.

3.6.5 Research Implications

The explorative nature of this review wished to provide an overview of preliminary evidence into pain assessment and pain treatment for community-dwelling people with dementia. To complement the exploratory nature, no studies were excluded based on their study design. Despite many studies exploring pain assessment and pain treatment for people with dementia using qualitative designs, all of these studies failed to include community-dwelling

people with dementia (Geddis-Regan et al., 2018). This highlights the need for qualitative research exploring pain assessment and pain treatment from the perspective of the community-dwelling person with dementia.

In regard to pain assessment, research comparing multiple pain assessment instruments for a range of dementia severities using a clear, and pre-defined protocol within a community sample is required. High quality evidence is essential to assess the psychometric properties and clinical utility of pain assessment instruments (including self- and informant-based measures, and behavioural observation pain tools) for community-dwelling people with dementia. Additionally, only one study examined pain identification and assessment at a population level using primary care records for people with dementia (Li et al., 2015), calling for an epidemiological investigation of pain identification and assessment in UK primary care (Jennings et al., 2018b).

Future research investigating treatments for pain should stratify analgesic medications by therapeutic classification, with a focus towards high quality longitudinal evidence. Longitudinal evidence would allow investigation into pain for people with dementia throughout the course of their condition. Such evidence is essential to provide a basis for future RCTs, alike to those conducted already in nursing home settings where patient benefit has been demonstrated (Husebo et al., 2011a; Husebo et al., 2014a).

3.7 Conclusion

This review identified a dearth of high quality studies exploring pain assessment and/or treatment for community-dwelling people with dementia. The following chapter provides an overview of the rationale, aims, and objectives of the mixed methods investigation employed in this thesis, and how such aims fill the knowledge gaps outlined in the literature review (Chapter Two), and this systematic review.

4 Chapter Four: Research Aim and Objectives

This chapter provides a brief overview of the gaps identified throughout the literature review (Chapter Two) and the systematic review (Chapter Three), providing a rationale for this investigation. Finally, the objectives and research questions that steered this thesis are provided.

4.1 Gaps in the literature and rationale

The prevalence of pain is high for people with dementia (Jensen-Dahm et al., 2012; Krulewitch et al., 2000; Gilmartin et al., 2015; Barry et al., 2016; Shega et al., 2004; Mäntyselkä et al., 2004). Limited and inconsistent experimental evidence has been conducted to explore the physiological implications of dementia upon the experience of pain (Defrin et al., 2015). However, research to date suggests that brain atrophy and lesions associated with dementia do not lead to clinical reductions in the pain experience (Defrin et al., 2015; Hadjistavropoulos, Fitzgerald & Marchildon, 2010). In fact, recent research suggests that people with dementia may have a heightened perception of pain (De Tommaso et al., 2017). These findings cause great concern; especially considering that the majority of research evidence throughout the literature and systematic review indicate that pain for people with dementia remains inadequately assessed, and suboptimally treated (Chen & Lin, 2016; Corbett et al., 2012).

Pain identification, assessment, and treatment has gained a great deal of research attention in nursing home settings at present, however little research has focused on community-dwelling people with dementia (Hunt et al., 2015). This point was illuminated in the systematic review which identified limited and low quality evidence for community-dwelling people with dementia (see Chapter Three). This is a significant omission within the present body of literature because the majority of people with dementia reside in community settings (Prince et al., 2014). Furthermore, pain identification, assessment, and treatment for community-dwelling people with dementia is likely to be distinct from nursing home populations. In nursing home populations, care and support is often provided by a team of

care professionals (e.g. care assistants and nursing home nurses). In contrast, many community-dwelling people with dementia do not have regular contact with qualified healthcare professionals (Cooper et al., 2016). Instead, the care and support for community-dwelling people with dementia is often provided in the first instance by family and friends (Lakey et al., 2012). Unlike care professionals, it is likely that family and friends in the community will have limited professional experience when providing care for people with dementia. Additionally, the relationship between the person with dementia and their family caregivers in the community is likely to be distinct from relationships formed in nursing home settings, with unique motivations (a sense of love, spiritual fulfilment, sense of duty) and strains (balancing other demands, financial challenges, social isolation) when providing care (Brodaty & Donkin, 2009). The distinct motivations and strains are likely to influence the family caregiver's approach to, and perspective towards pain identification, assessment, and management for people with dementia. If the family member or friend recognises the need for professional healthcare involvement, GPs are often the first point of contact for ongoing care and support in the community (Jennings et al., 2018b; Lakey et al., 2012). This clearly shows a series of interconnected mechanisms to access formal care and support for people with dementia in the community that differ to nursing home settings.

When GPs consider the need for specialist input, the GP acts as a gatekeeper to secondary care services (Sripa, Hayhoe, Garg, Majeed & Greenfield, 2019). The pain experienced by people with dementia may be expressed as pain behaviours and interpreted as behavioural and psychological symptoms (Flo, Gulla & Husebo, 2014; Husebo et al., 2011a; Pieper et al., 2013; Tampi et al., 2017). As a consequence, GPs may refer behavioural and psychological symptoms to specialist secondary care services (e.g. old age psychiatry) to determine the driver of the symptom (Bishara, Taylor, Howard & Abdel-Tawab, 2009; Banerjee, 2009), and anti-psychotic medication could be prescribed (Haw, Stubbs & Yorston, 2008). This may indicate the unique complexity of pain assessment and interpretation within community settings, with multiple levels of investigation and interpretation within and between informal caregivers, primary care, and secondary care.

Recent research has called for quantitative studies to examine pain assessment and analgesic prescribing for community-dwelling people with dementia (Jennings et al., 2018b), with many of the population-based prevalence studies to date being restricted to nursing home populations (Lövheim et al., 2008). The need for quantitative investigation was illuminated by the lack of high quality longitudinal research investigating pain assessment and pain treatment for community-dwelling people with dementia (see Chapter Three), with only two studies being conducted in the UK.

A recent meta-review identified the lack of qualitative evidence exploring pain assessment and management for people with dementia (Geddis-Regan et al., 2018). In particular, this review found that the perspectives of people with dementia towards pain identification, assessment, and treatment remain ignored in research, despite pain directly affecting their lives (Geddis-Regan et al., 2018). Six studies have explored the perspective of informal (often family) caregivers (Geddis-Regan et al., 2018; Kankkunen & Välimäki, 2014), however only one reflected upon pain in the community (Martin et al., 2005). Many studies have explored the perspective of healthcare professionals (including nurses, nursing assistants and care home managers) when identifying, assessing and managing pain in nursing home, hospice, and acute care settings (Geddis-Regan et al., 2018). To date, only two studies have explored the perspective of GPs (albeit reflecting upon a residential aged care setting; Chang et al., 2009, or pain assessment at the end of life; De Witt Jansen et al., 2018), with research highlighting that 'future qualitative research with GPs in this area would help gain a deeper understanding of the context and nuances that are involved in this complex area' (Jennings et al., 2018b, p. 8). Studies are yet to explore the perspective of GPs and old age psychiatrists despite their important role to identify pain, and determine the driver of behavioural and psychological symptoms for people with dementia living in the community (Geddis-Regan et al., 2018).

These gaps in the literature suggest a mixed methods investigation (using quantitative and qualitative data) would be appropriate to provide an in-depth and encompassing

understanding of pain for community-dwelling people with dementia. A mixed methods investigation will inform the development of interventions to improve pain management for community-dwelling people with dementia in primary care (Jennings et al., 2018b). Such interventions are essential to improve pain identification, assessment, and treatment for people with dementia to directly reduce the occurrence of falls (Stubbs et al., 2014; Crowe et al., 2017a), emergency department visits (Hunt et al., 2018), delirium (Feast et al., 2018), cognitive decline (Cook et al., 1999; Buffum et al., 2004), and mortality (Rajkumar et al., 2017). In addition to the direct benefits, improved pain management also has the potential to reduce behavioural and psychological symptoms for people with dementia, thus indirectly reducing the number of avoidable nursing home admissions, reducing anti-psychotic prescriptions, shortening hospital stays, and improving quality of life (Lichtner et al., 2014; Kales et al., 2015; Forester & Vahia, 2019; Ballard et al., 2009). Improved pain management therefore has the potential to contribute to UK recommendations and policy; to help reduce unnecessary anti-psychotic prescriptions for people with dementia (Department of Health, 2015; Napp Pharmaceuticals, 2014), indirectly supporting people with dementia to continue living in the community (Lakey et al., 2012).

4.2 Research aim and objectives

The overarching aim of this thesis was to investigate pain identification, pain assessment, and pain management for community-dwelling people with dementia.

This aim encapsulated a number of quantitative and qualitative focused research questions, in line with the convergent mixed methods design (Creswell & Plano Clark, 2018; see Section 5.4.2.1), which were conceptually captured by two research objectives:

Research objective 1: To investigate pain identification and pain assessment for community-dwelling people with dementia

Research questions:

- What are the incidence and prevalence rates of musculoskeletal consultations for people with dementia compared to older adults without dementia?
- What are the annual incidence and prevalence rates of musculoskeletal consultations over time for people with dementia?
- How do family caregivers and healthcare professionals identify and assess pain for community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain identification and assessment strategies for community-dwelling people with dementia?

Research objective 2: To investigate the management of pain for community-dwelling people with dementia

Research questions:

- What is the prevalence of analgesic prescriptions for people with dementia compared to older adults without dementia?
- What are the annual prevalence rates of analgesic prescription over time for people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals manage the pain experienced by community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain management strategies for community-dwelling people with dementia?

4.3 Conclusion

This chapter has provided an overview of the gaps in the literature, the rationale, and the research objectives of this study. The following chapters provide details of the mixed

methods approach adopted in this study (see Chapter Five), along with the quantitative and qualitative methods employed (see Chapter Six).

5 Chapter Five: Methodology

5.1 Introduction

This chapter provides an overview of ontology and epistemology, theoretical perspectives, and methodologies guiding social research. Throughout this chapter, the theoretical perspective, and mixed methodological approach of this thesis are discussed.

5.2 The four elements of social research

This thesis subscribes to Crotty's (1998) 'four elements' of social research. These elements guide the justification of the methodology and methods employed in this thesis. Justification is provided by giving an overview of ontology, epistemology, and theoretical perspectives, along with their inherent assumptions[1]. An overview of these four elements are provided in Figure 5.1

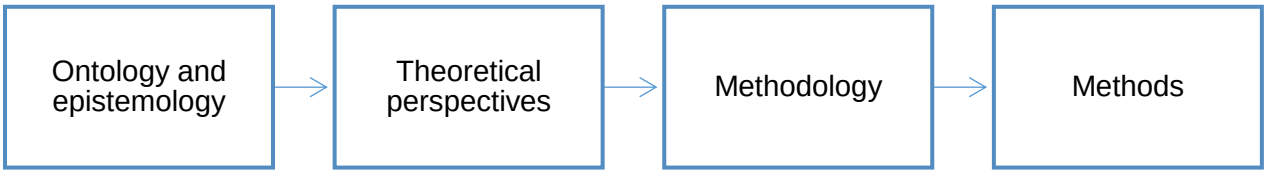


Figure 5.1. The four elements of social research (adapted from Crotty, 1998).

The first three elements of Crotty's (1998) framework are discussed sequentially throughout this Chapter. To aid explanation and to give a sense of the distinction and diversity between ontological, epistemological, and theoretical perspectives, I have chosen to use opposing perspectives that sit at either end of the continuum as guided by Moon and Blackman (2014; see Figure 5.2). I acknowledge that many additional philosophical and theoretical perspectives are also available to underpin research.

[1] Crotty (1998) does not include ontology due to his perspective that '*ontological issues and epistemological issues tend to emerge together'* (p. 10). However, this thesis provides a brief overview of ontology to provide context for the theoretical perspective of this thesis.

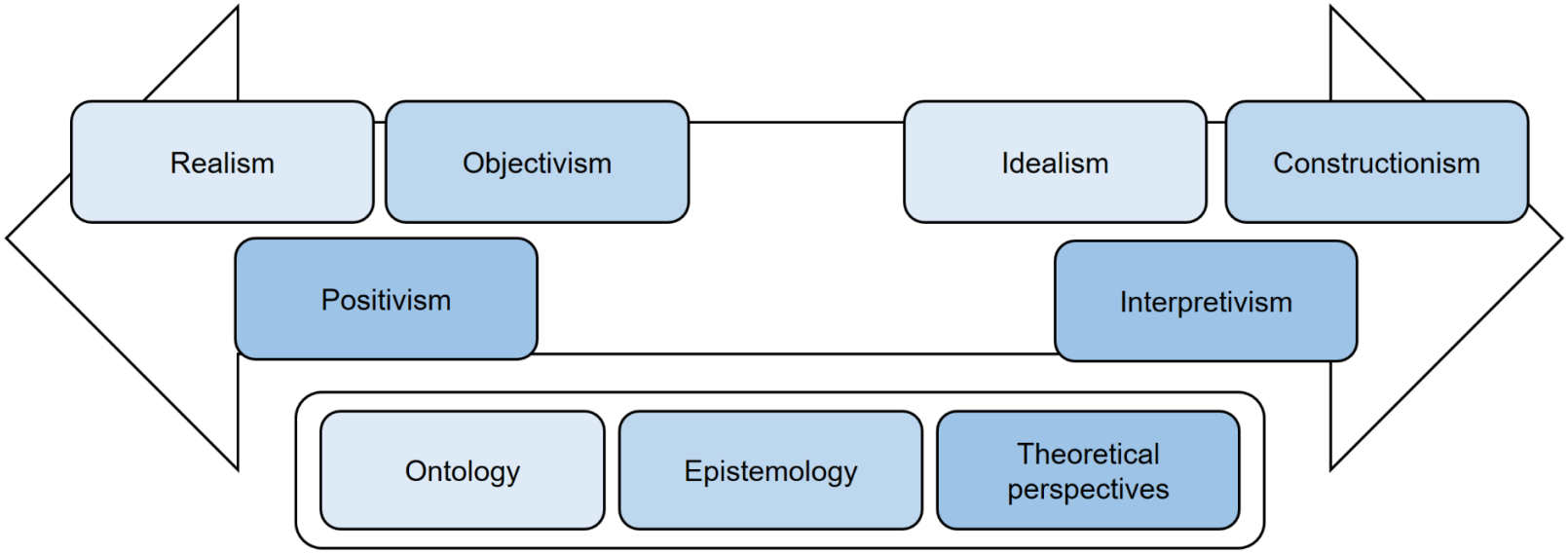


Figure 5.2. Opposing epistemological, ontological, and theoretical perspectives

For research in the social sciences, two key areas of philosophical debate underpin each theoretical perspective. The first of which concerns the nature of *reality*, and the social world, known as ontology (see Section 5.2.1). The second is epistemology that relates to the nature of *knowledge* (see Section 5.2.2). To facilitate the discussion of ontology and epistemology, in each section outlined below, I have used opposing examples (e.g. realism vs. idealism, objectivism vs. constructionism) that sit at either side of the ontological and epistemological spectrum. The presentation of opposing perspectives provides the contextual information essential to understand the theoretical perspective of this thesis (see Section 5.3.2).

5.2.1 What is ontology?

Ontology relates to the nature of *reality* or what is real. Ritchie, Lewis, Nicholls, and Ormston, (2013) identify two distinct, yet broad ontological positions; realism and idealism (see Figure 5.2). Realism suggests that an external reality exists independent of human interpretation, highlighting a distinction between 'reality' and our constructed beliefs and understanding of reality. In contrast, idealism (or similarly, relativism) believes that reality is dependant, and knowable only through the human mind and socially constructed meanings.

5.2.2 What is epistemology?

The second philosophical concept is epistemology, the theory of *knowing*, in other words, how we know what we know. Epistemology provides a philosophical grounding for what kind of knowledge is possible. Crotty (1998) identified objectivism and constructionism as opposing concepts within epistemological understanding (see Figure 5.2; Moon & Blackman, 2014). The key tenants of objectivism and constructionism are provided in Table 5.1.

Table 5.1. Epistemological perspectives: Objectivism and constructionism

Epistemological view	Key tenants
Objectivism	Objects exist as meaningful entities independently of consciousness and experience, that they have truth and meaning residing in them as objects
Constructionism	Truth or meaning comes into existence in and out of our engagement with the realities in our world. There is no meaning without mind. Meaning is not discovered, but rather constructed.

Definitions adapted from Crotty (1998).

5.3 Theoretical perspectives

Theoretical perspectives describe the philosophical stance and the assumptions that lie behind the methodology, guiding the researcher (Crotty, 1998). This thesis uses the term 'theoretical perspective' to illuminate the continuum of the philosophical spectrum. By doing so, I hope to move beyond the prescriptive connotations of the term 'paradigm' that has perpetuated the view that methods of enquiry are bounded or restricted (Shannon-Baker, 2016). There are many theoretical perspectives to research described in the literature (Crotty, 1998). However, for the purpose of this thesis, I will again provide an overview of the perspectives that are perceived to sit at alternate ends of the philosophical spectrum; positivism and interpretivism (Creswell, 2009; see Figure 5.2). These theoretical perspectives were chosen to align with the previously discussed tenants of ontological realism and idealism, and epistemological objectivism and constructionism (Creswell, 2009). Additionally, positivism and interpretivism provide a sense of the 'extremes' at either end of the philosophical spectrum.

5.3.1 Positivism and interpretivism

Positivism is traditionally linked to empirical sciences, emphasising the importance of theory verification and an objective and measurable truth that reflects a universal reality. Positivists are optimistic and faithful in scientific progress, with scientific knowledge holding a high

degree of objectivity, precision and certitude. Positivism is objectivist in nature, meaning that objects have meaning prior to, and independently of our consciousness of them, allowing the world to be measurable and free from subjectivity. In more recent years, an attenuated version of positivism evolved to combat the 'arrogance' of positivism (Crotty, 1998), called post-positivism. Post-positivism recognised science to have a degree of objectivity, rather than absolute objectivity, and reflected upon the probability rather than certainty of scientific knowledge. At the alternate end of the theoretical perspective spectrum, interpretivism emerged in contradistinction to positivism as a theoretical perspective to explain human and social reality. In contrast to the single absolute truth associated with the positivist theoretical perspective, interpretivists acknowledge the need to understand how an individual engages with, and understands the social world based on their cultural, historical, and social perspectives.

Each theoretical perspective is underpinned by an epistemological and ontological position, with restrictions as to *which* philosophical positions are appropriate for each theoretical perspective (Crotty, 1998). In the description of positivism (see above) it is clear to see the realist (ontology) and objectivist (epistemology) philosophical underpinnings (see Table 5.1). Similarly, in the description of interpretivism, the idealist (ontology) and constructionist (epistemology) philosophical underpinnings are clear. If positivism was not objectivist in nature, it would not be what we perceive it to be. Similarly, interpretivism could not have an objectivist epistemology, as this would go against the wish to explore subjective experiences of reality, shaped by culture and history.

The contentions between the positivist and interpretivist theoretical perspectives have been coined as the 'paradigm wars', with purists suggesting that the two research cultures cannot, and should not coalesce (Howe, 1988; Guba, 1990). Depending on the theoretical perspective underpinning the research, differing methodologies, and methods of research enquiry are likely to be chosen. For example, positivists' deterministic philosophy (meaning that the causes probably predict the outcome) often lead to quantitative based methodology

and methods (such as survey designs and experiments). Interpretivists seek to understand the world that we live in, by exploring individual's subjective perspectives, views, and experiences often leading to qualitative based methodology and methods (e.g. ethnography and interviews). The contentions between the epistemological and ontological foundations of each theoretical perspective, and their chosen methodologies and methods means that some researchers believe that quantitative and qualitative methods are incompatible and cannot be consolidated in a single project (Reichardt & Rallis, 1994; as cited in Sale, Lohfeld & Brazil, 2002).

Other researchers argue, however, that the contentions between positivists and interpretivists are because of political diversions between social scientists, when in fact, both perspectives share many epistemological and ontological commonalities. Both positivism and interpretivism wish to uncover 'truths' that best represent or correspond to reality (whether that is a universal reality, or multiple-socially constructed realities). Therefore, although I acknowledge that philosophical and theoretical perspectives underpin the methodology (and ultimately the methods) of choice (Greene & Hall, 2010; Creswell, 2009), I do not agree that terms such as 'quantitative' and 'qualitative' are synonymous with a particular theoretical perspective. Instead, I believe that these terms should be purely used to describe the method of enquiry.

5.3.2 Theoretical perspective for this thesis

Positivism and interpretivism have been discussed as theoretical perspectives sitting at either side of the philosophical continuum (see Section 5.3.1). Each perspective is underpinned by opposing ontological and epistemological assumptions, determining what kind of knowledge is possible. Alternatively, critical realism was formed in response to the polarisation created by the paradigm wars between positivism and interpretivism (see Figure 5.3), and is now the most prominent manifestation of realism in the social sciences (Maxwell, 2012; Maxwell & Mittapalli, 2010).

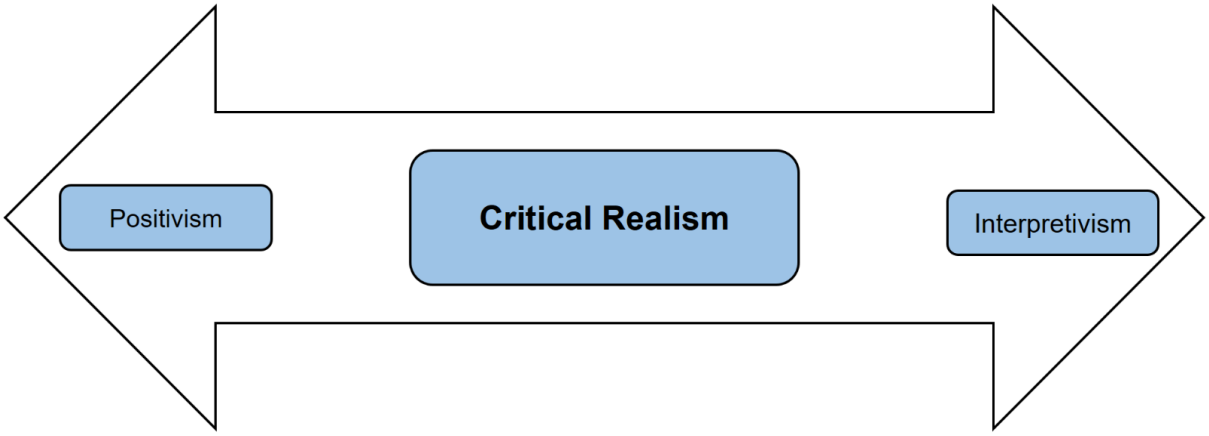


Figure 5.3. Critical realism in the theoretical spectrum

Critical realism is typically attributed to the work of Bhaskar (1978, 1989). The philosophical position of this thesis aligns with that described by Maxwell (2012) who draws upon various versions of 'realism', including critical realism, pragmatic realism, subtle realism, experiential realism, and emergent realism. This thesis uses the term 'critical realism' as a broad term to encompass the key common tenants of all of these versions of realism (Maxwell, 2012).

The integral element of the critical realist stance is the constructionist epistemology, with a realist ontology (Maxwell, 2012; McEvoy & Richards, 2006; Pilgrim, 2019). In other words, critical realism denies an 'objective' or certain knowledge of the world, suggesting that all knowledge is grounded by each individual's perspective. In line with this notion, a critical realist stance acknowledges that embedded structures, institutions, and bodily realities exist independent of our perception of them, however, each individual has their own subjective, real-world lived accounts shaped by culture, history, and experience (Williams, 1999; Williams, 2003). Therefore, knowledge is both constructed and based upon the reality of the world we experience and live in (Rogers & Pilgrim, 2014). This reflects my own ontological and epistemological perspective that bodily realities such as dementia and pain exist independent of our construction of them and therefore can be measured quantitatively. Each individual, however, has their own subjective perception dependent upon temporal and

contextual factors warranting qualitative exploration of perspective, views, and experience (Williams, 2003).

The constructionist epistemology, along with a realist ontology makes critical realism a philosophical perspective that validates and supports the use of mixed methods (Maxwell, 2012; Maxwell & Mattapalli, 2010; Creswell & Plano Clark, 2018).

5.4 Mixed methodology

Methodology is defined by Crotty (1998) as '*the strategy, plan of action, process or design lying behind the choice and use of particular methods'* (p. 3). Based upon this definition, the methodology underpinning this thesis is a mixed methodology. Mixed methods research (or as otherwise referred to as multi-method, integrated, convergence and combined research; Creswell & Plano Clark, 2018) broadly relates to the combination of quantitative and qualitative methods. Mixed methods was first introduced by Campbell and Fiske (1959), and has grown in popularity since this time. However, there remains no consensus about how mixed methods research should be defined or conducted. To illustrate, Johnson, Onwuegbuzie and Turner (2007) obtained 19 definitions of 'mixed methods' by contacting 31 methodologists. An analysis of these definitions was conducted, and on this basis, Johnson et al. (2007) provided their own broad definition of mixed methods research:

> *Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration.*
>
> Johnson, Onwuegbuzie and Turner, 2007, p. 123

The convergence of both quantitative and qualitative data provides a comprehensive understanding of the research problem, allowing a 'properly integrated methodology for the social sciences' (Morgan, 2007, p. 73). The inherent dichotomous nature of quantitative and

quantitative methods suggests that the limitations of one method are likely to be the strengths of the other (Tashakkori & Teddlie, 2010). Johnson et al. (2007) noted (in agreement with many other researchers Creswell, 2009; Tashakkori & Teddlie, 2010) that mixed methods are utilised when either quantitative or qualitative methods independently do not answer the research objective in sufficient depth or breadth. A mix of quantitative and qualitative methods are not only acceptable, but in fact doing so is desirable in social research to meet the research objectives (Greene et al., 2005; Denscombe, 2008).

Despite the strengths of mixed methods research, this methodology does pose limitations for the researcher, including the requirement for knowledge in both quantitative and qualitative methods, and the time-intensive nature of extensive data collection and analysis (Creswell, 2009).

5.4.1 Rationale for mixed methods

While mixing methods may pose challenges, it was deemed the most appropriate approach to meet the objectives of this thesis. Given the limited research exploring pain identification, assessment, and management for community-dwelling people with dementia (as highlighted within the literature and systematic review), a mixed methods investigation is desirable to gain a wider and deeper understanding of the phenomena. Quantitative nor qualitative data in isolation could fulfil all of the research questions (see Section 4.2). For example, although quantitative data could investigate an aspect of pain management for people with dementia by *examining* the *amount* or *frequency* of analgesic prescriptions through the quantification of primary care consultations, this data is unable to *explore* the *perspectives* towards analgesic medications (see Section 4.2).

5.4.2 Mixed method designs

There are many strategies and design aspects to consider when formulating a mixed methods study. These design aspects include the timing, weighting, and mixing of quantitative and qualitative elements of a research project. This thesis follows the Creswell and Plano Clark (2018) mixed methods framework. This framework outlines three core mixed

method designs, including the convergent, explanatory sequential, and exploratory sequential design (see Figure 5.4).

Convergent design	Explanatory sequential design	Exploratory sequential design
•Quantitative and qualitative data collection and analysis conducted concurrently •Results are merged and compared •Interpretation	•Quantitative data collection and analysis conducted first •Followed by qualitative data collection and analysis •Interpretation	•Qualitative data collection and analysis conducted first •Followed by quantitative data collection and analysis •Interpretation

Figure 5.4. Creswell and Plano Clark (2018) mixed methods designs

5.4.2.1 Convergent mixed methods design

The mixed methods design chosen for this thesis was the convergent mixed method design (or sometimes called parallel study, convergence model, or simultaneous triangulation). A convergent design means that the data collection and analysis for both the quantitative and qualitative streams were conducted in parallel (see Figure 5.4; Creswell & Plano Clark, 2018). A convergent mixed methods design was chosen for this thesis to obtain 'different but complementary data on the same topic' (Morse, 1991. p. 122). This was important for this thesis, as the quantitative and qualitative research questions (thus different data) were mapped to an overarching, complementary research objective to develop a 'complete' understanding of the phenomena (see Section 4.2; Creswell & Plano Clark, 2018). The complete understanding is obtained as the strengths of quantitative data often reflect the weaknesses of qualitative data, and vice versa.

In the nature of a convergent mixed methods design, the quantitative and qualitative data were collected, analysed, and integrated in parallel. Therefore, Creswell and Plano Clark (2018) recommend that the researcher does not employ multiple philosophical perspectives

to approach a convergent mixed methods design. In line with this recommendation, this thesis approached the research with critical realism as the 'umbrella' theoretical perspective, acknowledging the existence of reality, and each individual's subjective, real-world lived accounts shaped by culture, history, and experience (see Section 5.3.2), complementing the quantitative and qualitative methods (Creswell & Plano Clark, 2018).

A convergent design to mixed methods research has many advantages. Unlike sequential designs, convergent designs are more efficient, allowing the data collection and analysis to run in parallel during a single phase of the study. Additionally, traditional approaches to quantitative and qualitative data analysis can be employed prior to integration, allowing team members with different methodological expertise to work together. The convergent design has notable challenges that the researcher must overcome (alongside the general challenges of mixed method designs; see Section 5.4). Firstly, as quantitative and qualitative data produce vastly different outputs (statistical vs. lexical) the integration of the findings can be challenging, especially if each do not directly address the same concept. Additionally, during integration the researcher must identify convergence and divergence between the quantitative and qualitative findings. However, as both quantitative and qualitative design, data collection, and analysis were conducted in parallel (see Figure 5.5); interpretations of the qualitative analysis may have been influenced by the ongoing quantitative analysis (and vice versa). This may influence and alter my perception of convergence or divergence. Finally, if findings diverge, Creswell and Plano Clark (2018) recommend additional data collection and/or analysis to explore the divergence. This process would add time and complexity to the study.

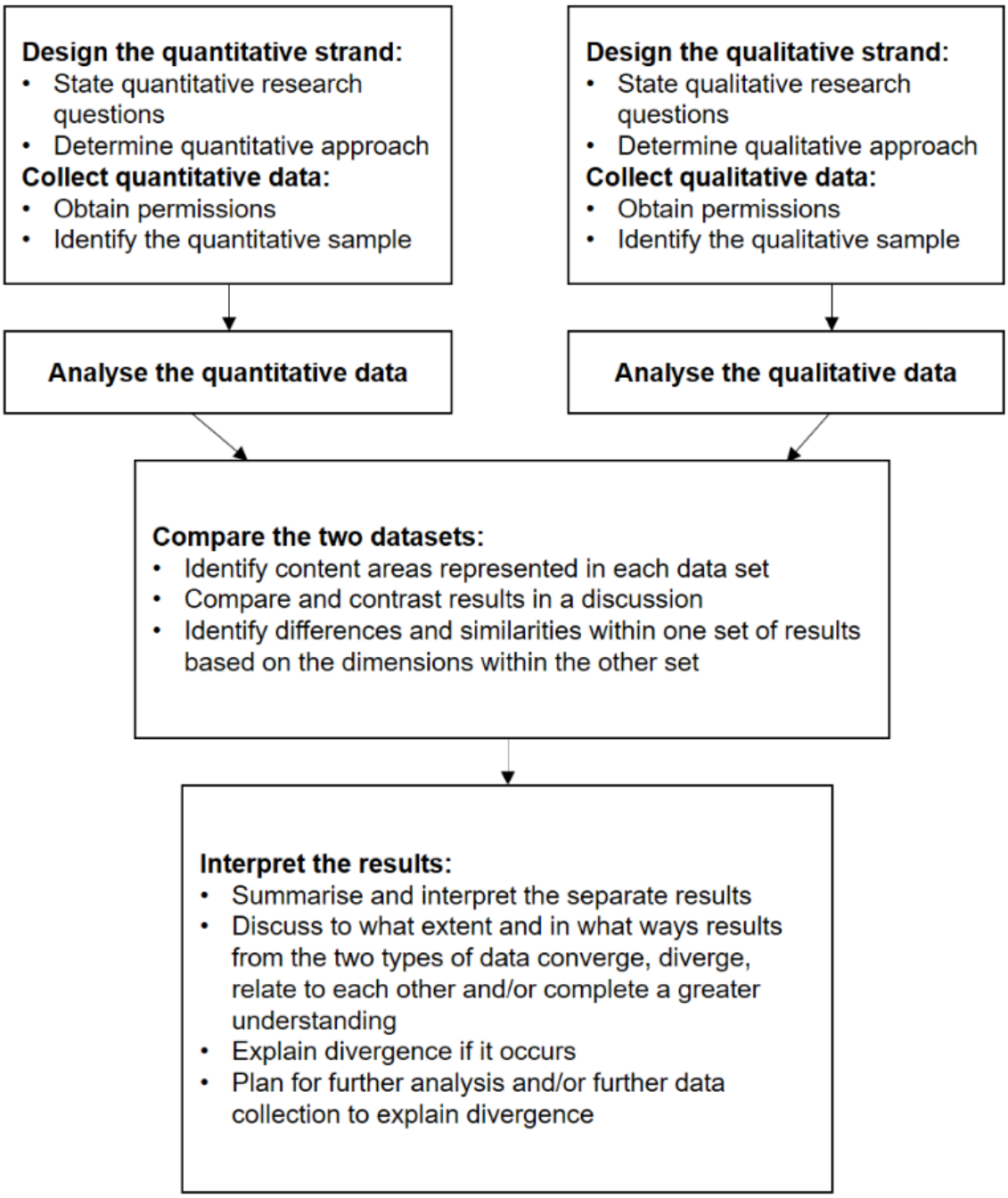


Figure 5.5. Procedural diagram to illustrate the convergent mixed methods design (adapted from Creswell & Plano Clark, 2018).

5.4.2.1.1 Data analysis

Following quantitative and qualitative design and data collection, the findings are analysed separately, using the most appropriate method for the data in question (see Figure 5.5). The analytical approach employed for the quantitative and qualitative methods are outlined in the following Methods Chapter (see Chapter Six). Each findings chapter provides the separate quantitative and qualitative findings (prior to integration) relating to each research objective sequentially:

- **Chapter Eight:** To investigate pain identification and pain assessment for community-dwelling people with dementia (research objective 1)
- **Chapter Nine:** To investigate pain management for community-dwelling people with dementia (research objective 2)

Following separate analysis, the quantitative and qualitative findings should be brought together to 'combine' or 'compare' the findings. This process in mixed methods is often called 'integration' (Creswell & Plano Clark, 2018). One challenge of the convergent mixed method design involves the integration of two sets of very different data in a meaningful way. Therefore, to aid the integration process, Creswell and Plano Clark (2018) described several methods of quantitative and qualitative data integration:

- **Data transformation** - typically transforming qualitative data into quantitative data to allow direct comparison
- **Joint display of data** – the researcher merges the two forms of data into a table or graph; effectively merging the data into a single visual display
- **Side-by-side comparison** – the researcher narratively reports the findings of one method (e.g. quantitative) and then discusses the findings from the alternate method (e.g. qualitative) that either confirm or disconfirm the findings

For this thesis, neither quantitative nor qualitative data were deemed 'dominant' approaches, with each providing a valuable, detailed, and nuanced understanding of the phenomena that

would be lost if transformed or minimised into a visual display. Therefore, side-by-side comparison was chosen as the most appropriate method of integration. This approach allows convergence and divergence between the statistical trends and the voice of the participants to be explored and inferred (Creswell & Plano Clark, 2018).

In this thesis, the quantitative and qualitative findings are integrated in the discussion chapter (see Chapter Ten); acting as a 'vehicle for merging the results' (Creswell & Plano Clark, 2018, p. 226). Quantitative and qualitative findings are presented side-by-side in a narrative discussion organised by the research objectives (Creswell & Plano Clark, 2018). This method of integration allows for reflection as to how well the quantitative and qualitative findings agree (converge) or disagree (diverge), allowing for an in-depth and complete understanding of the phenomena.

5.5 Conclusion

This chapter provided an overview of the philosophical approaches to social research by exploring the opposing ontological, epistemological, and theoretical perspectives. Deviating from the prescriptive 'paradigm wars', this thesis positions itself within the broad spectrum of 'critical realism'. The constructionist epistemology, with a realist ontology reflects my personal worldview, and provides a philosophical underpinning for the mixed methodology of this thesis. This chapter continued to discuss the rationale for using a mixed methods design, and provided an overview of the convergent design chosen to investigate pain identification, assessment, and management for community-dwelling people with dementia. The following chapter describes the quantitative and qualitative methods that encapsulate the convergent mixed methods design, and the analytical approach.

6 Chapter Six: Methods

6.1 Introduction

In the previous Chapter, the theoretical perspective and mixed methods approach to this thesis were discussed. This Chapter provides an overview of the quantitative and qualitative methods used to investigate pain identification, assessment, and treatment for community-dwelling people with dementia. Inherent with a convergent mixed methods design, the quantitative and qualitative data collection and analysis were conducted in parallel throughout the study; however, each are discussed sequentially for the purpose of this chapter.

6.2 Quantitative methods

Epidemiology is 'the study of the distribution and determinants of health-related states or events in specified population and the application of this study to control health problems' (Szklo & Nieto, 2014, p. 3). Three key inter-related characteristics encompass epidemiological principles – determinants, frequency, and distribution – all of which rely upon the availability of comprehensive data as a 'prerequisite for any systematic investigation' (Hennekens, Buring & Mayrent, 1987, p. 3). This study used epidemiological principles to determine numeric patterns and trends for a specific population, and specifically to answer the following research objectives and questions:

Research objective 1: To investigate pain identification and pain assessment for community-dwelling people with dementia

- What are the incidence and prevalence rates of musculoskeletal consultations for people with dementia compared to older adults without dementia?
- What are the annual incidence and prevalence rates of musculoskeletal consultations over time for people with dementia?

Research objective 2: To investigate the management of pain for community-dwelling people with dementia

- What is the prevalence of analgesic prescriptions for people with dementia compared to older adults without dementia?
- What are the annual prevalence rates of analgesic prescription over time for people with dementia?

6.2.1 Primary and secondary data

Both primary, and secondary analysis of existing data would be suitable to investigate the epidemiology of pain identification, assessment, and treatment for people with dementia. Primary data is collected by the researcher (or research team) for the purpose of the research question and analysis. Contrarily, secondary analysis of existing data is the 'analysis of data collected by someone else' (Boslaugh, 2007, p. ix), for example, national surveys, university records, government or census records, and electronic health records (EHR). Secondary analysis of existing data is primarily formulated in two ways: 'driven by the research question' or 'driven by the data available' (Cheng & Phillips, 2014). In most cases, the choice between these two drivers is an iterative process. In the first instance, the research may be driven by the research question, and datasets are found to suit such question, however specific variables may not be included, and therefore adaptations are driven by the available data.

Due to time-restrictions imposed by the nature of this project, it was not possible to collect primary data. For example, the recruitment of sufficient numbers of participants for the quantitative analysis was not feasible in terms of time (i.e. a number of years of follow up data were required to reflect the course of dementia over time) as well as issues of cost and study management. Therefore, secondary analysis of existing and suitable data was used for this study.

6.2.1.1 Electronic Health Records (EHR)

EHR most often provide rich, longitudinal records for large populations (Casey, Schwartz, Stewart & Adler, 2016). In the UK, 98% of the population are registered with a general practice (NHS Digital, 2012), and as part of the NHS attending the general practice is free,

thereby making primary care EHR an ideal representative sample base. Primary care clinicians are the first contact health services (for non-emergency), acting as the gatekeeper to secondary care services in the UK (Sripa et al., 2019). Additionally, patient information is communicated from secondary care to the patient's GP. Primary care EHR databases combine all of this information in one centralised record for patients and thereby contain extensive and varied routinely collected health-related information over a longitudinal period. Such factors have increased the use of primary care EHRs for research purposes generally (de Lusignan & van Weel, 2005; Weiskopf & Weng, 2013; Häyrinen, Saranto & Nykänen, 2008), and for dementia specifically (Dunn, Mullee, Perry & Holmes, 2005; Rait et al., 2010; Walters et al., 2016; Dell'Agnello et al., 2018). However, primary care databases do not come without their challenges with the potential for incomplete and inaccurate data (Porcheret et al., 2004; Glasgow, Kaplan, Ockene, Fisher & Emmons, 2012). An overview of the general strengths and limitations of EHR data are provided in Table 6.1.

Table 6.1. Strengths and limitations of secondary analysis of EHR

Strengths	**Weaknesses**
1. Low cost*	1. Missing data
2. Quick to gain longitudinal data	2. Incomplete, or incorrect data entries
3. Reduced likelihood of bias e.g. retrospective recall	3. Not inherently designed for the study in question
	4. Expensive to access
4. High quality data	
5. Breadth of data available	

**In relative terms compared to collecting new data for a study (Boslaugh, 2007)*

Many UK primary care databases are available, and, the three largest in terms of potential sample are the Clinical Practice Research Datalink (CPRD; https://www.cprd.com/), The Health Improvement Network (THIN; https://www.ucl.ac.uk/iehc/research/primary-care-and-

population-health/research/thin-database/database) and QResearch (https://www.qresearch.org/).

6.2.1.2 Clinical Practice Research Datalink

The CPRD (or as previously named, GPRD or VAMP) is a longitudinal primary care medical database. The CPRD GOLD contains data contributed by general practices using Vision software. As of June 2017, the GOLD dataset collected data from 693 contributing practices across England, Wales, Scotland, and Northern Ireland, and held information on 14.2 million research acceptable patients, of which 2.8 million were currently active (The Farr Institute, 2017). Research conducted in 2013 found that when compared to the UK 2011 census, patients contributing to CPRD were representative of the UK population in relation to age, gender, and ethnicity (see Figure 6.1; Herrett et al., 2015). CPRD is representative as it is based on NHS data, in a healthcare system free at the point of use. CPRD data therefore tends to be more generalisable of the entire UK population than healthcare data in other healthcare systems based upon data from a portion of the population with medical insurance.

CPRD GOLD includes all coding in general practice using practice and patient 'pseudo-identifiers' to maintain anonymity; including data on demographics, diagnoses, symptoms, signs, prescriptions, and tests. Primary care staff contributing data to CPRD GOLD were historically requested to record a diagnostic code for any new problem (Lawson, Sherman & Hollowell, 1998). Additionally, diagnoses made in secondary care are included in the CPRD GOLD providing letters are communicated to the general practice and recorded appropriately (Appleyard, Ashworth, Bedson, Yu & Peat, 2019). All prescriptions issued by GPs are automatically recorded (Herrett et al., 2015). If a medication started in secondary care was continued as a repeat prescription by the GP (who is largely responsible for a patient's ongoing prescription), this would appear in the CPRD GOLD data. Therefore, only one-off medication prescriptions initiated in secondary care may be missed.

Anonymised primary care patient data in CPRD GOLD can be individually linked to secondary care data, and other health and area-based datasets, such as the Hospital

Episode Statistics (HES), Death registration data, and Index of Multiple Deprivation (IMD). For this study, CPRD GOLD data was linked to Practice Level IMD data. Practices with linked data have been shown to be similar to practices without linkage (Gallagher, Puri & van Staa, 2011).

Despite the potential of CPRD for research purposes, there are limitations associated with CPRD (e.g. missing data and cost of access) that echo the limitations from EHR generally (see Table 6.1).

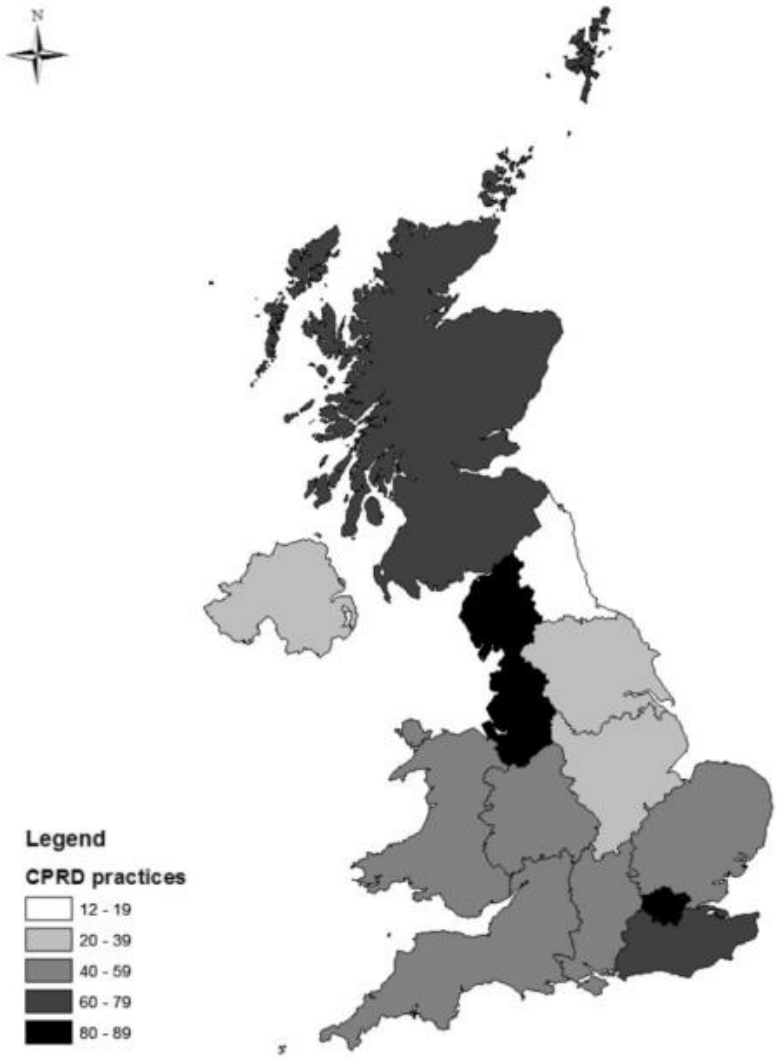


Figure 6.1. Distribution of CPRD practices by region in England, Wales, Scotland, and Northern Ireland (Herrett et al., 2015)

6.2.2 Epidemiological study designs

An important aspect of the investigation in this thesis was the longitudinal relationship between the exposure (dementia) and the outcome (consultations for potentially painful conditions and prescriptions of pain medication), rendering cross-sectional designs inappropriate. Cohort designs can be classified into retrospective or prospective depending upon the temporal relationship between the initiation of the study, and the outcome. An overview of retrospective and prospective cohort designs, as well as case-control designs are provided below.

6.2.2.1 Cohort design

Prospective designs recruit participants with the exposure, however the outcome has not yet occurred. A pictorial representation of a prospective cohort study design is provided in Figure 6.2.

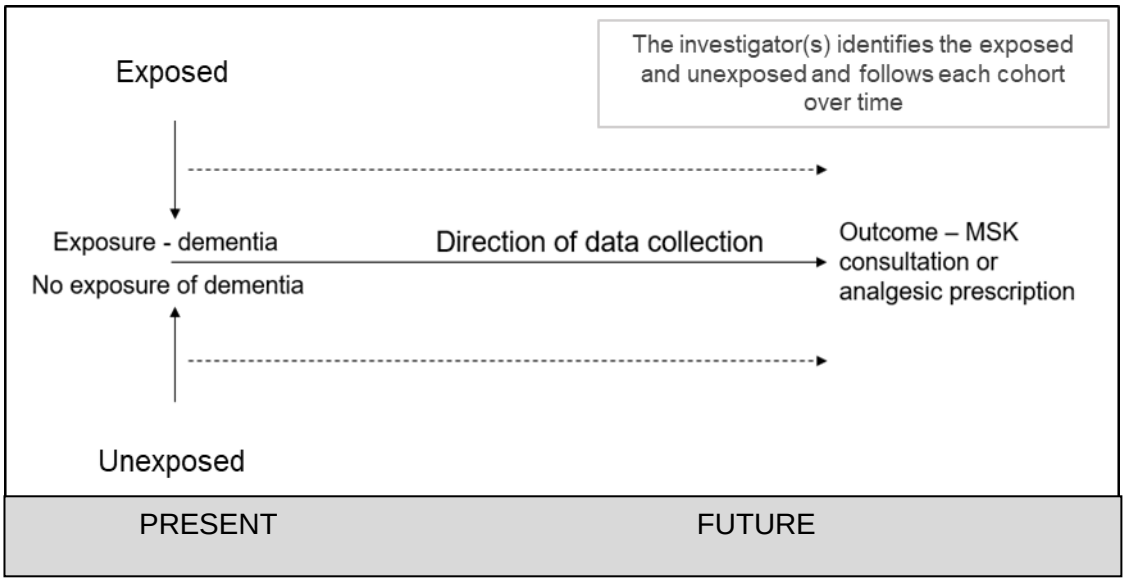


Figure 6.2. Pictorial representation of a prospective cohort design

Retrospective designs are initiated after the exposure and outcomes have been recorded. See Figure 6.3 for a pictorial representation of a retrospective cohort study design.

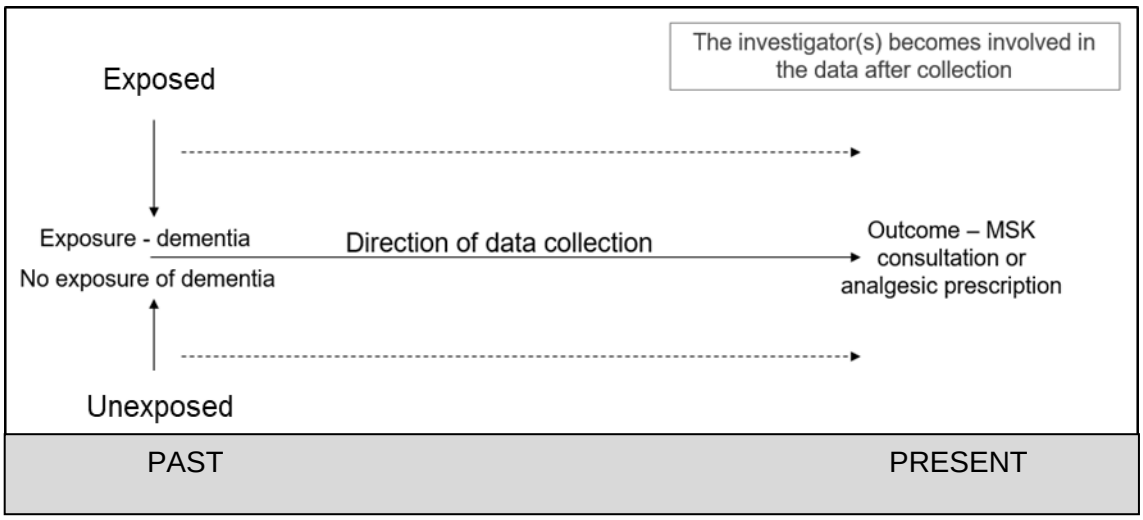


Figure 6.3. Pictorial representation of a retrospective cohort design

6.2.2.2 Case-control designs

Case-control designs are often confused with retrospective cohort designs. See Figure 6.4 for a pictorial representation of a case-control study design.

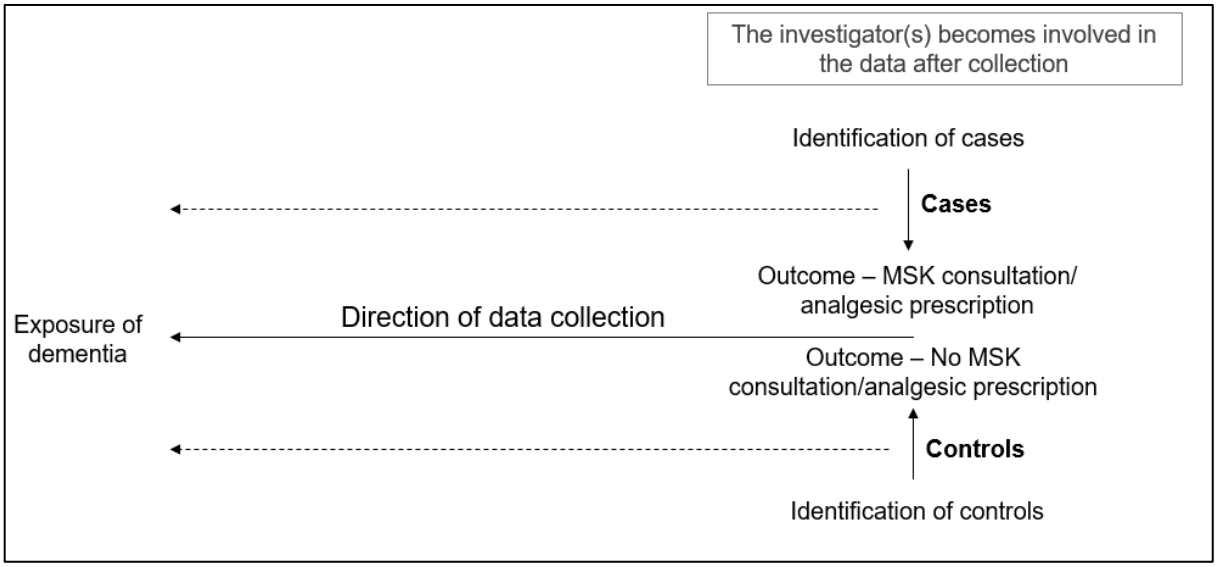


Figure 6.4. Pictorial representation of a case-control design

The main difference between a retrospective cohort design and a case-control design is the identification of each group. Namely, retrospective cohort designs identify each cohort based on their exposure status (e.g. the exposure cohort, and the unexposed cohort), following the cohort over time until the occurrence of the outcome. Alternatively, case-control designs identify cases and controls based on their outcome status and work backwards to identify

their exposure status. An overview of the strengths and limitations of each of these epidemiological study designs is provided in Table 6.2.

Table 6.2. Advantages and disadvantages of epidemiological designs

Study design	Prospective cohort design	Retrospective cohort design	Case-control design
Advantages	• Can measure incidence • Data collected is suited to the project • Accurate assessment of exposure and outcome status • Rare exposures can be studied • Recall bias minimised	• Can measure incidence • Rare exposures can be studied • Can utilise existing data (e.g. medical records)	• Rare outcomes/diseases can be studied • No loss to follow up • Allows investigation into multiple risk factors
Disadvantages	• Expensive • Time consuming • Labour intensive	• Can be limited to the available information • Missing data • Loss to follow up cannot be influenced • Poor for rare diseases	• Those with the outcome of interest are more likely to recall the exposure • Not suitable to investigate the rates of disease in exposed and unexposed individuals

6.2.3 Choice of study design

I selected a retrospective cohort study design as the most suitable to answer the above research questions (see Figure 6.3). In cohort studies, each cohort is identified and defined based on their exposure status. The exposed and unexposed cohorts are followed up over time until the occurrence of the outcome (or the end of the study period). Therefore, cohort studies (unlike case-control studies) allowed the incidence of musculoskeletal consultation for people with dementia to be examined.

Cross-sectional studies are often viewed as the most appropriate design to establish point prevalence ('the frequency of a disease or condition at a point in time' Szklo & Nieto, 2014, p. 71). However, cohort studies are able to estimate the period prevalence ('the frequency of an existing disease or condition during a defined period' Szklo & Nieto, 2014, p. 72) of an outcome for the cohort in question. For example, using a cohort study design, the period prevalence of musculoskeletal consultation and analgesic prescription can be established for a cohort of people with dementia. The period prevalence estimate has the potential to be generalised to the wider population of people with dementia, if the cohort is representative of the people with dementia in the UK. Additionally, cohort study designs have the ability to examine multiple outcomes, over a longitudinal time period. This is particularly important to examine musculoskeletal consultation *and* analgesic prescriptions from the time of diagnosis of dementia, and throughout the course of dementia progression.

Finally, when choosing between a retrospective and prospective cohort design, a retrospective design was chosen as CPRD data has already been collected; rendering a prospective design inappropriate (see Figure 6.2).

6.2.4 Data access and procedures

Access to CPRD data was subject to internal and external peer review and approval. Firstly, the CPRD committee within the School of Primary, Community and Social Care approved the

project following internal peer review. To gain external approval, a comprehensive study protocol was submitted to the Independent Scientific Advisory Committee (ISAC) for peer review. This committee included statisticians, epidemiologists, and clinicians familiar with CPRD data. The study protocol included information pertaining to the research questions, study design, exposures, outcomes and covariates, and analysis plan. The ISAC committee granted approval of the study protocol and provided access to the data (17_240RA; see Appendix 3).

6.2.5 Clinical codes

EHR data is largely collected in UK primary care using Read codes entered by members of primary care staff. Read codes are a standard, hierarchical vocabulary of clinical terms used to document various clinical information, including but not limited to symptoms, signs, diagnoses, and prescriptions (NHS Digital, 2018). At the time of this thesis, two versions of Read codes are used: version 2 (v2) or version 3 (CTV3 or v3).

The process of compiling clinical code lists to define, and identify the clinical entities of interest (i.e. the exposure, covariates, and outcome) is an important step when setting up a study utilising primary care EHR data (Springate et al., 2014). I used a four-step exercise to identify Read codes for the exposure, covariates, and outcomes used in this study:

1 I obtained clinical code lists from within the School of Primary, Community and Social Care (https://www.keele.ac.uk/mrr/) where available. All clinical code lists were developed using consensus exercises, and validated using a localised Primary Care EHR databases (e.g. the Consultations in Primary Care Archive; CIPCA).
2 Clinical Codes Repository was searched for suitable codes (www.clinicalcodes.org). This resource is a University of Manchester Institute of Population Health project funded by the NIHR School for Primary Care Research.
3 Clinical code lists were obtained from previously published CPRD studies (https://cprd.com/bibliography).

4 I searched the Clinical Terminology Browser v1.04 to identify additional codes for each clinical entity. This browser contains the hierarchical vocabulary of clinical terms.

Following the identification of codes, duplicates were removed and a consensus exercise with my supervisors JB (Academic General Practitioner with experience in EHR and code list development), and PC (Epidemiologist with experience in EHR and code list development) finalised each code list. This process resulted in a set of clinical code lists that represent the various variables used in this research project. Appendix 4 provides examples of each clinical code list. Full code lists are available upon request.

6.2.6 Data Refinement

The Research Data Manager within the School of Primary, Community and Social Care extracted CPRD data in March 2018. Data were retrieved from 1st January 1995 and 31st December 2017. Linked Practice Level Index of Multiple Deprivation (IMD) was also extracted (see Section 6.2.11.2).

6.2.6.1 Cohort definitions

6.2.6.1.1 Exposed: Dementia cohort

A total of 104,488 patients were identified by the Research Data Manager with an incident dementia diagnostic Read code, or dementia medicinal product code between 1st January 1997 and 31st December 2017 (see Section 6.2.7.2). Dementia was identified using 104 dementia diagnostic Read codes, and 107 dementia medicinal product codes documented in the patient's record. Table 6.3 provides examples of clinical codes used to define the patients included in the dementia cohort. Examples of each clinical code list are provided in Appendix 4, with full code lists available upon request.

Table 6.3. Examples of dementia diagnostic Read codes and dementia medicinal product codes

Read term	**Read code**
Senile dementia	E00..11
[X]Dementia in Alzheimer's disease, unspecified	Eu00z00
[X]Vascular dementia	Eu01.00
Product term	**Product code**
Aricept 10mg tablets (Eisai Ltd)	5247
Donepezil 10mg tablets	2931
Memantine 10mg tablets	6225

6.2.6.1.2 Unexposed: Older adult cohort

The Research Data Manager identified 157,271 older adults on the basis of no evidence of a dementia diagnostic Read code, or dementia medicinal product code during the entire study period (1st January 1997 to 31st December 2017). This cohort was matched for age, gender, and practice to the dementia cohort (see Section 6.2.11.1).

6.2.7 Date Setting

The longitudinal nature of the study period (1st January 1997 to 31st December 2017) means that patients and general practices enter and exit the dataset at different time points. Three dates are particularly important when conducting longitudinal investigation in CPRD, including the patient's entry date, index date, and exit date.

6.2.7.1 Entry date

The entry date for each patient was defined on two levels: i) a patient-level 'current registration date', and ii) a practice-level 'up to standard date'.

i) The 'current registration date' for each patient was provided by CPRD, defined as the 'date the patient's current period of registration with the practice began'. This date reflects when the patient began contributing to CPRD. For example, this may be the date that the patient joined a general practice that was contributing to CPRD.

ii) Each general practice had an 'up to standard' date. This date reflects a 'date at which the practice data is deemed to be of research quality'.

Therefore, each patient's entry date was defined as their 'current registration date' or the 'up to standard' date, whichever occurred last. For example, if the patient's current registration date was 6th January 2010, however the practice was not classified as 'up to standard' until 10th July 2011, the patient's entry date was defined as 10th July 2011.

6.2.7.2 Index date

- The index date for patients in the dementia cohort was defined as their incident dementia diagnostic Read code or dementia medicinal product code (whichever came first) from 1st January 1997 to 31st December 2017.
- The index date for patients in the matched older adult cohort was defined as the index date for their matched-pair.

6.2.7.3 Exit date

The exit date was identified for all patients. The patient's exit date considered both patient-level and practice-level dates, defined based on whichever of the following dates occurred first:

- Last collection date – 'Date of the last collection for the practice'
- Transfer out date – 'Date the patient transferred out of the practice, if relevant.'
- Death date – 'Date of death of patient'

- End of study period (31st December 2017)
- Cancer pain is distinct from non-malignant pain, and therefore outside the scope of the present study (see Section 6.2.8). Therefore, people in the dementia cohort and older adult cohort no longer contributed to the study six months prior to their first morbidity cancer Read code during follow up (between their index and exit dates). It cannot be assumed that prescriptions within this 6-month pre-diagnosis period were not due to a cancer related illness that had not yet been diagnosed. This assumption was supported by work that has shown the majority of delayed cancer diagnoses occur within six months of its onset, and most being diagnosed within one to three months (National Patient Safety Agency, 2010).

A pictorial representation of the 'entry date', 'index date', and 'exit date' is presented below for the incidence (see Figure 6.5) and prevalence investigation (see Figure 6.6).

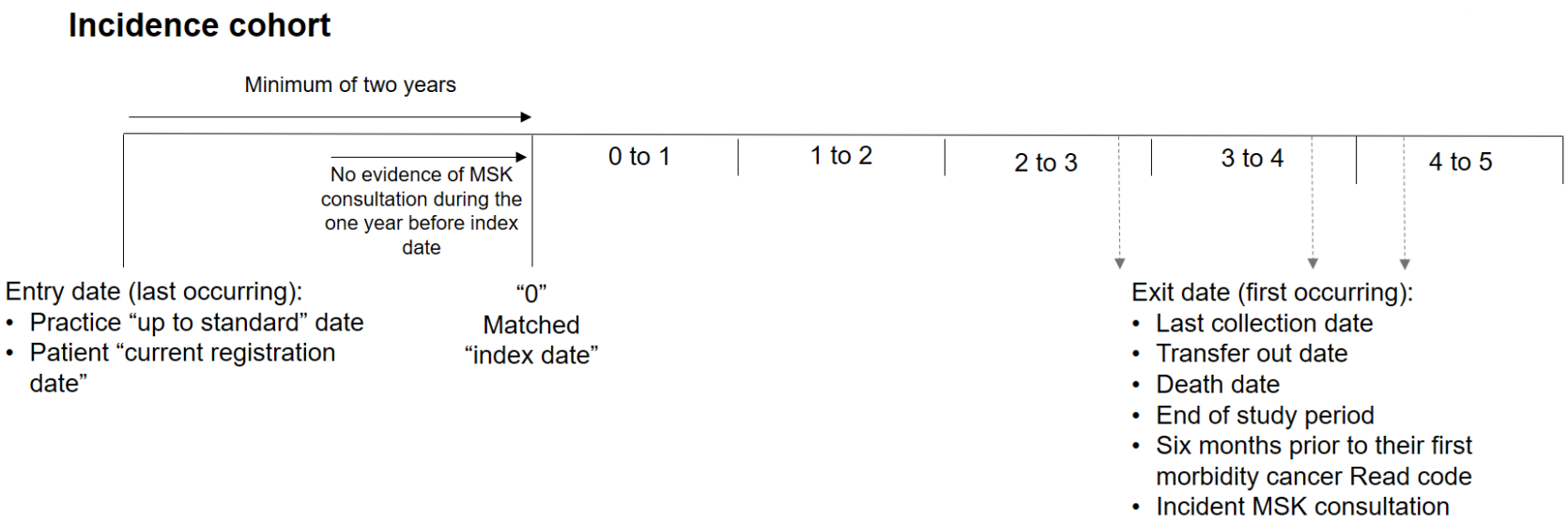


Figure 6.5. Pictorial representation of the study time points for dementia cohort and older adult cohort in the incidence investigation

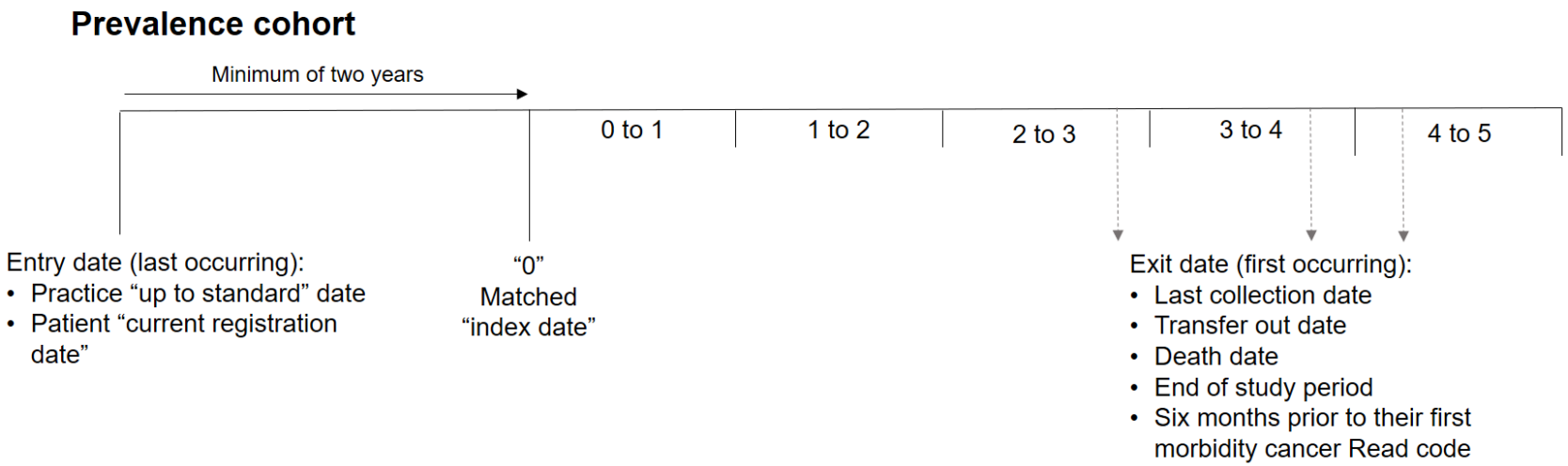


Figure 6.6. Pictorial representation of the study time points for dementia cohort and older adult cohort in the prevalence investigation

6.2.8 Inclusion/exclusion criteria

This section outlines the inclusion and exclusion criteria used to identify the dementia cohort and older adult cohort for both the prevalence and incidence investigations.

- All patients in the dementia cohort and the older adult cohort were 50 years old or older at their index date to be eligible. In 2012, only 0.3% of people with dementia in England were under the age of 50 years old (Prince et al., 2014). Thereby excluding people under the age of 50 reduced the chance of misclassifying a patient to the dementia cohort based on an erroneous clinical code indicative of dementia, whilst also minimising the amount of true dementia cases being excluded.

- This research wished to focus upon community-dwelling people with dementia (see Section 1.7). Therefore, all patients in the dementia cohort and the older adult cohort were excluded if they had evidence of a Read code indicative of formal care residence during the entire study period (1st January 1997 to 31st December 2017), as previous research identified formal care Read codes as a definitive marker of formal care residence (Shah et al., 2010). Read codes indicative of formal care residence were identified using the process outlined in Section 6.2.5 and are provided in Appendix 4.

- Patients in the dementia cohort and older adult cohort must have had evidence of a face-to-face or telephone consultation with a GP or nurse within a 90-day pre-and-post window of their (assigned) index date. This criterion minimised the chance that patients in the older adult cohort had dementia unknowingly to the healthcare professional. The 90-day period was chosen to reflect the general frequency of consultation for older adults. In 2008, females over the age of 65 consulted on average 7 times annually, with males over the age of 65 consulting on average 4-6 times annually (Hippisley-Cox, Fenty & Heaps, 2007). Since 2008, the average annual consultation frequency has steadily increased (Baird, Charles, Honeyman,

Maguire & Das, 2016). Based on these conservative estimates, the general population of adults over the age of 65 consult on average once every 3 months.

- All patients in the dementia cohort and the older adult cohort must have had at least a two-year time period between their entry date and their index date. This two-year time period was to:
    - Ensure that the index date reflected the incident dementia diagnosis Read code or dementia-related drug product code, and thus most accurately reflected the time of dementia diagnosis. A two-year period was chosen based upon the clinical justification that people with dementia should be reviewed at least once per year in general practice (Alzheimer's Society, 2016).
    - Investigate the presence/absence of baseline covariates (see Section 6.2.11.2)
    - Identify and exclude people with evidence of a Read code indicative of cancer diagnosis. People with evidence of a cancer Read code during follow up were also removed from the study six months prior to their first morbidity Read code (see Section 6.2.7.3). Examples of cancer Read codes are provided in Appendix 4.

6.2.8.1 Incidence cohort

In addition to those outlined above, an additional exclusion criteria were applied to the dementia cohort and older adult cohort to investigate the incidence of musculoskeletal consultation:

- Patients in the dementia cohort and the older adult cohort were excluded if they had evidence of a musculoskeletal consultation during the 12-month period before their index date. Research suggests that between 27% and 33% of older adults consult for a musculoskeletal condition during an annual time period (Jordan et al., 2010).

Excluding this population allowed an investigation into the incidence of musculoskeletal consultation without prevalent cases causing bias, with similar approaches conducted in comparable incidence investigation (Yu et al., 2017). A 12-month period was chosen, as a longer period may have resulted in healthy cohort bias (excluding unhealthier patients); thus leading to imprecise incidence estimates.

The data refinement process for dementia cohort and older adult cohort for the incidence and prevalence investigation are provided in Figure 6.7 and Figure 6.8.

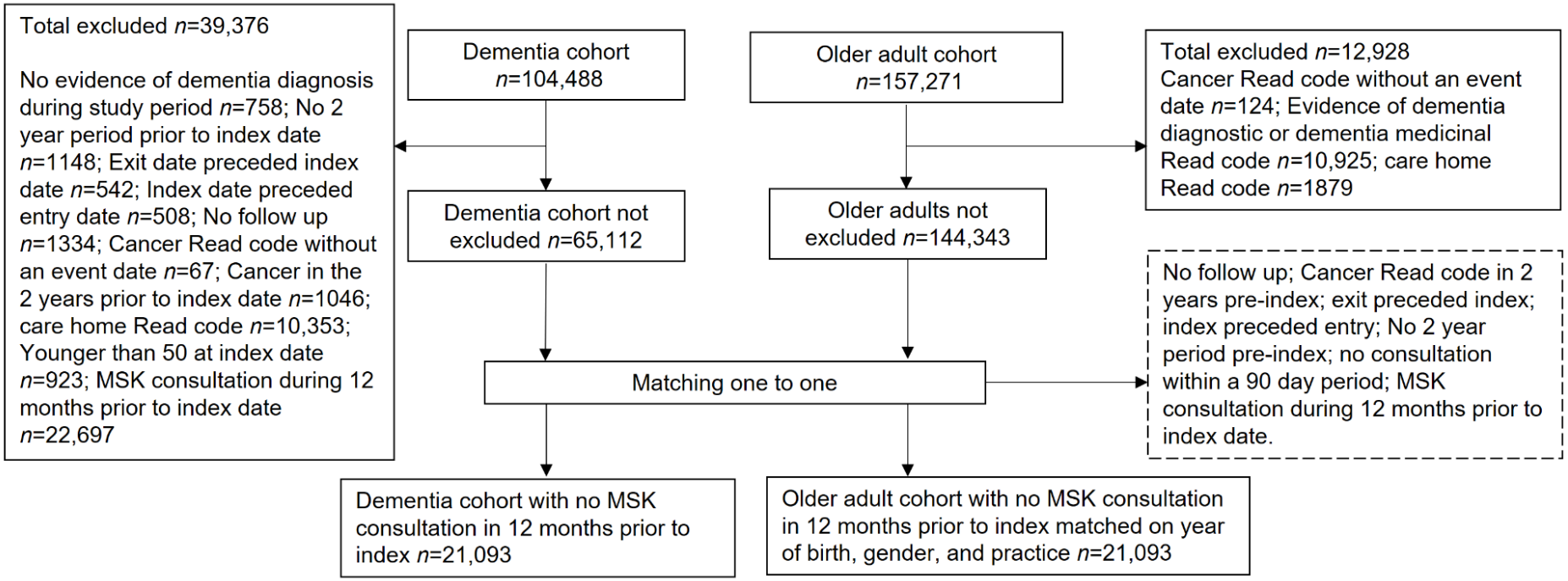


Figure 6.7. Flow diagram to represent the data refinement process for the incidence cohort

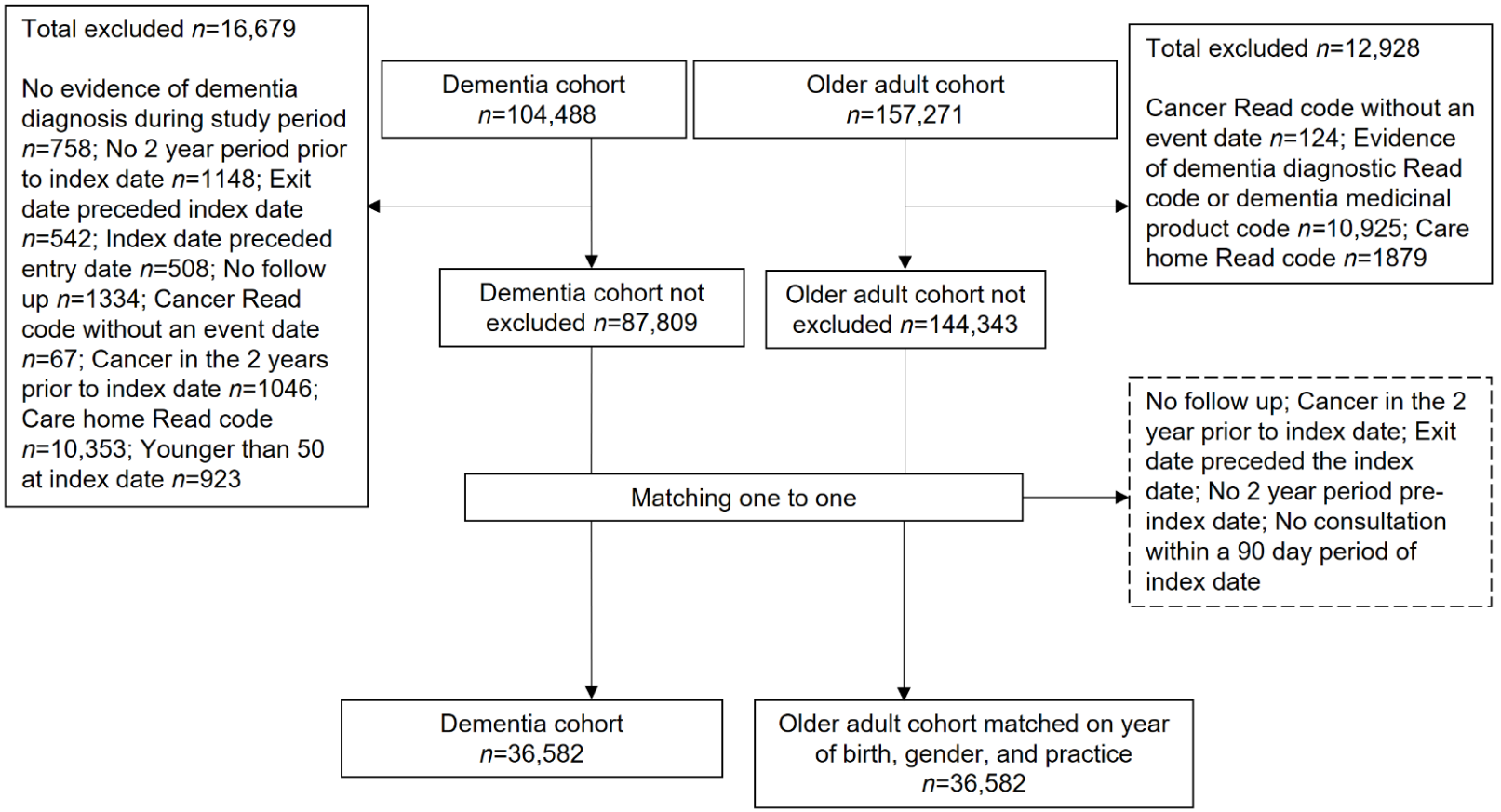


Figure 6.8. Flow diagram to represent the data refinement process for the prevalence cohort

6.2.9 Outcomes

6.2.9.1 Musculoskeletal consultation

Musculoskeletal pain includes neck, back, shoulder, elbow, hand, hip, knee, and multiple joint pain (Urwin et al., 1998). The primary cause of persistent pain for older adults, including people with dementia are musculoskeletal conditions (Corbett et al., 2012; Corbett et al., 2014), with research finding that 58% of people with dementia had pain that was musculoskeletal in nature (Husebo et al., 2010). Musculoskeletal consultations were used as a proxy for pain identification and assessment for a number of reasons:

- A code indicative of a (likely painful) musculoskeletal condition would suggest that pain has been identified, assessed, and coded by a clinician in primary care. This approach has been undertaken in previous research in the absence of pain identification and assessment data for people with dementia (Balfour & O'Rourke, 2003).
- The prevalence of musculoskeletal conditions for older adults with and without dementia (see Section 1.12.2), and the high association between musculoskeletal conditions and pain (Dunn et al., 2010; Muller, Bedson & Mallen, 2012) renders musculoskeletal consultation as an appropriate marker to encapsulate pain (and thus identification and assessment) in CPRD.
- Musculoskeletal conditions represent a more homogenous group of potentially painful conditions (in comparison to all-cause pain conditions), thereby minimising the various confounders requiring consideration, and ultimately the bias in the study (Richardson, Bedson, Chen, Lacey & Dunn, 2018).

Musculoskeletal consultations were identified by Read codes documented in the patient's record. Musculoskeletal Read codes have been developed and validated at the School of Primary, Community and Social Care (https://www.keele.ac.uk/mrr/morbiditydefinitions) and have since been used in numerous publications (Bedson et al., 2019; Bedson et al., 2016).

The table below provides a number of examples of clinical codes indicative of a musculoskeletal consultation (see Table 6.4). Appendix 4 provides an example list of the most commonly used musculoskeletal Read codes. Full clinical code lists are available on request.

Table 6.4. Examples of musculoskeletal consultation clinical codes

Read term	**Read code**
Osteoarthritis	N05..
Low back pain	N142.
Shoulder pain	N2457
Osteoarthritis NOS, of knee	N05zL

6.2.9.2 Analgesic prescription

Analgesic prescriptions were identified by Product codes or CPRD 'medcodes' documented in the patient's record. As there are over 300 analgesic preparations (Joint Formulary Committee, 2017) a hierarchical classification was used (Bedson et al., 2013). The analgesic hierarchical classification system was validated using a four-step consensus exercise and has previously been used in CPRD (Bedson et al., 2013). Analgesic prescriptions were categorised into six groups based on their analgesic potency, reflecting the World Health Organisation analgesic pain stepladder ([WHO], Ehrlich, 2003). A seventh group classified patients with evidence of any analgesic prescription, irrespective of potency. An overview of the analgesic hierarchical classification, along with an example of an analgesic product term and product code is provided in Table 6.5. An example list of the clinical codes is provided in Appendix 4, with full Read code lists available upon request.

Table 6.5. Analgesic hierarchical classification (Bedson et al., 2013)

Classification of prescription	Example product term	Product code
Any analgesic prescription	Any of the below	N/A
Basic analgesics	Paracetamol 500mg tablets	7
Weak analgesics	Co-codamol 8mg/500mg	625
Moderate analgesics	Nefopam 30mg tablets	4016
Strong analgesics	Tylex 30mg/500mg capsules	656
Very strong analgesics	Oramorph 10mg/5ml oral solution	1503
NSAIDs	Acemetacin 60mg capsules	344

NSAIDs non-steroidal anti-inflammatory drugs

Low dose Aspirin (300mg or less) is typically prescribed for its cardiovascular protective properties, and was not classified as an analgesic prescription (Hartikainen et al., 2005a). Analgesic prescriptions were considered if they occurred within a period starting 14 days before a musculoskeletal consultation, and up to 90 days following it. This timeframe generated a temporal association between the musculoskeletal consultation and the analgesic prescription, to provide greater confidence that the medication was being prescribed for a painful condition (Bedson et al., 2016; Bedson et al., 2019; Richardson et al., 2018).

6.2.10 Bias in observational designs

For observational studies, bias is important to identify and assess due to the ability to distort the association between the exposure and the outcome of interest. According to Hennekens et al. (1987) bias in observational studies can be classified into two overarching categories including selection bias and information bias.

6.2.10.1 Selection bias

Selection bias means that the sample selection does not reflect the target population, because of the recruitment or retention of participants (Szklo & Nieto, 2014). For example,

sampling bias may occur if participants self-select for the study, as they may be inherently the same as each other, but different than the rest of the population (that may not self-select for research). In regard to CPRD data, participants do not self-select to be included in the data, however there may be differences between those whom consult to primary care, and those who do not (and thus not included in CPRD data).

Loss to follow up or attrition becomes a potential for bias if there is 'systematic differences between groups in withdrawals from a study' (Higgins & Green, 2011). If the patients lost to follow up are different from the patients that remain in the study concerning the exposure and the outcome, the observed association may contain bias (Hennekens et al., 1987). Research suggests that the mortality rate for people with dementia is three times higher than older adults without dementia (Rait et al., 2010). In addition, a systematic review suggests that the rate of nursing home admission increased up to 17-fold for people with dementia (Luppa et al., 2010). Mortality and nursing home admission rates may mean that people with dementia have a higher attrition rate than older adults without dementia. The potentially high attrition rate for people with dementia may lead to immortal time bias, which is the 'period of follow-up during which, by design, death or the study outcome cannot occur' (Lévesque, Hanley, Kezouh & Suissa, 2010). In other words, people with dementia may not have sufficient follow up time for the outcome to occur. Healthy cohort effects refer to the potential bias when 'unhealthy' patients leave the study (i.e. due to mortality or nursing home admission), meaning that the cohort contains 'healthier' patients whom may be less likely to have the outcome.

6.2.10.2 Information bias

Information bias occurs when there is 'systematic differences in the way data on the exposure or outcome are obtained from the various study groups' (Hennekens et al., 1987, p 274). Different types of information bias include:

- **Misclassification bias** – This can occur when participants are defined on the basis of their exposure, disease, or outcome, but are incorrectly classified to the wrong group. In this retrospective cohort study, this might involve the exposure or the outcome being misclassified (i.e. an incorrect code being entered, musculoskeletal pain being missed (particularly so for people with dementia), or an individual with a musculoskeletal condition not consulting to primary care). Misclassification bias may become a problem if these incorrect allocations are not conducted at random, and instead are performed unequally between each cohort.

- **Recall bias -** This is a potential problem if the exposed cohort is likely to report their exposure experience as different, or with a different degree of completeness or accuracy than those that have not been exposed. In the context of CPRD, data is typically recorded at the time of consultation by the healthcare professional. Therefore, the exposure and the outcome are not dependent upon participants' recall.

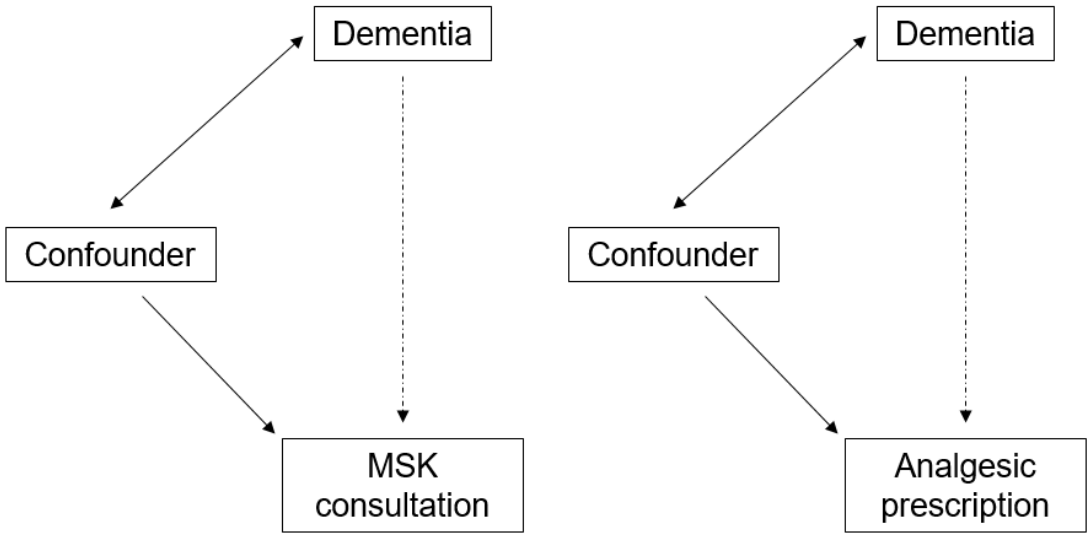
- **Interviewer bias –** This can occur if there are systematic differences in the recording or the interpretation of information from participants. For instance, in retrospective studies, if the interviewer is aware of the exposure status of the participant, the interviewer may use different techniques to gain information. In the context of this study, healthcare professionals were likely aware of the exposure status (dementia diagnosis), and although this might alter their recording of the outcome (musculoskeletal consultation) this in itself is an important finding.

6.2.10.3 Other bias

Medical surveillance (or detection) bias is apparent when the exposure leads to a closer observation of the outcome. In other words, as a consequence of the exposure (dementia), the individual may have more regular healthcare contact (e.g. more visits to primary care) meaning that the outcome may be more likely recognised, discussed, investigated, or treated by GPs.

6.2.11 Confounding

In addition to bias, confounding is also important to identify and assess in observational studies due to the ability to distort the association between the exposure and the outcome of interest. Confounding refers to when a 'non-causal association between a given exposure and an outcome is observed as a result of the influence of a third variable' (Szklo & Nieto, 2014, p.153). Confounders are causally associated with the outcome, and either causally or non-causally associated with the exposure, however do not lie on the causal pathway between the exposure and outcome (see Figure 6.9). A confounder may distort the association between the exposure and the outcome.



**The unidirectional arrow demonstrates a causal association, whereas the bidirectional arrow indicates a non-causal association.*

Figure 6.9. Pictorial representation of confounding (adapted from Szklo & Nieto, 2014).

6.2.11.1 Methods to control of confounders

There are many means of dealing with confounders in cohort studies, including restriction, matching, stratification, and multivariable adjustment (Kestenbaum, 2009). In this study, matching and multivariable methods were used.

Matching is the selection of participants with no evidence of the exposure, however similar concerning other important characteristics to the exposed cohort. Two types of matching are common in epidemiological research, *individual* and *frequency* matching (Szklo & Nieto, 2014).

- Individual matching ensures that for each exposed patient one or more unexposed patient is selected (1:n). Unexposed participants are identified on the basis of having the same specified criteria in the matched variable.
- Frequency matching selects the unexposed cohort to balance the distribution of the matched variable(s).

Matching is employed in cohort studies to create a balance of composition in the matched variable(s), allowing both cohorts to be comparable, and thus reducing the influence of confounders distorting the association between the exposure(s) and the outcome(s). However, matching may not always be suitable if there is not a sufficient pool of unexposed individuals to match to each exposed patient, especially depending on the rarity of matched variables. If a suitable unexposed patient is unavailable, the exposed participant may be lost. In relation to this project, a large pool of older adults without dementia were available for matching within the CPRD dataset, therefore matching on common factors was appropriate. Therefore, exposed and unexposed patients were matched one-to-one, based on their year of birth, gender, and practice. By doing so, the exposed and unexposed cohort were comparable with regards to age, gender, and general practice at baseline (Jordan et al., 2010; Patel, Guralnik, Dansie & Turk, 2013).

Multivariable analysis can handle a large number of covariates (including continuous and categorical variables) simultaneously. In epidemiology, linear regression, logistic regression, and proportional hazards (Cox) regression are multivariable analytical techniques that are frequently used (Szklo & Nieto, 2014). In this study, to examine time-to-event data, a proportional hazards (cox) regression was used. Additionally, to examine the association

between dementia and a categorical outcome, logistic regression was used. An in-depth overview of the analysis plan is provided in Section 6.2.13.

6.2.11.2 Potential confounders

Potential confounders were identified i) from the previous literature (in the literature and systematic review) and ii) guided by clinical knowledge of dementia as informed by clinicians involved in the research. All covariates were measured or observed during the two-year period before index date (with the exception of deprivation). Baseline covariates were used in this research (rather than time-varying covariates) as conditions were perceived as 'fixed-state', and therefore unlikely to change during follow up. Each of the potential confounders included in this research are discussed below.

Deprivation

Deprivation is a multi-dimensional construct, focused on a variety of domains such as health, education, and crime (Payne & Abel, 2012). In the UK, IMD is the official measure of relative deprivation (Department for Communities and Local Government, 2015). This study used linked data from CPRD GOLD to the 2010 English IMD (Department for Communities and Local Government, 2011). The English IMD was calculated using 38 indicators, across seven distinct domains. The domains are:

- Income
- Employment
- Health and disability
- Education skills and training
- Barriers to Housing and Other Services
- Crime
- Living Environment

Each domain was weighted to calculate an aggregate IMD score for each Lower layer Super Output Area (LSOA). In England, there is 32,844 LSOA, each of which represent a small homogenous area (Department for Communities and Local Government, 2015). The IMD ranks each LSOA in England on a continuum from 'least deprived' to 'most deprived' (Department for Communities and Local Government, 2011).

In this study, patients in the dementia cohort and older adult cohort were linked to practice-level IMD in accordance with other CPRD studies (Springate et al., 2017). Practice-level IMD was derived by mapping each general practice's latest available postcode to a LSOA boundary. To protect patient's area of residence, practice-level IMD was provided in quintiles, with 1 being the 'least deprived', to 5 being the 'most deprived'. IMD has commonly been used as a proxy for socioeconomic status (Heald et al., 2017). Many studies have found an association between having dementia and having a lower socioeconomic status (Russ et al., 2013; Kukull et al., 2002), with older adults with low socioeconomic status being more likely to have pain than older adults with a high socioeconomic status (Patel et al., 2013). Evidence also suggests that people with dementia classified as having the highest level of deprivation had an increased odds of analgesic prescription (compared to those with the lowest deprivation) than matched older adults without dementia (Hamina et al., 2017).

Depression

Depression was defined using Read codes indicative of depression or bipolar documented in the patient clinical record (see Appendix 4 for example codes). The Read codes were produced and validated in the School of Primary, Community and Social Care (https://www.keele.ac.uk/mrr/morbiditydefinitions) (Bedson et al., 2016; Burton, Campbell, Jordan, Strauss, & Mallen, 2012; Walker, Liddle, Jordan & Campbell, 2017) and in previous CPRD research (Windfuhr et al., 2016). Research suggests that people with dementia may be more likely to have depression (Bennett & Thomas, 2014). Research evidence also indicates that people with depression may experience pain differently (Li et al., 2015; Shega,

Paice, Rockwood & Dale, 2010b; Bhattacharjee, Oh, Reiman & Burke, 2017), and may be prescribed more analgesic medications than people without depression (Gilmartin et al., 2015).

Diabetes

Diabetes was defined using Read codes indicative of diabetes documented in the patient clinical record (see Appendix 4 for example codes). Read codes to define a diabetes diagnosis have been used and validated in previous CPRD studies (Tate et al., 2017; Joseph, Movahedi, Dixon, & Symmons, 2017; Zhong et al., 2018; NHS Health and Social Care Information Centre, 2012). Diabetes was included as a covariate due to the specific vascular sequelae that may impact the diagnosis of dementia, in particular vascular dementia (BMJ Best Practice, 2018; Perkins et al., 2004). People with diabetes are more likely to experience neuropathic pain, potentially leading to increased pain-related consultation and prescription (Rosenfeld, 2014).

Cardiovascular-related conditions

Cardiovascular disease (CVD), and other cardiovascular-related conditions were defined using Read codes documented in the patient's clinical record (see Appendix 4 for example codes). Cardiovascular-related conditions were included as a covariate due to their relationship with increased pain, and their specific vascular sequelae to vascular dementia, meaning that the dementia cohort may have a higher prevalence of cardiovascular-related conditions compared to the older adult cohort (BMJ, 2017; Perkins et al., 2004). Additionally, research suggests people with cardiovascular-related conditions are prescribed more and different types of analgesic medications (Pawlosky, 2013).

Morbidity count

A 'morbidity count' was calculated using the total number of unique British National Formulary (BNF) sections the patient was prescribed a medication from during the two years

before index date. For example, if a person with dementia had evidence of one Antimotility Drug (BNF section 1.4.2) prescription, three Respiratory Stimulant (BNF section 3.5.1) prescriptions, and two Selective Serotonin Re-Uptake Inhibitors (BNF section 4.3.3) prescriptions, their morbidity count would be three (due to having prescriptions from three unique BNF sections). The morbidity count acted as a proxy morbidity measure; indicating that patients with a higher frequency of prescriptions spanning a number of BNF sections have more morbid conditions. BNF prescription counts are equally effective as other complex morbidity measures in primary care databases (Perkins et al., 2004), and have been used as an indicator for morbidity in comparable studies (Bedson et al., 2019; Richardson et al., 2018). Research suggests that people with dementia have more morbidity, with research finding that comorbidities increased the likelihood of musculoskeletal consultations and analgesic prescriptions for people with dementia (Hamina et al., 2017).

Consultation frequency

'Consultation frequency' or the amount of consultations by each patient during the two years before index date was defined as 'any face-to-face or telephone consultation completed by a doctor or a nurse' (Stevens et al., 2017). During the two-year period before index date, all face-to-face or telephone consultations completed by a doctor or nurse were identified and totalled for each patient. Dementia diagnosis may contribute to a higher frequency of consultation to primary care (Shah, Mcniece & Majeed, 2001). If the patient consulted frequently to primary care, their musculoskeletal pain may be more likely recognised, discussed, investigated, or treated (see Section 6.2.10.2).

Length of follow up

The length of follow up for patients in the dementia cohort and older adult cohort was calculated from index date to exit date, in days. People with dementia were expected to have a shorter follow up time than older adults, potentially limiting their opportunity for musculoskeletal consultation and/or analgesic prescription (see Section 6.2.10.1).

Year of index date

The index date occurred at any time during the 20-year study period (1st January 1997 to 31st December 2017). The consultation and treatment of dementia and musculoskeletal conditions, including the prescribing of analgesic medications are likely to vary over this time period (Harkness, Macfarlane, Silman & McBeth, 2005; Bedson et al., 2013).

6.2.12 Missing data

Missing data is a known limitation of CPRD (Herrett et al., 2015; see Table 6.1). The variability of data completeness is likely to vary over time, and depend upon the clinical entity in question, with the morbidity coding of conditions with clear diagnostic features being more complete (Jordan, Porcheret & Croft, 2004). In line with this, lifestyle factors (such as smoking and obesity) are known to have a higher frequency of missing data (Herrett et al., 2015; Bhaskaran, Forbes, Douglas, Leon & Smeeth, 2013), and potentially coded more commonly for people with health conditions. Therefore, although lifestyle factors were important to consider as a potential confounder they were not included as a covariate in this analysis. However, by controlling for factors such as IMD, the confounding effect of lifestyle factors was potentially negated (Szklo & Nieto, 2014). Additionally, Jordan et al. (2007) suggests that for chronic conditions, each consultation may not be coded, potentially under-representing the prevalence of chronic conditions. Although missing data remained an important consideration, research continues to suggest reasonable correctness and completeness of morbidity coding in CPRD (Jordan et al., 2004).

For the exposure (dementia), covariates, and outcome (musculoskeletal consultation and analgesic prescription) used in this research, the absence of a Read code indicative of the clinical entity in question was interpreted as absence of the condition for the patient (Herrett et al., 2015). This had the potential of high 'positive predictive' values however lower sensitivity. This is partially attributed to patients not consulting to primary care (and therefore not being coded) despite having the condition (as discussed in Section 6.2.10), and the

miscoding of conditions. However, research suggests that the clinical recording of a variety of conditions in CPRD are comparable to other medical record databases, and questionnaire data (Nissen et al., 2017; Jordan et al., 2007; Quint et al., 2014). A systematic review conducted by Herrett et al. (2010) investigated studies that validated clinical codes used in CPRD. This review suggested that in general, the validity of clinical coding was high. Additionally, when analgesic medications are prescribed in primary care, they are automatically coded in CPRD and therefore missing data for this outcome was not anticipated (Bedson et al., 2013; Herrett et al., 2015).

6.2.13 Analysis

This section describes the analysis plan and the statistical methods employed. The analysis plan was created in collaboration with a statistician (YC) at the School of Primary, Community, and Social Care. Data were analysed using IBM SPSS Statistics version 24.0 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp).

6.2.13.1 Descriptive statistics

The distribution of each variable was examined for the dementia cohort and older adult cohort. Descriptive statistics were used to explore the similarities and differences between the dementia cohort and the older adult cohort in both the incidence and prevalence investigations. Demographic characteristics, covariates, and outcomes were explored using frequencies and percentages for categorical variables and distributions (means, standard deviations, medians, interquartile ranges) for continuous variables.

Independent t-tests and Person's chi-square tests examined the statistical differences between the dementia cohort and the older adult cohort. Independent t-tests were used when one variable was continuous, with Cohen's *d* being used as the effect size estimate when sample sizes were the same, and Hedges' *g* (*g*) when sample sizes were unequal. Cohen's *d* and Hedges' *g* were interpreted the same, with a small effect size 0.2, medium effect size

0.5, and large effect size of 0.8 (Cohen, 2013). Pearson's chi-square test were used when both variables were binary/categorical (as no cell frequency was lower than 5), with Cramer's V (V) used to determine the effect size (see Table 6.6; Kim 2017).

Table 6.6. Effect size for a chi-square test: Cramer's V

Degree of freedom	Small	Medium	Large
1	0.10	0.30	0.50
2	0.07	0.21	0.35
3	0.06	0.17	0.29
4	0.05	0.15	0.25

*Table adapted from Kim (2017)

6.2.13.2 Follow up time periods

Analysis described in the following sections were conducted for a number of time periods, including the i) five-year time period from index date, and ii) each annual time period from index date to five years after index date.

i. A five-year follow up period is in line with the average survival period of people with dementia diagnosed in primary care, with Rait et al. (2010) suggesting that approximately 50% of 60-69 year olds, and 25% of 80-89 year olds live for five years from primary care recording of dementia diagnosis.

ii. Stratification into annual time periods from index date allowed an insight into musculoskeletal consultation and analgesic prescription throughout the time living with a dementia condition. A similar approach was undertaken by Gilmartin et al. (2015) whom recruited people with dementia within one year of their dementia diagnosis and investigated their analgesic prescription prevalence during each annual period for five years.

Unlike all other analyses, cumulative incidence (Kaplan-Meier's approach), and Cox Proportional Hazards models were examined for the five-year period from index date, but not for each annual time period as each of these methods calculated the incidence at the exact time that the outcome occurred.

6.2.13.3 Testing Incidence

Incidence is the 'frequency of a new event' in a defined population over specified period of time (Szklo & Nieto, 2014). The types of 'incident' events commonly investigated are newly developed disease, reoccurrence of disease, development of a drug side effect, or in the case of this study, an incident musculoskeletal consultation. The basic principle of an incidence indicator is the number of events in a defined population during a specified period of time divided by the population at risk of an event during the same time period. There are two main types of incidence measures depending on the denominator, including i) incidence based on person-time at risk, and ii) incidence based on person at risk. This section will describe the incidence calculations included in this thesis to investigate the incidence of musculoskeletal consultation; including person-time incidence rates, followed by cumulative incidence.

For all incidence calculations, participants no longer contributed to the study following their exit date (see Section 6.2.7.3), or following their identified incident musculoskeletal consultation during follow up (see Figure 6.6). Participants were 'censored' if their exit date or the end of the study period (31st December 2017) occurred before evidence of identified incident musculoskeletal consultation.

6.2.13.3.1 Person-time incidence rates

Person-time incidence rates were calculated using the number of incident events within a specified time period divided by the amount of person-time contributed to follow up within the same specified time period for individuals at risk:

$$\frac{\text{number of incident events}}{\text{the amount of person time contributed}}$$

Person-time incidence rates are particularly useful when the amount of observation time is not constant for each person (i.e. people joining and leaving the study at different time points throughout follow up).

6.2.13.3.1.1 Incidence Rate Ratio

The incidence rate ratio (IRR) is the ratio of two incidence rates. The IRR used the person-time incidence rates described above (sometimes referred to as an incidence density ratio). The IRR allowed comparison between the person-time incidence rate for the dementia cohort and the person-time incidence rate for the older adult cohort:

$$IRR = \frac{Incidence\ rate\ in\ the\ exposed}{Incidence\ rate\ in\ the\ unexposed}$$

6.2.13.3.1.2 Attributable Rate

Attributable rate (or sometimes called 'excess fraction') is a measure of association based on the absolute difference between two person-time incidence rates (Szklo & Nieto, 2014). The calculation of incidence rate is analogous with attributable risk; however, incidence rates use person-time incidence rates (rather than the cumulative risk). The 'excess' rate can be attributed to the exposure, when assuming a cause-effect relationship between the exposure and outcome (no involvement of bias or confounding):

$$\text{ARexp } (Exposed\ \ person\ time\ incidence\ rate - Unexposed\ cohort\ person\ time\ incidence\ rate)$$

To express the attributable rate as a percentage, if the exposed (dementia) cohort has a higher incidence rate than the unexposed (older adult) cohort, the percentage attributable rate in the exposed ($\%AR_{exp}$) can be calculated:

$$\%ARexp\left(\frac{Risk\ in\ the\ exposed - Risk\ in\ the\ unexposed}{Risk\ in\ the\ exposed}\right) \times 100$$

If the exposed (dementia) cohort has a lower incidence rate than the unexposed (older adult) cohort, the 'preventable fraction among the unexposed' (%PR_u) can be calculated:

$$\%PFu\left(\frac{Risk\ in\ the\ unexposed - Risk\ in\ the\ exposed}{Risk\ in\ the\ nonexposed}\right) \times 100$$

This calculation determines the proportion (%) of incident musculoskeletal consultations in the older adult cohort that would be 'prevented' (or in the case of this study, unidentified, unassessed, or not coded) if they had evidence of the exposure (dementia). This percentage again assumes a causal-effect relationship between the exposure and outcome (no involvement of bias or confounding).

6.2.13.3.2 Cumulative incidence

Cumulative incidence investigated incidence based on persons at risk; the probability that a particular event will occur during a specific time period. Cumulative incidence forms the basis of survival analysis (Szklo & Nieto, 2014), including Kaplan-Meier approach, and Cox proportional hazards models.

6.2.13.3.2.1 Kaplan-Meier approach

The Kaplan-Meier approach calculates the probability of the outcome (musculoskeletal consultation) at the exact time that it occurred for patients in the dementia cohort and older adult cohort (as defined by an appropriate outcome coding within the dataset). The denominator for the Kaplan-Meier calculation was the amount of people at risk at the exact time of each events occurrence (Szklo & Nieto, 2014). The assumptions of the Kaplan-Meier approach are outlined in Table 6.7. Survival curves were plotted separately for the dementia cohort and the older adult cohort. The difference between the two cohorts was tested using the logrank test. The survival curves take into account patients whom were 'censored' (see Section 6.2.13.3). Both person-time based incidence rates and cumulative incidence have common assumptions that are important to consider (see Table 6.7).

Table 6.7. Assumptions of incidence calculations: person-time based incidence rates and cumulative incidence

Incidence calculation	Assumption
Person-time based incidence	1. Those censored had the same probability of an incident event as those still under observation 2. Lack of secular trends 3. Risk of the event remains approximately consistent during the time period of interest
Cumulative incidence	1. Those censored had the same probability of an incident event as those still under observation 2. Lack of secular trends

1. In this study, it was expected that there would be no difference in the risk of incident musculoskeletal consultation between censored patients in the dementia cohort and the older adult cohort compared to the difference between patients in the dementia cohort and older adult cohort that remain under observation.

2. Secondly, the lack of secular trends (e.g. a fluctuating risk of musculoskeletal consultation over time) was an important assumption to acknowledge in this study as patient index dates fall within a 20-year study period (from 1st January 1997 to 31st December 2017). During this time, musculoskeletal consultation rates were likely to fluctuate. Additionally, incentives to improve earlier diagnosis of dementia during this period (e.g. Quality Outcome Framework incentives; NHS Employers, 2016) were likely to fluctuate the rates of dementia diagnosis (and coding) in primary care. To investigate secular trends, Kaplan-Meier curves were plotted for early and late entrants (see Table 6.8).

3. Finally, the third assumption (not relevant for cumulative incidence) suggests that the risk of musculoskeletal consultation should remain consistent throughout the time period of interest. Szklo and Nieto (2014) described this as ‘n persons followed during t units of time’ being equivalent to ‘t persons followed during n units of time’ (p. 60). To minimise the risk of violating this assumption (especially for studies with a long follow up period), Szklo and Nieto (2014) suggest that the follow up period could be stratified into shorter time periods. In this study, the person-time incidence rates were stratified into annual time periods, with person-time incidence rates calculated for each time period (see Section 6.2.13.2).

6.2.13.3.2.2 Cox Proportional Hazards Regression

Cox Proportional Hazards regression is the most popular approach to model time-to-event data, modelling the data using the hazard scale (Szklo & Nieto, 2014). Unlike the Kaplan-Meier approach, the Cox Proportional Hazards model can be multivariable (and therefore accounting of potential confounding), with the ability to model continuous covariates. In this study, the univariate and multivariable Cox Proportional Hazards regression examined the incidence of musculoskeletal consultation over time of follow up from index date for the dementia cohort compared to the older adult cohort.

The coefficients in a Cox Proportional Hazards regression relate to hazard; a positive coefficient indicates an increased risk of the outcome and a negative coefficient indicates a decreased risk of the outcome for the variable in question. The hazard ratio (HR) is the exponent of its coefficient, and therefore a HR expresses the magnitude of difference between the dementia cohort and the older adult cohort. Specifically, a HR of >1 indicates that the dementia cohort had a higher rate of identified incident musculoskeletal consultation than the older adult cohort, with a HR of <1 denoting that the dementia cohort had a lower rate of identified incident musculoskeletal consultation than the older adult cohort.

To account for the matched cohort design of this study, the analysis was stratified by matched-pairs following previous methodology (Cummings, McKnight & Greenland, 2003). Assumptions of Cox Proportional Hazards Regression are described in Table 6.8.

Table 6.8. Assumptions of Cox Proportional Hazards Regression

Assumption	**How the assumption was tested**	
	Continuous predictors:	**Categorical predictors:**
Assumption of proportional hazards: Predictors have a multiplicative effect on the hazard (in other words, the ratio was assumed constant over time).	Scatter plot of Schoenfeld residuals vs. time until incident event. To meet the assumption, the scatter plot should look like a random scatter around zero	Investigation of the log minus log plots of the covariates entered as strata, against the log scale of time. To meet the assumption, curves should be approximately parallel and should not cross.*
Limited change in risk over time	Patients were sorted in ascending order by their index date. Patients were median split into 'early' and 'late' entrants. Kaplan-Meier curves with early and late entrants entered as a binary independent variable. The assumption was met if the logrank test was non-significant (p>.05), indicating limited change in risk over time.	

*****Some crossing at early time points during follow up may not constitute a violation of assumption, but rather be a product of noise in the survival estimates (George, Seals & Aban, 2014).

6.2.13.4 Testing Prevalence

Prevalence can be simply defined as the 'frequency of an existing event' (Szklo & Nieto, 2014). Different types of prevalence are available depending on the length of time under investigation, including point prevalence (the prevalence at that point in time), period

prevalence (the prevalence over a defined period of time, for example annual prevalence), and cumulative or life-time prevalence (including all cases in the past, to the present day). In this study, the period prevalence of musculoskeletal consultation and analgesic prescription was investigated for each time period (see Section 6.2.13.2). Patients were included in the prevalence estimates if they had complete follow up for each time period. Patients contributed to the numerator of the equation if they had evidence of the outcome (musculoskeletal consultation or analgesic prescription) at least once during the time period, with further consultations or prescriptions ignored, in line with similar work in this area (Jordan et al., 2010). Period prevalence was calculated as a percentage, with confidence intervals calculated using the Wilson Score (Brown, Cai & DasGupta, 2001):

$$\left(\frac{\text{total number of people with the outcome}}{\text{total number of people with a complete follow up}}\right) \times 100$$

6.2.13.4.1 Prevalence ratio

For each time period the prevalence ratio (PR) was calculated to examine the prevalence of the outcome (musculoskeletal consultation and analgesic prescription) for the dementia cohort compared to the older adult cohort:

$$PR = \frac{Prevalence\ of\ the\ outcome\ for\ the\ dementia\ cohort}{Prevalence\ of\ the\ outcome\ for\ the\ older\ adult\ cohort}$$

6.2.13.4.2 Conditional logistic regression

Conditional logistic regression (CLR) is an extension of traditional logistic regression models. CLR is typically used when analysing matched data to examine the association between the exposure and the outcome (Szklo & Nieto, 2014; Hosmer & Lemeshow, 2000). When analysing data using CLR, matched-pairs are entered into the model as individual strata. CLR provides parameter estimates of regression coefficients for covariates that vary within the strata. Therefore, CLR does not provide parameter estimates when there is no variation within the strata (such as matched variables, including gender, year of birth, and practice),

meaning that the coefficients are considered to be adjusted based on the matching variables (Szklo & Nieto, 2014). CLR analyses produce odds ratios (OR). OR examine the ratio of probability; or in other words, the odds of the outcome in the dementia cohort compared to the odds of the outcome in the older adult cohort for each time period. An OR of >1 means that the dementia cohort has a higher odds of the outcome compared to the older adult cohort. If the OR is <1 the dementia cohort has a lower odds of the outcome compared to the older adult cohort.

Univariate and multivariable CLR analyses also examine the ratio of the outcome, alike to the prevalence ratio, however, the CLR also accounts for potential covariates (in the multivariable analyses) and the matched-pair design, unlike the prevalence ratio. Despite the benefits of CLR models, it is important to acknowledge that the OR (produced by the CLR) may over exaggerate the magnitude of the association (especially for common outcomes) compared to the prevalence ratio (Szklo & Nieto, 2014).

The assumptions of CLR models are provided in Table 6.9. The first and second assumption were met prior to modelling. The third and fourth assumption were checked post-hoc using the methods described in Table 6.9 and discussed in the following findings chapters.

Table 6.9. Assumptions of Conditional Logistic Regression (CLR) models

Assumption	How the assumption was tested
1. A binary dependant variable	Dependant/outcome variable was: • Musculoskeletal consultation (yes/no) • Analgesic prescription (yes/no)
2. Independence of observations	All observations were independent, with no repeated measures in either cohort
3. Little or no multicollinearity among the independent variables	• Investigation of high correlations between variables • Investigation of VIF values greater than 10 • Investigation of tolerance values less than 0.1
4. Linearity of continuous covariates to the log of the outcome variable	The interaction terms of each continuous covariate and their log were entered into the model post-hoc. The assumption is met if the interaction term is non-significant (p>.05).

Assumptions from Field (2016); VIF Variance inflation factor

6.2.13.5 Sensitivity analysis

6.2.13.5.1 Formal care residence

Previous inclusion and exclusion criteria stipulated that any patient (in either cohort) with evidence of a Read code indicative of formal care residence was excluded (see Section 6.2.8) as a Read code was deemed a definitive marker of formal care residence (Shah et al., 2010). However, data checking revealed that only 11% of the dementia cohort had a Read code indicative of formal care residence, and this rate does not reflect UK statistics that suggest approximately 38.7% of people with dementia reside in formal care (Prince et al., 2014). Therefore, sensitivity analyses were conducted using additional (albeit not definitive) criteria of formal care residence in line with previous research using primary care datasets (Shah et al., 2010). Two additional markers were used to identify patients for the community sensitivity analysis:

i) A family number frequency indicating that equal to, or less than two older adults (≥50 years old) live in the same household

ii) No evidence of a consultation location in a formal care residence at any time during the study period (1st January 1997 to 31st December 2017).

The additional exclusion criteria have been used in previous research to identify community-dwelling populations (Cooper et al., 2016). The incidence cohorts lowered from *n*=21,093 to *n*=4850 and *n*=3477 for the dementia cohort and older adult cohort, respectively (see Figure 6.10). The prevalence cohorts lowered from *n*=36,582 to *n*=8875 and *n*=8349, for the dementia cohort and older adult cohort, respectively (see Figure 6.11).

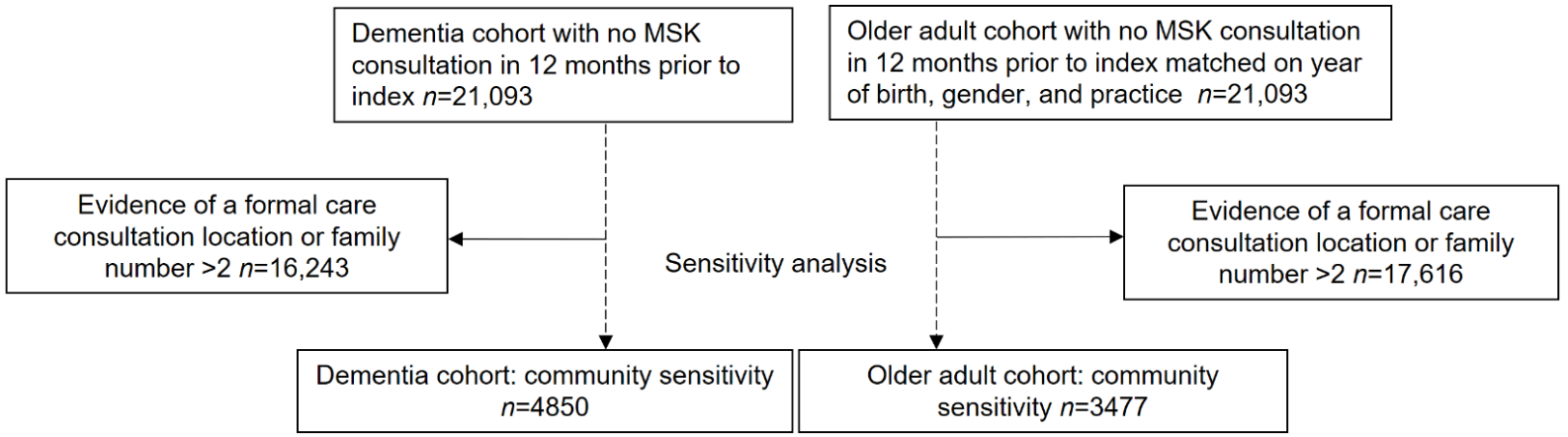


Figure 6.10. Incidence cohort: Community sensitivity

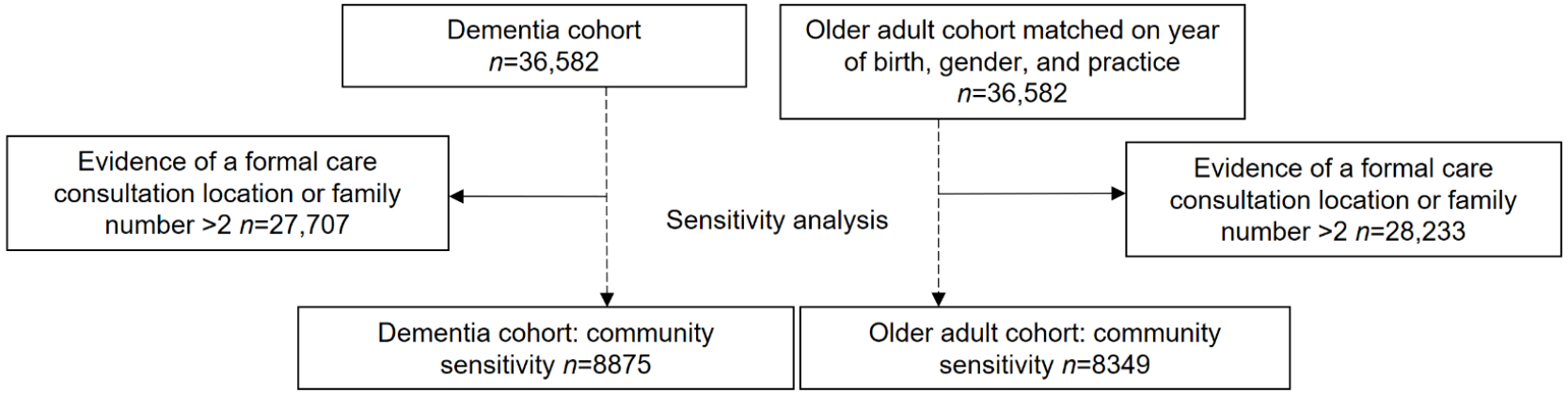


Figure 6.11. Prevalence cohort: Community sensitivity

This sensitivity analysis examined to what extent the main results reflect the restricted cohort of patients with a greater likelihood of living in the community. This sensitivity analysis from this point forward is referred to as a 'community sensitivity analysis'.

6.2.13.5.2 Healthy cohort

Prevalence rates in the main analysis only included patients that remained in the study for the entire follow up period in question (e.g. full five-year prevalence) (see Section 6.2.13.4). This might induce a 'healthy cohort' bias, especially for the five-year period, where the prevalence estimates only included patients that remained in the study for the entire five-year period after index date. Sensitivity analysis therefore investigated the prevalence of musculoskeletal consultation and analgesic prescription for patients eligible at the mid-time point of the five-year period from index date (912 days after index date) (Szklo & Nieto, 2014); see Sections 8.2.2.1.1.2 and Section 9.2.1.1.1.2.

6.2.13.5.3 Analgesic prescriptions not matched to musculoskeletal consultation

For the main analysis, analgesic prescriptions were considered if they occurred within a period starting 14 days before a musculoskeletal consultation, and up to 90 days following it (see Section 6.2.9.2). Sensitivity analysis examined all analgesic prescriptions irrespective of their temporal association with a musculoskeletal consultation. This analysis observed if the prevalence of analgesic prescriptions for potentially painful musculoskeletal conditions differed from analgesic prescriptions, irrespective of the pain driver.

6.2.13.5.4 Analgesic prescription in the one year before index date

Sensitivity analysis also investigated if the temporal trend of analgesic prescription prevalence changed over time if patients had received:

1. Any analgesic prescription in the one year before index date
2. No analgesic prescription in the one year before index date

This additional sensitivity analysis allowed investigation to see if previous analgesic prescription was related to analgesic prescription during follow up.

6.2.13.5.5 Non-stratified and unconditional models

Matched-pair stratified Cox Proportional Hazards models and CLR models account for the matching of the dementia cohort and the older adult cohort (see Section 6.2.13.4.2). Although one-to-one matching (of gender, year of birth, and practice) was completed at baseline, because of attrition, the amount of matched-pairs steadily reduced for each annual period of follow up (see Table 7.5). For example, in the first year (from index date to one year after index date), 73.5% of the matched-pairs remained, however by the final year of follow up (four years to five years after index date), only 15.9% of matched-pairs remained. The remaining 81.4% of patients were no longer matched. The reduction of matched-pairs over time means that the distribution of gender, year of birth, and practice did not remain equal (albeit they remained similar; see Table 7.5). Therefore, sensitivity analysis was conducted using non-stratified Cox Proportional Hazard models and univariate and multivariable logistic regression to account for the 'imbalance' of matched variables. These sensitivity analyses meant that the 'matched' covariates (year of birth, gender, and practice) could be included in the model as covariates to examine the impact of their 'imbalance'.

6.3 Qualitative Methods

This section of the chapter describes the qualitative methods used to investigate pain identification, assessment, and management for community-dwelling people with dementia. Qualitative research provides an in-depth and interpreted understanding of the social world through people's perspectives, views, and history (Snape & Spencer in Richie & Lewis, 2003), as reflected in the research questions below:

Research objective 1: To investigate pain identification and pain assessment for community-dwelling people with dementia

- How do family caregivers and healthcare professionals identify and assess pain for community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain identification and assessment strategies for community-dwelling people with dementia?

Research objective 2: To investigate the management of pain for community-dwelling people with dementia

- How do people with dementia, family caregivers, and healthcare professionals manage the pain experienced by community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain management strategies for community-dwelling people with dementia?

To answer the above research questions, qualitative methods must capture the views and perspectives of the three key parties involved in the community-dwelling person with dementia's pain; the person with dementia, the family caregiver of the person with dementia, and healthcare professionals.

6.3.1 Research ethics

To provide ethical guidance, the British Psychological Society Code of Ethics and Conduct (2009) was followed. The code is underpinned by the four main principles of respect, competence, responsibility, and integrity. The Mental Capacity Act (Department of Health, 2005) was also followed for the people with dementia participating in research. To complement this Act, the Mental Capacity Act 2005 Code of Practice (Department for Constitutional Affairs, 2007) was closely adhered to, shaping the way the Act was put into practice within a research context.

One of the responsibilities of the researcher outlined by the Code of Practice is the approval of the research by a research ethics committee recognised by the Secretary of State (Department for Constitutional Affairs, 2007, p. 206). On this basis, Research Ethics Approval and Health Research Authority approval was obtained from London - Bromley Research Ethics Committee on 29th October 2017 (IRAS number: 230583) (see Appendix 5).

6.3.2 Patient and Public Involvement and Engagement

Patient and Public Involvement and Engagement (PPIE) allows members of the public to be actively involved in research projects. By involving the patients and public in research, it ensures that research is 'carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.' (INVOLVE, 2017). PPIE has a large impact on health and social care research to improve the quality, and the appropriateness of the research (Brett et al., 2012). This is especially true of dementia research, with Alzheimer Europe promoting the inclusion of people living with dementia, and recognising the importance of championing people with dementia's unique perspective and contributions that have previously been ignored (Gove et al., 2018). Such recommendations have seen the inclusion of people with dementia as co-researchers (Swarbrick et al., 2016). However, in a recent scoping review, inclusion and involvement continues to be inadequately reported in dementia research (Bethell et al., 2018).

The PPIE team in the School of Primary, Community and Social Care operated a Dementia Research User Group (RUG) to facilitate research development. The RUG consists of lay people who meet regularly to give advice and feedback on grant applications and planned research studies. I initiated contact with the RUG, which included current and previous family caregivers of people with dementia. Unfortunately, although I attempted to involve people with dementia in the development of this research, there was no opportunities at the time of the initial project development. During the PPIE meeting, RUG members helped to co-produce the research questions, study design, and recruitment procedures. PPIE members also provided comment on participant facing documents (e.g. invitation letters, information leaflets, consent forms, consultee advice forms, etc.), interview guides, and lay summaries.

One way that the RUG group positively guided the development of this project was by emphasising the importance of 'situational sensitivity' when using the word dementia during interviews as the person with dementia may not be informed of, do not agree with, or may have forgotten their dementia diagnosis (Downs, Clibbens, Rae, Cook & Woods, 2002; Novek & Wilkinson, 2019). The RUG and I agreed that I would ask the family caregiver (prior to interview) about the insight of the person with dementia into their condition. If insight was uncertain, dementia was referred to as a 'memory problem' taking into account the ethical challenge of re-informing the individual with potentially distressing information (Heggestad, Nortvedt & Slettebø, 2013; Pesonen, Remes & Isola, 2011). This approach was deemed morally sensitive by the RUG group. Additional ways in which the RUG group aided the development of this study are discussed throughout this chapter.

6.3.3 Interviews

Reflecting on the research questions and theoretical perspective of this thesis, interviews were chosen as the method to explore the many dimensions of the participant's subjective views, perspective, and experiences of pain identification, assessment, and management (Rubin & Rubin, 2012). Interviews allow researchers to see the world through an alternate

perspective by talking to people that have knowledge, or experience of a phenomena, in line with the critical realist perspective that each individual has their own subjective, real-world lived accounts shaped by culture, history, and experience (McEvoy & Richards, 2006). Interviews within a qualitative context are typically dichotomised into unstructured (otherwise referred to as non-standardised or in-depth), or semi-structured interviews. I chose to use semi-structured interviews to allow the narrative to focus on the research topic, yet remain flexible in response to the participant narrative.

6.3.4 Interview guides

Interview guides (also known as topic guides, or interview schedules) provide the key aspects to be explored during the interview, broken down into different areas for discussion (Arthur & Nazroo, in Richie and Lewis, 2003). In this research, the interview guide was used as an aide-memoire, ensuring that all of the relevant issues were covered during the interview, while again, maintaining a degree of flexibility to explore each participant's personal perspective. For this study, I created two broad interview guides (see Appendix 6):

1 The person with dementia and their family caregiver

2 Healthcare professional

Interview guides for people with dementia and family caregivers were developed in collaboration with the PPIE Dementia RUG, based upon previous literature that had conducted semi-structured interviews with healthcare professionals and family caregivers about pain in people with dementia (Lichtner et al., 2016; Brorson, Plymoth, Örmon & Bolmsjö, 2014). Following the collaborative development of the interview guides, each guide was checked to ensure that they reflected the research questions. After each interview, the interview guide was adapted to incorporate participant's key ideas, notions, and experiences. The iterative and flexible adaptation and development of the interview guide facilitated the development of new insights not hitherto anticipated (Yeo et al. in Richie, Lewis, Nicholls & Ormston, 2013).

6.3.5 Person with dementia and family caregiver interviews

Interviews are the most common qualitative data collection method for people with dementia (Steeman de Casterle, Godderis & Grypdonck, 2006). However, people with dementia are often excluded from interview studies due to the perception that they are 'incapable' of talking about their subjective experiences, thoughts, and feelings (Hubbard, Downs & Tester, 2003; Quinn, 2017). In recent years, research has emphasised the inclusion of people with dementia in interview studies to promote social inclusion, and to challenge the stigmatised view of dementia (Pesonen et al., 2011; Hubbard, Downs & Tester, 2003; Quinn, 2017). Despite the importance of including people with dementia in qualitative research, it remains the researcher's moral obligation to consider the unique ethical and methodological challenges.

I chose to interview the person with dementia with their primary family caregiver, in a face-to-face 'dyadic' or 'joint' interview. Dyadic interviews bring together two participants, and are particularly advantageous when the participants are in a natural coupling, for example partners, parents and their children, caregivers and the person they care for (Morgan, Ataie, Carder & Hoffman, 2013). Dyadic interviews allowed collaborative discussion to provide a shared narrative by both parties (Eisikovits & Koren, 2010); allowing both participants to reflect upon, and draw comparisons with the other person's perspective. Previous research has highlighted the benefits of dyadic interviews for people with dementia and family caregivers to create a safe and comfortable environment to facilitate open and honest discussion (Morgan et al., 2013; Pesonen et al., 2011). Pragmatically, dyadic interviews also allow the family caregiver to be present for safeguarding purposes, and to act as a consultee if the person with dementia did not have capacity to provide informed consent (see Section 6.3.5.4.1).

When considering the ethical and methodological issues of dyadic interviews, the RUG group suggested that the person with dementia or family caregiver might wish to discuss something

that they would feel uncomfortable disclosing in the presence of the other person. However, no participants wished to complete a second interview on their own, suggesting that they had 'nothing to hide from each other'. Interviews were also offered to family caregivers on their own if the person with dementia was not eligible to participate (see Section 6.3.5.1).

6.3.5.1 Eligibility

This research aims to take an inclusive approach to dementia research and therefore did not include or exclude on the basis of cognitive test scores. Cognitive tests are criticised for their blanket approach to eligibility testing as they do not measure the amount an individual can discuss their experiences, perspective, and emotions (Pratt & Wilkinson, 2001; Heggestad et al., 2013). Excluding people with dementia in research goes against the principle of 'equality' and removes their right to a voice on their pain despite it directly affecting their life (Sherratt, Soteriou & Evans, 2007).

In contrast, recent research has emphasised the positives of including people with dementia in research; with people with dementia describing research interviews as therapeutic, an opportunity to validate own perspectives and experiences, and allowing them to feel 'capable' (Cahill et al., 2004). On these grounds, the present research adopted an inclusive approach to dementia research (Dewing, 2002; 2007; Hellström, Nolan, Nordenfelt & Lundh, 2007). To achieve this, the recruitment approach ensured that all people with the ability to take part in a dyadic interview were provided the opportunity, even though the interview may require adaptation (e.g. increased flexibility for breaks, multiple visits, etc.) because of this. This is reflected below in the inclusion and exclusion criteria for people with dementia (see Table 6.10).

Table 6.10. People with dementia and family caregivers: Inclusion and exclusion criteria

Person with dementia
Inclusion criteria
• Diagnosis of dementia as assumed by information provided in the Join Dementia Research records, or verbal confirmation from the person themselves or their caregiver • Live in the community (as defined in Section 1.7) • Have an informal caregiver willing to participate in a dyadic interview • Able to vocalise a willingness to take part in an interview • Verbally proficient in English
Exclusion criteria
• Cannot to contribute to an interview (e.g. no longer have the ability to verbally communicate) • Currently or recently experiencing any major psychological, physical distress, or emotive or stressful life event in which taking part in an interview may exacerbate (as asked to the caregiver)
Family caregivers
Inclusion criteria
• Self-identify as the current or previous primary caregiver for an individual diagnosed with dementia. This may include a family member, relative, neighbour, or friend who is involved in care or spends the most time with the person with dementia (Orgeta et al., 2015). • Willing to take part in an interview • Verbally proficient in English
Exclusion criteria
• Under the age of 16 years old

6.3.5.2 Sampling and recruitment

People with dementia and family caregivers were identified using a purposive sampling method using Join Dementia Research (JDR) (https://www.joindementiaresearch.nihr.ac.uk/). Briefly JDR is a platform to promote participation in dementia research by using a self-registration service that enables volunteers

with memory problems or dementia, caregivers of those with memory problems, or dementia and healthy volunteers to register their interest in taking part in research. In October 2018, JDR had 38,022 volunteers, 10,752 of which were enrolled onto research studies. JDR staff used the inclusion and exclusion criteria (see Section 6.3.5.1) to identify potentially eligible volunteers from their records. One hundred and thirty-two potential volunteers were identified within the West Midlands. I screened potential volunteers' records, choosing participants that were eligible, yet diverse in regard to other characteristics (age, cognitive ability score) in line with the purposive sampling method (see Section 6.3.5.2). All volunteers consented to be contacted during the JDR registration process. Those deemed eligible during the initial screening process were contacted using their 'preferred person to contact' (often the family caregiver) using their 'preferred method of contact', including text, telephone, email, or post.

During the first contact, I provided participants with more information about the study, and confirmed their eligibility. Following the initial contact, if the participant(s) was interested in the study, and was eligible to take part, I obtained permission to send the study pack in the post/via email (depending on the participant's preference). A study pack (see Appendix 8) included:

- An invitation letter
- Two information leaflets, one each for the person with dementia and the caregiver

After a minimum of 48 hours, I made follow up contact to the participant(s) to answer any questions, and to potentially arrange an interview. If the participant was happy to arrange an interview, the need for flexibility was required. I acknowledged that unfamiliar environments and the effects of sleep patterns might negatively affect the person with dementia's ability to complete the interview (Beuscher & Grando, 2009). Interviews were therefore scheduled at a time suitable for the person with dementia, with the option to complete the interview at the participant's own home. Conducting interviews with people with dementia in their own homes was perceived as protective, allowing them control over their own environment (Pesonen et

al., 2011). Choice and flexibility promotes inclusivity; providing participants with some control over the research process (Novek, & Wilkinson, 2019)

After organising the interview, I confirmed with the participant that they were happy for me to send a form (either by post or email) detailing the confirmed arrangements of the scheduled interview. This form reminded participants of the scheduled interview date, location, and time. The form also reminded the participant that I would telephone call them approximately one hour before the interview. This pre-interview telephone call was suggested by the RUG group, not only to act as an additional reminder, but also to ensure that participants were in a good state of wellbeing, acting as an additional safeguarding technique and the opportunity to ask any outstanding questions. A flow diagram presenting the recruitment process of people with dementia and family caregivers is outlined in Figure 6.12.

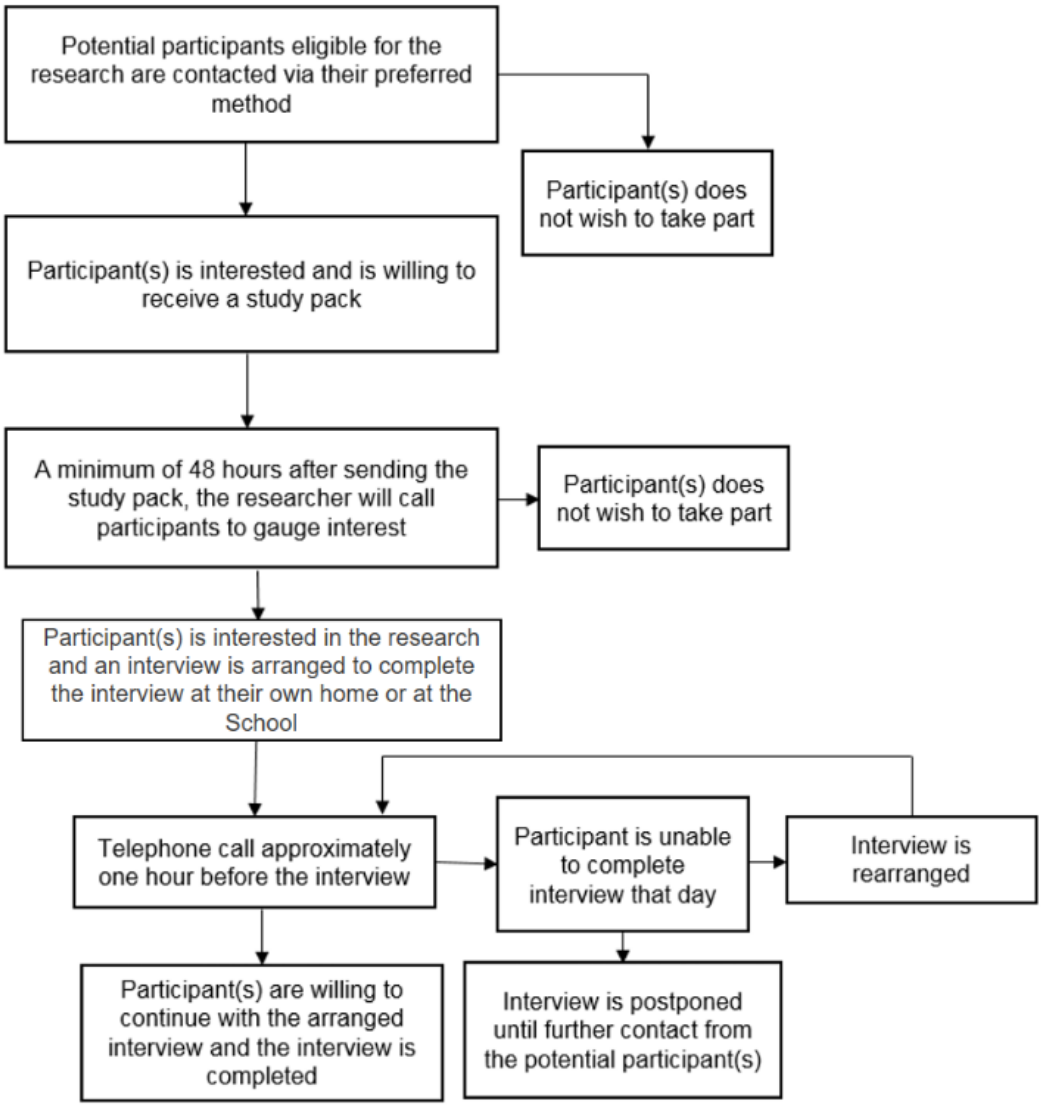


Figure 6.12. Flow diagram to illustrate recruitment through Join Dementia Research

6.3.5.3 The interview process

The following sections discuss the interview process and ethical considerations immediately before (see Section 6.3.5.4), during (see Section 6.3.5.5), and at the end of the interview (see Section 6.3.5.6).

6.3.5.4 Before the interview

Conducting interviews with people with dementia required thought and consideration to ensure that the most suitable environment was created. Building rapport with individuals prior to the actual interview is essential for all good research practice to allow the participant to feel comfortable sharing their thoughts and feelings. Building rapport based on trust, warmth, and empathy is even more important for people with dementia in the presence of potential power inequalities (Hellström et al., 2007). I began building rapport with the participant(s) by engaging in general conversation and providing information about myself. In addition, this allowed me to gain an initial insight into the person with dementia's capacity. Before the interview began, I emphasised that there was no right or wrong answers, and the wish to hear the person with dementia's thoughts before the family caregiver (see Section 6.3.5.5). Before the interview initiated, the information leaflets were discussed (see Appendix 8), during this process I highlighted the key information, including but not limited to a brief overview of the study, the contact details of the researcher, the researcher's duty of care, and data management and storage. Following discussion of the information leaflet, I gave the participants time to consider any potential questions or thoughts.

6.3.5.4.1 Capacity and informed consent

The Mental Capacity Act (Department of Health, 2005) and many other papers (Dewing, 2007; McKeown, Clarke, Ingleton & Repper, 2010; Welie & Welie, 2001; Heggestad et al., 2013) highlight that a diagnosis of dementia does not automatically result in lacking capacity. A person-centred approach emphasises that people with dementia should have the opportunity to participate in research that directly concerns their illness (Moore & Hollett, 2003).

To assess the person's capacity to participate in the research, I considered if the diagnosis of dementia means that the person is unable to make a decision if to, or if not to participate in

the interview at that time. To establish this, four key considerations as outlined by the Mental Capacity Act 2005 Code of Practice (Department for Constitutional Affairs, 2007) were:

- The person with dementia's general understanding of what decision they need to make and why they need to make it
- The person with dementia's general understanding of the likely consequences of taking part, or not taking part in the research
- The person with dementia's ability to understand, retain, use and weigh up their decision to participate in the interview
- The person with dementia's ability to communicate their decision

If the person with dementia was deemed to have informed consent, the person with dementia and the family caregivers signed an informed consent form (see Appendix 8). If the person with dementia lacked capacity to provide informed consent, I consulted the family caregiver in accordance with section 32 of the Act to determine whether the person would wish to be included in the research.

The consultee commented on two important aspects:

- Whether the person who lacks capacity should take part in the project
- What they think the person's feelings and wishes would be, if they had capacity to decide whether to take part.

If the family caregiver acted as a consultee, they were asked to read the consultee information sheet (see Appendix 8). This information sheet provided the information about the important aspects of the study, and the responsibilities of a consultee in research. Although the consultee was advising on the person with dementia's feelings and wishes, the person with dementia had to express a willingness to participate. The family caregiver was asked to sign the consultee advice form on behalf of the person with dementia (see Appendix

8), and informed consent for their own participation (see Appendix 8). If a family caregiver participated alone, they were asked to sign informed consent for their own participation (see Appendix 8).

To ensure an ethical and positive research experience for all parties, the process-consent method was utilised (Bartlett, 2012; Dewing, 2002; 2007). This framework reiterates the importance of gaining verbal confirmation at each stage of the research process that the participant is willing to continue and reminding participants that they can withdraw at any time, rather than consent being viewed as a priori research formality (Hubbard, Downs & Tester, 2003). This method is particularly beneficial when interviewing vulnerable populations, allowing each participant multiple occasions throughout the interview process to express their wish to continue participating. By monitoring ongoing consent, the research can be person-centred and inclusive, yet promote safety and personal well-being.

6.3.5.5 During the interview

6.3.5.5.1 Contextualising participants

At the start of the interview, after initiating the audio recorder, I provided an overview of myself. This allowed participants time to settle into the interview environment. Additionally, this information assisted in building rapport by allowing the participant(s) an insight into my life. After I provided an overview of myself, the participant(s) was asked to give an overview of themselves. If the participant did not naturally include all relevant demographic information (e.g. age, pain condition), I prompted for this information when their narrative naturally came to a close.

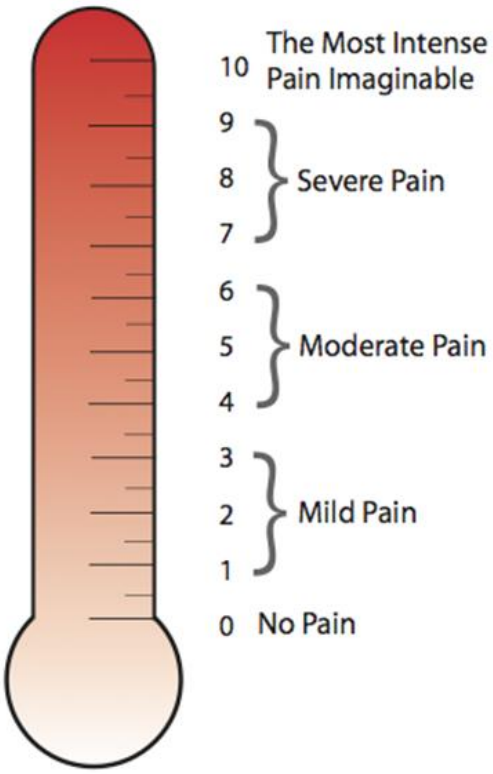
Assessment of pain

To add further contextual information to participants' accounts, it was important to gain an understanding of how people with dementia subjectively perceived their pain intensity. In the nature of this interview study, all people with dementia were able to verbally communicate,

and therefore self-reported pain was deemed appropriate (see Section 2.3.1). Throughout the literature review (see Chapter Two) and the systematic review (see Chapter Three) many self-report pain assessment tools were discussed. The Revised Iowa Pain Thermometer (IPT) demonstrated pain intensity with a thermometer graphic, accompanied with a Numerical Rating Scale (NRS) and verbal anchors (e.g. 'mild pain') to aid pain ratings (see Figure 6.13)

The NRS and verbal pain descriptions in the IPT allowed the participant(s) multiple avenues to describe their pain. Investigation into the IPT for people with cognitive impairment suggested that the scale was 'relatively easy to use and understand' (Ware et al., 2006), and is preferred over other methods of assessing pain intensity (Ware et al., 2015).

People with dementia were asked to 'pick a number on the Pain Thermometer that best represents the intensity of your pain right now' and 'on average over the last four weeks'. Following this, family caregivers provided an informant report of pain, and were asked to 'pick a number on the Pain Thermometer that best represents the intensity of [*person with dementia's name*] pain right now' and 'on average over the last four weeks'. Both the person with dementia and family caregivers were encouraged to qualitatively discuss their perspective of this pain assessment method.



Used with permission Keela Herr, PhD, RN, AGSF, FAAN, College of Nursing, The University of Iowa, Iowa City, IA, USA

Figure 6.13. Iowa Pain Thermometer (IPT) graphic

6.3.5.5.2 Conducting the interview

People with dementia may take longer to answer interview questions and may require a longer time to form their response (Pesonen et al., 2011). In many circumstances, this meant that I was comfortable with silence, allowing the person with dementia the time and space to form their response. In dyadic interviews, all interview questions were first directed towards the person with dementia. If the family caregiver initiated a response, I asked them to 'hold that thought' until the person with dementia had the opportunity to voice their perspective (Mastwyk, Ames, Ellis, Chiu & Bow, 2014). In addition, people with dementia may 'go off topic' or 'get stuck' on a particular topic. In this circumstance, I waited until the person with dementia reached a natural end to their narrative, before validating their response and

guiding the conversation topic back to the interview guide (Beuscher & Grando, 2009; Murphy, Jordan, Hunter, Cooney & Casey, 2014).

Throughout the interview process, it was important to offer sufficient opportunities for breaks for people with dementia. In addition to breaks, participants were given the option to complete the interview during multiple visits to gain the depth and breadth of information required without causing irritability or fatigue due to a longer interview (Pesonen et al., 2011). Multiple interviews were, however, not required.

6.3.5.6 Ending the interview

Researchers have previously noted the importance of ending the interview 'on a high' by praising and thanking the participants for their contribution (Murphy et al., 2014). After the audio recorder was turned off, I ensured that the person with dementia felt positive about their contribution by spending time with the person with dementia and the family caregiver to reiterate my gratitude for their involvement and hospitality. Although this is important for all research, it is particularly so for people with dementia who may feel a sense of failure from 'giving the wrong answer' or getting confused during the interview (Hellström et al., 2007; Murphy et al., 2014). Participants were offered a £10 voucher as a token of appreciation for their time.

6.3.6 Healthcare professional interviews

In addition to face-to-face interviews, alternative modes of interview are also frequently used, including telephone interviews. Research suggests that telephone interviews may require more frequent clarification of meaning, potentially lost nuances (due to the lack of facial expression and body language), and shorter interviews than face-to-face interview modes (Irvine, Drew & Sainsbury, 2012). Despite the potential limitations of telephone interviews, their inclusion was deemed necessary to overcome practical barriers of including healthcare professionals in research, such as time constraints and availability (Sturges & Hanrahan,

2004). Therefore, healthcare professionals were given the option to complete the interview face-to-face or via telephone, depending on their preference.

6.3.6.1 Eligibility

This study aimed to explore pain identification, assessment, and management from the perspective of healthcare professionals. The inclusion/exclusion criteria were left intentionally broad, however recruitment was targeted towards GPs and old age psychiatrists due to their involvement providing care for community-dwelling people with dementia (see Section 4.1). Inclusion and exclusion criteria are in Table 6.11. The restrictive nature of snowball sampling (see Section 6.3.6.2), along with the feasibility and scope of this study, meant that additional healthcare professionals (aside from GPs and old age psychiatrists) were not recruited.

Table 6.11. Healthcare professionals: Inclusion and exclusion criteria

Inclusion criteria
• Healthcare professional (e.g. GP or Old Age Psychiatrist) with experience of working with people with dementia in a professional capacity
• Willing to take part in an interview
• Verbally proficient in English
Exclusion criteria
• Not directly involved in the provision of care for people with dementia

6.3.6.2 Sampling and recruitment

Healthcare professionals were recruited using a snowball sample. Healthcare professionals were approached through existing clinical networks within the School of Primary, Community and Social Care. My supervisors made contact with colleagues (using the study invitation letter) known to them to ask if they would like to participate. Healthcare professionals were also asked to pass the study invitation letter on to their clinical colleagues who fitted the eligibility criteria to ask if they may also wish to take part. My contact details were provided

within the study invitation letter, and therefore, only those that expressed an interest in the study (by telephone or email) were contacted and provided with further information. A flow diagram presenting the recruitment process of healthcare professionals is outlined in Figure 6.14.

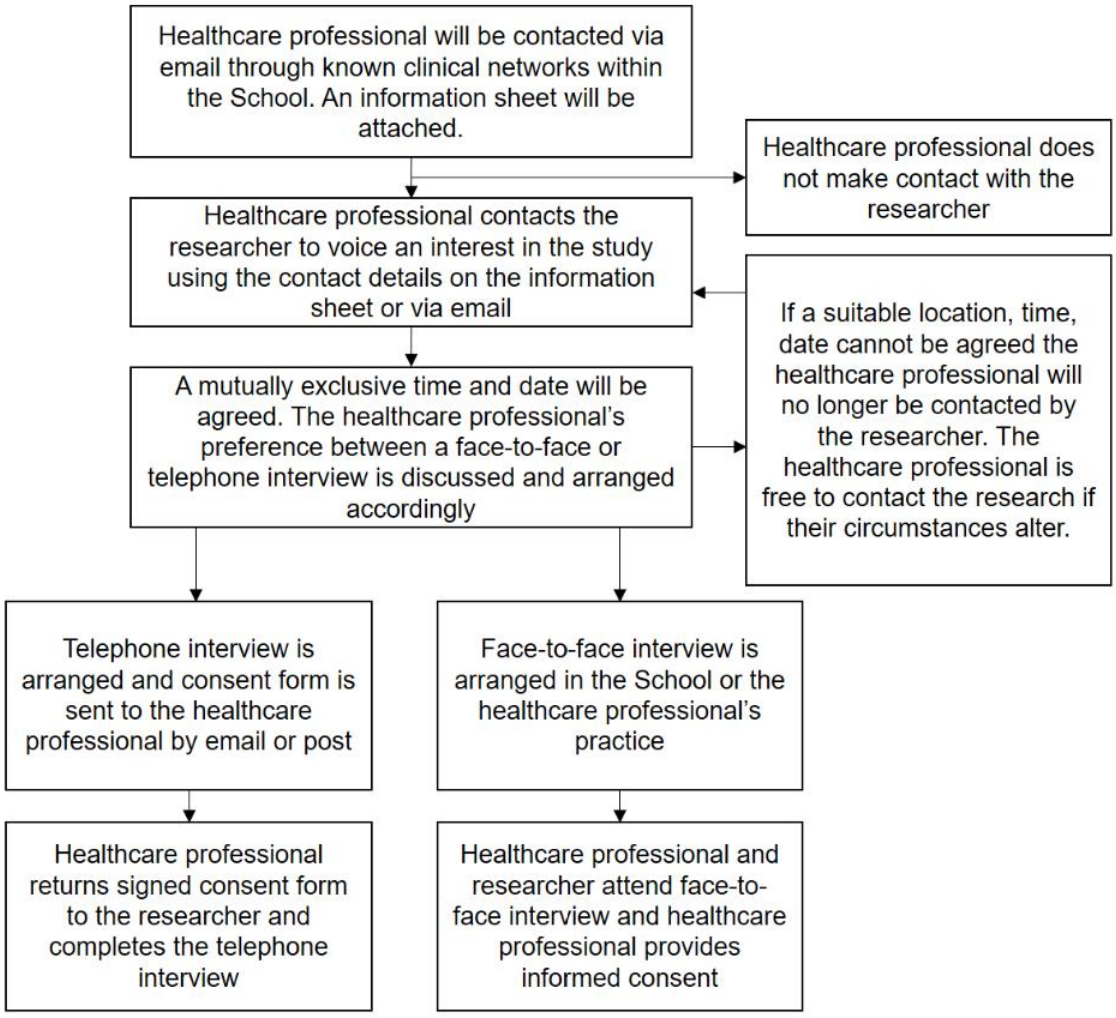


Figure 6.14. Flow diagram to illustrate healthcare professional recruitment

6.3.6.3 The interview process

When a healthcare professional provided an explicit expression of interest, a study pack was sent by post or email depending on the potential participant's preference, to allow the healthcare professional to read during their own time. A study pack (see Appendix 8) included:

- An invitation letter
- An information sheet
- Two copies of the consent form

If the healthcare professional expressed a willingness to participate, a mutually suitable time and mode of interview (i.e. face-to-face or telephone) was arranged.

Face-to-face interviews with healthcare professionals were completed within the School of Primary, Community and Social Care or within the healthcare professional's place of work, depending on the participant's preference. If the interview was arranged face-to-face within the School of Primary, Community and Social Care, I booked a room to complete the interview. If the interview was conducted on NHS premises, the healthcare professional was asked to choose a location suitable for a private interview. I discussed the information leaflet and consent form (see Appendix 8) with the healthcare professional before the interview to validate understanding, with time for participants to ask any questions. If the healthcare professional was happy to continue, written informed consent was obtained and countersigned before starting the interview.

If the healthcare professional wished to complete a telephone interview, I booked a room within the School of Primary, Community and Social Care. By doing so, the interview environment was private and the audio recording of the interview did not exit the building. Before the interview, participants were asked to complete the informed consent form (as included in the study pack sent by email or post) and return it before the scheduled interview date. When the informed consent form was returned, I counter-signed the consent form and returned a copy of the form to the healthcare professional for information purposes. At the start of the telephone call, time was provided to allow the healthcare professional to ask any questions. Following this, I reiterated the key tenants of the consent form with verbal confirmation of understanding and willingness to continue from the participant. At the start

and throughout the interview, the participant was made aware when I started and stopped the audio recording.

At the end of every interview, healthcare professionals were thanked for their time and offered reimbursement aligned to their hourly rate.

6.3.7 Additional ethical considerations

Throughout the previous sections, methodological and ethical considerations were discussed, most of which were appropriate for people with dementia and their family caregivers. The following sections discuss additional ethical considerations applicable to all interview studies, irrespective of the population.

6.3.7.1 Duty of care and breaking confidentiality

During the interview process, on rare occasions participants may divulge, incidentally, information that raises concern (for example, an expression of potential harm to themselves or to somebody else). I had a duty of care and responsibility to break confidentiality upon these grounds. This was explicitly outlined within the information leaflet and discussed prior to each interview. There were no instances in which such action was deemed necessary, however in such circumstances, I would have followed the Risk Protocol (see Appendix 9).

6.3.7.2 Withdrawal

All participants had the right to withdraw from the study at any time without implications to their care or legal rights. However, all participants were made aware that if they withdrew during or after the interview, their anonymous data would continue to be used, however no further information would be collected or contact made.

If the family caregiver acted as a consultee to provide advice on behalf of the person with dementia, the family caregiver had the right to withdraw the person with dementia from the research at any time (Department for Constitutional Affairs, 2007). If the person with dementia expressed a wish to withdraw from the study (implicitly or explicitly) during or after

the interview, this was acted upon regardless of informed consent or consultee advice. As part of the process-consent method, the interviewer reiterated that all participation was voluntary and that participants were free to withdraw at any time at each stage of the study (outlined in Section 6.3.5.4.1). The researcher remained vigilant for changes in the participant's presentation as upset or distress may be an implicit willing to withdraw from the research, especially for people with dementia.

All participants were signposted to relevant organisations (including the National Dementia Helpline). Additionally, my contact details (as outlined in the information sheet; see Appendix 8) were highlighted at the start, and upon closure of the interview.

6.3.7.3 Interviewer Safety

People with dementia and family caregivers could complete the interview in their own homes. Additionally, healthcare professionals could complete the interview on NHS premises. Although this approach was beneficial for the participants, safety was paramount. In these cases, I strictly abided by the Keele University Lone Working Policy. Before each visit, I completed the School of Primary, Community and Social Care visit proforma. This includes information such as the location and time of the interview, contact details for the researcher, or any notable risks. This information was shared with a nominated colleague. The visit proforma was destroyed after each visit to ensure confidentiality of personal information.

6.3.8 Data management and storage

All data management was in accordance with the Data Protection Act (1998) and General Data Protection Regulation (2018). All hard copies of consent forms were stored in a locked cabinet, within the lockable room at the School of Primary, Community and Social Care at Keele University (itself an electronically secure accessed building) and did not exit the School of Primary, Community and Social Care after the interview. Hard-copies of consent forms were stored for five years, as per Keele University policy at which point they were to be destroyed. All recordings and transcripts remained on a secure, password protected

computer at Keele University. Data were only accessible by myself or the supervisory team upon request.

During transcription, each participant was allocated both a participant number and pseudonym to ensure that the participants' personal details remain anonymous throughout the research process. When participants revealed personal information that may compromise their anonymity during the interview (i.e. address, place of work, name of relative, etc.), the identifiable information was deleted or replaced. The use of direct quotes was made explicit to all participants prior to interview. All anonymised transcripts were stored on a secure network drive with restricted access.

6.3.9 Qualitative data analysis

Thematic analysis is a method of identifying, analysing, and reporting patterns (or themes) across qualitative data in relation to the research question (Braun & Clarke, 2006). Braun and Clarke (2019) have recognised a 'tripartite typology of thematic analysis' (p. 593), including 'coding reliability', 'codebook' and 'reflexive approaches'. This study uses the thematic analysis described by Braun and Clarke (2006; 2018; 2019), which they now refer to as *reflexive* thematic analysis (Braun & Clarke, 2019). Themes in reflexive thematic analysis are conceptualised as patterns of shared meaning underpinned by a central organising concept (Braun & Clarke, 2019) that capture something important in relation to the research question (Braun & Clarke, 2006; 2014). Unlike other versions of thematic analysis, reflexive thematic analysis is distinct in acknowledging the researcher's role in knowledge production (Braun & Clarke, 2019).

I chose to analyse the data using reflexive thematic analysis for a number of reasons. Firstly, reflexive thematic analysis is suitable to explore people's behaviours or practices along with individual experiences, views and opinions (Braun & Clarke, 2013), thus aligning well with my research questions. Furthermore, thematic analysis identifies what is 'common' rather than unique or idiosyncratic perspectives (Braun & Clarke, 2014). This was important for my

research questions which wished to explore common themes across multiple participant populations. Additionally, reflexive thematic analysis offers a flexible approach compatible with many theoretical perspectives (Braun & Clarke, 2014). Therefore, researchers do not need to subscribe to a particular philosophical or theoretical approach to use thematic analysis (unlike many other qualitative data analysis methods). The theoretical flexibility of reflexive thematic analysis was particularly important for this study for two reasons. Firstly, the philosophical-free perspective complements the critical realist approach, and mixed methodology of this research, whereas alternative analytical approaches that are dependent on a particular philosophical position may cause tension with these approaches. Secondly, the flexibility may improve the accessibility of the findings when 'stepping outside of academia' (Braun & Clarke, 2014), with no need for the audience to be familiar with the deep-philosophical and theoretical commitments of some qualitative analytical methods. For this reason, thematic analysis is a useful approach for applied health research wishing to translate into practice (Braun & Clarke, 2014).

Despite being theoretically flexible, researchers should articulate their assumptions that informed the analysis to promote reflexivity and transparency. The reflexive thematic analysis in this study was underpinned and informed by a critical realist theoretical perspective (see Chapter Five). The realist aspect of this theoretical perspective means that semantic codes and themes were identified within the explicit or surface meanings of the data. This method fits with the critical realist perspective by acknowledging participants' individual perspectives that are based upon an assumed reality that is evident in the data. Regardless of the semantic approach to analysis, interpretation was essential to move beyond a 'description' of the data, to theorise the significance of the patterns and their broader meanings and implications (Braun & Clarke, 2013).

Critical realism also guided the inductive or deductive (theoretically-driven) approach to the reflexive thematic analysis (Braun & Clarke, 2006). An inductive approach means that the

data drives the development of themes, and therefore the generated themes are strongly linked to the data. An inductive approach may mean that the generated themes have little resemblance to the questions asked of participants. Alternatively, themes can be identified in a deductive manner, driven primarily by the researcher's theoretical or analytical interests to answer the pre-defined research questions. For this study, I primarily used an inductive approach to the analysis. The novelty of the research area and lack of previous qualitative exploration for community-dwelling people with dementia called for an inductive approach to ensure that the analysis was rich in detail and driven by the data. The inductive approach aligns with the constructionist epistemology associated with critical realism; allowing each individual's subjective experience of reality to shape the generation of themes. Despite approaching the collected data in an inductive manner, I acknowledge that the pre-defined research questions means that the findings are in part theoretically-driven (rather than entirely driven by the participant data).

6.3.9.1 The process of analysis

For many years, thematic analysis was inconsistently used, with limited guidance regarding the application of the analytical approach (Braun & Clarke, 2014). Braun and Clarke (2006) therefore developed a six-step process of conducting thematic analysis. The six steps, along with the operationalisation of each step as provided by Braun and Clarke (2006) is provided in Table 6.12. Each step is presented sequentially, however the analytical process was recursive; moving backward and forward between stages. Many stages of analysis were facilitated by NVivo 11 (QSR International), a qualitative data management software. This software was used to add 'memos' (e.g. reflections, thoughts, ideas), to code extracts of transcripts, and to collate themes.

Table 6.12. Thematic analysis: Braun and Clarke (2006)

Steps of thematic analysis	Braun and Clarke description	Operationalisation in this study
Step 1: Familiarising yourself with the data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas	I completed and transcribed all interviews to familiarise myself with the data. Following transcription, all transcripts were checked for accuracy while listening to the audio-recording. During this process, I noted down my initial thoughts and comments.
Step 2: Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code	Initial coding were generated for each participant group independently. After establishing initial codes, each participant group dataset were compared and contrasted to integrate the overall findings. All transcripts were systematically coded on paper, followed by coding using NVivo 11. Coding was conducted in an iterative, concurrent manner alongside data collection.
Step 3: Generating* themes	Collating codes into potential themes, fathering all data relevant to each potential theme	Using NVivo 11, coded data extracts were collated into potential overarching themes. Each data extract was checked to ensure that it reflected the theme in question. Initial thematic maps were developed
Step 4: Reviewing themes	Checking if the themes work in relation to the coded extracts (level 1) and the entire data set (level 2), generating a thematic map of the analysis	I first re-read each coded extract to ensure that it reflected the theme in question. Secondly, I re-read each transcript to ensure that the themes adequately reflected the entire dataset. Thematic maps were produced to provide a visual conceptualisation of the data and to creatively interrogate the links between themes

Table 6.12. Thematic analysis: Braun and Clarke (2006)

Steps of thematic analysis	Braun and Clarke description	Operationalisation in this study
Step 5: Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme	Themes were refined: collapsed into each other, or new themes were created if they were distinct. Thematic maps created in step 3 and 4 were developed further to reflect the overall story of the data (see Appendix 10 for a final thematic map). A document was created to outline the theme name, a descriptive overview of each theme (to outline the scope, depth, and diversity of each theme), followed by a number of illustrative (and contradictory) codes and data extracts from each population group (an adapted version is provided in Appendix 10). This method ensured that each theme contributed to the research questions, yet remained distinct from each other. The thematic maps, thematic document, and the provisional theme names were discussed, and finalised in collaboration with the supervisory team.
Step 6: Producing the report	Selection of vivid, compelling extract examples, relating back of the analysis to the research objectives and literature	Each theme was reported using an in-depth description, and a number of supportive and contradictory data extracts from each population group. Themes are presented and split by their corresponding research objective, and discussed throughout Chapter Eight and Chapter Nine.

* ‘Generating themes’ was updated from ‘searching for themes’ to highlight that themes are not are not ‘in’ the data awaiting retrieval by the researcher (Braun & Clarke, 2019)

6.3.10 Saturation

Saturation is used in qualitative research as a 'criterion for discontinuing data collection and/or analysis' (Saunders et al., 2017, p. 1894), and although the concept originates from grounded theory, saturation is an accepted aspect of qualitative research generally. Inductive thematic saturation relates to the identification of new codes (Saunders et al., 2017), in other words, saturation was conceptualised as the 'mounting instances of the same codes, but no new ones' (Urquhart, 2013, p. 194). Therefore, when no 'new codes' were identified during the analysis, a degree of saturation was reached. This does not suggest that if data collection and analysis continued that no 'new codes' would be identified, however new codes would not add to the overall story of the data (Saunders et al., 2017).

In this study, three participant groups were recruited. Data collection and data analysis was an iterative and concurrent process within and across each participant group. When new codes were no longer being identified for each participant group, I determined, along with my supervisors, that a sufficient degree of saturation was reached.

6.3.11 Quality and trustworthiness considerations

Trustworthiness is an important consideration for research; elements such as truth, applicability, consistency and neutrality are considered important for both quantitative and qualitative approaches (Lincoln & Guba, 1985). The assessment of these elements, however, differ between quantitative and qualitative research. Quantitative research often uses terms such as reliability, validity, generalisability, and objectivity. However, researchers suggest that an alternative language to assess the quality of qualitative research is essential to align with the principles of qualitative enquiry (Leininger, 1985; Agar, 1986), such as credibility, transferability, dependability and confirmability. This study used a variety of techniques to promote quality and trustworthiness of the qualitative findings, including:

- **Data triangulation** - Triangulation refers to the multiple methods or data sources in qualitative research to develop a comprehensive understanding of phenomena (Patton, 1999). By interviewing people with dementia, family caregivers, and healthcare professionals the findings reflected the accounts of multiple participant groups, increasing the credibility.
- **Analytical triangulation** - Members of the research team coded the interviews separately, and discussed their interpretations (Nowell, Norris, White & Moules, 2017). Triangulation of analysis allowed the opportunity to be reflexive on my assumptions.
- **Reflexivity -** Reflexive questioning moved me beyond my own 'taken for granted' assumptions. Reflexive approaches allowed variability and decisions to be 'audited' and therefore trackable throughout the research process. Additionally, reflexive practices ensured that I remained self-critical of how I might influence the interpretation of the data. Throughout the research process I engaged with a number of reflexive practices:
    - A self-critical journal of my concerns, thoughts, assumptions, and questions.
    - A contact summary sheet immediately after each interview (Miles & Huberman, 1994), allowing immediate reflection on pertinent aspects of the interview (see Appendix 11).
    - Meetings with my supervisors and discussions with colleagues and peers promoted reflexive questioning.

6.4 Conclusion

This chapter provided an overview of the quantitative and qualitative methods used to explore the phenomenon of pain identification, assessment, and management for community-dwelling people with dementia as part of the mixed methods approach. Firstly, this chapter discussed the quantitative methods employed to examine pain identification, assessment, and treatment for community-dwelling people with dementia using primary care

EHRs. Following this, the qualitative methods used to explore the perspective and views of people with dementia, family caregivers, and healthcare professionals were discussed to illuminate the subjective perspective of the phenomenon. The following chapter provides a descriptive overview of the populations and the people included in the quantitative and qualitative findings, acting as a contextual foundation in preparation for the findings chapters.

7 Chapter Seven: An Overview of the Populations and the People

7.1 Introduction

This chapter provides a description of the participants included in the quantitative and qualitative analysis. Firstly, the demographic characteristics of the incidence and prevalence cohorts are described. Secondly, an overview of the people with dementia, family caregivers, and healthcare professionals who took part in qualitative interviews are provided. This chapter therefore provides a descriptive overview of the participants included in the quantitative and qualitative methods in preparation for the subsequent findings chapters.

7.2 Overview of the CPRD study population

In the previous chapter, the identification and data refinement process of the dementia cohort and older adult cohort was discussed (see Section 6.2.6). Two sets of cohorts were identified to examine incidence and prevalence. This chapter provides a descriptive overview of the dementia cohort and older adult cohort used in the incidence and prevalence investigation.

7.2.1 Incidence cohort

To be included in the incidence cohort, all participants had no evidence of a musculoskeletal consultation in the 12 months before index date (see Section 6.2.8.1). Index date was defined as the incident dementia clinical code, or equivalent for the older adult cohort (see Section 6.2.7.2).

7.1.1.1 Comparison to the wider pool of participants

During the data refinement process, 65,112 patients with dementia were eligible (see Figure 6.7), however, 44,019 patients with dementia did not have an eligible matched older adult. The loss of eligible participants with dementia during the matching process called for an investigation to examine if patients with dementia with evidence of a matched older adult (*n*=21,093) differed from patients with dementia without evidence of a matched older adult (*n*=44,019) (see Table 7.1).

Table 7.1. Descriptive comparisons between people with dementia with (*n*=21,093) and without a matched older adult (*n*=44,019)

n	**21,093**	**44,019**	***p***	**Effect Size**
Gender, female % (n)	59.1 (12,479)	63.2 (27,819)	<.001**	V = .03
Age at index Mean (SD)	80.33 (8.20)	81.57 (8.52)	<.001**	G = .15
Year of index date Mean (SD)	2008.41 (4.97)	2009.07 (5.14)	<.001**	G = .13
Marital status % (n)			<.001**	V = .07
Single	0.9 (200)	2.6 (1133)		
Married	13.3 (2814)	15.9 (7011)		
Widowed	3.7 (0.6)	4.7 (2078)		
Divorced	0.6 (120)	0.5 (212)		
Unknown	81.4 (14,166)	76.1 (33,492)		
Other	0.1 (21)	0.2 (93)		
Transfer out reason % (n)			<.001**	V = .05
Death	34.9 (7360)	38.1 (16,780)		
Data not entered	29.0 (6107)	28.7 (12,621)		
Internal transfer	24.9 (5252)	23.6 (10,411)		
New health authority	7.7 (1617)	6.5 (2845)		
Other	3.6 (757)	3.1 (1362)		
Follow up (days) Median (IQR)	609 (241, 1182)	597 (237, 1170)	.84	G = .00

SD Standard Deviation; IQR interquartile range; **p<.001; *p<.05
Cramer's V (V) Effect size for chi-square
Hedges' *g* (G) Effect size for independent t-tests with unequal sample sizes

The descriptive data outlined in Table 7.1 highlighted significant differences between people with dementia with (*n*=21,093) and without a matched older adult (*n*=44,019) for all demographic characteristics (with the exception of follow up period). Despite significant differences brought about by the use of large sample size comparisons, the effect sizes indicate a small effect in differences. This would suggest that the dementia cohort identified for the incidence investigation (with a matched older adult) broadly reflects the original pool of eligible people with dementia.

7.1.1.2 Comparison between the dementia cohort and older adult cohort

After being matched one-to-one, a dementia cohort (*n*=21,093) and a matched older adult cohort (*n*=21,093) were identified to examine the incidence of musculoskeletal consultation. A descriptive overview of the dementia cohort and older adult cohort is provided in Table 7.2.

Table 7.2. Descriptive comparison between the dementia cohort (*n*=21,093) and older adult cohort (*n*=21,093)

n	**Dementia cohort** (*n*=21,093)	**Older adult cohort** (*n*=21,093)	***p***	**Effect size**
Gender, female % (n)[#]	59.1 (12,479)	59.1 (12,479)	Matched	Matched
Marital status % (n)			.01	V = .02
Single	0.9 (200)	0.9 (189)		
Married	13.3 (2814)	12.7 (2678)		
Widowed	3.7 (772)	3.4 (717)		
Divorced	0.6 (120)	0.4 (92)		
Unknown	81.4 (17166)	82.4 (17381)		
Other	0.1 (21)	0.2 (36)		
Transfer out reason			<.001**	V = .33
Death	34.9 (7360)	26.6 (5617)		
Data not entered	29.0 (6107)	59.7 (12591)		
Internal transfer	8.1 (1716)	3.0 (632)		
New health authority	7.7 (1617)	3.9 (824)		
Other	20.4 (4293)	6.8 (1429)		
Age at index date Mean (SD)	80.3 (8.2)	80.3 (8.2)	Matched	Matched
Year of index date Mean (SD)	2008.41 (4.97)	2008.41 (4.97)	Matched	Matched
Follow up (days) Median (IQR)	609 (241, 1182.5)	1246 (557, 2307)	<.001**	*d* = .58
Practice IMD[#]			Matched	Matched
1 – Least deprived	15.9 (3358)	15.9 (3358)		
2	19.0 (4013)	19.0 (4013)		
3	20.5 (4324)	20.5 (4324)		
4	21.1 (4460)	21.1 (4460)		
5 – Most deprived	23.4 (4938)	23.4 (4938)		
Morbidity (BNF) Median (IQR)[£]	9 (5, 15)	9 (5, 14)	<.001**	*d* = .11
Consultation freq[£] Median (IQR)	30 (16, 49)	25 (13, 42)	<.001	*d* = .18

CVD yes % (n) [£]	7.0 (1482)	5.6 (1184)	<.001**	V = .03
Depression/bipolar yes % (n) [£]	7.2 (1526)	2.2 (456)	<.001**	V = .12
Diabetes yes % (n) [£]	15.7 (3322)	14.2 (2997)	<.001**	V = .02

*p=<.05, **p=<.001; [#]Matched on year of birth, gender, general practice; [£]Measured during the 2-year period before index date
SD Standard Deviation; CVD cardiovascular-related conditions; IMD practice-level Indices of Multiple Deprivation; BNF British National Formulary, IQR interquartile range; Cramer's V (V) Effect size for chi-square; Cohen's *d* (*d*) Effect size for independent t-test

The dementia cohort and older adult cohort were 59.1% female, with a mean age of 80.3 (*SD*, 8.2) at index date. 15.9% of the dementia cohort and older adult cohort were classified as 'least deprived', with an incremental increase in the percentage for each level of deprivation, with 23.4% of the dementia cohort and older adult cohort classified as 'most deprived' based on their practice-level IMD. Matching on gender, year of birth, and general practice resulted in no statistical difference between the dementia cohort and the older adult cohort in these characteristics.

The dementia cohort had significantly shorter median follow up (in days) than the older adult cohort (609 vs. 1246, respectively), with a medium effect (d = 0.58).

Various characteristics were examined during the two-year period before index date, including morbidity count (BNF frequency), evidence of cardiovascular-related conditions, evidence of depression, and evidence of diabetes. As expected the dementia cohort had increased evidence of cardiovascular-related conditions, evidence of depression, and evidence of diabetes than the older adult cohort. Despite significant differences between the dementia cohort and the older adult cohort, effect sizes, again indicate a small effect in the differences reported.

7.2.2 Prevalence cohort

To examine the prevalence of musculoskeletal consultation and analgesic prescription, a prevalence cohort was developed. Unlike the incidence cohort described earlier, there was no need for the prevalence cohort to have a musculoskeletal consultation-free period before index date. The index date was defined as the incident dementia clinical code, or equivalent for the older adult cohort (see Section 6.2.7.2).

7.1.1.3 Comparison to the wider pool of participants

The previous chapter provided an overview of the data refinement process for the dementia cohort and older adult cohort established for the prevalence investigation. During the establishment of the dementia cohort, although 87,809 people with dementia were eligible, 51,227 with dementia did not have an eligible older adult match (see Figure 6.8). People with

dementia that did not have an eligible older adult match (*n*=51,227) were not included in the final dementia cohort. The loss of eligible people with dementia during the matching process called for an investigation to determine if people with dementia with a matched older adult (*n*=36,582) differed from people with dementia without an eligible match (*n*=51,227) (see Table 7.3).

Table 7.3. Descriptive comparisons between people with dementia with (*n*=36,582) and without a matched older adult (*n*=51,227)

n	**36,582**	**51,227**	***p***	**Effect size**
Gender, female % (n)	59.8 (21,860)	64.4 (32,992)	<.001**	V = .05
Year of index date Mean (SD)	2008.67 (4.9)	2009.17 (5.16)	<.001**	G = .10
Age at index Mean (SD)	79.94 (8.26)	81.83 (8.35)	<.001**	G = .23
Marital status % (n)			<.001**	V = .09
Single	0.9 (330)	2.7 (1394)		
Married	14.0 (5111)	17.0 (8700)		
Widowed	3.5 (1297)	5.0 (2583)		
Divorced	0.6 (224)	0.5 (270)		
Unknown	80.8 (29,576)	74.5 (38,163)		
Other	0.1 (44)	0.2 (117)		
Transfer out reason % (n)			<.001**	V = .08
Death	33.1 (12,175)	28.3 (19,645)		
Data not entered	31.6 (11,621)	28.8 (14,760)		
Internal transfer	24.4 (8969)	10.4 (5288)		
Removal to new health authority	7.5 (2740)	6.4 (3272)		
Other	3.4 (1267)	16.1 (8262)		
Follow up (days) Median (IQR)	621 (250, 1192)	605 (239, 1185)	.98	V = .00

*p=<.05, **p=<.001

SD standard deviation, IQR interquartile range

Cramer's V (V) Effect size for chi-square

Hedges' *g* (G) Effect size for independent t-tests for different sample sizes

The descriptive data outlined in Table 7.3 highlighted many significant differences between people with dementia with and without an eligible match (again, with the exception of follow up period). Although significant differences between the two cohorts were found, they often had small effect sizes indicating marginal differences. Such findings would suggest that the dementia cohort identified to examine prevalence (*n*=36,582) were broadly comparable to people with dementia without a matched older adult (*n*=51,227).

7.1.1.4 Comparison between the dementia cohort and older adult cohort

After being matched one-to-one, a dementia cohort (*n*=36,582) and a matched older adult cohort (*n*=36,582) were identified to examine the prevalence of musculoskeletal consultation and analgesic prescription. A descriptive overview of the dementia cohort and older adult cohort is provided in Table 7.4.

Table 7.4. Descriptive comparison between the dementia cohort (*n*=36,582) and older adult cohort (*n*=36,582)

	Dementia cohort (*n*=36,582)	**Older adult cohort** (*n*=36,582)	***p***	**Effect size**
Gender, female % (n)[#]	59.8 (21,860)	59.8 (21,860)	Matched	Matched
Marital status % (n)			.002	V = .02
Single	0.9 (330)	0.9 (326)		
Married	14.0 (5111)	13.4 (4912)		
Widowed	3.5 (1297)	3.4 (13.4)		
Divorced	0.6 (224)	0.5 (174)		
Unknown	80.8 (29576)	81.6 (29851)		
Other	0.1 (44)	0.2 (71)		
Transfer out reason % (n)			<.001**	V = .33
Death	33.1 (12110)	24.8 (9090)		
Data not entered	31.6 (11571)	67.9 (22644)		
Internal transfer	24.4 (8969)	7.9 (2889)		
Removal to new health authority	7.5 (2740)	3.9 (1413)		
Other	3.4 (1267)	1.5 (546)		
Year of index date Mean (SD) [#]	2008.67 (4.91)	2008.67 (4.91)	Matched	Matched
Age at index date Mean (SD) [#]	79.9 (8.3)	79.9 (8.3)	Matched	Matched
Follow up (days) Median (IQR)	621 (250, 1192)	1225 (551, 2246)	<.001**	*d* = .67
Practice IMD[#]			Matched	Matched
1 – Least deprived	16.3 (5958)	16.3 (5958)		
2	19.2 (7010)	19.2 (7010)		
3	19.8 (7259)	19.8 (7259)		
4	21.2 (7743)	21.2 (7743)		
5 – Most deprived	23.5 (8612)	23.5 (8612)		

Table 7.4. Descriptive comparison between the dementia cohort (*n*=36,582) and older adult cohort (*n*=36,582)

Morbidity (BNF) Median (IQR) [£]	11 (6, 16)	10 (6, 15)	<.001**	*d* = .11
Consultation freq Median (IQR)[£]	34 (19, 55)	28 (15, 47)	<.001**	*d* = .20
CVD yes % (n) [£]	7.4 (2705)	6.0 (2194)	<.001**	V = .03
Depression yes % (n) [£]	8.1 (2962)	2.6 (965)	<.001**	V = .12
Diabetes yes % (n) [£]	16.7 (6115)	14.9 (5459)	<.001**	V = .03

**p*=<.05, ***p*=<.001; SD Standard Deviation; CVD cardiovascular-related conditions disease; IMD practice-level Indices of Multiple Deprivation; BNF British National Formulary, IQR Interquartile Range

[#]Matched on year of birth, gender, practice; [£]Evidence during the 2 years before index date

Cramer's V (V) Effect size for chi-square

Cohen's *d* (*d*) Effect size for independent t-tests for equal sample sizes

The dementia cohort and older adult cohort were 59.8% female, with a mean year of birth of 1928.7 (*SD*, 9.8). 16.3% of the dementia cohort and older adult cohort were classified as 'least deprived', with an incremental increase in the percentage for each level of deprivation, with 23.5% classified as 'most deprived'.

Similarly to the incidence cohort examined previously (see Section 7.1.1.2), the dementia cohort had a significantly shorter median follow up (in days) than the older adult cohort (621 vs. 1225, respectively), with a medium to large effect (d = 0.67).

Various characteristics were examined during the two-year period before index date, including morbidity (BNF frequency), consultation frequency, evidence of cardiovascular-related conditions, evidence of depression, and evidence of diabetes were significantly higher for the dementia cohort than the older adult cohort. Despite significant differences between the dementia cohort and the older adult cohort, effect sizes indicate a small effect. These findings would again suggest marginal differences between the dementia cohort (n=36,582) and older adult cohort (n=36,582).

7.1.1.5 Annual stratification

Period prevalence was calculated for a five-year period from index date. In addition, annual period prevalence was calculated from index date to five years after index date (see Section 6.2.13.2). People in the dementia cohort and older adult cohort were included in each annual prevalence calculation if they remained in the study for each annual time period (see Section 6.2.13.4). Earlier comparison indicated that the dementia cohort had a significantly shorter median follow up than the older adult cohort (see Table 7.4). The difference in follow up between the dementia cohort and older adult cohort may cause concern if unhealthy members of the dementia cohort leave the study, meaning that the cohort becomes healthier with each annual time period (see Section 6.2.10.1). A descriptive overview of the dementia cohort and older adult cohort at each annual period is provided in Table 7.5.

Table 7.5. Descriptive characteristics of the dementia cohort and older adult cohort during each annual period

Annual Time period	**0 to 1**	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**
Matched-pairs %	**73.5**	**53.4**	**36.6**	**24.7**	**15.9**
			Dementia cohort		
n	**24,247**	**16,110**	**10,314**	**6471**	**3893**
Gender, female % (n)	59.7 (14473)	60.0 (9671)	60.7 (6259)	61.1 (3953)	61.7 (2403)
Age at index Mean (SD)	79.0 (8.2)	82.07 (6.6)	82.5 (6.0)	83.3 (5.6)	84.1 (5.4)
Year of index date Mean (SD)	2008.1 (4.7)	2007.5 (4.5)	2007.3 (4.2)	2006.6 (3.9)	2005.9 (3.6)
Morbidity (BNF) Median (IQR)[£]	10 (6, 15)	10 (6, 15)	9 (5, 14)	9 (5, 13)	9 (5, 14)
Consultation freq Median (IQR)[£]	30 (16, 51)	31 (16, 51)	31 (16, 51)	32 (17, 51)	31 (16, 51)
Follow up (days) Median (IQR)	966 (626, 1503)	1289 (968, 1801)	1614 (1322, 2142.3)	2463 (1889, 3319)	2346 (2046, 2833)
Practice IMD (%)					
1 – Least deprived	16.0 (3869)	15.8 (4083)	15.8 (1632)	15.9 (1030)	16.0 (624)
2	19.4 (4713)	19.2 (4737)	19.3 (1988)	19.5 (1259)	18.7 (729)
3	19.9 (4814)	19.6 (4793)	19.4 (2006)	19.3 (2146)	19.6 (764)
4	20.8 (5052)	20.9 (5184)	20.9 (2155)	21.1 (1366)	21.3 (828)
5 – Most deprived	23.9 (5799)	24.4 (5935)	24.6 (2533)	24.3 (1571)	24.4 (948)
CVD yes % (n)[£]	7 (1698)	6.9 (1106)	6.8 (705)	6.6 (430)	6.4 (784)
Depression yes % (n)[£]	8.4 (2035)	8.8 (1423)	9.3 (961)	9.8 (637)	10.6 (411)
Diabetes yes % (n)[£]	15.9 (3844)	15.0 (2421)	14.2 (1466)	13.4 (869)	12.4 (484)

Table 7.5. Descriptive characteristics of the dementia cohort and older adult cohort during each annual period

Annual Time period	**0 to 1**	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**
Matched-pairs %	**73.5**	**53.4**	**36.6**	**24.7**	**15.9**
			Older adult cohort		
n	**30,316**	**24,732**	**19,849**	**15,663**	**12,276**
Gender, female % (n)	60.1 (18,230)	60.4 (14946)	60.7 (12056)	61.2 (9582)	61.2 (7515)
Age at index Mean (SD)	79.6 (8.1)	81.68 (6.5)	83.0 (6.0)	83.8 (5.7)	84.5 (5.4)
Year of index date Mean (SD)	2008.4 (4.6)	2007.9 (4.4)	2006.8 (4.3)	2006.2 (4.0)	2005.5 (3.8)
Morbidity (BNF) Median (IQR)[£]	10 (6, 15)	9 (5, 14)	9 (5, 14)	9 (5, 13)	8 (5, 13)
Consultation freq Median (IQR)[£]	31 (17, 51)	31 (17, 51)	31 (17, 51)	32 (17, 51)	32 (17, 52)
Follow up (days) Median (IQR)	1507 (872, 2506)	1813 (1202, 2764)	2132 (1533, 3039)	2463 (1889, 3319)	2774 (2236.3, 3572)
Practice IMD % (n)					
1 – Least deprived	16.5 (4989)	16.5 (2551)	16.6 (3298)	16.9 (2641)	16.9 (2080)
2	19.2 (5811)	19.2 (3091)	19.2 (3816)	19.1 (2989)	19.2 (2353)
3	19.6 (5949)	19.4 (3165)	19.0 (3778)	18.8 (2946)	18.8 (2304)
4	20.9 (6328)	21.0 (3370)	21.0 (4176)	21.4 (3346)	21.2 (2597)
5 – Most deprived	23.9 (7239)	24.0 (3933)	24.1 (4781)	23.9 (3741)	24.0 (2942)
CVD yes % (n)[£]	6 (1825)	6.1 (1506)	5.1 (1214)	6.1 (951)	6.7 (262)
Depression yes % (n)[£]	2.6 (796)	2.7 (657)	2.7 (545)	2.8 (437)	2.7 (335)
Diabetes yes % (n)[£]	14.3 (4332)	13.8 (3402)	13.0 (2571)	12.1 (1889)	11.5 (1407)

CVD cardiovascular disease, SD Standard Deviation, IQR interquartile range, BNF British National Formulary, IMD Indices of Multiple Deprivation

The number of people that remained in the dementia cohort was lower than the older adult cohort (see Table 7.5), as expected by the shorter follow up period identified previously (see Table 7.4). Attrition throughout follow up means that the amount of matched-pairs lowered from 100% at baseline, to 15.9% at five years after index date.

For the dementia cohort and the older adult cohort, people in the final years of follow up (i.e. four to five years after index date) had an earlier year of index date and a longer follow up period than people in the first year of follow up. This is synonymous with their eligibility in the latter years of follow up.

It was important to investigate if the high attrition (especially for the dementia cohort) meant that 'unhealthy patients' were leaving the study (i.e. dying, being diagnosed with cancer, moving out of practice), meaning that as time from index date increased, the 'healthier' the cohorts became (see 6.2.10.1).

Firstly, the median consultation frequency remained relatively constant in each annual period throughout follow up for the dementia cohort and older adult cohort. The percentage of people with dementia with evidence of cardiovascular-related conditions during the two years before index date decreased from the first year to the final year of follow up (7% to 6.4%, respectively), with a similar trend for diabetes (15.9% to 12.4%, respectively). However, the percentage of people in the older adult cohort with evidence of cardiovascular-related conditions increased slightly from the first year to the final year of follow up (6% to 6.7%, respectively), whilst evidence of diabetes decreased from the first year to the final year of follow up (14.3% to 11.5%, respectively). However, the percentage of people with dementia with evidence of depression during the two years before index date increased from the first year to the final year of follow up (8.4% to 10.6%, respectively), whereas the percentage of older adults with evidence of depression during the two years before index date remained relatively stable throughout follow up. For the dementia cohort and the older adult cohort, the median morbidity count (BNF frequency) slightly decreased throughout follow up.

Overall, there was a slight decrease in factors such as morbidity, evidence of cardiovascular-related conditions, and evidence of diabetes for each annual period throughout follow up for the dementia cohort. Such decreases were, however minimal. This means that the dementia cohort and older adult cohort do not seem to diverge toward 'healthier' or 'unhealthier' in the latter years of follow up.

7.1.1.6 Community sensitivity

In the previous Chapter, the identification of people in the dementia cohort and older adult cohort living in the community was discussed (see Section 6.2.13.5.1). Sensitivity analysis was conducted using additional, strict criteria to identify a restricted cohort of people with a greater likelihood of living in the community:

- **Incidence cohort:** A total of *n*=4850 people with dementia, and *n*=3477 older adults without dementia were identified using the strict criteria (see Figure 6.10).
- **Prevalence cohort:** A total of *n*=8875 people with dementia, and *n*=8349 older adults without dementia were identified using the strict criteria (See Figure 6.11).

People with dementia identified using the strict criteria were compared to people with dementia not identified as eligible for the community sensitivity analysis. Additionally, older adults identified using the strict criteria were compared to older adults that were not identified as eligible for the community sensitivity analysis. These comparisons (see Appendix 12) suggest marginal differences between the characteristics of people with dementia and older adults identified for the community sensitivity analyses, and those not.

7.3 Participants in the qualitative study

This section of the Chapter shifts the focus from the populations identified for the quantitative sample, to the people who participated in the qualitative element of this thesis. Firstly, demographic characteristics of the people with dementia and family caregivers who participated within the interviews are presented. To provide contextual information, the self and informant reported pain scores are also given. Secondly, a description of the healthcare professionals who were interviewed are also presented.

7.3.1 People with dementia and family caregiver interviews

Nine interviews explored pain identification, assessment, and treatment from the perspective of the person with dementia and family caregivers of people with dementia. The sampling and recruitment methods are described in 6.3.5.2. Interviews included eight people with dementia and nine family caregivers of people with dementia (see Table 7.6).

Table 7.6. Demographic details of people with dementia and family caregivers of people with dementia participating in an interview

Pseudonym name		**Relationship**	**Age**	**Previous occupation**	**Diagnosis** (date)	**Cognitive test score** (test, date)[%$]
1	Patricia*	Wife	82	Occupational Therapist	AD (2014)	18/30 (MMSE, 2016)
	Robert	Husband	82	Aviation	Caregiver	-
2	James*	Husband	74	Purchaser	AD (2016)	87/100 (ACE-R, 2016)
	Mary	Wife	74	Personal Assistant	Caregiver	-
3	Barbara**	Wife	67	Teacher	PCA	-
	John	Husband	67	Electrician	Caregiver	-
4	William*	Husband	78	Lecturer	AD (2012)	24/30 (MMSE, 2014)
	Carol	Wife	74	Probation officer	Caregiver	-
5	Richard*	Father	83	Tile making	Mixed (2015)	Unknown
	David	Son	52	Catering[#]	Caregiver	-
6	Mark*	Husband	73	Probation officer	AD (2014)	81/100 (ACE-R, 2014)
	Brenda	Wife	68	Nurse	Caregiver	-
7	Steven*	Husband	57	Postman	Mixed/FTD (2017)	Mild (MMSE, 2017)
	Michelle	Wife	53	-	Caregiver	-
8	Linda*	Wife	77	Administrative	FTD (2017)	25/30 (MMSE, 2017)
	Charles	Husband	77	Optometrist	Caregiver	-
9	Greg*	Husband	64	Royal Air Force	Mixed/FTD (2017)	48/100 (ACE-R)
	Denise	Wife	66	Shop assistant	Caregiver	-

AD Alzheimer's Disease; FTD frontotemporal dementia; MMSE Mini Mental State Examination Score; ACE-R The Addenbrooke's Cognitive Examination Revised; PCA Posterior Cortical Atrophy. *Person with dementia participated in an interview; **Person with dementia did not participate in an interview [%]Self- or informant-reported during the interview; [$]Information obtained from Join Dementia Research records; [#]Currently employed

Eight people with dementia and their respective family caregiver completed interviews together in a joint, or dyadic style. Seven of the eight interviews were husband and wife dyads, with one father and son dyad. One family caregiver, John, completed the interview alone, with his wife, Barbara, present in a nearby room. All interviews were completed in the participants' home, located in the West Midlands. Interviews typically lasted for one and a half hours, ranging from 37 minutes to two hours in length. The length of interview was reflective of the dyadic nature, but also the time needed to remain flexible for the person with dementia to talk about their perspective without feeling pressured. The considerations needed when conducting interviews with people with dementia are discussed in Section 6.3.5.

Interviews included two female and six male people with dementia, with a mean age of 73.5 (range 57 to 83). All people with dementia were White British and retired. Half of the people with dementia had AD, three reported mixed dementias (two of which were mixed with AD and frontotemporal dementia (FTD), and one mixed with AD and vascular dementia), and one reported their diagnosis as FTD. Although Barbara did not participate in an interview, her husband reported her diagnosis as Posterior Cortical Atrophy. Steven and Greg were diagnosed with early-onset dementia, being diagnosed before 65 years old. The MMSE and The Addenbrooke's Cognitive Examination Revised (ACE-R) scores provide an insight into the person with dementia's cognitive ability; albeit the tests were often completed many years ago (e.g. Mark's last recorded test was in 2014).

Interviews were conducted with five female and four male family caregivers, with a mean age of 68 years (range 52 to 82). All family caregivers were White British. All family caregivers reported being retired, aside from David who continued to work in catering. Spousal caregivers cohabited with the person with dementia. Both Mark and Brenda, and Steve and Michelle lived with additional dependant family members. David (son) resided next door to his father with dementia, Richard, sharing caregiving responsibility with his Mother (Richard's wife). In each dyad, the family caregiver recognised themselves as (one of) the primary caregiver for the person with dementia. Mark (person with dementia) and Brenda (wife,

family caregiver) completed their interview as a dyad, however Brenda also reflected upon her Mother who also had a diagnosis of dementia. Brenda's mum lived alone (receiving care from her children), and was perceived by Brenda to have more advanced dementia than her husband, Mark. John's wife did not wish to participate in the interview, however she was happy for John to discuss his experiences as her family caregiver.

At the start of the interview, the person with dementia completed the IPT, rating their pain now and in the past four weeks. Following completion by the person with dementia, the family caregiver provided an informant rating of pain for the person with dementia. Pain ratings using the IPT are presented in Table 7.7, with pain conditions experienced by the person with dementia reported throughout the interview also presented.

Table 7.7. Overview of the types of pain, and severity of pain reported by people with dementia (self-report) and their family caregiver (informant report)

Pseudonym	**Current pain conditions***	**Pain now** Self-report Informant report	**Pain 4 weeks** Self-report Informant report
Patricia*	Spinal injury	Moderate	Moderate
Robert		Unable to judge	Unable to judge
James*	Arthritis (neck)	None	None
Mary		None	None
Barbara**	Neuralgia, osteoporosis	-	-
John		Severe	Moderate
William*	Arthritis (knees)	Mild	Mild
Carol		None	Mild
Richard*	Arthritis (back)	Moderate	Moderate
David		None	Mild
Mark*	Tooth pain	None	None
Brenda		None	Mild
Steven*	Back pain	None	Mild
Michelle		None	Mild
Linda*	Arthritis, gout	Mild	Unanswered
Charles		Moderate	Moderate
Greg*	Frozen shoulder, tennis elbow, spondylitis, arthritic hips	Moderate	Moderate
Denise		Moderate	Moderate

*Current pain conditions experienced by the person with dementia as reported at any point throughout the interview

**Person with dementia did not take part in the interview. Pain experienced by the person with dementia is reported by the family caregiver only.

Many of the pain conditions experienced by the person with dementia were musculoskeletal in nature. Most people with dementia and family caregivers perceived the pain experienced by the person with dementia to be mild to moderate pain, with John perceiving his wife's current pain caused by neuralgia as severe.

A number of people with dementia and family caregivers perceived the person with dementia to be experiencing 'no pain', despite painful conditions being noted and discussed throughout the interview. For Steven and Michelle, Carol and William, and Richard and David the rating of 'no pain' was attributed to the pain being exacerbated during activity, which was not the case when sitting to complete the interview. However, the rating of pain may have also been implicated by alternative factors, such as stoicism (see Section 8.4.1.1). Additionally, some family caregivers had difficulty providing an informant report of pain and were therefore classed as 'unable to judge' (see Section 8.4.3).

7.3.2 Healthcare professional interviews

Semi-structured interviews explored healthcare professionals' perspective on pain identification, assessment, and treatment for people with dementia. An overview of the healthcare professional characteristics are outlined in Table 7.8.

Table 7.8. Details of healthcare professionals participating in an interview

Pseudonym	Current profession(s)	Years of experience in current role
Tom	General Practitioner	12 years
Alan	General Practitioner	33 years
Jenny	General Practitioner	30 years
Jessica	General Practitioner	1 year
Muhammad	General Practitioner	3 years
Lisa	General Practitioner	11 years
Ishann	General Practitioner	1 year
Amy	General Practitioner	5 years
Chris	General Practitioner	7 years
Prisha	Consultant - Old Age Psychiatry	10 years
Hayma	Consultant - Old Age Psychiatry	8 years
Aska	Associate specialist - Old Age Psychiatry	11 years
Rina	Consultant - Old Age Psychiatry	3 years
Mel	Associate specialist - Old Age Psychiatry	18 years

All healthcare professionals were recruited from within the West Midlands. Each interview lasted for approximately 45 minutes, with a range from 31 minutes to 59 minutes.

Out of the 14 interviews, nine were General Practitioners (GPs), five males and four females. Face-to-face interviews were completed in the GP's practice, or in the School of Primary, Community and Social Care. Interviews with Tom and Amy were completed by telephone. Some GPs noted having an additional role or professional commitment, with Tom working as

a Consultant Geriatrician in a local hospital, and Lisa working in out-of-hours urgent care alongside being a GP. A snowball sampling technique through the contacts within the School of Primary, Community and Social Care meant that Muhammed, Jessica, Chris, and Ishann had additional research commitments. Aside from additional commitments, Jenny also discussed her specialist interest in end of life care, working closely with her local hospice. The years of experience working as a GP ranged from 1 year to 33 years, with a mean experience of 11.4 years.

Interviews were also conducted with five female old age psychiatrists, three of which were consultants, and two associate specialists. Three interviews were completed face-to-face within the School of Primary, Community and Social Care. Interviews with Rina and Mel were completed by telephone. Mean length of time working as an old age psychiatrist was 10 years (range 3 to 18 years). Before becoming an old age psychiatrist, Mel worked as a GP.

7.4 Summary of participants in the qualitative study

Twenty-three interviews were completed: eight people with dementia, nine family caregivers of people with dementia, nine GPs, and five old age psychiatrists explored their perspective of pain identification, assessment, and treatment for people with dementia.

7.5 Chapter Summary

This chapter provided an overview of the participants included in the quantitative and qualitative investigation. This chapter provides a contextual foundation for the subsequent findings chapters. In line with the mixed methods approach, each of the following findings chapters focus upon a research objective, rather than being separated by the method of enquiry (e.g. a quantitative chapter and a qualitative chapter). Chapter Eight therefore includes quantitative and qualitative findings to investigate pain identification and pain assessment for community-dwelling people with dementia (research objective 1). Chapter Nine also includes quantitative and qualitative findings to investigate pain management for community-dwelling people with dementia (research objective 2). This approach allows

complementary findings to sit sequentially, in preparation for integration in the Discussion Chapter (see Chapter Ten).

8 Chapter Eight: Pain Identification and Assessment

8.1 Introduction

This chapter meets the first research objective: to investigate pain identification and assessment for community-dwelling people with dementia (see Section 4.2) using quantitative and qualitative data. Quantitative data was drawn from analysis of two cohorts used to i) examine and report on incidence, and ii) to examine and report on prevalence, of musculoskeletal consultations for people with dementia (dementia cohort) compared with older adults without dementia (older adult cohort). Qualitative data was drawn from interviews with people with dementia, family caregivers, and healthcare professionals. The quantitative and qualitative findings are presented separately in line with the convergent mixed methods design described in Section 5.4.2.1. The quantitative and qualitative findings are narratively integrated in the discussion chapter to highlight inferences, interpretations, convergent, and divergent findings (Creswell & Plano Clark, 2018).

8.2 Pain identification and pain assessment: Quantitative findings

This section of the chapter examined musculoskeletal consultations for people with dementia (dementia cohort) compared to older adults without dementia (older adult cohort). Musculoskeletal consultations were used in this thesis as a marker for the identification and assessment of pain (as justified in Section 6.2.9.1). This section of the chapter answers the following research questions:

- What are the incidence and prevalence rates of musculoskeletal consultations for people with dementia compared to older adults without dementia?
- What are the annual incidence and prevalence rates of musculoskeletal consultations over time for people with dementia?

8.2.1 Incidence of musculoskeletal consultation

This section explores the incidence of musculoskeletal consultation for the dementia cohort compared with the older adult cohort. To calculate incidence for both cohorts, inclusion criteria stipulated that participants had no evidence of musculoskeletal consultation during

the 12 months before index date (see Section 6.2.8.1). Firstly, person-time incidence rates, and the incidence rate ratios determine the rate of identified incident musculoskeletal consultation occurring in the dementia cohort compared to the older adult cohort. Following this, the five-year cumulative incidence of musculoskeletal consultation for the dementia cohort and older adult cohort is presented, using the Kaplan-Meier approach and Cox Proportional Hazard models.

8.2.1.1 Incidence Rate and Rate Ratio

Person-time incidence rates were calculated to determine the number of incident musculoskeletal consultations for the dementia cohort and older adult cohort. The number of incident musculoskeletal consultations per time period was divided by the amount of person-time contributed during that time period (see Section 6.2.13.3.1). Following this, the incidence rate ratio (IRR) was calculated to examine the rate of musculoskeletal consultation for the dementia cohort compared to the older adult cohort during the specified time period (see Section 6.2.13.3.1.1). Calculations were completed for the five-year period from index date, and stratified into annual periods from index date to five years after index date. Annual time periods allowed investigation into the trends of incident musculoskeletal consulting from dementia diagnosis (index date) for the dementia cohort, and how this compares to the older adult cohort (see Table 8.1).

Table 8.1. Person-time incidence rate and incidence rate ratio of musculoskeletal consultation for the dementia cohort and older adult cohort stratified into annual time blocks

Time period (years)	**Incidence Rate** (95% CI) (per 100 person years)		**IRR** (95% CI)
	Dementia cohort	**Older adult cohort**	
0 to 5	16.28 (15.85 to 16.71)	22.22 (21.78 to 22.67)	.73 (.71 to .75)
0 to 1	19.53 (18.85 to 20.24)	26.98 (26.21 to 27.77)	.72 (.70 to .75)
1 to 2	15.37 (14.56 to 16.21)	21.72 (20.86 to 22.61)	.71 (.67 to .75)
2 to 3	12.73 (11.75 to 13.77)	18.17 (17.21 to 19.18)	.70 (.64 to .77)
3 to 4	10.69 (9.52 to 11.98)	17.64 (16.49 to 18.85)	.61 (.54 to .69)
4 to 5	9.35 (7.87 to 11.00)	14.91 (13.62 to 16.29)	.63 (.52 to .75)

IRR Incidence Rate Ratio; CI Confidence Interval

During the five-year period from index date, the incidence rate of musculoskeletal consultation was 16.3 per 100 person-years for the dementia cohort, compared to 22.2 per 100 person-years for the older adult cohort. The dementia cohort had 0.73 (95% CI 0.71 to 0.75) times the rate of incident musculoskeletal consultation compared to the older adult cohort.

The rate of incident musculoskeletal consultation in each annual period was consistently lower for the dementia cohort than older adult cohort per 100 person-years (see Figure 8.1). This was reflected in the incidence rate ratio, in which the dementia cohort had 0.72 (95% CI 0.70 to 0.75) times the rate of incident musculoskeletal consultation compared to the older adult cohort in the first annual time period. In the final annual period (four to five years after index date), the dementia cohort had 0.63 (95% CI 0.52 to 0.75) times the rate of incident musculoskeletal consultation compared to the older adult cohort.

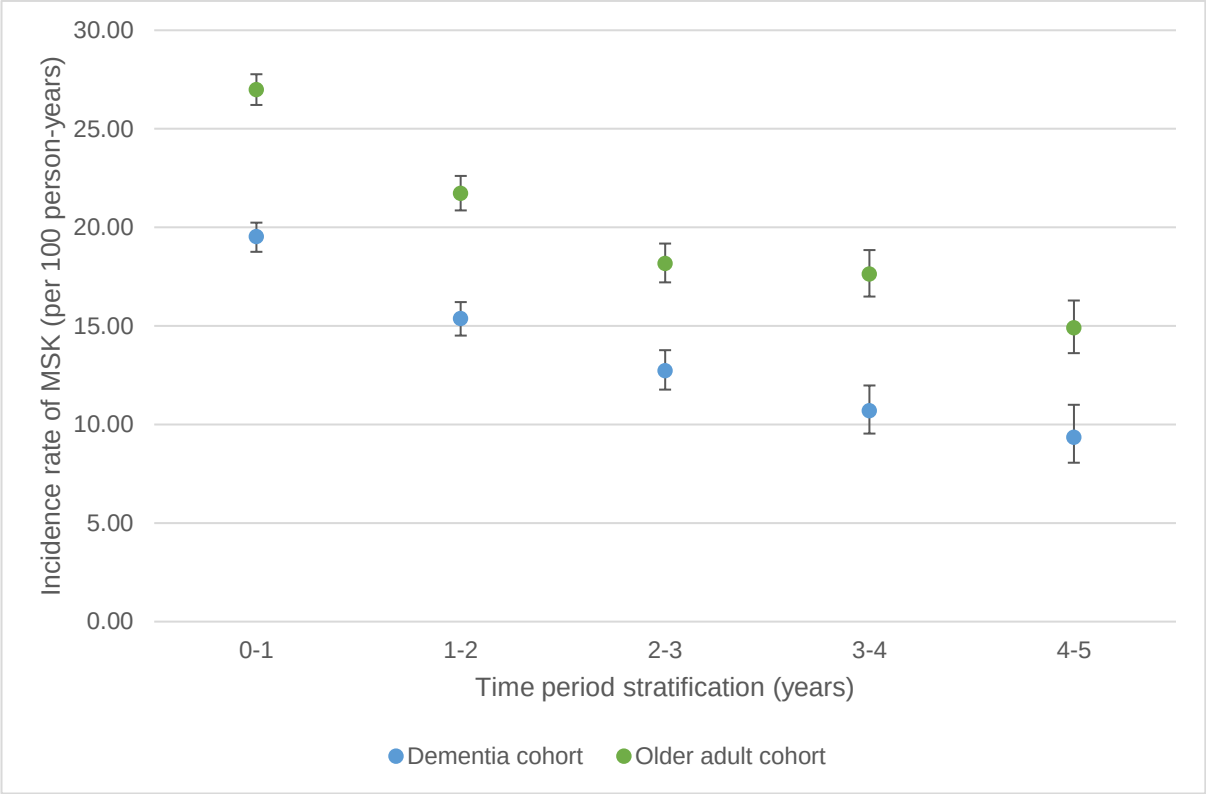


Figure 8.1. Person-time incidence rates of musculoskeletal consultation for the dementia cohort and older adult cohort stratified by annual periods from index date to five years after index date

8.2.1.2 Attributable rate

Attributable rate determines the amount of incident musculoskeletal consultation attributable to the exposure, in this case having dementia (see Section 6.2.13.3.1.2). In addition, the 'preventable fraction' among the older adult cohort was calculated to give a sense of the effect difference between cohorts overall and year by year (see Table 8.2).

Table 8.2. Attributable rate (AR_{exp}) and percentage preventable fraction ($\%PF_u$)

Time (years)	**Incidence rates** (95% CI)		**Attributable rate** (AR)	
	Dementia cohort	**Older adult cohort**	**AR_{exp}**	**$\%PF_u$**
0 to 5	16.28 (15.85 to 16.71)	22.22 (21.78 to 22.67)	-5.94	26.73%
0 to 1	19.53 (18.85 to 20.24)	26.98 (26.21 to 27.77)	-7.45	27.61%
1 to 2	15.37 (14.56 to 16.21)	21.72 (20.86 to 22.61)	-6.35	29.24%
2 to 3	12.73 (11.75 to 13.77)	18.17 (17.21 to 19.18)	-5.44	29.94%
3 to 4	10.69 (9.52 to 11.98)	17.64 (16.49 to 18.85)	-6.95	39.40%
4 to 5	9.35 (7.87 to 11.00)	14.91 (13.62 to 16.29)	-5.56	37.29%

Attributable rate (AR), Attributable rate (AR_{exp}), percentage attributable fraction ($\%PF_u$), CI Confidence Interval

During the five-year period from index date, 26.7% of the incident musculoskeletal consultations in the older adult cohort would have been unidentified, unassessed, or not coded (‘prevented’) if they had dementia. Additionally, the percentage of incident musculoskeletal consultations in the older adult cohort that would be unidentified, unassessed, or not coded if they had dementia increased from 27.6% in the first year of follow up to 37.3% in the final year of follow up. If assuming a causal association between the exposure (dementia) and identified incident musculoskeletal consultation (and therefore no evidence of bias or confounding), the reduction in incident musculoskeletal consultation can be ‘attributed’ to dementia.

8.2.1.3 Kaplan-Meier approach (five-year period)

When investigating cumulative incidence over the five-year period from index date, 15,015 incident musculoskeletal consultations were identified. During the five-year period, 74.3% of the dementia cohort and 54.6% of the older adult cohort were censored. The dementia cohort had a greater mean time until the occurrence of incident musculoskeletal consultation than the older adult cohort (1262.9 days vs. 1093.7, respectively). Figure 8.2 shows the Kaplan-Meier curves for the dementia cohort and older adult cohort from index date (day 0) to 5 years after index date (day 1825 of follow up).

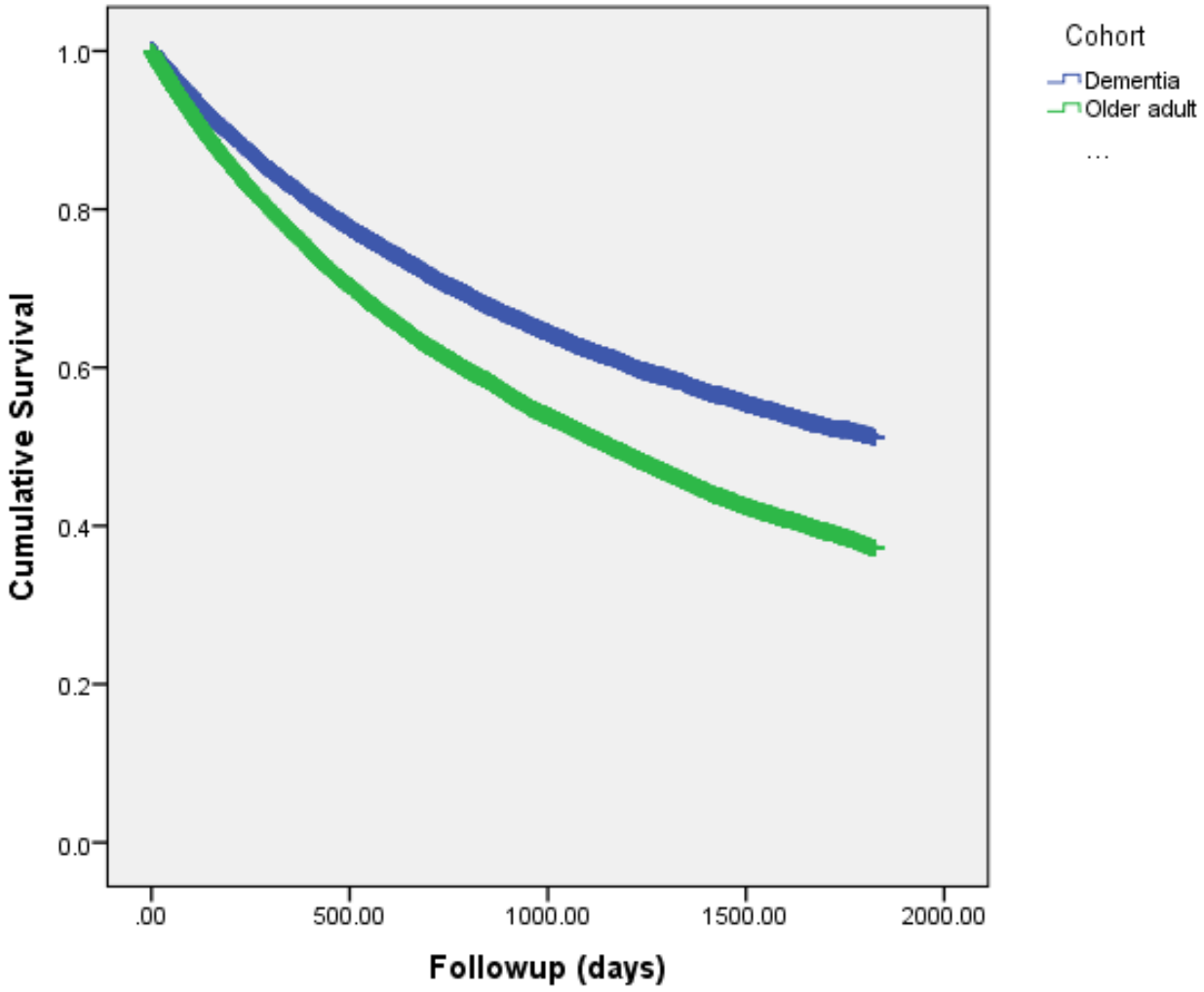


Figure 8.2. Kaplan-Meier curve to show cumulative incidence of musculoskeletal consultation from index date to five years (1825 days) after index date for the dementia cohort and older adult cohort

The logrank test identified a significant difference between the dementia cohort and older adult cohorts' time to musculoskeletal consultation during the five-year period (χ^2=430.7, *p*=<.001). The Kaplan-Meier curve demonstrates that the dementia cohort had a higher probability of not being coded for a musculoskeletal consultation than the older adult cohort during the five-year period from index date (see Figure 8.2).

8.2.1.4 Cox Proportional Hazards Regression Model

To build upon the Kaplan-Meier approach, The Cox Proportional Hazards Regression model examined the association between the cohort status (dementia cohort and older adult cohort) and identified incident musculoskeletal consultation (see Section 6.2.13.3.2.2).

Assumptions of Cox Proportional Hazards Regression models are outlined in detail in Table 6.8. Two important assumptions were tested post-hoc, including i) the assumption of proportional hazards, and ii) limited change in risk over time (i.e. that those at the start of data collection have the same risk of incident musculoskeletal consultation as those towards the end of data collection). To assess the assumption of proportional hazards, Schoenfeld residuals were plotted vs. time for continuous covariates, and log-log transformations of the Kaplan-Meier survival curves were investigated for categorical covariates. These tests indicated that each covariate fulfilled the assumption of proportional hazards. The second assumption was met as there was no significant difference in the risk of incident musculoskeletal consultation between patients with an index date between 1997 to 2009 and patients with an index date between 2009 to 2017 (χ^2=.90, *p*=.34, HR 0.98, 95% CI 0.95 to 1.02). Univariate and multivariable Cox Proportional Hazards Regression models, stratified by matched-pairs are provided in Table 8.3.

Table 8.3. Univariate and multivariable Cox Proportional Hazard Regression models to examine the association between cohort status and incident musculoskeletal consultation

Univariate Cox Proportional Hazards Model				
Covariate	**B (SE)**	**95% CI for Hazard Ratio**		
		Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)	-.33 (.02)**	.69	.72	.75
Model $\chi^2(1) = 248.20$, p=<.001.				
Multivariable Cox Proportional Hazards Model				
Covariate	**B (SE)**	**95% CI for Adjusted Hazard Ratio**		
		Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)	-.34 (.03)**	.68	.71	.75
CVD (yes=1)	-.08 (.07)	.81	.93	1.05
Depression (yes=1)	-.01 (.07)	.87	.99	1.14
Diabetes (yes=1)	.20 (.05)**	1.12	1.22	1.34
Morbidity (BNF)[£]	03 (.00)**	1.03	1.03	1.04
Follow up (days)[£]	.00 (.00)*	1.00	1.00	1.01
Consultation frequency[£]	.00 (.00)**	1.00	1.00	1.00

Model $\chi^2(7) = 571.64$, p=<.001. *p<.05, **p<.001

[£]Continuous covariates; Categorical reference categories = 0

SE Standard Error; BNF British National Formulary; CI Confidence Interval; CVD Cardiovascular related-conditions

The univariate Cox Proportional Hazards model found that during the five-year period from index date, incident musculoskeletal consultation was significantly lower for the dementia cohort than the older adult cohort (b = -.33, Wald $\chi^2(1) = 245.95$, p=<.001). The dementia cohort had a lower rate of incident musculoskeletal consultation than the older adult cohort (HR 0.72, 95% CI 0.69 to 0.75).

The multivariable Cox Proportional Hazards model used to adjust for potential confounders also found that during the five-year period from index date, incident musculoskeletal consultation was significantly lower for the dementia cohort than the older adult cohort (b = -.34, Wald $\chi^2(1) = 184.02$, p=<.001). The dementia cohort had a lower rate of identified incident musculoskeletal consultation than the older adult cohort during the five-year period (adjusted HR 0.71, 95% CI 0.68 to 0.75). The comparable findings in the univariate and multivariable models indicate minimal confounding. Similar findings were also evident in the

models that did not stratify by matched-pairs, but rather included 'matched' variables as covariates in the analysis (see Appendix 13a).

8.2.1.4.1 Sensitivity analysis

8.2.1.4.1.1 Community sensitivity

Sensitivity analysis was planned with a restricted sample of people with dementia and older adults without dementia with a greater likelihood of living in the community (see Section 6.2.13.5.1). Person-time incidence rates were therefore calculated with a reduced sample of the dementia cohort (*n*=4850) and older adult cohort (*n*=3477) with no evidence of a formal care consultation location, and a family number of ≤2 as a sensitivity analysis (see Table 8.4).

Table 8.4. Community sensitivity analysis: Person-time incidence rate and incidence rate ratio of musculoskeletal consultation for the dementia cohort and older adult cohort (per 100 person-years)

Time (years)	**Incidence Rate** (95% CI) (per 100 person years)		**Rate Ratio** (95% CI)
	Dementia cohort	**Older adult cohort**	
0 to 5	17.59 (16.64 to 18.59)	21.92 (20.83 to 23.04)	.80 (.76 to .85)
0 to 1	20.87 (19.39 to 22.44)	25.79 (23.93 to 27.76)	.81 (.75 to .88)
1 to 2	16.09 (14.33 to 18.01)	23.31 (21.12 to 25.67)	.69 (.61 to .78)
2 to 3	14.16 (11.92 to 16.70)	17.03 (14.76 to 19.57)	.83 (.70 to .99)
3 to 4	11.66 (8.94 to 14.95)	17.67 (14.85 to 20.86)	.66 (.53 to .89)
4 to 5	10.07 (6.69 to 14.56)	13.85 (10.81 to 17.47)	.73 (.49 to 1.07)

CI Confidence Interval

The sensitivity analysis found comparable person-time incidence rates as the main analysis (see Table 8.1). Person-time incidence rates were consistently lower for the dementia cohort than the older adult cohort irrespective of time period. The sensitivity analysis found that the dementia cohort had 0.80 (95% CI 0.76 to 0.85) times the rate of incident musculoskeletal consultation than the older adult cohort during the five-year period from index date. This

incidence rate ratio was smaller (attenuated to 1) than that found in the main analysis. During the final year of follow up (four to five years after index date) the dementia cohort had 0.73 (95% CI 0.49 to 1.07) times the rate of identified incident musculoskeletal consultation compared to the older adult cohort. Unlike the main analysis, this finding was not significant as the upper confidence interval crossed 1. Importantly, the cohort sample size and the amount of person-time contributed by the dementia cohort and older adult cohort reduced for each annual period after index date. For example, only 383 (out of *n*=4850) of the dementia cohort contributed person-time to the final year of follow up, potentially implicating the accuracy of this estimate.

Sensitivity analysis using the Kaplan-Meier's approach found that 73.9% of the dementia cohort and 55.8% of the older adult cohort were censored during follow up, with censoring reflecting the main analysis. The dementia cohort had a greater mean time until the occurrence of identified incident musculoskeletal consultation than the older adult cohort (1231.7 days vs. 1100.7, respectively). The logrank test found a significant difference between the cumulative incidence of musculoskeletal consultation for the dementia cohort compared to the older adult cohort, albeit with a smaller effect than found in the main analysis (χ^2=50.58, *p*=<.001). The findings of the sensitivity analysis were comparable to the main analysis (see Section 8.2.1.3).

Sensitivity analysis also investigated the incidence of musculoskeletal consultation using univariate and multivariable Cox Proportional Hazards models stratified by matched-pairs (see Table 8.5).

Table 8.5. Univariate and multivariable Cox Regression: Community sensitivity analysis

Univariate Cox Proportional Hazards Model				
Covariate	**B (SE)**	**95% CI for Hazard Ratio**		
		Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)	-.48 (.08)**	.52	.62	.75
Model $X^2(1) = 25.94$, p=<.001.				

Multivariable Cox Proportional Hazards Model				
Covariate	**B (SE)**	**95% CI for Adjusted Hazard Ratio**		
		Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)	-.48 (.112)**	0.50	0.62	0.77
CVD (yes=1)	-.04 (.31)	0.53	0.97	1.76
Depression (yes=1)	.33 (.30)	0.78	1.40	2.51
Diabetes (yes=1)	.42 (.21)*	1.01	1.52	2.29
Morbidity (BNF)[£]	.06 (.01)**	1.03	1.06	1.09
Consultation frequency[£]	-.00 (.00)	0.99	1.00	1.01
Follow up (days)[£]	.00 (.00)	1.00	1.00	1.000

Model $X^2(7) = 48.41$, p=<.001. *p<.05, **p<.001

[£]Continuous covariates; Categorical reference category = 0

SE Standard Error; BNF British National Formulary; CI Confidence Interval; CVD Cardiovascular related-conditions

Sensitivity analysis found an increased rate (away from 1) of identified incident musculoskeletal consultation for the dementia cohort compared to the older adult cohort using the univariate model (sensitivity analysis: HR 0.62, 95% CI 0.52 to 0.75; main analysis: HR 0.72, 95% CI 0.69 to 0.75). Similar findings were also evident for the multivariable analysis (sensitivity analysis: adjusted HR 0.62, 95% CI 0.50 to 0.77; main analysis: adjusted HR 0.71, 95% CI 0.68 to 0.75). Therefore, the sensitivity and main analysis agree that the dementia cohort continued to have a lower rate of identified incident musculoskeletal consultation than the older adult cohort.

8.2.2 Prevalence of musculoskeletal consultation

8.2.2.1 Period prevalence of musculoskeletal consultation

Period prevalence examines the frequency of people consulting for musculoskeletal consultation during a given period of time for the dementia cohort and older adult cohort (see Section 6.2.13.4). The number of patients in the dementia cohort and older adult cohort consulting for musculoskeletal conditions during the five-year period from index date was examined. Period prevalence calculations were also stratified into annual time blocks, starting from index date to five years after index date. For each annual period, the number of people consulting for musculoskeletal conditions (with a complete follow up for that year) was divided by the number of people with complete follow up for that year (see Section 6.2.13.4). An overview of the demographic characteristics of each annual cohort are provided in Table 7.5, showing that the demographic characteristics of the dementia cohort and the older adult cohort remained relatively stable throughout each follow up. The stratified annual prevalence estimates allowed investigation into trends in musculoskeletal consulting over time for the dementia cohort compared to the older adult cohort (see Table 8.6).

Table 8.6. Period prevalence of musculoskeletal consultations for the dementia cohort and the older adult cohort stratified by years from index date

	Dementia cohort		**Older adult cohort**		**Prevalence Ratio (PR)**
Time (years)	**Total *n***	**Prevalence %** (95% CI)	**Total n**	**Prevalence %** (95% CI)	**PR** (95% CI)
0 to 5	3,893	58.54 (56.99 to 60.08)	12,276	70.76 (69.95 to 71.56)	0.83 (0.80 to 0.85)
0 to 1	24,247	24.46 (23.92 to 25.00)	30,316	30.79 (30.27 to 31.31)	0.79 (0.77 to 0.82)
1 to 2	16,110	22.26 (21.62 to 22.90)	24,732	30.55 (29.98 to 31.12)	0.73 (0.70 to 0.75)
2 to 3	10,314	19.94 (19.18 to 20.73)	19,849	30.56 (29.92 to 31.21)	0.65 (0.62 to 0.68)
3 to 4	6,472	19.27 (18.33 to 20.25)	15,663	31.71 (30.99 to 32.44)	0.61 (0.58 to 0.64)
4 to 5	3,893	19.52 (18.29 to 20.80)	12,276	31.04 (30.23 to 31.87)	0.63 (0.59 to 0.67)

PR Prevalence Ratio; CI Confidence Interval
0 is index date; dementia diagnosis or equivalent for the older adult cohort

During the five-year period following index date, the dementia cohort had a 12.2% lower prevalence of musculoskeletal consultation than the older adult cohort (58.5% vs. 70.8%, respectively), with the dementia cohort having a 0.83 times lower prevalence ratio than the older adult cohort. The prevalence of musculoskeletal consultation for the dementia cohort gradually decreased in each annual time period from index date to five years after index date (24.5% to 19.5%, respectively). In contrast, the prevalence of musculoskeletal consultation for older adults remained relatively stable throughout follow up, with a slight increase in consultation prevalence during the latter time periods (see Table 8.6). The growing discrepancy in the prevalence of musculoskeletal consultation between the dementia cohort and older adult cohort from index date throughout follow up can be clearly seen in Figure 8.3.

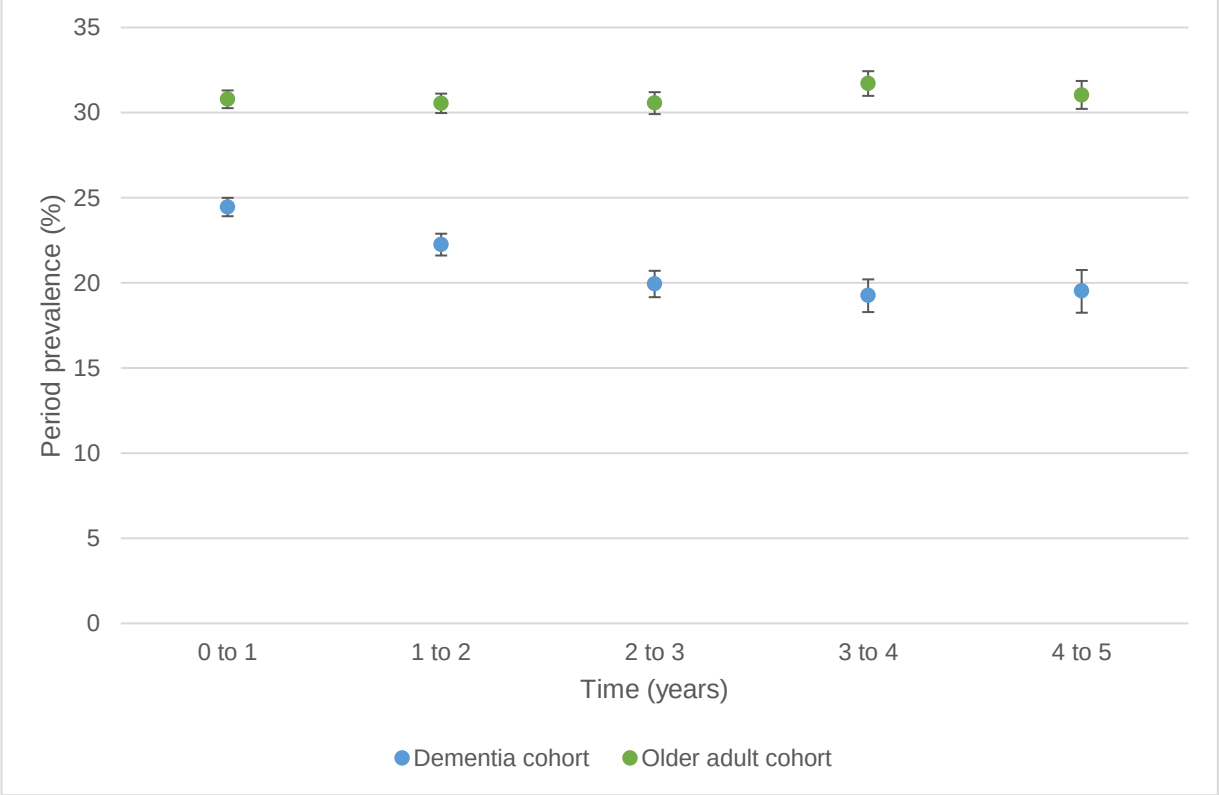


Figure 8.3. Period prevalence of musculoskeletal consultation for the dementia cohort and older adult cohort in each annual period

8.2.2.1.1 Sensitivity analysis

8.2.2.1.1.1 Community sensitivity

Sensitivity analysis examined the period prevalence estimates for the dementia cohort (*n*=8875) and older adult cohort (*n*=8349) with a family number frequency of ≤2, and no evidence of formal care consultation location (see Table 8.7).

Table 8.7. Period prevalence of musculoskeletal consultations for dementia cohort and older adult cohort stratified by years from index date: community sensitivity

	Dementia cohort		**Older adult cohort**	
Time (years)	**Total *n***	**Prevalence %** (95% CI)	**Total *n***	**Prevalence** % (95% CI)
0 to 5	808	60.40 (56.98 to 63.71)	2494	70.09 (68.26 to 71.85)
0 to 1	5700	25.47 (24.36 to 26.62)	6788	29.71 (28.64 to 30.81)
1 to 2	3648	22.67 (21.34 to 24.06)	5377	30.13 (28.92 to 31.37)
2 to 3	2243	20.86 (19.23 to 22.60)	4203	29.84 (28.47 to 31.24)
3 to 4	1370	20.00 (17.97 to 22.20)	3268	31.40 (29.83 to 33.01)
4 to 5	808	20.30 (17.67 to 23.21)	2494	31.11 (29.31 to 32.98)

CI Confidence Interval

Similar to the main analysis, the sensitivity analysis found that the dementia cohort had a lower prevalence of musculoskeletal consultation than the older adult cohort, irrespective of the time period. Additionally, the sensitivity analysis continued to demonstrate the lowering prevalence of musculoskeletal consultation during follow up for the dementia cohort, whilst the prevalence remained stable for the older adult cohort.

8.2.2.1.1.2 Healthy cohort effects

A sensitivity analysis was planned to account for potential 'healthy cohort' bias. The previous period prevalence investigation only included members of each cohort if they remained in the study throughout the five-year period from index date (see Section 6.2.13.4). Sensitivity analysis therefore examined the period prevalence of musculoskeletal consultation for the dementia cohort and older adult cohort that remained in the study at the mid-point of the five-

year period. This analysis therefore included people with and without dementia that remained in the study 912 days after their index date (as outlined in Section 6.2.13.5.2; see Table 8.8).

Table 8.8. Period prevalence of musculoskeletal consultations for the dementia cohort and older adult cohort stratified by years from index date: Healthy cohort effects sensitivity analysis

	Dementia cohort		**Older adult cohort**	
Time (years)	**Total n**	**Prevalence** % (95% CI)	**Total n**	**Prevalence** % (95% CI)
0 to 5	12967	51.92 (51.06 to 52.78)	22237	66.32 (65.69 to 66.94)

CI Confidence Interval

This sensitivity analysis indicated a lower prevalence of musculoskeletal consultation during the five-year period from index date for the dementia cohort (sensitivity analysis: 51.9% vs. main analysis: 58.5%) and the older adult cohort (sensitivity analysis: 66.3% vs. main analysis: 70.8%) than in the main analysis. This finding suggests that the sensitivity analysis using the mid-point cohort identified a lower period prevalence of musculoskeletal consultation for both cohorts. In line with the main analysis, the sensitivity analysis continued to find that the dementia cohort had a lower prevalence of musculoskeletal consultation than the older adult cohort (see Section 8.2.2).

8.2.2.2 Conditional Logistic Regression

The crude period prevalence investigation identified that the dementia cohort had a lower period prevalence than the older adult cohort (see Section 8.2.2.1). To build upon these findings, the association between dementia and musculoskeletal consultation was examined using univariate and multivariable conditional logistic regression models (see Section 6.2.13.4.2). Multivariable methods were used to discern and control for confounding variables (Szklo & Nieto, 2004).

The assumptions of conditional logistic regression models are provided in Table 6.9. Many of the assumptions were confirmed prior to modelling. The assumption of little or no multicollinearity was investigated and met for each multivariable model. When investigating

linearity of independent variables and log odds, however, various continuous covariates violated the assumption (with the exception of consultation frequency). Log and square root data transformations were performed with all continuous variables violating the assumption, however neither transformation was successful. To overcome this violation, morbidity (BNF) and follow up were categorised into quintiles with homogeneity within each strata implicitly assumed (see Table 8.9).

Table 8.9. Categorisation of continuous variables for the multivariable conditional logistic regression analyses

Covariate	Nº categories	Categorisation
Morbidity (BNF)	5	0-20%, 20%-40%, 40%-60%, 60-80%, 80-100%
Follow up	5	0-20%, 20%-40%, 40%-60%, 60-80%, 80-100%

BNF British National Formulary

Consultation frequency was entered into the model as a continuous covariate

Univariate and multivariable conditional logistic regression models were completed for the five-year period from index date, and each annual period from index date to five years after index date. The final univariate models included cohort status (dementia cohort vs. older adult cohort) as the predictor, with evidence of musculoskeletal consultation (yes/no) as the outcome. Multivariable models also included cohort status (dementia cohort vs. older adult cohort) as the predictor, and evidence of musculoskeletal consultation (yes/no) as the outcome. Additional covariates were also included in the multivariable models: evidence of cardiovascular-related conditions (CVD), evidence of diabetes, evidence of depression, morbidity count (BNF), follow up (days), and consultation frequency (see Table 8.9). Matched variables were accounted for in the analysis inherent with a conditional logistic regression model (see Section 6.2.13.4.2). Details of the univariate and multivariable conditional logistic regression models are provided in Table 8.10.

Table 8.10. Conditional logistic regression reporting odds ratio (OR) and adjusted OR for the dementia cohort compared to the older adult cohort: Musculoskeletal consultation

Time (years)	**OR** (95% CI)	**Adjusted OR** (95% CI)
0 to 5	.84 (.79 to .90)	.83 (.78 to .89)
0 to 1	.80 (.77 to .83)	.82 (.78 to .85)
1 to 2	.73 (.70 to .77)	.73 (.70 to .77)
2 to 3	.65 (.61 to .69)	.66 (.62 to .71)
3 to 4	.60 (.56 to .65)	.62 (.56 to .67)
4 to 5	.63 (.57 to .70)	.61 (.54 to .68)

OR Odds Ratio, CI Confidence Interval

Univariate and multivariable conditional logistic regression models indicate that the dementia cohort had a lower odds of musculoskeletal consultation than the older adult cohort, irrespective of time period. Negligible differences between the OR and adjusted OR indicated minimal confounding (see Table 8.10).

Multivariable conditional logistic regression models found that during the five-year period from index date, the dementia cohort had a 0.83 lower odds of musculoskeletal consultation than the older adult cohort (adjusted OR 0.83, 95% CI 0.78 to 0.89).

Stratification into annual time periods highlighted the trends of musculoskeletal consultation over time; that as the amount of time from index date increased, the lower the odds of musculoskeletal consultation for the dementia cohort (compared to the older adult cohort). To exemplify, during the first year of follow up (index date to one year after index date), the dementia cohort had a 0.82 lower odds of musculoskeletal consultation than the older adult cohort (adjusted OR 0.82, 95% CI 0.78 to 0.85). However, during the final year of follow up (four years to five years after index date), the dementia cohort had a 0.61 lower odds of musculoskeletal consultation than the older adult cohort (adjusted OR 0.61, 95% CI 0.54 to 0.68).

8.2.2.2.1 Sensitivity analysis

Univariate and multivariable models examined the association between cohort status (dementia cohort vs. older adult cohort) and musculoskeletal consultation using a variety of sensitivity analyses (see Section 6.2.13.5), including a community sensitivity, healthy cohort sensitivity, and unconditional (rather than conditional) logistic regression sensitivity analyses (see Appendix 13b). In line with the sensitivity analyses examined previously (see Section 8.2.2.1.1), findings of these sensitivity analysis reflected the findings of the main analysis.

8.3 Summary of the quantitative findings

- The incidence rate of musculoskeletal consultations was lower for the dementia cohort than the older adult cohort during the five-year period from index date, and consistently shown for each annual period from index date.
- During the five-year follow up period, a high percentage (26.7%) of incident musculoskeletal consultations for the older adult cohort would be unidentified, unassessed, or not coded if they had dementia. This percentage steadily increased from the first year of follow up (27.6%) to the final year of follow up (37.3%).
- When controlling for potential confounders, the dementia cohort had a significantly lower rate of identified incident musculoskeletal consultation than the older adult cohort (adjusted HR 0.71, 95% CI 0.68 to 0.75). All sensitivity analyses performed confirmed these findings.
- The period prevalence of musculoskeletal consultation was lower for the dementia cohort than the older adult cohort during the five-year period from index date (58.5% vs. 70.8, respectively).
- The annual period prevalence of musculoskeletal consultation lowered from index date for the dementia cohort (from 24.5% to 19.5% over a five-year period from index date), whilst remaining relatively stable for the older adult cohort (from 30.8% to 31.0% over a five-year period from index date).

- The dementia cohort had a consistently lower odds of musculoskeletal consultation than the older adult cohort, irrespective of the time period, even following multivariable adjustment. All sensitivity analyses bolstered these findings.

8.4 The identification and assessment of pain: Qualitative findings

To complement the quantitative findings presented above, qualitative data explored pain identification and assessment strategies for people with dementia, to answer the first research objective, as outlined at the start of this chapter (see Section 8.1). This section of the chapter answered the following qualitative research questions:

- How do family caregivers and healthcare professionals identify and assess pain for community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain identification and assessment strategies for community-dwelling people with dementia?

To answer these questions, the perspectives of people with dementia (*n*=8), family caregivers (*n*=9), GPs (*n*=9), and old age psychiatrists (*n*=5) were integrated, and three key themes were identified:

- Gathering information to identify pain
    - Disentangling the self-report of pain
    - Observing changes
- The importance of familiarity
- The use of pain assessment tools

Although the person with dementia's perspective is included throughout the following themes, due to the nature of pain identification and assessment, the views, perspectives, and experiences of the family caregiver and healthcare professional feature more heavily.

8.4.1 Gathering information to identify pain

To identify and assess the experience of the person with dementia, healthcare professionals gathered information and used their intuition in an attempt to build a comprehensive picture:

> *we shouldn't use the word gut feeling, because it's not a gut feeling, it's using all of the subtle signs*
>
> Chris, GP

> *This is where in dementia we really need to be like detectives… It's gathering as much information as possible*
>
> Amy, GP

> *So... it's about picking up the clues, and putting pieces together really...*
>
> Hayma, psychiatrist

Healthcare professionals often gathered information from various sources and investigations to exclude explanations for the presentation, as a 'process of elimination':

> *you just rule out things, you- you- it's a diagnosis by exclusion, so it's not a UTI, you do a blood test to make sure there's no inflammatory processes going on, you do a blood test to make sure there's no increase in development, poor sampling, that the liver function test, that their amylase is alright, and- and- and again you resort to objective veterinary techniques, because there's nowhere else you can go.*
>
> Alan, GP

> *so my experiences of seeing people with dementia are usually that, I'm eliminating other things, like... um.... like infections, urine retention, or constipation*
>
> Jessica, GP

Each piece of information gathered by the healthcare professional guided or 'narrowed' their understanding of the presentation:

one little sign can send you down a different pathway... It's the same with any patient, but particularly, with patients with dementia...

Lisa, GP

if I don't find information from the carers, and from the patient, then we do look into their records if you like, if- if- if I'm in doubt... I think it all depends on my findings from the first exercise, and then I would decide the second step, depending on my first.

Prisha, psychiatrist

The process of gathering information to identify and assess pain for people with dementia was, however, perceived as a complex task associated with uncertainty for many healthcare professionals:

I think it's- it's difficult, because it's trying to untangle a ball of wool.

Alan, GP

Ooh, sometimes it's just the facial expressions, or the sounds they produce, you can see that they're in pain, that they're not comfortable, they are restless, turning from one side to another... we just make guesses.

Rani, psychiatrist

Not all felt that this was the case, Jenny (GP) reported that she felt confident that the information gathered as part of a multidimensional assessment provided an accurate picture of the pain experienced by people with dementia:

You look at their records and see if they've suffered with things in the past (…) then you've got the history, now you might not be able to get that from the patient, but you might be able to get that from the carer (…) and then there's the basic assessment, so they- they- are they sweaty hot and clutching something? are they sort of, not peeing? or are they peeing too much? (…) and then, sort of, y'know physically looking at the patient, by the time you get to the examination, you've got an awful lot of

> *information that actually is probably going to be channelling you, narrowing down your decision making. So by the time you've done all of that you should have a pretty accurate assessment and then you have to make a decision. Y'know... and... common sense, and experience play into that as well...*
>
> Jenny, GP

Jenny described extensive experience working as a GP, with part of her post being in a local hospice. The broad exploration of pain identification and assessment described by Jenny, by virtue of her experience and knowledge of this area, aided her confidence when identifying and assessing pain for people with dementia (*'I'm very confident actually, but that's partly because of my palliative care experience*' Jenny, GP).

The following subthemes explore the strategies used by family caregivers and healthcare professionals to gather information about pain; including self-report and observation of changes in presentation (behavioural, psychological, and physical). Each of these strategies were perceived to have their own unique challenges which are highlighted in the following subthemes.

8.4.1.1 Disentangling the self-report of pain

This subtheme captures the importance of self-report to gather information, yet sometimes difficulty of disentangling and interpreting the self-reported pain provided by the person with dementia. Factors that impeded the interpretation of self-reported pain, as included in this subtheme were communication difficulties, the 'reliability' of the self-report, and stoical attitudes towards pain. Each of these factors made it difficult for family caregivers and GPs to determine if the self-report reflected the pain experienced by the person with dementia.

Family caregivers acknowledged the importance of self-reported pain to gather information, and to understand the pain experienced by the person with dementia:

> *I think because you're verbally- you're still very verbally articulate to actually explain that you've actually got a problem, I think that's- from Mark's view, but I think- and*

even my mum to a certain degree has articulation, so that she can explain (…). So articulation is important, even if it's not quite right, it's good that she can still do that, really.

Brenda, wife, daughter, caregiver

Communication was an integral element of pain identification and assessment for family caregivers, even when the self-report of pain was perceived as not being *'quite right*'. However, throughout the progression of dementia, self-reported pain became more challenging:

I would start by taking pain out of the question... How is our communication? Urm... Not good... Urm, because of Linda's cognitive ability it's difficult to have a conversation... then if you put into that equation her memory difficulty, having forgotten what she said in the previous sentence then... then conversation is, urm... very difficult

Charles, husband, caregiver

GPs also reflected upon the importance, yet sometimes challenge of self-report as a method of gathering information about the person with dementia's pain experience:

I would say that most people with mild to moderate dementia, you just treat them in the same way (…) but it's- it's more the severe end that I'm talking about here, where it's difficult having a conversation with someone, and sort of answering those [self-report and history] questions can sometimes be a tricky area...

Chris, GP

Um, I suppose... you- you can't rely on so much verbally on how they can- well, I try and see how much I can get verbally from them and I ask the relatives how much they're able to communicate as well, but sometimes it can fluctuate over time, so they may be able to express more at a different time in the day, how they were feeling

Jessica, GP

The ability to provide a self-report was perceived to diminish in line with the progression of dementia. Additionally, self-report becomes increasingly challenging due to fluctuations in cognitive ability throughout the day.

Despite the potential difficulty for people with dementia to self-report their pain (depending upon the severity of cognitive impairment), when a person with dementia provided a self-report of their pain, most family caregivers and healthcare professionals did not doubt or question their self-reported experience:

> *You can tell me when you're uncomfortable like you did... when you had your bladder cancer (...) I can understand that, and I believe that was real and that was right.*

Brenda, wife, caregiver

> *It's a basic- it's a basic primary modality, pain, so if people are- if people are able to say, then you can usually get an inkling, 'I've got a painful ankle' or 'I've hurt my wrist' or something, yea you can. I- I- I wouldn't ignore it. If somebody came in and said 'I've got a painful wrist', what you would do is exclude any pathology there, and if you didn't then you'd be a fool, because they're probably right.*

Alan, GP

> *If somebody uses the word pain, I think it's a strong word, I think it's one that you learn early in our lives, and I suspect it's one we lose late. So if someone responds to that word, and seems to react to it, then I would take that quite seriously... if somebody says they're in pain, you've got to believe it.*

Lisa, GP

Most family caregivers and GPs trusted that the self-report reflected the pain experienced by the person with dementia. The explicit use or response (verbal or non-verbal) to the word 'pain' was viewed as a strong indicator that required further investigation by the GP.

However, contrary to this, some family caregivers seemed to question to what extent the self-report reflected the pain experienced by the person with dementia:

> *Well sometimes you feel it [discomfort] in your back, don't you? But it only seems to be a problem when I want you to go and do something…*
>
> David, son, caregiver

> *What do I look for? I look for consistency. If it's consistent then I um... I accept that, that's the case. If it's- if it's looking more like an excuse, then I'm probably less sympathetic. She's- she's quite capable of using it in a manipulative way (…) when I'm trying to get her to get up in the morning, and- and she's using pain as a reason why she shouldn't...*
>
> Charles, husband, caregiver

Some family caregivers questioned the intentions of the person with dementia's self-report of pain. The disclosure of pain was viewed as a means for the person with dementia to avoid activities that they did not want to do. Consistent reports of pain increased family caregivers' confidence that the self-report of pain reflected the pain experienced by the person with dementia. However, the consistency of self-reported pain for people with dementia may be implicated by memory difficulties. The person with dementia may have difficulty remembering or reflecting upon their past pain experience, potentially contributing to discordant or inconsistent reports of pain over time:

> *Someone says, 'what were you like last week?' I haven't a clue. (…) The only one that you just have to go on is how it is now, there's no good saying is it any better than it was earlier on, because I can't remember what it was like earlier on...*
>
> Greg, husband, person with dementia

The inconsistent self-report of pain by the person with dementia may lead to discordance between the self-report and the family caregiver report of pain:

> *You will hear her overnight, because I sleep- stay over, and you'll hear her 'Oh! Ah!' [pain noises] and you have to go in, and you have to say 'Wh-what is it?' that kind of thing, and she- she 'it's my foot, it's my foot' (...) The interesting thing is that when she wakes up in the morning, if you actually say to her (…) 'do you remember waking up because you'd got pain in your foot?' ... 'I didn't!' No recollection of that experience y'see? So if you then were to get to the GP (…) she'd make you look a fool, that's- that's- that's quite difficult really (…) [from] the time you've had your issue, and the time you get somebody to look there's a complete mismatch in terms of... cause and effect if you like.*
>
> Brenda, daughter, caregiver

The inconsistency and tension between the self-report of the person with dementia and the family caregiver may create additional complexity for healthcare professionals attempting to disentangle the pain experience. This challenge was also echoed by GPs:

> *Lots of patients that will be brought in by family members and they're saying the patient is really struggling with knee pain, and then you talk to the patient and they're saying 'oh no I'm fine, everything is okay...' and it's that inconsistent history that makes y'know the diagnosis... the assessment challenging, and potentially inaccurate and therefore the management plan not always appropriate*
>
> Amy, GP

Disentangling the pain experienced by the person with dementia amid the inconsistent reports and history may lead to inaccurate assessment and inappropriate management of pain. In addition to the inconsistent history, GPs also reflected on the challenge of unravelling the experience of pain when there is tension between self-reported pain and the GP's clinical judgement:

> *I've seen a- a patients with dementia who if you ask them if they- if it hurts anywhere or whatever, they'll say no, and they're in significant pain, and conversely, I have*

seen patients with dementia if you ask them y'know 'are you in pain?' 'Oh yea, incredible pain' 'where's it hurt?' 'oh, everywhere' and actually in my perspective, in my clinical perspective, y'know they've not got any issues causing them pain, and it can be really challenging

Ishann, GP

Last year I had a lady come in urr, she'd snapped two bones here [holding wrist] in her hand, and it was really, really deformed, and she came in, and... Carer came in with her, this lady was really old, 96? I said 'is this painful?' 'No.' 'Is this painful?' 'No.' 'Is anything painful?' 'No.' I don't believe you can fracture two bones, and they weren't just fractured, they were comminuted, they were smashed- I don't- she slipped on the ice- I don't believe that wasn't painful.

Alan, GP

GPs sometimes perceived the observed painful condition to warrant self-reported pain, or a pain response from the person with dementia; however, the person with dementia denied experiencing pain. The opposite was also true, where the person with dementia self-reported pain, however, in the GP's clinical perspective, there was no obvious indication or cause of pain. The person with dementia may have the ability to respond to self-report questions, however the GP's clinical judgement may mean that the self-reported pain is perceived as an unreliable indication of the pain experience. When self-report was not deemed to reflect the pain experience, alternative strategies and indicators were used to disentangle the self-report, and to corroborate their clinical judgement:

…And even if the patient will nod and say 'no', you're not entirely confident that maybe that's accurate, in terms of what's going on, and I think sometimes you have to rely on other parameters and indicators, to actually help you in that assessment

Jenny, GP

> *We can't just rely on them just saying that they're in pain, it's all other things that indicate that they are in pain*
>
> Rani, psychiatrist

In addition to the factors mentioned above, a stoical attitude towards pain was an additional consideration when determining if the self-report of pain was a 'reliable indication' of the pain experienced by the person with dementia. Many people with dementia expressed a stoical attitude towards their pain:

> *I've lived with it for so long, it's, y'know it's something you live with, isn't it? You just get used to it, and live with it.*
>
> Greg, husband, person with dementia

> *Well there is nothing I can do about it. I've just got it. I've got to live with it.*
>
> Patricia, wife, person with dementia

> *I think you've got to realise that, y'know I'm going to be in some discomfort for the rest of my life (…) I think there will always be some discomfort around. Don't think I will ever be able to get rid of that.*
>
> Richard, father, person with dementia

People with dementia frequently used stoical phrases such as 'living with it'. Pain was often viewed as an inevitable part of their life that they had no choice but to 'live with'. The experience of pain in the past seemed to lower the expectation for pain to be alleviated in the future. When pain was viewed as a part of life that was not going away, people with dementia chose to get 'used to it'. Therefore, the length of time living with pain in the past, and the perceived inevitability of pain in the future were contributing factors influencing the person with dementia's acceptance, and ultimately, their stoical attitude towards their pain.

In addition to these factors, family caregivers reflected upon the perceived importance of pain as a priority amidst competing health conditions. In other words, people with dementia may accept their pain due to the perception that pain is a 'lower priority' problem:

> *The thing is Barbara wouldn't regard pain as a big factor in her life, it's the helplessness that's the big factor in her life, and all the things she can't do are far more important to her, than mere pain. I mean Barbara just accepts it*
>
> John, husband, caregiver

People with dementia and family caregivers also perceived that healthcare professionals viewed pain as a lower priority problem. In particular, the pressures of primary care negatively affected GPs' time to consider pain, with other conditions taking priority, potentially illustrating a hierarchy of consultation, in which pain is perceived to come second to many other conditions:

> Denise: *They probably haven't got time to be honest, they probably haven't got time.*
>
> Greg: *Right down the bottom of their to-do list.*
>
> Greg (person with dementia), and Denise (wife, caregiver)

> *I think most professionals are too busy to be- to be worried about pain, so I don't think that's on their spectrum, and it's strange when you think about it...*
>
> Charles, husband, caregiver

In addition to the reasons described above, pain was sometimes accepted as a 'normal' part of ageing, leading to a stoical attitude towards pain:

> *It's just arthritis, y'know. It's just old age, y'know. Your bones are aching […] But it's not like he's in agony, you know what I mean? When you get to our age you just expect to get a few, y'know, knees go, an' neck goes an' shoulders go. I dunno whether it's our age group, but we just get on with it. Y'know, we're not always at the doctors, are we? Saying I've got this, that, and the other.*

Mary, wife, caregiver

Some family caregivers normalised the pain experienced by the person with dementia as an expected part of ageing that they should 'just get on with'. This is particularly important as the family caregiver often managed the person with dementia's physical health, including the organisation of GP appointments. The acceptance towards pain as a normal part of ageing seems to act as a barrier to accessing primary care.

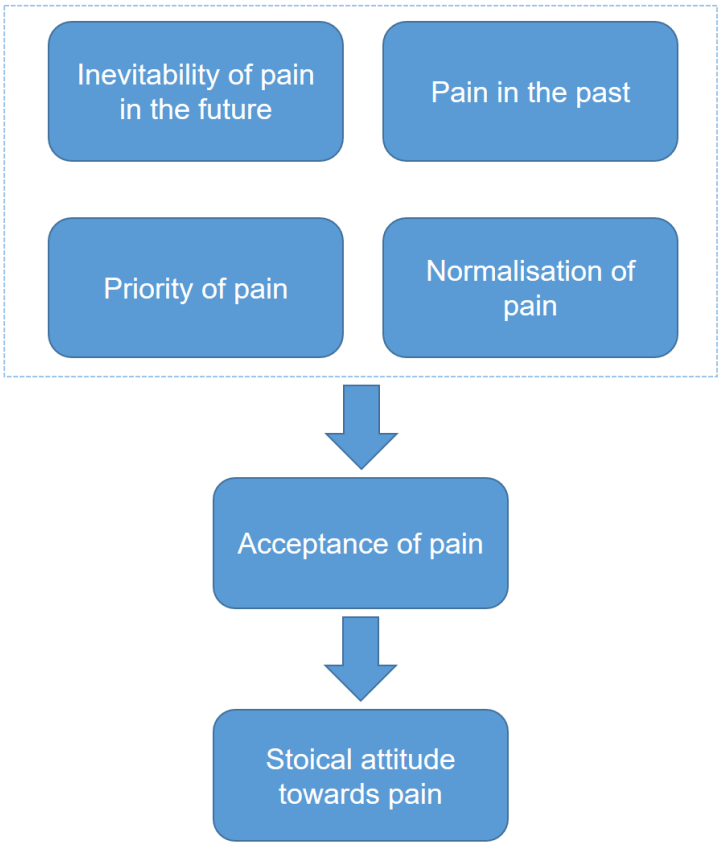


Figure 8.4. Factors contributing to a stoical attitude towards pain

The acceptance of pain, for the many reasons described above (see Figure 8.4), seemed to contribute to the person with dementia's stoical attitude towards pain. Consequently, a stoical attitude seemed to influence the self-report by the person with dementia:

> *I'm not the sort of person to sort of be- I tend to shrug off pain… So I never really talk about pain...*

Steven, husband, person with dementia

Similarly, family caregivers linked the person with dementia's stoical attitude (or *'high pain threshold'*) to a reduced self-report of pain:

> *I- It's interesting, if think if you asked Barbara, 'cause she's got an incredibly high pain threshold (…) I think she's such a stoic person that she's got... an ability to handle pain that a lot of people perhaps, won't have... she's not indulgent in any way. (…) she very rarely admits to anything (…) y'know I'm distracted by other things I don't notice anyway, so she could go... two or three hours in pain, and neither of us would know it... well... I wouldn't know it, and she wouldn't admit it.*
>
> John, husband, caregiver

> *He's not a moaner at all... I think he's got quite a high pain threshold, when his knee starts, then it does hurt him, but you- but you can tell that 'cause he can't walk...*
>
> Carol, wife, caregiver

The stoical attitude towards pain made it difficult for family caregivers to disentangle if the self-report of pain reflected the pain experienced by the person with dementia:

> *But the fact that she- she tolerates pain probably better than the average person... makes it hard to be certain*
>
> Charles, husband, caregiver

> *What concerns me, is if she had a really bad pain, or something was going on with- with- with her (…) she wouldn't be able to tell you very sensibly because her need is to be alright for everybody... Y'know her whole persona is 'I'm okay' she's always okay, the doctor comes and she's absolutely fine, even though she's deaf as a post, so actually there's no- there- there isn't a truth there.*
>
> Brenda, daughter, caregiver

Although family caregivers attributed the reduced self-report of pain to the person with dementia's stoical attitude or 'high pain tolerance' or 'threshold', it remains unclear if stoicism

is the reason for the lack of self-reported pain, or if the person with dementia had difficulty verbally articulating their pain experience (which may be incorrectly attributed by family caregivers as stoicism).

To support the findings from people with dementia and family caregivers, GPs also recognised that the stoical attitude held by older adults (including people with dementia) may influence the self-report of pain:

> *I still hear it quite a lot, still there's a hesitation from older adults to not trouble their GP, so they may actually- may actually result in them not telling you that they've got a new pain, or it's not getting any better, just hobble along, kind of, on walking sticks, and things.*
>
> Muhammed, GP

> *the pre-1948 attitude, that's the attitude that people have... because the NHS, of getting on with it, dealing with it yourself, not calling the doctor, not troubling the doctor*
>
> Alan, GP

GPs acknowledged older adults' (including people with dementia) reluctance to discuss pain with their GP, with older adults employing their own methods to 'live with' their pain, rather than troubling the doctor. The GP perspective illuminated previous reflections that stoicism may impede the self-report of pain and also impact on access to care. This demonstrates that people with dementia may hold stoical attitudes towards pain that may cause difficulty when attempting to disentangle if the self-report of pain reflects their pain experience. However, stoical attitudes seemed relevant for older adults generally (as evidenced by the family caregivers and GPs in this study), and therefore although relevant for people with dementia, they do not seem specific to people with dementia.

8.4.1.2 Observing changes

In addition to self-report, this subtheme presents an alternative strategy to gather information about the pain experienced by people with dementia; the observation of behavioural, psychological and physical changes. This subtheme illuminated the challenge of observing changes to identify and assess pain.

Many family caregivers described their observations that may indicate that the person with dementia was experiencing pain:

> *Lots of sighing and holding and... and [deep heavy breathing outwards], lots of that. And he will sort of- say if he's been in the garden, and he'll go a bit quiet, so I do notice*
>
> Michelle, wife, caregiver

> *she starts to get a little bit [pause] either ratty, or withdrawn. And just the look on her face and I know that y'know she- she's suffering.*
>
> John, husband, caregiver

Family caregivers reported changes in behaviour (lack of appetite, changes in sleep patterns, inactivity), facial expressions (grimacing, frowning), mood (ratty, withdrawn), body language (guarding), and non-verbal expressions (sighing, wincing) as indications of pain. Family caregivers vigilantly observed the person with dementia to identify and monitor changes that may be indicative of pain:

> *I think I'm not too worried about it [pain], simply because you observe... she can get up in the morning, she can walk, she can go to the loo, she doesn't complain about it most of the time, I think it's just an overnight thing, so it's just teasing out whether it's cramp, do you- that kind of thing. It's quite difficult to gauge if you're not observing... really...*
>
> Brenda, daughter, caregiver

GPs and old age psychiatrists echoed the observations of family caregivers, with behavioural changes, facial expressions, mood, and body language being associated with pain for people with dementia:

> *If it's more, say for example abdominal pain, it's being able to see them kind of y'know rubbing the area, or bending over, or leaning over, so it's an objective assessment. If they're becoming more aggressive, if they're more withdrawn, if they're- any of these more subtle changes that actually highlight that there's something else going on...*
>
> Amy, GP

> *I guess sometimes, there's body language cues, so they're rubbing their leg or whatever, ur... But I think a lot of it, and certainly as dementia progresses more I think a lot is much more non-verbal, urm... and just changes in pres- presentation and behaviour, urm... changes in appetite and sleep patterns, um... yea... agitation, things like that*
>
> Mel, psychiatrist

Many GPs and old age psychiatrists perceived observation as an objective method to gather information, especially for people with dementia who had difficulty providing a verbal self-report. Observation meant that changes in presentation could be identified; indicating that 'something else might be going on'. However, determining what that 'something else' might be was often difficult for GPs:

> *the chronic pain presentation can be so varying, from physical symptoms, to behavioural changes, to mental health symptoms, it can actually be very, very challenging.*
>
> Amy, GP

> *if I've got that distressed patient with dementia, and I think they might be in pain or they might not... that I think is- is I find that situation far more challenging...*

Ishann, GP

The presentation of the person with dementia when experiencing pain may be varied. If the observed change was not pain specific (such as a loss of appetite, a change in sleep patterns, or distress), it was challenging for the GP to determine the driver of the presentation. The challenge of determining the cause of the changed presentation may mean that pain is overlooked:

> *More troublesome, more demanding, more disruptive (…) People don't consider the pain as being a cause, they just don't consider it (…). You've got to think of the diagnosis before you can make the diagnosis, if they don't think of the diagnosis then you can't make the diagnosis, it just gets missed.*

Alan, GP

> *I think part of the job that's quite important, but difficult for us, is to assess whether changes in behaviour are due to changes in pain experience (…) it's very easy to overlook the pain issues, and I think you have to actively be enquiring and looking for signs of that, but again that can be really tricky to identify. Often people will say 'maybe it's a UTI', and there might be some other explanation for the change in behaviour which, y'know is easier to perhaps find evidence of a- a- of something like that, and try and treat that, because y'know it's quicker as well, and easier, um but actually, I think we're probably missing a lot of discomfort.*

Lisa, GP

GPs perceived pain to be overlooked as a potential driver of the changed presentation for people with dementia; especially when the GP was not actively investigating the presence of pain. This may be perpetuated by the pressures in primary care and the difficulty of determining the driver of behavioural and psychological changes. GPs might wish to identify a 'quick' and 'easy' fix, or resort to the identification of the 'usual suspects' that are associated with behavioural changes for people with dementia (e.g. a urinary tract infection).

The challenge of determining the underlying cause of behavioural changes may mean that they are attributed to dementia itself, rather than being perceived as an expression of an unmet need:

> *it's [pain] clearly an under recognised, and under diagnosed, urm... issue... urm... y'know I think dementia with psycho-behavioural disturbance, BPSD, and it's often just put down to the dementia itself*

Tom, GP

The difficulty of determining the underlying cause of the behavioural changes in primary care, and the attribution of behavioural changes as a direct 'symptom of dementia' may lead to inappropriate referrals to secondary care:

> *I think a lot of people look at this situation and think, oh gosh... I haven't got a clue what to do here, and therefore don't do anything... 'I don't have the expertise' yea... 'I'll refer- I'll tell the memory team that I'm not happy with this patient and then we'll see what they say', and then the memory team don't necessarily have the skills to address that, and then it just gets delayed and delayed and delayed, at the end of the day nothing has happened in 6 months or something... So... I think... I think it's- it is difficult for a lot of people...*

Jenny, GP

When asked about behavioural and psychological changes, old age psychiatrists emphasised the importance of investigating if they are driven by physical problems (such as pain), rather than automatically attributing symptoms to dementia itself:

> *I think that would be- the physical side of things, whether that's constipation, UTIs, or pain, or whatever, that's always something that we try to go through first before- before y'know coming to sort of psychiatric reasons, or psychiatric management of- of um... of the behavioural or psychological symptoms...*

Mel, psychiatrist

> *You always think, first think about physical discomfort, physical problems (...) I think that people who have dementia, they are, more so sort of pushed towards the mental side of things, rather than having a good service for their physical... Some people think it's all mental, it's all confusion... No... It's not that, the person is elderly, and they have physical problems...*

Aska, psychiatrist

Psychiatrists discussed that '*physical things*' (including pain) should be given priority when investigating the driver of behavioural and psychological symptoms for a person with dementia. However, psychiatrists continued to highlight that the label of 'dementia' may overshadow examination into physical conditions, and lead to (potentially inappropriate) referrals to secondary care. Despite acknowledging the association between 'physical things' and behavioural and psychological symptoms, psychiatrists did not view physical health as part of their job role*,* but rather the responsibility of the GP ('*we rely on our GP colleagues to do that'* Aska, psychiatrist). This sits in tension with GPs who previously discussed that pain is overlooked in primary care as a driver of behavioural and psychological changes. Therefore, psychiatrists reflected upon the need for GPs to recognise and investigate pain when behavioural changes are observed. By doing so, psychiatrists believed that avoidable referrals to secondary care could be reduced:

> *I think a more robust... intervention from GPs would be very helpful... I personally think that it shouldn't come to a psychiatric nurse, or a psychiatrist for someone with a physical problem, this should have been looked into by their own doctor.*

Aska, psychiatrist

Family caregivers, GPs, and old age psychiatrists each reflected upon behavioural changes that may suggest that the person with dementia was experiencing pain. However, it may be difficult for GPs to determine if pain or 'something else' was causing the observed change in

presentation, potentially leading to the under identification of pain and inappropriate referrals to secondary care.

In addition to observing behavioural and psychological changes as potential indications of pain, family caregivers also remained vigilant to observe physical changes that may be indicative of pain for people with dementia:

> *I had no idea that people got problems like this... none at all... We've managed to get to our age without these things... I think sometimes people forget that we haven't got a degree in Medicine (…) there's no manual, is there? Telling you what to do... Just I suppose a life time's experience dealing with your children, and a cat, and me mum, and me dad I suppose... that you think 'right let's have a look' and I saw, well it's all swollen, but you have to use your own common sense... there's no guide...*
>
> Carol, wife, caregiver

> *My mother had a little bit of a discharge, and I know she'd got a vaginal pessary, now she'd gone for the few years before regularly, to have that changed, all sorted in her own head, she hasn't picked up...I can't believe that she wasn't uncomfortable, because if she was, she wasn't telling us she was. (…) when she'd broke her foot she needed help and assistance. It gave us the way forward to begin to monitor... her body, her changes*
>
> Brenda, daughter, caregiver

The close care provided by family caregivers may aid the observation and monitoring of physical changes indicative of pain. Despite remaining vigilant, some family caregivers at times questioned their ability to identify pain-related changes (partly due to the lack of knowledge and guidance provided), drawing upon 'common sense' to guide their judgement. The importance of the close relationship between the person with dementia and the family caregiver was reiterated by GPs:

> *I think what's important is these carers provide close care to the patient, they urm... they provide the personal care, they toilet the patient, they assist with feeding, etc... So they're in close contact, and observation of the patient, and they can give a lot of information.*
>
> Tom, GP

The close care provided by the family caregiver may aid the observation and identification of physical changes indicative of pain that may otherwise go unnoticed. The close contact and familiarity of family caregivers was often relied upon by GPs (see section 8.4.2). Alike to family caregivers, many GPs also recognised the importance of observing and examining physical changes that may be indicative of pain for people with dementia:

> *Examination can be helpful too, depending on where you feel the pain is, I mean certainly if it's- if it's a joint, you can examine that joint, and if you elicit pain y'know it's all then, well they can move 90 degrees and it's causing them extreme pain it seems, you can kind of- urm... you- you can kind of identify the severity of things that way...*
>
> Chris, GP

> *If I'm pressing on an area, or examining an area to say that it is painful, y'know looking at their- looking at their body to see y'know if they urm clutching, or pulling away, looking at their face to see if they're grimacing*
>
> Ishann, GP

Many GPs discussed that physical examination may be a useful method to gather information regarding the potential pain experience, especially when the person with dementia can no longer self-report their pain. In particular, some GPs observed the reaction of the person with dementia (e.g. clutching, pulling away, and grimacing) during the examination to identify behaviours associated with the presence of pain. Behavioural changes during the examination may indicate to the GP that the examination had elicited

pain for the person with dementia. Despite the insights gained from physical examination as a pain identification strategy, it did not come without its own challenges:

> *You have to go through a fairly detailed... examination (…) the trouble with that, quite bluntly, takes a long time... we're meant to have 10 minutes, there's just no way in God's earth you can even get them on the couch in 10 minutes very often, you know, there's lot of coercion*
>
> Alan, GP

People with dementia may require more time and explanation during a physical examination. Some GPs, however, viewed the potential adaptations and flexibility required to examine a person with dementia to be difficult during the time-limited context of a GP consultation.

8.4.2 The importance of familiarity

Family caregivers and healthcare professionals recognised the importance of familiarity with the person with dementia to identify and assess pain. Family caregivers reflected upon how familiarity aided the identification of pain due to their in-depth knowledge of their pain history, and their ability to observe and recognise changes in their presentation:

> *I could see he wasn't well... because he wouldn't- he didn't want to eat, and he wanted to lie down, he wasn't well, he was sleeping a lot, and that's the kind of cue that I s'pose you only get because you know somebody very well, and you live with them*
>
> Carol, wife, caregiver

> *If you live with somebody long enough, you're normally tuned with them, and you know if something is wrong or out of place... So if he goes quiet for a length of time, I'm always asking if you're alright, aren't I?*
>
> Denise, wife, caregiver

Family caregivers reflected that knowing the person for a long time and knowing the person well (with extended exposure to their subtle behaviours) were key factors when identifying changes in the person with dementia's presentation that deviated from their 'normal'. Familiarity with the person with dementia aided pain identification, and thus prompting further questioning and investigation of the potential pain.

GPs echoed the perspective of family caregivers, recognising the importance of familiarity when identifying the pain experienced by people with dementia. Earlier in this chapter, GPs recognised the importance of identifying subtle changes in presentation that were 'out of character' (see Section 8.4.1.2). However, to aid the identification of subtle changes, the GP must be familiar with the person with dementia:

> *you can just observe, and I guess sometimes, urm, y'know you have patients you see quite regularly (…) if you know the patient before, and they seem pretty good, and suddenly they're not*
>
> Chris, GP

GPs acknowledged the benefits of knowing and being familiar with the person with dementia. Knowledge of the person with dementia could be used as a baseline comparison to their current presentation. Despite the benefits of familiarity to identify pain, many GPs continued to reflect upon the lack of continuity of care implicating their familiarity with the person with dementia. Their lack of familiarity may mean that subtle changes in the person with dementia's presentation are missed, and thus pain remains unidentified:

> *There is a huge problem in terms of continuity, and I think what, y'know the old GP would have been able to pick up as a change in Mrs Blogs, maybe now won't get noticed, so yea... so lost*
>
> Lisa, GP

In accordance with GPs, people with dementia also reflected upon the importance of relationship continuity with their GP:

I'd rather have a doctor that I see every time because they- they know your history then, you build up a, y'know they build up a knowledge of how you're like. You never get that. They don't even look back through the notes. I could go with this [painful shoulder], and they'll say 'well when did you have this done?' and I don't know when it was done, look in your notes!

Greg, husband, person with dementia

In particular, some people with dementia reflected that the lack of relationship continuity implicated GP's knowledge of their pain history. To buffer healthcare professionals' potential lack of familiarity with the person with dementia, GPs and old age psychiatrists relied upon family caregivers as a substitute familiarity, which the healthcare professional may no longer be able to provide:

Well I mean, urm... First of all, I mean... If I'm honest, I do rely a lot on relatives, or carers... because they're the people that know them, and I'm talking about an extreme, y'know at the more severe end here. But I rely on relatives, and carers, because they're the people that will see the change, and we often kind of, y'know sort of... you- they will be the ones who will be able to direct you sort of saying 'well she can normally put a jumper on but now they can't' y'know or... 'He doesn't seem to be using his right arm'

Chris, GP

As a doctor or a nurse you will see the snapshots in the middle, I go and see someone in one hour, I will have a good idea, but how the behaviour is in the evening I would not know... So it's very important the information I get... and I try my best to get detailed information from people who are closest to the person.

Aska, psychiatrist

Relatives are better at picking up the changes- the subtle changes in their loved ones behaviour, because they're there 24/7

Hayma, psychiatrist

Many healthcare professionals reflected upon the time-limited nature of their consultations, only gaining a short 'snapshot' perspective of the person with dementia. In antithesis, family caregivers were highly familiar, often spending many hours each day with the person with dementia. Therefore, many GPs and old age psychiatrists viewed family caregivers as a valuable asset. People with dementia may be unable to provide a history of their pain condition, or to provide a self-report of their pain. In these circumstances, family caregivers' familiarity means that they may be able to provide context and history as the person who knows them best. Additionally, family caregivers' familiarity and knowledge of the person with dementia's 'normal' provides greater opportunity to identify changes in presentation that may be indicative of pain. The family caregiver's ability to provide a surrogate history and to observe and report changes in presentation may provide direction to the healthcare professionals' investigation.

The family caregiver's familiarity and in depth knowledge was perceived as beneficial by all GPs, especially when the person with dementia was no longer able to communicate. However, some GPs also acknowledged the alternate perspective towards family caregiver's familiarity and involvement in the consultation:

> *I think they're probably essential [laugh] ur depending again on the level of cognitive impairment you've got... They can be actually... it's sometimes, an annoyance, if the person is actually perfectly capable of expressing themselves, the patient I mean, the caregiver sometimes y'know, you sometimes get the odd spouse, often... who will not keep quiet, and allow the person to talk*

Lisa, GP

> *Family members are proactive in looking after, y'know the relative's health, which is really positive, but it can over step the limit, and I have found that as well, where I'm trying to have a conversation with the patient (…). y'know 'my dad's in a lot of pain' so*

they're going to be quite emotive as well, which makes it more challenging for me, in that step to really have ur... a good connection with the patient.

Ishann, GP

GPs perceived that the in depth involvement of family caregivers might overshadow the perspective of the person with dementia. This may have a negative impact upon the relationship between the GP and the person with dementia.

8.4.3 The use of pain assessment tools

At the start of the interview, people with dementia were asked to rate their own pain using the IPT. Following the self-reported pain rating, family caregivers were also asked to rate the person with dementia's pain using the same tool (see 6.3.5.5.1). Some family caregivers reflected upon the difficulty of using a pain assessment tool to rate the person with dementia's pain.

[sigh] yea, I mean, it- numbers don't really tell the story anyway do they?

John, husband, caregiver

I have no way of judging [long pause] I know she has pain… But I wouldn't be able to describe the intensity [pause] since I am not feeling it.

Robert, husband, caregiver

John rated his wife's pain as 7 out of 10, classifying her pain as 'severe' (see Table 7.7). However, John did not believe that numbers adequately reflected his wife's experience of pain, suggesting that numbers fail to 'tell the story'. Similarly, Robert had difficulty describing the intensity of Patricia's (wife, person with dementia) pain. The abstract nature of pain may make informant pain assessment difficult for family caregivers, considering that they are not feeling the pain themselves.

GPs were asked to reflect on pain assessment tools that they used to assess the pain experienced by people with dementia:

No specific pain tools that I use, in practice generally actually, just kind of... urm a few pain questions. Sometimes I use the 1-10 scale, 10 being the most painful, I would ask a few questions around where the pain moves, and if it's there- the key things in older adults with dementia would be if you can get out of the, urm- the severity of the pain... I wouldn't rely on too much with a person with dementia, because that might not be accurate...

Muhammed, GP

so we ask for the symptoms, and 1-10, y'know severity scores, and those sorts of things don't compute at all

Lisa, GP

I'm not sure how effective our standard- on a scale of 1-10 are, in that sort of situation, because it's always a bit tricky to sort of discuss

Chris, GP

Many GPs were aware of rating pain using a numerical 1 to 10 scale. However, GPs perceived numerical pain assessment scales as potentially inappropriate for people with dementia; providing potentially inaccurate pain reports. This links to the previous finding, that some GPs questioned the extent self-reported pain reflected the pain experienced by the person with dementia (see Section 8.4.1.1). Unlike the majority of GPs, some were aware of other self-report tools, aside from the numerical rating of pain on a 1 to 10 scale:

I know there's the- the sort of smiley face charts, aren't there? With the- the different faces on... But to be honest, in routine practice, I don't use these... Um... perhaps something that I should consider [laughing] there's no specific tool that I use really...

Jessica, GP

obviously we need to ask the patient, and- and y'know use what we can, and I should probably use pain scores, and smiley face, and that kind of stuff more often...

Ishann, GP

Jessica and Ishann reflected upon alternative self-report pain assessment tools such as 'smiley face charts'. Despite their awareness of alternative pain assessment tools (albeit limited), Jessica and Ishann did not use a validated tool when assessing the person with dementia's pain, despite both reflecting that the incorporation of a tool into their practice may be worth considering.

The majority of GPs were unaware of pain assessment tools developed specifically for people with dementia, such as behavioural observation methods of pain assessment ('*you're going to tell me that there's a dementia pain scale...'* Chris, GP). Tom was the only GP that reflected upon a behavioural observation tool developed for people with dementia:

> *The Abbey Pain Scale, that's one scale... that we sometimes use... urm... but in my practice, and y'know there are some, ur... visual scales, of y'know facial expression for example, there are some other scales available that we sometimes use, urm... so yea... But you tend to really go by, urm... the observations of carers that formed a relationship with the patient, know the patient well, y'know over a period of time. Urm... they often provide the best source- the best and most reliable source of information, Ur and that- I value that the most in my own practice.*

Tom, GP

Despite Tom's awareness of the Abbey Pain Scale for people with dementia, he reflected upon his preference for the information and observations of family caregivers. Tom's preference for information provided by family caregivers echoes the earlier finding of the importance of familiarity when identifying and assessing pain for people with dementia, especially as their condition progresses, and verbal articulation of pain diminishes (see Section 8.4.2).

Psychiatrists did not perceive themselves to be *'the primary assessor'* of pain (Prisha, psychiatrist). Additionally, earlier in this chapter, psychiatrists suggested that 'physical health'

should be investigated by GPs before referring the person with dementia to secondary care (see Section 8.4.1.2). Therefore, rather than assessing pain for people with dementia directly, psychiatrists adopted a holistic approach by monitoring behavioural and psychological symptoms as an indication of the presence/absence of pain:

> *Our indicator of pain control, or good pain control, or rather the lack of it, is the behaviour, so the unsettled patient (…) we rely quite heavily on the GPs to look after the other side of the health, physical side of the health, and pain- pain control itself is under the GP's care, although we communicate in terms of assessing pain as such, we don't... We don't use it separately, we don't do it separately*
>
> Hayma, psychiatrist

Although psychiatrists did not view themselves as experts in pain ('*GPs have the expertise in physical health problems*' Mel, psychiatrist), and did not assess pain themselves, a number of psychiatrists were aware of dementia-specific behavioural observation pain tools:

> *Urm... I think I probably do- I don't know if it's a general doctor thing, I think my perception would be, maybe just anecdotal that doctors go much more on history urm, and nurses- and nursing staff are often very good at doing the more formalised assessments. I know our nurses use the Abbey Pain Scale, I know that's used in some of the nursing homes that we go to. Although there's the PAINAD scale, which I don't think we use as much, I think it's more the Abbey Pain Scale, but I guess that's for more advanced dementia, so may not be as relevant for people who are in their own home.*
>
> Mel, psychiatrist

> *There is something called the Abbey Pain Scale... Um... Some of the staff are using that as well... To be honest I don't personally rely on a particular scale or- or score, I just look at the whole picture, at the whole medication, and the whole physical history,*

> *and just try to give provisional diagnosis of provisional reasoning, and try to tackle them one by one.*
>
> Rani, psychiatrist

Despite being aware of behavioural observation pain assessment tools, psychiatrists relied upon alternative markers (e.g. history, caregiver reports; see section 8.4.2) and their clinical judgement to determine if the current presentation was driven by pain. Although the majority of healthcare professionals did not use validated pain assessment tools for people with dementia, some continued to reflect upon the benefits of incorporating a dementia-specific pain assessment tool into their practice:

> *If you could introduce a certain amount of objectivity in it, so that- so that there was some sort of decision making tool in terms of pain, and then- and then giving medication then that would be helpful...*
>
> Chris, GP

> *Because you have to depend a lot on the subjective information, so how do you make it more objective? (…) We use memory scales, we use other scales, like we call it activities of daily living scale, for example... why can't we use a pain scale? Obviously that's extra work, ur, but it's worth it because often that's what probably would give you a lot more information than anything else...*
>
> Prisha, psychiatrist

Some healthcare professionals perceived pain assessment tools as a way to add objectivity to an inherently subjective phenomenon. Despite the perceived benefits, adding a pain assessment scale into their practice was recognised as a potential source of burden for healthcare professionals (albeit the positives outweighing the negatives), potentially acting as a barrier to their incorporation.

8.5 Summary of qualitative findings

- A range of strategies were considered important to gather information about the pain experienced by people with dementia. These strategies included; self-report, family caregiver report, and observation of the presentation (including the observation of behavioural, psychological, and physical changes).
- Family caregivers and GPs reflected upon the importance, yet challenge of self-reported pain for people with dementia, especially as communication ability diminished in line with the progression of dementia.
- Most family caregivers and GPs did not question the self-reported pain provided by the person with dementia. In some circumstances, however, family caregivers and GPs questioned the extent that the self-report reflected the pain experienced by the person with dementia; especially if there were inconsistencies i) over time, ii) between the self-report of pain and family caregiver report of pain, and iii) between the self-reported pain and the GP's clinical judgement.
- A stoical attitude towards pain may also negatively influence the extent that the self-report of pain reflected the pain experience, and thus the identification and assessment of pain for people with dementia.
- Family caregivers and healthcare professionals observed many changes in presentation that may be indicative of pain for people with dementia. However, pain was perceived to be inadequately recognised as a differential diagnosis of behavioural and psychological symptoms.
- Observation of physical changes and physical examinations were an important means to gather information about the potential pain experience for people with dementia, especially if they could no longer provide a self-report of their pain.
- Family caregiver's familiarity with the person with dementia aided the ability to provide history and context, and to identify changes in presentation. Healthcare professionals were often unfamiliar with the person with dementia, relying upon the family caregiver as a surrogate familiarity.

- Healthcare professionals often did not use dementia-specific pain assessment tools (rather relying upon alternative markers), however acknowledged that incorporation of a tool may be a useful addition to their practice.

8.6 Conclusions

This chapter investigated pain identification and pain assessment for people with dementia using quantitative and qualitative methods. Findings from the quantitative and qualitative data were provided and summarised separately in line with the convergent mixed methods design. The quantitative and qualitative findings from this chapter are narratively integrated in Chapter Ten to highlight inferences, interpretations, convergent, and divergent findings. By doing so, the quantitative and qualitative findings provide an investigation of pain identification and pain assessment for people with dementia (Creswell & Plano Clark, 2018). The following chapter provides the quantitative and qualitative findings relating to the management of pain for people with dementia.

9 Chapter Nine: Management of pain

9.1 Introduction

This chapter meets the second research objective: to investigate the management of pain for community-dwelling people with dementia (see Section 4.2) using quantitative and qualitative data. Firstly, using the Clinical Practice Research Datalink (CPRD), quantitative data was used to examine the analgesic prescriptions for people with dementia compared to older adults without dementia as a key pain management strategy. Secondly, people with dementia, family caregivers, and healthcare professionals' views and perspectives of pain management strategies were explored using qualitative methods. These findings build upon the previous chapter investigating pain identification and pain assessment for people with dementia. The quantitative and qualitative findings are presented separately in line with the convergent mixed methods design described in Section 5.4.2.1. The quantitative and qualitative findings are narratively integrated in the discussion chapter (see Chapter Ten) to highlight inferences, interpretations, convergent, and divergent findings (Creswell & Plano Clark, 2018).

9.2 Management of pain: Quantitative findings

This section of the chapter examined analgesic medications prescribed to people with dementia (dementia cohort), compared to older adults without dementia (older adult cohort), as a key pain management strategy. All analysis was conducted using the dementia cohort (*n*=36,582) and older adult cohort (*n*=36,582) (see Figure 6.8). Firstly, the prevalence of analgesic prescriptions was calculated for both cohorts (see Section 6.2.13.4). Following this, conditional logistic regression models were used to examine the association between dementia and analgesic prescription. This section of the chapter answers the following research questions:

- What is the prevalence of analgesic prescriptions for people with dementia compared to older adults without dementia?

- What are the annual prevalence rates of analgesic prescription over time for people with dementia?

9.2.1 The prevalence of analgesic prescription

The prevalence of analgesic prescription, and prevalence ratio was calculated during the five-year period from index date (dementia diagnostic Read code, or dementia medicinal product code, or equivalent matched date for the older adult cohort) for the five years following index date. The annual period prevalence of analgesic prescription was also calculated starting from the index date to five years after index date (see Section 6.2.13.2). Stratification into annual time periods allowed the prevalence of analgesic prescription over time (trends) to be examined for both cohorts. Analgesic prescriptions were categorised into basic analgesic, weak analgesic, moderate analgesic, strong analgesic, very strong analgesic, or non-steroidal anti-inflammatory drugs (NSAIDs) based on their analgesic potency (further details regarding the classification of analgesic prescriptions is provided in Section 6.2.9.2). The prevalence of prescriptions for these six analgesic categories was also calculated and presented. For the analyses discussed in this chapter, analgesic prescriptions were matched within a 14-day pre, and 90-day post window of a musculoskeletal consultation to increase the likelihood of identifying analgesic prescriptions associated with the musculoskeletal consultation following previous methodology (Bedson et al., 2016; Bedson et al., 2019; Richardson et al., 2018). However, sensitivity analysis including all analgesic prescriptions (irrespective of matching to a musculoskeletal consultation) was also conducted (see Section 6.2.13.5.3).

Table 9.1 provides the period prevalence, and prevalence ratio estimates of analgesic prescription (matched to a musculoskeletal consultation) for the dementia cohort and the older adult cohort.

Table 9.1. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
Dementia cohort (*n*)	24,247	16,110	10,314	6471	3893	3893
Older adult cohort (*n*)	30,316	24,732	19,849	15,663	12,276	12,276
Dementia prevalence % (95% CI)	21.08 (20.57 to 21.60)	18.81 (18.21 to 19.42)	16.82 (16.11 to 17.56)	15.65 (14.79 to 16.56)	16.72 (15.58 to 17.93)	49.04 (47.47 to 50.61)
Older adult prevalence % (95% CI)	25.47 (24.99 to 25.97)	25.21 (24.68 to 25.76)	25.42 (24.82 to 26.03)	26.25 (25.56 to 26.94)	26.16 (25.39 to 26.94)	60.07 (59.20 to 60.93)
PR (95% CI)	.83 (.80 to .85)	.75 (.72 to .78)	.66 (.63 to .70)	.60 (.56 to .63)	.64 (.59 to .69)	.82 (.79 to .85)
Basic Analgesic						
Dementia prevalence % (95% CI)	14.74 (14.30 to 15.20)	13.38 (12.87 to 13.92)	11.99 (11.38 to 12.63)	11.14 (10.40 to 11.93)	11.56 (10.59 to 12.60)	36.89 (35.38 to 38.41)
Older adult prevalence % (95% CI)	16.44 (16.03 to 16.86)	16.40 (15.94 to 16.86)	16.73 (16.21 to 17.25)	17.57 (16.98 to 18.17)	18.03 (17.36 to 18.72)	44.61 (43.73 to 45.49)
PR (95% CI)	.90 (.86 to .93)	.82 (.78 to .86)	.72 (.67 to .76)	.63 .59 to .68)	.64 (.58 to .70)	.83 (.79 to .87)
Weak Analgesic						
Dementia prevalence % (95% CI)	5.82 (5.54 to 6.13)	5.00 (4.67 to 5.34)	4.61 (4.22 to 5.03)	4.31 (3.84 to 4.83)	4.55 (3.94 to 5.25)	18.39 (17.21 to 19.64)
Older adult prevalence % (95% CI)	7.38 (7.09 to 7.68)	7.47 (7.15 to 7.80)	7.56 (7.20 to 7.94)	8.00 (7.59 to 8.44)	7.90 (7.44 to 8.39)	25.11 (24.35 to 25.88)
PR (95% CI)	.79 (.74 to .84)	.67 (.62 to .73)	.61 (.64 to .75)	.54 (.47 to .61)	.58 (.49 to .67)	.94 (.68 to .79)

Table 9.1. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Moderate Analgesic						
Dementia prevalence % (95% CI)	2.95 (2.74 to 3.17)	2.65 (2.41 to 2.91)	2.27 (2.00 to 2.57)	2.15 (1.82 to 2.53)	2.62 (2.16 to 3.17)	9.40 (8.52 to 10.36)
Older adult prevalence % (95% CI)	4.12 (3.90 to 4.35)	3.94 (3.70 to 4.19)	3.87 (3.62 to 4.15)	4.00 (3.70 to 4.32)	3.72 (3.40 to 4.07)	13.37 (12.78 to 13.98)
PR (95% CI)	.72 (.65 to .78)	.67 (.60 to .75)	.59 (.51 to .68)	.54 (.45 to .64)	.70 (.57 to .87)	.70 (.63 to .78)
Strong Analgesic						
Dementia prevalence % (95% CI)	5.00 (4.84 to 5.28)	4.57 (4.26 to 4.90)	3.85 (3.50 to 4.24)	4.31 (3.84 to 4.83)	3.96 (3.39 to 4.62)	14.23 (13.17 to 15.36)
Older adult prevalence % (95% CI)	6.85 (6.57 to 7.14)	6.97 (6.66 to 7.30)	6.76 (6.42 to 7.12)	7.05 (6.66 to 7.46)	7.28 (6.84 to 7.76)	19.93 (19.23 to 20.64)
PR (95% CI)	.72 (.67 to .77)	.64 (.58 to .70)	.55 (.49 to .62)	.59 (.52 to .68)	.52 (.44 to .63)	.67 (.60 to .74)
Very Strong Analgesic						
Dementia prevalence % (95% CI)	.62 (.53 to .73)	.55 (.45 to .68)	.60 (.47 to .77)	.53 (.38 to .73)	.54 (.35 to .82)	1.62 (1.27 to 2.07)
Older adult prevalence % (95% CI)	.65 (.56 to .74)	.78 (.68 to .90)	.68 (.57 to .80)	.67 (.55 to .81)	.71 (.58 to .87)	1.94 (1.71 to 2.20)
PR (95% CI)	.96 (.78 to 1.19)	.71 (.55 to .91)	.89 (.66 to 1.20)	.78 (.53 to 1.15)	.76 (.47 to 1.22)	.83 (.63 to 1.10)
NSAIDs						
Dementia prevalence % (95% CI)	3.72 (3.49 to 3.97)	3.09 (2.83 to 3.36)	2.65 (2.35 to 2.98)	2.63 (2.26 to 3.05)	3.06 (2.56 to 3.65)	13.43 (12.40 to 14.54)

Table 9.1. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Older adult prevalence % (95% CI)	6.23 (5.97 to 6.51)	5.99 (5.70 to 6.30)	5.57 (5.26 to 5.90)	5.59 (5.24 to 5.96)	5.31 (4.93 to 5.72)	20.72 (20.02 to 21.45)
PR (95% CI)	.60 (.55 to .64)	.51 (.47 to .57)	.48 (.42 to .54)	.47 (.40 to .55)	.58 (.48 to .70)	.65 (.59 to .71)

CI confidence intervals; NSAID Non-Steroidal Anti-Inflammatory Drugs, PR prevalence ratio

The five-year prevalence from index date of analgesic prescription (irrespective of potency) was 11% lower for the dementia cohort compared to the older adult cohort (49% vs. 60%, respectively), with the prevalence ratio indicating a 0.82 lower prevalence for the dementia cohort than the older adult cohort (PR = 0.82, 95% CI 0.79 to 0.85).

Consideration over time, from index date, shows the annual prevalence of analgesic prescription steadily decreased from the first year of follow up (index date to one year after index date) until the final year of follow up (four years to five years after index date) for the dementia cohort (21.1% vs. 16.7%, respectively). Whereas the annual prevalence of analgesic prescription remained relatively stable (with indications of a slight increase) throughout follow up for the older adult cohort (25.5 vs. 26.2%, respectively) (see Figure 9.1). Consideration of the prevalence ratio in Table 9.1 shows that during the first year of follow up, the prevalence of analgesic prescription for the dementia cohort was 0.83 times lower than the older adult cohort (PR = 0.83, 95% CI 0.80 to 0.85). However, by the final year of follow up the prevalence of analgesic prescription for the dementia cohort was 0.64 times lower than the older adult cohort (PR = 0.64, 95% CI 0.59 to 0.69).

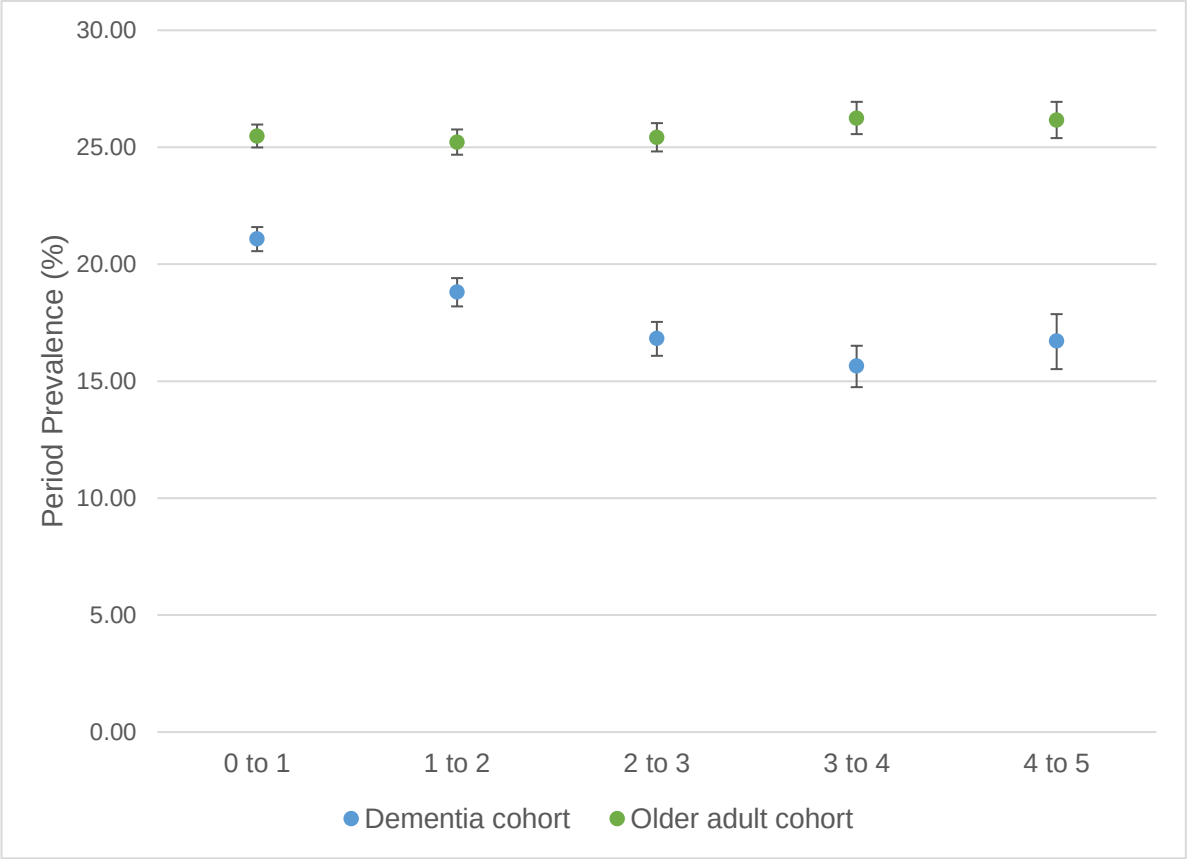


Figure 9.1. Period prevalence of being prescribed any analgesic

To investigate the prevalence of analgesic prescription further, period prevalence estimates were stratified by analgesic classification (see Table 9.1). The five-year prevalence estimates indicate that the prevalence of basic analgesics was highest for the dementia cohort and older adult cohort (36.9%, 44.1%, respectively), followed by weak analgesics, strong analgesics, moderate analgesics, NSAIDs, and lastly, very strong opioids (1.6%, 1.9%, respectively) (see Table 9.1). The dementia cohort had a lower prevalence of being prescribed any of the analgesic classifications, irrespective of potency, compared to the older adult cohort. The exception to this statement is for very strong analgesics where the percentage is lower for the dementia cohort compared to the older adult cohort (as with other categories) but the difference is statistically non-significant (PR = 0.83, 95% CI 0.63 to 1.10).

The annual prevalence of analgesic prescription was again, stratified into analgesic classifications. The dementia cohort had a lower annual prevalence of basic analgesic, weak analgesic, moderate analgesic, strong analgesic, and NSAID prescription compared to the

older adult cohort (see Table 9.1). For basic analgesics, weak analgesics, and strong analgesics, the discrepancy between the dementia cohort and the older adult cohort increased throughout follow up (see Figure 9.2). For moderate analgesics, the discrepancy between the dementia cohort and older adult cohort increased throughout follow up however decreased in the latter years of follow up (see Figure 9.2). The annual prevalence of very strong analgesic prescription was similar for the dementia cohort and older adult cohort throughout follow up, with prevalence ratios indicating no difference between the dementia cohort and older adult cohort (e.g. year 0-1 PR = 0.96, 95% CI 0.78 to 1.19; year 4-5 PR 0.76, 95% CI 0.47 to 1.22) (see Table 9.1).

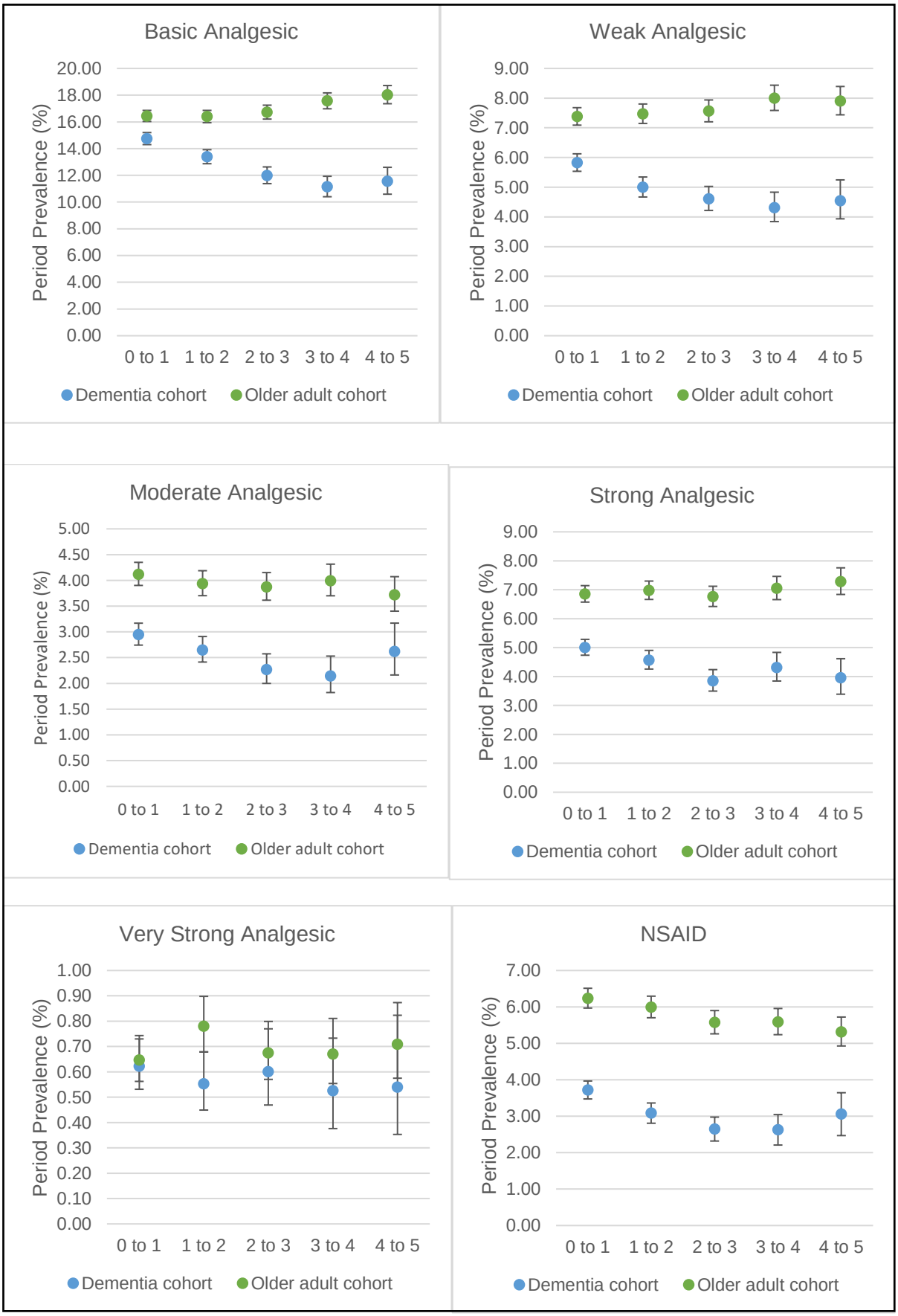


Figure 9.2. Period prevalence of analgesic prescriptions stratified by classification

9.2.1.1.1 Sensitivity analysis

9.2.1.1.1.1 Community sensitivity

As outlined in Section 6.2.13.5.1 a sensitivity analysis was planned to account for potential bias by the inclusion of persons who may reside within a formal care residence. This sensitivity analysis examined the period prevalence of analgesic prescription for the subgroup of the dementia cohort (*n*=8875) and older adult cohort (*n*=8349) with no evidence of a consultation location in a formal care residence, and a family number of ≤2. Similar to the analysis presented above, calculations were stratified into annual periods, and analgesic categories. The sensitivity analysis highlights minimal differences from the main analysis, with the dementia cohort having a lower prevalence of being prescribed any classification of analgesic medication compared with the older adult cohort (see Table 9.2).

Table 9.2. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period: Community sensitivity analysis

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
Dementia cohort (n)	5700	3648	2243	1370	808	808
Older adult cohort (n)	6788	5377	4203	3268	2494	2494
Dementia prevalence % (95% CI)	22.04 (20.98 to 23.13)	19.76 (18.50 to 21.09)	17.61 (16.09 to 19.24)	16.57 (14.69 to 18.63)	17.45 (14.99 to 20.22)	50.74 (47.30 to 54.18)
Older adult prevalence % (95% CI)	24.72 (23.71 to 25.76)	24.94 (23.80 to 26.11)	25.41 (24.12 to 26.75)	25.18 (23.73 to 26.70)	25.30 (23.63 to 27.04)	59.10 (57.16 to 61.02)
PR (95% CI)	0.89 (0.84 to 0.95)	0.79 (0.73 to 0.86)	0.69 (0.62 to 0.77)	0.66 (0.58 to 0.75)	0.69 (0.59 to 0.81)	0.86 (0.80 to 0.93)
Basic Analgesic						
Dementia prevalence % (95% CI)	15.56 (14.64 to 16.53)	14.01 (12.92 to 15.17)	12.35 (11.05 to 13.78)	11.39 (9.81 to 13.18)	12.13 (10.06 to 14.56)	38.74 (35.44 to 42.14)
Older adult prevalence % (95% CI)	15.57 (14.73 to 16.45)	16.25 (15.29 to 17.26)	16.63 (15.54 to 17.79)	16.77 (15.53 to 18.09)	17.04 (15.62 to 18.57)	43.22 (41.29 to 45.18)
PR (95% CI)	1.00 (0.92 to 1.09)	0.86 (0.78 to 0.95)	0.74 (0.65 to 0.85)	0.68 (0.58 to 0.80)	0.71 (0.58 to 0.87)	0.90 (0.81 to 0.99)
Weak Analgesic						
Dementia prevalence % (95% CI)	6.09 (5.50 to 6.74)	5.56 (4.87 to 6.36)	4.64 (3.84 to 5.59)	4.89 (3.87 to 6.16)	5.07 (3.76 to 6.81)	20.79 (18.14 to 23.73)
Older adult prevalence % (95% CI)	6.88 (6.30 to 7.51)	7.44 (6.77 to 8.17)	7.35 (6.60 to 8.18)	6.95 (6.12 to 7.87)	7.46 (6.49 to 8.56)	24.62 (22.97 to 26.35)
PR (95% CI)	0.88 (0.77 to 1.01)	0.75 (0.64 to 0.88)	0.63 (0.51 to 0.78)	0.70 (0.54 to 0.92)	0.68 (0.49 to 0.95)	0.84 (0.73 to 0.98)

Table 9.2. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period: Community sensitivity analysis

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Moderate Analgesic						
Dementia prevalence % (95% CI)	2.89 (2.49 to 3.36)	2.91 (2.41 to 3.50)	2.10 (1.58 to 2.78)	2.12 (1.48 to 3.02)	2.60 (1.71 to 3.94)	9.65 (7.80 to 11.88)
Older adult prevalence % (95% CI)	3.99 (3.55 to 4.49)	3.92 (3.44 to 4.48)	3.83 (3.29 to 4.45)	3.79 (3.19 to 4.51)	3.49 (2.84 to 4.28)	12.95 (11.69 to 14.33)
PR (95% CI)	0.72 0.60 to 0.88)	0.73 (0.59 to 0.93)	0.54 (0.40 to 0.75)	0.55 (0.37 to 0.83)	0.74 (0.47 to 1.19)	0.72 (0.59 to 0.94)
Strong Analgesic						
Dementia prevalence % (95% CI)	5.37 (4.81 to 5.98)	4.74 (4.10 to 5.48)	4.64 (3.84 to 5.59)	5.26 (4.19 to 6.57)	5.32 (3.98 to 7.09)	16.21 (13.83 to 18.91)
Older adult prevalence % (95% CI)	7.07 (6.49 to 7.71)	7.05 (6.40 to 7.76)	6.71 (5.99 to 7.51)	7.37 (6.53 to 8.32)	7.18 (6.23 to 8.26)	19.85 (18.33 to 21.46)
PR (95% CI)	0.76 (0.66 to 0.87)	0.67 (0.56 to 0.80)	0.69 (0.56 to 0.86)	0.71 (0.55 to 0.92)	0.74 (0.54 to 1.02)	0.82 (0.69 to 0.97)
Very Strong Analgesic						
Dementia prevalence % (95% CI)	0.88 (0.67 to 1.15)	0.63 (0.42 to 0.94)	0.76 (0.47 to 1.21)	0.58 (0.30 to 1.15)	0.37 (0.13 to 1.09)	2.23 (1.41 to 3.49)
Older adult prevalence % (95% CI)	0.72 (0.55 to 0.95)	0.84 (0.63 to 1.12)	0.74 (0.52 to 1.05)	0.70 (0.47 to 1.05)	1.04 (0.71 to 1.52)	2.45 (1.91 to 3.13)
PR (95% CI)	1.22 (0.82 to 1.80)	0.75 (0.46 to 1.24)	1.03 (0.57 to 1.85)	0.83 (0.37 to 1.85)	0.36 (0.11 to 1.17)	0.91 (0.54 to 1.53)
NSAIDs						
Dementia prevalence % (95% CI)	3.84 (3.37 to 4.37)	3.10 (2.58 to 3.71)	2.63 (2.05 to 3.38)	2.85 (2.09 to 3.87)	2.85 (1.90 to 4.24)	14.23 (11.99 to 16.81)

Table 9.2. Period prevalence of analgesic prescriptions for the dementia cohort and older adult cohort stratified by analgesic classification and annual time period: Community sensitivity analysis

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Older adult prevalence % (95% CI)	6.32 (5.77 to 6.92)	5.49 (4.91 to 6.13)	5.97 (5.30 to 6.73)	5.66 (4.92 to 6.51)	5.41 (4.59 to 6.37)	20.93 (19.38 to 22.57)
PR (95% CI)	0.61 (0.52 to 0.71)	0.56 (0.46 to 0.70)	0.44 (0.33 to 0.58)	0.50 (0.36 to 0.71)	0.53 (0.34 to 0.81)	0.68 (0.56 to 0.82)

CI confidence intervals; NSAID Non-Steroidal Anti-Inflammatory Drugs, PR prevalence ratio

9.2.1.1.1.2 Healthy cohort effects

A sensitivity analysis was planned to account for potential 'healthy cohort' bias. The previous period prevalence investigation only included members of each cohort if they remained in the study throughout each time period. This sensitivity analysis considered the prevalence of analgesic prescription using members of the dementia cohort (*n*=12,967) and older adult cohort (*n*=22,237) that remained in the study at the mid-point of the five-year follow up period (912 days after index date; see Section 6.2.13.5.2). Sensitivity analysis indicated minimal differences in the prevalence of analgesic prescription compared to the main analysis, with the dementia cohort having a lower prevalence of analgesic prescription than the older adult cohort (see Table 9.3).

Table 9.3. Period prevalence of analgesic prescription for dementia cohort and older adult cohort: Healthy cohort effects sensitivity analysis

	0 to 5 years
Dementia cohort (*n*)	**12,967**
Older adult cohort (*n*)	**22,237**
Any analgesic	
Dementia prevalence % (95% CI)	42.80 (41.95 to 43.65)
Older adult prevalence % (95% CI)	55.79 (55.14 to 56.44)
PR (95% CI)	0.77 (0.75 to 0.79)
Basic analgesic	
Dementia prevalence % (95% CI)	33.03 (32.23 to 33.84)
Older adult prevalence % (95% CI)	41.41 (40.77 to 42.06)
PR (95% CI)	0.80 (0.77 to 0.82)
Weak analgesic	
Dementia prevalence % (95% CI)	14.62 (14.02 to 15.24)
Older adult prevalence % (95% CI)	22.04 (21.50 to 22.59)
PR (95% CI)	0.66 (0.63 to 0.70)
Moderate analgesic	
Dementia prevalence % (95% CI)	7.88 (7.43 to 8.36)

Table 9.3. Period prevalence of analgesic prescription for dementia cohort and older adult cohort: Healthy cohort effects sensitivity analysis

Older adult prevalence % (95% CI)	12.27 (11.85 to 12.71)
PR (95% CI)	0.64 (0.60 to 0.69)
Strong analgesic	
Dementia prevalence % (95% CI)	11.71 (11.16 to 12.27)
Older adult prevalence % (95% CI)	18.63 (18.12 to 19.14)
PR (95% CI)	0.63 (0.60 to 0.66)
Very strong analgesic	
Dementia prevalence % (95% CI)	1.64 (1.44 to 1.88)
Older adult prevalence % (95% CI)	2.22 (2.04 to 2.42)
PR (95% CI)	0.74 (0.63 to 0.87)
NSAID	
Dementia prevalence % (95% CI)	9.33 (8.84 to 9.84)
Older adult prevalence % (95% CI)	17.17 (16.68 to 17.67)
PR (95% CI)	0.54 (0.51 to 0.58)

CI confidence intervals; NSAID Non-Steroidal Anti-Inflammatory Drugs, PR prevalence ratio

9.2.1.1.1.3 Analgesic prescriptions not matched to musculoskeletal consultation

This sensitivity analysis investigated the period prevalence of all analgesic prescriptions (not only prescriptions matched to a musculoskeletal consultation as shown in the main analysis above; see Section 9.2.1) the rationale for this sensitivity analysis is outlined in Section 6.2.13.5.3. As expected, this sensitivity analysis found that the prevalence of analgesic prescription increased for both cohorts, indicating additional analgesic prescriptions not connected to musculoskeletal pain consultations. For example, during the five-year period following index date, the prevalence of any analgesic prescription (matched to a musculoskeletal consultation) in the main analysis was 49% for the dementia cohort (see Table 9.1). This prevalence increased to 76.7% in the sensitivity analysis (see Table 9.4), meaning that 27.7% of analgesic prescriptions were not matched to a musculoskeletal consultation within the specified time window (14 days previous and 90 days after prescription).

Table 9.4. Period prevalence of analgesic prescription, not matched to a musculoskeletal consultation, for the dementia cohort and older adult cohort

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
Dementia cohort (*n*)	24247	16110	10314	6472	3893	3893
Older adult cohort (*n*)	30316	24732	19849	15663.00	12276.00	12276.00
Dementia prevalence % (95% CI)	51.73 (51.10 to 52.36)	50.55 (49.78 to 51.32)	49.20 (48.23 to 50.16)	48.64 (47.42 to 49.86)	49.58 (48.01 to 51.15)	76.73 (75.37 to 78.03)
Older adult prevalence % (95% CI)	54.18 (53.62 to 54.74)	54.41 (53.79 to 55.03)	54.55 (53.85 to 55.24)	55.14 (54.36 to 55.91)	55.73 (54.85 to 56.61)	78.99 (78.26 to 79.70)
PR (95% CI)	0.95 (0.94 to 0.97)	0.93 (0.91 to 0.95)	0.90 (0.88 to 0.92)	0.88 (0.86 to 0.91)	0.89 (0.86 to 0.92)	0.97 (0.95 to 0.99)
Basic Analgesic						
Dementia prevalence % (95% CI)	37.30 (36.69 to 37.91)	36.86 (36.12 to 37.61)	36.64 (35.71 to 37.57)	36.22 (35.06 to 37.40)	36.58 (35.08 to 38.10)	63.45 (61.92 to 64.95)
Older adult prevalence % (95% CI)	35.78 (35.24 to 36.32)	36.19 (35.60 to 36.79)	36.82 (36.15 to 37.50)	37.57 (36.81 to 38.33)	38.91 (38.05 to 39.78)	62.13 (61.27 to 62.98)
PR (95% CI)	1.04 (1.02 to 1.07)	1.02 (0.99 to 1.05)	1.00 (0.96 to 1.03)	0.96 (0.93 to 1.00)	0.94 (0.90 to 0.99)	1.02 (0.99 to 1.05)
Weak Analgesic						
Dementia prevalence % (95% CI)	13.61 (13.18 to 14.05)	12.68 (12.17 to 13.20)	12.19 (11.57 to 12.83)	11.28 (10.53 to 12.07)	10.97 (10.03 to 11.99)	31.34 (29.90 to 32.81)
Older adult prevalence % (95% CI)	15.49 (15.09 to 15.90)	15.58 (15.13 to 16.04)	15.46 (14.96 to 15.97)	16.18 (15.61 to 16.76)	16.49 (15.84 to 17.15)	36.49 (35.64 to 37.34)
PR (95% CI)	0.88 (0.84 to 0.92)	0.81 (0.77 to 0.86)	0.79 (0.74 to 0.84)	0.70 (0.65 to 0.75)	0.67 (0.60 to 0.73)	0.86 (0.82 to 0.90)
Moderate Analgesic						

Table 9.4. Period prevalence of analgesic prescription, not matched to a musculoskeletal consultation, for the dementia cohort and older adult cohort

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Dementia prevalence % (95% CI)	7.04 (6.73 to 7.37)	6.32 (5.95 to 6.71)	6.22 (5.77 to 6.71)	6.38 (5.81 to 7.00	6.40 (5.67 to 7.21)	17.98 (16.81 to 19.22)
Older adult prevalence % (95% CI)	8.52 (8.21 to 8.84)	8.48 (8.14 to 8.83)	8.29 (7.91 to 8.68)	8.03 (7.61 to 8.46)	7.83 (7.37 to 8.32)	22.15 (21.42 to 22.89)
PR (95% CI)	0.83 (0.78 to 0.88)	0.75 (0.69 to 0.80)	0.75 (0.69 to 0.82)	0.80 (0.71 to 0.89)	0.82 (0.71 to 0.93)	0.81 (0.75 to 0.87)
Strong Analgesic						
Dementia prevalence % (95% CI)	11.12 (10.73 to 11.52)	10.42 (9.95 to 10.90)	9.71 (9.16 to 10.30)	9.86 (9.16 to 10.61)	9.84 (8.94 to 10.81)	22.86 (21.57 to 24.21)
Older adult prevalence % (95% CI)	13.06 (12.68 to 13.44)	13.31 (12.90 to 13.74)	13.28 (12.81 to 13.75)	13.55 (13.02 to 14.09)	13.69 (13.09 to 14.30)	28.36 (27.57 to 29.17)
PR (95% CI)	0.85 (0.81 to 0.89)	0.78 (0.74 to 0.83)	0.73 (0.68 to 0.78)	0.73 (0.67 to 0.79)	0.72 (0.65 to 0.80)	0.81 (0.76 to 0.86)
Very Strong Analgesic						
Dementia prevalence % (95% CI)	1.35 (1.21 to 1.50)	1.40 (1.23 to 1.59)	1.41 (1.20 to 1.65)	1.17 (0.94 to 1.47)	1.54 (1.20 to 1.98)	2.90 (2.42 to 3.48)
Older adult prevalence % (95% CI)	1.30 (1.18 to 1.43)	1.42 (1.28 to 1.57)	1.39 (1.23 to 1.56)	1.33 (1.17 to 1.53)	1.40 (1.21 to 1.63)	3.01 (2.72 to 3.32)
PR (95% CI)	1.04 (0.89 to 1.20)	0.99 (0.84 to 1.17)	1.01 (0.83 to 1.24)	0.88 (0.68 to 1.14)	1.10 (0.82 to 1.47)	0.96 (0.78 to 1.19)
NSAIDs						
Dementia prevalence % (95% CI)	6.97 (6.66 to 7.30)	6.29 (5.92 to 6.67)	5.51 (5.08 to 5.96)	5.08 (4.57 to 5.65)	5.68 (4.99 to 6.45)	19.21 (18.01 to 20.48)
Older adult prevalence % (95% CI)	11.09 (10.74 to 11.44)	10.62 (10.24 to 11.01)	10.17 (9.76 to 10.60)	9.75 (9.29 to 10.22)	9.53 (9.02 to 10.06)	28.26 (27.47 to 29.06)
PR (95% CI)	0.63	0.59	0.54	0.52	0.60	0.68

Table 9.4. Period prevalence of analgesic prescription, not matched to a musculoskeletal consultation, for the dementia cohort and older adult cohort

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
	(0.59 to 0.66)	(0.55 to 0.64)	(0.49 to 0.59)	(0.46 to 0.59)	(0.52 to 0.68)	(0.63 to 0.73)

CI confidence intervals; NSAID Non-Steroidal Anti-Inflammatory Drugs, PR prevalence ratio

The sensitivity analysis found that the prevalence of analgesic prescription in the five-year period from index date was similar for the dementia cohort and older adult cohort (76.7% vs. 79.0%, respectively, PR = 0.97, 95% CI 0.95 to 0.99). This finding is discordant to the main analysis that found that the dementia cohort had a lower prevalence of analgesic prescription (when matched to a musculoskeletal consultation) than the older adult cohort (49% vs. 60.1%, respectively, PR = 0.82, 95% CI 0.79 to 0.85). However, the sensitivity analysis continued to find a growing discrepancy between the dementia cohort and the older adult cohort in each annual period after index date (see Table 9.4), this trend reflects the findings of the main analysis (see Table 9.1).

The sensitivity analysis also found that the prevalence of basic analgesic prescription in the five-year period from index date was similar for the dementia cohort and older adult cohort (63.5% vs. 62.1%, respectively, PR = 1.02, 95% CI 0.99 to 1.05). The prevalence of basic analgesic prescription also remained relatively stable in each annual period from index date for the dementia cohort and older adult cohort. This contrasts the main analysis that found that the dementia cohort had a lower prevalence of basic analgesic prescription (when matched to a musculoskeletal consultation) than the older adult cohort (36.9% vs. 44.6%, respectively, PR = 0.83, 95% CI 0.79 to 0.87), with the prevalence of basic analgesic prescription incrementally lowering for the dementia cohort in each annual period (Table 9.1).

Inspection of the prevalence of weak analgesics, moderate analgesics, strong analgesics, and NSAIDs showed comparable trends to the main analysis. In both the main and sensitivity analyses, the dementia cohort had a lower prevalence of prescription during the five-year period from index date compared to the older adult cohort. Additionally, the dementia cohort had a generally lowering prevalence of weak analgesic, moderate analgesic, strong analgesic, and NSAID prescription in each annual period from index date in both the sensitivity and main analyses.

Additionally, the sensitivity analysis found that the prevalence of very strong analgesic prescription was similar for the dementia cohort and older adult cohort, in the five-year period

from index date (2.9% vs. 3.0%, respectively, PR = 0.96, 95% CI 0.78 to 1.19). Finally, the sensitivity analysis found a similar prevalence of very strong analgesics in each annual time period from index date to five years after index date (see Table 9.4). This finding is comparable to the main analysis (see Table 9.1).

9.2.1.1.1.4 Analgesic prescription in the one year before index date

The main analysis investigated analgesic prescription prevalence for the dementia cohort and older adult cohort, irrespective of their analgesic prescription before index date. In this sensitivity analysis further stratification examined if previous analgesic prescription was related to analgesic prescription during follow up (see Section 6.2.13.5.4). The dementia cohort and older adult cohort were stratified into two subgroups:

- People with no evidence of analgesic prescription during the one year before index date
- People with evidence of any analgesic prescription during the one year before index date

No evidence of analgesic prescription

The prevalence of analgesic prescription for members of the dementia cohort and older adult cohort with no evidence of analgesic prescription during the one year before index date steadily increased throughout follow up. However, similar to the non-stratified prevalence trends described earlier (see Table 9.1), the prevalence of analgesic prescription was lower for the dementia cohort than the older adult cohort (see Figure 9.3). When the analysis was stratified by analgesic category, the dementia cohort had a lower prevalence of all analgesic category prescriptions than the older adult cohort (with the exception of very strong analgesic prescriptions; see Appendix 13c).

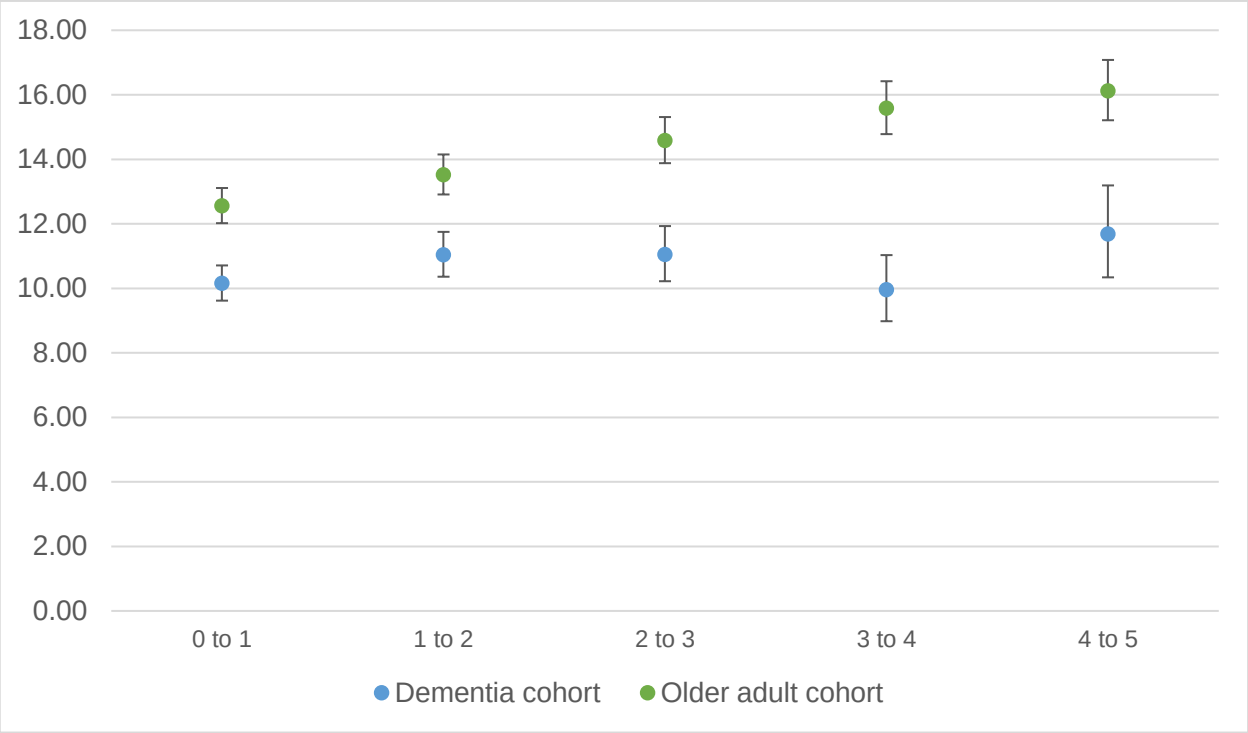


Figure 9.3. The prevalence of analgesic prescription for the dementia cohort and older adult cohort with no evidence of analgesic prescription during the one year before index date

Evidence of any analgesic prescription

The prevalence of analgesic prescription for members of the dementia cohort and older adult cohort with evidence of any analgesic prescription (irrespective of potency) during the one year before index date steadily decreased throughout follow up (see Figure 9.4). Again, the prevalence of analgesic prescription was lower for the dementia cohort than the older adult cohort, with the discrepancy between the cohorts growing over time.

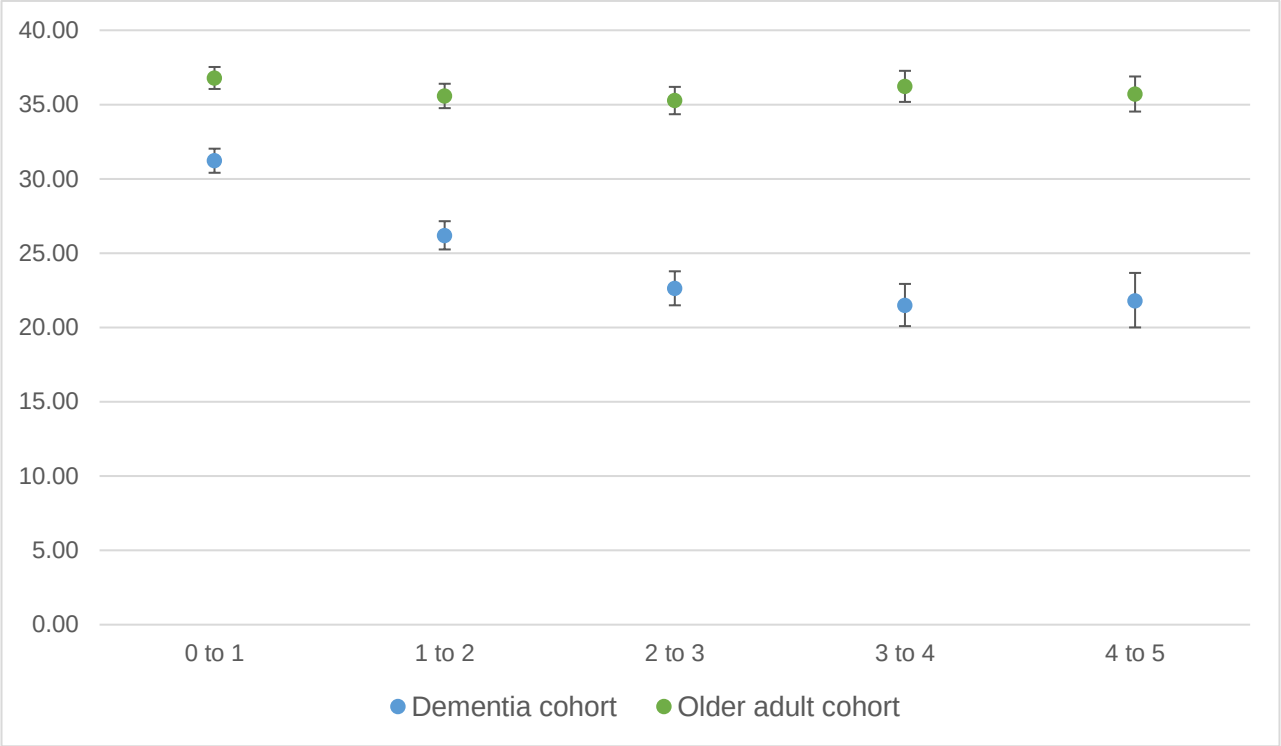


Figure 9.4. The prevalence of analgesic prescription for the dementia cohort and older adult cohort with evidence of any analgesic prescription during the one year before index date

When the analysis was stratified by analgesic category, the dementia cohort had a lower prevalence (again decreasing over time) of all analgesic category prescriptions than the older adult cohort, with the exception of very strong analgesic prescriptions (see Appendix 13c).

9.2.1.1.2 Conditional Logistic Regression

The previous section investigated the period prevalence of analgesic prescriptions for the dementia cohort and the older adult cohort. This section builds upon the period prevalence estimates by investigating the association between dementia and analgesic prescription, whilst controlling for potential confounders.

Associations were examined using univariate and multivariable conditional logistic regression analysis. An overview of conditional logistic regression is provided in Section 6.2.13.4.2. Univariate and multivariable conditional logistic regression analyses were conducted for the five-year time period from index date, and for each annual time period from index date to five years after index date.

Various assumptions of conditional logistic regression analyses were confirmed prior to modelling (see Table 6.9). The assumptions of little or no multicollinearity and linearity of independent variables and log odds were investigated for each multivariable model using the methods outlined in Table 6.9. Continuous covariates (with the exception of consultation frequency) violated the assumption of linearity of independent variables and log odds. Log and square root data transformations were performed with all continuous variables violating the assumption, however neither transformation was successful. All continuous covariates (other than consultation frequency) were categorised in which homogeneity within stratum was implicitly assumed (see Table 8.9) to overcome the violation. All reported models met the assumption of little to no evidence of multicollinearity (see Table 6.9).

Univariate conditional logistic regression models included cohort status as the predictor and evidence of analgesic prescription (yes/no) for each analgesic category as the outcome. Multivariable conditional logistic regression models included cohort status as the predictor. Baseline covariates also included; evidence of cardiovascular-related conditions (CVD), evidence of diabetes, evidence of depression, morbidity (BNF frequency), follow up (days), and consultation frequency. Evidence (yes/no) of analgesic prescription for each analgesic category was the outcome (see Table 9.5).

Table 9.5. Conditional logistic regression reporting odds ratio (OR) and adjusted OR for the dementia cohort compared to the older adult cohort: Analgesic prescription

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
OR (95% CI)	.84 (.80 to .87)	.76 (.72 to .80)	.67 (.63 to .71)	.60 (.55 to .65)	.66 (.59 to .74)	.84 (.78 to .90)
Adj OR (95% CI)	.85 (.81 to .89)	.76 (.71 to .80)	.68 (.63 to .74)	.61 (.55 to .67)	.63 (.56 to .72)	.82 (.76 to .88)
Basic Analgesic						
OR (95% CI)	.91 (.87 to .95)	.83 (.78 to .88)	.73 (.67 to .79)	.65 (.59 to .72)	.65 (.57 to .75)	.86 (.79 to .93)
Adj OR (95% CI)	.93 (.88 to .98)	.82 (.76 to .88)	.75 (.68 to .82)	.67 (.59 to .75)	.62 (.53 to .72)	.84 (.77 to .91)
Weak Analgesic						
OR (95% CI)	.79 (.74 to .85)	.70 (.63 to .77)	.60 (.53 to .69)	.52 (.44 to .62)	.62 (.50 to .76)	.75 (.67 to .84)
Adj OR (95% CI)	.79 (.72 to .86)	.72 (.64 to .81)	.62 (.53 to .71)	.55 (.45 to .67)	.65 (.51 to .83)	.75 (.66 to .84)
Moderate Analgesic						
OR (95% CI)	.74 (.67 to .81)	.79 (.69 to .90)	.67 (.56 to .80)	.47 (.37 to .59)	.77 (.56 to 1.03)	.74 (.63 to .87)
Adj OR (95% CI)	.78 (.69 to .88)	.76 (.65 to .90)	.67 (.54 to .83)	.46 (.35 to .62)	.68 (.48 to .96)	.72 (.60 to .87)
Strong Analgesic						
OR (95% CI)	.72 (.67 to .78)	.66 (.60 to .73)	.59 (.51 to .67)	.61 (.51 to .72)	.59 (.78 to .74)	.71 (.62 to .80)
Adj OR (95% CI)	.65 (.59 to .71)	.61 (.54 to .69)	.52 (.44 to .61)	.55 (.45 to .68)	.48 (.36 to .63)	.63 (.54 to .72)
Very Strong Analgesic						
OR (95% CI)	.96 (.76 to 1.21)	.75 (.56 to 1.00)	1.03 (.72 to 1.48)	.79 (.49 to 1.27)	.68 (.34 to 1.39)	.73 (.50 to 1.07)

Adj OR (95% CI)	.78 (.57 to 1.06)	.77 (.52 to 1.14)	1.01 (.59 to 1.73)	.47 (.21 to 1.05)	.36 (.09 to 1.53)	.57 (.33 to .98)
NSAIDs						
OR (95% CI)	.62 (.57 to .67)	.51 (.45 to .57)	.47 (.41 to .56)	.48 (.39 to .58)	.69 (.53 to .89)	.66 (.58 to .74)
Adj OR (95% CI)	.65 (.59 to .72)	.52 (.46 to .60)	.48 (.40 to .57)	.52 (.41 to .65)	.62 (.46 to .83)	.65 (.57 to .75)

OR Odds Ratio; Adj OR Adjusted Odds Ratio; NSAID Non-Steroidal Anti-Inflammatory Drugs; CI confidence interval

Adjusted for: evidence of cardiovascular-related conditions, evidence of diabetes, evidence of depression, morbidities (BNF), follow up (days), and consultation frequency. All analgesic prescriptions matched to musculoskeletal consultation.

During the five-year period from index date, the dementia cohort had 0.84 times lower odds of being prescribed analgesic medication than the older adult cohort during the five-year period (OR 0.84, 95% CI 0.78 to 0.90). The multivariable conditional logistic regression model identified minimal negative confounding (adjusted OR 0.82, 95% CI 0.76 to 0.88). When stratified by analgesic classification, the dementia cohort continued to have significantly lower odds of analgesic prescription compared to the older adult cohort, irrespective of classification, with the exception of very strong analgesics (see Table 9.5).

Analysis was also stratified into annual periods from index date to five years after index date. The odds of the analgesic prescription for the dementia cohort was significantly lower than the older adult cohort during the first year following the index date (adjusted OR 0.85, 95% CI 0.81 to 0.89). By the final year of follow up the odds of analgesic prescription for the dementia cohort was 0.63 times lower than the older adult cohort (adjusted OR 0.63, 95% CI 0.56 to 0.72). Adjusted OR were similar to crude OR, indicating minimal confounding. A similar trend was evident when the annual analysis was further stratified by analgesic classification. The odds, and adjusted odds of basic, weak, moderate, strong analgesic, or NSAID prescription were significantly lower for the dementia cohort compared to the older adult cohort during all annual periods (see Table 9.5), with the odds lowering (in general) as time from index date increased. The odds and adjusted odds of very strong analgesic prescription was lower for the dementia cohort than the older adult cohort during each annual period, however, the association was often non-significant.

9.2.1.1.2.1 Sensitivity analysis

A number of sensitivity analyses were conducted using conditional logistic regression to reflect previous sensitivity analyses (see Section 9.2.1.1.1). All sensitivity analyses reflected the key findings presented in the main analysis, and the sensitivity analysis presented previously (see Section 9.2.1.1.1) (see Appendix 13d).

9.3 Summary of quantitative findings

- The five-year prevalence of analgesic prescription was 11% lower for people with dementia compared to older adults without dementia (49% vs. 60%, respectively),
- The prevalence of basic analgesics was highest for the people with dementia and older adults without dementia (36.9%, 44.1%, respectively), followed by weak analgesics, strong analgesics, moderate analgesics, NSAIDs, and lastly, very strong opioids (1.6%, 1.9%, respectively). People with dementia had a consistent lower prevalence, and a consistent lower odds of analgesic prescription than older adults without dementia, with the exception of very strong analgesic prescriptions, which was shown to be more comparable between the people with and without dementia.
- Findings highlight a pattern of prevalence and odds over time from index date to five years after index date. The overall trend of analgesic prescription lowered with each additional year of follow up for people with dementia. Conversely, the overall trend remained relatively stable with each additional year of follow up for older adults without dementia.
- Sensitivity analysis including analgesic prescriptions not matched to a musculoskeletal consultation found a similar prevalence of any analgesic prescription, and basic analgesic prescription for the dementia cohort and older adult cohort. This finding was divergent from the main analysis. However, the dementia cohort continued to have a lower prevalence of weak analgesic, moderate analgesic, strong analgesic, and NSAID prescription than the older adult cohort, reflecting the main analysis.
- Additional sensitivity analyses were also conducted (including community, healthy cohort, and analgesic prescriptions during the one year prior to index date). The findings from the sensitivity analyses reflected those found in the main analysis, offering greater confidence in the findings.

9.4 Management of pain: Qualitative findings

To complement the quantitative findings presented above, qualitative data explored pain management strategies for people with dementia, to answer the second research objective, as outlined at the start of this chapter (see Section 9.1). This section of the chapter answered the following qualitative research questions:

- How do people with dementia, family caregivers, and healthcare professionals manage the pain experienced by community-dwelling people with dementia?
- How do people with dementia, family caregivers, and healthcare professionals perceive pain management strategies for community-dwelling people with dementia?

To answer these questions, interviews were conducted with people with dementia (*n*=8), family caregivers (*n*=9), GPs (*n*=9), and old age psychiatrists (*n*=5), and their perspectives integrated. Three key themes were identified:

- Non-drug management of pain
- Concerns related to analgesic medication
    - Side effects
    - Illness and treatment burden
    - Weighing up the concerns
- Responsibility of the caregiver to manage pain

9.4.1 Non-drug management of pain

This theme explores the non-drug strategies used to manage the pain experienced by people with dementia, and the perspectives of people with dementia, family caregivers, and healthcare professionals towards such strategies.

Many people with dementia and family caregivers used a variety of non-drug strategies in an attempt to alleviate pain. Some engaged with exercises recommended by a physiotherapist, or had regular physiotherapy sessions:

I mean I was already doing quite a few exercises (…) I know a fair few things to do myself without them [physiotherapists] telling me... A lot of the exercise I'm doing already… I'm doing them every morning… Even with the exercise they're [shoulders] slowly getting worse...

Greg, husband, person with dementia

Someone [physiotherapist] who we've very luckily found who comes 5 days a week (…) because of that, I personally feel, and I think mum does as well, that y'know dad's mobility- well we were amazed at the physio that he can y'know walk with one stick (…) but then there's a lot of 'oh me back hurts' and 'oh this hurts'

David, son, caregiver

People with dementia and family caregivers reflected upon the benefits of exercise for their pain, with David highlighting the improvement in his dad's (Richard, person with dementia) mobility, which he attributed to the regular physiotherapy sessions. Despite the perceived benefits of physiotherapy, exercises alone did not completely alleviate the pain experienced by the person with dementia, with some perceiving exercise to have short-term benefits. In accordance with people with dementia and family caregivers, GPs also considered the benefits of physiotherapy to improve the pain experienced by people with dementia:

Putting medicine aside for a minute y'know any exercises they can do, things they can do at home, elevating the joint, keeping active, physio referrals, making sure that we don't automatically just go to prescribing medication, because yes that's useful, but in the long term y'know keeping the joint active is much more beneficial than putting someone on co-codamol.

Amy, GP

the physio, and occupational therapy, they're definite things that I would consider, that I think they're useful alternatives, particularly if you think it's someone who's at high risk if you're going to give them opiates, or neuropathic pain killers...

Jessica, GP

Healthcare professionals commented upon the potential long-term benefits of exercise, especially for people with dementia. This contrasts the perspective of people with dementia whom reflected upon the limited long-term benefits for their pain. For healthcare professionals, the perceived long-term benefits of physiotherapy juxtaposed the short-term relief of analgesic medication. In addition to the long-term benefits of physiotherapy, non-drug strategies were perceived by GPs as useful alternatives to manage pain when reflecting upon their concerns related to analgesic medication for people with dementia (see Section 9.4.2). Although physiotherapy was regarded as important, healthcare professionals continued to reflect upon the lack of services in the community:

> *A lot of the pain is from more sedentary and less active lives that people with dementia in the community have, they would probably respond really well to physio, and- and y'know more movement and guided support with that. (…) but it's just not available (…) the services in the community just aren't there*

Mel, psychiatrist

Despite the support for physiotherapy to manage pain, some acknowledged the barriers to non-drug strategies, especially exercise, that required an element of self-management:

> *They [physiotherapist] gave me, urrr, urrr, [long pause] a card, or a- two or three- two page card with 'do these exercises'. Which I wasn't very good at following was I? I don't use them now, I should do. I should do. But I don't bother.*

James, husband, person with dementia

> *It can be difficult, and you do wonder if they're actually going to do it, I'll be honest... It can be difficult to convince people, um, and I think in the elderly particularly, that if I've got arthritis I shouldn't be using the joint, for example, that's still out there as a, sort a myth, it can be quite hard to overcome*

Lisa, GP

Some people with dementia did not persist with the exercises recommended by the physiotherapist. In accordance, GPs questioned 'adherence' to exercise, and the misconceptions held by older adults, including people with dementia, that may act as barriers to non-drug approaches. Persistence with non-drug strategies that required an element of self-management may rely upon input from family caregivers in the community (see Section 9.4.3).

Aside from exercise, many participants supported the use and reflected upon the benefits of regular massage to manage pain:

> *David: Definitely massage, and no matter what it [the problem] is, that always helps*
>
> *Richard: I don't think it does any harm, I think it helped...*

Richard (person with dementia) and David (son, caregiver)

> *I massage his feet with, um... sort of- body lotion every morning, um... and I check if there's any ulc- any open wounds, which is what you've got to be careful of... because there's some neuropathy in his feet, which I didn't realise before*

Carol, wife, caregiver

> *Other things that can be really helpful that I suggest often is massage. If it's sort of neck pain, shoulder pain, if it's very tense and tight (…) some gentle massage techniques...*

Lisa, GP

Massage involved minimal risk or harm for the person with dementia (in antithesis to perceptions of analgesic treatment; see Section 9.4.2) and could be easily completed by the family caregiver. Although massage was primarily perceived as a pain management strategy, Carol also used massage as an opportunity to proactively examine her husband's feet for potential indications of pain (see Section 8.4.1.2). In addition to massage, many family

caregivers reflected upon other at-home non-drug strategies to provide comfort and warmth when the person with dementia was experiencing pain:

> *She always has a hot water bottle at night, so she's always warm and comfortable, and all of that helps, y'see. From my point of view, that's what we do... common sense really, isn't it?*
>
> Brenda, daughter, caregiver

> Denise: *There's the old wheaty bag*
>
> Greg: *Those are good (…) I use it for my neck, my shoulder, I've even put it on my elbow before now (…) Helps my neck, definitely...*
>
> Greg (husband, person with dementia) and Denise (wife, family caregiver)

Non-drug treatments that provided comfort and warmth, and could be completed easily at-home were perceived as beneficial by people with dementia and family caregivers. In many circumstances, family caregivers prompted the person with dementia to engage with non-drug approaches when experiencing pain (see Section 9.4.3), with family caregivers perceiving warmth, comfort, and relaxation as 'common sense' strategies to manage pain for the person with dementia.

In addition to the strategies outlined above, people with dementia, family caregivers, and a small number of GPs discussed the importance of distraction techniques to cope with pain:

> *Well, you can forget it sometimes if you're chatting, or doing something, ya know? You're not worrying all of the time [pause] it's just there. I just put up with it. Sometimes if I am walking about doing something else, I forget that the pain is there.*
>
> Patricia, wife, person with dementia

> *We do- do we do word games together and we do cross words together, we do... urm... All sorts of, mainly word puzzles, urm... things together (…) I have found actually that by distracting her with a cross word... urm... y'know, just something other*

than just sitting in the chair suffering. (…) If she can concentrate on cross word clues being shouted at her (...) that will distract her from the pain. Doesn't necessarily mean that the pain has gone... just means that we're both coping better with it

John, husband, caregiver

Or distraction techniques, y'know? Rather than focusing on the pain, trying to go off and do something like listen to the radio, watch the television, have something else going on, or get out into the garden and potter about, and do a few odd jobs, and things like that.

Lisa, GP

Although distraction did not directly alleviate the pain, people with dementia seemed to cope better when their attention was re-directed away from their painful experience. For example, Patricia suggested that distraction helped her to forget about her pain, despite experiencing persistent moderate pain due to her spinal injury (five out of 10 on the IPT; see Table 7.7). This perspective was reiterated by family caregivers and Lisa (GP) who also acknowledged distraction as a method to avoid 'focusing on the pain', helping people with dementia to cope with their pain.

In addition to the many non-drug strategies already discussed (including exercise, massage, warmth and comfort strategies, and distraction), a minority of family caregivers voiced their perspective towards pain management strategies often classified as 'alternative' and 'complementary':

we've tended to go down the alternative medicine route (…) mum's a great one with the turmeric thing, and she's convinced that's working but urm I don't know whether it is or not

David, son, caregiver

I mean, we've thrown money at it… An acupuncturist was recommended to us… Well I mean people have mentioned mindfulness (...) some of it just sounds rather mad

> *new age stuff to me (…) you might regard them as quackery. What's the other one? Oh yes, we've got a pot of (…) aloe vera cream which she quite likes, I mean I don't know how effective it is, but she quite likes that, so I'll- I'll put that on her temples.*
>
> John, husband, caregiver

In an attempt to alleviate pain, a minority of family caregivers reflected upon a variety of complementary and alternative treatments, such as acupuncture, Indian head massages, facial massages, mindfulness, aromatherapy, and turmeric. Although some were completed at-home (e.g. facial massage and turmeric) most were completed by specialised services (such as acupuncture and Indian head massages). Despite trying many strategies, family caregivers seemed uncertain and sceptical of their usefulness for pain; with John describing alternative treatments as *'mad new age stuff'.* Many of the alternative treatments tried by John and Barbara (John's wife with dementia) were unavailable on the NHS, therefore having financial implications. John's willingness to '*throw money*' at alternative treatments that he was sceptical towards may illuminate John's desperation to identify an effective way to alleviate Barbara's severe pain (see Table 7.7), which she was reluctant to manage using analgesic medication (see Section 9.4.2).

Aside from family caregivers, GPs also reflected upon alternative and complementary treatments for pain experienced by people with dementia:

> *The reality is, unless- and there are- there are a few people who do have ur... Reiki, is it called? (…) Some will try acupuncture, and that works for some and not for others, some try hand massage, what the hell is a hand massage? (…) y'know I think these things are very nice, but I think they're an added extra by enlarge. I don't have access to them, they don't normally come into my- my cognisance when I'm thinking about these things. (…) If you're backed into a corner, and you're desperate, and you're in pain 24/7, you'll- you'll- you'll try anything (…) so I get why they're doing it, but in terms of part of the repertoire of- of treatment of the management pain- it wouldn't come into my mind...*

Alan, GP

> *In terms of other things like- there's a whole host of other complementary medicines… I generally don't offer them... Generally, I don't suggest them... I guess on occasion I have, but I generally don't suggest them (…) but my personal perspective I support it, I say yea, you can try it...*

Ishann, GP

> *suppose it's- it's not going to do them any harm, is it? So if it was something that they independently wanted to explore, um... it's not something that I have actively suggested*

Jessica, GP

Despite GPs' positive regard towards other non-drug strategies for pain (as discussed earlier in this theme), GPs did not regularly recommend complementary or alternative treatments for pain. In accordance with family caregivers, GPs were sceptical of alternative and complementary strategies, with many being perceived as an added extra, rather than a treatment option in isolation. Although many GPs were sceptical, they often seemed empathetic to their patient's desperation to identify an effective strategy to alleviate their pain. Therefore, although GPs often did not recommend alternative and complementary strategies, they continued to support their patient's wish to try a variety of treatment options as they were 'unlikely to cause harm'.

A number of GPs continued to discuss reasons why they felt unable to recommend alternative and complementary treatments to people with dementia for their pain:

> *We never... as doctors we can't prescribe those things, because they're not necessarily accessible on the NHS (…) It's just difficult to access them sometimes. The other thing is the cost implications, so people do go for alternative therapies, whatever that might be, there is a cost implication so... it's often deemed a bit unethical to tell patients 'you must have this' knowing that it's going to cost them £30*

a go. (…) I think as practitioners you have to practice evidence based medicine, so if there's not robust support for these things, then it's difficult.

Jenny, GP

There's lots of things about lavender, for example, or like aromatherapy, music, so there's loads of other things, that the whole- I mean none of them are conclusive as such (…) there's enough evidence to say that if not fully helping with the full symptom aetiology, they definitely help with the wellbeing, and overall wellness if you like...

Prisha, psychiatrist

Many non-drug treatments were not available on the NHS, and therefore GPs' were wary to recommend treatments with limited accessibility. Recommending non-drug treatments that were not available on the NHS had the potential for negative financial burden, as reflected earlier by family caregivers. Additionally, healthcare professionals reiterated the importance of practicing evidence-based medicine. Therefore, treatments without a large scientific evidence base may not be recommended for people with dementia, despite their potential to improve 'overall wellness'. These findings may provide explanation as to why exercise was viewed in higher regard by GPs than alternative and complementary treatments.

In addition to the *type* of non-drug strategy, healthcare professionals considered the *timing* and 'place' (i.e. appropriateness) of non-drug strategies to manage pain. Many GPs reflected upon the importance of recommending non-drug strategies for pain before initiating analgesic medication:

In terms of non-pharmacological management, I think that's really important (…) and that's something (…) I like to think before prescribing anything for this patient with dementia (…) if there is any non-pharmacological things that we can do that means that they potentially save them from being prescribed something (…) that's really, really important

Ishann, GP

> *I would always try non-pharmacological as much as I could... urm... urm... because, because once you get into the prescribing habits, urm... it just- the habit of prescribing things, it just does become a bit complicated...*
>
> Chris, GP

Many GPs viewed non-drug strategies as the first-line treatment for pain in people with dementia. By employing non-drug strategies, pharmacological burden may be minimised. If non-drug approaches are not sufficient in isolation, GPs seemed to consider a dual approach to pain treatment using both non-drug and drug approaches:

> *you always, before- before you go to pharmacology you must always do your non-pharmacological things first, y'know it's very, very important. You must, y'know prior, but y'know if that doesn't work, you may have to use a combination of that- with um pharmacology.*
>
> Tom, GP

Alternatively, psychiatrists often supported the use of non-drug approaches for people with dementia, however unlike GPs, non-drug strategies were viewed as a holistic approach to manage behavioural and psychological symptoms, rather than specific for pain:

> *the management plan would be quite... kind of urm... could be multi-targeted, and pain would be one of them (…) I don't y'know... think about pain management as such... for my patients with dementia, I don't think about it separately...*
>
> Hayma, psychiatrist

> *We often don't, urm, y'know delve that much into it... it's more of a holistic type of thing... (…) We don't specifically suggest any non-pharmacological for the pain, I think it would be non-pharmacological for BPS [behavioural and psychological symptoms] really. (…) What we tend to do is offer this non-pharmacological for a range of thing, not specifically for the pain if you like...*

Prisha, psychiatrist

Pain was perceived as a potential driver contributing to behavioural and psychological symptoms (see Section 8.4.1.2) that may be managed using non-drug strategies. However, psychiatrists did not use non-drug strategies to manage pain directly. In line with this perspective, some healthcare professionals questioned the appropriateness of non-drug treatments depending upon the severity of the pain experienced by the person with dementia:

> *But if somebody is in a lot of pain, then that's [non-drug treatments] not really going to relate to them at all... they're not gonna, not gonna hear that, I think*

Lisa, GP

> *If there is a pain, non-pharmacological... there's no place for that. If they're genuinely in pain, if they're in pain you can't really just ask them to do things while they're suffering. Control the pain first and then do whatever- or give any advice about non-pharmacological (…) otherwise they won't enjoy, or they won't participate*

Rani, psychiatrist

Healthcare professionals again reflected upon the idea of 'genuine' pain, highlighting the subjectivity and the challenge of disentangling the pain experienced by people with dementia (see Section 8.4.1.1). If a person with dementia was perceived to be experiencing a lot of pain, some healthcare professionals viewed non-drug strategies as potentially inappropriate as a first-line treatment.

9.4.2 Concerns related to analgesic medication

This theme explores the concerns of people with dementia, family caregivers, and healthcare professionals relating to analgesic medication for people with dementia. Old age psychiatrists did not perceive their role to involve analgesic medication (*'If it is pain killer, if it is analgesic, it's the GP'* Hayma, psychiatrist) and therefore their perspective often did not contribute to this theme.

Some people with dementia and family caregivers voiced no explicit concerns towards analgesic medications, with some even being open to their use and benefits for the pain experienced by people with dementia:

> *So [she] now wears a morphine patch and that has helped a lot. It is quite strong and all of that sort of thing and oh, that was it, urm, and she continued with that ever since. So it has helped. (…) I can see that there was a change once she had started and had– had- been on it for a little while, that she was a bit more comfortable with the pain, if that makes sense?*
>
> Robert, husband, family caregiver

> *I just take the pills... I've got no problem with anything to do with the pills, if the pills are going to help I take the pills, same for Mark really*
>
> Brenda, wife, caregiver

The benefits of analgesic medication for the person with dementia was determined by the family caregiver observing changes in their behaviour (see Section 8.4.1.2). Family caregiver's perspectives towards analgesic medication was particularly important as they were often in control of prompting the use of analgesic medication for their relative with dementia (see Section 9.4.3). Brenda's positive perspective towards analgesic medication may reflect her previous employment as a palliative care nurse. She perceived the knowledge, training, and experience of pain management gained during her career as '*a transfer of skills*' when caring for her husband (Mark, person with dementia) and mother with dementia.

The positive perspective towards analgesic medication was, however, over shadowed by the many people with dementia that were explicitly reluctant to use analgesic medications for their pain due to their concerns:

I hate taking tablets at the best of times, so I've got to be getting pretty bad before I'll take them… I've got an aversion to taking poisons... Every tablet is a poison of some kind

Greg, husband, person with dementia

I'll get a sudden lock, but it is painful... Urm...Sometimes I will get that in my legs as well they will lock, and that's painful, but like... as far as taking pain killers to sort of deal with things like that, I tend to shrug that off...

Steven, husband, person with dementia

Many people with dementia voiced their concerns towards analgesic medications, with the perception that analgesic medication was a last resort treatment for pain. Steven's reluctance to use analgesic medication appears to stem from his stoical attitude towards pain, especially when he perceived pain to be short lived or transient. In the previous chapter, the impact of stoicism upon pain assessment was discussed (see Section 8.4.1.1), with this further indicating that a stoical attitude may increase reluctance to take analgesics.

9.4.2.1 Side effects

In accordance with people with dementia, a number of family caregivers also seemed reluctant for the person with dementia to take analgesic medication. This reluctance was often linked to their concerns related to potential side effects:

I'm not a tablet person, I don't want people to give us medication, y'know? You'd probably get worse from the side effects of it!

Mary, wife, caregiver

We manage without it [analgesic medication]. I'm not very keen on him taking a lot of pain killers, I think sometimes you're just adding on another problem, urm, I dare say the stuff the doctor could give him, but I dunno… [Sigh] You've got to be careful of some of this stuff.

Carol, wife, caregiver

Many family caregivers reflected upon the side effects associated with analgesic medications. Carol's concerns were illuminated as she only prompted William (husband, person with dementia) to take analgesic medication if she *'really can't avoid him walking'.* William has arthritis in his knees, which triggers pain during impact. Therefore, to minimise the pain experience (and ultimately William's use of analgesic medications) William regularly used a wheelchair to avoid pain. This highlighted the extent that herself and William were willing to stretch to alleviate pain, without using analgesic medication.

In line with family caregivers, GPs were also concerned about the side effects associated with analgesic medication for people with dementia. Therefore, when deciding what analgesic to prescribe to the person with dementia, all GPs noted a preference for simple analgesic medications:

> *This is KISS, you know KISS? Keep It Simple, Stupid. Keep it simple, and go for the what- y'know there's an old adage in medicine, if you can't do any good, don't do any harm. The potential to do harm... particularly for this group... you've this group of patients that are particularly susceptible to side effects of certain drugs so you have to be careful, so you go with a drug which is the simplest... with the lowest side effect profile, and the staple one is paracetamol...*

Alan, GP

GPs considered the importance of avoiding analgesic medications that would cause side effects for the person with dementia. For this reason, paracetamol was preferred due to the good safety profile, thereby minimising the risk of side effects. Despite the preference towards simple analgesics (such as paracetamol) for this reason, some participants reflected upon the limited efficacy of paracetamol:

she takes paracetamol, she probably has one or two doses a day, which um... I think given the amount of pain, doesn't help a lot... She would need to be taking more than that, I think to- to cope with the pain...

Charles, husband, family caregiver

That's almost like going through the motions, 'cause she doesn't believe they [pain killers] work. I mean we both regard ordinary paracetamol as- as sweets to be honest… that that- doesn't cut the mustard.

John, husband, caregiver

If the simple measures deal with the problem, y'know like rubbing gels and things like that, absolutely fine, but I think it depends on the- on the type of pain, if there's- if there's significant pain from a significant problem... y'know it depends what the pain is, doesn't it?

Jenny, GP

Some family caregivers and GPs suggested that paracetamol was insufficient to provide pain relief, depending upon the severity of the pain experienced by the person with dementia. The perceived inefficacy of paracetamol was illuminated by John using a metaphor to compare the effectiveness of paracetamol to that of sweets (i.e. useless). Additionally, unlike all other GPs interviewed, that largely viewed paracetamol as a risk-free analgesic choice, Jessica also reflected upon her concerns related to the side effects associated with paracetamol:

I'd start with paracetamol, as... as long as I checked their weight because there is the risk if they're low weight of overdosing them if you give them the wrong dose

Jessica, GP

When reflecting upon alternative analgesics (other than paracetamol), such as NSAIDs and opioid medications, all interviewed GPs discussed their concerns of side effects:

> *Would you go for... non-steroidal anti-inflammatories? (…) They cause your stomach to bleed, they impair your renal function, they probably cause some electrolyte urm... disturbance, you need other medication to take with them so that you don't get a gastric ulceration. Urm... And particularly in the elderly, y'know you- y'know you're not asking for trouble, but it's a well-recognised fact that these people get into trouble with nonsteroidal anti-inflammatories.*
>
> Alan, GP

> *side effects in patients with dementia (…) they're more susceptible to any potential problems such as psychosis, with the opioids, urm... and y'know things like, constipation which might sound like a mild symptom, can actually end up progressing and causing significant problems*
>
> Amy, GP

Many GPs discussed the side effects associated with NSAIDs and opioid medications that are common for older adults, with the presence of dementia being perceived as an additional risk factor when considering the risk of side effects (e.g. opioid medications may exacerbate confusion for people with dementia). The concerns related to analgesic side effects may contribute to pain being undertreated for people with dementia:

> *opiate medication (…) can cause constipation and confusion and that can exacerbate dementia (…) it does worry me sometimes that y'know that maybe as a result of that, that we do under treat people's pain, but having said that, we're often told that we're over treating people's pain anyway, with all these opiates, and use of NSAIDs, so... y'know so you end up between a rock and a hard place really...*
>
> Chris, GP

The under treatment of pain for people with dementia was, however, in contention with the need to reduce NSAID and opioid prescribing in primary care.

9.4.2.2 Illness and treatment burden

In addition to the concerns of side effects, an additional expressed concern was the illness and treatment burden experienced by people with dementia:

> *He can only take paracetamol 'cause he's on warfarin he's very limited as to what other drugs he can take... He can't take things like ibuprofen... um... or aspirin...*
>
> Carol, wife, caregiver

> *if you're taking medication for urm... y'know for memory problems, taking them- it for gout, and thing and another, suddenly have another load of pills thrust at you, plus y'know paracetamol (…) Goodness knows what all of these other things will have an effe- y'know sort of an effect, y'know on...*
>
> David, son, caregiver

Comorbid conditions and their associated treatments may mean that certain analgesic medications were not appropriate, with Carol illuminating that her husband's heart condition limited the number of appropriate analgesic medications for his pain. Family caregivers were concerned about the effects of taking numerous medications for different health conditions.

In addition to potential contraindications, the sheer number of medications already being taken by the person with dementia may increase concerns and reluctance to take analgesic medication:

> *she's got... quite a lot of drugs to take so she doesn't really want extra...*
>
> John, husband, caregiver

> *He's on 10 tablets a day anyway, for his various conditions, so pain killers are over and above...*
>
> Denise, wife, caregiver

> Brenda: *You don't like taking extra pills, as you've got enough to take as you say...*

Mark: *That's right...*

Brenda: *He's got four boxes. So taking extra pills is a pain, isn't it really?* (…) *You got so frustrated with your pills, throw them all, threw the boxes, 'I don't want any more bloody medication' [imitating Mark] (…) so in terms of actually adding any more in... I don't know how much suffering you'd have to do for that to happen! We'd might have to look and see is there something we could lose?*

Mark (husband, person with dementia) and Brenda (wife, caregiver)

Many people with dementia had numerous conditions, including but not limited to their dementia diagnosis and their painful conditions. The treatment burden of taking numerous daily medications increased reluctance to add additional analgesics into their already extensive medication regimen. The number of medications being taken by many people with dementia had reached maximum capacity, meaning that a medication must be removed before an analgesic could be added. For many people with dementia, their pain was not perceived sufficient to warrant an analgesic medication replacing a different medication. This again may highlight that pain is perceived as a lower priority compared to other health conditions requiring medication (see Section 8.4.1.1).

In line with people with dementia and family caregivers, some GPs were also concerned about the number of comorbidities, and thus the amount of medications being taken by the person with dementia:

Often these people in the community with dementia are older adults, with other comorbidities, and then it may be vascular dementia as well, so if- if they have a history of heart problems, or a history of stomach ulcers, or bleeds in the gut, or if they have vascular dementia, we want to avoid anti-inflammatories, because they're not safe for those groups...

Jessica, GP

Before prescribing analgesic medication, GPs considered the potential contraindications with comorbidities and other medications. This was especially important for older adults who may

have many morbidities, and thus taking many different medications. The concerns when prescribing analgesic medications was further intensified for people with dementia, who were perceived to have additional risk factors (i.e. people with vascular dementia) above and beyond ageing alone.

9.4.2.3 Weighing up the concerns

People with dementia, family caregivers, and GPs had many concerns related to analgesic medications, including side effects, illness burden, and treatment burden, each of which contributed to a reluctance for people with dementia to take analgesics. To minimise and assess concerns, many GPs titrated up the strength of the analgesic medication:

> *What we want to do, is use the- is the minimum dose and minimum frequency that controls their pain, and it doesn't have to be completely gone, but sufficiently, that they're happy with that level of pain*
>
> Chris, GP

> *when it comes to prescribing it will be starting off at a very, very low dose, and then titrating, but slowly (…) because we know that there's more chance of side effects in patients with dementia*
>
> Amy, GP

> *First of all, paracetamol. Then you could consider moving up the analgesic ladder with caution really, because many of these patients... don't y'know don't tolerate, or they don't do well with opiates*
>
> Tom, GP

Upwards titration allowed GPs to identify the minimum possible analgesic medication that provided sufficient comfort for the person with dementia, while assessing for potential side effects. This process often meant that analgesic treatment started with paracetamol. Earlier in this theme, paracetamol was the preferred treatment option (due to its good safety profile).

However, many also noted that paracetamol was not always sufficient to provide adequate pain relief depending upon the severity of pain. In these circumstances, it was important for GPs to consider '*moving up the analgesic ladder with caution'* even amid the many concerns. Therefore, when prescribing NSAIDs or opioids, GPs often weighed up their concerns associated with each medication:

> *I think most things have an element of 'well I've got to do something, and I hope it's going to be okay' and it's really a risk benefit analysis that you make at that point really... and... the reality is, y'know if you're 88 and you're in pain, you have to do- you have to do something about that pain for the person, because even if it limits their life expectancy, or reduce- or reduces the life expectancy, you've still got to manage the pain. Sometimes you have to try these things… and say look, this is probably the best thing you can offer them, and there's still a risk associated with it, but shall we go for this, because we can't leave them like that...*
>
> Lisa, GP

> *you keep going until you feel you've got the best situation... y'know, because you don't want people- you've got to balance things up, a lot of medication we use for pain is quite... bad for the elderly in lots of ways, so... it's risk, benefit, harm, and all the rest of it*
>
> Jenny, GP

To identify the most suitable analgesic treatment, GPs weighed up and evaluated the pros and cons of each analgesic medication, in a 'risk benefit analysis'. GPs often viewed it as their professional responsibility to identify a suitable medication to provide pain relief to the person with dementia. To fully evaluate the effect of the analgesic medication, GPs often attempted a trial:

> *We would talk about the risks and benefits, and there's- it's not an absolute contraindication to give it to them, urm... so it's- it could be worth a small trial, but you*

have to make clear that it does come with some possible side effects, and then just keep observing how they go, it can get difficult sometimes

Muhammed, GP

But again, the pharmacology is very, very challenging because you know compliance, side effects, tolerance, and drug interactions, and opiate sensitivity, and allergies etc. So the whole pharmacological management it's extremely challenging, it's often trial and error

Tom, GP

GPs avoided medications with an absolute contraindication, yet acknowledged that many analgesics have their own specific concerns that require consideration. A trial of analgesic medication allowed investigation to see if the advantages (potential pain relief) out-weighed the potential disadvantages (concerns such as side effects and interactions with other medications). This method allowed GPs to try to identify the 'most appropriate' analgesic medication which the patient found tolerable, whilst monitoring for side effects and other related concerns. Despite efforts to identify the 'most appropriate' analgesic, the many concerns associated with analgesics contributed to GPs' sense of having 'limited' treatment options:

So you really are... trying to tailor analgesia for somebody who's y'know... maybe got a million and one things that you can't give, and that can be really, you can be quite boxed in quite quickly

Lisa, GP

you go round and round and round (…) you're really, really limited y'know [what you] can you go on to...

Alan, GP

The challenge of weighing up and determining the most suitable analgesic medication, among the 'limited' treatment options, may impede GPs' confidence when prescribing analgesics to people with dementia:

> *I think it's- it's [analgesic treatment] definitely much more challenging than in patients without dementia... urm... I think (…) so I'd say I'm less confident in- in managing patients with, ur... with pain and dementia then managing patients with pain in general...*
>
> Ishann, GP

> *Pain management is complex, in whatever field, but when you add complications like dementia into it, I think it becomes quite specialised, actually (…) I think their pain is often under treated because people are scared of making the situation worse*
>
> Jenny, GP

The multifactorial concerns inherent in analgesic medication were intensified by the presence of dementia. GPs suspected that concerns associated with analgesic medications contributed to the under treatment of pain for people with dementia, due to the fear of 'doing more harm than good'.

9.4.3 Responsibility of the caregiver to manage pain

This theme captured the responsibility for family caregivers to manage analgesic medications and non-drug strategies for the pain experienced by the person with dementia in the community. Firstly, the role of family caregivers to prompt analgesic medication use was highlighted:

> *I mean occasionally she'll ask for a pain killer, but, ur I'm offering her pain killers before she asks for them… I don't think she'd ever ask. Honestly don't think she'd ever ask.*
>
> John, husband, caregiver

My mother wouldn't automatically reach for medication (…) she doesn't instinctively, like she used to, actually think how do I solve the problem? She can't solve the problem... She- she wouldn't know what to do, she wouldn't reach for the paracetamol, she wouldn't instinctively get the gel to put- put on her foot, five years ago that would have been a logical thing to do

Brenda, daughter, caregiver

If it's just a one off 'oh' [wince, pain noise] I tend to ignore that, but if he does it again, then I say have some paracetamol and then- sometimes I have to get up and get the paracetamol or the ibuprofen for him 'cause he won't, I have to make him take them...

Michelle, wife, caregiver

The person with dementia may have difficulty recognising or fulfilling their need for pain relief. Therefore, family caregivers were responsible to observe and determine if the person with dementia required pain relief, and if so, prompt the person with dementia to take analgesic medication. This was particularly highlighted by Michelle who vigilantly observed Steven to identify behaviours that may be indicative of pain (see 8.4.1.2).

In accordance, GPs considered the benefits of family caregivers to prompt analgesic use for people with dementia in the community:

they're not going to remember when they last took it (…) If they have someone to prompt to give them the medications, you would be a bit more reassured

Amy, GP

there's always that nagging feeling that (…) the medications that you've prescribed despite telling- discussing y'know it's still not done right, you can never be 100% sure, unless of course they've got a relative who's going to do whatever you've prescribed for them... in which case you're sort of onto a bit more of a winner.

Chris, GP

> *So you have to sort of, give permission for the caregiver to take on that role almost, to initiate those things, and maybe say 'do you want some paracetamol?' 'are you in pain?' and sort of ask, rather than... 'hasn't asked for any therefore doesn't need any'*
>
> Jenny, GP

Most GPs reflected that analgesic medications may not be used as recommended. The memory of the person with dementia may impede their ability to remember to take regular analgesic medications. GPs identified the presence of a family caregiver as reassuring; relying upon family caregivers to proactively identify pain and prompt analgesic use in the community. In accordance with this, many GPs considered the care and support provided to the person with dementia when deciding upon the analgesic regimen:

> *you'd have to think about delivery, because it's okay me saying you have two of these four times a day, but if there isn't going to be somebody there four times a day, there's no point, so you would see if you could give long acting drugs or... or skin y'know or... y'know... patches. you'd have to... tailor it, so if it was somebody who for example lived with their daughter, who responded well to two paracetamol twice a day or three times a day, you'd leave it to that, because if they live with them then they- they- they- they- can do it.*
>
> Alan, GP

The analgesic regimen was tailored depending upon the extent and regularity of support and care provided to the person with dementia in the community. Longer lasting analgesic preparations may be considered if the person with dementia had less input from caregivers. When tailoring an analgesic regimen based upon the extent and regularity of support from family caregivers, the responsibility of analgesic management shifts from the GP to the family caregiver in the community. GP's reliance upon family caregivers was heightened when reflecting upon strong analgesic medication for people with dementia:

So it depends who they're with, who's going to be able to help them (…) say there's Oramorph [opioid analgesic medication] in the house, you've got to make damn sure there's someone there can administer it appropriately, who understands how much, how regularly, what to do if there's a problem, what to do if it's not working, etc, etc. So that can be difficult.

Lisa, GP

GPs reflected upon their role to ensure safe prescribing. GPs' concerns relating to the prescription of strong analgesic medication (as discussed in Section 9.4.2) seemed to be amplified if a family caregiver (or other support) was not present to prompt correct analgesic use. To aid the administration and prompting of analgesic medication in the community, a number of family caregivers and GPs reflected positively upon compliance aids:

It's a god send, it really is a god send [referring to the automatic pill dispenser].

Brenda, wife, caregiver

People really like blister packs for that reason, because they almost feel that the responsibility is taken from them then, they're not the person who's going to have to dole it out, and get it wrong, potentially, and cause problems. So, for that reason really, I try to stick to stuff that can be blister packed, or managed in an acceptable way.

Lisa, GP

Family caregivers and GPs viewed compliance aids as beneficial to minimise the responsibility for family caregivers to manage analgesic medications for the person with dementia. In particular, compliance aids ensured that the correct medication was easily prompted by family caregivers. Although a structured analgesic regimen reduces the

responsibility for family caregivers to initiate treatment, this strategy minimises the flexibility of 'as-required' analgesic treatment:

> *They may have these dosette boxes, they may be given medication by their carers, and then it becomes tricky, because you have to prescribe a given amount. It has to be x so many times a day (…) you can't say, well if you don't need them, then don't take them... (…) because then you sort of say, 'oh well, you're the carer, you can tell when they're in pain', and they say 'well I'm not clinical, it's not my job'*
>
> Chris, GP

Chris highlighted the shift of responsibility to the family caregiver to assess pain and determine when the person with dementia needed more or less analgesic medication. However, he continued to reflect upon family caregiver's resistance to be responsible for analgesic administration. Responsibility for analgesic treatment may be burdensome for family caregivers, especially when they have no previous knowledge or experience in pain management. Despite the potential burden, some family caregivers also discussed their wish to be in control of analgesic medications:

> *She's almost completely dependent upon me now... um... which- which is actually a bit of a relief to me, because she- she wouldn't let me do that, until relatively recently (...) we've had to be much more, what's the word? Over seeing... how she's dealing with her medications now... she generally allows me to do that now, which she resisted for a long, long time...*
>
> Charles, husband, caregiver

Despite resistance, Charles manages Linda's (wife, person with dementia) medications. The potential risk of overdose was a pressing concern for Charles, as Linda had recently accidently overdosed on '*some particularly nasty tablets'*. The risks associated with analgesic medications in conjunction with the symptoms of dementia (i.e. memory problems leading to

incorrectly taking medications) means that despite the potential burden of pain management, family caregivers may be relieved to take responsibility of analgesic use.

In addition to prompting analgesic medication in the community, GPs also relied upon family caregivers to monitor and feedback to the GP:

> *So I would say that would be the- the biggest- the biggest problem, there's nobody to monitor it, and there's nobody to feedback to us, whether the patient is improving, if they're taking their medication, if they're not taking their medication, it's sort of, cast to the individual patient, which is a bit unfair, or y'know, falls to the relatives.*
>
> Alan, GP

> *Give safety netting advice to the carers so they can... contact us if they're concerned, if they're getting bad side effects from the treatment...*
>
> Jessica, GP

GPs often relied upon family caregivers to monitor the effectiveness and potential side effects of analgesic treatment for the person with dementia. The responsibility placed upon family caregivers to manage analgesic medications for people with dementia was, again, perceived as burdensome or ‘unfair’, however, many GPs felt unable to adequately monitor analgesic medications themselves:

> *it would be nice to follow up a lot more patients really, but we just don't have the capacity really (…) I suppose in an ideal world, we would follow up everyone and have the time to do that, but sometimes we don't...*
>
> Chris, GP

the other big, big challenge is actually, the time to keep an eye on it... to monitor it... because other stuff will roll in, other acute things that take your eye off- you might want to go back and see Joe Blogs 10 days later, but you may not be able to...

Lisa, GP

The time-limited nature of primary care meant that GPs felt unable to follow up, or monitor analgesic medications prescribed to people with dementia. Therefore, the responsibility of pain management, including monitoring and feedback was shifted to the family caregivers in the community.

In addition to managing analgesic use for the person with dementia, the family caregiver was often responsible to manage non-drug pain management strategies as often seen in Section 9.4.1.

Brenda: *I got one of those heat- wheat bags… put it in the microwave, popped you back into bed and you put that on your cheek, and you found that was quite helpful*

Mark: *Yea... That's right.*

Brenda (wife, caregiver) and Mark (person with dementia)

Michelle: *it's really good... a bowl of water, put your feet in*

Steven: *That again is something that would be offered, rather than I'd do myself*

Michelle: *Yes, I'd suggest it, and I would say do it! It will help!*

Michelle (wife, caregiver), and Steven (person with dementia)

Family caregivers were often proactive, prompting and encouraging the person with dementia to engage with various non-drug comfort strategies for their pain. Although many family caregivers did not express any burden when prompting non-drug strategies, some continued to highlight the impact of this responsibility:

> *But y'know, this is another example of her helplessness, it- she can't do it herself, therefore I have to do it for her (…) that's the nature of- of living with someone with dementia, they can't do anything... so your time is their time.*
>
> John, husband, caregiver

Earlier in this chapter, John discussed the importance of distraction to help his wife, Barbara (person with dementia) to cope with her pain (see Section 9.4.1). John perceived Barbara as unable to distract herself from her own pain (largely because of her limited mobility and impaired vision). The need to distract Barbara from her pain was perceived as an additional care burden.

GPs relied upon family caregivers to take upon the responsibility of managing the pain experienced by the person with dementia using non-drug strategies (in addition to analgesic medication):

> *Some of the sort of self-management problems can be a bit tricky, because they do need to be self-management, and if they've- you've got someone who's got sort of severe dementia then- then they don't remember to do that self-management. When you're- unless you've got a relative who's a carer, it makes it a bit more straight forward, because they can help to exercise, and they can prompt and all that sort of thing.*
>
> Chris, GP

The symptoms associated with dementia may act as a barrier to the self-management of pain using non-drug strategies (as discussed previously in Section 9.4.1). In the circumstance that the person with dementia was unable to manage their own pain, GPs viewed family caregivers as integral to prompt and encourage engagement with non-drug strategies. In addition, GPs perceived family caregivers to be reasonably accepting of such simple ‘at-home’ non-drug strategies:

> *heat packs, cold packs, if it's the right thing, y'know that sort of thing... and those are nice and safe aren't they, and easier? Easier to manage, and people are surprisingly willing to, caregivers I mean, really quite keen to try those things, maybe because it is less threatening than tablets, more easy to comprehend, and understand.*
>
> Lisa, GP

Non-drug strategies were viewed as a 'safe' and 'easy' alternative to analgesic medication. In fact, some GPs, alike to Lisa, gave the indication that family caregivers were keen to try non-drug strategies, potentially highlighting the family caregiver's proactive approach towards pain management for the person with dementia. This positive perspective towards non-drug strategies does however, somewhat contrast to the perspective of John, who reflected upon the burden of non-drug strategies to managing his wife's pain, as discussed earlier in this theme.

9.5 Summary of qualitative findings

- A variety of pain management strategies were used by people with dementia, including analgesic and non-drug strategies.
- Non-drug strategies commonly used by people with dementia included exercise and other simple at-home strategies (such as massage, comfort, relaxation, and distraction techniques). People with dementia, family caregivers, and GPs seemed to have a positive regard for these treatments.
- A minority of people with dementia and family caregivers used or had tried other non-drug treatments for pain, which were largely classified as 'alternative or complementary therapies' (e.g. acupuncture). Such treatments were supported by GPs, but often not recommended. Family caregivers and GPs were sceptical of their efficacy. GPs also had concerns surrounding the accessibility and the evidence-base supporting these treatments.
- People with dementia, family caregivers, and GPs reflected upon their numerous concerns related to analgesic treatment for people with dementia, including potential

side effects, illness burden, and treatment burden. Each of these multifactorial concerns intensified the reluctance for people with dementia to use analgesic treatments. GPs often had the complex task of weighing up the need for pain relief against their numerous concerns to identify the 'most suitable' treatment option.

- Family caregivers were often responsible to manage analgesic medication for community-dwelling people with dementia, with GPs relying upon the presence of a family caregiver to manage the analgesic medication regimen in the community.

9.6 Conclusions

This chapter investigated pain management strategies for people with dementia using qualitative and quantitative methods. Findings from the qualitative and quantitative data relating to pain management were provided separately in line with the convergent mixed methods design (see Section 5.4.2.1). The quantitative and qualitative findings from this chapter are narratively integrated in the following chapter (along with the quantitative and qualitative findings related to pain identification and assessment) to highlight inference, interpretation, convergence and divergence between the findings (Creswell & Plano Clark, 2018).

10 Chapter Ten: Discussion

10.1 Introduction

This chapter begins by recapping the objectives of this thesis. A narrative discussion then follows, organised by the research objectives to provide an integrated summary of the quantitative and qualitative findings highlighting areas of convergence and divergence, all within the backdrop of the current published literature. The strengths and weaknesses of the mixed methods approach are also outlined. Finally, implications for practice, policy and future research are discussed.

This research was guided by the overarching aim to understand pain identification, pain assessment, and pain management for community-dwelling people with dementia.

Research objective 1: To investigate pain identification and pain assessment for community-dwelling people with dementia

Research objective 2: To investigate the management of pain for community-dwelling people with dementia

10.2 Summary of findings and comparison to previous literature

In a convergent mixed methods research design, following initial separate analysis the quantitative and qualitative findings should be summarised independently (see Chapter Eight and Chapter Nine). Following the separate analysis, the quantitative and qualitative findings should be narratively discussed to highlight inferences, interpretations, convergent, and divergent findings (Creswell & Plano Clark, 2018). The following section provides an integrated summary of the key quantitative and qualitative findings organised by each research objective, with reflection upon published literature from the literature review (see Chapter Two), and the systematic review (see Chapter Three).

10.2.1 Pain identification and assessment

This section provides an integrated summary of the key quantitative and qualitative findings to meet the following research objective:

Research objective 1: To investigate pain identification and pain assessment for community-dwelling people with dementia

Incidence of musculoskeletal consultation

Quantitative analysis found that the person-time incidence rate (i.e. the first recorded record) of musculoskeletal consultation was consistently lower (i.e. less incidence) for people with dementia compared to older adults, in the five-year period from index date, and at each annual time period following index date. Furthermore, people with dementia had a greater mean time until the occurrence of incident musculoskeletal consultation, with a significantly lower rate of incident musculoskeletal consultation than older adults without dementia (adjusted HR 0.71, 95% CI 0.68 to 0.75). Considering attributable rate during the five-year period from index date, a high percentage (26.7%) of incident musculoskeletal consultations for the older adult cohort would not have been coded if they had dementia. Each of these findings suggest the rate of identified incident musculoskeletal consultation was significantly lower for people with dementia compared to older adults without dementia. Such findings indicate a reduced recording of musculoskeletal consultation for people with dementia compared to older adults without dementia. This may suggest that fewer incident musculoskeletal conditions were identified or assessed for people with dementia compared to older adults without dementia, especially as the time from index date increased.

Research examining the incidence of pain for older adults is yet to be widely investigated (Shi et al., 2010), with a notable gap in the evidence examining the incidence of pain for people with dementia. Of the limited research to date, research found that the incidence of pain was 4.7 per 100-person years for older adults (Shi et al., 2010), with other studies indicating that the incidence ranged from 3.3% to 16% for older adults (Elliott et al., 2002; Thomas et al., 2007; Jordan et al., 2008; Magni et al., 1993). The incidence of pain found in this thesis sits at the higher end of this range (22.2 per 100-person years for older adults, and 16.3 per 100 person-years for people with dementia). The difference between previous findings, and the findings of this thesis may be due to the data collection method. To

exemplify, Shi et al. (2010) identified pain by asking survey participants: 'are you frequently troubled by pain?', this method may produce lower pain responses than direct primary care consultation records as used in this thesis as the question used by Shi et al considers not only presence of pain but also that it is frequent, and troubling to the person.

Prevalence of musculoskeletal consultation

The five-year prevalence of musculoskeletal consultation was 58.5% for people with dementia. Additionally, the annual prevalence of musculoskeletal consultation ranged from 19.3% to 24.5% (depending upon the annual period after index date) for people with dementia. Previous cross-sectional research shows highly variable estimates in the point prevalence of pain for community-dwelling people with dementia (16.7% to 87.5%) (Jensen-Dahm et al., 2012; Krulewitch et al., 2000; Barry et al., 2016; Shega et al., 2004; Mäntyselkä et al., 2004). The five-year prevalence of musculoskeletal consultation identified in this thesis is understandably towards the higher end of this range of point prevalence estimates due to the longer period of investigation. In nursing home settings, a systematic review found that the cross-sectional point prevalence of self-reported pain for people with dementia ranged from 15.0% to 42.6%, and staff ratings (observation or documentation in medical records) of pain ranged from 19.1% to 43.2% (Tan et al., 2015). Variation in the point prevalence estimates of pain reflect the different methods of identifying pain for people with dementia; using self-report, informant report, medical records, and behavioural observation tools. Additionally, the heterogeneous settings and sample characteristics are likely to contribute to the wide prevalence estimates (van Kooten, Smalbrugge, van der Wouden, Stek, & Hertogh, 2017; Takai, Yamamoto-Mitani, Okamoto, Koyama, & Honda, 2010; Björkman, Sorva & Tilvis, 2008; Chen et al., 2010). Despite the variations within the literature on prevalence there is comparable support that this cohort is in accordance and reflective of the wider dementia population. In a more comparable study, Jørgensen et al. (2018) investigated medical records and determined the point prevalence of musculoskeletal conditions for people with dementia in nursing home settings as 22.4%. This is comparable to the annual

prevalence of musculoskeletal consultation found for people with dementia in this study (19.3% to 24.5%), again, providing support that the findings of this thesis reflect the wider literature.

Although the five-year prevalence of musculoskeletal consultation was high for people with dementia, it was significantly lower than older adults without dementia (58.5% vs. 70.8%, respectively, adjusted OR 0.82, 95% CI 0.76 to 0.88). Additionally, the annual prevalence of musculoskeletal consultation was also significantly lower for people with dementia (19.3% to 24.5%) than older adults without dementia (30.6% to 31.7%). To support these findings, previous meta-analysis by Tan et al. (2015) found that people with dementia had a significantly lower prevalence of self-reported and staff ratings of pain (observation or documentation in medical records) than people without dementia (OR 0.36, 95% CI 0.28 to 0.45). Additionally, a number of studies have found that people with dementia may receive fewer pain and physical health assessments than older adults without dementia in nursing home settings (Nakashim et al., 2019; Jørgensen et al., 2018). Particularly, in line with the findings of this thesis, Jørgensen et al. (2018) found that the point prevalence of potentially painful musculoskeletal conditions was lower for people with dementia than older adults without dementia (22.4% vs. 29.8%, respectively). The findings from this thesis, along with evidence from the previous literature suggests a lower recording of musculoskeletal consultations, potentially indicating a lower identification and assessment of (potentially painful) musculoskeletal conditions for people with dementia.

Contradictory evidence has also been identified. In a similar study design, Hoffman et al. (2014) using health insurance claims data, found people with and without dementia had a similar prevalence of pain diagnosis during the first year after their incident dementia diagnosis (74.4% vs. 72.5%, respectively; p=0.11). This study included a number of painful conditions (in addition to musculoskeletal consultations) potentially explaining the heightened prevalence estimates compared to this thesis. This study by Hoffman et al. only examined

pain during the first year following dementia diagnosis and therefore cannot conclude if dementia progression reduced identification and assessment of pain.

When examining musculoskeletal consultation trends over time, the results of this thesis also show that the annual prevalence and odds incrementally lowered from the first year to the final year of follow up for people with dementia (24.5% to 19.5%, respectively). In contrast the annual prevalence of musculoskeletal consultation remained consistent over time for older adults without dementia. These findings suggest that the rate of potential identification and assessment of musculoskeletal conditions lowered as the time from dementia diagnosis (index date) increased for people with dementia. Similar findings were also highlighted in previous literature, with both Reynolds et al. (2008) and Jørgensen et al. (2018) finding that the identification of pain and potentially painful conditions lowered in line with increasing cognitive impairment.

10.2.1.1 Gathering information to identify pain

The qualitative findings provide a greater understanding and interpretation to the quantitative findings outlined above. Family caregivers and GPs used multiple pain identification and assessment strategies, including self-report, family caregiver report, and observation of changes in presentation (behavioural, psychological, and physical), in line with recommendations (Herr et al., 2011; Horgas & Miller, 2008; Schofield; 2018).

Many GPs, however, continued to perceive the presence of dementia as intensifying the challenge of pain identification and assessment. With many perceiving pain identification as a ‘process of elimination’. This finding is reflected in previous qualitative literature, in which nurses perceived pain assessment as a ‘complex process’ (Monroe et al., 2015; Kovach et al., 2000) that may lead to pain being inadequately identified, assessed, and treated (Kaasalainen et al., 2007). In accordance with these findings, the vast majority of nursing home managers (Barry et al., 2012), nurses (Burns & McIlfatrick, 2015b), and GPs (Jennings et al., 2018b) agreed that the presence of dementia can make pain assessment difficult (91.7%, 91%, 98%, respectively). The perceived complexity of pain identification and

assessment for people with dementia, as found in the qualitative findings, may provide potential explanation as to why people with dementia had a lower incidence and prevalence of musculoskeletal consultation (especially as time from index date increased) compared to older adults without dementia, as found in the quantitative findings.

It is also important to acknowledge divergent findings. Although the majority of GPs perceived pain identification and assessment as complex and inadequate for people with dementia, a minority of GPs were confident that by employing multiple pain identification and assessment strategies (along with common sense and experience) an accurate assessment of pain could be determined. This finding diverges from the quantitative findings, as if an accurate assessment was achieved, it would be expected the incidence and prevalence of musculoskeletal consultation was similar for older adults with and without dementia. Such discordance cannot be explained by healthy cohort bias, as the dementia cohort and older adult cohort remained stable over follow up concerning their baseline characteristics.

10.2.1.1.1 Disentangling the self-report of pain

Communication difficulties

This study found that family caregivers and healthcare professionals perceived self-reported pain as an important method of pain identification for people with dementia. However, as communication ability decreased, self-report became increasingly difficult. In previous literature using focus groups, nursing home staff and family caregivers perceived self-report as the ‘most meaningful assessment route’ for people with dementia (Corbett et al., 2016). The challenge of communication has, however, been well documented in the literature. A meta-ethnography of qualitative evidence exploring pain assessment for people with dementia found that reduced or altered verbal communication was a barrier to pain assessment and treatment for people with dementia (Geddis-Regan et al., 2018). Additionally, research has found that the percentage of people with dementia able to self-report pain or use a self-report measure reduces as the severity of dementia increases (Closs et al., 2004; Kunz et al., 2007; 2009; Lukas et al., 2013a). These findings were

concordant with the systematic review (see Chapter Three) suggesting that a large proportion of those who have moderate-to-severe dementia were unable to complete a self-report pain instrument. The challenge of self-report throughout the progression of dementia was reiterated as many healthcare professionals believed that 'a person with dementia is not able to accurately provide a self-report of their pain' (Jenning et al., 2018; Barry et al., 2012; Burns & McIlfatrick, 2015b). The challenge of self-report with increased cognitive impairment, provided further explanation to the lower musculoskeletal consultation for people with dementia compared to older adults, especially as time from index date increased, as reported in this thesis.

Self-report reflecting the pain experience

In the qualitative findings, most family caregivers and GPs did not doubt or question the self-report of the person with dementia. This finding is concordant with pain assessment guidelines emphasising that self-report remains the most reliable and accurate pain assessment method for people with dementia (Herr et al., 2011; Schofield, 2018). In previous qualitative research, nurses illuminated the importance of trusting the person with dementia's self-report of pain (Karlsson et al., 2014).

Discordant to these findings, this thesis found that some family caregivers questioned the intentions of their relative with dementia's self-reported pain. The disclosure of pain was viewed as a means for the person with dementia to avoid activities that they did not want to do; and therefore the motives behind self-reported pain were questioned. Additionally, a number of GPs questioned the extent that self-reported pain reflected the pain experienced by the person with dementia, further highlighting the complexity of interpretation of self-report. Previous qualitative research found that some family caregivers perceived the person with dementia's pain report as 'dramatic' as a means of gaining attention (Mentes et al., 2004), with family caregivers and nurses concerned that a person with severe dementia would be unable to provide an 'accurate and reliable' response to self-report questions (Martin et al., 2005). The challenge of disentangling the potentially 'unreliable' self-report of

pain was demonstrated by family caregivers of people with dementia in hospice settings, as they reflected upon the difficulty of differentiating between 'real' and 'imagined' pain due to communication barriers (Tarter et al., 2016).

When determining the extent that the self-report of pain reflected the pain experience, the findings of this thesis found consistency to be an important factor. Three main sources of inconsistency were identified; inconsistency between self-report ratings over time, inconsistency between the self-report and the family caregiver report; and inconsistency between the self-report and the GP's clinical judgement. The importance of consistency has not been explicitly identified in previous qualitative research. However, qualitative interviews with healthcare professionals in a hospital setting suggest that multiple pain assessments should be used to support or refute the self-reported pain (Dowding et al., 2016). These findings highlight the need to gather consistent information to support the self-report provided by the person with dementia, without a reliance upon self-report in isolation (McAuliffe et al., 2009).

The challenge of disentangling a self-report from the person with dementia provides clear interpretation to the quantitative findings that indicate people with dementia have a consistently lower incidence and prevalence of musculoskeletal consultation than older adults without dementia. Additionally, obtaining and disentangling a self-report was found increasingly challenging with the progression of dementia (due to various inconsistencies) and this does link as a potential explanation for the lowering prevalence of musculoskeletal consultation as the time from dementia diagnosis increases (and thus it is assumed as dementia progresses). Although it is acknowledged that with medical record data alone there is no way of knowing what was actually discussed in the consultation, or the severity of dementia at the time of the consultation, or indeed if a family caregiver was present.

Stoical attitude towards pain

An additional consideration when disentangling the self-reported pain of people with dementia is their often reported acceptance of pain, and consequently their stoical attitude

towards their pain experience. This meant that the person with dementia often ignored or 'shrugged off' their pain. Family caregivers and healthcare professionals perceived the stoical attitude held by people with dementia as impeding self-reported pain, and acting as a barrier to accurate pain identification. A stoical attitude towards pain may make it difficult to interpret if the self-report of pain reflects the pain experience. Previous qualitative research reflecting upon people with dementia living in nursing home settings found that family members of people with dementia (Mentes et al., 2004; Martin et al., 2005), older adults, and healthcare professionals (Martin et al., 2005) perceived stoicism as a barrier to pain identification and assessment, with people with dementia denying or minimising their pain experience. Whilst the qualitative findings have highlighted acceptance of pain as an important concept, the broader literature suggests this would be a uniform concept for older adults and not necessarily specific to dementia. Certainly, research suggests that older adults may hold attitudes, beliefs and expectations about pain, with stoicism reducing pain reporting for older adults, which may in turn delay identification, diagnosis, and treatment (AGS Panel, 2002; Blomqvist & Hallberg, 2001; McDonald, 2009; Cornally & McCarthy, 2011; Schofield & Abdulla, 2018; Gammons & Caswell, 2014). This broader literature suggests that the acceptance of pain is not specific to dementia and therefore not a likely explanation for the differences reported in the quantitative findings. Regardless, the attitudes held by older adults are important for people with dementia whom often receive care from their older adult relative in the community. The attitudes held by an older adult caregiver may reduce the identification, assessment, and treatment of pain for the person with dementia.

When exploring the acceptance of pain for people with dementia, the qualitative findings suggested that the many competing conditions taking priority might be one influential factor. In other words, pain may be relegated as 'a lower priority problem'. In line with this finding, this thesis also found that people with dementia and family caregivers also perceived pain experienced by the person with dementia to be a lower priority concern for healthcare professionals. Previous qualitative research by Sale et al. (2006) found that older adults' perceived non-pain related conditions as being more serious than pain. Therefore, Sale et al.

found that painful conditions were accepted because they were tolerable, and not life threatening. Research conducted by Bedson, Kadam, Muller and Peat (2011) found that consultations for musculoskeletal knee problems by older adults (50+ years) were preceded by a three-month period of fewer consultations for other persistent comorbid conditions. These findings suggest that older adults consulted for their knee problem when other comorbid conditions were no longer a priority. This literature suggests that older adults may view pain as a lower priority condition, thus the findings may not be specific to people with dementia. That said, clearly the defined cohort with dementia used within the quantitative analysis do have what may be interpreted as a 'priority' condition and this may give further explanation for the differences reported. These findings continue to raise an important issue about healthcare professionals being mindful of considering the wider health of the person with dementia when consulting.

In the context of this thesis, the acceptance of pain and ultimately the stoical attitude towards pain has been framed as a negative attitude (or barrier) due to entanglement with self-reported pain. Alternative research has however reflected upon the positives of accepting pain (Molton & Terrill, 2014). Older adults with stoical attitudes had lower levels of affective distress relative to their pain levels (Cook & Chastain, 2001), with stoicism being perceived as a means for older adults to exert control over their pain, which is considered a positive coping mechanism (Gammons & Caswell, 2014).

10.2.1.1.2 Observing changes

Family caregivers and healthcare professionals relied upon observation as a key strategy to identify and assess pain, especially when the person with dementia did not, or could not provide a self-report of their pain. These findings were reflected in a recent meta-ethnography of the qualitative evidence into pain assessment for people with dementia, in which non-verbal approaches were used to 'build a picture' of the potential pain experience (Geddis-Regan et al., 2018). The importance of non-verbal pain assessment was reiterated in questionnaire research, where the majority of GPs (Jenning et al., 2018) and community

pharmacists (Barry et al., 2013) agreed that observing behavioural and physiological indicators of pain are important when assessing pain in a person with dementia. These findings reflect UK national pain assessment guidelines for older adults (with a focus on cognitive impairment) that recognise behaviour, facial expressions, and changes in normal functioning as useful indicators that the person with dementia may be experiencing pain (Schofield, 2018).

When observing behavioural and psychological changes in a person with dementia, GPs discussed difficulty determining what was causing the presentation, especially if the behaviour was non-specific (e.g. a loss of appetite). GPs and old age psychiatrists were therefore concerned that pain was inadequately recognised as a driver of behavioural and psychological symptoms of dementia (BPSD). The difficulty of determining the cause of behavioural and psychological changes, along with the label of 'dementia' may mean that healthcare professionals do not look beyond the condition to explore *why* the person with dementia may be behaving differently. Such findings may suggest that behavioural and psychological changes continue to be attributed as a direct symptom of dementia. GPs and psychiatrists were concerned that changes in presentation may be inappropriately referred to secondary care rather than pain treatment being initiated in primary care. In accordance with the findings of this thesis, a literature review (McAuliffe et al., 2008), and previous qualitative findings (Martin et al., 2005; Gilmore-Bykovskyi & Bowers, 2013; Jennings et al., 2017) highlighted the difficulty of determining the reason for behavioural and psychological changes for people with dementia. Again, alike to this thesis, previous literature suspected that the difficulty may arise as behavioural and psychological changes are not a specific indication of pain (Zwakhalen et al., 2018), and may indicate many other pathologies (e.g. urinary tract infection or constipation), or a symptom of dementia itself (i.e. linked to neurobiological pathways due to neurodegeneration from disease; Proitsi et al., 2011; Liperoti, Pedone & Corsonello, 2008). The challenge of determining the driver of the observed presentation may lead to inadequate pain identification and assessment (Jennings et al., 2017). These qualitative findings, therefore, may provide further explanation to the lowering incidence and

prevalence of musculoskeletal consultation for people with dementia, especially as the time from dementia diagnosis increased, as the misattribution of behavioural and psychological changes are more likely in the advanced stages of dementia. Alternatively, BPSD may take 'clinical dominance' in a consultation, meaning that the behavioural and psychological symptoms are coded by the GP, with musculoskeletal codes, again relegated as a 'lower priority condition' (Jørgensen et al., 2018).

In addition to the observation of behavioural and psychological changes, family caregivers and GPs also observed physical changes and used physical examination to identify and assess pain for people with dementia. In particular, family caregivers and GPs reflected upon the importance of family caregivers providing close care (e.g. dressing, bathing, going to the toilet) to identify physical changes for the person with dementia. In accordance with these findings, in recent questionnaire studies, the majority of GPs (Jennings et al., 2018b) and nurses (Burns & McIlfatrick, 2015b) agreed that physiological indicators of pain (e.g. heart rate, blood pressure, temperature) were an important aspect of pain assessment for people with dementia. The importance of personal care by the family caregiver has not been explored in previous literature, however interviews with nursing assistants reflect upon the usefulness of physical examination during daily care tasks to identify physical changes that may be indicative of pain (Karlsson et al., 2012; De Witt Jansen et al., 2017a).

Although physical examination was beneficial to gather information about the potential pain experienced by a person with dementia, some GPs in this thesis reflected upon the difficulty of examination. The time-limited nature of primary care consultations intensified the challenge of persuading and encouraging the person with dementia to be comfortable and happy to be physically examined, in line with previous qualitative findings (Chang et al., 2009) which reflected upon the 'lack of co-operation' with the examination. This thesis is the first to qualitatively focus upon GPs' perspective of pain identification and assessment for people with dementia in primary care, which gives a uniqueness to this context (e.g. pressures of primary care with time-limited consultations) that are not explored in previous

literature. The challenge of observing physical changes for people with dementia, especially in the absence of a family caregiver providing close care, and the difficulty of physical examination (especially in the absence of self-report) may further explain the lower incidence and prevalence rates of musculoskeletal consultation for people with dementia compared to older adults; especially as the time from dementia diagnosis (or index date) increased based on the assumption of dementia progression over time.

10.2.1.2 The importance of familiarity

Familiarity with the person with dementia was an important factor when identifying and assessing pain. Family caregivers were close family members (spouse or child) of the person with dementia. The family caregiver often lived with the person with dementia, and had known them for many years before the onset of dementia. The in-depth knowledge of the person with dementia, along with the available time to observe the person with dementia (compared to the time-restricted observation period of the GP) allowed the family caregiver to have a greater insight into their pain history, and the ability to identify subtle changes in presentation. The benefits of familiarity or *'knowing the person'* for pain identification and assessment for people with dementia has been identified in previous studies, especially when the person with dementia is no longer able to verbally articulate their pain (Corbett et al., 2016; Geddis-Regan et al., 2018). Familiarity with the person with dementia allows for the identification of unusual or 'out of character' behaviour that may go unnoticed if the person's usual behaviour is unknown (Kovach et al., 2000; Liu, 2014; Mentes et al., 2004).

In contrast, healthcare professionals (both GPs and psychiatrists) often felt unfamiliar with the person with dementia, hindering their ability to have an in-depth knowledge of the patient's history or to identify subtle changes in presentation. In an attempt to overcome the lack of knowledge resulting from poor continuity, healthcare professionals relied upon family caregivers as a surrogate familiarity (and other markers of pain identification; including medical records, examination); to provide history, report their observations, and to guide examinations. This thesis provided the first qualitative exploration of pain identification and

assessment for people with dementia from the perspective of GPs in primary care and from psychiatrists involved in dementia services. However, previous literature has explored the importance of family caregivers to aid the identification and assessment of pain using quantitative methods, and alternative healthcare professionals. The majority of GPs (Jennings et al., 2018), community pharmacists (Barry et al., 2013), and nurses (Burns & McIlfatrick, 2015b) agreed that when assessing pain for people with dementia it was important to consider the family perspective. These studies were questionnaire-based, and therefore did not provide further exploration into the importance of family caregivers. However, Monroe et al. (2015) found that nurses were concerned that people with dementia who were not well known by staff would have their pain inadequately identified, assessed, and consequently treated. To clarify the presence of pain, nurses communicated with family members to gain a greater insight into the pain history or changed behaviour of the person with dementia (Monroe et al., 2015). Similarly, in hospital settings, family caregivers acted as 'messengers on behalf of the patient'; aiding interpretation of pain cues due to their knowledge of the person with dementia (Lichtner et al., 2016, p. 7). The findings of this thesis supported by previous research reiterate the importance of familiarity and the potential under identification of pain if the healthcare professional does not have relationship continuity with the person with dementia. The under identification may be further intensified if the family caregiver was not present to act as a surrogate familiarity; potentially explaining the lower incidence and prevalence rates of musculoskeletal consultation for people with dementia compared to older adults without dementia, as found in the quantitative findings.

10.2.1.3 The use of pain assessment tools

Some family caregivers reflected upon the challenge of providing an informant pain report on behalf of the person with dementia; with the IPT scores often highlighting a discrepancy between people with dementia and their family caregiver report of pain (see Table 7.7). These findings are concordant with the findings of the systematic review (see Chapter Three) that found a discrepancy between self and informant reports of pain for community-dwelling people with dementia. Evidence outside of community-dwelling people with dementia also

highlighted the challenge of providing an informant report of pain that reflects the self-report of pain (Ruben, Blanch-Hartigan & Shipherd, 2018), with the challenge increasing in line with the severity of dementia (Hemmingsson et al., 2017; Santos & Castanho, 2014).

Most GPs reflected upon the importance of self-report, suggesting that this was often their first method to investigate pain for people with dementia, however, GPs tended not to use standardised pain assessment tools to obtain the pain report, with only a small number of GPs reflecting upon a 1 to 10 numerical pain scale. GPs questioned the appropriateness of pain assessment tools for people with dementia despite the current UK national pain assessment guidelines suggesting that there are a number of valid and reliable self-report measures suitable for use with people with mild-to-moderate dementia (Schofield, 2018). In previous qualitative studies, observations and interviews were conducted in a hospital setting, and alike to the findings of this thesis, many healthcare professionals were cautious and did not trust pain assessment scores (Lichtner, Dowding & Closs, 2015; Dowding et al., 2016). Discordant to these findings, Li et al. (2015) found that pain assessment tools were documented in the medical record of 98% of community-dwelling people with dementia, 94% of which were standardised self-report pain assessment scales, such as the numerical rating scale. However, people with dementia in the Li et al. study were included if they had mild-to-moderate dementia, and a positive pain screen (by self-report and caregiver's confirmation). These factors (especially the positive pain screen) may have significantly increased the likelihood of pain being assessed using a self-report pain assessment tool within a healthcare setting.

Earlier in this chapter, healthcare professionals perceived behavioural changes to be inadequately recognised as a symptom of pain (see Section 10.2.1.1.2). This is aligned with the finding that most GPs were unaware of dementia-specific behavioural observation pain tools. These findings were supported by a previous study in which only 10% of GPs reported knowledge of their existence (Jennings et al., 2018b). Similarly, only 2% of pain assessments in outpatient medical records were 'appropriately modified' (e.g. measured behavioural

characteristics) for community-dwelling people with dementia (Li et al., 2015), with similar findings in nursing home settings (Allcock, McGarry & Elkan, 2002). However, as discussed in the systematic review (see Section 3.5.3), the study by Li et al. (2015) only recruited people with mild-to-moderate dementia, in which behavioural observation may not be necessary due to the ability to provide a self-report of pain (Schofield, 2018). In previous qualitative interviews, nurses and formal caregivers in nursing homes (Tordoff et al., 2017) and hospital settings (Lichtner et al., 2015; Harmon et al., 2019) had previously used behavioural observation tools for pain, however they reflected that no tool was commonly used in this context. The lack of adoption of a behavioural pain assessment tool in practice may reflect evidence that there is no one behavioural observation tool more reliable or valid than the others (Lichtner et al., 2014), with a clear lack of examination in community-dwelling or primary care settings (see Chapter Three).

In contrast to GPs, in this current study, most psychiatrists were aware of behavioural observation pain assessment tools, however similarly to GPs, psychiatrists continued to prefer a holistic approach; using alternative markers to identify and assess pain (e.g. medical history, caregiver reports, examination), in addition to their clinical experience and judgement. In accordance with these findings, research found that behavioural observation pain tools were perceived to 'add no value' for people with advanced dementia (Tordoff et al., 2017; Lichtner, Dowding & Closs, 2015; De Witt Jansen et al., 2018). Alternatively, alike to the findings of this thesis, healthcare professionals perceived a holistic assessment of pain (including examination, collateral history, medical records) as more thorough (De Witt Jansen et al., 2018). The limited use of adequately validated pain assessment tools may impede optimal pain identification and assessment for people with dementia especially where the condition and symptom severity has progressed (McAuliffe et al., 2008). Therefore, these qualitative findings may again contribute understanding to the quantitative findings; highlighting another potential reason why the incidence and prevalence of musculoskeletal consultation was lower for people with dementia compared to older adults without dementia, especially over time throughout follow up, based upon the assumption of increasing severity.

10.2.2 Management of pain

This section provides an integrated summary of the key quantitative and qualitative findings to meet the following research objective, whilst reflecting upon the previous literature:

Research objective 2: To investigate the management of pain for community-dwelling people with dementia

Quantitative findings indicated that the five-year prevalence of analgesic prescription for people with dementia was 49%, with an annual prevalence ranging from 21.1% to 15.7% (depending on the annual period following index date). The systematic review as part of this thesis (see Chapter Three) suggests that the prevalence of analgesic prescription ranged from 25% to 63% for community-dwelling people with dementia. The majority of the studies included in the systematic review were cross-sectional, providing a point prevalence of analgesic use for people with dementia. However, two studies provided a 180-day period prevalence of 34.9% (Hamina et al., 2016), and a four-year period prevalence of 26% for analgesic use for people with dementia (Gallini et al., 2013). Findings from the systematic review (see Chapter Three) are comparable to the findings of the prevalence investigation, especially those investigating period prevalence of analgesic prescription (Hamina et al., 2016; Gallini et al., 2013). Similarly, a systematic review of cross-sectional evidence shows that the point prevalence of analgesic prescription for people with dementia in nursing home settings ranges from 20.2% to 61.2% (Tan et al., 2015). The prevalence rates identified in this thesis broadly reflect the prevalence of analgesic prescriptions in previous studies, both within the community, and nursing home settings.

The quantitative findings of this thesis also found that during the five-year period from index date, the prevalence of analgesic prescription was 11% lower for people with dementia compared to older adults without dementia (49% vs. 60%, respectively). Conditional logistic regression testing showed this difference as a significantly lower odds of analgesic prescription for people with dementia (adjusted OR 0.82, 95% CI 0.76 to 0.88). This investigation included analgesic prescriptions matched to a musculoskeletal consultation.

However, in a sensitivity analysis all analgesic prescriptions were included (irrespective of matching). This analysis found minimal difference between the five-year prevalence for people with and without dementia (76.7% vs. 79%, respectively, adjusted OR 0.97, 95% CI 0.91 to 1.03). It is important to recognise that although the prevalence rates were similar, the prevalence of 'any analgesic prescription' was largely influenced by the high and similar prevalence of basic analgesic prescription for people with and without dementia (see Section 10.2.2.3.1.1). Previous literature within community samples (see systematic review in Section 3.5.4.1) show a mixed trend, with community-dwelling people with dementia having a lower (Mäntyselkä et al., 2004), similar (Hamina et al., 2016), and greater (Haasum et al., 2011) prevalence of analgesic medication use compared to community-dwelling older adults without dementia. The most comparable study to this thesis was by Hamina et al. (2016) who examined the period prevalence of analgesic prescription during the first 180-days after dementia diagnosis using medical record data. The findings by Hamina et al. reflect the sensitivity analysis in this thesis that also found no difference between people with dementia and older adults without dementia during the first annual period after index date. Importantly however, each of these studies only reported crude prevalence rates for people with and without dementia, and did not adjust for potential confounders when examining the association between cohort status and analgesic use or prescription. The findings of this thesis therefore contribute to the minimal evidence to date comparing the prevalence of analgesic medication for people with dementia to older adults without dementia, yet with the added robustness of multivariable adjustment and numerous sensitivity analyses.

In nursing home settings where the evidence is more established, a systematic review and meta-analysis revealed that residents with dementia had a significantly lower analgesic prevalence compared to residents without dementia (OR 0.58, 95% CI 0.41 to 0.82) (Tan et al., 2015). These findings support the main quantitative findings of this thesis suggesting that people with dementia have a lower prevalence, and a significantly lower odds of analgesic medication than older adults without dementia (yet discordant to the unmatched analgesic sensitivity analysis). The similar findings of the review by Tan et al. and this thesis question

the potential concern that people with dementia living in nursing homes may be incorrectly misclassified to the main analysis, despite wishing to only examine analgesic prescriptions for community-dwelling people with dementia (see Section 10.4.2.2). However, additional 'strict' community sensitivity analysis found comparable findings to the main analysis, minimising these concerns.

Importantly, the main analysis and sensitivity analyses found that there was a discrepancy between the annual prevalence of analgesic prescription for people with dementia and older adults, as the time from dementia diagnosis (index date) increased. Conditional logistic regression confirmed these trends showing the odds of analgesic prescription lowered for people with dementia compared to older adults without dementia as the time from index date increased. Previous literature examining analgesic prescription throughout the progression of dementia is limited. Gilmartin et al. (2015) found that the prevalence of analgesic use remained relatively consistent at each annual time point from baseline (0 to 5 months after dementia diagnosis) to the fifth year of follow up (13.6%, 10.6%, 13.7%, 16.8%, 15.3%, respectively). These findings, whilst similar in prevalence rates, are discordant to the findings of this thesis in terms of the trend over time. Several differences between the study by Gilmartin et al. and this thesis may explain the discordant results. In the study by Gilmartin et al. all analgesic medications 'still in use' were recorded in an interview with the family caregiver. Therefore, the Gilmartin et al. study included prescription and over-the-counter medications, whereas the investigation of this thesis only included prescribed analgesics. It may be that as time from diagnosis increases there is less consultation activity and therefore less chance of prescription, however, the person with dementia and/or their family caregivers may compensate by increasing over-the-counter medication. Additionally, the study by Gilmartin et al. only included a limited sample (*n*=236) of people with dementia at baseline, lowering to *n*=73 at five year follow up. Attrition was lower in the study by Gilmartin et al. due to the additional exclusion criteria in this thesis throughout follow up (such as cancer diagnosis, patient leaving general practice, general practice no longer contributing to CPRD) (69% vs. 89% attrition over 5 years, respectively). Despite the lower attrition rate, the small

sample in the fifth year of follow up for Gilmartin et al. may lead to less reliable prevalence estimates as compared to the large samples utilised within this thesis. As stated previously, research on prescription of analgesic medication over time is limited. However, other studies have shown that the prevalence of analgesic prescription incrementally lowered with a reduction in MMSE score (Neumann-Podczaska et al., 2016; Cornali et al., 2006) and this may be reflective of the results presented in this thesis if we are to accept the assertion that cognitive ability lowers over time from diagnosis for people with dementia.

Despite these complementary findings, research examining the temporal trend of analgesic prescription rates for people with dementia highlight discordance. In Norwegian nursing homes, Sandvik et al. (2016) found that people with dementia had a lower prevalence of analgesic prescription compared to nursing home residents without dementia at three cross-sectional time points (2000, 2004, and 2009), however there was no difference in analgesic prescription in 2011. These findings suggest a cohort effect in analgesic prescribing; a shift towards equal prescribing rates of analgesic medication for people with and without dementia in more recent years. However, this study by Sandvik et al. did not include the same participants at each time point, with significant demographic differences across the four cohorts. The main findings and sensitivity analyses in this thesis continued to find a discrepancy between the prevalence of analgesic prescription between people with dementia and older adults without dementia as the time from index date increased, even when each model was adjusted for potential cohort effects (the model was adjusted for the calendar year of index date). The discordance between the findings of this thesis and the study by Sandvik et al. may represent prescribing differences for people with dementia living in nursing homes compared to the community or prescribing differences between Norwegian and UK healthcare systems.

10.2.2.1 Pain identification and pain assessment

It is important to acknowledge that adequate pain identification and pain assessment is a prerequisite for optimal pain treatment (Schofield, 2018). Therefore, the challenges

associated with pain identification and pain assessment for people with dementia, as already discussed (see Section 10.2.1) may explain the lower prevalence of analgesic prescription compared to older adults without dementia.

Communication difficulties were recognised by family caregivers and GPs as a barrier to self-report (see Section 10.2.1.1.1). Additionally, communication difficulties limit the person with dementia's ability to express their need for pain relief (Corbett et al., 2016). The lack of expression for pain relief may be interpreted by family caregivers as a stoical or reticent approach to pain. Research has found that of nursing home residents with an MMSE of ≤17, residents who were classified as 'verbal' had a higher prevalence of analgesic prescription compared to residents that were classified as 'non-verbal' (Bauer et al., 2016). This finding may demonstrate how communication ability may impede optimal analgesic treatment for people with dementia.

Results also show a stoical attitude towards pain was perceived to impede pain identification and pain assessment for people with dementia (see Section 10.2.1.1.1). A stoical attitude towards pain was also a factor potentially implicating analgesic use, and accessing healthcare. This finding has also been recognised in previous research for people with dementia living in nursing homes, with stoicism being a key barrier to the administration of analgesic medication (Peisah et al., 2014). Earlier in this chapter, the qualitative research by Sale et al. was discussed; in which older adults accepted their painful conditions as 'tolerable' and 'not life threatening'. Such perceptions not only impeded pain identification, but also had negative implications for analgesic medication execution and persistence because other 'more important' medications took priority (Sale et al., 2006).

10.2.2.2 Non-drug management of pain

Qualitative findings of this thesis highlighted that people with dementia, family caregivers and GPs generally supported the use of non-drug strategies for pain for people with dementia. Many GPs recognised the importance of attempting non-drug strategies as a means to minimise pharmacological burden and their concerns towards analgesic medication for

people with dementia (see Section 10.2.2.3). The findings of this thesis reflect guidance recommending non-pharmacological strategies to manage pain for people with dementia (AGS Panel, 2009; Abdulla et al., 2013). It is important to note, however, that in this thesis, some healthcare professionals believed that there was 'no place' for non-pharmacological approaches until pain was controlled (using analgesic medication).

A variety of non-pharmacological approaches were used and supported by people with dementia; including exercise, massage, comfort, relaxation, and distraction techniques. Despite many acknowledging the benefits of such strategies for their pain, some perceived the benefits to be short-lived. Less commonly used non-drug strategies for pain included alternative and complementary treatments, such as acupuncture and Reiki; with family caregivers seeming sceptical of their efficacy. The use of non-drug strategies has been identified in a previous study (Mentes et al. 2004), however, studies to date have failed to unravel and explore the person with dementia and family caregiver's views or perspectives towards such strategies for the person with dementia's pain (i.e. their perspective of whether the strategy was useful). Therefore, the findings of this thesis whilst adding to our understanding of pharmacological management of pain for people with dementia, also provides new understanding about non-pharmacological approaches. Indeed many non-drug strategies were used when the person with dementia had concerns towards analgesic medication (for the many reasons described previously, see Section 9.4.2). This finding is supported in a previous qualitative meta-synthesis, in which older adults preferred the use of self-administered, non-drug treatments for their pain due to their resistance to take analgesic medication (Crowe et al., 2017b).

The qualitative findings within this thesis show that GPs generally supported the use of non-drug treatments for people with dementia; particularly exercise and other simple at-home strategies to relieve pain. Despite generally supporting non-drug approaches for pain, GPs' perspective seemed hierarchal, with a lower regard for non-drug treatments perceived as 'alternative' or 'complementary'. This was primarily due to their perceived unavailability in the

NHS (and therefore potential financial burden for the patient), and perceived minimal evidence-base. Previous qualitative studies with nurses (Kovach et al., 2000) and nursing assistants (Mentes, Teer & Cadogan, 2004; Liu, 2014) also highlighted their positive regard towards non-drug management strategies, each reflecting upon their efficacy and appropriateness when the person with dementia is reluctant to take analgesic medications (Geddis-Regan et al., 2018). Similarly, the findings of this thesis are supported by questionnaire studies where the majority of healthcare professionals agreed that non-pharmacological methods are useful in the management of pain for people with dementia (Barry et al., 2012; Barry et al., 2013; Jennings et al., 2018b). Despite support for non-drug strategies of pain relief, the systematic review (see Chapter Three) found evidence that non-drug approaches are underused for people with dementia in primary care (Li et al., 2015), however the evidence in this area is limited.

The current concerns towards analgesic medication for people with dementia as shown in the qualitative evidence and in similar literature (see Section 9.4.2 and 10.2.2.3) may lead to a preference for non-drug strategies. The lower prevalence of analgesic prescription for people with dementia, as found in the quantitative findings, may in part be associated with the use of non-drug strategies for pain.

10.2.2.3 Concerns related to analgesic medication

Qualitative findings from this thesis found that some people with dementia and family caregivers expressed no concerns towards analgesic medication for people with dementia, with some even reflecting upon the benefits of their use. This, however, was heavily overshadowed by the many concerns held by a number of people with dementia, family caregivers, and GPs. The concerns of people with dementia and family caregivers led to a reluctance to use analgesic medications, due to side effects, illness burden (the amount of conditions and consideration of priority), and treatment burden (the amount of medications being taken). Each of these factors are discussed in turn.

10.2.2.3.1 Side effects

This thesis found that potential side effects associated with analgesic medications were a key concern for many people with dementia and family caregivers. To support these findings, qualitative research also identified potential side effects to increase reluctance to use analgesic medication for older adults, with analgesics being a last resort to alleviate pain (Crowe et al., 2017b). Concerns relating to the side effects of analgesic medications for older adults were intensified with the presence and severity of dementia, due to increased risk of constipation, confusion, and nausea (Martin et al., 2005; Kaasalainen et al., 2007). These qualitative findings converge well with the quantitative findings, providing explanation for the lower prevalence of analgesic medications for people with dementia, especially as the time from dementia diagnosis (index date) increased.

Despite the largely converging findings presented above, it is important to also consider divergent findings. As previously highlighted, a minority of people with dementia and family caregivers did not express any concerns relating to the side effects of analgesic medications. These divergent findings do not provide clear justification or inference to the quantitative findings however, do only represent a minority of people with dementia and family caregivers whom participated in the qualitative study. Clearly, the quantitative results do show that some people with dementia are being prescribed analgesic medication, albeit at a lower rate compared to a matched cohort of older adults without dementia.

In this thesis, people with dementia and family caregivers spoke about their concern towards analgesic side effects generally, rather than attributing their concern towards any particular medications. In contrast, GPs' concerns regarding side effects were directly attributed to specific analgesic classifications (e.g. NSAID or opioid medications). These concerns are discussed and integrated with the quantitative findings in the following sections.

10.2.2.3.1.1 Basic or simple analgesics

The five-year prevalence of basic analgesic prescription in this thesis was 36.9% for people with dementia. The annual prevalence of basic analgesic prescription was 11.1% to 14.7%

(depending upon the annual period after index date) which is at a slightly lower but comparable rate to the prevalence range (14% to 32%) found in the systematic review (see Chapter Three). The comparability between the annual prevalence in this thesis, and the studies included in the systematic review reflect the time period of data collection. For example, basic analgesic medications were identified as 'in use' at the time of interview (Haasum et al., 2011; Barry et al., 2016), during a 180-day period from dementia diagnosis (Hamina et al., 2016), or during a one-year period (Brummel-Smith et al., 2002), and therefore comparable to the annual prevalence of this thesis. Furthermore, a previous systematic review investigating the cross-sectional prevalence of paracetamol use for people with dementia living in nursing homes ranged from 45.2% to 71.0% (Tan et al., 2015; Tan et al., 2016). The findings in nursing home settings show a higher prevalence of basic analgesic prescription, potentially highlighting differences depending upon residential setting.

As with the general trend reported for all analgesics, people with dementia had 8% lower five-year prevalence of basic analgesic prescription than older adults without dementia (36.9% vs. 44.6%, respectively). In line with these findings, during the five-year period from index date, people with dementia had a significant 0.84 times lower odds of being prescribed a basic analgesic than older adults without dementia. Each of these prevalence rates, however, only included analgesic prescriptions matched to a musculoskeletal consultation. Sensitivity analysis including all basic analgesic prescriptions (irrespective of matching to a musculoskeletal consultation) highlighted alternate findings. The prevalence of basic analgesic prescription was similar for people with and without dementia during the five-year period from index date (63.5% vs. 62.1%, respectively; adjusted OR 1.03, 95% CI 0.96 to 1.11). The findings of the sensitivity analysis are more comparable to previous literature. The systematic review (see Chapter Three) found that community-dwelling people with dementia had a higher prevalence of paracetamol use than community-dwelling people without dementia (Haasum et al., 2011; Hamina et al., 2016). In addition, within nursing home settings, people with dementia were found to have similar (Tan et al., 2016; Bauer et al., 2016), or higher (Lövheim et al., 2008; Haasum et al., 2011; Tan et al., 2015) rates of

paracetamol use compared to people without dementia. The sensitivity analysis conducted as part of this thesis also found that there was no difference in basic analgesic prescription between people with and without dementia throughout follow up. The findings of the sensitivity analysis were, again, more comparable to previous studies that found an increased prevalence of paracetamol use from the first year to the fifth year after dementia diagnosis (Gilmartin et al., 2015). This sensitivity analysis suggested that the prevalence of basic analgesic prescription for people with dementia was in line with older adults without dementia.

The discrepancy between the main analysis and the sensitivity analysis suggest that when prescribing basic analgesics to people with dementia in primary care there is a lack of temporal association to a musculoskeletal consultation. This finding may suggest that GPs are prescribing basic analgesics even when they have not recently coded for a musculoskeletal consultation. This finding may highlight that when GPs are unsure of the underlying diagnostic cause of the person with dementia's presentation, they may use a trial and error approach to analgesic treatment, as found in the qualitative findings (see Section 9.4.2). The idea that prescribing analgesic medication (typically paracetamol due to the high safety profile) even when unsure of the underlying diagnostic problem may help to identify if the presentation is caused by pain (see Section 2.3.5).

Qualitative exploration highlights convergence to the sensitivity analysis (yet divergence to the main analysis). In particular, healthcare professionals frequently expressed a preference for paracetamol for people with dementia due to the good safety profile associated with these drugs, thereby minimising their concerns of side effects. In a previous qualitative study using semi-structured interviews to generate data, nurses perceived paracetamol as the analgesic of choice for mild-to-moderate pain, reflecting upon the benefits of the low side effect profile, which was especially beneficial for people with dementia (Kovach et al., 2000). The preference towards paracetamol for people with dementia, as found in this thesis and in previous literature reflects national recommendations and research (Abdulla et al., 2013;

AGS Panel, 2009; McLachlan et al., 2011; Girard et al., 2019). The preference towards paracetamol for people with dementia, as identified in the qualitative findings, provides an explanation for the similar prevalence of basic analgesic prescription for people with and without dementia, as found in the sensitivity analysis.

Despite the convergence between the sensitivity analysis and the qualitative findings, again divergence is important to highlight. One GP reflected upon their concerns of overdose when prescribing paracetamol to people with dementia with a low weight. Concerns towards paracetamol have also been noted in previous qualitative studies, in which a focus group study found that physicians and nurses were particularly concerned about the toxicity, and the potential development of liver disease with chronic paracetamol use (Kaasalainen et al., 2007). This finding reflects recent evidence that questions the safety of paracetamol (Roberts et al., 2016), with NICE guidelines no longer recommending paracetamol as the first-line treatment for various musculoskeletal-related pain (Wise, 2014; NICE, 2014; NICE, 2016; Saragiotto et al., 2016).

10.2.2.3.1.2 Non-steroidal Anti-Inflammatory Drugs

The five-year prevalence of non-steroidal anti-inflammatory drug (NSAID) prescription was 13.4% for people with dementia, with an annual prevalence ranging from 2.6% to 3.7%. The sensitivity analysis including all analgesic prescriptions found that the annual prevalence ranged from 5% to 7%. The systematic review (see Section 3.5.4.2.2) found that the prevalence of NSAID use ranged from 5.9% to 21% for community-dwelling people with dementia. In nursing home settings, the prevalence of oral NSAID use for people with dementia ranged from 2.0% to 3.8% (Tan et al., 2015; Tan et al., 2016). Each of these findings show comparable prevalence estimates to the findings of the main and sensitivity analyses included in this thesis.

Results show the five-year prevalence of NSAID prescription was 7.3% lower for people with dementia than older adults without dementia (13.4% vs. 20.7%, respectively, adjusted OR 0.65, 95% CI 0.57 to 0.75), with similar findings for each sensitivity analyses. These findings

are supported by the systematic review (see Chapter Three) which found that the prevalence of NSAID use was lower for people with dementia compared to older adults without dementia (see Section 3.5.4.2.2). These findings are also supported from evidence in nursing home settings that identified a lower prevalence of NSAID use for people with dementia compared to older adults without dementia (de Souto Barreto et al., 2013; Tan et al., 2016), with limited studies suggesting a similar prevalence of NSAID prescription (Haasum et al., 2011).

The annual prevalence of NSAID prescription lowered from dementia diagnosis throughout follow up for people with dementia. These findings are supported by Gilmartin et al. (2015) who also identified a decreased prevalence of NSAID use from the first year to fifth year after diagnosis. Similarly, NSAID use for nursing home residents lowered in line with lowered MMSE score (indicating increased cognitive impairment) (Bauer et al., 2016). Based on the assumption of dementia progression over time, each of these findings indicate that increasing cognitive impairment reduces NSAID use for people with dementia.

These findings converged well with the qualitative findings, providing interpretation to explain why people with dementia may be prescribed less NSAIDs than older adults without dementia. GPs reflected upon their concerns when prescribing NSAIDs for people with dementia due to the increased risk of side effects due to the physiological changes associated with ageing. Such concerns were intensified by the presence and severity of dementia, especially vascular dementia. Minimal qualitative research has explored concerns related to NSAIDs for people with dementia, however Kovach et al. (2000) found that nursing assistants in nursing homes reflected upon the potential side effects (e.g. possible bleeding problems and stomach upset), and the consideration for preventative measures to minimise the risk of such events (e.g. antacids for stomach upset). The concerns towards NSAIDs reflect numerous guidelines recommending that such medications should be considered rarely for older adults, and only if safer therapies (e.g. paracetamol) have failed to relieve pain (AGS Panel, 2009; Abdulla et al., 2013; McLachlan et al., 2011). These findings raise the issue of whether GPs are being overly cautious when prescribing NSAIDs to people with

dementia, considering their lower prevalence rate compared to matched older adults without dementia.

10.2.2.3.1.3 Opioid prescriptions

Opioid prescriptions in this thesis were separated into four classifications based upon their potency; weak analgesics, moderate analgesics, and strong analgesics (each containing increasingly strong opioids used alone or in combination with paracetamol), and very strong analgesics (very strong single opioids such as morphine) following previous methodology (Bedson et al., 2013). The five-year prevalence of opioid prescription for people with dementia ranged from 18.4% for weak analgesic prescriptions (weak combination opioids such as codeine + paracetamol) to 1.6% for very strong analgesic prescriptions (e.g. morphine and oxycodone). These findings are comparable to the prevalence estimates found in the systematic review (see Chapter Three), that found that the prevalence of opioid prescription ranged from 3.6% to 27.5% for community-dwelling people with dementia.

The quantitative findings indicated that the five-year prevalence and odds of weak, moderate, and strong analgesic prescription was lower for people with dementia compared to older adults without dementia. Additionally, the prevalence and odds of prescription for each of these analgesic categories lowered over time from dementia diagnosis (index date) for people with dementia compared to older adults without dementia. The findings of this thesis build upon the mixed and limited evidence identified in the systematic review that found people with dementia had a lower (Bell et al., 2011), similar (Hamina et al., 2016) and a higher (Jensen-Dahm et al., 2015) odds of opioid use compared to older adults without dementia (see Section 2.4.2.6). Furthermore, the findings of this quantitative investigation are supported by a previous systematic review that examined opioid prescription rates for people with and without cognitive impairment, irrespective of residential setting (Griffioen et al., 2017a). The results of this review showed that 21 studies (out of the total 24 identified) found that people with cognitive impairment used equal or less opioids than people without cognitive impairment, supporting the findings of this thesis.

The qualitative findings support and converge well with the quantitative findings presented above. The qualitative findings found that GPs had many concerns related to the side effects specifically related to opioid medication. Such concerns increased their reluctance to prescribe this classification of analgesic for people with dementia. Importantly, GPs perceived such risks to be intensified by the presence of cognitive impairment (such as worsening confusion) for people with dementia. This finding was supported in a previous meta-review of qualitative studies (Geddis-Regan et al., 2018), with research reiterating that the side effects associated with opioid medications increased reluctance to prescribe stronger analgesics (Chang et al., 2009; Manias, 2012). So much so that family members, nurses, and care workers were resistant for opioids to be taken by the person with dementia even when they were prescribed (Peisah et al., 2014).

The side effects associated with opioid medications for people with dementia may be a barrier to optimal pain treatment (McAuliffe et al., 2008; AGS Panel, 2009). These findings reflect a 'negative social stigma' towards opioid medications for older adults, including people with dementia (AGS Panel, 2009) due to the well documented potential harms of opioid medications (AGS Panel, 2002; Abdulla et al., 2013; McLachlan et al., 2011). The findings in this thesis suggest that concerns specifically related to people with dementia (e.g. confusion) are added to an overall general concern of prescribing opioids in older adults. Recent UK guidelines recommend that GPs reduce opioid prescriptions, due to the rise in opioid prescription rates in recent years (Bedson et al., 2013; Bedson et al., 2016; Curtis et al., 2019; British Medical Association, 2017). These additional concerns further contribute to GPs' cautious approach to prescribing opioids. The qualitative findings, along with the previous literature provide a potential explanation to understand why people with dementia had a lower prevalence of opioid prescription (with the exception of very strong opioids), compared to older adults without dementia.

When focusing upon very strong opioids specifically, the quantitative findings indicated that the five-year prevalence was only slightly lower for people with dementia compared to older

adults without dementia (1.6% vs. 1.9%, respectively), somewhat diverging from the qualitative findings. When examining the odds of very strong analgesic prescription, people with dementia had a statistically significant 0.57 lower odds than older adults without dementia (adjusted OR 0.57 95% CI 0.33 to 0.98), however, the confidence intervals around this effect are noticeably wide suggesting some unreliability. Indeed, when considering the absolute difference between prevalence estimates it is only 0.3%. One potential reason for the lack of difference between people with and without dementia as reported in these results is that pain warranting such a strong analgesic may be more easily identifiable. One key challenge of pain identification and pain assessment was determining the underlying pathology of the changed presentation. However, very strong opioid prescriptions (such as morphine or Oxycodone) might be warranted when the pain source was more severe and easily identifiable (e.g. an acute injury). In this situation, the presence or absence of cognitive impairment was less likely to impede the identification of pain. A second potential reason relates to the small sample of people with and without dementia receiving a very strong analgesic prescription. To illustrate, during the five-year period from index date, only 63 (out of *n*=3893) people with dementia, and 238 (out of *n*=12,276) older adults without dementia were prescribed a very strong opioid. The rarity of very strong analgesic prescription in primary care may reduce the precision of the prevalence estimates, and make the absolute difference between people with and without dementia minimal.

10.2.2.3.2 Illness and treatment burden

Another concern expressed by people with dementia, family caregivers, and GPs towards analgesic medication was illness and treatment burden. The amount of health conditions (illness burden) and the amount of medications being taken by the person with dementia (treatment burden) lead to additional concerns towards analgesic medication. Comorbid conditions, or potential drug interactions from medications used to treat them, may mean that analgesics are contraindicated. Additionally, comorbidities may also increase the number of medications being prescribed and taken, again, increasing the risk of drug-drug interactions, as well as concerns regarding polypharmacy. In some of the interviews, it was expressed

that the amount of medications being taken by the person with dementia had reached maximum capacity, meaning that people with dementia were reluctant to take 'lower priority' medications, such as analgesics. In support of these findings, a meta-synthesis of qualitative research found that older adults were reluctant to take multiple medications for multiple health problems (Crowe et al., 2017b), illustrating the challenge of managing an extensive medication regimen, especially for people with dementia where execution and persistent with medications may be more challenging (Arlt et al., 2008). Additionally, previous qualitative interviews with staff in residential aged care facilities found that pain medication was rarely prioritised over physical care medications for people with dementia refusing medications (Peisah et al., 2014). The challenge of illness disease and treatment burden for people with dementia was explored by emergency nurses' whom reflected upon comorbidity and polypharmacy as an additional concern that limited the number of available and appropriate analgesic treatments (Fry, Chenoweth & Arendts, 2016). The findings of this thesis, along with the previous literature highlight the challenge for healthcare professionals to identify an effective, yet safe analgesic medication, whilst considering potential contraindications. This finding may provide further explanation for the discrepancy of analgesic prescribing between people with dementia and older adults without dementia, identified in the quantitative findings.

10.2.2.3.3 Weighing up the concerns

The concerns relating to side effects (see Section 10.2.2.3.1), and illness and treatment burden (see Section 10.2.2.3.2) each contributed to a sense of reluctance to use analgesic medication for people with dementia. Healthcare professionals perceived dementia as a factor providing additional complexity to an already challenging task; prescribing analgesic medication for an older adult. These findings, in addition to the challenges of pain identification and assessment described previously provide greater understanding to why analgesic prescription prevalence was significantly lower for people with dementia than older adults without dementia at a population level.

The multifactorial concerns towards analgesic medications for people with dementia often meant that GPs had the challenging task of weighing up and determining the most effective analgesic, whilst also considering potential side effects, drug-drug, and drug-disease interactions. The multifactorial considerations inherent in analgesic prescribing led to many GPs feeling limited or restricted when prescribing analgesic medication to people with dementia. This finding was supported in previous qualitative studies, in which analgesic prescription was perceived as 'complex' and 'restricted' for people with dementia (Corbett et al., 2016; Griffioen et al., 2017a; Martin et al., 2005).

To identify or 'weigh up' the 'most appropriate' analgesic, GPs recognised the importance of upwards titration, or as commonly referred 'starting low and going slow', until the person with dementia was comfortable with their pain. Previous studies support these findings; with many healthcare professionals following a stepped approach to analgesic treatment for people with dementia as a means to assess potential side effects and interactions (Barry et al., 2012; Barry et al., 2013; Kovach et al., 2000; Kaasalainen et al., 2007). In line with the principles of upwards titration, GPs had a preference towards paracetamol, for reasons outlined previously, however paracetamol was not always perceived effective depending upon the severity of the pain experienced. When considering escalation and upwards titration to alternative analgesic medications (e.g. NSAIDs or opioids), GPs reported many concerns, such as their association with side effects and potential drug-drug or drug-disease interactions. GPs weighed up their concerns related to each analgesic, sometimes trialling analgesic medications to identify the most 'appropriate' treatment. In previous research, nurses described this process as a 'balancing act' (Fry et al., 2016; Kaasalainen et al., 2007).

Importantly, GPs perceived the complexity and perceived 'limited choice' of appropriate treatments to have negative implications; leading to the under treatment of pain for people with dementia, due to the concern of 'doing more harm than good'. These findings therefore contribute to the understanding of the quantitative findings that indicate people with dementia were prescribed less analgesic medication than older adults without dementia.

10.2.2.4 Responsibility of the caregiver to manage pain

The qualitative findings of this thesis suggest that family caregivers were often responsible to manage the pain experienced by the person with dementia in the community by prompting them to engage with non-drug strategies and to take analgesic medication. Additionally, GPs were often reliant upon the presence of a family caregiver to manage analgesic medications in the community; with the presence of a family caregiver minimising many of the concerns discussed throughout this chapter. To exemplify, GPs were resistant to prescribe opioids to people with dementia in the absence of a family caregiver or support in the community. The presence of family caregivers reduced the perceived risk of opioids (and other analgesics) being incorrectly managed. This was a concern for opioids in particular due to the risk of side effects, addiction, and overdose, providing further explanation for the discrepancy of opioid prescription between older adults with and without dementia.

The responsibility for family caregivers to manage pain was, however, sometimes perceived as burdensome. To counteract the burden, family caregivers and GPs recognised the benefits of medication management strategies (e.g. blister packs, dosette boxes, and automatic pill dispensers) to reduce the sense of responsibility felt by the family caregiver to correctly administer medications. Conversely, this thesis also found that some family caregivers expressed relief (rather than burden) to take control of the medication taken by the person with dementia. Qualitative research exploring pain treatment for community-dwelling people with dementia is lacking; with this thesis highlighting the unique challenges of pain management in the community. Despite the lack of directly comparable findings, Maidment et al. (2017) explored medication management (without a specific focus upon analgesic medications) from the perspective of people with dementia, family caregivers, and health and social care professionals using semi-structured interviews. This study by Maidment et al. also highlighted the utility of compliance packs to manage medication regimens, and reflected upon the emotional burden felt by family caregivers when managing multiple medications in the community. This thesis built upon the findings of Maidment et al. by focusing upon pain management specifically and by also illuminating the potential relief

felt by some family caregivers when managing the person with dementia's analgesic medication regimen to avoid adverse events (e.g. overdose).

The findings of this thesis show that many GPs were cautious to prescribe analgesic medications (especially strong medications) in the absence of a family caregiver, or close support in the community. Such findings may contribute additional understanding to the reported lower prevalence of analgesic prescriptions for people with dementia compared to older adults without dementia, as identified in the quantitative findings, especially if a family caregiver is not present in the community to take on this role.

10.3 Unique contributions

This thesis provides the first mixed methods investigation into pain identification, assessment, and pain management for community-dwelling people with dementia. Previous research focusing upon community-dwelling people with dementia is limited, of low quality, with particularly limited research conducted in the UK (see Chapter Three).

This thesis was also the first to examine pain identification, assessment, and treatment for community-dwelling people with dementia, using UK primary care electronic health record data, especially concerning the trend of musculoskeletal consultation and analgesic prescription over time, with the presumption of disease progression. Unlike many of the studies included in the systematic review (see Chapter Three), this study also identified a matched older adult cohort, to allow for direct comparison. The quantitative findings of this study therefore build upon previous evidence, providing unique insights into musculoskeletal consultation and analgesic prescriptions in a large population of people with dementia in primary care likely to be representative of the primary care population as a whole.

Previous research that aimed to explore pain identification, assessment, and treatment for people with dementia has only interviewed older adults without dementia (i.e. formal/informal caregivers; Martin et al., 2005), or only included the person with dementia in observational based designs (Lichtner et al., 2015; Lichtner et al., 2016). A previous study which included family caregivers and persons with dementia in dyadic interviews explored medication

management generally (Maidment et al., 2017) and did not consider the specifics of managing pain. It is well established that pain and emotion are linked (Lumley et al., 2011) and it may be argued that the experience of pain and emotional expression within a dyadic relationship is different to the experience of other medical problems or issues, certainly research has shown emotional influences between couples and family members when one member expresses pain (Campbell, Shraim, Jordan & Dunn, 2015; Campbell, Jordan & Dunn, 2012). Importantly this thesis was the first to explore the person with dementia's perspective and experience of their own pain identification, assessment, and management, irrespective of setting (Geddis-Regan et al., 2018).

A small number of qualitative studies have explored pain identification, assessment, and treatment from the perspective of family caregivers of people with dementia (Lichtner et al., 2015; Lichtner et al., 2016; Martin et al., 2005; Mentes et al., 2004). In these studies, however, the family caregivers reflected upon their relative with dementia currently living in a nursing home setting, or during a hospital stay. In nursing home and hospital settings, pain identification, assessment, and treatment are different from a community or primary care perspective. For example, in nursing home and hospital settings, healthcare professionals are regularly available and responsible to manage pain for the person with dementia. Alternatively, this thesis provides novel insights into the experience and perspective of family caregivers who felt responsible to provide the primary source of care and support for their community-dwelling relative with dementia.

Previous qualitative studies have examined pain identification, assessment, and treatment for people with dementia from the perspective of healthcare professionals (Geddis-Regan et al., 2018). The majority of these studies investigated nurses, nursing assistants, and healthcare assistants' perspective of pain for people with dementia living in formal care settings (including nursing home, palliative, and acute care settings; Geddis-Regan et al., 2018). Only two studies provide an insight into pain identification, assessment, and treatment for community-dwelling people with dementia (Karlsson et al., 2014; Karlsson et al., 2012),

with both studies only exploring a nurse perspective. In the community, GPs often provide ongoing care and support for people with dementia, including the identification and assessment of pain, and the prescription of analgesic medications. When GPs consider the need for specialist input, the GP acts as a gatekeeper to secondary care services such as old age psychiatrists. Despite their direct involvement in pain care and the management of behavioural and psychological changes for people with dementia living in the community, limited previous research has explored the perspective of GPs and old age psychiatrists. This research therefore provides unique, and much needed insight into the perspective and experience of GPs and psychiatrists, with a focus upon pain identification, assessment, and treatment for community-dwelling people with dementia (Jennings et al., 2018b).

10.4 Strengths, challenges, and limitations

The following sections discuss the strengths, challenges, and limitations of this thesis, focusing upon the mixed methods approach as a whole, followed by the quantitative and qualitative elements in turn.

10.4.1 Mixed Methods

The mixed methods approach to this thesis allowed the quantitative findings to provide a clear picture of pain identification, assessment, and treatment for a large population of people with dementia. Whereas the qualitative semi-structured interviews provided a detailed exploration and discussion of the participants' perspectives, providing rich detail to the picture. The use of both quantitative and qualitative methods therefore allowed for a more complete understanding of the phenomena.

Of the three core mixed method designs outlined by Creswell and Plano Clark (2018), a convergent mixed methods design was chosen to investigate pain identification, assessment, and management for people with dementia. A convergent mixed methods design allowed the quantitative and qualitative data to be collected and analysed concurrently, using traditional methods most suitable for the data (e.g. statistical analysis for quantitative data, and thematic analysis for qualitative data). The convergent design (rather than a sequential

design; see Section 5.4.2) therefore had pragmatic benefits within a time restricted project. For a convergent mixed methods design, Creswell and Plano Clark recommend that the quantitative and qualitative approaches should investigate similar concepts to facilitate integration. Quantitative and qualitative findings were integrated in a narrative discussion throughout this chapter (see Section 10.2). The integration found that the qualitative findings supported, explained, and contributed to an in-depth understanding of the quantitative results and vice versa. However, there was instances where the quantitative and qualitative findings could not be integrated as easily. For example, the qualitative findings highlighted non-drug strategies to manage pain, however information about non-drug strategies were unavailable for investigation in the CPRD hindering complete integration.

Finally, Creswell and Plano Clark (2018) reiterate the potential consequences of integrating quantitative and qualitative approaches that have vastly different sample sizes. In this study, the different sample sizes had no negative consequences for integration. The quantitative and qualitative findings provide a 'complementary picture about the phenomenon' (Creswell & Plano Clark, 2018, p. 188). In fact, different sample sizes are essential to ensure a rigorous high-powered quantitative, and a rigorous in-depth qualitative investigation.

10.4.2 Quantitative methods

10.4.2.1 Study design

The general strengths and limitations of electronic healthcare record databases, including CPRD were outlined in Table 6.1. CPRD data provided the opportunity to examine longitudinal consultation and treatment trends in primary care, using a representative sample of people with dementia and older adults in the UK.

Electronic health records are frequently used in research (Cowie et al., 2017; Herrett et al., 2015), however data is not recorded with research purposes in mind. Secondary analysis of CPRD data therefore required an iterative process driven by the aim of the research followed by the available data (Cheng & Phillips, 2014). For this study, the analysis was initially driven

by the first research objective: to investigate pain identification and assessment for community-dwelling people with dementia; however, CPRD does not provide explicit pain identification or assessment details. Therefore, the analysis was partially driven by the available data, utilising Read codes indicative of a musculoskeletal consultation to illustrate that a potentially painful condition was identified, investigated, and coded by the clinician in accordance with previous methodology (Richardson et al., 2018; see Section 6.2.9.1). Although this method provided an insight into (often painful) musculoskeletal condition identification and assessment in primary care, pain caused by other factors (e.g. head pain) and the severity of the pain could not be examined, potentially underestimating the prevalence of pain for people with dementia. To avoid this limitation, I could have collected data that was designed with the objective of the research in mind (e.g. using a survey design to ask GPs about pain identification and assessment for people with dementia). However, primary collected data would have obtained a smaller sample (as the set-up of a multisite recruitment design may have taken time and organisation beyond the expectation for a PhD study), it would not have covered the five year period as used in this current analysis (with the constraints of a 3 year PhD), there would have been considerable cost associated with this more traditional research recruitment approach (beyond the funding structure), and it may not be representative of older adults in primary care at a population level. For example, on this last point, people that respond to surveys may be inherently the same as each other, but different from the rest of the population (selection bias).

10.4.2.2 Sample

Approximately 98% of people in the UK are registered with a general practice, with primary care being the first point of healthcare contact in the community (Herrett et al., 2015). Research has found that CPRD is representative of the UK population in relation to age, gender, and ethnicity (Herrett et al., 2015), making CPRD an ideal representative sample base for health service research at a population level.

Patients in the dementia cohort were identified using Read codes and product codes indicative of a dementia diagnosis (see Section 6.2.6.1.1). The recorded rate of dementia diagnosis in UK primary care data has increased from 40% in 2009 to 67% in 2015, with a concomitant increase in the prescription of anti-dementia drugs (Mukadam, Livingston, Rantell & Rickman, 2014). Despite improvements in detection rates (Donegan et al., 2017), there may be a large proportion of people with dementia residing in the community that were not recorded as having a diagnosis, or anti-dementia drug in primary care records. This has implications for this study, as people with dementia without a recorded dementia diagnostic Read code, or anti-dementia drug prescription may have been misclassified to the older adult cohort, especially so during the earlier years of the study period (i.e. 1997) where reporting and detection rates have been shown to be lowest. Despite this limitation, this study ensured that all older adults were 'active consulters' (consulting within a 90 day pre-and-post window of index date), minimising the chance that the older adult had dementia unknowingly to the healthcare professional. Additionally, the cohort design of this study allowed dementia diagnosis to be investigated over a long period (up to 20 years). This period of investigation minimised the chance that people with dementia were misclassified into the older adult cohort (and vice versa), compared to alternative epidemiological designs (e.g. cross-sectional designs) which would rely upon a much shorter period of time (often a single time-point) to identify evidence (or absence) of dementia. Finally, to mitigate these limitations, recent research has found a high agreement between dementia identified in CPRD, Hospital Episode Statistics data, and GP survey data; suggesting acceptable identification of people with dementia in CPRD (Brown et al., 2016).

The focus of this project was community-dwelling populations, defined as people living at home alone or with family members, in assisted living facilities, retirement communities, or in a residential home (Hunt et al., 2015; see Section 1.7). This definition was strictly implemented in the systematic review and qualitative recruitment. However, important limitations are essential to consider regarding the CPRD investigation. Firstly, all patients with a Read code indicative of formal care residence were excluded, as this was a definitive

marker of formal care residence in line with previous EHR research (Shah et al., 2010). It became evident, however, that clinicians inconsistently used these specific status codes (as opposed to diagnosis codes for example); therefore, people living in formal care settings may (incorrectly) remain in the main analysis. To investigate the implication of this potential misclassification bias, sensitivity analysis was conducted, with two additional markers to identify and exclude people living in a formal care residence i) a household of greater than two people over the age of 50 and ii) a consultation location in a formal care setting (see Section 6.2.13.5.1). Excluding patients with evidence of these additional markers allowed for the identification of a 'strict' or 'hard' population of older adults with and without dementia with a higher likelihood of living in the community. The sensitivity analysis findings reflected the main analysis findings, showing limited impact of potential misclassification. Secondly, information was often unavailable in CPRD to distinguish between people living in a nursing home and people living in a residential home. For example, Read codes often referred to 'care homes' or 'institutions' rather than explicitly coding if the person lived in a residential or nursing home, with further complexity for dual-registered homes (providing residential and nursing care). Furthermore, households with greater than two people over the age of 50 were excluded from the sensitivity analysis. Both of these methods facilitated the identification and exclusion of nursing home residents; however, people living in residential homes may have been incorrectly excluded from the main and sensitivity analysis.

10.4.2.3 Analysis

This research aimed to investigate the pattern of musculoskeletal consultation and analgesic prescriptions in conjunction to expected dementia progression over time. To investigate this trend, the incidence and prevalence analysis was stratified into annual periods from the index date, defined as the incident dementia-related clinical code (or equivalent matched date for older adults without dementia). Research and UK policy have highlighted the untimely coding of a dementia diagnosis in primary care records, with a small number of patients only receiving a recording of dementia during the latter, and more severe stages of the condition (Bradford, Kunik, Schulz, Williams & Singh, 2009; Department of Health, 2009). The untimely

diagnosis of dementia in primary care may implicate the accuracy of longitudinal temporal analysis starting from an index date representing 'dementia diagnosis' (Russell et al., 2013). Additionally, the temporal interpretation in this thesis relies upon the assumption that cognitive ability of people with dementia declines during the five-year period from their first dementia-related clinical code, in line with similar studies (Gilmartin et al., 2015). This method was used due to the unavailability of codes to determine cognitive ability (e.g. MMSE score) within consultation records. I acknowledge that this approach does not take into account that the progression of cognitive impairment for people with dementia is individual to the person, and the subtype of dementia.

The results show that the dementia cohort had a shorter follow up from index date than the older adult cohort (see Table 7.5). The dementia cohort also had a reduced incidence and prevalence of musculoskeletal consultation and analgesic prescription, especially as time from index date increased. The difference between the dementia cohort and the older adult cohort may be explained by immortal time bias; meaning that the 'period of follow-up during which, by design, death or the study outcome cannot occur' (Lévesque et al., 2010). In other words, 'unhealthier' patients in the dementia cohort may have left the study (e.g. due to death, transfer to nursing home), leaving a healthier cohort of patients with dementia that did not have musculoskeletal pain, or require analgesic medication. Despite this being an important consideration, it was found that the dementia cohort and the older adult cohort that remained in the study during the last annual time period from index date (year four to five) were similar concerning a range of baseline characteristics as people included in the first year after index date (see Table 7.5). This finding indicates that the dementia cohort and older adult cohort did not seem to become progressively 'healthier' throughout follow up because of attrition.

Musculoskeletal conditions are the most prevalent cause of pain for older adults with and without dementia (Corbett et al., 2012; Corbett et al., 2014; Husebo et al., 2010). For this reason, and many others (see Section 6.2.9.1), musculoskeletal consultation Read codes

were used as a proxy indicator for the identification and assessment of a painful condition in primary care. Earlier in this Chapter, the priority of health conditions and coding was discussed (see Section 10.2.2.3.2), with research finding that codes for musculoskeletal conditions were only coded when other comorbid conditions were no longer a priority (Bedson et al., 2011). For people with dementia, this may mean that other health problems that have 'clinical dominance' may be coded by the GP (such as BPSD) even when pain has been identified and assessed (Jørgensen et al., 2018). This may contribute to the lower incidence and prevalence of musculoskeletal consultations for people with dementia compared to older adults.

CPRD only captures musculoskeletal consultations and analgesic prescriptions occurring in primary care (Herrett et al., 2015). Therefore, the absence of a musculoskeletal consultation does not necessarily mean an absence of musculoskeletal condition for the individual. People with dementia may consult less (although this was not the case at baseline; see Table 7.4) due to restricted access to primary care (Pratt, Clare & Kirchner, 2006; Bunn et al., 2016) resulting in a lower rate of musculoskeletal consultation and analgesic prescriptions. Similarly, CPRD does not capture over-the-counter analgesic medications. Older adults regularly obtain paracetamol over-the-counter to self-manage pain (Roumie & Griffin, 2004), with many family caregivers choosing to manage the pain experienced by the person with dementia using over-the-counter analgesics when living in the community (Mentes et al., 2004). The prevalence estimates of analgesic prescription in this study are therefore likely to under estimate the true prevalence of analgesic medications that are widely available over-the-counter (e.g. paracetamol and some NSAIDs).

Finally, this study only included medications with a primary analgesic property (defined as drugs within the Anatomical Therapeutic Chemical (ATC) groups N02 or M01A). Pain may, however, also be treated using gabapentinoids (e.g. gabapentin and pregabalin) (Appleyard et al., 2019). This may be especially true for people with dementia, as gabapentinoids are perceived as a 'dual-action' medication to target both pain and anxiety (Appleyard et al.,

2019). The 'off-label' prescription of gabapentinoids (which may be more likely for people with dementia) may explain the discrepancy in analgesic prescription for people with and without dementia.

10.4.3 Qualitative methods

The strengths and limitations of qualitative study designs are discussed throughout Chapter Six. This section reflects upon some of the pertinent strengths, challenges and limitations identified when reflecting upon the study design, sample, and analysis.

10.4.3.1 Study design

Unlike previous research (see Section 10.3), this thesis wished to include people with dementia to explore their perspective and experience of pain identification, assessment, and management. Dyadic interviews including the person with dementia and their family caregivers have been praised in previous research, with the dyadic interview facilitating a safe and comfortable environment for open and honest discussion (Morgan et al., 2013; Pesonen et al., 2011). Dyadic interviews also overcome many ethical concerns (see Section 6.3.5). Despite the positives of dyadic interviews for people with dementia, dyadic interviews sometimes 'interfered' with the person with dementia's voice being heard (Morgan et al., 2013; Pesonen et al., 2011 p. 656). To balance the power dynamics in dyadic interviews, I employed various techniques to illuminate and focus upon the perspective of the person with dementia (see Section 6.3.5). However, I acknowledge that such techniques may not have fully addressed the imbalance of power, with some family caregivers continuing to take control of the interview. Consequently, the perspective of the person with dementia was sometimes expressed by the family caregiver, on behalf of the person with dementia, despite the person with dementia having the ability to describe their own thoughts and experiences. Although dyadic interviews may have meant that the family caregiver perspective over-powered the voice of the person with dementia, I viewed this as a worthy compromise to ensure the safety and wellbeing for the person with dementia, in line with previous research in this area (Pesonen et al., 2011).

Additionally, two GPs completed a telephone interview. The convenience of telephone interviews improved the recruitment of healthcare professionals in this study. Telephone interviews seemed shorter, and felt more procedural (rather than exploratory) due to lost nuances, the challenge of building rapport, and lack of non-verbal cues (Irvine et al., 2012).

10.4.3.2 Sample

People with dementia were only eligible for the study if they had a family caregiver that was also willing to be interviewed, as part of a dyadic interview, for reasons previously discussed (see Section 6.3.5). Although this study did not stipulate that the person with dementia must live with a family caregiver, due to the nature of recruitment, none of the people with dementia lived alone. Therefore, this study was unable to explore the unique perspectives, experiences, and challenges of pain identification, assessment, and management for people with dementia that did not live with a close family caregiver.

Similarly, inclusion criteria stipulated that the person with dementia must be able to communicate their experiences verbally, as part of the interview methodology. This meant, however, that the unique challenges of pain identification, assessment, and management for people with advanced dementia that could no longer verbally communicate were not explored. It cannot be assumed that the experiences of people with dementia in this study reflect the experiences of people with advanced dementia that are unable to contribute to an interview. It is important to remain mindful that the findings of this study therefore reflect the experiences of a sub-group of people with dementia. For example, in this study, a stoical attitude towards pain was viewed as a factor impeding the self-report of pain. However, this may only affect people with dementia that have ‘relatively intact insight’ during the early stages of dementia progression according to previous research (Chopra & Smith, 2006).

When interviewing people with dementia and family caregivers, all but one of the dyadic relations were husband and wife dyads. Furthermore, all people with dementia and their family caregivers were white British, meaning that the unique experiences for other cultures and ethnic groups could not be explored. The restricted nature of the sample may limit the

transferability of the findings to alternative dyadic relationships (e.g. parent and child) and ethnic groups.

In terms of recruitment, all people with dementia and their family caregivers were recruited through Join Dementia Research (JDR). Therefore, the person with dementia or their family caregiver must be actively interested in participating in research. Additionally, healthcare professionals were recruited using a snowball sample through existing clinical networks within the School of Primary, Community and Social Care. Healthcare professionals recruited in this study may have had an increased awareness of pain research due to their connections with the School. Each of these recruitment strategies are important when considering the transferability of findings to other populations.

10.4.3.3 Analysis

This study used thematic analysis to explore the collective meanings of pain identification, assessment, and management for people with dementia, offering an insight into patterns of meaning across the dataset (Braun & Clarke, 2012). Thematic analysis therefore does not facilitate the exploration of unique and idiosyncratic perspectives and experiences found only within a single data item (rather than *across* the dataset), like other alternative analytical approaches (e.g. narrative analysis, Interpretative Phenomenological Analysis). However, to reflect the research questions (see Section 4.2), it was important to identify the collective meaning of the key parties involved in the care of community-dwelling people with dementia, making thematic analysis an appropriate analytical approach. When choosing thematic analysis, there was a number of theoretical and analytical decisions to make (see Section 6.3.9). The analysis in this thesis was underpinned by a critical realist theoretical perspective (see Section 5.3.2), and thus the interpretation was directly focused upon the explicit or surface meanings of the data. Therefore, it was not the purpose of this analysis to conceptually interrogate the underlying meaning of the data, however research of this nature may be useful.

10.5 Reflections on the study

I approached this study with a background in Health Psychology. This equipped me with the knowledge and experience of both quantitative and qualitative methods, but also an understanding of the detrimental impact of persistent pain. Before starting the PhD, I provided day care support to people with dementia living in the community at a local charity. Alongside this role, I worked in the NHS as a Clinical Studies Assistant regularly collecting data for a number of dementia and mental health studies. During this employment, I collected data for the MARQUE project (based at University College London) which aimed to increase knowledge about agitation or distress behaviours for people with dementia in nursing home settings. Despite having previous experience of witnessing the challenges of living with dementia (as part of my day care role), and being aware of the agitation or distress behaviours in nursing homes (as part of my employment), my understanding of pain for people with dementia was limited.

This study was underpinned by the theoretical perspective of critical realism. Therefore, I believe that pain, musculoskeletal conditions, and analgesic medications are external realities that exist independent of our construction of them. I also believe that each participant had their own subjective, real-world lived accounts of pain identification, assessment, and treatment shaped by culture, history, and experience (Maxwell, 2012; McEvoy & Richards, 2006). The use of quantitative methods allowed musculoskeletal conditions and analgesic medications to be measured as an 'external reality'. Qualitative methods allowed insight and exploration into participants' individual perspectives. This perspective was shaped by my own beliefs, experiences in education, employment, and the specific interests and expertise of my supervisory team.

Despite having a knowledge of quantitative methods, I had not previously worked with 'big data' or EHR. This thesis therefore gave me the opportunity to advance my understanding and skills 'cleaning' and analysing population-level data using epidemiological principles. My

experience working with health record data as part of this thesis has given me the confidence to use this data as part of future projects.

I have conducted qualitative interviews previously as part of my education and employment, however, this study was the first time that I had conducted qualitative interviews with people with dementia. Immersing myself within the literature related to interviewing people with dementia (a review of which is provided by Novek and Wilkinson, 2019), and gaining advice from PPIE members was important to gain an understanding of the potential encounters that I may face during the interviews. Although I had not previously conducted qualitative interviews with people with dementia, my previous involvement in dementia research means that I have determined if a person with dementia has the capacity to consent in research. I have previously undertaken training courses such as 'An Introduction to the Valid Informed Consent Process', and 'Informed Consent with Adults Lacking Capacity' (both through the Clinical Research Network). Additionally, in previous employment, I was supervised when determining capacity to consent, and was deemed competent by senior research staff. Despite the training and experiences gained before the PhD, it was essential to remain continually reflexive before, during, and after the consent process (using the methods outlined in Section 6.3.11).

Before conducting interviews with people with dementia and their family caregivers, I preconceived that participants may view me as the 'young lady from the university'. This preconception in hindsight was formed based upon my previous caregiving role, in which I felt I had a granddaughter-like relationship with the people with dementia that attended the day care service. Additionally, I felt that my 'student' status may have influenced the data collected; with some participants questioning my interest in dementia by asking *'do you have a grandparent with dementia?'*. In contrast, however, some people with dementia and family caregivers viewed me as an 'expert' in dementia, asking for my opinion on the symptoms experienced and the care provided to the person with dementia. Such questions highlighted the blurred role of the researcher. In such circumstances, I re-established my role as a

researcher, and the kinds of questions that I could, and could not answer. Similarly, I also preconceived that my 'student' status and social science background (rather than being a qualified health professional) would place me as an 'inferior' in the eyes of GPs and psychiatrists. Before entering my first GP interview, I perceived the GP as the 'expert' and myself merely as an interested PhD student. This preconception was quickly readdressed as many GPs viewed me as the expert in pain for people with dementia, using phrases such as *'you probably already know all of this'* and *'you're going to tell me that there's a dementia pain scale'.* When reflecting upon the data, my 'expert' status seemed to make GPs cautious to express their feelings, thoughts and experiences that deviated from the 'right answer'. In an attempt to overcome this, at the start of each interview I explained to all participants that there was 'no right or wrong answers', rather I was interested in their thoughts, feelings, perspectives and experiences.

10.6 Implications

The findings of this study have implications for family caregivers, healthcare professionals, and policy, each of which are discussed in turn.

10.6.1 Family caregivers

UK policy and guidance recognised that family caregivers provide the majority of care to people with dementia (Department of Health, 2009). Therefore, family caregivers should receive the support that will enable them to assist the person with dementia to live as well as possible with dementia (Thompson et al., 2007). However, this study continues to highlight the responsibility and potential burden upon family caregivers to identify, assess, evaluate, treat, and monitor pain in the community. It is therefore essential that we equip family caregivers with the knowledge and support to identify and manage pain for the person with dementia (Napp Pharmaceuticals, 2014). This may involve exploring the person with dementia and the family caregiver's beliefs and attitudes towards pain, and their understanding of pain for people with dementia. This would allow potential misconceptions to be explored and allow a basis for further education. For example, it might be helpful to

educate family caregivers about the signs of pain (and other unmet needs), especially for people with dementia that may have difficulty verbally communicating their pain. This is especially important for signs that are behavioural or psychological in nature that may be incorrectly attributed to dementia itself.

10.6.2 Healthcare professionals

This study, in line with previous literature, found that some family caregivers and healthcare professionals questioned if the self-reported pain of the person with dementia reflected their pain experience. Such beliefs contributed to the perspective that self-reported tools for people with dementia are inappropriate. Such findings are concerning considering that guidance recommends that self-report tools should be attempted to identify and assess pain for people with dementia irrespective of the severity of cognitive impairment (Schofield, 2018). Recommendations should continue to emphasise the importance of attempting self-report for people with dementia as part of a multidimensional assessment.

Many healthcare professionals reflected upon the importance of investigating 'behavioural and psychological symptoms' as a potential indication of pain for people with dementia. Despite this, many expressed concern that behaviours associated with pain continue to be incorrectly attributed as a symptom of dementia. In accordance with this finding, in large, healthcare professionals were unaware of, or chose not to use dementia-specific assessment tools, despite recent UK pain management guidelines recommending the incorporation of behavioural observation tools in clinical practice (Schofield, 2018; NICE, 2018). These findings highlight a disconnection between policy, research, and clinical practice when assessing pain for people with dementia in UK primary and secondary care. Healthcare professionals should be given the necessary support and training to implement behavioural observation pain tools in primary and secondary care as part of the multidimensional assessment of pain.

This research identified many concerns relating to analgesic medications for people with dementia, including side effects, illness burden, and treatment burden. This was reflected in

the potential under treatment of pain, as identified in the quantitative findings. To address this issue, healthcare professionals should:

- Engage with non-drug strategies as a first-line or combined approach for pain
- Identify the optimal analgesic treatment that balances the benefits of pain relief against the risk of side effects, drug-disease and drug-drug interactions
- Regularly assess the efficacy of the analgesic medication, along with the evaluation of potential side effects, interactions, and functioning

Despite the importance of regularly assessing and evaluating pain for people with dementia (as discussed above), GPs viewed this as challenging in the time-limited context of primary care. The responsibility (and sometimes burden) of pain assessment, evaluation, monitoring, and feedback often fell upon the shoulders of family caregivers in the community. It is therefore essential to promote a 'whole system' approach in the community, including primary and secondary care teams and family caregivers, but also other community services, such as pharmacists, home care, third sector services, admiral and district nurses. Each of these professions have the opportunity to play a role in pain care, with the inclusion and consideration of pain in care plans for people with dementia (Department of Health, 2009; Maidment et al., 2017), given adequate support, education, and training is in place.

10.6.3 Policy

The UK Dementia Strategy emphasised the importance of supporting people with dementia to continue living in their own homes for as long as possible (Department of Health, 2009). BPSD are often recognised as the primary reason for nursing home and hospital admission (Finkell, 2000; Luppa et al., 2010), largely due to the impact on family caregivers of people with dementia (Chiao, Wu & Hsiao, 2015). BPSD is commonly treated using anti-psychotic medication despite risks of mortality and evidence of limited efficacy (Kales et al., 2012; Forester & Vahia, 2019). To reflect this, research and policy suggests that anti-psychotic medications should only be prescribed to people with dementia in exceptional circumstances (Department of Health, 2015). In addition, policy recommends that pain should be

investigated as a potential driver of BPSD for people with dementia (Department of Health, 2015) with trial evidence (nursing home based) indicating that the administration of analgesic medication can lead to reductions in BPSD (see Section 1.2.3; Husebo et al., 2011a; Pieper et al., 2013). This thesis found that the identification and assessment of painful conditions was lower for people with dementia at a primary care population level, with qualitative findings highlighting the difficulty of determining if changes in presentation were related to pain, an alternative unmet need, or were a direct symptom of dementia. Clearly from the evidence presented, pain and pain conditions are very common in people with dementia and in line with these findings, guidance has called for a national public health campaign to educate people about the signs of pain in people with dementia (Napp Pharmaceuticals, 2014). A campaign of this nature would aim to improve the recognition of pain, and its role as a potential driver of BPSD. Such action would possibly reduce inappropriate referral to secondary care services (e.g. old age psychiatry), and potentially lower the use of harmful anti-psychotic prescriptions; increasing quality of life for people with dementia and family caregivers.

10.7 Future research

The findings from this thesis indicates that the following research is needed:

1. To test the psychometric properties and clinical utility of behavioural observation pain tools for people with dementia in primary care settings. Behavioural observation tools are recommended by UK guidelines (Schofield, 2018), however research has yet to investigate the clinical utility, suitability, and appropriateness of these pain assessment methods for a GP in a primary care setting (Corbett et al., 2014; see Section 2.3.3.1). Research of this nature is essential when implementing a behavioural observation tool in clinical practice.
2. To examine pain management for community-dwelling people with dementia in the UK. This study would use a nationwide longitudinal interview survey design. Such research should overcome the limitations associated with longitudinal primary care

consultation data, particularly the restrictive nature of using EHR (as outlined elsewhere, see Section 10.4.2.1). Surveys would be facilitated by a research assistant, with information obtained by the person with dementia (where able) or the caregiver (informal or formal). The survey could include a detailed investigation of:

- The general health of the person with dementia
- The stage and severity of dementia
- Examination of pain (e.g. measures of severity and impact)
- Pharmacological pain management
- Non-pharmacological strategies for pain

Importantly (and currently missing from the literature), surveys would be completed during the first year following dementia diagnosis, and each year there onwards until nursing home admission, death, or the end of the study period. Although survey designs come with their own limitations (see Section 10.4.2.1) this method would allow for the first longitudinal investigation of pharmacological (including over-the-counter and prescribed medication) and non-pharmacological management for people with dementia in the UK throughout the progression of their condition. This may help to identify individuals at an increased risk of a poor outcome (early nursing home admission, mortality) and whether pain and complications about the assessment and management of pain contribute to those outcomes. Having knowledge about risk factors is the first step for future intervention design.

3. A mixed methods investigation of an educational intervention to improve pain identification and pain assessment for people with dementia in primary care. Primary care team members (e.g. GPs, nursing staff, healthcare members) would receive a training package based upon up to date UK guidelines and evidence (Abdulla et al., 2013; Schofield, 2018). The training package would include information and practical guidance on:

    - Self-report (The Numerical Rating Scale or verbal descriptors; Schofield, 2018)

- Behavioural observation (PAINAD and Doloplus-2 scale; Schofield, 2018)
- Clinical guidelines for non-pharmacological and analgesic prescription for people with dementia (AGS Panel, 2009; Abdulla et al., 2013).

Primary care team members would be provided with educational resources reiterating the messages provided in the training. A qualitative evaluation, with interviews with trainees would assess the feasibility and appropriateness of the intervention as a process evaluation to determine integration and implementation of the educational intervention into practice. Quantitative analysis would examine the prescription of analgesics for people with dementia prior to and after the intervention.

10.8 Conclusion

This chapter provided an overview of the key findings of this thesis, organised by each research objective, with comparison to previous relevant literature identified throughout the literature and systematic review. An overview of the strengths, challenges, and limitations pertaining to the mixed methods approach, including the quantitative and qualitative elements were considered. Key reflections on the study, and implications of this research for family caregivers, practice, and policy were highlighted, with suggestions for future research.

11 References

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12 Appendices

Appendix 1: MEDLINE Ovid Search Strategy

Appendix 2: Systematic review quality assessment

Appendix 3: ISAC CPRD study approval

Appendix 4: Clinical code lists

Appendix 5: NHS Research Ethics Committee and Health Research Authority approvals

Appendix 6: Interview guides

Appendix 7: Pre-interview checklist

Appendix 8: Study packs

Appendix 9: Risk protocol

Appendix 10: Thematic analysis

Appendix 11: Contact summary sheet

Appendix 12: Comparison of community sensitivity cohort

Appendix 13: Sensitivity analysis

Appendix 1: Medline Ovid Search Strategy

1	exp Analgesics/
2	analgesi*.ti,ab.
3	drug*.ti,ab.
4	("drug*" adj3 "trial").ti,ab.
5	medication*.ti,ab.
6	prescription*.ti,ab.
7	pharmacolog*.ti,ab.
8	("pain" adj3 "manag*").ti,ab.
9	assess*.ti,ab.
10	treat*.ti,ab.
11	opioid*.ti,ab.
12	paracetamol.ti,ab.
13	acetaminophen.ti,ab.
14	tylenol.ti,ab.
15	panadol.ti,ab.
16	NSAIDS.ti,ab.
17	(non?steroidal adj3 anti?inflammatory).ti,ab.
18	morphine.ti,ab.
19	codeine.ti,ab.
20	narcotic.ti,ab.
21	opium.ti,ab.
22	buprenorphine.ti,ab.
23	dextromoramide.ti,ab.
24	diphenoxylate.ti,ab.
25	dipipanone.ti,ab.
26	dextropropoxyphene.ti,ab.
27	propoxyphene.ti,ab.
28	diamorphine.ti,ab.
29	dihydrocodeine.ti,ab.
30	alfentanil.ti,ab.
31	fentanyl.ti,ab.
32	remifentanil.ti,ab.
33	meptazinol.ti,ab.
34	methadone.ti,ab.
35	nalbuphine.ti,ab.
36	oxycodone.ti,ab.
37	papaveretum.ti,ab.

38	pentazocine.ti,ab.
39	meperidine.ti,ab.
40	pethidine.ti,ab.
41	phenazocine.ti,ab.
42	hydrocodone.ti,ab.
43	hydromorphone.ti,ab.
44	levorphanol.ti,ab.
45	oxymorphone.ti,ab.
46	butorphanol.ti,ab.
47	dezocine.ti,ab.
48	sufentanil.ti,ab.
49	ketobemidone.ti,ab.
50	Gabapentin.ti,ab.
51	Pregabalin.ti,ab.
52	Amitriptyline.ti,ab.
53	Duloxetine.ti,ab.
54	Capsaicin cream.ti,ab.
55	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54
56	exp Exercise/
57	exp Cognitive Therapy/
58	therap*.ti,ab.
59	non?pharmacol*.ti,ab.
60	physiotherap*.ti,ab.
61	rehabilitation.ti,ab.
62	aromatherap*.ti,ab.
63	art therap*.ti,ab.
64	acoustic stimulation.ti,ab.
65	(colo?r adj3 therap*).ti,ab.
66	music.ti,ab.
67	(play adj3 therap*).ti,ab.
68	movement.ti,ab.
69	role play.ti,ab.
70	tai chi.ti,ab.
71	Qigong.ti,ab.
72	motion.ab,ti.
73	aerobic*.ti,ab.

74	strength*.ti,ab.
75	reminisc*.ti,ab.
76	guided imag*.ti,ab.
77	mindful*.ti,ab.
78	re?ki.ti,ab.
79	biofeedback.ti,ab.
80	transcutaneous electric* nerve stimulation.ti,ab.
81	TENS.ti,ab.
82	physical therap*.ti,ab.
83	cognitive behavio?ral therap*.ti,ab.
84	CBT.ti,ab.
85	acupuncture.ti,ab.
86	psychosocial.ti,ab.
87	massage.ti,ab.
88	danc*.ti,ab.
89	hypnosis.ti,ab.
90	(hot adj3 therap*).ti,ab.
91	(cold adj3 therap*).ti,ab.
92	(watching adj3 TV).ti,ab.
93	(watching adj3 television).ti,ab.
94	rest*.ti,ab.
95	breath*.ti,ab.
96	(nutrition* adj3 supplement*).ti,ab.
97	herbal preparation*.ti,ab.
98	self management.ti,ab.
99	educati*.ti,ab.
100	exercis*.ti,ab.
101	physical activit*.ti,ab.
102	cycling.ti,ab.
103	swim*.ab,ti.
104	gym*.ab,ti.
105	walk*.ti,ab.
106	treadmill*.ti,ab.
107	yoga*.ti,ab.
108	program*.ti,ab.
109	56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108

110	exp Pain Measurement/
111	(pain adj3 tool).ti,ab.
112	(rating adj3 pain).ti,ab.
113	(scale* adj3 pain).ti,ab.
114	(measur* adj3 pain).ti,ab.
115	(assess* adj3 pain).ti,ab.
116	(pain adj3 behavio?r).ti,ab.
117	(observat* adj3 pain).ti,ab.
118	(identif* adj3 pain).ti,ab.
119	110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118
120	exp Pain/
121	discomfort.ti,ab.
122	nociception.ti,ab.
123	pain*.ti,ab.
124	120 or 121 or 122 or 123
125	exp Primary Health Care/
126	exp General Practitioners/
127	exp Community Health Services/
128	communit*.ti,ab.
129	community dwelling.ti,ab.
130	domestic.ti,ab.
131	(home adj3 dwelling).ti,ab.
132	general practi*.ti,ab.
133	family practi*.ti,ab.
134	family doctor.ti,ab.
135	GP.ti,ab.
136	GPs.ti,ab.
137	doctor*.ti,ab.
138	outpatient*.ti,ab.
139	physician.ti,ab.
140	(practice adj3 nurse).ti,ab.
141	(primary adj3 care).ti,ab.
142	(primary adj3 health adj3 care).ti,ab.
143	(district adj3 nurse).ti,ab.
144	clinician*.ti,ab.
145	psychiatr*.ti,ab.
146	pharmac*.ti,ab.
147	(community adj3 nurse).ti,ab.
148	occupational therap*.ti,ab.

149	(ambulatory adj3 care).ti,ab.
150	physiotherap*.ti,ab.
151	Community Health Service*.ti,ab.
152	125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148 or 149 or 150 or 151
153	exp Dementia/
154	dement*.ti,ab.
155	(cognitive* adj3 impair*).ti,ab.
156	Alzheimer*.ti,ab.
157	lewy* bod*.ti,ab.
158	pick* disease.ti,ab.
159	creutzfeldt.ti,ab.
160	huntington*.ti,ab.
161	binswanger*.ti,ab.
162	Wernicke Korsakoff.ti,ab.
163	153 or 154 or 155 or 156 or 157 or 158 or 159 or 160 or 161 or 162
164	55 or 109 or 119
165	164 and 124 and 152 and 163

Appendix 2: Systematic review quality assessment

Quality of observational studies using the National Institute of Health Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies

Study	**Quality assessment criteria[a]**														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Overall
Barry et al	✓	✓	-	✓	×	×	×	-	✓	×	-	-	-	×	Fair
Bell et al	✓	✓	✓	✓	×	×	×	✓	✓	×	✓	-	-	×	Fair
Breland,et al	✓	×	-	✓	×	✓	×	✓	✓	×	-	-	-	-	Fair
Brummel-Smith et al	✓	✓	✓	-	×	-	×	✓	×	×	×	-	-	-	Poor
Gallini et al	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	-	-	×	✓	Fair
Gilmartin et al	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	-	×	✓	Good
Grace et al	✓	✓	✓	✓	✓	×	×	-	✓	×	-	-	-	-	Fair
Haasum, et al	✓	✓	✓	✓	×	×	×	✓	✓	×	×	-	-	✓	Fair
Hamina et al (2016)	✓	✓	✓	✓	×	✓	×	×	✓	×	✓	-	×	-	Fair
Hamina et al (2017)	✓	✓	✓	✓	×	✓	×	×	✓	×	✓	-	✓	✓	Good
Hamina et al (2018)	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	×	-	-	Good
Hartikainel et al (2005b)	✓	✓	✓	✓	×	×	×	×	✓	×	✓	-	-	-	Fair
Hartikainen et al (2005a)	✓	✓	✓	✓	×	×	×	×	✓	×	✓	-	-	×	Fair
Hunt et al	✓	✓	✓	✓	×	×	×	-	×	×	-	-	-	✓	Poor
Jensen-Dahm, et al (2012)	✓	✓	✓	✓	×	✓	×	×	✓	×	✓	-	-	×	Fair
Jensen-Dahm, et al (2015)	✓	-	✓	✓	×	×	×	-	✓	×	-	-	-	-	Fair
Krulewitch et al	✓	-	✓	-	×	✓	×	-	✓	×	✓	✓	-	-	Poor
Li et al (2015)	✓	✓	-	✓	×	×	×	×	✓	×	✓	-	-	-	Fair
Mäntyselkä, et al	✓	✓	✓	✓	×	×	×	-	✓	×	-	-	-	×	Fair

Orgeta et al	✓	✓	-	-	×	×	×	✓	✓	×	×	-	-	×	Fair
Reigier & Gitlin	✓	✓	-	-	-	×	×	-	✓	×	-	-	-	-	Fair
Schmader et al	✓	✓	✓	✓	×	-	×	×	✓	×	-	-	-	-	Fair
Shega et al (2006)	✓	✓	✓	-	×	×	×	✓	✓	×	✓	-	-	-	Fair
Shega, et al (2004)	✓	✓	✓	-	×	×	×	✓	✓	×	✓	-	-	-	Fair
Shega, et al (2005)	✓	✓	✓	-	×	-	×	✓	✓	×	✓	×	-	-	Fair
Snow et al	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	×	-	✓	-	Good
Thakur et al	✓	✓	✓	-	×	×	×	×	✓	×	-	-	-	-	Fair

"✓", yes; "×", no; "-", not applicable, not known, cannot determine.

[a] (1) Was the research question or objective in this paper clearly stated? (2) Was the study population clearly specified and defined? (3) Was the participation rate of eligible persons at least 50%? (4) Were all the subjects selected or recruited from the same or similar populations? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants? (5) Was a sample size justification, power description, or variance and effect estimates provided? (6) For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured? (7) Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed? (8) For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)? (9) Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? (10) Was the exposure(s) assessed more than once over time? (11) Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants? (12) Were the outcome assessors blinded to the exposure status of participants? (13) Was loss to follow-up after baseline 20% or less? (14) Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?

Quality of observational studies using the National Institute of Health Quality Assessment Tool for Case-Control Studies

Study	**Quality assessment criteria**[a]												
	1	2	3	4	5	6	7	8	9	10	11	12	Overall
Gallini, et al	✓	✓	✓	✓	×	✓	✓	×	×	✓	×	✓	Fair

"✓", yes; "**×**", no; "-", not applicable, not known, cannot determine.

[a]1. Was the research question or objective in this paper clearly stated and appropriate? 2. Was the study population clearly specified and defined? 3. Did the authors include a sample size justification? 4. Were controls selected or recruited from the same or similar population that gave rise to the cases (including the same timeframe)? 5. Were the definitions, inclusion and exclusion criteria, algorithms or processes used to identify or select cases and controls valid, reliable, and implemented consistently across all study participants? 6. Were the cases clearly defined and differentiated from controls? 7. If less than 100 percent of eligible cases and/or controls were selected for the study, were the cases and/or controls randomly selected from those eligible? 8. Was there use of concurrent controls? 9. Were the investigators able to confirm that the exposure/risk occurred prior to the development of the condition or event that defined a participant as a case? 10. Were the measures of exposure/risk clearly defined, valid, reliable, and implemented consistently (including the same time period) across all study participants? 11. Were the assessors of exposure/risk blinded to the case or control status of participants? 12. Were key potential confounding variables measured and adjusted statistically in the analyses? If matching was used, did the investigators account for matching during study analysis?
**Study by Gallini is a nested case-control within a cohort design, and therefore quality assessment was conducted using two assessment tools.

National Institute of Health Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group

Study	**Quality assessment criteria** [a]											
	1	2	3	4	5	6	7	8	9	10	11	Overall
Elliott & Horgas	✓	✓	-	-	×	✓	✓	✓	×	×	-	Poor
Park	✓	✓	-	-	-	×	×	✓	✓	×	-	Poor
Nakanishi et al	✓	×	✓	-	×	-	×	✓	✓	×	-	Poor

"✓", yes; "×", no; "-", not applicable, not known, cannot determine.

[a] 1. Was the study question or objective clearly stated? 2. Were eligibility/selection criteria for the study population prespecified and clearly described? 3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest? 4. Were all eligible participants that met the prespecified entry criteria enrolled? 5. Was the sample size sufficiently large to provide confidence in the findings? 6. Was the test/service/intervention clearly described and delivered consistently across the study population? 7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants? 8. Were the people assessing the outcomes blinded to the participants' exposures/interventions? 9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis? 10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p values for the pre-to-post changes? 11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)? 12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?

National Institute of Health Quality Assessment Tool for Controlled Intervention Studies

Study	**Quality assessment criteria**[a]														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Overall
Benedetti et al	×	×	✓	-	-	-	✓	✓	✓	-	✓	×	✓	✓	Fair
Kunik et al	✓	✓	✓	✓	✓	✓	-	✓	✓	×	✓	×	✓	×	Poor

"✓", yes; "×", no; "-", not applicable, not known, cannot determine.

[a] 1. Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT? 2. Was the method of randomization adequate (i.e., use of randomly generated assignment)? 3. Was the treatment allocation concealed (so that assignments could not be predicted)? 4. Were study participants and providers blinded to treatment group assignment? 5. Were the people assessing the outcomes blinded to the participants' group assignments? 6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)? 7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment? 8. Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower? 9. Was there high adherence to the intervention protocols for each treatment group? 10. Were other interventions avoided or similar in the groups (e.g., similar background treatments)? 11. Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants? 12. Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power? 13. Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)? 14. Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?

Appendix 3: ISAC CPRD study approval

ISAC EVALUATION OF PROTOCOLS FOR RESEARCH INVOLVING CPRD DATA

FEEDBACK TO APPLICANTS

12.1 CONFIDENTIAL		***by e-mail***	
12.2 PROTOCOL NO:	12.3 17_240RA		
12.4 PROTOCOL TITLE:	Dementia and Musculoskeletal Pain: Consultation and Treatment Patterns in Primary Care		
12.5 APPLICANT:	Dr John Bedson Keele University j.bedson@keele.ac.uk		
12.5.1 APPROVED **12.5.2** ☐	**APPROVED WITH COMMENTS** **(resubmission not required)** ☒	**REVISION/ RESUBMISSION REQUESTED** ☐	**REJECTED** ☐

INSTRUCTIONS:

Protocols with an outcome of 'Approved' or 'Approved with comments' do not require resubmission to the ISAC.

REVIEWER COMMENTS:

It isn't completely clear how the family number will be used, this is an identifier that links individuals in the same 'household' rather than a number indicating how many people are resident. Presumably the applicants will be deriving the information they need from this variable.

DATE OF ISAC FEEDBACK:	11/12/18
DATE OF APPLICANT FEEDBACK:	

Appendix 4: Clinical code lists

Each table below includes clinical codes (starting from the most commonly recorded to least commonly recorded) for each clinical entity. If the code list included more than 100 codes, only the first 100 are included below. Full clinical codes available upon request.

i. Dementia diagnostic and product codes
ii. Musculoskeletal condes
iii. Analgesic prescription codes
iv. Cancer codes
v. Formal residence codes
vi. Cardiovascular-related codes
vii. Depression/bipolar codes
viii. Diabetes codes

i. Dementia diagnostic codes

Dementia diagnosis codes		
Medcode	**Read code**	**Read term**
12710	6AB..00	Dementia annual review
1350	E00..12	Senile/presenile dementia
1917	F110.00	Alzheimer's disease
6578	Eu01.00	[X]Vascular dementia
4693	Eu02z00	[X] Unspecified dementia
1916	E00..11	Senile dementia
7664	Eu00.00	[X]Dementia in Alzheimer's disease
7323	E000.00	Uncomplicated senile dementia
5931	1461	H/O: dementia
2882	E00z.00	Senile or presenile psychoses NOS
4357	Eu02z14	[X] Senile dementia NOS
55023	66h..00	Dementia monitoring
2731	F11z.11	Cerebral atrophy
8195	Eu00z11	[X]Alzheimer's dementia unspec
8634	E004.11	Multi infarct dementia
33707	E00..00	Senile and presenile organic psychotic conditions
26270	Eu02500	[X]Lewy body dementia

19477	E004.00	Arteriosclerotic dementia
30706	Eu00200	[X]Dementia in Alzheimer's dis, atypical or mixed type
5651	F11z.00	Cerebral degeneration NOS
15249	E00y.00	Other senile and presenile organic psychoses
9509	Eu02300	[X]Dementia in Parkinson's disease
15165	E001.00	Presenile dementia
25386	E041.00	Dementia in conditions EC
7572	F116.00	Lewy body disease
11379	Eu00112	[X]Senile dementia,Alzheimer's type
11175	Eu01100	[X]Multi-infarct dementia
29386	Eu00z00	[X]Dementia in Alzheimer's disease, unspecified
31016	Eu01300	[X]Mixed cortical and subcortical vascular dementia
19393	Eu01z00	[X]Vascular dementia, unspecified
9565	Eu01.11	[X]Arteriosclerotic dementia
32057	F110100	Alzheimer's disease with late onset
38678	Eu00100	[X]Dementia in Alzheimer's disease with late onset
12621	Eu02.00	[X]Dementia in other diseases classified elsewhere
27342	E012.11	Alcoholic dementia NOS
16797	F110000	Alzheimer's disease with early onset
21887	E002100	Senile dementia with depression
29512	F112.00	Senile degeneration of brain
26323	Eu10711	[X]Alcoholic dementia NOS
18386	E002000	Senile dementia with paranoia
37015	E003.00	Senile dementia with delirium
49263	Eu00000	[X]Dementia in Alzheimer's disease with early onset
42279	E004z00	Arteriosclerotic dementia NOS
11136	F111.00	Pick's disease
27935	Eu02z15	[X] Senile psychosis NOS
23835	E040.11	Korsakoff's non-alcoholic psychosis
8934	Eu01200	[X]Subcortical vascular dementia
44674	E002.00	Senile dementia with depressive or paranoid features
55313	Eu01y00	[X]Other vascular dementia

38438	E001z00	Presenile dementia NOS
9415	R201.00	[D]Senescence
37014	Eu02200	[X]Dementia in Huntington's disease
28402	Eu02000	[X]Dementia in Pick's disease
27759	Eu02z16	[X] Senile dementia, depressed or paranoid type
30032	E001200	Presenile dementia with paranoia
27677	E001300	Presenile dementia with depression
43089	E004000	Uncomplicated arteriosclerotic dementia
53446	Eu04100	[X]Delirium superimposed on dementia
34944	Eu02z13	[X] Primary degenerative dementia NOS
49513	E001100	Presenile dementia with delirium
48531	F11x700	Cerebral degeneration due to Jakob - Creutzfeldt disease
64267	Eu02y00	[X]Dementia in other specified diseases classif elsewhere
38286	A411.00	Jakob-Creutzfeldt disease
43292	E004300	Arteriosclerotic dementia with depression
43346	Eu00113	[X]Primary degen dementia of Alzheimer's type, senile onset
48501	Eu02z11	[X] Presenile dementia NOS
47555	F11x000	Cerebral degeneration due to alcoholism
46488	Eu01000	[X]Vascular dementia of acute onset
46762	Eu00111	[X]Alzheimer's disease type 1
25704	Eu00011	[X]Presenile dementia,Alzheimer's type
47619	Eu02z12	[X] Presenile psychosis NOS
54106	Eu02100	[X]Dementia in Creutzfeldt-Jakob disease
96860	F11x900	Cerebral degeneration in Parkinson's disease
55467	E004200	Arteriosclerotic dementia with paranoia
54744	F11x200	Cerebral degeneration due to cerebrovascular disease
42602	E001000	Uncomplicated presenile dementia
41089	E002z00	Senile dementia with depressive or paranoid features NOS
55838	Eu01111	[X]Predominantly cortical dementia
34976	F11y.00	Other cerebral degeneration
31524	F11yz00	Other cerebral degeneration NOS
56912	E004100	Arteriosclerotic dementia with delirium

60059	Eu00012	[X]Primary degen dementia, Alzheimer's type, presenile onset
62056	BBC9.11	[M]Pick's tubular adenoma
61528	Eu00013	[X]Alzheimer's disease type 2
59122	Fyu3000	[X]Other Alzheimer's disease
55222	ZS7C500	Language disorder of dementia
44592	F11xz00	Cerebral degeneration other disease NOS
47658	F11x500	Cerebral degeneration due to myxoedema
93372	F103.00	Cerebral degeneration in diseases EC

Dementia drug product codes

Prodcode	Product name
2931	Donepezil 10mg tablets
2930	Donepezil 5mg tablets
39240	Memantine 20mg tablets
6225	Memantine 10mg tablets
7361	Galantamine 24mg modified-release capsules
5247	Aricept 10mg tablets (Eisai Ltd)
14309	Galantamine 16mg modified-release capsules
11751	Rivastigmine 3mg capsules
37132	Rivastigmine 9.5mg/24hours transdermal patches
4597	Rivastigmine 1.5mg capsules
5400	Aricept 5mg tablets (Eisai Ltd)
11635	Galantamine 12mg tablets
10255	Galantamine 8mg modified-release capsules
11654	Galantamine 8mg tablets
36976	Rivastigmine 4.6mg/24hours transdermal patches
11752	Rivastigmine 4.5mg capsules
9786	Rivastigmine 6mg capsules
35088	Donepezil 10mg orodispersible tablets sugar free
11837	Memantine 10mg/ml oral solution sugar free
35179	Donepezil 5mg orodispersible tablets sugar free
24088	Reminyl XL 24mg capsules (Shire Pharmaceuticals Ltd)
10187	Galantamine 4mg tablets
48443	Donepezil 10mg orodispersible tablets
20140	Reminyl XL 16mg capsules (Shire Pharmaceuticals Ltd)
37957	Exelon 9.5mg/24hours transdermal patches (Novartis Pharmaceuticals UK Ltd)
18800	Ebixa 10mg tablets (Lundbeck Ltd)
55720	Gatalin XL 24mg capsules (Aspire Pharma Ltd)
56709	Gatalin XL 16mg capsules (Aspire Pharma Ltd)
7329	Galantamine 20mg/5ml oral solution sugar free
48442	Donepezil 5mg orodispersible tablets

18587	Reminyl XL 8mg capsules (Shire Pharmaceuticals Ltd)
5334	Reminyl 12mg tablets (Shire Pharmaceuticals Ltd)
11827	Rivastigmine 2mg/ml oral solution sugar free
18062	Reminyl 8mg tablets (Shire Pharmaceuticals Ltd)
39363	Ebixa 20mg tablets (Lundbeck Ltd)
11716	Exelon 3mg capsules (Novartis Pharmaceuticals UK Ltd)
37444	Exelon 4.6mg/24hours transdermal patches (Novartis Pharmaceuticals UK Ltd)
39362	Ebixa tablets treatment initiation pack (Lundbeck Ltd)
11546	Exelon 1.5mg capsules (Novartis Pharmaceuticals UK Ltd)
9966	Ebixa 5mg/0.5ml pump actuation oral solution (Lundbeck Ltd)
61921	Luventa XL 24mg capsules (Fontus Health Ltd)
37188	Aricept Evess 10mg orodispersible tablets (Eisai Ltd)
38976	Memantine 5mg+10mg+15mg+20mg Tablet
56421	Gatalin XL 8mg capsules (Aspire Pharma Ltd)
9854	Reminyl 4mg tablets (Shire Pharmaceuticals Ltd)
56631	Rivastigmine 13.3mg/24hours transdermal patches
5616	Exelon 6mg capsules (Novartis Pharmaceuticals UK Ltd)
29288	Reminyl 4mg/ml oral solution (Shire Pharmaceuticals Ltd)
20404	Exelon 4.5mg capsules (Novartis Pharmaceuticals UK Ltd)
53882	Rivastigmine 2mg/ml oral solution
62164	Alzest 9.5mg/24hours transdermal patches (Dr Reddy's Laboratories (UK) Ltd)
61676	Donepezil 1mg/ml oral solution sugar free
66899	Memantine 20mg orodispersible tablets sugar free
63360	Luventa XL 16mg capsules (Fontus Health Ltd)
36848	Aricept Evess 5mg orodispersible tablets (Eisai Ltd)
61920	Luventa XL 8mg capsules (Fontus Health Ltd)
59993	Galzemic XL 16mg capsules (Creo Pharma Ltd)
60493	Galzemic XL 24mg capsules (Creo Pharma Ltd)
66934	Memantine 10mg orodispersible tablets sugar free
62780	Alzest 4.6mg/24hours transdermal patches (Dr Reddy's Laboratories (UK) Ltd)
18556	Exelon 2mg/ml oral solution (Novartis Pharmaceuticals UK Ltd)
58780	Voleze 9.5mg/24hours transdermal patches (Focus Pharmaceuticals Ltd)

62868	Gazylan XL 24mg capsules (Teva UK Ltd)
61618	Nemdatine 20mg tablets (Actavis UK Ltd)
48015	Galsya XL 24mg capsules (Consilient Health Ltd)
60192	Galzemic XL 8mg capsules (Creo Pharma Ltd)
57171	Erastig 9.5mg/24hours transdermal patches (Teva UK Ltd)
63226	Prometax 9.5mg/24hours transdermal patches (Novartis Pharmaceuticals UK Ltd)
61385	Nemdatine 10mg tablets (Actavis UK Ltd)
63405	Galsya XL 16mg capsules (Consilient Health Ltd)
61476	Acumor XL 24mg capsules (Mylan Ltd)
57627	Erastig 4.6mg/24hours transdermal patches (Teva UK Ltd)
64982	Memantine 20mg tablets (Teva UK Ltd)
48482	Galsya XL 8mg capsules (Consilient Health Ltd)
62867	Gazylan XL 16mg capsules (Teva UK Ltd)
68792	Memantine 10mg/ml oral solution sugar free (Chanelle Medical UK Ltd)
69638	Memantine 5mg/10mg/15mg/20mg 4 week treatment initiation pack (Lupin (Europe) Ltd)
65573	Gazylan XL 8mg capsules (Teva UK Ltd)
62925	Acumor XL 16mg capsules (Mylan Ltd)
59330	Voleze 4.6mg/24hours transdermal patches (Focus Pharmaceuticals Ltd)
65501	Eluden 4.6mg/24hours transdermal patches (Mylan Ltd)
63951	Rivastigmine 9.5mg/24hours transdermal patches (Actavis UK Ltd)
68493	Nemdatine tablets treatment initiation pack (Actavis UK Ltd)
58937	Exelon 13.3mg/24hours transdermal patches (Novartis Pharmaceuticals UK Ltd)
68845	Memantine 10mg/ml oral solution sugar free (A A H Pharmaceuticals Ltd)
65761	Eluden 9.5mg/24hours transdermal patches (Mylan Ltd)
65333	Memantine 10mg/ml oral solution sugar free (Alliance Healthcare (Distribution) Ltd)
69595	Marixino 20mg tablets (Consilient Health Ltd)
59871	Donepezil 10mg/5ml oral suspension
53842	Aricept 5mg tablets (Waymade Healthcare Plc)
53922	Donepezil 10mg orodispersible tablets (Consilient Health Ltd)
58709	Donepezil 10mg tablets (A A H Pharmaceuticals Ltd)
56600	Donepezil 5mg tablets (Zentiva)

57139	Ebixa 10mg tablets (DE Pharmaceuticals)
55928	Exelon 4.5mg capsules (Waymade Healthcare Plc)
56771	Rivastigmine 3mg capsules (Dr Reddy's Laboratories (UK) Ltd)
60723	Rivastigmine 6mg capsules (Waymade Healthcare Plc)
68802	Donepezil 5mg tablets (Waymade Healthcare Plc)
68494	Rivastigmine 6mg capsules (A A H Pharmaceuticals Ltd)
69564	Prometax 4.6mg/24hours transdermal patches (Novartis Pharmaceuticals UK Ltd)

ii. Musculoskeletal codes

Medcode	Readcode	Read term
154	N142.11	Low back pain
123	N131.00	Cervicalgia - pain in neck
198	N245.17	Shoulder pain
9517	1M10.00	Knee pain
3324	16C6.00	Back pain without radiation NOS
313	N143.00	Sciatica
153	16C2.00	Backache
3763	16C5.00	C/O - low back pain
554	N094611	Knee joint pain
396	N05..11	Osteoarthritis
286	N094K12	Hip pain
557	N145.00	Backache, unspecified
1219	N245.16	Leg pain
855	N245.13	Foot pain
5864	N094.00	Pain in joint - arthralgia
360	N213211	Tennis elbow
1258	N245.11	Ankle pain
5780	N245200	Pain in leg
734	N217900	Plantar fasciitis
1330	N094512	Hip joint pain
822	N245.12	Arm pain
17799	1M11.00	Foot pain
587	N06z.11	Arthritis
2786	16C..00	Backache symptom
202	N094000	Arthralgia of unspecified site
3518	R065A00	[D]Musculoskeletal chest pain
874	N210.12	Frozen shoulder
3057	N05..00	Osteoarthritis and allied disorders
2519	182B.00	Rib pain
5787	N245700	Shoulder pain
2025	N245.14	Hand pain
2487	N05zL00	Osteoarthritis NOS, of knee
1946	N245111	Toe pain
665	N05z611	Knee osteoarthritis NOS
771	N110.11	Cervical spondylosis
2881	N110.00	Cervical spondylosis without myelopathy
2521	N094311	Wrist joint pain
1338	N241000	Myalgia unspecified
1497	R00z211	[D]General aches and pains
2494	N245.15	Heel pain
5762	N245300	Pain in arm
1209	N217400	Achilles tendinitis
495	N213300	Olecranon bursitis
5440	N241012	Muscle pain
2532	N245400	Calf pain
1335	N142.00	Pain in lumbar spine
2284	N242000	Neuralgia unspecified
5776	N05z.00	Osteoarthritis NOS

Medcode	Readcode	Read term
6044	N094M00	Arthralgia of knee
6496	N14z.00	Back disorders NOS
3677	N0z..00	Arthropathies NOS
743	N236.00	Dupuytren's contracture
3322	N245012	Finger pain
1129	N221.00	Bunion
3252	N224.00	Ganglion and cyst of synovium, tendon and bursa
3546	N215700	Trochanteric bursitis
6520	N245000	Hand pain
4544	N245.00	Pain in limb
1339	N245011	Thumb pain
4795	N213200	Lateral epicondylitis of the elbow
1104	N053512	Hip osteoarthitis NOS
12189	16CA.00	Mechanical low back pain
864	N21z211	Tendonitis NOS
1212	N147200	Coccygodynia
827	N210.00	Adhesive capsulitis of the shoulder
10231	16C9.00	Chronic low back pain
1166	N074.00	Chondromalacia patellae
1287	N217200	Metatarsalgia NOS
1418	N094900	Arthralgia of multiple joints
237	N224300	Ganglion unspecified
1646	N094211	Elbow joint pain
11962	1M00.00	Pain in elbow
1455	R01z200	[D]Musculoskeletal pain
1604	N324400	Osgood-Schlatter's dis - osteochondrosis of tibial tubercle
1866	N245.18	Thigh pain
6704	N145.12	Back pain, unspecified
471	N350.00	Hallux valgus - acquired
2380	N220300	Trigger finger - acquired
99477	1M01.00	Pain in wrist
1726	N211.00	Rotator cuff shoulder syndrome and allied disorders
4948	N141.00	Pain in thoracic spine
4353	N050.00	Generalised osteoarthritis - OA
1720	N142.14	Lumbago
5489	N212500	Shoulder tendonitis
717	N248.00	Fibromyalgia
332	N216500	Prepatellar bursitis
6695	1D22.11	C/O - a chest wall symptom
5999	N094F00	Arthralgia of wrist
1606	N146z11	Sacroiliac strain
443	N090611	Knee joint effusion
5916	N141.11	Acute back pain - thoracic
3536	N135.00	Torticollis unspecified
6166	N094W00	Anterior knee pain
730	N213111	Golfer's elbow
14823	R065200	[D]Anterior chest wall pain
2175	Nz...00	Musculoskeletal and connective tissue diseases NOS
19322	1M13.00	Ankle pain

Medcode	Readcode	Read term
5923	N145.11	Acute back pain - unspecified
1355	16A2.00	Stiff neck
6313	1D13111	C/O - pain in big toe

iii. Analgesic prescription codes

Basic analgesic		
Prodcode	**Product name**	**Substance strength**
7	Paracetamol 500mg tablets	500mg
15	Ibuprofen 400mg tablets	400mg
139	Paracetamol 500mg capsules	500mg
332	Ibuprofen 5% gel	50mg/1gram
1609	Paracetamol 500mg soluble tablets	500mg
156	Diclofenac 1.16% gel	11.6mg/1gram
416	Ibuprofen 200mg tablets	200mg
1113	Movelat cream (Genus Pharmaceuticals Ltd)	2mg/1gram + 20mg/1gram
434	Aspirin 300mg gastro-resistant tablets	300mg
1544	Piroxicam 0.5% gel	5mg/1gram
377	Aspirin 300mg dispersible tablets	300mg
1653	Movelat gel (Genus Pharmaceuticals Ltd)	20mg/1gram + 2mg/1gram
827	Voltarol 1.16% Emulgel (GlaxoSmithKline Consumer Healthcare)	11.6mg/1gram
262	Paracetamol 250mg/5ml oral suspension	50mg/1ml
5701	Algesal cream (Thornton & Ross Ltd)	100mg/1gram
2938	Ibuprofen 100mg/5ml Oral suspension	100mg/5ml
559	Traxam 3% gel (AMCo)	30mg/1gram
4186	Paracetamol 250mg/5ml oral suspension sugar free	250mg/5ml
254	Aspirin 300mg tablets	300mg
5767	Ibuprofen 10% gel	100mg/1gram
1156	Ibugel 5% gel (Dermal Laboratories Ltd)	50mg/1gram
2858	Feldene 0.5% gel (Pfizer Ltd)	5mg/1gram
2606	Ketoprofen 2.5% gel	25mg/1gram
1739	Brufen 400mg tablets (Mylan Ltd)	400mg
6231	Capsaicin 0.025% cream	250microgram/1gram
3587	Felbinac 3% gel	30mg/1gram
10265	Fenbid 5% gel (AMCo)	50mg/1gram

5393	Intralgin gel (3M Health Care Ltd)	50mg/1gram + 20mg/1gram
10093	Diethylamine salicylate 10% cream	10%
1137	Nu-seals aspirin ec 300mg Gastro-resistant tablet (Eli Lilly and Company Ltd)	300mg
1270	Ibuleve 5% gel (Dendron Ltd)	50mg/1gram
48326	Ibuprofen 100mg/5ml oral suspension sugar free	20mg/1ml
9421	Powergel 2.5% gel (A. Menarini Farmaceutica Internazionale SRL)	25mg/1gram
112	Ibuprofen 5% cream	50mg/1gram
7141	Ibugel Forte 10% gel (Dermal Laboratories Ltd)	100mg/1gram
3077	Oruvail 2.5% gel (Sanofi)	25mg/1gram
33710	Paracetamol 500mg caplets (A A H Pharmaceuticals Ltd)	500mg
6115	Diclofenac sodium 3% gel	30mg/1gram
7817	Benzydamine 3% cream	30mg/1gram
1808	Capsaicin 0.075% cream	750microgram/1gram
5748	Salicylic acid 2% / Mucopolysaccharide polysulfate 0.2% cream	2mg/1gram + 20mg/1gram
1621	Brufen 200mg tablets (Abbott Laboratories Ltd)	200mg
6208	Voltarol 1.16% Emulgel P (GlaxoSmithKline Consumer Healthcare)	11.6mg/1gram
1339	Ditropan 5mg tablets (Sanofi)	5mg
4980	Salicylic acid 2% / Mucopolysaccharide polysulfate 0.2% gel	20mg/1gram + 2mg/1gram
2693	Proflex 5% cream (Novartis Consumer Health UK Ltd)	50mg/1gram
8510	Ibuprofen 5% spray	50mg/1ml
5025	Zacin 0.025% cream (Teva UK Ltd)	250microgram/1gram
26159	Fenbid Forte 10% gel (AMCo)	100mg/1gram
1862	Paracetamol 500mg/5ml oral suspension sugar free	500mg/5ml
43479	Paracetamol 500mg caplets (Actavis UK Ltd)	500mg
10338	Felbinac 3.17% foam	31.7mg/1gram
13083	Deep Relief gel (The Mentholatum Company Ltd)	50mg/1gram + 30mg/1gram
10149	Ibuprofen 200mg capsules	200mg

5896	Ibuleve Maximum Strength 10% gel (Dendron Ltd)	100mg/1gram
484	Equagesic Tablet (Wyeth Pharmaceuticals)	
15930	Ibuprofen 5% / Levomenthol 3% gel	50mg/1gram + 30mg/1gram
7692	Axsain 0.075% cream (Teva UK Ltd)	750microgram/1gram
3520	Movelat Relief gel (Genus Pharmaceuticals Ltd)	20mg/1gram + 2mg/1gram
4648	Ibuspray 5% spray (Dermal Laboratories Ltd)	50mg/1ml
5243	Paracetamol 500mg suppositories	500mg
360	Brufen 100mg/5ml syrup (Mylan Ltd)	20mg/1ml
56558	Voltarol 12 Hour Emulgel P 2.32% gel (GlaxoSmithKline Consumer Healthcare)	23.2mg/1gram
2794	Co-codamol 30mg/500mg tablets (Wockhardt UK Ltd)	30mg + 500mg
9201	Ibuleve 5% spray (Dendron Ltd)	50mg/1ml
784	Ibuprofen 300mg modified-release capsules	300mg
27459	Paracetamol 500mg caplets (Zentiva)	500mg
48597	Paracetamol 500mg caplets (Alliance Healthcare (Distribution) Ltd)	500mg
11540	Diclofenac 16mg/ml topical solution	16mg/1ml
49105	Paracetamol 500mg caplets (Teva UK Ltd)	500mg
4196	Paracetamol 240mg suppositories	240mg
9712	Paracetamol 250mg orodispersible tablets sugar free	250mg
5323	Paracetamol 250mg suppositories	250mg
9176	Movelat Relief cream (Genus Pharmaceuticals Ltd)	2mg/1gram + 20mg/1gram
15178	Radian B Pain Relief spray (Thornton & Ross Ltd)	14mg/1ml + 10mg/1ml + 5.4mg/1ml + 6mg/1ml
23716	Paracetamol 500mg caplets (IVAX Pharmaceuticals UK Ltd)	500mg
6435	Pennsaid 16mg/ml cutaneous solution (Movianto UK Ltd)	16mg/1ml
11074	Ralgex Heat spray (G.R. Lane Health Products Ltd)	60mg/1ml + 16mg/1ml
208	Tensoplast bandage 5cm x 4.5m (BSN medical Ltd)	5cm
14901	Diclofenac 1% transdermal patches	10mg/1gram
49417	Paracetamol 500mg caplets (Kent Pharmaceuticals Ltd)	500mg

14964	Solpadeine Plus soluble tablets (Omega Pharma Ltd)	8mg + 500mg + 30mg
49575	Paracetamol 500mg caplets (Vantage)	500mg
31257	Paracetamol 500mg caplets (Galpharm International Ltd)	500mg
18151	Voltarol Pain-eze 1.16% Emulgel (GlaxoSmithKline Consumer Healthcare)	11.6mg/1gram
8882	Feldene 0.50% Sports gel (Pfizer Ltd)	5mg/1gram
11805	Ralgex Freeze spray (G.R. Lane Health Products Ltd)	677.7mg/1gram + 144.1mg/1gram + 100mg/1gram
28344	Paracetamol 500mg caplets (Wockhardt UK Ltd)	500mg
31054	Phorpain Maximum Strength 10% gel (AMCo)	100mg/1gram
20068	Paracetamol 250mg/5ml oral suspension sugar free	250mg/5ml
11550	Nurofen Meltlets 200mg tablets (Reckitt Benckiser Healthcare (UK) Ltd)	200mg
9630	Feldene P 0.5% gel (Pfizer Ltd)	5mg/1gram
1468	Ibuprofen 200mg Soluble tablet	200mg
20967	Phorpain 5% gel (AMCo)	50mg/1gram
7261	Cuprofen 5% gel (SSL International Plc)	50mg/1gram
39708	Diclofenac 4% cutaneous spray	4%
48535	Paracetamol 500mg caplets (Rusco Ltd)	500mg
37972	Ibuleve Speed Relief 5% gel (Dendron Ltd)	50mg/1gram
207	Clindamycin 75mg capsules	75mg
56566	Paracetamol 500mg caplets (J M McGill Ltd)	500mg
Weak analgesics		
Prodcode	**Product name**	**Substance strength**
11	Co-dydramol 10mg/500mg tablets	500mg + 10mg
19	Co-codamol 8mg/500mg tablets	500mg + 8mg
57	Co-codamol 8mg/500mg effervescent tablets	8mg + 500mg
58	Bendroflumethiazide 5mg tablets	5mg
625	Co-codamol 8mg/500mg capsules	500mg + 8mg
687	Tramacet 37.5mg/325mg tablets (Grunenthal Ltd)	37.5mg + 325mg
6558	Tramadol 37.5mg / Paracetamol 325mg tablets	37.5mg + 325mg
9457	Paracetamol 500mg with codeine phosphate 8mg tablet	500mg + 8mg

2986	Co-codaprin 8mg/400mg dispersible tablets	8mg + 400mg
2047	Co-codaprin 8mg with 400mg tablets	8mg+400mg
37904	Co-codamol 12.8mg/500mg tablets	12.8mg + 500mg
42332	Tramacet 37.5mg/325mg effervescent tablets (Grunenthal Ltd)	37.5mg + 325mg
7063	Co-dydramol 10mg/500mg/5ml oral suspension	2mg/1ml + 100mg/1ml
28780	Co-dydramol 10mg/500mg tablets (A A H Pharmaceuticals Ltd)	500mg + 10mg
42280	Tramadol 37.5mg / Paracetamol 325mg effervescent tablets sugar free	37.5mg + 325mg
11945	Syndol Tablet (SSL International Plc)	
10122	Dihydrocodeine 10mg with paracetamol 500mg/5ml oral suspension sugar free	10mg + 500mg/5ml
34229	Co-codamol 8mg+500mg Dispersible tablet (Rhone-Poulenc Rorer Ltd)	8mg + 500mg
7469	Df118 10mg/5ml Oral solution (Martindale Pharmaceuticals Ltd)	2mg/1ml
47071	Co-dydramol (dihydrocodeine and paracetamol) 10mg with 500mg/5ml oral suspension	10mg + 500mg/5ml

Moderate analgesics

Prodcode	**Prodcode**	**Substance Strength**
4	Paracetamol/Dextropropoxyphene hydrochloride	325mg + 32.5mg
382	Codeine phosphate	15mg
7072	Codeine phosphate/Paracetamol	15mg + 500mg
152	Codeine phosphate	3mg/1ml
2871	Pholcodine	1mg/1ml
7555	Buprenorphine	5microgram/1hour
10205	Buprenorphine	10microgram/1hour
4016	Nefopam hydrochloride	30mg
7236	Buprenorphine	10microgram/1hour
7334	Buprenorphine	5microgram/1hour
5955	Dihydrocodeine tartrate/Paracetamol	30mg + 500mg
9855	Paracetamol/Dihydrocodeine tartrate	500mg + 20mg
1617	Codeine phosphate	3mg/1ml
396	Buprenorphine hydrochloride	200microgram
2040	Paracetamol/Dihydrocodeine tartrate	500mg + 20mg
46729	Codeine Phosphate/paracetamol	15mg + 500mg

3522	Buprenorphine hydrochloride	200microgram
3794	Nefopam hydrochloride	30mg
1708	Ibuprofen/Codeine phosphate	300mg + 20mg
6547	Buprenorphine hydrochloride	2mg
6056	Buprenorphine hydrochloride	8mg
10176	Codeine phosphate/Paracetamol	15mg + 500mg
46511	Codeine phosphate/Paracetamol	15mg + 500mg
4805	Codeine Phosphate	15mg/5ml
37979	Nefopam hydrochloride	30mg
12076	Dextropropoxyphene Napsylate	60mg
46898	Codeine Phosphate/paracetamol	15mg + 500mg
124	Paracetamol/Dextropropoxyphene hydrochloride	325mg + 32.5mg
35681	Buprenorphine hydrochloride/Naloxone hydrochloride	2mg + 500microgram
35682	Buprenorphine Hydrochloride/naloxone Hydrochloride	8mg + 2mg
Strong analgesics		
Prodcode	**Product name**	**Substance strength**
86	Tramadol 50mg capsules	50mg
96	Co-codamol 30mg/500mg tablets	30mg + 500mg
53	Dihydrocodeine 30mg tablets	30mg
158	Codeine 30mg tablets	30mg
800	Co-codamol 30mg/500mg capsules	30mg + 500mg
11665	Zapain 30mg/500mg tablets (AMCo)	30mg + 500mg
810	Co-codamol 30mg/500mg effervescent tablets	30mg + 500mg
656	Tylex 30mg/500mg capsules (UCB Pharma Ltd)	30mg + 500mg
4114	Tramadol 100mg modified-release capsules	100mg
1640	Kapake 30mg/500mg tablets (Galen Ltd)	30mg + 500mg
2211	Solpadol 30mg/500mg effervescent tablets (Sanofi)	30mg + 500mg
3156	Solpadol 30mg/500mg caplets (Sanofi)	30mg + 500mg
2041	Dihydrocodeine 60mg modified-release tablets	60mg
21880	Zapain 30mg/500mg capsules (AMCo)	30mg + 500mg
6215	Tramadol 200mg modified-release capsules	200mg
4115	Tramadol 100mg modified-release tablets	100mg

701	Tramadol 50mg modified-release capsules	50mg
8456	DHC Continus 60mg tablets (Napp Pharmaceuticals Ltd)	60mg
9516	Kapake 30mg/500mg capsules (Galen Ltd)	30mg + 500mg
3239	Meptazinol 200mg tablets	200mg
5955	Paracetamol 500mg / Dihydrocodeine 30mg tablets	30mg + 500mg
13300	BuTrans 20micrograms/hour transdermal patches (Napp Pharmaceuticals Ltd)	20micrograms/hour
4834	Tramadol 150mg modified-release capsules	150mg
2450	Pethidine 50mg tablets	50mg
6234	Dihydrocodeine 120mg modified-release tablets	120mg
539	Codeine 60mg tablets	60mg
7238	Buprenorphine 20micrograms/hour transdermal patches	20micrograms/hour
187	Zydol 50mg capsules (Grunenthal Ltd)	50mg
9313	Dihydrocodeine 90mg modified-release tablets	90mg
767	Solpadol 30mg/500mg capsules (Sanofi)	30mg + 500mg
3644	Zydol SR 100mg tablets (Grunenthal Ltd)	100mg
9001	Diconal tablets (Amdipharm Plc)	30mg + 10mg
3378	Tramadol 50mg soluble tablets sugar free	50mg
40249	Maxitram SR 100mg capsules (Chiesi Ltd)	100mg
8447	Meptid 200mg Tablet (Shire Pharmaceuticals Ltd)	200mg
4823	Dihydrocodeine 40mg tablets	40mg
6879	Buprenorphine 35micrograms/hour transdermal patches	35microgram/1hour
9275	DHC Continus 120mg tablets (Napp Pharmaceuticals Ltd)	120mg
3064	Buprenorphine 400microgram sublingual tablets sugar free	400microgram
3435	Tylex 30mg/500mg effervescent tablets (UCB Pharma Ltd)	30mg + 500mg
5936	Transtec 35micrograms/hour transdermal patches (Napp Pharmaceuticals Ltd)	35microgram/1hour
9209	DHC Continus 90mg tablets (Napp Pharmaceuticals Ltd)	90mg
38950	Remedeine Forte tablets (Crescent Pharma Ltd)	30mg + 500mg
40254	Maxitram SR 50mg capsules (Chiesi Ltd)	50mg
3029	CO-CODAMOL EFF 30MG/500MG TAB	
39811	Maxitram SR 200mg capsules (Chiesi Ltd)	200mg
6917	Buprenorphine 52.5micrograms/hour transdermal patches	52.5microgram/1hour

11584	Buprenorphine 70micrograms/hour transdermal patches	70microgram/1hour
6040	Transtec 52.5micrograms/hour transdermal patches (Napp Pharmaceuticals Ltd)	52.5microgram/1hour
1929	GranuGEL Hydrocolloid Gel dressing (ConvaTec Ltd)	
6181	Transtec 70micrograms/hour transdermal patches (Napp Pharmaceuticals Ltd)	70microgram/1hour
2367	Pentazocine 25mg tablets	25mg
37021	Tramadol 200mg modified-release tablets	200mg
328	Pentazocine 50mg capsules	50mg
5169	Zydol SR 200mg tablets (Grunenthal Ltd)	200mg
8017	Temgesic 400microgram sublingual tablets (Indivior UK Ltd)	400microgram
9396	Zamadol SR 100mg capsules (Meda Pharmaceuticals Ltd)	100mg
57900	Co-codamol 30mg/500mg caplets (A A H Pharmaceuticals Ltd)	30mg + 500mg
50862	Marol 200mg modified-release tablets (Teva UK Ltd)	200mg
2794	Co-codamol 30mg/500mg tablets (Wockhardt UK Ltd)	30mg + 500mg
36993	Co-codamol 30mg/500mg capsules (Teva UK Ltd)	30mg + 500mg
1261	Co-codamol 30mg/500mg effervescent powder sachets sugar free	30mg + 500mg
13813	Zamadol 50mg capsules (Meda Pharmaceuticals Ltd)	50mg
46021	Tapentadol 50mg modified-release tablets	50mg
11734	Tramadol 50mg orodispersible tablets sugar free	50mg
36732	Tramadol 50mg modified-release tablets	50mg
9917	Kapake Insts 30mg/500mg effervescent powder sachets (Galen Ltd)	30mg + 500mg
39709	Marol 200mg modified-release tablets (Morningside Healthcare Ltd)	200mg
21797	Zamadol SR 200mg capsules (Meda Pharmaceuticals Ltd)	200mg
37020	Tramadol 150mg modified-release tablets	150mg
4236	Palfium 5mg tablets (Roche Products Ltd)	5mg
7104	Kapake 30mg/500mg effervescent tablets (Galen Ltd)	30mg + 500mg
11748	Tramadol 400mg modified-release tablets	400mg
49323	Marol 150mg modified-release tablets (Teva UK Ltd)	150mg
9389	Zamadol SR 50mg capsules (Meda Pharmaceuticals Ltd)	50mg
11746	Tramadol 300mg modified-release tablets	300mg
11559	Tramadol 50mg effervescent powder sachets sugar free	50mg

39750	Marol 150mg modified-release tablets (Morningside Healthcare Ltd)	150mg
23981	Zamadol SR 150mg capsules (Meda Pharmaceuticals Ltd)	150mg
11101	Zydol 50mg soluble tablets (Grunenthal Ltd)	50mg
35656	Tradorec XL 100mg tablets (Endo Ventures Ltd)	100mg
35651	Tradorec XL 200mg tablets (Endo Ventures Ltd)	200mg
9739	Tramadol 100mg effervescent powder sachets sugar free	100mg
38970	DF 118 Forte 40mg tablets (Martindale Pharmaceuticals Ltd)	40mg
38013	Pethidine 50mg capsules	50mg
29860	Tramadol 50mg capsules (IVAX Pharmaceuticals UK Ltd)	50mg
20310	Zamadol Melt 50mg tablets (Meda Pharmaceuticals Ltd)	50mg
21397	Zydol XL 400mg tablets (Grunenthal Ltd)	400mg
15871	Kapake Insts 60mg/1000mg effervescent powder sachets (Galen Ltd)	60mg + 1gram
44210	Kapake 15mg/500mg tablets (Galen Ltd)	15mg + 500mg
36035	Tradorec XL 300mg tablets (Endo Ventures Ltd)	300mg
4518	DF 118 30 MG TAB	
14490	Tramake 50mg capsules (Galen Ltd)	50mg
19993	Dromadol SR 100mg tablets (Teva UK Ltd)	100mg
21947	Zydol XL 150mg tablets (Grunenthal Ltd)	150mg
24383	Tramake Insts 100mg sachets (Galen Ltd)	100mg
14602	Co-codamol 60mg/1000mg effervescent powder sachets sugar free	60mg + 1gram
16271	Zydol XL 300mg tablets (Grunenthal Ltd)	300mg
23625	Dromadol SR 150mg tablets (Teva UK Ltd)	150mg
11549	Tramadol 75mg modified-release tablets	75mg

Very strong analgesics

Prodcode	Product name	Substance Strength
1503	Oramorph 10mg/5ml oral solution (Boehringer Ingelheim Ltd)	2mg/1ml
495	MST Continus 10mg tablets (Napp Pharmaceuticals Ltd)	10mg
2957	MST Continus 30mg tablets (Napp Pharmaceuticals Ltd)	30mg
13114	Zomorph 10mg modified-release capsules (Ethypharm UK Ltd)	10mg
5840	Morphine sulfate 10mg/5ml oral solution	2mg/1ml

13117	Zomorph 30mg modified-release capsules (Ethypharm UK Ltd)	30mg
4477	MST Continus 60mg tablets (Napp Pharmaceuticals Ltd)	60mg
5599	OxyContin 10mg modified-release tablets (Napp Pharmaceuticals Ltd)	10mg
3919	Sevredol 10mg tablets (Napp Pharmaceuticals Ltd)	10mg
7389	OxyContin 20mg modified-release tablets (Napp Pharmaceuticals Ltd)	20mg
5681	Morphine 10mg modified-release tablets	10mg
5714	MST Continus 15mg tablets (Napp Pharmaceuticals Ltd)	15mg
4280	MST Continus 5mg tablets (Napp Pharmaceuticals Ltd)	5mg
5843	Oxycodone 10mg modified-release tablets	10mg
6557	OxyNorm 5mg capsules (Napp Pharmaceuticals Ltd)	5mg
6608	Oxycodone 20mg modified-release tablets	20mg
5585	Oxycodone 10mg capsules	10mg
6790	Oxycodone 5mg capsules	5mg
15964	Zomorph 60mg modified-release capsules (Ethypharm UK Ltd)	60mg
5991	MST Continus 100mg tablets (Napp Pharmaceuticals Ltd)	100mg
9973	OxyNorm 10mg capsules (Napp Pharmaceuticals Ltd)	10mg
4266	Morphine 10mg tablets	10mg
9927	OxyContin 40mg modified-release tablets (Napp Pharmaceuticals Ltd)	40mg
7875	Morphine 30mg modified-release tablets	30mg
5907	Lamotrigine 100mg dispersible tablets sugar free	100mg
6002	Morphine 10mg modified-release capsules	10mg
9874	OxyNorm liquid 5mg/5ml oral solution (Napp Pharmaceuticals Ltd)	1mg/1ml
7167	OxyContin 5mg modified-release tablets (Napp Pharmaceuticals Ltd)	5mg
5670	Diamorphine hydrochloride 10mg powder for injection solution	10mg
6708	Oxycodone 40mg modified-release tablets	40mg
4693	Oramorph 10mg/5ml oral solution unit dose vials (Boehringer Ingelheim Ltd)	2mg/1ml
6609	Oxycodone 5mg/5ml oral solution sugar free	1mg/1ml
7275	Oxycodone 20mg capsules	20mg
7372	OxyNorm 20mg capsules (Napp Pharmaceuticals Ltd)	20mg

14063	Zomorph 100mg modified-release capsules (Ethypharm UK Ltd)	100mg
10021	OxyContin 80mg modified-release tablets (Napp Pharmaceuticals Ltd)	80mg
6769	Oxycodone 5mg modified-release tablets	5mg
18881	Morphgesic SR 10mg tablets (AMCo)	10mg
8822	Morphine 60mg modified-release tablets	60mg
6948	Oxycodone 80mg modified-release tablets	80mg
8876	Oramorph 20mg/ml concentrated oral solution (Boehringer Ingelheim Ltd)	20mg/1ml
7197	Morphine sulphate 12 30mg Modified-release capsule	30mg
9602	Morphine 5mg modified-release tablets	5mg
9557	Morphine 15mg modified-release tablets	15mg
19449	Morphgesic SR 30mg tablets (AMCo)	30mg
9137	Morphine 20mg tablets	20mg
45745	OxyContin 30mg modified-release tablets (Napp Pharmaceuticals Ltd)	30mg
39477	Targinact 10mg/5mg modified-release tablets (Napp Pharmaceuticals Ltd)	10mg + 5mg
8039	MST Continus 200mg tablets (Napp Pharmaceuticals Ltd)	200mg
39478	Targinact 20mg/10mg modified-release tablets (Napp Pharmaceuticals Ltd)	10mg + 20mg
9183	Morphine 100mg modified-release tablets	100mg
655	Morphine sulfate 10mg/5ml oral solution unit dose vials sugar free	2mg/1ml
45827	Oxycodone 30mg modified-release tablets	30mg
39475	Oxycodone 10mg / Naloxone 5mg modified-release tablets	10mg + 5mg
6366	Sevredol 50mg tablets (Napp Pharmaceuticals Ltd)	50mg
9960	Morphine sulphate 12 60mg Modified-release capsule	60mg
40645	Targinact 5mg/2.5mg modified-release tablets (Napp Pharmaceuticals Ltd)	5mg + 2.5mg
45788	OxyContin 15mg modified-release tablets (Napp Pharmaceuticals Ltd)	15mg
19471	Morphgesic SR 60mg tablets (AMCo)	60mg
7406	OxyNorm 10mg/ml concentrate oral solution (Napp Pharmaceuticals Ltd)	10mg/1ml
607	MST Continus Suspension 20mg granules sachets (Napp Pharmaceuticals Ltd)	20mg
6269	Morphine sulfate 20mg/ml oral solution sugar free	20mg/1ml

39498	Oxycodone 20mg / Naloxone 10mg modified-release tablets	10mg + 20mg
9342	MXL 60mg capsules (Napp Pharmaceuticals Ltd)	60mg
15950	Zomorph 200mg modified-release capsules (Ethypharm UK Ltd)	200mg
9337	MXL 30mg capsules (Napp Pharmaceuticals Ltd)	30mg
11342	Oramorph 30mg/5ml oral solution unit dose vials (Boehringer Ingelheim Ltd)	6mg/1ml
11405	Oxycodone 10mg/ml oral solution sugar free	10mg/1ml
40961	Targinact 40mg/20mg modified-release tablets (Napp Pharmaceuticals Ltd)	40mg + 20mg
9371	MXL 120mg capsules (Napp Pharmaceuticals Ltd)	120mg
9381	MXL 90mg capsules (Napp Pharmaceuticals Ltd)	90mg
45929	Oxycodone 60mg modified-release tablets	60mg
40616	Oxycodone 5mg / Naloxone 2.5mg modified-release tablets	5mg + 2.5mg
5138	Hydromorphone 1.3mg capsules	1.3mg
15815	Morphine 50mg tablets	50mg
12900	MST Continus Suspension 30mg granules sachets (Napp Pharmaceuticals Ltd)	30mg
14050	Morphine sulphate 12 100mg Modified-release capsule	100mg
5137	Hydromorphone 2.6mg capsules	2.6mg
19477	Morphgesic SR 100mg tablets (AMCo)	100mg
9325	Hydromorphone 4mg modified-release capsules	4mg
17936	MXL 200mg capsules (Napp Pharmaceuticals Ltd)	200mg
45830	OxyContin 120mg modified-release tablets (Napp Pharmaceuticals Ltd)	120mg
40785	Oxycodone 40mg / Naloxone 20mg modified-release tablets	40mg + 20mg
15798	Hydromorphone 8mg modified-release capsules	8mg
4476	MST Continus Suspension 60mg granules sachets (Napp Pharmaceuticals Ltd)	60mg
15792	Hydromorphone 2mg modified-release capsules	2mg
3990	Dextromoramide 5mg tablets	5mg
5555	Sevredol 10mg/5ml oral solution (Napp Pharmaceuticals Ltd)	2mg/1ml
5563	Morphine sulphate 12 20mg Modified-release capsule	20mg
11838	Morphine 200mg modified-release tablets	200mg
6736	Morphine 20mg modified-release granules sachets sugar free	20mg

14156	Morphine sulfate 30mg/5ml oral solution unit dose vials sugar free	6mg/1ml
12604	MST Continus Suspension 100mg granules sachets (Napp Pharmaceuticals Ltd)	100mg
9332	Palladone SR 2mg capsules (Napp Pharmaceuticals Ltd)	2mg
9331	Palladone SR 4mg capsules (Napp Pharmaceuticals Ltd)	4mg
26283	Filnarine SR 10mg tablets (Teva UK Ltd)	10mg
9615	Palladone 1.3mg capsules (Napp Pharmaceuticals Ltd)	1.3mg
22756	Filnarine SR 30mg tablets (Teva UK Ltd)	30mg
9330	Palladone 2.6mg capsules (Napp Pharmaceuticals Ltd)	2.6mg
21275	Palladone SR 8mg capsules (Napp Pharmaceuticals Ltd)	8mg
NSAIDs		
Prodcode	**Product name**	**Substance strength**
40	Diclofenac sodium 50mg gastro-resistant tablets	50mg
807	Naproxen 500mg tablets	500mg
661	Naproxen 250mg tablets	250mg
1086	Ibuprofen 600mg tablets	600mg
2243	Meloxicam 7.5mg tablets	7.5mg
1469	Meloxicam 15mg tablets	15mg
162	Arthrotec 50 gastro-resistant tablets (Pfizer Ltd)	50mg + 200microgram
1073	Mefenamic acid 500mg tablets	500mg
3053	Naproxen 500mg gastro-resistant tablets	500mg
580	Diclofenac sodium 75mg modified-release tablets	75mg
5254	Celecoxib 200mg capsules	200mg
474	Celecoxib 100mg capsules	100mg
2386	Voltarol Retard 100mg tablets (Novartis Pharmaceuticals UK Ltd)	100mg
917	Diclofenac sodium 50mg tablets	50mg
177	Indometacin 25mg capsules	25mg
649	Diclofenac sodium 25mg gastro-resistant tablets	25mg
5455	Etodolac 600mg modified-release tablets	600mg
259	Mefenamic acid 250mg capsules	250mg
3431	Naproxen 250mg gastro-resistant tablets	250mg
518	Rofecoxib 12.5mg tablets	12.5mg

1392	Ibuprofen 800mg modified-release tablets	800mg
1984	Diclofenac sodium 100mg modified-release tablets	100mg
706	Rofecoxib 25mg tablets	25mg
2387	Arthrotec 75 gastro-resistant tablets (Pfizer Ltd)	75mg + 200microgram
4880	Diclofenac sodium 75mg gastro-resistant / Misoprostol 200microgram tablets	75mg + 200microgram
650	Etoricoxib 60mg tablets	60mg
736	Indometacin 50mg capsules	50mg
1233	Diclofenac sodium 75mg modified-release tablets	75mg
2234	Nabumetone 500mg tablets	500mg
5812	Etoricoxib 90mg tablets	90mg
1446	Voltarol 50mg Tablet (Novartis Pharmaceuticals UK Ltd)	50mg
977	Minulet tablets (Wyeth Pharmaceuticals)	75microgram + 30microgram
838	Oruvail 200mg Modified-release capsule (Hawgreen Ltd)	200mg
141	Piroxicam 10mg capsules	10mg
1755	Piroxicam 20mg capsules	20mg
296	Ponstan Forte 500mg tablets (Chemidex Pharma Ltd)	500mg
417	Diclofenac 50mg dispersible tablets sugar free	50mg
1210	Indometacin 75mg modified-release capsules	75mg
1866	Naprosyn 500mg tablets (Atnahs Pharma UK Ltd)	500mg
4506	Volsaid Retard 75 tablets (Chiesi Ltd)	75mg
3043	Ketoprofen 200mg modified-release capsules	200mg
928	Diclofenac sodium 25mg tablets	25mg
1116	Diclofenac 100mg suppositories	100mg
2904	Diclofenac sodium 75mg gastro-resistant modified-release capsules	75mg
341	Feldene 10mg capsules (Pfizer Ltd)	10mg
2257	Surgam SA 300mg capsules (Sanofi)	300mg
2235	Relifex 500mg tablets (Meda Pharmaceuticals Ltd)	500mg
5080	Celebrex 200mg capsules (Pfizer Ltd)	200mg
1766	Voltarol sr 75mg Modified-release tablet (Novartis Pharmaceuticals UK Ltd)	75mg
2288	Naprosyn 250mg tablets (Atnahs Pharma UK Ltd)	250mg

5175	Celebrex 100mg capsules (Pfizer Ltd)	100mg
4625	Voltarol 75mg SR tablets (Novartis Pharmaceuticals UK Ltd)	75mg
126	Ponstan 250mg capsules (Chemidex Pharma Ltd)	250mg
3852	Diclomax 100mg Modified-release capsule (Provalis Healthcare Ltd)	100mg
1496	Indocid R 75mg capsules (Merck Sharp & Dohme Ltd)	75mg
850	Mobic 7.5mg tablets (Boehringer Ingelheim Ltd)	7.5mg
526	Aceclofenac 100mg tablets	100mg
120	Indocid 25mg capsules (Merck Sharp & Dohme Ltd)	25mg
666	Vioxx 25mg tablets (Merck Sharp & Dohme Ltd)	25mg
3935	Feldene 20 capsules (Pfizer Ltd)	20mg
1139	Voltarol 25mg Tablet (Novartis Pharmaceuticals UK Ltd)	25mg
5938	Etoricoxib 120mg tablets	120mg
6464	Arcoxia 60mg tablets (Grunenthal Ltd)	60mg
11168	Volsaid Retard 100 tablets (Chiesi Ltd)	100mg
4216	Brufen 600mg tablets (Mylan Ltd)	600mg
3275	Benoral 2g/5ml oral suspension (Sanofi-Synthelabo Ltd)	400mg/1ml
3326	Oruvail 100mg Modified-release capsule (Hawgreen Ltd)	100mg
3901	Naprosyn EC 500mg tablets (Atnahs Pharma UK Ltd)	500mg
919	Indometacin 100mg suppositories	100mg
5266	Lodine sr 600mg Modified-release tablet (Shire Pharmaceuticals Ltd)	600mg
10033	Etodolac 300mg capsules	300mg
1571	Ketoprofen 100mg modified-release capsules	100mg
2382	Tiaprofenic acid 300mg modified-release capsules	300mg
9409	Ethilon suture 2gauge 45cm length with 26mm curved reverse cutting needle W320 Blue (Ethicon Ltd)	Gauge 2.0/45cm (blue)
3974	Tenoxicam 20mg tablets	20mg
344	Acemetacin 60mg capsules	60mg
6498	Arcoxia 90mg tablets (Grunenthal Ltd)	90mg
3939	Napratec OP tablets (Pfizer Ltd)	
12075	Mobiflex 20mg Tablet (Roche Products Ltd)	20mg
499	Diclofenac 50mg suppositories	50mg
3182	Froben 50mg tablets (Abbott Laboratories Ltd)	50mg

8544	Fenbufen 450mg tablets	450mg
920	Indocid 100mg suppositories (Aspen Pharma Trading Ltd)	100mg
2258	Emflex 60mg capsules (Merck Serono Ltd)	60mg
1470	Mobic 15mg tablets (Boehringer Ingelheim Ltd)	15mg
6249	Froben 100mg tablets (Abbott Laboratories Ltd)	100mg
37587	Etoricoxib 30mg tablets	30mg
3266	Flurbiprofen 50mg tablets	50mg
589	Voltarol 50mg dispersible tablets (Novartis Pharmaceuticals UK Ltd)	50mg
2366	Flurbiprofen 100mg tablets	100mg
7688	Rheumox 600mg tablets (Mercury Pharma Group Ltd)	600mg
7522	Lederfen 300mg Tablet (Wyeth Pharmaceuticals)	300mg
3972	Naprosyn EC 250mg tablets (Atnahs Pharma UK Ltd)	250mg
10558	Flexin-75 Continus tablets (Napp Pharmaceuticals Ltd)	75mg
389	Ketoprofen 50mg capsules	50mg
8062	Motifene 75mg modified-release capsules (Daiichi Sankyo UK Ltd)	75mg
1231	Ketoprofen 100mg capsules	100mg
3739	Rheumox 300mg capsules (Mercury Pharma Group Ltd)	300mg
2622	Ibuprofen 800mg tablets	800mg
157	Voltarol 100mg Suppository (Novartis Pharmaceuticals UK Ltd)	100mg

v. Cancer codes

Medcode	Readcode	Read term
3968	B34..00	Malignant neoplasm of female breast
780	B46..00	Malignant neoplasm of prostate
348	B34..11	Ca female breast
1624	BB2A.00	[M]Squamous cell carcinoma NOS
779	B49..00	Malignant neoplasm of urinary bladder
1220	B13..00	Malignant neoplasm of colon
2587	B22z.11	Lung cancer
3903	B22z.00	Malignant neoplasm of bronchus or lung NOS
865	B32..00	Malignant melanoma of skin
2272	BB5..11	[M]Adenocarcinomas
3445	B33..16	Epithelioma basal cell
3197	BB03.00	Malignant neoplasm of female breast
1800	B141.00	Malignant neoplasm of prostate
1940	B33..13	Ca female breast
13569	B590.00	[M]Squamous cell carcinoma NOS
93352	B338.00	Malignant neoplasm of urinary bladder
8625	B641.00	Malignant neoplasm of colon
1062	B10..00	Lung cancer
4944	B630.00	Malignant neoplasm of bronchus or lung NOS
3604	B627.00	Malignant melanoma of skin
8166	B17..00	[M]Adenocarcinomas
4632	B33..00	Epithelioma basal cell
4403	B577.11	[M]Neoplasm, metastatic
3152	BB13.00	Malignant neoplasm of rectum
1483	BBg1.11	Rodent ulcer
1986	B440.11	Disseminated malignancy NOS
9470	B34z.00	Squamous cell carcinoma of skin
6170	B590.11	Chronic lymphoid leukaemia
7967	BB2..12	Malignant neoplasm of oesophagus
13243	B22..00	Multiple myeloma

Medcode	Readcode	Read term
2462	B61..00	Non - Hodgkin's lymphoma
8386	B11..00	Malignant neoplasm of pancreas
2492	B33z.00	Other malignant neoplasm of skin
7805	B440.00	Liver metastases
5901	B141.12	[M]Carcinoma, metastatic, NOS
579	BBE1.00	[M]Lymphoma NOS
1056	B5z..00	Cancer of ovary
4865	B10z.11	Malignant neoplasm of female breast NOS
7483	BBE1.12	Carcinomatosis
2890	B430200	[M]Squamous cell neoplasms
7654	B585.00	Malignant neoplasm of trachea, bronchus and lung
2747	B41..00	Hodgkin's disease
5842	B58..00	Malignant neoplasm of stomach
3672	BBn0.12	Malignant neoplasm of skin NOS
9118	B13z.11	Malignant neoplasm of ovary
8695	BB12.00	Rectal carcinoma
3811	B134.00	[M]Malignant melanoma NOS
12335	B62y.00	Malignant neoplasm of other and unspecified site NOS
4413	B650.00	Oesophageal cancer
2815	B133.00	[M]Melanoma NOS
5199	B583200	Malignant neoplasm of endometrium of corpus uteri
5637	B53..00	Secondary malignant neoplasm of bone and bone marrow
11628	B1z0.11	Malignant neoplasm of cervix uteri
4137	B570.00	Secondary malignant neoplasm of other specified sites
14800	B11z.00	[M]Myeloma NOS
14825	BA0..00	Colonic cancer
8930	BB52.00	[M]Carcinoma NOS
15103	B577.00	Malignant neoplasm of caecum
31102	B49z.00	Malignant lymphoma NOS
319	B21..00	Acute myeloid leukaemia
7484	B226.00	Malignant neoplasm of sigmoid colon

Medcode	Readcode	Read term
1599	B4A0.00	Cerebral metastasis
3230	B41..11	Malignant neoplasm of thyroid gland
8523	BBb0.11	Cancer of bowel
6436	BB43.00	Secondary malignant neoplasm of lung
2744	B40..00	Malignant neoplasm of stomach NOS
18617	B51..00	Neoplasm of unspecified nature
6115	B6y0.00	[M]Adenocarcinoma NOS
8711	BB5D100	Secondary malignant neoplasm of liver
10395	BBm7.00	Malignant neoplasm of urinary bladder NOS
9575	BBbL.11	Malignant neoplasm of larynx
68236	B550.00	Mesothelioma
13559	B4A..00	Malignant neoplasm of kidney parenchyma
10726	B651.00	Cervical carcinoma (uterus)
93490	B33z.11	[M]Glioma NOS
10283	B01..00	[M]Transitional cell carcinoma NOS
4250	B68z.00	Malignant neoplasm of uterus, part unspecified
3371	BBg2.11	Malignant neoplasm of brain
8547	BBbB.00	Myeloproliferative disorder
5198	B583000	[M]Cholangiocarcinoma
8085	BBF1.00	[M] Monoclonal gammopathy
7693	BBE..00	[M]Glioblastoma multiforme
3923	BB5R.00	Malignant neoplasm of head, neck and face
7046	B43..00	Malig neop of kidney and other unspecified urinary organs
8101	BB5a.00	Chronic myeloid leukaemia
30700	B10z.00	Squamous cell carcinoma of skin NOS
4251	B640.00	Malignant neoplasm of tongue
12870	B221.00	Leukaemia NOS
1044	BA06.00	[M]Non Hodgkins lymphoma
5455	BB53.00	[M]Astrocytoma NOS
25886	B222100	Secondary malignant neoplasm of brain
15148	B47..00	[M]Sarcoma NOS

Medcode	Readcode	Read term
21868	BB02.00	[M]Naevi and melanomas
28163	B13z.00	[M]Carcinoid tumours
5034	B33..12	Malignant neoplasm of body of uterus
7219	B141.11	[M]Renal adenoma and carcinoma
7176	B65..00	Malignant neoplasm of oesophagus NOS
9291	BB1J.00	Acute lymphoid leukaemia
12006	B621.00	Malignant neoplasm of main bronchus
22187	B150300	Neoplasm of unspecified nature of brain
100 of the most commonly recorded cancer clinical codes (of a total 2152)		

vii. Formal residence codes

Medcode	Read codes	Read terms
13359	13F6100	Lives in a nursing home
49681	13FX.00	Lives in care home
93998	9b0i.00	Residential home visit note
24956	13FK.00	Lives in a residential home
13360	13F6.00	Nursing/other home
101003	9NFR.00	Home visit request by residential institution
11419	13F7200	Lives in an old peoples home
107602	9NFW100	Care home visit for follow-up patient review
100080	8Ce5.00	Preferred place of care - residential home
7101	9N1F.12	Seen in old people's home
107443	9NFW000	Care home visit for initial patient assessment
107757	9NFW.00	Care home visit
73321	9b1P.00	Nursing home
101078	949D.00	Patient died in care home
107390	8Ce5.11	Preferred place of care - care home
27425	13F5.00	Part III accommodation
101152	94ZC.00	Preferred place of death: care home
45650	T704.00	Place of occurrence of accident/poisoning, residential house
73083	9b0Y.00	Nursing home visit note
42191	ZLG3.00	Discharge to residential home
24828	Z177F00	Nursing home care
104115	94ZE.00	Preferred place of death: residential home
24816	Z177C00	Residential care
59548	13FT.00	Lives in an old peoples home
98758	13Zo.00	Previously lived in care home
27360	13F5100	Part III accomodation arranged
43709	ZV70H00	[V]Examination for admission to residential institutions
36096	13F5.11	Part 3 accomodation
68005	13FV.00	Lives in a welfare home
47609	T77..00	Place of accident or poisoning, residential institution

Medcode	Read codes	Read terms
56326	U3K1.00	[X]Assault by bodily force occurrn in residential institut'n
61569	TK70.00	Suicide+selfinflicted injury-jump from residential premises
102230	M270100	Nursing home acquired pressure ulcer
48549	ZLG3100	Discharge to private residential home
66371	TN70.00	Injury ?accidental, fall from residential premises
56969	T77z.00	Accident/poisoning occurred in residential institution NOS
46642	9b79.00	Other residential care homes managed by local authority
46222	T774.00	Place of occurrence of accident/poisoning, old people's home
53140	Z177D00	Local authority residential care
69028	ZLG3200	Discharge to part III residential home
69762	U106100	[X]Fall involving bed occurrence in residential institution
66122	13F5111	Part 3 accomodation arranged
67903	U105100	[X]Fall involvng wheelchair occurrence residential instit'n
100389	U321.00	[X]Assault by pesticides occurrn in residential institution
99120	U193100	[X]Victim of lightning, occurrn in residential institution
48733	U198100	[X]Victim of flood, occurrence in residential institution
107927	U1B4100	[X]Lack of water, occurrence in residential institution
99110	U10F100	[X]Fall from cliff, occurrence in residential institution
111109	U124100	[X]Bitten/struck by dog occurrnce in residential institut'n
111795	U1B3100	[X]Lack of food, occurrence in residential institution

ix. Cardiovascular-related codes

Medcode	Read code	Read term
1430	G33..00	Angina pectoris
240	G3...00	Ischaemic heart disease
1469	G66..00	Stroke and cerebrovascular accident unspecified
241	G30..00	Acute myocardial infarction
1792	G3...13	IHD - Ischaemic heart disease
1517	G73z000	Intermittent claudication
1298	G66..11	CVA unspecified
1677	G30..15	MI - acute myocardial infarction
14658	G30z.00	Acute myocardial infarction NOS
10562	G307100	Acute non-ST segment elevation myocardial infarction
3530	G73z.00	Peripheral vascular disease NOS
2760	G73zz00	Peripheral vascular disease NOS
1344	G340.12	Coronary artery disease
1431	G311.13	Unstable angina
1676	G3z..00	Ischaemic heart disease NOS
11983	G311500	Acute coronary syndrome
3149	G64z.00	Cerebral infarction NOS
7347	G311100	Unstable angina
5943	G73..00	Other peripheral vascular disease
12229	G30X000	Acute ST segment elevation myocardial infarction
6116	G66..13	CVA - Cerebrovascular accident unspecified
5051	G61..00	Intracerebral haemorrhage
2099	G575.00	Cardiac arrest
6853	G73z011	Claudication
28554	G33zz00	Angina pectoris NOS
1678	G308.00	Inferior myocardial infarction NOS
1826	G73..12	Ischaemia of legs
6960	G61..11	CVA - cerebrovascular accid due to intracerebral haemorrhage
4017	G32..00	Old myocardial infarction
1655	G340.11	Triple vessel disease of the heart

Medcode	Read code	Read term
4325	G73yz00	Other specified peripheral vascular disease NOS
5413	G340.00	Coronary atherosclerosis
1414	G33z300	Angina on effort
25842	G33z.00	Angina pectoris NOS
5602	G64z.12	Cerebellar infarction
12804	G33z700	Stable angina
5640	G70..00	Atherosclerosis
6253	G66..12	Stroke unspecified
3999	G340000	Single coronary vessel disease
7780	G667.00	Left sided CVA
4656	G311.11	Crescendo angina
6155	G64..13	Stroke due to cerebral arterial occlusion
12833	G668.00	Right sided CVA
569	G64..12	Infarction - cerebral
5254	G340100	Double coronary vessel disease
2491	G30..12	Coronary thrombosis
16517	G640.00	Cerebral thrombosis
3704	G307.00	Acute subendocardial infarction
14897	G301z00	Anterior myocardial infarction NOS
36523	G311.00	Preinfarction syndrome
9276	G31y000	Acute coronary insufficiency
20095	G330.00	Angina decubitus
20416	G3...12	Atherosclerotic heart disease
1318	G700.00	Aortic atherosclerosis
7320	G343.00	Ischaemic cardiomyopathy
33543	G6X..00	Cerebrl infarctn due/unspcf occlusn or sten/cerebrl artrs
5387	G301.00	Other specified anterior myocardial infarction
9985	G64z200	Left sided cerebral infarction
18604	G61..12	Stroke due to intracerebral haemorrhage
10504	G64z300	Right sided cerebral infarction
3535	G61z.00	Intracerebral haemorrhage NOS

Medcode	Read code	Read term
12139	G300.00	Acute anterolateral infarction
52517	Gyu3.00	[X]Ischaemic heart diseases
17307	G311200	Angina at rest
13564	G613.00	Cerebellar haemorrhage
17322	G664.00	Cerebellar stroke syndrome
8935	G302.00	Acute inferolateral infarction
23671	G63y000	Cerebral infarct due to thrombosis of precerebral arteries
17464	G32..12	Personal history of myocardial infarction
8443	G663.00	Brain stem stroke syndrome
15019	G641.00	Cerebral embolism
23078	G34y100	Chronic myocardial ischaemia
36854	G332.00	Coronary artery spasm
32450	G33z400	Ischaemic chest pain
26424	G64z400	Infarction of basal ganglia
17872	G301100	Acute anteroseptal infarction
18889	G34z000	Asymptomatic coronary heart disease
9507	G307000	Acute non-Q wave infarction
36717	G640000	Cerebral infarction due to thrombosis of cerebral arteries
12986	G331.00	Prinzmetal's angina
8610	G76z000	Iliac artery occlusion
24783	G3...11	Arteriosclerotic heart disease
22383	G3y..00	Other specified ischaemic heart disease
25407	G575.11	Cardio-respiratory arrest
28138	G34..00	Other chronic ischaemic heart disease
23892	G304.00	Posterior myocardial infarction NOS
21195	G575100	Sudden cardiac death, so described
25615	G64z000	Brainstem infarction
30202	G617.00	Intracerebral haemorrhage, intraventricular
19655	G311.14	Angina at rest
29421	G344.00	Silent myocardial ischaemia
14898	G305.00	Lateral myocardial infarction NOS

Medcode	Read code	Read term
15661	G310.11	Dressler's syndrome
26863	G33z600	New onset angina
29643	G303.00	Acute inferoposterior infarction
53745	Gyu6400	[X]Other cerebral infarction
33499	G665.00	Pure motor lacunar syndrome
33899	G575000	Cardiac arrest with successful resuscitation
17689	G30..17	Silent myocardial infarction
13571	G30..16	Thrombosis - coronary
100 of 190 clinical codes		

xi. Depression codes

Medcode	Read code	Read term
324	E2B..00	Depressive disorder NEC
655	E200300	Anxiety with depression
543	Eu32z11	[X]Depression NOS
1996	1B17.00	Depressed
4639	Eu32.00	[X]Depressive episode
1131	E204.00	Neurotic depression reactive type
1908	2257	O/E - depressed
9211	Eu32100	[X]Moderate depressive episode
2970	Eu32z00	[X]Depressive episode, unspecified
6932	E113.11	Endogenous depression - recurrent
5987	Eu32z14	[X] Reactive depression NOS
6950	E112.13	Endogenous depression first episode
595	E112.14	Endogenous depression
4323	E2B1.00	Chronic depression
6482	E113700	Recurrent depression
10610	E112.00	Single major depressive episode
5879	E112.11	Agitated depression
6874	Eu31.00	[X]Bipolar affective disorder
1055	E135.00	Agitated depression
11717	Eu32000	[X]Mild depressive episode
3292	Eu33.00	[X]Recurrent depressive disorder
11913	Eu41200	[X]Mixed anxiety and depressive disorder
9667	Eu32200	[X]Severe depressive episode without psychotic symptoms
15099	E113.00	Recurrent major depressive episode
3291	Eu32z12	[X]Depressive disorder NOS
10667	Eu32400	[X]Mild depression
2741	Eu30000	[X]Hypomania
6546	E112.12	Endogenous depression first episode
5726	Eu3..00	[X]Mood - affective disorders
16889	6657.11	Lithium monitoring

Medcode	Read code	Read term
2923	62T1.00	Puerperal depression
7953	Eu34100	[X]Dysthymia
9055	Eu32.11	[X]Single episode of depressive reaction
14709	E113200	Recurrent major depressive episodes, moderate
1531	Eu31.11	[X]Manic-depressive illness
15155	E112200	Single major depressive episode, moderate
29520	Eu33100	[X]Recurrent depressive disorder, current episode moderate
8567	E11..11	Bipolar psychoses
7604	Eu32.13	[X]Single episode of reactive depression
14784	E117.00	Unspecified bipolar affective disorder
16506	E112100	Single major depressive episode, mild
22564	6657	On lithium
2560	E11..12	Depressive psychoses
15220	Eu34114	[X]Persistant anxiety depression
7749	Eu41211	[X]Mild anxiety depression
14656	E11..00	Affective psychoses
12099	Eu32300	[X]Severe depressive episode with psychotic symptoms
1533	E290.00	Brief depressive reaction
8826	Eu33.15	[X]SAD - Seasonal affective disorder
13307	Eu53011	[X]Postnatal depression NOS
14728	E110100	Single manic episode, mild
10825	E118.00	Seasonal affective disorder
9183	E11z200	Masked depression
8902	Eu33.13	[X]Recurrent episodes of reactive depression
7737	Eu34113	[X]Neurotic depression
44300	Eu33z00	[X]Recurrent depressive disorder, unspecified
8851	Eu33.11	[X]Recurrent episodes of depressive reaction
7011	E112z00	Single major depressive episode NOS
22806	Eu32212	[X]Single episode major depression w'out psychotic symptoms
16632	E291.00	Prolonged depressive reaction
6854	Eu32y00	[X]Other depressive episodes

Medcode	Read code	Read term
12173	Eu30.00	[X]Manic episode
98414	Eu32700	[X]Major depression, severe without psychotic symptoms
25563	E113z00	Recurrent major depressive episode NOS
4678	Eu30z11	[X]Mania NOS
11548	146D.00	H/O: manic depressive disorder
15219	E112300	Single major depressive episode, severe, without psychosis
21540	Eu34000	[X]Cyclothymia
29784	Eu33000	[X]Recurrent depressive disorder, current episode mild
29342	E113100	Recurrent major depressive episodes, mild
33469	Eu33200	[X]Recurr depress disorder cur epi severe without psyc sympt
98252	Eu32600	[X]Major depression, moderately severe
27584	Eu31700	[X]Bipolar affective disorder, currently in remission
31316	E116.00	Mixed bipolar affective disorder
6710	Eu31.12	[X]Manic-depressive psychosis
2972	E2B0.00	Postviral depression
34390	E112000	Single major depressive episode, unspecified
37070	E110.00	Manic disorder, single episode
8584	Eu34111	[X]Depressive neurosis
25697	E113300	Recurrent major depressive episodes, severe, no psychosis
20110	E110000	Single manic episode, unspecified
18909	E110.11	Hypomanic psychoses
16808	Eu31000	[X]Bipolar affective disorder, current episode hypomanic
13024	Eu30100	[X]Mania without psychotic symptoms
11329	Eu33211	[X]Endogenous depression without psychotic symptoms
12831	E115.11	Manic-depressive - now depressed
47009	Eu33300	[X]Recurrent depress disorder cur epi severe with psyc symp
11596	E11y000	Unspecified manic-depressive psychoses
21065	Eu30200	[X]Mania with psychotic symptoms
9521	Eu30.11	[X]Bipolar disorder, single manic episode
26161	E11..13	Manic psychoses
33751	Eu31z00	[X]Bipolar affective disorder, unspecified

Medcode	Read code	Read term
19696	Eu33.12	[X]Recurrent episodes of psychogenic depression
22116	Eu33400	[X]Recurrent depressive disorder, currently in remission
24112	Eu32313	[X]Single episode of psychotic depression
101054	Eu32900	[X]Single major depr ep, severe with psych, psych in remiss
17385	E114.11	Manic-depressive - now manic
4677	E115.00	Bipolar affective disorder, currently depressed
98346	Eu32500	[X]Major depression, mild
3702	E114.00	Bipolar affective disorder, currently manic
100 of 216 clincial codes		

xiii. Diabetes codes

Medcode	Readcode	Read term
9897	9OL..00	Diabetes monitoring admin.
3550	66A..00	Diabetic monitoring
6125	66AS.00	Diabetic annual review
2379	9N1Q.00	Seen in diabetic clinic
13194	9OL4.00	Diabetes monitoring 1st letter
26666	2G5E.00	O/E - Right diabetic foot at low risk
26667	2G5I.00	O/E - Left diabetic foot at low risk
758	C10F.00	Type 2 diabetes mellitus
711	C10..00	Diabetes mellitus
608	66A2.00	Follow-up diabetic assessment
11094	9NND.00	Under care of diabetic foot screener
11471	8B3l.00	Diabetes medication review
1684	66A4.00	Diabetic on oral treatment
13195	9OL5.00	Diabetes monitoring 2nd letter
31157	2G5F.00	O/E - Right diabetic foot at moderate risk
31156	2G5J.00	O/E - Left diabetic foot at moderate risk
18311	68A7.00	Diabetic retinopathy screening
13197	9OL1.00	Attends diabetes monitoring
101801	66At100	Type II diabetic dietary review
10977	66Ac.00	Diabetic peripheral neuropathy screening
13067	66AZ.00	Diabetic monitoring NOS
8836	66AR.00	Diabetes management plan given
2378	66AJ.00	Diabetic - poor control
11348	9h42.00	Excepted from diabetes quality indicators: Informed dissent
7563	66A3.00	Diabetic on diet only
12213	8BL2.00	Patient on maximal tolerated therapy for diabetes
12030	9OL6.00	Diabetes monitoring 3rd letter
1323	F420.00	Diabetic retinopathy
506	C100112	Non-insulin dependent diabetes mellitus
1549	C10E.00	Type 1 diabetes mellitus

Medcode	Readcode	Read term
4513	C109.00	Non-insulin dependent diabetes mellitus
7069	F420000	Background diabetic retinopathy
11433	2BBP.00	O/E - right eye background diabetic retinopathy
11041	9h41.00	Excepted from diabetes qual indicators: Patient unsuitable
13192	9OLA.00	Diabetes monitor. check done
11129	2BBQ.00	O/E - left eye background diabetic retinopathy
9974	9N1v.00	Seen in diabetic eye clinic
9145	9N4I.00	DNA - Did not attend diabetic clinic
13074	13B1.00	Diabetic diet
47032	8CS0.00	Diabetes care plan agreed
8842	66A5.00	Diabetic on insulin
13057	679L.00	Health education - diabetes
83532	66Ao.00	Diabetes type 2 review
10983	C11y300	Impaired fasting glycaemia
12675	66AQ.00	Diabetes: shared care programme
13071	66AI.00	Diabetic - good control
31171	2G5G.00	O/E - Right diabetic foot at high risk
31172	2G5K.00	O/E - Left diabetic foot at high risk
13196	66AD.00	Fundoscopy - diabetic check
8414	8CA4100	Pt advised re diabetic diet
17859	C109.12	Type 2 diabetes mellitus
6813	1434	H/O: diabetes mellitus
22823	66Ab.00	Diabetic foot examination
31141	9OL8.00	Diabetes monitor.phone invite
47144	2BBM.00	O/E - diabetic maculopathy absent both eyes
47011	8Hj0.00	Referral to diabetes structured education programme
10042	R10E.00	[D]Impaired glucose tolerance
1038	C100011	Insulin dependent diabetes mellitus
30648	9N4p.00	Did not attend diabetic retinopathy clinic
93854	9OLM.00	Diabetes structured education programme declined
50175	66AW.00	Diabetic foot risk assessment

Medcode	Readcode	Read term
11677	8H7r.00	Refer to diabetic foot screener
38078	66A9.00	Understands diet - diabetes
12307	66AU.00	Diabetes care by hospital only
31240	9OL7.00	Diabetes monitor.verbal invite
1789	R105712	[D]Hyperglycaemia
31241	9OLZ.00	Diabetes monitoring admin.NOS
8446	L180811	Gestational diabetes mellitus
6430	9NM0.00	Attending diabetes clinic
9958	42W..00	Hb. A1C - diabetic control
3837	F420400	Diabetic maculopathy
1647	C108.00	Insulin dependent diabetes mellitus
21689	13AB.00	Diabetic lipid lowering diet
12262	8I3X.00	Diabetic retinopathy screening refused
18824	8I3W.00	Diabetic foot examination declined
10642	ZC2C800	Dietary advice for diabetes mellitus
14889	C100111	Maturity onset diabetes
10824	9N1i.00	Seen in diabetic foot clinic
93657	8Hj4.00	Referral to DESMOND diabetes structured education programme
12247	8I6G.00	Diabetic foot examination not indicated
13191	9OL..11	Diabetes clinic administration
10791	R10D000	[D]Impaired fasting glycaemia
13069	66A8.00	Has seen dietician - diabetes
35383	9OLD.00	Diabetic patient unsuitable for digital retinal photography
20900	9OLA.11	Diabetes monitored
18167	66AT.00	Annual diabetic blood test
28769	66AV.00	Diabetic on insulin and oral treatment
93870	8Hj5.00	Referral to XPERT diabetes structured education programme
17236	14P3.00	H/O: insulin therapy
14803	C100100	Diabetes mellitus, adult onset, no mention of complication
10755	F420600	Non proliferative diabetic retinopathy
1407	C10FJ00	Insulin treated Type 2 diabetes mellitus

Medcode	Readcode	Read term
1682	C101.00	Diabetes mellitus with ketoacidosis
22130	9OL3.00	Diabetes monitoring default
16230	C106.00	Diabetes mellitus with neurological manifestation
26604	66AY.00	Diabetic diet - good compliance
20696	66AA.11	Injection sites - diabetic
52237	9360	Patient held diabetic record issued
19739	68A9.00	Diabetic retinopathy screening offered
13108	2BBX.00	O/E - left eye diabetic maculopathy
100 of 580 clinical codes		

Appendix 5: NHS Research Ethics Committee (REC) and Health Research Authority (HRA) approval

a. NHS REC approval

Health Research Authority

London - Bromley Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8044

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

29 October 2017

Miss Laurna Bullock
PhD student
Keele University
Research Institute for Primary Care & Health Sciences
Newcastle-under-Lyme
ST5 5BG

Dear Miss Bullock

Study title:	**An investigation into the views and experiences of pain in community-dwelling people with dementia**
REC reference:	**17/LO/1646**
Protocol number:	**RG-0119-16-IPCHS**
IRAS project ID:	**230583**

Thank you for your letter of 10 October 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Committee Member.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

A Research Ethics Committee established by the Health Research Authority

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

b. HRA Approval

NHS
Health Research Authority

Miss Laurna Bullock
PhD student
Keele University
Research Institute for Primary Care & Health Sciences
Newcastle-under-Lyme
ST5 5BG

Email: hra.approval@nhs.net

31 October 2017

Dear Miss Bullock

Letter of HRA Approval

Study title:	**An investigation into the views and experiences of pain in community-dwelling people with dementia**
IRAS project ID:	**230583**
Protocol number:	**RG-0119-16-IPCHS**
REC reference:	**17/LO/1646**
Sponsor	**Keele University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

Appendix 6: Interview guides

a. Person with dementia and family caregiver interview guide

General:	**1. Tell me a bit about yourself?**
If not covered:	
Age:	1. If you don't mind me asking, how old are you?
Occupation:	1. Do you currently work? 2. What did you used to do?
Living situation:	1. Tell me a little about where you both live? 2. Have you lived in this house for long? 3. Who lives with you?
Comorbidity:	1. Do you have any health problems? Do these cause you any pain? 2. When did this come about? How long have you had _____ for?
Dementia	1. So you've mentioned memory problems, can you tell me more about this? 2. How long have you/they experienced this? 3. Tell me about how much this affects you? 4. Have seen a doctor about your memory problems in the past? 5. Have you been given a diagnosis? When was this? 6. Do you currently see a healthcare professional about your memory problems?

The current or previous experience of pain	
Iowa Pain Thermometer • Point to the word that best describes how bad their pain is now • Point to the word that best describes how bad their pain has been in the past 4 weeks	
Person with dementia	**Family caregiver**
Tell me about your pain How would you describe the pain?	Tell me about _____'s pain How would you describe their pain?
The impact of pain	
How do you think that pain affects you? • What kind of things do you do differently now?	**How do you think that pain affects _____?** • What kind of things do they do differently now?
Experience of pain assessment	
Tell me about how you both communicate about pain	Tell me about how you both communicate about pain

Tell me what you do when you're in pain or are uncomfortable In your opinion, can other people (e.g. professionals) see when you're in pain?	How you tell when they're in pain or are uncomfortable? What sort of signs do you look for? What makes it difficult to tell if they are in pain? In your opinion, can other people (e.g. professionals) see when _____ is in pain? Do they ask you?
Experience of pain management	
What do professionals do when you tell them about your pain? What do you do to help when you are in pain? How do you tell if they have worked? What other things help you to feel better when you're in pain?	What do professionals do when you tell them about _____'s pain? What do you do to help when ____ is in pain? How do you tell if they have worked? What do you think could have been done better to help with their pain/discomfort? What other things help them to feel better when they're in pain?
Healthcare and support	
Support for your pain?	Support for their pain?

Is there anything else you'd like to say?

Before we finish, I will just check if there is anything that we have forgotten to discuss.

Close the interview and thank the interviewee for their participation.

b. Healthcare professional interview guide

General:	So, tell me about yourself?
If not covered:	
Occupation:	What is your profession? How long have you worked as _____ for? What is your role in regard to pain for people with dementia?

The impact of pain
How does pain can affect a person with dementia?
Experience of pain assessment
Could you talk me through your *typical* method to assess pain in people with dementia? What factors may flag to you that a person with dementia might be experiencing pain? • Tell me about self-reported pain for patients with dementia • What if the person with dementia cannot communicate? • What things would you be looking for to indicate a person with dementia may be in pain? • How does this method differ from older populations without dementia? Any tools in use for pain assessment, and if any, for use with patients with dementia? The role of carers in the process? How comfortable/confident are you when assessing pain in people with dementia? • What factors increase/decrease your confidence?
Experience of pain management

Could you talk me though your *typical* response for a patient with dementia who you believe is experiencing pain?
• Analgesia
  ○ What are the treatment options?
  ○ When would treatment be offered?
  ○ What other treatment options are available?
  ○ Does this differ to people without dementia?
• Other pain management techniques?
How do you decide which treatments to offer?

The role of carers in the process? How comfortable/confident are you when treating pain in people diagnosed with dementia? • What factors increase/decrease your confidence?
Healthcare and Support
What are the challenges for you as a practitioner? What things would be helpful for you, or your colleagues to support the management of pain in people with dementia? What are the challenges for services more broadly?

Is there anything else you'd like to say?

Before we finish, I will just check if there is anything that we have forgotten to discuss

Close the interview and thank the interviewee for their participation.

Appendix 7: Pre-interview checklist

Pre Interview Checklist

Caregiver name: _____

Person with dementia participating: Yes / No

Person with dementia name: _____

Location: Home Keele University

Address:_____

_____

_____

Time: _____am/pm

Any special requirements?* *Is the person with dementia aware of their diagnosis? Will the person with dementia be present (if caregiver is participating alone)? Parking? Other?*

_____

_____

Appendix 8: Study pack

a. Person with dementia and family caregiver invitation letter

Pain in People with Dementia Study

Dear Sir/Madam,

My name is Laurna Bullock and I am a PhD student at the Research Institute of Primary Care and Health Sciences at Keele University. I am very interested in understanding normal everyday aches and pains experienced by people with dementia (e.g. osteoarthritis, headache, back pain, knee pain), and how this is recognised, assessed, and treated. I would like to talk to people with dementia and carers of those with dementia about their experiences. This research will allow people with dementia and carers of people with dementia a voice into something that directly affects their life, with the aim to improve pain management and treatment for people with dementia.

I have learned your name and contact details as you were recommended for the study by **Approach Staffordshire**, or through **Join Dementia Research**.

If you are interested in taking part, you can call or email me (contact details are at the end of this letter). Alternatively, you can complete the contact slip (enclosed with this pack) and return it to me using the pre-paid envelope included in this pack, and I will call you back at a convenient time. During this conversation, we will discuss the research further, answer any questions, and arrange a time/place convenient to you to complete the interview (including your own home if you prefer). On the day of the interview, I will call approximately one hour before, to check that the interview can go ahead. The visit is likely to last approximately 60-90 minutes and will involve talking about the person with dementia's pain experience. The researcher would be interested to chat to the **carer of the person with dementia** and **the person with dementia together**. This may mean that the carer agrees that the person with dementia would wish to take part. However, if the person with

dementia cannot, or does not wish to take part, the interview can be completed **alone** with the carer. The interview can be **flexible** to suit your needs.

I have included two information leaflets (one for the carer and one for the person with dementia) about the study with this letter. These leaflets contain more information about the study to help you to decide if you would wish to take part.

If you are interested in taking part or have any questions, please contact me.

Yours sincerely,

Laurna Bullock 01782 734985 / l.bullock@keele.ac.uk

b. Person with dementia information leaflet

DO I HAVE TO TAKE PART?

You do not have to take part. Choosing not to take part will **not** affect your treatment or care now or in the future. If you do decide to take part, you can stop the interview at any time without giving a reason. If you withdraw your anonymised data will be included in the research, however further information will not be collected, and no further contact will be made to you.

WHO IS FUNDING THE RESEARCH?

Keele University ACORN studentship is funding this research.

WHAT IF I HAVE A CONCERN?

Please contact Dr Paul Campbell on p.campbell@keele.ac.uk; 01782 734828.
If you remain unhappy about the research and/or wish to raise a complaint please write to:
Clark Crawford – Head of Research Integrity
Keele University, Staffordshire, ST5 5NH
Telephone: 01782 733371
E-mail:
research.governance@keele.ac.uk

WHAT TO DO NOW?

If you wish to take part, you can:

- Call me on **01782 734985**
- Email me on l.bullock@keele.ac.uk
- Complete the consent to contact slip and return it to me in the pre-paid envelope in your study pack and I will call you at a convenient time for you.

NEED MORE INFORMATION OR WISH TO TAKE PART?

I'm very happy to discuss the research in person or over the phone.

Contact me at:
Laurna Bullock
Research Institute for Primary Care and Health Sciences,
Keele University,
Staffordshire,
ST5 5BG
01782 734985
Email: l.bullock@keele.ac.uk

Keele University

Understanding Pain in People with Dementia

Research Information Leaflet

Person with dementia

Version No: 1.1

Date: 04/10/2017

London - Bromley Research Ethics Committee

IRAS Project ID: 230583

RG-0119-16-IPCHS

THE PROJECT

Not all people with dementia experience pain, however not much is known about the experiences of those that do when living at home. This research aims to explore the views of pain in people with dementia by interviewing you and your relative/friend/caregiver **together**.

WHY HAVE I BEEN INVITED?

You have been invited to take part in this study because of your contact with Approach Staffordshire, and/or Join Dementia Research as a user of their services.

WHO WANTS TO KNOW?

I'm Laurna Bullock. I have an interest in studying dementia, and I'm doing this research as part of my PhD at Keele University. My supervisors are Dr Paul Campbell, Dr John Bedson and Dr Bernadette Bartlam.

WHAT WILL HAPPEN IF I TAKE PART?

Taking part will involve an informal conversation with you and your relative/friend/caregiver at the same time. I will call you approximately one hour before the arranged interview. The interview will last approximately 60-90 minutes at a place and time that suits you (including your own home if you prefer). With your permission, I will audio record our conversation.

HOW WILL MY INFORMATION BE USED?

Information from our discussion will be stored on a password protected computer at the University. Only my supervisors and I will have access to it. The information I gather will be made anonymous and will be included in my PhD thesis and in other publications and presentations. When the research is finished, identifying information and the audio recordings will be destroyed. But, all the anonymous information will be kept for at least 10 years and may be used in future studies.

HOW WILL YOU PROTECT MY PRIVACY?

The recordings will be typed up and made anonymous. This will be done by removing any names or details of your friends and family, or any other person you may mention. This means that it will not be possible to know who you are. Direct quotes from the interview may be used in my research report. These quotes will be made anonymous. Your consent form and contact details will be stored securely and separately at the University. In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act 1998. This would usually be discussed with you first. The researcher will ask you for your GP's contact details. Your GP may be contacted if we are concerned for your, or somebody else's safety.

WHAT ARE THE BENEFITS TO TAKING PART?

If you participate, you will help to increase understanding of the pain experienced by people with dementia. This information can then help GPs and other health care professionals to plan better assessments and treatments for those with dementia who have pain. You will also be given a £10 voucher as a thank you for taking part.

WHAT ARE THE RISKS OF TAKING PART?

There are no real risks to taking part in this interview. However discussing your experiences of pain may be upsetting. You can ask for the interview to be stopped at any point without reason, and you can change your mind about taking part. For advice, you may find it helpful to ring the National Dementia Helpline on 0300 222 11 22 for information, or support.

c. Family caregiver information leaflet

WHAT ARE THE RISKS OF TAKING PART?

There are no real risks to taking part in this interview. However discussing your relative/friend's experiences of pain may be upsetting. You can ask for the interview to be stopped at any point, and you can change your mind about taking part at anytime. For advice, you may find it helpful to ring the National Dementia Helpline on 0300 222 11 22 for information or support.

DO I HAVE TO TAKE PART?

You do not have to take part. Choosing not to take part will **not** affect you or your relative/friend's treatment or care now or in the future. If you do decide to take part, you can stop the interview at any time without giving a reason. If you withdraw, your anonymised data will be included in the research, however further information will not be collected, and no further contact will be made to you.

WHO IS FUNDING THE RESEARCH?

Keele University ACORN studentship is funding this research.

WHAT IF I HAVE A CONCERN?

Please contact Dr Paul Campbell on p.campbell@keele.ac.uk; Telephone: 01782 734828.

Version no: 1.1

Date: 04/10/2017

If you remain unhappy about the research and/or wish to raise a complaint please write to:
Clark Crawford – Head of Research Integrity
Keele University, Staffordshire, ST5 5NH
Telephone: 01782 733371
E-mail: research.governance@keele.ac.uk

WHAT TO DO NOW?

If you wish to take part, you can:

- Call me on **01782 734985**
- Email me on l.bullock@keele.ac.uk
- Complete the consent to contact slip and return it to me in the pre-paid envelope in your study pack and I will call you.

NEED MORE INFORMATION OR WISH TO TAKE PART?

I'm very happy to discuss the research in person or over the phone.

Laurna Bullock
Research Institute for Primary Care and Health Sciences,
Keele University, Staffordshire, ST5 5BG
Telephone: 01782 734985
Email: l.bullock@keele.ac.uk

Participant Information Leaflet Carer

Keele University

Understanding Pain in People with Dementia

Research Information Leaflet

Carers of people with dementia

London - Bromley Research Ethics Committee

IRAS Project ID: 230583

RG-0119-16-IPCHS

THE PROJECT

Not all people with dementia experience pain, however not much is known about the experiences of those that do when living at home. This research aims to explore the views of pain in people with dementia from the perspective of:

- The carer of a person with dementia
- The person with dementia themselves

WHY HAVE I BEEN INVITED?

You have been invited to participate in this study because of your contact with Approach Staffordshire, and/or Join Dementia Research as a **current** or **previous** carer of a person with dementia.

WHO WANTS TO KNOW?

I'm Laurna Bullock. I have an interest in studying dementia, and I'm doing this research as part of my PhD at Keele University. My supervisors are Dr Paul Campbell, Dr John Bedson and Dr Bernadette Bartlam.

WHAT WILL HAPPEN IF I TAKE PART?

Taking part will involve an informal conversation. You can take part on your own **or** together with the person you care for if you are a current carer. This will depend on you and your relative/friend's wish and ability to take part. The interview will last approximately 60 minutes at a place and time that suits you (including your own home if you prefer). With your permission, I will audio record the interview.

HOW WILL MY INFORMATION BE USED?

Information from our discussion will be stored on a password protected computer at the University. Only my supervisors and I will have access to it. The information I gather will be made anonymous and will be included in my PhD thesis and in other publications and presentations. When the research is finished, identifying information and the audio recordings will be destroyed. But, all the anonymous information will be kept for at least 10 years and may be used in future studies.

HOW WILL YOU PROTECT MY PRIVACY?

The recordings will be typed up and made anonymous. This will be done by removing any names or details of your friends and family, or any other person you may mention. This means that it will not be possible to know who you are. Anonymous quotes from the interview may be used in my research report. Your consent form and contact details will be stored securely and separately at the University. In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act 1998. This would usually be discussed with you first. The researcher will ask you for your GP's contact details. Your GP may be contacted if we are concerned for your, or somebody else's safety.

COMPLETING THE INTERVIEW TOGETHER

If you believe that your relative/friend with dementia is able to, and may wish to take part, interviews can be completed together. As their carer, you may be asked to be a personal consultee, as you are the person that knows them best, indicating that you believe that your relative/friend would in your view want to take part in the study if they could decide.

WHAT ARE THE BENEFITS TO TAKING PART?

If you participate, you will help to increase understanding of the pain experience in people with dementia. This information can then help GPs and other healthcare professionals plan better assessments treatments for those with dementia who have pain.

d. Person with dementia informed consent form

Study ID Number

PIP-D Study Person with Dementia Interview Consent Form

Name and contact details of Principal Investigator:

Laurna Bullock, Research Institute for Primary Care & Health Sciences, Keele University, Staffordshire, ST5 5BG, 01782 734889, l.bullock@keele.ac.uk

Please initial

1. I confirm that I have read and understand the information leaflet (version 1.1, dated 04/10/2017)..... ☐
2. I understand that my participation is voluntary, and that I am free to withdraw at any time..... ☐
3. I have had the opportunity to ask questions, and have had these answered by the researcher..... ☐
4. I understand that personal information I provide will be made anonymous for research results and will remain confidential..... ☐
5. I agree to take part in an interview..... ☐
6. I agree to keep the issues discussed by the other participant confidential..... ☐
7. I understand that the content of the interview will be recorded and written up for analysis used to form our results ..... ☐

☐

8. I agree for my anonymised quotes to be used in research results (e.g. publications, presentations)…..…….

9. I agree for the information that has been made anonymous to be stored and to be used for further analysis ……..…..……...

10. I wish to receive a copy of the results when the project is completed……..

Please sign and date on the line below:

i. Name of Participant	i. Date	i. Signature
(Please Print)		
/. Name of Researcher	/. Date	
(Please Print)		Signature

Thank you for your help with this research study

e. Family caregiver informed consent form

Study ID Number:	

PIP-D Study Caregiver Interview Consent Form

Name and contact details of Principal Investigator:

Laurna Bullock, Research Institute for Primary Care & Health Sciences, Keele University, Staffordshire, ST5 5BG, 01782 734889, l.bullock@keele.ac.uk

Please initial

1. I confirm that I have read and understand the information leaflet (version 1.0, dated 15/05/2017)..... ☐
2. I understand that my participation is voluntary, and that I am free to withdraw at any time..... ☐
3. I have had the opportunity to ask questions, and have had these answered to my satisfaction by the researcher..... ☐
4. I understand that personal information I provide will be made anonymous for research outputs and will remain confidential..... ☐
5. I agree to take part in an interview..... ☐
6. I understand that the content of the interview will be recorded and written up for analysis and used to form the study results..... ☐
7. I agree for my anonymous quotes to be used in research results (e.g. publications, presentations)..... ☐
8. I agree for the information that has been made anonymous to be stored and ☐

to be used for further analysis ……

9. I wish to receive a copy of the results when the project is completed…….. ☐

If completing the interview with a relative/friend with dementia:

10. If participating in a joint interview, I agree to keep the issues discussed by the other participant confidential……..... ☐

General Practitioner's name: _____

General Practice: _____

Please sign and date on the line below:

i. Name of Participant	i. Date	i. Signature
(Please Print)		
/. Name of Researcher	/. Date	
(Please Print)		Signature

Thank you for your help with this research study

f. Consultee information sheet

Pain in People with Dementia (PIP-D)

Consultee Information Sheet

You are being invited to act as a 'consultee' for _____ because s/he is unable to make a decision for him/herself. You are being asked to advise the researcher about this person's wishes and feelings and whether they would have wished to join this research. Before you decide, it is important you understand what being a consultee means, why the research is being done and what it will involve. Please take time to read this information carefully and talk to others about the study if you wish. Ask us if anything is not clear or if you would like more information. Take time to decide whether you wish to be a consultee.

WHAT DOES IT MEAN TO BE A CONSULTEE?

A consultee is someone who knows a person who does not have capacity well and is willing and able to offer an opinion on what that person's wishes would have been if they were still able to decide themselves whether to take part. You do not have to act as a consultee if you do not want to. If you decide to act as consultee, you will be asked to sign a Consultee Form. If you think that this person would not have wanted to take part, then the researchers will respect this. Please remember that you are not being asked for your personal views on the research but only what the person's wishes would have been were they being asked to take part in this research. Think about the broad aims of the research, the risks and benefits and what taking part will mean for this person. At any stage, you can advise the researcher that in your opinion the person would no longer wish to remain in the study.

WHY HAVE I BEEN ASKED TO BE A CONSULTEE?

You have been asked because you know the patient personally, as a friend, partner, or relative, and they would trust you to help with this decision.

THE PROJECT

Not all people with dementia experience pain, however not much is known about the experiences of those that do when living at home. This research aims to explore the views of pain in people with dementia from the perspective of:

- The relative/friend/caregiver of a person with dementia
- The person with dementia themselves

WHY HAVE THEY BEEN INVITED?

They have been invited to take part in this study because of their contact with Approach Staffordshire as a user of their services or as a volunteer through Join Dementia Research.

WHO WANTS TO KNOW?

I'm Laurna Bullock, I'm doing this research for my PhD at Keele University as I have an interest in studying dementia. My supervisors are Dr Paul Campbell, Dr John Bedson, and Dr Bernadette Bartlam.

WHAT WILL HAPPEN IF THEY TAKE PART?

If the person with dementia takes part, they will take part in an interview with you, as their consultee. I will call you approximately one hour before the arranged interview. The interview will last approximately 60-90 minutes at a place and time that suits you and the person with dementia. With your permission, I will audio record our conversation.

DOES THE PERSON WITH DEMENTIA HAVE TO TAKE PART?

No. The person themselves will be asked first if they wish to take part or not. When the person is unable to decide we are asking for advice from other people. If you're willing to be a consultee we will record your advice on a consultee form. If at any time, you or the person with dementia no longer wish for them to take part, the interview will end, with no affect to either of your care.

HOW WILL THEIR INFORMATION BE USED?

Information from the interview will be stored on a password protected computer at the University. Only my supervisors and I will have access to it. The information I gather will be made anonymous and will be included in my PhD thesis and in other publications and presentations. When the research is finished, personal information and the audio recordings will be destroyed. But, all the anonymous information will be kept for at least 10 years and may be used in future studies.

HOW WILL YOU PROTECT THEIR PRIVACY?

The recordings will be typed up and made anonymous. This will be done by removing any names or details of their friends and family, or any other person they may mention. Quotes from the interview may be used in my research report, however all quotes will be made anonymous. The consultee form and contact details will be stored securely and separately at the University. In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act 1998. This would usually be discussed with you first.

WHAT ARE THE BENEFITS TO TAKING PART?

If they participate, they will help to increase understanding of the pain experienced by people with dementia. This information can then help GPs and other health care professionals to plan better assessments and treatments for those with dementia who have pain. When completing the interview together, both you and the person with dementia will be given a £10 voucher as a thank you for taking part.

WHAT ARE THE RISKS OF TAKING PART?

There are no obvious risks to taking part. However, if they do find themselves feeling upset by any of the issues raised we can discuss the best support for them and look at how to access this.

You or the person with dementia can ask for the interview to be stopped at any point without reason, and you can change your mind about taking part. For advice, you may find it helpful to ring the Alzheimer's Society National Dementia Helpline on 0300 222 11 22 for information, or support.

DO THEY HAVE TO TAKE PART?

No. Choosing not to take part will **not** affect their treatment or care now or in the future. If you do decide to act as a consultee on behalf of your relative/friend, you or the person themselves can stop the interview at any time without giving a reason. You can also withdraw all of the interview data at any point. If you withdraw, your relative/friend's anonymised data will be included in the research, however further information will not be collected, and no further contact will be made to you or your relative/friend.

WHO IS FUNDING THE RESEARCH?

Keele University ACORN studentship

WHO HAS APPROVED THIS STUDY?

The research have been approved by London - Bromley Research Ethics Committee. The research is sponsored by Keele University (RG-0119-16-IPCHS)

WHAT IF I HAVE A CONCERN?

Please contact Dr Paul Campbell on p.campbell@keele.ac.uk; Telephone: 01782 734828.
If you remain unhappy about the research and/or wish to raise a complaint please write to: Clark Crawford – Head of Research Integrity
Keele University, Staffordshire, ST5 5NH
Telephone: 01782 733371
E-mail: research.governance@keele.ac.uk

NEED MORE INFORMATION?

I'm very happy to discuss the research in person or over the phone.

Contact me at:
Laurna Bullock
Research Institute for Primary Care and Health Sciences,
Keele University, Staffordshire, ST5 5BG
Telephone: 01782 734985
Email: l.bullock@keele.ac.uk

g. Consultee advice form

Study ID Number

PIP-D Study Consultee Interview Form

Name and contact details of Principal Investigator:

Laurna Bullock, Research Institute for Primary Care & Health Sciences, Keele University, Staffordshire, ST5 5BG, 01782 734889, l.bullock@keele.ac.uk

Please initial

1. I advise that _____ would in my view want to take part in the above study if they could decide…… ☐

2. I confirm that I have read and understand the information leaflet (version 1.1, dated 04/10/2017)..... ☐

3. _____ and I have had the opportunity to ask questions, and have had these answered to my satisfaction by the researcher..... ☐

4. I understand that the participation of the person about whom I am giving advice is voluntary, and that I am free to advise that they should be withdrawn at any time without implication to their care…… ☐

5. I understand that personal information provided will be made anonymous for research outputs and will remain confidential…… ☐

☐

6. I understand that the content of the interview will be recorded and written up for analysis and used to form results……..

7. I agree to the researcher interviewing _____…….....

8. I agree for the information that has been made anonymous to be stored and to be used for further analysis ……

9. I agree for anonymous quotes to be used in research results (e.g. publications, presentations)……..

10. I wish to receive a copy of the results when the project is completed……..

Please sign and date on the line below:

13.1.1 Name of Participant	13.1.2 Date	13.1.3 Signature
(Please Print)		

13.1.4 Name of Researcher	13.1.5 Date	
(Please Print)		Signature

Thank you for your help with this research study

h. Healthcare professional invitation sheet

Pain in People with Dementia Study (PIP-D)

Dear Sir/Madam,

My name is Laurna Bullock and I am a PhD student at the Research Institute of Primary Care and Health Sciences at Keele University. I am very interested in understanding the pain experienced by people with dementia, and how this is recognised, assessed, and treated in primary care.

By interviewing healthcare professionals we hope to gain a better understanding of pain assessment and treatment processes for community-dwelling people with dementia. This research will allow healthcare professionals to discuss a potentially challenging aspect of their role with the aim to improve pain practices for people with dementia.

I have learned your name and contact details through your association or connections with the Research Institute of Primary Care and Health Sciences. To take part, you will work in primary care, and often work with people with dementia living in the community, including the assessment and treatment of pain.

If you take part in this study, we will arrange the interview for a time and place convenient to you. This may be over the telephone, at your work place, or at the Research Institute, whichever is most convenient for you. The interview will take no more than 30 minutes and will involve talking about people with dementia's pain, pain assessment, and pain management.

I have attached an information leaflet about the study with this letter for further information.

If you are interested in taking part or have any questions, please contact me.

Yours sincerely,

Laurna Bullock

01782 734985 / l.bullock@keele.ac.uk

Approach
Supporting your life, your way

i. Healthcare professional information sheet

Pain in People with Dementia (PIP-D)

THE PROJECT

Not much is known about the experiences pain in people with dementia, especially those living in the community. This research aims to explore:

- Healthcare professional's views of pain in community-dwelling people with dementia
- The processes used by healthcare professionals to assess and manage pain in community-dwelling people with dementia

WHY HAVE I BEEN INVITED?

You have been invited to participate in this study because you are a primary healthcare professional who works with people with dementia.

WHO WANTS TO KNOW?

I'm Laurna Bullock, I'm doing this research for my PhD at Keele University as I have an interest in studying dementia. My supervisors are Dr Paul Campbell, Dr John Bedson, and Dr Bernadette Bartlam.

WHAT WILL HAPPEN IF I TAKE PART?

If you choose to participate, you will be asked to complete one interview (approximately 30 minutes duration) about your experiences of pain, and the assessment and treatment of pain in people with dementia. Location and time of these will be chosen by you, in order to best suit your convenience, alternatively, the interview can be completed over the telephone. Laurna Bullock, PhD Research Student at Keele University, will ask about your experiences of pain in people with community-dwelling people with dementia. With your permission, she will audio record the conversation. All the information will be anonymised, so your privacy as a participant can be maintained according to Keele University requirements and the Data Protection Act 1998. Information from our conversation will be transcribed and anonymised, and some parts of it will be included in my doctoral thesis and other academic publications.

If you were to participate, reimbursement for costs will be provided aligned to appropriate hourly rates.

HOW WILL MY INFORMATION BE USED?

Information from our conversation will be stored in a password protected computer and locked filing cabinet at the Primary Care and Health Sciences Research Institute at Keele University. Pseudonyms will be used to protect anonymity, and all identifiable information will be removed during transcription. Information from our conversation, including anonymised direct quotes, may be used when presenting findings in my doctoral thesis, academic papers, and conference presentations. Audio-recordings from our conversation will be destroyed at the end of the study (September 2020). All other study data will be archived for 10 years at the Research Institute of Primary Care and Health Sciences at Keele University. After this time period, information will be safely destroyed.

HOW WILL YOU PROTECT MY PRIVACY?

After the interview, I will put the recording on a password protected computer at the University. Your consent form will be put in a locked filing cabinet. The only people who will have access to your information will be me and my supervisors.

WHAT ARE THE BENEFITS TO TAKING PART?

If you choose to participate, you will contribute to the understanding of pain in people with dementia. This can have further implications such as informing healthcare professional's assessment and management of pain for people with dementia in the community, and where support may be needed.

WHAT ARE THE RISKS OF TAKING PART?

There are no obvious risks to taking part. However, if you do find yourself feeling upset by any of the issues raised we can discuss the best support for you and look at how to access this. In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act 1998. This would usually be discussed with you first.

DO I HAVE TO TAKE PART?

You do not have to take part. And if you do, you can stop the conversation at any time without giving a reason and implication to your legal rights or care. If you do decide to take part, your anonymised data will be included in the research, however further information will not be collected, and no further contact will be made to you.

WHO IS FUNDING THE RESEARCH?

Keele University ACORN studentship

WHO HAS APPROVED THIS STUDY?

The research have been approved by London - Bromley Research Ethics Committee. The research is sponsored by Keele University (RG-0119-16-IPCHS)

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Telephone: 01782 734828.
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Keele University, Staffordshire, ST5 5NH
Telephone: 01782 733371
E-mail: research.governance@keele.ac.uk

WHAT TO DO NOW?

If you wish to take part, you can:

- Call me on **01782 734985**
- Email me on l.bullock@keele.ac.uk

NEED MORE INFORMATION?

I'm very happy to discuss the research in person or over the phone.

Contact me at:
Laurna Bullock
Research Institute for Primary Care and Health Sciences,
Keele University,
Staffordshire,
ST5 5BG
Telephone: 01782 734889
Email: l.bullock@keele.ac.uk

j. Healthcare professional consent form

Study ID Number

PIP-D Study Healthcare Professional Interview Consent Form

Name and contact details of Principal Investigator:
Laurna Bullock, Research Institute for Primary Care & Health Sciences, Keele University, Staffordshire, ST5 5BG, 01782 734889, l.bullock@keele.ac.uk

	Please initial
1. I confirm that I have read and understand the information sheet (version 1.1, dated 04/10/2017).....	
2. I understand that my participation is voluntary, and that I am free to withdraw at any time.....	
3. I have had the opportunity to ask questions, and have had these answered to my satisfaction by the researcher.....	
4. I understand that personal information I provide will made anonymous for research outputs and will remain confidential.....	
5. I agree to take part in an interview today.....	
6. I understand that the content of the interview will be recorded and written up for analysis.....	
7. I agree for my anonymous quotes to be used in research outputs (e.g. publications, presentations).....	
8. I agree for anonymised data to be archived at the end of the study for possible future reuse and secondary analysis.....	
9. I would like to receive a copy of the results when the research is complete.	

Please sign and date on the line below:

Name of Participant (Please Print)	Date	Signature
Name of Researcher (Please Print)	Date	Signature

Thank you for your help with this research study

Appendix 9: Risk protocol

Pain in People with Dementia (PIP-D)

Risk Protocol

If before, during, or after the interview the participant(s) becomes upset or distressed, the researcher will work together with the participant(s) to provide adequate support. The researcher will signpost the participant(s) to support networks, including local resources. In addition, the telephone number for the National Dementia Helpline is provided in the information leaflet.

In the rare circumstance that a participant discloses potential harm to self, or somebody else, before, during, or after the interview it is within the researcher's duty of care to ensure the safety or well-being of the participant.

The name of the participant's General Practice and Practitioner will be collected during the consent process. The request for this information is outlined in the participant information leaflet.

If information that causes concern is disclosed, the researcher will immediately discuss the information with the nominated General Practitioner (GP – John Bedson) working on the study team. In the event that the nominated General Practitioner is unavailable, a member of the GP Research Facility Network based at the Research Institute of Primary Care and Health Sciences will be contacted to make the clinical judgement based on the disclosed information.

The nominated General Practitioner in collaboration with the study team will make a clinical judgement depending on the severity of the information disclosed:

1. No further action required
2. Contact the participant's General Practitioner.
3. Contact the Staffordshire and Stoke-on-Trent Adult Safeguarding Partnership
4. Contact the police

If the participant does not provide their General Practitioner's details, the information sheet states that:

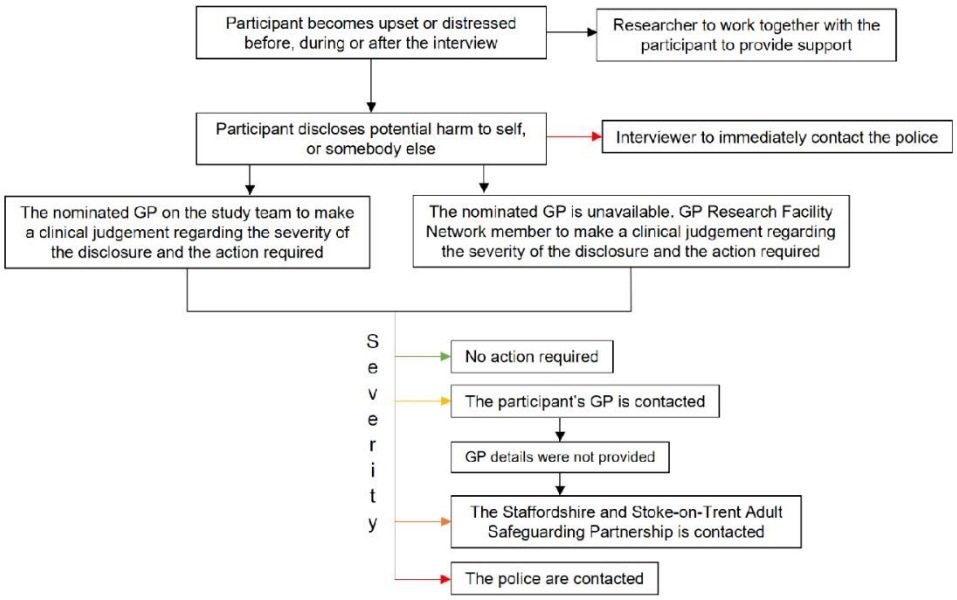
> *"In certain exceptional circumstances where you or others may be at significant risk* of harm, the researcher may need to report this to an appropriate authority, in accordance with the UK Data Protection Act 1998. This would usually be discussed *with you first."*

On this basis, if information is disclosed during the interview that raises significant concern, the interviewer will immediately call the police.

1. Researcher: Miss Laurna Bullock, Tel: 01782 734985
2. Nominated General Practitioner: Dr John Bedson, Tel: 01782 734873
3. Staffordshire and Stoke-on-Trent Adult Safeguarding Partnership

- If the adult lives in Stoke-on-Trent: 0800 561 0015
- If the adults lives in Staffordshire: 0345 604 2719/0345 604 2886

Figure 1. Pro forma



Appendix 10: Thematic analysis

a. Overview of themes and codes

Theme	Description of theme	Example codes	Example quotes
Gathering information to identify pain	This theme captured the methods used to identify and assess the pain experienced by the person with dementia. Healthcare professionals and family caregivers gathered information using a variety of methods to build a picture of the pain experience.	Multiple methods to identify pain	**"***y'know... there's all sorts of things that you can pick up on*." Jenny, GP "*I just look at the whole picture, at the whole medication, and the whole physical history, and just try to give provisional diagnosis of provisional reasoning, and try to tackle them one by one*." Rani, psychiatrist
		Narrowing approach	**"***sometimes, you just have to sit and go through things, do blood tests, sometimes you have to do the x-rays, it starts with a careful history, the history mainly, and then a diligent examination, so you just have to be prepared for anything*" Alan, GP "*you've got an awful lot of information that actually is probably going to be channelling you, narrowing down your decision making*" Jenny, GP
		Diagnosis by exclusion	***"****I'm eliminating other things, like... um.... like infections, urine retention, or constipation, as I mentioned, before I'm thinking this is a long term pain that I potentially need to treat"* Jessica, GP ***"****you just rule out things, you- you- it's a diagnosis by exclusion"* Alan, GP
Subtheme: Disentangling the self-report of pain	Health care professionals and family caregivers acknowledged the importance, yet sometimes difficulty of	Communication implicating self-report	*"her ability to give factual information which is what the GP needs and wants is very poor now."* Charles, family caregiver *"if it's kind of early dementia, they'd probably be able to give a relatively good history, if it's end stage dementia, y'know not so much..."* Amy, GP *"I would say that most people with mild to moderate dementia, you just treat them in the same way, the normal questioning, where's the pain? How severe is it? What*

	disentangling the self-reported pain of the person with dementia. Disentangling the report become increasingly challenging as the condition progressed, and communication ability worsened. Some participants questioned the if self-reported pain reflected the experience of pain especially if the reports were inconsistent, or the person with dementia was perceived as 'stoic'		*does it stop you from doing? Etc. etc. etc... but it's- it's more the severe end that I'm talking about here, where it's difficult having a conversation with someone, and sort of answering those questions can sometimes be a tricky area..."* Chris, GP
		'Reliability' of self-report 'Accuracy' of self-report	*"there's a lot of "oh me back hurts" and "oo this hurts" and sometimes, I do wonder dad if it is in your mind with the greatest respect"* David, caregiver *"think it would be reliable, pretty reliable"* Alan, GP *"it is challenging to be honest to get an accurate history in patients that have dementia*" Amy, GP *"even if the patient will nod and say "no", you're not entirely confident that maybe that's accurate"* Jenny, GP
		Stoicism Stoicism implicating self-report Inevitability of pain	*"As I say it's very difficult, because she very rarely admits to anything"* John, caregiver Laurna: *"How do you tell other people that you're in pain, Richard?"* Richard: *"I think I'm very lucky that I can put up with what pain or discomfort there is"* *"because if you don't ask if someone's got pain, they won't necessarily tell you, they might just accept it"* Jenny, GP *But at the end of it, he said well I - I – I'm sorry, but there wasn't really anything [pause] there wasn't really anything... nothing new it was just- carry on living with it... sort of thing.* Charles, husband family caregiver
		Inconsistency in reports	*"it's very difficult to judge, and the answers you will get y'know will be- could be quite diff- y'know different [pause] and again, there's nothing wrong with that dad, but that's y'know how- how things are."* David, caregiver *"when- she's in bed, she's all glammed up, she's 90 and she's glamorous, isn't she? My mother, isn't she? Glammed up, nice young chap, chatting away, "I'm fine! Nothing the matter with me" "I hear you had a little fall?" "Did I? I don't remember?"* Brenda, caregiver

			"it's that inconsistent history that makes y'know the diagnosis... the assessment challenging.. sometimes in patients with dementia, y'know you can examine a joint, and they're screaming out in pain, but the joint looks fine" Amy, GP *"I have seen patients with dementia if you ask them y'know "are you in pain?" "Oh yea, incredible pain" "where's it hurt?" "oh, everywhere" and actually in my perspective, in my clinical perspective, y'know they've not got any issues causing them pain"* Ishann, GP
Subtheme: Observing changes	Family caregivers and healthcare professionals observed changes (particularly, behavioural, psychological, and physical) in the person with dementia as a potential indication of pain. Despite acknowledging the link between behavioural and psychological symptoms and pain, there remained challenges determining	Facial changes Behavioural changes Mood changes Change from "normal"	"*either ratty, or withdrawn. And just the look on her face and I know that y'know she-she's suffering*." John, caregiver *"he didn't want to eat, and he wanted to lie down, he wasn't well"* Carol, caregiver *"Distress, y'know clear facial distress, um obvious things y'know like guarding a limb, not wanting to utilise an arm"* Lisa, GP *"if he got angry about something, or something like that, I would know- I would definitely know there was something wrong, because he never does that."* David, caregiver *"body language cues, so they're rubbing their leg or whatever, ur... But I think a lot of it, and certainly as dementia progresses more I think a lot is much more non-verbal, urm... and just changes in pres- presentation and behaviour, urm... changes in appetite and sleep patterns, um... yea... agitation"* Mel, psychiatrist *"if they have dementia you can see it from facial expressions, you can see it from non-verbal expressions*" Muhammed, GP.
		Vigilance	*"I'm watching Will a lot because I don't want anything to go wrong..."* Carol, caregiver *"When he goes quiet for a length of time I'm always asking if you're alright, aren't I?"* Denise, caregiver

	the driver of this presentation.		*“keep an eye on things, and- I think- I think it was almost left to me… under the microscope... Aren't you?”* Brenda, caregiver
		Changes in functionality	*“Do they get up to the shops, y'know? Has their daily routine changed? What activities can they do?”* Amy, GP *“so it's more about that- that deterioration of function rather than people presenting and saying "I’m in pain""* Chris, GP *“it might be lack of engagement with activities, it might be sort of, not getting- not wanting to get out of bed, not wanting to get dressed, all sorts of signs really”* Jenny, GP *“People seem to go along steadily, and then um, it can cause a sudden decline in their capacity to carry out normal activities of daily living”* Lisa, GP
		Link between BPSD and pain Recognising pain as a differential diagnosis BPSD overlooked as a symptom Determining the reason for BPSD	*“People don't consider the pain as being a cause, they just don't consider it…there's an old adage in medicine... if you don't think of the diagnosis, you won’t make the diagnosis, but you don't examine the patient diligently, and carefully, you won’t make the diagnosis either, and that gets missed, across the board it gets missed”* Alan, GP *“I definitely have it on my radar as one of the differential diagnoses, but I think any clinician would find it challenging... and always y'know there's room for improvement.”* Amy, GP *“BPSD can be caused by, and triggered by many things, it can be triggered by one thing, but maintained by another thing, or other things, y'know? So urm... usually these things are multifactorial, an important point is that pain should not be missed, and I don't think we have missed it.”* Hayma, psychiatrist
		Physical observation	*“we wouldn't have needed to go to the loo with her before, but when she'd broke her foot she needed help and assistance, and that gave us the- that, it gave us the way*

		Physical examination	*forward to begin to monitor... her body, her changes, and that particularly."* Brenda, caregiver *"are they weeing okay, are they pooing okay? are they sort of, y'know physically examine someone as well, which sometimes is difficult with dementia patients, if they won't allow it, or agitated"* Jenny, GP
The importance of familiarity	This theme captures the importance of familiarity to determine the presence of pain for a person with dementia, and the potential lack of familiarity between the healthcare professional and the person with dementia.	Familiarity of caregiver	*"If you live with somebody long enough, you're normally tuned with them, and you know if something is wrong or out of place... So if he goes quiet for a length of time, but I'm always asking if you're alright, aren't I?"* Denise, caregiver *"it's actually the carers that know, if you've been with somebody for 40 odd years, it- you are- you know that person inside out, y'know?"* Brenda, caregiver
		Continuity of care Limited familiarity	*"I remembered her from Christmas time, when she- when she came urm... we had a similar problem then..."* Alan, GP *"if you know the patient before, and they seem pretty good, and suddenly they're not, y'know it's about that"* Chris, GP *"that background history can vary completely, the assessment can vary completely, urm... and so it really is important that y'know having an allocated GP actually means that, and not just for your records"* Amy, GP *"there is a huge problem in terms on continuity, and I think what, y'know the old GP would have been able to pick up as a change in Mrs Blogs, maybe now won't get noticed, so yea... so lost, isn't it?"* Lisa, GP *"If you see a different doctor each time, they don't notice"* Michelle, caregiver

			"I think, in order to make that sort of assessment you really got to see the whole picture, rather than a snapshot [pause] which is what the health professionals get" Robert, caregiver
		Surrogate familiarity	*"You might be able to get that from the carer, or the spouse, or whoever is looking after that patient, and those people are in far more close contact with that patient, and will have a far better idea if they think they're agitated"* Jenny, GP *relatives, caregivers, would be the best source of information if the patient can't give it me... So finding out how they compare to their usual self, and what their ideas and concerns are about what would be affecting the person...* Jessica, GP *"so if they've come with someone, whoever it is, urm... who can urm, add a bit more picture to the story, give me a bit more, help with the examination, in terms of urm, if they know them best"* Muhammed, GP *"Relatives are better at picking up the changes- the subtle changes in their loved ones behaviour, because they're there 24/7."* Hayma, psychiatrist
The use of pain assessment tools	This theme captured the perspectives towards pain assessment tools, and their use for people with dementia.	Unaware of behavioural observation scales	*"you're going to tell me that there's a dementia pain scale..."* Chris, GP *"I think if there was um... a... specific pain assessment tool of some description... urm... which you're probably going to tell me that there is that I don't know about"* Lisa, GP
		Holistic assessment	*"I think pain scores are available, and I think even the picture ones and things, depending on their level of cognition, but to be honest, I mean when I- I often go a lot in terms of what the carers are saying on that, and that's more how I find the most useful information"* Ishaan, GP

			“Sometimes use the Abbey Pain Scale, that's one scale... that we sometimes use... urm... but in my practice, and y'know there are some, ur... visual scales, of y'know facial expression for example, there are some other scales available that we sometimes use, urm... so yea... But you tend to really go by, urm... the observations of carers, and the use of behaviour charts” Tom, GP *“I don't know if it's a general doctor thing, I think my perception would be, maybe just anecdotal that doctors go much more on history urm, and nurses- and nursing staff are often very good at doing the more formalised assessments.”* Mel, Psychiatrist
		Appropriateness of self-report scales	*“Yea, I mean, it- numbers don't really tell the story anyway do they?”* John, caregiver *“I’m not sure how effective our standard- on a scale of 1-10 are, in that sort of situation, because it's always a bit tricky to sort of discuss”* Chris, GP *“so we ask for the symptoms, and 1-10, y'know severity scores, and those sorts of things don't compute at all”* Lisa, GP

Non-drug management of pain	Many people with dementia used a variety of non-drug treatments for their pain. Irrespective of the many considerations (and potential scepticism) associated with non-drug treatments, there was a general support towards such approaches for pain, especially as a method to reduce pharmacological burden	Comfort and relaxation for pain Positive regard for physiotherapy	*"Rub some cream on it, or something, have a hot nice bath. Y'know, relax. Just get on with it."* Mary, caregiver *"you will deal with that by measures that we have, that is putting gel on and giving paracetamol, hot water bottle calming her down..."* Brenda, caregiver *"I know one, that I tell you to do, and it's really good... a bowl of water, put your feet in"* Michelle, caregiver *"Relaxation, try to relax... We do recommend that, we do discuss it when we discuss the patient, what does he like to do? What makes him feel good?"* Aska, psychiatrist *"He tends to feel better when she's, urm... when she's been in a more relaxed state... so if she has managed to get some sleep or erm... [Pause] just be distracted by a simple activity"* John, caregiver *"Well, you can forget it sometimes if you're chatting, or doing something, ya know? You're not worrying all of the time [pause] it's just there."* Patricia, person with dementia Laurna: *"How did you find physio?"* James: *"Helped, yea… I do think that it helps. And... I won't say [pause] it- it's did enough to stop it, but it did help."* Laurna: *"And how do you feel towards the physio?"* Richard: *"I think it has improved things..."* *"I mean I was already doing quite a few exercises, because I know I've done a lot of sports, so I've looked at a lot of sports physio as well, so I know a fair few things to do myself without them telling me... a lot of the exercise I'm doing already, I'm doing them every morning."* Greg, person with dementia

		Sceptical of alternative or complementary Evidence-based medicine	*"Physio might... I might send people for- for physio."* Alan, GP *"you might regard them as quackery, I don't know but er... we've got erm... lavender oil, which I put... ur... on her forehead... and... And... What's the other one? Oh yes, we've got a pot of this, erm... aloe vera cream..."* John, caregiver *Well… The reality is, unless- and there are- there are a few people who do have ur... reiki, is it called? To be fair these are used for better of patients... they have reiki... [Hushed tone]I don't know what it is... I pretend I know what it is, but I don't...* Alan, GP "*I think as practitioners you have to practice evidence based medicine, so if there's not robust support for these things, then it's difficult..."* Jenny, GP

		Self-management challenge	*“Which I wasn't very good at following was I?”* James, person with dementia *“but some of the sort of self-management problems can be a bit tricky, because they do need to be self-management”* Chris, GP *“Yes it can be quite challenging to tell somebody to do regular knee strengthening exercises”* Amy, GP *“you do wonder if they're actually going to do it, I'll be honest... it can be difficult to convince people, um, and I think in the elderly particularly, that if I've got arthritis I shouldn't be using the joint, for example, that's still out there as a, sort a myth, it can be quite hard to overcome.”* Lisa, GP
		Lack of resources Financial burden	*“Ur... Indian head massage, I think it’s called y'know... and that just exacerbated the thing... she's had urm, facial massages and so on... I mean, we've thrown money at it.”* John, caregiver *“Well we never- we never... as doctors we can't prescribe those things, because they're not necessarily accessible on the NHS.”* Jenny, GP
		Supportive of non-drug	*“I would say "well try it if you want..."* Alan, GP *“guess this is not something that I back up with evidence or anything else, but my personal perspective I support it, I say yea, you can try it...”* Ishann, GP *“we certainly don't have a "no you can't have that" treatment approach”* Jenny, GP *“Urm... but certainly these things would not do any harm, urm, even if they're not evidence based, you're still encouraging urm, they may help because the evidence may not be there for populations, but it may help for that individual”* Muhammed, GP

Concerns related to analgesic medication	This theme captured the number of concerns held by people with dementia, family caregivers, and healthcare professionals that contributed resistance to use analgesic medication	Reluctance to use analgesia	*"Only as a last resort for me, I hate taking tablets at the best of times, so I've got to be getting pretty bad before I'll take them"* Greg, person with dementia *"I don't think pills solve anything, I think you need to go a little bit deeper and y'know, so I'm- [pause] I wouldn't advocate just having pills at all."* Mary, caregiver *"You do see a lot of anxiety around tablets... from the caregivers point of view, they get really anxious about it"* Lisa, GP
Subtheme: Side effects	People with dementia, family caregivers, and healthcare professionals each reflected upon the side effects associated with analgesic medications that are intensified by the presence and severity of dementia. Such concerns led to a preference for paracetamol, and caution towards NSAIDs and opioids.	Side effects and adverse events Preference for simple analgesics Reluctance towards NSAIDs Reluctance towards opioids	*I mean- we manage without it... I'm not very keen on him taking a lot of pain killers, I think sometimes you're just adding on another problem, urm, I dare say the stuff the doctor could give him, but I dunno… [Sigh] you've got to be careful of some of this stuff. Carol, caregiver* *I think co-codamol, I will have to have a word with mum about that, but there's definitely one that doesn't sort of agree, as in, the side effects and things... John, caregiver* *It's simple to say that... but there's a lot of adverse reaction to a lot of the analgesics available... um... and um... I can accept that in end of life care there's um... there's a lot of, there's a lot of common sense in the argument that- that you don't have to die of extreme pain- or you don't have to die in extreme pain... I accept that because the side effects etc. then aren't the issue that you're going to be bothered about... But I think for somebody that is expected to live, then I think you have a very different set of circumstances...* Charles, caregiver *"very strong pain medications have got significant side effects like, constipation and things like that. And we know anti-inflammatory's can upset your stomach..."* Brenda, caregiver

			"you've- this group of patients are particularly susceptible to... side effects of certain drugs so you have to be careful, so you go with a drug which is the simplest... with the lowest side effect profile" Alan, GP *y'know some mild opiates, and then you think "oh god, that's going to constipate them", and they've probably already got constipation, or they've got some allergy to codeine, and then there's all this stuff, so there's no one size fits all, that's for certain"* Lisa, GP
Subtheme: Illness and treatment burden	People with dementia had a number of conditions in addition to dementia and pain. Additionally, the person with dementia took numerous medications to treat their conditions. Each of these factors, again, created additional concerns when 'adding in' an analgesic medication.	Comorbidities Amount of medications	*"He can only take paracetamol 'cause he's on warfarin he's very limited as to what other drugs he can take... he can't take things like ibuprofen... um... or aspirin... or so."* Carol, caregiver *"and then things like y'know various groups, often with these patients there's going poly-pharmacy anyway, they'll have multiple comorbidities, so thinking about any medications that are contra-indicators urm, looking at their renal function, have they got any allergies"* Amy, GP *"often these people in the community with dementia are older adults, with other comorbidities, and then it may be vascular dementia as well, so if- if they have a history of heart problems, or a history of stomach ulcers, or bleeds in the gut, or if they have vascular dementia, we want to avoid anti-inflammatories"* Jessica, GP *"she's got... quite a lot of drugs to take so she doesn't really want extra..."* John, caregiver *"that's another one of my things, if you're taking medication for urm... y'know for memory problems, taking them- it for gout, and thing and another, suddenly have another load of pills thrust at you, plus y'know para- y'know even if we buy some day nurse they say at the counter, "are you having any paracetamol?" Goodness knows what all of these others things will have an effe- y'know sort of an effect, y'know on..."* David, caregiver

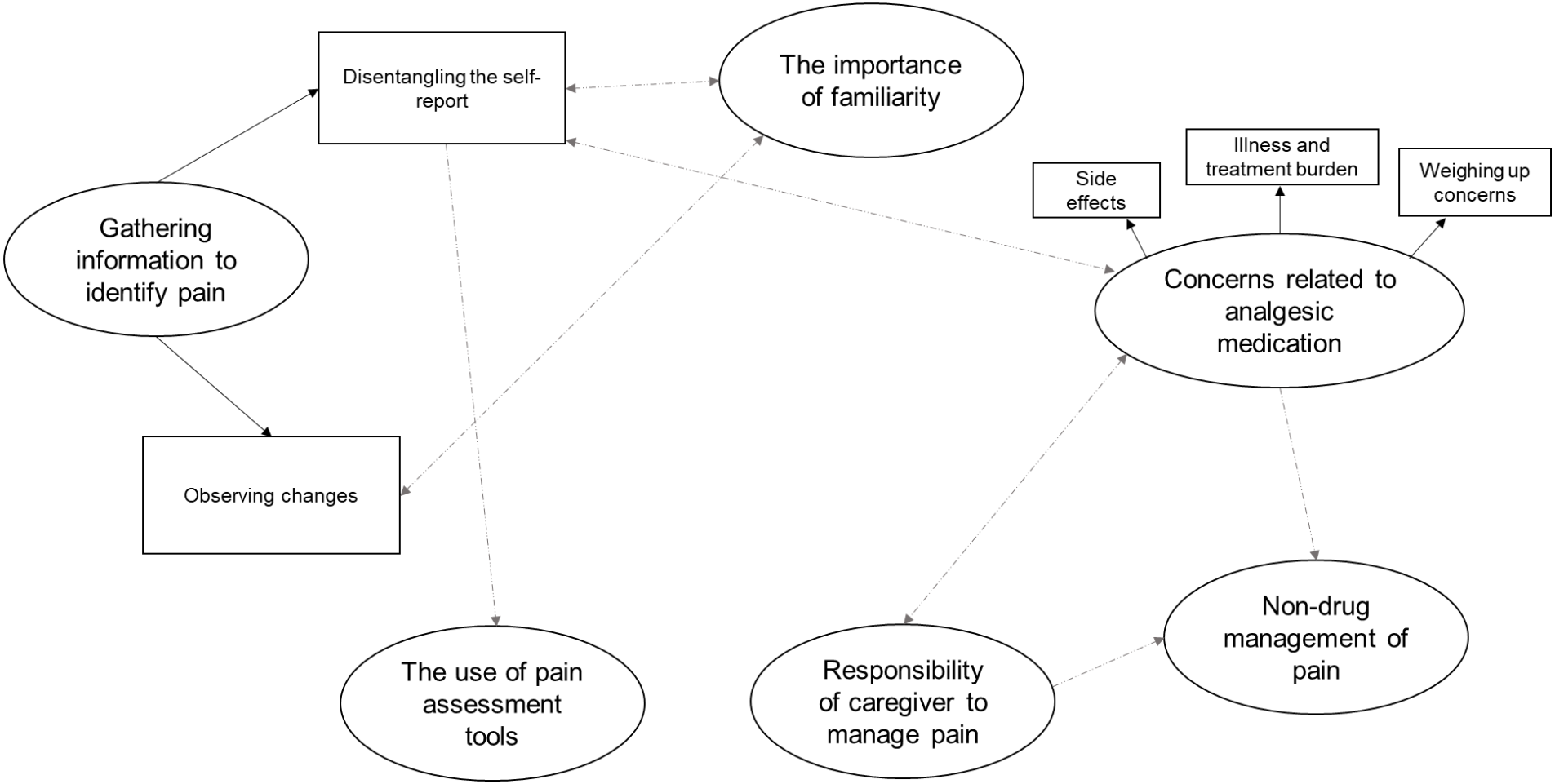
			"he's on 10 tablets a day anyway, for his various conditions, so pain killers are over and above..." Denise, caregiver *"do wonder sometimes, y'know we give them all for the right reasons, and guidelines tell us to give them all, what guidelines don't do, they don't account for multi morbidity, and they don't kind of say, the guideline for gout, and the guideline for high blood pressure, and it's all best practice, but when you put them all together, to tailor for the individual they're on 20 medications all of a sudden..."* Chris, GP *"the more medications we give to them, the more challenging it's going to be, the more likely they're going to be to fall, it's going to impair their dementia, impair their condition."* Ishann, GP
Subtheme: Weighing up the concerns	Healthcare professionals weighed up their concerns, "starting low and going slow" and trialling analgesic medication to identify the 'most appropriate' treatment when the options are perceived as limited.	Weighing up Reaching the limit of treatment	*"say look, this is probably the best thing you can offer them, and there's still a risk associated with it, but shall we go for this, because we can't leave them like that..."* Lisa, GP *"you've got to balance things up, a lot of medication we use for pain is quite... bad for the elderly in lots of ways, so... it's risk, benefit, harm, and all the rest of it."* Jenny, GP *"it's balancing the risks, do they urm... need the pain relief badly enough, urm versus do- how- how will this affect their dementia?"* Jessica, GP *"He can only take paracetamol 'cause he's on warfarin he's very limited as to what other drugs he can take... he can't take things like ibuprofen... um... or aspirin... or so..."* Carol, caregiver *"But at the end of it, he said well I - I – I'm sorry, but there wasn't really anything [pause] there wasn't really anything... nothing new it was just- carry on living with it... sort of thing [pause]. I can only imagine that there isn't any magic, y'know."* Robert, caregiver

		Starting low and going slow	"*you go round and round and round, so you try to keep away from- so if you look at it, in those terms, you're really really limited y'know can you go on to..."* Alan, GP *"So you really are... trying to tailor analgesia for somebody who's y'know... maybe got a million and one things that you can't give, and that can be really, you can be quite boxed in quite quickly"* Lisa, GP *"yea when it comes to prescribing it will be starting off at a very, very low dose, and then titrating, but slowly"* Amy, GP *"you always sort of go for the most straight forward, y'know lowest strength analgesia and work up"* Ishaan, GP *"I would be starting at the lowest possible dose, and monitoring them regularly."* Jessica, GP *"you always sort of go for the most straight forward, y'know lowest strength analgesia and work up"* Jenny, GP *"What we want to do, is use the- is the minimum dose and minimum frequency that controls their pain, and it doesn't have to be completely gone, but sufficiently, that they're happy with that level of pain"* Chris, GP
Responsibility of the caregiver to manage pain	This theme captured the role of caregivers to manage and monitor pain (both analgesic and non-drug) in the community for the person with dementia. This role was an important consideration	Caregiver's role to manage	*"She will ask me if I want to take something"* Steven, person with dementia *"I deal with the medications"* Denise, caregiver *"I mean occasionally she'll ask for a pain killer, but, ur I'm offering her pain killers before she asks for them"* John, caregiver
		Reliance on the caregiver	*"so if it was somebody who for example lived with their daughter, who responded well to two paracetamol twice a day or three times a day, you'd leave it to that, because if they live with them then they- they- they- they- can do it*" Alan, GP "*If they have someone to prompt to give them the medications, you would be a bit more reassured"* Amy, GP

	for healthcare professionals when choosing the pain management strategy for their patients with dementia.		*"you have to sort of, give permission for the caregiver to take on that role almost, to initiate those things, and maybe say "do you want some paracetamol?" "are you in pain?" and sort of ask, rather than... "hasn't asked for any therefore doesn't need any"* Jenny, GP *"it certainly influences the safety, doesn't it? If you've got no one actively monitoring them"* Jessica, GP
		Burden of analgesic medication	*"people really like blister packs for that reason, because they almost feel that the responsibility is taken from them then, they're not the person who's going to have to dole it out, and get it wrong, potentially, and cause problems"* Lisa, GP
		Caregiver to initiate non-drug treatment	*"if the caregiver is willing to do some gentle massage techniques..."* Lisa, GP *"because the carer can manage it, they can do gentle massage or warm baths, y'know any sort of behavioural things that can help with pain but if the carer is completely rung out themselves, which they often are, they haven't got the resources themselves to help manage so..."* Mel Psychiatrist

b. Final thematic map

Final thematic map to highlight the interconnections between themes



Appendix 11: Contact summary sheet

Contact Summary Form

Interview type:

Dyadic ☐ Independent ☐

Face to face ☐ Telephone ☐

Contact date: _____

Today's date: _____

1. Overview of the interview characteristics
    a. E.g. where was the interview completed? Whom was present? Were breaks required?

2. What is your impression of how the interview went?

3. What were the main issues or themes that struck you in this contact? Did the contact highlight new themes and issues not previously explored?

4. New (or remaining) questions to consider in the next interview?

5. Anything else that struck you as salient, interesting, illuminating, or important?
    a. E.g. distress or emotional displays, power relations in the dyad, body language and facial expressions, tone of voice, the environment/surroundings

Appendix 12: Comparison of community sensitivity cohort

a. Incidence cohort

In the methods chapter, the identification of participants in the dementia cohort and older adult cohort living in the community was discussed. Sensitivity analysis was conducted using additional, strict criteria to identify a restricted cohort of patients with a greater likelihood of living in the community. The application of the strict criteria allowed the sensitivity analysis to examine to what extent the main results reflect the restricted cohort of patients with a greater likelihood of living in the community. A total of *n*=4850 people with dementia, and *n*=3477 older adults without dementia were identified using the strict criteria. Table A.1 compares the people with dementia, using the strict criteria included in the community sensitivity analysis (*n*=4850), to people with dementia that were not included (*n*=16,243). Additionally, Table A. 1 compares the older adults using the strict criteria included in the community sensitivity analysis (*n*=3477) to older adults that were not included (*n*=17,616).

Table A.1. Incidence cohort: Comparison between participants in the dementia cohort and older adult cohort in and out of the community sensitivity analysis

	Dementia cohort (n=21,093)				**Older adult cohort** (n=21,093)			
	Non-community	**Community**	***p***	**Effect size**	**Non-community**	**Community**	***p***	**Effect size**
Total *n*	16,243	4850			17,616	3477		
Gender, female % (n)	59.8 (9709)	57.1 (2767)	.001**	V = .02	58.9 (10,372)	60.5 (2104)	.07	V = .01
Marital status % (n)			.01*	V = .03			<.001**	V = .04
Single	0.8 (138)	1.3 (62)			0.8 (142)	1.4 (47)		
Married	13.0 (2115)	14.4 (699)			12.5 (2199)	13.8 (479)		
Widowed	3.6 (585)	3.9 (187)			3.4 (591)	3.6 (126)		
Divorced	0.6 (93)	0.6 (27)			0.4 (65)	0.8 (27)		
Unknown	81.9 (13,296)	79.8 (3870)			82.9 (14595)	80.1 (2786)		
Other	0.1 (24)	0.1 (5)			0.1 (24)	0.3 (12)		
Year of birth Mean (SD)	1927.56 (5.32)	1929.84 (10.09)	<.001**	*g* = 0.34	1928.01 (9.67)	1928.45 (9.94)	.02*	*g* = 0.04
Age at index Mean (SD)	80.64 (8.06)	79.30 (8.56)	<.001**	*g* = 0.16	80.34 (8.14)	80.28 (8.48)	.71	*g* = 0.01
Follow up (days) Median (IQR)	624 (246, 1205)	564 (224, 1098.25)	<.001**	*g* = 0.09	1255 (561, 2321)	1201 (532, 2247)	.001*	*g* = 0.01
Practice IMD % (n)			.003*	*r* = .00			.003*	*r* = .00
1 - Least	15.8 (2569)	16.3 (789)			15.6 (2756)	17.3 (602)		
2	19.2 (3120)	18.4 (893)			19.5 (3435)	16.6 (578)		
3	21.1 (3424)	18.6 (900)			21.0 (3699)	18.0 (625)		

4	21.4 (3482)	20.2 (978)			21.1 (3713)	21.5 (747)		
5 - Most	22.5 (3648)	26.6 (1290)			22.8 (4013)	26.6 (925)		
Morbidity (BNF) Median (IQR) [£]	9 (5, 15)	10 (5, 15)	0.43	*g* = 0.01	9 (5, 14)	9 (5, 14)	.19	*g* = 0.03
Consultation frequency[£] Median (IQR)	30 (16, 49)	30 (16, 50)	0.29	*g* = 0.02	25 (13, 42)	25 (12, 42)	.62	*g* = 0.01
CVD yes % (n) [£]	7.1 (1155)	6.7 (327)	.38	V= .01	5.6 (984)	5.8 (200)	.70	V = .00
Depression/bipolar yes % (n) [£]	7.3 (1192)	6.9 (334)	.29	V= .01	2.1 (366)	2.6 (90)	.06	V = .01
Diabetes yes % (n) [£]	15.2 (2470)	17.6 (852)	<.001**	V = .03	14.2 (2504)	14.2 (493)	.96	V = 00
Transfer out reason % (n)			<.001**	V = .07			.11	V = .02
Death	36.4 (5914)	29.8 (1446)			26.8 (4713)	26.0 (904)		
Data not entered	27.7 (4494)	33.3 (1613)			59.8 (10536)	59.1 (2055)		
Internal transfer	8.4 (1364)	7.3 (352)			3.0 (525)	3.1 (107)		
New health authority	7.5 (1215)	8.3 (402)			3.8 (663)	4.6 (161)		
Other	20.0 (3256)	21.4 (1037)			6.7 (1179)	7.2 (250)		

*p=<.05, **p=<.001

[£]During the 2 years before index date

SD Standard Deviation; CVD cardiovascular disease; IMD practice-level Indices of Multiple Deprivation; BNF British National Formulary

Cramer's V (V) Effect size for chi-square

Hedges' g (*g*) – Effect size for independent t-tests with different sample sizes

Pearson's *r (r)* Effect size for chi-square test for independence

Participants identified for the community sensitivity analysis were identified on the basis of: 1) no evidence of a Read code indicative of formal care residence; 2) a family number frequency of equal to, or less than two, and 3) no evidence of consultation location occurring in a residential or nursing home during follow up.

Descriptive comparison between people with dementia, using the strict criteria included in the community sensitivity analysis (*n*=4850), to people with dementia that were not included (*n*=16,243) indicated minimal, but significant differences in many characteristics. When exploring the effect sizes, only small effects were identified. When comparing older adults using the strict criteria included in the community sensitivity analysis (*n*=3477) to older adults that were not included (*n*=17,616) similar, significant differences were evident, however with a small effect size. These comparisons suggest marginal differences between the characteristics between people with dementia and older adults identified for the community sensitivity analyses, and those not.

People with dementia (*n*=4850) and older adults (*n*=4850) identified using the strict "community" criteria were used as a sensitivity analysis to examine the potential impact on the incidence of musculoskeletal consultation.

b. Prevalence cohort

Similarly to the incidence cohort (see above), sensitivity analysis was conducted using additional, strict criteria to identify a restricted cohort of patients with a greater likelihood of living in the community. A total of *n*=8875 people with dementia, and n=8349 older adults without dementia were identified using the strict criteria. Table A.2 compares the people with dementia, using the strict criteria included in the community sensitivity analysis (*n*=8875), to people with dementia that were not included (*n*=27,707). Additionally, Table A.2 compares the older adults using the strict criteria included in the community sensitivity analysis (*n*=8349) to older adults that were not included (*n*=28,233).

Table A.2. Prevalence cohort: Comparison between participants in the dementia cohort and older adult cohort in and out of the community sensitivity analysis

	Dementia cohort (*n*=36,582)				**Older adult cohort** (*n*=36,582)			
	Non-community	**Community**	***p***	**Effect size**	**Non-community**	**Community**	***p***	**Effect size**
Total *n*	**27,707**	**8875**			**28,233**	**8349**		
Gender, female % (n)	60.4 (16,736)	57.7 (5124)	<.001**	V = .02	59.9 (16,912)	59.3 (4948)	.30	V = .01
Marital status % (n)			<.001**	V = .05			<.001**	V = .05
Single	0.8 (221)	1.2 (109)			0.8 (223)	1.2 (103)		
Married	13.5 (3751)	15.3 (15.3)			13.0 (3668)	14.9 (1244)		
Widowed	3.5 (975)	3.6 (322)			3.4 (951)	3.6 (297)		
Divorced	0.5 (150)	0.8 (74)			0.4 (103)	0.9 (71)		
Unknown	81.5 (22580)	78.8 (6996)			82.3 (23247)	79.1 (6604)		
Other	0.1 (30)	0.2 (14)			0.1 (41)	0.4 (30)		
Year of birth Mean (SD)	1928.07 (9.59)	1930.81 (10.18)	<.001**	*g* = .28	1928.32 (9.62)	1930.14 (10.29)	<.001**	*g* = .19
Age at index Mean (SD)	80.33 (8.10)	78.72 (8.65)	<.001**	*g* = .20	80.17 (8.1)	79.16 (8.74)	<.001**	*g* = .12
Follow up (days) Median (IQR)	636 (256, 1219)	576 (232, 1102)	<.001**	*g* = .09	1259 (567, 2306)	1105 (500, 2050)	<.001**	*g* = .13
Morbidity (BNF) Median (IQR) [£]	10 (6, 16)	11 (6, 16)	.001**	*g* = .03	10 (6, 15)	10 (6, 15)	.31	*g* = .05
Consultation freq Median (IQR) [£]	33 (19, 55)	28 (15, 46)	.02*	*g* = .03	28 (15, 47)	34 (19, 56)	.37	*g* = .02

CVD yes % (n) [£]	7.6 (2097)	6.9 (608)	.03	V = .01	6.1 (1724)	5.6 (470)	.11	V = .01
Depression/bipolar yes % (n) [£]	8.2 (2264)	7.9 (698)	.36	V = .01	2.6 (746)	2.6 (219)	.92	V = .001
Diabetes yes % (n) [£]	16.0 (4427)	19 (1688)	<.001**	V = .04	14.7 (4147)	15.7 (1312)	.02*	V = .01
Practice IMD % (n)			.006*	r = .00			.05	r = .00
1 - Least	16.1 (4465)	16.8 (1493)			16.1 (4512)	17.0 (1416)		
2	19.6 (5423)	17.9 (1587)			19.4 (5473)	18.4 (1537)		
3	20.1 (5572)	19.0 (1687)			20.4 (5750)	18.1 (1509)		
4	21.2 (5883)	21.0 (1860)			21.0 (5937)	21.6 (1806)		
5 - Most	23.0 (6364)	25.3 (2248)			23.1 (6531)	24.9 (2081)		
Transfer out reason % (n)			<.001**	V = .09			<.001**	V = .04
Death	26.9 (2391)	35.1 (9719)			25.6 (7239)	22.2 (1851)		
Data not entered	37.2 (3301)	29.8 (8270)			61.3 (17311)	63.9 (5333)		
Internal transfer	7.1 (626)	7.9 (2192)			2.9 (815)	3.1 (256)		
Removal to new health	16.8 (1491)	16.6 (4606)			5.1 (1433)	4.6 (385)		
authority	8.1 (715)	7.3 (2011)			3.8 (1063)	4.2 (350)		
Other	4.0 (351)	3.3 (909)			1.3 (372)	2.1 (174)		

*p=<.05, **p=<.001

[£]During the 2 years before index date

SD Standard Deviation; CVD cardiovascular disease; IMD practice-level Indices of Multiple Deprivation; BNF British National Formulary

Cramer's V (V) Effect size for chi-square

Hedges' g (g) – Effect size for independent t-tests with different sample sizes

Pearson's *r (r)* Effect size for chi-square test for independence

Participants identified for the community sensitivity analysis were identified on the basis of: 1) no evidence of a Read code indicative of formal care residence; 2) a family number frequency of equal to, or less than two, and 3) no evidence of consultation location occurring in a formal residence during follow up.

Descriptive comparison between people with dementia, using the strict criteria included in the community sensitivity analysis (*n*=8875), to people with dementia that were not included (*n*=27,707) indicated minimal, but significant difference in many characteristics. However, when exploring the effect sizes, only small effects were identified. When comparing older adults using the strict criteria included in the community sensitivity analysis (*n*=8349) to older adults that were not included (*n*=28,233) similar, significant differences were evident, however with a small effect size. These comparisons suggest marginal differences in the characteristics between people with dementia and older adults identified for the community sensitivity analyses, and those not.

People with dementia (*n*=8875) and older adults (*n*=8349) identified using the strict "community" criteria were used as a sensitivity analysis to examine the potential impact on the prevalence of musculoskeletal consultation and analgesic prescription.

Appendix 13: Sensitivity analysis

a. Proportional Hazards Models: Not stratified by matched-pairs

Table A.3: Univariate and multivariable Cox Regression to examine the association between cohort status (dementia cohort and older adult cohort) for incident musculoskeletal consultation

Univariate Cox Proportional Hazards Model					
Covariate		**B (SE)**	**95% CI for Hazard Ratio**		
			Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)		-.35 (.02)**	.68	.70	.73
Model $\chi^2(1) = 437.88$, p=<.001. *p<.05, **p<.001					
Multivariable Cox Proportional Hazards Model					
Covariate		**B (SE)**	**95% CI for Adjusted Hazard Ratio**		
			Lower	**Hazard Ratio**	**Upper**
Cohort (dementia cohort=1)		-.37 (.02)**	.67	.69	.72
Gender (female=1)		.12 (.02)**	1.10	1.13	1.17
IMD	1 – Least deprived	-	-	-	-
	2	-.07 (.03)*	.88	.93	.98
	3	-.16 (.03)**	.81	.86	.90
	4	-.10 (.03)**	.86	.90	.95
	5 – Most deprived	-.13 (.03)**	.84	.88	.93
CVD (yes=1)		.04 (.03)	.97	1.04	1.11
Depression (yes=1)		.06 (.04)	.98	1.06	1.14
Diabetes (yes=1)		-.19 (.03)**	.79	.83	.87
BNF frequency[£]		.03 (.00)**	1.02	1.03	1.03
Follow up (days)[£]		.00 (.00)**	1.00	1.00	1.00
Year of index date[£]		-.01 (.00)**	.99	1.00	1.00
Consultation frequency[£]		.00 (.00)**	1.00	1.00	1.01
Age at index date[£]		-.01 (.00)**	.99	.99	.99

Model $\chi^2(14) = 1540.47$, p=<.001.
*p<.05, **p<.001
[£]Continuous covariates
Categorical reference categories = 0

b. Conditional logistic regression sensitivity: Association between dementia and musculoskeletal consultation

i. Community sensitivity analysis (Table A.4)

ii. Healthy cohort sensitivity analysis

iii. Logistic regression analysis (Table A.5)

i. **Community sensitivity analysis:** Conditional logistic regression to examine the association between dementia cohort and musculoskeletal consultation

Table A.4. Crude and adjusted odds ratio (OR) stratified into year time periods: Community sensitivity

Time (yrs)	**OR** (95% CI)	**Adjusted OR** (95% CI)
0 to 5	.78 (.59 to 1.03)	.72 (.53 to .98)
0 to 1	.83 (.73 to .94)	.86 (.74 to .99)
1 to 2	.77 (.65 to .92)	.73 (.60 to .90)
2 to 3	.65 (.52 to .83)	.61 (.46 to .80)
3 to 4	.59 (.43 to .82)	.56 (.39 to .81)
4 to 5	.49 (.32 to .77)	.44 (.26 to .73)

0 is index date; dementia diagnosis or equivalent for older adults.
Multivariable model adjusted for: evidence of cardiovascular-related conditions, diabetes, depression, morbidity (BNF), follow up (days), and consultation frequency

ii. **Healthy cohort sensitivity analysis:** Conditional logistic regression to examine the Association between dementia cohort and musculoskeletal consultation (index date to five years after index date).

Univariate analysis:

Omnibus Tests of Model Coefficients[a]

	Overall (score)			Change From Previous Step			Change From Previous Block		
-2 Log Likelihood	Chi-square	df	Sig.	Chi-square	df	Sig.	Chi-square	df	Sig.
8847.971	11.833	1	.001	11.837	1	.001	11.837	1	.001

a. Beginning Block Number 1. Method = Enter

Variables in the Equation

	B	SE	Wald	df	Sig.	Exp(B)	95.0% CI for Exp(B) Lower	Upper
casecontrol	-.086	.025	11.826	1	.001	.917	.874	.964

Multivariable analysis:

Omnibus Tests of Model Coefficients[a]

	Overall (score)			Change From Previous Step			Change From Previous Block		
-2 Log Likelihood	Chi-square	df	Sig.	Chi-square	df	Sig.	Chi-square	df	Sig.
8319.169	520.005	11	.000	540.638	11	.000	540.638	11	.000

a. Beginning Block Number 1. Method = Enter

Variables in the Equation[b]

	B	SE	Wald	df	Sig.	Exp(B)	95.0% CI for Exp(B) Lower	Upper
casecontrol	-.120	.029	16.858	1	.000	.887	.837	.939
CVD_covariate	.104	.073	2.039	1	.153	1.109	.962	1.279
depression_covariate	.013	.075	.030	1	.863	1.013	.875	1.173
diabetes_covariate	.147	.054	7.506	1	.006	1.159	1.043	1.287
splitBNF			455.779	4	.000			
splitBNF(1)	-1.292	.066	382.703	1	.000	.275	.241	.313
splitBNF(2)	-.659	.062	113.201	1	.000	.517	.458	.584
splitBNF(3)	-.426	.058	54.480	1	.000	.653	.583	.731
splitBNF(4)	-.145	.058	6.166	1	.013	.865	.772	.970
followupsplit			2.451	2	.294			
followupsplit(1)	-.057	.072	.641	1	.423	.944	.820	1.087

followupsplit(2)	.047	.054	.744	1	.388	1.048	.942	1.165
yearofdiagnosissplit			.	0[a]	.			
Consultationfrequ	.000	.001	.165	1	.685	1.000	.999	1.001
IMD			.	0[a]	.			
gender			.	0[a]	.			
agesplit			.	0[a]	.			

a. Degree of freedom reduced because of constant or linearly dependent covariates

b. Constant or Linearly Dependent Covariates S = Stratum effect. yearofdiagnosissplit(1) = .0477 + S ; yearofdiagnosissplit(2) = .0857 + S ; yearofdiagnosissplit(3) = .1682 + S ; yearofdiagnosissplit(4) = .2196 + S ; yearofdiagnosissplit(5) = .2634 + S ; yearofdiagnosissplit(6) = .1948 + S ; IMD(1) = .1668 + S ; IMD(2) = .1963 + S ; IMD(3) = .1814 + S ; IMD(4) = .2085 + S ; gender = .3564 + S ; agesplit(1) = .028 + S ; agesplit(2) = .1043 + S ; agesplit(3) = .3931 + S ; agesplit(4) = .4216 + S ;

iii. Logistic Regression analysis

Table A.5. Crude and adjusted odds ratio (OR) stratified into year time periods: Logistic regression sensitivity analysis

Time (yrs)	**Dementia cohort prevalence**	**Older adult cohort prevalence**	**OR** (95% CI)	**Adjusted OR** (95% CI)
0 to 5	58.54%	70.76%	.58 (.54 to .63)	.54 (.50 to .59)
0 to 1	24.46%	30.79%	.73 (.70 to .76)	.72 (.69 to .75)
1 to 2	22.26%	30.55%	.65 (.62 to .68)	.66 (.63 to .69)
2 to 3	19.94%	30.56%	.57 (.54 to .60)	.58 (.54 to .61)
3 to 4	19.27%	31.71%	.51 (48 to .55)	.53 (.49 to .56)
4 to 5	19.52%	31.04%	.54 (.49 to .59)	.53 (.48 to .58)

0 is index date; dementia diagnosis or equivalent for older adults.
Predictor: Dementia cohort vs. older adult cohort
Outcome: Musculoskeletal consultation: yes/no
Multivariable models adjusted for: gender, deprivation (IMD), evidence of cardiovascular-related conditions, diabetes, depression, age at index, morbidity (BNF), follow up, year of index date, and consultation frequency
*Consultation frequency entered as a continuous covariate. All other covariates were categorical.

c. Annual prevalence of analgesic prescription stratified by pre-index date analgesic prescription for each analgesic classification

Table A.6: No analgesic during the one year before index date

	Any % (95% CI)	**Basic** % (95% CI)	**Weak** % (95% CI)	**Moderate** % (95% CI)	**Strong** % (95% CI)	**Very strong** % (95% CI)	**NSAID** % (95% CI)
0-1							
Dementia cohort	10.15 (9.68 to 10.71)	6.84 (6.39 to 7.31)	2.66 (2.39 to 2.97)	0.95 (0.79 to 1.14)	1.29 (1.10 to 1.51)	0.10 (0.06 to 0.18)	1.83 (1.61 to 2.09)
Older adult cohort	12.56 (12.02 to 13.11)	7.17 (6.76 to 7.61)	3.17 (2.89 to 3.47)	1.39 (1.21 to 1.60)	2.04 (1.82 to 2.28)	0.10 (0.06 to 0.17)	3.08 (2.81 to 3.38)
1 – 2							
Dementia cohort	11.04 (10.36 to 11.75)	7.76 (7.19 to 8.37)	2.73 (2.39 to 3.11)	1.16 (0.95 to 1.42)	1.29 (1.06 to 1.56)	0.09 (0.04 to 0.18)	1.71 (1.44 to 2.02)
Older adult cohort	13.52 (12.91 to 14.15)	7.82 (7.35 to 8.33)	3.46 (3.14 to 3.81)	1.45 (1.25 to 1.69)	2.69 (2.41 to 3.00)	0.16 (0.10 to 0.26)	3.49 (3.17 to 3.83)
2 – 3							
Dementia cohort	11.05 (10.22 to 11.93)	7.86 (7.16 to 8.62)	3.17 (2.73 to 3.69)	1.22 (0.95 to 1.56)	1.35 (1.07 to 1.71)	0.12 (0.05 to 0.25)	1.65 (1.33 to 2.03)
Older adult cohort	14.58 (13.88 to 15.31)	8.42 (7.87 to 8.99)	3.97 (3.60 to 4.38)	1.50 (1.28 to 1.77)	2.46 (2.16 to 2.79)	0.17 (0.10 to 0.28)	3.46 (3.11 to 3.85)
3 – 4							
Dementia cohort	9.96 (8.98 to 11.03)	7.03 (6.20 to 7.95)	2.66 (2.16 to 3.27)	0.95 (0.67 to 1.34)	1.89 (1.48 to 2.42)	0.06 (0.02 to 0.22)	1.68 (1.29 to 2.18)

Older adult cohort	15.58 (14.78 to 16.42)	9.74 (9.09 to 10.43)	4.32 (3.89 to 4.80)	1.81 (1.53 to 2.14)	2.68 (2.34 to 3.07)	0.19 (0.11 to 0.31)	3.38 (3.00 to 3.82)
4 – 5							
Dementia cohort	11.69 (10.34 to 13.19)	8.05 (6.92 to 9.34)	2.77 (2.13 to 3.59)	1.54 (1.08 to 2.19)	1.49 (1.04 to 2.13)	0.21 (0.08 to 0.53)	2.00 (1.47 to 2.72)
Older adult cohort	16.12 (15.21 to 17.08)	10.46 (9.71 to 11.26)	4.28 (3.79 to 4.82)	1.69 (1.39 to 2.05)	3.36 (2.93 to 3.85)	0.20 (0.11 to 0.35)	3.43 (2.99 to 3.92)

CI Confidence Interval

Table A.7: Any analgesic during the one year before index date

	Any % (95% CI)	**Basic** % (95% CI)	**Weak** % (95% CI)	**Moderate** % (95% CI)	**Strong** % (95% CI)	**Very strong** % (95% CI)	**NSAID** % (95% CI)
0-1							
Dementia cohort	31.22 (30.41 to 32.03)	22.08 (21.37 to 22.82)	8.75 (8.27 to 9.26)	4.80 (4.44 to 5.19)	8.45 (7.98 to 8.95)	1.11 (0.94 to 1.30)	5.47 (5.09 to 5.88)
Older adult cohort	36.79 (36.05 to 37.53)	24.56 (23.90 to 25.23)	11.07 (10.59 to 11.56)	6.51 (6.14 to 6.90)	11.07 (10.59 to 11.56)	1.13 (0.97 to 1.30)	9.00 (8.56 to 9.45)
1 – 2							
Dementia cohort	26.19 (25.25 to 27.15)	18.72 (17.90 to 19.58)	7.15 (6.62 to 7.73)	4.07 (3.66 to 4.51)	7.68 (7.13 to 8.28)	0.99 (0.80 to 1.23)	4.39 (3.97 to 4.86)
Older adult cohort	35.58 (34.76 to 36.40)	23.99 (23.27 to 24.73)	11.02 (10.50 to 11.57)	6.14 (5.74 to 6.56)	10.78 (10.26 to 11.32)	1.33 (1.15 to 1.54)	8.21 (7.76 to 8.70)
2 - 3							
Dementia cohort	22.62 (21.49 to 23.78)	16.15 (15.17 to 17.18)	6.04 (5.42 to 6.73)	3.32 (2.87 to 3.85)	6.35 (5.72 to 7.05)	1.09 (0.84 to 1.41)	3.65 (3.17 to 4.20)
Older adult cohort	35.27 (34.35 to 36.19)	24.27 (23.46 to 25.10)	10.82 (10.24 to 11.43)	6.03 (5.59 to 6.50)	10.67 (10.09 to 11.28)	1.13 (0.95 to 1.36)	7.49 (7.00 to 8.01)
3 – 4							
Dementia cohort	21.48 (20.09 to 22.93)	15.35 (14.14 to 16.64)	6.00 (5.23 to 6.88)	3.38 (2.80 to 4.06)	6.78 (5.96 to 7.71)	1.00 (0.71 to 1.41)	3.59 (3.00 to 4.30)
Older adult cohort	36.22 (35.18 to 37.27)	24.89 (23.96 to 25.84)	11.44 (10.76 to 12.15)	6.04 (5.54 to 6.58)	11.13 (10.46 to 11.83)	1.12 (0.92 to 1.38)	7.65 (7.09 to 8.25)

4 – 5							
Dementia cohort	21.78 (20.00 to 23.67)	15.09 (13.56 to 16.75)	6.33 (5.33 to 7.51)	3.71 (2.95 to 4.64)	6.44 (5.43 to 7.62)	0.88 (0.55 to 1.40)	4.12 (3.32 to 5.10)
Older adult cohort	35.70 (34.53 to 36.89)	25.23 (24.17 to 26.31)	11.35 (10.59 to 12.16)	5.66 (5.12 to 6.26)	11.02 (10.27 to 11.81)	1.19 (0.95 to 1.49)	7.11 (6.50 to 7.77)

CI Confidence Interval

d. Conditional logistic regression sensitivity: Association between dementia and analgesic prescription

i) Community sensitivity analysis (Table A.8)
ii) Healthy cohort sensitivity analysis (Table A.9)
iii) All analgesic prescriptions sensitivity analysis (Table A.10)
iv) Logistic regression sensitivity analysis (Table A.11)

i. Community sensitivity analysis

Table A.8. Community sensitivity analysis: Conditional logistic regression

	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	0 – 5
Analgesic category	**OR (95% CI)**					
Any analgesic	.88 (.76 to 1.01)	.79 (.65 to .95)	.60 (.46 to .78)	.56 (.39 to .80)	.47 (.29 to .76)	.78 (.58 to 1.06)
Basic analgesic	.91 (.77 to 1.08)	.83 (.66 to 1.04)	.67 (.49 to .92)	.58 (.37 to .92)	.52 (.28 to .94)	.77 (.54 to 1.10)
Weak analgesic	.93 (.71 to 1.21)	.76 (.53 to 1.09)	.50 (.30 to .84)	.40 (.19 to .83)	.64 (.25 to 1.64)	.74 (.46 to 1.17)
Moderate analgesic	.88 (.60 to 1.28)	1.03 (.63 to 1.68)	.64 (.28 to 1.49)	.53 (.22 to 1.35)	.29 (.06 to 1.38)	.68 (.34 to 1.39)
Strong analgesic	.71 (.54 to .92)	.56 (.40 to .82)	.70 (.43 to 1.16)	.63 (.31 to 1.30)	.82 (.34 to 1.97)	.66 (.39 to 1.11)
Very strong analgesic	1.67 (.82 to 3.41)	2.00 (.50 to 8.00)	4.00 (.85 to 18.84)	.50 (.13 to 2.00)	.33 (.04 to 3.21)	.83 (.25 to 2.73)
NSAID	.71 (.53 to .96)	.58 (.37 to .90)	.36 (.19 to .68)	.39 (.18 to .85)	.33 (.13 to .84)	.62 (.38 to 1.01)

Predictor: Dementia cohort vs. older adult cohort
Outcome: Analgesic category: yes/no
Multivariable model could not be computed due to the small numbers in each cell

ii. Healthy cohort sensitivity analysis

Table A.9. Healthy cohort sensitivity analysis: from index date to five years after index date

Analgesic category	**OR (95% CI)**	**Adjusted OR (95% CI)**
Any analgesic	.77 (.74 to .80)	.81 (.77 to .84)
Basic analgesic	.83 (.77 to .84)	.85 (.81 to .89)
Weak analgesic	.68 (.64 to 72)	.73 (.67 to .78)
Moderate analgesic	.69 (.64 to .76)	.71 (.64 to .79)
Strong analgesic	.63 (.59 to .67)	.60 (.56 to .66)
Very strong analgesic	.77 (.64 to .93)	.70 (.55 to .91)
NSAID	.54 (.50 to .58)	.58 (.53 to .64)

Predictor: Dementia cohort vs. older adult cohort
Outcome: Analgesic category: yes/no
Multivariable models adjusted for: evidence of cardiovascular-related conditions, evidence of diabetes, evidence of depression, morbidity (BNF), follow up (days), consultation frequency

iii. All analgesic prescriptions: not matched to a musculoskeletal consultation

Table A.10. All analgesic prescriptions (not matched to a musculoskeletal consultation): Conditional logistic regression sensitivity analysis

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
OR (95% CI)	97 (.94 to .99)	.94 (.92 to .98)	.94 (.90 to .98)	.91 (.86 to .96)	.91 (.85 to .98)	.98 (.93 to 1.05)
Adj OR (95% CI)	.96 (.93 to .99)	.93 (.90 to .97)	.92 (.88 to .96)	.90 (.85 to .96)	.89 (.83 to .97)	.97 (.91 to 1.03)
Basic Analgesic						
OR (95% CI)	1.06 (1.03 to 1.09)	1.05 (1.01 to 1.09)	1.05 (1.00 to 1.11)	1.03 (.96 to 1.10)	.97 (.89 to 1.05)	1.05 (.99 to 1.13)
Adj OR (95% CI)	1.05 (1.02 to 1.09)	1.03 (.98 to 1.08)	1.04 (.98 to 1.11)	1.01 (.93 to 1.09)	.95 (.87 to 1.05)	1.03 (.96 to 1.11)
Weak Analgesic						
OR (95% CI)	.91 (.86 to .95)	.87 (.81 to .92)	.85 (.78 to .92)	.72 (.64 to .80)	.72 (.63 to .84)	.88 (.81 to .97)
Adj OR (95% CI)	.90 (.85 to .96)	.87 (.80 to .93)	.85 (.77 to .93)	.77 (.68 to .88)	.73 (.62 to .85)	.86 (.78 to .95)
Moderate Analgesic						
OR (95% CI)	.86 (.80 to .92)	.81 (.74 to 89)	.84 (.74 to .94)	.73 (.63 to .85)	.84 (.69 to 1.03)	.79 (.70 to .89)
Adj OR (95% CI)	.86 (80 to .94)	.78 (.70 to .87)	.82 (.71 to .94)	.72 (.60 to .85)	.77 (.61 to .97)	.74 (.65 to .85)
Strong Analgesic						
OR (95% CI)	.84 (.80 to .89)	.76 (.71 to .81)	.73 (.67 to .80)	.72 (.64 to .81)	.71 (.61 to 83)	.77 (.70 to .86)
Adj OR (95% CI)	.77 (.72 to .82)	.71 (.65 to .77)	.64 (.58 to .72)	.65 (.57 to .74)	.61 (.51 to .73)	.70 (.62 to .78)
Very Strong Analgesic						

OR (95% CI)	1.00 (.85 to 1.17)	1.03 (.84 to 1.26)	1.14 (.88 to 1.47)	.83 (.60 to 1.16)	.93 (.61 to 1.43)	.84 (.63 to 1.13)
Adj OR (95% CI)	.78 (.63 to .97)	.91 (.70 to 1.18)	.94 (.66 to 1.34)	.75 (.49 to 1.13)	1.03 (.55 to 1.94)	.83 (.57 to 1.22)
NSAIDs						
OR (95% CI)	.64 (.60 to .68)	.56 (.54 to .64)	.54 (.48 to .60)	.54 (.46 to .62)	.64 (.53 to .78)	.68 (.61 to .76)
Adj OR (95% CI)	.66 (.62 to .71)	.59 (.54 to .65)	.54 (.48 to .61)	.57 (.48 to .67)	.61 (.80 to .76)	.68 (.61 to .76)

Predictor: Dementia cohort vs. older adult cohort. Outcome: Analgesic category: yes/no.
Multivariable models adjusted for: evidence of cardiovascular-related conditions, evidence of diabetes, evidence of depression, morbidity (BNF), follow up (days), consultation frequency.
Consultation frequency entered as a continuous covariate. All other covariates were categorical.

iv. Logistic regression analysis

Table A.11 Association between dementia cohort/older adult cohort and analgesic prescription, stratified by analgesic potency and time period from index date: Logistic regression (rather than conditional) sensitivity analysis

	0 to 1	**1 to 2**	**2 to 3**	**3 to 4**	**4 to 5**	**0 to 5**
Any Analgesic Classification						
OR (95% CI)	.78 (.75 to .81)	.69 (.65 to .72)	.59 (.56 to .63)	.52 (.48 to .56)	.57 (.51 to .62)	.64 (.60 to .69)
Adj OR (95% CI)	.74 (.71 to .77)	.65 (.62 to .69)	.57 (.54 to .61)	.50 (.47 to .55)	.54 (.49 to .59)	.59 (.55 to .64)
Basic Analgesic						
OR (95% CI)	.88 (.84 to .92)	.89 (.75 to .83)	.68 (.63 to .73)	.59 (.54 to .64)	.59 (.53 to .66)	.73 (.67 to .78)
Adj OR (95% CI)	.84 (.80 to .88)	.75 (.71 to .80)	.65 (.60 to .70)	.57 (.52 to .63)	.56 (.50 to .63)	.70 (.65 to .76)
Weak Analgesic						
OR (95% CI)	.78 (.73 to .83)	.65 (.60 to .71)	.59 (.53 to .66)	.52 (.45 to .59)	.56 (.47 to .65)	.67 (.61 to .74)
Adj OR (95% CI)	.76 (.71 to .81)	.64 (.59 to .70)	.59 (.53 to .66)	.52 (.46 to .60)	.56 (.47 to .66)	.66 (.60 to .72)
Moderate Analgesic						
OR (95% CI)	.71 (.64 to .78)	.66 (.59 to .75)	.58 (.50 to .67)	.53 (.44 to .64)	.70 (.56 to .87)	.67 (.59 to .76)
Adj OR (95% CI)	.69 (.63 to .76)	.66 (.58 to .74)	.57 (.49 to .66)	.53 (.44 to .64)	.69 (.55 to .86)	.67 (.59 to .76)
Strong Analgesic						
OR (95% CI)	.72 (.67 to .77)	.64 (.58 to .70)	.55 (.49 to .62)	.59 (.52 to .68)	.52 (.44 to .63)	.67 (.60 to .74)
Adj OR (95% CI)	.64 (.59 to .69)	.59 (.54 to .65)	.51 (.45 to .58)	.55 (.48 to .64)	.48 (.40 to .57)	.57 (.52 to .64)
Very Strong Analgesic						
OR (95% CI)	.96 (.78 to 1.19)	.71 (.55 to .91)	.89 (.66 to 1.20)	.78 (.53 to 1.15)	.76 (.47 to 1.23)	.83 (.63 to 1.10)
Adj OR (95% CI)	.80 (.65 to 1.00)	.63 (.49 to .82)	.81 (.60 to 1.11)	.74 (.50 to 1.09)	.69 (.42 to 1.13)	.69 (.52 to .93)

NSAIDs						
OR (95% CI)	.58 (.54 to .63)	.50 (.45 to .55)	.46 (.40 to .53)	.46 (.39 to .54)	.56 (.46 to .69)	.59 (.54 to .66)
Adj OR (95% CI)	.55 (.50 to .59)	.50 (.45 to .55)	.47 (.41 to .54)	.46 (.39 to .55)	.56 (.46 to .69)	.54 (.49 to .61)

OR Odds Ratio; Adj OR Adjusted Odds Ratio; NSAID Non-Steroidal Anti-Inflammatory Drugs; CI confidence interval
Multivariable models adjusted for: evidence of cardiovascular related-conditions, evidence of diabetes, evidence of depression, morbidity (BNF), follow up (days), consultation frequency, year of index date, age at index date, deprivation (IMD), gender.
*All analgesic prescriptions matched to musculoskeletal consultation.
Consultation frequency entered as a continuous covariates. All other covariates were categorical.

Appendix 14: Thesis dissemination

Peer reviewed publications

Bullock, L., Bedson, J., Jordan, J. L., Bartlam, B., Chew-Graham, C. A., & Campbell, P. (2019). Pain assessment and pain treatment for community-dwelling people with dementia: A systematic review and narrative synthesis. *International Journal of Geriatric Psychiatry, 34*(6), 807-821. doi: 10.1002/gps.5078

Oral presentations

Bullock, L., Richardson, J., Bedson, J., Campbell, P (2017). *Dementia and pain: Consultation and treatment patterns in primary care.* Primary Care and Health Sciences Postgraduate Symposium. Keele University, UK.

Bullock, L., Richardson, J., Bedson, J., Campbell, P (2017). *Dementia and Pain: Consultation and Treatment in Primary Care.* New Horizons in 3D (Delirium, Dementia and Depression): Clinical Research in Older Adults. South Staffordshire and Shropshire NHS Foundation Trust, UK.

Bullock, L., Richardson, J., Bedson, J., Campbell, P (2017). *Dementia and Pain: Consultation and Treatment in Primary Care.* Annual Social Science Symposium, Keele University, UK.

Bullock, L., Richardson, J., Bedson, J., Campbell, P (2017). *Dementia and Pain: Consultation and Treatment in Primary Care*. Staffordshire University Postgraduate Research Conference, UK.

Bullock, L., Bedson. J., Bartlam, B., Chew-Graham, C. A., & Campbell, P. (2017). *Pain assessment and pain treatment in people with dementia living in the community: A systematic review.* Society for Academic Primary Care North Conference, UK.

Bullock, L., Chew-Graham, C. A., Bedson, J., Campbell, P. (2018). *"I don't think pills solve anything": Exploring pain and pain management for community-dwelling people with dementia. A qualitative study.* Primary Care and Health Sciences Postgraduate Symposium. Keele University, UK.

Bullock, L., Bartlam, B., Bedson, J., Chew-Graham, C. A., & Campbell, P. (2018). *"I don't think pills solve anything": Exploring the experience of pain and pain management among community-dwelling people with dementia.* Society for Academic Primary Care Conference, UK.

Bullock, L., Bedson, J., Chew-Graham, C.A., Chen, Y., & Campbell, P. (2019). *Does the prevalence of pharmacological pain treatments differ between people with dementia*

and those without dementia? A retrospective observational cohort study of the UK Clinical Practice Research Datalink (CPRD). Alzheimer's Research UK Conference 2019, UK. ***Won the Laura Pulford Prize for the best oral presentation during the Early Careers Day.**

Bullock, L., Chew-Graham, C. A. Bedson, J Bartlam, B. & Campbell, P. (2019). *Exploring the views and perspectives of analgesic medication for pain in people with dementia.* Division of Health Psychology Annual Conference 2019, UK.

Bullock, L., Bedson, J., Chew-Graham, C.A., & Campbell, P. (2019). *Pain in community-dwelling people with dementia: a mixed methods study.* Higher Education Dementia Network Meeting, Keele University.

Poster presentations

Bullock, L., Bedson. J., Bartlam, B., Chew-Graham, C. A., & Campbell, P. (2018). *Pain assessment and pain treatment for community-dwelling people with dementia: A narrative systematic review.* Institute of Liberal Arts and Sciences Postgraduate Conference, Keele University, UK. ***Won best poster prize.**

Bullock, L., Bedson. J., Bartlam, B., Chew-Graham, C. A., & Campbell, P. (2018). *Pain assessment and pain treatment for community-dwelling people with dementia: A narrative systematic review.* Midlands Health Psychology, UK. ***Abstract won a free place at the conference.**

Bullock, L., Bedson. J., Bartlam, B., Chew-Graham, C. A., & Campbell, P. (2018). *Pain assessment and pain treatment for community-dwelling people with dementia: A narrative systematic review.* Midlands Academy of Medical Sciences Midlands, UK.

Bullock, L., Bedson, J., Chew-Graham, C.A., Chen, Y., & Campbell, P. (2019). *Musculoskeletal consultations for people with dementia: a retrospective cohort study of the UK Clinical Practice Research Datalink (CPRD).* Alzheimer's Research UK Conference 2019, UK.

Bullock, L., Bedson, J., Chen, Y., Chew-Graham, C.A., & Campbell, P. (2019). *The annual prevalence of musculoskeletal consultation after diagnosis of dementia: a retrospective cohort study of the UK Clinical Practice Research Datalink (CPRD).* 11th Congress of the European Pain Federation (EFIC), Valencia, Spain.

Bullock, L., Bedson, J., Chen, Y., Chew-Graham, C.A., & Campbell, P. (2019). *Reduced incident musculoskeletal consultation for patients with dementia: a retrospective cohort study of the UK Clinical Practice Research Datalink (CPRD)*. 11th Congress of the European Pain Federation (EFIC), Valencia, Spain.

Bullock, L., Chew-Graham, C. A., Bedson. J., Bartlam, B., & Campbell, P. (2019). *Analgesic medication for people with dementia: the perspectives of people with dementia, family caregivers, and healthcare professionals.* 11th Congress of the European Pain Federation (EFIC), Valencia, Spain.