Primary care decision-making for shoulder pain: identifying treatment effect moderators using clinical expertise

Volume I

Cliona McRobert

Ph.D.

June 2018

Keele University

ABSTRACT

Background

Shoulder pain is a common, costly condition with variable prognosis. Commonly used treatments for shoulder pain in primary care include: (i) advice & analgesia, (ii) exercise and/or manual therapy, and (iii) corticosteroid injection. Current guidelines do not assist clinicians in optimal treatment selection for this condition. Prognostic factors help identify subgroups likely to have poor prognosis, however their potential to help clinicians decide between different treatments is unclear.

Methods

A systematic review identified which patient attributes modify effects of these three treatments. Clinical consensus workshops were conducted with 21 UK-based clinicians who manage shoulder pain to identify patient attributes relevant to treatment decision-making. The impact of these attributes on treatment choice was studied in a conjoint analysis study of decision-making for shoulder pain.

Results

The review identified 20 potential treatment effect moderators, with low quality evidence. Clinical consensus workshops identified 12 salient patient attributes. The conjoint study received responses from 387 clinicians (31 countries, 64% UK). Results showed that 11 of the 12 attributes discriminated between treatment choices, following adjustment for responders' country, profession, and experience. Recommending injection was most

strongly associated with lack of improvement (OR 2.81, 95%CI 2.16; 3.65), previous positive response to injection (2.79, 2.07; 3.76), and patient preference (2.41, 1.82; 3.19). Recommending physiotherapy was most strongly influenced by patient preference (2.77, 2.16; 3.55), presence of weakness/instability (2.05, 0.79; 1.23) and previous positive response to physiotherapy (2.22, 1.76; 2.80). Not recommending corticosteroid injection was associated with traumatic onset and unstable diabetes or cardiac issues, whereas not recommending physiotherapy was associated with sleep disturbance and high pain.

Discussion

The relative importance of patient attributes that influence shoulder treatment selection was quantified. Logical clinical patterns emerged suggesting that specific patient attributes guide clinicians treatment selection. Future research is indicated to assess if identified attributes indeed modify treatment effects.

ACKNOWLEDGEMENTS

Sincerest thanks to my supportive and encouraging supervisory team: Prof Danielle van der Windt; Dr Jonathan Hill; and Prof Elaine Hay. Your wealth of experience, unwavering focus and open minds helped me develop, no end. Your kindness and nurturing guidance made a successful return to the PhD post-injury possible. Thank you for being wonderful mentors, both academically and personally. It has been my privilege to learn from and work with you.

Thanks to the National Institute for Health Research School for Primary Care Research for funding my PhD. Thanks to Prof John F.P. Bridges for helping me to realise my vision for the conjoint study. Dr John Belcher, my thanks for your advice and support with the statistical analysis for the conjoint study but especially for your patience and good humour. Mr. Tim Smale, I am beyond grateful that you ignored all advice regarding 'never say yes to a PhD student's request for help', thanks for allowing me to capitalise upon your specialist skills to design the survey platform for the conjoint study. Thank you Hermionie Blake and Liz Orton for your invaluable mentorship.

A lifetime of humble and heartfelt appreciation for the clinical expertise and compassion I received from the neurosurgery team at The Walton Centre, Liverpool, especially Mr Broadbelt, Prof Young, Dr Bashford and Ms Slawson. Thanks to my parents, for their continuous love, support and prayers. Thanks to my brothers, sisters-in-law, nieces and nephew, your messages, calls, photos, and perspective-giving banter are hugely appreciated. To my lovely friends, Keele PhD alumni and Keele colleagues, thanks especially for the distracting calls and messages and for dragging me away from the desk for day-light, play-time, laughter, brunches, much needed bike rides, walks on the beach and for somehow always knowing the right time to ask how everything was going and when to just pour me yet another cup of tea.

Finally, to my amazing husband Allistair, there are no words with which to express my thanks for all of your endless love and support. For all the cups of tea delivered to my desk with words of encouragement, for managing my frequent existential crises on the stairs and for always believing in me when health and thesis challenges felt insurmountable, thank you.

“Education is not the filling of a pail,

but the lighting of a fire.”

~ William Butler Yeats (1865–1939)

TABLE OF CONTENTS

VOLUME 1

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

CHAPTER 1 - INTRODUCTION

1.1 Epidemiology of Shoulder Pain

Musculoskeletal (MSK) shoulder pain is common, with estimates of the one month period prevalence ranging from 14 to 48% (Pope et al. 1997) and lifetime incidence rate estimated at 50% of the population (Geraets et al. 2006; Urwin et al. 1998). Shoulder pain is the third most common MSK condition to present in UK Primary Care (Geraets et al. 2005; Jordan et al. 2010; Peters et al. 1994), with some affected individuals experiencing significant reductions in functional capacity, quality-of-life (Beaton & Richards, 1996; Gartsman et al. 1998) and work capacity (Kuijpers et al. 2006). The actual cost of shoulder pain in the UK is unknown but estimates from primary care in Sweden indicate an annual per patient cost of €4139 (£3777) with time-off-work accounting for 84% of the total costs (Virta et al. 2012).

1.2 Shoulder Pain in Primary Care

Often primary care is the first point of healthcare access for individuals with shoulder pain, and therefore effective first-line management is paramount in improving the quality of life and social and occupational productivity of affected individuals. Although half of those with shoulder pain consult their GP only once (Dorresteijn et al. 2011; Greving et al. 2012), primary care consultation rates for

shoulder disorders are disproportionately higher than for other MSK conditions amongst working individuals (Jordan et al. 2010; Ostergren et al. 2005). This is an indication of the significant impact that shoulder pain can have on some working-aged individuals. Furthermore, shoulder pain has a poor pattern of recovery (prognosis), with estimates that; over 70% have pain for longer than 6 weeks (Kuijpers et al. 2006), only half of all new episodes demonstrate complete recovery within six months (Croft et al. 1996; van der Windt et al. 1996; Winters et al. 1999a); and at one year post consultation, only 60% of new episodes demonstrate complete recovery (van der Windt et al. 1996). These figures highlight that effective primary care treatment of MSK shoulder pain remains a significant clinical challenge.

1.3 Current Guidance on the Clinical Management of Shoulder Pain

Current UK primary care management of shoulder pain draws from an abundance of commonly accepted conservative treatment options such as; exercise and/or manual therapy (typically delivered by a physiotherapist), advice on activity modification and relative rest, non-steroidal anti-inflammatory drugs, and corticosteroid injections. Exercise has been shown to beneficial in the short-term with greater functional benefit accrued with a combination of exercise plus manual therapy (Page et al. 1996). Although in the longer term, no differences in outcome have been found between manual therapy and exercises compared to corticosteroid injection (Page et al. 1996), corticosteroid injection has been shown to be more effective in reducing pain and dysfunction than physiotherapy treatment (exercise and/or manual therapy) in the short-term (RR for 'cured' 3.72

(1.88, 7.37)) however, effects are short-lived with no differences in the longer term (short term cure RR 1.23 (0.47, 3.26)) (Green et al. 2003). Therefore, questions remain about the relative superiority, duration of treatment effects and optimal timing of these treatments (Blanchard et al. 2010; Buchbinder et al. 2013a; Page et al. 1996). National and international guidelines for the management of shoulder pain (Carr & Rees, 2012; Hanchard et al. 2004; Kulkarni et al. 2015) generally recommend all of the above conservative treatments, but lack any guidance about how best to match individual patients to specific treatments. National research priorities therefore, highlight the need to find ways to improve treatment outcomes in primary care and to better understand which treatments should be provided for whom (Rankin et al. 2012).

1.4 Current Approaches to Clinical Management of Shoulder Pain

Routine UK primary care practice for shoulder pain currently involves a stepped care model where advice and analgesia are offered as the first tier of treatment (Artus et al. 2017). Typically, after a period of analgesia only, those patients whose shoulder pain persists are then offered either referral to physiotherapy or corticosteroid injection (Winters et al. 1999a). If these first-line treatments fail, then the next tier is usually a referral to secondary care for consideration of shoulder surgery via diagnostic interface services, such as those led by extended scope physiotherapists. However, due to spiraling frequency and costs of shoulder surgery (Judge et al. 2014, Ensor et al. 2013) in addition to a lack of clear evidence that orthopaedic surgery delivers superior clinical outcome to conservative management (Ryösä et al. 2016), important questions remain about

whether early primary care treatment decision-making for these patients, such as initial first-line treatment selection, could be optimised.

1.5 Current Research Approaches

Typically, the superiority or inferiority of a treatment in a particular sample of patients has been determined using treatment group mean scores in randomised controlled trials (RCTs). However unsurprisingly, this approach has failed to yield a universally effective treatment for shoulder disorders (Green et al. 2003). Considering the volume of existing research in this field that has tested and compared various treatments for superiority, it is perhaps time to re-conceptualise how MSK shoulder pain research is conducted.

A traditional critique of randomised controlled trials is that group mean scores do not reflect the path of an individual, therefore Priestman & Baum (1976) advised that attention is paid to the path of individual patients through a trial, asserting that group mean change scores reflect the intervention effect on either no one or at most, a few individuals. Judgement of treatment effectiveness based solely on group mean change forfeits understanding of individual response as not all patients' problems necessarily change in the same direction or to the same degree (Priestman & Baum, 1976). In clinical trials, considerable individual variation in treatment response may be seen in the standard error of the mean effect, resulting in wide confidence intervals. Such a broad variety of responses summarised in one mean score may add to an explanation for why many trials have been unable

to detect statistically significant treatment differences. Variation in patient characteristics and prognosis highlights potential explanatory relationships between an individual's characteristics and prognosis. Research focus is beginning to shift towards understanding how each patient's individual attributes impact on clinical outcome, i.e., identification of specific patient or disease characteristics that predict which patients responds better to a specific treatment, compared to others.

1.6 Clinical Challenges

In common with other medical and healthcare fields, a clear diagnosis often underpins clinical management of a patient's presentation. However, the clinical management of shoulder pain suffers in this respect, as ascertaining an exact and accurate clinical diagnosis in patients with shoulder pain is challenging, even with the input of musculoskeletal imaging techniques such as ultrasound (Saulle & Gellhorn, 2017). Specific orthopaedic symptom provocation tests are highly sensitive to pain but lack the specificity that enables confident identification of the structure(s) that underlies or causes the presenting pain and/or dysfunction (Hegedus et al. 2012).

A recent meta-analysis found that no single test demonstrated superior clinical performance but that the best performing tests (with respective sensitivity and specificity) include; supraspinatus test for diagnosing not just supraspinatus tears but any full thickness tendon tear (0.43 (0.31,0.56), 0.89 (0.67, 0.97); the

Compression-Rotation test for diagnosing a SLAP injury (0.58 (0.50, 0.66), 0.67 (0.47, 0.83)) and the Hawkins test for subacromial impingement syndrome (0.74 (0.39,0.92), 0.77 (0.69, 0.83)) (Gismervik et al. 2017). Therefore, even with reliance on these three best available tests, the sensitivity and specificity of specific orthopaedic tests remains low. Furthermore disagreement exists on whether physical tests and symptom reporting alone can accurately inform specific clinical diagnosis (Cadogan et al. 2013; Carter et al. 2012; McFarland et al. 2010). Existing attempts to help clinicians manage this diagnostic uncertainty and the limitations of making decisions for individual patients based on how a group responded in a RCT have drawn upon various methods of subgrouping shoulder patients on the basis of diagnostic classification systems. However such systems demonstrate inter-rater variability (percentage agreement) of 60-80% amongst physiotherapists (Carter et al. 1999) and remain incompletely evidenced in terms of their impact on treatment decision-making and subsequent patient outcomes across the variety of clinical environments in which patients with shoulder pain present.

1.7 Using Prognosis Research to Inform Clinical Practice

Prognosis research has sought to identify patient attributes that estimate a patient's likely outcome in the context of their chosen clinical management. With respect to shoulder pain, a number of patient attributes including more intense pain at baseline, longer symptom duration, gradual history of symptoms, frequent discomfort, more resting, being less energetic, and middle-age, low education level and, multisite musculoskeletal pain have been found to predict poorer

outcome, in the context of the various types of healthcare received in the cohort studies (Bot et al. 2005; Engebretsen et al. 2010; Feleus et al. 2007; Hoare et al. 2010; Kuijpers et al. 2006; Kuijpers et al. 2004). As outlined in the PROGRESS Partnership's framework for prognosis research, establishing which patient attributes are associated with poor outcome is the first step in the development of models of stratified care that seek to match individual patients with the treatment most likely to result in positive outcome (Hemingway et al. 2013; Riley et al. 2013). The next stage requires building multivariable prognostic models to ascertain risk of specific outcomes in individual patients (Steyerberg et al, 2013).

Clinical applications of multivariable prognostic models which can produce risk predictions for individual patients include the development of: (i) prognostic or prediction rules or (ii) decision tool/aids. Based on predictive or prognostic models containing variables obtained from patient history, physical examination and/or simple diagnostic tests, prediction rules are designed to predict outcome in the context of the type of treatment provided and are intended to provide a probability for the likelihood of a future event on the basis of the patient's clinical profile (Laupacis et al. 1997). Likelihood of a future event in a prediction rule may be classified as low, medium or high risk. This is of some clinical utility but such tools do not provide guidance on a treatment decision for individual patients.

Distinctions between 'prediction rule', 'prediction guide', 'decision rule' and 'decision guide' are subtle with some arguing that decision rules/guides are the

same as prediction tools/guides (Fritz, 2009; Hebert & Fritz, 2012; Schneider et al. 2012). Prediction models or rules are designed to optimally predict (using baseline clinical information) a specific outcome for individual patients (Reilly & Evans, 2006). This can inform treatment decisions, especially where the decision concerns treatments that carry risks as well as benefits, and the aim is to only offer treatment to those for whom the benefits of treatment outweigh the risks. In specific circumstances, a clinical prediction rule based on risk can validly suggest a therapeutic course of action. In the context of a disease such as osteoporosis for example, use of specific risk assessment tools to estimate risk of fracture can guide decisions on the appropriateness, or not of relevant intervention (e.g. prescription of medication to reduce fracture risk) (NICE, 2017).

In contrast, in the context of shoulder pain, decision rules are proposed to assist with treatment decisions that are not based on risk associated with likely future outcomes or course of symptoms but rather, on predictors of response to specific treatments. This may be problematic as it assumes that the prognostic model underpinning the rule has been designed specifically to identify which prognostic variables are associated with a particular direction of response for each treatment under consideration. Prediction rules that intend to support treatment decision-making have in the past mistakenly been developed using single arm of a trial or observational data where only one treatment is studied. In such cases, it is not clear whether the patients who respond well to the intervention would have responded the same, better or worse to another intervention. Furthermore, it is

unclear which patients simply have a good prognosis and are highly likely to achieve a good outcome, irrespective of receipt of treatment.

Few clinical prediction rules that recommend treatment decisions have undergone formal validation, replication or clinical and cost effectiveness impact analysis (as per (McGinn et al. 2000) to determine whether they improve real world decision-making and outcomes when used in clinical practice (Steyerberg et al. 2013). Therefore, given the lack of clarity and evidence of clinical impact, a more cautious and discriminative approach to the definition of terms in this field has been advised. Foster et al. (2013) suggest a distinction between prognostic models and clinical decision tools: prognosis could guide the decisions about whether treatment is indicated or not on the basis of likely outcome whilst approaches targeting mechanisms could support decision-making about specific treatments for individual patients. As different clinical questions require specific research methods to be appropriately answered, the clinical question therefore in this situation also drives the decision to create either a prediction tool or clinical decision tool. A prognostic model will provide useful information when the clinical question centres on identifying the risk of poor outcome. If however, the clinical question centres on specific treatment selection in order to gain a positive outcome, a decision tool is required and this requires a slightly different methodology. A decision tool should be based on a prognostic model that demonstrates an interaction between prognostic variables and the effect of treatment over the control intervention effect, e.g., if gender interacted with treatment, a different response would be observed for males compared with

females in response to the same treatment. This approach may appropriately enable identification of patients who are uniquely likely to respond to a specific treatment in comparison to other specific treatments or control, thereby allowing clinicians to 'match' individual patients to the most beneficial treatment, i.e., conduct evidence based treatment selection for individual patients.

Decision tools can also be based on a mix of prognostic information and treatment targeting. The STarT-Back Tool helps to distinguish between patients who can be reassured (low risk); who need more help, e.g. by a physiotherapist (medium risk); and those who need to more intensive combined physical and psychologically informed treatment (high psychosocial risk) (Hill et al. 2008). The psychologically informed intervention matched to patients with high psychosocial risk was based on the assumption that an interaction exists between scoring highly on the psychological subscale of the tool and response to the psychologically informed intervention, although this interaction is currently under investigation and has yet to be demonstrated. The STarT-Back approach, where clinicians use the prognostic tool to inform decision-making, has been demonstrated to be more clinically and cost effective than usual care (delivering greater reduction in disability, healthcare utilisation and time off work and greater functional gains whilst also being more cost effective (with average annual savings of £34.39 per patient) (Hill et al. 2011). On-going work seeks to understand the mechanisms underpinning the particular success of this approach to targeted treatment (Mansell et al. 2013). The academic field of shoulder disorders, including its evidence base and mass of literature is less mature than low back pain. Therefore, an opportunity exists to define a system of treatment targeting in

shoulder disorders constructed upon understanding of how patient attributes are responsible for differential treatment response at the individual patient level.

1.8 Moderators of Treatment Effect as Drivers of Clinical Decision-Making

This differential treatment effect can be termed moderation. Treatment effect moderators (also termed treatment effect modifiers) are patient attributes which enable researchers to identify who responds to a given treatment and who does not (Kraemer et al. 2008). Moderators of treatment effect are patient characteristics measured at baseline that influence the relationship between a specific intervention and outcome (Hill & Fritz, 2011). Moderators of treatment effect are ideally identified with *a priori* hypothesis in large RCTs investigating interventions of interest (Pincus et al. 2011), however a recent review of moderators in the more mature field of low back pain research suggests that this is not yet commonplace (Gurung et al. 2015). It is often stated that RCTs are required to test for moderation as attempting to identify potential moderators in a single arm cohort study do not allow for comparison of the interaction between the prognostic factor and each of the interventions of interest, i.e., it is not possible to determine whether the patient attribute has a moderating effect in that treatment alone or in some but not other treatments (Hancock et al. 2009), or if a patient attribute is a generic prognostic factor, predicts outcome regardless of the type of treatment. However, it could also be possible to test moderators of treatment effect in a sufficiently large cohort study containing the treatments of interest if a priori hypotheses were stated, with careful attention paid to the baseline characteristics of each treatment group and sufficient adjustment for confounding

is incorporated in the analysis, since randomisation is not a feature of a cohort study.

1.9 Rationale for this Thesis

Despite the common usage of conservative treatment options such as; exercise and/or manual therapy (typically delivered by a physiotherapist), advice on activity modification and relative rest, non-steroidal anti-inflammatory drugs, and corticosteroid injections in UK primary care, clear indications for the selection of optimal treatment tailored for each individual with MSK shoulder pain is lacking. Given this paucity of evidence on how to target treatment for shoulder disorders, identification of moderators of treatment effect for these treatments and definition of profiles of patients who are likely to respond to specific treatments is indicated to guide treatment decision-making for individual patients.

This PhD aims to contribute to the evidence for primary care practice by identifying factors that potentially moderate response to three commonly used treatment options: (i) advice and analgesia, (ii) exercise and/or manual therapy as delivered by a physiotherapist and (iii) corticosteroid injection. It is anticipated that the outcome of this PhD will be the formulation of clinically derived and weighted profiles of patients most likely to respond to the above-mentioned treatments. It is anticipated that these factors and profiles will inform a future treatment decision tool and a future RCT of stratified care using this approach in primary care patients with shoulder pain.

1.10 Thesis Aims

This thesis aims to use appropriate and robust methods to derive a list of candidate moderators of treatment response suitable for testing in future purposive research by:

Identifying and summarising available evidence relevant to moderators of response to: (i) advice and analgesia, (ii) exercise and/or manual therapy and (iii) corticosteroid injection

Using clinical expertise to identify patient characteristics that may moderate patient response to: (i) advice and analgesia, (ii) exercise therapy and/or manual therapy and (iii) corticosteroid injection

Identifying candidate moderators of treatment effect for each of the above three treatments based on healthcare practitioners expertise and opinion regarding differential decision-making for shoulder pain.

This thesis will identify and quantify the impact of clinically relevant candidate moderators on differential decision-making for patients with shoulder pain using a variety of relevant and sequential methodologies. Firstly, a systematic review will identify and summarise existing evidence on moderators of treatment effect for the three conservative primary care treatments for shoulder pain. Theories of expertise and decision-making will be portrayed in light of differential treatment decision-making for patients with shoulder pain. The potential of studying the

experientially constructed knowledge of clinical experts to identify additional potential moderators of treatment effect will be discussed. Findings from the review will be supplemented by clinical expertise in a series of focus groups using nominal group technique to arrive at a parsimonius list of highly clinically relevant attributes of patients with shoulder pain that assist clinicians with differential first-line treatment decision-making. A multi-modal recruitment strategy will be used to recruit a multi-disciplinary and international sample of clinicians who routinely manage patients with shoulder pain to the final study of clinical decision-making. The impact of each of the patient attributes on differential decision-making will be quantified in an empirical study of clinical decision-making using conjoint analysis.

CHAPTER 2: MODERATORS OF TREATMENT RESPONSE IN PATIENTS WITH MUSCULOSKELETAL SHOULDER PAIN: A SYSTEMATIC REVIEW

2.1. Introduction

In spite of numerous high quality randomised controlled trials (RCTs) in shoulder pain that demonstrate short-term effectiveness of several interventions including exercise and corticosteroid injection (Abdulla et al. 2015; Dong et al. 2015; Littlewood et al. 2012; Murphy & Carr, 2010; Page et al. 2014; Song et al. 2014), evidence regarding long-term effectiveness and clinically directive differences in treatment effect is lacking. The variable prognosis of patients with shoulder pain (Croft et al. 1996; van der Heijden et al. 1997; Winters et al. 1999a), coupled with acknowledged diagnostic challenges (Hegedus et al. 2012), has prompted clinicians and researchers alike to search for strategies to identify patients at risk of poor outcome. Recent systematic reviews of prognostic factors in shoulder pain have focused on identifying predictors of outcome irrespective of treatment (prognostic factors) or predictors of outcome in patients receiving a single treatment only (Chester et al. 2013; Vergouw et al. 2011). However, predictors of outcome of a single treatment do not aid understanding of how individual patient outcomes may vary in response to different treatments.

Distinct from prognostic factors, moderators of treatment effect are patient attributes or clinical characteristics measured at baseline that influence the effect of the treatment on the outcome (Hill & Fritz, 2011). Treatment effect moderators (also termed treatment effect modifiers) therefore facilitate identification of who is likely to respond or not respond to given treatments (Kraemer et al. 2008). Evidence of moderation of effect of specific treatments exists in analyses concerning other musculoskeletal conditions such as low back pain, tempo-mandibular joint and chronic musculoskeletal pain (Miles et al. 2012; Turner et al. 2007; Underwood et al. 2007). As such, a wide range of potential predictive factors are now recognised, but to date little is known about the patient attributes that specifically moderate the effect of the commonly used primary care interventions for shoulder pain: (i) advice & analgesia, (ii) exercise and/or manual therapy delivered by a physiotherapist and (iii) corticosteroid injection, and indeed which subgroups of patients with shoulder pain are most likely to respond to each of these specific and commonly offered treatments.

It is hypothesised that moderators of treatment effect for patients with shoulder pain and profiles of likely best responders to specific treatments exist, however these have not thus far been studied or identified. It is therefore logical that targeting treatment to patients whose clinical attributes match the profile of likely best responder is likely to result in clinical improvements in pain and dysfunction in these subgroups as well as health economic benefits in those unlikely to respond by avoiding costs and potential harm from less effective treatments (Hingorani et al. 2013). Investigation of treatment moderation in principle requires

a randomised controlled trial to explore or test the interaction between the patient factor(s) expected to moderate treatment effect and the different treatment options, a vital component in establishing whether the factor has a moderating effect in that treatment alone or in some but not other treatments (Hancock et al. 2009), or if it concerns a generic prognostic factor, predicting outcome regardless of the type of treatment.

Considering that the focus of recent shoulder studies and reviews has been on identifying predictors of outcome in general or of outcome of specific single treatments (Chester et al. 2013; Engebretsen & Soberg, 2010), the extent of evidence for moderators of treatment effect in musculoskeletal shoulder pain is currently unclear. Therefore, this review aims to take the first step in the identification of treatment moderators by summarising available evidence for moderation and identify suggested potential moderators of outcome of three commonly used primary care treatments: advice and analgesia, exercise and/or manual therapy and corticosteroid joint injection.

2.2 Aims of Review

A systematic review was undertaken to identify and appraise the evidence for potential moderators of the effects of education, advice, analgesia, exercise and/or strengthening exercise and corticosteroid injections in patients with musculoskeletal shoulder pain.

2.3 Objectives of Review

This systematic review:

1) Searched for randomised controlled trials in shoulder pain that either analysed moderation or included suggestions regarding potential moderators of effect of commonly used first line treatments in primary care treatments: a) education, advice, analgesia, b) exercise and/or strengthening exercise and c) corticosteroid injections

2) Identified and appraised the statistical methods used to identify potential moderators of treatment effect

3) Taking strength of evidence into account, identified patient attributes that potentially moderate effect of: a) advice and analgesia, b) exercise and/or strengthening exercise and c) corticosteroid injections in patients with musculoskeletal shoulder pain.

2.3 Methods

A systematic review was undertaken. Criteria for the identification and selection of studies included in this review are described below.

2.3.1 Types of studies

Included studies were randomised controlled trials that conducted treatment effect moderation analysis or any form of subgroup analysis where patients were

grouped on the basis of pre-determined prognostic factors and the treatment effect was compared across subgroups. As randomised controlled trials are the gold standard for revealing moderators of outcome, other study types were not included in this review (Kraemer et al. 2002; Pincus et al. 2011). In line with minimum recommended sample size for the identification of moderators of treatment effect, included studies had a minimum number of 10 participants in the smallest subgroup (Sun et al. 2011). Therefore at the inclusion/exclusion stage of the review, studies with less than 20 participants in the trial were excluded, i.e., at least 10 participants per arm as they were unlikely to have sufficient sample size in which to determine meaningful subgroup effects (Sun et al. 2010).

2.3.2 Types of participants

Studies were selected if they included adult patients (aged 18 years or older) with non-traumatic unilateral musculoskeletal shoulder pain. Non-traumatic musculoskeletal shoulder pain for the purposes of this review was defined as soft tissue strains/sprains, tendonitis, bursitis, capsulitis within or local to the gleno-humeral joint. Studies including patients with traumatic, rheumatological or degenerative conditions were excluded from this review. Shoulder pain arising from trauma was excluded from this review as traumatic onset is considered a red flag for shoulder pain and an indication for urgent shoulder clinic review (Carr & Rees, 2012). Sign(s) or diagnosis of an inflammatory condition are considered as rheumatological red flags and an indication for review in rheumatology, rheumatological conditions were therefore excluded from this review (Carr & Rees, 2012). Separate guidelines exist for the shoulder osteoarthritis management,

therefore trials in patients with osteoarthritis of the shoulder joints were also excluded from this review (AAOS, 2009).

2.3.3 Types of interventions

Included studies involved one or more of the following primary care interventions:

(i) Education, advice and/or pain relief delivered by a healthcare practitioner

(ii) Mobilising or strengthening exercise or manual therapy treatment to joints and/or soft tissue delivered by a physiotherapist or physical therapist (USA definition)

(iii) Corticosteroid injection delivered by a GP, rheumatologist, orthopaedic surgeon, physiotherapist or physical therapist

2.3.4 Outcomes of interest

Studies were included if they had at least one functional (including joint assessment, disability, work) or pain-related outcome, either individually or combined.

2.3.5 Search Methods for Identifying Studies

Databases searched include: Medline, Embase, PsycINFO, CINAHL, AMED,

Pedro, and Cochrane. Database searches began at the earliest date offered by each database and were completed in January 2015. No backward date limit was applied so that all possible hits were returned. All publications that were published by January 2015 were eligible for inclusion in the review. Search terms for shoulder conditions and relevant interventions were identified from reviews conducted by the Cochrane Musculoskeletal Review Group (Buchbinder et al. 2013a; Green et al. 2003) and key words gained from previous reviews and relevant research studies were used as search terms. The specific methods filter for randomized controlled trials was used to identify RCTs (Cochrane, 2011). Search terms for Medline are included in table 2.1. Search terms were modified as required in order to optimally search each of the listed databases. Electronic database searches were supplemented by searching the reference lists of included articles and liaison with clinical and academic experts in the field of shoulder pain to check that any additional publications or grey literature had not been omitted.

Table 2.1: Systematic Review Search Terms

1	Shoulder Pain/
2	Shoulder Impingement Syndrome/
3	Rotator Cuff/
4	((shoulder* or rotator cuff) adj5 (bursitis or frozen or impinge* or tendinitis or tendonitis or pain*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
5	rotator cuff.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
6	adhesive capsulitis.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
7	capsular syndrome.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
8	exp Bursitis/
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10	exp Rehabilitation/
11	exp Physical Therapy Modalities/
12	exp Musculoskeletal Manipulations/
13	exp Exercise Movement Techniques/
14	(rehabilitat* or physiotherap* or physica therap* or manual therap* or exercise* or mobilis*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
15	10 or 11 or 12 or 13 or 14
16	exp Injections/
17	((steroid* or corticosteroid* or subacromial or sub-acromial) adj5 inject*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
18	Injections, Intra-Articular/

19	"joint inject*".mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
20	((corticosteroid or triamcinolone or lederspan or hydrocortisone or methylprednisolone or depo medro* or anti inflammat*) adj inject*).ab,ti.
21	16 or 17 or 18 or 19 or 20
22	clinical trial.pt.
23	random*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
24	((single or double) adj (blind* or mask*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
25	placebo*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]
26	22 or 23 or 24 or 25
27	9 and 15 and 21 and 26

2.3.6 Study Selection

Studies were selected on the basis of the criteria outlined in table 2.2. CM applied the selection criteria to the titles of publications retrieved by the search, retaining any ambiguous or unclear results for review at the abstract stage. CM repeated this process to ensure that potentially included studies were not excluded in error. At abstract stage, two reviewers independently reviewed each abstract: CM & DvdW (first half in alphabetical author order), and CM & JH (second half). A sample of 10 abstracts was triple reviewed (CM, DvdW, JH) to ensure consistency of application of the selection criteria. Full texts were subjected to data extraction, risk of bias assessment and methodological appraisal (see appendix 1) by CM &

DvdW. CM and JH conducted data extraction, risk of bias and methodological appraisal on publications where DvdW declared conflict of interest by authorship or collaboration.

Table 2.2: Selection Criteria for studies to be included in the review

Inclusion Criteria	Exclusion Criteria
RCT design	Non-RCT design
Adult human participants	Non-human or child participants
Musculoskeletal shoulder pains: Dysfunction, pain or symptoms in the glenohumeral region +/- surrounding soft tissue including but not limited to: soft tissue strains/sprains, tendonitis, bursitis, capsulitis	Traumatic shoulder pains e.g., fracture or dislocation
Comparison of one or more of the below against each other or any other intervention: (i) Advice, education and pain relief (delivered by G.P.) (ii) Manual therapy and/or strengthening and/or mobilising exercises delivered by a Physiotherapist or Physical Therapist (iii) Corticosteroid injection (+/- analgesia)	Comparison of any of the below exclusively against a control: (i) Advice, education and pain relief (delivered by G.P.) (ii) Manual and/or strengthening and/or mobilizing exercises delivered by a Physiotherapist or Physical Therapist (iii) Corticosteroid injection Non-steroid and/or analgesic injections e.g., hyaluronic acid
Any attempt at subgroup analysis	Failure to conduct any form of subgroup analysis
Outcome measured using multiple measures: Physical, functional or pain	Solely occupational/work function or absenteeism/presenteeism outcome measures
More than 20 participants in trial (minimum 10 per arm)	Less than 20 participants in trial (under 10 per arm)

2.3.7 Data Extraction

The data extraction and appraisal form was trialed using a publication that described a secondary data analysis of a large RCT in low back pain (UK BEAM trial, Underwood et al. 2007) and then amended to improve clarity and consistency. Data extracted included: inclusion criteria, primary outcome measures, follow-up periods, interventions studied, statistical methods used for moderation analysis, prognostic factors tested and findings of moderation analysis. The data extraction from included risk of bias assessment and assessment of methodological quality of moderation analysis.

2.3.8 Assessment of Bias

Bias is a systematic error or deviation from the truth in results or inferences (Cochrane, 2011). The Cochrane Risk of Bias (ROB) tool estimates the risk of systematic error in each included study in order to provide an estimation of the likelihood that the reported intervention effect is true, i.e., the extent to which the results of a study present a valid estimate. The Cochrane ROB tool is domain rather than scale based. Domain-based tools are preferable as they do not imply equal weighting of each domain or imply a cumulative effect (Higgins et al. 2011). Each of the seven questions pertaining to the five domains of bias are answered with “Yes, No or Unclear’ and scored separately, which allows assessment of the risk of bias for each specific domain.

Pilot application of the data extraction and methodological evaluation tools in the paper reporting the moderation analysis of the UK BEAM trial highlighted the shortage of detail regarding general trial methods in the moderation analysis paper, making it difficult to judge the RoB. Therefore original trial papers were accessed and subjected to ROB assessment for those studies that reported moderation analyses in a separate publication. Although this review focused on the analysis of moderation, the Cochrane RoB tool was used to assess the risk of systematic error in the original or full trials in which the moderation analyses were conducted. Explanation of the agreed meaning of each question including guidance notes for completion of each question was provided to authors prior to their independent completion of data extraction, risk of bias assessment and methodological appraisal (see appendix 2).

2.3.9 Assessment of Methodological Quality of Moderation Analysis

Assessment of bias may be distinguished from quality assessment, quality assessment suggests investigation of the extent to which study authors conducted their research to the highest possible standards (Cochrane, 2011). Assessment of moderation analysis may be conducted in a number of ways. Currently, two primary approaches to appraisal of moderation analysis exist (Pincus et al. 2011; Sun et al. 2010). For the purposes of this review, the quality of the moderation analysis conducted in included studies were assessed using criteria defined by Pincus et al. (Pincus et al. 2011). These criteria were chosen as they recommend a more conservative adjustment of the *p* value to take into consideration the risk of type I error (incorrectly rejecting the null hypothesis) when multiple moderators are

tested in a trial. Furthermore at the recommended minimum subgroup sample size of 20, the Pincus criteria attempts to minimise the risk of a type 2 error (incorrectly accepting the null hypothesis), where small sample size makes it more likely that a true effect will be missed (Pincus et al. 2011). The Pincus criteria produce a score that aligns with a judgement on the quality of the analysis providing an estimation of the level of moderation evidence. The tool contains 19 questions in total however only 5 criteria are considered when making a judgement on the overall level of moderation evidence. Each question is answered with a yes or no response. Each criterion is scored as either met or not met, resulting in a total score ranging from 0-5. A score of 5 out of a maximum 5 allows findings to be regarded as confirmatory evidence, while the presence of the final three criteria allow findings to be regarded as exploratory evidence (Pincus et al. 2011).

The 5 criteria considered when scoring each study for level of evidence for moderation are:

(i) *A priori* hypothesis It is agreed that *a priori* statement of hypotheses is vital in order to ensure adequate statistical power and to prevent subjecting the sample to the testing of every single potential moderator (Sun et al. 2011; 2012).

(ii) Theory or evidence-based selection of moderators to be tested The importance of testing potential moderators that are theoretically or evidence-based is founded upon the scientific ideal that hypotheses are “initially theory driven, then empirically confirmed, and finally clinically evaluated to establish their real-world existence” (Nicholson et al. 2005).

(iii) Measurement of moderators prior to randomisation Measurement of

moderators prior to randomisation ensures that potential presence of, or variance within moderators is similar among treatment groups.

(iv) Quality of measurement of baseline factors As moderation analysis can be highly prone to type 1 error (false positive, rejection of the null hypothesis when it should be accepted) when a large number of moderators are tested, as well as type 2 error (false negative, when the null hypothesis is accepted when it should have been rejected) due to insufficient statistical power (Good, 1983), measurement properties of all included variables must meet stringent levels of internal consistency and validity in order to protect against type I and II error. Risk of type I error and type II error is increased in moderation and subgroup analyses due to the effective sample size being reduced by only a proportion of the treatment arm sample matching the level of attribute being tested (e.g., females receiving physiotherapy treatment).

Evidence of validity and reliability of the measures used to assess potential moderators allows us to gauge whether the measurement error of the instrument is likely to be sufficiently small to detect the differences between sub-groups (or predictive value of moderators) that are likely to be important. For the purposes of this review, simple and common clinical constructs such as age, gender, treatment preference etc., which are commonly observed and easily understood are not required to demonstrate validity and responsiveness data. More complex clinical observations or measures, tools or scales require presentation of validity and responsiveness data (e.g. questionnaires to assess psychological factors; physical examination tests).

(v) Explicit test of interaction between moderators and treatment A statistical test for interaction between a baseline factor and treatment is required in order to test whether the difference in treatment effect between subgroups is statistically significant, or a moderator has a statistically significant association with treatment effect (Brookes et al. 2001).

2.3.10 Evidence Synthesis

Studies included in this review were divided into two groups: (i) studies with formal moderation or subgroup analysis that constituted the main purpose of the publication, and (ii) studies that suggested potential moderators of treatment effect without formal analyses. Formal and valid moderation analysis in a randomized controlled trial generally consists of stratified or subgroup analysis defined *a priori* in the trial protocol, ideally powered to detect significant differences with presentation of treatment effects for categories of the potential moderator (Brookes et al. 2001; Hingorani et al. 2013). Testing of significance of the subgroup effect (moderation) is generally carried out using regression analysis by adding a 'moderator * treatment' interaction term to the regression model, which also includes the treatment and predictor variable) (Hingorani et al. 2013). The results of this review are presented in two parts. Description and results of studies that conducted a formal analysis of potential treatment moderators are presented separately to studies that make reference to potential treatment moderators but did not formally analyse potential treatment moderators. Assessment of risk of bias and quality appraisal was conducted only on studies that had conducted moderation analysis. In the studies without moderation analysis, the results

regarding proposed potential moderators were narratively synthesized and were not subjected to Cochrane Risk of Bias assessment or moderation methodological critique, as these studies do not provide empirical evidence of moderation. A meta-analysis or meta-regression was not possible because of the substantial differences in patient population, settings, interventions, and outcomes used.

2.4 Results

A PRISMA flow diagram (Moher et al. 2009) of this systematic review is presented in figure 2.1 below. Electronic database searches identified a total of 1675 citations. After the removal of duplicates, titles of the 1081 citations were screened against the criteria outlined in table 2.2 and 702 studies not pertaining to the purpose of this review were removed. After two reviewers independently applied the selection criteria, and consensus was reached, a further 293 studies were removed. Eighty-six full texts were read and 21 articles were deemed to be relevant by both reviewers. Screening of the reference lists of relevant papers and all published Cochrane reviews in the field identified seven further articles, one of which was included in the review. In total 22 studies are included in this review. Studies were presented into two groups: (i) studies formally evaluating moderation and (ii) studies suggesting potential moderators. Table 2.3 outlines the design of each of the included studies that have conducted a formal analysis of potential treatment moderators. Data on inclusion and exclusion criteria, primary outcome, follow-up, interventions studies and treatment duration are presented. Table 2.4 details the moderation analysis design of each study listed in table 2.3.

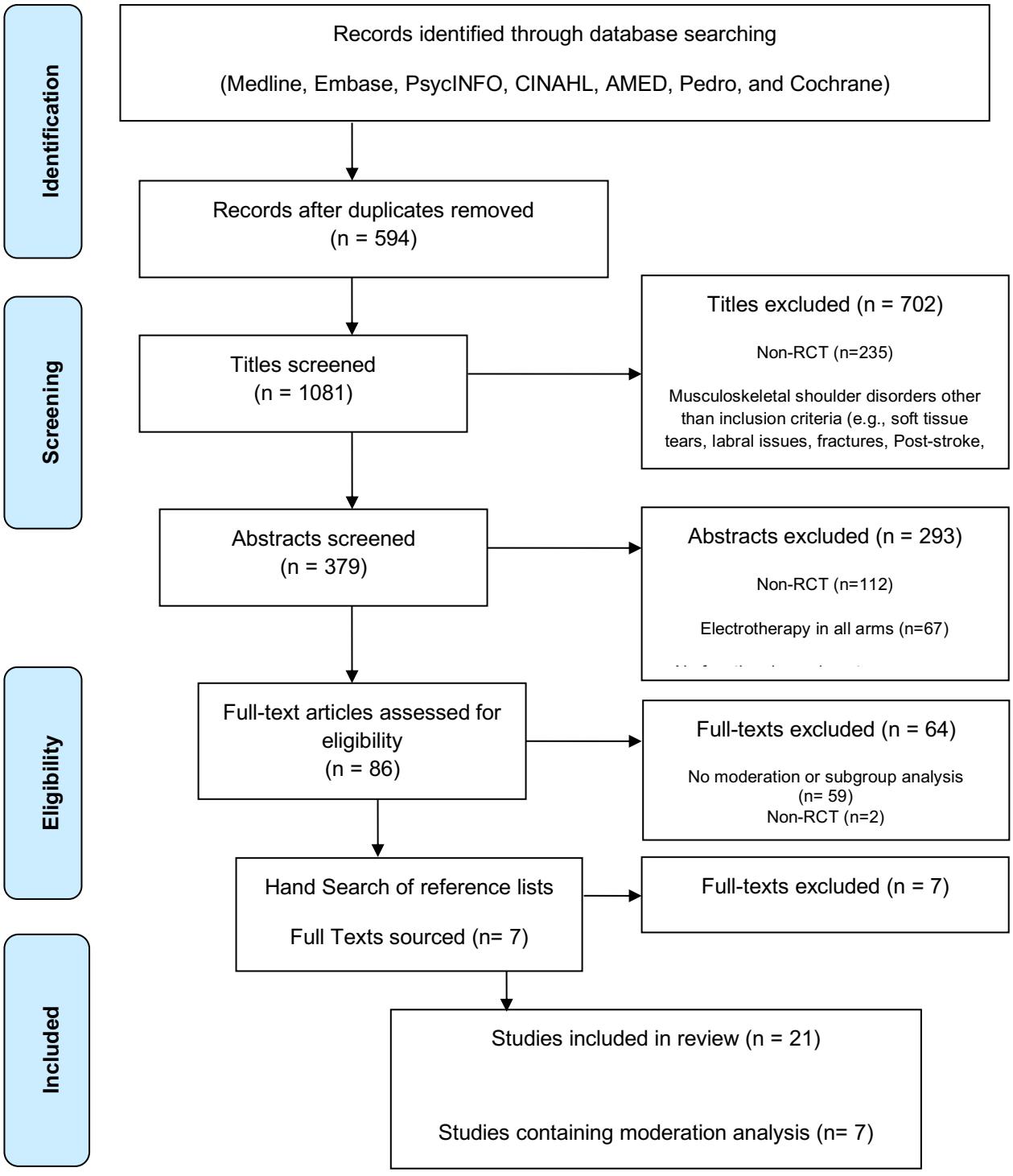


Figure 2.1: PRISMA Systematic Review Flow Chart

Table 2.3: Description of Studies Containing Moderation Analysis

Author, Date, Setting, Country	Inclusion Criteria	Primary Outcomes	Follow-Up	Interventions Studied
Geraets et al. 2005, Primary Care, Netherlands	Chronic shoulder complaints > 3 month duration, living in Limburg, the Netherlands	Main Complaints Instrument, Shoulder Disability Questionnaire (SDQ), Perceived recovery (yes/no)	12/52	Up to 18 graded exercise therapy sessions (60mins) during 12 weeks Usual care as per the Dutch College of General Practitioners
Hsu et al. 2011, Long-term care home residents, Canada	> 50 years; self-reported impairments or bothersome symptoms of the upper extremity limiting function	Nursing Home Physical Performance Test (NHPPT), modified Physical Activity Enjoyment Scale (PACES), Numeric Rating Scale (NRS), active ROM, Global Perceived Rating of Change (GPRC)	4/52	Standard exercise regimen 20 min simulated bowling video game via the Nintendo Wii gaming system plus standard exercise regimen, twice weekly
Thomas et al. 2004, Primary Care, UK	Patients consulting with an episode of unilateral shoulder pain	Shoulder Disability Questionnaire (SDQ)	6/52, 6/12	Up to 8 20 min. physiotherapy sessions (exercise, manual therapy) (20mins) during 6 weeks One local corticosteroid injection
van der Windt et al. 2000, Primary Care, The Netherlands (Secondary	Patients who consulted their general practitioner (GP) for a painful stiff shoulder were considered for participation	General improvement, Main complain severity, Pain, Functional disability	3/52, 7/52 post treatment, 3/12, 6/12, 12/12 post randomisation	Up to 3 intra-articular 40 mg triamcinolone acetonide injections during 6 weeks 6 week physiotherapy programme (joint mobilisation, exercise)

Analysis of van der Windt, 1998)				
Zheng et al. 2005, Primary Care, Netherlands (Secondary Analysis of van der Windt, 1998)	Painful restriction of glenohumeral mobility, aged >18 years	General improvement according to the patient, severity of main complaint, pain, and functional disability	3/52, 7/52 post treatment, 3/12, 6/12, 12/12 post randomisation	Up to 3 40 mg tri-amcinolone acetonide intra-articular injections during 6 weeks Physiotherapy (6 weeks) (joint mobilization, exercise)
Yang et al. (Man. Ther.), 2012, Secondary Care, Taiwan	Shoulder complaints > 3 months & > 50% loss of passive range in 2 or more of: forward flexion, abduction, or external rotation in neutral); and >3 months complaint duration	Shoulder ROM, disability assessment (FLEX-SF), Shoulder complex kinematics (FASTRAK motion analysis system)	4/52, 8/52	Control and criteria-control groups: passive mobilization & stretching techniques, electrotherapy modalities, and active exercises, twice weekly, 3 months. End-range mobilization/scapular mobilization treatment approach (EMSMTA): control treatment PLUS mobilization and scapular mobilization, twice weekly, 3 months.
Yang et al. (BMC), 2012, Secondary Care, Taiwan	Patients with glenohumeral internal rotation limitation & tightness in posterior shoulder region	Glenohumeral ROM and muscle tightness measurements of posterior deltoid, infraspinatus, and teres minor muscles	4/52	Massage on the posterior deltoid, infraspinatus, and teres minor, 18 mins, twice weekly for 4 weeks Placebo Control: Light hand touch on the muscles, 10 mins, twice weekly for 4 weeks

Table 2.4: Results of Moderation Statistical Analysis

Author, Date	Prognostic Factors Tested as Potential Moderators	Moderation Statistical Analysis Methodology	Moderation Findings Reported	Level of Moderation Evidence (from Table 2.5)
Garaets et al. (2005)	Passive range of external rotation, active range of abduction/elevation, and presence of painful arc, anxiety, depression, somatisation, distress, treatment preference	On outcomes, main complaint instrument and shoulder disability questionnaire, multiple linear regression analyses with stepwise forward procedure ($p < 0.10$) tested influence of prognostic factors and post-randomisation differences between groups. Regression coefficients adjusted for interaction between treatment and painful arc at baseline and change in pain intensity.	**Painful arc**: Less improvement in the shoulder disability questionnaire scores with graded exercise therapy in patients with a painful arc at baseline.	Confirmatory
Hsu et al. (2011)	N/A	Outcomes analysed by group with Student's t-test or Wilcoxin's sign-rank test for paired samples. A subgroup analysis was performed to identify baseline patient attributes that could discriminate between responders and non-responders to the Wii intervention.	**Shoulder & hand complaints**: Responders to Wii intervention more likely to have shoulder symptoms & hand symptoms	Insufficient
Thomas et al. (2004)	Treatment preference	Demographic and baseline clinical attributes were compared across the three groups of pre-randomisation treatment preference (no preference, preference for physiotherapy, preference for injection). The relationship of pre-randomisation treatment preference and functional outcome was examined within three groups: those with no treatment preference, those who received preferred treatment, and those who did not receive preferred	**Treatment preference:** Outcome was not affected by having preference or whether preference was met.	Insufficient

		treatment.		
van der Windt et al. (2000)	Treatment preference	All patients disclosed treatment preferences before randomisation. Exploratory subgroup analyses compared treatment success rates across 6 subgroups: 3 groups relating to those who received injection (patients receiving their preference, patients who did not receive their preference, patients without a preference) and 3 groups for those who received physiotherapy (patients receiving their preference, patients who did not receive their preference, patients without a preference).	**Patient preference**: Allocation of preferred treatment moderates treatment effect for injections but not physiotherapy	Insufficient
Xheng et al. (2005)	Age, gender, pain duration of the current episode, previous trauma, previous episode of shoulder pain, overuse of shoulder due to usual activities and overuse of shoulder due to unusual activities preceding shoulder pain	Analyses performed in three steps: (i) Principal components analysis (PCA) and cluster analysis used to classify patients into persistent-recurrent and recovery groups. (ii) Asymptotic regression models used to fit the shoulder pain recovery profiles; estimates of three parameters were included in the models: pain severity at baseline, pain severity at week 52, and logarithm of the decline rate of pain severity over time (recovery rate). (iii) Covariates, such as age, gender, pain duration of the current episode, previous trauma, previous episode of shoulder pain, overuse of shoulder due to usual activities and overuse of shoulder due to unusual activities preceding shoulder pain, and type of treatment (an indicator variable, 1 for injection and 2 for physiotherapy) examined to explain between-patient variations using univariate regression analysis.	**Age**, **gender**: In the injection group (mostly younger than 60 years old and male), pain severity reduced faster than in those treated with physiotherapy.	Insufficient
Yang et al. (2012) (Man. Ther.)	Scapular orientation relative to thorax: rotation about protraction/retraction (Z°s), rotation about downward/upward rotation (Y°s), and rotation about posterior/ anterior tipping (X°s)	All subjects had at least 50% loss of passive shoulder movement of the shoulder joint, in 2 or more of 3 directions and complaints for >3 months. Baseline variables compared between groups using independent analysis of variance (ANOVA) tests. Testing for a difference of treatment efficacy among the control, criteria control and criteria intervention groups and controlling for baseline differences between groups, 2-factor ANCOVA mixed models with the initial outcome data as covariate and factors of group and time (follow-up data at 4 and 8 weeks) performed on all outcomes.	**8°scapular posterior tipping, 97° humeral elevation, and 39° humeral external rotation during arm elevation** moderated ROM and shoulder kinematics improvements following	Insufficient

			standardized treatment	
Yang et al. (2012) (BMC)	Sex, age, BMI, duration of symptoms, glenohumeral internal rotation, muscle tightness in each muscle, and FLEX-SF score	2-factor ANOVA mixed models with factors of treatment group and time (initial and 4 weeks) performed on each outcome to test for a difference of treatment efficacy. Potential predictors for massage treatment evaluated by comparing responders versus non-responders with chi-square or t test. Predictor variables with a p-value ≤ .10 entered into a logistic regression model. Variables with least predictive value removed one by one, in a backwards, stepwise fashion until all predictors in the model had p-values ≤ 0.05.	**Less baseline symptom duration, muscle tightness & shoulder function** in responder group	Insufficient

2.4.1 Characteristics of Studies Formally Evaluating Moderation

Of the 21 studies included in this review, seven studies formally evaluated moderation, as outlined in Table 2.1. These were conducted in a variety of settings: four studies were set in primary care, three in the Netherlands and one in the UK. Two studies were set in secondary care in Taiwan, and one in a long-term care home in Canada. Diagnoses of included trial participants in this review varied greatly: three studies involved patients with chronic shoulder pain, one study involved patients with shoulder pain, one study painful stiff shoulder, one study unilateral shoulder pain, and one study upper limb disorder. Interventions studied were wide-ranging: Seven studies examined a form of physiotherapy or exercises (mobilising, stretching or strengthening exercises, joint mobilisations or soft tissue massage, three studies trialed corticosteroid injection and one study examined electrotherapy (pulsed ultrasound, short wave diathermy, laser and radial extracorporeal shockwave treatment). Regarding outcomes tested for the moderation analysis: all seven studies used outcomes for function, disability, and/or work whilst three used visual analogue scales (VAS) for pain, however, different instruments were used to assess function or disability.

2.4.2 Risk of Bias

Risk of bias was assessed using the information presented in the included publications (figure 2.2). In the cases where moderation analysis was presented in a separate article and additional information was required to judge risk of bias, the primary trials or protocols were sourced. The Cochrane Risk of Bias tool (Higgins

et al. 2011) identified four trials with minimum risk of bias (Geraets et al. 2005; Hay et al. 2003; Hsu et al. 2011; Yang 2012a). The remaining three trials demonstrated some potential for bias. Van der Windt et al. (1998) and Zheng et al. (2005) (separate analysis of the same trial) demonstrated potential for selection bias and attrition bias as the attrition rate and sequence generation methods were not reported. Furthermore as only one subgroup analysis was reported and long-term data not presented by either van der Windt et al. (2000) and Zheng et al. (2005), there is potential for selection reporting bias as presence or absence of moderating effect of the other baseline patient attributes is unclear. Yang et al. (2012b) demonstrated potential for bias in attrition and selective reporting by failing to present reasons for attrition and for only presenting incomplete short-term data.

2.4.3 Quality Appraisal of Statistical Methods for Moderation

Moderators may be conventionally identified through testing of the interaction between a prognostic factor and the treatment variable (Baron & Kenny, 1986; Gartsman et al. 1998), and/or through *a priori* defined subgroup analyses. However this review has identified a variety of methods of identifying potential moderators of treatment effect. Table 2.4 outlines the approaches taken to identify potential moderators of treatment effect in studies included in this review. Table 2.5 shows how each of the studies performed when considered against the Pincus criteria (Pincus et al. 2011) for the identification of moderators.

Figure 2.2: Review authors' judgments about each risk of bias item for studies containing moderation analysis

Table 2.5: Methodological Assessment of Moderation Analysis (as per Pincus et al. 2011)

Study	*A priori* Hypothesis	Theory and/or Evidence driven hypothesis	Moderators measured prior to randomisation	Valid and reliable baseline and process factors	Explicit test of interaction	Total Score	Level of Moderation Evidence
Garaets (2005)	Yes	Yes	Yes	Yes	Yes	5	Confirmatory
Hsu (2011)	No	No	Yes	Yes	No	2	Insufficient
Thomas (2004)	Yes	Yes	Yes	Yes	No	4	Insufficient
van der Windt (2000)	No	No	Yes	Yes	No	2	Insufficient
Xheng (2005)	Yes	Yes	Yes	Yes	Unclear	4	Insufficient
Yang (2012) (Man. Ther.)	Yes	Yes	Yes	Yes	No	4	Insufficient
Yang (2012) (BMC)	No	No	Yes	Yes	No	2	Insufficient

Levels of Moderation Evidence:

Confirmatory Evidence: All 5 items met;

Exploratory Evidence: Final 3 items met;

Insufficient Evidence: Failure to meet final 3 items

One of the seven studies, only Geraets et al. (2006) demonstrated 'confirmatory' evidence of moderation of the effect of graded exercise treatment by presence of painful arc. On methodological grounds, all other trials included in this review demonstrated insufficient evidence of moderation of treatment effect. Aside from Geraets *et al.* (2006), the six other trials included in this review (Hsu et al. 2011; Thomas et al. 2004; van der Windt et al. 2000; Yang et al. 2012a; Yang et al. 2012b; Zheng et al. 2005) lacked a specific test of interaction between the moderator and treatment. In addition to lacking a specific test of interaction, three trials (Hsu et al. 2011; van der Windt et al. 2000; Yang at al. 2012b) also lacked a description of the theory or evidence based hypotheses of moderation. All trials demonstrated measurement of moderators prior to randomisation using valid and reliable measurement tools. This review identified a variety of methods of identifying potential moderators of treatment effect. Only one study (Geraets et al. 2005) followed the conventional method of identifying moderators of treatment effect by testing the interaction between a known predictor of outcome and the treatment variable and subsequent presentation of subgroup effects (Baron & Kenny, 1986; Kraemer et al. 2002).

2.4.4 Results of studies investigating moderation

One study Geraets *et al.* (2006), demonstrated that painful arc moderates graded exercise therapy with confirmatory level evidence as per the Pincus criteria (Pincus et al. 2011). Five studies (Hsu et al. 2011; Thomas et al. 2004; Yang et al. 2012a; Yang et al. 2012b; Zheng et al. 2005) identified moderators with insufficient evidence as they did not explicitly test the interaction between the potential

moderator and the treatment. Moderators of treatment effect with insufficient evidence include: treatment preference, age, gender, symptom duration, muscle tightness and shoulder function (Thomas et al. 2004; van der Windt et al. 2000; Yang et al. 2012a; Yang et al. 2012b). Many moderators were examined in one study only.

2.4.4.1 Painful Arc

In a trial of graded exercise therapy compared with usual care in patients with shoulder pain lasting longer than three months Geraets et al. (2006) demonstrated that the presence of a painful arc at baseline was associated with the effect of graded exercise therapy on outcome (disability reduction). A regression model adjusted for presence of painful arc indicated that graded exercise therapy was more effective in patients without a painful arc. In patients receiving graded exercise therapy, reduction in shoulder disability (SDQ) score for graded exercise compared with usual care was lower in the subgroup with a painful arc (-0.2) compared with the subgroup without a painful arc (7.3) (standard deviation data not published). As demonstrated in table 2.4, Geraets et al. (2006) employed a methodologically sound approach to moderation analysis by pre-specifying *a priori* hypotheses that are evidence/theory based, measured the moderator before randomisation, used adequate instruments to assess outcome measures, and conducted an explicit test of interaction between the moderator and treatment. This study provides confirmatory evidence that painful arc moderates outcome of graded exercise therapy (table 2.5).

2.4.4.2 Gender

Zheng et al. (2005) conducted subgroup analysis based on gender that showed with an insufficient level of moderation evidence that gender demonstrates potential to moderate the effect of joint injection in patients with a painful, stiff shoulder. When treated with corticosteroid injection (compared with physiotherapy), male patients attained faster recovery than females.

2.4.4.3 Treatment Preference

Two studies identified treatment preference as a potential moderator of treatment effect with insufficient level of moderation evidence (Thomas et al. 2004; van der Windt et al. 2000). Thomas et al. (2004) examined the relationship between pre-randomisation treatment preference and functional outcome within the preference groups: those with no treatment preference, those who did receive their preferred treatment, and those who did not receive their preferred treatment. Outcome was not affected by whether preference was met or not (good outcome in those receiving preferred treatment = 56%; not receiving preferred treatment = 69%) and outcome was similar in spite of treatment allocation (good outcome in those receiving preferred treatment = 55% injection, 58% physiotherapy; not receiving preferred treatment = 71% injection, 68% physiotherapy). Therefore treatment preference did not moderate outcome of either steroid injection or physiotherapy in patients with unilateral shoulder pain in this trial, although interaction between treatment preference and treatment was not explicitly tested.

Although supportive of results by Thomas et al. (2004), the study by van der Windt (2000) also constituted insufficient evidence to identify treatment preference as a moderator of outcome. Van der Windt et al. (2000) employed comparative subgroup analysis on patient preference for treatment and success rate of treatment (complete recovery or considerable recovery) on a randomised controlled trial comparing the effects of corticosteroid injections and physiotherapy for patients with a painful stiff shoulder. Treatment preference for joint injection was associated with higher recovery success rate following injection, while this pattern was not observed for physiotherapy. Although this subgroup finding suggests a moderation effect, the association between treatment preference and treatment was not tested.

2.4.4.4 Age

One study in this review examined a potential moderating effect of age on treatment effect. Zheng et al. (2005) found that in patients who were younger than 60 years of age, symptom severity reduced faster in the group of patients who received injection compared with those who received physiotherapy. Thus, age appears to have potential to moderate the effect of joint injection in patients with a painful, stiff shoulder, however the interaction between age and treatment was not specifically tested, providing insufficient level of moderation evidence.

2.4.4.5 Symptom Duration, Muscle tightness & Shoulder Function

One study (Yang et al. 2012a) showed using logistic regression analysis that

duration of symptoms, shoulder function (FLEX-SF score), and muscle tightness (posterior deltoid slope) correlated with outcome in the massage group ($p < 0.05$). However, predictors of response were analysed in the massage group only, therefore it is not known if these factors also predict outcome of the placebo massage or any other intervention. Therefore this study provides insufficient evidence of moderation. A further study by Zheng et al. (2005) examined all covariates including pain duration, however pain duration was not significant in univariable analysis and therefore not carried forward into multivariable prognostic models.

2.4.4.6 Specific Degrees of Shoulder Range of Movement

One study (Yang et al. 2012b) used 2-factor ANCOVA mixed models to show that patients who met the criteria of < 8° scapular posterior tipping, 97° humeral elevation, and 39° humeral external rotation during arm elevation had improvements when they received end-range mobilization/scapular mobilization treatment approach (EMSMTA) plus standard treatment, but similar patients did not improve when receiving standard treatment alone. However, this study did not test for a specific interaction between meeting the criteria and treatment. Despite concordance with the Pincus criteria in all four other criteria (table 2.5), there is insufficient evidence to confirm 8° of scapular posterior tipping, 97° of humeral elevation, and 39° of humeral external rotation during arm elevation as moderators of EMSMTA outcome.

2.4.4.7 Hand Complaint

One study Hsu et al. (2011) conducted a trial of standard exercise and standard exercise plus Nintendo Wii shoulder flexion exercises in residents of long-term care with an upper extremity dysfunction. Hsu identified a subgroup of responders to the Wii intervention. Responders were more likely to report hand complaint ($X^{2=}6.35$; p=0.012) at baseline compared to non-responders. As Hsu et al. only conducted subgroup analysis for one intervention group, this study did not hypothesise that there would be a differential treatment response or conducted a specific test of interaction between potential moderator and treatment. It is therefore not possible to ascertain whether responders and non-responders to the standard treatment group would have been similar to the Wii group. Therefore this study meets two of the five Pincus criteria, providing insufficient evidence of moderation of treatment effect.

All results on moderators of treatment effect identified in the review are caveated by the observation that only Zheng et al. (2005) actually use the term treatment effect modifier. All other studies did not mention moderation analysis, moderators, treatment effect modification, or treatment effect modifiers.

2.4.5 Results of Studies Suggesting Suggesting Moderation (Not Formally Reviewed)

This review identified 14 additional studies that suggest or consider factors that may be moderators of a treatment effect in shoulder patients. As explained in the

methods (paragraph 2.3.10) these studies were not included in table 2.4, and not subjected to Cochrane Risk of Bias assessment or methodological appraisal. Table 2.6 outlines the 14 studies that suggest potential moderators. Study setting, interventions and suggested potential moderators are indicated and suggested potential moderators are marked with 'A', 'B' or 'C'. 'A' indicates a study that reported exploratory subgroup findings without clear presentation of the methods and results of these analyses, 'B' indicates a study that reported prognostic factors or potential confounders but without moderation or subgroup analysis and 'C' indicates a study that narratively suggests potential moderators in the discussion of the trial findings.

2.4.6 Studies Reporting Exploratory Subgroup Analysis Without Sufficient Methodological Detail

Hay et al. (2003) conducted a trial of physiotherapy and joint injection in patients with a new episode of unilateral shoulder pain. Hay et al. included gender, age, symptoms duration, shoulder restriction, painful arc and neck restriction in exploratory subgroup analyses. No significant subgroup effects were found and data from the subgroup analyses were not shown, limiting methodological critique and assessment of potential for moderation effects.

2.4.7 Studies Reporting Prognostic Factors or Potential Confounders but Without Moderation or Subgroup Analysis

Four studies (Arslan & Celiker, 2001; Bron et al. 2011; Crawshaw et al. 2010; Engebretsen et al. 2009) explored the prognostic value of baseline patient attributes, without investigating whether these factors moderated the effects of treatment. Factors included baseline symptom duration (Arslan & Celiker, 2001), number of muscles with active trigger points, passive shoulder range of movement and baseline DASH score (Bron et al. 2011), baseline pain and disability scores (Crawshaw et al. 2010), and gender (Engebretsen et al. 2009).

Table 2.6: Results of Studies Suggesting Potential Moderators

Author, Date, Setting, Country	**Inclusion Criteria**	**Primary Outcomes**	**Follow-Up**	**Interventions Studied**	**'Potential Moderators' Suggested**
Abdelshafi, 2011, Rheumatology & Rehabilitation Out-Patient Depts., Egypt	Chronic shoulder pain > 3 months duration, unresponsive to conventional treatment	Active and passive ROM, Shoulder pain and disability index (SPADI)	1/52, 4/52, 12/52	Rehabilitation program only (Exercises, Ultrasound, Short Wave), three times weekly, duration unclear Continuous supra-scapular nerve block (SSNB) under ultrasound guidance in addition to rehabilitation program, three times weekly, duration unclear Intra-articular corticosteroid injection in addition to rehabilitation program	In those who received SSNB, having a **diagnosis of rheumatoid arthritis (B)** was associated with improvement in pain (p= 0.018) and pain and disability (p=0.018 & 0.04) and **having frozen shoulder (B)** was associated with improvement in pain and disability (SPADI) (p=0.02)
Arslan, 2001, Dept Physical Medicine & Rehabilitation, Turkey	Total range of motion <50%	ROM, Pain VAS	2/52, 12/522	Local corticosteroid injection Physiotherapy and a non-steroidal anti-inflammatory drug	Analysis stratified by **baseline symptom duration (B)** but no differences were found

Bennell, 2010	Chronic rotator cuff disease	Shoulder pain and disability index (SPADI), Pain VAS, Participants' perceived global rating of change overall	11/52, 22/52	10 active treatments comprised a manual therapy and home exercise programme, 10 weeks 10 Placebo treatment comprised inactive ultrasound therapy and application of an inert gel, 10 weeks	Whether **pain, dysfunction, or both are the patients primary problems (C)** may help indicate what kind of treatment is appropriate **(C)**
Bron, 2011, Primary Care, Netherlands	Unilateral non-traumatic shoulder pain for > 6 months, aged 18 and 65 years	Passive ROM, Number of trigger points, Disabilities of the arm and shoulder (DASH), Quality of life (RAND-36), Beck Depression Infantry (BDI-II)	6/52, 12/52	Intervention Group (Trigger point release, intermittent ice application, stretching exercises), weekly up to 12 weeks Wait-and-See	**No. of muscles with active trigger points (B), Passive ROM (B), Baseline Disability (DASH) (B)**
Carette, 2003, Out-patient Rheumatology clinics, Canada	Adhesive capsulitis of <1 year's duration	Shoulder pain and disability index (SPADI), quality of life (SF-36), Active and passive ROM	6/52, 3/12, 6/12, 12/12	All patients were taught a simple, 10-minute exercise program and randomized into 1 of 4 groups: Corticosteroid injection followed by supervised physiotherapy) Corticosteroid injection alone Saline injection followed by supervised	**Pain at rest, pain frequency, pain on movement, night pain and joint end-feel (C)** implied as different treatment provided for acute and chronic patients

				physiotherapy Saline injection alone	
Crawshaw, 2010, Primary Care, UK.	Adults >40 years with sub-acromial impingement syndrome, moderate or severe shoulder pain	Shoulder pain and disability index (SPADI)	12/52	Injection plus exercise Exercise only, up to 12 weeks	Baseline **pain and disability** score **(B)**, baseline **pain VAS (B)**
Dickens, 2005, Secondary Care, UK.	Subacromial impingement syndrome	Constant Score	6/12	Physiotherapy (individualised treatment), < 6 months Control (No treatment)	Younger **age (C)**, higher **baseline disability** (Constant) score **(C)**
Diercks, 2004, Secondary Care, Netherlands	Idiopathic frozen shoulder syndrome	ROM: Forward elevation, lateral elevation, external & internal rotation.	3/12, 6/12, 9/12, 12/12, 15/12, 18/12, 21/12, 24/12	Intensive physical rehabilitation treatment (stretching group), 2 X 45 min. exercise sessions weekly, up to 12 weeks Supportive therapy and exercises within the pain limits (supervised neglect group)	**Stage of Frozen Shoulder (C)**
Engebretsen, 2009, Outpatient	Subacromial shoulder pain lasting at least	Shoulder pain and disability index	6/52, 12/52,	Supervised exercise regimen, 2 X 45 min. exercise sessions weekly, up to 12 weeks	**Gender** (adjusted for in regression and analysis stratified for gender) **(B)**

physical medicine and rehabilitation, Norway	three months	(SPADI)	18/52	Radial extracorporeal shockwave treatment (REST), weekly for 4-6 weeks	
Gialanella, 2011, Secondary Care, Italy	Full thickness rotator cuff tears	Constant–Murley scale, Pain VAS	3/12, 6/12	Single intra-articular injection Two injections at 21-day intervals No treatment (control group)	**Failure of conservative treatments**, increasing **night pain**, **acute or inflammatory stages of disease (all C)**
Hay, 2003, Primary Care, UK	Those > 18 years, consulting general practitioner with new episode of unilateral shoulder pain	Shoulder disability questionnaire (SDQ)	6/52, 6/12	Corticosteroid injections Community based physiotherapy, up to 8 20 min sessions in 6 weeks	**Age, sex, symptom duration**, **shoulder restriction, painful arc of movement, restricted neck movements (all A)**
Pajareya, 2004, Rehabilitation Dept, Thailand.	Shoulder pain, limitation of passive ROM, interference with activities of daily living	Shoulder pain and disability index (SPADI), ROM,	3/52	Ibuprofen Ibuprofen and physical therapy, 3 times weekly, 3 weeks	**Patient treatment preference (C)**
Petri, 1987, Veterans Screening &	Painful abduction, painful arc**, or**	Active and passive ROM, presence of painful arc, whether	2/52, 4/52	1) subacromial bursa injection with 4 cc of 1% lidocaine, plus naproxen	**Symptom duration (C), pre-treatment clinical index (C)**

Rheumatology Clinics, USA	tenderness over the supraspinatus insertion	shoulder pain was exacerbated by resisted internal or external rotation pain VAS, limitation of function		2) subacromial bursa injection with 3 cc of 1%lidocaine and 1cc of 40 mg/ml triamcinolone, plus naproxen 3) subacromial bursa injection with 3 cc of 1% lidocaine and 1 cc of 40 mg/ml triamcinolone, plus placebo pill 4) subacromial bursa injection with 4 cc of 1% lidocaine, plus placebo pill	
Ryans, 2005, Primary Care, UK	Adhesive capsulitis	SF-36, Hospital Anxiety and Depression Scale (HADS), Active and passive ROM, Shoulder Disability Questionnaire (SDQ)	6/52, 16/52, 24/52	1)Intra-articular triamcinolone injection 2) Physiotherapy, 8 session, 4 weeks 3) Injection plus physiotherapy 4) Saline injection alone	**Baseline disability (C)**

A = Exploratory Subgroup Analysis

B = Prognostic factors or potential confounders but not tested as moderator

C = Attributes mentioned or discussed as potential moderators but not tested in a way as a moderator

2.4.8 Studies Suggesting Potential Moderators in the Discussion of Trial Findings

In addition, to obtain the broadest and most inclusive approach to the identification of potential moderators of treatment effect, suggestions regarding potential moderators were extracted from other studies included in this review (Table 2.6). These studies used a variety of methods suggestive of potential moderation including: using factors as potential confounders or prognostic factors (without formal moderation analysis), conducting exploratory subgroup analyses without reporting full methods or results for these analyses or making untested or supported suggestion(s) or observation(s) regarding potential moderators based on their trial (e.g. in the discussion section of the paper). Table 2.6 outlines study inclusion criteria, primary outcomes, follow-up, interventions studied, treatment duration and details the potential moderators suggested. Studies listed in table 2.6 were not subjected to risk of bias assessment or methodological critique for moderation analysis as no formal tests of moderation were conducted. Suggestions are briefly summarised narratively in the results section of this review.

Seven studies (Bennell et al. 2010; Carette et al. 2003; Diercks & Stevens, 2004; Gialanella & Prometti, 2011; Pajareya et al. 2004; Ryans et al. 2005), made narrative suggestions regarding potential moderators of outcome in the discussion section of their paper on the basis of their trial findings. Authors suggested that potential confounding variables, unevenly distributed across groups at baseline, may have influenced their study results, and might potentially be associated with different treatment effects. Studies from which these suggestions arise are

outlined in table 2.5 and ‘C’ denotes patient variables discussed as potential moderators in table 2.6.

Suggested potential moderators of the effects of physiotherapy treatments include: presence of pain, dysfunction or pain and dysfunction (Bennell et al. 2010), pain at rest, pain frequency, pain on movement, night pain and joint end-feel (Carette et al. 2003), age (Dickens et al. 2005), stage of frozen shoulder (Diercks & Stevens, 2004), baseline disability (Ryans et al. 2005). Suggested potential moderators of the effects of steroid injection include: presence of pain, dysfunction or pain and dysfunction (Bennell et al. 2010), pain at rest, pain frequency, pain on movement, night pain and joint end-feel (Carette et al. 2003), baseline disability (Ryans et al. 2005), failure of other conservative treatments, increased resting or night pain, in acute or inflammatory stages of disease (Gialanella & Prometti, 2011), treatment preference (Petri et al. 1987), symptom duration and pre-treatment clinical index (Pajareya et al. 2004). Suggested potential moderators of the effects of pain relief and analgesic agents include: presence of ‘pain, dysfunction or pain and dysfunction’ (Bennell et al. 2010), symptom duration and pre-treatment clinical index (Pajareya et al. 2004).

2.5 Discussion

2.5.1 Brief Summary of Findings

This review aimed to systematically identify moderators or potential moderators of the effects of three commonly used treatments in primary care: advice and pain relief, strengthening and/or mobilising exercise delivered by a physiotherapist, and corticosteroid injection in patients with musculoskeletal shoulder pains. Seven relevant randomised controlled trials that included an evaluation of potential treatment moderators, and 14 trials that included suggestions regarding potential moderators, but did not formally investigate these, were identified. Only one study provided a methodologically valid and statistically confirmed moderator of treatment effect: the presence of a painful arc led to significantly less disability reduction with graded exercise therapy than in patients without a painful arc. Affected by methodological issues, 12 other potential moderators of outcome supported by exploratory level evidence were identified by six other studies in this review. Table 2.7 summarises the findings of this review.

2.5.2 Methodological Issues Identified

This review highlights many potential methodological and statistical pitfalls in identifying moderators of treatment effect, including the importance of *a priori*, evidence-based hypotheses, adequate statistical power, and crucially the importance of testing interaction between the potential moderator and treatment. Although it is accepted that interactions between potential moderators and outcome are likely to be statistically insignificant due to the original trials being

underpowered to detect moderators of treatment effect. Pincus et al. (Pincus et al. 2011) recommend less than 5 *a priori* subgroup hypotheses in order to minimise the risk of type 1 error (i.e. incorrectly rejecting a null hypothesis of no moderation). Furthermore, recommendation of (i) *a priori* hypothesis and (ii) evidence or theory-based hypothesis in the moderation methodological assessment criteria (Pincus et al. 2011) encourage development of clinically relevant, plausible hypotheses. In line with such increasing risk of type 1 error, application of the more conservative *p* value, $p < 0.01$ is recommended when testing more than three hypotheses (Turner et al. 2007). All studies identified by this review failed to adhere to this recommendation. Adjustment of *p* values should be considered in future moderation analyses.

This review demonstrates that suggestion of moderation or moderators occurred post-hoc or as secondary analysis in many of the trials in Table 2.4. Therefore, it is important to highlight that post hoc moderation or sub group analyses are especially prone to error due to multiplicity or insufficient sample sizes (Sleight, 2000). Pincus et al. (2011) updated the arbitrary cut-point of at least 10 in smallest study arm to sub-groups below 20 being considered unlikely to be informative. Given the need for an appropriate sample size for moderation analysis, preferably underpinned by a formal sample size calculation, none of these trials were powered to support moderation analysis, even if *a priori* moderation analysis were planned. Many potential reasons exist for this review's finding of more exploratory subgroup analyses than pre-planned moderation analysis. Difficulty in gaining funding for moderation analysis is likely especially

Table 2.7: Summary of Review Findings

Patient Factor	Level of Evidence Found					
	Potential Moderator			Moderator Suggested		
	Confirmatory Evidence	Exploratory Evidence	Insufficient Evidence	Exploratory subgroup analysis	Potential confounding effect	Without statistical analyses
Painful arc	✓					
Gender			✓	✓	✓	
Shoulder restriction				✓		
< 8° of scapular posterior tipping			✓			
< 97° of humeral elevation			✓			
< 39° of humeral external rotation during arm elevation			✓			
Symptom Duration			✓	✓		
Functional Limitation			✓			
Muscle Tightness			✓			
Treatment Preference			✓			✓
Age			✓	✓		
Shoulder Complaint			✓			
Hand Complaint			✓			
Neck restriction				✓		

Diagnosis of rheumatoid arthritis					✓	
Diagnosis of frozen shoulder					✓	
Baseline symptom duration					✓	✓
Number of muscles with active trigger points					✓	
Baseline disability					✓	✓
Baseline pain					✓	
Presence of pain, dysfunction or both pain and dysfunction						✓
Pain at rest						✓
Pain frequency						✓
Pain on movement						✓
Night pain						✓
Joint end feel						✓
Stage of frozen shoulder						✓
Failure of conservative treatments						✓
Pre-treatment clinical index						✓

when adequately powered analysis requires at least four times the sample size to test for interaction between prognostic factors and treatment (Brookes et al. 2004).

The stringent criteria employed for the methodological assessment of moderation analysis in the Pincus tool (Pincus et al. 2011) set a high bar and may prompt the disregard of potentially valid moderators. This review concludes that only one trial offered sufficient evidence for moderation according to published quality criteria. Reflective of the current level of evidence available in the field of musculoskeletal shoulder pains, this conclusion may disappoint clinicians and researchers who are keen to progress knowledge in relation to clinical decision-making. To progress towards the development of such tools, the work of Pincus et al. (2011), Sun et (2011; 2012), the special series on subgroup analysis by The LANCET (Rothwell, 2005) and The PROGnosis RESearch Strategy (PROGRESS) Partnership (Hingorani et al. 2013) all highlight the importance of robust methodology and statistical analysis in providing clinically informative moderation and sub-group analysis. Existing prognosis studies provide a valuable springboard for the crucial developmental work required prior to undertaking large moderation studies. On the basis of these, this review provides: a) a reminder of the clinical relevance of sound moderation analysis, b) a list of identified potentially important factors in need of further evaluation.

2.5.3 Comparison with other Reviews and Studies

To date, previous studies investigating prognostic factors in musculoskeletal shoulder pain have produced a very similar list of patient attributes to that identified by this review. A systematic review by Chester et al. (2013) aimed to specifically identify predictors of response to physiotherapy treatment in patients with musculoskeletal shoulder pain. Chester et al. aimed to review the predictors of outcome of physiotherapy, however prediction of outcome of physiotherapy is not an equivalent to the identification of moderators of physiotherapy outcome or other treatment. Prediction of outcome of one treatment does not necessarily assist in the clinical decision of which patient should get which treatment. In spite of this, some findings were similar to this review: increased baseline disability and longer symptom duration were predictors of outcome of physiotherapy treatment, with inconsistent findings for age and baseline range of movement.

This review's finding that gender is a potential treatment effect moderator in patients with shoulder disorders is also in line with Blangsted et al. (2008) whose occupational study looking at an intervention designed to prevent musculoskeletal conditions demonstrated an interaction between gender and treatment in a subgroup analysis; women had less symptom development when treated with specific resistance training rather than encouragement to be active & health vigilant, whereas men had less symptom development with specific resistance training than all-round physical exercise.

Authors examining other musculoskeletal concerns have sought to identify moderators of the effect of specific interventions. In the field of back pain, Underwood et al. (2007) conducted secondary data analysis of the UK BEAM trial to assess the impact of baseline participant attributes on response to treatment. Underwood et al. tested for the statistical significance of the interaction between treatment allocation, baseline patient attributes and outcome. Results suggested that allocation to combined treatment in those with a positive treatment expectation gains an additional 4.0 and 3.8 points improvement on the Roland Morris Disability Questionnaire (RMDQ) at 1yr when compared with those who did not think the treatment would be helpful. Not dissimilar, this review identified treatment preference as an insufficiently evidenced potential moderator indicating that patient attitudes and beliefs about their physiotherapy intervention may affect outcome of treatment.

Similar to this review, Gurung et al. (2015) conducted a systematic review of moderators of treatment effect in low back pain identifying low quality data on moderators. Gurung et al. suggest that strong evidence exists that age, employment status, narcotic medication use, treatment expectation and education moderate treatment response in patients with low back pain. In contrast, this review did not find confirmatory evidence that age or treatment expectation were moderators of response to treatment in patients with shoulder pain. Gurung et al. also suggest that weaker evidence exists that gender, psychological distress, pain/disability and quality of life moderate response to treatment in patients with low back pain. This review also indicates that there is at best, exploratory level

evidence to suggest that age and pain/disability and quality of life moderate treatment effect in patients with shoulder pain.

Although this review identified 20 patient attributes thought to potentially moderate treatment effect, attributes absent from this review include psychological attributes such as anxiety, depression, psychosocial determinants of health and well-being including work-load and sport participation, chronic widespread pain, multi-site pain, employment status, analgesic medication and education. Although many of these attributes have already been identified as predictors of outcome in shoulder pain (Kennedy et al. 2006a; Kennedy et al. 2006b; Vergouw et al. 2011), it is not currently known whether they moderate treatment effect of the three commonly used primary care interventions for musculoskeletal shoulder disorders.

Moderation analysis to enable treatment targeting is of relevance to many disciplines of health and medicine and is increasingly used in analysis of interventions such as self-management and Cognitive Behavioural Therapy (CBT), with some evidence of this in musculoskeletal pain (Miles et al. 2012; Turner et al. 2007). Miles et al. (2012) conducted a systematic review and meta-regression to test the impact of age and gender on effectiveness of self-management intervention in musculoskeletal pain, however no moderating effect was found. In secondary data analysis of a trial of patients with chronic pain undergoing CBT, Turner et al. (2007) found a number of predictors of worse response to CBT (greater baseline somatization, greater depressive symptoms, higher number of

pain sites, more rumination, catastrophising, and higher perceived stress), however, moderators of treatment effect were not identified. These studies identified a number of psychological patient attributes in patients with chronic pain that were not identified by this review, indicating that future investigation of the relevance of psychological and social factors as treatment effect moderators is indicated.

2.5.4 Strengths of the Review

In the absence of the currently most advocated approach to the identification of moderators of outcome, that is meta-analysis of multiple trials or meta-analysis based on individual patient data from multiple trials (Moher et al. 2009; Riley et al. 2010), systematic review of potential moderators of outcome represents a worthy starting point. This is the first systematic review to attempt to identify moderators and potential moderators of effect of commonly used primary care treatments in patients with musculoskeletal shoulder disorders. Use of search strategies from existing systematic reviews (Buchbinder et al. 2013a; Green et al. 2003) in the field ensured that searches were appropriately specified and risk of missing relevant publications minimised. Classification of results into two categories of evidence of moderation: (i) studies with moderation analysis, and (ii) studies suggesting potential moderators, allows for clear interpretation of the level of evidence offered by each of the identified studies. Methodological appraisal of moderation analyses was conducted using a previously published appraisal tool that enabled a robust and justly cautious approach to the identification of potential moderators.

2.5.5 Weaknesses of the Review

Due to the variety of interventions and diagnoses studied, meta-analysis methods were not possible, therefore only a narrative synthesis was conducted. Aside from the potential moderators identified by this review (table 2.4), other suggested moderators identified (table 2.6) are heavily caveated, as they have not been statistically tested. However, these suggestions could be considered in the design of studies for future testing.

Caution is advised in the interpretation of the results of this review. This review did not reveal a clear-cut set of patient attributes that differentially moderate response to commonly used treatments for musculoskeletal shoulder pain in primary care. Instead, this review identified only one methodological sound and statistically valid moderator of the effect of one specific treatment. Therefore this review offers a glimpse of the potential for better targeting of treatments that may be derived from sound statistical analysis of randomised controlled trials relevant to clinical practice. Given studies included in this review varied in respect to the optimal methodological considerations in moderation analysis (table 5), the fundamental issues with trial design as evidenced by the Risk of Bias assessment must also be noted (figure 2.2).

Aside from the potential moderators identified by trials conducting some form of moderation analysis (table 2.4), other suggested moderators identified by this review (diagnosis of rheumatoid arthritis, diagnosis of frozen shoulder, stage of

frozen shoulder, symptom duration, patient's primary problem (pain, dysfunction or both), number of muscles with active trigger points, passive range of shoulder movement, pain, failure of conservative treatment, increasing night pain, acute or inflammatory stage of disease, shoulder restriction, and restricted neck range of movement) are heavily caveated as they constitute suggestions and observations of trial authors which have not been adequately analysed or statistically tested. These patient attributes are mere suggestions to be considered in the design of future studies. Subgroup analyses are often post-hoc and conducted as 'hypotheses generating' exercises and therefore, despite these results being heavily caveated, important lessons on conducting trials with an *a priori* intention of including moderation analysis may be learned.

2.5 Conclusions & Next Steps

This review demonstrates the potential utility of individual patient attributes as moderators of treatment effect. Moderators of treatment effect have strong relevance to clinical practice as they can aid understanding of why certain patients respond differently to specific interventions. Future research should take into account the different approaches required for identifying generic prognostic factors (non-treatment specific) and moderators of treatment effect. This field would benefit from studies to test the predictive performance of the identified potential moderators in appropriately designed and adequately powered randomised controlled trials, although it is accepted that challenges to this are numerous. Further research is required in order to develop a clinical decision tool to assist primary care clinicians in the management of musculoskeletal shoulder disorders.

Although this review has begun this process by populating a list of 20 patient attributes thought to moderate or potentially moderate treatment effect, many commonly considered patient attributes do not feature in this review. Attributes absent from this review include psychological attributes such as anxiety or depression, other determinants of health and wellbeing including workload and sport participation and chronic widespread pain or multi-site pain. Although these attributes have already been identified as predictors of outcome in shoulder pain in earlier studies (Kennedy et al. 2006a; Kennedy et al. 2006b; Vergouw et al. 2011), it is not currently known whether they moderate treatment effect of the three commonly used primary care interventions for musculoskeletal shoulder pain. Expert clinician consensus has previously been shown to reflect most statistically selected predictors and also suggests additional predictors not identified by statistical selection (Vergouw et al. 2011). Therefore, future research should seek to identify expert clinician consensus on the likely most appropriate patient attributes to include in an *a priori*, appropriately powered and statistically robust moderation analysis in shoulder pain.

CHAPTER 3: ROLE OF EXPERTISE AND CLINICAL DECISION-MAKING IN THE MANAGEMENT OF SHOULDER PAIN

3.1 Background

The overall aim of this PhD is to underpin the development of a model of stratified care for musculoskeletal shoulder pain in Primary Care by identifying the clinical attributes of patients with shoulder pain thought to potentially moderate response to three commonly used primary care treatments. Chapter 2 presented a systematic review of shoulder pain RCTs that identified the patient attributes thought to potentially moderate or interact with these treatments. Evidence from the review of moderation of treatment effect highlighted the considerable challenges in conducting methodologically sound moderation analyses including: identifying testable hypotheses, having sufficiently large sample sizes, appropriate statistical analysis and avoiding reporting bias. The review identified 29 potential moderators of treatment effect in the management of shoulder pain. However, several known prognostic factors expected to moderate treatment effects in patients with shoulder conditions were not identified as candidate moderators, such as psychosocial factors (Westman et al. 2012), physical work-load (Miranda et al. 2008), chronic widespread pain or multi-site pain (Coggon et al. 2013), and overuse from certain activities or hobbies (Lo et al. 1990).

In order to develop a clinically relevant as well as parsimonious model for stratified care for shoulder pain, a comprehensive list of relevant hypothetical moderators is required, alongside some understanding about which of the identified moderators are likely to be the most salient for treatment decision-making. It is therefore clear that the review, although representative of the current literature, did not identify a fully comprehensive list of potentially important attributes of patients with shoulder pain. It is therefore hypothesised that further patient attributes might exist that clinicians also value to guide decisions about recommendation of specific treatments to individual patients with shoulder pain. The range of clinical and patient variables considered by clinicians when making treatment decisions for patients with musculoskeletal shoulder pain has not yet been reported. Furthermore, how clinicians process such clinical information in order to make a reasoned clinical treatment selection decision for patients with shoulder pain is currently unknown.

Therefore, exploration of the clinical decision-making processes of experienced clinicians who clinically manage the care of patients with shoulder pain could: (i) identify salient clinical attributes that guide treatment decision-making for patients with shoulder pain and (ii) assist the development of a meaningful and useable treatment decision tool, which has strong face validity among clinicians.

3.2 Theoretical Models of Clinical Decision-Making

Development of appropriate and feasible research studies to achieve these aims required an understanding of the existing theories of how clinicians make treatment decisions. Clinical decision-making is understood as the process of choosing between treatment alternatives (Thompson & Dowding, 2002). Thompson et al. (2004) outline a range of types of clinical decisions including three of relevance to this PhD: diagnostic, intervention/effectiveness and targeting decisions. Diagnostic decisions involve the classification of signs and symptoms as a basis for clinical treatment strategy (Thompson et al. 2004). Conversion of knowledge into action occurs when making intervention or targeting decisions. Intervention decisions involve choosing a treatment from many possible options (Thompson et al. 2004). Targeting decisions are a sub-category of effectiveness decisions that relate to subgroups of best responders to one particular treatment (Thompson et al. 2004). In context of this thesis, such intervention and targeting decisions involve clinicians deciding between treatments for a patient with shoulder pain, whilst thinking about exactly which treatment is most likely to work best or 'match' an individual patient.

Many theories of clinical decision-making exist that attempt to describe the processes involved in clinical decision-making. Theories exist on a spectrum ranging from scientific, logic driven Bayesian approaches to the experiential knowledge domains of clinical expertise and intuition. Ashby & Smith (2000) describe the potential for Bayesian approaches in clinical decision-making. This approach involves consideration of the prior probability of effectiveness of a

treatment based on existing evidence or clinical experience/expertise, with effectiveness probability being modified by the addition of single pieces of clinical evidence (clinical features, observation, test results) until a final posterior probability is reached which drives the treatment decision. In the context of this thesis, a Bayesian approach might involve methodical calculation of the likelihood of each competing clinical hypothesis as information is received. Bayesian approaches are therefore very logical and thorough methods of arriving at a diagnosis but also highly cognitively taxing and time intensive.

Alternatively it is suggested that whilst clinicians are logical, rational clinical decision-makers (Thompson & Dowding, 2002), a variety of clinical reasoning approaches are employed in tandem to streamline decision-making. It is thought that this combination of approaches potentially begins with use of a Bayesian approach to collating clinical evidence. The information-processing model (Joseph & Patel, 1990) further argues that clinicians adopt analytical hypothetico-deductive strategies in order to guide information gathering facilitating arrival at a diagnosis or clinical decision. The hypothetico-deductive approach is divided into a series of logical stages including: cue recognition or cue acquisition, hypothesis generation, cue interpretation and finally, hypothesis evaluation (Tanner et al. 1987). Distinct from a systematic Bayesian method, diagnosis using a hypothetico-deductive approach employs a guided information search in response to emerging information where possible diagnosis hypotheses prompt additional information gathering, thus enabling the ruling in/out of possible diagnoses (Elstein et al. 2002). The hypothetico-deductive approach is a largely rule-governed decision

process. Rule governed decision processes involve highly rational and sequential consideration of each piece of clinical information against a series of accepted facts or truths. Application of such rule-based thinking in the context of this thesis would involve, for example, the attempt to arrive at a diagnosis based on the interpretation of specific clinical signs and symptoms. Therefore this is also a relatively slow and cognitively demanding process (Kahneman, 2003). Two barriers to the seamless application of such processes to clinical decision-making for shoulder pain exist: (i) the imperfect correlation between clinical sign and symptoms and diagnosis and, (ii) the unclear relevance of diagnosis to outcome (Cadogan et al. 2012; Hegedus et al. 2012; McFarland et al. 2010; Saulle & Gellhorn, 2017). Therefore, rule-based decision processes do not offer a complete theoretical underpinning for clinical decision-making in the assessment or management of shoulder pain. Yet, clinicians still manage to arrive at reasoned treatment decisions. Given that human reason is limited by the extent of long-term memory, cognitive strategies have evolved to enable more refined interaction with complex information and to expedite arrival at clinical judgements and decisions (Elstein et al. 2008).

"*It's interesting that. Don't you get a feel, because I always get a feel that this person is going to respond to an injection but you can't say why. You try to work out, well, why do I think that? You try to think why? It would be interesting if you could try to do a little project there*." (Personal communication with a Physiotherapist).

Elstein et al.'s (2002) challenge of the hypothetico-deductive model suggests that clinical problem solving proficiency varies amongst clinicians and is highly dependent on the clinician's mastery of the clinical area. Experienced clinicians often use shortcuts, heuristics or 'rules of thumb' to simplify the complexity of decision-making task by comparing examination findings to previous successfully diagnosed or managed patients using pattern recognition (Cioffi & Markham, 1997). Pattern recognition, also termed similarity recognition or a categorisation approach, concerns the comparison of clinical signs and symptoms of a presenting patient to experienced and/or remembered patterns of symptoms (Pelaccia et al. 2011). Pattern recognition is often associated with intuition, perception and expertise (Benner & Tanner, 1987), constructs that are difficult to observe and measure. A review by Banning (2008) highlights that intuition has been defined in many ways including: a gut feeling, 'understanding without a rationale' (Benner & Tanner, 1987), and 'a component of complex judgment, the act of deciding what to do in a perplexing, often ambiguous and uncertain situation' with an immediacy that does not require conscious reasoning.

Dreyfus & Dreyfus (2004) outlined their model of professional expertise (Dreyfus & Dreyfus, 2004) which deals with clinical decision-making skill acquisition and proposes that differences exist at various stages of professional development. Intuitive decisions are proposed to occur more readily in later expertise and mastery stages compared to in the novice, competence and proficiency stages (Dreyfus & Dreyfus, 2004). The Intuitive-Humanist Model (Benner, 1984) focuses on the relationship between clinical experience and exposure and progression of

clinical decision-making capacity. Strategies such as the hypothetico-deductive approach used by novice decision makers to deal with and learn from the vast array of potential clinical clues do not appear to be the same strategies as those used by experienced clinicians; experienced clinicians are said to form higher quality diagnostic hypotheses more rapidly than novices (Elstein et al. 2002). Furthermore, it is now accepted that logic based and intuition/expertise based approaches are not mutually exclusive but are used interchangeably by clinicians (Pelaccia et al. 2011).

It is probable that experienced physicians use a hypothetico-deductive strategy only with difficult cases that do not fit with existing recognized clinical patterns and that pattern recognition is a more efficient, less cognitive decision strategy for more routine or familiar clinical reasoning (Elstein et al. 2002). Therefore the dual process theory, which highlights the inter-play between intuitive judgement and cognitive use of contextual clinical factors is a seemingly more robust theory to describe how clinicians make decisions (Pelaccia et al. 2011). Indeed a variety of cognitive processes including hypothetico-deductive and diagnostic pattern recognition approaches, have been witnessed to facilitate clinical decision-making during shoulder pain assessment amongst expert physiotherapists (May et al. 2008).

3.3 Role of Diagnosis and Prognosis in First-line Decision-Making for Shoulder Pain

First-line treatment decisions in UK Primary Care for shoulder pain patients include the choice between three commonly used treatment options each with good evidence of effectiveness: General Practitioner (GP)-provided advice and analgesia, exercise and/or manual therapy as delivered by a physiotherapist, and corticosteroid injection. In context of diagnostic uncertainty, it is unsurprising that evidence suggests that clinicians including GPs, rheumatologists and physiotherapists make variable and often inconsistent diagnoses, develop variable and sub-optimal management plans and that clinical confidence in making treatment decisions for patients with shoulder pain is low (Artus et al. 2017), as evidenced by the high reliance on imaging to inform diagnosis and subsequent management plans (Buchbinder et al. 2013b; Miller-Spoto & Gombatto, 2014; Liesdek et al. 1997; Johal et al. 2008; Patel el al. 2010).

To improve diagnosis, clinical management and outcome of shoulder pain by GPs in primary care, Farmer (2014) developed a clinical decision support system consisting of 34 subjective questions and objective orthopaedic tests to suggest a likely clinical diagnosis. Whilst this system has a high level of validity and reliability (Farmer, 2014), if the purpose of a clinical decision support system or clinical decision tool is to support treatment decision-making, it is unclear how such a probabilistic diagnostic model can provide the subsequent treatment recommendations offered (Hill & Fritz, 2011). Such treatment recommendations assume that diagnosis is central to treatment decision-making. In the clinical

scenario where clinical management serves to directly target and eliminate a specific identifiable disease, disease process or bodily insult, diagnosis is of paramount importance (Croft et al. 2015). However, with musculoskeletal shoulder pain, where more serious conditions have been excluded, patho-anatomical diagnoses are not clearly related to treatment effectiveness (Dinant et al. 2007). Therefore the case for the use of prognostic information in complementing a diagnostic framework, to strengthen clinical decision-making has been made (Dinant et al. 2007; Croft et al. 2015).

The accuracy of diagnostic labels to classify shoulder pain is questionable with most orthopaedic special tests failing to demonstrate sensitivity or specificity with poor correlation between symptoms, diagnosis and imaging (Magarey et al. 2016; Wylie et al. 2016). Although the same clinical factors can act as both a prognostic factor and a diagnostic factor, it would be remiss to assume that factors that indicate diagnosis are the same factors that predict overall outcome or indeed moderate response to treatment. Uncertainty therefore remains about whether diagnosis is a sound or necessary basis for first-line treatment decisions in patients with shoulder pain. Instead, a prognostic approach to clinical decision-making seeks to use an individual patient's unique characteristics to inform their prognosis as well as their likely response to specific treatments (Croft et al. 2015).

3.4 Understanding How Clinicians Navigate Clinical Uncertainty in Treatment Decision-Making for Shoulder Pain

Current primary care guidelines for the management of shoulder pain do not advocate specific treatments for specific patients but rather suggest a range of treatments (as discussed in chapter 1, introduction). Therefore for patients with non-traumatic shoulder pain, clinicians routinely choose between: (i) exercise and manual therapy, (ii) corticosteroid injection and (iii) advice and analgesia, without specific guidance from guidelines. It can be assumed that clinicians recommend the treatment they believe to be most likely to work for each individual patient. However, in light of the reported variable patient prognosis (Croft et al. 1996; van der Windt et al. 1996; Winters et al. 1999b), it is clear that some patients do well in response to this first-line decision-making whilst over half of patients do not.

A main hypothesis of this thesis is that clinicians make decisions on the basis of experientially constructed knowledge about which treatments individual patients are likely to respond well to and therefore, which patients are suitable candidates for specific treatments. It is currently not understood how clinicians use and weigh up the breadth of available clinical information to inform these first-line treatment decisions for patients with shoulder pain. Specifically, it is unknown if and how clinicians make treatment recommendations on the basis of potential moderators of treatment response using experience and observations gained from their own clinical practice and experience.

The comparative performance of statistically derived versus expertise driven models for estimating the prognosis of musculoskeletal conditions remains unclear. Vergouw et al. (2011) found that a statistically derived prognostic model for estimating prognosis of shoulder pain was slightly superior to a clinically derived model. However, Vergouw et al. highlight that the result is less than clear cut, as the performance of the statistically derived model may be over-stated, because it was tested in the same dataset as it was derived from when compared to the externally clinically derived model. In addition, in Vergouw et al.'s work, clinicians suggested a range of clinical factors that were not identified by the statistical model indicating that clinicians consider a breadth of clinical factors when estimating prognosis including those not previously studied, as also demonstrated by the systematic review in chapter 2.

In addition to the narrow range of clinical factors available in current moderation analyses, the review (chapter 2) highlighted the challenges in gaining clinically applicable insights from moderation analysis and meta-analysis due to lack of power, design consistency in existing studies. Furthermore since clinicians do not consider patient attributes in isolation when making treatment recommendations, but instead use pattern recognition to inform clinical judgements. Since clinicians are managing to make first-line treatment recommendations for patients with shoulder pain in the absence of guidance, individual clinicians are likely to have developed their own unique clinical short cuts or heuristics. Therefore, a collective wisdom is likely to exist amongst the range of clinicians who manage patients with shoulder pain. Therefore, this thesis will use clinician input to identify potential

moderators of first-line treatment effect in patients with shoulder pain.

3.5 Role of Clinical Decision-Making in this Thesis

To achieve this, a formal study of clinical decision-making for shoulder pain was planned and is outlined in full detail in chapters 5-8. This decision-making study aimed to examine how clinicians respond to systematically-varied hypothetical patient presentations to assess the impact of relevant clinical factors (patient attributes) on decision-making. To begin the process of designing this formal study of clinical decision-making, a list of highly relevant attributes of patients with shoulder pain was required. Since the systematic review began this process but provided an incomplete picture of the clinical considerations for decision-making, additional input from experienced clinicians who frequently manage the care of patients with shoulder pain was required to obtain an inclusive and parsimonious list of patient attributes that may drive differential treatment decisions. The next chapter outlines a study that addressed this aim.

CHAPTER 4: USING EXPERIENTIALLY CONSTRUCTED KNOWLEDGE OF CLINICIANS WHO MANAGE PATIENTS WITH SHOULDER PAIN TO IDENTIFY CLINICALLY RELEVENT MODERATORS OF TREATMENT RESPONSE

4.1 Background

The previous chapter outlined the theories of clinical decision-making relevant to how clinicians make treatment decisions for patients with shoulder pain, highlighting that pattern recognition is likely to be combined with logical information-seeking approaches. Therefore, in order to identify the range of patient attributes considered as relevant in treatment decision-making for patients with shoulder pain, a study that enables clinicians to gather their clinical experiences using the recognisable format of pattern recognition was conducted.

4.2 Aim

This study aimed to populate a list of clinical and patient attributes considered as important for first-line clinical decision-making by experienced clinicians who routinely make treatment decisions for patients with shoulder pain.

4.3 Methods

An efficient way to obtain the clinical breadth of patient attributes relevant to the differential treatment response of shoulder patients is to involve clinicians with experience of managing shoulder pain in a structured, clinical consensus research exercise. This study used a pragmatic and iterative mixed methods approach to identify the patient attributes considered by experienced clinicians when making treatment recommendations for patients with musculoskeletal shoulder pain. A number of methods have precedence in eliciting the experience and opinions of expert clinicians including the Delphi technique and focus group methods (Gooberman-Hill et al. 2007; Rankin et al. 2012). The Delphi technique offers a systematic aggregation of judgments from expert participants over a series of rounds but was not selected for this study due to lack of clinician interaction (Sim & Wright, 2000). Interaction between clinicians was considered particularly important in this study in order to achieve lists of patient attributes that are both internally and externally valid and make shared logical sense to the variety of professionals involved and it would have been difficult to study pattern recognition. Whilst focus groups offer clinician interaction, it was anticipated that the clinicians would identify a sizeable list of potential patient attributes; therefore a method for quantification of consensus on the most relevant factors was needed.

The focus group using nominal group technique (NGT) is described as a hybrid of focus groups and Delphi technique (Sim & Wright, 2000), and is said to be ‘semi quantitative and qualitative’ (Perry & Linsley, 2006). NGT offer the benefits of focus group interaction in stimulating clinical discussion as well as the

quantification of consensus using anonymous voting. Furthermore, relative to other qualitative techniques, NGT is less time consuming and more productive at producing a ranked series of ideas which can easily be translated into questionnaire items or studied further (He et al. 2014). NGT also offers a highly structured and time efficient process, helps balance individual participation levels by providing equal opportunity to suggest relevant factors followed by anonymous, private individual voting to identify the most relevant patient attributes (He et al. 2014).

The conventional steps of a nominal group technique (Delbecq, 1971) were used:

1. Introduction and Explanation
2. Generating Ideas
3. Recording Ideas
4. Discussion
5. Voting

To facilitate time efficient and focused data collection, participants were asked to complete clinical case vignettes from their own clinical practice prior to attending the workshop (Perry & Linsley, 2006). Participants were asked to think about patients encountered during their own clinical practice and:

(a) Complete a clinical vignette to outline the clinical attributes of patients that either had responded well or were likely respond well to the three commonly used shoulder treatments: (i) advice and analgesia, (ii) exercise

and/or manual therapy delivered by a physiotherapist and (iii) corticosteroid injection (table 4.1).

(b) Identify the key patient attributes from their own patient vignettes that explained the patient's response or likely response to the specific intervention.

In line with the purpose of the silent idea generation stage of the NGT process, completion of the vignettes prior to attending and/or at the very beginning of the workshop enabled participants to generate their own thoughts and ideas without interruption or influence from other members of the group (Perry & Linsley, 2006).

4.3.1 Running of Workshops

All workshops took place in a meeting room at the Arthritis Research UK Primary Care Centre at Keele University. Democratic group working was facilitated by seating participants around an oblong table in a level room (Perry & Linsley, 2006) with the group facilitator at front of the room noting emerging patient attributes suggested by the participants on an electronic smart board.

Table 4.1: Example of a vignette for physiotherapy completed by a respondent

Patient Vignette 1 - Physiotherapy	
1) Think about the last patient with shoulder pain that you referred to / provided with **physiotherapy**, confident that they would achieve a positive clinical outcome.	
2) Without identifying the patient, please describe the patient's presentation (demographics, clinical features, clinical observations, tests results etc..).	*Young patient with impingement symptoms and subtle instability. 29 years old new mum, baby 6 months old. Pain with repetitive movements, pain with movement overhead. Worse at night, unable to sleep on shoulder. Pain in lateral arm. No cervical spine or neural irritation.* *Slim built lady. Normal scapular position. Normal cervical and thoracic posture. Good cervical spine movement. Shoulder flexion full, pain at end of range only.* *Shoulder abduction –pain 120 degrees to end of range.* *Pain end of range lateral rotation, reduced hand behind back by pain to T10.* *Normal cuff strength in neutral but resisted low load lateral rotation demonstrated poor humeral head centering.* *Positive Hawkins Kennedy, positive Neer sign.* *No acromio-clavicular findings.*
3) What was it about this patient or this patients presentation that made you feel confident that the patient was likely to achieve a positive clinical outcome with physiotherapy treatment?	*Minor associated problems. No neural irritation or cervical or thoracic influence apparent.* *Likely to be change in habit and increased loading – overload for cuff – secondary impingement.*
4) Which characteristics were most important in guiding this decision?	*Recognising normal findings around spine and scapula. Accurately diagnosing subtle movement fault and poor cuff control.*
5) Can you think of any other characteristics, not present in the above patient which might have led you to also refer /provide a patient with shoulder pain with physiotherapy treatment?	*Lots – this is just one example!* *Patients with movement faults causing pain/poor function.*

4.3.2 Participants

According to Surowiecki (2004), groups of people work well under certain circumstances and less well under others. Surowiecki suggests two basic principles need to be met in order for a crowd to be 'smart', i.e., collectively reach the correct decision: diversity and independence. Diversity in the context of this study was achieved by extending the invitation to all medical and allied health professionals who treat patients with shoulder pain in the context of the UK National Health Service (NHS) (i.e., physiotherapists, GPs, orthopaedic surgeons and rheumatologists). Independence was achieved by using the NGT method where the collective group decision on the importance of an attribute is achieved by aggregating each participant's impression of importance of the attribute to produce a collective group judgment that represents:

"not what any one person in the group thinks but rather,

in some sense, what they all think" (Surowiecki, 2004, pg. XIX).

The study invited medical and allied health professionals who identified themselves as having a recognised expertise or special interest in the assessment and treatment of musculoskeletal shoulder pain, this included those with experience of managing patients with shoulder pain as part of their clinical practice. Jones et al. (1995) state that there are no rules about who to include as participants in clinical consensus research "except that each must be justifiable as in some way "expert" on the matter under discussion" pg. 383. Qualification for invitation included currently working as a clinical specialist in shoulder or upper

limb musculoskeletal disorders and/or having a specific clinical interest in the clinical management of musculoskeletal shoulder disorders. In addition to clinicians most likely to be identified as experts in shoulder disorders (physiotherapists and orthopaedic surgeons), general practitioners and rheumatologists were also invited to contribute in order to gain a broad sense of the patient attributes considered by clinicians who encounter shoulder patients in the course of their clinical practice. Jones et al (Jones & Hunter, 1995) recommend this approach as a way of gaining alternative clinical viewpoints when it is anticipated that the research output will:

"*have impact beyond a particular specialist field*" pg. 383.

The purpose of the consensus workshops was to obtain consensus on the patient characteristics likely to affect treatment response from clinicians who are experts in the clinical management of musculoskeletal conditions. Other professionals and non-experts were excluded from participation as they lack the specific clinical expertise and experience of undertaking the clinical decision-making process related to patients with shoulder disorders. A discussion was held with the lead for Patient and Public Involvement and Engagement (PPIE) at the Arthritis Research UK Primary Care Centre at Keele University about the potential for utilising PPIE to check that factors relevant to patients had not been omitted. It was agreed following informal discussion that as the focus was not on patients' perspective or indeed shared decision-making that involvement of PPIE would appear tokenistic and not prove to be a worthwhile experience for patients or other members of the public.

4.3.3 Recruitment

Expert clinicians were identified using the professional, research and local network contacts of the research team and Arthritis Research UK Primary Care Centre at Keele University. Clinicians were invited to participate in consensus workshops via email from senior members of the Centre. In addition, email invitations were sent to upper limb physiotherapists, GPs, rheumatologists and orthopaedic surgeons local to Keele University (including Staffordshire, Cheshire, Merseyside, Greater Manchester, Shropshire, South Yorkshire, and Derbyshire). An advert for the study was also posted on the social media platform Twitter and on Physiopedia (a website with a dedicated page for adverts for health and medical professionals to get involved in research). The study invitation contained a brief overview of the study aim and invited interested clinicians to indicate their interest in taking part by contacting the PhD student via the email address provided.

The study invitation used the phrase ‘expert in managing musculoskeletal shoulder disorders’. Shortly after recruitment commenced, it was expressed to the team that experienced clinicians were not comfortable applying the word ‘experts’ to themselves. Clinicians who made contact with the research team were reassured that a variety of clinical experience and special clinical interest in the management of shoulder disorders was sufficient. Clinical academics with an interest in the clinical management of shoulder pain were also invited to participate in the workshops.

4.3.4 Ethical Approval and Informed Consent

Ethical approval was obtained from Keele University's ethical approval panel in February 2013 (ERP 2157) (appendices 3 and 4). Participants were asked to sign and complete a consent form before each workshop, providing consent for participation in the workshop, permission to audio record the workshop and permission to use any relevant quotations from the workshop discussions (appendix 3). After providing consent, participants were asked to complete a brief anonymised form to obtain participants' characteristics at the beginning of each workshop (appendix 3).

4.4 Workshop Objectives

This series of workshops consisted of three iterative phases that aimed to:

(i) Identify using consensus methods the patient attributes that potentially moderate response to the three commonly used primary care treatments:
   a. Exercise and/or manual therapy delivered by a physiotherapist
   b. Corticosteroid injection
   c. Advice and analgesia

(ii) Consolidate the suggested attributes under parent attributes

(iii) Agree final attribute & relevant clinical question wording

Due to differences in attendance and availability amongst professional groups,

phases 1 and 2 were run twice using the same approach by the same researcher. Phase 3 included a single group of clinicians and clinical academics with an interest in shoulder pain consisting of participants who had contributed to either or both phase 1 and 2.

4.5 Phase 1- Clinical Attribute Identification Workshops

4.5.1 Phase 1 Aim

This phased aimed to use experienced clinicians with a special clinical interest in the management of patients with shoulder pain, to obtain a list of patient attributes relevant to predicting outcome of individual patients with shoulder pain in response to either: advice and analgesia, exercise and/or manual therapy delivered by a physiotherapist or corticosteroid injection.

4.5.2 Phase 1 Method: Modified Nominal Group Technique with Categorisation Exercise

4.5.2.1 Step 1: Introduction and Explanation

The workshop purpose and plan was outlined and results of the systematic review were shared in order to provide examples of treatment moderators that have been suggested in existing literature. Participants were free to draw upon and suggest these examples during the workshop as relevant patient attributes, however participants voted only patient attributes suggested by the group, whether or not these were also contained in the systematic review.

4.5.2.2 Step 2: Round Robin Idea Generation

Workshop participants took it in turn to use examples from their clinical case vignettes to share descriptions of patients who they were confident would achieve a good clinical outcome in response to the specific treatments. To identify potential moderators of treatment effect, each participant suggested the most salient clinical features of their patients that prompted the decision to refer to each treatment. This process was repeated for each of the treatments ((i) physiotherapy, (ii) corticosteroid injection and (iii) advice and analgesia) until the group suggested no new ideas.

4.5.2.3 Step 3: Consolidation of Ideas, Removal of Duplicates

Participants discussed the suggested attributes to determine their clarity, relevance and importance. Although this is at odds with the usual approach taken in an NGT, where idea generation and voting is done without discussion, it was decided that this would better enable the workshop objectives to be met by helping to create a comfortable, positive, discursive and philosophical environment for clinicians to participate in. All potential moderators noted on the smart board were copied into a power point presentation and made ready for electronic voting. Although some attributes were correlated, these were included if it was felt by the group that each attribute constituted a distinct moderator of treatment effect. Attributes were amalgamated at the discretion of the group, but only if the group agreed that the new wording still represented the original ideas (Perry & Linsley, 2006), otherwise the original wording of the patient attributes as suggested by the

respondents was retained. Participants were not permitted to suggest removal of attributes from the list at this stage.

4.5.2.4 Step 4: Consensus Exercise using Anonymous Voting

Participants agreed by consensus a small set of highly clinically relevant patient attributes to test in the planned conjoint analysis study. Attributes were projected singularly on a large screen and participants were asked to indicate how important each attribute was for guiding selection of a shoulder pain treatment by selecting one response on the 5-point Likert scale: 'Very important, important, neither important nor unimportant, unimportant, or very unimportant'. Respondents voted without conferring. Consensus agreement was defined as an attribute having been selected as 'agree' or 'strongly agree' by more than 50% of the participants present at the time of voting. Voting was confidential and blinded using real-time electronic voting using the classroom voting technology system, Turning Point (Turning Technologies, UK).

4.5.2.5 Step 5: Post-workshop Attribute Consolidation

To distil the findings of phase 1, suggested attributes were collated into logical categories by the research team in a categorisation exercise. Options for the categorization of clinical attributes were considered, namely thematic analysis using the long table method (Guest et al. 2012). However, since data collection in this study occurred over specific and limited time periods (during scheduled workshops), it was not practical to continue to sample participants until theoretical

saturation was achieved, the point at which no new attributes, concepts or themes were identified (Glazer & Strauss, 1967). Thematic analysis was therefore not considered likely to provide meaningful interpretation of the data over the simple categorization exercise conducted. Instead a more straightforward categorisation exercise was conducted.

The categorisation exercise grouped the list of suggested attributes into clinical clusters of patient attributes that relate to similar areas of clinical decision-making e.g., the parent attribute 'Pain' was comprised of the attributes: pain location, pain intensity/severity, pain/symptom frequency and pain type (extreme or distressing pain). These categories were then provided with a clinically sensible parent attribute label that described the category, where possible using terminology from the list of characteristics suggested in Phase 1. The PhD student and supervisory team (CJM, DvdW & JH) reviewed the categories to guard against biases of one individual researcher.

4.6 Phase 2: Clinical Attribute Definition

The conjoint analysis study proposed for the next stage of the PhD seeks to understand how clinicians use patient attributes to make treatment decisions and to identify potential profiles of likely best responders to the three treatments of interest. A number of constraints to the generation of attributes for a conjoint analysis study exist. Increasing the number of attributes in a conjoint analysis increases the number of questions each respondent is required to answer, the

sample size and the risk of non-convergence (failure of the underpinning statistical model). Furthermore, an important consideration in deciding how many attributes to include is an estimation of how many attributes a clinician will be able to cognitively engage with. Definitive guidance on absolute maximum recommended number of attributes to include in a conjoint analysis study is lacking. However, the average number of attributes is seven or eight and the absolute maximum number of attributes recommended is 12 (Carson et al. 1994; Ryan et al. 2008). It is essential that attributes are mutually exclusive, i.e., not dealing with the same underpinning construct as any other attribute and that the level of each attribute is theoretically combinable with any level of any other attribute. Many attributes from workshop 1 such as 'psychosocial complexity' lack clear cut-off points or categories from existing literature. Therefore, phase 2 aimed to agree appropriate levels for each final attribute and identify simple, clinically relevant questions that represent each of the final attributes. Phase 2 also aimed to further consolidate and reduce the total number of suggested attributes suggested in phase 1 to be taken forward to the conjoint analysis study.

4.6.1 Phase 2 Aims

Use the categorisation exercise as a platform for discussion to enable participants to:

1) Collapse the list of attributes into as few clinically sensible parent attributes as possible that encompass the suggested attributes
2) Identify clinically relevant levels/categories for each parent attribute

3) Consider whether any relevant clinical information is absent
4) Define the clinical questions that cover each parent attribute

4.6.2 Phase 2 Method: Clinical Attribute Definition Workshops using Consensus Groups

Participants for phase 2 workshops were invited from the pool of individuals who responded to the initial study invitation. Consensus group methodology (List, 2001) was used to facilitate discussion and amendments to the categorisation exercise summary of phase 1. Whilst both focus and consensus groups are participatory methods, in a focus group, the facilitator loosely steers the direction of the group and collates the findings, where as in consensus groups, the group negotiate and decide the findings themselves (List, 2001). The small groups consisted of members who were familiar with and shared ownership of the phase one material. Formal consensus voting was not conducted, as group numbers were small. Groups were instead instructed to self-regulate, involve all members and to organically edit the phase one output into a more meaningful consensus agreed version. The group facilitator posed questions to the group to clarify agreement and consensus when decisions were being made. Participants verbally agreed or disagreed with amendments proposed by the group. If new parent attributes were suggested, the group checked whether the new parent attribute still expressed all of the previous attributes contained in the previous parent attribute.

Each parent attribute was allocated appropriate levels that the group was satisfied represented the attributes in the parent attribute and did not over-simplify or lose information relevant to differential treatment decision-making. This process was repeated until the group was content with the wording of all of the parent attributes names and levels on the map. A further consensus exercise was required to decide upon the final parent attributes to be included in the conjoint analysis from those identified and to decide the most optimal wording for each parent attribute. To facilitate the next workshop, output from both phase 2 workshops were compared. A traffic light system of agreement was applied: green (attribute and levels dealt with the same constructs and worded very similarly), amber (attribute and levels dealing with the same constructs, but worded differently) and red (different attribute and level suggested by each group).

4.7 Phase 3- Clinical Attribute Finalising

Assessment of logical and content validity of the attributes was indicated before beginning the design of the conjoint analysis study. In addition, the number of attributes suggested in phase 3 of this study exceeded the maximum recommended number of attributes (12) for a conjoint analysis study, participants were asked to discuss how best to approach this challenge i.e., consolidate and/or remove some of the parent attributes. Consensus group methods, as used in phase two, were repeated with a group of academics with experience of developing large programmes of research, randomised controlled trials and a model for stratified care in order to guard against potential biases of the PhD student and the supervisory team. Participants discussed where the attributes

over-lapped and suggested the final 12 attributes. The discussion focused on agreeing wording for the amber-coloured attributes and discussing which of the red-coloured attributes were most relevant to differential decision-making for shoulder pain in primary care. This phase ensured the translation of clinical opinion into a series of testable scientific hypotheses. Meeting attendees used the colour-coded output of phase 2 as the basis for group-led discussion of their preferences on the wording, appropriateness and conciseness of the attribute, levels and clinical questions suggested.

4.8 Results

In total, 21 UK-based clinicians took part in this series of consensus groups. Table 4.2 outlines demographics of the participants. Participants consisted of experienced clinicians from a range of professional backgrounds including physiotherapists, GPs, rheumatologists and orthopaedic surgeons working clinically and managing patients with shoulder pain in the National Health Service setting (UK NHS). Number of years of clinical experience of all participants in phase 1 and 2 was (mean (S.D.)) 18.4 (7.7) years. All participants took part in phase 1 but due to participant availability, not all participants who took part in phase 1 subsequently took part in phases 2 and/or 3.

4.8.1 Phase 1 Results

Clinical attributes identified by the consensus workshop participants in phase 1 are listed in table 4.3 with percentage agreement on importance of each attribute in

treatment decision-making. Additional attributes identified after the workshops using the audio transcripts of the workshops are also included. Clinicians suggested 63 patient attributes relevant to treatment decision-making in patients with shoulder conditions. Of these, 53 attributes were voted as 'important' or 'Very Important' during the voting stage of the NGT. As table 4.3 shows, the 53 attributes demonstrate the breadth of clinical information considered by clinicians when making a treatment decision for patients with shoulder pain. Results of the categorisation exercise of the 53 attributes can been seen in figure 4.1. During the categorisation exercise, eight attributes were removed. Table 4.4 outlines rationale for the removal of these attributes.

Table 4.2: Demographic characteristics of participants of the first two phases of the consensus study

	Workshop				
	1a **n = 8**	**1b** **n = 14**	**2a** **n = 4**	**2b** **n = 7**	**3** **n = 6**
Clinical Background (n,%)	Rheum. (1/8) GP (5/8) Physio. (1/8) Ortho. Surg. (1/8)	Physio. (13/14) Ortho. Surg. (1/14)	GP (2/4) Physio. (2/4)	Physio. (7/7)	Physio. (2/6) GP(3/6) Rheum. (1/6)
Currently Treats Shoulder Pain	5/8	12/14	2/4	7/7	6/6
Treatments currently provided (n,%) Education, advice & analgesia	7/8	10/14	3/4	7/7	4/6
Analgesia	7/8	7/14	2/4	5/7	4/6

Physiotherapy	5/8	10/14	1/4	7/7	2/6
Corticosteroid Injection	6/8	5/14	1/4	3/7	3/6
Other	0/8	Acupu. (1/14) Surg. (1/14)	0/4	0/7	0/6
Mean (SD) Clinical Exp. (years)	22.5 (10.5)	18.4 (7.7)	20.5 (13.2)	19.2 (8.5)	20 (11.8)
Post-graduate training in shoulder pain	6/8	8/14	4/4	6/7	6/6
Mean (SD) age (years)	45.2 (9.8)	41.4 (8.7)	44.5 (12.7)	42.8 (9.6)	44 (14.3)
Female	4/8	11/14	2/4	6/7	3/6
Clinical Practice in West Midlands, UK	5/8	6/14	3/4	5/7	4/6

Rheum. = Rheumatologist, GP =General Practitioner

Physio. = Physiotherapist, Ortho. Surg.= Orthopaedic Surgeon,

Acupu. = Acupuncture, Surg. = Surgery

Table 4.3: Patient attributes proposed as relevant by clinicians in shoulder treatment decision-making (Phase 1)

	Attribute Name	Suggested by Systematic Review (Y/N)	Workshop 1a 8	Workshop 1b 14	Attribute later identified in audio transcripts of workshops (Y/N)	Discuss in next round? (Y/N)
			(% voted very important or important)			
1	Employment status/ Occupation/ self-employment	Y	5/8	14/14	N	Y
2	Gender	Y	-	2/14	N	N[$]
3	Compensation claim/ Litigation pending	Y	-	7/14	N	Y
4	No. of previous episodes	Y	-	-	N	Y
5	No. of muscles with active trigger points	Y	-	-	N	N[$]
6	Restricted ROM	Y	7/8	-	N	N[$]
7	Neck involvement / neck range restriction	Y	-	-	N	Y
8	Pain location	Y	-	-	N	Y
9	Pain intensity	Y	-	-	N	Y
10	Pain Type (Extreme or distressing pain)	Y	6/8	-	N	Y
11	Symptom duration	Y	7/8	14/14	N	Y

12	**Work Impact (Dysfunction/disability)**	Y	-	-	N	Y
13	**Functional deficit (Dysfunction/disability)**	Y	-	-	N	Y
14	**Affected limb dominance**	Y	-	-	N	Y
15	**Painful arc**	Y	-	-	N	Y
16	**Patient treatment preference**	Y	8/8	14/14	N	Y
17	**Age**	Y	5/8	4/14	N	Y
18	**Previous treatment response (separately for each treatment)**	Y	7/8	14/14	N	Y
19	**Diagnosis**	Y	7/8	14/14	N	Y
20	**Pain type (pain or stiffness)**	Y	5/8	-	N	Y
21	**Nighttime pain**	Y	7/8	12/14	N	N[$]
22	**Impact on Quality of Life**	Y	-	-	N	Y
23	**Otherwise fit & well / Comorbidity (e.g., diabetes, RA)**	Y	7/8	12/14	N	Y
24	**Pain severity**	N	-	14/14	N	Y
25	**Usual level of physical activity**	N	3/8	9/14	N	Y
26	**Over-use / Over-head activities / racquet sports**	N	-	7/14	N	Y
27	**Cognitive capacity**	N	-	9/14	N	N[$]

28	**Psychosocial complexity: Psychosocially burdened / Psychological problems**	N	6/8	14/14	N	Y
29	**Health literacy/understanding**	N	7/8	9/14	N	Y
30	**Motivation**	N	7/8	-	N	Y
31	**Patient Compliance**	N	7/8	14/14	N	Y
32	**Self-efficacy**	N	7/8	-	N	Y
33	**Pain elsewhere / isolated clinical problem**	N	5/8	9/14	N	Y
34	**Re-assurance re: diagnosis/ Diagnostic certainty**	N	7/8	9/14	N	Y
35	**Current response to analgesia/ Painkiller response**	N	-	7/14	N	Y
36	**Inadequate previous treatment / Incomplete previous physiotherapy**	N	7/8	-	N	Y
37	**Muscle weakness**	N	7/8	-	N	Y
38	**Instability / recurrent dislocation**	N	7/8	14/14	N	Y
39	**History of injury: trauma or over-use**	N	-	12/14	N	Y
40	**Sleep disturbance/problems sleeping**	N	6/8	14/14	N	Y
41	**Response to physical test**	N	7/8	-	N	Y
42	**Imaging results**	N	7/8	-	N	Y
43	**Modifiable biomechanics**	N	-	9/14	N	Y

44	**Symptoms / pain frequency**	N	5/8	-	N	Y
45	**Course of symptoms (improving/deteriorating)**	N	7/8	-	N	Y
46	**Active Inflammatory process**	N	-	12/14	N	Y
47	**Red flags/serious pathology**	N	7/8	14/14	N	Y
48	**Not a surgical candidate**	N	-	-	Y	N[$]
49	**Benefit/ Welfare Concerns**	N	-	-	Y	Y
50	**Is analgesia already optimised?**	N	-	-	Y	Y
51	**No. of previous injections**	N	-	-	Y	Y
52	**Capsular pattern**	N	-	-	Y	Y
53	**Socio-cultural issues (language or cultural difficulties)**	N	3/8	-	N	Y ^
54	**Litigation or retired or on benefits**	N	1/8	-	N	N[@]3
55	**Fear avoidance**	N	6/8	-	N	N[@]28
56	**Positive outlook, coping**	N	6/8	-	N	N[@]28
57	**Patient expectations and assumptions**	N	8/8	14/14	N	N[@]10
58	**Medication compliance**	N	6/8	-	N	N[@]34
59	**Mechanism of injury**	N	-	14/14	N	N[@]44
60	**Need to RTW/activity quickly / Speed of treatment results**	N	6/8	12/14	N	N*

61	**Speed of treatment access**	N	-	14/14	N	N*
62	**No further indication for treatment / Good prognosis**	N	5/8	-	N	N*
63	**Physical immobility/General mobility/Physically active or sporty**	N	-	-	Y	N@25

$ = Not taken forward to next round, see Table 4.4

^ = Not agreed by consensus but research team thought it was worth exploring this attribute further

@ = Covered by another attribute

* = A health service-related factor, not a patient attribute

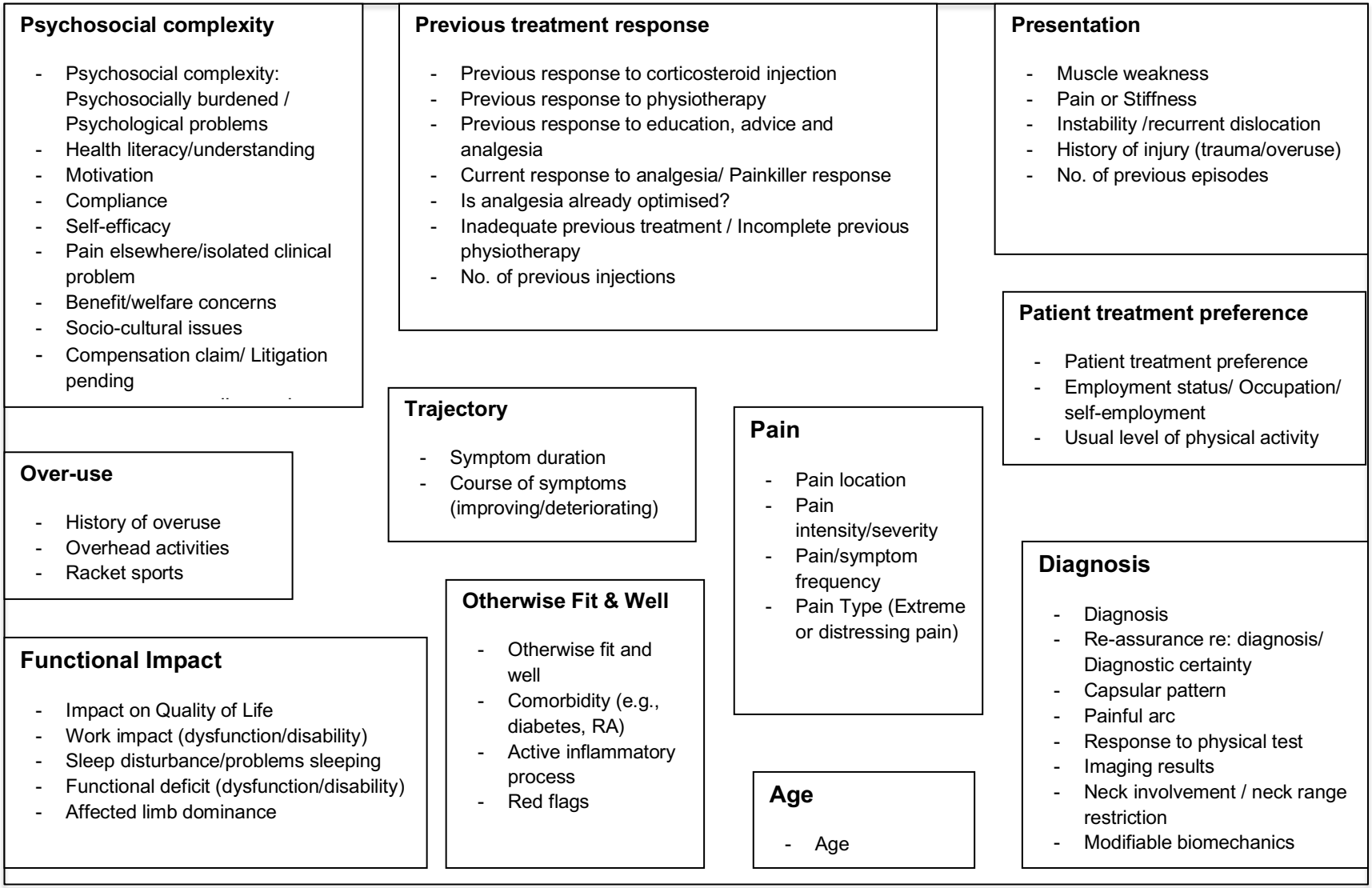


Figure 4.1: Output from categorisation exercise (Phase 1)

Table 4.4: Attributes removed during Phase 1

Attribute	Reason for removal
No. of muscles with active trigger points	Not an easily identifiable clinical factor by GPs
Restricted ROM	All patients with shoulder pain have restricted ROM, not a moderator
Not a surgical candidate	Not relevant to primary care, unlikely to be a moderator
Usual level of physical activity	Included in sport and work impact attributes
Cognitive capacity	Potential moderators, but unethical criteria upon which to base treatment decisions
Education level	
Gender	
Night pain	Similar to sleep impact, also reflected in active inflammatory process

4.8.2 Phase 2 Results

Both parallel workshops in phase two succeeded in re-organising the categorisation exercise into a smaller number of parent attributes namely: psychosocial complexity, previous treatment response, presentation, trajectory, diagnosis, over-use, pain, otherwise fit and well, functional impact, patient treatment preference and age (see figure 4.1). Table 4.5 shows that each group identified 13 parent attributes to describe all of the suggested attributes. Agreement between the two groups is depicted using a traffic light system in table 4.5. Five parent attributes, shaded green were very similar between both groups. Five parent attributes were shaded yellow address very similar constructs but were worded differently. Each group identified three parent attributes (shaded red) that were not identified by the other group.

Participants of workshop 2 acknowledged that this process of reducing and consolidating the number of attributes was highly pragmatic and that there may be inconsistencies or errors. Repeating this process in two separate clinical groups helped to mitigate possible effects of this limitation. Member checking was conducted to further assist this process by sending a copy of the final workshop output to workshop participants and asking them to respond with any suggestions or amendments. The researcher also presented the final attributes and questions to three specialist physiotherapists who were unable to attend the workshops in order to check the external validity of the final workshop output. No new attributes were identified through these steps.

Table 4.5: Parent attributes suggested by participants of Workshops 2a and 2b (Phase 2)

Workshop 2a	Workshop 2b
(Green: Perfect agreement on constructs and clinical wording between groups)	
Otherwise fit & well?	Otherwise fit & well?
Positive Previous Treatment Response	Positive Previous Treatment Response
Improving?	Improving?
Patient treatment preference?	Strong patient treatment preference?
Significant functional impact?	Substantial functional impact?
(Yellow: Constructs agreed but clinical wording not agreed between groups)	
Recent injury +/- overuse?	History of injury?
Pain severity	Severe pain?
Primary problem	Primary presenting problem
Complex Contributing Psychosocial Issues?	1+ psychosocial issue/yellow flag +/- widespread pain?
Neck involvement	Symptoms indicative of a local shoulder pathology
(Red: Different constructs identified by the two groups)	
Episode type	No. of previous injections
Inflammatory process	Age
Urgency of need of treatment	Disturbed sleep due to shoulder?

4.8.4 Phase 3 Results

This stage involved the removal of four attributes from the red-coloured list from table 4.5, attributes that were suggested by one of but not both of the previous

consensus groups. Participants suggested that the number of previous injections was important but since no actual guidance exists on maximum number of injections that it would be very difficult to agree upon logical categorical levels to test in a future conjoint analysis study. Urgency of need of treatment was removed since participants expressed that they struggled with the concept that one patient's urgency of need for resolution of symptoms was more urgent than another patient's. Participants acknowledged that although this was not a patient factor, their knowledge of local waiting times for access to physiotherapy or for an injection was likely to be a factor in their decision. Participants also removed the attribute of age, as although it was acknowledged that certain conditions such as rotator cuff tears and osteoarthritis become more prevalent with age, participants did not feel that age on its own was likely to be a moderator of treatment effect for the primary care treatments under consideration. Although participants recognised that it would be helpful to know whether patients have any relevant and/or additional active or ongoing inflammatory process, when given the task of reducing the final 13 attributes to 12, in order to meet the design requirements for the arising conjoint study, participants opted to remove this attribute.

Table 4.6 shows the final 12 attributes deemed appropriate for studying in the next phase of the PhD, the conjoint analysis. Participants agreed upon a simple clinical question and either dichotomous or trichotomous response options for each of the 12 attributes. Three attributes (pain severity, previous treatment response and patient treatment preference) were considered to need three response options, while the remaining nine could be answered using dichotomous (Yes/No)

responses. This output was edited by the research team so that each clinical question gave rise to distinct attributes and variables that could be studied in the planned conjoint analysis (column 3 in Table 4.6). Specifically, two revisions to the list of attributes were made. The attribute 'primary problem' was proposed by workshop attendees to contain stiffness. The research team opted to remove the word stiffness as a primary problem as stiffness is a strong diagnostic indicator for adhesive capsulitis (Page et al. 2014). Since establishing strong diagnostic signals was not the aim of the conjoint study, stiffness was removed. Pain elsewhere was removed from the attribute 'neck involvement' as there was consensus that the main attribute of interest was neck pain specifically, rather than pain elsewhere. Whilst neck pain in the context of shoulder pain could be understood as relevant pain elsewhere (Littlewood et al. 2012), pain elsewhere could also be understood as a sign of a multi-site pain presentation (Vergouw et al. 2011), other signs of which were suggested as included in the psychosocial complexity attribute. The research team felt that these two edits made the final list of attributes more distinct and suitable for a conjoint study. Table 4.6 summarises the above-discussed changes.

Table 4.6: Final 12 Patient Attributes of Relevance to Treatment Decision-Making for Shoulder Pain (Phase 3)

No.	Attribute	Clinical Question Suggested During Phase 3	Final Wording Used in the Conjoint Study
1	**Otherwise fit & well**	Is the patient otherwise fit & well without significant co-morbidity (e.g., diabetes, unstable cardiovascular issues)? **(i)** Yes **(ii)** No	As in Phase 3
2	**Positive Previous Treatment Response**	Did the patient have a positive treatment response for joint injection? **(i)** Yes **(ii)** No Did the patient have a positive treatment response for physiotherapy? **(i)** Yes **(ii)** No	Edited to: (i) Previous positive treatment response to injection (ii) Previous positive treatment response to physiotherapy (iii) No previous treatment
3	**Improving**	Is the patient's shoulder condition improving? **(i)** Yes **(ii)** No	As in Phase 3
4	**Patient Treatment Preference**	Does the patient have a strong treatment preference for joint injection? **(i)** Yes **(ii)** No	Edited to: (i) Patient treatment preference for injection (ii) Patient treatment preference for physiotherapy (iii) No patient treatment preference

		Does the patient have a strong treatment preference for physiotherapy? **(i)** Yes **(ii)** No	
5	**Functional Impact**	Is there significant interference with work or leisure? **(i)** Yes **(ii)** No	As in Phase 3
6	**Sleep Disturbance**	Is there significant sleep disturbance due to the shoulder? **(i)** Yes **(ii)** No	As in Phase 3
7	**Onset**	Traumatic onset? **(i)** Yes **(ii)** No	As in Phase 3
8	**Overuse**	Over-use linked to sport, hobbies or work? **(i)** Yes **(ii)** No	As in Phase 3
9	**Pain Severity**	What degree of pain does the patient report? **(i)** Mild **(ii)** Moderate **(iii)** Severe	As in Phase 3

10	**Primary Problem**	Is stiffness the predominant problem reported? **(i)** Yes **(ii)** No	Removed by research team as stiffness is a strong diagnostic indicator for adhesive capsulitis.
		Is there significant instability and/or weakness? **(i)** Yes **(ii)** No	As in Phase 3
11	**Psychosocial Complexity**	Does the patient have any psychosocial issues? **(i)** Yes **(ii)** No	As in Phase 3
12	**Neck Involvement**	Does the patient have concomitant neck pain and/or pain elsewhere? **(i)** Yes **(ii)** No	Edited to: (i) Also presents with neck pain (ii) Does not present with neck pain The research team removed 'pain elsewhere' in order to enable study of whether presence of neck pain specifically was an important factor in clinical decision-making.

4.9 Discussion

This study used a three-phase method to gain consensus among clinicians regarding the patient attributes relevant to first-line treatment decision-making in patients with shoulder pain. Figure 4.2 provides an overview of the study process and Table 4.7 provides a visual summary of the categorization process that occurred during the three phases of the study culminating in the 12 patient attributes. Beginning with the 29 potential moderators identified by the previous review, clinicians initially suggested 53 patient attributes that were clinically relevant to differential first-line treatment decisions in patients with shoulder pain. Following the consensus process a final list of 12 attributes were agreed as highly relevant to this clinical decision, six of these patient attributes (previous positive treatment response, pain severity, patient treatment preference, functional impact, neck involvement and nature of primary problem) have been previously explored as potential predictors of treatment effect. In addition to the findings of the systematic review presented in the previous chapter, this study also identified six patient attributes that have not been previously suggested as potential moderating factors or examined in existing randomised controlled trials (general health status relating to diabetes and heart disease, traumatic onset, over-use, improving, psychosocial complexity, sleep disturbance).

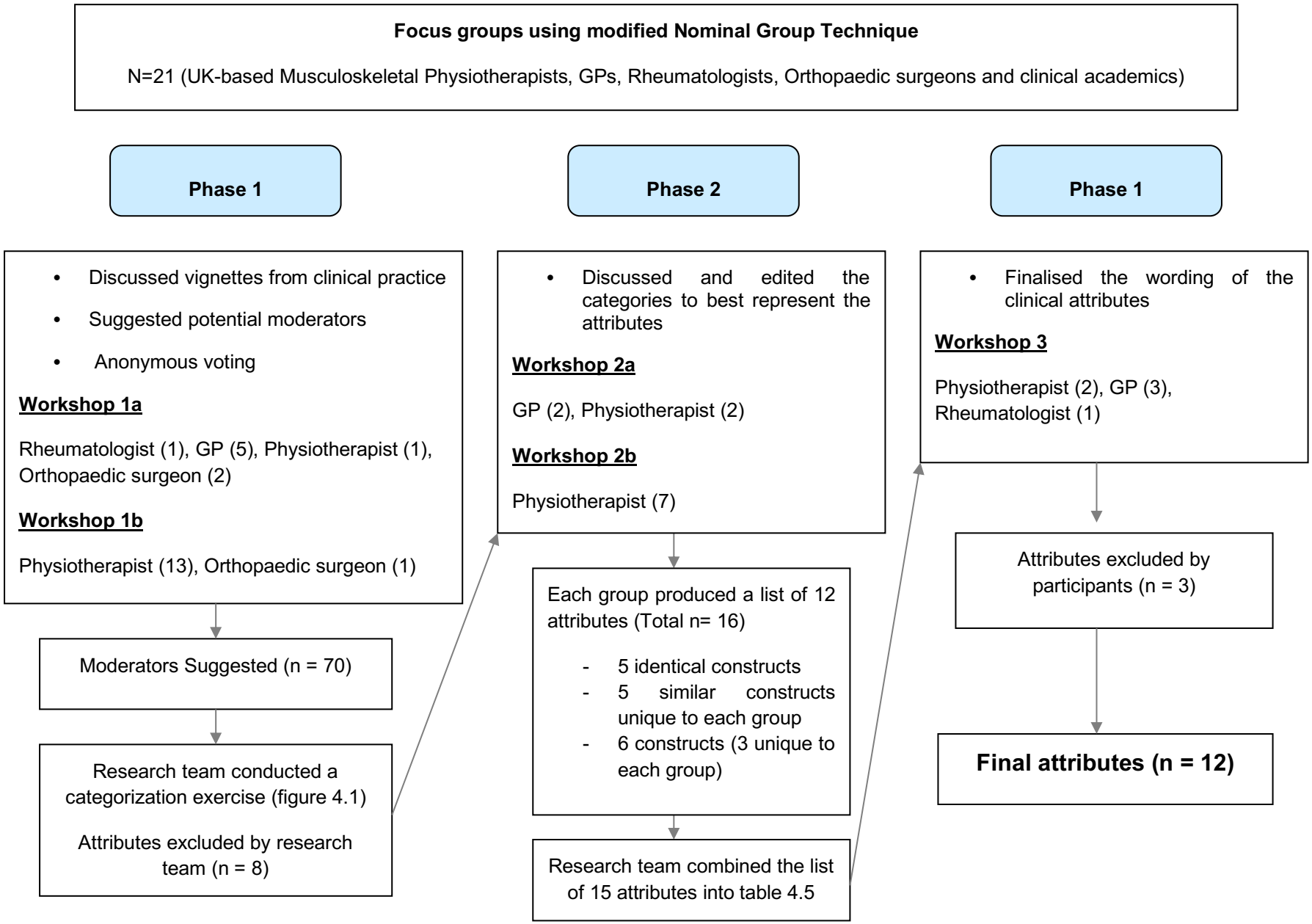


Figure 4.2: Overview of the Focus Groups using Nominal Group Technique

Table 4.7: Tracking of attributes across the study phases

	Attribute Name	Phase 1	Phase 2	Phase 3
		Category Name	Excluded Became Attribute on it's own Brought forward to phase 3	*Final Attributes*
28	Psychosocial complexity: Psychosocially burdened / Psychological problems	Psychosocial complexity	Brought forward to phase 3	Psychosocial Complexity
29	Health literacy/understanding			
30	Motivation			
31	Patient Compliance			
32	Self-efficacy			
33	Pain elsewhere / isolated clinical problem			
49	Benefit/ Welfare Concerns			
53	Socio-cultural issues (language or cultural difficulties)			
3	Compensation claim/ Litigation pending			
26	Over-use / Over-head activities / racquet sports	Over-Use	Brought forward to phase 3	Over-use linked to sport, hobbies or work
22	Impact on Quality of Life	Functional Impact	Brought forward to phase 3	Significant functional impact on work or leisure
12	Work Impact (Dysfunction/disability)			
13	Functional deficit (Dysfunction/disability)			

14	**Affected limb dominance**			
40	**Sleep disturbance/problems sleeping**		**Became Attribute on it's own**	**Sleep disturbance due to the shoulder**
18	**Previous treatment response (separately for each treatment)**	**Previous Treatment Response**	**Brought forward to phase 3**	**Previous treatment response**
35	**Current response to analgesia/ Painkiller response**			
50	**Is analgesia already optimised?**			
36	**Inadequate previous treatment / Incomplete previous physiotherapy**			
51	**No. of previous injections**		**Became Attribute on it's own**	**Excluded**
11	**Symptom duration**	**Trajectory**	**Brought forward to phase 3**	**Improving**
45	**Course of symptoms (improving/deteriorating)**			
23	**Otherwise fit & well / Comorbidity (e.g., diabetes, RA)**	**Otherwise Fit & Well**	**Brought forward to phase 3**	**Otherwise Fit & Well**
47	**Red flags/serious pathology**			
46	**Active Inflammatory process**		**Became Attribute on it's own** Inflammatory Process	**Excluded**
8	**Pain location**	**Pain**	**Brought forward to phase 3**	**Pain severity**
9	**Pain intensity**			

24	**Pain severity**			
44	**Symptoms / pain frequency**			
17	**Age**	**Age**	**Became Attribute on it's own**	**Excluded**
37	**Muscle weakness**	**Presentation**	**Brought forward to phase 3** Primary Presenting Problem	**Instability +/- weakness**
20	**Pain type (pain or stiffness)**			
38	**Instability / recurrent dislocation**			
39	**History of injury: trauma or over-use**		**Became Attribute on it's own** History of Injury	**Traumatic onset**
4	**No. of previous episodes**		**Became Attribute on it's own** Episode type (first/not)	**Excluded**
16	**Patient treatment preference**	**Patient Treatment Preference**	**Brought forward to phase 3**	**Patient Treatment Preference**
1	**Employment status/ Occupation/ self-employment**		**Became Attribute on it's own** Urgency of need of treatment	**Excluded**
19	**Diagnosis**	**Diagnosis**	**Excluded**	**Excluded**
34	**Re-assurance re: diagnosis/ Diagnostic certainty**			
52	**Capsular pattern**			

15	**Painful arc**			
41	**Response to physical test**			
42	**Imaging results**			
7	**Neck involvement / neck range restriction**		**Became Attribute on it's own** Neck involvement	**Neck involvement**
43	**Modifiable biomechanics**		**Became Attribute on it's own** Symptoms indicative of a local shoulder pathology	**Excluded**

Several authors have outlined strategies and tools intended to guide treatment decision-making for patients with shoulder pain (Carter et al. 2012; De Winter et al. 1999; Lewis, 2009). However existing studies largely focus on use of diagnostic factors to guide diagnostic classification (Farmer, 2014) or prognostic factors to guide treatment decisions (Lewis, 2009; van Kampen et al. 2014) and often relate to the outcome of a single treatment only, for example physiotherapy (Chester et al. 2013). The shoulder diagnosis system defined by Farmer (2014) consists of 27 questions and observations and provides an indication of probable diagnosis. Of the 12 patient attributes suggested by this study, just four are in common with Farmer (2014) (instability or weakness, pain severity, diabetes, type of onset). Farmer (2014) identified clinical variables from the literature that were used to diagnose shoulder pain alongside the expert opinion of the author (Farmer) and two additional experts. However, the processes were not described in detail, limiting an assessment of the scientific rigour and potential for bias. The attributes identified by this study were generated through broad insight gained from a large sample of multi-disciplinary clinicians involved in this study, which offered a diverse and generalisable list of patient attributes considered relevant to the treatment decision-making for shoulder pain.

In line with Menendez et al. (2015) who identified psychosocial variables as being highly relevant to the prognosis of shoulder pain, this study suggests that the presence of psychosocial factors is considered by clinicians as relevant to their differential decision-making. Cho et al. (2013) described the association between psychosocial factors and shoulder pain, reporting that anxiety and depression

were highly prevalent in patients with shoulder pain for longer than three months. These results were supported by Wylie et al. (2016) who demonstrated that in patients with a complete tear in the rotator cuff, mental health had the strongest correlation with patient's level of pain intensity. Furthermore, Chester et al. (2016) showed that psychological factors were associated with outcome of physiotherapy intervention for shoulder pain. Similarly, chronic shoulder pain is associated with sleep disturbance (Cho et al. 2013, Mulligan et al. 2015), although the role of sleep disturbance in moderating response to treatment is currently unknown.

4.9.1 Strengths of the study

A variety of shoulder pain clinicians from different disciplines accepted the invitation to take part in this consensus study confirming the importance of identifying factors that may help to optimally target first-line interventions to those patients likely to benefit most. As a result, output is likely to reflect the determinants required for clinical decision-making from a variety of relevant professional perspectives. Each phase of this study offered opportunity for the participants to discuss their unique experience and perspective on the challenges and potential routes forward for the field. Use of clinical case vignettes to elicit potential moderators appeared to resonate with the participants who were very engaged in contributing to the tasks required of them in the workshop. Patient vignettes in this context efficiently enabled participants to reflect on their own clinical practice and relate their clinical experiences to the research task in a time efficient manner.

A particular strength of this study was that the differences between generic prognostic factors and specific treatment moderators were explained throughout each consensus phase, ensuring that participants consistently considered the extent to which attributes inform their decisions between different treatments rather than there assessment of the probability of a favourable outcome in general. Feedback from participants indicated that they felt the process allowed their voices to be equally heard and that they gained a lot from the workshops, including the opportunity to examine their own approach to treatment decision-making from hearing the perspectives offered by other participants. Participants also valued that the definition of each potential attribute was clarified prior to the voting stage, which ensured that the participants understood clearly what the group meant by each attribute. Electronic voting using the classroom voting technology was a reliable and engaging means of enabling concealed/blind voting, as respondents were not able to influence or be influenced by each other's voting preferences.

4.9.2 Weaknesses of the study

The purpose of this study was to identify the most relevant clinical attributes in differential first-line treatment decision-making for shoulder pain to inform the design of the conjoint analysis study presented in chapters 5-8. Participants were informed that the maximum number of clinical attributes that would be accepted in the final phase was 12, as the maximum number of attributes that is considered appropriate/feasible for inclusion in a conjoint analysis study (Carson et al. 1994;

Ryan et al. 2008). In an ideal world, investigators would have taken all attributes agreed by consensus forward into the decision analysis study to test their relative importance. However, the use of the conjoint analysis method restricted the number of attributes that could be carried forward to the next stage in order to generate valid and meaningful data. This may have resulted in the omission of a few potentially relevant attributes. However, the likelihood of this was reduced by the replication of each workshop phase with different professional groups, which also served to reflect the variety of perspectives offered by the different clinical backgrounds.

As frequently noted, threat to representativeness of research findings exists because people who volunteer may have different or stronger opinions than those who do not volunteer. There is also a risk of a geographical selection bias due to the workshops taking place in a single location. This may have resulted in a participation barrier for clinicians who were not local or available on the workshop dates. To counteract this issue, clinicians who expressed an interest in taking part but were unable to attend, submitted their completed case vignettes to the workshop facilitator who included their ideas in the workshops in their absence.

There is some potential for researcher bias in that one investigator initially conducted the categorisation exercise of the output of phase 1. In order to minimise any potential biases introduced in this step, the whole research team subsequently reviewed the analysis, with further iterations to the analysis made.

Revision of audio recordings confirmed that the group facilitator did not lead or steer any of the group's discussion in any way and that similarities in output between groups are likely to be reflective of clinical practice. When participants struggled to express what they meant, the facilitator offered synonyms and examples to clarify attributes suggested by participants.

4.10 Conclusions

This chapter described the identification of patient attributes relevant to first-line treatment decision-making by clinicians for patients with shoulder pain, using focus groups with nominal group technique. Employing an iterative series of clinical consensus method groups, this study successfully identified 12 of the most salient attributes of patients with shoulder pain. The relative importance of each of these clinical attributes in differential decision-making is unknown and will be studied in a clinical decision analysis study.

CHAPTER 5: INTRODUCTION TO CONJOINT ANALYSIS

5.1 Background

The purpose of this PhD is to examine how treatment effect modifiers can be identified and used to underpin the development of an individualised or targeted approach to the management of shoulder pain. In the absence of such knowledge, clinicians continue to make decisions with their patients about selecting treatment for patients with shoulder pain. How exactly clinicians arrive at such individual treatment selection for patients with shoulder pain has not yet been explored. The rationale underpinning the clinical decision to manage individual patients with shoulder pain with education, advice and analgesia in primary care or whether to provide/refer them for steroid injection or physiotherapy is currently unknown.

In chapter 4, a series of expert consensus workshops suggested a list of 12 patient attributes thought to potentially moderate differential shoulder treatment response (table 4.6). There is merit and potential in using novel experimental approaches to quantitatively appraise clinical decision-making. Therefore the next logical step to identify any existing patterns and to develop understanding of how differential treatment recommendations are made. Therein, the experientially constructed clinical knowledge may be quantified, compared across professional groups and countries and the collective clinical opinion gained and quantified.

5.2 Study Aim

Such knowledge has potential to inform the design of a future clinical decision tool for GPs and other first-line health professionals, which may facilitate better targeting of treatments for patients with shoulder pain. Therefore, this study aimed to identify the drivers of clinical decision-making for patients with shoulder pain.

5.3 Rationale for Using Clinical Vignettes to Study Clinical Decision-Making

Clinical vignettes or hypothetical patients are often used in health and medical education to enable teaching and learning of common clinical patterns such as those that fit with diseases and disorders and are often used to study clinical decision-making (Converse et al. 2015). Vignettes allow researchers to experimentally manipulate the clinical attributes of interest and observe the effect on clinical decision-making in an isolated, distraction free environment (Veloski, 2005). Therefore an experimental method of studying clinical treatment decisions when presented with a clinical pattern in the form of a hypothetical patient vignette was required.

Vignettes have been used in existing research to study clinical decision-making for shoulder pain (Artus et al. 2017, Buchbinder et al. 2013b). The present study sought to quantify the impact of each of the patient attributes identified in chapter 4 on differential treatment decision-making, not individually but when considered together in clinical patterns. Although a vignette study would allow researchers to identify associations between treatment choice and patient attributes, vignette

studies rely heavily on the composition of the vignette. Profiles of likely responder and non-responders to each of the three interventions of interest were not known at the outset of this study, therefore the most useful vignette composition to offer in a research survey were not clear. Since clinicians make clinical decisions on the basis of recognisable patterns of patient attributes, the composition of patient vignette offered for consideration was very important. Therefore instead of a vignette study, a method capable of studying the individual impact of each patient attribute when considered as part of a clinical pattern was required.

Such a study would indicate based on clinician decision-making patterns, whether or not identified patient attributes are associated with specific treatment decisions. Specific differential treatment decisions of relevance to UK primary care include the decision to offer the patient with shoulder advice & analgesia or (i) refer the patient for assessment and management by a physiotherapist or (ii) provide the patient with a corticosteroid injection.

5.4 Studying Decisions and Preferences using Discrete Choice Experiments

Understanding how people make decisions relies on understanding individuals' preferences for the ideal composition of a product, service or item under consideration. Two forms of preference exist, revealed preferences and stated preferences. Revealed preferences are based on real observed decisions and are conclusions from data drawn from the real choices, actions, behaviours of an

individual (Bridges et al. 2007). Stated preferences are responses gained from individuals in experimental settings that reveal what an individual says they like/do/behave/choose. Stated preferences are elicited using rigorous scientific research methods (Bridges et al. that involve study of the choices or preferences that individuals exhibit. Revealed preferences could logically be assumed to provide accurate preference data since they are less prone to recall and social desirability bias. However, revealed preferences are highly situated in the physical, emotional and financial contexts in which the decisions occur (Bridges et al. 2007) and it is often not possible, practical, or ethical to experimentally study revealed preferences.

Stated preference methods enable understanding and quantification of the relative importance of various attributes (Johnson et al. 2013). In experimental settings these studies, three synonymous terms are used to describe these studies: discrete choice experiments (DCE's), stated choice experiments or stated preference experiments. In a DCE, respondents consider a series of hypothetical scenarios and indicate their decision based on each scenario (Ryan et al. 2008). Each scenario consists of specially chosen and highly relevant attributes of the decision (e.g., if studying how people choose to purchase a car, relevant attributes of the car might include it's price, colour, number of doors, fuel economy, and other relevant features of a car). The experimental setting offered by stated preference research offers the benefits of focused attention on the experimental task itself, and reduction of environmental influences, allowing participants to respond to the questions exactly as they would like to, not how they feel that they

should or are encouraged to as per social or work roles or within the constraints of their current reality.

5.5 Theoretical Background to Discrete Choice Experiments

Underpinning discrete choice experiments are a series of theories and assumptions that are common across many aspects of economics. It is assumed under consumer theory that respondents are rational decision-makers. Originating in the field of mathematical psychology, utility theory concerns statistical modelling of choice behaviour, and importantly the determinants underlying a choice (Thurstone, 1994). Lancaster's (1966) utility theory postulates that a consumer's choice of a product, based on preferences for components of any given product choice, are ordinal and can be measured and ordered. The facet of utility theory that makes preferences measurable is that individuals have testable transitive preferences i.e.,

> "*if A is preferred to B and B is preferred to C, then one can conclude that A is preferred to C*" (Bridges et al. 2007, pg. 6).

Random utility theory (McFadden, 1978) suggests that individuals innately, whether they realise it or not, hold a set of preferences or beliefs about what their ideal product (car/food/house/restaurant/book/credit card/concept being studied) looks like and that they place a value at the time of choice on all offered options based on the attributes comprising the object (Ryan et al. 2008). This utility is said to be random in the sense that at the general population level, it is an individually

constructed set of preferences, unique to the individual. Consumer theory suggests that consumers choose the product option that represents the maximum value or utility to them, i.e., meets the invisible list of ideals in their mind, whilst being balanced by the costs associated with that purchase (price, time, physical space etc.).

These assumptions form the basis for the design and conduct of discrete choice experiments. Luce & Tukey (1964) proposed the concept of conjoint measurement, the measurement of the impact of attributes when presented together in bundles. When presented with a series of purchasing options comprising of the same attributes but different combinations of these attributes (bundles) i.e., different versions of the desired products, consumers assign value to each combination based on the composition of the bundles. In doing so, individuals make trade-offs to settle upon an ideal balance between costs and benefits of the product (Bridges et al. 2011). Therefore, gaining consumer responses/reactions to a number of different bundles can allow identification of the impact of each attribute on an individual's decision-making. Marketers try to identify different types of shoppers based on how they make product selection decisions. This information is then used to guide how best to specify the minimum number of product versions that will best appeal to the maximum number of potential shoppers in the market.

5.6 Use of Discrete Choice Experiments in Health and Medical Research

In contrast to how economists use DCE's in marketing research, health economists use DCE's to study how individuals, patients, medical professionals and funders differentiate between the costs and benefits involved in decisions about health and health care. Although considered a subset of DCE's, the standard convention in the healthcare literature, although contentious (Louviere et al. 2010), is to call DCE's conjoint analysis (Bridges et al. 2011). Studies using DCE's and conjoint analysis in this way have seen increased application to a broad range of research involving decision-making in healthcare (Bridges et al. 2008; Ryan & Farrar, 2000). However, a large proportion of these studies concern how patients, care-givers or health professionals weigh up decisions about single treatments (Bouma et al. 2001; Danishevski et al. 2007; Kee et al. 1998; 1997; MacCormick & Parry, 2006; Witt et al. 2009) or indicate the individual likelihood of choosing specific treatments (Timmermans et al. 1997).

5.7 Conjoint Analysis to Study Determinants of Differential Decision-Making

In contrast, use of conjoint analysis to study differential decision-making making between multiple treatment options by either patients or healthcare providers has less precedence. A review of medical decision-making studies that used DCE or conjoint analysis revealed that a variety of methods were used to study a range of different clinical decisions (Bachmann et al. 2008) with few studies assessing clinicians' treatment decision-making. The authors are aware of just a few studies that have used a form of DCE to quantify the determinants of differential decision-

making in this way (Caldon et al. 2007; de Bekker-Grob et al. 2013; Hifinger et al. 2017; Langenhoff et al. 2007; McKinlay et al. 1997; Nathan et al. 2011). Table 5.1 outlines four of the most common designs of DCE's specifically in relation to how they could be used to study clinical decision-making by health care professionals. In order to study the determinants of differential decision-making, studies need to show respondents hypothetical clinical cases and collect data on treatment choices. Menu-based conjoint analysis can be used to study the determinants of differential decision-making in this way.

Table 5.1 Forms of conjoint analysis and how they relate to clinical decision-making studies

Discrete Choice Experiment Type	Task Format	Question Format	Output	Relation to Identification of likely moderators of differential treatment response
Conjoint Analysis	View one hypothetical clinical case at a time	Do you think that this patient is likely to respond well to treatment X? (Yes/No)	Statistical weighting of each patient attribute that signifies respondents' thinking on which patient is likely to respond well to treatment X. Statistically weighted profiles of likely best responder, where impact of each other attribute is accounted for in the analysis.	Similar to a single treatment prognosis study, this study would provide insight into the clinical attributes that clinicians think predict response to treatment X. Even if repeated three times for different treatment options, this does not assist with differential treatment decision-making as the attributes would not necessarily discriminate between (expected) response to different treatment options.
Choice based conjoint analysis	View two or more hypothetical clinical cases at once	Which of these patients would do you think would respond well to treatment X? (Choose a patient)		
Maximum difference scaling / best worst scaling	View one hypothetical clinical case at a time	Signal one aspect of the patient's presentation makes you think that: ***(i)*** This patient is likely to respond to treatment X. ***(ii)*** This patient is not likely to respond to treatment X	Statistical weighting of patient attributes on respondents thinking about the attributes that are involved in whether a patient responds to treatment X. In ranked list form, from most to least likely to influence response.	Single treatment – as above. Even if repeated for many treatments, the data is in list form and not a profile. Does not help with identification of patient profiles or assist with identifying who will respond to specific treatment options differently.

Menu-based conjoint analysis	View one hypothetical clinical case at a time	Choose which of the three treatments you think that this patient is most likely to respond best to.	Attributes are weighted statistically for their impact on likelihood that one treatment is chosen over another. Where Treatment A is kept as the constant, weighted profile data is gained on the patient most likely to be recommended to receive: (i) Treatment B versus A (ii) Treatment C versus A	Multiple treatment options considered at once. Relates to differential treatment decision-making. Data quantifies strength of impact of each attribute on likelihood to choose different treatments. Provides quantified stated preference on clinical decision-making using the included attributes.

5.8 How Does Conjoint Analysis Work?

The word conjoint means: 'combining all or both people or things involved' (OED, 2016). In conjoint analysis, the item under consideration is deconstructed into attributes and levels so that the impact of each attribute and level on decision-making can be quantified. In this thesis, the item under consideration is the patient with shoulder pain and the decision being studied is which treatment to recommend. Attributes refer to the patient attributes deemed relevant to decision-making, as suggested by clinicians during the consensus workshops (chapter 4). Attributes and levels are systematically varied and combined to form hypothetical combinations and presented as a series of decision tasks (or patient vignettes in the case of deciding between shoulder pain treatments) that is relevant and meaningful to the respondents. Conjoint analysis focuses on the trade-offs that respondents make in response to each decision task (Bridges et al. 2008). The attributes and levels are the independent variables and the decisions made about the concept are the dependent variables. Based on responses over a series of decision tasks, statistical techniques such as regression analysis can be used to regress the independent variables on the dependent variables to determine the utility, value or impact of each attribute or level on decision-making at either an individual or group level (Bridges et al. 2008; Veldwijk et al. 2016). For example, Nathan et al (Nathan et al. 2011) used a conjoint analysis study to determine how seven specific attributes of patients with hepatocellular liver cancer were used by surgeons to decide on treatment. Respondents viewed ten case vignettes made up of various combinations of the attributes and indicated their preferred treatment from a choice of four treatment options. Multinomial logistic regression was used

to identify which of the seven patient attributes aligned with the decision to refer to each of the treatments.

5.9 Role of Conjoint Analysis in this Thesis

Conjoint analysis, a form of discrete choice experiment, is a robust experimental and quantitative methodology that can be applied to the study of clinical decision-making. It offers advantages over Delphi studies and vignette studies namely; ability to present hypothetical patient profiles when the known best responder patient profile is unknown and the quantification of the impact of each attribute on decision-making, with the impact of every other attribute controlled for. The design and conduct of conjoint analysis studies require several methodological decisions in order to ensure valid results. These decisions are outlined in the context of a study of how clinicians choose treatment for patients with shoulder pain in chapter 6.

CHAPTER 6: METHODOLOGY FOR CONJOINT ANALYSIS STUDY OF CLINICAL DECISION-MAKING FOR PATIENTS WITH SHOULDER PAIN

6.1 Background

Chapter 5 introduced the conjoint analysis method and outlined the relevance and benefits of using a conjoint analysis study to quantify the determinants of clinical decision-making. The rationale for the methodology used in the survey of clinical decision-making for shoulder pain is outlined below. The methodology is based on the checklist for good practice in conjoint analysis studies produced by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (figure 6.1) (Bridges et al. 2011).

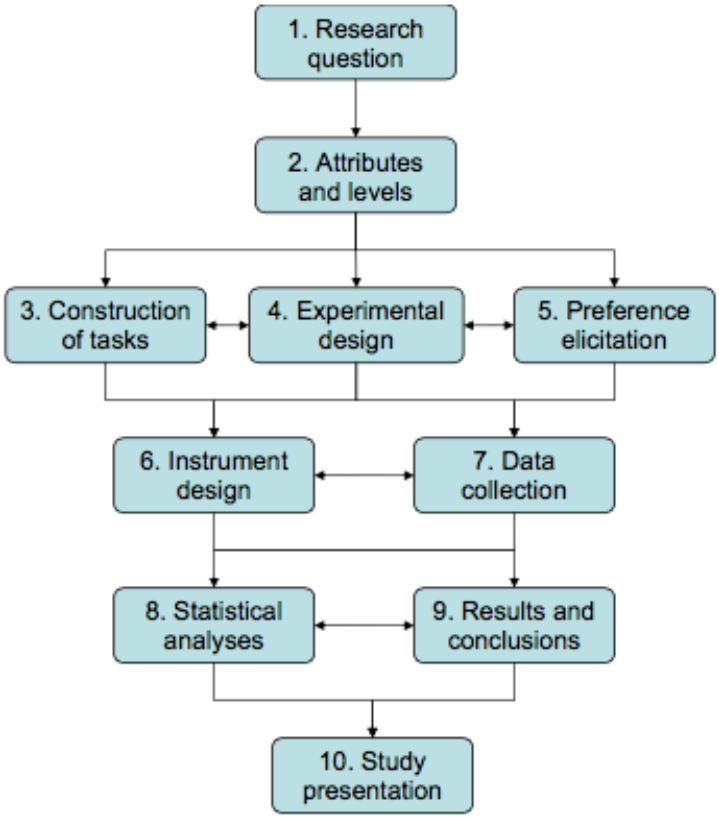


Figure 6.1: Checklist of conjoint analysis in healthcare (from Bridges et al. 2011)

6.2 Aim

This study aimed to identify the relative importance of patient attributes in the decision to refer to GP-led care, physiotherapy or steroid injection in hypothetical patients with a shoulder disorder.

6.3 Research Question

An online conjoint analysis study was designed to investigate clinical decision-making of health and medical professionals who manage patients with shoulder disorders. Although there are accepted differences between what clinicians do and

what they say they do, conjoint analysis presents the opportunity to study clinical decision-making in a scientific and controlled manner using hypothetical yet realistic clinical scenarios that are meaningful to clinicians. Gaining insight into how clinicians' trade-off potential combinations of the 12 clinical attributes identified in chapter 4 to make differential treatment decisions could aid development of a future first-line clinical decision tool. Conjoint analysis is well suited to quantifying trade-offs made by decision-makers in a clinical context (Bridges et al. 2011).

6.4 Methods

6.4.1 Attributes and Levels

Inclusion of each attribute in a conjoint analysis study must be justified by a strong theoretical rationale. Attributes in this study were identified on the basis of a systematic review of the literature (chapter 2) and a series of mixed methods expert consensus workshops (chapter 4). This mixed methods work was undertaken specifically to identify the most parsimonious list of patient attributes perceived by clinicians as needed to make an informed differential treatment decision. Use of expert, clinical opinion and qualitative research is advised in order to identify the most salient clinical features so that the study design may be based on commonly considered and logical clinical information (Bridges et al. 2011; de Salis et al. 2013).

Clinicians involved in this developmental work were made aware that output from the work would be used in this conjoint analysis study and as such a number of conditions for the selection of attributes were stipulated: (i) relevance of attributes to the decision being studied, (ii) that attributes were mutually exclusive, (iii) that any level of an attribute must be theoretically combinable with any level of the other attributes and (iv) the final number of attributes is not infinite (Orme, 2002).

6.4.1.1 Relevance of Attributes to the Decision

As described in chapter 4 (workshops), the early lists of suggested moderators were very broad and included a wide range of clinical attributes of patients with shoulder pain. Consideration of the relevance of each attribute to the decision being studied was advised (Bridges et al. 2011), in this case relevance of attributes to differential treatment decision-making for shoulder pain. It is also suggested that attributes should be considered in the specific context of the decision being studied (Bridges et al. 2011). For this study, clinicians were asked to consider the common first-line treatment decision-making scenario: a patient presents to a clinician with shoulder pain, and the clinical history alone, as presented at that time, is used to guide first-line differential clinical decision-making.

6.4.1.2 Mutual Exclusivity of Attributes

In conjoint analysis, best convergence of the statistical model occurs when attributes are not correlated with each other (Bridges et al. 2008; 2011). This was

difficult to apply to the context of a patient with shoulder pain where for example, the attribute of pain severity is likely to be highly correlated with levels of dysfunction, immobility and impact of pain on the affected individuals life, work and hobbies. Although correlation between attributes could not be avoided, the final attributes were selected on the basis that they each represented different clinical concepts.

6.4.1.3 Theoretical Combinations of Attribute Levels

Since this study concerns a patient with shoulder pain, as theorised under the expertise and pattern recognition frameworks (see chapter 3), certain common and naturally occurring patterns in patient attributes are likely to exist in the clinical presentation of patients with shoulder pain. Furthermore, there are likely to be some instances where a level of one attribute is theoretically but not logically combinable with a level of another attribute, e.g., although it is possible that a patient could have high pain intensity yet report low impact on sleep or no impact on work, hobbies or sport, this is not very likely or indeed logical. Where patients present with illogical clinical presentations in clinical practice, clinicians seek additional information for clarification. Therefore possible instances such as these were viewed as a pragmatic limitation of the conjoint analysis method. Since this is the first conjoint analysis study in shoulder pain, how clinicians might overcome such illogical attribute combinations in an experimental setting was unknown. Conjoint analysis was deemed to have more benefits than downsides in addressing this research question.

6.4.2 Number of Final Attributes

The number of attributes in a conjoint analysis study affects the complexity of the decision tasks that respondents are presented with, as each decision task (or patient vignette) will be a combination of multiple attributes. Conjoint analysis studies typically include three to seven attributes in a study, with most studies having six attributes and up to four attribute levels (Marshall et al. 2010). A study with a large number of attributes therefore demands a high degree of concentration and respondents often resort to simplification strategies (see section 6.4.3, (Orme, 2002)). Although no exact 'rules' exist on the maximum number of attributes in a conjoint analysis study, researchers need to consider the impact of the number of attributes on the cognitive burden of completing the tasks for respondents. 'Rules of thumb' suggest that five to seven attributes is a reasonable number of attributes to include in a conjoint analysis study (Marshall et al. 2010). Six to eight attributes is commonly recommended to reduce potential measurement error due to inattention (Bachmann et al. 2008), although examples of successful studies with larger numbers of attributes exist (Bouma et al. 2001). In spite of the extensive preliminary work undertaken to reduce the list of attributes to be included in this study, it was agreed that 12 attributes should be included, even though this is remains a large number for a conjoint analysis study.

6.4.3 Construction of Decision Tasks

Decision tasks in a conjoint analysis study are the profiles that respondents view and are required to make decisions based on. Good task design is central to

designing an engaging conjoint analysis study that produces reliable data. Tasks may be presented using all of the attributes using full-profile methods or alternatively, tasks may be presented based on just some of the attributes by using partial-profile methods. Partial profile methods allow greater focus on the attributes shown however this does not often reflect reality and respondents may feel that they do not get a full sense of the object under consideration. Although full-profile methods generate more difficult decision tasks, this complexity reflects clinical reality hence, it is usual practice to offer full-profile methods in healthcare conjoint analysis studies (Bridges et al. 2011).

It has been suggested that when respondents are asked to deal with decision tasks with greater than six attributes in a full-profile design they resort to simplification strategies or heuristics to manage the complex decisions presented, which can lead to over-estimation of importance of too few attributes (Orme, 2002). A clinical heuristic from clinical practice may manifest in a conjoint analysis study where respondents may select a specific treatment option based on only one or two attributes, whilst effectively ignoring other attributes, an example in the context of this study could be the selection of corticosteroid injection every time a profile contained high pain intensity or sleep disturbance, regardless of other attributes. Whilst this is a valid concern, the purpose of this study was to identify these very heuristics that clinicians use to decide on treatments for specific patients with shoulder pain. Given that clinicians are accustomed to weighing up the many complex facets of each individual patient's clinical presentation, it was considered unlikely that clinicians would employ inappropriately reductive

simplification tactics. Use of full-profile task in this study was undertaken accepting therefore that estimates might be deflated due to the selective inattention caused by the clinically realistic, yet complex decision task design.

A number of possible conjoint analysis study designs, were considered to study the impact of the 12 attributes on differential decision-making for shoulder pain treatment. As outlined in table 5.1 (types of conjoint analysis), it is possible to show one or multiple hypothetical profiles at once and there are different questions that may be asked of respondents facing these profiles. In this study, one hypothetical patient profile was shown at a time in each decision task since this most closely replicated typical differential treatment decision-making scenarios encountered by clinicians during routine clinical practice. Conjoint analysis studies may allow respondents to opt out of decision tasks or respond by choosing a status quo response if they are uncertain of how best to respond to a specific task (Bridges et al. 2011). These options were not offered in this study, as clinical practice demands that patients are treated in spite of any clinical uncertainty.

6.4.4 Experimental Design

Experimental design involves systematically creating decision tasks using the attributes and levels to create hypothetical scenarios for respondents to view and respond to (Kinter et al. 2012). Experimental design involves a series of design decisions on: (i) full factorial or partial factorial design, (ii) use of orthogonal array, (iii) balancing design efficiency and statistical efficiency, (iv) blocked design, and

(v) dealing with implausible combinations.

6.4.4.1 Full Factorial or Partial Factorial Design

A full factorial design contains all possible combinations of attributes and levels, enabling estimation of all main effects and interactions (Ryan et al. 2008). To calculate the number of possible combinations of the attributes, attributes are grouped based on the number of levels in each attribute. For each group, the number of levels is risen to the power of number of attributes containing that number of levels. This number is then multiplied by the next level group to the power of the number of attributes with that number of levels. This study contains nine attributes with two levels each and three attributes with three levels each therefore, the calculation for number of possible combinations is: 2^9 x 3^3 (alternatively denoted $2^9 3^3$) = 13824 possible combinations. As is the case with this study, a common disadvantage of a full factorial design is that the number of decision tasks is very large (Ryan et al. 2008).

Since it would not be possible or sensible to ask that respondents respond to all 13824 combinations of attributes, researchers typically select a smaller, or fractional subset of potential combinations to study (Ryan et al. 2008). A fractional factorial design offers this but at the cost of reduced capacity to study interactions between attributes, which is an accepted limitation of conducting conjoint analyses with large numbers of attributes (Ryan et al. 2008). In such circumstances, a main effects only design, not estimating all interactions between attributes, can be constructed using an orthogonal array.

6.4.4.2 Orthogonal Array

An orthogonal array is a design matrix that indicates which attributes and levels should be grouped together into profiles whilst avoiding unnecessary repetition of attribute combinations, data redundancy, and allowing representation of the attributes and levels in an unbiased manner (Bridges et al. 2008; Kinter et al. 2012). Thus, an orthogonal array is a very important stage in the design of an efficient experimental design (Kinter et al. 2012). A good experimental design reduces the number of tasks required of respondents so that respondent interest and focus are retained (Kinter et al. 2012). An orthogonal array can be applied to study main effects only where the number of decision tasks is mathematically defined and reduced compared to also studying interactions (Kinter et al. 2012; Louviere, 1988; Ryan & Gerard, 2003). A (2^9)(3^3) main effects orthogonal design identified from the SAS catalogue of orthogonal arrays (Kuhfeld, 2005) was applied to this study and 36 decision tasks were recommended.

In a fractional factorial design such as this one, where not all possible combinations are used, the statistical efficiency of the experimental design is dependent on the degree of orthogonality (Kinter et al. 2012). Orthogonality relates to the degree to which correlation/co-linearity between the attributes has been removed within the experiment (Johnson et al. 2013). Therefore, having chosen attributes that are as independent of each other as possible and using an orthogonal array as a mathematically modeled method of designing the conjoint analysis study, researchers can be confident that the study will return efficient

estimation of respondents' preferences with a low degree of measurement error (Hensher et al. 2005; Kinter et al. 2012). The final array used to inform the experimental design in this study was also visually examined for level balance, i.e., to ensure that each level was shown next to every other level a similar number of times (see appendix 6) (Johnson et al. 2013). Composition of the 36 decision tasks arising from orthogonal array may be found in appendix 7.

6.4.4.3 Balancing Design Efficiency and Statistical Efficiency

An optimal experimental design for a conjoint analysis study is one that accepts the inherent limitations that arise from balancing statistical efficiency and response efficiency (Johnson et al. 2013). Orthogonal designs achieve statistical efficiency when studying main effects only. However due to their complex design, decision tasks or including tasks that contain implausible combinations may negatively impact upon response efficiency (Johnson, 2008; Louviere et al. 2008). Response efficiency relates to the impact of cognitive effects such as simplifying heuristics, respondent fatigue, confusion or inattention on the degree of measurement error (Johnson et al. 2013). Response efficiency was achieved by reducing the number of decision tasks that each respondent was asked to complete using a blocked design.

6.4.4.4 Blocked Design

The number of decision tasks arising from the orthogonal array (n = 36) is a much more feasible number than the total number (n = 13824) of possible combinations.

However, undertaking 36 decision tasks could still take a considerable amount of time and effort, and response fatigue amongst respondents is likely to occur and impact upon response efficiency. A review of conjoint analysis studies showed that most contained the recommended maximum number of seven to sixteen decision tasks per respondent (Bridges et al. 2011; Coast et al. 2006; Marshall et al. 2010). Where the number of tasks exceeds this recommendation, the design can be partitioned into a set number of separate blocks of tasks to be presented to subgroups of respondents, to reduce the number of tasks shown to each respondent, therein reducing burden on respondents (Kinter et al. 2012).

Therefore in order to minimize time and cognitive effort required of each respondent and to maximise chances of gaining high quality data, the experimental design was split into three blocks containing 12 decision tasks (Johnson et al. 2013). Prior to fielding the study, level balance was manually checked within each block of 12 tasks to ensure that each attribute level was shown an equal number of times. Any profiles that appeared to have similar combinations or obvious patterns in attribute levels were randomly allocated to different blocks. Respondents were randomly allocated one of three versions of the survey, each version containing 12 decision tasks consisting of hypothetical patient profiles with 12 attributes in each profile. Allocation to a block of tasks and within block randomisation of the tasks was conducted using randomisation sequences from Microsoft Excel.

6.4.4.5 Dealing with Implausible Combinations

Implausible combinations of attributes can be a feature of statistically efficient orthogonal designs, since all attributes vary independently and randomly to produce a time-efficient subset of potential combinations of attributes and levels (Johnson et al. 2013). As discussed previously (section 6.4.4.3), there were a small number of implausible combinations in this study. It is possible to remove implausible combinations by either removing the affected tasks or to stipulate combinations of levels that are prohibited, however whilst these measures may improve response efficiency they would do so at the cost of reducing design efficiency, leading to imprecise estimation of or inability to calculation the impact of each attribute, therefore it is advised to use prohibitions very sparingly or not at all (Orme, 2002).

Therefore implausible combinations were left in the design as removing them would have compromised design efficiency by interfering with the orthogonal design and potentially leading to imprecise estimation of or inability to calculate the impact of each attribute (Bridges et al. 2011). Since 12 attributes were being tested, which is a large number of attributes by conventional standards, it was anticipated that this would amount to a high respondent burden with some resultant loss of response efficiency. However, rather than remove tasks or use prohibitions to improve response efficiency, the study was run using a blocked, full factorial design so that statistical efficiency was retained. Therefore respondents were warned that implausible combinations may be present in some of the

hypothetical cases, and they were advised to respond as best they could, in spite of confusion or difficulty (Orme, 2002).

6.4.5 Preference Elicitation

Both the experimental design and framing of the decision task have potential to affect how respondents make decisions. The aims and future applications of the study were outlined and respondents were introduced to the tasks. To reduce the impact of professional habits, previous experiences, or beliefs, respondents were asked to consider only the clinical information in the hypothetical profiles when making their treatment choices and to consider all other, absent clinical information to be equal across profiles (Danishevski et al. 2007) (see instructions for survey completion, figure 6.2).

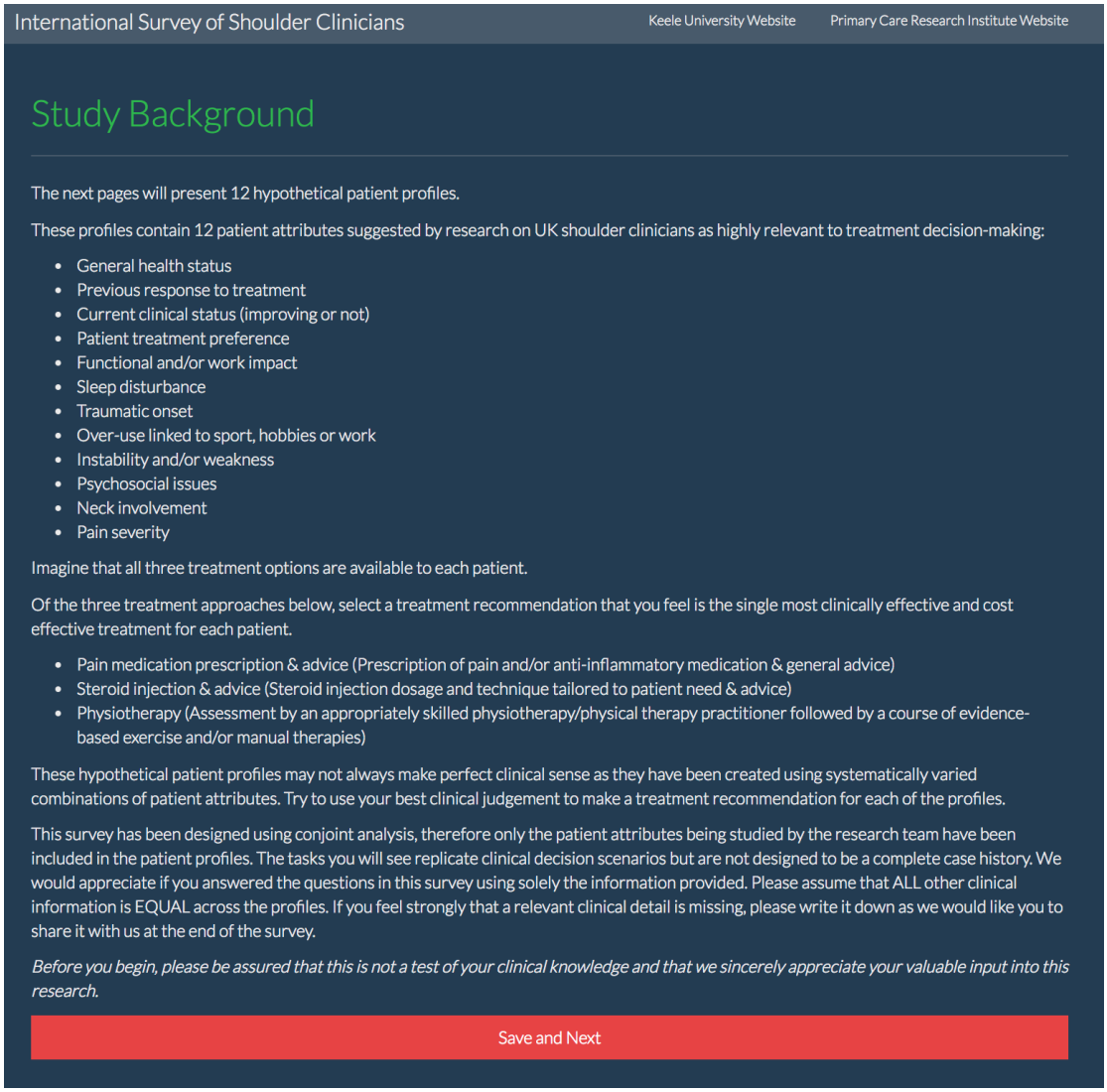


Figure 6.2: Screenshot of the first page of the survey, including a list of the patient attributes included in the study and instructions for completion

Each decision task in this study was designed to replicate the routine clinical decision-making scenario that occurs when a patient with shoulder pain presents to a clinician in clinical practice and a decision on which treatment to recommend is needed (figure 6.3). It is accepted that in clinical practice, treatments for patients with shoulder pain are often offered as part of a multimodal intervention. The systematic review earlier in this thesis (chapter 2) identified very limited conclusive findings on moderators of treatment effect, yet the output of the clinical consensus

workshops (chapter 4) indicate that clinicians have clear ideas about how they use a broad range of information and their experiential knowledge to guide treatment decision-making. Whilst it makes sense in clinical practice to offer treatments in combination, especially where there is good evidence that the treatment shows some effect and is unlikely to be harmful, in this study, respondents were only permitted to recommend a single treatment in response to each hypothetical clinical case. A single treatment recommendation was requested in order to direct clinicians to really think about their decision-making strategies and to choose a treatment that was likely to work based on the information provided, rather than allowing respondents to choose their habitual, locally common, or departmentally preferred combination of treatments that usually work for many of their patients. Thus, the act of choosing between treatments enabled investigation of which clinical factors are most relevant in differential treatment decision-making.

In order to maximise statistical efficiency, respondents were required to provide a response to all decision-making tasks. Lack of response was not permitted since it is logical that all presenting patients to a healthcare setting receive a treatment decision, even if that decision is just one-off delivery of advice and education. For the purposes of the survey, the scenario was defined as every hypothetical patient having unilateral shoulder pain. Three treatments options were available: (i) education, advice and pain relief, (ii) steroid injection and advice, (iii) physiotherapy. Each treatment was defined as per figure 6.3. When little is known *a priori* about how specific decisions are made, such as in this study, it is fair that the experimental design method assumes that respondents do not have a

favourite single treatment and that only the variability in the profiles presented to the respondent impacts upon the decision made, (Kinter et al. 2012).

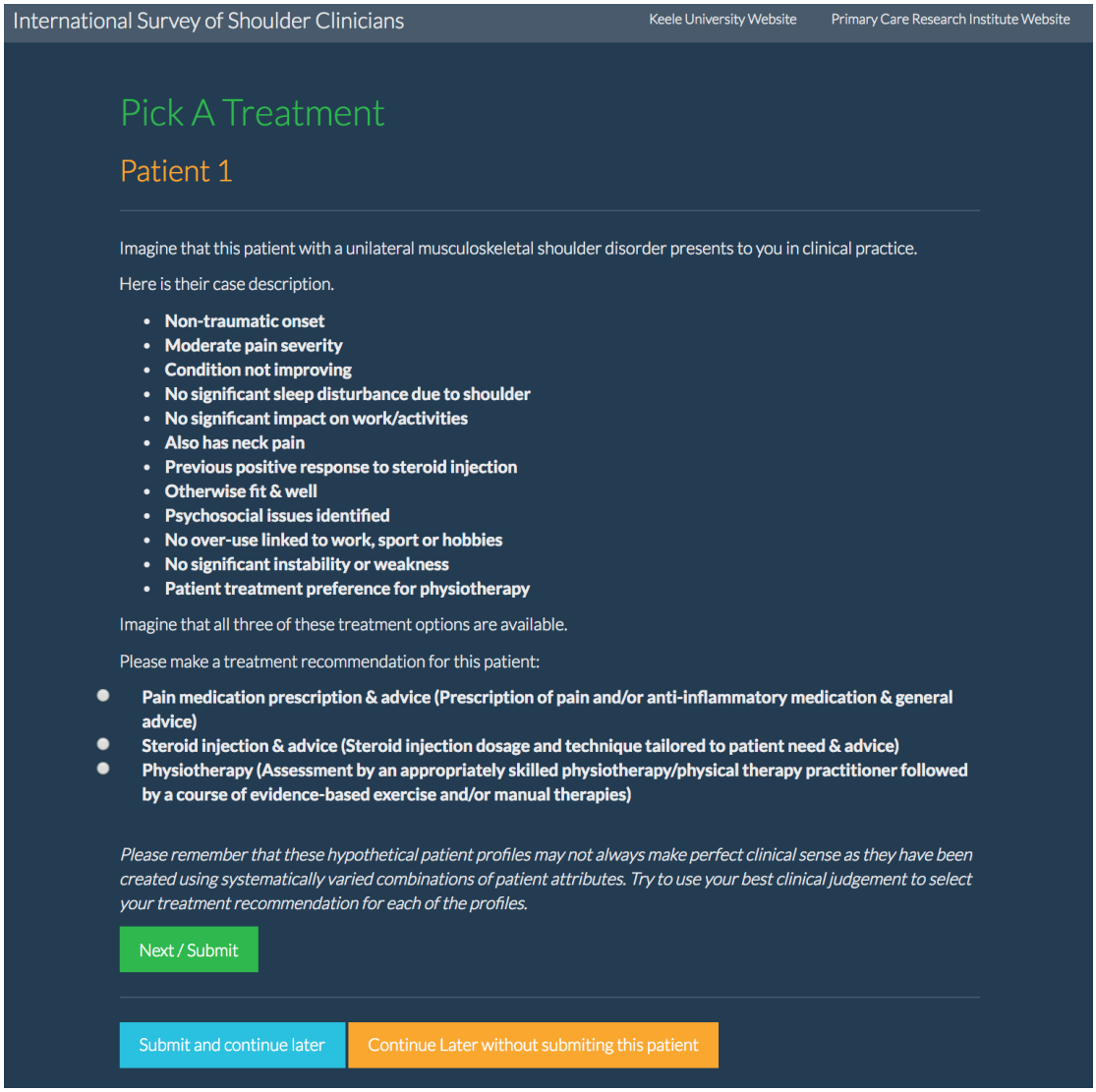


Figure 6.3: Example of a decision task

6.4.5.1 Assessing Validity through Decision Stability

It is increasingly common to qualify validity of response data by collecting additional data on respondent's level of confidence in responses to the decision

tasks (Bridges et al. 2011). The validated decisional conflict scale (O'Connor, 1995) was originally designed to assess how comfortable and confident patients feel with their treatment decision to undergo influenza vaccination or breast cancer screening. This scale contains a range of questions about the determinants of such health decisions. In the context of assessing the validity of a survey designed to study clinical decision-making by health and medical professionals it was deemed more relevant to include a range of distinct questions to indicate respondents' satisfaction with the process of taking part in the survey, how complete respondents felt the clinical case descriptions were, how likely clinicians were to stick with their decision if asked again and also how the survey instrument was perceived. Some questions from the original scale were not deemed relevant to differential treatment decision-making by health professionals and were therefore not used, whilst others were amended to meet this purpose.

Since the wording and constructs of the validated scale were changed, the scored and scale elements of the scale are no longer valid. Therefore the modified decisional conflict questions will be used and reported separately using descriptive statistics. The questions were posed to respondents after the decision tasks as a proxy measure for validity of the conjoint analysis data. Table 6.1 outlines the original decisional conflict scale and as well as the modified questions used in this study.

Table 6.1: Modified decisional conflict questions

Validated Decisional Conflict Scale			**Modified Decisional Conflict Questions**	
Response options: Strongly Agree, Agree, Neither Agree Or Disagree, Disagree & Strongly Disagree				
Original Question Wording		**Action taken for this study**	**Question Wording Used**	
1	I know which options are available to me.	Re-worded	1	When I made the decisions, I felt that I did not know enough about the treatment alternatives
2	I know the benefits of each option.	Not relevant to this study		
3	I know the risks and side effects of each option.	Re-worded	2	I believe that patients would fully understand the risks and benefits of the prescribed treatments
4	I am clear about which benefits matter most to me.	Re-worded	3	I understood the patients' views when I made these decisions
5	I am clear about which risks and side effects matter most.	Not relevant to this study		
6	I am clear about which is more important to me (the benefits or the risks and side effects).	Re-worded	4	When I made the decisions, it was hard to decide if the benefits of the treatment were more important than the risks
7	I have enough support from others to make a choice.	Re-worded	5	All considerations that affected the decision were identified
8	I am choosing without pressure from others.	Not relevant to this study		

9	I have enough advice to make a choice.	Re-worded	6	I had trouble making the decisions because important information was unknown
10	I am clear about the best choice for me.	Not relevant to this study		
11	I feel sure about what to choose.	Re-worded	7	I was unsure about which treatment would really be best for each patient
12	This decision is easy for me to make.	Re-worded	8	The decisions were hard to make
13	I feel I have made an informed choice	Not relevant to this study		
14	My decision shows what is important to me.	Not relevant to this study		
15	I expect to stick with my decision.	Re-worded	9	If asked again, I would expect to stick with my decisions
16	I am satisfied with my decision.	Re-worded	10	I am satisfied with the decisions I have made
		Additional question	11	I am satisfied that the process (i.e., survey design) used to make the decisions was as good as it could be
		Additional question	12	I believe that patients would comply with the prescribed treatment

6.4.6 Survey Instrument Design

Conjoint analysis is a research methodology that morphs survey design with experimental features such as randomisation and inferential statistical analysis. As will be outlined in chapter 7, the Internet offers the potential to run complex survey designs driven by computer logic. In this study, the survey required individual respondents to be randomised to receive one of three versions of the survey and also the order of main survey questions were randomised to limit any potential learning or fatigue effects. Online survey delivery allowed seamless delivery of the necessary block randomisation and within block randomisation procedures. Online delivery also offered the advantage of providing respondents with prompts to minimise missing data through accidental data entry errors, e.g. when respondents accidently skip questions or follow the skip question pattern incorrectly which are not possible using a paper survey. Furthermore given that the source population for this study was unknown, the online survey allowed collection of demographic information on respondents who completed the survey as well as those who began the survey but did not complete it.

As existing survey software was unable to host a survey using block randomisation, the survey instrument was custom designed by a computer programmer (Mr. Tim Smale, E-Learning Fellow, Keele University). Data was housed on a secure server at the University with Mr. Smale only having access to this data on the secure server. In addition to data on treatment recommendations and decision stability, demographic information was collected from respondents on: professional background, years of clinical experience, proportion of clinical time spent treating patients with shoulder pain, country of clinical practice,

proportion of clinical practice that is Government/State funded, post-graduate training relevant to management of shoulder pain, and stated frequency of offering or referring for each treatment ((i) education, advice and analgesia, (ii) physiotherapy and advice, (iii) steroid injection). This data was used to characterise the sample and also to explore variability in differential treatment decision-making based on professional background and country of clinical practice.

Attributes and levels were listed at the beginning of the survey. As these were gained from developmental work (chapter 4) with a variety of clinicians who were similar to those invited to take part in this study, an explanation of the meaning of each patient attribute was not deemed necessary as a pre-curser to the clinical decision tasks. Respondents were reassured that the survey was not a test and that there was no single correct response to any decision task. The issue of implausible combinations potentially being included in the hypothetical cases (as outlined above) was explained to respondents.

Although evidence suggests that health professionals are more likely to complete web surveys in one sitting, in less time and during work hours (Chizawsky et al. 2011), a 'save and return to survey later' option was included in the survey instrument to enable busy clinicians to complete the survey in multiple sittings if required. A progress status bar was included at the bottom of every page of the survey to help motivate respondents to keep responding to the survey. Some conjoint analysis researchers advocate use 'cheap talk', positive motivational

statements throughout a conjoint analysis study to encourage completion (Bridges et al. 2011). This approach was not deemed appropriate for use with a professional audience since it could be considered time-wasting or insincere which may have the opposite to the desired effect. A paper version of the conjoint analysis study may be found in appendix 8.

6.4.6.1 Piloting

The survey was piloted on a mixed group of ten clinicians either in person or via telephone. Respondents gave real-time feedback on their understanding of instructions, questions and tasks as they worked through the survey. Respondents were invited to attempt to complete the survey incorrectly, skip questions and to attempt to 'break the survey' in any way so that the built-in error messages could be tested. The pilot indicated that perception of the survey design and fielding was positive and that planned error messages worked. Clinicians gave feedback that the original order of the attributes in the hypothetical clinical cases did not make clinical sense, and made reading each case more difficult. Attributes were therefore re-ordered as shown in figure 6.2, allowing the profile to be presented in a way that better aligns with the results of a clinical history as routinely conducted.

6.4.7 Data Collection

6.4.7.1 Consent

As data collection and consent for this study was conducted entirely online, the

participant information sheet appeared on the first page of the survey. Respondents were required to indicate that they had read and understood the participant information sheet and met the inclusion criteria using a series of tick boxes (figure 6.4). Entry to survey required that all boxes were ticked. Failure to tick all boxes resulted in respondents being shown a message that stated that this survey required only those who met the inclusion criteria to take part and thanked them for their interested in the survey. Respondents were advised that they could withdraw their consent to participate in the study either simply by closing the browser or at a later date, by emailing the lead researcher.

The survey was open for data collection for a three-month period (17th March - 16th June 2015). The data collection plan including sample, recruitment, justification for mode of delivery and ethical approval will be outlined in detail in chapter 7.

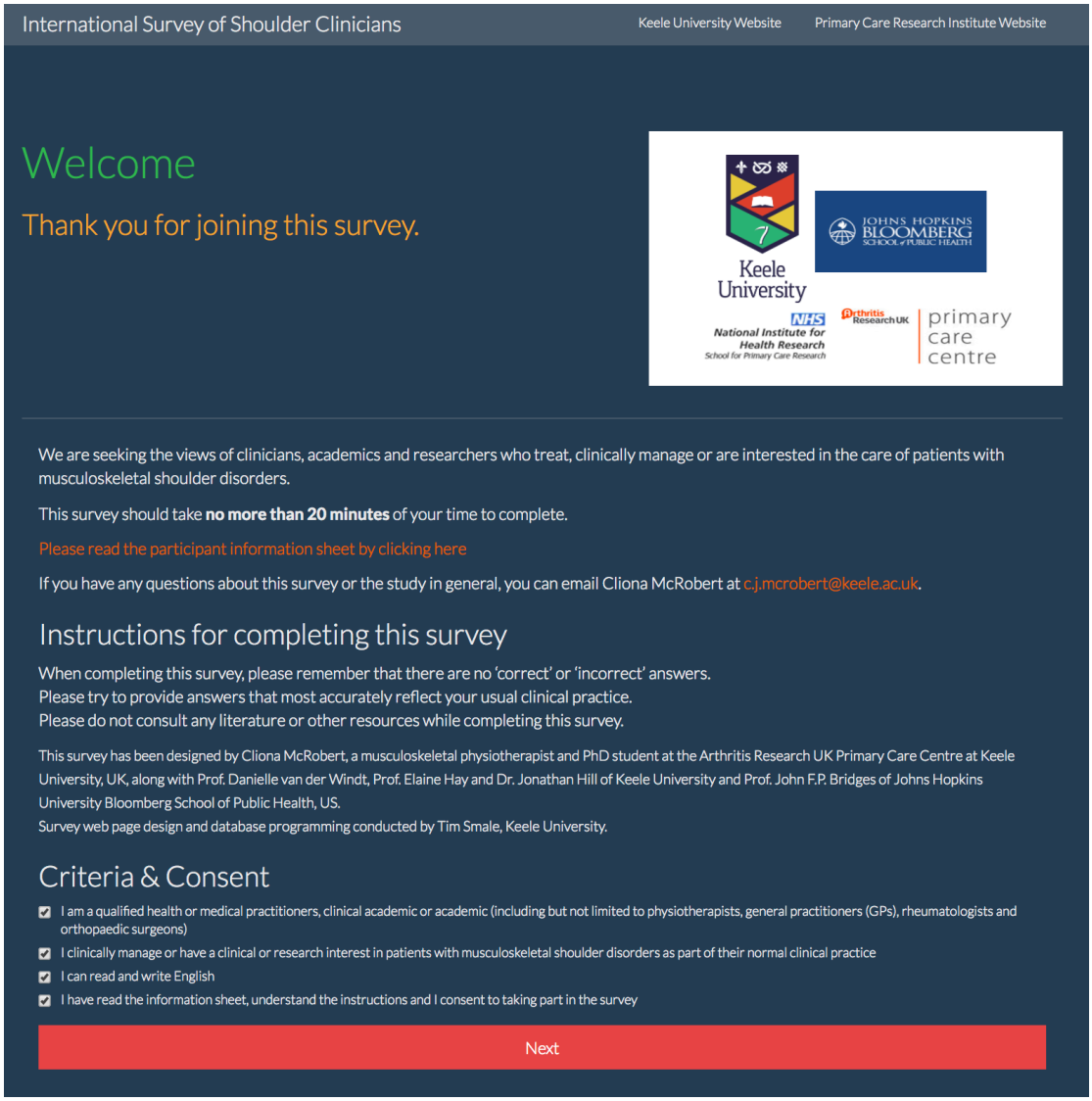


Figure 6.4: Consent process

6.4.8 Statistical Analysis

Only data from those who completed the 12 decision tasks was included in the analysis. A 'save and return to the survey later' option was built in to the survey. If respondents used this feature data was only analysed from those who managed to return to the survey later and completed the 12 decision tasks. Following data checking and cleaning, analysis included descriptive, statistical and thematic analyses to address the research aims. Descriptive statistics were used to

describe the characteristics of survey respondents. Demographic information was reported for: (i) those who completed the survey, (ii) those who started the survey and did not complete it (i.e., assumed withdrawal of consent) and (iii) those who started the survey, ran out of time and opted to save and return to the survey later. Demographic details provided by respondents were assessed to estimate sampling and response bias.

A main effects model was run in this study to gain insight into the impact of patient attributes on treatment decisions (Kohn & Corrigan, 2000). Multinomial logistic regression analysis can be used to model an outcome with more than two categories using multiple predictors (Langenhoff et al. 2007). The treatment recommendation in the decision task (three outcome categories) was defined as the dependent variable while the 12 patient attributes were defined as the independent variables.

In the stepped care model, GP-provided advice and analgesia is a common initial treatment approach. Therefore, recommendations for patients to receive either exercise and/or manual therapy or corticosteroid injection in this study was compared to advice and analgesia in order to ascertain which patient attributes drive alternative treatment decisions in patients with shoulder pain. Taking 'advice and analgesia' as the reference treatment category, odds ratios and associated 95% confidence intervals were presented in order to highlight the effects of each attribute on treatment choice for either corticosteroid injection or exercise/manual therapy. Those intervals not containing the null value of 1 were considered to

reflect statistically significant results.

Clustering is defined as the degree to which responses are similar within anticipated portions of the data. In this study, since individual respondents provided multiple responses and the study design was blocked (i.e., respondents provided data to one of three versions of the study), clustering was anticipated at both block and subject level. Descriptive statistics were generated for the demographics of the sample and to summarise the distribution of baseline variables across blocks (presented in chapter 8). In the event of the randomisation being considered to have been unsuccessful, due to failing to produce similar characteristics across each of the three blocks, models were to be run containing the nested term for both block and subject. If however, the randomisation procedure was considered to have been successful and resulted in similar demographics across the blocks, a block term for respondent would not be entered into the models.

A term for subject was included in the model given that each respondent provided 12 responses and data was expected to cluster at the level of the individual. Therefore, a random intercept model was used reflecting the hierarchical structure of the data with potential clustering of responses within respondents. This may also improve model convergence. Anticipated confounders likely to impact on patterns of clinical decision-making were controlled for (professional background, country of clinical practice and years of clinical experience). Sequential models were fitted to first assess the association of each individual attribute with treatment

decisions, and subsequently of all attributes (independent variables) with treatment decisions (dependent variable). These are defined as:

- Model 1: multinomial models including each individual attributes only
- Model 2: including each individual attribute adjusted for the confounding variables
- Model 3: including all attributes adjusted for confounding variables.

Descriptive statistics were used to present data from the modified decisional stability questions to ascertain respondents' perception of the process of completing the conjoint analysis study and it's acceptability. Free text responses to the 'any additional clinical information required to make this decision' question were mapped against the results regarding potential treatment moderators derived from the systematic review and proposed during the workshops to inform judgment of whether all relevant clinical information was considered in the process of selecting attributes for the conjoint analysis study.

6.4.8.1 Sample Size

Deciding on sample size for conjoint analysis in healthcare is challenging (Bridges et al. 2011) as a precise formula for estimation of sample size do not exist (Marshall et al. 2010). Estimates from previous studies or routinely collected data are not available for treatment preferences, treatment decision behaviour, and weighted relevance of each attribute in the decision to refer to each of the three treatments. In addition, it is not possible to perform an entirely accurate sample size calculation for a study that uses a hierarchical (random effects) multinomial

logistic model where the outcome is one of three response categories (personal communication with a statistician who posed this question to a panel of experienced statisticians at Keele University). Therefore, a pragmatic and cautious approach was applied.

An event per variable approach can be applied as a rule of thumb to try and estimate the sample size required to derive a model that sufficiently discriminates between the three treatment recommendations. Typically, in binary logistic regression analysis, an event per variable rate of 10 is deemed sufficient for a stable regression-based statistical model (Hosmer et al. 2013; Peduzzi et al. 1996). In the context of multinomial regression with three (rather than two) outcome categories, the analysis concerns two comparisons (here: injections versus advice & analgesics, and exercise/mobilisation versus advice & analgesics) and requires two regression coefficients to be estimated for each attribute. Based on these suggestions and what is feasible, a minimum sample size of 10 events (in each of the 3 treatment outcome categories) per variable was applied.

Variations in decision-making on the basis of respondent characteristics can therefore be incorporated as confounders into statistical analysis (Bridges et al. 2011). The number of variables in the model is based on the number of attributes and confounders being studied and how many levels each attribute or confounder has. The total number of dummy variables was estimated (table 6.2) and 25 variables were entered into the model. Therefore the minimum number of responses required was (25X10X3) 750. However, the figure 750 does not

represent a precise sample size estimate but a cautious minimum number of responses to decision tasks for this study on the basis of event per variable rate and number of response categories only.

Table 6.2: Dummy variables for regression model

Variable	Number of Categories	Number of Dummy Variables required
Pain severity	3	2
Onset	2	1
Current Clinical Status	2	1
Sleep Disturbance	2	1
Functional and/or Work Status	2	1
Neck Involvement	2	1
Previous response to treatment	3	2
General Health Status	2	1
Psychosocial Issues	2	1
Overuse due to Sport, Hobbies or Work	2	1
Instability and/or Weakness	2	1
Patient Treatment Preference	3	2
Country of Clinical Practice	6	5
Professional Background	5	4
Year of Clinical Experience	1	1
Total number of Dummy variables		25

Clusters can be problematic in statistical models as data at aggregate level consists of multiple responses from individuals. Therefore the data from this sample is not as varied as a random sample without clustering would be, potentially reducing the impact of the sample size (Shackman, 2001). This loss of

variability caused by clustering is called the design effect, defined as the ratio of actual variance to the variance estimated as if in a random sample (Shackman, 2001). Therefore where clustering is anticipated due to a design effect, the sample size needs to be adjusted to take this into account. In order to estimate the design effect, data from the first 100 respondents was analysed to ascertain the degree of clustering (the intra-class co-efficient).

Preliminary analysis on data from the first 100 respondents revealed that the average cluster size was 12. This showed that each respondent provided 12 responses, i.e., that the data did indeed cluster at the level of respondents as hypothesised. The intra-class co-efficient, determined using the variance term gained from a multinomial logistic regression model run on data received from the first 100 respondents, was calculated as 0.133. The design effect was thus estimated as 1 + (ICC * (cluster size - 1)) = 2.46. The number of responses needed to account for the design effect was calculated as (design effect X sample size estimate = 2.46 X 750) 1845. Given that each respondent provides 12 responses each, a recommended minimum number of respondents was calculated as (number of respondents needed/number of responses given by each respondent = 1845/12) 153.75, rounded up to 154 respondents.

In comparison, an event per variable rate of 20 and multiplied by the number of response categories has been recommended for robust multinomial logistic regression (Biesheuvel et al. 2008; Hosmer et al. 2013; Pincus et al. 2011). On the basis of this and following the same calculation stages outlined above, this

amounted to a recommended sample size of 308.

These sample size estimates take into consideration the event per variable rates of 10 and 20, the 12 patient attributes and three confounders, the three response categories, the expected clustering of data based on a preliminary analysis run on the first 100 participants, and the resulting design effect. Since the average sample size for conjoint analysis studies in health is 100-300 (Marshall et al. 2010), it was felt that aiming to achieve complete data from 200 respondents represented the mid-way point between recommended sample size based on the event per variable rates of 10 and 20 and therefore set a safe minimum sample size to set for the study.

6.5 Summary

This chapter provided an overview of the methodological and design considerations involved in conducting a robust conjoint analysis study of clinical differential decision-making for patients with shoulder pain. The challenges of designing a conjoint analysis study that effectively balances both statistical and response efficiency have been explored and the final design constitutes a practical balance between the two. A strategy for the recruitment of a multidisciplinary and international sample of clinicians who manage patients with shoulder pain is outlined in the chapter 7.

CHAPTER 7: DEVELOPMENT OF A MULTI-MODAL RECRUITMENT STRATEGY USING SOCIAL MEDIA AND INTERNET-BASED METHODS TO RECRUIT A MULTIDISCIPLINARY SAMPLE OF CLINICIANS TO AN ONLINE, INTERNATIONAL RESEARCH STUDY

7.1 Background

In order to study the impact of each of the 12 patient attributes identified in chapter 4 on differential first-line treatment decisions for patients with shoulder pain, a conjoint analysis study was conducted. The rationale and design of this online, international research survey was outlined in the previous chapter (6). This chapter is focused on the design of a novel multi-modal recruitment strategy to the online survey and includes description and discussion of the recruitment results.

As previously discussed in chapter 3 (theoretical underpinning to workshops), first-line management of shoulder pain is usually carried out by GPs, although in some places alternatives exist such as direct access physiotherapy, or musculoskeletal assessment/triage services where first-line treatment decisions are made. First contact professionals (i.e., GPs and physiotherapists in primary care roles) may have developed slightly different approaches to managing patients with shoulder pain compare to physiotherapists, who in turn may differ from specialist clinicians

(such as rheumatologists and orthopaedic surgeons) who typically see patients further along the clinical pathway. It could be hypothesised that for shoulder pain, where diagnosis is a challenge, management approaches may also be internationally diverse. To date, there has not been a study to explore the collective in first-line clinical decision-making for shoulder pain using a multidisciplinary and international sample of clinicians, including but not limited to GPs, physiotherapists, rheumatologists, and orthopaedic surgeons, also involving academic shoulder pain researchers. An international comparison of clinical decision-making for shoulder pain has not been conducted. Such a study would inform future research and/or the design of a widely applicable clinical decision tool to assist clinical decision-making for shoulder pain.

The target population for the planned conjoint survey, investigating clinical decision-making for shoulder pain was therefore both international and involved clinicians who routinely manage patients with shoulder pain such as GPs, physiotherapists, rheumatologists, orthopaedic surgeons, other allied health professionals and researchers. To achieve a multidisciplinary and geographically inclusive sample from this population, careful consideration was given to a recruitment strategy that might prove effective for the needs of the study.

7.1.1 The Challenges of Recruiting Clinicians to Participate in Research Surveys

To maximise generalisability and minimise recruitment bias, the source population should ideally replicate the target population intended for the future clinical tool as closely as possible. However, access to clinicians for research purposes can be challenging (Kellerman & Herold, 2001). Barriers to the engagement and recruitment of clinicians in research studies commonly include lack of time, lack of interest in the research question (Braithwaite, 2003; Kellerman & Herold, 2001; Rahman et al. 2011) and, the tension for clinicians between clinical practice and participating in a study that does not reflect clinical reality, due to the constraints and limitations of empirical scientific enquiry. For data protection reasons, researchers are typically granted limited access to national and international databases of clinicians in healthcare systems or professional societies (Braithwaite, 2003; Rahman et al. 2011). Therefore large-scale studies involving clinicians as research subjects are challenging.

Despite some national professional registration bodies and professional interest societies such as those in the UK (Chartered Society of Physiotherapy (CSP), Royal College of General Practitioners (RCGP), British Society for Rheumatology (BSR), and British Orthopaedic Association (BOA)) having existing databases and mailing lists, member confidentiality precludes researchers having access to these databases and using these to recruit survey participants. Furthermore, accessing equivalent international mailing databases could prove difficult and a lengthy process. An alternative method of approaching clinicians by post or email is to use

commercial clinician databases such as the UK's Binley's databases. However, using such commercial databases internationally would be costly and would not give a specific list of clinicians interested in shoulder pain management.

In addition, since this study was part of a PhD, a number of further practical issues required consideration: the study needed to recruit a sufficiently large sample within a relatively short period of time and at minimal cost. Given these challenges to the recruitment of a valid, representative and generalisable sample, a systematic framework to target this unfixed international population of relevant professionals was required. The opportunities and challenges of common and internet-mediated methods for recruitment are outlined in table 7.1.

7.1.2 Using the Internet to Recruit Research Participants

The Internet has progressed from being a resource that offered one-way interaction via Web 1.0 where information was received only, to an interactive medium via Web 2.0. Web 2.0 enables participation and interaction with online content. The Internet has changed from what once was a place for transaction and non-social communication to a social medium (Veletsianos, 2011), where users can interact socially and maintain and develop personal, social and professional connections. This change means that the Internet can be utilised in research studies for data collection but also has potential for use as a recruitment tool.

A variety of internet-mediated methods for attracting research participants are already in existence and include email invitations, Internet advertising, online message boards and more recently social media (Twitter, Facebook, LinkedIn, Google+) (Lane et al. 2015). Internet-based recruitment methods have been shown to be effective at reaching large, diverse pools of potential respondents aiding external validity whilst also reducing cost compared to traditional recruitment methods (Lane et al. 2015; Ryan, 2013). Furthermore there are many potential benefits of internet-based research, which include: being less costly to set up; recruit to and deliver in reduced time; lower risk of error in data entry compared to paper surveys; easier, quicker and more enjoyable to complete for respondents (perception of novelty); greater anonymity than paper surveys; increased pool of potential participants (increased generalisability); and researchers have control over the content, timing and initial targeting of online recruitment (Ahern, 2005).

Table 7.1 Advantages and disadvantages of survey recruitment methods

Recruitment Method	Advantages	Disadvantages
Word of mouth	Low effort. Low cost. Fast.	Narrow reach. Relies on access to population. Difficult to calculate response rate.
Conferences & **Networking events**	Access to engaged and relevant audience.	More effort. Appropriateness of invitation depends on attendee demographics on that specific occasion. Difficult to calculate response rate.
Postal flyers	Personal delivery of invitation in physical form to relevant individuals. Possible to calculate response rate.	Need access to postal or email address lists of relevant professionals. Moderate cost. Time intensive
Notice boards	Low cost. Low effort.	Narrow reach. Difficult to calculate response rate.
Email invitations	Low effort. Low cost. Quick and easy to forward. Possible to calculate response rate.	Spam filters may block emails. Easy to ignore.
Radio/Television	Broad reach. Novelty.	High cost. High effort. Targeting of specific audience demographic or numbers difficult. Difficult to calculate response rate.
Online message boards	Low cost. Low effort. Novelty.	Potentially wider reach. No guarantee on audience. Difficult to calculate response rate.
Local/network/professional/ society **mailing lists**	Access to large volume of relevant potential respondents. Possible to calculate response rate	Access not guaranteed due to data protection policy of each organisation. Variable cost. Limited to information held on individuals. Potential for information being out of date.
Commercial mailing lists	Access to large volume of relevant potential respondents. Possible to calculate response rate.	High cost. Each mailing list relevant to one country and one professional group only. Mailing lists often not specific to

		clinical interest within professional group.
Personal/professional networks	Access to relevant potential respondents. Personal/professional connection may increase response rate. Low effort. Low cost. Fast.	Reach limited only to those known to the researchers.
Internet approaches (study adverts on professional society/interest websites)	Moderate effort. Fast. Low cost. Likely to be viewed by relevant professionals.	No control over impact of advert.
Social media	Low cost. Fast. Broad potential reach. Uses existing personal/professional networks. Acceptable to approach those who are not in researcher's network. Facilitates social sharing/snowballing. Crosses professional and geographical boundaries.	Challenging to achieve good engagement. Relies on pre-existence of a diverse and functioning social network.
Multi-modal approach	Cover broader demographic and geographical. Take advantages of existing networks as well as opportunities offered by Internet-mediated methods.	More time, effort and cost required. Unable to calculate a response rate for entire approach.

In spite of the many studies that have shown that Internet-mediated research and recruitment are effective, concerns still prevail regarding the risk of selection bias in an internet-based study, as Internet mediated research is less likely than traditional recruitment methods to include certain sections of a population e.g., older people and those without access to the Internet (Frandsen et al. 2014). Early studies that employed Internet methods for recruitment and/or data collection reported that respondents were younger, more educated, predominantly white and were of a higher socioeconomic classification compared to paper-based surveys (Houston & Fiore, 1998). Whilst this is a valid research concern, a review by Ahern (2005) found numerous studies that report no differences in respondent characteristics between respondents when comparing Internet and traditional paper and pen research. As use of both Internet and social media continues to increase, the demographics of users expand to represent the general population more closely.

Lack of access is reported to be a significant limitation of Internet-based studies and a greater issue than simply a lack of willingness to participate (Couper, 2007; Gjestland, 1996). Whilst this was probably a valid concern in 1996, some 20 years later a 2016 report on the use of media by UK adults by the communications regulator, Ofcom (2016) suggests that the use of the Internet, email and social media has increased substantially over the last 10 years with 87% of the UK population using the Internet at least once weekly. Time spent online by UK adults has almost doubled since 2005 and although the computer (desktop, laptop or

notebook) is the primary Internet access device, two thirds of adults now use alternative devices including smart phones and tablets. It is estimated that 79% of UK adults who use the Internet, use email on a weekly basis on a range of devices. Increasing from 30% in 2005, in 2016 73% of UK adult Internet users have at least one social media account, of whom 65% access social media daily. Although younger people (aged 16-24 years) have traditionally been and remain the highest users of social media, adults in all other age categories shown markedly increasing use of social media (the last ten years have seen 68% increase in those of 35-44 years, 61% increase in those of 45-54 years, 41% in those of 55-64 years and 25% increase in those over 65 years) (Ofcom, 2015). Thus Ofcom Internet usage statistics demonstrate an ever-increasing uptake in internet and social media usage across age ranges which suggests that in the UK at least, previously reported differences in Internet access and uptake of Internet-mediated research on the basis of age alone appear to be less stark than previously thought.

As this study aimed to recruit qualified health professionals, it was assumed with a high degree of confidence that general utility of the Internet, email and social media would be high enough to warrant use of an Internet and social media recruitment strategy. Confirmation exists that health and medical professionals already use social media and online resources for the purposes of professional interaction and digital scholarship research, interaction and promotion of existing and current studies through the Internet (Thackeray et al. 2012; Ventola, 2014).

These developments are likely to lead to an increase in response rate to online research surveys compared with 20 or even five years ago. With the increased online population, the anticipated source population is likely to increase. Higher response rates may lead to obtaining a sample that better reflects the target population, reducing the risk of selection bias, as explained above. Furthermore, higher response rates may also increase precision of estimates drawn by any such study.

7.1.3 Internet-mediated Recruitment Methods To Sample From A Known Source Population

Using email to distribute invitations to participate in research to known pre-defined lists of health professionals and researchers is the modern equivalent of posting invitations to participate in research. Whilst other methodological possibilities for using the Internet to recruit individuals exist, these come with challenges such as; differentiating between known and unknown populations, and weighing the pros of access versus the cons of bias. Pre-existing groups on Internet forums or social media websites can share some of the same characteristics as a predefined mailing list in that they are easily located and the number of individuals in the group is quantifiable. Although it is difficult to estimate how many group members still use the online group at the time in which the research is conducted, this is also a consideration with traditional mailing lists.

7.1.4 Internet-Mediated Recruitment Methods To Sample From An Unknown Source Population

Traditional recruitment methods include delivery of research invitations via word of mouth such as in person during conferences or shoulder-specific professional events. These methods are likely to capture a specific audience, but require orchestration and are time intensive. Therefore additional methods of interacting with and gaining input from relevant professionals were indicated, including internet-mediated snowballing methods using Internet and social media. For all these approaches, the source population is unknown, which means that a clear sampling frame cannot be defined, and response rates cannot be estimated.

Social media can be defined as the various online platforms used as modes of connection with a wide variety of people. Recruitment to health and medical research studies via Internet and social media platforms is increasingly prevalent (Bull et al. 2013; Frandsen et al. 2014; Kapp et al. 2013; Ramo & Prochaska, 2012) however, few studies of which we are aware, have used Internet and social media platforms to recruit clinicians as research participants. Woodfield et al. (2013) describe social media as providing multiple channels for communicating with potential research participants. Success of an Internet-based recruitment strategy relies upon tailoring existing approaches to recruitment and the use of creative and engaging communication methods (Moloney et al. 2009). Much in the same way as traditional research relies on clarity, transparency and the reputation of the research team; social media creates the opportunity to rapidly build an

online network of relevant individuals. In the approach described as 'networking the networks' (Madia, 2011), the developed network may then act both as part of the sample and also assist with the recruitment approach.

7.1.5 Multi-modal Recruitment Strategy

Several studies on recruitment to online studies state that good uptake and response rate from the population of interest is obtained when multi-modal methods of study advertising and recruitment are applied (Frandsen et al. 2014; 2016; Khatri, et al. 2015; Topolovec-Vranic & Natarajan, 2016). Having considered the alternatives, it was clear that a novel sampling and recruitment methodology to overcome the limitations of traditional survey recruitment methods was required and that this may involve using social media. Therefore, in order to overcome potential challenges of recruiting a broad, international group of clinicians and researchers, a hybrid approach to recruitment was considered that involved both traditional and internet-mediated methods. This hybrid approach sought to blend traditional offline methods inviting specific, predefined groups, with Internet-mediated and social media-driven approaches, using snowball-sampling techniques. The approach is described in detail here, as despite the increasing use of social media as a research and recruitment tool, few studies have provided insight into the development of their social media strategy when Facebook or other forms of social media or Internet resources have been used as the primary recruitment method (Alessi & Martin, 2010).

Using social media is a cost effective means of efficiently engaging with and recruiting a diverse range of people in health research studies (Ryan, 2013). In the context of research, social media is a highly advantageous vehicle to facilitate social recruitment and to maximise the impact and distribution capacity of an existing professional network beyond solely those known personally to the researcher. Sharing the research invitation on social media facilitates snowball sampling. When an individual, group, society or business view the research invitation and opt to share or 're-tweet' the research invitation, endorsement or support of the research invitation is implied (Temple & Brown, 2011). Such implied support indicates that the invitation was well received which enables the invitation to permeate another degree of social connection, therein delivering the invitation to individuals who the researcher would not have had connection with or direct access to otherwise. Child et al. (2014) refer to this social sharing as lateral communication that has a 'multiplier effect'. In the context of online surveys, the snowball sampling approach, whereby invitation is sent to the researchers professional and personal network for redistribution is an efficient and valid approach to recruiting an unknown population (Benfield & Szlemko, 2006). Although Internet-mediated recruitment methods lend themselves more readily to this social sharing or snowball sampling method, the same principles apply to traditional recruitment methods of word of mouth, poster displays, and postal invitations as potential respondents are asked to share the research invitation with their professional network.

There are a number of potential challenges to the utility of a multi-modal recruitment strategy in addition to the known challenges from traditional survey recruitment methods, such as the differences between those who typically respond and those who do not (Couper, 2007). Coverage errors can occur where there is a mismatch between the target population and those actually sampled, for example, if some of those invited are not regular internet users (Couper et al. 2007). As a consequence, the multi-modal recruitment approach has been designed to try to take these limitations into consideration. An additional limitation is that open, unrestricted online surveys, have to accept the risk that respondents may not actually be who they say they are and even that computer programmes may have been used to create spam data or that respondents may have completed the survey multiple times to create a 'ballot box stuffing' effect (Couper, 2007). This chapter describes the development and operationalization of the hybrid recruitment strategy used to address these limitations and recruit to this online, international research survey.

7.2 Methods

7.2.1 Multimodal Recruitment Strategy

Recruitment to this study occurred over a three-month period between 18.03.15 and 18.06.15. Eligibility criteria for the survey were: being a qualified clinician (general practitioner, orthopaedic surgeon, rheumatologist, physiotherapist of other professional) who manages shoulder pain as part of their routine clinical practice or researcher/academic with an interest in the management of shoulder pain. The recruitment target was to collect complete data from 200 participants during this 13-week period. A multi-modal recruitment strategy was designed to maximise the networking potential of the study team and professional networks in a co-ordinated manner to distribute and spread the survey invitations as widely as possible across professional and geographical boundaries (table 7.2).

Traditional recruitment methods in this study included:

I. Flyers advertising the research survey with a web link were displayed in the Research Institute and University's Physiotherapy & Medical Schools, and also sent to local and regional hospitals with physiotherapy and shoulder rehabilitation departments (n=120)
II. In-person survey invitations were delivered during an invited guest talk at an international conference (n= 180) and research flyers distributed at a multi-disciplinary shoulder rehabilitation training course in the UK (n=360)

III. Postal research flyer invitations were sent to professional networks (n=1000) including local, regional and national general practice doctors, rheumatologists, orthopaedic surgeons and physiotherapists known to the study team

Internet-mediated snowball recruitment methods in this study included:

I. Survey invitations were distributed to the professional network of the study team and Research Institute via e-mail
II. Study adverts were placed on websites of relevant professional bodies and special interest groups (table 7.3)
III. Study adverts distributed via the electronic/email newsletters of relevant professional societies/groups (table 7.3)
IV. Study adverts placed on social networking websites (Twitter, Facebook, LinkedIn, and Google +) using a targeted social media strategy

Table 7.2: Overview of the Targeted Recruitment Strategy for the Conjoint Survey

Method	Professional Background Targeted					Country Targeted	
	General Practitioner	Physiotherapist	Orthopaedic Surgeon	Rheumatologist	Other relevant professional	UK	Non-UK
In Person	- Network	- Network	- Network	- Network	- Network	- Yes	Norway Sweden Denmark
Displayed Flyer	- N/A	- Network - S.R.U.	- Network - S.R.U.	- N/A	- Network	- Yes	- N/A
Postal Flyer	- Network	- Network - Shoulder Units	- Network - Shoulder Units	- Network	- Network	- Yes	- N/A
Twitter	- Network - Societies - Individuals	- Network - Societies - Individuals	- Network - Societies - Individuals	- Network - Societies - Individuals	- N/A	- Yes	Worldwide
Facebook	- N/A	- Network	- N/A	- N/A	- N/A	- Yes	Worldwide
LinkedIn	- Network	- Network	- Network	- Network	- Network	- Yes	Worldwide
Google+	- Network	- Network	- Network	- Network	- Network	- Yes	Worldwide

E-mail invitation from Study Team	- Network	- Network	- Network	- Network	- Network	- Yes	Worldwide
E-mail invitation via other party	- Societies	- Societies	- Societies	- Societies	- Societies	- Yes	Worldwide
Internet adverts	- N/A	- Network - Societies	- N/A	- N/A	- N/A	- Yes	Worldwide
Abbreviations:	N/A = Not applicable Network = Professional Network of the Research Institute for Primary Care Sciences, Keele University Shoulder Units = Shoulder Rehabilitation Units in the National Health Service (NHS, UK) Societies = Professional Body/Society/Organisation relevant to professional background and clinical practice as a shoulder specialist Individuals = Relevant individuals with Twitter accounts identified via the Hootsuite computer application						

Table 7.3: Additional recruitment measures used for the shoulder pain conjoint analysis study

Parties Sharing Research Invitations on behalf of the Study Team	Mode of Recruitment	Relevance to Target Population	Professional Background Targeted	Country Targeted
British Society of Rheumatology (BSR)	Email mailing list	Professional association	Rheumatologists	UK
European Society for Elbow and Shoulder Rehabilitation (EUSSER)	Email mailing List	Professional Interest Group	Physiotherapists & Shoulder Surgeons	Europe
Irish Society of Chartered Physiotherapists (ISCPT)	Email mailing list	Professional Body	Physiotherapists	Republic of Ireland
British Orthopaedic Association	Email mailing list	Professional association	Shoulder Surgeons	UK
Society for Orthopaedic Medicine (SOM)	Email mailing list	Professional Interest Group	Physiotherapists	International
Primary Care Rheumatology Society	Email mailing list	Professional Interest Group	Physiotherapists & Shoulder Surgeons	UK
European League Against Rheumatism (EULAR)	Email mailing list	Professional Interest Group	Physiotherapists & Shoulder Surgeons	Europe
Physiospot	Online study advert	Professional interest website	Physiotherapists	International
Chartered Society of Physiotherapy (CSP)	Online study advert	Professional Body	Physiotherapist	UK

The professional network of the study team consisted of the informal professional (clinical and research) email contacts of the study team members and a few departmental colleagues. Prior to this study, members of the team were not active professional social media users but set up social media accounts specifically for recruitment purposes for this study. Examples of individuals within this network include: members of national and international professional bodies, shoulder pain clinical interest groups, authors of randomised controlled trials in the field of shoulder pain conducted within the last 10 years, editors of journals that routinely publish research on shoulder pain, and clinicians working as clinical shoulder specialists. When contacted, recipients were requested to distribute the invitation onwards through their individual networks i.e., snowball distribution of the survey invitation, where the initial distribution was targeted to those who met the eligibility criteria. The professional bodies and special clinical interest targeted for the survey (table 7.3) were relevant to the topic of the survey (clinical management of shoulder pain), but exact information regarding active membership of each of these groups was not known, as the study team did not have direct access to mailing lists.

7.2.1.1 Targeted Social Media Strategy

An effective social media recruitment strategy needed to be broad enough to target all relevant professionals with an interest in shoulder pain, both nationally and internationally. Generic invitations, personal invitations and group invitations were extended via social media networking sites. All invitations specifically included the request to share the invitation with further personal and professional networks. Generic invitations consisted of a brief outline of the study and who was

required to complete it. Study adverts were placed periodically on LinkedIn (LinkedIn, Co., California, USA) (figure 7.1) and Google+ (Google, Inc., California, USA) (eight times), and (figure 7.2). A specific profile page for the study named 'Physio Shoulder Researcher' was set up on Facebook (Facebook, Inc., California, USA) (figure 7.3). Adverts were placed on the Facebook page (eight times). On each social media platform, visitors could re-post information or updates for others in their network to view, interact with or share. Tables 7.2 and 7.3 show the variety of over-lapping traditional and recruitment methods used to recruit individuals from each professional group. Figure 7.5 (in results section) shows the timing of delivery of each strand of the recruitment strategy.

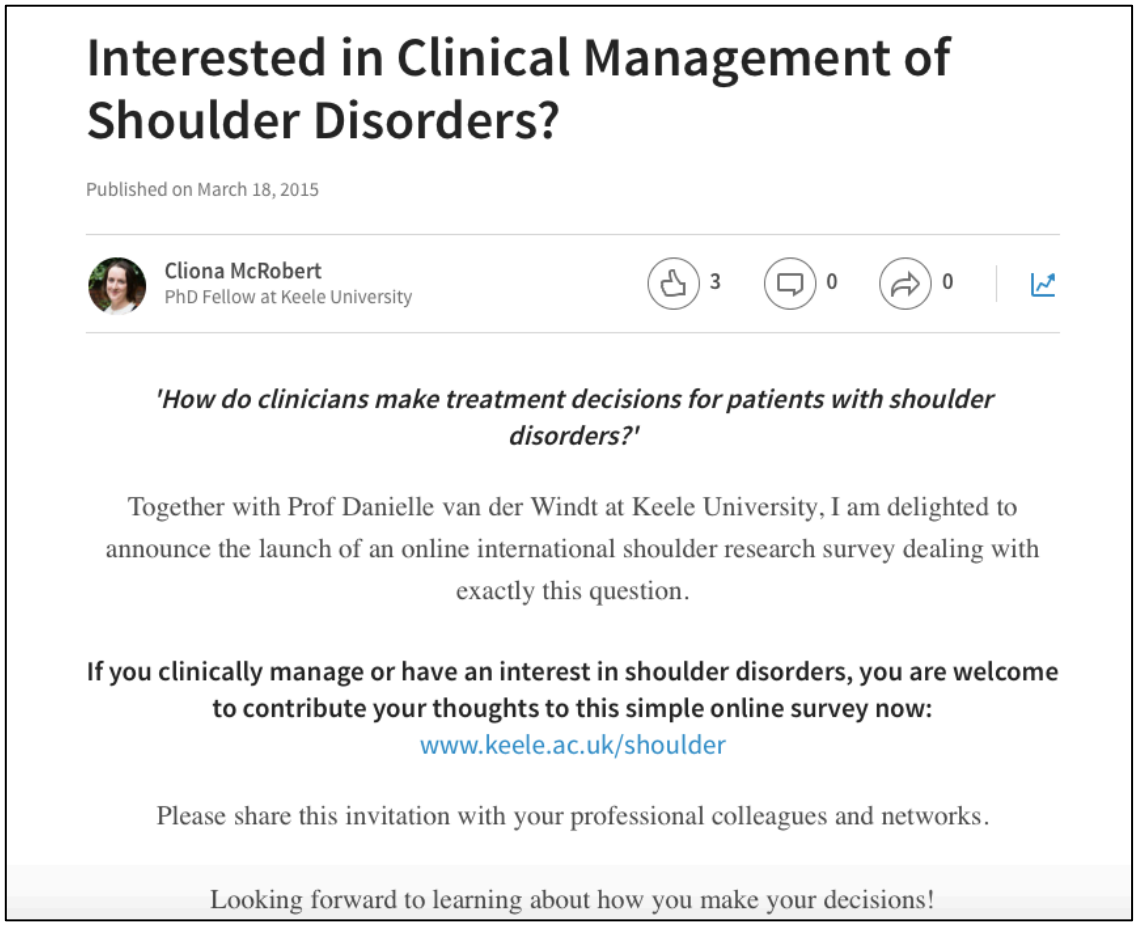


Figure 7.1: Example of Recruitment Post on LinkedIn website

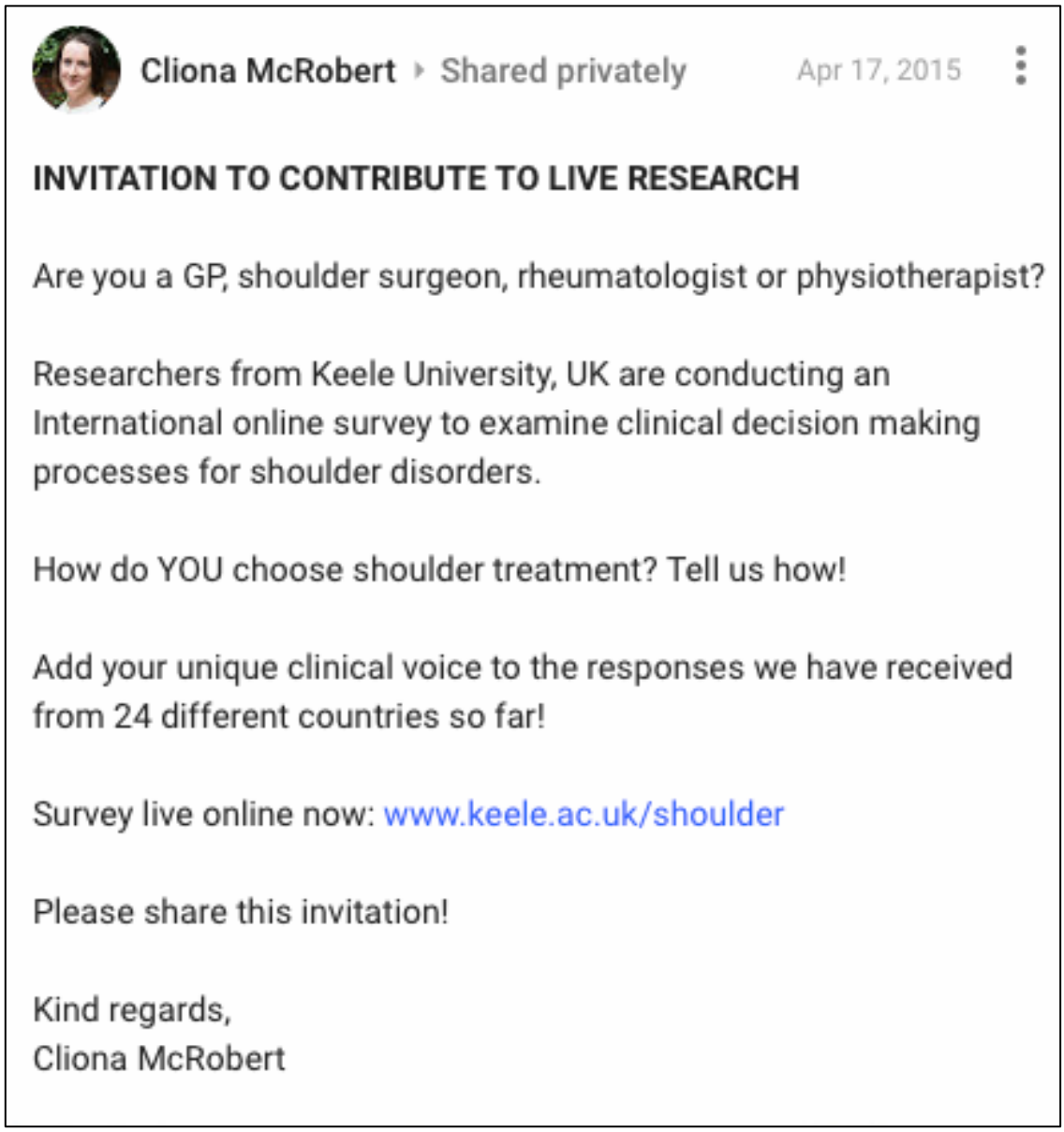


Figure 7.2: Example of Recruitment Post on Google+

The social media website Twitter was extensively used to extend both individual personal and group invitations to participate in this research study (figure 7.4). Blogging is the term for creation and curating of online Internet content. Distinct from the other forms of social media listed above, Twitter is a form of micro-

blogging, whereby the content of each post, message or ‘tweet’ is limited to 140 characters. Twitter is a very fast and concise mode of communication and social networking and is therefore, an attractive recruitment method for delivering short, enticing messages to individuals, groups and professional bodies that meet the inclusion criteria.

Figure 7.3: Example of Recruitment Post on Facebook

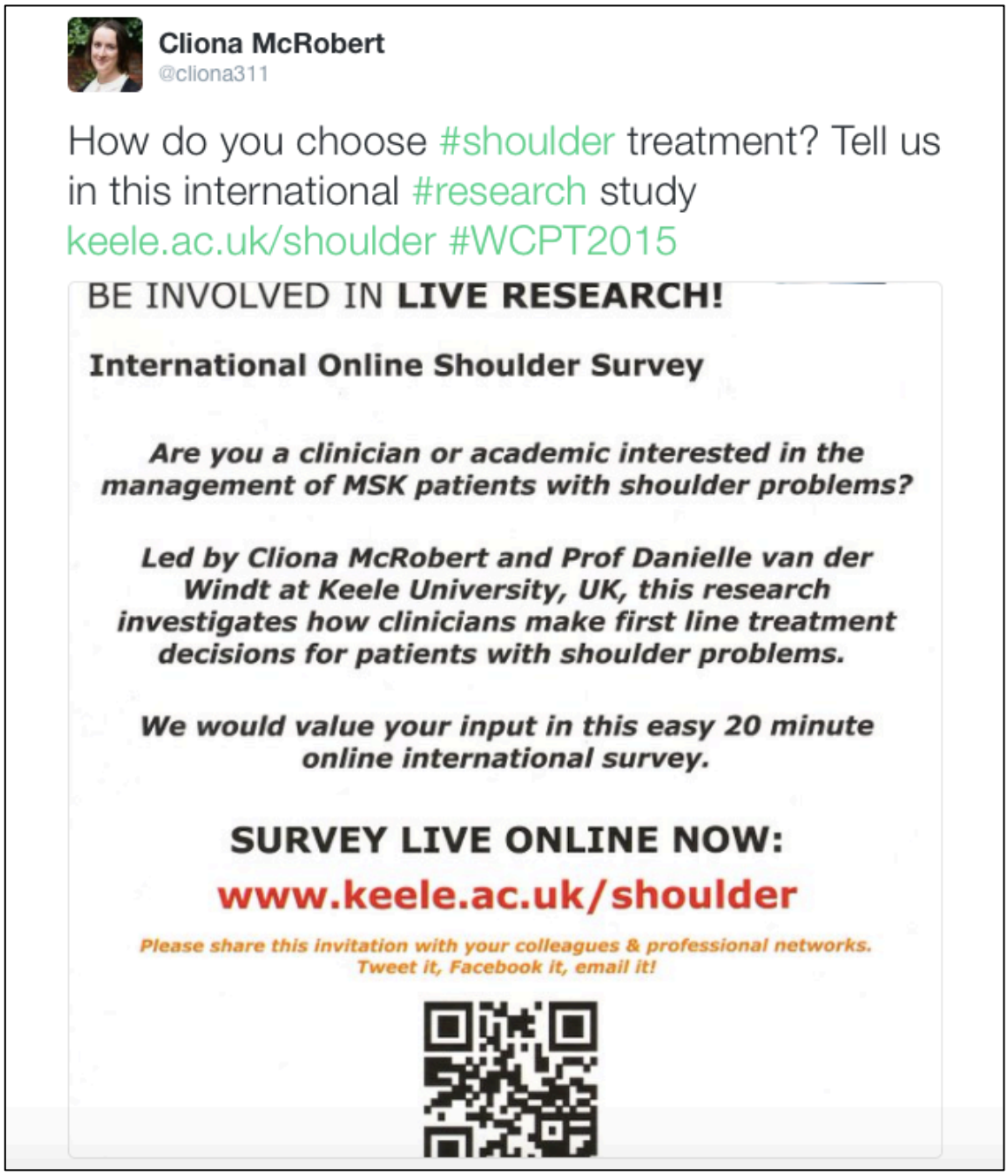


Figure 7.4: Example of Recruitment Post on Twitter

7.2.1.2 Optimisation of Twitter as a Recruitment Tool

In total, 363 tweets were sent from the Twitter account of the researcher during the recruitment period. The majority of tweets sent by the researcher contained a URL web link the study (www.keele.ac.uk/shoulder), requested for the invitation to

be shared, and used informal and friendly language to encourage interaction and participation. The computer application FollowerWonk was used in conjunction with the personal and professional networks of the research team, to identify individuals, societies, groups and organisations matching the inclusion criteria.

Followerwonk was used to search the biographical information provided on Twitter users' profiles for the keywords: shoulder, upper limb, physiotherapy, physical therapy, medicine, doctor, general practitioner, family medicine, rheumatologist, orthopaedic surgeon. A list of relevant accounts of relevant individuals, groups and societies with high 'social capital' was formed and these became the recruitment targets for this study (appendix 9). Followerwonk was also used to provide an indication of the most active times for the identified Twitter profiles. Tweets were sent to the recruitment targets as personalised, friendly yet professional invitations. On the basis of the identified most active times of Twitter profiles followed by and followers of the researcher (7am, 11a, 1am, 3pm, 4pm, 7pm, 9pm and, 11pm) social media posts were scheduled to be sent during these times using a computer application, Hootsuite (Hootsuite Media, Inc., Vancouver, Canada). Hootsuite was used in order to optimise time and resource management throughout the recruitment period and also to ensure that the research invitation featured regularly on the stream of tweets appearing on Twitter.

In order to widen the international reach of the recruitment strategy, tweets were sent in multiple languages (Spanish, French, & Italian) to large international professional organisations including many large professional bodies. To make the

tweets impactful on the Twitter page, pictures of shoulders, a QR code for the study website and twitter hashtags #ShoulderResearch, #shoulder and #research were interchangeably used. Use of Twitter in the recruitment strategy evolved iteratively as the researcher monitored the level of interactions with tweets and amended the strategy as indicated.

7.3 Results

7.3.1 Observed Trends in Recruitment Modes of Access

In total, the survey was accessed 2700 times by 2326 individuals during the three-month survey recruitment period. Data was received from 1915 respondents. Data was categorized into complete data, partial data and unusable data. Complete data, defined as having provided an answer to every question on the survey was received from 387 individuals (20.2% of those who began the survey and 12.3% of those who accessed the survey). Partial data, defined as having completed at least all of the demographic data, was received from 178 individuals. Unusable data, defined as having started the survey but not completed the demographics questions, was received from 1350 individuals.

Data from Google Analytics (http://www.google.com/analytics) (appendix 10) was used to determine how each respondent accessed the survey and also to explore the performance and impact of each of the recruitment methods (table 7.4). The greatest proportion of respondents accessed the survey via a direct internet address link (n=1029, 54%), most likely to have been gained from either a direct or

snowball circulated email from the researcher or from a postal flyer that was either individually received at a conference, via postal mail or seen displayed in a hospital or university setting. Internet-mediated and social media recruitment approaches accounted for 46% of the total survey data. Of these internet-mediated approaches, Twitter accounted for 29% of the survey data with other approaches contributing smaller proportions. Over 30% of the complete and partially complete data (n=565) was received within the first week, 50% within four weeks and 75% within 6 weeks (table 7.5). The survey was closed after 13 weeks.

Table 7.4: Respondents by survey access mode

Access Route	**No. of Respondents**	**% of Total Respondents**
Email or flyer (Direct webpage link)	1029	54%
Twitter	552	29%
Facebook	100	10%
Physiospot	72	4%
CSP	52	3%
Google	41	2%
LinkedIn	1	<1%
Other online sources	68	4%
Total	1915	100%

Table 7.5: Response Rate over Time

Week	Responses Received	% of Total	Cumulative Total
1	176	31%	31%
2	53	9%	41%
3	11	2%	42%
4	44	8%	50%
5	42	7%	58%
6	29	5%	63%
7	61	11%	74%
8	41	7%	81%
9	72	13%	94%
10	12	2%	96%
11	8	1%	97%
12	9	2%	99%
13	7	1%	100%

Demographic details of those classified as complete responders and partial responders are presented in table 7.6. Data was received from 31 different countries, which were grouped according to similarities in model of healthcare provision. Physiotherapists (66% of respondents) and professionals from UK & Republic of Ireland (64% of respondents) constituted the largest professional group and geographical region respectively of responders to the survey. Complete responders had more years of clinical experience (16.3 versus 13.1 Years), and more complete responders than partial responders reported that their primary clinical role was working in a state-funded healthcare system (100% versus 88%).

Table 7.6: Demographics of Complete and Partial Survey Responders

	Total Responders (n=565)	**Complete Responders (n=387, %n)**	**Partial Responders (n=178, %n)**
Professional Background			
Physiotherapist/ Physical Therapist	371	255 (66%)	116 (66%)
General Practitioner/ Family Doctor/ Primary Care Medical Physician	75	60 (16%)	15 (8%)
Rheumatologist	36	21 (5%)	15 (8%)
Orthopaedic Surgeon	15	8 (2%)	7 (4%)
Other relevant professionals	68	43 (11%)	25 (14%)
Country of Clinical Practice			
UK & Republic of Ireland	352	263 (68%)	89 (50%)
Netherlands, Norway, Sweden & Denmark	67	43 (11%)	24 (13%)
Germany	3	2 (<1%)	1 (<1%)
Australia & New Zealand	28	20 (5%)	8 (5%)
USA & Canada	50	26 (7%)	24 (13%)
Rest of World	65	33 (9%)	32 (18%)
Years of clinical experience: Mean (std. dev.)	565	16.3 (9.8)	13.1 (10)
Primary clinical role in state-funded health system	565	387 (100%)	157 (88%)

The 363 recruitment tweets were viewed on average 1400 times per day over the first 60 days of recruitment with a total of over 85000 views over the three-month recruitment period. Tweets were shared in total 286 times via retweets, likes and on nine instances via email. Each tweet received on average 235 views. Of the 85575 tweet views, the Internet address link was accessed in 0.0065% of views (563 times).

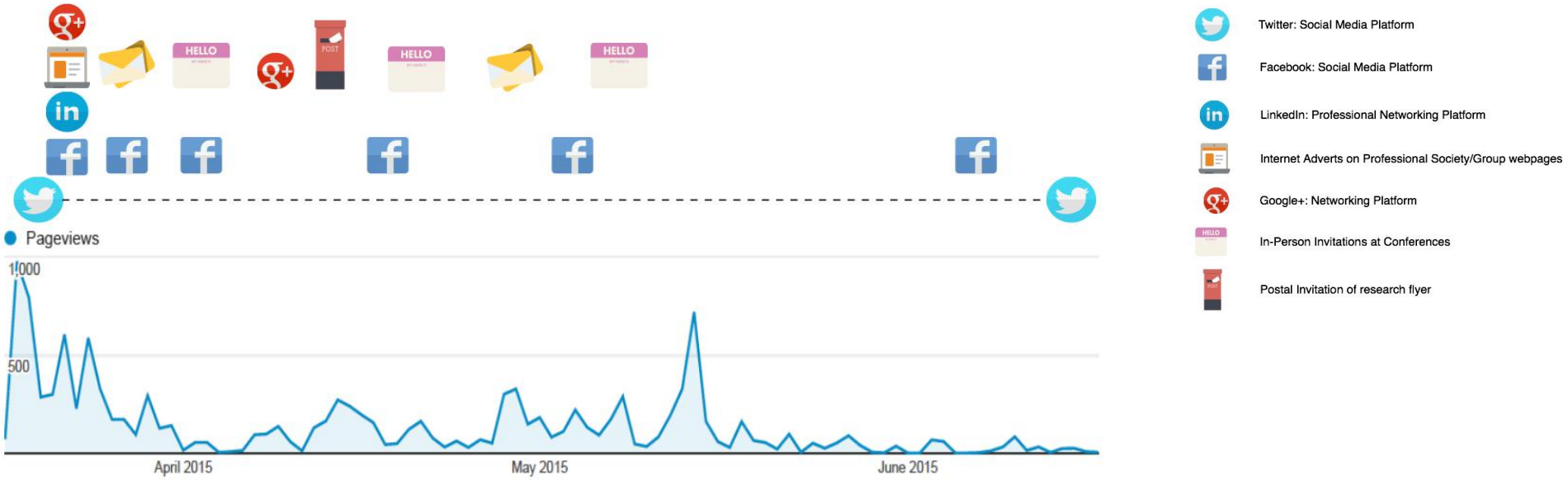


Figure 7.5: Recruitment Timeline

7.4 Discussion

This chapter provided a detailed description of a multi-modal international recruitment strategy for an online survey involving a range of health professionals and researchers interested in the management of patients with shoulder pain. The recruitment strategy was considered successful as it exceeded the recruitment target of complete data from a multi-disciplinary and international sample of 240 participants within the defined recruitment period, with 387 complete responses received. Respondent demographics (Table 7.6) indicate that the multi-modal recruitment strategy enabled recruitment of a sample from a large number of countries, professional disciplines, healthcare settings and ranging experience. Respondent demographics indicate that participants were similar to the intended target population, and that characteristics of complete responders were largely similar to partial responders.

Given that recruitment used professional network-based snowball methods, it was not possible to calculate a response rate, however the survey access/completion rate was 20.2%. This access/completion rate is lower than the average 33% response rate in web surveys of the general public (Shih & Fan, 2009). In comparison, response rate amongst health professionals appears to vary according to professional background with Bishop et al. (2008) reporting an average response rate of 38% in a postal cross-sectional population survey of clinicians (22% for GPs and 55% for physiotherapists), and with physiotherapists also returning a higher response rate of 58% in a more recent postal survey (Bishop et al. 2016; Kellerman et al. 2001). However the access/completion rate in

this study is in line with the 21-26% average response rate observed in cross-sectional postal surveys of GPs (Lane et al. 2015; Cottrell et al. 2015).

7.4.1 Strengths of the Multimodal Strategy

The main strengths of the multimodal strategy used were that barriers of geographical boundaries, international timelines, cost and time spent were minimised, with participants successfully recruited across international borders and professional backgrounds (table 7.6), in a short period of time and at minimal cost. Limited scope for international participation has been cited in the past as a weakness of web surveys (Lane et al. 2015; Ahern, 2005; Ryan 2013). However, using a multi-modal internet-mediated recruitment strategy, this study obtained response data from 31 different countries over a three-month period. The combination of multi-modal recruitment strategies delivered in parallel and in sequence resulted in a high level of engagement with the survey; with over 30% of survey data received within the first week (figure 7.5). This indicates that the multi-modal research strategy delivered on its potential to rapidly engage and direct an unknown, professionally diverse and geographically spread target population to an online survey. Furthermore, the observation that nine individuals shared a tweet sent by the researcher via email indicates that the target population does indeed use multiple forms of communication including social media to collate and share information with peers. These emails represent multi-modal recruitment snowballing in action; an occurrence that itself generates momentum in sharing a research invitation with further, potentially untapped pockets of the target population. It cannot be known how many other such snowballs were generated

via the multi-modal approaches taken to recruitment in this survey, but this observation evidences the connectedness of everyday health and research professionals and also their willingness to participate in social sharing of research recruitment invitations. Collaboration and social interaction are inter-twined and social media is a current method of maximising the potential of the internet in a research capacity.

Use of internet-mediated and social media methods to recruit health professionals to research studies is relatively new (Ahern 2005; Khatri et al. 2015). Use of existing computer applications such as FollowerWonk and Hootsuite facilitated time-efficient identification of key individuals who were invited to act as new 'snowballs' for recruitment of their professional network. One example from this study is the tweet sent to a physiotherapist with a clinical interest in shoulder pain, whose Twitter account had over 30,000 followers. Followerwonk identified this individual as a key recruitment target and this single tweet sent from the researchers account reached over 5000 individuals internationally with an interest in shoulder pain, a reach that would have been almost impossible relying on just the professional network of the study team and prior to the advent of social media. At least 46% of the respondent data can be directly attributed to recruitment using internet-mediated methods including social media. Use of Twitter to engage with and recruit health professionals and researchers in a research survey had little precedence at the time of designing the survey (early 2015), and use of a researcher's personal Twitter account to recruit individuals to an international research survey was considered relatively novel. Since the lead researcher's professional background and affiliations were clearly outlined on all internet

platforms employed, as well as in all of the recruitment material, it was intended that such transparency would make it easy to judge credibility of the researcher, the study team, and the study itself.

Use of 'broadcast' methods as recruitment tool has been previously outlined (Lane et al. 2015; Ofcom 2016), whereby researchers pay social media companies to display study adverts on the timeline/live feed of individuals who meet the inclusion criteria. Weaknesses of broadcasting approaches include cost per individual, the degree to which 'adverts' are ignored or mistrusted on otherwise free to use social media platforms, and that broadcasting relies on an individual being online during a specific time-period that the researcher has paid the platform to broadcast within. In comparison, peer-led, socially shared, snowballing methods amongst clinical and research colleagues such as those outlined in this study were hypothesised by the study team to have greater credibility and impact as a recruitment strategy, and has the advantage of being cost-free. This targeted approach also has the advantage of being specifically targeted to individuals likely to meet survey inclusion criteria. This may have helped to increase the response rate as well as generate a powerful snowballing recruitment effect amongst other professionals who were unknown to the study team or perhaps not included in the international professional societies targeted. However, it is accepted that individuals, societies or groups may have been missed as the strategy relied on individuals including their specific professional interests and social media biography.

Although the online survey was provided exclusively in English, the recruitment strategy included a number of steps intended to specifically include and invite international participation. These included contacts with relevant professional bodies, societies and organisations across the world, and tweets translated by native speakers into Spanish, French and Italian. The online nature of the study also enabled participants to respond in a time that best suited them and the 'save and return later' facility enabled busy clinicians and researchers to fit in completing the survey between tasks or duties. Use of a web survey over a paper survey in this study facilitated immediate receipt of responses to a secure database.

Given high degree of interaction in the form of retweets and 'likes', it is clear that health professionals and researchers have adopted Twitter as a platform for engagement on professional issues. Furthermore, it is also clear that such individuals are happy to be contacted for research purposes via this medium. It is therefore unsurprising that recruitment to more recent surveys of health professionals has begun to include Internet-mediated and social media approaches (Frandsen et al. 2016). A particular strength of the social media aspect of the strategy is that respondents felt able to contact the researcher directly to express interest in the topic, ask more about the study, the researcher's PhD and how the research will inform clinical practice.

Further strengths of the study include that data was anonymously gathered from

respondents. The research team strived to collect only the necessary information required to characterise but not identify the sample. The online nature of the study also enabled participants to respond in a time that best suited them and the 'save and return later' facility enabled busy clinicians to fit in completing the survey between tasks or duties. Use of a web survey over a paper survey in this study enabled immediate receipt of responses to a secure database without delays due to post or manual data entry (Ilieva et al.2002). This enabled the research team to run preliminary statistical analysis to determine the variability of the characteristics of the sample obtained from the source population in order to inform a sample size target (see section 6.4.8.1).

7.4.2 Weaknesses of the Multimodal Strategy

Recruitment, retention and representativeness are as much a challenge in an internet-mediated research study as in any other research. A significant obstacle for this study was in defining a strategy to attract and recruit an unknown population. There is an unavoidable degree of self-selection bias in any survey, where certain individuals are more likely to respond to surveys than others (Frandsen et al. 2014; van Horn et al. 2009). However in the case of an unknown population, it is more difficult to assess the risk of bias.

A criticism of using social media as a recruitment tool for research studies is that respondents recruited via social media tend to be younger than those from more traditional recruitment methods (Frandsen et al. 2014; Houston & Fiore, 1998).

However, data on number of years experience was collected and shows that respondents who provided complete data had more years of clinical experience on average (mean 16.3 (SD 9.8) years) than those who provided incomplete data (mean 13.1 (SD 10.0) years).

Response rate is difficult, if not impossible, to calculate for this survey as recruitment happened in person, via postal invitation, via email and online using planned internet-mediated approaches. The difficulty with response rate calculation in this context lies in the lack of methodology used to track what happens to research invitations once they are placed online. Whilst the Google Analytics data provided insight into how each of the social media platforms and professional websites on which an advert was placed performed, one and the same web link was used to allow access to the survey website. Therefore it was not possible to see how the different recruitment routes compared in terms of achieving survey participation. The Twitter metrics showed how often each tweet was shared and on certain websites (PhysioSpot and Chartered Society of Physiotherapy websites) how often the webpage containing the recruitment invitation was shared. However, this study did not include a data capture method that could inform the researchers about the exact access route to the survey taken by each individual responder, making it impossible to gain insight into the access to completion rates across different recruitment or social media routes. For example, it may be possible that some social media platforms generated lower traffic to the survey than others, but were more successful in generating complete versus incomplete survey data. Future online surveys should include a question to assess how participants heard about and accessed the survey, which will enable

analysis of the impact of each recruitment method on generation of: (i) traffic to the survey and (ii) complete response data. Also, future researchers could consider stratifying recruitment methods over time, using one method alone for a defined period before moving on to the next. Whilst this would have the disadvantage of potentially limiting the accumulation of online presence and visibility during a defined period, it would allow researchers to quantify how many respondents came from each method and whether different recruitment methods attract respondents with different characteristics.

The sample obtained is unbalanced by geography (64% from the UK & Republic of Ireland) and professional background (66% of sample were physiotherapists). In spite of advertising the study in other languages, the survey was conducted exclusively in English due to known issues with translation and loss of culturally imbued meaning (Aherm, 2005; Harkness et al. 2003), and several recruitment approaches specifically targeted organisations (Table 7.3) or potential participants (e.g. distribution of flyers) in the UK. Response to the survey from GPs, orthopaedic surgeons and rheumatologists was low, with physiotherapists providing 66% of responses. The strong contribution from physiotherapists may be explained in part by the lead researcher's professional background. Steps taken to address this potential bias included specifically identifying and targeting national and international professional interest groups for non-physiotherapists as outlined in table 7.3 and targeting recruitment flyers to GPs with a special interest in musculoskeletal conditions and shoulder and upper limb orthopaedic surgeons and rheumatologists known to the study team. Potential reasons for low response rate may include perception that the research area is not of relevance to the

physician's clinical practice, that they are already too busy, or simply that they do not participate in research surveys (van Geest et al. 2007). Impact of participation incentives for physicians to boost response rates have been not been shown to be effective amongst GPs (Kellerman et al. 2001; Cottrell et al. 2015; Kaner et al. 1998) and were therefore not used in this study. However since it is traditionally difficult to achieve high response rates amongst physicians (Couper et al. 2007; Gjestland, 1996; Grava-Gubins et al. 2008), further research is indicated to improve participation and response rates amongst clinicians in research surveys, including the potential for using a multi-modal recruitment strategy in conjunction with commercially available databases of clinicians, accepting the cost implications of such an approach.

A further challenge for the use of internet-mediated research in general is gaining complete data. Analytic data from Twitter and some of the professional Internet websites indicated that it is relatively easy to encourage potential respondents to click on the survey web address. Data from this study shows that the survey website was accessed 2700 times, with 1916 respondents submitting some data but complete data only being received from 387 individuals. Precise reasons for providing incomplete data are not clear, but since the survey was fielded only in English individuals who accessed the survey but were not fluent in the English language may have opted to leave the survey without providing complete data. A more extensive discussion of the potential reasons for incomplete data is presented in chapter 8.

Similar challenges in retaining respondents' levels of interest and engagement to the end of the survey have previously been reported (Lane et al. 2015; Thackeray et al. 2012; Ventola, 2014; Kapp et al. 2013). Respondent anonymity and the physical distance from the researcher may be a factor as individuals are less likely to feel an obligation to the researcher to complete the survey. The same challenge may occur in paper-based surveys, however with paper-based studies people decide to either complete it or not to respond at all, resulting in fewer partially completed surveys. Despite the large proportion of incomplete data, the demographic information provided indicated that respondents who provided complete data were largely similar to those providing incomplete data, and representative of the target population.

A common concern about the use of web-based surveys is that respondents are anonymous and that the authenticity of data often cannot be confirmed (Lane et al. 2015; Ahern, 2005; Ryan 2013; Frandsen et al. 2014; Ramo & Prochaska, 2012; Bull et al. 2012; Kapp et al. 2013). Although it was possible to retake the survey, all data were screened for total completion times less than five minutes. No such responses were found, indicating that on balance, the data is likely to be legitimate, given the expected completion time of 15 minutes. An additional limitation is that open, unrestricted online surveys have to accept the risk that respondents may not actually be who they say they are and even that computer programmes may have been used to create spam data or that respondents may have completed the survey multiple times to create a 'ballot box stuffing' effect (Couper et al. 2007; Frandsen et al. 2016; Khatri et al. 2015).

7.4.3 Ethical Considerations

The research team considered the ethical issues surrounding the use of a multimodal and Internet-mediated recruitment strategy. Specifically with regard to using social media to contact potential respondents, the important distinction between public and private use of social media was considered. Use of social media as a recruitment tool raises some potential considerations about respondent's privacy and right to anonymity (McKee, 2013). Specific details pertinent to the acquisition of ethical approval for the study included anonymity and security of the data provided. To maintain respondents' anonymity, demographic questions were kept to the minimum required to characterize the sample (professional background, number of years experience, relevant post-graduate training, country of clinical practice), and Internet protocol (IP) addresses were not collected in order to protect respondents' anonymity. Data was stored on the physically and electronically secure, restricted access Keele University server, which is routinely backed up and which was accessible only by the study team.

Ethical approval was gained from the University ethical approval panel for this online, international, survey of healthcare professionals (ERP 324) (appendices 11 and 12). The survey consisted of non-identifiable demographic questions, questions about frequency of use of a number of common treatments not concerning patients, and asked for respondent's choice of treatment suggestions in response to a series of hypothetical clinical cases. Questions were not specific to NHS setting although some respondents were likely to be NHS employees; therefore relevant checks were carried out with a local NHS Research Ethics

Committee (NREC) who recommended that specific approval from the NHS was not required and that approval from the University ethical approval panel would suffice.

Guidance on the ethical issues involved in conducting Internet-mediated research from the British Psychological Society (BPS, 2013) indicates that participants in a study might come from a number of countries. As the research survey was open to any person meeting the inclusion criteria, from any country, it was made clear in the participant information sheet that the study adhered to Keele University's Research Ethics Policy. Therefore the ethical approval granted by Keele University was considered by the ethical review panel to constitute sufficient approval to conduct an international study.

7.5 Conclusion

Using a multi-modal traditional and Internet-mediated recruitment strategy was successful in recruiting a professionally diverse international sample of health and research professionals with an interest in clinical management of shoulder pain. A social media strategy involved identification of most relevant societies, organisations and individuals and sending of targeted research invitations were via social media (Twitter, Facebook, Google+ and LinkedIn) and traditional methods. Of the 565 respondents who provided data in response to this survey, social media accounted for 46%, indicating that clinicians were happy to be contacted

and recruited to the research survey via social media and internet-mediated methods as well as traditional methods.

Social media can be used as an effective, time and resource efficient online survey recruitment and engagement tool. In order to maximise the potential of social media as a recruitment tool, dedicated preparation and pre-planning is required. Consideration of ethical issues related to Internet-mediated research is advised. Employment of social media can be a time consuming task, therefore computer applications which help to optimise development of a target list and automate the scheduled delivery of social media posts is highly beneficial. Researchers can therefore consider using a multi-modal research strategy to recruit health professionals to future online studies. Whilst acknowledging limitations of the method, this approach offers a pragmatic, easy to use strategy that can be used in future studies. A multi-modal survey recruitment proforma has been developed to assist future researchers achieve the potential offered by these methods (appendix 13).

CHAPTER 8: WHAT INFLUENCES TREATMENT DECISION-MAKING IN PRIMARY CARE FOR PATIENTS WITH SHOULDER PAIN? A MULTI-DISCIPLINARY, INTERNATIONAL CONJOINT ANALYSIS STUDY

8.1 Background Summary

In order to derive a robust, evidence-based set of hypotheses of candidate moderators to inform a future treatment decision-making strategy, a choice-based conjoint analysis study was designed to identify which patient attributes influenced decision-making for selecting treatment in primary care for patients presenting with shoulder pain, (full methodology outlined in chapter 6). This study was conducted using an online survey targeting an international sample of healthcare practitioners and shoulder pain experts. Chapter 7 outlined the development, operationalization and appraisal of a multi-modal recruitment strategy for a conjoint analysis study. In response to 12 hypothetical patient cases, respondents were asked to choose their optimal recommended first-line treatment option from either: (i) advice and analgesia, (ii) exercise and/or manual therapy delivered by a physiotherapist, or (iii) steroid injection.

8.2 Brief Summary of Statistical Analysis

Descriptive statistics were generated for the demographics of the sample and to summarise the distribution of baseline variables across blocks (table 8.1). Three

main multinomial statistical models were: (i) separate models for each individual attribute, (ii) separate models for each individual attribute adjusting for confounders and, (iii) multivariable model including all attributes adjusted for the confounding variables. Taking the treatment 'advice and analgesia' as the reference category, odds ratios and associated 95% confidence intervals were presented in order to highlight the association between patient attributes and treatment choice. Those intervals not containing the null value of 1 will be highlighted as being statistically significant. Responses to the modified decisional conflict questions were summarised using descriptive statistics. Responses to the open-ended questions about absence of relevant clinical information were summarised and compared to the suggested patient attributes obtained during the clinical consensus workshops (chapter 4).

8.3 Results

As described in chapter 7 (recruitment chapter), the survey was accessed 2700 times by 2326 individuals over a three-month survey recruitment period (March – June 2015). The survey was started 1915 times, although 1350 individuals failed to complete all the questions. There were 565 respondents who completed all the demographic questions, of whom 387 individuals completed every question on the survey (20.2% of those who began the survey and 12.3% of those who accessed the survey) and 178 individuals provided partial data. Demographics of responders are shown in table 8.1. This shows that the randomisation procedure worked and produced similar respondent characteristics across the three blocks. A model containing nested terms for both block and subject was initially considered.

However when executed, the model containing the term for block accounted for only neglible overall variability and the parameter estimates remained unchanged with it removed. Therefore, a block term for respondent was not entered into the models.

Table 8.1: Respondent demographics by block

	Block 1 n=123 (33%)	**Block 2** n=129 (35%)	**Block 3** n=122 (32%)	**Total** n=374 (100%)
Country of Clinical Practice (n,%)				
UK & ROI	83 (67%)	87 (67%)	82 (67%)	252 (67%)
Netherlands, Norway, Sweden & Denmark	18 (15%)	12 (9%)	13 (11%)	43 (1%)
Australia & New Zealand	5 (4%)	8 (6%)	7 (6%)	20 (5%)
Germany	1 (1%)	0 (0%)	1 (1%)	2 (1%)
USA & Canada	4 (3%)	11 (9%)	10 (8%)	25 (7%)
Rest of World	12 (10%)	10 (8%)	9 (7%)	31 (8%)
Professional Background (n, %)				
Physiotherapist	79 (64%)	86 (67%)	79 (65%)	244 (65%)
General Practitioner	23 (19%)	22 (17%)	15 (13%)	60 (16%)
Rheumatologist	7 (6%)	4 (3%)	10 (8%)	21 (6%)
Orthopaedic Surgeon	4 (3%)	1 (1%)	2 (2%)	7 (2%)
Other	10 (8%)	15 (12%)	16 (13%)	41 (11%)
Years of Clinical Experience (Mean, SD)	16.6 (10.6)	15.5 (9.2)	16.8 (9.7)	
Percentage of clinical practice funded by state	73.6 (38.7)	70.8 (40.0)	70.0 (40.4)	

Results of the multinomial logistic regression depicting the odds of health professionals choosing corticosteroid injection over advice and analgesia and the odds of choosing physiotherapy above advice and analgesia, are shown in tables 8.2 and 8.3 respectively. Comparison of univariable models unadjusted and adjusted for confounders (Models 1 and 2, tables 8.2 and 8.3) shows that estimation of associations between the patient attributes and treatment decisions were very similar with the addition of confounders compared to without. Compared to the adjusted univariable model, estimates from the multivariable model do vary in magnitude and direction, indicating that some attributes may be interrelated. In addition to confounders, the multivariable model takes into account all other patient attributes, more completely representing how patterns of patient attributes affect decisions rather than attributes in isolation. Since clinicians make decisions using patterns of patient attributes and were presented with patterns of attributes in the decision task, the multivariable model represents clinical decision-making more accurately than the univariable model, and will be summarized here.

From the multivariable model, eleven of the 12 patient attributes studies were significantly associated with treatment choice at the level of $p < 0.05$ for either injection or exercise/mobilisation (pain severity, onset, sleep disturbance, current clinical status, functional and/or work impact, neck involvement, previous response to treatment, general health status, overuse (linked to sport, hobbies or work), instability and/or weakness, patient treatment preference). The presence of psychosocial issues was the only attribute that was not significantly associated

with treatment choice, with the association with treatment decisions being very weak (OR (95% C.I.) corticosteroid injection (0.97 (0.75, 1.27) and physiotherapy (0.96 (0.79, 1.16)).

8.3.1 Multivariable Associations for Recommending a Corticosteroid Injection:

Multivariable multinomial logistic regression analysis revealed that respondents were more likely to recommend corticosteroid injection rather than advice and analgesia when a patient presented as: condition not improving (OR 2.81 (2.16, 3.65)), previous positive treatment response (steroid injection (2.79 (2.07, 3.76)), physiotherapy (1.61 (1.16, 2.23)), patient treatment preference for injection (2.41 (1.82, 3.19) but not for physiotherapy), moderate or high pain severity (1.66 (1.19, 2.31) and 1.79 (1.29, 2.47) respectively), significant instability and/or weakness (1.74 (1.30, 2.32)),or sleep disturbance (1.49 (1.14, 1.94)).

8.3.2 Multivariable Associations for Not Recommending a Corticosteroid Injection:

Multivariable analysis revealed that respondents were less likely to recommend corticosteroid injection over advice and analgesia when patients presented with traumatic onset or unstable diabetes and/or cardiac issues (traumatic onset (0.55 (0.42, 0.71)), unstable diabetes and/or cardiac issues (0.72 (0.56, 0.94)).

Table 8.2: Results of statistic models showing likelihood of recommending 'corticosteroid injection' over 'advice and analgesia'

Variables		Model 1(*) OR (95% CI)	Model 2(†) OR (95%CI)	Model 3(+) OR (95% CI)
Pain Severity	*Low*	1	1	1
	Moderate	2.11(1.58,2.82)	2.11(1.58,2.86)	1.66(1.19,2.31)
	High	2.23(1.67,2.97)	2.27(1.70,3.03)	1.79(1.29,2.47)
Onset	*Non-Traumatic onset*	1	1	1
	Traumatic onset	0.53(0.43,0.66)	0.53(0.43,0.66)	0.55(0.42,0.71)
Current Clinical Status	*Condition Improving*	1	1	1
	Condition not Improving	3.19(2.54,4.03)	3.14(2.49,3.95)	2.81(2.16,3.65)
Sleep Disturbance	*None*	1	1	1
	Sleep disturbance	1.24(0.99,1.57)	1.25(1.00,1.57)	1.49(1.14,1.94)
Functional and/or Work Status	*No Impact*	1	1	1
	Significant Impact on activities/work	1.19(0.95,1.48)	1.20(0.96,1.49)	1.61(1.25,2.08)
Neck Involvement	*None*	1	1	1
	Also presents with neck pain	0.74(0.59,0.93)	0.74(0.59,0.92)	0.92(0.71,1.19)
Previous response to treatment	*No previous treatment*	1	1	1
	Previous positive response to steroid injection	2.53(1.96,3.27)	2.49(1.93,3.22)	2.79(2.07,3.76)
	Previous positive response to physiotherapy	1.23(0.91,1.65)	1.21(0.89,1.62)	1.61(1.16,2.23)
General Health Status	*Otherwise fit & well*	1	1	1
	Unstable diabetes and/or cardiac issues	0.86(0.69,1.07)	0.86(0.69,1.07)	0.72(0.56,0.94)
Psychosocial Issues	*None*	1	1	1
	Psychosocial issues present	0.60(0.48,0.75)	0.61(0.49,0.76)	0.97(0.75,1.27)
Overuse due to	*None*	1	1	1

Sport, Hobbies or Work	*Over-use linked to sport, hobbies or work*	0.99(0.79,1.25)	1.01(0.80,1.27)	1.06(0.81,1.39)
Instability and/or Weakness	*None*	1	1	1
	Significant Instability	1.65(1.30,2.09)	1.66(1.31,2.10)	1.74(1.30,2.32)
Patient Treatment Preference	*None*	1	1	1
	Preference for Injection	2.77(2.15,3.56)	2.79(2.17,3.60)	2.41(1.82,3.19)
	Preference for Physiotherapy	1.15(0.82,1.62)	1.13(0.80,1.59)	1.00(0.69,1.46)

(*) Attribute Entered Only

(†) Attribute plus confounders

(+) All Attributes plus confounders (professional background, country of clinical practice and years of clinical experience)

OR=Odds Ratio, CI = Confidence Interval, Shaded cells highlight p <0.05

8.3.3 Multivariable Associations for Recommending Physiotherapy:

The multivariable multinomial logistic regression analysis indicated that clinicians were more likely to recommend physiotherapy rather than advice and analgesia when the patient presented with: patient treatment preference for physiotherapy (OR 2.77 (2.16, 3.55), but not for injection), previous positive treatment response (physiotherapy (2.22 (1.76, 2.80)), corticosteroid injection (1.44 (1.14, 1.81)), significant instability and/or weakness (2.05 (1.64, 2.57)), not improving (1.90 (1.55, 2.33)), neck pain (1.47 (1.21, 1.80)), or overuse due to work, sport or hobbies (1.34 (1.09, 1.66)).

8.3.4 Multivariable Associations for Not Recommending Physiotherapy:

Presence of sleep disturbance and high pain were significant predictors of being less likely to recommend corticosteroid injection over advice and analgesia (sleep disturbance (OR 0.66 (0.54, 0.81)), high pain (0.71 (0.55, 0.89); association not significant for moderate pain)).

Table 8.3: Results of statistic models showing likelihood of recommending 'physiotherapy treatment' over 'advice and analgesia'

Variables		Model 1(*) OR (95% CI)	Model 2(†) OR (95%CI)	Model 3(+) OR (95% CI)
Pain Severity	*Low*	1	1	1
	Moderate	1.04(0.84,1.29)	1.04(0.84,1.29)	0.98(0.77,1.26)
	High	0.77(0.62,0.96)	0.76(0.62,0.95)	0.71(0.55,0.89)
Onset	*Non-Traumatic onset*	1	1	1
	Traumatic onset	0.82(0.69,0.97)	0.82(0.69,0.98)	0.83(0.68,1.01)
Current Clinical Status	*Condition Improving*	1	1	1
	Condition not Improving	1.89(1.57,2.26)	1.88(1.57,2.26)	1.90(1.55,2.33)
Sleep Disturbance	*None*	1	1	1
	Sleep disturbance	0.74(0.63,0.88)	0.73(0.61,0.87)	0.66(0.54,0.81)
Functional and/or Work Status	*No Impact*	1	1	1
	Significant Impact on activities/work	0.99(0.84,1.18)	0.99(0.84,1.18)	1.12(0.92,1.37)
Neck Involvement	*None*	1	1	1
	Also presents with neck pain	1.34(1.13,1.60)	1.36(1.14,1.62)	1.47(1.21,1.80)
Previous response to	*No previous treatment*	1	1	1

treatment	*Previous positive response to steroid injection*	1.37(1.11,1.68)	1.35(1.10,1.66)	1.44(1.14,1.81)
	Previous positive response to physiotherapy	1.94(1.57,2.41)	1.96(1.57,2.43)	2.22(1.76,2.80)
General Health Status	*Otherwise fit & well*	1	1	1
	Unstable diabetes and/or cardiac issues	0.97(0.82,1.15)	0.97(0.82,1.16)	0.95(0.78,1.17)
Psychosocial Issues	*None*	1	1	1
	Psychosocial issues present	1.03(0.86,1.23)	1.04(0.87,1.24)	0.96(0.79,1.16)
Overuse due to Sport, Hobbies or Work	*None*	1	1	1
	Over-use linked to sport, hobbies or work	1.16(0.97,1.39)	1.17(0.98,1.40)	1.34(1.09,1.66)
Instability and/or Weakness	*None*	1	1	1
	Significant Instability	2.18(1.80,2.65)	2.14(1.76,2.59)	2.05(1.64,2.57)
Patient Treatment Preference	*None*	1	1	1
	Preference for Injection	1.11(0.91,1.36)	1.10(0.90,1.35)	0.99(0.79,1.23)
	Preference for Physiotherapy	2.66(2.11,3.36)	2.67(2.110,3.37)	2.77(2.16,3.55)

(*) Attribute Entered Only

(†) Attribute plus confounders (professional background, country of clinical practice and years of clinical experience)

(+) All Attributes plus confounders

OR=Odds Ratio, CI = Confidence Interval, Shaded cells highlight p <0.05

8.3.5 Modified Decisional Conflict Questions

Summary of data related to respondent perception of task complexity and completeness of the hypothetical clinical cases are shown in table 8.4. If asked again, 68% or respondents expressed that they would not expect to stick with their recommended treatment decisions and 66% of respondents reported feeling unsatisfied with their treatment decisions. Over half (51%) of respondents stated that it was clear which treatment would be best for each patient and half (50%) of respondents reported not having trouble making their treatment decisions compared with 25% who did and 25% who neither had nor had not trouble making their treatment decisions. Responses to open (free-text) questions regarding important information related to the hypothetical patient (question 5) and any other considerations that affected the decision (question 7) were collected. Respondents indicated 12 additional factors that had not been included in this conjoint analysis study (table 8.5). These factors were mainly greater depth of information in the 12 patient attributes included in the conjoint analysis and additional patient medical history. The most commonly suggested of these factors including; aggravating and easing factors and full diabetes and cardiac history.

Table 8.4: Modified Decisional Conflict Responses

	Question	Strongly Agree		Agree		Neither Agree or Disagree		Disagree		Strongly Disagree	
		n=374, %n									
1	The decisions were hard to make	**24**	6%	**99**	26%	**82**	22%	**143**	38%	**26**	7%
2	I was unsure about which treatment would really be best for each patient	**23**	6%	**114**	30%	**82**	22%	**144**	39%	**10**	3%
3	It was clear which treatment would be best for each patient	**21**	6%	**169**	45%	**86**	23%	**84**	22%	**14**	4%
4	When I made the decisions, I felt that I did not know enough about the treatment alternatives	**34**	9%	**134**	36%	**59**	16%	**114**	30%	**33**	9%
5	I had trouble making the decisions because important information was unknown	**13**	3%	**83**	22%	**92**	25%	**133**	36%	**53**	14%
6	When I made the decisions, it was hard to decide if the benefits of the treatment were more important that the risks.	**30**	8%	**136**	4%	**100**	27%	**98**	26%	10	3%
7	All considerations that affected the decision were identified	**26**	7%	**141**	38%	**114**	30%	**83**	22%	**10**	3%
8	I am satisfied with the decisions I have made	**3**	1%	**36**	10%	**86**	23%	**221**	59%	**28**	7%
9	I am satisfied that the process used to make the decisions was as good as it could be	**22**	6%	**82**	22%	**98**	26%	**151**	40%	**21**	6%
10	If asked again, I would expect to stick with my decisions.	**1**	0%	**18**	5%	**100**	27%	**225**	60%	**30**	8%

n = Total Sample (374)

Table 8.5: Free-text responses to modified Decisional Conflict Questions on missing clinical information (with frequency of responses)

Attribute	Frequency	NEW	Discussed in preparatory work	Accepted limitation of study	Included in conjoint analysis
Objective findings	72		X		
Combination of treatment	44			X	
Age	43		X		
Imaging results	42		X		
Symptom duration	36		X		
Diagnosis	30		X		
Injury mechanism	27		X		
Shoulder range of Movement	20		X		
Already tried analgesics	16		X		
Type of work/hobbies	15		X		
Pain mechanism	8		X		
Specific muscle weakness	8		X		
Past medical history	8		X		X
Previous physiotherapy	8		X		
What sort of psychosocial issues	7		X		
Patient goals	7		X		
Aggravating /	7	X			

Attribute	Frequency	NEW	Discussed in preparatory work	Accepted limitation of study	Included in conjoint analysis
easing factors					
Red flags	6		X		
Contradictory information	6				X
Treatment expectation	6		X		
Full diabetes information	6	X			
Social history	6		X		
Full cardiac information	5	X			
Movement pattern	5		X		
Inflammatory condition	5		X		
Referred pain	4		X		X
Patient perspective	4	X			
Could patient tolerate physiotherapy	3		X		
Gender	3		X		
JL shoulder symptom modification procedure	3		X		
Neurological or Bobath examination	4		X		
(Severity, Irritability, Nature) SIN factors	2		X		
Cleared by orthopaedics	2	X			

Attribute	Frequency	NEW	Discussed in preparatory work	Accepted limitation of study	Included in conjoint analysis
Contra-indications for shoulder injection	2		X		
Drug history	2	X			
Time since last injection	3	X			
Understanding of treatment	2		X		
Posture	2		X		
Previous shoulder problems	2		X		
Lying on side	2		X		
Patient training age/ fitness level	2		X		
Physiotherapy waiting time	2		X		
Extent of positive response to injection	2	X			
Driving impact	1		X		
Could patient tolerate injection	1		X		
Whether patient knows proper sleep position	1	X			
Dressing impact	1	X			
Self management to date	1		X		
Patient	1		X		

Attribute	Frequency	NEW	Discussed in preparatory work	Accepted limitation of study	Included in conjoint analysis
awareness					
Injection location	1	X			
Insurance limitations	1	X			
Time constraints	1		X		
Inflammatory condition	1		X		
Pain location	1		X		
Coping strategies	1		X		
Patients main complaint	1		X		
Dominant arm	1		X		
Period symptom free between treatments	1		X		
Sleep loss distress	1		X		
Patient treatment preference	1				
How many previous injections	1		X		
Evidence of spinal protective behaviour	1		X		
Reason for preferences	1	X			
Patient treatment preference					X
Progression of	1				X

Attribute	Frequency	NEW	Discussed in preparatory work	Accepted limitation of study	Included in conjoint analysis
symptomology					
Patient motivation for self-help	1				X
Pain levels	5				X
Neck exam findings	5				X
Degree of impairment	1				X
Work impact	1				X
Function	1				X
Yellow flags	2				X

8.4 Discussion

8.4.1 Main Findings

Twelve patient attributes were suggested in the mixed methods study by a range of experienced shoulder clinicians as being highly relevant to first-line treatment decision-making for shoulder pain for the three treatments in question. Using a conjoint analysis study and hierarchical multinomial logistic regression to analyse the results, this study provides insight into the association of these 12 patient attributes with differential first-line treatment decision-making. Figure 8.1 provides a visual overview of results of the multivariable model showing the independent association of each patient attribute with the likelihood of recommending corticosteroid injection or physiotherapy treatment. The single most important patient attribute that influenced healthcare practitioners' decision to recommend corticosteroid injection was current clinical status, i.e., whether the patient was

improving, or not ((OR, 95%) (2.81 (2.16, 3.65). The decision to recommend physiotherapy over advice and analgesia was influenced by three additional factors: preference for physiotherapy (2.77 (2.16, 3.56)), previous positive response to physiotherapy (2.22 (1.76, 2.80)) and significant instability and/or weakness (2.05 (1.64, 2.57)).

Some commonalities in the determinants of recommending either corticosteroid or physiotherapy treatments include: being more likely to recommend a treatment when the patient was not improving, patient preference for the treatment or had a previous positive response to the treatment previously. In contrast, results indicate that the patient attributes: traumatic onset, pain severity and sleep disturbance guide differential treatment decision-making. Traumatic onset was significantly associated with the likelihood to recommend corticosteroid injection (0.55 (0.42, 0.71)), but not physiotherapy (0.83 (0.68, 1.01)). This is a clinically intuitive finding as evidence that corticosteroid injection may pre-dispose to rotator cuff tear is increasingly accepted and (recent) trauma may be considered a contra-indication for injection by many healthcare providers (Mohamadi et al. 2016).

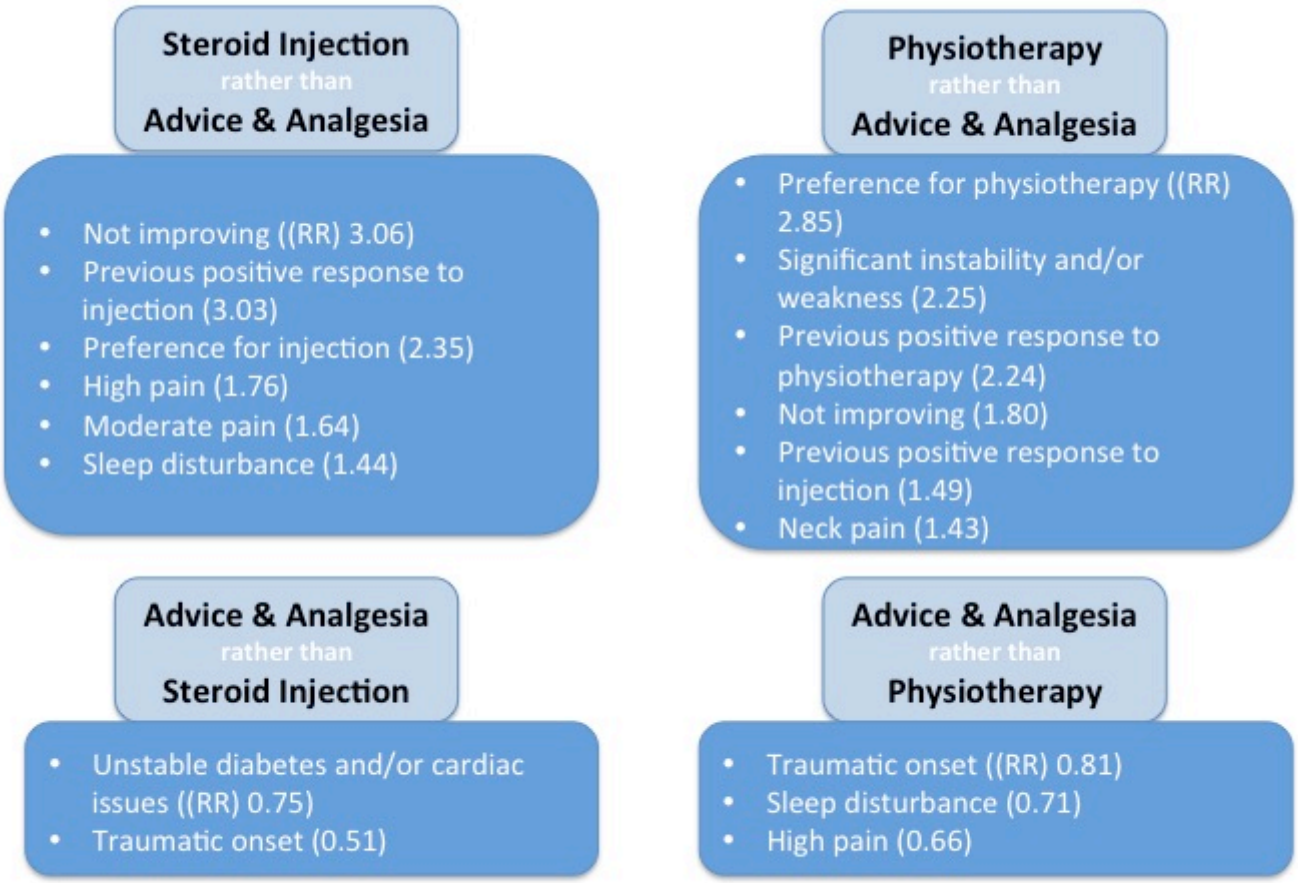


Figure 8.1: Results overview

Pain severity impacted upon respondents' likelihood to refer to either corticosteroid injection or physiotherapy treatment; high or moderate pain was associated with greater likelihood to refer a patient for corticosteroid injection (1.79 (1.29, 2.47) and 1.66 (1.19, 2.31), respectively) with high pain being associated with lower likelihood of referring a patient for physiotherapy treatment (0.71 (0.55, 0.89)). This indicates that there may be a perception amongst respondents that adequate pain relief is an important first-line treatment goal and that physiotherapy is more likely to be effective in patients with lower or better-controlled pain. This in spite of suggestion that exercising the shoulder through some pain is not as detrimental to recovery as previously thought, in fact may incur some benefit (Littlewood et al. 2014; Smith et al. 2017).

Similarly, sleep disturbance prompted greater likelihood of referral for corticosteroid injection and less likelihood for referral for physiotherapy treatment than advice and analgesia (corticosteroid injection: 1.49 (1.14, 1.94), physiotherapy treatment: 0.71 (0.55, 0.89)). The co-occurrence of musculoskeletal pain and sleep disturbance in patients with shoulder pain (Cho et al. 2013; Mulligan et al. 2015) as well as in the general population has been reported (Baker et al. 2017). Therefore the finding that sleep disturbance prompts similar treatment decisions to high pain indicates that sleep disturbance is perceived as indicative of high pain, which are both logical targets for pain reduction and are therefore important clinical drivers of decision-making. Free text responses regarding clinical information considered missing by survey respondents also indicated that clinicians preferred to further ascertain information about whether the sleep disturbance was due to the painful shoulder or not, the degree of distress causes

by the sleep disturbance, whether the pain was at rest, (Kempf & Kongsted, 2012) or when lying on the affected side, and whether the patient had identified a sleep posture that reduced their pain. Therefore, future research should investigate sleep in more detail as a potential moderator of treatment effect for corticosteroid injection and physiotherapy treatment.

Although the attribute 'general health' (with levels (i) unstable diabetes and/or cardiac issues and (ii) otherwise fit and well), reduced the likelihood of respondents recommending corticosteroid injection over advice and analgesia (0.72 (0.56, 0.94)), respondents indicated in free text responses that a much more complete clinical picture on both diabetes and cardiac issues was preferred before a confident treatment decision could be made. Furthermore, free text responses suggested that respondents hold a range of views on the relevance of diabetes when considering corticosteroid injection: diabetes being a contraindication, a clinical scenario to be managed cautiously, or an unimportant patient factor. One NHS guideline for example, includes the recommendation that diabetes is treated as a caution to be dealt with by informing patient of potential risk of elevated blood sugar level (Harris, 2017) However, this recommendation represents the clinical opinion of the guideline authors only and therefore further research is indicated to determine the relevance and patient safety implications of diabetes in differential treatment decision-making for shoulder pain.

8.4.2 Role of Diagnosis in Treatment Decision-Making

Presence of significant instability and/or weakness increased the likelihood that healthcare professionals recommended physiotherapy over advice and analgesia (2.05 (1.64, 2.57)) and also corticosteroid injection over advice and analgesia (1.74 (1.30, 2.23)). Free text responses on attributes perceived as missing in the hypothetical patient cases suggest that respondents consider instability and weakness to be potentially indicative of distinct shoulder pathologies. Respondents also suggested in free-text responses that knowing a patient's diagnosis or imaging results can prevent potential known harms of corticosteroid injection such as tissue degradation.

This indicates respondents perceive diagnosis as being strongly intertwined with treatment decision-making, although it is increasingly accepted that establishing a confident clinical diagnosis is a challenge (McFarland et al. 2010; Mitchell, et al. 2005; Smidt & Green, 2003). The observed reasoning amongst respondents that a diagnosis is necessary before making a treatment recommendation, is likely to represent the standard approaches to treatment planning learned by clinicians during both under and post-graduate specialist training. As discussed in chapters 1 and 3, such systematic data collection to inform judgement of diagnosis is commonplace in clinical practice, where the clinician seeks to prove or disprove competing diagnostic hypotheses during the objective examination in order to make reasoned and justifiable treatment plans for patients. This clinical framework is advocated in the British Orthopaedic Association (BOA) and British Elbow and

Shoulder Surgery Society (BESS) guideline on management of subacromial pain, which states:

> *"Making the correct diagnosis is very important and will ensure an efficient and optimum treatment experience for the patient"* (Kulkarni et al. 2015, *pg. 136*).

However as Raynor et al. (2015) showed, although specific patient features are associated with specific diagnoses, diagnostic labels do not seem to be predictive of outcome. Therefore the value of pursuing diagnosis for the purposes of informing treatment decision-making for shoulder pain requires further investigation.

8.4.3 Relevance of Psychosocial Issues in Shoulder Pain

The presence or absence of psychosocial issues was the only patient attribute that was not significantly associated with treatment choice for shoulder pain over and beyond the other attributes in the model. Free text responses in this study suggest that respondents desired further information on aspects of likely patient adherence, understanding of treatments, yellow flags, patient motivation for self-help, carer role, work information, impact on work and information on sport and hobbies, much of which would inform a clinical judgement on the psychosocial complexity of the patient's shoulder problem. Furthermore, some respondents indicated they were unclear about the meaning, extent and relevance of the attribute psychosocial issues. This suggests that the attribute psychosocial issues was considered too broad and lack the detail respondents required to include it as part of decision-making. Rich evidence exists in the field of low back pain that

psychosocial issues are important prognostic factors that can guide clinical management (Hill et al. 2011) and there are studies that demonstrate psychosocial issues are associated with the extent of shoulder disability and symptom intensity (Chester et al. 2016; Menendez et al. 2015), but the evidence as yet is limited. It may be that respondents and/or clinicians managing patients with shoulder pain do not yet associate psychosocial issues, psychological distress or social issues with poor prognosis in patients with shoulder pain. Also the role of these factors as a moderator of treatment effect is currently unclear (van der Windt et al. 2007).

8.4.4 Respondent Perceptions of Conjoint Analysis Method to Study Clinical Decision-Making

Since the conjoint analysis method had not, prior to this study, been used to study clinician decision-making in musculoskeletal pain using a multi-disciplinary and international sample of clinicians and researchers, gaining an insight into how the method was received as a research study was valuable. This was ascertained using the modified decisional conflict questions (table 8.4). Responses provided insight into respondent perception of task complexity and completeness of the hypothetical clinical cases, indicated mixed perception of difficulty in undertaking the conjoint analysis tasks.

Whilst the majority of respondents indicated that the hypothetical clinical cases did contain all of the necessary clinical information upon which to base a treatment recommendation, many respondents were not satisfied with the decision they

made and did not expect to stick to them if asked again. Approximately half of respondents were clear about which treatment would really be best for each patient (51% versus 26% unclear and 23% unsure) with 50% of respondents reporting not having trouble making decisions due to important information being missing compared with 25% who had trouble and 25% who were unsure. A greater proportion of respondents also reported feeling that all considerations that affected the decision were identified (45% compared with 25% who disagreed and 30% who were unsure).

In spite of many respondents reporting that they could make the treatment decisions based on the presented information, the majority of respondents (66%) reported feeling unsatisfied with their decisions. There was mixed contentment about the process for making decisions in the survey with 46% reporting that the process was not as good as it could have been, 36% feeling unsure and 28% feeling content with the process. Free text responses to this question suggest that clinicians did not find it easy to apply their extensive clinical knowledge and skill to a fixed and purposively designed clinical decision experiment as it did not fully replicate their usual clinical practice.

Main reasons provided for how the experimental task differed from clinical practice included the inability to select multiple treatments at once and lack of objective assessment information. Respondents reported that they felt that treatments for shoulder pain were not mutually exclusive and in clinical practice were often offered in various combinations. They indicated that in specific clinical situations,

the order of treatment in these combinations depended on whether pain relief was the primary objective ahead of beginning physiotherapy treatment (i.e., recommending injection first) or whether physiotherapy had failed and an injection was then indicated.

8.4.5 Strengths of Study

It is noteworthy that in spite of the free text data suggesting that respondents did not feel comfortable, confident or enjoy completing the survey and that the hypothetical patient cases were too short and lacked detail, the statistical model converged and clinically sensible patterns in decision-making emerged. The study demonstrated that it is possible and productive to combine individual level data to form a group of expert opinions from which the signals of differential decision-making can be drawn out from the noise of individuality by using a robust conjoint analysis study design and appropriate statistical model for analysis. The analysis gave rise to logical clinical patterns that can be used in future research to further explore the potential explanatory power of moderators of treatment effect as drivers for treatment decision-making.

High level of engagement with the study (1915 potential respondents accessed the survey online) indicates that research concerning differential treatment decision-making appears to be a clinical question/approach that is of interest and relevance to professionals managing patients with shoulder disorders. To the authors' knowledge this is the first study of its kind to recruit a multidisciplinary and

international sample of clinicians and researchers with special interest in the management of shoulder pain for the purposes of understanding how clinicians use patient information to guide clinical decision-making. A strength of conjoint analysis is that the final output of the study represents not the opinion of one single professional, professional group or set of individuals from a particular geographical region, but is the sum of the combined experience and knowledge of the entire sample.

8.4.6 Weaknesses of Study

Potential risks of bias in a conjoint analysis study may arise from framing effects (question and/or attribute wording), ordering (of attributes or decision tasks) effects, sampling issues and any other features of the study that respondents protest against (Rakotonarivo, Schaafsma, & Hockley, 2016). As previously outlined (in chapter 6), pilot work was conducted to ensure that the decision task, attribute wording and order of attributes made sense to the relevant clinical audience. A fractional factorial design with random allocation of a limited number of decision tasks to respondents (chapter 6) also helped to reduce the impact of respondent fatigue and inattention. Issues around sampling have been previously been discussed in detail (chapter 7).

Whilst two thirds of respondents reported being unsatisfied with the survey research experience, it must be highlighted that protests against features of conjoint analysis studies are very common and are reported in up to 90% of

conjoint analysis studies (Rakotonarivo et al. 2016). The nature of the tradeoff faced by researchers in the design of a conjoint study between construct validity (i.e., how closely the study replicates reality being constructed), content validity (whether descriptions of attributes make logical sense), and experimental design (with a limitation of an orthogonal array design being the presence of occasional illogical combinations of patient attributes), means that the resultant survey experience may feel somewhat unreflective of reality, restrictive and lacking in clinical depth. Unavoidable weaknesses of using vignette-based methods to study clinical decision-making therefore exist, specifically the loss of real-world patient-clinician interaction and clinical observation is likely to impact on the decision-making processes used by healthcare practitioners (Lutfey et al. 2008).

When using an orthogonal array to design a conjoint analysis study there is a risk of generating vignettes with illogical combinations of patient attributes (see 6.4.4.5). Free text response data from respondents suggested that this occurred in two of the 36 clinical cases included in the study. It cannot be known how these reportedly confusing clinical case descriptions impacted on the clinical decision-making of respondents who viewed them, or how respondents managed to overcome the challenges that this presented i.e., whether respondents ignored the nonsense attribute or focused on their preferred clinical attributes when making their treatment decision. Further research is indicated to explore the impact of this on decision-making.

In addition to recognising that conjoint analysis studies are most often cognitively

demanding and challenging for respondents to complete, the potential for over or under-estimation of associations of patient attributes with treatment choices due to the hypothetical bias exists (Orme, 2014). A blocked design was used to limit the number of hypothetical clinical cases that each respondent was asked to consider in the survey. Each respondent viewed and made treatment recommendations for 12 clinical cases. However feedback was received that indicated that respondents felt that the survey was tedious, boring, long and repetitious. This feedback aligns with previously reported high degree of cognitive burden imposed on respondents during a conjoint analysis study (Orme, 2014; Johnson et al. 2013).

Hypothetical bias and respondent inattention can arise because respondents are not making 'real life' decisions with tangible consequences, i.e., impacting positively or negatively on whether a patient improves or not (Orme, 2014; Johnson et al. 2013). Whilst this is likely to be a potential issue in some studies, respondent feedback highlighted areas of the study that did not match with clinical practice indicating that they had tried to employ their usual thinking in the survey but were not fully able due to limitations imposed upon them by the survey design.

The unavoidable bias in this study is due to the hypothetical nature of conjoint analysis data. Since the purpose of the study was to understand which factors drive treatment decision-making by clinicians, an area where little evidence exists for subgrouping, a benchmark for identifying the 'correct answer' does not exist. Furthermore, Bateman et al. (2002) also state that there is no way to assess the level of potential discrepancy between results of a conjoint analysis study and

reality. Therefore although the emergent response profiles appeared to be logical (from the perspectives of the candidate, supervisory team and a selection of local shoulder clinicians), there is potential with conjoint analysis that due to the hypothetical nature of the study respondents may have made treatment decisions that do not reflect their usual clinical practice.

Respondents indicated in free text responses a degree of dissatisfaction with the dichotomisation and perceived over-simplification of the patient attributes included in hypothetical clinical cases. It is accepted that real-life patients in clinical practice are not merely a combination of simple dichotomised patient attributes and that the actual patterns that exist in clinical practice are indeed much more complex. The decision to dichotomise the patient attributes for inclusion in this study was made in collaboration with a variety of experienced clinical professionals with expertise in the management of shoulder pain (chapter 4). It is also accepted that the reductionist approach taken to the description of clinical attributes for this study limits the external validity of the findings since the descriptions used in the study may not match those used in real clinical practice. However, use of additional and/or more richly detailed patient attribute descriptions would have increased the complexity of the study, potentially necessitating a larger sample size, and the risk of respondents misunderstanding the meaning of the patient attributes and time taken to respond to each hypothetical case.

Current statistical guidance for analysing associations between dichotomised patient attributes and outcome questions the practice of dichotomising variables

given the likelihood that important data with explanatory or predictive performance will be lost (Riley et al. 2013; Vergouw et al. 2010). This challenge is not unique to this study and Vergouw (2010) summarised exactly this tension between the preference of researchers for increased data points and the preference of clinical tool users (clinicians) for simple, quick and easy to use tools. Therefore, whilst it is accepted that some statistical power may have been lost through the reductionist approach taken to the patient attribute descriptions, the pragmatic and endpoint focused goal of informing a future simple, easy-to-use clinical decision aid guided final study design decisions.

Table 8.5 (pg. 218) contains a further 12 patient attributes suggested as being highly relevant to differential treatment decision-making by survey respondents but that were not included in the study. Of note is the low frequency of which each of the 12 new attributes was suggested (maximum seven times, minimum by just one respondent). This suggests that attributes included in this study and those considered in the preparatory research (chapter 4), mirror the general perception of the respondents. Of these 12 attributes, the request for full diabetes information, full cardiac information and full drug history represents a request for a fully comprehensive clinical assessment. For the purposes of a brief clinical decision tool, such detailed questions are not feasible, and when used in routine practice, additional information can always be collected on attributes that give raise to concern. Therefore, it is accepted that the necessary brevity of a decision tool limits the depth of clinical information that can be obtained using the tool alone. The suggestion by respondents to consider aggravating/easing factors among the patient attributes did not arise from previous research, but warrants further

attention as a potential moderator of treatment effect as aggravating and easing factors may provide valuable insights into the mechanisms through which a treatment might achieve its effect, i.e. a mediator of treatment effect could potentially also moderate response to specific treatments. Time since last injection and extent of previous response to injection are also new suggestions that warrant further investigation in future research.

8.5 Conclusion

This study quantified the impact of the 12 patient attributes for differential decision-making for shoulder pain. In spite of respondent burden, the pragmatic limitations of the design (single treatment options and being forced to make treatment recommendations on the basis of limited and pre-specified patient attributes), and the hypothetical nature of the clinical cases, respondents still managed to complete the survey and provide meaningful responses so that the statistical model converged and clear conclusions could be drawn. This preliminary work to identify the patient attributes of relevance to clinical decision-making appears to have generated novel and informative data in the identification of highly relevant, if not some of the most salient patient attributes in differential treatment decision-making.

Caution is always advised in interpreting and implementing findings of an empirical study but especially in the context of a conjoint analysis study since findings are born of hypothetical scenarios and responses driven by respondents' unique,

professional perspectives. Surowiecki's book 'The Wisdom of The Crowds: Why the Many Are Smarter Than the Few' (2004) outlined many examples from fields of science, law, psychology, computing and politics of how each member of a crowd contributes their experiential knowledge, so that the aggregate response is often more accurate than the response of any one individual. Conjoint analysis was used in this study to deliver the collective wisdom of clinicians on the composition of patient profiles of likely good response to specific primary care treatments.

Limiting the number of attributes to be included in the conjoint analysis study to 12 was a pragmatic decision made on the basis of the implications of the complexity of conjoint analysis studies with large numbers of attributes, namely increased sample size and elevated respondent cognitive burden. The processes undertaken (systematic review and expert consensus workshops using focus groups with nominal group technique) to arrive at the final 12 patient attributes included in the conjoint analysis study were robust, methodologically sound and therefore the final data represented the clinical experience of relevant healthcare professionals and researchers.

Eleven of the 12 patient attributes studied were identified by clinicians as highly relevant to making decisions in the management of shoulder pain and were found to influence differential treatment decision-making. The presence or absence of psychosocial issues was the only patient attribute studied that was not significantly independently associated with differential treatment choice, over and beyond the

other attributes in the model. This conjoint analysis study enabled investigation of the stated clinical decision-making behaviour in a large number of professionals in a highly time and cost-efficient manner, whilst avoiding the practical, ethical or financial challenges of clinical observation methods or medical record reviews (Lutfey et al. 2008). Robust design and statistical analysis of the conjoint analysis method allow confidence in the findings of the study.

It seems that the challenging conjoint analysis questions forced respondents to consciously employ their clinical simplification strategies and clinical heuristics, which are reflected by the results. The study suggests that logical patterns in clinical decision-making exist among experienced clinicians who frequently manage the care of patients with shoulder pain. It is a logical assumption that clinicians chose the treatment they believed was most likely to result in the best outcome for each patient. Therefore the observed pattern represents clinician's perception of likely best responders to physiotherapy and corticosteroid injection as well as profiles of patents that they do not believe should receive steroid injection or physiotherapy. However, this study has not provided evidence as to whether these patterns contain moderators of treatment effect that be used to identify patients most likely to respond to particular treatments. Future studies should assess whether these patient attributes are indeed moderators of treatment effect, ideally using data from a randomised controlled trial using appropriate methodology and sample size, or by using data from multiple existing trials providing relevant data on both patient attributes and treatment effects.

Primary care decision-making for shoulder pain: identifying treatment effect moderators using clinical expertise

Volume II

Cliona McRobert

Ph.D.

June 2018

Keele University

CHAPTER 9: THESIS SUMMARY AND DISCUSSION

As current clinical guidelines do not assist clinicians with optimal treatment selection for patients with shoulder pain, the central aim of this thesis was to identify (combinations of) patient attributes that help clinicians decide between different treatments in primary care, using existing trial evidence and clinical expertise/opinion. At the outset of the thesis, the distinction between prognostic factors and moderators of treatment effect and potential utility in informing treatment selection had not been discussed within the shoulder pain literature (see systematic review, chapter 2). Whilst prognostic research to identify the prognosis of shoulder patients was available, there was little research on the moderators of the effect of specific treatments or how to choose between treatments for patients with shoulder pain. This thesis, therefore, aimed to use appropriate methodologies to differentiate between prognostic factors and moderators of treatment effect for patients with musculoskeletal shoulder pain. Studies constituting this thesis were strongly underpinned by clinical expertise to inform the identification of statistically and clinically relevant candidate moderators and therein, the foundations for a future model of stratified care for shoulder pain. In this final chapter, an overview of thesis findings and applications of the research to date will be presented, followed by a critical reflection on the merits and limitations of the methodologies employed in this thesis. Applications of findings from the thesis to date will be discussed. Finally, this chapter will conclude with the research and clinical implications of this thesis.

9.1 Summary of Thesis Findings

9.1.1 Systematic Review

In chapter 2, a systematic review was undertaken to identify potential moderators of treatment effect in patients with shoulder pain and to assess the quality of the current evidence. The review focused on identifying randomised controlled trials of adults with musculoskeletal shoulder pain that studied any of the three commonly used primary care interventions of interest; (i) advice and analgesia, (ii) physiotherapy treatment (manual therapy and/or exercise) and (iii) corticosteroid injections. Twenty-two studies were included in the review and assessed using the Cochrane risk of bias tool (Cochrane, 2011) and the Pincus criteria for assessment of methodological quality of moderation analysis (Pincus et al. 2011). Although numerous factors were considered or proposed in the 14 studies as potential moderators of treatment effect, the review identified just seven trials (based on data from six trials) that had conducted either a full moderation analysis or subgroup analyses where interactions were tested. Within these seven trials, 13 patient attributes were specifically examined using processes that could be considered to be a form of moderation analysis. Of these, only 'presence of painful arc' was identified as a moderator treatment effect with confirmatory level evidence. All other potential moderators had insufficient or exploratory level evidence, highlighting common methodological issues in the current conduct of moderation analysis in this field. This review concluded that existing evidence of moderation of treatment effect for shoulder pain was limited. The review also highlighted that the conduct of appropriate, high quality moderation analysis is challenging. The requirement of moderation analysis to utilise large sample sizes to test identified pre-specified moderation hypotheses means that at the time of

conducting the systematic review moderators of treatment effect had not been identified with confidence.

The conclusion of this review gave rise to much consideration of the logical next steps to advance this field. At this juncture, I, as a musculoskeletal physiotherapist with experience of managing patients with shoulder pain, along with my supervisory team who also had the benefit of relevant clinical and epidemiological insight, felt that the list of 29 potential moderators (13 potential moderators and 16 additional un-tested suggestions) identified from the systematic review was both overlong as well as incomplete, in that some potentially relevant patient attributes appeared to be missing (e.g., psychological attributes such as anxiety, depression, psychosocial determinants of health and well-being including work-load and sport participation, chronic widespread pain, multi-site pain, employment status, analgesic medication and education). Therefore, given that the review conclusions were based solely on the clinical factors that had already been studied as potential moderators in randomised controlled trials, the logical next step was to ascertain a more complete picture of the patient attributes that are likely to be potential moderators of treatment effect prior to conducting future, a priori defined moderation analyses.

A number of research and methodological options were considered at this time. An option could have been a purposive randomised controlled trial of the common primary care interventions of interest, in which to conduct a full-scale moderation analysis, but this was not feasible within the remit of this PhD. Additional concerns

arose that such a moderation analysis, based on an incomplete yet large list of potential moderators could represent a data-driven approach that is likely to produce spurious findings due to the large number of interactions being investigated, as well as risking the omission of potentially relevant genuine moderators of treatment effect.

Instead, it was considered that the identification of a highly clinically relevant yet short, parsimonius list of potential moderators of treatment effect was likely to be of greater benefit to future researchers and clinicians alike. Since first-line clinicians make treatment decisions with patients with shoulder pain on a daily basis, it was deemed logical and appropriate to next draw upon the knowledge and clinical skills of relevant healthcare professionals to populate a list of potential moderators of treatment effect and progress the field. Therefore, chapter 3 outlined the rationale for studying clinical decision-making and its relevance to the identification of moderators of treatment effect.

9.1.2 Clinical Consensus Studies

Chapter 3 outlined the theoretical models of clinical decision-making in the context of first-line treatment decision-making for shoulder pain. In the absence of recent national guidance (e.g. from NICE) to support primary care treatment decision-making for shoulder pain, little was known at the outset of the thesis about how clinicians chose treatments for patients with shoulder pain or indeed which patient attributes were deemed most important to guide differential treatment selection.

Instead, it was considered likely that clinicians have developed and follow series of individual and experientially constructed clinical heuristics or cognitive shortcuts that enable them to make recommendations for treatment selection on the basis of prior clinical knowledge and clinical experience. The design of a series of studies to explore these decision-making processes in order to understand and identify the patient attributes that drive decision-making was indicated. Chapter 3 outlined this theoretical basis for studying decision-making in order to identify potential moderators of treatment effect.

Although it is accepted that expert opinion constitutes the lowest form of evidence in the hierarchy of evidence (Sackett et al. 1997) as chapter 3 outlined, experts do not often make uninformed decisions. Rather, ranges of decision-making strategies are employed in conjunction with reflection on current evidence, as well as clinical experience to systematically arrive at a sound and logical clinical diagnosis and treatment decision. Since two of the main studies in this thesis made use of expert opinion, potential for scientific critique of this method was accepted.

"There are in fact two things, science and opinion;

the former begets knowledge, the latter ignorance."

- Hippocrates (460-377 BCE)

This thesis presented a good opportunity to expand on this presumed dichotomy by utilising a hybrid approach to study the largely qualitative entity of clinical decision-making using scientific and rigorous quantitative research methods. Therefore, it was conceived that opportunity and value existed in the conduct of sound mixed method research to inform identification of the constructs and decision-making strategies of relevant professionals. The high degree of external validity gained from drawing upon the knowledge and skills of a variety of experienced multidisciplinary healthcare professionals outweighed any concern about the potential for qualitative or mixed methods to result in highly individual, unrepresentative or professionally biased data. Chapter 4 outlines the various (mostly qualitative) options that were considered as potential appropriate methodologies for studying the nature, content and processes of clinical decision-making for shoulder pain. An opportunity existed in this thesis to employ and develop methodologies to study clinical decision-making for shoulder pain in a way that would yield insightful and novel data and also in a way that had not previously been conducted.

Chapter 4 outlines a series of focus groups using nominal group technique and consensus workshops that aimed to obtain the clinical breadth of patient attributes considered pertinent to differential treatment response. Focus group and workshop participants consisted of a professionally diverse group of 21 UK-based healthcare professionals and researchers with experience and interest in the management of patients with shoulder pain who convened on six dates to participate in a series of focus groups. In the focus groups, clinicians suggested 63 patient attributes considered relevant to differential decision-making for shoulder pain, of which 53

were voted as important. The same participants reorganised the attributes into 13 parent attributes in focus group two. In workshop three participants agreed upon simple clinical questions to describe the information contained in each of the parent attributes. Output from this series of focus groups consisted of 12 clinical questions with defined categorical response options that were deemed highly relevant to differential treatment decision-making for shoulder pain.

Of these 12 clinical attributes, six had not been previously studied as potential moderators of treatment effect or examined in existing randomised controlled trials (general health status relating to diabetes and heart disease, traumatic onset, overuse, current clinical status, psychosocial complexity, sleep disturbance). The output from chapter 4 represented insight into the clinical attributes considered highly relevant to differential treatment decision-making by clinicians and provided new direction to the next phase of investigating decisions between three commonly used first-line treatments for shoulder pain and thereby identify potential moderators of treatment effect.

9.1.3 Introduction to Conjoint Analysis

At the outset of chapter 5, the relative importance of the 12 patient attributes in differential decision-making for shoulder pain was not known. The next phase of the thesis sought to develop understanding of how these patient attributes are valued by clinicians to arrive at treatment decisions. Chapter 5 outlined a variety of methods that have previously been used to study clinical decision-making and also

to provide the rationale for and the merit of using a novel experimental approach to develop understanding of differential treatment decision-making for patients with shoulder pain. An overview of the conjoint analysis methodology and specifically it's potential to quantify the influence of each of the attributes on specific differential treatment decisions was provided.

Particular challenges encountered in the design phase of the conjoint study (chapter 6) included determination of the optimum balance between statistical efficiency and response efficiency. Statistical efficiency was assured through the use of an orthogonal design and response efficiency was achieved through use of blocking with random allocation of tasks to limit the number of decision tasks required of each respondent. Much consideration was given during the design phase of the study to the likely impact that potential illogical combinations of clinical attributes arising from the orthogonal array could have on response efficiency. The final design represented the perceived optimal balance between obtaining sound data and designing the conjoint analysis study in a way to best represent the clinical reality. Achieving both aims at once, in one study is accepted to be difficult (Marshall et al. 2010). Therefore, the final study design represented a trade-off between these two aims. Particular strengths of the study include navigating sample size calculation for our study type where no known convention exists and designing the custom-built survey platform to host the randomisation and data collection features required for the survey. These aspects of the thesis were conceptually driven by the PhD student, and supported technically by a statistician and an IT specialist, respectively.

9.1.4 Multimodal Recruitment Strategy for the Conjoint Study

The target population for the conjoint analysis study was an international and multidisciplinary population of medical, health and research practitioners with an interest in the clinical management of shoulder pain, either clinical or research. As outlined in chapter (7), numerous challenges exist in recruiting clinicians for the purposes of survey research, namely lack of access to complete registries of shoulder specialist clinicians as well as the time and cost inefficiencies associated with using some of the traditional methods of recruitment. Therefore, it was deemed necessary to develop an alternative, novel recruitment strategy that involved both traditional and Internet mediated methods of recruitment. Chapter 7 outlined the background, rationale and appraisal of the final recruitment strategy, surmising that on balance, the multi-modal strategy developed was successful as it delivered complete data from enough respondents to meet the minimum sample size within the defined recruitment period and at almost zero material cost.

9.1.5 Conjoint Analysis Study of Clinical Decision-Making

As outlined in chapter 8, complete survey data was received from 387 respondents and partially complete data was received an additional 178 respondents. The statistical analysis depicted the odds of respondents choosing either corticosteroid injection or physiotherapy above advice and analgesia for each attribute. The conjoint analysis indicated that logical patterns of decision-making exist using the 12 attributes studied. Specific patient attributes were

associated with either increased or decreased likelihood of respondents choosing corticosteroid or physiotherapy above advice analogies. The results suggest that clinicians do indeed use patient attributes to guide differential treatment decision-making for patients of shoulder pain and that different patient profiles exist that respondents considered to be more and less likely to respond to the specific interventions.

Since the design of the conjoint analysis was relatively complex as well as novel, it was deemed pertinent to ascertain a measure of acceptability and completeness of the survey as an experimental representation of the clinical decision-making process. Data were therefore gained on respondent perception of task complexity and completeness of the hypothetical clinical cases. The results indicated that respondents found completing the conjoint analysis tasks difficult. Although the study was piloted in a small group of respondents similar to the intended target population for the study (chapter 6), the small-scale pilot did not identify frustration with either the illogical attribute combinations or the limited response options offered in the study. Free text response data indicated that respondents to the actual survey felt that a number of relevant patient attributes were missing from the study. When the attributes suggested as being relevant by respondents were compared to the attributes that fed into the design of the conjoint analysis study, the majority of items suggested were similar to those considered during the developmental work, lending credence to the developmental study design methods. Of the twelve clinical factors newly suggested by the responders, nine were not deemed relevant to a brief clinical tool or not applicable to an NHS context. However, three had not previously considered in the developmental work

for this study and warrant investigation in future research: aggravating/easing factors, time since last injection, and extent of previous response to corticosteroid injection. These are worthy of investigation in future research.

The primary strength of the conjoint analysis study was that it enabled quantification of the impact of specific patient attributes on differential treatment decision-making. A large sample size was achieved facilitating convergence of the statistical model and emergence of clinically sensible patterns of decision-making for shoulder pain. The high degree of engagement with the study from a range of relevant professionals internationally indicated that the research question was of relevance to clinicians. In addition, the conjoint analysis methods facilitated consolidation of data received from individual respondents into patterns of clinical decision-making that represent the input from the multitude of professional disciplines relevant to management shoulder pain. The weaknesses of any conjoint analysis study are the hypothetical nature of the study, the limited and tightly defined question formats and response options required to achieve testable hypotheses, and that only specific attributes can be offered for consideration and quantified during the study. In spite of these limitations, respondents managed to provide meaningful data that constitutes a list of clinically relevant candidate moderators of treatment effect and profiles of likely responders to each intervention. These patient attributes and profiles warrant further investigation in future research to determine their moderating effect on the actual outcomes of treatments received by patients with shoulder pain.

9.2 Originality of This Thesis

This thesis has several original elements and combines insights from a variety of methodological fields. Consideration of moderators of treatment effect for musculoskeletal conditions has less precedence than in fields such as cardiovascular and cancer research. This thesis therefore represents a methodological step forward for the field of musculoskeletal pain management.

Investigation of clinical decision-making and the use of the conjoint analysis method are not new, however application of the conjoint analysis methodology to study differential treatment decision-making by clinicians is relatively new. This thesis utilised menu-based conjoint analysis, a form of conjoint analysis more regularly applied in the field of marketing to study the determinants of differential decision-making when choosing between three potentially viable treatment options (most often consumer choices surrounding food and products). Specifically, there was no precedence for the use of the experimental design of the conjoint analysis in a clinical decision scenario with a large number of patient attributes and three treatment options. Also, since no known convention existed to determine appropriate sample size and statistical analysis approaches steps taken during this thesis constituted methodological steps forward in the practical application of conjoint analysis in empirical research. The use of a multidisciplinary and international sample of researchers and clinicians for the conjoint analysis study is also novel and provides results of the study with good external validity. Specifically, the development of a multimodal recruitment strategy to identify, invite and recruit this multidisciplinary sample to participate in the conjoint analysis study

represents new recruitment methodology development and innovative use of information communication technologies (a proforma for use in other studies may be found in appendix 13).

9.3 Critical Reflection of Methods Used

In spite of using robust systematic review methods and review tools (Cochrane Risk of Bias tool and the Pincus tool for assessment of moderators), conclusions drawn from the systematic review are limited by the extent of patient attributes included in each study and also the statistical analysis conducted in existing trials of interventions for shoulder pain. Therefore, the review does not present data or a conclusion on every possible moderator of treatment effect or a clear-cut set of patient attributes that differentially moderate response to commonly used treatments for musculoskeletal shoulder pain in primary care, but rather a summary of the current application of moderation and subgroup analysis in studies concerning the management of patients with shoulder pain. Nonetheless, the review was valuable as it identified the methodological and clinical gaps in moderation analysis in this field, which informed the next steps taken in this thesis.

The clinical consensus focus groups and workshops aimed to develop a list of the most relevant patient attributes to differential treatment decision-making for patients with shoulder pain. Although conducted with sound clinical consensus methods, concern existed about the maximum number of attributes that the planned conjoint analysis study could manage. This forced the application of the

limit of 12 patient attributes, an upper limit reasoned on the basis of previous conjoint analysis studies (outlined in chapter 5). In spite of achieving consensus agreement on the final 12 most salient patient attributes, it is possible that some informative data may have been lost to the conjoint survey due to the potential for omission of highly relevant patient attributes from the final list or by virtue of the way in which final combinations of patient information were grouped together into parent attributes by the participating clinicians. Also, since the expert consensus workshops were conducted on a single site in the UK, some geographical bias might have existed. Steps were taken to counteract each of these issues but they may have persisted nonetheless. Future expert clinical consensus research could incorporate either multiple geographical locations nationally or internationally or target a pre-existing and well-attended international conference as an opportunity to engage relevant international clinicians in the consensus research exercise.

Although the recruitment strategy employed for the conjoint analysis study was deemed successful as it managed to recruit the target number of responders providing a complete set of response data, methodological reflections were made on how the recruitment strategy could be improved for future research studies. Specifically, future use of the recruitment strategy should include a single question related to mode of entry to the survey. Also different web addresses could be used for specific strands of the recruitment strategy, which could inform analysis on the impact of each strand of the recruitment strategy.

The conjoint study was fielded from the UK and was also open to international clinicians. The recruitment strategy was based on a convenience snowball sampling method that drew upon the professional network of the PhD student and supervisory team. In spite of the multimodal recruitment strategy (chapter 7), the final sample was unbalanced both by professional background and by country of clinical practice (64% of sample were from the UK & Republic of Ireland and 66% were physiotherapists). It is anticipated that this was in part due to the increased likelihood that physiotherapists may be more interested in a research survey that relates to referral to physiotherapist-led interventions (amongst other treatment decisions) than other professionals. The sample imbalance is also likely to be due to the strong physiotherapy research network the Research Institute has developed and the professional background in physiotherapy of both the PhD student and supervisor (Dr. Jonathan Hill), meaning that invitations were more likely to be well received by respondents who shared this professional background. Access to and recruitment of medically trained professionals to research surveys has been shown to be challenging (Cottrell et al. 2015). Further research is required on the optimal way to engage and recruit medically trained health professionals, especially to multidisciplinary research. Future research aiming to recruit a balanced international and multidisciplinary sample should consider identifying recruitment champions in each country of interest and in each professional background interest to ensure optimal professional credibility and visibility.

Data from Google Analytics showed that the survey website was accessed 2700 times, indicating that it was relatively easy to encourage potential respondents to

click on the survey web address. However, of the 2700 times the survey was accessed, 1916 respondents submitted some data but complete data was received from only 387 individuals. Precise reasons for respondents providing incomplete data are unclear, but since the survey was fielded only in English, it is possible that individuals who accessed the survey but not fluent in the English language may have opted to leave the survey without providing complete data. Offering the survey exclusively in the English language created an obvious geographical and language bias. However this avoided the significant, recognised challenges associated with assuring translation validity, internal consistency and face validity in a translated survey (Litwin & Fink, 1995). Future surveys that aim to recruit an international sample should consider translating the survey and recruitment materials into the languages spoken in the countries of interest, as well as conducting the necessary piloting to ensure consistency across translations.

The pragmatic decision in the design of the conjoint survey to limit the number of treatment choices for each hypothetical scenario to just one and preclude selecting a combination of treatment choices resulted in both methodological and practical strengths and limitations. It was hypothesised that respondents might opt to select both physiotherapy and corticosteroid injection as a combined treatment as their first line treatment decision. Free text responses provided by survey responders indicated that respondents were frustrated by the lack of option to combine treatments and reported that the survey did not accurately depict clinical reality. Future conjoint analysis studies should take this valid criticism into account and offer the option to select both single and combined treatments considered

most likely to achieve positive treatment effect to enable analysis of the impact of patient attributes on clinicians' decision between routinely available treatment options.

The multi-modal recruitment strategy developed in this thesis has been successfully applied by another research team in a separate study (Salt et al. 2018). Salt et al operationalised the strategy and recruited 529 physiotherapists (492 of whom were eligible for inclusion in analysis) to a survey on the use of suprascapular nerve blocks in patients with persistent shoulder pain. In comparison to the sample obtained in the conjoint study in this thesis, where complete data was received from 387 clinicians, 255 of whom were physiotherapists, Salt et al's recruitment appears to have been more successful. It is thought that the comparatively larger sample size achieved by Salt et al is due their survey being much more conventional (i.e., similar to other previous surveys of treatment options used in everyday clinical practice), and comparatively shorter and easier to complete. In contrast, the conjoint survey in this thesis was, to the best of author's knowledge, the first conjoint analysis study to have been conducted on clinical decision-making in musculoskeletal pain, therefore clinicians will not have been familiar with the format and limitations of the study type. The conjoint survey was also longer, required responses to 12 cognitively demanding hypothetical, clinical decision-making scenarios, and also included a series of decision stability questions whereby respondents had to reflect upon decisions made. Furthermore responses to the decision stability questions revealed, as previously discussed in this thesis, that the conjoint study format was perceived by respondents to be challenging and reductive. These limitations have been

reflected on throughout the thesis and on balance, it is felt that they do not strongly affect the validity of the findings of this thesis.

9.4 This Thesis' Impacts on Future Primary Management of Shoulder Pain

At the very outset of conceptualising this thesis, how a PhD thesis could contribute to the future development of a model for stratified care for shoulder pain was considered. As demonstrated with a systematic review (chapter 2), the research field of shoulder pain is relatively young, therefore this thesis aimed to make a conceptual as well as methodological step towards the development of a model for stratified care shoulder pain, through the identification of clinically valid candidate moderators of treatment effect.

Given the methodological challenges encountered in moderation analysis and the quantitative study of clinical decision-making, the output of this thesis represents a logical and sequential series of steps undertaken to develop knowledge on moderators of treatment effect for shoulder pain in the face of the current lack of data from RCTs and methodological barriers. The future of shoulder pain management in primary care could logically be based on an evidence-based model of stratified care underpinned by moderators of treatment effect. Further research involving testing of the candidate moderators identified in this thesis including those additional moderators suggested by clinicians in the conjoint analysis study in existing trial data datasets or in a new trial is required before any such model can be confidently proposed.

9.5 Relevance of the Thesis Findings for Practice

Although this thesis has no immediate or direct implications for clinical practice, the underpinning of the thesis highlights the importance of differentiating between generic prognostic factors and moderators of treatment effect, therein offering potential learning opportunities for all clinicians who engage in differential treatment decision-making, irrespective of the clinical presentation being addressed. Extending understanding of this important methodological distinction is likely to assist clinicians in everyday clinical practice in using the available evidence to inform sound differential clinical treatment decisions.

Confirmation is first needed from appropriate trials or large cohorts about the impact of the candidate moderators suggested by this thesis. However, the existing survey format has potential for further future development for on-going research as well as an education tool for clinicians if the candidate moderators are indeed found to moderate treatment effect. If in the future, the conjoint analysis study methods could be scaled up sufficiently and include the range of treatment choices suggested by respondents to the survey (i.e., combinations of conservative treatments and also the option to refer to secondary care specialists), this could enable longer-term data collection and also include other currently un-explored potential moderators (such as imaging findings, genetic biomarkers, metabolic factors or inflammatory markers). Longitudinal data collection could also be used in place of surveys of current practice to investigate changes in opinion and decision-making over time, and analyse the impact of new guidelines, seminal

trials, new interventions, models of care or other significant drivers of clinical behaviour change on clinical attitudes, beliefs and decision-making behaviour. Since not formally addressed in this thesis, examination of differences in treatment decision-making across countries and between professionals could be also be pre-specified and modeled in future data collection using an appropriate recruitment strategy.

The survey also has development potential to as act as an educational resource for clinicians, if it was possible in the future to format the survey so that clinicians could complete the survey and compare their results with the results of members of their profession as well as in the international multidisciplinary sample as a whole. If in the future this could be supported by data from a large cohort study or trial about the usual clinical course of patients with shoulder pain who present with specific attributes (prognosis) or patterns of symptoms, a summary of the clinicians current decision-making strategies could be compared with data on how each clinical factor affects prognosis, and which patterns of patient attributes are considered by expert clinicians to be associated with positive or negative response to specific treatments.

This could also, if successful, become integrated into a computer application for use by patients and clinicians to inform treatment decisions. In clinical practice, a patient's characteristics could be entered into the application that would then use the data already gained from international and multidisciplinary professionals to indicate how other clinicians would manage a similar patient. This information

could also be combined with insights gained from the forthcoming individual patient data meta-analysis planned as part of the Prognostic and Diagnostic Assessment of Shoulder Pain (PANDA-S) programme of research (outlined in section 9.8) to provide predicted likely response statistics based on similar patients in previous research studies. A simple and clinically useful output of this would be predicted treatment response statistics for each of the treatments being considered.

9.6 Implications for Research

The next step from this thesis is to investigate the predictive performance and clinical utility of the candidate moderators of treatment effect of interventions for shoulder pain identified in this thesis. Once their predictive performance in clearly defined patient groups has been established, a model of stratified care can be defined. Within the forthcoming PANDA–S research programme, due to begin at Keele University in 2018, the predictive performance of candidate moderators, including those suggested by this thesis will be investigated. This will inform the design of a model of stratified primary care for shoulder pain, in which optimal diagnostic and prognostic information will be used to target shoulder pain interventions to patient subgroups likely to benefit most or experience least harm.

Additional future research could also include analysis of the impact of the multi-modal recruitment strategy that has been applied so far in other studies involving clinicians or other specific target groups. A systematic review of such studies could

inform reflection on the application of the strategy and the comparative strengths and opportunities for strategic development of its component streams. Such a review could guide its future iteration and development for use in other studies. Although broadcast recruitment methods (adverts placed on social media website, programmed by the social media company to appear on the timeline of individuals who match the demographics of the source population) have been used successfully to recruit patients to research on sensitive topics (Frandsen et al. 2014; Lane et al. 2015), the impact of additional potential social media-based recruitment streams in the recruitment of clinicians to a research survey is unknown. Therefore, future research could also investigate the cost-effectiveness of such advertisements for a study on Facebook, Twitter, LinkedIn etc., compared to the low cost recruitment strategy developed in this thesis.

A weakness of the conjoint analysis that has been discussed in this thesis is the request for additional treatment response options and the option of multiple treatment combinations, for example corticosteroid injection and referral to physiotherapy. Additional insights could also be gained if respondents were asked to indicate their first single treatment recommendation (as in this study) and also recommend a combination of treatments if they felt it was indicated. Future application of conjoint analysis in the field of treatment decision-making for shoulder pain in primary care could, in addition to the three primary care treatments of interest, include the option to refer for further assessment by an advanced practice musculoskeletal physiotherapist or refer to an orthopaedic surgeon. This clinical consensus could be used as a basis for future intervention studies.

Of greatest relevance to future research is the replicable sequential approach to investigating clinical decision-making that has value in its potential future application to progress other clinical areas where diagnosis and clinical decision-making are currently unclear or rely on 'clinical instinct' or 'gut feeling' outlined in this thesis. As discussed throughout this thesis, within shoulder pain, areas of clinical uncertainty currently are likely to include: (i) which patients are likely to benefit from surgical repair of rotator cuff tears, (ii) the role of ultrasound imaging in diagnosis of shoulder pain, (iii) the implications of diagnosis for treatment decision-making in shoulder pain and, beyond the remit of this thesis but of clinical relevance to clinicians who manage shoulder pain, (iv) early recognition of patients who have suffered a dislocation who are likely to repeatedly dislocate and therefore require surgical management. Development of the above potential research ideas into a clinically informative mix of clinical expertise-driven decision support and treatment success probability estimates obtained from data collected in similar 'real' patients could have meaningful potential to improve decision-making and outcome for many patients.

9.7 Applications/Output from this Thesis

1) Output from the thesis has been incorporated in a research programme led by Keele University recently funded by the National Institute for Health Research (NIHR) and Arthritis Research UK entitled 'Prognostic and Diagnostic Assessment of Shoulder Pain (PANDA-S)'. This programme of research will test the candidate moderators identified in this thesis, alongside other candidate predictors, using an individual patient data (IPD) meta-analysis of existing trial data. A cohort study will provide a context to examine the profiles of likely best responders as identified in the IPD meta-analysis. Finally, a model of stratified care for shoulder pain will be developed, partly based on confirmed treatment moderators, and tested in a randomised controlled trial that will compare the clinical and cost-effectiveness of using the stratified care model with usual care for shoulder pain.

2) The approaches used in this thesis to identify relevant patient attributes in a clinically uncertain decision context and also quantify their impact on decision-making inspired a portion of a recently EU Horizon 2020-funded research project entitled 'Personalised Prognostic Models to Improve Well-being and Return to Work After Neck and Low Back Pain – Back-Up' led by the Instituto de Biomechanica in Valencia (Spain), in which Keele researchers (Hill, van der Windt and Wynn-Jones) are co-applicants. For one of the work-packages, the Back-Up programme will draw upon

procedures developed and methodological insights gained during this thesis and design a multimodal recruitment strategy to recruit a multi-disciplinary, international sample of clinicians to a conjoint analysis study investigating clinical decision-making in the management of spinal pain across Europe.

3) The multi-modal recruitment strategy developed for the conjoint analysis study appears to have appeal as a pragmatic survey recruitment methodology. I have been invited to apply the methodology in two separate studies to date:
    a. Dr. Emma Salt (Research Intern, Keele University) et al's (in preparation for publication) online survey of current clinical utility of suprascapular nerve blocks (SSNBs) amongst specialist physiotherapists, achieving 529 respondents in six weeks.
    b. Mr Ahmad Almari's (PhD candidate, Sheffield Hallam University) online survey of UK-based physiotherapist's management on neck pain, achieving in excess of 2100 respondents in four weeks (in progress).

4) Dr. Elizabeth Cottrell (Academic GP, Keele University) has included a conjoint analysis study as part of a proposed research project to determine the optimal clinical explanation of osteoarthritis for GPs to give in order to inform, equip and inspire patients to partake in evidence-based management approaches (exercise and weight management). Practical knowledge and insights gained during my PhD regarding the challenges of conjoint analysis study design, likelihood of and measures available to

counteract respondent burden and on necessary preliminary studies have been applied to this research question.

9.8 Final Conclusion

This thesis used a variety of quantitative and qualitative methods to systematically and empirically draw upon multidisciplinary clinical expertise in order to derive a list of candidate moderators of the effect of commonly used first-line treatments for shoulder pain. The series of studies contained within this thesis forms a logical sequence of progressive research that that provided novel and rich data regarding decision-making processes in clinicians responsible for the management of patients with shoulder pain. Although based on hypothetical decision-making and accepting limitations in terms of question format and sample balance, the conjoint analysis study offered new, novel and quantified insights into how 12 specific patient attributes drive differential decision-making for shoulder pain (pain severity, onset, clinical status, sleep impact, work/sport/hobby impact, neck involvement, previous treatment response, general health status, psychosocial issues, overuse, instability and/or weakness and patient treatment preference). The profiles of likely responders and non-responders to the three specific treatments derived from the conjoint survey also make logical and clinical sense, therefore strengthening the potential of these candidate moderators as predictors of differential treatment effect.

Methods developed during this thesis may have potential for research application in other clinical presentations that require co-ordinated, evidence-based healthcare intervention and where hypotheses exist that specific subgroups of patients are likely to respond differently to specific interventions. The next research steps arising from this thesis are the testing of the predictive performance of the candidate moderators suggested by this thesis using data from RCTs and if genuine evidence of moderation of treatment effect is found, this would indicate the design and impact evaluation of a resultant clinical decision tool for primary care management of shoulder pain.

REFERENCES

AAOS (2009). The Treatment of Glenohumeral Joint Osteoarthritis: Guideline and Evidence Report. *American Academy of Orthopedic Surgeons (AAOS)*. pp. 1-201.

Abdulla, S. Y., Southerst, D., Côté, P., Shearer, H. M., Sutton, D., Randhawa, K., et al. (2015). Manual Therapy. *Manual Therapy*, *20*(5), 646–656. http://doi.org/10.1016/j.math.2015.03.013

Ahern, N. R. (2005). Using the Internet to conduct research. *Nurse Researcher*, *13*(2), 55–70. http://doi.org/10.7748/nr2005.10.13.2.55.c5968

Alessi, E. J., & Martin, J. I. (2010). Conducting an internet-based survey: Benefits, pitfalls, and lessons learned. *Social Work Research*, *34(2)*, 122-128. http://doi.org/10.1093/swr/34.2.122.

Arslan, S., & Celiker, R. (2001). Comparison of the efficacy of local corticosteroid injection and physical therapy for the treatment of adhesive capsulitis. *Rheumatol Int.* 21(1), 20-3.

Artus, M., van der Windt, D.A., Afolabi, E.K., Buchbinder, R., Chesterton, L.S., Hall, A., et al. (2017). Management of shoulder pain by UK general practitioners (GPs): a national survey. *BMJ Open*, *7(6)*, e015711. http://doi.org/10.1136/bmjopen-2016-015711

Ashby, D., & Smith, A.F. (2000). Evidence-based medicine as Bayesian decision-making. *Statistics in Medicine*, *19*(23), 3291–3305.

Austin, P.C., & Steyerberg, E.W. (2017). Events per variable (EPV) and the relative performance of different strategies for estimating the out-of-sample validity of logistic regression models. *Statistical Methods in Medical Research*, *130*, 096228021455897. http://doi.org/10.1214/07-STS242

Bachmann, L.M., Mühleisen, A., Bock, A., Riet, ter, G., Held, U., & Kessels, A.G. (2008). Vignette studies of medical choice and judgement to study caregivers' medical decision behaviour: systematic review. *BMC Medical Research Methodology*, *8*(1), 50. http://doi.org/10.1186/1471-2288-8-50

Baker, S., McBeth, J., Chew-Graham, C.A., Wilkie, R. (2017). Musculoskeletal pain and co-morbid insomnia in adults; a population study of the prevalence and impact on restricted social participation. BMC Family Pract 18(1); 1–9. doi: 10.1186/s12875-017-0593-5

Banning, M. (2008). A review of clinical decision making: models and current research. *Journal of Clinical Nursing*, *17*(2), 187–195. http://doi.org/10.1111/j.1365-2702.2006.01791.x

Baron, R.M., & Kenny, D.A. (1986). The moderator-mediator variable distinction in

social psychological research: conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*, *51*(6), 1173–1182.

Bateman, I.J., Carson, R.T., Day, B., Hanemann, M., Hanley, N., Hett, T., Jones-Lee, M., Loomes, G., Mourato, S., Ozdemirog lu, E., Pearce, D.W., Sugden, R., Swanson, J. (2002). Economic Valuation with Stated Preferences Techniques: A Manual. Cheltenham: Edward Elgar.

Beaton, D.E., & Richards, R.R. (1996). Measuring function of the shoulder. A cross-sectional comparison of five questionnaires. *The Journal of Bone and Joint Surgery. American Volume*, *78*(6), 882–890.

Benfield, A.J., & Szlemko, J.W. (2006). Internet-based data collection: Promises and realities. *Journal of Research Practice, 2(2)*, D1. Retrieved from http://jrp.icaap.org/index.php/jrp/article/view/30/51

Bennell, K., Wee, E., Coburn, S., Green, S., Harris, A., Staples, M., Forbes, A., Buchbinder R. (2010). Efficacy of standardised manual therapy and home exercise programme for chronic rotator cuff disease: randomised placebo controlled trial [with consumer summary]. *BMJ, 340:C2756*. http://doi.org/10.1136/bmj.c2756

Benner, P. (1984). *From Novice to Expert: Excellence and Power in Clinical Nursing Practice*. Menlo Park, California: Addison-Wesley Publishing.

Benner, P., & Tanner, C.A. (1987). How expert nurses use intuition. *American Journal of Nursing*, *87*(1), 23–34.

Biesheuvel, C.J., Vergouwe, Y., Steyerberg, E.W., Grobbee, D.E., & Moons, K.G.M. (2008). Polytomous logistic regression analysis could be applied more often in diagnostic research. *Journal of Clinical Epidemiology*, *61*(2), 125–134. http://doi.org/10.1016/j.jclinepi.2007.03.002

Bishop, A., Holden, M.A., Ogollah, R.O., Foster, N.E., & Ease Back Study Team (2016). Current management of pregnancy-related low back pain: a national cross-sectional survey of UK physiotherapists. *Physiotherapy*, *102*(1), 78–85. http://doi.org/10.1016/j.physio.2015.02.003

Bishop, F.L., & Lewith, G.T. (2008). A Review of Psychosocial Predictors of Treatment Outcomes: What Factors Might Determine the Clinical Success of Acupuncture for Pain? *Journal of Acupuncture and Meridian Studies*, *1*(1), 1–12. http://doi.org/10.1016/S2005-2901(09)60001-7

BPS (2013). *Ethics Guidelines for Internet-Mediated Research* (pp. 1–28). The British Psychological Society (BPS). Retrieved from http://www.bps.org.uk/publications/policy-and- guidelines/research-guidelines-policy- documents/research-guidelines-poli: 03.03.15

Blanchard, V., Barr, S., & Cerisola, F.L. (2010). The effectiveness of corticosteroid

injections compared with physiotherapeutic interventions for adhesive capsulitis: A systematic review. *Physiotherapy, 96(2)*: 95-107. http://doi: 10.1016/j.physio.2009.09.003.

Blangsted, A.K., Sogaard, K., Hansen, E.A., Hannerz, H., & Sjogaard, G. (2008). One-year randomized controlled trial with different physical-activity programs to reduce musculoskeletal symptoms in the neck and shoulders among office workers. *Scandinavian Journal of Work, Environment & Health 2008 Feb;34(1):55-65*.

Bot, S.D.M., van der Waal, J.M., Terwee, C.B., van der Windt, D.A.W.M., Scholten, R.J.P.M., Bouter, L.M., & Dekker, J. (2005). Predictors of outcome in neck and shoulder symptoms: a cohort study in general practice. *Spine*, *30*(16), E459–70.

Bouma, B.J., van der Meulen, J.H., van den Brink, R.B., Arnold, A.E., Smidts, A., Teunter, L.H., Lie, K.I., Tijssen, J.G. (2001). Variability in treatment advice for elderly patients with aortic stenosis: a nationwide survey in The Netherlands. *Heart (British Cardiac Society)*, *85*(2), 196–201.

Braithwaite, D. (2003). Using the Internet to conduct surveys of health professionals: a valid alternative? *Family Practice*, *20*(5), 545–551. http://doi.org/10.1093/fampra/cmg509

Bridges, J.F.P., Hauber, A.B., Marshall, D., Lloyd, A., Prosser, L.A., Regier, D.A., Johnson, R., Mauskopf, J. (2011). Conjoint Analysis Applications in Health—a Checklist: A Report of the ISPOR Good Research Practices for Conjoint Analysis Task Force. *Value in Health*, *14*(4), 403–413. http://doi.org/10.1016/j.jval.2010.11.013

Bridges, J.F.P., Onukwugha, E., Johnson, R., & Hauber, A.B. (2007). Patient Preference Methods A Patient Centered Evaluation Paradigm. *ISPOR Connections*, (13), 4–7. As accessed from: https://www.ispor.org/news/articles/Dec07/Bridgesetal2007-Patientpreferencemethods.pdf on 17.04.14.

Bridges, J.F.P., Kinter, E.T., Kidane, L., & Heinzen, R.R. (2008). Things are looking up since we started listening to patients. *Patient, 1;1(4):*273-82. http://doi: 10.2165/01312067-200801040-00009

Bron, C., de Gast, A., Dommerholt, J., Stegenga, B., Wensing, M., & Oostendorp, R.A.B. (2011). Treatment of myofascial trigger points in patients with chronic shoulder pain: a randomized, controlled trial. *BMC Medicine 2011 Jan 24;9(8):Epub*. http://dx.doi.org/10.1186/1741-7015-9-8

Brookes, S.T., Whitely, E., Egger, M., Smith, G.D., Mulheran, P.A., & Peters, T.J. (2004). Subgroup analyses in randomized trials: risks of subgroup-specific analyses. *Journal of Clinical Epidemiology*, *57*(3), 229–236. http://doi.org/10.1016/j.jclinepi.2003.08.009

Brookes, S.T., Whitley, E., Peters, T.J., Mulheran, P.A., Egger, M., & Smith, G.D. (2001). Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives. *Health Technology Assessment (Winchester, England)*, *5*(33), 1–56.

Buchbinder, R., Green, S., & Youd, J.M. (2013a). Corticosteroid injections for shoulder pain. *Cochrane Database Systematic Review*, (1), CD004016. http://doi.org/10.1002/14651858.CD004016

Buchbinder, R., Staples, M.P., Shanahan, E.M., & Roos Juliana, F. (2013b). General Practitioner Management of Shoulder Pain in Comparison with Rheumatologist Expectation of Care and Best Evidence: An Australian National Survey. *PLoS ONE*, *8*(4), e61243. http://doi.org/10.1371/journal.pone.0061243.s002

Bull, S.S., Levine, D., Schmiege, S., & Santelli, J. (2013). Recruitment and retention of youth for research using social media: Experiences from the Just/Us study. *Vulnerable Children & Youth Studies, 8*(2), 171–181. http://doi.org/10.1080/17450128.2012.748238

Cadogan, A., Laslett, M., Hing, W., McNair, P., & Taylor, S. (2012). Clinical predictors of a positive response to guided diagnostic block into the subacromial bursa. *J Rehabil Med*, *44*(10), 877–84.

Cadogan, A., McNair, P., Laslett, M., & Hing, W. (2013). Shoulder pain in primary care: diagnostic accuracy of clinical examination tests for non-traumatic acromioclavicular joint pain. *BMC Musculoskeletal Disorders*, *14*, 156. http://doi.org/10.1186/1471-2474-14-156

Caldon, L.J.M., Walters, S.J., Ratcliffe, J., & Reed, M.W.R. (2007). What influences clinicians' operative preferences for women with breast cancer? An application of the discrete choice experiment. *European Journal of Cancer*, *43*(11), 1662–1669. http://doi.org/10.1016/j.ejca.2007.04.021

Canivet, C., Östergren, P.O., Choi, B., Nilsson, P., Sillén, U.A., Moghadassi, M., Karasek, R., Isacsson, S.O. (2008). Sleeping problems as a risk factor for subsequent musculoskeletal pain and the role of job strain: Results from a one-year follow-up of the Malmö shoulder neck study cohort. *International Journal of Behavioral Medicine*, *15*(4), 254–262. http://doi.org/10.1080/10705500802365466

Carette, S., Moffet, H., Tardif, J., Bessette, L., Morin, F., Frémont, P., Bykerk, V., Thorne, C., Bensen, W., Blanchette, C. (2003). Intraarticular corticosteroids, supervised physiotherapy, or a combination of the two in the treatment of adhesive capsulitis of the shoulder: a placebo-controlled trial. Arthritis Rheum. 48(3), 829-38.

Carr, A., & Rees, J. (2012). *Pathway Guidelines for Subacromial Shoulder Pain* (pp. 1–16). British Elbow and Shoulder Society. As accessed from: http://www.bess.org.uk/media/Research%20Committee/National%20Guideline

s/Subacromial%20Shoulder%20Pain.pdf on 17.19.14

Carson, R.T., Louviere, J.J., Anderson, D.A., Arabie, P., Bunch, D.S., Hensher, D.A., Johnson, R.M., Kuhfeld, W.F., Steinberg, D., Swait, J., Timmerman, H., Wiley, J.B. (1994). Experimental analysis of choice. *Marketing Letters*, *5*(4), 351–367.

Carter, T., Hall, H., McIntosh, G., Murphy, J., MacDougall, J., & Boyle, C. (2012). Intertester reliability of a classification system for shoulder pain. *Physiotherapy*, *98*(1), 40–46. http://doi.org/10.1016/j.physio.2010.12.003

Chester, R., Jerosch-Herold, C., Lewis, J., & Shepstone, L. (2016). Psychological factors are associated with the outcome of physiotherapy for people with shoulder pain: a multicentre longitudinal cohort study. *British Journal of Sports Medicine*, pii: bjsports-2016-096084. http://doi: 10.1136/bjsports-2016-096084

Chester, R., Shepstone, L., Daniell, H., Sweeting, D., Lewis, J., & Jerosch-Herold, C. (2013). Predicting response to physiotherapy treatment for musculoskeletal shoulder pain: a systematic review. *BMC Musculoskeletal Disorders*, *14*(1), 1–1. http://doi.org/10.1186/1471-2474-14-203

Child, R.J.H., Mentes, J.C., Pavlish, C., & Phillips, L.R. (2014). Using Facebook and participant information clips to recruit emergency nurses for research. *Nurse Res, 21*(6), 16–21. http://doi.org/10.7748/nr.21.6.16.e1246

Chizawsky, L.L.K., Estabrooks, C.A., & Sales, A.E. (2011). The feasibility of Web-based surveys as a data collection tool: a process evaluation. *Applied Nursing Research*, *24*(1), 37–44. http://doi.org/10.1016/j.apnr.2009.03.006

Cho, C.H., Jung, S.W., Park, J.Y., Song, K.S., Yu, K.I. (2013). Is shoulder pain for three months or longer correlated with depression, anxiety, and sleep disturbance? *J Shoulder Elbow Surg, 22(2)*, 222–228. http://doi: 10.1016/j.jse.2012.04.001

Cioffi, J., & Markham, R. (1997). Clinical decision-making by midwives: managing case complexity. *Journal of Advanced Nursing*, *25*(2), 265–272.

Coast, J., Flynn, T.N., Salisbury, C., Louviere, J., & Peters, T.J. (2006). Maximising responses to discrete choice experiments: a randomised trial. *Applied Health Economics and Health Policy*, *5*(4), 249–260.

Cochrane. (2011). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org. Wiley-Blackwell.

Coggon, D., Ntani, G., Palmer, K.T., Felli, V.E., Harari, R., Barrero, L.H., Felknor, S.A., Gimeno, D., Cattrell, A., Vargas-Prada, S., Bonzini, M, Solidaki, E., Merisalu, E., Habib, R.R., Sadeghian, F., Masood, K.M, Warnakulasuriya, S.S., Matsudaira, K., Nyantumbu, B., Sim, M.R., Harcombe, H., Cox, K., Marziale, M.H., Sarquis, L.M., Harari, F., Freire, R., Harari, N., Monroy,

M.V., Quintana, L.A., Rojas, M., Salazar, Vega, E.J., Harris, E.C., Serra, C., Martinez, J.M., Delclos, G., Benavides, F.G., Carugno, M., Ferrario, M.M., Pesatori, A.C., Chatzi, L., Bitsios, P., Kogevinas, M., Oha, K., Sirk, T., Sadeghian, A., Peiris-John, R.J., Sathiakumar, N., Wickremasinghe, A.R., Yoshimura, N., Kelsall, H.L., Hoe, V.C., Urquhart, D.M., Derrett, S., McBride, D., Herbison, P., Gray, A. (2013). Patterns of multisite pain and associations with risk factors. *Pain*, *154*(9), 1769–1777. http://doi.org/10.1016/j.pain.2013.05.039

Converse, L., Barrett, K., Rich, E., & Reschovsky, J. (2015). Methods of Observing Variations in Physicians' Decisions: The Opportunities of Clinical Vignettes. *Journal of General Internal Medicine*, *30*(S3), 586–594. http://doi.org/10.1007/s11606-015-3365-8

Cottrell, E., Roddy, E., Rathod, T., Thomas, E., Porcheret, M., & Foster, N.E. (2015). Maximising response from GPs to questionnaire surveys: do length or incentives make a difference? *BMC Medical Research Methodology*, *15*(1), 3. http://doi.org/10.1186/1471-2296-15-136

Couper, M.P. (2007). Issues of Representation in eHealth Research (with a Focus on Web Surveys). *American Journal of Preventative Medicine*, *32(5)*, S83–S89. http://doi.org/10.1016/j.amepre.2007.01.017

Couper, M.P., Kapteyn, A., Schonlau, M., & Winter, J. (2007). Noncoverage and nonresponse in an Internet survey. *Social Science Research*, *36*(1), 131–148. http://doi.org/10.1016/j.ssresearch.2005.10.002

Crawshaw, D.P., Helliwell, P.S., Hensor, E.M.A., Hay, E.M., Aldous, S.J., & Conaghan, P.G. (2010). Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial. *BMJ, 340:*c3037. https://doi.org/10.1136/bmj.c3037

Croft, P., Pope, D., & Silman, A. (1996). The clinical course of shoulder pain: prospective cohort study in primary care. Primary Care Rheumatology Society Shoulder Study Group. *BMJ: British Medical Journal*, *313*(7057), 601.

Croft, P., Altman, D.G., Deeks, J.J., Dunn, K.M., Hay, A.D., Hemingway, H., LeResche, L., Peat, G., Perel, P., Petersen, S.E., Riley, R.D., Roberts, I., Sharpe, M., Stevens, R.J., van der Windt, D.A., von Korff, M., Timmis, A.. (2015). The science of clinical practice: disease diagnosis or patient prognosis? Evidence about "what is likely to happen" should shape clinical practice. *BMC Medicine 13*, 20. http://doi.org/10.1186/s12916-014-0265-4

Danishevski, K., Mckee, M., Sassi, F., & Maltcev, V. (2007). The decision to perform Caesarean section in Russia. *International Journal for Quality in Health Care*, *20*(2), 88–94. http://doi.org/10.1093/intqhc/mzm070

de Bekker-Grob, E.W., Bliemer, M. C. J., Donkers, B., Essink-Bot, M-L., Korfage, I. K., Roobol, M. J., Gnagma, C.H., Steyerberg, E.W. (2013) Men's preferences for prostate cancer screening: a discrete choice experiment. *British Journal of Cancer, 109,* 633-640. doi: 10.1038/bjc.2013.5.

de Salis, I., Whiting, P., Sterne, J.A.C., & Hay, A.D. (2013). Using qualitative research to inform development of a diagnostic algorithm for UTI in children. *Family Practice*, *30*(3), 325–331. http://doi.org/10.1093/fampra/cms076

De Winter A.F, Jans, M.P., Scholten, R.J., Deville, W., van Schaardenburg, D., & Bouter, L.M. (1999). Diagnostic classification of shoulder disorders: interobserver agreement and determinants of disagreement. *Annals of the Rheumatic Diseases*, *58*(5), 272–277.

Delbecq, A.L. (1971). A Group Process Model for Problem Identification and Program Planning. *The Journal of Applied Behavioral Science*, *7*(4), 466–492. http://doi.org/10.1177/002188637100700404.

Dickens, V.A., Williams, J.L., & Bhamra, M.S. (2005). Role of physiotherapy in the treatment of subacromial impingement syndrome: a prospective study. *Physiotherapy;91(3):159-164*. http://doi.org/10.1016/j.physio.2004.10.008.

Diercks, R.L., & Stevens, M. (2004). Gentle thawing of the frozen shoulder: a prospective study of supervised neglect versus intensive physical therapy in seventy-seven patients with frozen shoulder syndrome followed up for two years. *Journal of Shoulder and Elbow Surgery; 13(5):499-502*. http://doi.org/10.1016/j.jse.2004.03.002

Dinant G.J.G.,, Buntinx F.F., Butler C.C. The necessary shift from diagnostic to prognostic research. *BMC Family Practice*. (2007); 8:53. http://doi:10.1186/1471-2296-8-53.

Dong, W., Goost, H., Lin, X.B., Burger, C., Paul, C., Wang, Z.L., Zhang, T.Y., Jiang, Z.C., Welle, K., Kabir, K. (2015). Treatments for Shoulder Impingement Syndrome. Medicine, 94(10), e510. http://doi.org/10.1097/MD.0000000000000510.

Dorresteijn, J.A.N., Visseren, F.L.J., Ridker, P.M., Wassink, A.M.J., Paynter, N.P., Steyerberg, E.W., van der Fraaf, Y., Cook, N.R. (2011). Estimating treatment effects for individual patients based on the results of randomised clinical trials. *BMJ (Clinical Research Ed.)*, *343*, d5888–d5888. http://doi.org/10.1136/bmj.d5888

Dreyfus, S. E. (2004). The Five-Stage Model of Adult Skill Acquisition. *Bulletin of Science, Technology and Society*, *24*(3), 177–181. http://doi.org/10.1177/0270467604264992

Elstein, A.S., Schwartz, A., & Schwarz, A. (2002). Clinical problem solving and diagnostic decision making: selective review of the cognitive literature. *Bmj*, *324*(7339), 729–732. http://doi.org/10.1136/bmj.324.7339.729

Elstein, A.S., Shulman, L.S., & Sprafka, S.A. (2008). Medical problem solving: a ten-year retrosepctive. *Evaluation and the Health Professions*, *13*, 5–38.

Engebretsen, K., & Soberg L,H. (2010). Exercise therapy alone and exercise therapy after corticosteroid injection are equally effective after 12 weeks for moderate to severe shoulder pain. *Journal of Physiotherapy*, *56*(4), 278–278.

Engebretsen, K., Grotle, M., Bautz-Holter, E., Ekeberg, O.M., & Brox, J.I. (2010). Predictors of Shoulder Pain and Disability Index (SPADI) and work status after 1 year in patients with subacromial shoulder pain. *BMC Musculoskeletal Disorders*, *11*(1), 218. http://doi.org/10.1186/1471-2474-11-218

Engebretsen, K., Grotle, M., Bautz-Holter, E., Sandvik, L., Juel, N.G., Ekeberg, O.M., & Brox, J.I. (2009). Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. *Bmj*, *339*(sep15 1), b3360–b3360. http://doi.org/10.1136/bmj.b3360

Ensor, K.L., Kwon, Y.W., DiBeneditto, M.R., Zuckerman, J.D., & Rokito, A.S. (2013). The rising incidence of rotator cuff repairs. *Journal of Shoulder and Elbow Surgery*, *22*(12), 1628–1632. http://doi.org/10.1016/j.jse.2013.01.006

Feleus, A., Bierma-Zeinstra, S.M.A., Miedema, H.S., Verhagen, A.P., Nauta, A.P., Burdorf, A., Verhaar, J.A., Koes, B.W. (2007). Prognostic indicators for non-recovery of non-traumatic complaints at arm, neck and shoulder in general practice--6 months follow-up. *Rheumatology*, *46*(1), 169–176. http://doi.org/10.1093/rheumatology/kel164

Farmer, N. (2014). An update and further testing of a knowledge-based diagnostic clinical decision support system for musculoskeletal disorders of the shoulder for use in a primary care setting. *J Eval Clin Pract.* 2014 Oct;20(5):589-95. http://doi: 10.1111/jep.12153

Foster, N.E., Hill, J.C., O'Sullivan, P., & Hancock, M. (2013). Stratified models of care. *Best Practice & Research Clinical Rheumatology*, *27*(5), 649–661. http://doi.org/10.1016/j.berh.2013.10.005

Frandsen, M., Thow, M., & Ferguson, S.G. (2016). The Effectiveness Of Social Media (Facebook) Compared With More Traditional Advertising Methods for Recruiting Eligible Participants To Health Research Studies: A Randomized, Controlled Clinical Trial. *JMIR Res Protoc, 5(3)*, e161. http://doi: 10.2196/resprot.5747.

Frandsen, M., Walters, J., & Ferguson, S. G. (2014). Exploring the Viability of Using Online Social Media Advertising as a Recruitment Method for Smoking Cessation Clinical Trials, *16*(2), 247–251. http://doi.org/10.1093/ntr/ntt157

Fritz, J. M. (2009). Clinical Prediction Rules in Physical Therapy: Coming of Age? *Journal of Orthopaedic and Sports Physical Therapy*, *39*(3), 159–161. http://doi.org/10.2519/jospt.2009.0110

Gartsman, G.M., Brinker, M.R., Khan, M., & Karahan, M. (1998). Self-assessment of general health status in patients with five common shoulder conditions. *Journal of Shoulder and Elbow Surgery*, *7*(3), 228–237.

Geraets, J.J., Goossens, M.E., de Groot, I.J., de Bruijn, C.P., De Bie R.A, Dinant, G.J., van der Heijden, G., van den Heuvel, W.J. (2005). Effectiveness of a graded exercise therapy program for patients with chronic shoulder complaints. *Australian Journal of Physiotherapy 2005;51(2):87-94*. http://doi.org/10.1016/S0004-9514(05)70037-4

Geraets, J., Goossens, M., de Bruijn, C.P.C., de Groot, I.J.M., Koke, A.J.S., Pelt, R., et al. (2006). Cost-effectiveness of a graded exercise therapy program for patients with chronic shoulder complaints. *International Journal of Technology Assessment in Health Care, 22(1):76-83*.

Gialanella, B., & Prometti, P. (2011). Effects of corticosteroids injection in rotator cuff tears. *Pain Med.,12*(10):1559-65. http://doi: 10.1111/j.1526-4637.2011.01238.x.

Gismervik, S.Ø., Drogset, J.O., Granviken, F., Rø, M., & Leivseth, G. (2017). Physical examination tests of the shoulder: a systematic review and meta-analysis of diagnostic test performance. *BMC Musculoskeletal Disorders*, 1–9. http://doi.org/10.1186/s12891-017-1400-0

Gjestland, L. (1996). Net? Not yet. Marketing Research, 8(1), 26-29.

Glaser, B. G., Strauss, A. L. (1967) The discovery of grounded theory: Strategies for qualitative research. New York, NY: Routledge. ISBN: 9781351522168.

Gooberman-Hill, R., Woolhead, G., MacKichan, F., Ayis, S., Williams, S., & Dieppe, P. (2007). Assessing chronic joint pain: Lessons from a focus group study. *Arthritis & Rheumatism*, *57*(4), 666–671. http://doi.org/10.1002/art.22681

Good, I.J. (1983). Good Thinking: The Foundations of Probability and Its Applications. Minneapolis, MN: University of Minnesota Press.

Grava-Gubins, I., & Scott, S. (2008). Effects of various methodologic strategies: survey response rates among Canadian physicians and physicians-in-training. *Can Fam Physician,54(*10):1424-30.

Green, S, Buchbinder, R, Hetrick, S.E. (2003) Physiotherapy interventions for shoulder pain. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD004258. DOI: 10.1002/14651858.CD004258.

Greving, K., Dorrestijn, O., Winters, J.C., Groenhof, F., Van Der Meer, K., Stevens, M., & Diercks, R. L. (2012). Incidence, prevalence, and consultation rates of shoulder complaints in general practice. *Scandinavian Journal of Rheumatology*, *41*(2), 150–155. http://doi.org/10.3109/03009742.2011.605390

Guest, G., Macqueen, K., & Namey, E. (2012). Applied Thematic Analysis. Sage, London. IBN:10.4135/9781483384436.

Gurung, T., Ellard, D. R., Mistry, D., Patel, S., & Underwood, M. (2015). Identifying potential moderators for response response to treatment in low back pain: A systematic review. *Physiotherapy, 101(3*):243-51. http://doi: 10.1016/j.physio.2015.01.006

Hanchard, N., Cummins, J., & Jeffries, C. (2004). *Evidence-based clinical guidelines for the diagnosis, assessment and physiotherapy management of shoulder impingement syndrome*. The Chartered Society of Physiotherapy. As accessed: http://www.csp.org.uk/publications/evidence-based-clinical-guidelines-diagnosis-assessment-physiotherapy-management-should 19.02.14.

Hancock, M., Herbert, R.D., & Maher, C.G. (2009). A Guide to Interpretation of Studies Investigating Subgroups of Responders to Physical Therapy Interventions. *Physical Therapy*, *89*(7), 698–704. http://doi.org/10.2522/ptj.20080351

Harkness, J.A., Van De Vijver, F.J.R., & Mohler, P.P.H. (2003). Cross-Cultural Survey Methods. John Wiley & Sons.

Harris, M. (2017, January 2). Protocol for Injection of Intra-articular, Peri-articular or Soft Tissue Corticosteroid. Southern Health NHS Foundation Trust. As accessed: http://www.southernhealth.nhs.uk/_resources/assets/inline/full/0/42387.pdf on 01.04.17.

Hay, E.M., Thomas, E., Paterson, S.M., Dziedzic, K., & Croft, P.R. (2003). A pragmatic randomised controlled trial of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care. *Annals of the Rheumatic Diseases*, *62*(5), 394–399.

He, G., Cerin, E., Huang, W.Y., & Wong, S.H. (2014). Understanding Neighborhood Environment Related to Hong Kong Children's Physical Activity: A Qualitative Study Using Nominal Group Technique. *PLoS ONE*, *9*(9), e106578. http://doi.org/10.1371/journal.pone.0106578.t003

Hebert, J.J., & Fritz, J.M. (2012). Clinical decision rules, spinal pain classification and prediction of treatment outcome: A discussion of recent reports in the rehabilitation literature. *Chiropractic & Manual Therapies*, *20*(1), 19. http://doi.org/10.1186/2045-709X-20-19

Hegedus, E.J., Goode, A.P., Cook, C.E., Michener, L., Myer, C.A., Myer, D.M., & Wright, A.A. (2012). Which physical examination tests provide clinicians with the most value when examining the shoulder? Update of a systematic review with meta-analysis of individual tests. *British Journal of Sports Medicine*, *46*(14), 964–978. http://doi.org/10.1136/bjsports-2012-091066

Hemingway, H., Croft, P., Perel, P., Hayden, J.A., Abrams, K., Timmis, A., Briggs, A., Udamyan, R., Moons, K.G.M., Steyerberg, E.W., Roberts, I., Schroter, S., Altman, D.G., Rile, R.R. (2013). Prognosis research strategy (PROGRESS) 1:

A framework for researching clinical outcomes. *BMJ*, *346*(1), e5595–e5595. http://doi.org/10.1136/bmj.e5595

Hensher, D.A., Rose, J.M., & Greene, W.H. (2005). Applied Choice Analysis. Cambridge University Press. http://doi.org/10.1007/9781316136232

Hifinger, M., Hiligsmann, M., Ramiro, S., Watson, V., Severens, J.L., Fautrel, B., Uhlig, T., van Vollenhoven, R., Jacques, P., Detert, J., Canas da Silva, J., Scire, C.A., Berghea, F., Carmona, L., Pentek, M., Keat, A., Boonen, A. (2016) In uence of disease activity on RA treatment choices in countries with restricted access to expensive, innovative drugs: a discrete choice experiment among rheumatologists. *Annals of Rheumatic Diseases, 76(1)*, 126-132. http://doi:10.1136/ rmdopen-2017-000453.

Higgins, J.P.T., Altman, D.G., Gøtzsche, P.C., Juni, P., Moher, D., Oxman, A.D., , J., Schulz, K.F., Weeks, L., Sterne, J.A.C.,Cochrnae Bias Methods Group, Cochrane Statistical Methods Group. (2011). The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ (Clinical Research Ed.)*, *343*(2), d5928–d5928. http://doi.org/10.1136/bmj.d5928

Hill, J.C., & Fritz, J.M. (2011). Psychosocial influences on low back pain, disability, and response to treatment. *Physical Therapy*, *91*(5), 712–721. http://doi.org/10.2522/ptj.20100280

Hill, J.C., Dunn, K.M., Lewis, M., Mullis, R., Main, C.J., Foster, N.E., & Hay, E.M. (2008). A primary care back pain screening tool: Identifying patient subgroups for initial treatment. *Arthritis & Rheumatism*, *59*(5), 632–641. http://doi.org/10.1002/art.23563

Hill, J.C., Whitehurst, D.G.T., Lewis, M., Stirling, B., Dunn, K.M., Foster, N.E., Konstantinou, K., Main, C.J., Mason, E., Somerville, S., Sowden, G., Vohora, K., Hay, E.M. (2011). Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *The Lancet*, *378*(9802), 1560–1571. http://doi.org/10.1016/S0140-6736(11)60937-9

Hingorani, A.D., Windt, D.A.W.M., Riley, R.D., Abrams, K., Moons, K.G.M., Steyerberg, E.W., Schroter, S., Sauerbrei, W., Altman, D.G., Hemingway, H. (2013). Prognosis research strategy (PROGRESS) 4: Stratified medicine research. *BMJ*, *346*(1), e5793–e5793. http://doi.org/10.1136/bmj.e5793

Hoare, B.J., Wallen, M.A., Imms, C., Villanueva, E., Rawicki, H.B., & Carey, L. (2010). Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy (UPDATE). Cochrane *Database Systematic Review, 20*;(1):CD003469. http://doi: 10.1002/14651858.CD003469.pub4.

Hosmer, D.W., Lemeshow, S., & Studivant, R.X. (2013). Applied Logistic Regression (3rd ed.). John Wiley & Sons.

Houston, J.D., & Fiore, D.C. (1998). Online medical surveys: using the Internet as a research tool. MD Comput, *15*(2), 116–120.

Hsu, J.K., Thibodeau, R., Wong, S.J., Zukiwsky, D., Cecile, S., & Walton, D.M. (2011). A “Wii” bit of fun: The effects of adding Nintendo Wii Bowling to a standard exercise regimen for residents of long-term care with upper extremity dysfunction. *Physiotherapy Theory and Practice, 27(3):185-193*. http://doi.org/10.3109/09593985.2010.483267

Ilieva, J., Baron, S., & Healey, N.M. (2002). On-line surveys in international marketing research: pros and cons. *International Journal of Market Research, 44(3)*, 361–367.

Judge, A., Murphy, R.J., Maxwell, R., Arden, N.K., Carr, A.J. (2014) Temporal trends and geographical variation in the use of subacromial decompression and rotator cuff repair of the shoulder in England. *Bone Joint Journal, 96(1)*:70-4. http://doi: 10.1302/0301-620X.96B1.32556.

Johal, P., Martin, D., Broadhurst, N. Managing shoulder pain in general practice - assessment, imaging and referral. (2008). Managing shoulder pain in general practice - assessment, imaging and referral. *Aust Fam Physician, 37(4),* 263–265.

Johnson, R.F. (2006). Measuring conjoint stated preferences for pharmaceuticals: a brief introduction. *RTI Health Solutions, Research Triangle Park*.

Johnson, R.F., Lancsar, E., Marshall, D., Kilambi, V., Mühlbacher, A., Regier, D. A., Bresnahan, B.W., Kanninen, B,. Bridges, J.F. (2013). Constructing Experimental Designs for Discrete-Choice Experiments: Report of the ISPOR Conjoint Analysis Experimental Design Good Research Practices Task Force. *Value in Health*, *16*(1), 3–13. http://doi.org/10.1016/j.jval.2012.08.2223

Jones, J., & Hunter, D. (1995). Qualitative Research: Consensus methods for medical and health services research. *BMJ (Clinical Research Ed.)*, *311*(7001), 376–380. http://doi.org/10.1136/bmj.311.7001.376

Jordan, K.P., Kadam, U.T., Hayward, R., Porcheret, M., Young, C., & Croft, P. (2010). Annual consultation prevalence of regional musculoskeletal problems in primary care: an observational study. *BMC Musculoskeletal Disorders*, *11*(1), 144. http://doi.org/10.1186/1471-2474-11-144

Joseph, G.M., Patel, V.L. (1990). Domain knowledge and hypothesis genenation in diagnostic reasoning. *Med Dec Making, 10(1)*:31-46. http://doi/abs/10.1177/0272989X9001000107

Kahneman, D. (2003). A perspective on judgment and choice: Mapping bounded rationality. *American Psychologist*, *58*(9), 697–720. http://doi.org/10.1037/0003-066X.58.9.697

Kaner, E.F., Haighton, C.A., & McAvoy, B.R. (1998). 'So much post, so busy with practice--so, no time!‘: a telephone survey of general practitioners’ reasons for

not participating in postal questionnaire surveys. *British Journal of General Practice, 48*, 1067–1069.

Kapp, J.M., Peters, C., & Oliver, D.P. (2013). Research Recruitment Using Facebook Advertising: Big Potential, Big Challenges, J Cancer Ed, *28*(1), 134–137. http://doi.org/10.1007/s13187-012-0443-z

Kee, F., McDonald, P., Kirwan, J.R., Patterson, C.C., & Love, A.H.G. (1998). Urgency and priority for cardiac surgery: a clinical judgment analysis. *BMJ (Clinical Research Ed.)*, *316*(7135), 925–929. http://doi.org/10.1136/bmj.316.7135.925

Kee, F., McDonald, P., Kirwan, J.R., Patterson, C.C., & Love, G. (1997). The stated and tacit impact of demographic and lifestyle factors on prioritization decisions for cardiac surgery. *QJM: Monthly Journal of the Association of Physicians*, *90*(2), 117–123. http://doi.org/10.1093/qjmed/90.2.117

Kellerman, S.E., & Herold, J. (2001). Physician response to surveys. A review of the literature. Am J Prev Med, *20*(1), 61–67.

Kempf, B., Kongsted, A.(2012). Association Between the Side of Unilateral Shoulder Pain and Preferred Sleeping Position: A Cross-Sectional Study of 83 Danish Patients. J Maipulative Physiol Ther, *35*(5), 407–412. http://doi: 10.1016/j.jmpt.2012.04.015

Kennedy, C.A., Haines, T., & Beaton, D.E. (2006a). Eight predictive factors associated with response patterns during physiotherapy for soft tissue shoulder disorders were identified. *Journal of Clinical Epidemiology*, *59*(5), 485–496. http://doi.org/10.1016/j.jclinepi.2005.09.003

Kennedy, C.A., Manno, M., Hogg-Johnson, S., Haines, T., Hurley, L., McKenzie, D., & Beaton, D.E. (2006b). Prognosis in soft tissue disorders of the shoulder: predicting both change in disability and level of disability after treatment. *Physical Therapy*, *86*(7), 1013–32– discussion 1033–7.

Khatri, C., Chapman, S.J., Glasbey, J., Kelly, M., Nepogodiev, D., Bhangu, A., Fitzgerald, J.E., & Committee (2015). Social Media and Internet Driven Study Recruitment: Evaluating a New Model for Promoting Collaborator Engagement and Participation. *PLoS ONE*, *10*(3), e0118899. http://doi.org/10.1371/journal.pone.0118899

Kinter, E.T., Prior, T.J., Carswell, C.I., & Bridges, J. (2012). A comparison of two experimental design approaches in applying conjoint analysis in patient-centered outcomes research. *Patient, 5(4)*:279-94. http://doi: 10.2165/11641100-000000000-00000.

Kohn, L.T., & Corrigan, J.M. (2000). To Err Is Human: Building a Safer Health System. (Committee on Quality of Health Care in America, Institute of Medicine, Ed.) (pp. 1–312). Washington, D.C.: National Academies Press. http://doi.org/10.17226/9728

Kraemer, H.C., Wilson, G.T., Fairburn, C.G., & Agras, W.S. (2002). Mediators and moderators of treatment effects in randomized clinical trials. *Archives of General Psychiatry*, *59*(10), 877–883.

Kraemer, H.C., Kiernan, M., Essex, M., & Kupfer, D.J. (2008). How and why criteria defining moderators and mediators differ between the Baron & Kenny and MacArthur approaches. *Health Psychology*, *27*(2, Suppl), S101–S108. http://doi.org/10.1037/0278-6133.27.2(Suppl.).S101.

Kuhfeld, W.F. (2005). *Orthogonal Array Lists* (pp. 1–55). SAS Institute. As from http://support.sas.com/ techsup/technote/ts723.html on 13.03.13.

Kuijpers, T., van der Windt, D.A.W.M., Boeke, A.J.P., Twisk, J.W.R., Vergouwe, Y., Bouter, L.M., & van der Heijden, G.J.M.G. (2006a). Clinical prediction rules for the prognosis of shoulder pain in general practice. *Pain*, *120*(3), 276–285. http://doi.org/10.1016/j.pain.2005.11.004

Kuijpers, T., van der Windt, D.A.W.M., van der Heijden, G.J.M.G., & Bouter, L.M. (2004). Systematic review of prognostic cohort studies on shoulder disorders. *Pain*, *109*(3), 420–431. http://doi.org/10.1016/j.pain.2004.02.017

Kuijpers, T., van der Windt, D.A., van der Heijden, G.J., Twisk, J.W., Vergouwe, Y., & Bouter, L.M. (2006b). A prediction rule for shoulder pain related sick leave: a prospective cohort study. *BMC Musculoskeletal Disorders*, *7*(1), 97. http://doi.org/10.1186/1471-2474-7-97

Kulkarni, R., Gibson, J., Brownson, P., Thomas, M., Rangan, A., Carr, A.J., & Rees, J.L. (2015). BESS/BOA Patient Care Pathways: Subacromial shoulder pain. *Shoulder & Elbow*, *7*(2), 135–143. http://doi.org/10.1177/1758573215576456

Lancaster, K.J. (1966). A New Approach to Consumer Theory. *Journal of Political Economy*, *74*(2), 132–157.

Lane, T.S., Armin, J., & Gordon, J.S. (2015). Online Recruitment Methods for Web-Based and Mobile Health Studies: A Review of the Literature. *J Med Internet Res, 17(7)*, e183. http://doi: 10.2196/jmir.4359.

Langenhoff, B.S., Krabbe, P.F.M., & Ruers, T.J.M. (2007). Computer-based decision making in medicine: A model for surgery of colorectal liver metastases. *European Journal of Surgical Oncology (EJSO)*, *33*, S111–S117. http://doi.org/10.1016/j.ejso.2007.09.023

Laupacis, A., Sekar, N., & Stiell, I.G. (1997). Clinical prediction rules. A review and suggested modifications of methodological standards. *JAMA: the Journal of the American Medical Association*, *277*(6), 488–494.

LeBlanc, M., & Fitzgerald, S. (2000). Research design and methodology section: Logistic regression for school psychologists. *School Psychology Quarterly*, *15*(3), 344–358.

Lewis, J.S. (2009). Rotator cuff tendinopathy/subacromial impingement syndrome: is it time for a new method of assessment? *British Journal of Sports Medicine*, *43*(4), 259–264. http://doi.org/10.1136/bjsm.2008.052183

Liesdek, C., van der Windt, D.A., Koes, B.W., & Bouter, L.M. (1997). Soft-tissue disorders of the shoulder: a study of inter-observer agreement between general practitioners and physiotherapists and an overview of physiotherapeutic treatment. *Physiotherapy*, *83*(1), 12–17.

Linstone, H.A. & Turoff, M. (2002). The Delphi Method: Techniques and Applications (18 ed.). Reading, Mass.: Addison-Wesley Pub. Co., Advanced Book Program.

List, D. (2001) The consensus group technique in social research. Field Methods, 13(3): 277-290. https://doi.org/10.1177/1525822X0101300304

Littlewood, C. (2012) Contractile dysfunction of the shoulder (rotator cuff tendinopathy): an overview. *J Man Manip Ther*. *20*(4): 209–213. https://doi: 10.1179/2042618612Y.0000000005

Littlewood, C., Ashton, J., Chance-Larsen, K., May, S., & Ben Sturrock. (2012). Exercise for rotator cuff tendinopathy: a systematic review. *Physiotherapy*, *98*(2), 101–109. http://doi.org/10.1016/j.physio.2011.08.002

Littlewood, C., Malliaras, P., Mawson, S., Walters, S.J. (2014). Self-managed loaded exercise versus usual physiotherapy treatment for rotator cuff tendinopathy: a pilot randomised controlled trial. *Physiotherapy, 100*(1), 54–60. http://doi: 10.1016/j.physio.2013.06.001

Litwin, M.S., & Fink, A. (1995). How To Measure Survey Reliability and Validity. The Survey Kit. (7 ed.). Thousand Oaks, California: Sage.

Lo, Y.P., Hsu, Y.C., & Chan, K.M. (1990). Epidemiology of shoulder impingement in upper arm sports events. *British Journal of Sports Medicine*, *24*(3), 173–177.

Louviere, J.J. (1988). Conjoint Analysis Modelling of Stated Preferences. *Journal of Transport Economics and Policy*, *22*(1), 93–119.

Louviere, J.J., Flynn, T., & Carson, R.T. (2010). Discrete Choice Experiments Are Not Conjoint Analysis. *Journal of Choice Modelling*, *3*(3), 57–72.

Louviere, J.J., Islam, T., Wasi, N., Street, D., & Burgess, L. (2008). Designing Discrete Choice Experiments: Do Optimal Designs Come at a Price? *Journal of Consumer Research*, *35*(2), 360–375. http://doi.org/10.1086/586913

Luce, R.D., & Tukey, J.W. (1964). Simultaneous conjoint measurement: A new type of fundamental measurement. *Journal of Mathematical Psychology*, *1*(1), 1–27.

MacCormick, A.D., & Parry, B.R. (2006). Judgment Analysis of Surgeons' Prioritization of Patients for Elective General Surgery. *Medical Decision Making*, *26*(3), 255–264. http://doi.org/10.1177/0272989X06288680

Madia, S.A. (2011). Best practices for using social media as a recruitment strategy, *10*(6), 19–24. http://doi.org/10.1108/14754391111172788

Magarey, M.E., Jones, M.A., Cook, C.E., Hayes, M.G. (2016). Does physiotherapy diagnosis of shoulder pathology compare to arthroscopic findings? *Br J Sports Med, 50*(18), 1151–1157. http://doi.org/10.1136/bjsports-2012-091492

Mansell, G., Kamper, S.J., & Kent, P. (2013). Best Practice & Research Clinical Rheumatology. *Best Practice & Research Clinical Rheumatology*, *27*(5), 685–697. http://doi.org/10.1016/j.berh.2013.10.001

Marshall, D., Bridges, J.F.P., Hauber, B., Cameron, R., Donnalley, L., Fyie, K., & Johnson, F.R. (2010). Conjoint Analysis Applications in Health - How are Studies being Designed and Reported?: An Update on Current Practice in the Published Literature between 2005 and 2008. *The Patient*, *3*(4), 249–256. http://doi.org/10.2165/11539650-000000000-00000

May, S., Greasley, A., Reeve, S., & Withers, S. (2008). Expert therapists use specific clinical reasoning processes in the assessment and management of patients with shoulder pain: a qualitative study. *Australian Journal of Physiotherapy*, *54*(4), 261–266.

McFadden, D. (1978). Modelling the Choice of Residential Location. In *Spacial Interaction Theory and Planning Models* (pp. 75–96). Amsterdam: North Holland Pub.

McFarland, E.G., Garzon-Muvdi, J., Jia, X., Desai, P., & Petersen, S.A. (2010). Clinical and diagnostic tests for shoulder disorders: a critical review. *British Journal of Sports Medicine*, *44*(5), 328–332. http://doi.org/10.1136/bjsm.2009.067314

McGinn, T.G., Guyatt, G.H., Wyer, P.C., Naylor, C.D., Stiell, I.G., & Richardson, W.S. (2000). Users' guides to the medical literature: XXII: how to use articles about clinical decision rules. Evidence-Based Medicine Working Group. *JAMA: the Journal of the American Medical Association*, *284*(1), 79–84.

McKee, R. (2013). Ethical issues in using social media for health and health care research. *Health Policy*, *110*(2-3), 298–301. http://doi.org/10.1016/j.healthpol.2013.02.006

McKinlay, J.B., Burns, R.B., Durante, R., Feldman, H.A., Freund, K.M., Harrow, B. S., Irish, J.T., Kasten, L.E., Moskowitz, M.A. (1997). Patient, physician and presentational influences on clinical decision making for breast cancer: results from a factorial experiment. *Journal of Evaluation in Clinical Practice*, *3*(1), 23–57.

Menendez, M.E., Baker, D.K., Oladeji, L.O., Fryberger, C.T., McGwin, G., & Ponce, B.A. (2015). Psychological Distress Is Associated with Greater Perceived Disability and Pain in Patients Presenting to a Shoulder Clinic. *The Journal of Bone and Joint Surgery. American Volume*, *97*(24), 1999–2003. http://doi.org/10.2106/JBJS.O.00387

Miles, C.L., Pincus, T., Carnes, D., Homer, K.E., Taylor, S.J.C., Bremner, S.A., Rahman, A., Underwood, M. (2012). Review: Can we identify how programmes aimed at promoting self-management in musculoskeletal pain work and who benefits? A systematic review of sub-group analysis within RCTs. *European Journal of Pain*, *15*(8), 775.e1–775.e11. http://doi.org/10.1016/j.ejpain.2011.01.016

Miller-Spoto M., Gombotto, S.P. (2014) Diagnostic labels assigned to patients with orthopedic conditions and the influence of the label on selection of interventions: a qualitative study of orthopaedic clinical specialists. *Phys Ther, 94(6)*:776-91. http://doi:10.2522/ptj.20130244

Miranda, H., Punnett, L., Viikari-Juntura, E., Heliovaara, M., & Knekt, P. (2008). Physical work and chronic shoulder disorder. Results of a prospective population-based study. *Annals of the Rheumatic Diseases*, *67*(2), 218–223. http://doi.org/10.1136/ard.2007.069419

Mitchell, C., Adebajo, A., Hay, E.M., & Carr, A. (2005). Shoulder pain: diagnosis and management in primary care. *BMJ*, *331*(7525), 1124–1128. http://doi.org/10.1136/bmj.331.7525.1124

Mohamadi, A., Chan, J.J., Claessen, F.M., Ring, D., Chen, N.C. (2016). Corticosteroid Injections Give Small and Transient Pain Relief in Rotator Cuff Tendinosis: A Meta-analysis. Clin Orthop Relat Res, *475*(1), 232–243. http://doi: 10.1007/s11999-016-5002-1

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Medicine*, *6*(7), e1000097–e1000097. http://doi.org/10.1371/journal.pmed.1000097

Moloney, M.F., Aycock, D.M., Cotsonis, G.A., Myerburg, S., Farino, C., & Lentz, M. (2009). An Internet-Based Migraine Headache Diary: Issues in Internet-Based Research, *49*(5), 673–686. http://doi.org/10.1111/j.1526-4610.2009.01399.x

Mulligan, E.P., Brunette, M., Shirley, Z., Khazzam, M. (2015). Sleep quality and nocturnal pain in patients with shoulder disorders. J Shoulder Elbow Surg, *24*(9), 1452–1457. http://doi: 10.1016/j.jse.2015.02.013

Murphy RJ, Carr AJ. (2010) Shoulder pain. Systematic review 1107. *BMJ Clinical Evidence.* As accessed: http://www.clinicalevidence.com/x/systematic-review/1107/overview.html. on 26.09.14.

Nathan, H., Bridges, J.F.P., Schulick, R.D., Cameron, A.M., Hirose, K., Edil, B.H., Wolfgang, C.L., Segev, D.L., Choti, M.A., Pawlik, T.M. (2011). Understanding surgical decision making in early hepatocellular carcinoma. *Journal of Clinical Oncology*, *29*(6), 619–625. http://doi.org/10.1200/JCO.2010.30.8650

NICE. (2017). Osteoporosis: assessing the risk of fragility fracture (CG146) 1–14. National Institute for Health and Care Excellence (NICE). As accessed: https://www.nice.org.uk/guidance/cg146 on 27.03.15.

Nicholson, R.A., Hursey, K.G., & Nash, J.M. (2005). Moderators and mediators of behavioral treatment for headache. *Headache: the Journal of Head and Face Pain*, *45*(5), 513–519.

O'Connor, A. (1995). Validation of a Decisional Conflict Scale. *Medical Decision Making*, *15*, 25–30.

Ofcom. (2015) *Adults' media use and attitudes* (pp. 1–197). The Office of Communications (Ofcom). As accessed: https://www.ofcom.org.uk/__data/assets/pdf_file/0014/82112/2015_adults_media_use_and_attitudes_report.pdf on 03.07.15.

Ofcom. (2016). Adult's media use and attitudes, 1–203. The Office of Communications (Ofcom). As accessed: https://www.ofcom.org.uk/__data/assets/pdf_file/0026/80828/2016-adults-media-use-and-attitudes.pdf on 05.04.16.

Orme, B. (2002). Formulating Attributes and Levels in Conjoint Analysis. Sequin, WA.: Sawtooth Software, Inc. As accessed: https://www.sawtoothsoftware.com/download/techpap/formatt.pdf on 14.02.14

Orme, B.K. (2014). Getting Started With Conjoint Analysis. Strategies for Product Design and Pricing Research (3rd ed.). Glendale: Research Publishers LLC. ISBN: 9780972729741

Ostergren, P.O., Hanson, A.B.S., Balogh, I., Ektor-Andersen, J., Isacsson, S.O., Malmo Shoulder Neck Study Group. (2005). Incidence of shoulder and neck pain in a working population: effect modification between mechanical and psychosocial exposures at work? Results from a one year follow up of the Malmo shoulder and neck study cohort. *Journal of Epidemiology & Community Health*, *59*(9), 721–728. http://doi.org/10.1136/jech.2005.034801

OED (2016) Oxford English Dictionary Online. https://en.oxforddictionaries.com/definition/conjoint). As accessed on 03.08.16

Page, M.J., Green, S., Kramer, S., Johnston, R.V., McBain, B., Chau, M., & Buchbinder, R. (2014). Manual therapy and exercise for adhesive capsulitis (frozen shoulder). *Cochrane Database of Systematic Reviews*, (8), 225. http://doi.org/10.1002/14651858.CD011275

Pajareya, K., Chadchavalpanichaya, N., Painmanakit, S., Kaidwan, C., Puttaruksa,

P., & Wongsaranuchit, Y. (2004). Effectiveness of physical therapy for patients with adhesive capsulitis: a randomized controlled trial. *Chotmaihet Thangphaet [Journal of the Medical Association of Thailand],87(5):473-480*.

Patel, S., Hossain, F.S., Colaco, H.B., El-Husseiny, M., Lee, M.H. (2010). The accuracy of primary care teams in diagnosing disorders of the shoulder, *J Eval Clin Pract*. *17*(1), 118–122. http://doi.org/10.1093/rheumatology/kep008

Peduzzi, P., Concato, J., Kemper, E., Holford, T. R., & Feinstein, A. R. (1996). A simulation study of the number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology*, *49*(12), 1373–1379.

Pelaccia, T., Tardif, J., Triby, E., & Charlin, B. (2011). An analysis of clinical reasoning through a recent and comprehensive approach: the dual-process theory. *Medical Education Online*, *16*(0), 223. http://doi.org/10.1056/NEJMra054782

Perry, J., & Linsley, S. (2006). The use of the nominal group technique as an evaluative tool in the teaching and summative assessment of the inter-personal skills of student mental health nurses. *Nurse Education Today*, *26*(4), 346–353. http://doi.org/10.1016/j.nedt.2005.11.004

Peters, D., Davies, P., & Pietroni, P. (1994). Musculoskeletal clinic in general practice: study of one year's referrals. *British Journal of General Practice*, *44*(378), 25–29.

Petri, M., Dobrow, R., Neiman, R., Whiting-O'Keefe, Q., & Seaman, W.E. (1987). Randomized, double- blind, placebo- controlled study of the treatment of the painful shoulder. *Arthritis Care & Research*, *30*(9), 1040–1045.

Pincus, T., Miles, C., Froud, R., Underwood, M., Carnes, D., & Taylor, S.J. (2011). Methodological criteria for the assessment of moderators in systematic reviews of randomised controlled trials: a consensus study. *BMC Medical Research Methodology*, *11*(1), 14. http://doi.org/10.1186/1471-2288-11-14

Pope, D.P., Croft, P.R., Pritchard, C.M., & Silman, A.J. (1997). Prevalence of shoulder pain in the community: the influence of case definition. *Annals of the Rheumatic Diseases*, *56*(5), 308–312.

Priestman, T.J., & Baum, M. (1976). Evaluation of quality of life in patients receiving treatment for advanced breast cancer. *Lancet*, *1*(7965), 899–900.

Rahman, S., Majumder, A., Shaban, S., Rahman, N., Ahmed, S.M., Abdulrahman, K., & Dsouza. (2011). Physician participation in clinical research and trials: issues and approaches. *Advances in Medical Education and Practice*, 85. http://doi.org/10.2147/AMEP.S14103

Rakotonarivo, O.S., Schaafsma, M., & Hockley, N. (2016). A systematic review of the reliability and validity of discrete choice experiments in valuing non-market environmental goods. *Journal of Environmental Management*, *183*(1), 98–109. http://doi.org/10.1016/j.jenvman.2016.08.032

Ramo, D.E., & Prochaska, J.J. (2012). Broad Reach and Targeted Recruitment Using Facebook for an Online Survey of Young Adult Substance Use. *J Med Internet Res, 14*(1), e28. http://doi.org/10.2196/jmir.1878

Rankin, G., Rushton, A., Olver, P., & Moore, A. (2012). Chartered Society of Physiotherapy's identification of national research priorities for physiotherapy using a modified Delphi technique. *Physiotherapy*, *98*(3), 260–272. http://doi.org/10.1016/j.physio.2012.03.002

Raynor, M.B., Kuhn, J.E. (2015). Utility of features of the patient's history in the diagnosis of atraumatic shoulder pain: a systematic review. *J Shoulder Elbow Surg, 25(4)*; 1–7. http://doi: 10.1016/j.jse.2015.09.023

Reilly, B.M., & Evans, A.T. (2006). Translating clinical research into clinical practice: impact of using prediction rules to make decisions. *Annals of Internal Medicine*, *144*(3), 201–209.

Riley, R.D., Hayden, J.A., Steyerberg, E.W., Moons, K.G.M., Abrams, K., Kyzas, P.A., Malats, N., Briggs, A., Schroter, S., Altamna, D.G., Hemingway, H. (2013). Prognosis Research Strategy (PROGRESS) 2: Prognostic Factor Research. *PLoS Medicine*, *10*(2), e1001380. http://doi.org/10.1371/journal.pmed.1001380.s002

Riley, R.D., Lambert, P.C., & Abo-Zaid, G. (2010). Meta-analysis of individual participant data: rationale, conduct, and reporting. *BMJ (Clinical Research Ed.)*, *340*(1), c221–c221. http://doi.org/10.1136/bmj.c221

Rothwell, P.M. (2005). Subgroup analysis in randomised controlled trials: importance, indications, and interpretation. *The Lancet*, *365*(9454), 176–186.

Ryan, G.S. (2013). Online social networks for patient involvement and recruitment in clinical research. *Nurse Res, 21*(1), 35–39. http://doi.org/10.7748/nr2013.09.21.1.35.e302

Ryan, M., & Farrar, S. (2000). Using conjoint analysis to elicit preferences for health care. *British Medical Journal*, *320*(7248), 1530–1533.

Ryan, M., & Gerard, K. (2003). Using discrete choice experiments to value health care programmes: current practice and future research reflections. *Applied Health Economics and Health Policy*, *2*(1), 55–64.

Ryan, M., Gerard, K., & Amaya-Amaya, M. (2008). Using Discrete Choice Experiments to Value Health and Health Care. (M. Ryan, K. Gerard, & M. Amaya-Amaya, Eds.) (1st ed.). Dordrecht: Springer Netherlands. http://doi.org/10.1007/978-1-4020-5753-3

Ryans, I., Montgomery, A., Galway, R., Kernohan, W. G., & McKane, R. (2005). A randomized controlled trial of intra-articular triamcinolone and/or physiotherapy in shoulder capsulitis. Rheumatology (Oxford), 44(4), 529-35.

Ryösä, A., Laimi, K., Äärimaa, V., Lehtimäki, K., Kukkonen, J., & Saltychev, M. (2016). Surgery or conservative treatment for rotator cuff tear: a meta-analysis. *Disability & Rehabilitation*, *39*(14), 1357–1363. http://doi.org/10.1136/bmj.39465.451748.AD

Sackett, D.L., Richardson, W.S., Rosenberg, W., & Haynes, R.B. (1997). Evidence-Based Medicine—How to Practice and Teach EBM (2nd ed.). New York: Churchill Livingstone.

Saulle, M., & Gellhorn, A.C. (2017). Approach to the diagnosis of shoulder pain using physical exam and ultrasound: an evidence-based approach. *Curr Phys Med Rehabil Rep,* 1–11. http://doi.org/10.1007/s40141-017-0149-6

Schneider, G.M., Jull, G., Thomas, K., & Salo, P. (2012). Screening of patients suitable for diagnostic cervical facet joint blocks: A role for physiotherapists. *Manual Therapy*, *17*(2), 180–183. http://doi.org/10.1016/j.math.2011.11.004

Shackman, G. (2001). Sample size and design effect (pp. 1–7). Presented at the Albany Chapter of American Statistical Association. As accessed from: http://faculty.smu.edu/slstokes/stat6380/deff%20doc.pdf on 01.02.15

Shih, T.H., & Fan, X. (2009). Comparing response rates in e-mail and paper surveys: A meta-analysis. *Educational Research Review*, *4*(1), 26–40. http://doi.org/10.1016/j.edurev.2008.01.003

Sim, J., & Wright, C. (2000). Research in Health Care. Concepts, Methods and Designs. Cheltenham: Nelson Thornes.

Sleight, P. (2000). Debate: Subgroup analyses in clinical trials: fun to look at-but don't believe them! *Current Controlled Trials in Cardiovascular Medicine*, *1*, 25–27.

Smidt, N., & Green, S. (2003). Is the diagnosis important for the treatment of patients with shoulder complaints? *The Lancet*, *362(9399)*, 1867–1868. http://doi.org/10.1016/S0140-6736(03)14997-5

Smith, B.E., Hendtrick, P., Smith, T.O., Bateman, M., Moffattm F., Rathleff, M.S., Selfe, J., Logan, P. (2017). Should exercises be painful in the management of chronic musculoskeletal pain? A systematic review and meta-analysis. *Br J Sports Med, Published Online First: 08 June 2017.* doi: 10.1136/bjsports-2016-097383

Song, A., Higgins, L.D., Newman, J., & Jain, N.B. (2014). Glenohumeral corticosteroid injections in adhesive capsulitis: a systematic search and review. *The Journal of Injury, Function, and Rehabilitation*, *6*(12), 1143–56.

Steyerberg, E.W., Moons, K.G.M., van der Windt, D.A., Hayden, J.A., Perel, P., Schroter, S., Riley, R.D., Hemingway, H., Altman, D.G. (2013). Prognosis Research Strategy (PROGRESS) 3: Prognostic Model Research. *PLoS Medicine*, *10*(2), e1001381. http://doi.org/10.1371/journal.pmed.1001381.s002

Sun, X., Briel, M., Busse, J.W., You, J.J., Akl, E.A., Mejza, F., Bala, M.M., Bassler, D., Mertz, D., Diaz-Granados, N., Vandvik, P.O., Malage, G., Srinathan, S.K., Dahm, P., Johnston, B.C., Alonso-Coello, P., Hassouneh, B., Truoung, J., Dattani, N.D., Heels-Ansdell, D., Bhatnagar, N., Altman, D.G., Guyatt, G.H. (2011). The influence of study characteristics on reporting of subgroup analyses in randomised controlled trials: systematic review. *BMJ, 342*, d1569.

Sun, X., Briel, M., Busse, J. W., You, J. J., Akl, E. A., Mejza, F., Bala, M.M., Bassler, D., Mertz, D., Diaz-Granados, Vandvik, P.O., Srinathan, S.K., Dahm, P., Johnston, B.C., Alonso-Coello, P., Hassouneh, B., Walter, S.D., Heels-Ansdell, D., Bhatnagar, N., Altman, D.G., Guyatt, G.H. (2012). Credibility of claims of subgroup effects in randomised controlled trials: systematic review. *BMJ (Clinical Research Ed.)*, *344*(mar15 1), e1553–e1553. http://doi.org/10.1136/bmj.e1553

Sun, X., Briel, M., Walter, S.D., & Guyatt, G.H. (2010). Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. *Bmj*, *340*(mar30 3), c117–c117. http://doi.org/10.1136/bmj.c117

Sundstrup, E., Jakobsen, M.D., Brandr, M. Aagaard, P., Andersen, L.L. (2016). Associations between biopsychosocial factors and chronic upper limb pain among slaughterhouse workers: cross sectional study. BMC Musculoskelet Disord. 17:104. http: doi: 10.1186/s12891-016-0953-7.

Surowiecki, J. (2004). The Wisdom of Crowds. Why the Many Are Smarter Than the Few. London: Abacus.

Tanner, C.A., Padrick, K.P., Westfall, U.E., & Putzier, D.J. (1987). Diagnostic reasoning strategies of nurses and nursing students. *Nurs Res, 36(6);* 358–363.

Temple, E., & Brown, R.F. (2011). A Comparison of Internet-Based Participant Recruitment Methods: Engaging the Hidden Population of Cannabis Users in Research, *7*(2), D2.

Thackeray, R., Neiger, B.L., Smith, A.K., & Van Wagenen, S.B. (2012). Adoption and use of social media among public health departments, *12*(1), 242. http://doi.org/10.1186/1471-2458-12-242

Thomas, E., Croft, P.R., Paterson, S.M., Dziedzic, K., & Hay, E.M. (2004). What influences participants' treatment preference and can it influence outcome? Results from a primary care-based randomised trial for shoulder pain [with consumer summary]. *British Journal of General Practice,54(499):93-96*.

Thompson, C., & Dowding, D. (2002). Clinical Decision Making and Judgement in Nursing. (D. Dowding, Ed.) (1st ed.). Edinburgh: Churchill Livingstone.

Thompson, C., Cullum, N. McCaughan, D., Sheldon, T., Raynor, P. (2004). Nurses, information use, and clinical decision making—the real world potential

for evidence-based decisions in nursing, *Evidence-Based Nursing* 2004;**7:**68-72.

Thurstone, L.L. (1994). A law of comparative judgment. *Psychological Review*.

Timmermans, D., Gooszen, A. W., & Geelkerken, R. H. (1997). Analysis of the variety in surgeons' decision strategies for the management of left colonic emergencies. *Medical Care*. *35(7)*:701-13.

Topolovec-Vranic, J., & Natarajan, K. (2016). The Use of Social Media in Recruitment for Medical Research Studies: A Scoping Review. *J Med Internet Res, 18(11)*, e286. http://doi.org/10.2196/jmir.5698

Turner, J.A., Holtzman, S., & Mancl, L. (2007). Mediators, moderators, and predictors of therapeutic change in cognitive–behavioral therapy for chronic pain. *Pain*, *127*(3), 276–286. http://doi.org/10.1016/j.pain.2006.09.005

Underwood, M.R., Morton, V., Farrin A, on behalf of the UK BEAM trial team. (2007). Do baseline characteristics predict response to treatment for low back pain? Secondary analysis of the UK BEAM dataset [ISRCTN32683578]. *Rheumatology*, *46*(8), 1297–1302. http://doi.org/10.1093/rheumatology/kem113

Urwin, M., Symmons, D., Allison, T., Brammah, T., Busby, H., Roxby, M., Simmons, A., Williams, G. (1998). Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. *Annals of the Rheumatic Diseases*, *57*(11), 649–655.

van der Heijden, G.J.M.G., van der Windt, D.A.W.M., & De Winter A.F. (1997). Physiotherapy for patients with soft tissue shoulder disorders: A systematic review of randomised clinical trials. *BMJ, 5*;315(7099):25-30.

van der Windt, D.A., Koes, B.W., Boeke, A.J., Deville, W., De Jong, B.A., & Bouter, L.M. (1996). Shoulder disorders in general practice: prognostic indicators of outcome. *British Journal of General Practice*, *46*(410), 519–523.

van der Windt, D.A., Koes, B.W., Deville, W., Boeke, A.J.P., De Jong, B.A., & Bouter, L.M. (1998). Effectiveness of corticosteroid injections versus physiotherapy for treatment of painful stiff shoulder in primary care: randomised trial [with consumer summary]. *BMJ 1998 Nov 7;317(7168):1292-1296*.

van der Windt, D.A., Koes, B.W., van Aarst, M., Heemskerk, M.A., & Bouter, L.M. (2000). Practical aspects of conducting a pragmatic randomised trial in primary care: patient recruitment and outcome assessment. *Br J Gen Pract, 50(454)*:371-4.

van der Windt, D.A., Kuijpers, T., Jellema, P., van der Heijden, G.J., Bouter, L.M. (2007). Do psychological factors predict outcome in both low-back pain and

shoulder pain? *Ann Rheum Dis. 66(3)*, 313–319. http://doi.org/10.1136/ard.2006.053553

Van Geest, J.B., Johnson, T.P., & Welch, V.L. (2007). Methodologies for Improving Response Rates in Surveys of Physicians: A Systematic Review. *Eval Health Prof, 30(4)*, 303–321. http://doi.org/10.1177/0163278707307899

Van Horn, P.S., Green, K.E., & Martinussen, M. (2009). Survey Response Rates and Survey Administration in Counseling and Clinical Psychology: A Meta-Analysis. *Educational and Pschological Measurement, 69(3)*, 389–403. http://doi.org/10.1177/0013164408324462

van Kampen, D.A., van den Berg, T., van der Woude, H.J., Castelein, R.M., Scholtes, V.A., Terwee, C.B. Willems, W.J. (2014). The diagnostic value of the combination of patient characteristics, history, and clinical shoulder tests for the diagnosis of rotator cuff tear. *J Orthop Surg Res, 7(9);*70 doi: 10.1186/s13018-014-0070-y

Veldwijk, J., Determann, D., Lambooij, M.S., van Til, J.A., Korfage, I.J., de Bekker-Grob, E.W., & de Wit, G.A. (2016). Exploring how individuals complete the choice tasks in a discrete choice experiment: an interview study. *BMC Medical Research Methodology*, 1–11. http://doi.org/10.1186/s12874-016-0140-4

Veletsianos, G. (2011). Higher education scholars' participation and practices on Twitter. *Journal of Computer-Assisted Learning, 28(4),* 336–349. http://doi.org/10.1111/j.1365-2729.2011.00449.x

Veloski, J. (2005). Clinical Vignette-Based Surveys: A Tool for Assessing Physician Practice Variation. *American Journal of Medical Quality*, *20*(3), 151–157. http://doi.org/10.1177/1062860605274520

Ventola, C.L. (2014). Social media and health care professionals: benefits, risks, and best practices. *Pharmacy & Therapeutics, 39(7)*, 491–520.

Vergouw, D., Heymans, M.W., de Vet, H.C., van der Windt, D.A., & van der Horst, H.E. (2011). Prediction of persistent shoulder pain in general practice: Comparing clinical consensus from a Delphi procedure with a statistical scoring system. *BMC Family Practice*, *12*(1), 63. http://doi.org/10.1186/1471-2296-12-63.

Vergouw, D., Heymans, M.W., Peat, G.M., Kuijpers, T., Croft, P.R., de Vet, H.C., van der Horst, H.E., van der Windt, D.A. (2010). The search for stable prognostic models in multiple imputed data sets. *BMC Medical Research Methodology*, *10*(1), 81. http://doi.org/10.1186/1471-2288-10-81

Virta, L., Joranger, P., Brox, J.I., & Eriksson, R. (2012). Costs of shoulder pain and resource use in primary health care: a cost-of-illness study in Sweden. *BMC Musculoskeletal Disorders*, *13*(1), 17. http://doi.org/10.1186/1471-2474-13-17

Westman, A., Linton, S.J., Öhrvik, J., Wahlén, P., & Leppert, J. (2012). Do psychosocial factors predict disability and health at a 3-year follow-up for

patients with non-acute musculoskeletal pain? A validation of the Örebro Musculoskeletal Pain Screening Questionnaire. *European Journal of Pain*, *12*(5), 641–649. http://doi.org/10.1016/j.ejpain.2007.10.007

Winters, J.C., Jorritsma, W., Groenier, K.H., Sobel, J.S., Meyboom-de Jong, B., & Arendzen, H.J. (1999a). Treatment of shoulder complaints in general practice: long term results of a randomised, single blind study comparing physiotherapy, manipulation, and corticosteroid injection. *BMJ 1999 May 22;318(7195):1395-1396*.

Winters, J. C., Sobel, J. S., Groenier, K. H., Arendzen, J. H., & Meyboom-de Jong, B. (1999b). The long-term course of shoulder complaints: a prospective study in general practice. *Rheumatology (Oxford, England)*, *38*(2), 160–163.

Witt, J., Scott, A., & Osborne, R.H. (2009). Designing choice experiments with many attributes. An application to setting priorities for orthopaedic waiting lists. *Health Economics*, *18*(6), 681–696. http://doi.org/10.1002/hec.1396

Woodfield, K., Morriell, G., Metzler, K., Blank, G., Salmons, J., Finnegan, J., & Lucraft, M. (2013). *New social media, new social research: Developing a network to explore the issues faced by researchers negotiating the new research landscape of online social media platforms* (pp. 1–26). National Centre for Research Methods (NCRM) Networks for Methodological Innovation.

Wylie, J.D., Suter, T., Potter, M.Q., Granger, E.K., Tashjian, R.Z. (2016). Mental Health Has a Stronger Association with Patient-Reported Shoulder Pain and Function Than Tear Size in Patients with Full-Thickness Rotator Cuff Tears. *J Bone Joint Surg Am, 98(4)*, 251–256. http://doi.org/10.2106/JBJS.O.00444

Yang, J.L., Jan, M.H., Chang, C.W., & Lin, J.J. (2012a). Effectiveness of the end-range mobilization and scapular mobilization approach in a subgroup of subjects with frozen shoulder syndrome: a randomized control trial. *Manual Therapy, 17(1): 47-52*. http://doi.org/10.1016/j.math.2011.08.006

Yang, J.L., Chen, S.Y., Hsieh, C.L., & Lin, J.J. (2012b). Effects and predictors of shoulder muscle massage for patients with posterior shoulder tightness. *BMC Musculoskeletal Disorders*, *13*, 46. http://doi.org/10.1186/1471-2474-13-46

Zheng, X., Simpson, J.A., van der Windt, D.A.W.M., & Elliott, A.M. (2005). Data from a study of effectiveness suggested potential prognostic factors related to the patterns of shoulder pain. *Journal of Clinical Epidemiology*, *58*(8), 823–830. http://doi.org/10.1016/j.jclinepi.2005.01.011

APPENDICES

Appendix 1: Data Extraction, Risk of Bias & Methodological Appraisal Form

Systematic review data extraction form

Data Extraction	
Author:	**Year:**
Journal:	
Setting	
Country	
No. of Participants:	**Participants completed:**
Selection Criteria	
Intention to Treat Analysis performed:	Yes No Unclear
Interventions Studied	
Control Group	
Duration of Treatment	
Frequency of Treatment	
Follow-up Periods	

Outcome

Measures

Cochrane Risk of Bias Tool			
Bias Domain	**Source of Bias**	**Judgement** Yes = low risk of bias, No = high risk of bias, Unclear = insufficient information to assess	**Description**
Selection Bias	**Adequate sequence generation ?**		
	Allocation concealment?		
Performance Bias	**Blinding (Patient-reported outcomes) ?**		
Attrition Bias	**Incomplete outcome data addressed? (Short-term outcomes (2-6 wks))**		
	Incomplete outcome data addressed? (Longer-term outcomes		

	(>6 wks))
Reporting Bias	**Free of selective reporting?**
Other Bias	**Free of other bias?**

Methodological criteria for the assessment of Moderators

Pincus et al (2011)

Rationale

(1) A priori hypothesis	Yes=1 No=0	**(2) Theory driven and/or evidence driven Yes=1, No=0**

Method

Moderation analysis:	Equal distribution of moderators at baseline	Yes No
	(3) Moderators measured prior to randomisation	**Yes=1** **No=0**

Power

Power analysis of moderator effect reported:	Yes	A priori	(Optimal)
		Post-hoc	Using a priori effect size (Correct)
			Observed effect (Incorrect)
	No		
Adequate sample size for moderation	Yes (at least 4 times the required sample size for main treatment effect in the lowest sub-group for the moderator factor)		

analysis

	If no, were there at least 20 people in the smallest sub-group of the moderator?	Yes No	Have authors employed analysis to compensate for insufficient power (i. e. boot-strapping techniques?)	Yes No

Correction for multiple comparisons

Was the regression significant at P < 0.05?	Yes No	Or, (if more than three comparisons) corrected or significance adjusted to P < 0.01?	Yes No
Did the authors explore residual variances of interactions if carrying out multiple two-way interactions?	Yes No		

Measurement validity & measurement error

(4i) Was measurement of baseline and process factors reliable and valid (from published information) in target population?	Yes=1 No=0
(4)ii Is there evidence that the measurement error of the instrument is	Yes=1

likely to be sufficiently small to detect the differences between sub-groups that are likely to be important?	No=0
Did the authors comment on measurement validity in reference to construct validity, face validity etc?	Yes No

Analysis

(5) Contains an explicit test of the interaction between moderator and treatment (e.g. regression)?	Yes=1 No=0
Was there adjustment for other baseline factors?	Yes No
Is there an explicit presentation of the differences in outcome between baseline sub-groups (e.g. standardised mean difference between groups, Cohen's d)?	Yes No

Results

Clinical plausibility of results

Are differences between subgroups clinically plausible?	Yes
	No
Were results of sub-group analysis reported even when magnitude of the difference was too small to support differing recommendations for different groups?	Yes
	No

TOTAL SCORE FOR PINCUS TOOL (max 5): __ / 5

Confirmatory Evidence (All 5 items): Yes/No

Exploratory Evidence (Final 3 items): Yes/No

Appendix 2: Guidance notes for reviewers for completion of data extraction, risk of bias assessment and methodological appraisal of included articles

Shoulder Moderation Systematic Review Guidance Notes

In order to ensure uniform and complete information and data extraction for the purposes of risk of bias and methodological appraisal, please follow the below notes for guidance on how to complete the form.

Criteria	Guidance Notes
	Data Extraction
Author	Surname of first author
Year	Year of publication
Journal	Title of journal
Setting	E.g., Primary Care, Secondary Care, Tertiary etc.
Country	Country
No. of Participants	No. of participants recruited
Participants completed:	No. of participants completed
Selection criteria	Define selection/inclusion criteria
Intention to Treat Analysis performed	Yes/No/Unclear. Copy and paste any further info here
Interventions studied	List interventions studied including who delivered it, duration of intervention
Control Group	Describe what happened to control group (e.g., waiting list, placebo/sham, routine intervention)
Duration of Treatment	No. of consecutive weeks treatment was delivered over
Frequency of Treatment	Weekly, monthly etc.
Follow-up Periods	When were the data collection time-points (list in weeks)
Outcome Measures	List all outcome measures, indicate which outcome measures were tested with relation to

moderation analysis

Cochrane Risk of Bias Tool		
		Review Authors Judgement – Assess as low, unclear or high risk of bias) *Assessments should be made for each main outcome or class of outcomes.
Domain	**Description Required**	Answer the **bolded question** "yes, unclear, or no", where Yes = low risk of bias, No = high risk of bias, Unclear = insufficient information to assess whether an important risk of bias exists; or insufficient rationale or evidence that an identified problem will introduce bias
Adequate sequence generation?	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	**Was the allocation sequence adequately generated?** Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
Adequate concealment?	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during	**Was allocation adequately concealed?** Selection bias (biased allocation to interventions) due to inadequate concealment of

	enrolment	allocations before assignment
Blinding (Patient-reported outcomes)?	Describe all measures used, if any, to blind outcome assessment from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	**Was knowledge of the allocated intervention adequately prevented during the study?** Detection bias due to knowledge of the allocated interventions by outcome assessment
Incomplete outcome data addressed? (Short-term outcomes (<2 weeks), Medium term (2-24 weeks) Long term (>24 weeks)	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any reinclusions in analyses for the review	**Were incomplete outcome data adequately addressed?** Attrition bias due to amount, nature, or handling of incomplete outcome data
Free of selective reporting?	State how selective outcome reporting was examined and what was found	**Are reports of the study free of suggestion of selective outcome reporting?** Reporting bias due to selective outcome reporting
Free of otbias?	State any important concerns about bias not covered in the other domains in the tool	**Was the study apparently free of other problems that could put it at a high risk of bias?** Bias due to problems

not covered elsewhere

Pincus Tool		
Criteria	**Judge yes or no** **Criteria for a judgement of *'yes'***	**Scoring** **(NS = not scored)** **Yes = 1** **No = 0**
(1) A priori hypothesis	Mention of explicit hypothesis planned in protocol stating which sub-groups will be tested for which outcome	Yes = 1 No = 0
(2) Clinical and/or theory-based hypothesis	A clinical and/or theoretical hypothesis provided	Yes = 1 No = 0
Method	Describe analysis content and analysis method in as full detail as paper allows	NS
Equal distribution of moderators at baseline	Ideally, a-priori stratification in design	NS
(3) Moderators measured prior to randomisation	Report what/wasn't was measured prior to randomisation	Yes = 1 No = 0
Power analysis of moderator effect	Sufficient power to detect small/moderate effects in moderator analysis has been defined as at least four times that of the main effect	NS
Adequate sample size for moderation analysis	Yes = At least 4 fold the required sample size for main treatment effect in the lowest sub-group	NS

	for the moderator factor If no, were there at least 20 people in the smallest sub-group of the moderator?	
Have authors employed analysis to compensate for insufficient power?	i.e., any boot-strapping techniques	NS
Was the regression significant at P < 0.05?	P < 0.05 or (if more than three comparisons) corrected or significance adjusted to P < 0.01)	NS
Did the authors explore residual variances of interactions if carrying out multiple two-way interactions?	Residual variances explored to assess statistical reliability prior to making a statement about relative importance of factors.	NS
(4i) Was measurement of baseline and process factors reliable and valid (from published information) in target population?	Supporting references provided or reliability and validity well established in the field	Yes for one or both = 1 No = 0
(4ii) Is there evidence that the measurement error of the instrument is likely to be sufficiently small to detect the differences between sub- groups that are likely to be important?	Estimates of reliability of measures should be reported	
Did the authors comment on measurement validity in reference to construct validity, face validity?	Construct validity and face validity etc	NS
Contains an explicit test of the interaction between moderator and treatment?	e.g. regression or path analysis using regression, structural equation modelling etc	Yes = 1 No = 0

Was there adjustment for other baseline factors?	Report any adjustments made or expected	NS
(5) Is there an explicit presentation of the differences in outcome between baseline sub-groups?	**e.g. standardised mean difference between groups, Cohen's d**	
Are differences between subgroups clinically plausible?	Selection of characteristics should be motivated by biological and clinical hypotheses, ideally supported by evidence from sources other than the included studies	NS
Were results of sub-group analysis reported even when magnitude of the difference was too small to support differing recommendations for different groups?	i.e., where the magnitude of a difference between subgroups will not result in different recommendations for different subgroups	NS
TOTAL SCORE FOR PINCUS TOOL (max 5):		X / 5
Confirmatory Evidence (All five items):		Yes/No
Exploratory Evidence (Final three items):		Yes/No

Appendix 3: Ethical approval documents for consensus workshops

ETHICAL REVIEW PANEL

Application Form (Staff and PGR Students)

- To be completed for every research project involving human participants/subjects;
- The form must be authorised by your Research Institute Director / (or for applicants who are members of RI Social Sciences the application can be signed off by your Research Centre Head)/Supervisor /Head of School as appropriate
- Both an electronic copy & hard copy of all documentation must be provided.

APPROVAL MUST BE OBTAINED <u>BEFORE</u> potential participants are approached to take part in any research.

Information regarding the completion of the ethical review panel application form:

Section A – To be completed by all applicants.

Section B – To be completed by applicants who have already obtained Ethics Approval from a separate committee.

Section C – To be completed by applicants requiring approval from a University Ethical Review Panel

Section D – To be completed by all applicants.

Further information regarding the completion of the application can be found in Section E (at the end of this document)

SECTION A (to be completed by all applicants)

Project Title:	Musculoskeletal Shoulder Disorders: Which Treatment for Whom?
Proposed start date:	1st February 2015
Proposed end date for 'field work' (eg interviews):	31th October 2015
Name of Researcher (applicant):	Cliona McRobert
Status:	**POSTGRADUATE RESEARCH STUDENT**

Research Institute or School if not in an Research Institute	Primary Care Sciences
Keele Email address:	c.j.mcrobert@keele.ac.uk
Correspondence address:	Arthritis Research UK Primary Care Centre Primary Care Sciences Keele University Staffordshire, ST5 5BG
Keele Telephone number:	01782 734889

SECTION B **(to be completed by applicants who have already obtained ethics approval from a separate committee)**

Has your project already been approved by an ethics committee? (for example, an NHS research ethics committee) If **YES** the following documentation should be sent directly to the Chair of the University Research Ethics Committee, C/O Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306		NO
A completed and signed hard copy of this application form (please complete Sections A, B and D) and an electronic copy should also be e-mailed to n.leighton@keele.ac.uk	Signed hard copy: Electronic copy:	N/A N/A
Evidence of prior ethics approval from the hosting institution.	Copy of approval document:	N/A

SECTION C **(to be completed by applicants who have NOT already obtained ethics approval from a separate committee)**

<table>
<tr><td colspan="3">If your project requires approval by a University Ethical Review Panel (ERP).

The following documentation should be forwarded to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, telephone 01782 733306. An electronic copy of the application form and all necessary documentation should also be e-mailed to uso.erps@keele.ac.uk An application cannot be considered until a signed copy is received and accompanied by an electronic copy.</td></tr>
<tr><td>A completed and signed hard copy of this application form (please complete Sections A, C and D) and an electronic copy should also be e-mailed to uso.erps@keele.ac.uk</td><td>Signed copy attached:

Electronic copy:</td><td>YES

YES</td></tr>
<tr><td colspan="2">A hard copy of the summary document attached to this form, NO MORE THAN two sides of A4

It may help the review of your project if you include a diagram to clearly explain the project (eg what activities will undertaken, by whom and when)

An electronic copy of the summary document

Please ensure that the version number and date is clearly stated in footer of the summary document (approval may be delayed if these details are not included)</td><td>YES

YES</td></tr>
<tr><td colspan="3">And, if (and only if) they are appropriate given the study’s design and approaches;</td></tr>
<tr><td colspan="2">A letter of invitation for participants

Please ensure that the version number and date is clearly stated in the footer of the letter (approval may be delayed if these details are not included)</td><td>YES

(including combined participant information sheet)</td></tr>
<tr><td colspan="2">An information sheet which should normally include the following sections:

o Why the participant has been chosen;
o What will happen to participants if they take part
o A discussion of the possible disadvantages, risks and benefits of taking part
o The procedures for ensuring confidentially and anonymity (if appropriate)
o The proposed use of the research findings
o Contact details of the principal investigator plus details of additional support agencies (if Necessary)</td><td>YES

(Combined with invitation letter)</td></tr>
</table>

○ **Version number and date is clearly stated in the footer of the information sheet (approval may be delayed if these details are not included)** A template for a participant information sheet is available from the Research & Enterprise Services website via the following link http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/	
A copy of the participant consent form/s; **Please ensure that the version number and date is clearly stated in the footer of the consent form (approval may be delayed if these details are not included)** Templates for consent forms are available from the Research & Enterprise Services website via the following link http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/ Health professionals will decide if they wish to participate after reading the combined invitation letter and participant information sheet. Consent to participate is implied by clicking next on the first page of the online survey and proceeding to provide responses to the questions. PLEASE NOTE: there is only one online survey to be completed for this study.	NO
Copies of any questionnaire, interview schedules or topic guides. **Please ensure that the version number and date is clearly stated in the footer of these documents (approval may be delayed if these details are not included)**	YES

(PARTICIPANTS' CONSENTS)

1. Will the researchers inform participants of all aspects of the research that might reasonably be expected to influence willingness to participate and in particular, any negative consequences that might occur?	YES
If YES, please give details: Participants will be provided with a combined letter of invitation and participant information sheet detailing why they have been chosen to participate, the purpose of the study, anticipated length of time taken to complete the survey, what is expected of them, the possible disadvantages of taking part and their right to withdraw from the survey at any point. Other than the use of their time, no negative consequences or harm to respondents associated with taking part are anticipated. The survey does not have an actual 'escape survey' button but respondents may choose to close the internet browser window at any point in order to escape the survey. In the event of a respondent not providing responses to the 12 patient cases, this will be understood as having dropped out from the study. As the planned statistical analysis relies upon complete data i.e., responses to all 12 patient cases, only data from respondents who have provided responses to all 12 patient cases will be analysed. The number of participants starting the survey but dropping out at any point will be recorded. **If NO**, please explain:	
2. Will all participants be provided with a written information sheet and be provided with an opportunity to provide (or withhold) written consent?	
If YES, please ensure that these documents are attached (see above). This study is an online survey. The combined participant invitation and information sheet will be available via a hyperlink on the first page of the online survey. Page 1 of the survey states that by clicking the 'next' button that they are indicating that they have read the combined participant invite and information sheet and that they imply their consent to take part in the survey. **If NO**, please explain why written consent &/or information is not appropriate for this study.	YES

3. Is consent being sought for the dataset collected to be used for future research projects? Results from this survey will inform the design of a future individual patient data analysis study which seeks to assess the validity of the result of this survey. The actual data from this survey will not be used in this future study. **4. What are the exclusion/inclusion criteria for this study (i.e. who will be allowed to / not allowed to participate)?** **Inclusion:** Health or medical practitioners, clinical academics or academics (including but not limited to physiotherapists, general practitioners (GPs), rheumatologists and orthopaedic surgeons) who: (i) Clinically manage or have a clinical or research interest in patients with musculoskeletal shoulder disorders as part of their normal clinical practice (ii) Practice in a country where healthcare services are government, state or national insurance funded (iii) Can read and write English **Exclusion:** Individuals who: (i) Are not practicing health or medical practitioners, clinical academics or academics (ii) Practice in a country where healthcare is predominantly privately funded (iii) Have no clinical or academic interest in musculoskeletal shoulder disorders (iv) Do not read or write English **5. Please explain briefly (and in 'lay' terms) why you plan to use these particular criteria?** *The purpose of the survey is to assess how clinicians from across the world make treatment decisions in the care for patients with shoulder pain in the context of publicly funded healthcare systems such as the NHS in the U.K. In privately-funded and capitalist ideated healthcare systems patient preference/choice exerts a greater influence on treatment decision-making processes. Therefore we aim to include respondents who practice in a healthcare setting similar to the U.K. i.e., publicly funded where the patient is a partner in the decision, not a consumer of healthcare.*	NO
6. Will people who are vulnerable be allowed to take part in this study? For these purposes, vulnerable participants are those whose abilities to protect their own interests are impaired or reduced in comparison to the population as a whole. Vulnerability may arise from personal characteristics (such as mental or physical impairment) or from social context and disadvantage (e.g. lack of power, education, or resources). Prospective participants, who are at high risk of consenting under duress, or as a result of manipulation or coercion, should also be considered as vulnerable. All children and	NO

adults who lack mental capacity are presumed to be vulnerable. **If NO**, please outline the rationale for excluding them: *Participants will be health professionals and/or academics with a special interest in shoulder disorders.* **If YES**, what special arrangements (if any) are in place to protect vulnerable participants' interests?	
7. Does the research activity proposed require a Disclosure & Barring Scheme (DBS) disclosure? (information concerning activities which require DBS checks are required can be accessed via https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance and http://www.keele.ac.uk/hr/policiesandprocedures/crbsafeguarding/ If you are unsure whether a DBS disclosure is required please contact Human Resources or Nicola Leighton prior to submission of this application form. If you answer YES please complete the relevant section below. If you answer no please go to question 8.	NO
STAFF ONLY **7a** Have you (and other individuals who will be working on the research project) had a DBS disclosure initiated by Keele University?	
7b If you have answered **YES to question 7a** please contact Human Resources to obtain a confirmation note indicating that a DBS disclosure has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?	N/A
If you have answered **NO to question 7a** please contact Human Resources immediately to arrange for a DBS disclosure to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Human Resources indicating that a DBS disclosure has been undertaken and is satisfactory. Has Human Resources been contacted about this?	N/A
HOME/EU STUDENTS ONLY 7c Have you (and other individuals who will be working on the research project) had a DBS Disclosure (or equivalent) initiated by Keele University?	N/A

7d If you have answered **YES to question 7c** please contact the Admissions Officer, Admissions to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?	
If you have answered **NO to question 7c** please contact the Admissions Officer immediately to arrange for a DBS disclosure (or equivalent) to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Nicola Leighton indicating that a DBS disclosure has been undertaken and is satisfactory. I confirm the Admissions Officer has been contacted and a DBS disclosure (or equivalent) has been initiated.	NO
I have contacted the Home/EU Admissions Officer, and was informed that a CRB disclosure is not required for this project, as I am not dealing with patients, minors or vulnerable adults but healthcare practitioners only	
	N/A
INTERNATIONALSTUDENTS ONLY Please contact Nicola Leighton on 01782 733306 or e-mail n.leighton@keele.ac.uk before completing this section	
7e Have you (and other individuals who will be working on the research project) had a DBS Disclosure (or equivalent) initiated by Keele University?	
7f If you have answered **YES to question 7e** please contact the appropriate person (as advised by Nicola Leighton) to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form.	
If you have answered **NO to question 7e** please contact the appropriate person (as advised by Nicola Leighton) immediately to arrange for a DBS disclosure (or equivalent) to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Human Resources indicating that DBS disclosure has been undertaken and is satisfactory. I confirm the relevant person has been contacted and a DBS disclosure (or equivalent) has been initiated.	
8. Will the study involve participants who are unable to give valid (informed)	NO

consent (e.g. children and adults lacking mental capacity)? **If YES**, what procedures will be in place to ensure that informed consent is obtained, where appropriate, from third parties (e.g. parents or carers)? And what procedures will be in place (if any) to give the participants an opportunity to have their objections recognised and respected?	
9. Does the investigation involve observing participants unawares? **If YES**, what efforts will be made to respect their privacy, values and well-being?	NO
10. Will the confidentiality of participants be maintained? **If NOT**, please give rationale: **If YES**, how? Any information provided by a respondent during the course of the research will be kept strictly confidential. Respondents will not be asked to provide information that could be used to identify them. Demographic data collected will be limited to profession, postgraduate training specific to musculoskeletal shoulder disorders, country of clinical practice, percentage of clinical time funded by government/state and privately funded, and frequency of referral/recommendation to three commonly used treatments. This survey will be hosted by Keele University on a secure password protected and backed up server. Once the sample size has been met and data collection has been completed, the link to the survey will be disabled and the survey will no longer be available for access online. All data will be maintained in an anonymous form that cannot be linked with any respondent. A separate password protected database (accessible only by Tim Smale, software programmer and the research team) will be maintained for respondents who email the student to indicate that they would like to receive notification of results. Individuals populating this database will receive two sets of results, results of the survey and results of a further study that will assess the validity of the results. This database will be destroyed after the second results email has been sent. Data will be stored on the secure University server, which is password protected with only designated members of the research team and survey development team authorised to access it. All research staff work to robust data security procedures and have explicit duties of confidentiality, equivalent to the duty placed on NHS staff, written into their employment contracts, in line with the Data Protection Act (1998) and the NHS Research Governance Framework.	YES

11. Will participants require any support to take part in the research (eg. disability support, interpreter)? **If YES**, what sort of support is required and how will it be delivered?	NO

(PROCEDURES)

12. Does the research involve people being investigated for a condition or disorder which has received medical, psychiatric, clinical psychological or similar attention? **If YES**, please give details:	NO
13. Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? **If YES**, please give details and justify:	NO
14. Will blood or other bodily fluids/tissues (including hair, nails and sebum) be obtained from **participants?** **If YES**, please give details and justify:	NO
15. Is pain or more than mild discomfort likely to result from the study? **If YES**, please give details and justify:	NO

(RESEARCH PROCESS)

16. Will participants receive any reimbursements or other payments **If YES**, please give details:	NO
17. Does the research involve the analysis of data participants will not realise would be used by you for research purposes (e.g. confidential criminal, medical or financial records)? **If YES**, please give rationale:	NO
18. Does the research involve the possible disclosure of confidential information to other participants (e.g. in focus groups)? **If YES**, please explain how this will be handled:	NO
19. Will the researchers de-brief participants to ensure that they understand the nature of the research and to monitor possible misconceptions or negative effects? **IF YES**, how will this be done? *Participants will be provided with links to the combined participant invite and information sheet and consent at the beginning of each survey. Opportunity will be provided for participants to contact the student or the students' lead supervisor and the university's Research Governance Officer in the event of any misunderstandings or misconceptions*. **If NO**, please explain why not:	YES
20. Are there any <u>other</u> ethical issues that you think might be raised by the research?	NO

If YES, please give details:	

(Health & Safety)

21. Does the project have any health & safety implications for the researcher? **If YES**, please outline the arrangements which are in place to manage these risks:	NO
FOR STAFF ONLY **22. Does your research involve travel overseas?** **If YES,** Have you consulted the Foreign and Commonwealth Office website for guidance/travel advice? http://www.fco.gov.uk/en/travel-and-living-abroad/ Have you completed and submitted the risk assessment form? Available from http://www.keele.ac.uk/finance/insurance/travelinsurance/travellingoverseas-policyriskassessment/	N/A N/A N/A

FOR STUDENTS ONLY	
23. Will any research take place outside the UK?	NO
This is an online survey that will be completed by respondents internationally. The researcher does not need to travel in order to obtain the data.	
If YES	
For home students - have you consulted the Foreign and Commonwealth Office website for guidance/travel advice? http://www.fco.gov.uk/en/travel-and-living-abroad/	N/A
For international students - have you also sought advice/guidance from the Foreign Office (or equivalent body) of your country?	N/A
For all students - will you be visiting any areas for which particular risks have been identified or for which the advice given is not to travel to this area?	N/A
If YES (a) Please give details	
(b) Please outline the arrangements in place to manage these risks.	
24. What insurance arrangements are in place? (Please contact Alan Slater on 01782 733525 to ascertain if you will be covered by University Insurance)	

	N/A

SECTION D (to be completed by all applicants)

Please complete the checklist below to indicate the version number and date of any supporting documents included with this application.

Document(s)	Version Number	Date
Summary document	**V1.0**	**16.12.14**
Combined participant invitation letter and information sheet	**V1.0**	**16.12.14**
Questionnaire(s) (paper copy)	**V1.0**	**16.12.14**
Consent Form(s)	**N/A**	**N/A**
Consent Form(s) for use of quotes	**N/A**	**N/A**
Interview Topic Guide(s)	**N/A**	**N/A**

Signatures	**Signatures**
Principal Investigator / Research Student: I understand that I must comply with the University's regulations and other applicable codes of ethics at all times.  Cliona McRobert **Research Student**	The following permissions must be obtained before this form is submitted: - for **staff who are members of a research institute**, the signature of your Research Institute Director (or, for RI Social Sciences, Research Centre Head); - for **staff who are NOT members of a research institute**, the signature of your Head of School (of, if not in a School, other line manager) - for **postgraduate research students**, the signature of your lead supervisor. I have read this application and confirm that:- • The academic and/or scientific quality of the application is satisfactory.

16/12/14  Professor Danielle van der Windt **Lead supervisor** 16/12/2014	• Arrangements are in place for the management and governance of this project …….. **Research Institute Director / Research Centre Head / Supervisor / Head of School / Other Line Manager** …… Date *please delete as appropriate

Please ensure when submitting your application that you have provided a hard copy and e-mailed a copy of <u>all</u> the documentation to Hannah Reidy, ERP Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, Keele, e-mail uso.erps@keele.ac.uk

Applicants who have already obtained ethics approval from a separate committee should forward documentation to

Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306.

Applications which require approval by an University Ethical Review Panel should forward documentation to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail uso.erps@keele.ac.uk, telephone 01782 733306.

Please note that it is your responsibility to follow the University's Code of good research practice http://www.keele.ac.uk/researchsupport/researchgovernance/ and any relevant academic or professional guidelines in the conduct of your study. **This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data.** Any significant change in the question, design or conduct over the course of the research

should be notified to the Research Institute Director/Supervisor and may require a new application for ethics approval.

This form was developed from the Ethics application forms used within Humanities and Social Sciences with kind permission from the HUMSS Research Ethics Committee.

SECTION E

Information regarding the completion of the ethical review panel application form

Section A – To be completed by all applicants.

Section B – To be completed by applicants who have already obtained Ethics Approval from a separate committee.

Section C – To be completed by applicants requiring approval from a University Ethical Review Panel

Section D – To be completed by all applicants.

PLEASE NOTE: Ethics Approval for Research Projects

All projects involving human research participants/subjects and/or data about identifiable individuals, need to be approved by an ethics committee before the fieldwork for projects can commence. The University has established Ethical Review Panels to review proposed research projects to be undertaken by staff and postgraduate research students. The information below provides more details about the role of these panels and the documents that need to be submitted to support the review process.

---

1. If your project has already been approved by a recognised ethics committee (for example, an NHS research ethics committee), the following documentation should be sent directly to the Chair of the University Research Ethics Committee, C/o Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306.

    - A completed and signed ethical review application form (Sections A, B and D) accompanied by an electronic copy;
    - Evidence of prior ethics approval from the hosting institution.

2. If your project requires approval by a University Ethical Review Panel, the following documentation should be sent directly to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail uso.erps@keele.ac.uk, telephone 01782 733306

    - A completed and signed ethical review application form (Sections A, C and D) accompanied by an electronic copy of the application form and relevant documentation. An application cannot be considered until a signed copy is received and also by an electronic copy;
    - A summary document, **NO MORE THAN** two sides of A4 paper;
      And, if they are applicable given the study's design and approaches,

    - A letter of invitation for participants;
    - An information sheet which should normally include following sections: invitation paragraph; the purpose of the study; why the participant has been chosen; what will happen to participants if they take part; a discussion of the possible disadvantages, risks and benefits of taking part; the procedures for ensuring confidentiality and anonymity, if any; the proposed use of the research findings; and contact details of the principal investigator plus details of additional support agencies (if necessary);
    - A copy of the participant consent form;

- Copies of any questionnaire, interview schedules or topic guides.

3. The review will be undertaken at the next available ethical review panel meeting. Please access http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/ for a list of meeting dates and submission deadlines. Following the review process you will be informed of the panel's decision which will be either:

   - Study approved;
   - Study approved subject to clarification of issues, modification of design or provision of additional information which will be itemised in the letter of response;
   - Study rejected with supporting reasons.

4. If ethical approval is not granted, applicants have the right of appeal to the University's Research Ethics Committee.

5. Correspondence informing applicants of the outcome of the panel's decision will be copied to the relevant Research

Administrators. It is the responsibility of applicants to keep their respective Institutes informed of their research activities

for the purposes of research governance.

Keele University

Arthritis Research UK | primary care centre

Letter of Invitation

22nd January 2013

Dear Professional Colleague,

Musculoskeletal Shoulder Disorders: Which Treatment for Whom?

As a musculoskeletal physiotherapist and current PhD student at the Arthritis Research UK Primary Care Centre at Keele University, I am currently researching the predictors of response to commonly used clinical treatments for musculoskeletal shoulder conditions.

As you know, musculoskeletal shoulder disorders are common and cause considerable reductions in social and work functional and quality of life. Achieving consistently successful outcomes for patients with shoulder disorders has proven difficult to achieve with over 70% of primary care patients still report pain after 6 weeks and 50% still report pain after 6 months. Although prognostic studies been able to identify some of the characteristics predicting who will improve or not improve over time, i.e., the predictors of outcome irrespective of treatment, currently, very little is known about predicting which patients are likely to respond to commonly used treatment such as: (i) education, advice and pain relief, (ii) physiotherapy treatment or (iii) joint injection. These sorts of predictors are known as 'treatment moderators' and are useful for helping to subgroup patients to better target treatment based on an individual patient's clinical profile, an approach often termed 'stratified care'.

The aim of my PhD is to address our current gap in knowledge and evidence regarding stratified care for musculoskeletal shoulder disorders. A systematic review has been conducted to identify the clinical factors already known to be 'treatment moderators'. The next stage of the research plan is to gain consensus from clinical experts on the clinical factors which are felt to be useful for identifying patients who are likely to respond positively to these commonly used treatments and so, inform a future clinical decision-aid tool.

I am writing to ask you, as an expert clinician in musculoskeletal shoulder disorders, if you would like to be involved with this research. Your involvement would require your attendance at two (or if unavailable for both, either of the) 2-hour evening consensus workshops, which are to **begin** in Keele in April 2013, and 10 minutes homework between workshops 1 and 2 (received via email). Further information about the study and what you will be required to do can be found in the enclosed information sheet.

If you would like to be involved in this research or would like further information, please contact me at c.j.mcrobert@keele.ac.uk or on the telephone number below.

Best wishes and kind regards,

Cliona McRobert, Principal Investigator; Danielle van der Windt, Academic Supervisor

e-mail: c.j.mcrobert@keele.ac.uk or telephone: 01782 734889

e-mail: d.van.der.windt@keele.ac.uk or telephone: 01782 734830

Participant Information Sheet

Study Title: Musculoskeletal Shoulder Disorders: Which Treatment for Whom?

Invitation

You are being invited to consider taking part in the research study: Musculoskeletal Disorders: Which Treatment for Whom? This project is being undertaken by Cliona McRobert, a physiotherapist and PhD student within the Arthritis Research UK Primary Care Centre at Keele University who is under the academic supervision of Prof. Danielle van der Windt, Prof. Elaine Hay and Dr. Jonathan Hill. Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and ask us if there is anything that is unclear of if you would like more information.

Aims of Research

This study aims to progress existing knowledge on how patient attributes (e.g., pain, disability, age and gender) influence the clinical effectiveness of three commonly used treatment options: (i) advice & pain relief, (ii) physiotherapy, and (iii) joint injection in patients with shoulder disorders. Using the knowledge and experience of expert shoulder clinicians, we aim to identify the patient attributes agreed to potentially predict the response to specific treatment (i.e., moderators of clinical outcome) in musculoskeletal shoulder disorders, agreed levels of each patient attribute (e.g., patient-reported pain measured on a visual analogue scale may be understood in the three clinically sensible cut-offs: VAS 0-3, VAS 4-6, VAS 7-10) and agreed profiles of likely responders to individual treatments. This new information will be used to design an online survey of international expert shoulder clinicians in order to create patient profiles of likely optimal responders to these three commonly used treatments and later, inform a future clinical decision-aid tool.

Why have I been invited to participate?

You have been invited to take part because you have a recognised expertise or special interest in the assessment and treatment of musculoskeletal shoulder disorders.

Do I have to take part?

It is up to you to decide whether or not you take part. If you decide to take part, you will be asked to attend two (or if unavailable for both, either of the) 2-hour consensus workshops, which we plan to organise outside your working hours in the evening, and do around 10 minutes of homework between workshops 1 and 2, which will involve reading through the results of workshop 1 which will be sent to you. If you decided to take part, copies of the consent forms will be available for you to complete at each workshop. You will be free to withdraw at any time and without giving a reason. This decision will not affect you or your rights in any way. You will be provided with a light meal and refreshments at each workshop. Any travel expenses that you incur as a result of your attendance at Keele for these workshops will also be reimbursed.

What will happen if I take part?

If you would like to take part please respond to this e-mail or contact Cliona McRobert at c.j.mcrobert@keele.ac.uk or leave a message at the telephone number below. The principal investigator will then be in touch to arrange dates for you to attend two (or if unavailable for both, either of the) 2-hour consensus workshops at Keele where you will be asked to identify, discuss, and prioritise patient attributes which are felt to moderate the outcome of commonly used treatments in musculoskeletal shoulder disorders.

What are the possible benefits (if any) of taking part?

There are no direct benefits to you taking part in this study. However, we are hoping that the data collected from you and other expert clinicians will contribute to the improvement of treatment of musculoskeletal shoulder disorders in primary care. The results of the consensus workshops will be written up and submitted to peer-reviewed scientific journals and to relevant conferences. Your contribution will be acknowledged in the publication.

What are the possible disadvantages of taking part?

There are no major disadvantages to taking part other than attending the nominal group consensus workshops will take up to 4 hours of your time if you decide to attend both of the 2 hour workshops (excluding travel), and you will be required to read through the results of workshop 1 prior to attendance at workshop 2, which should take no more than 10 minutes of your time.

How will information about me be used?

Information regarding your professional position, duration in clinical practice, age, gender, post-graduate qualification, and geographical region in which you work will recorded and

combined with similar information from all other group members. Descriptive statistics will later be used to summarise and describe the make-up of the group of expert clinicians involved in each consensus workshop. All data collected during the consensus workshops will be audio-recorded, analysed and reported anonymously.

Who will have access to information about me?

The use of any information that identifies you during the course of the research will be kept strictly confidential. This information will be kept in a secure place (locked filing cupboard or password protected computer) and only people involved in the study or authorised individuals will have access to it.

What happens when the research stops?

Data obtained from each workshop will be analysed and participants will be notified of the results. The output of the consensus workshops will be submitted for publication in a peer reviewed scientific journal and presented at a relevant conference. The output of the workshops will inform the design of an online survey of international expert clinicians. You will also be most welcome to partake in this online survey on international expert clinicians. Results from this survey will be subjected to further statistical analysis in order to identify predictors of treatment response in primary care patients with shoulder disorders, and define clinical profiles of patients who are likely to respond well to specific treatments. This work will then inform the design of future interventions studies.

Who is funding and organising the research?

Cliona McRobert is supported by the Arthritis Research UK Primary Care Centre at Keele University and is funded by NHS R&D funding for new Medical Schools.

Who has reviewed this research?

This study including the PhD as a whole in which this study is nested has undergone independent peer review by academic members of the Arthritis Research UK (ARUK) Primary Care Centre at Keele Univeristy. The scientific quality of this study has therefore been approved as part of the PhD development phase.

What if there is a problem?

If you have a concern about any aspect of this study, you may wish to speak to the researcher who will do her best to answer your questions. You should contact Cliona McRobert on c.j.mcrobert@keele.ac.uk. Alternatively, if you do not wish to contact the researcher you may contact Danielle van de Windt on danielle.van.der.windt@keele.ac.uk. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of the way that you have

been appraoched or treated during the course of the study, please write to Nicola Leighton who is the University's contact for complaints regarding research at the following address:

Nicola Leighton

Research Governance Officer

Research & Enterprise Building

Dorothy Hodgkin Building

Keele University

ST5 5BG

E-mail: n.leighton@keele.ac.uk

Contact for further information

If you would like any further information please contact:

Cliona McRobert e-mail: c.j.mcrobert@keele.ac.uk or telephone: 01782 734889

Danielle van der Windt e-mail: d.van.der.windt@keele.ac.uk or telephone: 01782 734830

Keele University

Arthritis Research UK | primary care centre

CONSENT FORM

Title of Project: Musculoskeletal Shoulder Disorders: Which Treatment for Whom?

Name and Contact Details of Principal Investigator:

Cliona McRobert

Arthritis Research UK Primary Care Centre, Primary Care Sciences

Keele University

Staffordshire, ST5 5BG

Tel: 01782 734889

Email: c.j.mcrobert@keele.ac.uk

Please tick box if you agree with the statement

I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions	☐
I understand that my participation is voluntary and that I am free to withdraw at any time	☐
I agree to take part in this study	☐
I understand that data collected about me during this study will be anonymised before submission for publication.	☐
I agree to the consensus workshop being audio recorded	☐
I agree to allow the dataset collected to be used for future research projects	☐
I agree to be contacted about possible participation in future research projects	☐
I agree for any quotes to be used anonymously	☐
I do not agree for any quotes to be used, even if anonymised	☐
I agree to keep the issues discussed in the workshop confidential and in particular, to avoid identifying any participant in relation to individual comments made during the session	☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature

PARTICIPANT DESCRIPTIVES FORM

Title of Project: Musculoskeletal Shoulder Disorders: Which Treatment for Whom?

Name and Contact Details of Principal Investigator:

Cliona McRobert

Arthritis Research UK Primary Care Centre, Primary Care Sciences

Keele University

Staffordshire, ST5 5BG

Tel: 01782 734889

Email: c.j.mcrobert@keele.ac.uk

Please complete this table to help create an anonymous summary of this workshop's participants. Please note that this data collection sheet will not be linked to your consent form.

Clinical Speciality		
Are you currently involved in the clinical management of shoulder disorders?	Yes	No
Which clinical management options do you routinely use for shoulder disorders?	Education & Advice Pain Relief Physiotherapy Joint Injections Other (please specify) ……	
Duration in clinical practice		

<table>
<tr><td colspan="2">Post-graduate Qualifications</td><td colspan="4"></td></tr>
<tr><td>Age</td><td></td><td colspan="2">Gender</td><td>Male</td><td>Female</td></tr>
<tr><td rowspan="3"><u>Region</u> in which you practice

(Please circle)</td><td>East</td><td>East Midlands</td><td>London</td><td>North East</td></tr>
<tr><td>North West</td><td>Northern Ireland</td><td>Scotland</td><td>South East</td></tr>
<tr><td>South West</td><td>Wales</td><td>West Midlands</td><td>Yorkshire &
The Humber</td></tr>
</table>

Appendix 4: Ethical approval for consensus workshops

Keele University

RESEARCH AND ENTERPRISE SERVICES

7th November 2013

Cliona McRobert
Arthritis Research UK Primary Care Centre
Primary Care
David Weatherall Building
Keele University

Dear Cliona,

Re: 'Musculoskeletal shoulder treatments: Which treatment for whom?'

Thank you for submitting your application to amend study for review.

I am pleased to inform you that your application has been approved by the Ethics Review Panel.

The following documents have been reviewed and approved by the panel as follows:

Document	Version	Date
Summary Proposal	2	29/10/2013
Supporting Documents	2	29/10/2013

If the fieldwork goes beyond the date stated in your application you must notify the Ethical Review Panel via the ERP administrator at uso.erps@keele.ac.uk stating ERP2 in the subject line of the e-mail.

If there are any other amendments to your study you must submit an 'application to amend study' form to the ERP administrator stating ERP2 in the subject line of the e-mail. This form is available via http://www.keele.ac.uk/researchsupport/researchethics/

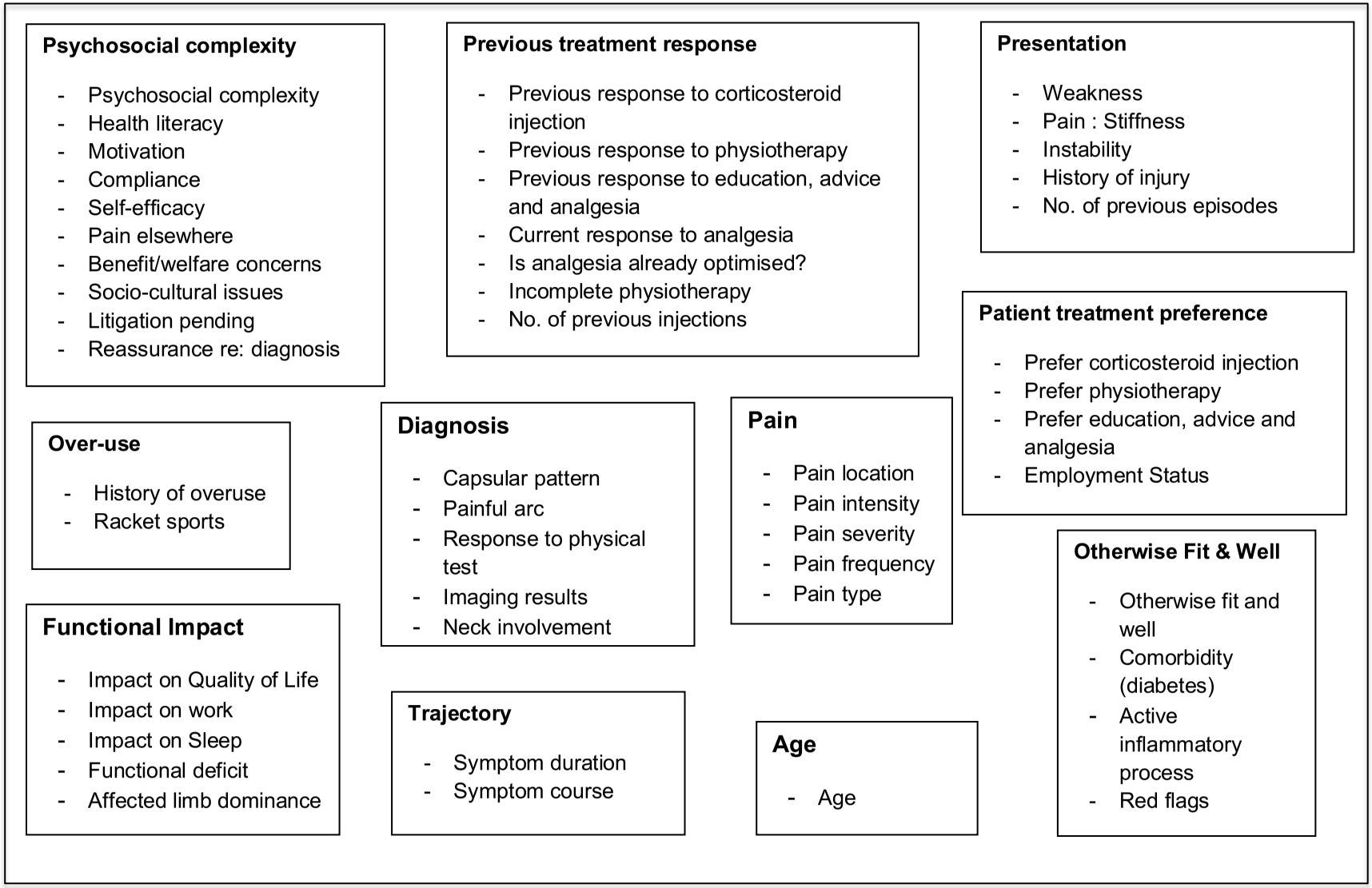
If you have any queries, please do not hesitate to contact me via the ERP administrator on uso.erps@keele.ac.uk stating ERP2 in the subject line of the e-mail.

Yours sincerely

Dr Bernadette Bartlam
Chair – Ethical Review Panel

CC RI Manager

Appendix 5: Edited results of categorisation exercise (Phase 1)



Appendix 5: Edited results of categorisation exercise (Phase 1)

Appendix 6: Orthogonal array for the conjoint analysis study

1	Patient
Attribute 1	1 Level 2
Attribute 2	2 Level 2
Attribute 3	Level 2
Attribute 4	Level 1
Attribute 5	Level 1
Attribute 6	Level 2
Attribute 7	Level 1
Attribute 8	Level 1
Attribute 9	Level 1
Attribute 10	Level 1
Attribute 11	Level 2
Attribute 12	Level 3
	Choose one
Treatment 1	
Treatment 2	
Treatment 3	

2	Patient
Attribute 1	1 Level 1
Attribute 2	2 Level 1
Attribute 3	3 Level 1
Attribute 4	4 Level 1
Attribute 5	5 Level 1
Attribute 6	6 Level 1
Attribute 7	7 level 1
Attribute 8	8 Level 1
Attribute 9	9 Level 1
Attribute 10	10 Level 2
Attribute 11	11 Level 2
Attribute 12	12 Level 1
	Choose one
Treatment 1	
Treatment 2	
Treatment 3	

3	Patient
Attribute 1	2
Attribute 2	2
Attribute 3	1
Attribute 4	2
Attribute 5	2
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	2
Attribute 10	2

Attribute 11	1
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

4 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	1
Attribute 7	1
Attribute 8	2
Attribute 9	1
Attribute 10	3
Attribute 11	2
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

5 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	1
Attribute 4	2
Attribute 5	1
Attribute 6	1
Attribute 7	2
Attribute 8	2
Attribute 9	1
Attribute 10	2
Attribute 11	2
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

6 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	1

Attribute 4	2
Attribute 5	2
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	2
Attribute 10	3
Attribute 11	2
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

7 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2
Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	1
Attribute 8	2
Attribute 9	2
Attribute 10	3
Attribute 11	2
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

8 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1
Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	1
Attribute 11	3
Attribute 12	1

Choose one
Treatment 1

Treatment 2
Treatment 3

9 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	1
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	1
Attribute 10	1
Attribute 11	1
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

10 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	1
Attribute 5	1
Attribute 6	2
Attribute 7	1
Attribute 8	1
Attribute 9	1
Attribute 10	2
Attribute 11	3
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

11 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2
Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	1

Attribute 8	2
Attribute 9	2
Attribute 10	1
Attribute 11	3
Attribute 12	2
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

12 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1
Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	2
Attribute 9	1
Attribute 10	3
Attribute 11	1
Attribute 12	1
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

13 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	2
Attribute 8	2
Attribute 9	2
Attribute 10	1
Attribute 11	1
Attribute 12	2
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

14 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2
Attribute 4	1
Attribute 5	2
Attribute 6	1
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	2
Attribute 11	2
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

15 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	1
Attribute 4	2
Attribute 5	2
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	2
Attribute 10	1
Attribute 11	3
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

16 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	2
Attribute 9	2
Attribute 10	2

Attribute 11	2
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

17 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	1
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	1
Attribute 10	1
Attribute 11	1
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

18 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	1
Attribute 10	3
Attribute 11	1
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

19 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2

Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	1
Attribute 8	2
Attribute 9	2
Attribute 10	2
Attribute 11	1
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

20 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	1
Attribute 10	2
Attribute 11	3
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

21 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	2
Attribute 8	2
Attribute 9	2
Attribute 10	2
Attribute 11	2
Attribute 12	3

Choose one
Treatment 1

Treatment 2
Treatment 3

22 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	1
Attribute 10	1
Attribute 11	2
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

23 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	2
Attribute 4	2
Attribute 5	2
Attribute 6	1
Attribute 7	1
Attribute 8	2
Attribute 9	1
Attribute 10	1
Attribute 11	3
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

24 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	1
Attribute 4	2
Attribute 5	1
Attribute 6	1
Attribute 7	2

Attribute 8	2
Attribute 9	1
Attribute 10	1
Attribute 11	1
Attribute 12	1
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

25 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1
Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	2
Attribute 11	1
Attribute 12	2
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

26 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	1
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	1
Attribute 8	1
Attribute 9	1
Attribute 10	3
Attribute 11	3
Attribute 12	2
Choose one	
Treatment 1	
Treatment 2	
Treatment 3	

27 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1
Attribute 4	2
Attribute 5	1
Attribute 6	2
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	3
Attribute 11	2
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

28 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	1
Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	1
Attribute 8	2
Attribute 9	2
Attribute 10	3
Attribute 11	1
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

29 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	1
Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	1
Attribute 8	2
Attribute 9	2
Attribute 10	1

Attribute 11	2
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

30 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2
Attribute 4	1
Attribute 5	2
Attribute 6	1
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	3
Attribute 11	3
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

31 Patient	
Attribute 1	1
Attribute 2	1
Attribute 3	2
Attribute 4	1
Attribute 5	2
Attribute 6	1
Attribute 7	2
Attribute 8	1
Attribute 9	2
Attribute 10	1
Attribute 11	1
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

32 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1

Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	2
Attribute 9	1
Attribute 10	2
Attribute 11	3
Attribute 12	3

Choose one
Treatment 1
Treatment 2
Treatment 3

33 Patient	
Attribute 1	1
Attribute 2	2
Attribute 3	1
Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	1
Attribute 8	2
Attribute 9	2
Attribute 10	2
Attribute 11	3
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

34 Patient	
Attribute 1	2
Attribute 2	1
Attribute 3	1
Attribute 4	1
Attribute 5	2
Attribute 6	2
Attribute 7	2
Attribute 8	2
Attribute 9	1
Attribute 10	1
Attribute 11	2
Attribute 12	2

Choose one
Treatment 1

Treatment 2
Treatment 3

35 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	1
Attribute 5	1
Attribute 6	2
Attribute 7	1
Attribute 8	1
Attribute 9	1
Attribute 10	3
Attribute 11	1
Attribute 12	2

Choose one
Treatment 1
Treatment 2
Treatment 3

36 Patient	
Attribute 1	2
Attribute 2	2
Attribute 3	2
Attribute 4	1
Attribute 5	1
Attribute 6	1
Attribute 7	2
Attribute 8	2
Attribute 9	2
Attribute 10	3
Attribute 11	3
Attribute 12	1

Choose one
Treatment 1
Treatment 2
Treatment 3

Appendix 7: Decision tasks for the conjoint analysis study

1	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	High pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

2	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues

Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

3	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	High pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

4	Patient

General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

5	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain

Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

6	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

7	Patient
General health status	Otherwise fit & well

Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Low pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

8	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	No previous physiotherapy or steroid injection

Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

9	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

10	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving

Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Low pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

11	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy

Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

12	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	No patient treatment preference
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

13	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities

Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	Moderate pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

14	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Moderate pain

	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

15	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

16	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder

Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Moderate pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

17	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	High pain
	Choose one

Physiotherapy
Steroid Injection
Education, Advice & Pain Relief

18	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	No patient treatment preference
Pain Severity	High pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

19	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset

Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	High pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

20	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Moderate pain
	Choose one
Physiotherapy	

Steroid Injection Education, Advice & Pain Relief

21	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	High pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

22	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use

Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Low pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

23	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No significant instability or weakness
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	High pain
	Choose one
Physiotherapy	
Steroid Injection	

Education, Advice & Pain Relief

24	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	Low pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

25	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness

Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

26	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

27	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	No significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	High pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

28	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues

Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	No patient treatment preference
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

29	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	High pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

30	Patient

General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	High pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

31	Patient
General health status	Otherwise fit & well
Current Clinical Status	Condition improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	No neck pain

Previous response to treatment	No previous physiotherapy or steroid injection
Patient treatment preference	No patient treatment preference
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

32	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	High pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

33	Patient
General health status	Otherwise fit & well

Current Clinical Status	Condition not improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to steroid injection
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Low pain
	Choose one
Physiotherapy	
Steroid Injection	
Education, Advice & Pain Relief	

34	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition improving
Functional and/or work impact	Significant impact on activities/work
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Non-traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	No previous physiotherapy or steroid injection

Patient treatment preference	Patient treatment preference for steroid injection
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

35	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving
Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	No over-use
Instability and/or weakness	Significant instability and/or weakness
Psychosocial issues	Psychosocial issues
Neck involvement	Con-comittant neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	No patient treatment preference
Pain Severity	Moderate pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

36	Patient
General health status	Unstable diabetes and/or cardiac issues
Current Clinical Status	Condition not improving

Functional and/or work impact	No significant impact on work/activities
Sleep Disturbance	Significant sleep disturbance due to shoulder
Onset	Traumatic onset
Over-use linked to work, sport, or hobbies	Over-use linked to work, sport or hobbies
Instability and/or weakness	No significant instability or weakness
Psychosocial issues	No psychosocial issues
Neck involvement	No neck pain
Previous response to treatment	Previous positive response to physiotherapy
Patient treatment preference	Patient treatment preference for physiotherapy
Pain Severity	Low pain
	Choose one
Physiotherapy Steroid Injection Education, Advice & Pain Relief	

Appendix 8: Paper version of the conjoint analysis study

Page 1 Welcome

Thank you for joining this survey.

We are seeking the views of clinicians who treat or are involved in the care of patients with musculoskeletal shoulder disorders as part of their practice.

This survey should take **no more than 20 minutes** of your time to complete.

Please read the participant information sheet by clicking here (electronic link to participant invitation & information sheet) (may be found as a separate document)

If you have any questions about this survey or the study in general, you can email Cliona McRobert at c.j.mcrobert@keele.ac.uk.

Instructions for completing this survey

When completing this survey, please remember that there are no 'correct' or 'incorrect' answers.

Please try to provide answers that most accurately reflect your usual clinical practice.

Please do not consult any literature or other resources while completing this survey.

This survey has been designed by Cliona McRobert, a musculoskeletal physiotherapist and PhD student at the Arthritis Research UK Primary Care Centre at Keele University, UK, along with Prof. Danielle van der Windt, Prof. Elaine Hay and Dr. Jonathan Hill of Keele University and Prof. John F.P. Bridges of Johns Hopkins University Bloomberg School of Public Health, US.

Survey web page design and database programming conducted by Tim Smale, Keele University.

Inclusion Criteria & Consent

I am a qualified health or medical practitioners, clinical academic or academic (including but not limited to physiotherapists, general practitioners (GPs), rheumatologists and orthopaedic surgeons) who (INSERT TICK BOX)

I clinically manage or have a clinical or research interest in patients with musculoskeletal shoulder disorders as part of their normal clinical practice (INSERT TICK BOX)

I can read and write English (INSERT TICK BOX)

I have read the information sheet, understand the instructions and I consent to taking part in the survey (INSERT TICK BOX)

Next Page

Page 2 Unique Identifier Number

Please find below your unique identifier number. This number relates to your responses in this survey. Please write it down, take a screen shot or enter your email address below to receive an automated email containing your unique identifier number.

----(unique identifier number here)----

Enter your email address here to receive an email containing your unique identifier number (Box for email address)

Please use this number if you are unable to complete the survey all in one sitting and would like to save your responses and return to complete the survey later. You may do this at any time by pressing the 'Save responses and return to survey later' button.

If you decide after completing the survey that you wish to withdraw from the study, please contact the lead researcher at c.j.mcrobert@keele.ac.uk quoting your unique identifier number and your responses will be removed from the database.

Page 3 Please tell us about you...

This information will in no way identify you or your responses.

All responses are strictly confidential.

Please select your professional background:

Physiotherapist/Physical Therapist

General Practitioner/Family Doctor/ Primary Care Medical Physician

Rheumatologist

Orthopaedic Surgeon

Other (please state below)

……..

Have you completed any post-graduate training specific to the management of musculoskeletal shoulder disorders?

Yes - Please detail below

No

…….

In which country do you practice clinically?

United Kingdom

Republic of Ireland

The Netherlands

Australia

New Zealand

Norway

Sweden

USA

Canada

Other (please state below)

……..

How many years clinical experience do you have?

… years

What percentage of your current clinical work is funded by the state/government/complulsory health insurance? (Examples of state/government funded healthcare include: UK - National Health Service (NHS) and Republic of Ireland- Health Service Executive (HSE) and examples of compulsory health insurance funded healthcare systems include the Netherlands, Germany and Switzerland)

…%

What percentage of your current clinical role involves treating patients with musculoskeletal shoulder disorders?

…%

Please estimate the proportion of patients with shoulder pain that you provide/recommend/refer to each of the below treatments:

…%

Pain medication prescription & advice (radio check boxes for each response)

All patients

Most patients

Some patients

Few patients

No patients

Steroid injection & advice (radio check boxes for each response)

All patients

Most patients

Some patients

Few patients

No patients

Physiotherapy (radio check boxes for each response)

All patients

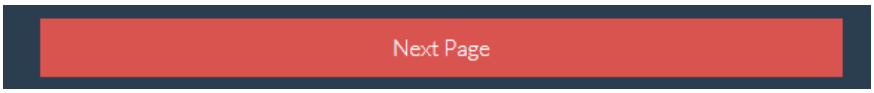
Most patients

Some patients

Few patients

No patients

Save responses now and return to survey later



Page 4 Study Background

The next pages will present 12 hypothetical patient profiles.

These profiles contain 12 patient attributes suggested by research on UK shoulder clinicians as highly relevant to treatment decision-making:

•General health status

•Previous response to treatment

•Current clinical status (improving or not)

•Patient treatment preference

•Functional and/or work impact

•Sleep disturbance

•Traumatic onset

•Over-use linked to sport, hobbies or work

•Instability and/or weakness

•Psychosocial issues

•Neck involvement

•Pain severity

Imagine that all three treatment options are available to each patient.

Of the three treatment approaches below, select a treatment recommendation that you feel is the single most clinically effective and cost effective treatment for each patient.

•Pain medication prescription & advice (Prescription of pain and/or anti-inflammatory medication & general advice)

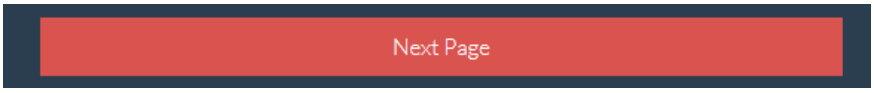
•Steroid injection & advice (Steroid injection dosage and technique tailored to patient need & advice)

•Physiotherapy (Assessment by an appropriately skilled physiotherapy/physical therapy practitioner followed by a course of evidence-based exercise and/or manual therapies)

These hypothetical patient profiles may not always make perfect clinical sense as they have been created using systematically varied combinations of patient attributes. Try to use your best clinical judgement to make a treatment recommendation for each of the profiles.

This survey has been designed using conjoint analysis, therefore only the patient attributes being studied by the research team have been included in the patient profiles. The tasks you will see replicate clinical decision scenarios but are not designed to be a complete case history. We would appreciate if you answered the questions in this survey using solely the information provided. Please assume that ALL other clinical information is EQUAL across the profiles. If you feel strongly that a relevant clinical detail is missing, please write it down as we would like you to share it with us at the end of the survey.

Before you begin, please be assured that this is not a test of your clinical knowledge and that we sincerely appreciate your valuable input into this research.



Page 5 Pick a Treatment

Patient 1

Imagine that this patient with a unilateral musculoskeletal shoulder disorder presents to you in clinical practice.

Here is their case description:

•Non-traumatic onset

•Condition not improving

•Moderate pain severity

•Significant sleep disturbance due to shoulder

•Significant impact on activities/work

•No psychosocial issues identified

•No over-use linked to sport hobbies or work

•No neck pain

•Significant instability and/or weakness

•No patient treatment preference

•Otherwise fit & well

•Previous positive response to physiotherapy

Imagine that all three of these treatment options are available.

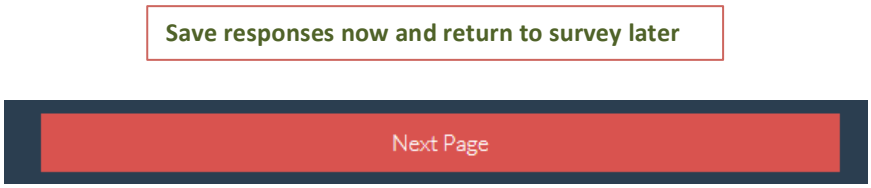
Please make a treatment recommendation for this patient (radio check boxes by each response):

Pain medication prescription & advice (Prescription of pain and/or anti-inflammatory medication & general advice)

Steroid injection & advice (Steroid injection dosage and technique tailored to patient need & advice)

Physiotherapy (Assessment by an appropriately skilled physiotherapy/physical therapy practitioner followed by a course of evidence-based exercise and/or manual therapies)

Please remember that these hypothetical patient profiles may not always make perfect clinical sense as they have been created using systematically varied combinations of patient attributes. Try to use your best clinical judgment to select your treatment recommendation for each of the profiles.



(Each respondent will view 12 randomly ordered clinical cases. Each case will be presented in this way with only the clinical attributes varying between cases)

Page 16 Final Questions

Considering the clinical decisions you have just made in the previous tasks, please answer the following questions:

(presented in a table format with 5 response options across the top from left to right: Strongly Agree, Agree, Neither Agree Or Disagree, Disagree & Strongly Disagree)

1 - The decisions were hard to make

2 - I was unsure about which treatment would really be best for each patient

3 - It was clear which treatment would be best for each patient

4 - When I made the decisions, I felt that I did not know enough about the treatment alternatives

5 - I had trouble making the decisions because important information was unknown

6 - When I made the decisions, it was hard to decide if the benefits of the treatment were more important than the risks

7 - All considerations that affected the decision were identified

8 - I understood the patients' views when I made these decisions

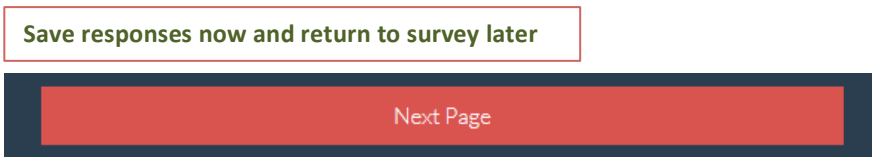
9 - I believe that patients would fully understand the risks and benefits of the prescribed treatments

10 - I believe that patients would comply with the prescribed treatment

11 - I am satisfied with the decisions I have made

12 - I am satisfied that the process (i.e., survey design) used to make the decisions was as good as it could be

13 - If asked again, I would expect to stick with my decisions



Page 16 **Your responses have been submitted**

Thank you for your time.

If you have any questions about this survey, the study in general or would like to hear about the results, you can email Cliona McRobert at c.j.mcrobert@keele.ac.uk.

Your responses are extremely valuable to us. We are looking for an international sample of physiotherapists/physical therapists, general practitioners/family doctors, rheumatologists and orthopaedic surgeons. Do you know any other clinicians who might be able to help with this survey? Please distribute this survey widely.

Tweet about this survey (link out to twitter with suggested tweet):

"Shoulder clinicians required for brief online international research survey: http://goo.gl/Zo4K7X #shoulders #StratifiedCare PLS RT"

Facebook share and Google+ share options also.

Appendix 9: Twitter targetted recruitment list

Social Media Strategy

A) Twitter

Used application called Followerwonk, to access google analytics.
Analysis 1: cliona311 // analyse people I follow

Send tweet to the people I follow with Highest Social Authority (According to Follower Wonk):
Adam Meakins
AM Cunningham
RCGP
MelloJonny
DocAndrewMurray
physiotalk
Dr Ridge DPT
Greg Lehman
Steve Nawoor
Dr John Orchard
Neil O'Connell
APA Physio
theCSP
NSRiazat
gerardgreenphy
rogerKerry
Richard56
ArthritisResearch UK
Sport Injury Matt
PhysioCan
NakedPhysio
Peter Gettings
Emma Stokes
Chris Littlewood
Paula Woods
Prof Gill Cook
Ciaran O Sullivan
MACP
Dr Pete Malliaras
ShoulderDoc UK
myOrthoDoc
ISPC
WCPT
FysioNederland
JeremyLewis
PhysioNZ

OntarioPT
Shoulderarth

Scheduled tweet TIMES using hootsuite:
7am, 11a, 1am, **3pm**, 4pm, 7pm, **9pm**, 11pm

Analysis 2: cliona311 // analyse people who follow me

Highest Social Influence
Adam Meakins
thecsp
joe mcveigh
physiowizzio
pain physio
derek griffin
Paula Woods
Physiopedia
physiotalk

People I know:
Peter O'Sullivan

Most active times for followers of:
7am, 12:00, 2pm, 8pm

Tweet wording:
1) Launching PhD survey on how clinicians choose shoulder treatments. www.keele.ac.uk/shoulder Would appreciate your support @AdamMeakins PLS RT
2) Do you 1st line manage patients with shoulder problems? International online survey live now: http://bit.ly/1DP4LQe Please share! #shoulder
3) How do you choose treatment for patients with shoulder disorders? International online survey: http://bit.ly/1DP4LQe PLS RT! #shoulder
4) Launching international survey of shoulder clinicians. How do you choose first line treatments? http://bit.ly/1DP4LQe PLS RT! #shoulder
5) Hi @thecsp Launching international survey of interest to shoulder clinicians. How do we choose treatments? http://bit.ly/1DP4LQe PLS RT!
6) Have you seen this @thecsp? International survey of shoulder clinicians. How do you pick 1st line treatments http://bit.ly/1DP4LQe PLS RT!
7) Would be brilliant if you shared this far and wide! International shoulder survey:how do we choose treatments? http://bit.ly/1DP4LQe
8) This will make you think. International shoulder survey for clinicians/academics: how do we pick 1st line

treatments? http://bit.ly/1DP4LQe
9) Shoulder clinicians, get your cogs turning here. International shoulder survey: how do we pick 1st line treatments? http://bit.ly/1DP4LQe
10) Interested in shoulders-Get your thinking caps on! International shoulder survey: how do we pick 1st line
treatments? http://bit.ly/1DP4LQe
11) Doc, my shoulder hurts! How do health/medical professionals choose 1st line treatment for people with #shoulder pain? http://bit.ly/1DP4LQe

Appendix 10: Google Analytics drill-down

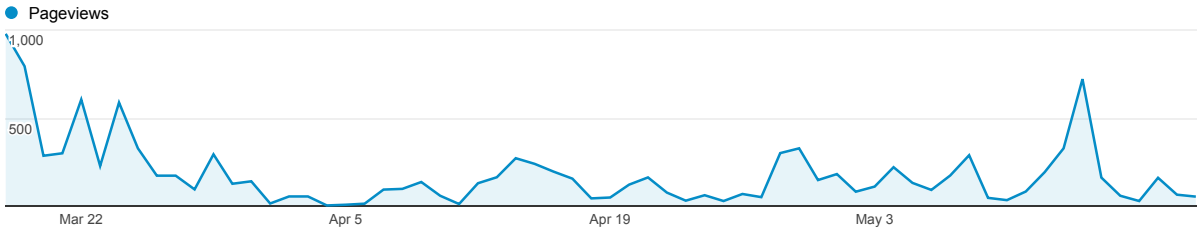
Content Drilldown

Mar 18, 2015 - May 20, 2015

ALL » PAGE PATH LEVEL 1: /sur141013/

All Sessions
47.98%

Explorer



	Page path level 2	Source	Pageviews	Unique Pageviews	Avg. Time on Page	Bounce Rate	% Exit
			11,448 % of Total: 47.98% (23,860)	5,226 % of Total: 53.38% (9,791)	00:00:50 Avg for View: 00:01:13 (-31.59%)	56.65% Avg for View: 33.50% (69.08%)	15.58% Avg for View: 16.53% (-5.70%)
1.	/	(direct)	2,097 (18.32%)	1,820 (34.83%)	00:01:03	54.90%	39.34%
2.	/	BHPR enews	4 (0.03%)	4 (0.08%)	00:00:00	100.00%	100.00%
3.	/	BSR e-newsletter recipients	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
4.	/	csp.org.uk	78 (0.68%)	66 (1.26%)	00:01:10	45.45%	29.49%
5.	/	exchange14.net.addenbrookes.nhs.uk	2 (0.02%)	2 (0.04%)	00:00:15	0.00%	0.00%
6.	/	facebook.com	25 (0.22%)	17 (0.33%)	00:00:49	30.00%	40.00%
7.	/	flipboard.com	2 (0.02%)	2 (0.04%)	00:00:00	100.00%	100.00%
8.	/	google	8 (0.07%)	8 (0.15%)	00:00:43	40.00%	25.00%
9.	/	keele.ac.uk	9 (0.08%)	3 (0.06%)	00:01:35	0.00%	0.00%
10.	/	linkedin.com	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
11.	/	m.facebook.com	78 (0.68%)	41 (0.78%)	00:01:16	63.89%	44.87%
12.	/	mail.google.com	3 (0.03%)	3 (0.06%)	00:00:03	100.00%	66.67%
13.	/	physiospot.com	15 (0.13%)	12 (0.23%)	00:01:40	50.00%	26.67%
14.	/	rightrelevance.com	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
15.	/	t.co	370 (3.23%)	339 (6.49%)	00:00:52	70.26%	55.95%
16.	/	twitter.com	3 (0.03%)	3 (0.06%)	00:00:15	50.00%	33.33%
17.	/	uk-mg42.mail.yahoo.com	3 (0.03%)	3 (0.06%)	00:00:22	50.00%	33.33%
18.	/a1.aspx	(direct)	1,335 (11.66%)	135 (2.58%)	00:00:39	100.00%	2.02%
19.	/a1.aspx	csp.org.uk	48 (0.42%)	4 (0.08%)	00:00:40	0.00%	0.00%
20.	/a1.aspx	keele.ac.uk	2 (0.02%)	1 (0.02%)	00:00:08	0.00%	50.00%
21.	/a1.aspx	physiospot.com	4 (0.03%)	1 (0.02%)	00:01:22	0.00%	25.00%
22.	/a1.aspx	t.co	137 (1.20%)	15 (0.29%)	00:00:30	0.00%	2.19%

23.	/a1.aspx	uk-mg42.mail.yahoo.com	13 (0.11%)	1 (0.02%)	00:01:16	0.00%	0.00%
24.	/a2.aspx	(direct)	1,252 (10.94%)	125 (2.39%)	00:00:39	50.00%	1.52%
25.	/a2.aspx	csp.org.uk	102 (0.89%)	9 (0.17%)	00:00:45	0.00%	0.98%
26.	/a2.aspx	dub128.mail.live.com	12 (0.10%)	1 (0.02%)	00:00:33	0.00%	0.00%
27.	/a2.aspx	exchange14.net.addenbrookes.nhs.uk	12 (0.10%)	1 (0.02%)	00:00:24	0.00%	0.00%
28.	/a2.aspx	facebook.com	12 (0.10%)	1 (0.02%)	00:00:24	0.00%	0.00%
29.	/a2.aspx	google	13 (0.11%)	1 (0.02%)	00:00:23	0.00%	0.00%
30.	/a2.aspx	m.facebook.com	12 (0.10%)	1 (0.02%)	00:00:32	0.00%	0.00%
31.	/a2.aspx	physiospot.com	16 (0.14%)	2 (0.04%)	00:00:32	0.00%	6.25%
32.	/a2.aspx	t.co	142 (1.24%)	16 (0.31%)	00:00:35	100.00%	2.82%
33.	/a2.aspx	web.nhs.net	11 (0.10%)	1 (0.02%)	00:00:59	0.00%	0.00%
34.	/a3.aspx	(direct)	1,292 (11.29%)	125 (2.39%)	00:00:36	0.00%	1.08%
35.	/a3.aspx	csp.org.uk	50 (0.44%)	5 (0.10%)	00:00:32	0.00%	2.00%
36.	/a3.aspx	dub130.mail.live.com	12 (0.10%)	1 (0.02%)	00:00:33	0.00%	0.00%
37.	/a3.aspx	google	12 (0.10%)	1 (0.02%)	00:01:14	0.00%	0.00%
38.	/a3.aspx	m.facebook.com	2 (0.02%)	1 (0.02%)	00:00:02	0.00%	0.00%
39.	/a3.aspx	t.co	175 (1.53%)	17 (0.33%)	00:00:35	0.00%	1.71%
40.	/demograph.aspx	(direct)	1,433 (12.52%)	916 (17.53%)	00:00:57	57.14%	6.49%
41.	/demograph.aspx	csp.org.uk	48 (0.42%)	41 (0.78%)	00:01:16	0.00%	6.25%
42.	/demograph.aspx	exchange14.net.addenbrookes.nhs.uk	2 (0.02%)	2 (0.04%)	00:00:31	0.00%	0.00%
43.	/demograph.aspx	facebook.com	6 (0.05%)	3 (0.06%)	00:00:42	0.00%	16.67%
44.	/demograph.aspx	google	7 (0.06%)	5 (0.10%)	00:00:39	0.00%	14.29%
45.	/demograph.aspx	keele.ac.uk	6 (0.05%)	2 (0.04%)	00:00:16	0.00%	0.00%
46.	/demograph.aspx	m.facebook.com	15 (0.13%)	6 (0.11%)	00:01:12	0.00%	0.00%
47.	/demograph.aspx	physiospot.com	15 (0.13%)	8 (0.15%)	00:00:46	0.00%	6.67%
48.	/demograph.aspx	t.co	186 (1.62%)	133 (2.54%)	00:00:45	80.00%	10.75%
49.	/demograph.aspx	twitter.com	2 (0.02%)	2 (0.04%)	00:00:47	0.00%	50.00%
50.	/demograph.aspx	uk-mg42.mail.yahoo.com	3 (0.03%)	2 (0.04%)	00:01:30	0.00%	0.00%
51.	/Demograph.aspx	(direct)	17 (0.15%)	10 (0.19%)	00:00:47	0.00%	17.65%
52.	/Demograph.aspx	keele.ac.uk	2 (0.02%)	1 (0.02%)	00:13:53	0.00%	0.00%
53.	/FinalQs.aspx	(direct)	1,093 (9.55%)	312 (5.97%)	00:01:00	40.00%	2.01%
54.	/FinalQs.aspx	csp.org.uk	60 (0.52%)	16 (0.31%)	00:00:56	0.00%	1.67%
55.	/FinalQs.aspx	dub128.mail.live.com	3 (0.03%)	1 (0.02%)	00:00:49	0.00%	0.00%
56.	/FinalQs.aspx	dub130.mail.live.com	9 (0.08%)	2 (0.04%)	00:00:56	0.00%	11.11%
57.	/FinalQs.aspx	exchange14.net.addenbrookes.nhs.uk	5 (0.04%)	1 (0.02%)	00:00:12	0.00%	0.00%
58.	/FinalQs.aspx	facebook.com	4 (0.03%)	2 (0.04%)	00:02:51	0.00%	0.00%
59.	/FinalQs.aspx	google	7 (0.06%)	2 (0.04%)	00:00:35	0.00%	0.00%
60.	/FinalQs.aspx	m.facebook.com	3 (0.03%)	1 (0.02%)	00:02:02	0.00%	0.00%
61.	/FinalQs.aspx	physiospot.com	3 (0.03%)	1 (0.02%)	00:01:11	0.00%	0.00%
62.	/FinalQs.aspx	t.co	122 (1.07%)	34 (0.65%)	00:00:50	0.00%	1.64%

63.	/FinalQs.aspx	uk-mg42.mail.yahoo.com	3 (0.03%)	1 (0.02%)	00:01:49	0.00%	0.00%
64.	/FinalQs.aspx	web.nhs.net	3 (0.03%)	1 (0.02%)	00:02:10	0.00%	0.00%
65.	/FinalQs.aspx	webmail.vgregion.se	1 (0.01%)	1 (0.02%)	00:00:09	0.00%	0.00%
66.	/guid.aspx	(direct)	2 (0.02%)	2 (0.04%)	00:00:13	0.00%	0.00%
67.	/guid.aspx	t.co	2 (0.02%)	1 (0.02%)	00:00:38	0.00%	50.00%
68.	/guidend.aspx?sender=a1	(direct)	14 (0.12%)	9 (0.17%)	00:03:32	0.00%	50.00%
69.	/guidend.aspx?sender=a1	t.co	3 (0.03%)	1 (0.02%)	00:00:24	0.00%	33.33%
70.	/guidend.aspx?sender=a2	(direct)	14 (0.12%)	10 (0.19%)	00:00:25	0.00%	50.00%
71.	/guidend.aspx?sender=a2	t.co	2 (0.02%)	2 (0.04%)	00:00:44	0.00%	50.00%
72.	/guidend.aspx?sender=a3	(direct)	18 (0.16%)	11 (0.21%)	00:00:15	0.00%	55.56%
73.	/guidend.aspx?sender=a3	t.co	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
74.	/pre.aspx	(direct)	492 (4.30%)	435 (8.32%)	00:01:08	23.91%	12.20%
75.	/pre.aspx	csp.org.uk	24 (0.21%)	22 (0.42%)	00:01:21	50.00%	16.67%
76.	/pre.aspx	dk-mg5.mail.yahoo.com	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
77.	/pre.aspx	dub118.mail.live.com	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
78.	/pre.aspx	dub128.mail.live.com	1 (0.01%)	1 (0.02%)	00:00:54	0.00%	0.00%
79.	/pre.aspx	dub130.mail.live.com	2 (0.02%)	2 (0.04%)	00:01:33	0.00%	0.00%
80.	/pre.aspx	exchange14.net.addenbrookes.nhs.uk	1 (0.01%)	1 (0.02%)	00:00:16	0.00%	0.00%
81.	/pre.aspx	facebook.com	2 (0.02%)	2 (0.04%)	00:00:31	0.00%	0.00%
82.	/pre.aspx	google	3 (0.03%)	2 (0.04%)	00:01:14	0.00%	0.00%
83.	/pre.aspx	keele.ac.uk	3 (0.03%)	1 (0.02%)	00:00:04	0.00%	0.00%
84.	/pre.aspx	m.facebook.com	4 (0.03%)	2 (0.04%)	00:00:33	0.00%	0.00%
85.	/pre.aspx	outlook.office365.com	1 (0.01%)	1 (0.02%)	00:00:00	100.00%	100.00%
86.	/pre.aspx	physiospot.com	3 (0.03%)	3 (0.06%)	00:00:59	0.00%	0.00%
87.	/pre.aspx	t.co	55 (0.48%)	53 (1.01%)	00:00:51	100.00%	10.91%
88.	/pre.aspx	uk-mg42.mail.yahoo.com	3 (0.03%)	2 (0.04%)	00:00:55	100.00%	33.33%
89.	/pre.aspx	web.nhs.net	1 (0.01%)	1 (0.02%)	00:00:07	0.00%	0.00%
90.	/pre.aspx	webmail.vgregion.se	5 (0.04%)	1 (0.02%)	00:00:09	0.00%	20.00%
91.	/thankyou.aspx	(direct)	301 (2.63%)	299 (5.72%)	00:02:14	100.00%	93.02%
92.	/thankyou.aspx	csp.org.uk	20 (0.17%)	18 (0.34%)	00:00:17	100.00%	85.00%
93.	/thankyou.aspx	dub128.mail.live.com	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
94.	/thankyou.aspx	dub130.mail.live.com	2 (0.02%)	2 (0.04%)	00:00:07	0.00%	50.00%
95.	/thankyou.aspx	exchange14.net.addenbrookes.nhs.uk	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
96.	/thankyou.aspx	facebook.com	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
97.	/thankyou.aspx	google	3 (0.03%)	2 (0.04%)	00:06:24	0.00%	66.67%
98.	/thankyou.aspx	m.facebook.com	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
99.	/thankyou.aspx	physiospot.com	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
100.	/thankyou.aspx	t.co	33 (0.29%)	33 (0.63%)	00:11:34	0.00%	93.94%

101.	/thankyou.aspx	uk-mg42.mail.yahoo.com	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%
102.	/thankyou.aspx	web.nhs.net	1 (0.01%)	1 (0.02%)	00:00:00	0.00%	100.00%

Rows 1 - 102 of 102

Appendix 11: Ethical approval application for conjoint analysis study

ETHICAL REVIEW PANEL
Application Form (Staff and PGR Students)

- To be completed for every research project involving human participants/subjects;
- The form must be authorised by your Research Institute Director / (or for applicants who are members of RI Social Sciences the application can be signed off by your Research Centre Head)/Supervisor /Head of School as appropriate
- Both an electronic copy & hard copy of all documentation must be provided.

APPROVAL MUST BE OBTAINED BEFORE potential participants are approached to take part in any research.

Information regarding the completion of the ethical review panel application form:
Section A – To be completed by all applicants.
Section B – To be completed by applicants who have already obtained Ethics Approval from a separate committee.
Section C – To be completed by applicants requiring approval from a University Ethical Review Panel
Section D – To be completed by all applicants.

Further information regarding the completion of the application can be found in Section E (at the end of this document)

SECTION A (to be completed by all applicants)

Project Title:	Musculoskeletal Shoulder Disorders: Which Treatment for Whom?
Proposed start date:	17th March 2015
Proposed end date for 'field work' (eg interviews):	31th October 2015
Name of Researcher (applicant):	Cliona McRobert
Status:	**POSTGRADUATE RESEARCH STUDENT**
Research Institute or School if not in an Research Institute	Primary Care Sciences
Keele Email address:	c.j.mcrobert@keele.ac.uk
Correspondence address:	Arthritis Research UK Primary Care Centre Primary Care Sciences Keele University Staffordshire, ST5 5BG
Keele Telephone number:	01782 734889

SECTION B (to be completed by applicants who have already obtained ethics approval from a separate committee)

Has your project already been approved by an ethics committee? (for example, an NHS research ethics committee) If **YES** the following documentation should be sent directly to the Chair of the University Research Ethics Committee, C/O Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306		NO
A completed and signed hard copy of this application form (please complete Sections A, B and D) and an electronic copy should also be e-mailed to n.leighton@keele.ac.uk	Signed hard copy: Electronic copy:	N/A N/A
Evidence of prior ethics approval from the hosting institution.	Copy of approval document:	N/A

SECTION C **(to be completed by applicants who have NOT already obtained ethics approval from a separate committee)**

If your project requires approval by a University Ethical Review Panel (ERP).

The following documentation should be forwarded to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, telephone 01782 733306. An electronic copy of the application form and all necessary documentation should also be e-mailed to uso.erps@keele.ac.uk An application cannot be considered until a signed copy is received and accompanied by an electronic copy.

A completed and signed hard copy of this application form (please complete Sections A, C and D) and an electronic copy should also be e-mailed to uso.erps@keele.ac.uk	Signed copy attached: Electronic copy:	YES YES
A hard copy of the summary document **attached** to this form, **NO MORE THAN** two sides of A4 It may help the review of your project if you include a diagram to clearly explain the project (eg what activities will undertaken, by whom and when) An electronic copy of the summary document **Please ensure that the version number and date is clearly stated in footer of the summary document (approval may be delayed if these details are not included)**		YES YES
And, if (and only if) they are appropriate given the study's design and approaches;		
A letter of invitation for participants **Please ensure that the version number and date is clearly stated in the footer of the letter (approval may be delayed if these details are not included)**		YES (including combined participant information sheet)
An information sheet which should normally include the following sections: ○ Why the participant has been chosen; ○ What will happen to participants if they take part ○ A discussion of the possible disadvantages, risks and benefits of taking part ○ The procedures for ensuring confidentially and anonymity (if appropriate) ○ The proposed use of the research findings ○ Contact details of the principal investigator plus details of additional support agencies (if Necessary) ○ **Version number and date is clearly stated in the footer of the information sheet (approval may be delayed if these details are not included)** A template for a participant information sheet is available from the Research & Enterprise Services website via the following link http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/		YES (Combined with invitation letter)
A copy of the participant consent form/s; **Please ensure that the version number and date is clearly stated in the footer of the consent form (approval may be delayed if these details are not included)** Templates for consent forms are available from the Research & Enterprise Services website via the following link http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/ Health professionals will decide if they wish to participate after reading the combined invitation letter and participant information sheet. Consent to participate is implied by clicking next on the first page of the online survey and proceeding to provide responses to the questions. PLEASE NOTE: there is only one online survey to be completed for this study.		NO
Copies of any questionnaire, interview schedules or topic guides. **Please ensure that the version number and date is clearly stated in the footer of these documents (approval may be delayed if these details are not included)**		YES

(PARTICIPANTS' CONSENTS)

1. Will the researchers inform participants of all aspects of the research that might reasonably be expected to influence willingness to participate and in particular, any negative consequences that might occur? **If YES**, please give details: Participants will be provided with a combined letter of invitation and participant information sheet detailing why they have been chosen to participate, the purpose of the study, anticipated length of time taken to complete the survey, what is expected of them, the possible disadvantages of taking part and their right to withdraw from the survey at any point. Other than the use of their time, no negative consequences or harm to respondents associated with taking part are anticipated. The survey does not have an actual 'escape survey' button but respondents may choose to close the internet browser window at any point in order to escape the survey. At the end of the data collection period, in the event of a respondent not providing responses to the 12 patient cases, this will be understood as having dropped out from the study. As the planned statistical analysis relies upon complete data i.e., responses to all 12 patient cases, only data from respondents who have provided responses to all 12 patient cases will be analysed. The number of participants starting the survey but dropping out at any point will be recorded. **If NO**, please explain:	YES
2. Will all participants be provided with a written information sheet and be provided with an opportunity to provide (or withhold) written consent? **If YES**, please ensure that these documents are attached (see above). **If NO**, please explain why written consent &/or information is not appropriate for this study. This study is an online survey. The combined participant invitation and information sheet will be available via a hyperlink on the first page of the online survey. Page 1 of the survey states that by ticking the consent box the respondent indicates that they have read the combined participant invite and information sheet and provide consent to take part in the survey.	NO
3. Is consent being sought for the dataset collected to be used for future research projects? Results from this survey will inform the design of a future individual patient data analysis study which seeks to assess the validity of the result of this survey. The actual data from this survey will not be used in this future study. **4. What are the exclusion/inclusion criteria for this study (i.e. who will be allowed to / not allowed to participate)?** **Inclusion:** Health or medical practitioners, clinical academics or academics (including but not limited to physiotherapists, general practitioners (GPs), rheumatologists and orthopaedic surgeons) who: (i) Clinically manage or have a clinical or research interest in patients with musculoskeletal shoulder disorders as part of their normal clinical practice (ii) Can read and write English **Exclusion:** Individuals who: (i) Are not practicing health or medical practitioners, clinical academics or academics (ii) Have no clinical or academic interest in musculoskeletal shoulder disorders (iii) Do not read or write English **5. Please explain briefly (and in 'lay' terms) why you plan to use these particular criteria?** *The purpose of the survey is to assess how clinicians from across the world make treatment decisions in the care for patients with shoulder pain. Clinicians who do not treat shoulder disorders or unqualified individuals do not hold the necessary qualification, experience or knowledge will not be able to provide data for this survey.*	NO
6. Will people who are vulnerable be allowed to take part in this study? For these purposes, vulnerable participants are those whose abilities to protect their own interests are impaired or reduced in comparison to the population as a whole. Vulnerability may arise from personal characteristics (such as mental or physical impairment) or from social context and disadvantage (e.g. lack of power, education,	NO

or resources). Prospective participants, who are at high risk of consenting under duress, or as a result of manipulation or coercion, should also be considered as vulnerable. All children and adults who lack mental capacity are presumed to be vulnerable. **If NO**, please outline the rationale for excluding them: *Participants will be health professionals and/or academics with a special interest in shoulder disorders.* **If YES**, what special arrangements (if any) are in place to protect vulnerable participants' interests?	
7. Does the research activity proposed require a Disclosure & Barring Scheme (DBS) disclosure? (information concerning activities which require DBS checks are required can be accessed via https://www.gov.uk/government/publications/dbs-check-eligible-positions-guidance and http://www.keele.ac.uk/hr/policiesandprocedures/crbsafeguarding/ If you are unsure whether a DBS disclosure is required please contact Human Resources or Nicola Leighton prior to submission of this application form. If you answer YES please complete the relevant section below. If you answer no please go to question 8.	NO
STAFF ONLY **7a** Have you (and other individuals who will be working on the research project) had a DBS disclosure initiated by Keele University?	N/A
7b If you have answered **YES to question 7a** please contact Human Resources to obtain a confirmation note indicating that a DBS disclosure has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?	N/A
If you have answered **NO to question 7a** please contact Human Resources immediately to arrange for a DBS disclosure to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Human Resources indicating that a DBS disclosure has been undertaken and is satisfactory. Has Human Resources been contacted about this?	N/A
HOME/EU STUDENTS ONLY 7c Have you (and other individuals who will be working on the research project) had a DBS Disclosure (or equivalent) initiated by Keele University?	NO
7d If you have answered **YES to question 7c** please contact the Admissions Officer, Admissions to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form?	N/A
If you have answered **NO to question 7c** please contact the Admissions Officer immediately to arrange for a DBS disclosure (or equivalent) to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Nicola Leighton indicating that a DBS disclosure has been undertaken and is satisfactory. I confirm the Admissions Officer has been contacted and a DBS disclosure (or equivalent) has been initiated. *I have contacted the Home/EU Admissions Officer, and was informed that a CRB disclosure is not required for this project, as I am not dealing with patients, minors or vulnerable adults but healthcare practitioners only*	
INTERNATIONALSTUDENTS ONLY Please contact Nicola Leighton on 01782 733306 or e-mail n.leighton@keele.ac.uk before completing this section	
7e Have you (and other individuals who will be working on the research project) had a DBS	

Disclosure (or equivalent) initiated by Keele University? 7f If you have answered **YES to question 7e** please contact the appropriate person (as advised by Nicola Leighton) to obtain a confirmation note indicating that a DBS disclosure (or equivalent) has been previously initiated by Keele and that it was satisfactory. Is the confirmation note attached to this form. If you have answered **NO to question 7e** please contact the appropriate person (as advised by Nicola Leighton) immediately to arrange for a DBS disclosure (or equivalent) to be applied for. You will still be able to apply for ethical approval in parallel to applying for a DBS disclosure. However, your project will not be approved by the ERP until you have forwarded the confirmation note from Human Resources indicating that DBS disclosure has been undertaken and is satisfactory. I confirm the relevant person has been contacted and a DBS disclosure (or equivalent) has been initiated.	
8. Will the study involve participants who are unable to give valid (informed) consent (e.g. children and adults lacking mental capacity)? **If YES**, what procedures will be in place to ensure that informed consent is obtained, where appropriate, from third parties (e.g. parents or carers)? And what procedures will be in place (if any) to give the participants an opportunity to have their objections recognised and respected?	NO
9. Does the investigation involve observing participants unawares? **If YES**, what efforts will be made to respect their privacy, values and well-being?	NO
10. Will the confidentiality of participants be maintained? **If NOT**, please give rationale: **If YES**, how? Information provided by respondents (up to 260 respondents) during the course of the research will be kept strictly confidential. Respondents will not be asked to provide information that could be used to identify them. Demographic data collected will be limited to profession, postgraduate training specific to musculoskeletal shoulder disorders, country of clinical practice, percentage of clinical time funded by government/state and privately funded, and frequency of referral/recommendation to three commonly used treatments. This survey will be hosted by Keele University on a secure password protected and backed up server. Once the sample size requirements have been met and data collection has been completed, the link to the survey will be disabled and the survey will no longer be available for access online. All data will be maintained in an anonymous form that cannot be linked with any respondent. A separate password protected database (accessible only by Tim Smale (software programmer) and the research team comprising of the lead researcher, lead researcher's three academic supervisors and the statistical advisor on the project) will be maintained for respondents who email the researcher to indicate that they would like to receive notification of results. Individuals populating this database will receive two sets of results, results of the survey and results of a further study that will assess the validity of the results. This database will be destroyed after the second results email has been sent. Data will be stored on the secure University server, which is password protected with only designated members of the research team and survey development team authorised to access it. All research staff work to robust data security procedures and have explicit duties of confidentiality, equivalent to the duty placed on NHS staff, written into their employment contracts, in line with the Data Protection Act (1998) and the NHS Research Governance Framework.	YES
11. Will participants require any support to take part in the research (eg. disability support, interpreter)? **If YES**, what sort of support is required and how will it be delivered?	NO

(PROCEDURES)

12. Does the research involve people being investigated for a condition or disorder which has received medical, psychiatric, clinical psychological or similar attention? **If YES**, please give details:	NO
13. Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? **If YES**, please give details and justify:	NO
14. Will blood or other bodily fluids/tissues (including hair, nails and sebum) be obtained from participants? **If YES**, please give details and justify:	NO
15. Is pain or more than mild discomfort likely to result from the study? **If YES**, please give details and justify:	NO

(RESEARCH PROCESS)

16. Will participants receive any reimbursements or other payments **If YES**, please give details:	NO
17. Does the research involve the analysis of data participants will not realise would be used by you for research purposes (e.g. confidential criminal, medical or financial records)? **If YES**, please give rationale:	NO
18. Does the research involve the possible disclosure of confidential information to other participants (e.g. in focus groups)? **If YES**, please explain how this will be handled:	NO
19. Will the researchers de-brief participants to ensure that they understand the nature of the research and to monitor possible misconceptions or negative effects? **IF YES**, how will this be done? **If NO**, please explain why not: As participants cannot be identified, they will not be individually de-briefed.	NO
20. Are there any <u>other</u> ethical issues that you think might be raised by the research? **If YES**, please give details:	NO

(Health & Safety)

21. Does the project have any health & safety implications for the researcher? **If YES**, please outline the arrangements which are in place to manage these risks:	NO

FOR STAFF ONLY **22. Does your research involve travel overseas?** **If YES,** Have you consulted the Foreign and Commonwealth Office website for guidance/travel advice? http://www.fco.gov.uk/en/travel-and-living-abroad/ Have you completed and submitted the risk assessment form? Available from http://www.keele.ac.uk/finance/insurance/travelinsurance/travellingoverseas-policyriskassessment/	N/A N/A N/A
FOR STUDENTS ONLY **23. Will any research take place outside the UK?** *This is an online survey that will be completed by respondents internationally. The researcher does not need to travel in order to obtain the data.* **If YES** **For home students** - have you consulted the Foreign and Commonwealth Office website for guidance/travel advice? http://www.fco.gov.uk/en/travel-and-living-abroad/ **For international students - h**ave you also sought advice/guidance from the Foreign Office (or equivalent body) of your country? **For all students -** will you be visiting any areas for which particular risks have been identified or for which the advice given is not to travel to this area? **If YES** (a) Please give details (b) Please outline the arrangements in place to manage these risks. **24. What insurance arrangements are in place?** (Please contact Alan Slater on 01782 733525 to ascertain if you will be covered by University Insurance)	NO N/A N/A N/A N/A

SECTION D (to be completed by all applicants)

Please complete the checklist below to indicate the version number and date of any supporting documents included with this application.

Document(s)	Version Number	Date
Summary document	**V2.0**	**02.02.15**
Combined participant invitation letter and information sheet	**V2.0**	**30.01.15**
Questionnaire(s) (paper copy)	**V2.0**	**02.02.15**
Consent Form(s)	**N/A**	**N/A**
Consent Form(s) for use of quotes	**N/A**	**N/A**
Interview Topic Guide(s)	**N/A**	**N/A**

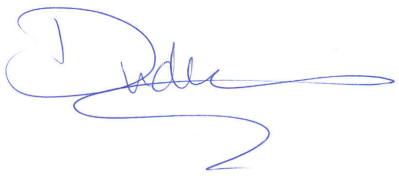
Signatures

Principal Investigator / Research Student:

I understand that I must comply with the University's regulations and other applicable codes of ethics at all times.

Cliona McRobert
Research Student

02.02.15



Professor Danielle van der Windt
Lead supervisor

02.02.15

Signatures

The following permissions must be obtained before this form is submitted:

- for **staff who are members of a research institute**, the signature of your Research Institute Director (or, for RI Social Sciences, Research Centre Head);
- for **staff who are NOT members of a research institute**, the signature of your Head of School (of, if not in a School, other line manager)
- for **postgraduate research students**, the signature of your lead supervisor.

I have read this application and confirm that:-

- The academic and/or scientific quality of the application is satisfactory.
- Arrangements are in place for the management and governance of this project

……..
Research Institute Director / Research Centre Head / Supervisor / Head of School / Other Line Manager

……
Date

*please delete as appropriate

Please ensure when submitting your application that you have provided a hard copy and e-mailed a copy of all the documentation to Hannah Reidy, ERP Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, Keele, e-mail uso.erps@keele.ac.uk

Applicants who have already obtained ethics approval from a separate committee should forward documentation to Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306.

Applications which require approval by an University Ethical Review Panel should forward documentation to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail uso.erps@keele.ac.uk, telephone 01782 733306.

Please note that it is your responsibility to follow the University's Code of good research practice http://www.keele.ac.uk/researchsupport/researchgovernance/ and any relevant academic or professional guidelines in the conduct of your study. **This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data.** Any significant change in the question, design or conduct over the course of the research should be notified to the Research Institute Director/Supervisor and may require a new application for ethics approval.

This form was developed from the Ethics application forms used within Humanities and Social Sciences with kind permission from the HUMSS Research Ethics Committee.

SECTION E

Information regarding the completion of the ethical review panel application form
Section A – To be completed by all applicants.
Section B – To be completed by applicants who have already obtained Ethics Approval from a separate committee.
Section C – To be completed by applicants requiring approval from a University Ethical Review Panel
Section D – To be completed by all applicants.

PLEASE NOTE: Ethics Approval for Research Projects
All projects involving human research participants/subjects and/or data about identifiable individuals, need to be approved by an ethics committee before the fieldwork for projects can commence. The University has established Ethical Review Panels to review proposed research projects to be undertaken by staff and postgraduate research students. The information below provides more details about the role of these panels and the documents that need to be submitted to support the review process.

- -

1. If your project has already been approved by a recognised ethics committee (for example, an NHS research ethics committee), the following documentation should be sent directly to the Chair of the University Research Ethics Committee, C/o Nicola Leighton, University Research Ethics Committee Administrator, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail n.leighton@keele.ac.uk, telephone 01782 733306.
    - A completed and signed ethical review application form (Sections A, B and D) accompanied by an electronic copy;
    - Evidence of prior ethics approval from the hosting institution.

2. If your project requires approval by a University Ethical Review Panel, the following documentation should be sent directly to Nicola Leighton, Research & Enterprise Services, Dorothy Hodgkin Building, e-mail uso.erps@keele.ac.uk, telephone 01782 733306
    - A completed and signed ethical review application form (Sections A, C and D) accompanied by an electronic copy of the application form and relevant documentation. An application cannot be considered until a signed copy is received and also by an electronic copy;
    - A summary document, **NO MORE THAN** two sides of A4 paper;
    And, if they are applicable given the study's design and approaches,
    - A letter of invitation for participants;
    - An information sheet which should normally include following sections: invitation paragraph; the purpose of the study; why the participant has been chosen; what will happen to participants if they take part; a discussion of the possible disadvantages, risks and benefits of taking part; the procedures for ensuring confidentiality and anonymity, if any; the proposed use of the research findings; and contact details of the principal investigator plus details of additional support agencies (if necessary);
    - A copy of the participant consent form;
    - Copies of any questionnaire, interview schedules or topic guides.

3. The review will be undertaken at the next available ethical review panel meeting. Please access http://www.keele.ac.uk/researchsupport/researchgovernance/researchethics/ for a list of meeting dates and submission deadlines. Following the review process you will be informed of the panel's decision which will be either:
    - Study approved;
    - Study approved subject to clarification of issues, modification of design or provision of additional information which will be itemised in the letter of response;
    - Study rejected with supporting reasons.

4. If ethical approval is not granted, applicants have the right of appeal to the University's Research Ethics Committee.

5. Correspondence informing applicants of the outcome of the panel's decision will be copied to the relevant Research Administrators. It is the responsibility of applicants to keep their respective Institutes informed of their research activities for the purposes of research governance.

Participant Invitation & Information Sheet

Study Title: Musculoskeletal Shoulder Disorders Which Treatment for Whom?

2nd Feb. 2015

Dear Professional Colleague,

I invite you to take part in an online international survey on the topic: clinical management of musculoskeletal shoulder disorders. This survey may be accessed via the web link www.keele.ac.uk/shoulder. My name is Cliona McRobert, I am a musculoskeletal physiotherapist undertaking a PhD at the Arthritis Research UK Primary Care Centre, Keele University (UK), where my PhD is funded by the National Institute of Health Research (NIHR) School for Primary Care Research. I am leading this research in a research team with Prof Danielle van der Windt (Professor in Primary Care Epidemiology), Prof Elaine Hay (Professor of Community Rheumatology) and Dr Jonathan Hill (Arthritis Research UK Senior Lecturer), Dr John Belcher (Senior Lecturer in Biostatistics), Mr Tim Smale (E-Learning Fellow) of Keele University and Prof John F.P. Bridges (Associate Professor in the Departments of Health Policy and Management and International Health, Johns Hopkins Bloomberg School of Public Health, US).

As you know, musculoskeletal shoulder disorders are common and cause considerable reductions in social function, work ability and quality of life. Achieving consistently successful outcomes for patients with shoulder disorders has proven difficult to achieve. Although some characteristics predicting who will improve or not improve over time have already been identified, currently very little is known about which patients are likely to respond to commonly used treatments such as: (i) prescription of pain medication and advice, (ii) physiotherapy treatment or (iii) steroid injection and advice. This research will develop the foundation for a model of shoulder 'stratified care': a treatment targeting method that enables patients to be provided with specific treatments that they are most likely to respond to.

We conducted a systematic review, which identified the clinical factors already known to predict response to these specific treatments i.e. 'treatment moderators'. Our research with UK-based clinical experts highlighted additional clinical characteristics considered by shoulder clinicians when identifying patients likely to respond to these treatments. We do not currently know how or if these clinical characteristics combine to form profiles of likely best responders to these three treatments. This online international survey of clinicians is based on a method called conjoint analysis. Conjoint analysis allows us, the research team, to tap into clinical expertise by asking you to tell us how you would deal with hypothetical clinical scenarios. This enables us to analyse your responses using statistical techniques to identify the international clinical impression of likely best responders to each of the three treatments.

I invite you, a clinician working with musculoskeletal shoulder disorders, to be involved with this research via the web link www.keele.ac.uk/shoulder. Your involvement would require completing a brief and simple online survey (approximately 20 minutes). Firstly, you will be required to tell us a little about yourself, including your profession, number of years of experience, country of clinical practice, funder of your clinical role, how often you treat shoulders and how often you refer to common treatments. Secondly, you will be required to indicate a treatment

recommendation for 12 hypothetical patients and finally answer some short questions about how easy or difficult you found answering the clinical case questions. Your responses will enable us to understand more about how clinicians make treatment decisions for patients with shoulder disorders. We do not anticipate any harm or risk to you by taking part in this survey.

Consent to take part is indicated by ticking a box on the first page next to the statement 'I have read the information sheet, understand the instructions and consent to taking part in this survey' and by submitting responses during the survey. After ticking the consent box and clicking next on the first page, you will be shown your unique identifier number. This number is unique to you and relates to the responses provided by you during the survey. You will be prompted to write this number down and store it in a safe place and/or take a screen shot. You are free to withdraw from the survey at any time. You may withdraw from the study either by not ticking the consent box or at any time during the survey by closing the web browser. Should you choose to exit the survey before completing all questions, your responses will be excluded from the planned statistical analyses. Should you wish to withdraw your consent after the survey has been completed, you may contact the research team to indicate this quoting your unique identifier number. Your responses will be then excluded from the analyses.

All responses will be strictly confidential and it will not be possible to identify you from the information that you will be asked to provide. Your responses will be stored on a password-protected database on a secure server at Keele University accessible only by members of the research team. Your responses will be combined with responses from others participants and will be analysed using statistical techniques to answer the research questions. At the end of the survey, you will be given an opportunity to indicate via email to the research team that you would like to receive notification of results of the survey. If you indicate that you would like to be contacted with results, the research team will contact you via email as soon as survey results are available and again when the output of the survey has been tested in a further validation study. The research team will store your responses in a separate password-protected database on a secure server at Keele University. This email database will be destroyed after the second results email has been sent. All anonymised electronic data will be stored securely for a minimum of five years and according to Keele University regulations.

Contact for further information. If you require any further information regarding this study please contact Cliona McRobert by email on c.j.mcrobert@keele.ac.uk.

If you experience any problems completing this survey or have any concerns about any aspect of the study, you may wish to speak to the researchers who will do their best to answer your questions. You can contact Cliona McRobert at c.j.mcrobert@keele.ac.uk or via telephone on 01782 734889 or Danielle van der Windt on d.van.der.windt@keele.ac.uk or via telephone on 01782 734830. Alternatively, if you do not wish to contact the researchers you may contact Nicola Leighton, Research Governance Officer on n.leighton@keele.ac.uk. If you remain unhappy about the research and/or wish to raise a complaint about any aspect of your experience whilst taking part in the study please write to Nicola Leighton who is the University's contact for complaints regarding research at n.leighton@keele.ac.uk,

or at the following address: Nicola Leighton, Research Governance Officer, Research & Enterprise Services, Innovation Centre 1, Keele University, ST5 5BG.

Best wishes and kind regards,

Cliona McRobert, Principal Investigator; Danielle van der Windt, Academic Supervisor
e-mail: c.j.mcrobert@keele.ac.uk or telephone: 01782 734889
e-mail: d.van.der.windt@keele.ac.uk or telephone: 01782 734830

Arthritis Research UK | primary care centre

Research Institute for Primary Care and Health Sciences
+44 (0)1782 733905
Fax: +44 (0)1782 733911
www.keele.ac.uk/pchs

Keele University, Staffordshire ST5 5BG, UK
www.keele.ac.uk +44 (0)1782 732000

Appendix 12: Ethical approval for conjoint analysis study

Keele University

RESEARCH AND ENTERPRISE SERVICES

Ref: ERP324

12th February 2015

Cliona McRobert
Arthritis Research UK Primary Care Centre
Keele University

Dear Cliona,

Re: Musculoskeletal Shoulder Disorders: Which treatment for whom?

Thank you for submitting your application for review. I am pleased to inform you that your application has been approved by the Ethics Review Panel.

The following documents have been reviewed and approved by the panel as follows:

Document	Version	Date
Summary Document	2	02/02/2015
Letter of Invitation and Information Sheet Combined	2	30/01/2015
Questionnaires	2	02/02/2015

If the fieldwork goes beyond the date stated in your application, you must notify the Ethical Review Panel via the ERP administrator at uso.erps@keele.ac.uk stating ERP3 in the subject line of the e-mail.

If there are any other amendments to your study you must submit an 'application to amend study' form to the ERP administrator stating ERP3 in the subject line of the e-mail. This form is available via http://www.keele.ac.uk/researchsupport/researchethics/

If you have any queries, please do not hesitate to contact me via the ERP administrator on uso.erps@keele.ac.uk stating ERP3 in the subject line of the e-mail.

Yours sincerely

pp

Val Ball
Vice Chair – Ethical Review Panel

CC RI Manager

Appendix 13: Social Media recruitment proforma

Social Media Recruitment Strategy Proforma

Study Title				
Study Live Period	Beginning		Ending	
Pre-launch activity plan				
Sample Frame - Inclusion criteria - Exclusion criteria				
Method of identification of key individuals/organisations - Social Media Analytics Software (e.g., FollowerWonk or similar) - Key posting times - Key individuals - Key groups/organisations				
Social media post wording: - Twitter - Facebook - LinkedIn - Google+ - Other				
Visual resources: - Photograph of study team/lead researcher - QR code - Study logo (for use as email banner, social media) - Other				
Final Social Media Recruitment Schedule - Daily plan - Weekly plan - Monthly plan - Automated scheduling system (e.g., Hootsuite or similar) - Review/Iteration plan				

Additional study invitation dissemination plans: - Newsletters/Blogs - Email - Postal - Noticeboards - Other	