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Predictors of outcome in psychological therapy for co-morbid long-term health conditions and common mental health problems: an observation cohort study

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Abstract

Co-morbid long-term conditions (LTCs) and common mental health problems are highly prevalent and continue to be associated with poorer health and social outcomes. Recent policy frameworks have endorsed the need to expand mental health provision for patients with LTCs by providing greater access to psychological therapies in Talking Therapies services. However, current evidence suggests patients with long-term health problems accessing psychological therapies experience poorer outcomes than patients without a LTC. The reasons for this are yet to be fully established, but there are suggestions that a number of patient, service level, and treatment factors may be involved.

Accordingly, this study aimed to investigate the influence pre-treatment patient characteristics, the organisation delivery of psychological therapies, and early improvement in treatment have on end of treatment outcomes for people with co-occurring physical and common mental health problems.

Using a 2-year retrospective observational cohort design, anonymised data from 583 patients accessing a Talking Therapies services were analysed using unadjusted binary logistic regression models. Several pre-treatment demographic and clinical patient characteristics, stepped-care factors (type of treatment and number of sessions), and early reliable improvement (ERI) in treatment were used as predictor variables to establish their relationship with reliable recovery.

The results found 54% of patients achieved reliable recovery which is above the national benchmark of 50%. Several predictors were found to influence end of treatment outcomes. Multimorbidity, the number of previous treatment episodes, and the severity of baseline depression, anxiety and functional impairment, were found to *negatively influence reliable recovery. Age, employment status, the number of treatment sessions provided, and early reliable improvement (ERI), had a positive association with reliable recovery.*

Unlike previous research into this area, the results found patients with LTCs achieved comparable outcomes to patients without LTCs. Most notably, early reliable improvement was found to have the most significant positive association with reliable recovery. This has clinical implications as it suggests a focus on outcome monitoring in the early phase of treatment may have an important role in identifying patients who are likely to achieve recovery, and conversely, those who may not be on track to achieve positive treatment outcomes. Thus, it provides the opportunity to adapt treatment early to increase the chances of improved end of treatment outcomes.

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Acknowledgements

'A journey of a thousand miles begins with a single step' – Laozi

Coming to the end of this thesis has felt like a journey of 1000 miles, but at each step there have been a number of people that require acknowledgement, whether that be through their support, motivation, or insightful direction and knowledge.

Firstly, I would like to thank my supervisors, Dr A. Pooler and Professor J. Sim. Both have not only provided me with guidance throughout my research endeavour, but have consistently encouraged, shared their wisdom, and believed in me, keeping me on track to achieve my goal even when the pressures of full-time clinical practice and life events have challenged the progress of the study.

I would also like to thank three clinical colleagues. Firstly, Louisa Pickford and Dr Mark Kenwright, who have both provided me with the support and encouragement to follow my dream to complete a Doctorate, and secondly, Dr C. Fieldhouse, who has consistently shown a belief in me as we embarked on this academic journey together. I would also like to share my heartfelt gratitude to a number of clinical colleagues, the names of whom would be too long to list here, who have in various different ways shown me support throughout my clinical and academic life.

Finally, to the most important people in my life, my wife Katy, and my children, Kitty, Nell, and Isaac. Without you all I am in no doubt that I would not have achieved my goal. My wife's continuous encouragement, patience, and occasional direct motivational speeches, alongside my children's idiosyncratic acknowledgments of the challenge this has been has driven me on throughout. So, it is only fitting that I share and dedicate this achievement to them.

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Abbreviations	Full term
ACT	Acceptance & commitment therapy
AMED	Allied and Complimentary Medicine Database
ANOVA	Analysis of variance
BNI	British Nursing Index
CBT	Cognitive behavioural therapy
CFS	Chronic fatigue syndrome
CHD	Coronary heart disease
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COPD	Chronic obstructive pulmonary disease
CS-SRM	Common-sense self-regulatory model
CT	Cognitive therapy
DoH	Department of Health
EBM	Evidence-based medicine
ED	Eating disorder
EMBASE	Excerpta Medica Database
ERI	Early reliable improvement
GAD-7	Generalised anxiety disorder questionnaire
GEL	Good enough level
GMM	Growth mixture models
GSH	Guided self-help
HBE	Health Business Elite
HIT	High intensity treatment
HMIC	Health Management and Policy Database
IAPT	Improving Access to Psychological Therapies
IBS	Irritable bowel syndrome
I-CBT	Internet delivered cognitive behavioural therapy
LIT	Low intensity treatment
LTC	Long-term condition
MDD	Major depressive disorder
NICE	National Institute for Health & Care Excellence
OCD	Obsessive compulsive disorder
PBE	Practice-based evidence

PHQ-9	Patient health questionnaire
PICO	Population, intervention, comparison, and outcomes
PRISMA	Preferred reporting items for systematic reviews & meta-analysis
PROMs	Patient reported outcome measures
PTSD	Post-traumatic stress disorder
RCSI	Reliable & clinically significant improvement
RCT	Randomised controlled trial
TPB	Theory of planned behaviour
TRA	Theory of reasoned action
TT	Talking Therapies
WASA	Work & social adjustment scale

Chapter 1

Introduction

Chapter 1 - Introduction

1.1 - *Introduction*

The following study aimed to investigate predictors of outcomes in psychological therapy for people experiencing co-morbid long-term health conditions and common mental health problems, namely anxiety disorders and depression. In doing so it considers the extent to which pre-treatment patient characteristics, a ‘stepped-care’ model of delivering psychological therapy, and early improvements in therapy influence end of treatment psychological therapy outcomes for people with physical and mental health problems.

By way of an introduction, this chapter commences with a description of how the initial idea of the study emerged against the backdrop of a model of clinical science for psychological therapies. Subsequently, the chapter presents a broader background to the study drawing on literature through which its specific focus was formed. In the final part of the chapter, a summary of each subsequent chapter is presented.

1.2 - *From clinical curiosity to research endeavour*

Having worked clinically for over a decade as a cognitive behavioural psychotherapist, I have been privileged to be part of the increasing prominence of psychological therapies in the treatment of emotionally related problems. Central to this dramatic development has been an approach to psychological therapies (e.g. cognitive behavioural therapy) underpinned by a model of clinical science; a model fundamentally driven by the relationship between clinical practice, theory, and research, in which clinicians adopt the role of scientist-practitioners to make clinical decisions that are both theoretically driven and empirically based (Hoffman, 2013; Salkovskis, 2002).

As illustrated in Figure 1.0, at the heart of this cyclical model is the role of clinical practice which provides the starting point to how patients' psychological problems can be understood. By taking time to talk, observe, and listen to patient problems, clinical hypotheses can be formed about how a problem has developed and is maintained, what treatment interventions may be effective, and what factors may be associated with treatment failures. In doing so, clinical practice provides the fundamental basis to stimulate the advancement of theory and research to aid the development of innovative psychological treatments (Clark, 2004; Salkovskis, 2002).

Figure 1.0 – Model of clinical science underpinning psychological therapies (adapted from Salkovskis, 2002)

Numerous examples of this model of clinical science in action underpin the development of psychological therapies. Take Clark's (1986) seminal work on panic disorder. Up until this point, the effectiveness of psychological therapies for panic disorder was limited. However, Clark (1986) noted from observations in clinical practice that patients with panic disorder appeared to catastrophically misinterpret the symptoms of panic as meaning, for example, 'I am having a heart attack'. Subsequently, these types of appraisals were found to lead patients to use a range of safety behaviours (e.g. reduced activity) to protect themselves from what was perceived as an impending catastrophe resulting in panic disorder problems persisting. This clinical observation shaped the cognitive theory of panic disorder (Clark, 1986) and led to a host of experimental and outcome research endeavours aimed at developing a range of efficacious treatment interventions (Clark et al., 1997; Craske and Freed, 1995). As a result, not only did these advances inform national clinical guidance (NICE, 2004), but also stimulated research into their effectiveness in real world clinical practice through practice-based research (Addis et al., 2004).

It is against this backdrop of clinical science that the idea for this study emerged. As a practising cognitive behavioural therapist working in a Talking Therapies service (formerly known as Improving Access to Psychological therapies services (IAPT)) treating anxiety disorders and depression, it became clear overtime that the level of complexity in patients accessing psychological therapy was increasing. Indeed, the co-occurrence of common mental health problems was a frequent observation and arguably reflected the high rates of co-morbidity of anxiety and depression in health care settings (Kessler et al., 2007). Typically, this required treatment to not only focus on the primary presenting common mental health problem, but also on transdiagnostic processes evident across a range of psychological problems such as worry, rumination, and avoidance (Harvey et al., 2004). Thus, in essence, requiring treatment to move away from uniform protocol driven treatments for single disorders in order to incorporate empirically grounded clinical interventions that could be applied across disorders (Salkovskis, 2002).

One area that highlighted this change emerged from observations in clinical practice which revealed many patients accessing psychological therapy also experienced co-morbid long-term conditions and/or medically unexplained symptoms (LTC/MUS).[1] Spending time curiously listening to these patients' experiences trying to understand the nuances of their difficulties was revealing. What was discovered was a group of patients who experienced an array of biopsychosocial challenges that appeared to directly impact on their emotional wellbeing resulting in periods of heightened anxiety and low mood, which in turn negatively affected the self-management of their health conditions. Discussions with clinical colleagues also uncovered similar reflections, but also exposed a collective view that people with co-morbid LTCs and anxiety disorders and/or depression experience poorer end of treatment outcomes.

Subsequently, a preliminary examination of theory and research also revealed people with LTCs tended to experience poorer psychological treatment outcomes in comparison to people without a LTC. Furthermore, it also found limitations in knowledge and research regarding the impact of co-occurring physical and mental health problems had on psychological therapy treatment outcomes in routine clinical practice, specifically in Talking Therapies services in England where there had been significant investment to develop LTCs psychological therapy pathways.

Collectively, this initial foray into theory and research underpinned by clinical observations stimulated a number of questions aimed at understanding 'if and why' people with LTCs and co-morbid anxiety and /or depression experienced poorer psychological therapy outcomes in routine practice. Were there specific patient characteristics that influenced end of treatment outcomes? Could the way treatment was delivered in Talking Therapies services have an impact? And whilst people were in treatment were there clinical changes that could indicate if treatment was likely to

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[1] For ease of reading, this thesis will subsequently use the term long-term conditions (LTCs) to refer to both long-term conditions and medically unexplained symptoms (LTC/MUS)

be successful or not? Accordingly, these questions merged to form the foundations for this research endeavour.

1.3 – ***Background***

The impact of long-term conditions (LTCs) is reported to be a major challenge facing today's society (Nolte and McKee, 2008; World Health Organization, 2002). Currently, 30% of people in England are affected by long-term health problems (Department of Health, 2012; Naylor et al., 2012), with this figure predicted to rise as a result of advances in medical science and increases in life expectancy (Department of Health, 2014). In turn, these factors have also been found to contribute to increasing rates of multiple long-term conditions, or multimorbidity as it is commonly known, which in itself has become a pressing challenge for healthcare systems across the world (Academy of Medical Sciences, 2018).

Unfortunately, for those people living with chronic physical health problems, it is not only their physical health that is affected. Research indicates 30%-46% of people living with a LTC experience depression and/or anxiety disorders, or as they are typically coined 'common mental health problems', due to their higher level of prevalence in comparison to other mental health problems (Barnett et al., 2012; Layard and Clark, 2014; Naylor et al., 2012; White, 2001). For example, Livermore et al (2012) found people diagnosed with chronic obstructive pulmonary disease (COPD) were 10 times more likely to experience panic disorder, whilst Moussavi et al (2007) observed people diagnosed with diabetes to be 2-3 times more likely to experience depression, findings that are echoed by an abundance of studies elsewhere (DiNicola, 2013; Melvyn et al., 2011; Usmani et al., 2017; Vamos et al., 2009; Yohannes and Alexopoulos, 2014).

The impact of living with co-morbid long-term conditions and common mental health problems is profound. From an individual perspective, multiple studies have shown them to result in poorer health and social outcomes (Abrams et al., 2011; Coulter et al., 2013; Dalton, 2014; Gudmundsson et al., 2005; Pooler & Beech, 2014), a higher likelihood of adopting unhealthier lifestyles (McManus et al., 2016), and difficulties engaging with treatment (Whooley et al., 2008). Furthermore, from a wider health care perspective, the combination of physical and mental health problems reportedly increases health expenditure by 50% (Naylor et al., 2012; Weich et al., 2013). Yet, despite this disabling impact two thirds of people with a mental health problem in the context of LTCs remain undiagnosed and untreated (McManus et al., 2016; Fritzshe et al., 2011), whilst the provision of care largely remains segregated into separate physical and mental health treatment silos (Goodrich and Cornwell, 2008).

In attempting to address these issues, a care approach that meets both physical and mental health needs concurrently through the integration of mental and physical health services has been advocated (Archer et al., 2012; Coventry et al., 2014; Department of Health, 2011, 2012; Lemmens et al., 2015). In particular, the provision of psychological therapies into routine physical health care through the expansion of the Talking Therapies programme (Department of Health, 2016); a programme that started in 2008 having combined clinical and economic resources to influence health policy with the aim of providing greater access to evidence-based psychological therapies for people experiencing anxiety and depression (Clark et al., 2009, Clark, 2011).

As such, in the Talking Therapies LTC programme psychological therapies are delivered through integrated pathways of care in conjunction with physical health services. Consistent with the general Talking Therapies programme, a model of ‘stepped-care’ is utilised to deliver approved psychological treatment (National Institute for Health and Care Excellence (NICE), 2004, 2007, 2009) whereby less intensive psychological therapy (e.g. guided self-help) is initially provided followed by more intensive costly psychological interventions (e.g. cognitive behavioural therapy (CBT)) for those who do not experience improvement on measures of anxiety and depression (Bower and Gilbody, 2005). Consequently, routine session-by-session patient reported outcome measures (PROMs) of anxiety and depression are used to evaluate treatment response and to support decisions regarding being ‘stepped-up’ to a different treatment intensity (Clark, 2011).

Within this context, evidence purports psychological therapy, most notably Cognitive Behavioural Therapy (CBT), to be an empirically supported treatment for co-existing anxiety or depression and LTCs, specifically when interventions are adapted to focus on both problems simultaneously (Chiles et al., 1999; Gullikson et al., 2011; Hiller et al., 2003; Howard and Dupont, 2012; Kinsinger, 2017; Layard and Clark, 2014; Lewin et al., 2009; Moussavi et al., 2007; Sharpe et al., 2007; Simon et al., 2007; Smith et al., 2017; Williams et al., 2012; White et al., 2011). However, whilst these studies reflect some promising convergent results, they have typically produced small-modest treatment effects in comparison to the large effects found in CBT for anxiety and depression alone and have, by and large, been investigated in highly specialised clinics for specific long-term health problems (Hoffman et al., 2012; Twomey et al., 2015).

These outcomes arguably raise important considerations. Firstly, that the presence of LTCs appears to attenuate the efficacy of psychological therapies; secondly, if the treatment effects in efficacy trials from specialised LTC services result in small-to-modest effects, how effective are psychological therapies when introduced into naturalistic clinical settings using a ‘stepped-care’ model such as those provided by Talking Therapies LTC services? and thirdly, are there specific factors that influence treatment outcomes for people with LTCs?

Attempts to identify what factors predict psychological therapy outcomes for people with co-existing physical and mental health problems have recently become a focus of research. In particularly, as research has found people with the same diagnosis but with differing demographic and clinical characteristics respond differently to treatment (Hoffman, 2012; Hoffman and Smits, 2008; Norton and Price, 2007), interest in the influence that pre-treatment patient variables have on outcomes has emerged.

Currently, research indicates a myriad of pre-treatment patient characteristics to influence therapy outcomes. More specifically, demographic (age, gender, social deprivation) (Falconnier, 2009; Grant et al., 2012; Knopp et al., 2013; Saxon et al., 2007), clinical (mental health problem, LTCs, chronicity and severity, treatment episodes) (Bower et al., 2013; Brabban et al., 2009) and psychological features (e.g. personality disorders) (Goddard et al., 2013; Kampman et al., 2008). Whilst these studies have without doubt advanced our understanding of the impact these variables have on therapy outcomes, there remains limited consensus about the strength of their association with end-of-treatment outcomes for people with co-morbid physical and mental health problems.

In addition, the organisational delivery of psychological therapy has also been reported to influence therapy outcomes for anxiety and depression (Clark et al., 2009). Whilst the dominant model of ‘stepped-care’ adopted by Talking Therapies services has been purported to be clinically and cost-effective (Araya et al., 2006; Clark et al., 2017), alternative models such as ‘stratified-care’, whereby patients are allocated to different types of therapy based on the severity of their condition, have also been considered clinically effective (Lovell et al., 2008). Indeed, efficacy studies comparing the impact that ‘stepped-care’ and ‘stratified-care’ have on therapy outcomes for patients without LTCs contend there to be no clinically significant differences between the two (Seekles et al., 2011), with recent research suggesting ‘stratified-care’ to be more efficacious and cost-effective (Delgadillo et al., 2022).

In the case of co-morbid LTCs and common mental health problems, recent studies evaluating the impact of psychological therapies delivered in a ‘stepped-care’ model have found this model of treatment delivery to lead to improvements in mood and self-management of health conditions (Marks et al., 2016; Wroe et al., 2018). Yet, elsewhere, its effectiveness has been questioned. For example, Delgadillo et al (2017) found a significantly higher proportion of patients with LTCs required more costly ‘stepped-care’ interventions and experienced poorer outcomes on measures of anxiety and depression in comparison to those without a LTC. To this end, debate remains regarding the effectiveness of ‘stepped-care' psychological treatment for people with co-existing LTCs and anxiety and/or depression.

Whilst pre-treatment patient characteristics and the organisational delivery of psychological therapy may influence end of treatment outcomes, attempts to predict outcomes in psychological therapy have also considered the influence early therapeutic improvement has on treatment outcomes in patients without a LTC (Carlier et al., 2012). More specifically, ‘early reliable improvement’ (ERI), a concept defined as a statistically reliable positive change on validated measures of anxiety and depression (i.e. more than the measurement error of a scale), occurring in the first four to eight sessions of treatment has been found to predict favourable end-of-treatment outcomes (Delgadillo et al., 2014; Stiles et al., 2003; Strunk et al., 2010), whilst its absence has been shown to identify patients at risk of poor response to treatment (Finch et al., 2001; Shimokawa et al., 2010). Yet, in contrast, research has also shown early therapeutic improvement to be an inconsistent predictor of positive final treatment outcomes (Forand and DeReubis, 2013), particularly as patients with more complex co-morbid psychological problems (for example, co-morbid LTCs) require more time in treatment to make positive measurable gains (Lambert et al., 2018). Against this backdrop of divergent evidence, the role of ERI as a predictor in outcome in patients with co-occurring long-term conditions and anxiety and/or depression has yet to be established.

In synthesising the evidence to date, it is clear a number of uncertainties persist. Firstly, it remains unclear how much pre-treatment patient characteristics influence therapy outcomes for people with co-morbid physical and mental health problems. Secondly, the dominant model of ‘stepped-care’ adopted in the Talking Therapies LTC programme appears to lack evidence to demonstrate its effectiveness in LTC populations and, as such, raises questions about its widespread implementation. Thirdly, whether ERI is a major predictor of positive end of treatment outcomes is unknown for people with co-morbid LTC and anxiety and/or depression.

Consequently, this study sets out to investigate the predictors of outcome in psychological therapy for co-morbid long-term health problems and common mental health problems in routine clinical settings. In particular, it examines the extent to which pre-treatment patient characteristics, ‘stepped-care’, and early reliable improvement (ERI) influence end of treatment outcomes.

1.4 - ***Overview of subsequent chapters***

The following chapters are ordered in a logical sequence to illustrate the development, focus, and outcomes of the study. In Chapter 2, a literature review is presented focusing on the three areas under investigation, namely, pre-treatment patient characteristics, the ‘stepped-care’ model of delivering psychological therapy, and ERI in treatment. Chapter 3 follows with a discussion on the study’s philosophical position of neo-positivism and continues with a focus on its theoretical underpinnings. Building on these foundations, Chapter 4 outlines the methodological framework and methods used to achieve its aims. In Chapter 5, the results of the study are presented, and this is followed by a discussion of the results including its implications for clinical practice in Chapter 6. Finally, Chapter 7 provides a number of recommendations for clinical practice, training, and future research.

Chapter 2

Literature Review of Predictor Variables

Chapter 2 – Literature Review of Predictor Variables

2.1 – *Introduction*

As noted in the previous chapter, emerging evidence suggests psychological therapy outcomes for people with co-morbid physical and mental health problems may be influenced by a range of factors (Delgadillo et al., 2017). Prominent amongst these are the role pre-treatment patient characteristics, models of delivering psychological therapies such as ‘stepped-care’, and early reliable improvement have on therapy outcomes (Clark et al., 2018; Delgadillo et al., 2016a; Robinson et al., 2020; Shimokawa et al., 2010).

Accordingly, this chapter presents a review of contemporary research literature regarding their predictive association with psychological therapy outcomes. The chapter commences with an outline of the reviews overarching literature search strategy followed by the search terms and databases used, selection criteria, data collection and study selection processes. Subsequently, a critical literature review (Grant and Booth, 2009) is presented which analyses and evaluates existing research in relation to their association with end of treatment outcomes. Finally, the chapter concludes with an overview of the review’s main findings.

2.1.1 - *Literature search strategy*

A systematic and comprehensive search strategy was used to identify and retrieve relevant research and literature. The strategy focused on the following topics: pre-treatment characteristics including demographics, clinical, and psychological factors, the ‘stepped-care’ model of delivering psychological therapy incorporating the type of treatment and number of clinical sessions offered, and early reliable improvement in psychological therapy. Recommended guidance was utilised to ensure the review was of a valid, reliable and replicable standard to produce a high quality and informative critical review. This included guidance on the core principles and methods associated with producing quality critical reviews, for example, frameworks for identifying relevant research evidence, databases, study selection, and quality assessment tools (Bouwmeester et al., 2012; Centre for Reviews and Dissemination, 2009; Petticrew and Roberts, 2006; Sanderson et al., 2007; Tooth et al., 2005; von elm et al., 2007).

2.1.2 - *Literature review search terms*

A comprehensive range of search terms were used to account for the specific predictors considered in the study. These are outlined in Tables 2.0, 2.1, and 2.2 with an example of the sequence of search terms entered into the databases illustrated in Appendix 1.0. As per good practice guidance, controlled vocabulary terms and related terms were utilised separately and combined using Boolean operators (And and OR), alongside synonyms and truncations (Centre for Reviews and Dissemination, 2009). Search terms were identified using a population, intervention, comparator, and outcomes (PICO) strategy (Petticrew and Roberts, 2006).

Table 2.0 – *Literature review search terms for pre-treatment characteristics*

Population	**Intervention**	**Comparison**	**Outcome**
Long-term condition LTC Multimorbidity Medically unexplained MUS Anxi* Anxiety Depress* Depression	CBT Cognitive behavioural therapy Cognitive behave* therapy Psychological interventions Psychotherapy	Primary care Community Predictors Demographic Clinical	Anxiety Depression Recovery PHQ-9 GAD-7

Table 2.1 – *Literature review search terms for stepped-care*

Population	Intervention	Comparison	Outcome
Anxi*	CBT	Primary care	Anxiety
Anxiety	Cognitive behavioural therapy	Community	Depression
Depress*	Cognitive behave* therapy	Stepped-care	Recovery
Depression	Psychological interventions	IAPT	PHQ-9
	Psychotherapy		GAD-7

Table 2.2 – *Literature review search terms for early reliable improvement*

Population	Intervention	Comparison	Outcome
Anxi*	CBT	Primary care	Anxiety
Anxiety	Cognitive behavioural therapy	Community	Depression
Depress*	Cognitive behave* therapy	Early change	Recovery
Depression	Psychological interventions	Early improvement	PHQ-9
	Psychotherapy		GAD-7

2.1.3 - *Databases*

Due to the studies focus on the integration of physical and mental health care, nine databases were searched (EMBASE, Psychinfo, AMED, HBE, PubMed, BNI, HMIC, CINAHL, and Medline) to identify titles, abstracts, and keywords. The search was limited to peer reviewed articles and books published in English. Unless identified as seminal pieces of work, only studies from the year 2000 onwards were included in the review. This was to ensure the review focused on contemporary up-to-date research whilst guaranteeing the amount of literature remained within a manageable level for the practical undertaking of this thesis.

2.1.4 - *Literature selection criteria*

The inclusion criteria applied in the review was used across each of the predictor domains to ensure consistency and is shown in Table 2.3. An exclusion criteria was also applied to ensure the literature reviewed remained aligned to the focus of the study. This is outlined in Table 2.4.

Table 2.3 – *Inclusion criteria of literature selection*

Inclusion Criteria
Adults aged 18 and over
Patients with psychological disorders and symptoms (anxiety and depression),
Patients with a physical health problem (long-term condition and/or medical unexplained symptoms)
Use of validated clinical outcome measures
Studies with experimental, quasi-experimental, and observational cohort designs
Treated with a range of psychological therapy but must have included cognitive behavioural therapy (CBT)

Table 2.4 – *Exclusion Criteria of literature selection*

Exclusion Criteria
Participants with a primary diagnosis of personality disorder
Participants with a primary diagnosis of organic illness or learning disability
Received counselling, psychodynamic therapy, integrative therapy only

Following an initial scope of literature, amendments to the eligibility criteria for the role of stepped-care and early reliable improvement were made to include participants with common mental health problems with or without long-term health conditions. This decision was taken due to the current paucity of literature pertaining to co-morbid physical and mental health problem in relation to the predictive domains under review. Additionally, studies selected in the review of ‘stepped-care’ and ‘early reliable improvement’ only included observational studies from routine care. The rationale to exercise this parameter was twofold. Firstly, as routine care often provides variable treatment durations, in contrast to controlled trials which set specific treatment parameters, it was deemed this would provide more informative findings to explore the role of early improvement across variable treatment lengths. Secondly, the use of naturalistic samples was considered to be more valuable as they enable results to be generalised to routine psychological treatment that reflects the context of this study.

2.1.5 - *Data collection*

An initial literature search commenced in 2018 at the start of the researcher's Doctorate programme. This became refined overtime, evolving in tandem with the studies research protocol. A final literature search was undertaken using the specific strategy outlined between January 2022 and March 2022. Further literature checks were made in late 2023 to ensure the review had not overlooked any new pertinent research.

2.1.6 - *Study selection*

A staged study selection process was undertaken by the researcher only. After duplicates were removed, titles and abstracts were screened and from this assessment, full-text studies that met the inclusion criteria were reviewed. Following on, backward citations and reference lists of eligible studies were searched to identify any further relevant literature and/or studies. PRISMA diagrams summarising the selection process for each predictor variable (e.g. pre-treatment patient characteristics, stepped-care, and early reliable improvement) are presented overleaf.

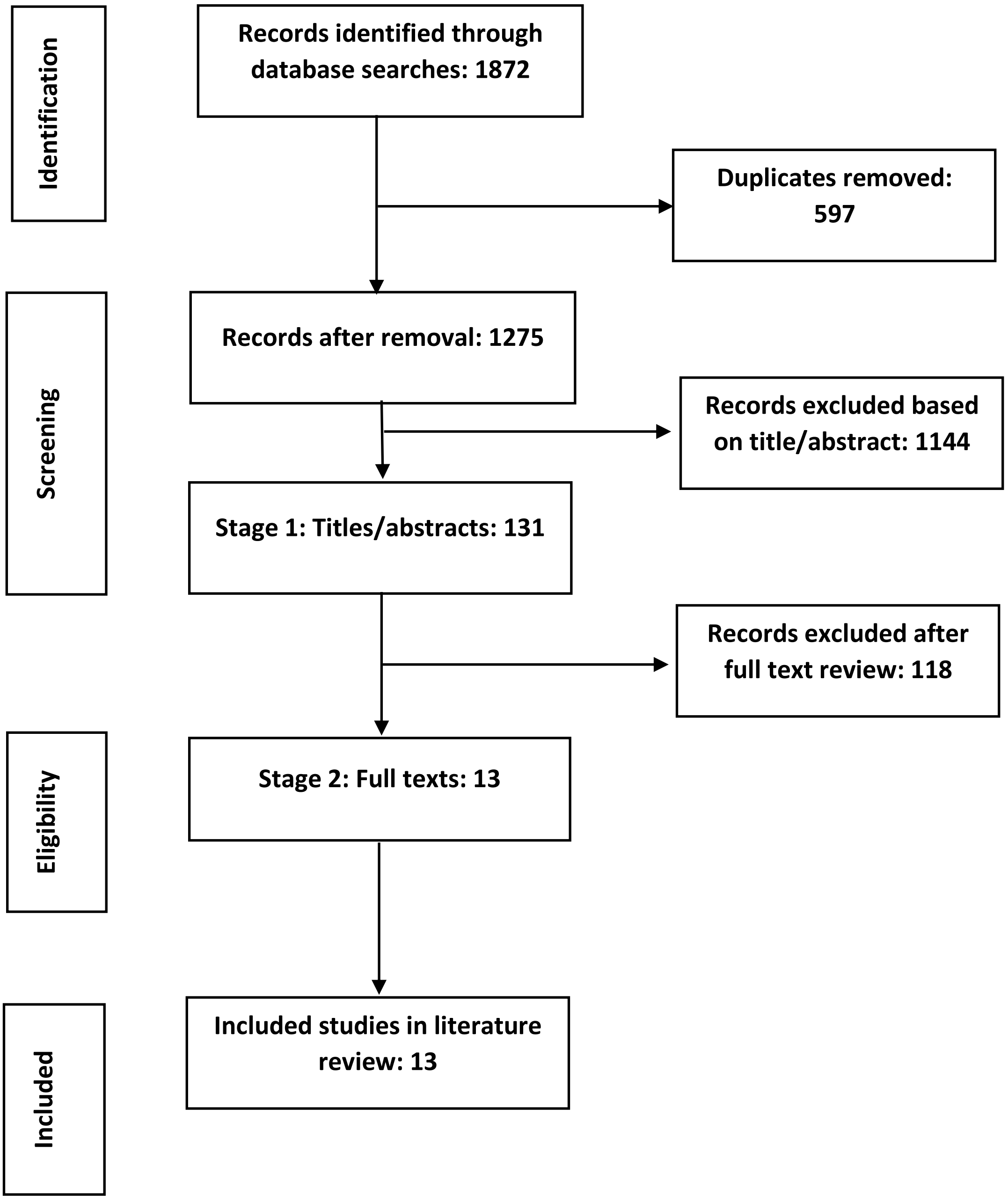

Figure 2.0 - PRISMA flow diagram of study selection process for pre-treatment patient characteristics

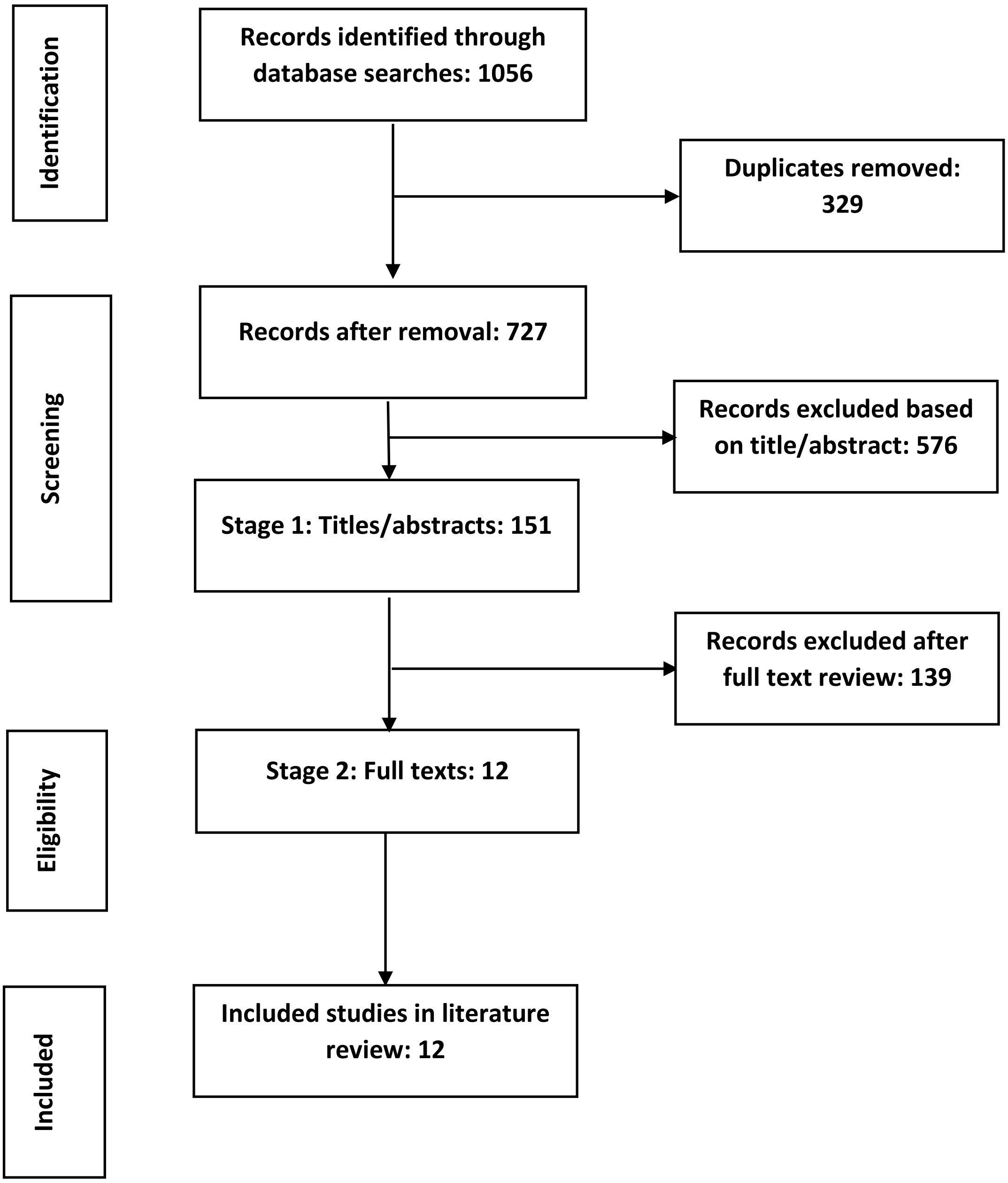

Figure 2.1 - PRISMA flow diagram of study selection process for stepped-care

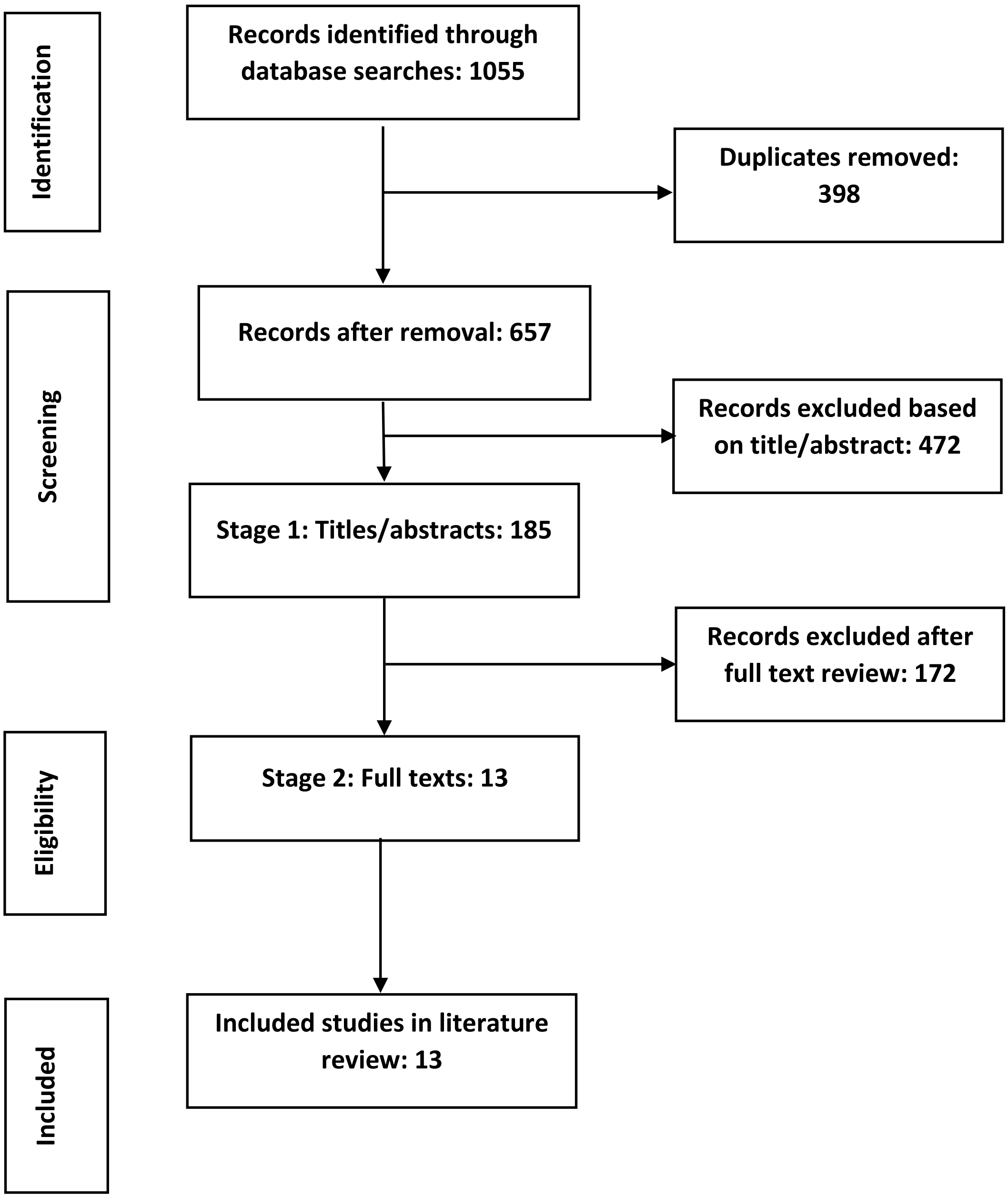

Figure 2.3 - PRISMA flow diagram of study selection process for early reliable improvement

2.2 - ***Pre-treatment patient characteristics affecting psychological therapy outcomes***

Over the past 20 years, the role pre-treatment patient characteristics have on therapy outcomes has received a steady stream of empirical attention. As a result, a sizeable number of studies have investigated their relationship with CBT outcomes for people with common mental health problems (Duncan et al., 2010; Saunders et al., 2021), thirteen of which are included in this review as they met the selection criteria. Collectively these studies suggest pre-treatment patient characteristics, such as age, marriage, severity, co-morbidity etc. to all influence therapy outcome, although their weight of associations are variable. For example, some patient baseline characteristics have been found to have a statistically and clinically significant interaction that change the size (or direction) of the relationship between an intervention and outcome (Kraemer et al., 2006), whereas some appear to have little influence. As such, studies have yet to yield consistent results, whilst their range of heterogeneous and largely contradictory findings coupled with methodological shortcomings (e.g. small samples) continue to limit their ability to influence clinical practice.

Given this current landscape, it is difficult to confidently declare their predictive value or if their strength of association translates into different population groups, for example, long-term health conditions. Indeed, a comparatively minimal amount of research has investigated the influence pre-treatment patient predictors have on people receiving psychological therapy with co-morbid physical and common mental health problems. Of the research undertaken in this area, a number of varying predictors emerge, which when synthesised using recommended guidelines (Clarke, 2007; Fournier et al., 2009) can be classified into three separate, but inter-related predictive domains, namely; demographics, clinical, and psychological factors. Each are now reviewed in turn.

2.2.1 - ***Demographic predictors***

Demographics may be viewed as a set of particular characteristics of a population, for example, age, gender, ethnicity, and marital status (Salkind, 2010). Their role in research is long standing, distributed equally between their role in determining if a studies population is representative of the target population for generalisation purposes and acting as independent variables within correlational studies (Leone, 2010). Numerous examples proliferate health research. From epidemiological and morbidity studies (Barnett et al., 2012; McManus et al., 2014; Sun et al., 2020; WHO, 2014), to the influence they have on mental health outcomes generally (Amati et al., 2017; Kendler and Gardner, 2014; Joutsenniemi et al., 2012), their use in health research remains integral and far reaching.

The extent to which demographics influence therapy outcomes for people with long-term health conditions (LTCs) has been led by a small number of studies. A study by Janse et al (2019) aimed to determine which pre-treatment variables predicted long-term outcome from CBT for people with chronic fatigue syndrome (CFS). Using data from a sample of 511 patients captured between 1 and 10 years post-treatment, they found a younger age at baseline to be positively correlated to improved CBT outcomes, in particularly a higher sense of control over fatigue and improved physical functioning. An unexpected outcome that was not shared by previous studies of psychological treatment for CFS (Darbishire et al., 2005; Quarmby et al., 2007).

In contrast, whilst Hynninen et al (2013) found group cognitive therapy for people with COPD and anxiety and/or depression to be an effective intervention that alleviates symptoms of anxiety and depression, they also noted age did not have an effect on outcomes. Despite this main finding, further control group analysis revealed age to have a differential effect, whereby younger patients experienced worsening symptoms of anxiety and depression overtime compared to older patients. Interesting outcomes, albeit within the confines of a small sample (*n* = 25 in CBT group and *n* = 26 in the control group).

The effect of gender has also led to similar contrasting conclusions. For example, the aforementioned study by Hynninen et al (2010) found women in their CBT group intervention to have both higher baseline and post-treatment symptoms of anxiety and depression relative to men. Meanwhile, a study by Sandler et al (2002) considered the outcomes and predictors of response to a CBT based intervention for people with post-cancer fatigue and chronic fatigue syndrome (CFS) (*n* = 264). They found males coupled with higher fatigue scores at baseline to be predictive of non-response, although overall, despite being limited by the absence of a control group, their study revealed a CBT based programme to be an effective treatment for fatigue.

A study by Dobkin et al (2012) considered the predictors of outcome in CBT for depression with people diagnosed with Parkinson's disease using data from a previous RCT (Dobkin et al., 2011). They found both age and gender to have no predictive influence on depression outcomes but observed marital status to be positively correlated to outcome, although the overall effect size was small in relation to other baseline clinical predictors. From this perspective, it may be suggested marital status has a greater influential effect on outcome when caregivers (e.g. spouses) mediate the effects of treatment by being actively involved in therapy (Neal and Radomsky, 2020).

Similarly, contrasting results were also found in an observational cohort study by Delgadillo et al (2017) using data from a host of primary care Talking Therapy services. Using a large scale sample (n = 28,498), Delgadillo and colleagues found gender and marital status to have no correlation with CBT outcomes, whilst age was found to have a small but significantly positive correlation with outcomes on measures of anxiety and depression. Delgadillo et al (2017) also noted ethnicity to be predictive of higher post-treatment distress. A particularly interesting finding when considering the ethnic profile of participants in studies elsewhere that are comparatively overly represented by white causations. Furthermore, Delgadillo and colleagues also revealed people from socioeconomically deprived areas to have higher post-treatment symptom severity suggesting a positive correlation between levels of deprivation and symptom severity at the end of treatment.

However, a number of studies have revealed demographics to have no significant influence on outcomes altogether. Using secondary analysis of data from a RCT of CBT for Type 1 and 2 Diabetes, Tovote et al (2017) concluded demographics to have no prognostic influence on measures of depression. Although, their high attrition rates and small sample size limited their results. Similarly, demographics were found not to predict outcomes in a study by Turner et al (2007) who investigated the efficacy of CBT for chronic pain. Meanwhile, in a study by Ljótsson et al (2013) several baseline factors were investigated to consider their predictive influence on symptom improvement after CBT for irritable bowel syndrome (IBS). Analysing data from a previous RCT, Ljótsson et al (2013) also concluded individual pre-treatment characteristics did not influence therapy outcomes.

2.2.2 - *Clinical predictors*

Clinical predictors represent a broad array of characteristics pertaining to mental health problems and physical diseases (Tovote et al., 2017). This may include specific diagnosis, severity and history, and its functional impact, to name but four domains. Significant interest in how these pre-treatment characteristics influence outcomes have been subject to an abundance of research investigations covering areas such as psychotherapy outcomes to the relatively recent covid-19 pandemic (Fu et al., 2020).

In the field of psychotherapy, in particularly CBT, examination of the direction and magnitude of the relationship clinical factors have on CBT outcomes has focused on identifying subpopulations of patients who are most likely to benefit from CBT treatment and also those at risk of poorer therapeutic response (Driessen and Hollon, 2010; Hamilton and Dobson, 2002; Schottenbauer et al., 2008). Collectively, these studies provide a cogent argument that illustrates baseline patient clinical factors to have an influence of therapy outcomes (Anderson and Lambert, 2001; Kampman et al., 2008).

However, the extent of their association remains variable and somewhat dependent on the methodology underpinning a particular study whereby less methodologically robust studies often reveal stronger associations (Gaskell et al., 2022). Moreover, whether these findings are replicated with people who experience co-morbid physical and mental health problems remains less clear with the outcomes of studies revealing both homologous and conflicting findings.

A RCT by Hundt et al (2018) examined the predictors of outcome in brief CBT for people with cardiopulmonary conditions and anxiety and/or depression. Using multivariable linear regression, they concluded the severity of baseline diagnosis of anxiety, depression, and functional impairment to be significant predictors of outcome. Accordingly, Hundt et al (2018) observed patients with lower severity in these areas were associated with greater improvement at the end of 6-12 sessions of CBT treatment on measures of anxiety and depression. Although lacking in specificity with regards to the type of anxiety disorders involved in the study, the study raised attention to the negative impact severe illnesses may have on people trying to engage in therapy, particularly if this is associated with high levels of distress.

Similar results have been found in research elsewhere. A study by Dobkin et al (2012) used regression analysis to identify predictors of outcome in CBT for patients with Parkinson's disease and depression. As such, Dobkin et al (2012) concluded the severity of baseline depression and functional impairment alongside psychiatric co-morbidity negatively influenced change in depression outcome scores overtime. Carney et al (2016) studied a sample of participants (*n*=157) with stable coronary heart disease (CHD) and major depressive disorder (MDD) who received 16 weeks of CBT treatment. Analysis of covariance (ANCOVA) was used to examine whether baseline clinical characteristics predicted change in post-treatment depression outcomes. Carney et al (2016) concluded severe depression at baseline to be a clinically significant predictor that negatively influenced depression outcomes, whilst further analysis revealed a history of prior treatment episodes and anxiety symptoms did not predict outcomes. Despite their interesting findings, they may be viewed as being limited due to the questionable introduction of an antidepressant mid-treatment for people who had not responded initially to CBT.

In contrast, Delgadillo et al (2018) large scale observational study using regression analysis revealed the number of previous treatment episodes to be a significant negative predictor of therapy outcomes. A conclusion echoed by Tovote et al (2017) who also found people with a history of psychological treatment episodes experienced less favourable treatment effects when compared with those without a history. Furthermore, Delgadillo et al (2018) also found the type of mental health diagnosis (namely obsessive compulsive disorder (OCD), post-traumatic stress disorder (PTSD) and eating disorders (ED)) to be associated with higher post-treatment results on measures of anxiety and depression. A result that arguably reflects the lower effect sizes found in CBT outcome studies for these disorders when compared with other anxiety disorders (Cuipers et al., 2013).

Alongside these insights, Delgadillo and colleagues revealed the most significant predictor to be the presence of a long-term health conditions, most notably, musculoskeletal problems, COPD, and diabetes, which appeared to attenuate clinical outcomes on measures of anxiety and depression. Indeed, similar conclusions are found elsewhere, whereby the presence and severity of a health condition appears to influence outcomes. For example, Janse et al (2019) concluded lower fatigue levels at baseline in CBT treatment for CFS were positively associated with outcomes at the end of treatment, implying more severe CFS conditions did not respond as well.

Similarly, the pre-treatment presence of pain has also been found to be a significant predictive factor. Using data from a previously reported RCT of CBT for chronic orofacial pain, Turner et al (2007) investigated the relationship a range of pre-treatment factors had on treatment outcome. Whilst Turner et al (2007) found change in perceived pain control to be the largest mediator to positively influence outcome, reflecting outcomes of studies elsewhere (Ecclestone et al., 2009; Zannini et al., 2018), they also revealed the severity of pain and number of pain sites to limit responses to psychological therapy post-treatment. Similarly, an experimental study by Sandler et al (2006) used a large sample (n = 243) to consider the predictors of response to an integrated treatment of graded exercise and CBT for unexplained chronic fatigue states. Whilst the study was limited by the absence of a control group, they found higher pain scores at baseline were predictive of non-response to CBT treatment.

However, despite a level of convergence to suggest the presence and severity of mental health and physical health problems to negatively influence outcomes, studies elsewhere refute this. Using hierarchical regression analysis, Tovote et al (2016) found baseline severity of mental health and disease specific characteristics (type and severity) did not predict outcomes for CBT for co-morbid depression and diabetes. Moreover, in a study by Zonneveld et al (2012b) using data from a RCT (Zonnevold et al., 2012a), multiple regression analysis was used to predict the outcomes of CBT group treatment for participants (*n*=162) with medically unexplained physical symptoms (MUS). Interestingly, whilst they noted CBT to be an effective treatment for MUS, no baseline predictors were associated with outcomes overtime. A result that mirrors the outcome of other studies focusing on CBT for unexplained physical symptoms (Ljótsson et al., 2010).

2.2.3 - *Psychological predictors*

Previous investigations into the role of psychological factors have to date mainly focused on the role of personality from the perspective of personality traits and disorders. Whilst a review of the theory of personality is discussed in the next chapter, it is generally accepted that an individual’s personality is relatively stable and enduring (John et al., 2008), and as such, has led theorists to define personality by a number of either *types* or *traits* (Eysenck and Eysenck, 1985). For example, extroversion, agreeableness, openness, conscientiousness and neuroticism, or idiographic in which personality is considered unique to every individual (Allport, 1961). In contrast, personality disorders may be categorised as a range of clinically significant conditions and behaviours that are persistent and characterised by an individual’s lifestyle and mode of relating to self and others (World Health Organisation, 2016).

This differentiation has subsequently informed how research considers the effects personality has on treatment outcomes. From a personality disorder perspective, numerous studies have indicated disorders of personality to impact on treatment outcomes. In an observational study by Goddard et al (2015) using routine data from participants (*n* = 1249) in a primary psychological therapy service, the active presence of a personality disorder was found to adversely affect end of treatment outcomes. Such outcomes have also been observed in clinical trials of CBT for personality difficulties (National Collaborating Centre for Mental Health, 2018). Yet, a limited number of studies have considered the influence of personality disorders have on psychological therapy outcomes for people with co-morbid health conditions. This is despite evidence suggesting personality disorders are associated with long-term effects on physical health, namely; increased risk of chronic illness and mortality, poorer physical functioning, and high healthcare utilisation (Powers and Oltmanns, 2012). Of those undertaken, whilst the presence of a personality disorder increased attrition rates, they have also been found to have no negative effect on outcomes (Leibbrand et al., 1999). In contrast, the aforementioned study by Zonneveld et al (2012) investigating predictors of outcome in CBT for persistent physical symptoms concluded fewer personality disorder characteristics were associated with improved clinical outcomes at the end of treatment, albeit they did not seem to predict outcomes consistently over time.

In comparison, the role of personality traits has been subject to wider investigations, both in terms of their general negative effect on physical health (Goodwin et al., 2006) and the influence they exert on CBT outcomes. Amongst the latter, studies have revealed high levels of neuroticism to result in less favourable outcomes (Bagby et al., 2008; Quilty et al., 2008), albeit other studies have not validated these outcomes (Mulder, 2002; Nyklicek and Irrmischer, 2016).

Despite this interest, a limited number of studies have considered their effects in the context of people with co-morbid physical health problems and anxiety and/or depression. The previously discussed study from Tovote et al (2017) explored the role of neuroticism on outcomes and found neuroticism did not predict final outcomes in CBT treatment. Similar results were found by Turner et al (2007) who also found neuroticism and openness did not influence outcomes in CBT treatment for pain. Given this general paucity of research into this specific area, further investigations would serve to bolster our understanding of their influence on therapy outcomes.

2.2.4 - *Summary*

Arguably, these findings highlight the on-going debate regarding the effects pre-treatment demographic, clinical and psychological factors have on CBT outcomes for people with co-morbid long term conditions and anxiety and/or depression. However, on balance, they reveal a trend that suggest a number of baseline characteristics (summarised in Table 2.5) do influence treatment outcomes, whether acting alone or in tandem with other variables. To what extent though remains uncertain. Thus, it reveals a need for more targeted predictor variable studies focusing on their influence across different physical and common mental health diagnosis in naturalistic observational studies that reflect the clinical realities of psychological treatment provision (Robinson et al., 2019), rather than the use of secondary analysis of RCT data conducted in specialised clinics. To this end, it remains to be seen the degree of influence pre-treatment characteristics have on outcomes in the national expansion of the Talking Therapies programme for people with co-morbid common mental health and physical health problems.

Table 2.5 – *Pre-treatment predictors of outcome*

Demographics	**Clinical**	**Psychological**
Age Gender Ethnicity Employment Marital status Sociodemographic status	Common mental health diagnosis(s) Long-term health condition(s) diagnosis Number of treatment episodes Severity measures of depression Severity measures of anxiety Severity of functional impairment	Presence of a personality Disorder

2.3 - *Stepped-Care*

Across the world, the prevalence of anxiety and depression appear to be on the rise and continue to be associated with significant personal burden, disability functional impairment, reduced quality of life and economic encumbrance (Centre for Economic Performance, 2006; Das-Munshi et al., 2008; McManus et al., 2016, 2020; World Health Organisation, 2017). Moreover, research continues to suggest the presence of anxiety and depression forms a major risk factor for somatic disease (Brosschot et al., 2016; Tully et al., 2013), whilst those diagnosed with long-term health conditions are themselves at increased risk of developing anxiety and depression (Layard and Clark, 2014). A reciprocal interaction that cumulatively magnifies the personal and social impact of co-morbid mental health and physical health problems whilst increasing healthcare expenditure (Abrams et al., 2011; Barnett et al., 2012; Dalton, 2014; Moussavi et al., 2007; Naylor et al., 2012; Sartorius, 2018).

Within England, addressing this need has been given national priority, as reflected in the establishment of the Talking Therapies programme in 2008; an ambitious programme underpinned by clinical, economic, and health policy initiatives (Clark, 2011, Layard et al., 2006; Layard et al., 2007; Mind, 2010; National Institute for Health and care Excellence, 2011) that aimed to provide greater public access to efficacious and cost-effective psychological treatments for common mental health problems. Whilst this programme continues to expand, most notably with the provision of psychological treatment for people with co-morbid health conditions (Department of Health, 2019; National Collaborating Centre for Mental Health, 2018), it remains concordant with its fundamental pillars of providing evidence-based psychological treatments delivered in a stepped-care model, alongside the systematic collection of routine outcome data (Clark et al., 2018; Wakefield et al., 2020).

Currently, the Talking Therapies programme receives over 1.9 million referrals annually, 87% of which commence treatment within 6 weeks, with 67 % making reliable improvement (NHS Digital, 2018) and over 50% moving to recovery (NHS Digital, 2020). Remarkably, these outcomes continued during the covid-19 pandemic with the rapid coherent transition of these services to provide remote delivery of psychological therapies to meet the on-going escalating psychological needs of many in society (Cole et al, 2020). Given this success, it has gained international traction with the replication of the programme being trail blazed across the world (Cromarty et al., 2016; Naeem et al., 2017).

Now over 10 years old since its implementation, the programmes focus on monitoring routine outcome data continues to provide publicly available outcome data (NHS Digital, 2020). Moreover, the availability of routinely collected data has stimulated an abundance of research (Wakefield et al., 2020) covering a variety of topic areas, for example, outcomes for older people (Prina et al., 2014) and people with differing sexual orientations (Rimes et al., 2018), to studies focusing on therapist effects (Green et al, 2014). Whilst this output of practice-based evidence has served to demonstrate its success, it has also been pivotal in identifying significant variation in outcomes across Talking Therapies services and as such, the programme remains a work in progress (Clark, 2019).

So how can we account for these variations in outcomes? One specific area of interest is how the organisational system used to deliver psychological treatments, commonly referred to as service delivery models (Firth et al., 2015), influence clinical outcomes. As previously noted, a key feature of the Talking Therapies programme has been the delivery of approved evidence-based psychological treatments for common mental health problems, with or without co-morbid health conditions, in a ‘stepped-care’ model (NICE, 2011). A model of service delivery whereby treatment is provided in a progressively intensive framework commencing with low-intensity guided self-help (GSH) (Lovell et al., 2008; Richards and Farrand, 2010) and ‘stepping-up’ to longer individual high-intensity psychological treatments if patients do not improve (Bower and Gilbody, 2005). The exceptions to this guidance being when evidence only supports the allocation of higher-intensity treatments for the treatment of specific disorders, for example, post-traumatic stress disorder, chronic fatigue syndrome, persistent pain to name but three.

Previous clinical trials of stepped-care and its relationship with recovery outcomes, however, have found mixed results. Studies have shown no differential effects on outcomes compared to usual care or enhanced care (Seekles et al., 2011), moderate effects (van Stratten et al., 2015) and large effects (Nordgreen et al., 2016). Meanwhile, Firth et al (2015) systematic review of stepped-care for depression concluded significant differences favouring stepped care when compared with usual care (Davidson et al., 2010; Patel et al., 2010, 2011). More recently, a RCT by Salmonsson et al (2018) found stepped-care for depression and anxiety disorders to be both clinically and cost-effective, particularly when patients who did not improve with guided self-help were rapidly 'stepped-up' to intensive CBT.

How these findings translate into clinical practice at scale has stimulated a number of studies that have sought to investigate the effects of stepped-care. An early study by Clark et al (2009) examined initial data from two Talking Therapies early implementer sites in England. Using an observational prospective cohort design, Clark et al (2009) found significant improvements in outcomes on standardised IAPT measures of anxiety (GAD-7) (Spitzer et al., 2006) and depression (PHQ-9) (Kroenke et al., 2001) at post- treatment using a stepped-care model, with large effect sizes (1.06 - 1.19) and an overall recovery rate of 57% post-treatment. These results were widely maintained by 42% of patients at follow-up. Whilst it may be suggested that the exclusion of patients who only received a single session may have influenced outcomes, Clark et al's (2009) study may be viewed as influential for two specific reasons. Firstly, that the treatment provided was effective with recovery rates greater than 50%, and secondly, this could be achieved with the introduction of a stepped-care model to deliver psychological therapies at scale. Thus, laying the foundations for further roll-out of Talking Therapies services

Following on from an earlier study by Richards and Suckling (2009), Richards and Borglin's (2011) large-scale prospective cohort study used a procedure analogous to intention-to-treat analysis to ensure outcomes for all patients (n = 4183) were analysed. Using the standard measures of anxiety and depression adopted in Talking Therapy services, Richards and Borglin (2011) found pre-post effect sizes >1.0 with 46% of patients achieving 'recovery' and 55% making reliable and clinically significant change. Moreover, these results were realised using a stepped-care model whereby the majority of treatment was deemed low-intensity and treated in less than six sessions. Although, one may cite the uncontrolled nature of the study cannot offset the potential that some patients may have experienced spontaneous remission of symptoms (Kendrick et al., 2006; Posternak and Miller, 2001), Richards and Borglin's (20011), these early findings suggested the provision of low-intensity treatment delivered in stepped-care model at scale could be highly effective for a significant number of patients.

Building on these findings, Hammond et al (2012) investigated the comparative effectiveness of low intensity treatment when delivered by telephone or face-to-face treatment. Using an observational cohort design, Hammond et al (2012) analysed data from a large sample (n = 4,106) of treatment completers. Their results revealed low intensity treatment delivered over the telephone was of equivalent effectiveness to treatment delivered face-to-face, albeit the exception being those with more severe difficulties where face-to face treatment was found to be superior. Whilst the absence of assigned clinical diagnosis within the sample prevented an assessment of the differential effectiveness, Hammond et al (20102) study provided important insights into the effectiveness of different formats of treatment delivery. Most notably, low intensity treatment delivered in a stepped-care model via telephone could be significantly effective for people with common mental health problems.

Writing about the durability of low intensity CBT, Ali et al (2017) longitudinal cohort study examined relapse rates (n = 439) over a 12-month period post-low intensity treatment. Using survival analysis to observe time-to-relapse in months, their results indicated 53% of participants relapsed within 12 months, with 73% of relapses occurring in the first 6 months. More specifically, their findings indicated those individuals with residual depression symptoms at the end of low intensity treatment were at increased risk (80% probability) of relapse post-treatment. Whilst the author's importantly note the relapse rates reported may be somewhat conservative given their sample represented approximately 25% of potential eligible participants, it also highlighted the need for a more effective use of the stepped-care. Thus, ensuring patients with marked residual symptoms at the end of low intensity treatment were offered further higher intensity treatment.

An observational cohort study by Gyani et al (2013) investigating the effectiveness of stepped-care used outcomes from across five Talking Therapies services to report on reliable recovery rates and specific predictors of recovery using a large sample of participants (n = 19,395). Their results revealed 40.3% recovered post-treatment, whilst 63.7% achieved reliable improvement on measure of anxiety and depression. Moreover, Gyani et al (2013) discovered that higher recovery rates could be predicted by higher average number of sessions, the provision of NICE recommended treatments, experienced staff, and a higher step-up rate among those individuals who started with low-intensity treatment. Although the absence of specific provisional diagnoses in a large proportion of participants limited its analysis, Gyani et al (2013) study may be seen as pivotal in providing insights into how higher recovery rates could be achieved at scale with the systematic use of ‘stepping-up’ to higher intensity treatments when individuals do not improve with low-intensity treatment.

Using a retrospective observational cohort design, Delgadillo et al (2014) used routine outcome data (n = 1,850) to examine the role of early change in low-intensity treatment using an outcome prediction model. Whilst their main outcomes regarding early change are reported in the following sub-section of this chapter, Delgadillo et al (2014) study also made an important contribution to our understanding of stepped-care. Most notably, individuals showing limited improvement or signs of deterioration by session 4-6 of low intensity treatment would benefit from being ‘stepped-up’ to higher intensity treatment as they were unlikely to improve with further low-intensity treatment. From this perspective, the use of routine outcome monitoring may be seen as pivotal in the early identification of individuals who may need to be ‘stepped-up’ to higher intensity treatments in a timely fashion to potentially increase their chances of achieving recovery.

In response to the national driver to expand the Talking Therapies programme to meet the psychological needs of people with anxiety and/or depression and co-morbid LTCs (Department of Health, 2011a). Wroe et al (2015) investigated the impact of a modified low-intensity treatment for people experiencing co-morbid anxiety and/or depression in the context of Type 2 Diabetes. Treatment was provided over 6 sessions in collaboration with a General Practitioner and Health Psychologist and focused on addressing problems with mood and self-management by directly linking diabetes with a CBT approach. Their results indicated that low-intensity treatment specifically adapted for people with Type 2 diabetes was more effective, both psychologically and physically, than generic low-intensity interventions. Although, Wroe et al’s (2014) conclusion may be viewed with some degree of uncertainty due to their small sample size (n = 95), it appeared to suggest modified forms of low-intensity treatment targeting both mood and physical health problems were critical additions if treatment was to be successful for people with a physical health co-morbidity.

Such conclusions are brought into focus when considering Kellett et al's (2016) retrospective observational study that analysed outcomes from an early pathfinder site. Using a pilot sample of 1,016, Kellett et al (2016) considered patient outcomes following stepped-care treatment. Their results revealed intake scores of anxiety and depression were significantly higher in comparison to patients without a LTC and observed suppressed outcomes with small-modest effect sizes post-treatment. Whilst Kellett et al (2016) findings raise questions over the effectiveness of stepped-care for people with co-occurring LTC, a closer inspection of the study revealed 80% of the sample received low intensity treatment alone, with only 14.5% of participants being stepped-up to high intensity. Moreover, additional training for therapists focused on using Acceptance Commitment Therapy (ACT) rather than specific modified CBT training for LTCs. Given these outcomes, this study importantly highlighted several key points. Firstly, the need to promptly step-up to a higher intensity if patients make minimal improvement in low intensity treatment, secondly, the need to ensure the treatment provided is NICE approved for specific condition (e.g. high intensity for MUS, chronic pain), and thirdly, the provision of appropriate additional training to ensure practitioners are able to modify treatment to meet the needs of LTC patients.

Similar suppressed outcomes were also found by Seaton et al (2022) cohort study. Using a large sample (n = 6610) of routinely collected data from a large inner city Talking Therapies service, they sought to compare outcomes of LTC and non-LTC patient groups whilst also identifying demographic and clinical factors associated with outcomes. Seaton et al (2022) found patients with a LTC were more likely to be female, from ethnic backgrounds, and have greater social deprivation and that its presence negatively affects end of treatment outcomes across measures of anxiety, depression, and functional impairment. Indeed, in terms of reliable recovery, only 32% achieved recovery in comparison to 39% of the non-LTC group. Whilst this may demonstrate the impact on outcomes of having an LTC, somewhat strikingly, both groups achieved a recovery rate less than the national benchmark of 50% (Clark et al., 2009). Arguably, this may be partially explained by the study taking place during the 1st wave of the covid-19 pandemic during which services came to an abrupt temporary halt due to social restrictions leading to increased early discharges without treatment being completed. As a result, reliable recovery rates were artificially supressed nationally (NHS Digital, 2020). Moreover, whilst treatment was delivered in a ‘stepped-care’ model, their results did not specify the number of patients who received low intensity or high intensity treatment and their associated outcomes, which perhaps limited their findings to some degree.

To assess the effectiveness of stepped-care for people with LTC’s, Delgadillo et al (2017) used routinely collected outcome data from a large sample (n = 28,498) to also compare response rates to psychological therapies for people with and without LTCs. They concluded the presence of a LTC to be associated with greater odds of accessing higher-intensity treatments whilst post-treatment outcomes were comparatively poorer for conditions such as musculoskeletal pain, chronic obstructive pulmonary disease (COPD), and diabetes. As such, Delgadillo et al (2017) suggested standard stepped-care interventions to be insufficient to meet the psychological needs of people with co-morbid health conditions and called for a focus on an integrative collaborative multidisciplinary approach. Yet, it is important to note the timing of their study which used outcome data prior to the implementation of the Talking Therapies-LTC programme (Department of Health, 2016) and before the national roll-out of LTC top-up training (National Collaborating Centre for Mental Health, 2018). From this perspective, further studies that evaluate outcomes following these developments are required.

To this end, Kenwright et al (2017) investigated the psychological therapy outcomes of irritable bowel syndrome (IBS) sufferers with or without bowel control anxiety (BCA), when delivered in a stepped-care model by clinicians who had received additional training in CBT treatment for IBS. Adopting an observational cohort design, routinely collected outcomes from 138 IBS sufferers (n = 52 with BCA, n = 86 without BCA) were analysed post-treatment and at 6-month follow-up. Their results found a significant proportion of participants were either stepped up to higher intensity CBT (24%) or received CBT alone (45%), in comparison to low-intensity treatment alone (31%). Clinically significant improvements were observed across the sample group (*d* = 2.0) with participants with BCA showing greater improvements at 6-month follow-up. Although limited by a low sample size, Kenwright et al (2017) study indicates psychological therapy for IBS sufferers to be effective, particularly when clinicians had received additional training in CBT treatment for IBS. Thus, suggesting the adjunct of additional top-up training may be a critical component when considering therapy outcomes delivered in a stepped-care model for people with co-morbid health conditions.

2.3.1 - *Summary*

In summarising these findings, it appears that a weight of evidence points towards the ‘stepped-care’ model of delivering psychological therapy to be effective. The model in itself may be seen as ‘self-correcting’, enabling different intensities of treatment to be provided based on patients progress and in doing so can be delivered at scale. Yet, the majority of these studies have focused on patients with an anxiety disorder or depression alone, and when including patients with co-morbid health conditions its effectiveness has been questioned, perhaps as a result of the added layer of presenting complexity co-morbid health conditions create requiring more intensive treatment (e.g. high intensity cognitive behavioural therapy). It is therefore a necessary step for further research to consider the effectiveness of a stepped-care model for patients with co-morbid long-term conditions and anxiety or depression.

2.4 - *Early reliable improvement (ERI)*

A review of current literature provides definitive accounts of both the efficacy and effectiveness of CBT for a range of clinical problems. Whilst these evaluations are extremely valuable, it may be suggested that they also conceal differences in the treatment trajectory of individuals (Stulz and Lutz, 2007), important information that may inform the refinement of treatment interventions or identify patients who need additional interventions (Brady et al., 2015).

Interest in this area has led researchers to consider the trajectory of change in psychotherapy in further detail. These include investigations into the role of rapid session-to-session sudden gains experienced by patients in therapy often in the early phases of treatment (Stiles et al., 2003) and the role of early treatment effects in psychotherapy as a whole (Tadić et al., 2010). As such, the concept of ‘Early Reliable Improvement’ (ERI) has emerged and whilst specific definitions vary due to the time point or period that defines early change (Lambert, 2010; Shimokawa et al., 2010), they generally converge on the notion that ERI reflects the symptomatic improvement that occurs in the early stages of psychological therapy that is both clinically and statistically significant (Beard and Delgadillo, 2019). Within this framework, meaningful ERI is achieved when a clinical and reliable change occurs that is greater than the measurement of error of the outcome measure being used (Hansen et al., 2002).

First emerging in the mid-eighties as a component of Howard et al (1986) seminal study exploring the relationship between the quantity and frequency of sessions and the probability of improvement in psychological therapy, ERI has borne witness to a number of studies across a range of treatment domains which suggest the majority of symptomatic improvement occurs in the initial sessions of treatment. Despite this, significant questions remain regarding how you specifically define ERI in terms of number of clinical sessions, the magnitude and direction of its association with final treatment outcomes, and its replicability across subpopulations, for example, people with co-morbid physical and mental health problems.

Although no study to date has examined this relationship with co-morbid physical and mental health problems, a number of studies have investigated the role of ERI in naturalistic outpatient settings for people experiencing common mental health problems. An early attempt to illuminate the role of ERI by Wolgast et al (2003) used routinely collected outcome data from participants (*n* = 788) accessing psychotherapy to assess session-to-session change over time. Although limited by their heterogeneous sample and their use of non-specific therapies using a mix of counselling and CBT, Wolgast et al (2003) results echoed similar studies of the time (Anderson and Lambert, 2001) in that half of all the patients met the criteria for ERI by session 14.

Schibbye et al (2014) used the percentage of symptom change pre and post-treatment to investigate the role of early change in internet based CBT (I-CBT). Their results indicated Session 4 to be the most optimal time point to predict treatment outcome, albeit the studies outcomes may be seen as being at risk of significant bias due to their use of a low sample size (n=112) when using regression analysis (Austen and Steyerberg, 2017).

Using a similar method, Schlagert and Hiller (2017) used the percentage of symptom change pre and post-treatment to explore the role of early change in CBT treatment for 639 people with depressive disorders, whereby early improvement was defined within the parameters of the first 10 sessions of CBT. Schlagert and Hiller (2017) found early response was highly predictive (*OR* = 8.75 and 5.32) of positive end of treatment outcomes and that early nonresponse was associated with later deterioration of symptoms. However, it is important to temper these findings with the knowledge the average number of session in the study was 40 and it is unclear if their outcomes could be replicated within the treatment parameters of NICE guidance for common mental health problems where a lesser number of sessions are recommended (NHS Digital, 2020).

Delgadillo et al (2014) investigated the relationship between ERI, number of sessions and final outcomes in brief guided self-help interventions based on CBT (maximum of 10 sessions) for 1850 people with anxiety and/or depression. Using regression analysis, two significant findings emerged. Firstly, patients who achieved ERI were twice as likely to fully recover at the end of treatment compared to those without ERI. Secondly, at least four sessions were required for 50% of patients to achieve ERI with improvements declining in treatment longer than six sessions. Although limited by the absence of more intensive treatments (e.g. individual CBT) and the exclusion of other potential patient variables that could influence outcome (diagnosis, co-morbidity), Delgadillo et al (20l4) findings has important implications for the delivery of guided self-help in TT services as it suggested that if there is limited improvement by session six, clients may need more intensive treatment.

Arguably, Delgadillo et al (2014) study examines the reliability of one aspect of what has become known as the ‘dose-effect’ model of change in psychotherapy; a model of change that proposes the relationship between the dose of treatment (e.g. length, frequency, number of sessions) and probability of improvement has a negatively accelerating relationship (Howard et al., 1986). However, this concept has been viewed as somewhat limited due to a number of fundamental assumptions. Firstly, that the rate of change during therapy is the same for all patients, secondly, that the rate of change will not vary according to the number of sessions provided, and thirdly, longer therapy leads to better outcomes (Stiles et al., 2008). In contrast, different models of change have been proposed. One of the most prominent models to be investigated is the ‘’Good-Enough Level’ (GEL) model of change. A model of change that proposes rates of change will vary according to the individual with people remaining in therapy until they determine they have sufficiently improved (Barkham et al., 2006).

As such, several studies have attempted to examine the attributes of each model. Using a large sample of retrospective observational data (*n* = 4676), Baldwin et al (2009) investigated the ‘dose-effect’ and ‘good-enough levels’ (GEL) of change using growth mixture models (GMM). Baldwin et al (2006) concluded that rates of change in therapy occurred at different rates as a function of total number of sessions. For example, small numbers of sessions were related to faster change, whereas a higher number of sessions were related to slower rates of change. Whilst it is unclear what proportion of clients received CBT, similar trends have been reported in other studies.

Falkenström et al (2016) utilised routine outcome data and multilevel GMM to determine whether the rate of change varied according to treatment length (e.g. the number of sessions attended). Their results indicated limited support for the 'dose-effect' of negatively accelerating improvement but noted greater support for the GEL model of change as patients improved at different times. For example, a number of participants improved quickly and had fewer sessions, whilst a number of participants took much longer to improve and required more sessions. Moreover, Falkenström et al (2016) found patients receiving longer treatment achieved more symptom change pre and post-treatment, despite having slower rates of improvement. Although casting doubt over the notion of ERI predicting final outcomes, a closer inspection of their results revealed a statistically significant more number of patients (n =220) achieved ERI by session 12 in comparison to those achieving ERI after session 12 (n = 18).

Meanwhile, other studies have considered the trends of early change using GMM, for example, Stulz et al (2007) who used routine outcome data from 197 outpatients to consider the shapes of early change in therapy. Their findings provided further support for the GEL model of change as they observed early change to be associated with different client groups characterised by high initial impairment, low initial impairment, early improvement, medium impairment with continuous progress, and medium impairment with discontinuous treatment progress. In addition, they also found pre-treatment variables to influence outcome, for example, diagnosis and age, although other potential confounding pre-treatment variables were outside of their scope of focus.

Elsewhere, researchers have considered the effect of session frequency on models of change. Reese et al (2011) built on the notion that clients who experience a faster rate of change received fewer sessions by investigating the influence of session frequency.

Using GMM to analyse routine outcome data they concluded that rates of change were influenced by session frequency, for example, clients who attended more sessions per week experienced greater rapid improvement.

Similarly, Erekson et al (2015) examined the relationship with speed of recovery and the frequency of treatment sessions with a large sample of clients (n = 21,488). Their results indicated weekly sessions were associated with a faster speed of recovery with 50% of individuals achieving a reliable change within 8 weeks. However, the association with final outcomes was less clear as both weekly and fortnightly appointments achieved similar final outcomes, albeit achieving a similar level of recovery with fortnightly sessions took a significantly longer period of time. Although both Reese et al (2011) and Erekson et al (2015) studies illustrate the predictive influence of session frequency, each study would have benefited from greater specificity regarding the diagnosis being treated to try and elucidate any differences between rates of change in psychotherapy and mental health diagnosis.

Building on an earlier study (Stiles et al., 2008), Stiles et al (2015) used retrospective data from a large sample in routine clinical practice (*n* = 26430) to examine improvement trends and treatment duration across various sectors including primary care (*n* = 8788). Their results revealed patients tended to end therapy when their gains had reached a ‘good-enough level’ and that patients seen for higher numbers of sessions experienced no greater improvement than those seen for fewer sessions. Moreover, they also found patients generally achieved a level of reliable improvement early in treatment (< 10 sessions).

A slightly different, but nonetheless, interesting focus was undertaken by Lewis et al (2012) who investigated the role of change and pre-treatment variables in predicting response to CBT for anxiety and depression. Using data from a routine outpatient clinic, Lewis et al (2012) found that an early reduction in depressive symptomology in the first five sessions of CBT predicted positive end of treatment outcomes. Although limited by their small sample size (*n* = 173), their outcomes replicate those from earlier studies (Santor and Segal, 2001; Gilboa-Schechtman and Shahar, 2006), albeit the introduction of a specific anxiety outcome measure to compare early rates of change for participants with anxiety disorders would have enhanced their results.

In a similar vein, Sembill et al (2019) considered whether early reliable change was related to different outcome domains, namely; wellbeing, symptoms, and interpersonal functioning. Using data from a routine outpatient clinic, they observed positive rates of large early change to be associated with wellbeing and symptom improvement, whilst the trajectory of change for interpersonal problems was slower and took a greater number of sessions. As such, their study suggested adapted treatment planning was required depending on the domains focused on in treatment. However, although offering some interesting insight, their conclusions were limited by their small-to-modest sample size (*n* = 352) for observational study designs.

Finally, Lutz et al (2005) considered whether a different analytical approach would provide greater accuracy when predicting change in psychotherapy. Using a 'nearest neighbour' (*NN*) approach in which each clients' rate of change and session-by-session variability were analysed against outcome trajectories of previously treated patients (nearest neighbour), they concluded NN to have greater predictive power than standard methods for predicting change in psychotherapy outcomes. Whilst Lutz et al (2005) study illustrated the benefits of using what many may deem a more internally validated model of prediction (e.g. nearest neighbour) (Brabec & Meister, 2001), further evaluation of their outcome data revealed that, regardless of analytical technique used, early reliable improvement in the first 8 sessions of treatment predicted positive final outcome.

2.4.1 - *Summary*

The quest to establish the role of early positive change and its relationship with end of treatment outcomes has led researchers to adopt a range of different approaches. As such, relatively simple methods based on clinically significant early reliable improvement and end of treatment criteria (Delgadillo et al., 2014) have been used alongside more complicated growth mixture models (GMM) (Baldwin et al., 2009; Falkenström et al., 2016) or ‘nearest neighbour’ (Lutz et al., 2005). Whilst these latter approaches are viewed as more sophisticated, it may be suggested their clinical application is reduced due to their computational demands whilst in some cases their sensitivity to observe reliable changes can be questionable (Rubel et al., 2014). This is brought into sharp focus when comparing it with the clinical applicability of using simple methods to measure ERI in the early stages of treatments (<8 sessions) and its relationship with outcome.

Aside from debates as to the most suitable methodology to use in order to investigate the association early reliable change has on end of treatment outcomes, a convergent trend of evidence suggests the presence of ERI to predict positive end of treatment outcomes. However, whether the influence ERI has on end of treatment outcomes is transferable to psychological treatment for people with co-morbid physical health and common mental health problems remains debatable and yet to be established, as no study to date has investigated its predictive role in this clinical context.

2.5 – *Conclusion*

This literature review chapter has used a broad scope of current evidence to consider the influence pre-treatment characteristics, ‘stepped-care’, and early reliable improvements has on psychological therapy end of treatment outcomes. In doing so, it has identified specific factors within these areas that warrant further investigation in this study. Accordingly, to delve further into these areas, the following chapter considers this study’s underpinning philosophical and theoretical perspectives.

Chapter 3

Philosophical and Theoretical Perspectives

Chapter 3 – Philosophical and Theoretical Perspectives

3.1 – *Introduction*

Locating research endeavours within a wider philosophical and theoretical context and examining how they inform empirical research is pivotal in establishing a coherent robust research architecture (Salkovskis, 2002). Accordingly, this chapter explores the philosophical and theoretical perspectives underpinning this study. The chapter commences with a discussion of the study's ontological and epistemological position. Firstly, by drawing on philosophy of science literature to introduce the study's neo-positivist foundations with reference to prediction-orientated health research, and secondly, by exploring its relationship within psychological therapies, namely cognitive behavioural therapy, the treatment intervention focused upon in this study. Subsequently, the chapter presents a number of theoretical perspectives that have influenced the direction of the study. This includes a range of theories from dualism to biopsychosocial theories of health, along with models regarding the organisational delivery of psychological therapy and collaborative care.

3.2 – *Philosophical perspectives of prediction-orientated health research and psychological therapies*

The concept of prediction is something familiar to all of us. Defined as a statement of what a person thinks will happen in the future (Oxford English Dictionary, 2020), as humans we are well versed in making predictions within the narrative of daily life. Such predictions are often procured from some underlying facts, trends or evidence that we may be aware of and are used to determine some degree of certainty in what we perceive will occur.

Yet, as revealed in this study that identifies specific predictors that influence psychological therapy outcomes in routine clinical practice for people with long-term conditions and co-morbid anxiety and depression, scientifically driven prediction is much more than this. Not only as it is based on objective evidence, theories, and statistical models (Jenkins et al., 2018), but also its fundamental ontological and epistemological philosophical assumptions.

For many researchers, early scientific approaches to research are seen as inextricably linked to positivism (Giddens, 1974). A deeply established field of research philosophy, positivist ontologically assumed there to be one defined reality that is fixed, measurable, and observable and that genuine knowledge (epistemology) must be objective and quantifiably (Marchal et al., 2013). In the field of health research, it remains highly influential. In particularly within the biomedical model of health, where ontologically physical illness is viewed as a deviation from healthy functioning whilst mental diseases are manifestations of pathology of the brain (David et al., 2012), and through objective science physiological explanations for physical and mental illness can be epistemologically established (Wade and Halligan, 2004).

However, positivist philosophy has evolved since its inception, in part due to far reaching ontological and epistemological deliberation on what could be considered ‘scientific’ and construed as ‘meaningful and meaningless’ (Achinstein and Barker, 1969; Giddens, 1979; Godfrey-Smith, 2010). As such, neo-positivism emerged using the laws of the natural sciences to explain social human phenomena underpinned by objective, empirical, and logical analysis with a distinct focus on the language of science (Jackson, 2016; Siemens, 1971). From this perspective, only scientifically verifiable statements buttressed by objective reality and empiricism are considered meaningful and truth laden (Ayer, 1968; Boeselager, 1975). Thus, illuminating the neo-positivism principle of verification (Ayer, 2001), a principle that was formerly revised by Popper (1992) who focused on falsification as a way to demarcate science from non-science. Within this realm, theories need to be operationalised, defined precisely and informed by empirically observable behaviours that are quantifiable and mathematically analysed (Popper, 1992).

The application of neo-positivisms fundamental philosophical position is far reaching within health research. Predictor-orientated research is one such example that in itself draws upon the concept of correlation (Mohr, 1982) in seeking to determine associations between variables. An approach characterised by the use of statistical techniques to quantify the association between a predictor variable (independent variable) and criterion variable (dependent variable), such studies provide the opportunity to establish insights into the direction and magnitude of correlations between variables that can advance predictive models or specific hypothesis (Laurer and Collins, 2010). Accordingly, it is in this context that this study's neo-positivist philosophical foundations are located, as it seeks to identify specific measurable predictors that influence end of treatment outcomes in psychological therapy for co-occurring physical and mental health problems that are subsequently statistically analysed to illustrate their association.

This philosophical approach to research underpins a wrath of observational studies within the field of health and have particular value in practice-based evidence (PBE) (Barkham et al., 2001), in which original investigations are undertaken to gain new insights into outcome variability in clinical populations within routine care (Kellett et al., 2021). Moreover, on a broader level, a review of psychologically informed literature today bares further witness to the influence of neo-positivism whereby specific hypothesis emerge from theories that can be falsifiable by statistically analysing observable data, thus, reflecting Popper's original hypothetico-deductive model where theories direct empirical research rather than being inductively built from it (Bonell et al., 2018; Nola and Sankey, 2007). Examples of this approach abound within the field of cognitive behavioural therapy, particularly in the establishment of empirically grounded clinical interventions (Barlow et al., 2013; Salkovskis, 2002). In turn, they have not only contributed to the development of proven efficacious treatments for a range of anxiety disorders and depression, but also continue to inform clinical guidelines (NICE, 2004, 2009, 2011) that has provided the empirical basis to support the national roll-out of the Talking Therapies programme (Clark, 2011, 2018).

However, such ontological and epistemological debates are not the sole concern of the philosophy of research itself. A closer inspection of philosophical underpinnings of psychotherapy also reveal commentary regarding the ontological and epistemological legitimacy of differing schools of psychotherapy. As McLeod (1998) articulates, whilst approaches to psychotherapy appear to broadly represent different strategies for helping people struggling with emotional difficulties, beneath the surface of practical interventions lie a range of philosophical positions.

A closer inspection of the philosophical bedrock of cognitive behavioural therapy provides an acute illustration of such considerations. Behavioural therapy (Skinner, 1971), in its time a groundbreaking clinical intervention for a range of emotional problems and the precursor to the development of cognitive behavioural therapy (Beck, 1979), noted the only legitimate science to be one directly linked with observable events. Accordingly, behaviourist scientific advances in the concepts of classical and operant conditioning focused on observable behavioural events located within a person's environment that could be objectively and scientifically measured (Grant, 1964). Through this lens, whilst behaviourism acknowledged the existence of cognition (thoughts, memories, imagery), from an epistemological perspective, they viewed it as functionalist and redundant and believed it to have no bearing on a persons' behavioural observable responses (Bandura, 1996).

By contrast, cognitive behavioural therapy sought to consider the mechanisms that may explain the relationships between observable events, for example, the mediating role of cognition. Fundamental to this concept was the evolution of humans and their capacity for thought, which we use to understand, comprehend, and engage with our environment (Bandura, 1996). An ontological perspective suggesting the nature of existence to be born out of our mind and body's interplay with the environment (Bendelow & Williams, 1995; Hodgkin, 1996; Kockelman, 2013). From this standpoint, what is epistemologically understood to be important are the beliefs (thoughts, memories, images) developed as a product of this interaction, which subsequently influences our behavioural, physiological and emotional responses (Harvey et al., 2007).

Within the clinical realm this may be seen as how a person interprets situations that for some may be thought of as being 'dangerous' leading to fear (emotion) and avoidance (behaviour). As such, this perspective laid the foundations of the cognitive-behavioural model of emotion. A development that through empirical investigations revealed themes of cognitive phenomena related to specific emotional disorders that translated into the emergence of models that explain the key cognitive and behavioural mechanisms that perpetuate a problem (Veale, 2007). For example, panic disorder was found to be associated with the catastrophic misinterpretation of bodily sensations (Clark, 1986), whilst in the case of obsessive-compulsive disorder (OCD) experiencing intrusive thoughts were found not to be the problem per se, but rather the meaning an individual attaches to them (see **Figure 3.0**) (Rachman, 1998; Salkovskis, 1999).

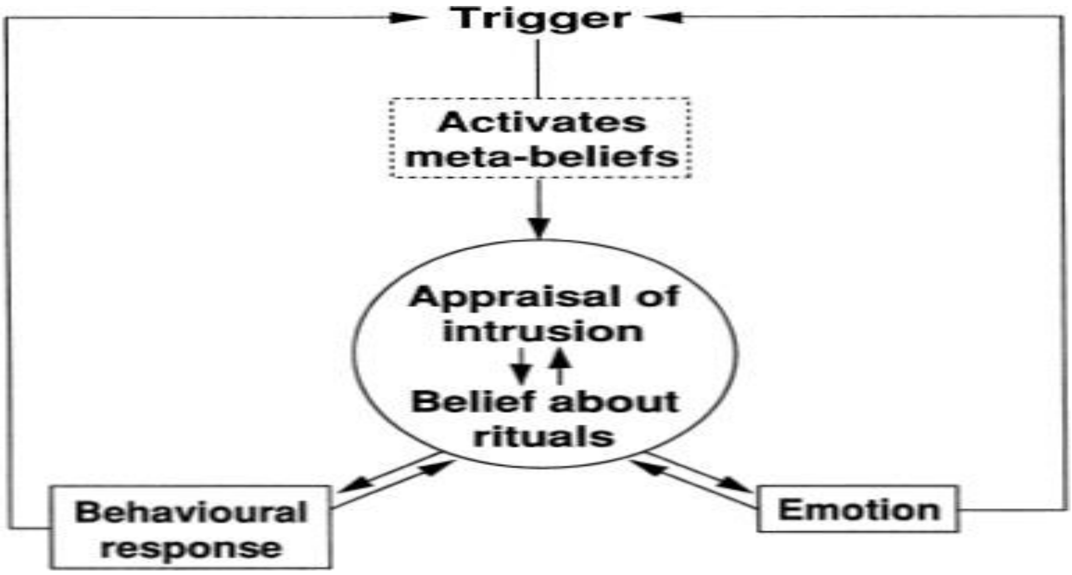

Figure 3.0 – A cognitive model of obsessive compulsive disorder (based on Salkovskis et al., 1998)

Arguably, this ontological and epistemological perspective not only augments and underpins cognitive behavioural theories of emotional disorders, but also extends to a constellation of theories ranging from biopsychosocial perspectives of health and health beliefs to name but two. Theories that share some common ground in their philosophical positions, but as will be illustrated in the following part of this chapter, vary in their empirical validity.

3.3 - *Theoretical perspectives*

3.3.1 - *Dualism*

The theory of mind-body dualism continues to evoke polemic debate (Van Oudenhove & Cuypers, 2014). Whilst essentially credited to the work of Descartes in the 17th century, mind-body discourse has long-standing foundations, from Greek antiquity (Duerlinger, 2005; Green and Groff, 2003) through to present day theology and western philosophy (Heidegger, 2010; Giddens, 1984; Rorty, 2009).

Hamilton and Hamilton (2005) posit Descartes ‘mind-body’ dualism to have been highly influential due to its reformulation on how the mind and body were understood. Accordingly, Descartes considered humans to consist of distinct binary features, the mind and the body, which operated without unity (Descartes, 1998). In such context, the mind is viewed as an immaterial thinking substance and the body as purely material and subject to material laws of causation (Kim, 2006).

Duncun (2000) contends that Descartes theoretical views continue to pervade in modern society. Recent studies appear to echo this sentiment. For example, a study by Demertzi et al (2009) found more than half their sample of undergraduate students believed the mind and body to be two separate entities and, somewhat interestingly, that this view was also shared by almost half of a large sample of health care professionals (n=1850).

The enduring and resilient nature of dualism has also been illustrated in studies considering the attributions people with long-term health problems ascribe to their symptoms, with a tendency to focus on physical explanations without any psychological consideration (Henningson et al., 2005; Kauffmann et al., 2014; Kirmayer et al., 2004; Scharloo et al., 2007). Moreover, dualistic views of health have been reported to be reinforced both socially and culturally (Astuti, 2001), whilst many suggest humans in themselves to be innately dualistic (Archavski, 2006; Bloom, 2005; Charmers, 2006). As such, against the backdrop of this study’s focus, it is important to acknowledge that for many people accessing psychological therapies for co-morbid long-term conditions and anxiety/depression some will hold the view that these remain two separate entities.

3.3.2 – *Reductionism and biomedicine*

The sphere of knowledge emanating from Descartes' dualistic formulation found further strength in its scientific application. Building on earlier fundamental theories of reductionism, Descartes' mind-body distinction conveyed the notion that complex processes could be deconstructed into component parts to enable them to be studied individually (Klein, 2009; Mehta, 2011)). To this end, Nurse (1997) noted reductionism enabled analytical methods to be applied within the natural sciences, thus creating the basis for the scientific revolution.

This movement provided the groundwork for the emergence of biomedical theories with its focus on disease and the codification of diseases as biological defects (Beresford, 2010). Accordingly, the biomedical model has dominated medicine through the twentieth century and onwards with its success being defined by advances that have contributed to the decline in infectious diseases and the increase in life expectancy (Moses and Martin, 2011; Nabel, 2009). Proponents of biomedical theory also point towards its pivotal impact in the development of medical treatments following the identification of underlying biological defects, for example, insulin replacement in type 1 diabetes (Miller et al., 2012), whilst also enriching our understanding of chronic conditions, such as chronic obstructive pulmonary disease (COPD) (Barnes, 2017).

In doing so, advocates of the biomedical model propose a number of biological features that may predict the long-term outcome of people experiencing chronic physical health problems. For example, studies have identified age, gender, illness severity, and co-morbidity/multimorbidity to be key determinants (Benzo, 2010; Gudmundsson et al., 2005; Heneghan et al., 2015; Mewes et al., 2014; Nevins &

Epstein, 2001; Picquet et al., 2007; Snow et al., 2001; Tinetti et al., 2011; Wang et al, 2017). As such, in acknowledging the influence of these biological features in determining the outcomes of people with long-term health problems, many are included as distinct variables in this study to help identify their influence in predicting outcomes in psychological therapy for people with long-term health conditions.

For many, the legacy of the biomedical model has found further legitimacy in the rise of evidence-based medicine (EBM) (Bandello, 2009), which continues to influence health policy and clinical practice (GOLD, 2013; NICE, 2010; Travers et al., 2007). Now common parlance within healthcare, proponents of EBM suggest its development to have enhanced the provision of healthcare as it provides a focus on scientifically valid treatments that are safer and cost-effective (Hill et al., 2011; Pope, 2003).

Yet, despite its contribution in modern healthcare, limitations to the biomedical model are said to persist (Moranda, 2011). For example, Alonso (2012) notes that it limits the concept of health and reduces it to a unidimensional view that serves to perpetuate the delivery of physical and mental healthcare into separate treatment silos (Alonso, 2012). Elsewhere, Greenhaigh (2012) contends biomedical theories to have done little to address the challenges faced by healthcare due to the increased prevalence of long-term conditions, co-morbidities and multimorbidity's. Indeed, Beresford (2010) suggests biomedical models of health risk oversimplifying complex processes and potentially disregard salient features of a phenomena, whilst Banduru (1996) asserts its application based on the laws of the natural sciences alone cannot fully account for the complex nature of human behaviour and psychology within the context of health. Arguably, the focus of this study highlights these pertinent issues, particularly as overwhelming evidence suggest that a persons' mental and physical health do not exist independently but are an inextricably linked double helix that is directly influenced by our social environment and psychological perspectives (Tyron, 2014; Woods, 2019).

3.3.3 - *Co-morbidity and multimorbidity*

Despite the term ‘co-morbidity’ being frequently cited in health literature, there continues to be no agreed meaning of how one may define it, albeit it is generally accepted to be present ‘in a patient with a particular index disease, (whereby) the term co-morbidity refers to any additional co-existing ailment’ (Feinstein, 1970, pg. 467). Debates over its underpinning theory have led to discussions on whether it relates to two co-occurring independent diseases or whether it is best viewed as a scenario whereby an index disease correlates with another disease (Krueger and Markon, 2006). In the case of the latter, identifying which condition is the index and which is the co-morbid condition is often not self-evident and may vary depending on the disease that prompted medical intervention (Valderas et al., 2009).

Co-morbidity, however, is not limited to physical diseases as large-scale epidemiological studies (Kessler et al., 2005) have found mental health disorders frequently co-occur than would be expected by chance (Krueger and Markon, 2016). Furthermore, as highlighted in the focus of this study, anxiety disorders and depression have been found to be highly prevalent in people with long-term health conditions (Eisner, 2010, Hill et al., 2008, Hynninen et al., 2005, Jones et al., 2012, Mewes et al., 2016, Scharloo et al., 2000). Indeed, research frequently demonstrates the prevalence of anxiety and depression to be at least two-three times higher in LTC populations in comparison to the general population (DiNicola, 2013, Melvyn et al., 2011, Yohannes et al., 2006, Usmanti et al., 2017).

The presence of anxiety and/or depression in the context of long-term conditions has been found to be far reaching. A systematic review by Pooler and Beech (2014) revealed the presence of anxiety and depression, in the context of other variables such as COPD symptomology and socioeconomic features, to statistically increase the likelihood of hospitalisation as a result of COPD exacerbations. Findings that echo the outcome of previous studies indicating anxiety and depression to increase the risk of morbidity and healthcare utilisation (Abrams et al., 2011, Gudmundsson et al., 2005).

Similar problems arise when considering the impact of multimorbidity which is frequently described as the presence of two or more long-term physical and/or mental health problems (Skou et al., 2022). Worldwide, it is approximated that 30% of the population experience multimorbidity with its prevalence significantly increasing with age and socioeconomic deprivation (Ho et al., 2022). The impact of multimorbidity is well established and has been found to be associated with reduced life expectancy and quality of life, functional problems, polypharmacy, and increased costs to healthcare (Barnett et al, 2012). Theories of how a person develops multiple conditions is in itself a complex phenomenon. It may be viewed as a result of one disease impacting on the function of another bodily system, through the accumulation of risk factors (age, obesity, smoking), genetics, by coincidence without a causal connection, or iatrogenesis (Turabian, 2020). Regardless of its path however, its very presence increases the likelihood of mental health problems (Cassell et al., 2018).

Yet, despite their disabling impact, research continues to suggest only one third of people with co-morbid (or multiple) physical and common mental health problems are being treated, with many being undiagnosed and untreated (Fritzshe et al., 2011, Maurer et al., 2008). A problem exacerbated by poor access to treatment (Robb et al., 2003) and the impact of co-morbidity and multimorbidity has on the practical commitment of engaging in therapy (Coventry and Gallatly, 2008, Fitzpatrick et al., 2010).

3.3.4 - *Variability in outcomes: A move towards practice-based evidence (PBE)*

Evidence derived from robust scientific research methodologies, most notably in the form of randomised controlled trials (RCTs) or meta-analysis, has been suggested to be the cornerstone of evidence-based practice. Indeed, without question, the use of evidence from RCTs has enriched psychotherapy research, particularly demonstrating the efficacy of CBT for a range of clinical problems (Hoffmann et al., 2012; Ijaz et al., 2018; Uphoff et al., 2020).

In spite of this, literature also reveal outcomes vary significantly even within methodologically sound RCTs of psychological therapy for common mental health problems with or without long-term health problems (Huibers et al., 2015). Whilst a number of studies report aggregated clinically significant improvements of between 50-70% (Butler et al., 2006; Cuijpers et al., 2013, Hoffman and Smits, 2008, Twomey et al., 2014 in Goddard), other studies report 15%-45% make no clinically significant improvement (Hansen et al., 2002). Arguably, this heterogeneity in outcomes appears to suggest people with the same diagnosis, but with differing demographic and clinical characteristics, respond differently to treatment (Delgadillo et al., 2016a; Delgadillo et al., 2016b; Delgadillo et al., 2016c; Fournier et al., 2009; Garfield, 1996; Hoffman, 2012; Hoffman and Smits, 2008).

Explaining variability in outcomes may be said to have long standing foundations. Osler (1904) famously observed ‘variability is the law of life, and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike…’ (Cushing, 1940, *pg. 94*). Despite this proclamation dating back to the early part of the last century, the concept of variation continues to intrigue clinicians and scientists, and its presence is clearly at play in present day health care. Allied to this notion of variability, variance and correlation have emerged to offer statistical accounts to explain the concept. Variance, as a statistical index, remains an essential tool to analyse the result of a study and is frequently used in research as a way to account for variance in specific areas of interest (Ford et al., 2014). For example, differences that may be found between groups receiving a treatment and variance within groups receiving the same treatment. As such, it may provide an explanatory basis to understand changes to dependent variables in terms of independent variables. In conjunction, correlation considers the relationships between variables in order to reveal the direction and magnitude of their association (Hosmer and Lemeshow, 2000).

These approaches to understand variability in clinical outcomes have led to a focus on developing research weighted towards external validity by studying treatment outcomes using heterogeneous clinical populations representative of routine care (Kellett et al., 2021), and as such, underpins the methodology adopted in this study. This movement towards practice-based evidence (PBE) offers unique insights into the effectiveness of treatments in real-world clinical scenarios, in contrast to evidence from EBM that do not account for clinical variability and has limited external validity. Moreover, PBE does not aim to generalise the effectiveness of an intervention, but instead observes for variations in care and outcomes and considers how to implement research-based treatments (Lambert, 2010).

Accordingly, as outlined in the previous chapter, numerous factors have been found to be associated with variability in outcomes in psychological treatments for people with both physical and mental health problems which when collated reveal a range of biological, psychological and social factors. This not only highlights the need to see research in the round, but also a wider theoretical perspective of what is considered to influence health and treatment outcomes.

3.3.5 - *Seeing the 'person' as a whole: A biopsychosocial perspective*

Within contemporary healthcare, the need to holistically address the healthcare needs of people as a whole continues to be a key objective. Arguably, Engel's (1977) unveiling of the biopsychosocial theory of health, one that represented a philosophical and theoretical shift as it attempted to unify mind and body by acknowledging the interconnecting influence of our physiological, psychological and social sense of self (Gilbert, 2005), may be viewed as a critical catalyst to this change.

Engel's biopsychosocial model drew its development from General Systems Theory (von Bertalanify, 1968). A theoretical model that has aided the understanding of highly complex systems (Melchert, 2011) by proposing all relative systems to be connected structurally and functionally with continuous feedback loops (von Bertalanify, 1968). That is to say, from a human perspective, a person's health is determined by the continual interaction of biological, psychological and social determinants. Indeed, a central feature of this study, in essence, considers the reciprocal influence health conditions have on a persons' mental health and vice versa, whilst also considering the impact they have on end of treatment outcomes in psychological therapies.

Within clinical practice, Mead and Bower (2000) suggest the biopsychosocial theory to have found traction through the concept of person-centeredness (Balint, 1964). A concept widely adopted within the delivery of current healthcare practice (Carr and Higginson, 2001), particularly in the field of nursing where it is said to provide a medium through which therapeutic relationships can be established (Mead and Bower, 2000). In doing so, people are placed at the centre of a care approach, enabling their holistic beliefs about their health and care to be understood in the context of shared decision making (Davidsen et al., 2016).

Yet, despite its adoption in healthcare the central tenets of the biopsychosocial model are not without criticism. Most notably, several authors question the validity of the biopsychosocial model, highlighting it as being too general (Ghaemi, 2009; Smith et al., 2013) and theoretically underdeveloped (Van Oudenhove, 2014), resulting in marked challenges in evaluating its effectiveness (McLaren, 1998). In accounting for such limitations, the biopsychosocial model may be viewed as a catalyst for a wider consideration of health and illness, one that laid the foundations for further theoretical refinement and research focused on the interaction of biological, social and psychological determinants that may help predict what influences health outcomes.

3.3.6 – *Theoretical models of health behaviours and illness beliefs*

The growing recognition of the interplay between these factors during the late 1970's, in the midst of the changing nature of illness, led to a consideration that behavioural and psychological factors were major contributors to the morbidity and mortality of long-term conditions (Newman et al., 2004). In light of these developments, the role of psychological principles in understanding how people adjust, maintain or prevent ill health became prominent (Armitage and Conner, 2000) and led to the emergence of a number of continuum theories that are outlined below that aimed to identify what influenced behavioural change and the likelihood of this change being enacted (Weinstein et al., 1998). Taken together, these theories arguably set out the necessary conditions for behaviour change and have influenced the focus of contemporary psychological therapies. In particularly, cognitive behavioural therapy, the treatment intervention focused upon in this study, which draws upon the theory of behavioural change to help people overcome anxiety disorders and depression, with or without long-term health conditions (Michie et al., 2014).

3.3.6.1 - *The health belief model (HBM*)

The health belief model (HBM) (Rosenstock, 1966) was considered an early innovator and has undergone further refinement over time (Becker, 1974). Central to its foundation was the idea that the likelihood of an individual taking health preventative action was a function of four components, namely;

- Beliefs about susceptibility to an illness
- Beliefs regarding the severity of an illness
- Beliefs that the specific measure will reduce risk
- Beliefs about the benefits and costs of undertaking behaviour change

Studies evaluating the predictive quality of the HBM in relation to behaviour change cite its positive impact in relation to health screening programmes (Champion, 1994). However, Taylor et al (2006) note the model to have limited predictive power, whilst Zimmerman and Vernberg (1994) contest HBM to be a myriad of variables rather than a coherent theory that establishes clear relationships between its core components.

3.3.6.2 - *Stress and coping model*

Lazarus and Folkman's (1984) influential model of stress and coping proposed emotional responses to difficult life events to be fashioned by two critical interlinked processes: appraisal and coping. Within this realm, appraisals of personal significance in the form of potential harm and loss influence a person's view of their coping resources for self-managing an event and its emotional impact (Hudson and Moss-

Morris, 2019). Sequentially, Lazarus and Folkman (1984) suggested these appraisals to directly inform the cognitive and behavioural coping responses used by individuals to alleviate distress that may be viewed as either problem-focused and/or emotional-focused coping. From this context, Folkman and Greer (2000) posit greater perceived control over 'stressors' to increase problem-focused coping, whilst conversely lower perceived control is associated with emotional-focused coping, for example, avoidance, denial.

Thus, Lazarus and Folkman's (1984) model assists the disentanglement of illness distress from psychopathology, whilst highlighting the importance of the perception of control and coping resources. However, whilst the model remains a significant contributor to our understanding of the impact of illness beliefs and coping, Hudson and Moss-Morris (2019) propose it falls short in considering specific illness beliefs and behaviours, for example, perceived course of illness and avoidance, which are potentially critical in helping a person manage illness distress.

3.3.6.3 - *Common-sense self-regulatory model (CS-SRM)*

Leventhal et al (1998) considered how an individuals' own beliefs about their illness were intrinsic in understanding how they cope and understand illness. Leventhal et al (2016) proposed a self-regulatory framework containing five specific dimensions of illness beliefs: *identify* of the illness (the diagnosis), the *perceived cause* of the illness, the *timeline* about how long the illness will last, the *consequences* of the illness, and its *curability and controllability*. In essence, emphasising the subjective experience of a person's perspective on their illness, whilst viewing them as an active problem solver in managing their health condition in the context of social factors (Leventhal et al., 2003).

Elaborations of this model led Leventhal et al (2016) to propose these domains to also influence treatment cognitions which include considerations of lifestyle changes, strategies to utilise when experiencing specific symptoms and appraising treatment efficacy. In doing so, Leventhal and colleagues introduced the idea that a person's illness and treatment beliefs shape the choice of coping behaviours such as self-management (Hagger et al., 2017). Indeed, the relationship between illness and treatment cognitions and self-management behaviours has received research empirical support (Kaptein et al., 2010; Richardson et al., 2016) and has helped to identify specific illness and treatment beliefs that directly influence procedural self-management plans (Petrei et al., 2012). Yet, emerging evidence also suggests many people holding pessimistic illness beliefs may be at elevated risk of developing anxiety and depression (Richardson et al., 2016), and as such, merely targeting illness and treatment beliefs may not address any associated mental health problems or emotional regulation needs.

3.3.6.4 - *Locus of control*

Conceptualised by Rotter (1966), the theory of locus of control was developed from social learning theory (Bandura, 1977) and focused upon the expectations of an individual and how they relate to reinforcements. Within this context, the greater the strength of self-efficacy, the greater the belief that reinforcements were determined by a person's own efforts (Goslin, 1969). Thus, from an illness perspective, the course of illness is dependent on a person's own behaviour, with a high internal locus of control being linked with improved quality of life and high resilience (Stewart and Yuen, 2011).

Central to its functional application is the role of self-efficacy. A construct that has been widely studied within literature in terms of its relationship with self-management for long-term health problems. For example, higher levels of self-efficacy have been found to be associated with lower levels of breathlessness in COPD (Simpson and Jones, 2013) and to enhance the effects of self-management programmes (Effing et al., 2009; Jerant et al., 2008, Lorig et al., 2001).

3.3.6.5 - *Theory of reasoned action (TRA) and the theory of planned behaviour (TPB)*

The Theory of Reasoned Action (TRA) and the Theory of Planned Behaviour (TPB) are two closely related cognitive theories. Evolving from the health belief model, the TRA focused upon two key belief variables, notably ‘behavioural attitudes’ and ‘the subjective norm’ (Fischbein and Ajzen, 1975). As such, the model proposed intention to be a key predictor of behaviour, whereby intention results from the variety of attitudes held towards a specific behaviour. Building on this framework, The Theory of Planned Behaviour (TBP) (Ajzen, 1991) drew inspiration from social cognitive theory and the role of self-efficacy (Bandura, 1986). Accordingly, the TBP added the dimension of perceived behavioural control, to represent the perceived ease or challenge with which a person was able to carry out behavioural change (Ajzen, 1991).

Utilised in a range of different health settings, a volume of research has indicated the TRA and TPB to be more accurate in predicting health behaviours in comparison to the Health Belief Model (Armitage and Conner, 2001). In particular, the TBP has been found to be able to predict 20% of the variance in behaviour change brought about by interventions (Downs and Hausenblas, 2005). Although, in a similar fashion to the Health Belief Model, it has yet to result in a coherent set of clinical interventions that result in behaviour change (Webb et al., 2010).

3.3.6.6 - *Trans-theoretical model*

The Trans-Theoretical Model developed by Prochaska and Diclemente (1993) proposed a number of stages of change along a continuum of behavioural change. A theory drawn from a range of cognitive theories it proposed five distinct levels of motivational ‘readiness’ (Heimlich and Ardoin, 2008), namely: pre-contemplation, contemplation, preparation, action, and maintenance, with the transition between stages being modified by self-efficacy and decision balance (the pros and cons of a behaviour) (Armitage et al., 2004).

Widely used in the field of addictions, Nisbet and Gick (2008) attest that its strength lies in its ability to account for both social and psychological drivers that influence a person’s motivation towards change. However, when compared with other behavioural change models, behavioural outcomes have not been found to be superior (Adams and White, 2005). Moreover, there remains limited evidence to support the model’s principles that there are common definable stages of change that span across differing populations (Littell and Girvin, 2002).

3.3.7 - *Cognitive behavioural theory of emotion*

As presented earlier in this chapter, Cognitive Behavioural Therapy (CBT) has witnessed a remarkable growth since the early pioneering work of Aaron Beck (Beck, 1976) with a range of interventions developed to help understand and treat a wider range of disorders (Clark, 1985, Salkovskis, 1985). Cognitive behavioural therapy derives from a combination of behavioural and cognitive therapy. Behavioural therapy emerged during the 1950s and was underpinned by learning theory alongside the theories of behaviour change presented previously. At its heart was the theory of conditioning: operant conditioning, which suggests the strength of a behaviour is modified by the behaviour's consequences, such as reward or punishment, and classical conditioning, which identified that a potent stimulus (e.g. fear) can be paired with previously neutral stimulus (Eysneck, 1952). As such, behavioural therapy focused on developing an empirical approach to theory testing in clinical practice, focusing on changing behavioural patterns that appeared central to the maintenance of a person's problems (Hollon and Beck, 2003).

Early outcome studies illustrated behaviour therapy to have benefits in the treatment of phobias and obsessive compulsive disorder (Bennett-levy et al.,2004). Despite early success, limitations to its theoretical framework (Rachman, 1997) led to the consideration of the role of cognition (appraisals and beliefs), stimulating the development of cognitive therapy (CT). An active, structured, time-limited therapy, CT aimed to help a person identify and reality-test unhelpful thoughts related to underlying emotional distress and behaviours (Beck, 1976). A symbiosis of the two approaches producing the CBT we know today that has been found to be an effective treatment for a range of anxiety problems and depression (Hofmann et al., 2012).

Despite its prevalent success, CBT's core theory has been questioned. Gilbert (2000) argues that CBT does not have a comprehensive theory of mind, suggesting it to be a set of heuristic values, such as beliefs and schemas. Moreover, the actual treatment focus on beliefs and schemas has also been questioned with treatment component analysis finding cognitive change to have little causal effect in symptomatic improvements (Borkovec et al., 2002, Dimidjian et al., 2006, Jacobson et al., 1996).

3.3.8 – *From personality traits to personality disorders*

Theoretical focus has also considered the role of personality traits in chronic illness. As noted in the previous chapter, personality traits reflect relatively stable, enduring patterns of thinking, perceiving, and relating to self and others in the world (APA, 2013). Mostly observed in the field of psychiatry, the development of a five-factor model of personality enabled researchers to consider the influence of personality in greater detail (Costa & McCrae., 2002). Accordingly, the model proposes 5 specific domains; neuroticism, extraversion, openness, agreeableness and conscientiousness.

Evaluation of this theory has subsequently identified neuroticism and conscientiousness to be associated with a greater sense of burden when living with a long-term condition (Erlin et al., 2013, Sutin et al., 2013). The exact mechanism in which trait personality impacts on long-term conditions remains under explored, however, many suggest high neuroticism generates greater intensity and frequency of negative emotions which alongside behavioural patterns (e.g. smoking and other substance misuse) increase the risk of developing a chronic disease (Dennollet et al., 2000, Turiano et al., 2012). Likewise, research on the general impact personality traits have on people with LTC's have revealed similar findings (Stilley et al., 2005). For example, a study by Alma et al (2016) focusing on the relationship between personality traits and health status in COPD found higher personality trait scores to be associated with poorer health status, with a moderate correlation discovered between neuroticism and health status.

Whilst we all have personality traits, for some people their traits may become so pervasive, rigid, and maladaptive that they create significant long-lasting impairment in various domains of their lives, in particularly their interpersonal and social functioning. Such difficulties generally create significant distress for the person and those people around them, and if coming into contact with health services may lead to a diagnosis of a personality disorder (Morgan et al., 2022).

Currently, it is estimated that nine per cent of the population have a personality disorder, of which there are ten different classifications, each of which differ in their presenting characteristics (ICD-10, 2016). Current psychological theory suggests the foundations of personality disorders emerge during a person's developmental stage of their lives as a result of (but not in all cases) difficult experiences, for example, trauma or mistreatment, which for some people may be in combination with biological predispositions (Young et al., 2003). For many, these experiences shape the development of fixed, rigid, and unhelpful beliefs about themselves, the world, their future, along with problematic pervasive behavioural responses (Beck et al., 2015).

Research frequently reports people with personality disorders to experience high levels of physical health co-morbidity, such as cardiovascular disease, arthritis, and chronic pain (Fishbain et al., 2011; Powers and Oltmanns, 2013). The mechanism underpinning the prevalence of co-occurring physical health problems in personality disorders is yet to be clearly established. However, it is suggested a biopsychosocial framework to understanding this may hold value (Dixon-Gordon et al., 2015). Certainly, research in this area has found biological vulnerabilities (Roepke et al, 2010), psychological and behavioural factors that exacerbate biological vulnerabilities, for example, overeating, smoking, and substance misuse (Frankenburg and Zanarini, 2006), and social risk factors such as environmental stressors (Mamabolo et al., 2012), to predict the development of physical health problems in people with personality disorders.

3.3.9 - *Psychosocial factors*

Psychosocial factors have also been observed to predict how a person responds to ill health within a biopsychosocial context (Mewes et al., 2016). Within this realm, sociodemographic effects have been found to influence the course of LTC outcomes. Most notably, people from socioeconomic disadvantaged backgrounds have been found to have greater chance of developing LTC's and to have poorer outcomes when they do (Coventry et al., 2013, NICE, 2016). Relationships with family members have also been deemed to have an impact on LTC self-management, particularly in relation to symptom burden and the impact this can have on familial relationships (Annegarn et al., 2012). Thus, suggesting the quality of social relationships to be a determinant in LTC health outcomes (Janssen et al, 2012).

Elsewhere, alternative explanations to understanding the causes of these associations have also been explored. For example, the relative deprivation hypothesis; a hypothesis that attempts to explain why health inequalities negatively influence a person's health (Caner and Yigit, 2020). Central to this idea is the notion that a person's health or health related behaviour is a consequence of both their own resources (income, educational attainment) and by their status in terms of resources (how much people have in comparison to others) (Smith et al., 2012). As such, studies have indicated higher levels of relative deprivation to be linked to poor health outcomes, albeit further research is required to establish this further.

3.3.10 - Psychological therapies for long-term conditions

Given the high prevalence of anxiety disorders and depression in LTC populations, attention has not only focused upon pharmacological treatment, but also specific psychological interventions that may help alleviate and manage their conditions from a biopsychosocial stance**.** Much of the earlier approaches to psychological therapies for LTCs were based upon psychoanalytical treatments that aimed to help patients manage their condition. However, an absence of clear empirical evidence demonstrating effectiveness subsequently led to interest from other domains of psychological interventions. In particularly, CBT’s role in the treatment of co-morbid physical and mental health problems.

3.3.10.1 - Cognitive behavioural therapy for long-term health problems

Overtime, interest has become focused upon theories that consider how illness appraisals and behavioural factors increase and maintain distress in people with long-term health problems (Kaptein et al., 2009). As such, CBT has aimed to theoretically formulate an understanding of anxiety, depression, and illness beliefs in the context of health conditions, integrating this knowledge with empirically driven transdiagnostic and disorder-specific processes that perpetuates a person’s difficulties (Harvey et al, 2007) and limits their self-management (Smith et al., 2017). Such processes include behavioural avoidance, experiential avoidance (e.g. denial, suppression), self-focused attention, rumination and worry (Dudley et al., 2011). For example, in COPD the dominant symptom of dyspnoea has been conceptualised to increase the likelihood of catastrophic misinterpretation, with such health appraisals increasing the likelihood of physiological symptoms typically associated with a normal anxiety response. The model subsequently proposes that these symptoms become the subject of further misinterpretation due to increasing levels of fear. The result being the avoidance of physical exertion to prevent dyspnoea that in turn increases the likelihood of further deconditioning (Livermore et al., 2015).

A promising array of clinical studies support this theoretical position resulting in CBT being seen as an effective treatment for people with COPD (Howard and Dupont, 2014; Heslop and Foley, 2009, Hynninen et al., 2010; Kunik et al., 2008; Livermore et al., 2015), diabetes (Safeen et al., 2017), persistent physical symptoms (Menon et al., 2017), functional neurological disorders (Gutkin et al., 2020) to name but four illnesses. However, uncertainty remains as to the effectiveness of CBT for LTCs and whilst this highlights methodological issues found in some studies, even within robustly developed RCTs their results indicate small-to-modest effect sizes. This is particularly interesting when compared to CBT studies for anxiety disorders and depression alone, which report large effect sizes (Hoffmann et al., 2012). Thus, confirming a need for further theoretical developments.

3.3.11 - *Collaborative integrated care*

As noted in previous chapters, in the UK alone, 16.5 million people struggle with a LTC, of which 30% have co-morbid mental health problems (DoH, 2012; Naylor et al., 2012). Moreover, the presence of co-morbid mental health problems has not only been found to reduce quality of life outcomes (Dalton, 2014; Moussavi et al., 2007) but also increase healthcare costs by 50% (Dorning et al., 2015; Hutter et al., 2011; Naylor et al., 2012).

Despite this, very few people have access to treatment that addresses both their physical and mental health needs concurrently (DoH, 2008, 2011a, 2011b). As such, there appears to be a ground swell of acknowledgement that care for people experiencing co-morbid LTC's and mental health problems could be enhanced through 'collaborative integrative care' (Goodrich and Cornwell, 2008). Central to this proposed framework for practice is its aims to place the client at the centre of care decisions and enhance care through the use of structured patient management plans, regular follow-up, and enhanced professional communication (Gunn et al., 2006). In addition, by bringing together multi-disciplinary professionals, collaborative care provides an opportunity to form communities of practice that can enhance knowledge and practice whilst promoting shared learning (Wenger et al., 2002).

In comparison to routine care, Archer et al (2012) found collaborative care to deliver improved outcomes for people with co-morbid chronic illness and common mental health problems. Indeed, one example of collaborative care has been the introduction of psychological therapies into physical health pathways. From this perspective, a systematic review by Coventry et al (2013) noted the adjunct of psychological interventions in the context of collaborative care for COPD resulted in significant improvements in anxiety and depression, albeit with modest effect sizes. Moreover, Coventry et al's (2014) multi-centred RCT of collaborative care for people with depression and co-morbid diabetes or cardiovascular disease found introducing psychological therapies within an integrated package of care reduced depression and improved self-management.

However, the integration of collaborative care is not without challenges. Most notably, 'institutional and cultural barriers, separate payment systems…and the trend of sub-specialisation in professional education' (Naylor et al., 2012, p.6). Elsewhere, Knowles et al's (2015) qualitative study on the management of depression with co-morbidity in collaborative care found participants wanted to discuss their emotional wellbeing outside of their LTC clinics, questioning the role of integrated multi-disciplinary co-located clinics. Despite these challenges, the integration of psychological therapies into collaborative care for LTC's remains a policy priority and can arguably be seen as one way forward to limit the continuation of separate treatment pathways for physical and mental health care.

3.3.12 - *Organisational delivery of psychological therapies*

The Talking Therapies programme was designed to provide evidence based psychological therapies for people experiencing common mental health problems (Clark, 2011; DoH, 2008; Layard, 2006; London School of Economics, 2006). Whilst the programme has been found to be clinical and cost-effective (Clark, 2011), interest has risen in its ‘stepped care’ delivery of psychological therapies and its underlying theoretical principles.

3.3.12.1 - Stepped-care

‘Stepped-Care’ represents a theoretical model that focuses on providing the most effective treatment delivered in the least restrictive option but is still likely to provide significant gain (Bower and Gilbody, 2005). Thus, in essence, aiming to use limited resources to their greatest impact on a population basis (Von Korff and Tiemans, 2000). At its core is a number of fundamental beliefs. Firstly, that patients should not wait for treatment, secondly, that people require different levels of treatment, thirdly, finding the correct treatment requires a focus on outcomes, and fourthly, the movement from less to more intensive treatment increases the effectiveness and lowers costs overall (O’Donohue and Draper, 2013). As such, this framework has been proposed as an effective model for the delivery of a range of services at scale, from chronic disease to mental health problems.

As noted, a critical component to the operationalisation of stepped-care is the need for different intensities of treatment. Within the field of psychological therapies, this means the provision of low-intensity guided self-help (Step 2) to higher-intensity therapies (Step 3) such as CBT. Accordingly, within the model, treatment response is closely monitored with individuals not showing signs of significant improvement being ‘stepped-up’ to a higher intensity of treatment in a self-correcting fashion (Clark, 2011) to maximise the opportunity for improved outcomes. Although in theory, initial treatment is based on the least restrictive option, it is also tailored to account for patient preference, severity and complexity, and evidence based guidelines (Korff and Tiemans, 2000).

The relative effectiveness of this organisational treatment delivery model for psychological therapies was considered in the previous chapter, with evidence suggesting it to be somewhat effective. Yet, to date, questions remain regarding its suitability and effectiveness for people with long-term conditions, and it is from this perspective that its role is an important feature focused upon in this study.

3.3.13 - Early response to psychotherapy

Whilst the organisational delivery of treatment has received attention due to its potential relationship with outcomes, one further area of clinical interest has been the role of early change in psychotherapy and its relationship with end of treatment outcomes. Who, how, and why people respond differently to psychological treatment is a question that both researchers and clinicians continue to toil with and arguably struggle to answer convincingly with precision particularly for people with co-morbid difficulties.

Several factors have been cited to increase the likelihood of early change in treatment. These range from common factors present across all psychological therapies to specific therapeutic techniques. Common factors that have been found to influence early change include the development of a therapeutic relationship, a healing setting, the plausible explanation of a patient’s problems, and the expectancy that treatment will be successful by both the patient and therapist (Aderka and Shalom, 2021; Frank and Frank, 1991). Other factors such as the installation of hope, the time given to deeply explore a patient's problems, support, and advice, have also been found to aid early change (Lambert, 2010).

Elsewhere, specific therapeutic factors aligned to modalities of treatment have also been suggested to increase the likelihood of early change. In cognitive behavioural therapy, patients who are able to engage in a structured action-orientated treatment, capture and re-evaluate their thoughts and beliefs, change their behaviours through experimentation, and engage in out-of-session practice, have been observed to increase the chances of early therapeutic gains (Bennett-Levy et al., 2004; Lee et al., 2024; Mansell et al., 2008).

In contrast, other component studies aimed at identifying the specific active elements of an effective treatment have failed to find specific activities that improve the likelihood of early change (Ahn and Wampold, 2001). Moreover, Lambert (2010) notes that in some quarters of research the focus on identifying the specific active ingredients has in itself perpetuated conflict within the field of psychotherapy, as it pitches one treatment against another resulting in the slowing down of progress.

3.3.13.1 - *Early reliable improvement*

Regardless of the debate on how and why patients make early change or not, one promising (and perhaps unifying) feature that has been found to predict positive end of treatment outcomes is the role of early reliable improvement (ERI) on validated outcome measures. Several practice-based studies have demonstrated that patients with anxiety disorders and depression, but without long-term health problems, who make early reliable improvement to be more likely to achieve recovery at the end of treatment (Delgadillo et al., 2014). This pattern of early changes has been cited to follow the path of a ‘dose-effect’ that is characterised by a curvilinear relationship, whereby the majority of symptomatic improvement occurs in the early stages of treatment (Robinson et al., 2020). Defining what is meant by the early stages of treatment in itself varies from disorder to disorder as research has found trajectories of change to be heterogeneous and dependent on a number of factors, such as severity, complexity, and co-morbidity (Barkham et al. 2006; Lincoln et al., 2016). Despite these challenges, the role of early reliable improvement appears to have clinical utility in predicting whether a person is ‘on track’ to recovery or ‘at risk’ of not making recovery, and in the case of the latter enabling proactive treatment changes to be made early to increase the chances of benefitting from treatment.

3.3.14 - *Conclusion*

This chapter has presented the salient philosophical and theoretical perspectives that informed this research study. In doing so, it has shown how the study positions itself within a neo-positivism philosophical framework, whilst highlighting a range of theories that underpin the study. This is diagrammatically represented in Table 3.0, and as such, provides the fundamental basis from which this study evolved and informed the study’s choice of methodology and methods that are introduced in the next chapter.

Table 3.0 – *Overview of philosophical and theoretical perspectives*

<table>
<tr><td colspan="7">Philosophical</td></tr>
<tr><td colspan="7">Neo-positivism</td></tr>
<tr><td colspan="7">Theoretical
<i>Main Themes</i></td></tr>
<tr><td>Dualism</td><td>Variance in Outcome</td><td>Biopsychosocial Theories of health</td><td>Psychological Therapies</td><td>Collaborative Care</td><td>Organisational Delivery of Psychological Therapies</td><td>Early Response to Psychological Therapy</td></tr>
<tr><td colspan="7">Theoretical
<i>Sub-themes</i></td></tr>
<tr><td><i>Reductionism and Biomedical Models of Health</i>
<i>Co-morbidity & Multimorbidity</i></td><td><i>Practice-based Evidence</i></td><td><i>Models of Health Behaviours</i>
<i>Psychosocial Influences on Health</i></td><td><i>Behavioural Theories</i>
<i>Cognitive Theories</i>
<i>Cognitive Behavioural Therapy for Long-Term Health Conditions</i></td><td><i>Integration</i></td><td><i>Stepped-Care</i></td><td><i>Early Reliable Improvement (ERI)</i>
<i>Dose-effect</i></td></tr>
</table>

Chapter 4

Methodology and Methods

Chapter 4 – Methodology and Methods

4.1 - *Introduction*

Following on from the previous chapter, this chapter focuses on its overall methodological approach and the specific research methods used to establish how pre-treatment patient level factors, organisational delivery of psychological therapy, and early reliable improvement, predict end of treatment psychological therapy outcomes for people with long-term conditions. The chapter commences with an introduction to the study's underpinning methodology. This is followed by a description and rationale for the research methods employed, focusing on its design, aims and objectives, study population and interventions, sample technique, sample size, outcome and predictor variables, data collection and management, data analysis, and ethical considerations.

4.2 - *Research methodology*

Decisions regarding the methodological approach employed in research are integral to the research process as they aim to explain a research study's strategy, its design, and the process of scientific enquiry undertaken (Punch, 2005). In doing so, Crotty (1998) asserts that research methodology not only governs and shapes the choice of specific methods in order to provide valid evidence to answer the research questions under investigation, but also illustrates the relationship that exists between the theoretical and philosophical assumptions that underlie research itself.

Within the field of psychological therapy, quantitative methodology underpinned by neo-positivist and positivist research philosophies continues to be the dominant research framework. Whilst the type of quantitative research approach remains dependent on the area of interest being investigated, these approaches typically fall into two categories: experimental and non-experimental. Whilst both experimental and non-experimental quantitative research represent approaches on a continuum of quantitative research design, differences exist in their fundamental aims. Experimental studies attempt to determine cause-effect relationships through the employment of controls and the manipulations of interventions in their designs. In contrast, non-experimental quantitative studies, for example, correlation research, largely represent a group of research approaches where there is no attempt to randomly assign participants to groups or to actively introduce or manipulate an intervention (Carlson and Morrison., 2009; Cook and Cook., 2008).

Quantitative experimental studies epitomised by randomised controlled clinical trials (RCT) are frequently acknowledged as particularly powerful when evaluating health care interventions (Department of Health, 2005). Indeed, often revered as the most scientifically rigorous, valid, and unbiased method to test specific hypotheses to measure the efficacy of an intervention (Kraemer et al., 2002, Verhagen, 2001), experimentation remains the primary approach advocated to evaluate complex health interventions (Craig et al., 2008). Notwithstanding the contribution this approach to research has made to the evidence base of psychological therapies, debate ensues over its tenuous relationship with external validity due to the unintended consequences of the rigour applied in controlled trials (Rothwell, 2005). Moreover, experimental research has been reported to be expensive, time consuming, and difficult to implement in real world clinical settings (Norwood, 2010).

Accordingly, complementary non-experimental quantitative approaches to psychological therapy research have become increasingly widespread (Brandenburg, 2017). Correlational research is one such approach that seeks to identify the direction and strength of relationships that may exist between two or more variables without the manipulation of an intervention to change an outcome (Grove et al., 2014). In doing so, correlational research enables the relationships between variables to be quantified, explained and predicted often using real world clinical data (Vogt and Johnson, 2012). Thus, correlational research offers a valuable contribution in psychological therapy research using practice-based evidence by; firstly, uncovering relationships between variables that may enable predictions to be determined, and secondly, by offering insights for future experimental research through the identification of relationships that may potentially be causal (Curtis et al., 2016).

Given the study's underpinning philosophical and theoretical underpinnings, combined with its focus on seeking to explain and quantify the relationship between a range of predictor variables and outcomes using routine clinical outcome data, the study adopted a quantitative correlational methodology.

4.3 - *Research methods*

4.3.1 - *Design*

During the initial design phase, a number of factors were considered which influenced the choice of design. These included the study's philosophical, theoretical and methodological approach in combination with its aim and objectives. In addition, factors such as the population, intervention, the availability of completed data, and other practical issues such as cost and timeliness to complete the study, were also factored into the choice of design.

In accounting for these factors, a 2-year retrospective observational cohort design was chosen. This design is commonly associated with predictor-finding studies to reveal the associations between variables, understand variability in treatment response, and/or the effectiveness of an intervention in heterogeneous clinical populations (Carlson and Morrison, 2009; Euser et al., 2009; Moons et al., 2009). Moreover, it enables participants from natural clinical populations to be followed over time providing an opportunity to gather a large dataset of routine clinical outcomes for analysis (Barkham and Mellor-Clark, 2003). Thus, in this study the design enabled a large sample of participants accessing psychological treatment to have their routine clinical outcomes observed overtime, in order to examine the association between specific predictor variables (pre-treatment patient characteristics, stepped-care, and early reliable improvements) and the outcome variable of reliable recovery.

As the design introduced a temporal dimension, due consideration was given to the use of a retrospective or prospective observational cohort design. Whilst both options have advantages and disadvantages, a prospective study was not chosen due to the need for a long duration of follow-up which was considered difficult to undertake given the time constraint of the study and its vulnerability to losing participants during follow-up (Song and Chung, 2010). As such, a retrospective study was adopted due to its advantageous timeliness and inexpensive nature. Although a well-documented weakness of retrospective studies is the reported limited control a researcher has over data collection (Mann, 2003), this was mitigated by utilising the standardised and mandated data used within the national Talking Therapies-LTC programme whereby data completion rates are reportedly over 98% for all mandated outcomes (Clark et al., 2017). This level of data completion was confirmed in a preliminary unpublished pilot study in which a smaller sample of 358 patients provided a routine data completion rate of 98.6%.

Decisions regarding the length of time needed to attain a large enough data set for the study drew on the outcome of the aforementioned pilot study. In this pilot, full data sets for 358 patients who met the pilot criteria was collected during a 6-month window. Based on this finding, it was envisaged a 2-year window would provide data for over 600 patients which represented an adequate sample size and data set for analysis to support the validity of findings (see section 4.3.7 for further detail on sample size).

Although widely recognised for their external validity, observational studies are commonly cited to be at inherent risk to a range of potential biases due to the absence of randomisation of homogeneous patient populations, independent assessment of treatment adherence and outcomes, and the impact of confounding variables leading to the potential for overestimated treatment effects (Benson et al., 2000). Whilst it may be suggested that appraising an observational study from a similar standpoint to that of an efficacy trial design is not wholly appropriate, addressing the inherent risks in observational studies requires the use of specific methods to mitigate such risks.

To account for these risks, the study used some desirable features of efficacy studies, for example, repeated outcome measures, including all patients who met the inclusion criteria in the data analysis, and close treatment supervision. In addition, the risk of bias within the study was assessed using a Critical Appraisal Skills Programme tool for Observational Studies (Critical Skills Appraisal Programme (CASP), 2018). This 12 question checklist revealed the study had an overall low level of bias, albeit one area of concern identified by the CASP was the length of follow-up. Whilst all participants in the study were followed up for three months post-discharge as per standard guidelines for Talking Therapies services (National Collaborating Centre for Mental Health, 2021), it may be suggested that a longer follow-up period would have reduced any potential uncertainty about the study’s results. However, achieving this within the confines of using routine outcome data from a real world clinical setting was beyond the timescale to complete the study.

Despite these limitations, the use of similar observational designs have been widely used to evaluate the Talking Therapies programme in England, with the aim to understand predictors of outcomes and the real-world effectiveness and limitations of empirically supported psychological therapies offered to people experiencing common mental health problems (Clark et al., 2009, 2011; Delgadillo et al., 2013, 2016a, 2017a, 2017b; Firth et al., 2015; Gyani et al., 2011; Kenwright et al., 2017; Prina et al., 2014; Richards and Borglin, 2011; Richards and Suckling, 2009; Wakefield et al., 2020). These studies have not only shown comparable results between observational studies and randomised controlled trials (RCTs) but have also demonstrated the value of observational studies in complementing RCTs in hypothesis generation and establishing further questions for future RCTs.

4.3.2 - *Aims of the study*

The overall aim of the study was to examine how pre-treatment patient level factors, organisational delivery of psychological therapy, and early reliable improvement in treatment influence outcomes in psychological therapy for people with co-morbid long-term health conditions (LTCs) and common mental health problems (e.g. depression and/or anxiety disorders) in routine care.

4.3.3 - *Objectives*

The study’s specific objectives examined the extent to which:

- Pre-treatment patient characteristics predicted outcome in psychological therapies for LTCs

- A ‘stepped-care’ model influenced outcome in the delivery of psychological therapy for people with LTCs
- Early reliable improvement (ERI) predicted outcome in psychological therapy for LTCs

4.3.4 - *Study population and intervention*

As noted previously, the study used anonymised secondary data which had been routinely collected by a Talking Therapies service for people aged 18 and over with co-morbid physical and mental health problems. Situated in the West Midlands, the service covers a population of 250,000 people and operates in a large geographical area, both urban and rural, with a range of social deprivation and high levels of LTCs (Stoke-on-Trent and Staffordshire Clinical Commissioning Group, 2014).

Clients accessed the service by self-referral via telephone or web referral or by a clinical professional referral (e.g. General Practitioner, Community Physical Health Teams). Following a referral, clients were offered a one-hour initial assessment to ascertain their main presenting problem and a diagnostic label was assigned to each patient based upon the International Classification of Disease (ICD-10) codes (World Health Organization, 2010). Clients were then offered a choice of NICE approved psychological therapies.

The service provided low intensity (LIT) and high intensity treatment (HIT) delivered in a ‘stepped-care’ model as part of the national Talking Therapies-LTC programme (National Collaborating Centre for Mental Health, 2021). LIT consisted of up to 10 sessions of brief (30 minute) guided self-help interventions based on cognitive behavioural therapy (CBT) delivered by psychological wellbeing practitioners (PWPs).

HIT was longer in both duration (at least 60 minutes) and number of sessions (maximum of 20 sessions) and focused on the delivery of CBT provided by psychotherapists.

Both PWPs and psychotherapists were trained to an accredited national standard at post-graduate level (Bennett-Levy et al., 2010; Roth and Pilling, 2008) (Appendix 2) to deliver protocol driven evidence-based treatment consistent with treatment guidelines (NICE, 2010). The accreditation of post-graduate level training courses was formally assessed by regulating bodies, the British Association for Behavioural and Cognitive Psychotherapies and the British Psychological Society, to demonstrate clinical competency. All clinicians in the service received weekly individual supervision to maintain their accreditation status. In addition, all therapists in the service had received additional specialist LTC training to meet a new national LTC competency framework (Roth and Pilling, 2015) (Appendix 3).

Individual therapy was delivered using a ‘stepped-care’ model where the aim was for the majority of patients to initially receive LIT followed by HIT if required. However, where the option to commence LIT was declined by patients or contra-indicated by clinical complexity or where there was only evidence to support a specific HIT intervention, for example, chronic pain management, post-traumatic stress disorder, patients were offered HIT alone (NICE, 2016).

4.3.5 – *Sample technique*

The study used data from a nonprobability consecutive sample (Van den Broeck and Brestoff, 2013) of clients who met the eligibility criteria outlined below. This type of sampling is a commonly adopted sampling technique used in observational studies (Delgadillo et al., 2017; Gyani et al., 2013; Clark et al., 2009).

As per standard Talking Therapies reports on clinical outcomes, completed treatment was defined as having had an initial assessment and at least one treatment session prior to discharge (Clark et al., 2017). This definition of completed treatment accounts for the fact that participants who only received one session would have only received an assessment without a significant component of treatment and separate pre-post outcome scores could not be collected if there was only one session. Clients referred during the two-year timeframe of the study who had not completed treatment were excluded.

4.3.6 Eligibility Criteria*:*

Inclusion Criteria -

1. Diagnosed common mental health problem
2. Diagnosed long-term physical health problem
3. The severity of anxiety and/or depression at assessment is in 'clinical caseness'. This is defined as being above the clinical cut-off scores for reliable recovery (Department of Health, 2011b) on standard measures for anxiety (Spitzer et al., 2006) and depression (Kroenke et al., 2010)
4. Registered with a GP in the services locality
5. Aged 18 and over
6. Able to read, write and understand the English language
7. Received an initial assessment and one or more treatment sessions
8. Completed treatment during April 2018-March 2020. This includes participants who had either a planned discharge, an agreed early ending or dropped-out of treatment

Exclusion Criteria –

1. Had a primary psychiatric diagnosis of personality disorder
2. Had a diagnosed organic illness or learning disability
3. Had a diagnosed psychiatric condition for which they are currently under the care of a Secondary Mental Health Service (Community Mental Health Team)

4.3.7 - *Sample size*

To establish a sample size that was able to detect statistical differences, the study used a recommendation of ’20 events per variable’ (EPV) to calculate an adequate sample size when using binary logistic regression (Austin and Steyerberg, 2017), the study’s data analytic approach. Whilst the use of a simple ratio has been suggested to be an oversimplification that may influence accuracy of results (Courvoisier et al., 2011), it nevertheless remains a widely used recommendation that can approximately inform a suitable sample size (Heinz et al., 2017)

To estimate a suitable sample size using this formula, the study utilised data from a 1-year preliminary pilot study. This found thirty percent (*n* = 806) of people accessing psychological treatment from the study site had co-existing physical and mental health problems, and of these, 368 (46%) met the inclusion criteria outlined for this study. Based on this, the study anticipated 46% of the total people accessing the service with LTCs would go on to meet the study’s criteria. As a total of 16 predictors was used, a sample size formula established a target sample of 696 patients (16 x 20/0.46) (Dumas-Mallett et al., 2017). In total, the study used data from 583 participants who met the eligibility criteria. This represented 84% of the target sample.

4.3.8 - *Predictor Variables*

The study used a background knowledge framework using the literature review in Chapter 2 to select the study’s predictor variables. This approach to identifying key variables has been found to reduce bias in variable selection which can influence the overall accuracy of predictions (Maltby et al., 2010), help to consider both the chronology of measurement collection and the quality of the measurement (Norwood, 2010; Polit and Tatano Beck, 2012), and account for the availability of data to be collected in routine clinical practice (Heinze et al., 2017).

To this end, a number of patient, service level, and clinical factors that have been found to influence end of treatment outcomes in psychological therapy, albeit in non-LTC populations, were used as predictor variables. These were pre-treatment patient characteristics, a ‘stepped-care’ delivery model of psychological therapies, and early reliable improvement.

4.3.9 - *Predictor variable 1 – Pre-treatment patient characteristics*

The study used a range of pre-treatment patient characteristics previously found to be associated with predicting outcomes in psychological therapy. These were grouped into demographic and clinical domains and align themselves with the demographic and clinical information routinely collected at assessment from people accessing Talking Therapies services. These are summarised in Table 4.0.

Demographic information used ratio data for age, discrete nominal data for gender, employment, marital status, and ordinal data from the English Index of Multiple Deprivation (IMD) (Department for Communities and Local Government, 2011) to establish sociodemographic status. Clinical information included primary mental health diagnosis, LTC diagnosis based on ICD-10 classifications, the presence of multimorbidity, and the number of previous treatment episodes.

To establish the influence of baseline severity, interval level data from validated self-reporting measures was utilised. For anxiety, the Generalised Anxiety Disorder Scale-7 (GAD-7; Spitzer et al., 2006) was used (see Appendix 4). The GAD-7 provides severity ratings on a 0-21 scale with a cut off score of ≥ 8 detecting an anxiety disorder.

The Patient Health Questionanire-9 (PHQ-9) was used as the outcome measure to detect depression (Kroenke et al., 2010, 2001) (see Appendix 5). The PHQ-9 provides severity ratings on a 0-27 scale with a cut off score ≥ 10 indicating depression. Psychosocial functioning was assessed using the Work and Social Adjustment Scale (WASA; Mundt et al., 2002) (see Appendix 6). The WASA measures the level of impairment experienced in daily activities across a range of domains including work, home management, private and social activities and relationships. It provides severity ratings on a 0-40 scale with a cut off score ≥ 10 indicating functional impairment.

To consider the influence of the presence of a personality disorder, the Standard Assessment of Personality Abbreviated Scales (SAPAS; Moran et al, 2003) was used (Appendix 7). The SAPAS is a self-reported questionnaire used to screen for personality disorders in clinical populations on a 0-8 severity scale with a score >3 indicating the presence of personality disorder.

Table 4.0 - *Pre-treatment predictor variables*

Demographic and clinical
Age
Gender
Ethnicity
Employment status
Marital status
Sociodemographic status - English Index of Multiple Deprivation (Department for Communities and Local Government, 2011)
ICD-10 Primary mental health diagnosis
Presence of multimorbidity
Number of previous treatment episodes
Severity of depression - Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001)
Severity of anxiety - Generalised Anxiety Disorder Questionnaire (GAD-7) (Spitzer et al., 2006)
Severity of functional impairment - Work and Social Adjustment Scale (WASA) (Mundt et al., 2002)
Presence of a Personality Disorder - Standard Assessment of Personality - Abbreviated Scale (SAPAS) (Moran et al., 2003)

4.3.10 – *Predictor variable 2 - Stepped-care*

As noted in earlier chapters, the use of a ‘stepped-care’ model has been widely adopted in the expansion of the Talking Therapies-LTC programme (Clark, 2011; National Collaborating Centre for Mental Health, 2009). The central tenet of the model proposes clients accessing treatment should be offered treatment at the lowest suitable service level (Step 2 low intensity treatment (LIT); guided self-help) and stepped up to more advanced treatment (Step 3 high intensity treatment (HIT); cognitive behavioural therapy) if no clinical progress is made (Salomonsson et al., 2017). However, to date, relatively little is known about the influence of a stepped-care model on outcomes in Talking Therapies-LTC services, with only one previous study specifically investigating this model finding LTC populations required a greater proportion of high intensity treatment and were associated with poorer outcomes (Delgadillo et al., 2017).

To consider the relationship of ‘stepped-care’ in LTC populations accessing psychological therapy, the study firstly investigated whether the type of treatment delivered, for example, LIT, HIT, or a combination of both influenced end of treatment outcomes. In conjunction, the study also examined the impact of ‘step-up’ rates, for example, stepping up from LIT (Step 2) to HIT (Step 3) and its relationship with end of treatment outcomes. Previous studies have found higher ‘step-up rates’ to be associated with a greater chance of achieving reliable recovery (Gyani et al., 2013; National Collaborating Centre for Mental Health, 2021), albeit this has only been shown in non-LTC populations to date.

Subsequently, the study examined whether the number of sessions provided at Step 2 (LIT) alone, Step 3 (HIT) alone, or a combination of Step 2 and 3 (LIT and HIT) influenced end of treatment outcomes. In doing so, the study also considered whether there was a ‘dose-response effect’, whereby response to therapy is characterised by a curvilinear relationship in which the majority of improvement is observed in the early stages after which the level of improvement from therapy declines (Levy et al., 2020).

4.3.11 – *Predictor Variable 3 - Early reliable improvement (ERI)*

To consider the extent to which Early Reliable Improvement (ERI) influenced final outcomes in psychological therapy, the study examined its association with end of treatment outcomes. The study used session-by-session data of measures of anxiety and depression mandated in the Talking Therapies-LTC programme. This enabled the study to monitor clinical progress for each patient in order to identify if reliable improvement was made, and if it was, at which session (Clark et al., 2011).

The Patient Health Questionnaire (PHQ-9) was used as the measure for depression. In addition, the study used the Generalised Anxiety Disorder (GAD-7) questionnaire and a range of anxiety disorder specific measures (ADSMs) depending on the anxiety disorder diagnosed at assessment (Appendix 8, 9, 10, 11, 12, 13). As per standard practice in Talking Therapies reporting, in the case of missing ADSM data, the Generalised Anxiety Disorder Questionnaire (GAD-7) was used as the default measure for anxiety (Richards and Borglin, 2011).

Each measure has clear clinical ‘cut-offs’ to indicate when a person is in ‘caseness’ to a mild, moderate or severe degree (Richards and Borglin, 2011). They also have a validated measure of reliable improvement which identifies the degree of change considered to be statistically reliable and not due to the chance of measurement error (Richards and Borglin, 2011). The measures used in the study are summarised in Table 4.1 and includes associated diagnosis, clinical cut-off for ‘caseness’, and ‘reliable improvement’ scores**.** Within this context, ERI was defined as having occurred if a patient who was above ‘caseness’ at the start of treatment and made a reliable improvement on either a measure of anxiety and/or depression during:

1) The first four sessions of LIT (Delgadillo et al., 2014)

   Or

2) The first eight sessions of HIT (Bradford et al., 2011, Fennell and Teasdale, 1987)

   Or

3) The first eight sessions of HIT following being ‘stepped-up’ from LIT due to minimal progress at LIT (Gyani et al., 2013)

In doing so, a categorical outcome of either achieving ERI or not could be confirmed.

Table 4.1 - *Clinical measures with reliable improvement scores*

Measure	Diagnosis	Range	Clinical Caseness	Reliable Improvement
Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2011)	Depressive disorders	0 – 27	≥ 10	≥ 6
Generalised Anxiety Disorder (GAD-7) (Spitzer et al., 2006)	Generalised anxiety disorder	0 – 21	≥ 8	≥ 5
Social Phobia Inventory (SPIN) (Connor et al., 2000)	Social phobia	0 – 68	≥ 19	≥ 10
Impact of Event Scale (IES-R) (Creamer et al., 2003)	Post-traumatic stress disorder	0 - 88	≥ 33	≥ 9
Mobility Inventory (MI) (Chambless et al., 1985)	Panic disorder with agoraphobia	1 - 5	2.3 per item average	≥ 0.73
Obsessive Compulsive Inventory (OCI) (Foa et al., 1998)	Obsessive compulsive disorder	0 - 168	≥ 40	≥ 32
Health Anxiety Inventory (sHAI) (Salkovskis et al., 2002)	Health anxiety	0 - 54	≥ 18	≥ 4
Panic Disorder Severity Scale (PDSS) (Shear et al., 2001)	Panic disorder	0 - 28	≥ 8	≥ 5

4.3.11 – *Outcome Variable – Reliable recovery*

To consider the aforementioned predictor variables relationship with end of treatment outcomes, the study used the criteria of ‘Reliable Recovery’. This is a standardised measure used in Talking Therapies-LTC services (Clark et al., 2011) and is deemed to have been achieved if a reliable and clinical significant improvement (RCSI) has been achieved on both a measure of anxiety and of depression. Each measure of anxiety and depression have clearly defined clinical cut-off scores to determine whether RCSI has been achieved and these are these are summarised in Table 4.2**.** As per standard Talking Therapies-LTC reporting, overall reliable recovery was guided by the criteria outlined by Jacobson and Truax (1991) and was considered to have been met if:

I. Clients received an assessment and at least one treatment session

II. Pre-treatment scores were in the clinical range (caseness) for scores on measures of depression or anxiety, or both

III. All post-treatment scores on measures of anxiety and depression were below clinical cut-offs

IV. Reliable Improvement was achieved on both measures of anxiety and depression

This data provided a categorical outcome of whether or not a patient achieved reliable recovery at the end of treatment.

Table 4.2 - *Clinical measures with reliable and clinical improvement scores*

Measure	Diagnosis	Range	Clinical Caseness	Reliable Recovery (RCSI)
Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2011)	Depression disorders	0-27	≥ 10	≤ 9
Generalised Anxiety Disorder (GAD-7) (Spitzer et al., 2006)	Generalised anxiety disorder	0-21	≥ 8	≤ 7
Social Phobia Inventory (SPIN) (Connor et al., 2000)	Social anxiety disorder	0-68	≥ 19	≤ 19
Impact of Event Scale (IES-R) (Creamer et al., 2003)	Post-traumatic stress disorder	0-88	≥ 33	≤ 32
Mobility Inventory (MI) (Chambless et al., 1985)	Agoraphobia	1-5	2.3 per item average	≤ 2.3
Obsessive Compulsive Inventory (OCI) (Foa et al., 1998)	Obsessive-compulsive disorder	0-168	≥ 40	≤ 32
Health Anxiety Inventory (sHAI) (Salkovskis et al., 2002)	Health anxiety (short version)	0-54	≥ 18	≤ 18
Panic Disorder Severity Scale (PDSS) (Shear et al., 2001)	Panic disorder	0-28	≥ 8	≤ 7

Note. RCSI = Reliable and Clinically Significant Improvement

4.3.13 - *Data analysis*

On receipt of the data, it was organised into an Excel spread sheet format and imported into SPSS Statistics (Statistical Product and Service Solutions - Version 27) for analysis. Anonymised patient data was given numerical values to aid analytical procedures and predictor variables were identified as ‘scaled’ or ‘nominal’. Scaled variables represented a variable with a numerical values, for example, age and PHQ-

9 for the severity of depression at baseline, whilst nominal variables represented categories with no intrinsic ranking and were given a numerical value (e.g. 0, 1, 2, 3), for example, multimorbidity (0 = no multimorbidity, 1 = presence of multimorbidity). Similarly, the primary outcome variable of achieving or not achieving reliable recovery was given a numerical value whereby 0 equated to not achieving reliable recovery and 1 represented achieved reliable recovery.

The study used data from all participants who met the inclusion criteria, including those who dropped out of treatment. In the case of drop-outs, the study used the scores from the most recently completed outcome measure on anxiety and depression prior to drop-out (Delgadillo et al., 2014; Spinelli et al., 2015). This reduced the risk of unrealistic optimistic results if only including participants who had completed a full course of treatment (Wakefield et al., 2020).

Data analysis was performed in two sequential steps. In step 1, descriptive statistics were used to report on the studies sample size, frequencies of age, gender, ethnicity, employment status, marital status, primary mental health diagnosis, long-term condition (LTC), multimorbidity, number of treatment episodes and pre-treatment base rates of anxiety, depression, functional impairment and presence of a personality disorder. In addition, descriptive statistics was used to describe the type of treatment patients received, the mean number of sessions delivered at each stage of the stepped-care model, the number of patients who achieved Early Reliable Improvement (ERI), and the number of patients who achieved reliable recovery at the end of treatment. Subsequently, descriptive statistics were used to summarise reliable recovery rates by each predictor variable.

Step 2 of the analysis focused on examining the relationship between the predictor variables of pre-treatment patient characteristics, stepped-care and early reliable improvement (ERI) and end of treatment outcome (reliable recovery). Given that the outcome variable was categorical as it focused on whether a patient had or had not achieved reliable recovery at the end of treatment, binary logistic regression was used for statistical analysis due to its ability to predict categorical outcomes when using a range of predictor variables (Field, 2009).

With respect to the aims of this study, separate unadjusted binary logistic regression models were used to explore the extent to which each predictor variable influenced reliable recovery. This method was used due to its powerful and reliable ability to model and predict the relationship between predictors and a binary outcome variable (Hosmer et al., 2013). Moreover, it was deemed the most suitable statistical option due to its focus on establishing probabilities of an outcome rather than fixed predictions, its capability to model non-linear relationships, its flexibility to use a variety of independent variables, for example, continuous and categorical data, its effectiveness with medium sized data-sets, and its application in complex healthcare domains where multiple factors may influence an outcome (Riley et al., 2013). As such, given its focus on complex healthcare outcomes, this study used a range of predictor variables. These were not only drawn from previous research, but also research guidance indicating the need to evaluate multiple factors that may influence health outcomes to support the targeting of specific interventions and contribute to the development of future prediction models in clinical practice (Steyerberg et al, 2013). Accordingly, each predictor's relationship with the binary outcome variable of reliable recovery was explored separately to quantify its association.

Preliminary analysis was performed to ensure there was no violation of the assumptions relating to binary logistic regression. As per standard practice in logistic regression, odds ratios (OR) were used to quantify the relationship between the predictor and outcome variable and represented the ‘ratio of the odds of an event occurring in one group compared to another’ (Field, 2009, p. 79). This was established by calculating the proportionate change in the odds of an event occurring after a unit change in a predictor by the odds before that change. As such, an OR greater than 1 indicates as the predictor increases, so does the odds of the outcome occurring, where as an OR less than 1 indicates as the predictor increases, the odds of the outcome occurring decreases.

4.3.14 - *Data collection*

The study used anonymised secondary data primarily sourced from the routine collection of data over a 2-year period (April 2018 – March 2020) stored on a secure clinical data system designed specifically for IAPT services. The data collected was mandated and standardised within the national IAPT-LTC programme with the primary aim of evaluating the effectiveness of IAPT services nationally (National Collaborating Centre for Mental Health, 2018; Department of Health, 2011b).

Initial information was collected during a clients’ problem-focused assessment. This provided baseline demographic and clinical information. Subsequently, the study used data routinely collected during treatment which included the type of treatment provided (LIT or HIT, or both) along with session-by-session collection of outcome data from the aforementioned validated measures of depression and anxiety.

As such, the specific stages of data collection for the study were as follows:

Stage 1 – Pre-treatment patient characteristic data collected at assessment

Stage 2 – Session-by-session outcome measures on anxiety and depression and number of sessions during treatment

Stage 3 – End of treatment outcomes on anxiety and depression

For illustrations purposes, a flow chart of routinely collected data is shown overleaf.

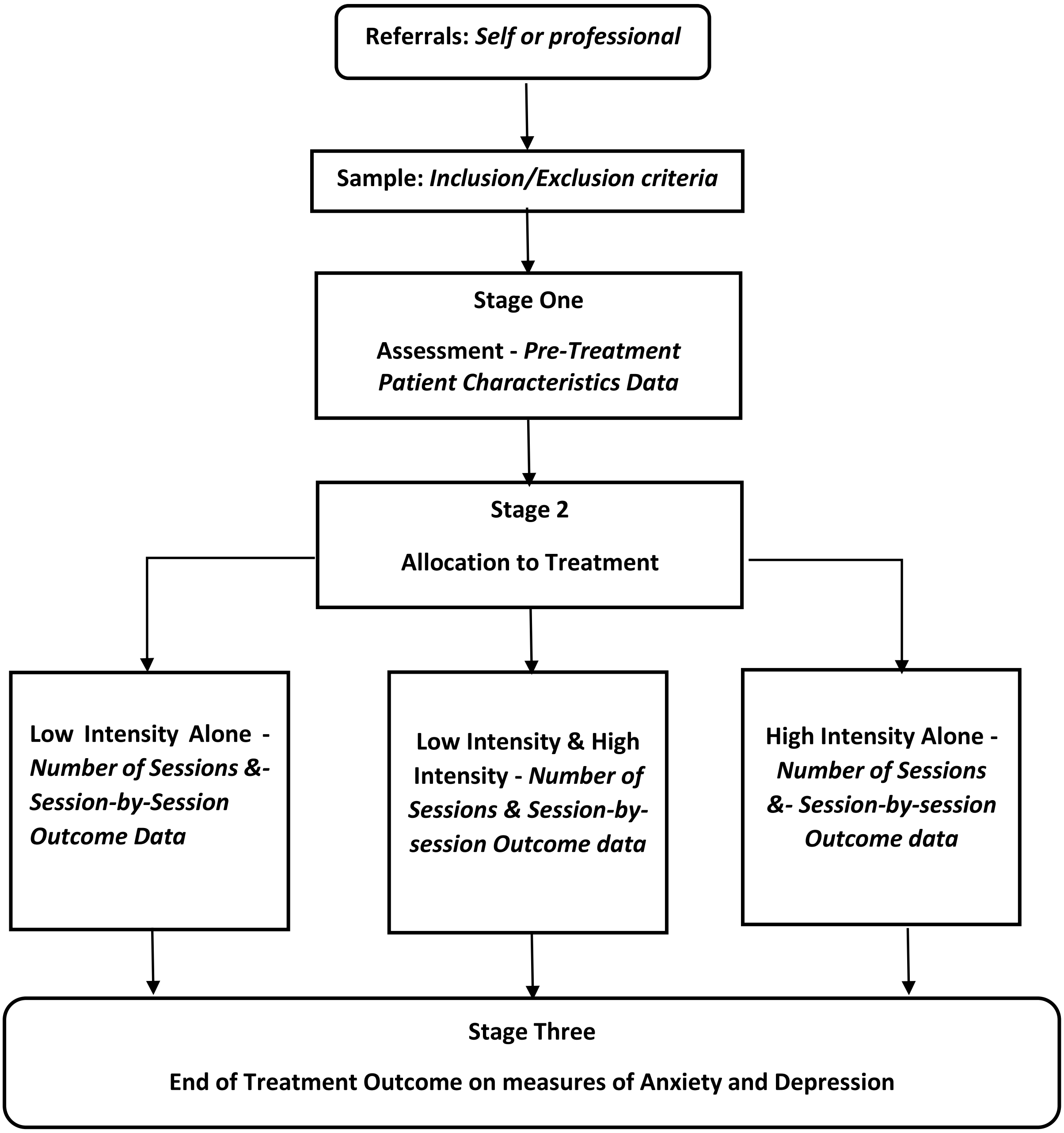

Figure 4.0 – *Routine data collection flow chart*

4.3.15 - *Data management*

A standard data anonymisation process applied by all Talking Therapies-LTC services was used to send anonymised patient and service level data to NHS Digital on a quarterly basis for analysis and public reporting (Clark et al., 2017). This included all demographic and clinical data gathered during assessment and treatment. Data held by the service on their clinical system was initially collected by the NHS Trust Data Lead who anonymised the data before its onward release to the principal investigator. This standard process ensured no personal identifiable information was contained in the data. Consent to use the data was provided by the services Clinical Lead and their associated NHS Research and Development Department. This process is in concordance with new updated NHS guidelines with regard to the General Data Protection Regulation (NHS Digital, 2018) and the use of depersonalised data for secondary analysis and UK Governance Arrangements for Research Ethics Committees (Section C4) (Department of Health, 2011c).

Data was handled in strict concordance with Keele University research governance procedures. All data was stored securely on a password protected Keele University computer drive that complied with the university’s security governance policy for the handling of research data. Only the principal investigator had access to the electronically stored data. Following on from the study, electronic data will be stored for 5 years in a locked filling cabinet within Keele University’s School of Medicine.

4.10 - *Ethical considerations*

The study was conducted in line with UK Health Departments and the Health Research Authority (HRA) guidance which states research involving NHS patients is reviewed independently to ensure it meets ethical standards (Health Research Authority, 2020). As such, ethical approval was gained from the Health Research Authority (HRA) (IRAS

Project ID – 271325) (Appendix 14), Keele University Ethics Committee (Appendix 15), and the study sites National Health Service (NHS) Trust (Appendix 16) through their respective Research Ethics processes. Additionally, the National Institute of Health Research Clinical Research Network (NIHR CRN) Good Clinical Practice (GCP) training was completed by the principal investigator prior to the study commencing and was updated in 2021. GCP is the ethical, scientific and practical standard which all clinical researchers are required to abide by in the conduct of their research (Health Research Authority, 2020).

4.5 - *Conclusion*

This chapter has outlined the methodology and methods used in the study. At each stage, a description of the rationale and how the methodology and methods were applied in the study has been provided in order to demonstrate the study's validity and rigour. In doing so, the study was able to produce a range of results to meet its aim and objectives and these are presented in the following chapter.

Chapter 5

Results

Chapter 5 - Results

5.1 - *Introduction*

Following on from Chapter 4 in which the study's methodological framework and methods was presented, Chapter 5 reports on the results of the study. The chapter commences by revisiting the research questions along with a summary of the predictor and outcome variables used in the study. A description of the study's patient cohort is subsequently presented followed by descriptive statistics focusing on the outcome variable of reliable recovery and secondly, on each predictor variable under investigation and their relationship with reliable recovery. In the final part of the chapter, results from the binary logistic regression analysis for each predictor variable is provided.

5.2 - *Research question and study variables*

As detailed in previous chapters, the overall aim of the study was to examine how pre-treatment patient characteristics, a 'stepped-care' model of delivering psychological therapy, and early reliable improvement in treatment influence outcomes in psychological therapy for people with co-morbid long-term conditions (LTCs) and common mental health problems.

To achieve this, the research questions investigated the extent to which:

- Pre-treatment patient characteristics predict outcomes in psychological therapies for long-term health conditions on measures of anxiety and depression
- A ‘stepped-care’ model influences outcome in psychological therapy for people with long-term health conditions
- Early Reliable Improvement (ERI) predicts outcome in psychological therapy for people with long-term health conditions

Table 5.0 provides an overview of the predictor variables used in the study. As illustrated, pre-treatment patient characteristics were grouped into demographics and clinical factors, stepped-care predictors included type of treatment and number of treatment sessions, and the in-session change predictor focused on early reliable improvement (ERI).

Table 5.0 - *Overview of pre-treatment patient characteristics, stepped-care and early reliable improvement predictor variables*

Predictor variables	**Sub-categories**
Pre-treatment characteristics	***Demographics***
	age gender ethnicity marital status employment status socioeconomic status
	Clinical
	primary mental health diagnosis presence of multimorbidity severity of depression severity of anxiety severity of functional impairment presence of a personality disorder number of previous treatment episodes
Stepped-care model	type of treatment number of treatment sessions
Early reliable improvement	

The outcome variable used in the study was based on whether or not a patient had achieved reliable recovery at the end of treatment. This was determined using end of treatment outcome data from interval level measures of depression (PHQ-9) and anxiety (GAD-7). As discussed in the previous methods chapter, the study also used anxiety disorder specific measures (ADSMs) (where appropriate), although the GAD-7 was used as the default measure for anxiety in the case of missing ADSM scores as per standard Talking Therapies practice.

Each measure has a clearly defined clinical cut-off score to illustrate reliable and clinically significant improvement (RCSI), whereby RCSI is considered as a standard measure of ‘reliable recovery’ in the Talking Therapies-LTC services (Clark et al., 2009, 2011). These were summarised in Table 4.2 found in Chapter 4. Reliable recovery was guided by the criteria outlined by Jacobson and Truax (1991) and was considered to have been met if:

I. Clients received an assessment and at least one treatment session
II. Pre-treatment scores were in the clinical range (caseness) for scores on depression or anxiety, or both
III. Post-treatment scores were below clinical cut-offs
IV. Reliable Improvement was achieved on both measures of anxiety and depression

5.3 - *Patient cohort*

From April 1st, 2018, to 31st March 2020, 1313 people with co-morbid common mental health problems and long-term conditions were referred to the service either by a self-referral (n = 853) or a professional referral (n = 460). Twenty-one percent (n = 281) of total referrals were uncontactable or declined the service, 1,032 patients had an initial assessment and of these, 94 patients had an initial assessment and were subsequently referred to Community Mental Health Teams, 55 patients were referred onto voluntary agencies and 100 patients did not need any further treatment. A total of 149 patients were found to have entered treatment but had not completed treatment in the timeframe window of the study, whilst 50 patients had entered treatment but were not at ‘caseness’ at baseline and so were all excluded from the study. As a result, an initial cohort of 583 patients met the eligibility criteria of the study having both entered and completed treatment in the 2-year timeframe of the study. However, whilst data completeness was high (>99%), one patient had missing data and was removed from detailed analysis leaving a final cohort of 583 patients. Figure 5.0 diagrammatically summarises the patient cohort used in the analysis.

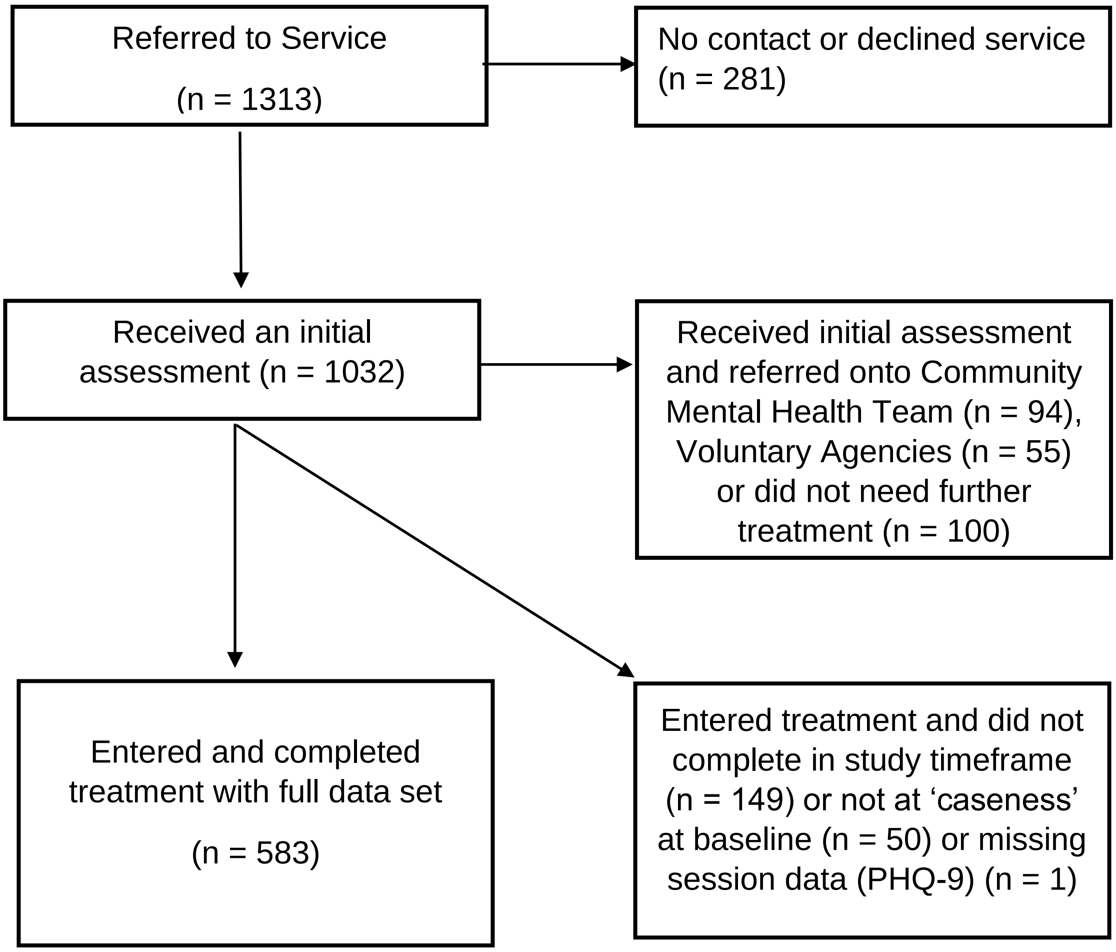

Figure 5.0 - *Patient cohort used in the study*

5.4 - *Descriptive statistics of outcome variable*

5.4.1 – Reliable recovery

Overall, 55.6% (*n* = 324) of patients achieved reliable recovery at the end of treatment and 44.4% (*n* = 259) did not. The results indicate the reliable recovery rates in the study to be higher than the 50% national recovery benchmark target for the Talking Therapies services (Clark et al., 2011). In comparison, it was also found to be higher than in previous Talking Therapies cohort studies for people with co-morbid long-term health conditions and common mental health problems (Delgadillo et al., 2017; Kellett et al.,2016).

5.5 – Descriptive statistics of predictor variables

5.5.1 - *Pre-treatment patient characteristics*

As previously reported, a range of pre-treatment patient characteristics including both demographic and baseline clinical predictor variables were utilised in the study. Descriptive statistics regarding each pre-treatment predictor variable are now presented along with their association with reliable recovery rates.

5.5.2 - *Age*

Age in the patient cohort ranged from 19 to 88 years (*n* = 583). There were 151 (25.7%) patients over the age of 65 years and 52 (8.9%) patients aged 75 years and over. The mean age for all patients was 52.57 (*SD* = 15.97). The mean age of those who achieved reliable recovery was 54.14 (*SD* = 16.21) which was higher than the mean age of those who did not achieve recovery (M = 50.59; *SD* = 15.47).

5.4.3 - *Gender*

From the 583 patients in the study, over twice as many females entered and completed treatment (n = 407) in comparison to males (*n* = 176). Table 5.1 summarises the reliable recovery rates for both genders. This illustrates both genders achieved reliable recovery rates above the national benchmark of 50% (Clark et al., 2011), with 6% more males achieving reliable recovery in comparison to females.

Table 5.1 - *Summary of end of treatment outcomes based on reliable recovery by gender*

Gender	Achieved reliable recovery Number (%)	Did not achieve reliable recovery Number (%)
Female	219 (54)	188 (46)
Male	106 (60)	70 (40)

Note. Reliable recovery based on reliable and clinically significant improvement

5.4.4 - *Ethnicity*

In terms of ethnicity, 570 (98%) patients were White British. Only seven (1%) patients were Black British, four were Asian British (<1%) and three (<1%) were of other ethnic groups. The results indicate less than 2% of the patient cohort were from Black and Minority Ethnic (BAME) groups. In the White British group, a total of 318 patients (56%) achieved reliable recovery whilst seven patients (53%) from BAME backgrounds achieved recovery.

5.4.5 – *Employment status*

A total of 258 (44%) patients in the study were in employment, 163 (28%) were on long-term sickness, 139 (24%) were retired, and 23 (4%) were students. As illustrated in Figure 5.1, 145 (56%) employed patients achieved reliable recovery at the end of treatment in comparison to patients on long-term sickness where 71 (44%) reliably recovered. Only 23 (4%) patients were students in full or part-time education and of these 63% (*n* = 15) achieved reliable recovery. Of the total of 139 retired patients in the study, 94 (68%) reliably recovered. The results found retired patients achieved the highest overall percentage of reliable recovery (68%) whereas those on long-term sickness had the lowest (44%).

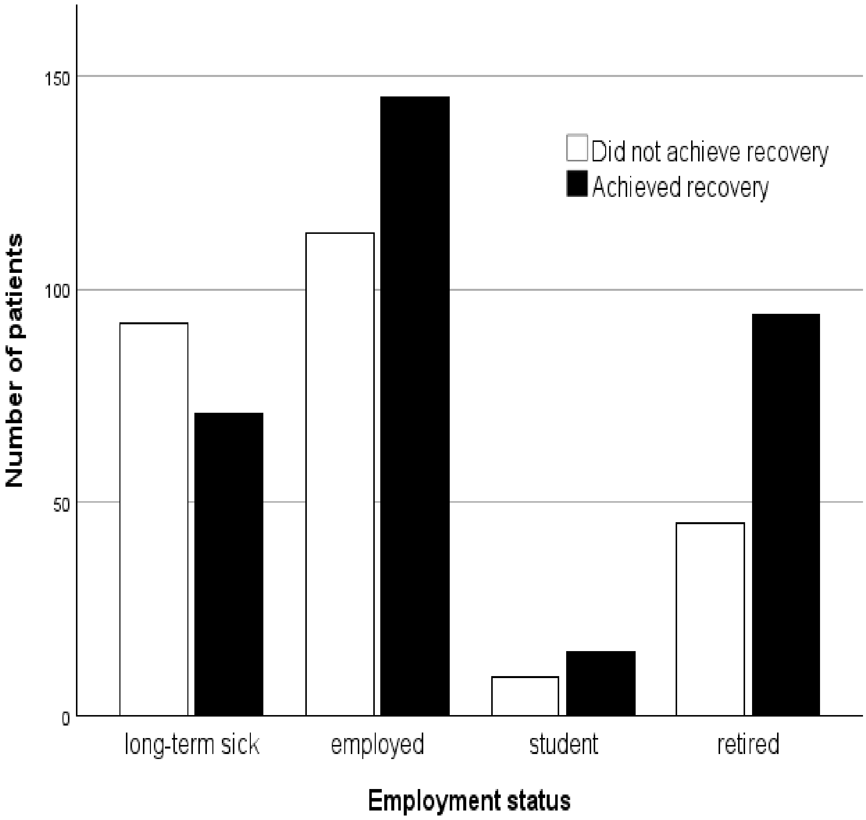

Figure 5.1 - *Employment status by reliable recovery*

5.4.6 - *Marital status*

Of the 583 patients in the study, 354 (61%) were married or co-habiting and 229 (39%) were single or widowed. The results showed 207 (58%) married patients and 118 (52%) of single or widowed patients reliably recovered. The results demonstrate a greater proportion of married and co-habiting participants achieved reliable recovery in comparison to single or widowed patients.

5.4.7 - *Socioeconomic status*

As detailed in the previous chapter, sociodemographic status was established using the Index of Multiple Deprivation (IMD) in England (Department for Communities and Local Government, 2011). The IMD provides a ranking of deprivation from 1 to 335, where 1 represents the most deprived areas. The study focused on two areas in the West Midlands. Area 1 is 151st on the IMD and Area 2 is ranked 206th. Area 1 had the highest number of patients (*n* = 438), with 55% of patients in both Area 1 and 2 achieving reliable recovery. The results indicate there was no difference in recovery rates across the two different socioeconomic areas.

5.4.8 - *Primary mental health diagnosis*

Of the total patients, 320 (55%) were identified as having a primary mental health diagnosis of depression and 263 (45%) of having an anxiety disorder. A number of different anxiety disorders were reported, and these are summarised in Table 5.3. This shows the most common anxiety disorder was generalised anxiety disorder (GAD) (*n* = 121) and the least common was obsessive compulsive disorder (OCD) (*n* = 3).

Table 5.2 - *Summary of common mental health problems in the patient cohort*

Type of common mental health problem	**% of patient cohort**
Depression	55
Generalised anxiety disorder	21
Panic disorder	9
Somatoform disorder	6
Post-traumatic stress disorder	4
Health anxiety	2
Phobias	2
Obsessive compulsive disorder	<1

As seen in Figure 5.2, when grouped into depression or anxiety disorders, 55% (*n* = 176) of patients with a primary mental health problem of depression and 57% (*n* = 150) of participants with an anxiety disorder achieved reliable recovery indicating no differences in recovery rates between depression and anxiety disorders.

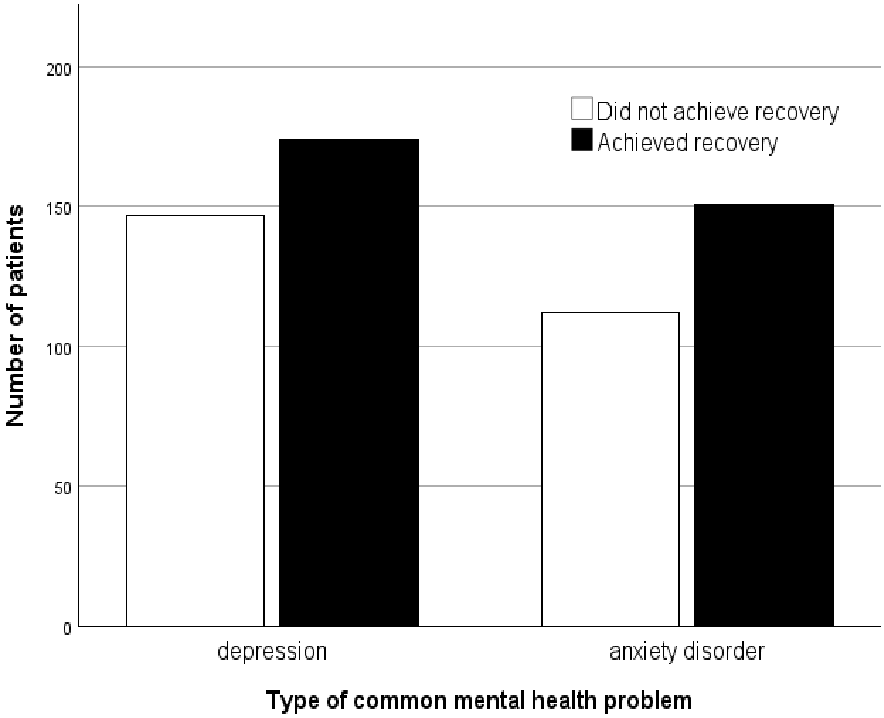

Figure 5.2 - *Reliable recovery rate by* **c***ommon mental health problem*

5.4.9 - *Multimorbidity*

Patients in the study experienced a range of long-term health conditions. The most common long-term health condition was musculoskeletal pain which was reported by 192 (33%) of patients. Persistent physical symptoms (medically unexplained symptoms (MUS)) was the second most common health problem with 123 (21%) patients, followed by 77 (13%) patients with Type 1 or Type 2 diabetes and 64 (11%) people with respiratory problems. Cancer (*n* = 29), coronary heart disease (n = 42), neurological diseases (*n* = 32) and other conditions (*n* = 24) (gastrointestinal, thyroid and autoimmune) were also reported. The results revealed 197 (34%) of patients experienced multimorbidity and 386 (66%) had one long-term health condition. As can be seen in Figure 5.3, the results show a higher proportion of patients with one long-term health condition achieved reliable recovery (61%; *n* = 235) in comparison to patients reporting multimorbidity (45%; n = 89).

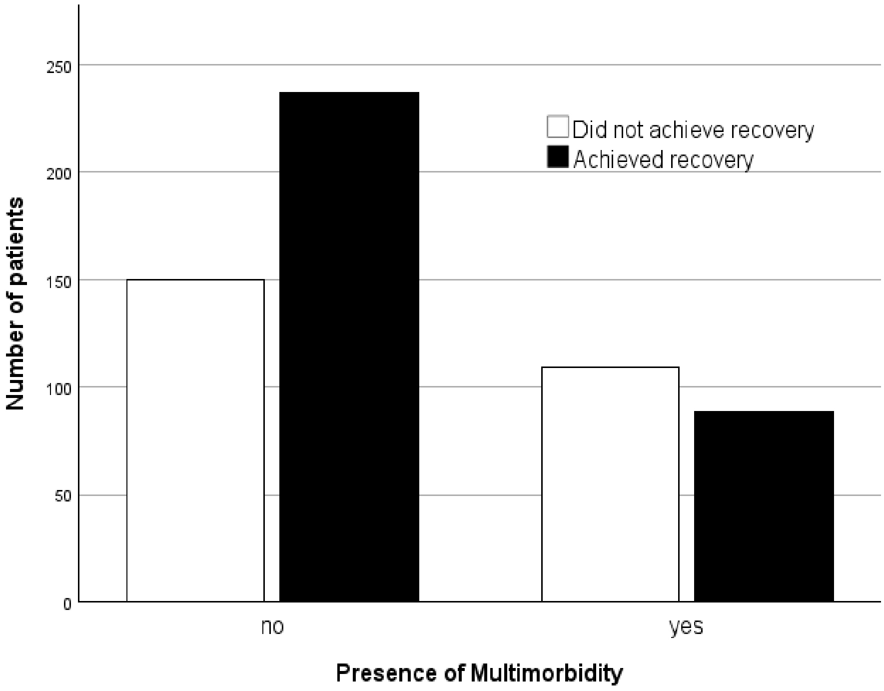

Figure 5.3 - *Reliable recovery by the presence of multimorbidity*

5.4.10 - *Number of previous treatment episodes*

The number of previous treatment episodes ranged from 0-to-5 episodes. Almost two thirds of patients (n = 343; 59%) had no previous episodes with only 3 (<1%) patients having had 5 previous episodes. Of the patients who had no previous treatment episodes, 208 (61%) achieved reliable recovery, whilst 108 (45%) participants who had two or more episodes reliably recovered. The results found differences in rates of reliable recovery between patients with no previous treatment episodes and those who had two or more episodes.

5.4.11 - *Severity of depression*

Baseline PHQ-9 severity scores in the study cohort ranged from 10 - 27 (27 = severe). The mean PHQ-9 score was 16.93 (*SD* = 4.72). On the basis of PHQ-9 published norms (Kroenke et al., 2001), patients were divided into three severity groups; moderate scoring 10-14 on the PHQ-9, moderate-severe scoring 15–19, and severe scoring 20-27. Two hundred and five (35%) patients were in the moderate range, 185 (32%) were in the moderately-severe range, and 193 (33%) were in the severe range.

Overall, the mean baseline PHQ-9 score of patients who achieved reliable recovery was 16.31 (*SD* = 4.49) and for those patients who did not achieve recovery it was 17.70 (*SD* = 4.91). Of those who scored in the moderate range, 127 (62%) patients reliably recovered. Likewise, 110 (60%) patients in the moderate-severe range and 88 (46%) in the severe range achieved reliable recovery at the end of treatment. As illustrated in Figure 5.4, patients who scored higher on the PHQ-9 score at baseline achieved the lowest rate of reliable recovery whereas patients in the moderate range achieved the highest levels of recovery.

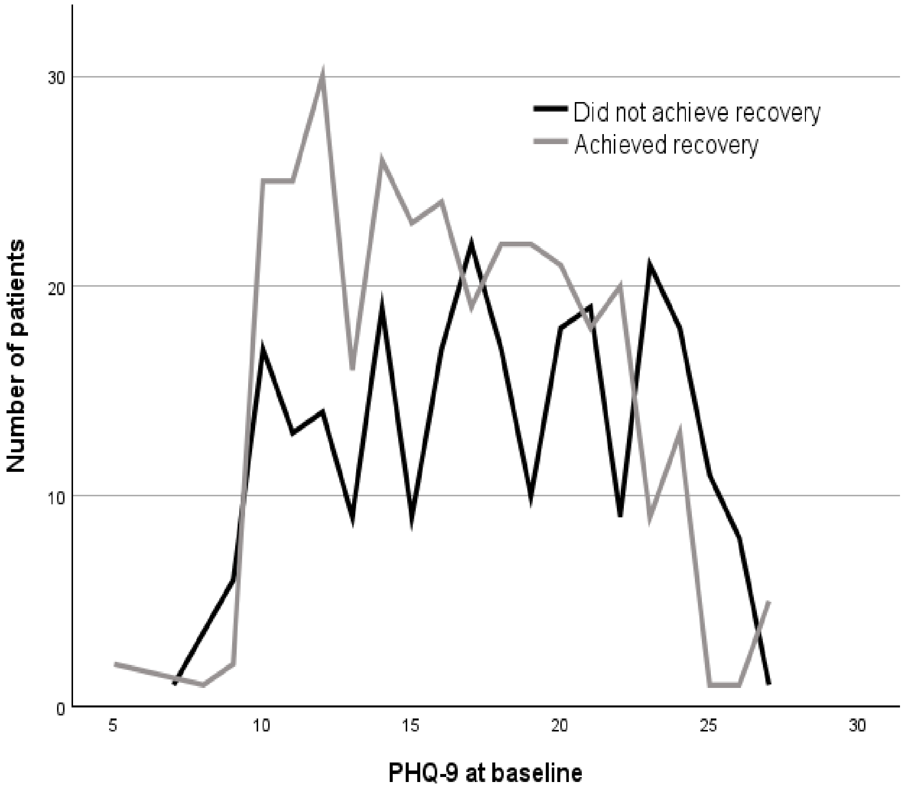

Figure 5.4 - *Reliable recovery by baseline severity of depression*

5.4.12 - *Severity of anxiety*

Baseline GAD-7 severity scores in the study cohort ranged from 8 to 21 (21 = severe). Utilising GAD-7 published norms to classify severity (Spitzer et al., 2006), patients were grouped into mild (scoring 5-9), moderate (10-15) or severe (16-21). Approximately half of the patients (n = 295) scored in the severe range at baseline, 186 (32%) participants were in the moderate range and 102 (17%) participants were in the mild range but were in the clinical range to be considered in 'caseness'.

The overall mean GAD-7 score was 14.35 (*SD* = 4.31). The mean GAD-7 score of patients who achieved reliable recovery was 13.97 (*SD* = 4.07) and for those patients who did not it was 14.83 (*SD* = 4.57). Of those who scored in the severe range, 145 (49%) patients reliably recovered. In comparison, 124 (67%) participants in the moderate range and 56 (55%) participants in the mild range achieved reliable recovery. Figure 5.5 shows a greater proportion of patients in the mild-moderate anxiety range at baseline achieved reliable recovery in comparison to patients with the severest baseline anxiety.

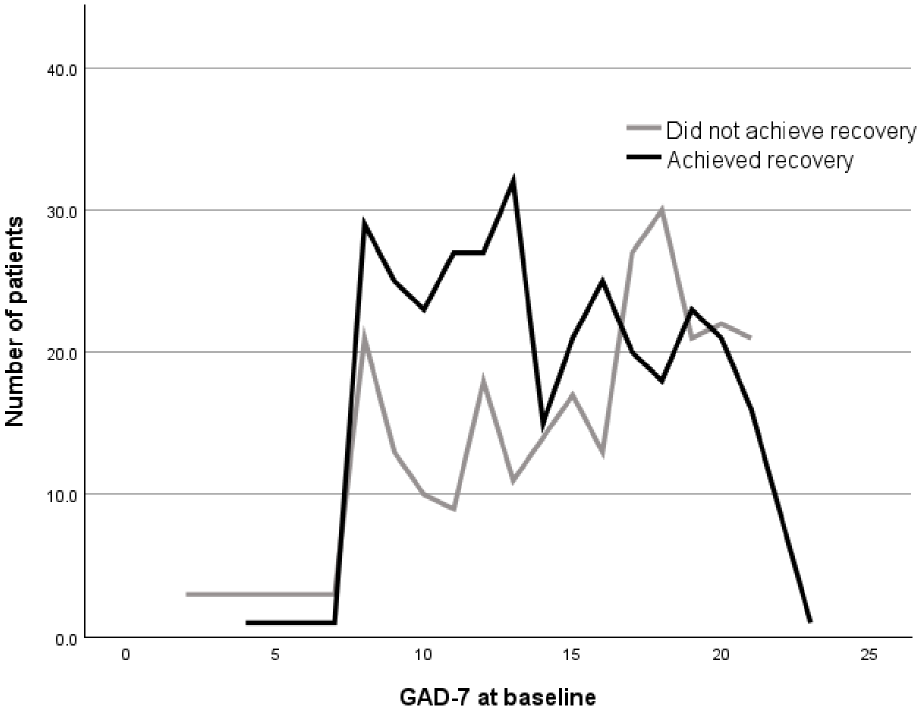

Figure 5.5 - *Reliable recovery by baseline severity of anxiety*

5.4.13 – Severity of functional impairment

As a reminder, the work and social adjustment scale (WASA) scoring ranges from 0 to 40 with distinct cut-off points to indicate low (0–9), moderate (10–19), and severe (20–40) impairment. In the study, baseline WASA scores ranged from 1 to 40 in the participant cohort with a mean score of 21.41 (*SD* = 8.66). Nearly two thirds of patients (n = 343; 59%) reported severe impairment at baseline, 187 (32%) moderate impairment and 53 (9%) mild impairment. Reliable recovery was achieved by 52% (n = 178) of patients in the severe range, 59% (n = 110) in the moderate range, and 70%

(n = 37) in the mild range. The result demonstrates patients who were less functionally impaired at baseline achieved higher rates of reliable recovery.

5.4.14 - *Presence of personality disorder*

As outlined in the previous chapter, the Standard Assessment of Personality Abbreviated Scale (SAPAS) (Moran et al., 2003) was used to screen for the presence of personality disorder in the patient cohort. The SAPAS scoring ranges from 0 to 8 with scores above 3 correctly identifying the presence of a personality disorder in 90% of cases (Moran et al., 2018). In the patient cohort, the mean SAPAS score was 3.45 (*SD* = 1.69). The presence of a personality disorder (scores of 4 and above on the SAPAS scale) was identified in 44% (n = 256) of the patient cohort with 56% (n = 328) of patients scoring 3 or less.

In patients scoring 3 or less, 57% (n = 187) achieved reliable recovery in comparison to 54% (n = 137) of patients scoring 4 and above. Of the 73 patients scoring at the severe end of the SAPAS (6 and above), 45% (n = 33) reliably recovered. The results indicate patients who scored in the severe range on the SAPAS scale were less likely to reliably recover at the end of treatment.

5.4.15 - *Stepped-care*

To consider the influence of a ‘stepped-care’ model of delivering psychological therapy, the study considered the association between the type of treatment provided and the number of treatment sessions delivered had on reliable recovery rates.

5.4.16 - *Type of treatment*

Of the total 583 patients, 391 (67%) received high intensity (HI) treatment, 112 (19%) received low intensity (LI) treatment, and 80 (14%) patients were ‘stepped-up’ from LI to HI treatment (LI + HI) The results indicate over two-thirds of patients were allocated to HI treatment with only a small proportion (14%) being stepped-up to HI treatment following an initial course of LI treatment.

Figure 5.6 summarises reliable recovery rates by treatment type. The results found 54% (n = 213) of patients who received HI treatment reliably recovered in comparison to 56% (n = 112) who received LI treatment. For those patients who were stepped-up from LI to HI treatment, 61% (n = 49) achieved reliable recovery. For those who were stepped-up, a greater proportion reliably recovered (61%) when compared to LI or HI treatment alone. The results show patients who were ‘stepped-up’ to have the highest rates of recovery, albeit the number of patients who were ‘stepped-up’ was low in comparison to the number of patients who received HI treatment only.

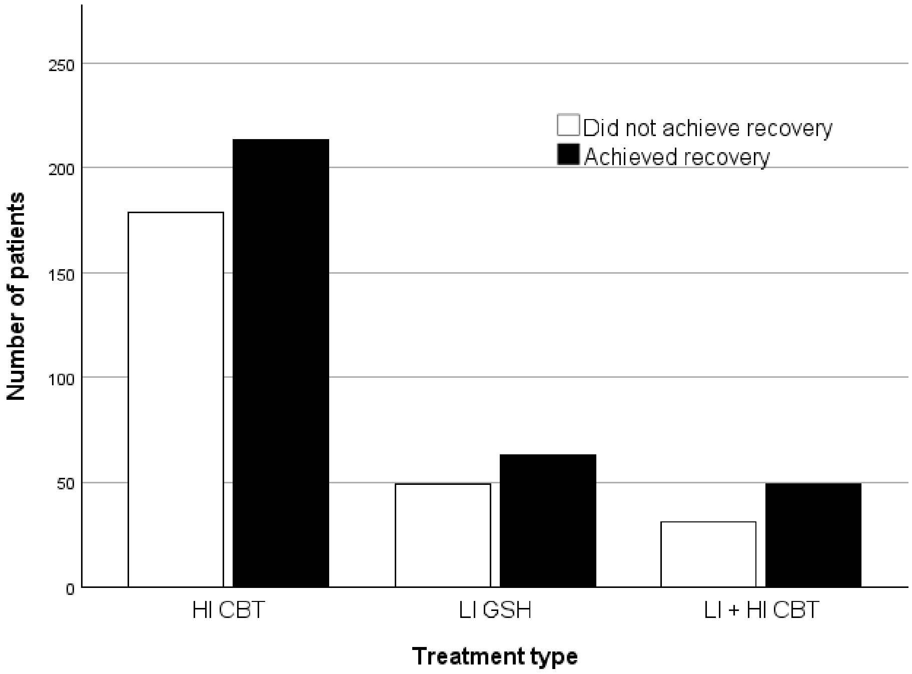

Figure 5.6 - *Reliable recovery rates by treatment type*

5.4.17 - *Number of sessions*

The number of treatment sessions provided ranged from 2 to 20. The overall mean number of total sessions delivered was 8.85 (*SD* = 5.05). The mean number of sessions for HI treatment was 9.39 (*SD* = 5.09), for LI treatment it was 4.89 (*SD* = 2.33) and for patients 'stepped-up' from LI to HI treatment it was 11.76 (*SD* = 4.54). As shown in Figure 5.7, across all treatment groups, patients who received who received a higher mean number of treatment sessions achieved greater rates of reliable recovery.

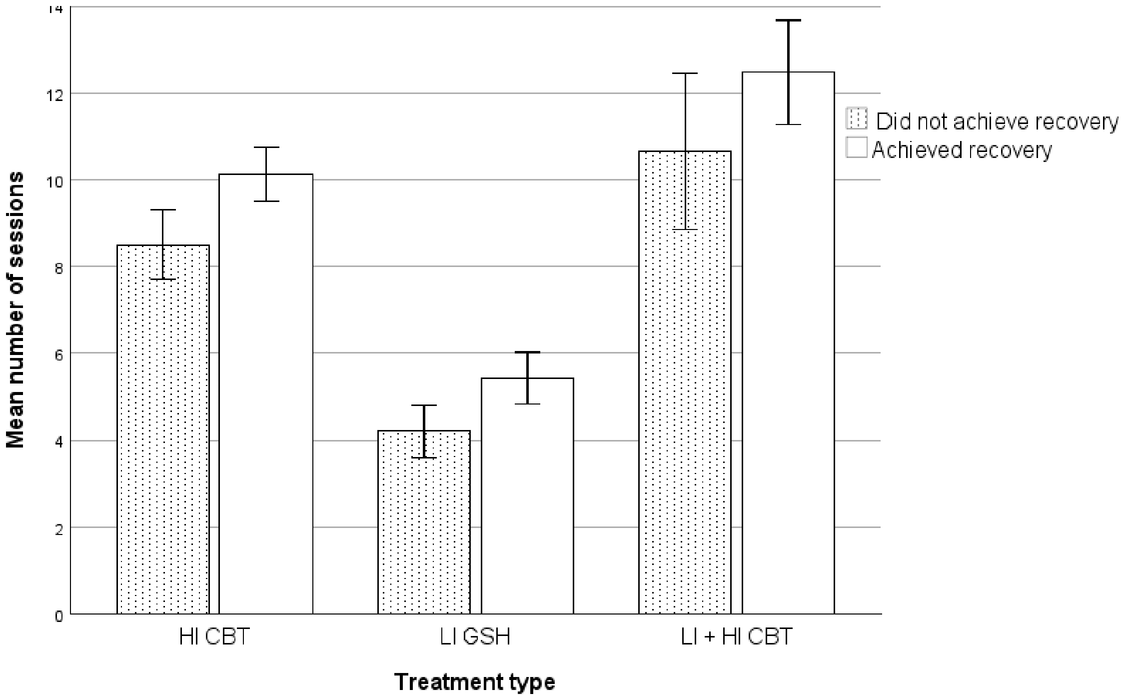

Figure 5.7 - *Reliable recovery rates by treatment type and number of treatment sessions (error bars represent 95% confidence intervals)*

5.4.18 - *Early reliable improvement (ERI)*

Within the total patient cohort, 450 (77%) showed early reliable improvement (ERI) and of these 304 (68%) subsequently achieved reliable recovery. For those who did not achieve ERI (n = 134), 113 (84%) did not reliably recover. Figure 5.8 shows a large proportion of patients who achieved ERI recovered on measures of anxiety and depression at the end of treatment, whilst in contrast, a large proportion of patients who did not achieve ERI also did not achieve reliable recovery.

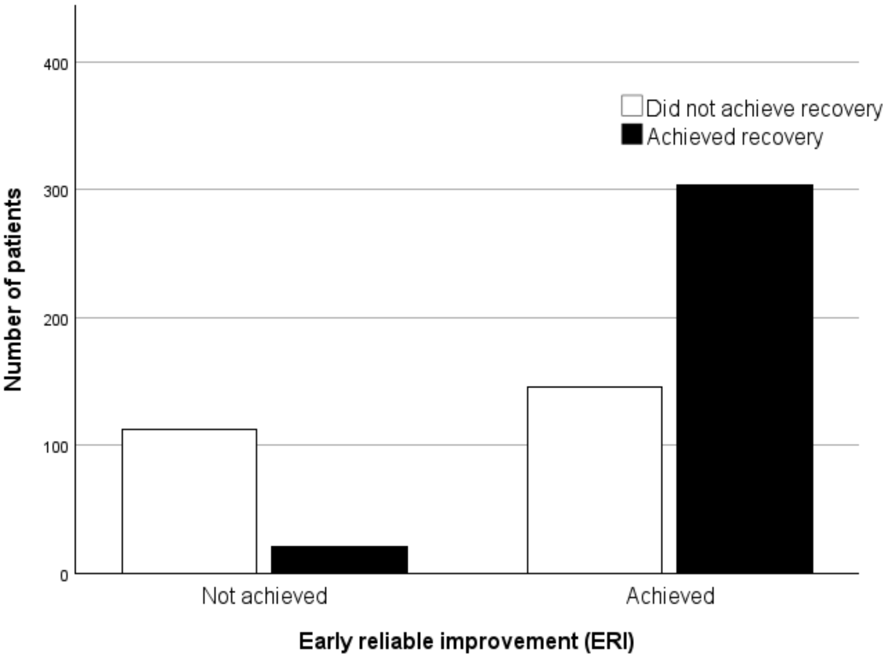

Figure 5.8 - *Reliable recovery by the early reliable improvement*

When configured into treatment groups, 296 (76%) of the HI treatment group showed ERI and of these 55% (n = 213) went on to recover, whilst in the LI treatment group, 83 (74%) showed ERI and of these patients 56% (n = 63) reliably recovered. In the ‘stepped-care’ group in which patients were stepped-up to HI treatment following limited improvement with LI treatment, 71 (88%) showed ERI in the early stages of HI treatment and of these 49 (61%) went on to achieve reliable recovery. The results show a large proportion of patients across the different treatment groups achieved ERI (74% - 88%) and subsequently achieved recovery, with patients in the ‘stepped-care’ group achieving the highest overall reliable recovery rates. In addition, the study also found 22% (n = 133) of patients did not achieve ERI and did not reach recovery either.

In contrast, the results revealed a proportion of patients in each treatment group who achieved ERI did not reliably recover. Twenty eight per cent (n = 83) of the HI treatment group, 20% (n = 20) of the LI treatment group and 31% (n = 22) of the ‘stepped-care’ group, all showed ERI but did not achieve reliable recovery at the end of treatment.

5.5 – *Binary logistic regression results*

Binary logistic regression analysis was undertaken to assess the association of pre-treatment characteristics, stepped-care and early reliable improvement (ERI) to reliable recovery at the end of treatment. As previously noted, pre-treatment characteristics included a number of demographic and clinical factors. However, as descriptive statistics found less than 2% (n = 7) of the patient cohort were from BAME backgrounds, ethnicity was removed from the analysis as a demographic factor as this would not have provided a representative ethnic sample.

Preliminary analysis was performed to ensure there was no violation of the assumptions relating to binary logistic regression. This confirmed the outcome variable was binary, each observation was independent of others, no predictor variable perfectly predicted the outcome variable of reliable recovery (see classification tables below), and the study used an adequate sample size. In addition, the linearity assumption between continuous predictor variables found to have an association with the binary outcome (reliable recovery) and the logit of reliable recovery were evaluated. These are illustrated visually using scatterplots (see Appendix XVII) and verify the linearity assumption of binary logistic regression.

In total, the results revealed nine unadjusted predictor variables influenced the odds of achieving reliable recovery. Seven were pre-treatment demographic and clinical predictors, one a stepped-care predictor, along with early reliable improvement. These were age, employment status, multimorbidity, baseline severity of depression, anxiety, and functional impairment, number of previous treatment episodes, number of treatment sessions received and ERI. In contrast, gender, marital status, socioeconomic status, primary mental health diagnosis, presence of personality disorder, and the type of treatment were not found to have an association with reliable recovery (see Appendix XVIII for SPSS output for each predictor variable).

For age, the odds ratio was 1.014 (OR 1.014, 95% CI 1.00, 1.03, *p* = 0.008) meaning for every additional year of age, the odds of achieving reliable recovery increased by 1.4% ((1 – 1.014) x 100). Given that age ranged from 19 – 88, the results found older adults were more likely to recover than younger adults. As shown in Table 5.3, the models overall predicted accuracy for age was 55.1%, with better performance found for identifying positive predictions (82.2% sensitivity).

Table 5.3 - Classification table of patients predicted to achieve reliable recovery based on age

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*55*	*203*	*21.2*
Yes	*58*	*267*	*82.2*
Overall percentage			*55.1*

In terms of employment status, where the reference group was long-term sickness, the results revealed patients in full-time employment were 66% more likely to achieve reliable recovery than those on long-term sickness (OR 1.663, 95% CI 1.120, 2.469, *p* = 0.012). Moreover, retired patients were 2.7 times more likely to achieve reliable recovery than those on long-term sickness (OR 2.707, 95% CI 1.690, 4.336, *p* = <0.001). In contrast, students were not found to have any statistically significant difference in their likelihood to achieve recovery compared to the long-term sickness group (OR 2.160, 95% CI, *p* = 0.087). As presented in Table 5.4, the models overall predicted accuracy for employment status was 59.2%, with better performance found for identifying positive predictions (78.2% sensitivity).

Table 5.4 - Classification table of patients predicted to achieve reliable recovery based on employment status

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*92*	*167*	*35.5*
Yes	*71*	*254*	*78.2*
Overall percentage			*59.2*

Patients with multimorbidity were also found to have a negative relationship with reliable recovery. The results revealed the odds of achieving recovery for patients with multimorbidity were 49% lower (OR 0.511, 95% CI 0.361, 0.723, p = <0.001) than those with one long-term condition, whilst the overall predictive accuracy of this model was 59.2% (see Table 5.5 below).

Table 5.5 - Classification table of patients predicted to achieve reliable recovery based on the presence of multimorbidity

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*109*	*150*	*42.1*
Yes	*88*	*237*	*72.9*
Overall percentage			*59.2*

The results also found that pre-treatment severity of reduced the odds of achieving reliable recovery, albeit its influence was weak overall (OR 0.939, 95% CI 0.91, 0.97, *p* = <0.001). As such, for every additional point scored on the PHQ-9, the odds of achieving reliable recovery decreased by 6.1% ((1 – 0.939) x 100). The results indicate more severely depressed patients at baseline to be less likely to achieve reliable recovery in comparison to those with milder depression. As shown in Table 5.6, the model's overall predicted accuracy was 59.1%, with better performance found for identifying positive predictions (79.4% sensitivity).

Table 5.6 - Classification table of patients predicted to achieve reliable recovery based on pre-treatment severity of depression

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*87*	*172*	*33.6*
Yes	*67*	*258*	*79.4*
Overall percentage			*59.1*

Pre-treatment severity of anxiety revealed a similar picture. The results found the greater the severity of pre-treatment anxiety, the less likely someone would achieve reliable recovery with an odds ratio of 0.954 (95% CI 0.92, 0.99, *p* = 0.017). This suggests for every additional point scored on the GAD-7 at baseline, the odds of achieving reliable recovery reduced by 4.6% ((1 – 0.954) x 100). The model's overall predicted accuracy was 56.5% with better performance for predicting positive predictions (88.3% sensitivity).

Table 5.7 - Classification table of patients predicted to achieve reliable recovery based on pre-treatment severity of anxiety

Achieved reliable recovery	Predicted to achieve reliable recovery		Percentage correct (%)
	No	**Yes**	
No	*43*	*216*	*16.8*
Yes	*38*	*287*	*88.3*
Overall percentage			*59.1*

The severity of pre-treatment functional impairment was also found to have a negative association with achieving reliable recovery. The results suggest a unit increase in the severity of functional impairment on the Work and Social Adjustment Scale at baseline to decrease the odds of achieving recovery by 2.5% (OR = 0.975; 95% CI 0.96, 0.99, *p* = 0.011) and that the overall predictive accuracy of the model was 56.5% as shown below.

Table 5.8 - Classification table of patients predicted to achieve reliable recovery based on pre-treatment severity of functional impairment

Achieved reliable recovery	Predicted to achieve reliable recovery		Percentage correct (%)
	No	**Yes**	
No	*51*	*208*	*19.7*
Yes	*46*	*279*	*85.8*
Overall percentage			*56.5*

The number of previous treatment episodes was also found to reduce the odds of achieving recovery (OR 0.768, 95% CI 0.65, 0.92, *p* = 0.003) with every additional previous treatment episode decreasing the odds by 23.2% ((1 – 0.768) x 100)). As such, patients with 5 previous episodes were significantly less likely to achieve recovery than those engaging in treatment for the first time and that the overall prediction of the model was accurate in 57.4% of cases (see Table 5.9).

Table 5.9 - Classification table of patients predicted to achieve reliable recovery based on the number of previous episodes of treatment

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*52*	*207*	*20.1*
Yes	*42*	*283*	*87.1*
Overall percentage			*57.4*

In terms of 'stepped-care', the results that as the number of sessions provided increased, so did the likelihood of achieving reliable recovery (OR 1.068, 95% CI 1.03, 1.12, *p* = <0.001), with every additional treatment session provided increasing the odds by 6.8% ((1 – 1.068) x 100). Moreover, when comparing the likelihood of achieving recovery across the range of treatment sessions provided (2 - 20 sessions), the results suggest patients who received 20 sessions of treatment were 2.9 (OR 1.068^{18}) times more likely to achieve recovery in comparison to patients who received 2 sessions. Overall, the predictive accuracy of the model was 61.5% with greater sensitivity for predicting positive cases (76.9%).

Table 5.10 - Classification table of patients predicted to achieve reliable recovery based on the number of treatment sessions provided

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*111*	*148*	*42.9*
Yes	*76*	*249*	*76.6*
Overall percentage			*61.6*

A significant positive association was also found with reliable recovery and early reliable improvement (ERI). To this end, the results found the odds of achieving reliable recovery were 11.204 (OR 11.204, CI 6.76, 18.58, *p* = <0.001) times higher for those patients who achieved ERI in treatment in comparison to those who did not. In this model, the overall predictive accuracy was 71.4 %, albeit the specificity of predictions was 43.6% with a number of patients falsely predicted to achieve recovery (n = 146) as illustrated below.

Table 5.11 - Classification table of patients predicted to achieve reliable recovery based on early reliable improvement

Achieved reliable recovery	**Predicted to achieve reliable recovery**		**Percentage correct (%)**
	No	**Yes**	
No	*113*	*146*	*43.6*
Yes	*21*	*304*	*93.5*
Overall percentage			*71.4*

The overall results for each significant predictor variable are shown in Table 5.9.

Table 5.12 – *Separate unadjusted binary logistic regression results for age, multimorbidity, severity of depression, anxiety, functional impairment, previous treatment episodes, number of sessions and early reliable improvement*

Predictor variable	**Coef (B)**	**Odds Ratio (Exp (B))**	**95% CI**		***P*-value**
			Lower	**Upper**	
Age	0.01	1.014	1.004	1.025	0.008
Employment status[1]		1.000			
employed	0.51	1.663	1.120	2.469	0.012
retired	1.00	2.707	1.690	4.336	<0.001
Multimorbidity[2]	-0.67	0.511	0.361	0.723	<0.001
Severity of depression	-0.06	0.939	0.906	0.973	<0.001
Severity of anxiety	-0.05	0.954	0.918	0.992	0.017
Severity of functional impairment	-0.03	0.975	0.957	0.994	0.011
Previous treatment episodes	-0.26	0.768	0.645	0.915	0.003
Number of sessions	0.66	1.068	1.033	1.105	<0.001
Early reliable improvement[3]	2.42	11.204	6.756	18.581	<0.001

Note. For socioeconomic status the reference category [1] was long-term sickness; for multimorbidity the reference category was the presence of one long-term condition only; for early reliable improvement (ERI) the reference category [3] was did not achieve ERI;

5.6 - Conclusion

This chapter has set out to report both descriptive and inferential results of an investigation into the extent to which pre-treatment characteristics, a ‘stepped-care’ model of treatment delivery and early reliable improvement in treatment influences end of treatment outcomes. In doing so, the chapter has revealed a range of results which will now be evaluated and interpreted in relation to their relationship with current research, the study’s theoretical and philosophical underpinnings and their clinical implications.

Chapter 6

Discussion

Chapter 6 - Discussion

6.1 - *Introduction*

In this chapter, the results of the study are discussed with each of the major findings explored in light of existing literature and with reference to the literature review presented earlier. The chapter proceeds to discuss the results in relation to the study's philosophical and theoretical framework followed by its implications for clinical practice. Finally, the limitations to the study are outlined.

6.2 - Reliable recovery

Since the inception of the Talking Therapies-LTC programme recovery rates of 50% on measures of anxiety and depression have been reported for patients with a LTC (Gill, 2017). In comparison, this study found 56% (n = 324) of the total cohort of patients achieved reliable recovery based on reliable and clinically significant improvement (RCSI) at the end of treatment. Whilst this finding is above the national recovery benchmark for Talking Therapies-LTC services of 50% (Clark et al., 2018), it also compares favourably to a small number of previous studies which have statistically investigated the outcomes of routinely delivered psychological treatment for people with LTCs in Talking Therapies services. Of these both Delgadillo et al (2017) and Kellett et al (2015) found that LTC patients experienced poorer clinical outcomes compared to non-LTC patients, albeit they did not report overall recovery rates. However, more recently, Seaton et al (2022) found only 32% of LTC patients achieved reliable recovery in comparison to 39% of patients without an LTC.

This variability in outcomes is consistent with previous practice-based evidence, with a number of IAPT benchmarking studies having attempted to quantify the magnitude of treatment effects in routine care and evaluate their outcomes relative to efficacy trials, albeit in patient groups without LTC (McAleavey et al., 2019). Collectively these studies have found the delivery of psychological treatment in routine care to be beneficial with overall favourable effect sizes. However, they have also identified significant variability in outcomes (Delgadillo et al., 2014; Gyanni et al., 2013; Wakefield et al., 2021) with suggested sources of heterogeneity found to be both clinical and methodological (Gaskell et al., 2022).

In the case of this study, one plausible reason for the difference in reliable recovery rates in comparison to earlier research (Kellett et al., 2015; Delgadillo et al., 2017) may be a result of these studies being undertaken prior to the national implementation of Talking Therapies-LTC guidance (National Collaborating Centre for Mental Health, 2018. As a result, they did not benefit from additional therapist IAPT-LTC competency framework training and supervision (Roth and Pilling, 2016). Consequently, the absence of specific training to address LTC-specific challenges linked to anxiety and or depression, self-management, and illness uncertainty may have resulted in poorer clinical outcomes (Highfield et al., 2016; Seaton et al., 2022). Certainly, studies have highlighted a positive correlation between appropriately LTC therapists and higher recovery rates in comparison to therapists without additional LTC training (Kenwright et al., 2017; Nobis et al., 2015).

In contrast, Seaton et al (2022) study did use outcomes following the national implementation of Talking Therapies-LTC and, as noted earlier, found significantly suppressed reliable recovery rates (32%) in comparison to this study (56%). It is important to note that the outcomes used in Seaton et al (2022) study were collected during the first wave of the covid-19 pandemic. This temporal factor appears important as not only were increased levels of anxiety and depression reported during the initial phase of the pandemic, but also a significant proportion of Talking Therapies patients ended psychological treatment abruptly without completing a full course of treatment due to the immediate disruption to routine services. Accordingly, this resulted in a significant reduction in Talking Therapies recovery rates nationally (NHS Digital, 2022) which had been artificially suppressed due to the pandemics impact.

Despite these differences, the findings of this study shared similarities with studies elsewhere in terms of the disproportionate small representation of certain LTC conditions whereby some, such as diabetes and COPD, were found to be under-represented in comparison to their prevalence in the general population (Weich et al., 2013). These discrepancies, as noted by Delgadillo and colleagues, may have been due to patients with certain conditions being less likely to access psychological treatment, but could also be a result of the sporadic use of routine mental health screening for people with specific LTCs in primary care as found in the case of coronary heart disease and diabetes (Coventry et al., 2011).

On a broader context, this study's reliable recovery rate also appears to compare favourably to outcomes from psychotherapy controlled trials for people with long-term health conditions and anxiety and/or depression. Whilst this evidence has revealed some promising results, specifically when interventions are adapted to focus on both anxiety/depression and the specific health condition simultaneously, they also reveal comparatively small effect sizes compared to non-LTC populations (Mousavi et al., 2007; Williams et al., 2012). These findings have led to a suggestion that the presence of LTCs suppresses psychological therapy outcomes (Delgadillo et al., 2017).

However, several studies have shown the severity of long-term health conditions to be a critical determinant rather than its mere presence (Dobkin et al., 2012; Hundt et al., 2018). As such, the severity of physical illness and functional impairment of homogeneous samples used in efficacy trials may play a key factor in attenuating outcomes, and consequently, may not be an accurate representation of the clinical profile of patients seen in primary care Talking Therapies-LTC services.

In addition, many efficacy trials for co-morbid physical and mental health problems have been found to utilise eclectic psychological therapy approaches (Power et al., 2022), particularly those outside of the UK and US whereby there may be less emphasis on evidence-based practice. It is possible that the UKs emphasis on Talking Therapies services delivering empirically supported treatment underpinned by national clinical guidelines (NICE, 2011) may offer some explanation in outcome variability for people with LTCs across different continents. Indeed, evidence continues to demonstrate that patients who receive NICE approved psychological treatments experience improved clinical outcomes at the end of treatment (Power et al., 2022).

Whilst it is clear that the degree of benefit patients with co-morbid health conditions experience with the adjunct of psychological therapy varies, on balance, there is a general trend that indicates psychological therapies can be effective. Moreover, the reliable recovery rate in this study may offer an important insight as it suggests the provision of Talking Therapies-LTC services can be effective with comparable outcomes to those in non-LTC patient groups.

6.3 - *Predictor variables*

Establishing what factors influence psychological therapy outcomes has led researchers to search for mediators to explain causal mechanisms or, as in the case of this study, specific moderating factors which affect the strength and direction of the relationship between end-of-treatment reliable recovery outcomes (Kraemer et al., 2002). Several studies have established that a range of demographic, clinical and service delivery factors influence end-of-treatment outcomes in psychological therapy for people with anxiety and/or depression, but without co-morbid physical health complaints (Amati et al., 2017; Delgadillo et al., 2016; Firth et al., 2015; Salmonsson et al., 2018). Of the small number of studies that have investigated the impact of similar demographic, clinical and service delivery factors in LTC patient groups results have been somewhat mixed. To this end, some studies have shown these factors to influence treatment outcomes (Hynninen et al., 2013; Delgadillo et al., 2017), whereas others have found there to be none or at best very limited association (Turner et al., 2007; Zonneveld et al., 2012b). Given this there remains little consensus about which specific factors influence on end of treatment reliable recovery outcomes in Talking Therapies-LTC services.

6.3.1 - *Pre-treatment characteristics*

This study found that a number of pre-treatment characteristics, both demographic and clinical, predicted end of treatment outcomes. These were age, employment status, multimorbidity, previous treatment episodes and severity of depression, anxiety and functional impairment at baseline. In contrast, gender, ethnicity, marital status, socioeconomic status, primary mental health problem, and the presence of a personality disorder were found to have no association.

6.3.2 - *Age*

The results found that a wide range of age groups (19 – 88 years) accessed treatment with a higher than average mean age (M = 53) in comparison to patients accessing Talking Therapies services nationally (M = 41) (Clark et al., 2018). In addition, the study also revealed a higher proportion of patients aged 65 years and over accessed treatment (26%) in comparison to national Talking Therapies figures whereby they remain largely underrepresented with only 4.5% of the clinical population being over 65 years (Clark et el., 2018; Office for National Statistics, 2022). It is plausible that the higher proportion of older people in this study merely reflects the higher rates of physical health problems and co-morbid anxiety and depression found in older people (Hazel et al., 2019; NHS England, 2017). Yet, it may also indicate that a higher proportion of older people are more likely to access psychological services when treatment is tailored to address both physical and mental health problems (Health Innovation Network, 2018). It is also possible that the increased prevalence of older people in this study can be partially explained by the focus on integrating psychological therapy into routine physical health care pathways (Department of Health, 2016; National Collaborating Centre for Mental Health, 2018), thus potentially increasing opportunities for access.

Overall, age was found to be statistically significant ($p = 0.008$), although the predictive association with reliable recovery was weak (OR = 1.014). This result shares similarities with previous research using comparable clinical patient groups and settings, but with larger sample sizes (Delgadillo et al., 2017; Saunders et al., 2022; Seaton et al., 2022). Whilst these studies found age to have a weak association with treatment outcomes, several other studies have observed age to have no effect at all. For example, age has been found to have no effect in CBT treatment for COPD (Hynninen (2013), Parkinson’s disease (Dobkin et al., 2012), and Type I and II diabetes (Tovote et al., 2017)

However, this result shows that the odds of achieving reliable recovery increased incrementally with every additional year of age suggesting older people with long-term conditions may have a higher likelihood of achieving recovery in comparison to younger people. A recent study by Saunders et al (2021) found similar results and concluded older people with LTCs were more likely to achieve higher recovery rates than working-aged people with or without LTCs. Investigations into the variability of recovery rates across age groups have found that once engaged in treatment older people have higher levels of engagement in therapy (e.g. appointment attendance) in comparison to younger people (Davis et al., 2020; Saunders et al., 2021). This may be of particular importance given that reliable recovery rates have a strong positive correlation with attendance and conversely, a negative correlation with high attrition rates (e.g. drop-out) (Delgadillo et al., 2014).

6.3.3 – *Employment status*

The study revealed a higher rate of employed patients in comparison to previous studies (Delgadillo et al., 2017) and revealed patients who were employed (OR = 1.663, $p = 0.012$) or retired (OR = 2.707, $p = <0.001$) were significantly more likely to achieve reliable recovery in comparison to those who were on long-term sickness. Differences were also observed in recovery rates, with retired participants achieving higher reliable recovery rates in comparison to those on long-term sickness respectively. These findings echo the results from previous studies that have found employment and retirement to be positive predictors of outcome, whilst unemployment has been observed to predict higher end of treatment scores on measures of anxiety and depression (Delgadillo et al., 2017; Firth et al., 2015; Knapstad et al., 2018).

It may be suggested these results illustrate the value of employment in maintaining emotional wellbeing (Verbist et al., 2022), particularly when considering the negative impact anxiety and depression has on an individual’s ability to find and sustain employment (Harvey et al., 2009). Moreover, the aforementioned problems worsen for those people suffering with co-morbid LTCs (Naylor et al., 2012). It is against this backdrop that the Talking Therapies programme has supported the national roll-out of Employment Advisors (EAs) working directly in their clinical services (Department of Works and Pensions, 2022). To this end, a recent evaluation reported the adjunct of Employment Advisor's increased the likelihood of patients on statutory sick pay returning to work, which had a positive association with improved mental health (Purdon et al., 2022).

6.3.4 - *Multimorbidity*

Over the past 10 years, the prevalence of multimorbidity, typically defined as the presence of more than one long-term condition has increased (Kingston et al., 2018). Although not confined to older adults, 50% of people aged 65 years and over experience at least two chronic diseases (Ronaldson et al., 2021; Salive, 2013), with the number of additional diseases per person increasing with age (Barnet et al., 2012). This increase in the presence of multimorbidity has also led researchers to investigate its impact on mental health and has revealed it to not only increase psychological distress (Read et al., 2017), but also increase the risk of depression (Yao et al., 2020) and anxiety disorders (Gould et al., 2016).

In line with these findings, multimorbidity was found to have a negative association with reliable recovery (OR = 0.511, p = <0.001). In total, 34% of patients in the study reported multimorbidity, with only 45% achieving reliable recovery in comparison to 61% of patients with one health condition. As such, patients with multiple conditions were found to be over one third less likely to achieve reliable recovery in comparison to patients with one long-term health condition. This result is consistent with the findings of Coventry et al (2015) who whilst concluding low-intensity treatment for depression and multimorbidity to be of benefit, found the number who achieved reliable recovery on measures of anxiety and depression were significantly lower than the pre-specified effect for the study.

This finding may be of value as it offers insight into the impact of multimorbidity in routinely delivered psychological therapy in comparison to previous studies that have only reported on outcomes of patients with one self-reported health condition (Delgadillo et al., 2017; Kellett et al., 2015). Fully understanding the reasons for this outcome is out of scope of this study, although it may be explained by evidence suggesting depression in multimorbidity not only exacerbates LTCs (Gunn et al., 2012), but also has a greater impact on quality of life and disability than living with one condition (Ho et al., 2014; Jones et al., 2016). It is also possible that this finding reflects the reported barriers to psychological therapy. Several studies have found a lack of understanding of the impact of multiple health conditions, difficulties attending appointments, and fear of psychological therapy to negatively affect people with multiple health conditions accessing therapy (Peppin et al., 2009; Wuthrich and Frei, 2015). In acknowledging these barriers, Read et al's (2020) clinical trial of internet-delivered cognitive behavioural therapy for older people with multiple health problems found it to be effective in reducing the risk of developing depression, although the study only included patients with subthreshold depression and is yet to be replicated in depressed multimorbidity individuals. Given the current understanding of the negative impact it appears to have on psychological therapies, combined with its predicted rise, it would appear a greater understanding of its impact in psychological therapy is required.

6.3.5 - *Severity of depression*

Severity of baseline depression was also found to have a negative correlation with outcome, although the predictive association was weak (OR = 0.939, *p* = <0.001). As such, the study found that patients who scored more severely on the PHQ-9 depression measure at baseline achieved a lower rate of reliable recovery compared to patients with scores in the moderate-severe range.

This finding is consistent with previous Talking Therapies-LTC cohort studies which found depression severity to negatively predict final treatment outcomes (Delgadillo et al., 2017; Kellett et al., 2015; Seaton et al., 2022). Elsewhere, various randomised controlled trials have also revealed similar results. For example, Dobkin et al (2012) found severity of baseline depression negatively influenced end of treatment depression outcomes in CBT for people living with Parkinson’s disease. Similar results were also found by Carney et al (2016) who found severe baseline depression predicted poorer end of treatment outcomes for CBT in patients with coronary heart disease.

Whilst many severely depressed patients may not meet the threshold for reliable recovery, some studies have found patients with severe depression can make reliable improvements during psychological treatment. A large scale study by Bower et al (2013) found more severely depressed patients at baseline demonstrated larger treatment effects than less severely depressed patients when provided with low intensity treatment. Moreover, Clark (2018) commenting on Talking Therapies outcomes on a broader national scale, noted a substantial proportion of severely depression patients do make reliable improvement from either low and high intensity treatment or a combination of both.

Collectively, this evidence seems to suggest that in the context of long-term health conditions, severe depression negatively predicts reliable recovery rates in psychological therapy (Amati et al., 2018). The mechanism for this is less clear and arguably multi-factorial, although it may be suggested that the persistence of severe depression accentuates the severity of physical health conditions. Thus, overtime, hindering a person's ability to self-manage whilst exacerbating the impact of physical illness on their quality of life overtime (Dos Santos et al., 2017; Ronaldson et al., 2021). In doing so, a perpetuating cycle emerges that negatively effects a person's ability to achieve durable improvements from psychological therapy longitudinally.

6.3.6 - *Severity of anxiety and functional impairment*

In echoing the outcomes of previous research, this study also discovered both severity of anxiety (OR = 0.954, $p = 0.017$) and functional impairment (OR = 0.975, $p = 0.011$) to have negative association with outcome. Delgadillo et al (2017) found these baseline factors in conjunction with a LTC negatively predicted end of treatment outcomes. Seaton et al (2022) found similar results with the addition of greater severity of functional impairment at the end of treatment. It may be that in a similar fashion to the severity of depression, the presence of pre-treatment severe anxiety and functional impairment further limits an individual's capacity to manage their health condition, thus impacting on their potential to make significant durable gains in psychological therapy.

Moreover, a closer evaluation of previous studies illustrates baseline measures of anxiety and functional impairment to have been placed into discrete groups replicating published norms of the scales used (e.g. mild, moderate, and severe). Interestingly, when these groupings were applied to this study those scoring most severely at baseline achieved lower overall reliable recovery rates in comparison to those in the mild to moderate groups. As such, it may be that categorising these continuous variables into groups may influence their predictive power further as opposed to using them as a continuous measure.

6.3.7 - *Previous treatment episodes*

The study found evidence to indicate the number of previous treatment episodes to have a significant negative association with reliable recovery at the end of treatment (OR = 0.768, p = 0.003). Moreover, it revealed patients with more than 5 previous episodes of treatment were less likely to achieve reliable recovery at the end of treatment in comparison to patients with 2 previous treatment episodes. This finding converges with previous observations that also revealed a negative association between with the number of treatment episodes and end of treatment outcomes (Delgadillo et al., 2017; Tovote et al., 2017). Indeed, studies have shown an incremental relationship with each additional previous treatment episode increasing the severity of post-treatment scores on measures of anxiety and depression in both LTC and non-LTC populations (Davis et al., 2020; Delgadillo et al., 17; Gyani et al., 2013).

Accounting for the reasons behind why multiple treatment episodes occur is complex. Clinically, the chronic or recurring course of severe depression (DeRubeis et al., 2020) and certain anxiety disorders, for example, obsessive compulsive disorder (Levy et al., 2021), have been found to increase the need for psychological therapy overtime, and therefore may increase the likelihood of further treatment episodes. Similarly, the enduring and unpredictable nature of long-term health conditions may in itself increase the likelihood of recurrent episodes of depression and/or anxiety disorders that require further treatment. If this is the case, it highlights the need for treatment to also be adapted to focus on the enduring nature of co-occurring physical and mental health problems.

Elsewhere, the role of engagement in psychological therapy has been cited to be critical, as patients who are able to attend regularly and engage in the active components of treatment, such as in-session and out-of-session behavioural experiments, experience better outcomes (Constantino et al., 2011). In contrast, non-attendance and high attrition rates are frequently associated with poorer reliable recovery rates in Talking Therapies services (Chan and Adams, 2014). In a study by Saunders et al (2020), non-attendance along with increased waiting times were found to negatively influence treatment outcomes. Moreover, non-attendance itself has also been found to be associated with referral source with patients who self-refer more likely to attend treatment appointments (Davis et al., 2020). Furthermore, higher levels of attrition have also been reported in the early stages of treatment, leading to a sub-optimum doses of treatment being received (Schindler et al., 2013), that in turn increases the likelihood of relapse and need for further therapy.

Engagement itself has also been found to be associated with patient expectations. For example, optimism about the role of therapy and recovery has been found to predict greater symptomatic improvement (Harrison et al., 2019). Other factors such as perceived self-efficacy (Bandura, 1986) and motivation to change have also been cited as predictors of engagement (Verbist et al., 2022). Given this, it appears important to consider the barriers to engagement, particularly for those who have had more than two episodes of treatment and have struggled to engage to a sufficient degree to realise the potential benefits of psychological therapy.

6.3.8 - *Gender*

Whilst the study found a greater proportion of females engaged in treatment in comparison to males echoing the findings of previous studies (Kellett et al., 2015; Seaton et al., 2022), gender had no association with reliable recovery. This finding is shared by prior studies which also indicated gender did not correlate with end of treatment outcomes (Delgadillo et al., 2017; Dobkin et al., 2012). In contrast, Seaton et al (2022) found the presence of a LTC increased end of treatment distress on measures of depression and anxiety in females compared to males, whilst Sandler et al (2002) observed males with higher levels of baseline distress predicted a poorer response to treatment.

This study did, however, find gender differences in rates of reliable recovery with more males achieving recovery than females. Arguably, this suggests that where treatment can be adapted to address factors such as stigma to increase help-seeking in men and overcome traditional masculine views on mental health, the benefits of psychological therapy may be realised.

6.3.9 - *Ethnicity*

Due to the absence of ethnic diversity the study was unable to include this as a potential predictor in the analysis. Previous studies reporting on patient outcomes from ethnically diverse groups have found mixed outcomes. Seaton et al (2022) noted a greater proportion of Black/Black British and other ethnic groups to have LTCs compared to white British backgrounds, albeit this may be partially explained by the highly multicultural population of the study's setting. However, they concluded ethnicity alone had no association with outcome. In contrast, Delgadillo et al (2017) found patients from South Asian and other ethnically diverse backgrounds had higher post-treatment distress when compared to White British backgrounds. More recently, Amati et al (2023) reported the role of ethnicity was attenuated by other factors, such as employment, social deprivation and morbidity, and concluded these factors to be disproportionately present in greater intensity in some ethnic minority populations, and as such, predicted poorer outcomes.

Within this study, the significant absence of ethnic diversity was stark with only 3% of the patient group identifying as being non-White British. Arguably this may simply reflect the scale of ethnic diverse communities within the study's localities whereby 2-4% identify as non-White British (Office of National Statistics, 2021). Yet, it may also be partially attributable to a nationally recognised problem in that people from ethnic diverse backgrounds remain under-represented in Talking Therapies services and their clinical outcomes can be poorer (Baker et al., 2018). Clearly, addressing issues of engagement and ensuring treatment is culturally adapted is warranted. Without this, there is an innate risk of marginalising ethnically diverse community's access to psychological therapy further in predominantly White British areas.

6.3.10 - *Marital status*

Marital status was also found to have no association with reliable recovery and concurs with the findings observed by Delgadillo et al (2017). However, on the whole the investigation of the potential role of marital status in LTC populations has been limited due to its exclusion from other prior Talking Therapies-LTC studies (Kellett et al., 2015; Seaton et al., 2022). Outside of the Talking Therapies-LTC programme, the predictive role of marital status on therapy outcomes has also been mixed. Dobkin et al (2011) found marital status to have a small but positive correlation with outcomes, whereas various non-LTC studies have revealed marital status to have no such association (Knapstad et al., 2018; Salomonsson et al., 2019).

6.3.11 - *Socioeconomic status*

Somewhat surprisingly given the evidential reports of the negative influence social deprivation has on psychological therapy outcomes (Delgadillo et al., 2015), this study found socioeconomic status to have no relationship with reliable recovery at the end of treatment. Previous studies have not only concluded social deprivation to be associated with a greater prevalence of LTCs, but also a significant predictor of poorer clinical outcome on measures of reliable recovery and reliable improvement (Delgadillo et al., 2017; Seaton et al., 2022).

It is possible that this finding may be explained by the socioeconomic status of the areas under investigation in this study, which were not deemed as severely deprived on the English indices of social deprivation (McLennan et al., 2019). If this is the case, it appears a follow the trend in that more severely deprived areas have poorer reliable recovery rates in comparison to less deprived areas, as in the case of this study. Yet, the effect of social deprivation may be partially reduced by other factors. A national review of Talking Therapies outcome data (Clark et al., 2018) suggested in areas of high social deprivation, focusing on lowering waiting times, allocation to the correct NICE recommended treatment, and the provision of an adequate dose of treatment, may offset the effect of social deprivation. Clearly addressing these factors is warranted, although achieving this requires targeted and adequate funding to address workforce arrangements to ensure there is an adequately trained workforce to meet demand.

6.3.12 - *Primary mental health diagnosis*

The study found patients with a range of primary mental health diagnosis accessed treatment. However, the absence of a suitably representative sample precluded the study's ability to perform separate analysis for different types of mental health problems. Therefore, it was unable to report on their relationship with reliable recovery. Nonetheless, the study found having depression or an anxiety disorder did not influence reliable recovery. This is somewhat similar to a number of Talking Therapies studies, with or without LTCs, where the type of mental health diagnosis has not been found to have a strong association with end of treatment outcome.

6.3.13 - *Presence of personality disorder*

The presence of a personality disorder was also not found to be associated with reliable recovery, albeit lower reliable recovery rates were observed in patients who scored in the severe range of the SAPAS measure. Somewhat interestingly, no previous Talking Therapies-LTC study has considered the role of personality disorder in the context of long-term conditions and co-morbid anxiety and depression despite evidence to suggest its presence to be associated with chronic illness (Powers and Oltsmanns, 2012) and to adversely affect treatment outcomes (Goddard et al., 2015). Prior efficacy trials have also found the presence of personality disorders to have no negative effect on treatment outcome (Liebbrand et al., 1999) except in the case of patients presenting with persistent physical symptoms, where Zonneveld et al (2012) found fewer personality disorder traits to be associated with improved clinical outcomes.

Within the broader Talking Therapies programme, a study by Hepgul et al (2016) found 69% of their patient population were at high risk of personality disorder. However, by way of contrast, this study found only 44% of the LTC patient cohort to have scored positively for the presence of a personality disorder. It is possible that in this study a proportion of patients presenting with more severe personality difficulties were referred on to more suitable services, and as such, were excluded from the analysis. Clearly if a person's main problem is related to a personality disorder their specific psychological needs may be best served by accessing the most recommend treatment, for example, dialectic behavioural therapy (National Collaborating Centre for Mental Health, 2015), which remains outside of the Talking Therapies programme remit. Given the paucity of research into the impact of personality disorders have on outcomes in LTC patients accessing Talking Therapies servcies, further investigation is required.

6.4 - Stepped-care model

To understand the impact the organisational delivery of psychological therapy for people with co-morbid physical health problems and anxiety and/or depression has on outcomes, the study focused on the Talking Therapies preferred clinical model of 'stepped-care'. In doing so, this study considered the type of NICE recommended treatment offered and number of sessions provided.

6.4.1 - *Number of treatment sessions*

The study found the number of treatment sessions completed to be positively associated with reliable recovery, although the relationship was relatively weak (OR = 1.068, p = <0.001). As such, it suggests as the number of sessions completed increased so did the likelihood of improved end of treatment outcomes and this was indicated across all treatment groups, low-intensity, high-intensity or a combination of both. Overall, the mean number of sessions provided was 9 which is comparable with the national non-LTC Talking Therapies mean number of sessions (NHS Digital, 2016). Moreover, the study revealed patients who received fewer than 5 sessions were less likely to achieve reliable recovery across the treatment groups.

This study appears to be the first to consider the role of number of sessions has on end of treatment outcomes in routinely delivered psychological treatment for co-morbid health conditions and anxiety and/or depression. In doing so, it may offer some important insights; firstly, the average number of sessions provided in the study was equivalent to those in non-LTC Talking Therapies patients groups (Clark et al., 2018); secondly, it mirrors previous findings in non-LTC populations that providing a higher average number of sessions increases the likelihood of achieving higher rates of reliable recovery with the optimal mean number being 9-10 sessions (Gyani et al., 2013); and thirdly, some patients need more than the average and some less to achieve recovery (Clark et al., 2018).

However, it is important to note that previous studies have also shown that offering unlimited number of treatment sessions does not necessarily equate to improved reliable recovery rates as the likelihood of achieving recovery with each additional session has been shown to plateau overtime (Delgadillo et al., 2014). Arguably, the prescribed number of sessions recommended by NICE for specific problems would appear to support this view with limited evidence to suggest offering more than 12-16 sessions for people with anxiety disorders and/or depression to be of benefit.

6.4.2 - *Type of treatment*

Overall, the study did not find the type of treatment offered to be a predictor of reliable recovery. The study did, however, reveal patients with LTCs were more likely to receive high intensity treatment (67%) compared to low intensity treatment (19%) or a combination of both low and high intensity interventions (14%). In comparison, within non-LTC Talking Therapies patient groups, 28% receive high intensity treatment, 36% low intensity and 28% receive both (NHS Digital, 2016). The allocation to treatment in this study replicates the findings of Delgadillo et al (2017) and may be indicative of the higher levels of impairment and symptom distress often found in LTC patient groups. As such, these findings appear to confirm the workforce guidance offered by the Talking Therapies-LTC implementation guide (National Collaborating Centre for Mental Health, 2018) that acknowledged the requirement for more high intensity therapists to meet the clinical needs of people with LTCs.

Reliable recovery rates across treatments also varied. Relatively equivalent recovery rates were seen in both low and high intensity treatment when offered as a standalone treatment. From a low intensity treatment perspective, prior research found low intensity treatment for LTCs to have poorer outcomes (Kellett et al., 2015) albeit it may be possible that this outcome reflected the disproportionate number of patients offered low intensity treatment alone with minimal use of high intensity treatment. In contrast, low intensity treatment has been reported to have beneficial effects elsewhere, for example, a trial by Wroe et al (2014) demonstrated low intensity treatment specifically adapted for Type 2 diabetes to be efficacious. Given this it would appear that there is a need to ensure low intensity treatment is adapted to focus on LTC management as this would potentially provide greater options for clients accessing psychological therapy rather than a reliance on more costly high intensity treatment (Delgadillo et al (2017)

Patients who were ‘stepped-up’ to high intensity treatment following low intensity interventions achieved higher reliable recovery rates (61%). This mirrors the outcomes from a number of non-LTC studies, where ‘stepping-up’ to higher intensity treatment has been found to increase recovery rates (Clark et al., 2009; Gyani et al., 2013).

However, similar to Kellett et al (2015), the step-up rate was low (14%) in comparison to the national average for non-LTC patient groups (36%) (Clark et al., 2018).

Given the high number of LTC patients requiring high intensity treatment and low levels of ‘step-up’-rates, the overall suitability of a ‘stepped-care’ model for Talking Therapies-LTC has been questioned with some concluding the role of the ‘stepped-care’ model to be insufficient to meet LTC patient needs (Delgadillo et al., 2017). Previous studies regarding the role of ‘stepped-care’ in non-LTC populations have also found mixed results. Salmonsson et al’s (2018) efficacy trial demonstrated stepped-care for depression and anxiety disorders to be a clinical and cost-effective model for delivering psychological therapy specifically where patients were rapidly ‘stepped-up’ to high intensity treatment. Yet, Delgadillo et al (2022) efficacy trial found stratified care, where patients are matched to either low or high intensity treatment at initial assessment, to be more efficacious and cost-effective than stepped care for depressed adults. Given this current evidence, whilst it is clear the ‘stepped-care’ model provides a framework to provide psychological treatment at scale, its effectiveness in maximising patient outcomes for people with co-morbid LTCs requires further investigation.

6.5 - *Early reliable improvement (ERI)*

The study found early reliable improvement across all types of treatment to be the strongest predictor of reliable recovery with a large positive association (OR = 11.204, *p* = <0.001). As such, patients who showed ERI were significantly more likely to achieve reliable recovery. These results replicate a number of studies which have found reliable improvement in the early phases of treatment to have a positive association with end of treatment outcomes (Delgadillo et al., 2014; Schlagert and

Hiller, 2017). However, research has also indicated rates of reliable improvement in psychological therapy vary from person to person (Stiles et al., 2009) and are influenced by the severity of impairment (Stulz et al., 2007) and the frequency and total number of sessions provided (Erikson et al., 2015). Yet on balance, the weight of evidence does seem to indicate early reliable improvement may predict end of treatment outcomes and that this relationship is applicable in both LTC and non-LTC populations.

In addition, given the study's strong association between early reliable improvement and reliable recovery, it is plausible that LTC patients who do not make reliable improvement in the early phases of treatment may be at risk of poorer end of treatment outcomes. If this is the case, identifying patients early in treatment who are unlikely to achieve reliable recovery offers an opportunity to make clinical changes to maximise the chances of improvement. The early detection of patients who are at risk of poorer outcomes has been the focus of psychotherapy feedback research in non-LTC patient groups for two decades. Collectively, these studies have found a focus on routine outcome feedback to monitor progress improves clinical outcomes (de Jong et al., 2021; Harmon et al., 2007; Lambert et al., 2008). Indeed, a recent meta-analysis (Delgadillo et al., 2022) found a focus on outcome monitoring to track patient progress in treatment and feeding back this information to therapists helped reduce the variation between more and less effective therapists, leading to more effective treatment overall. Clearly there is some way to go to establish whether this can be replicated in LTC patient groups, albeit the initial signs emanating from the findings of this study are promising and suggest a need for further investigation.

6.6 - ***Philosophical and theoretical perspective - Revisited***

Given the previous discussion of results, it follows that discussing the study's results in relation to its underlying philosophical and theoretical context is warranted. For ease of reference the original framework is presented in Table 6.0 overleaf.

This study's philosophical underpinnings were originally nestled within the continuum of positivism and arguably represented the ontological and epistemological stance of neo-positivism. The findings emanating from this study support this perspective. The findings present a view of reality and truth which is objective, empirical and underpinned by the natural laws of science to uncover a range of predictors which influence of treatment outcomes in psychological therapy. In doing so, specific knowledge regarding the most influential predictors were reflected in the findings. Age, multimorbidity, severity of depression, previous treatment episodes, number of sessions and early reliable improvement were found to be the most highly influential predictors having been empirically realised through a formal process of logical inquiry and statistical analysis based on the falsification process proposed by Popper (1992).

Furthermore, the findings reflect the stance that an absolute certainty does not exist. As such, it supports the study's focus on variance in outcomes using practice-based evidence to identify relationships and trends through which further investigation can not only develop our knowledge but also enhance its clinical utility.

Table 6.0 – *Overview of philosophical and theoretical perspectives revisited*

Philosophical						
Neo-positivism						
Theoretical **m*ain themes***						
Dualism	Variance in Outcomes	Biopsychosocial theories of health	Psychological Therapies	Collaborative Care	Organisational Delivery of Psychological Therapies	Early Response to Psychological Therapy
Theoretical ***sub-themes***						
Reductionism and Biomedical Models of Health	*Practice-based evidence*	*Models of Health Behaviours* *Psychosocial Influences on Health*	*Behavioural Theories* *Cognitive Theories* *Cognitive Behavioural Therapy for Long-Term Health Conditions*	*Integration*	*Stepped-Care*	*Early Reliable Improvement (ERI)* *Dose effect*

The findings in the study hold no support for the theory of dualism (Descartes, 1998), as they clearly illustrate a relationship with factors such as age and multimorbidity, and their attenuating effect on psychological therapy outcomes for people with long-term health conditions and mental health problems. In doing so, the results refute the notion that are mind and body are separate entities (Duncun, 2000), but by contrast suggest an interacting effect in that what affects humans physically also affects our mind (our emotional state) and vice-versa. Similarly, whilst the biological features of age and multi-morbidity may indicate some support for biomedical theories of health and the impact they have on chronic physical illness (Bonzo, 2010), the results suggest this to be a narrow perspective as it does not fully account for other factors which the findings reveal influence end of treatment outcomes.

Accordingly, the study revealed a range of biological (e.g. age), psychological (e.g. severity of depression and anxiety) and sociological factors (e.g. long-term sickness) influence end of treatment outcomes for people with co-morbid physical and mental health problems. This finding appears to not only reflect Engel's (1977) biopsychosocial theory of health, but also suggests how people adjust, maintain and prevent ill health to be influential, albeit the results do not provide an empirical account of their direct influence. Having said that, it may be suggested that for a psychological treatment to be effective these aspects need to be addressed. As such, the study's promising reliable recovery rate appears to hold some support for adapted treatment underpinned by a cognitive behavioural theory of emotion which targets theories regarding health beliefs (Rosenstock, 1966), stress and coping (Lazarus and Folkman (1984), self-regulation (Leventhal et al., 1998), locus of control (Rotter, 1966), self-efficacy (Banduru, 1986) and behavioural change (Ajzen, 1991; Prochaska and Diclemente, 1993).

Whilst these theories go some way to explain the impact of ill health on a person and conceptualise behaviour change, they do not fully account for the role of co-morbidity in relation to physical and mental health problems. This study found support for the theory of co-morbidity and its negative impact (Pooler and Beech, 2014) as it found severe baseline depression, anxiety, and functional impairment to be highly prevalent and to negatively influence end of treatment outcomes. The number of previous treatment episodes was also found to negatively influence outcomes and as mentioned previously, it may be that the presence of co-morbidity increases the likelihood of further treatment given the enduring nature of long-term health problems and their interaction with anxiety and depression. Certainly, cognitive behavioural theories of relapse in depression indicate unhelpful beliefs about the world, self and future can be re-activated by any event (e.g. deterioration in health) (Beck and Bredemeier, 2016), and that the risk of relapse increases with each additional episode of depression and/or anxiety (Bockting et al., 2015). Taken collectively, these findings arguably provide further theoretical evidence about the disabling impact co-morbidity in the context of health conditions can have.

A striking finding of this research was the negative impact the presence of multimorbidity had on end of treatment outcomes. Theoretically, this finding clearly suggests the interacting nature of multiple physical health problems has on a person not only increases the likelihood of anxiety and/or depression, but also highlights how multi-morbidity limits the benefit people can experience from psychological therapy. Fully understanding the nuances of this interaction are beyond the scope of this study, other than to empirically confirm its presence significantly attenuated end of treatment outcomes. However, it may be suggested the findings reinforce the view that a purely biological view of multimorbidity does not fully account for the impact of living with multiple conditions. Thus, it appears imperative that future research focuses on developing biopsychosocial interventions to meet the needs of people with multimorbidity.

In contrast, the impact of psychosocial factors such as social-economic status (Baker et al., 2020) had limited influence on end of treatment outcomes. However, as suggested previously it may be that the degree of deprivation in the geographical areas under investigation were too similar and not particularly deprived based on the index of multiple deprivation ranking. If this is the case, it may be that psychosocial theories of health play a role in explaining the differences in outcomes between less deprived and highly deprived areas, with the latter having been found to negatively influence psychological therapy outcomes (Clark et al., 2018; Delgadillo et al., 2018).

Attempts to meet the needs of people with co-morbid physical and mental health problems have led to some reform in approaches to care with one such model being collaborative care. From this perspective, the results indicate that the adjunct of psychological therapy into routine care offers some support for the role of collaborative integrated care (Coventry et al., 2013), particularly if viewing therapy as part of a wider integrated package of care. In this context, the findings suggest additional therapist training focusing on tailoring psychological interventions to address the challenges associated with living with LTCs and anxiety and/or depression, may increase the likelihood of improved psychological therapy outcomes (Seaton et al., 2022). However, it is difficult to establish full support for the model of collaborative care as the study did not directly investigate other facets of its proposed framework, such as enhanced professional communication and multi-disciplinary working (Gunn et al., 2006)

From an organisational delivery of psychological therapies perspective, the study found partial support for the theory of stepped-care, in that patients were allocated to various treatments at scale and found to have reliably recovered, albeit a significant proportion of patients only received high intensity treatment. This may reflect the levels of complexity of people presenting with co-morbid difficulties, but also that national clinical guidance only indicates high-intensity treatment for certain health conditions, for example, chronic pain (NICE, 2021). As such, the notion of ‘stepping-up’ from low to high intensity treatment, a key factor in the theory of stepped-care, was significantly lower in comparison to non-LTC studies. This may suggest the model of stepped-care in this clinical population has distinct limitations.

In conjunction, whilst the findings demonstrated the type of treatment was not significantly associated with end of treatment reliable recovery, the number of sessions received was positively associated. This finding implies support for the ‘dose-effect’ response whereby a negatively accelerating relationship exists between the number of treatment sessions completed and the probability of improvement (Howard et al., 1986; Robinson et al., 2019). Yet, whilst the results found less people recovered over longer courses of treatment (up to 20 sessions) in comparison to shorter courses of treatment suggesting diminishing improvements overtime, it was not able to clearly demonstrate this conclusively. However, as noted earlier in this chapter, significant support was found for the positive association between early reliable improvement (ERI) in the early stages of treatment and reliable recovery.

This finding appears to not only offer support for the role of the dose-effect theory in the context of ERI, in that the greatest gains were made during the early stages of treatment, but also supports theories regarding early change in psychological therapy and its predictive relationship with end of treatment outcomes (Stulz et al., 2008). Making inferences about the active mechanisms involved with early change and end of treatment outcomes was always going to be outside the scope of this study, but theorists cite a number of possible reasons, for example, gaining rapid insights from treatment interventions (Lambert, 2007) to treatment expectations (Constantino et al., 2018).

Despite its strong support for the theory of early reliable improvement predicting positive end of treatment outcomes, it also revealed a number of patients who achieved early reliable improvement, did not achieve reliable recovery at the end of treatment. This finding seems to indicate the predictive power of early reliable improvement to vary within patient groups. From this perspective, it is plausible that highly impaired patients at baseline were able to make initial early reliable improvements, but due to the continuous nature of their problems, for example, multimorbidity, they were not able to achieve reliable recovery at the end of treatment. Given this, it appears further theoretical and empirical investigation is required to establish a more comprehensive understanding of the role of early reliable improvement in LTC patient groups.

In summary, the results of this study have both held support and refuted some of its original theoretical framework. It therefore appears appropriate to revise these initial considerations and present a new theoretical framework which is cognisant with its findings (see Table 6.1 overleaf).

Table 6.1 – *New philosophical and theoretical themes and sub-themes*

<table>
<tr><td colspan="6">**Philosophical**</td></tr>
<tr><td colspan="6">Neo-positivism</td></tr>
<tr><td colspan="6">**Theoretical main themes**</td></tr>
<tr><td>*Variance in Outcomes*</td><td>Biopsychosocial theories of health</td><td>Psychological Therapies</td><td>Collaborative Care</td><td>Organisational Delivery of Psychological Therapies</td><td>Early Response to Psychological Therapy</td></tr>
<tr><td colspan="6">**Theoretical Sub-themes**</td></tr>
<tr><td>*Practice-based evidence*</td><td>*Models of Health Behaviours*</td><td>*Cognitive Behavioural Therapy for Long-Term Health Conditions*</td><td>*Integration*</td><td>*Stepped-Care*</td><td>*Early Reliable Improvement (ERI)*</td></tr>
<tr><td>*Reductionism*</td><td>*Psychosocial Influences on Health*</td><td></td><td></td><td></td><td>*Dose-effect*</td></tr>
<tr><td>*Co-morbidity & Multimorbidity*</td><td>*Cognitive behavioural theory of emotion*</td><td></td><td></td><td></td><td></td></tr>
</table>

6.7 - *Clinical implications*

This study follows in the recent traditions of practice-based evidence by investigating the effects of routinely delivered psychological therapy. This tradition has been found to not only inform service improvements, but also highlight treatment delivery factors associated with patient outcomes (Saunders et al., 2020). However, unlike the majority of previous practice-based evidence, its focus on co-morbid long term health problems offers unique insights to accompany the handful of research previously undertaken in Talking Therapies services (Delgadillo et al., 2017; Kellett et al., 2016; Seaton et al., 2022). As such, its findings offer several clinical implications that merit future consideration by clinicians, NHS Talking Therapies services, and the wider research fraternity.

As noted previously, this investigation found 56% of patients with co-morbid long-term health problems and anxiety/depression were able to achieve reliable recovery. This is above the national benchmark for non-LTC populations of 50% populations, and higher than the national recovery rate average rate (Clark et al., 2018). Accordingly, it not only represents a departure from the findings of previous studies (Delgadillo et al., 2017; Seaton et al., 2022) which found LTC patients had poorer outcomes in Talking Therapies services, but also indicates the national roll-out of integrated LTC pathways can be beneficial (NHS England, 2018).

It is plausible that this level of reliable recovery rate was achieved as a result of a number of factors which have clinical implications nationally. Firstly, it used outcomes from an established Talking Therapies service which was underpinned by the three fundamental principles of Talking Therapies services, namely, the provision of NICE approved evidence based treatment matched to a primary mental health problem and long-term condition, delivered in a ‘stepped-care’ model whereby the intensity and duration optimised outcomes. Secondly, all the LI and HI therapists’ delivering psychological therapy had completed additional long-term conditions training to meet the national LTC competency framework (Roth and Pilling, 2016) and were supervised by more experienced therapists. Thirdly, the use of routine outcomes measures on a session-by-session basis to monitor patient progress (National Collaborating Centre for Mental Health, 2021).

In addition, the study site was also part of an Early Implementer programme of Integrated LTC pathways (National Collaborating Centre for Mental Health, 2018). This meant they had received additional funding to enhance their workforce to meet the needs of LTC patient groups and had established local integrated pathways with community physical health teams, frequently delivering treatment in co-located clinics. As such, some of their local physical health teams had received additional training from the Talking Therapies team about the impact of mental health problems on long-term conditions and had embedded mental health screening into their routine practice. This seems to indicate when a service offers treatment consistent with the fundamental pillars of the Talking Therapies service framework and has established LTC integrated pathways, outcomes can be comparable with non-LTC patient's groups.

Arguably this suggests the expansion of Talking Therapies services as part of the NHS Long Term Plan (DoH, 2019) and Mental Health Implementation Plan (NHS England, 2019) to deliver psychological treatment as part of routine physical care can be successful. Certainly, a review of previous Talking Therapies LTC research, which in some cases was before the national implementation of LTC pathways and without the additional training and workforce (Delgadillo et al., 2017; Kellett et al., 2015), would suggest these to be key issues to be addressed for a successful national roll-out.

This research finding that older people with co-morbid LTCs can benefit from psychological therapy echoes the findings from previous practice based evidence studies (Prina et al., 2014; Saunders et al., 2021). This dispels the clinical myth that psychological therapy may not be suitable for older adults and indicates once engaged with therapy, positive outcomes can be achieved. Yet despite these encouraging outcomes, evidence continues to demonstrate far less people aged 65 and over access psychological therapy in comparison to other age groups (Clark et al., 2018); an unequal distribution that worsens with increasing age despite the over 65s being the fastest growing group demographically (Collins and Corna, 2018).

Barriers to older people accessing psychological therapy are well established and include stigma and a lack of understanding about mental health, a focus on physical health over mental health derived from a traditional dualistic view on health, and low mood being seen as a natural part of ageing (Pettit et al., 2017). Moreover, it appears older people themselves do not get referred by health professionals to psychological therapy. This may be in part due to a lack of routine mental health screening, but also gaps in knowledge about the impact of physical health has on mental health, and the benefits of psychological therapy (Collins and Corna, 2018; Lavingia et al., 2020).

The production of Positive Practice Guides for Older People (BABCP, 2021) goes some way to drive Talking Therapies services to address these issues with suggestions such as, age appropriate promotion, integrated referral pathways, developing older people's champions roles, and adherence to the Older People's Mental Health Competency Framework (Health Education England, 2020). However, it may be suggested this is just one part of a wider system which requires change. From this perspective, both physical and mental health services need to move towards adopting a biopsychosocial perspective in the care they provide, rather than the current provision of treatment silos for physical and mental health care. This cultural shift, although widely applauded as a way forward, is still lacking but is clearly needed as it would provide an opportunity for greater integration of services to meet the holistic needs of older people with co-morbid long-term health problems and anxiety and/or depression.

Similarly, the study also revealed an absence of patients from ethnic and diverse communities with long-term health conditions accessing psychological therapy. This finding mirrors the national picture in NHS Talking Therapies services whereby ethnically diverse communities are not only under-represented, but even after accessing services are less likely to complete treatment and achieve reliable recovery in comparison to White British backgrounds (Baker, 2018). Much in the same vein as older people, positive practice guides have been published (Beck et al., 2019) to help shape how Talking Therapies services address access rates through greater engagement with ethnic communities, by increasing the diversity of their workforce, and by ensuring treatment in culturally sensitive. To date, whilst these guidelines have increased awareness, evidence is yet to illustrate their benefit, and it is clear more focus is required to achieve these ambitions in order to serve our multicultural communities.

The findings also revealed a number of baseline clinical factors appear to increase the risk of poorer outcomes, namely, multimorbidity, severity of depression, anxiety and functional impairment, along with the number of previous treatment episodes. Whilst severity of depression, anxiety, functional impairment, and the number of previous episodes of treatment have previously been found to negatively affect treatment outcomes, albeit predominantly in non-LTC populations, this study appears to be the first to demonstrate the association of poorer outcomes with multimorbidity.

Whilst the identification of these factors may be viewed as valuable in that they raise clinical awareness of their influence on treatment outcomes, this should not be seen as an end in itself as further replication studies are required to validate its findings. Indeed, further investigation is required to fully understand the interaction between multimorbidity and severity of depression, anxiety and functional impairment, in order to develop treatment interventions that maximise the potential for positive treatment outcomes. Similarly, the number of treatment episodes provides an opportunity to proactively explore treatment barriers that contribute to multiple treatment episodes. For example, treatment expectancy factors, the choice of treatment, and engagement difficulties. In doing so, this may increase the probability of successful treatment and avoid the replication of patients receiving sub-optimum doses of treatment.

The findings also clearly illustrate that LTC Talking Therapies services need to offer adequate number of treatment sessions to increase the probability of achieving reliable recovery. This echoes the findings from a number of previous practice based studies (Clark et al., 2018; Gyani et al., 2013). From this perspective, it appears important that services are commissioned so that they can offer the right dose of treatment and avoid ‘capping’ the number of sessions to less than what is clinically recommended by NICE guidelines (National Collaborating Centre for Mental Health, 2021). Unfortunately, it appears the commissioning of some NHS Talking Therapies services in some areas in England under the competitive ‘any qualified provider’ tendering process does not always allow this to prevail.

Perhaps the most significant finding in the study was the strong positive relationship between early reliable improvement and reliable recovery across all treatment groups. From a clinical perspective, this presents a potential opportunity for clinicians to use early outcome data to monitor progress and empirically predict whether someone is ‘on track or not’ to achieve reliable recovery at the end of treatment. More specifically, it may be suggested the identification of patients who do not achieve early reliable improvement can provide a trigger to consider adaptations to treatment, or the ‘stepping-up’ to different treatments. This focus on early symptom change has been found to be effective in previous studies (Delgadillo et al., 2014) but is the first to consider its utility for people with co-morbid physical health problems with anxiety and/or depression. To achieve this would require a greater focus on regular progress feedback in treatment between patients and therapists, and in supervision between therapist and supervisor. Recent research would appear to support this, with the use of routine progress feedback with patients and in supervision not only improving outcomes in non-LTC patients, but also reducing variation in outcomes attributed to therapists (‘therapist effects’), which can positively and adversely affect outcomes (Delgadillo et al., 2022).

6.8 - *Limitations*

Similar to all research, this study had a number of limitations. From a methodological choice, insights gained from observational studies may be somewhat limited due to the absence of controls which increase the influence heterogeneous sources can have on of treatment outcomes. Nonetheless, it is widely acknowledged that observational studies offer an opportunity to establish real world evidence to form a collective body of evidence, identifying trends and patterns overtime, that can then be generalised or empirically investigated. Furthermore, it may be suggested the use of separate unadjusted binary logistic regression models did not account for potential confounding interactions that may have influenced both the predictors and outcome variable used in the study, and as such, could be viewed as presenting an oversimplification of a complex real-world interaction. However, given the study represented an initial exploration to highlight potential predictors of outcome, its use appears justified in it provided the building blocks for future predictor orientated research whereby these predictors could be investigated using adjusted models.

It may also be suggested that the inclusion of a comparison group of non-LTC patients would have been beneficial. This would have provided greater insight into the similarities and differences in outcomes for the predictors under investigation across two groups of patients who access Talking Therapies services. Furthermore, the sample size was not only smaller than similar LTC Talking Therapy studies (Delgadillo et al., 2017; Seaton et al., 2022), but also precluded the ability to analyse outcomes for different diagnostic groups and specific long-term health conditions. This may be of particular importance as associations with end of treatment outcomes have been found to vary based on these clinical factors. For example, Delgadillo et al (2017) observed patients with musculoskeletal problems, chronic obstructive pulmonary disease (COPD), and diabetes, to all have higher post-treatment symptoms in comparison to asthma, cancer, cardiovascular disease, and epilepsy. Moreover, like all previous Talking Therapies LTC studies, the type of long-term conditions identified may have been a further source of bias as they solely relied on self-reported diagnosis from patients and were not confirmed by any formal medical diagnosis.

Whilst it was clear Early Reliable Improvement (ERI) had the strongest positive association with reliable recovery, it also identified a number of false positives, whereby patients achieved ERI but did not go on to achieve reliable recovery. This may suggest the criteria for ERI was too liberal (up to four sessions for low intensity treatment and up to eight sessions for high intensity treatment), particular when you consider the average treatment duration was nine sessions. Whilst previous research has found four sessions of low intensity treatment to be a reliable parameter to measure ERI, future research may decide to use more conservative parameters of ERI in high intensity treatment. Alternatively, as people with more complex problems (e.g. LTCs) are said to respond to treatment at different rates, and therefore may take longer to achieve reliable improvement, a different analytical approach (e.g. multi-level modelling), may have been more sensitive and insightful.

In addition, but equally significant, was the absence of a measure of early reliable deterioration, which could have been used to identify patients early on in treatment who may have been at risk of not achieving reliable recovery. Using such a measure would have also provided an opportunity to analyse the relationship between early reliable deterioration and end of treatment outcomes, whilst offering a further comparison group for analysis.

The study was also limited by the absence of longitudinal follow-up to determine the durability of outcomes overtime. Accordingly, we can only be sure that the high intensity treatment patients who had a 3-month follow-up appointment after leaving treatment were durable, but only for a short period of time. This is of particular importance when considering that the durability of low intensity treatment has been found to be weak overtime (Ali et al., 2017).

Finally, this study used outcome data just prior to the first national lockdown for the Covid-19 pandemic. At this time, all high intensity treatment was provided face-to-face, and as such, it is difficult to establish whether these outcomes would be replicated in the current clinical world whereby a hybrid approach to high intensity treatment is provided using either face-to-face or video consultation. Clearly further research is needed to establish whether outcomes vary with hybrid working.

6.9 - *Conclusion*

This chapter has set out to discuss the results of the study in the context of current literature. In doing so, it has identified critical predictor variables of end of treatment outcomes which have direct theoretical, empirical and clinical implications. Arguably, given the scarcity of research in this area, along with the continued expansion of Talking Therapies-LTC services in England, the study offers unique insights which in turn has the potential to inform future developments of LTC services.

Chapter 7

Recommendations

and

final reflections

Chapter 7 – Recommendations and final reflections

7.1 - *Introduction*

In this final chapter, a number of recommendations are proposed based on the findings of this study. The recommendations are categorised into three areas, namely, clinical practice, training, and future research. Whilst a number of recommendations are unique to the findings of this thesis, others add further support to recommendations cited elsewhere and align with government policy regarding the integration of psychological therapy for people living with long-term conditions (LTCs) and anxiety and/or depression. Finally, the chapter concludes with some final reflections about this research endeavour to complete this thesis.

7.2 - *Recommendations for clinical practice*

Critical to the impact of practice-based research is its potential influence on clinical practice. The findings of this study reveal a number of areas that may benefit Talking

Therapies-LTC and physical health services if the following recommendations were adopted. These are:

- All Talking Therapies services in England should develop long-term conditions pathways to enable patients with co-morbid needs to access timely effective psychological treatment with appropriately trained clinicians. This is in line with the expansion of Talking Therapies services as outlined in Government guidance (NHS England, 2018)
- Talking Therapies-LTC servcies should focus on integrating with primary, secondary, and tertiary care physical health teams to establish clear referral pathways. This would enable patients with co-morbid long-term health problems and anxiety and/or depression to access treatment for both physical and mental health problems concurrently in order to meet their holistic needs (Mental Health Taskforce, 2016)
- Where possible, co-located clinics should be developed with physical and mental health services. This will aid the process of integration and reduce the traditional separation of physical and mental health services
- Physical health teams should routinely use validated mental health screening tools, for example, Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) and the Generalised Anxiety Disorder Assessment (GAD-7; Spitzer et al., 2006). These should be completed during an initial assessment and be ongoing throughout a patient's engagement with a service. This will aid the early identification of mental health problems and help to consider the option of a referral to Talking Therapies-LTC services
- Talking Therapies-LTC teams need to expand their workforce to ensure an adequate mix of low and high intensity therapists. Given the greater need for

high intensity treatment in this patient group, the expansion of the high intensity therapist workforce should be prioritised. This is in keeping with NHS workforce guidance for integrated pathways (Mental Health Taskforce, 2016), and will require strategic funding at both national and integrated care board level

- Talking Therapies-LTC pathways should maintain fidelity to the fundamental pillars of talking therapies services, namely: the provision of approved evidence-based psychological treatments, the adoption of a ‘stepped-care’ model of treatment delivery, and the use of session-by-session routine outcome measures to evaluate progress (National Collaborating Centre for Mental Health, 2021)
- Psychological treatment for LTCs need to be adapted to address coping with symptoms, management of physical health problems, and illness-specific concerns, rather than focusing on single disorder treatment protocols. Given the results of the study, this is of particular importance for patients experiencing multi-morbidity coupled with severe depression due to their negative influence on patient outcomes
- A focus is needed on overcoming barriers to engagement in psychological treatment. Firstly, by addressing issues related to multiple treatment episodes that was found to have a negative association with end of treatment outcomes. This includes addressing treatment expectancy factors and the choice and format of treatment. Secondly, by adopting positive practice guidance for under-represented groups, namely older people and ethnically diverse communities (BABCP, 2021; Beck et al., 2019)
- Talking Therapies-LTC services need to ensure the number of treatment sessions offered is in line with approved clinical guidance for psychological

treatment. This will increase the likelihood of achieving reliable recovery. In doing so, services require a focus on providing treatment rather than assessment only (Clark et al., 2018)

- A greater focus should be directed to monitoring for early reliable improvement (or not) in the early stages of treatment due to its relationship with end-of-treatment outcomes. This could be achieved if clinicians use clinical supervision to routinely identify and discuss patients ‘on track’ to achieve early reliable improvement, and those ‘not on track’ to achieve such improvement. For those ‘not on track’, this will enable clinicians to identify barriers to improvement and make early adaptations to treatment. This may include a ‘stepping-up’ to a higher intensity of treatment, changes to the focus of treatment, or the offer of a different psychological treatment.

7.3 - ***Recommendations for training and education***

To achieve the clinical practice recommendations outlined above, it is imperative that healthcare professionals possess the necessary knowledge and skills. This study identified an array of training needs that span both psychological therapy and physical health servcies. Accordingly, if these training needs were realised, they may contribute to the vision of integrated person-centred care advocated by health service guidance (NHS Long Term Plan, 2019). Therefore, the following recommendations for training and education are suggested:

- Psychological therapists treating patients with long-term health problems in Talking Therapist-LTC servcies should receive additional top-up training to meet LTC competency frameworks (Roth and Pilling, 2016). This includes the role of adapting treatment to incorporate disease self-management and specific-disease related beliefs

- Psychological therapists should receive training in outcome monitoring to ensure a focus on early reliable improvement is embedded into routine clinical practice. This would include training on explaining the rationale for outcome monitoring to patients and how to use outcome monitoring in supervision (Rousmaniere, 2017; Swift et al., 2015)
- Healthcare professionals in physical health teams need to receive routine training on mental health awareness, the impact of LTCs on mental health, the use of mental health screening tools, and the role of psychological treatments

7.4 - *Recommendations for research*

The findings of this study revealed a number of opportunities for future research to aid the development of psychological treatment for people experiencing long-term health problems and anxiety and/or depression. As a whole, it uncovered a general paucity of Talking Therapies research into the outcomes for people with long-term conditions. It also identified a number of variables that appear to be associated with positive and negative end of treatment outcomes that require further research attention. Accordingly, the following recommendations are proposed:

- Increased research focus on outcomes for people with co-morbid long-term conditions and anxiety/depression accessing Talking Therapies-LTC services. This needs to incorporate a focus on outcomes for different mental health diagnostic groups and specific long-term health conditions
- Development of specific psychological treatment interventions for people with multimorbidity and severe depression and anxiety

- Development of low-intensity treatment interventions for people with long-term health problems
- Research to establish the effectiveness of a ‘stepped-care’ versus a stratified ‘matched-care’ model for delivering routine psychological therapy in Talking Therapies-LTC services
- Replication studies building on this research using similar predictor variables but adjusted for other potential confounding variables
- Further research on the role of early reliable improvement in the psychological treatment for people with LTCs. In doing so, it is envisaged an outcome prediction model could be developed and prospective studies undertaken to evaluate its benefits in real world clinical practice

7.5 - *Conclusion*

This chapter has drawn upon the findings of this study to provide recommendations for clinical practice, training, and research. As noted, some may add weight to recommendations emanating from previous research, whilst others, most notably, the role of early reliable improvement in psychological treatment for LTCs, offer new insights that may pave the way for future research endeavours. Taken together, it is hoped the adoption of these recommendations provides further hope to those people who continue to struggle living with concurrent physical and mental health problems.

7.6 - *Final reflections*

There is no escaping the fact that for many people with long-term health conditions their mental health also suffers. However, up until recently access to psychological therapy has been limited. The roll-out of the national programme to expand Talking

Therapies for people with LTCs is one attempt to improve their care. Yet, whilst this development has been widely applauded, its effectiveness had been questioned. It is against this backdrop, coupled with the author's own clinical observations that this research endeavour emerged.

As such, this study may be seen as unique as it is the first to illustrate that psychological therapy for people with LTCs, delivered in routine Talking Therapies servcies, can achieve comparable positive end of treatment outcomes to people without chronic health problems. In addition, it has identified a number of predictor variables that influence end of treatment outcomes that require further research exploration.

In coming to an end, this thesis marks the closure to an incredible journey. A journey of discovery that has not only enhanced the author's understanding of research methodology and statistical analysis, but more importantly, has helped him unearth a level of self-determination and perseverance that he did not know he possessed.

Yet whilst this realisation has been personally enlightening, it pales into insignificance when considering the plight and suffering many people with long-term health conditions and mental health problems endure on a daily basis. It is with this in mind that this thesis ends with a tribute to the millions of people who continue to suffer with these conditions.

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Appendices

Appendix 1

An example of the sequence of search terms entered into database for pre-treatment characteristics

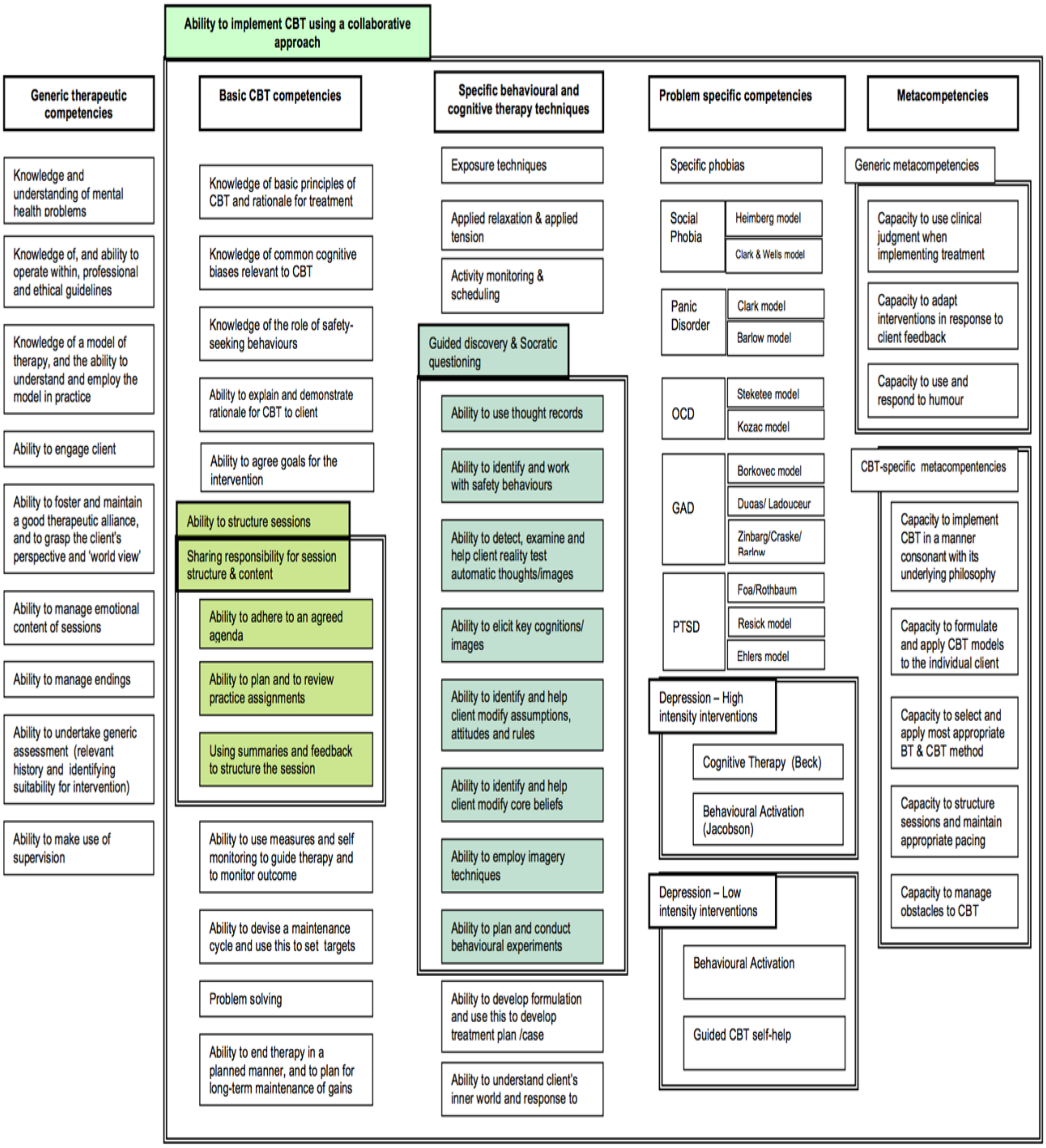
An example of the sequence of search terms entered into database for pre-treatment characteristics

Search terms
1. Long-term condition
2. LTC
3. Multimorbidity
4. 1 or 2
5. 1 or 2 or 3
6. 3 or 4
7. Medically unexplained
8. MUS
9. 8 or 9
10. 2 or 8 or 9
11. Anxiety
12. Anxi*
13. 11 or 12
14. 2 and 11 and 12
15. 3 and 11 and 12
16. Depression
17. Depress*
18. 16 or 17
19. 2 and 16 or/and 17
20. Cognitive behave* therapy
21. CBT
22. 2 and 20 or/and 21
23. 3 and 20 or/and/ 21
24. 5 and 20 or/and 21
25. 7 and 20 or/and 21
26. Psychotherapy
27. 2 and 26
28. 3 and 26
29. 5 and 26
30. 7 and 26

Appendix II

The CBT competence framework

(Roth and Pilling, 2008)



Ability to implement CBT using a collaborative approach

Generic therapeutic competencies

- Knowledge and understanding of mental health problems
- Knowledge of, and ability to operate within, professional and ethical guidelines
- Knowledge of a model of therapy, and the ability to understand and employ the model in practice
- Ability to engage client
- Ability to foster and maintain a good therapeutic alliance, and to grasp the client's perspective and 'world view'
- Ability to manage emotional content of sessions
- Ability to manage endings
- Ability to undertake generic assessment (relevant history and identifying suitability for intervention)
- Ability to make use of supervision

Basic CBT competencies

- Knowledge of basic principles of CBT and rationale for treatment
- Knowledge of common cognitive biases relevant to CBT
- Knowledge of the role of safety-seeking behaviours
- Ability to explain and demonstrate rationale for CBT to client
- Ability to agree goals for the intervention
- Ability to structure sessions
- Sharing responsibility for session structure & content
  - Ability to adhere to an agreed agenda
  - Ability to plan and to review practice assignments
  - Using summaries and feedback to structure the session
- Ability to use measures and self monitoring to guide therapy and to monitor outcome
- Ability to devise a maintenance cycle and use this to set targets
- Problem solving
- Ability to end therapy in a planned manner, and to plan for long-term maintenance of gains

Specific behavioural and cognitive therapy techniques

- Exposure techniques
- Applied relaxation & applied tension
- Activity monitoring & scheduling
- Guided discovery & Socratic questioning
  - Ability to use thought records
  - Ability to identify and work with safety behaviours
  - Ability to detect, examine and help client reality test automatic thoughts/images
  - Ability to elicit key cognitions/ images
  - Ability to identify and help client modify assumptions, attitudes and rules
  - Ability to identify and help client modify core beliefs
  - Ability to employ imagery techniques
  - Ability to plan and conduct behavioural experiments
- Ability to develop formulation and use this to develop treatment plan /case
- Ability to understand client's inner world and response to

Problem specific competencies

- Specific phobias
- Social Phobia
  - Heimberg model
  - Clark & Wells model
- Panic Disorder
  - Clark model
  - Barlow model
- OCD
  - Steketee model
  - Kozac model
- GAD
  - Borkovec model
  - Dugas/ Ladouceur
  - Zinbarg/Craske/ Barlow
- PTSD
  - Foa/Rothbaum
  - Resick model
  - Ehlers model
- Depression – High intensity interventions
  - Cognitive Therapy (Beck)
  - Behavioural Activation (Jacobson)
- Depression – Low intensity interventions
  - Behavioural Activation
  - Guided CBT self-help

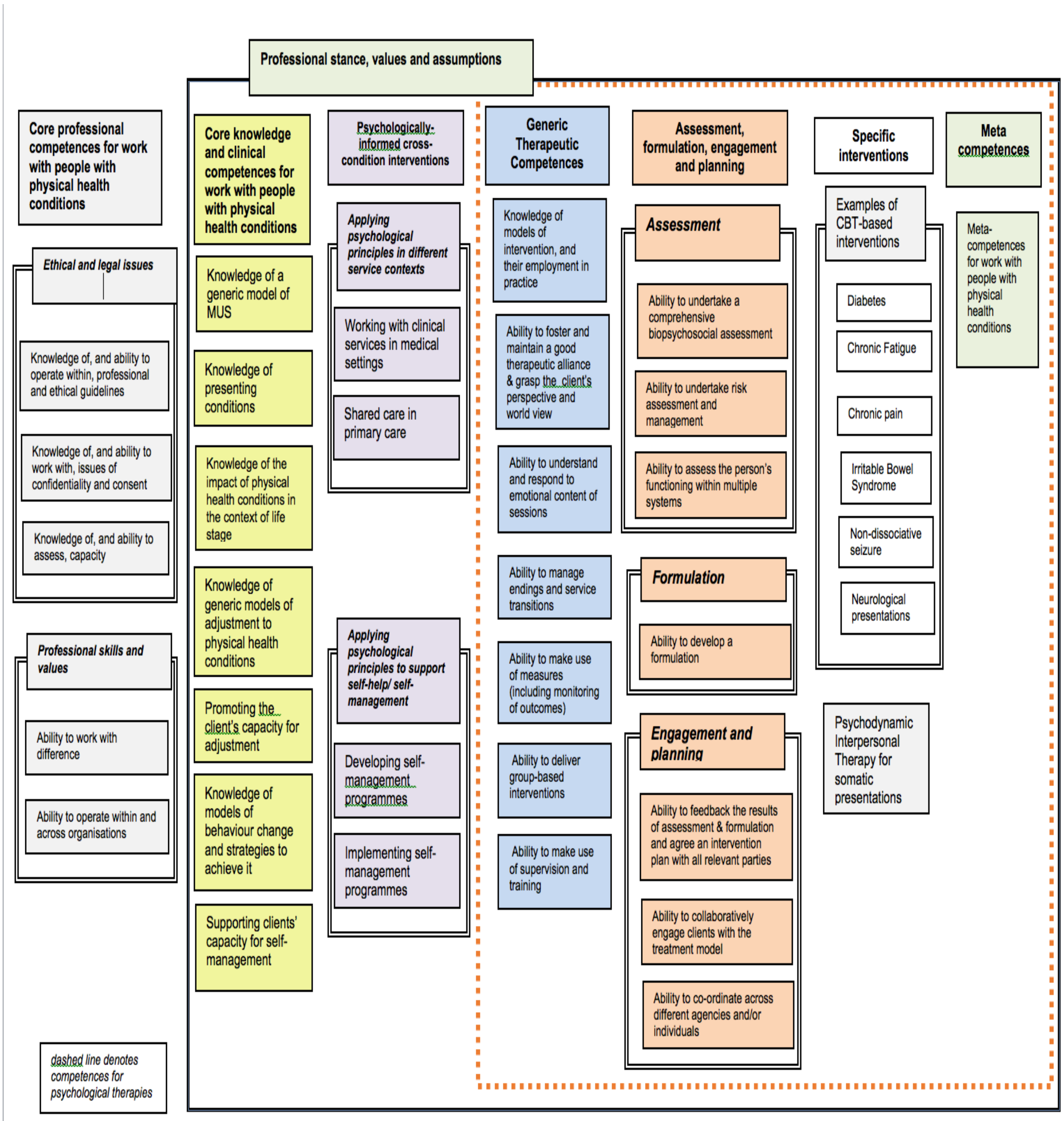
Metacompetencies

- Generic metacompetencies
  - Capacity to use clinical judgment when implementing treatment
  - Capacity to adapt interventions in response to client feedback
  - Capacity to use and respond to humour
- CBT-specific metacompentencies
  - Capacity to implement CBT in a manner consonant with its underlying philosophy
  - Capacity to formulate and apply CBT models to the individual client
  - Capacity to select and apply most appropriate BT & CBT method
  - Capacity to structure sessions and maintain appropriate pacing
  - Capacity to manage obstacles to CBT

Appendix III

Competence framework for psychological interventions for people with persistent physical health conditions

(Roth and Pilling, 2016)


Professional stance, values and assumptions
Core professional competences for work with people with physical health conditions
Ethical and legal issues
Knowledge of, and ability to operate within, professional and ethical guidelines
Knowledge of, and ability to work with, issues of confidentiality and consent
Knowledge of, and ability to assess, capacity
Professional skills and values
Ability to work with difference
Ability to operate within and across organisations
Core knowledge and clinical competences for work with people with physical health conditions
Knowledge of a generic model of MUS
Knowledge of presenting conditions
Knowledge of the impact of physical health conditions in the context of life stage
Knowledge of generic models of adjustment to physical health conditions
Promoting the client's capacity for adjustment
Knowledge of models of behaviour change and strategies to achieve it
Supporting clients' capacity for self-management
Psychologically-informed cross-condition interventions
Applying psychological principles in different service contexts
Working with clinical services in medical settings
Shared care in primary care
Applying psychological principles to support self-help/ self-management
Developing self-management programmes
Implementing self-management programmes
Generic Therapeutic Competences
Knowledge of models of intervention, and their employment in practice
Ability to foster and maintain a good therapeutic alliance & grasp the client's perspective and world view
Ability to understand and respond to emotional content of sessions
Ability to manage endings and service transitions
Ability to make use of measures (including monitoring of outcomes)
Ability to deliver group-based interventions
Ability to make use of supervision and training
Assessment, formulation, engagement and planning
Assessment
Ability to undertake a comprehensive biopsychosocial assessment
Ability to undertake risk assessment and management
Ability to assess the person's functioning within multiple systems
Formulation
Ability to develop a formulation
Engagement and planning
Ability to feedback the results of assessment & formulation and agree an intervention plan with all relevant parties
Ability to collaboratively engage clients with the treatment model
Ability to co-ordinate across different agencies and/or individuals
Specific interventions
Examples of CBT-based interventions
Diabetes
Chronic Fatigue
Chronic pain
Irritable Bowel Syndrome
Non-dissociative seizure
Neurological presentations
Psychodynamic Interpersonal Therapy for somatic presentations
Meta competences
Meta-competences for work with people with physical health conditions
dashed line denotes competences for psychological therapies

Appendix IV

Generalised anxiety disorder (GAD-7) questionnaire

(Spitzer et al., 2006)

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

Appendix V

Patient health questionnaire (PHQ-9)

(Kroenke et al., 2011)

PATIENT HEALTH QUESTIONNAIRE-9
(PHQ-9)

Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems? *(Use "✓" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING __*0*__ **+** _______ **+** _______ **+** _______

=Total Score: _______

Appendix VI

Work and social adjustment scale (WASA)

(Mundt et al., 2002)

work and social adjustment scale (w&sas)

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems look at each section and determine on the scale provided how much your problem impairs your ability to carry out the activity.

*1.) **work –** if you are retired or choose not to have a job for reasons unrelated to your problem, please tick here*

0 1 2 3 4 5 6 7 8

not at all slightly definitely markedly very severely

2.) ***home management–*** cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc

0 1 2 3 4 5 6 7 8

not at all slightly definitely markedly very severely

3.) ***social leisure activities –*** with other people, e.g. parties, pubs, outings, entertaining etc

0 1 2 3 4 5 6 7 8

not at all slightly definitely markedly very severely

4.) ***private leisure activities–*** done alone, e.g. reading, gardening, sewing, hobbies, walking etc

0 1 2 3 4 5 6 7 8

not at all slightly definitely markedly very severely

5.) ***family and relationships–*** form and maintain close relationships with others including the people that I live with

0 1 2 3 4 5 6 7 8

not at all slightly definitely markedly very severely

Appendix VII

Standardised assessment of personality – abbreviated scale

(Moran et al., 2003)

Standardised Assessment of Personality – Abbreviated Scale (Moran)

Please ask your patients the following questions. Only tick a response if the patient thinks that the description applies most of the time and in most situations.

1. In general, do you have difficulty making and keeping friends? … Yes … No
2. Would you normally describe yourself as a loner? … Yes … No
3. In general, do you trust other people? … Yes … No
4. Do you normally lose your temper easily? … Yes … No
5. Are you normally an impulsive sort of person? … Yes … No
6. Are you normally a worrier? … Yes … No
7. In general, do you depend on others a lot? … Yes … No
8. In general, are you a perfectionist? … Yes … No

Responses in bold should be scored as 1, those not in bold as 0.

A total score of 3/8 or more indicates personality disorder is likely. (A score of 3 or more on this tool correctly identified 90% of psychiatric patients with DSM-IV personality disorder. Sensitivity 0.94 and specificity 0.85)

Appendix VIII

Social phobia inventory scale (SPIN)

(Connor et al., 2000)

Social Phobia Inventory Scale

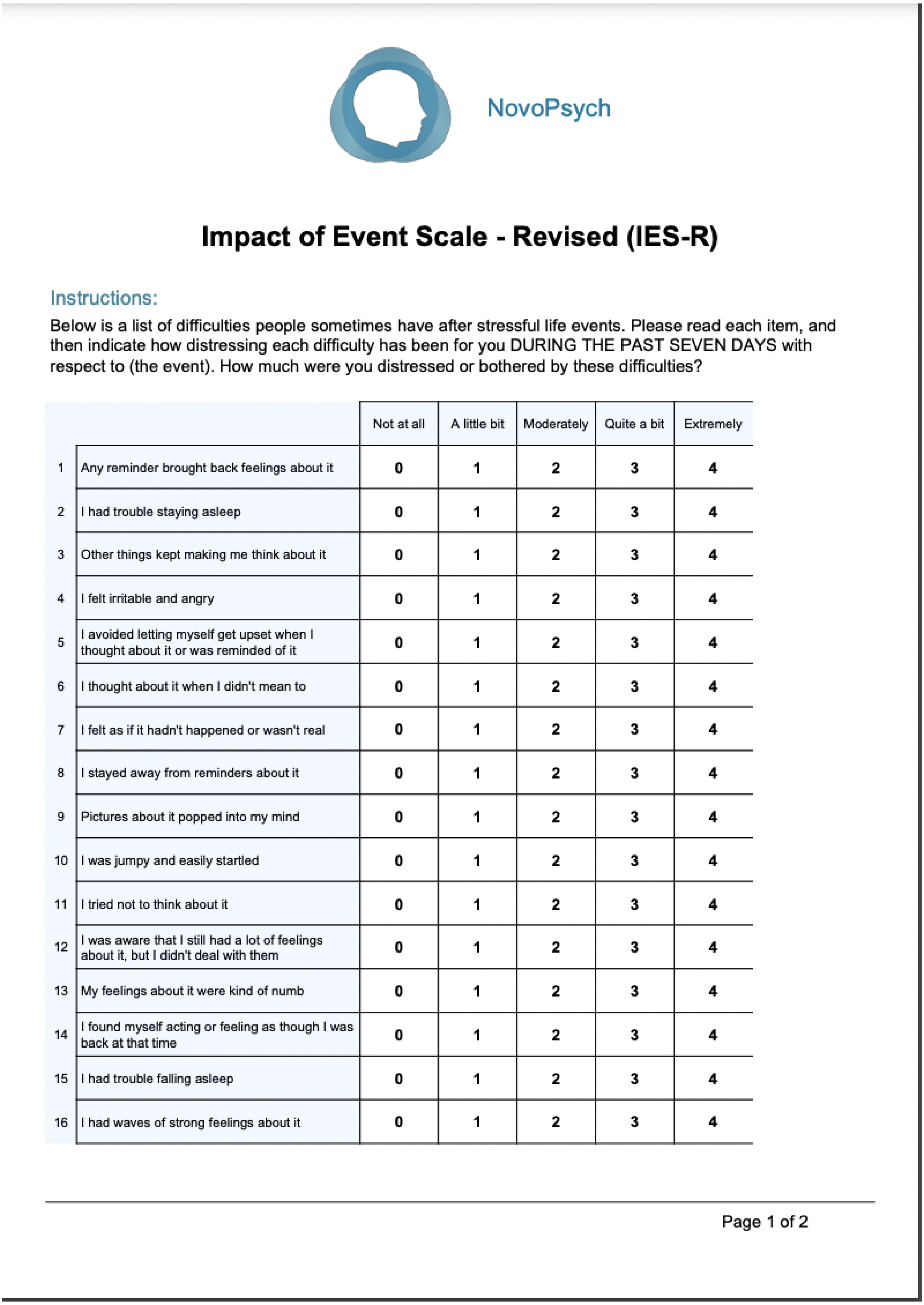
For each statement below, please select the number that best describes how you have been feeling during the last week:

		Not at all	A little bit	Somewhat	Very much	Extremely
1.	I am afraid of people in authority	0	1	2	3	4
2.	I am bothered by blushing in front of people	0	1	2	3	4
3.	Parties and social events scare me	0	1	2	3	4
4.	I avoid talking to people I don't know	0	1	2	3	4
5.	Being criticized scares me a lot	0	1	2	3	4
6.	I avoid doing things or speaking to people for fear of embarrassment	0	1	2	3	4
7.	Sweating in front of people causes me distress	0	1	2	3	4
8.	I avoid going to parties	0	1	2	3	4
9.	I avoid activities in which I am the centre of attention	0	1	2	3	4
10.	Talking to strangers scares me	0	1	2	3	4
11.	I avoid having to give speeches	0	1	2	3	4
12.	I would do anything to avoid being criticized	0	1	2	3	4
13.	Heart palpitations bother me when I am around people	0	1	2	3	4
14.	I am afraid of doing things when people might be watching	0	1	2	3	4
15.	Being embarrassed or looking stupid are among my worse fears	0	1	2	3	4
16.	I avoid speaking to anyone in authority	0	1	2	3	4
17.	Trembling or shaking in front of others is distressing to me	0	1	2	3	4

Appendix IX

Impact of events scale (IES-R)

(Creamer et al., 2003)



NovoPsych

Impact of Event Scale - Revised (IES-R)

Instructions:

Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you DURING THE PAST SEVEN DAYS with respect to (the event). How much were you distressed or bothered by these difficulties?

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Any reminder brought back feelings about it	**0**	**1**	**2**	**3**	**4**
2	I had trouble staying asleep	**0**	**1**	**2**	**3**	**4**
3	Other things kept making me think about it	**0**	**1**	**2**	**3**	**4**
4	I felt irritable and angry	**0**	**1**	**2**	**3**	**4**
5	I avoided letting myself get upset when I thought about it or was reminded of it	**0**	**1**	**2**	**3**	**4**
6	I thought about it when I didn't mean to	**0**	**1**	**2**	**3**	**4**
7	I felt as if it hadn't happened or wasn't real	**0**	**1**	**2**	**3**	**4**
8	I stayed away from reminders about it	**0**	**1**	**2**	**3**	**4**
9	Pictures about it popped into my mind	**0**	**1**	**2**	**3**	**4**
10	I was jumpy and easily startled	**0**	**1**	**2**	**3**	**4**
11	I tried not to think about it	**0**	**1**	**2**	**3**	**4**
12	I was aware that I still had a lot of feelings about it, but I didn't deal with them	**0**	**1**	**2**	**3**	**4**
13	My feelings about it were kind of numb	**0**	**1**	**2**	**3**	**4**
14	I found myself acting or feeling as though I was back at that time	**0**	**1**	**2**	**3**	**4**
15	I had trouble falling asleep	**0**	**1**	**2**	**3**	**4**
16	I had waves of strong feelings about it	**0**	**1**	**2**	**3**	**4**

Page 1 of 2

Appendix X

Mobility inventory (MI)

(Chambless et al., 1985)

MOBILITY INVENTORY

1. Please indicate the degree to which you avoid the following places or situations because of discomfort or anxiety. Rate your amount of avoidance when you are with a trusted companion and when you are alone. Do this by using the following scale:

1	2	3	4	5
Never avoid	Rarely avoid	Avoid about half of the time	Avoid most of the time	Always avoid

Circle the number for each situation or place under both conditions: when accompanied and when alone. Leave blank situations that do not apply to you.

Places	When accompanied					When alone				
Theaters	1	2	3	4	5	1	2	3	4	5
Supermarkets	1	2	3	4	5	1	2	3	4	5
Shopping malls	1	2	3	4	5	1	2	3	4	5
Classrooms	1	2	3	4	5	1	2	3	4	5
Department stores	1	2	3	4	5	1	2	3	4	5
Restaurants	1	2	3	4	5	1	2	3	4	5
Museums	1	2	3	4	5	1	2	3	4	5
Elevators	1	2	3	4	5	1	2	3	4	5
Auditoriums/stadiums	1	2	3	4	5	1	2	3	4	5
Garages	1	2	3	4	5	1	2	3	4	5
High places	1	2	3	4	5	1	2	3	4	5
Enclosed spaces	1	2	3	4	5	1	2	3	4	5

Open spaces	When accompanied					When alone				
Outside (e.g., fields, wide streets, courtyards)	1	2	3	4	5	1	2	3	4	5
Inside (e.g., large rooms, lobbies)	1	2	3	4	5	1	2	3	4	5

Riding in	When accompanied					When alone				
Buses	1	2	3	4	5	1	2	3	4	5
Trains	1	2	3	4	5	1	2	3	4	5
Subways	1	2	3	4	5	1	2	3	4	5
Airplanes	1	2	3	4	5	1	2	3	4	5
Boats	1	2	3	4	5	1	2	3	4	5

Driving or riding in a car	When accompanied					When alone				
At anytime	1	2	3	4	5	1	2	3	4	5
On expressways	1	2	3	4	5	1	2	3	4	5

Situations	When Accompanied					When Alone				
Standing in lines	1	2	3	4	5	1	2	3	4	5
Crossing bridges	1	2	3	4	5	1	2	3	4	5
Parties or social gatherings	1	2	3	4	5	1	2	3	4	5
Walking on the street	1	2	3	4	5	1	2	3	4	5
Staying home alone						1	2	3	4	5
Being far away from home	1	2	3	4	5	1	2	3	4	5
Other (specify):	1	2	3	4	5	1	2	3	4	5

2. After completing the first step, circle the five items with which you are most concerned.Of the items listed, these are the five situations or places where avoidance/anxiety most affects your life in a negative way.

Appendix XI

Obsessive compulsive inventory (OCI)

(Foa et al., 1998)

Obsessive-Compulsive Inventory (OCI)

Identifier Date

Please read each statement and select a number 0, 1, 2, 3 or 4 that best describes how much that experience has **distressed or bothered you during the past month**. There are no right or wrong answers. Do not spend too much time on any one statement. This assessment is not intended to be a diagnosis. If you are concerned about your results in any way, please speak with a health professional.

0 = Not at all 1 = A little 2 = Moderately 3 = A lot 4 = Extremely

1 Unpleasant thoughts come into my mind against my will and I cannot get rid of them

I think contact with bodily secretions (sweat, saliva, blood, urine, etc.)
may 2 contaminate my clothes or somehow harm me

3 I ask people to repeat things to me several times, even though I understood them the first time

4 I wash and clean obsessively

5 I have to review mentally past events, conversations and actions to make sure that I didn’t do something wrong

6 I have saved up so many things that they get in the way

7 I check things more often than necessary

8 I avoid using public toilets because I am afraid of disease or contamination

9 I repeatedly check doors, windows, drawers etc .

10 I repeatedly check gas / water taps / light switches after turning them off

11 I collect things I don’t need

12 I have thoughts of having hurt someone without knowing it

13 I have thoughts that I might want to harm myself or others

14 I get upset if objects are not arranged properly

15 I feel obliged to follow a particular order in dressing, undressing and washing
myself

16 I feel compelled to count while I’m doing things

17 I am afraid of impulsively doing embarrassing or harmful things

18 I need to pray to cancel bad thoughts or feelings

19 I keep on checking forms or other things I have written

I get upset at the sight of knives, scissors or other sharp objects in case I
lose 20 control with them

21 I am obsessively concerned about cleanliness

I find it difficult to touch an object when I know it has been touched by
strangers 22 or certain people

23 I need things to be arranged in a particular order

24 I get behind in my work because I repeat things over and over again

25 I feel I have to repeat certain numbers

26 After doing something carefully, I still have the impression I haven't finished it

27 I find it difficult to touch rubbish or dirty things

28 I find it difficult to control my thoughts

29 I have to do things over and over again until it feels right

30 I am upset by unpleasant thoughts that come into my mind against my will

31 Before going to sleep I have to do certain things in a certain way

32 I go back to places to make sure that I have not harmed anyone

33 I frequently get nasty thoughts and have difficulty getting rid of them

34 I avoid throwing things away because I am afraid I might need them later

35 I get upset if others have changed the way I have arranged my things

I feel that I must repeat certain words or phrases in my mind I order to wipe
out 36 bad thoughts, feelings or actions

37 After I have done things, I have persistent doubts about whether I really did them

38 I sometimes have to wash or clean myself simply because I feel contaminated

39 I feel that there are good and bad numbers

40 I repeatedly check anything that might cause a fire

41 Even when I do something very carefully I feel that it is not quite right

42 I wash my hands more often, or for longer than necessary

Appendix XII

Health anxiety inventory (HAI)

(Salkovskis et al., 2002)

Health Anxiety Inventory (HAI)

Each question in this section consists of a group of four statements. Please read each group of statements carefully and then select the one which best describes your feelings OVER THE PAST WEEK.

1

a. I do not worry about my health

b. I occasionally worry about my health

c. I spend much of my time worrying about my health

d. I spend most of my time worrying about my health

2

a. I notice aches/pains less than most other people (of my age)

b. I notice aches/pains as much as most other people (of my age)

c. I notice aches/pains more than most other people (of my age)

d. I am aware of aches/pains in my body all the time

3

a. As a rule I am not aware of bodily sensations or changes

b. Sometimes I am aware of bodily sensations or changes

c. I am often aware of bodily sensations or changes

d. I am constantly aware of bodily sensations or changes

4

a. Resisting thoughts of illness is never a problem

b. Most of the time I can resist thoughts of illness

c. I try to resist thoughts of illness but am often unable to do so

d. Thoughts of illness are so strong that I no longer even try to resist them

5

a. As a rule I am not afraid that I have a serious illness

b. I am sometimes afraid that I have a serious illness

c. I am often afraid that I have a serious illness

d. I am always afraid that I have a serious illness

6

a. I do not have images (mental pictures) of myself being ill

b. I occasionally have images of myself being ill

c. I frequently have images of myself being ill

d. I constantly have images of myself being ill

7

a. I do not have any difficulty taking my mind off thoughts about my health

b. I sometimes have difficulty taking my mind off thoughts about my health

c. I often have difficulty taking my mind off thoughts about my health

d. Nothing can take my mind off thoughts about my health

8

a. I am lastingly relieved if my doctor tells me there is nothing wrong

b. I am initially relieved but the worries sometimes return later

c. I am initially relieved but the worries always return later

d. I am not relieved if my doctor tells me there is nothing wrong

9

a. If I hear about an illness I never think I have it myself

b. If I hear about an illness I sometimes think I have it myself

c. If I hear about an illness I often think I have it myself

d. If I hear about an illness I always think I have it myself

10

a. If I have a bodily sensation or change I rarely wonder what it means

b. If I have a bodily sensation or change I often wonder what it means

c. If I have a bodily sensation or change I always wonder what it means

d. If I have a bodily sensation or change I must know what it means

11

a. I usually feel at very low risk of developing a serious illness

b. I usually feel at fairly low risk of developing a serious illness

c. I usually feel at moderate risk of developing a serious illness

d. I usually feel at high risk of developing a serious illness

12

a. I never think I have a serious illness

b. I sometimes think I have a serious illness

c. I often think I have a serious illness

d. I usually think that I am seriously ill

13

a. If I notice an unexplained bodily sensation I don't find it difficult to think about other things

b. If I notice an unexplained bodily sensation I sometimes find it difficult to think about other things

c. If I notice an unexplained bodily sensation I often find it difficult to think about other things

d. If I notice an unexplained bodily sensation I always find if difficult to think about other things

14

a. My family/friends would say I do not worry enough about my health

b. My family/friends would say I have a normal attitude to my health

c. My family/friends would say I worry too much about my health

d. My family/friends would say I am a hypochondriac

Appendix XIII

Panic disorder severity scale (PDSS)

(Shear et al., 2001)

Panic Disorder Severity Scale

Several of the following questions refer to panic attacks and limited symptom attacks. For this questionnaire we define a panic attack as a sudden rush of fear or discomfort accompanied by at least 4 of the symptoms listed below. In order to qualify as a sudden rush, the symptoms must peak within 10 minutes. Episodes like panic attacks but having fewer than 4 of the listed symptoms are called limited symptom attacks. Here are the symptoms to count:

- Rapid or pounding heartbeat
- Sweating
- Trembling or shaking
- Breathlessness
- Feeling of choking
- Chest pain or discomfort
- Nausea
- Dizziness or faintness
- Feelings of unreality
- Chills or hot flushes
- Fear of losing control or going crazy
- Fear of dying
- Numbness or tingling

1. How many panic and limited symptoms attacks did you have during the week?

☐ 0 No panic or limited symptom episodes

☐ 1 Mild: no full panic attacks and no more than 1 limited symptom attack/day

☑ 2 Moderate: 1 or 2 full panic attacks and/or multiple limited symptom attacks/day

☐ 3 Severe: more than 2 full attacks but not more than 1/day on average

☐ 4 Extreme: full panic attacks occurred more than once a day, more days than not

2. If you had any panic attacks during the past week, how distressing (uncomfortable, frightening) were they while they were happening? (If you had more than one, give an average rating. If you didn't have any panic attacks but did have limited symptom attacks, answer for the limited symptom attacks.)

☐ 0 Not at all distressing, or no panic or limited symptom attacks during the past week

☐ 1 Mildly distressing (not too intense)

☑ 2 Moderately distressing (intense, but still manageable)

☐ 3 Severely distressing (very intense)

☐ 4 Extremely distressing (extreme distress during all attacks)

3. During the past week, how much have you worried or felt anxious about when your next panic attack would occur or about fears related to the attacks (for example, that they could mean you have physical or mental health problems or could cause you social embarrassment)?

☐ 0 Not at all

☐ 1 Occasionally or only mildly

☑ 2 Frequently or moderately

☐ 3 Very often or to a very disturbing degree

☐ 4 Nearly constantly and to a disabling extent

Appendix XIV

Health Regulation Authority (HRA) approval letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Alison Pooler

c/o Keele University, Clinical Education Centre

Newcastle Road, Stoke-on-Trent

ST4 6QG

Email: hra.approval@nhs.net

HCRW.approvals@wales.nhs.uk

27 January 2020

Dear Dr Pooler

HRA and Health and Care

Study title:	**Predictors of Outcome in Psychological Therapy for CoMorbid Long-Term Health Conditions and Common Mental Health Problems**
IRAS project ID:	**271325**
Protocol number:	**RG-0305-19**
Sponsor	**Keele University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

Appendix XV

Keele University’s Faculty of Medicine and Health Sciences Research Ethics Committee (FMHS FREC) approval letter

Keele University FMHS Faculty Research Ethics Committee health.ethics@keele.ac.uk

19 June 2019

Dear Jason,

Project Title:	Predictors of Outcome in Psychological Therapy for Co-Morbid Long-Term Health Conditions and Common Mental Health Problems
REC Project Reference:	MH-190029
Type of Application	Main application

Keele University's Faculty of Medicine and Health Sciences Research Ethics Committee (FMHS FREC) reviewed the above application.

Favourable Ethical opinion

The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation. There are no conditions attached to this opinion, but the Committee did raise a number of additional points for you to consider.

1.	The committee would be interested to know whether - patients have been made aware that their data may be used for research purposes (perhaps this has been recorded by IAPT-LTC?) - the study authors have considered the effects of ethnicity on outcomes.

Reporting requirements

The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including: notifying substantial amendments, notifying issues which may have an impact upon ethical opinion of the study, progress reports, and notifying the end of the study

Approved documents

The documents reviewed and approved are:

Document	**Version**	**Date**
All documents submitted with Ethics Application MH-190029		21/5/2019

Yours sincerely,

Ed Chadwick

Dr Ed Chadwick Committee Chair

Appendix XVI

NHS Confirmation of Capacity and Capability at North Staffordshire Combined Healthcare NHS Trust approval letter

Dear Jason

NHS Confirmation of Capacity and Capability at North Staffordshire Combined Healthcare NHS Trust

Short Title:	Predictors of outcome in psychological therapy for co-morbid long term health conditions and common mental health problems
IRAS ID.:	271325
R&D ID.:	CHC0193/RS
Principal Investigator:	Jason McDonald

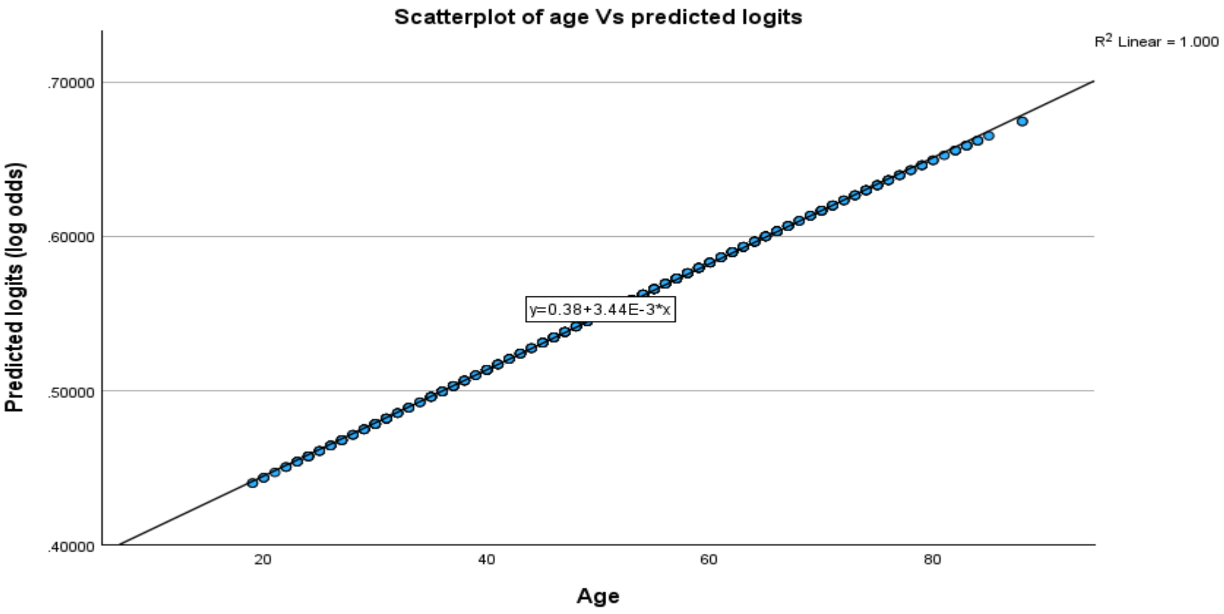
This email confirms that North Staffordshire Combined Healthcare NHS Trust has the capacity and capability to deliver the above referenced study. Please find attached our agreed Organisation Information Document as confirmation. We agree for you to start this study from the date of this email confirmation.

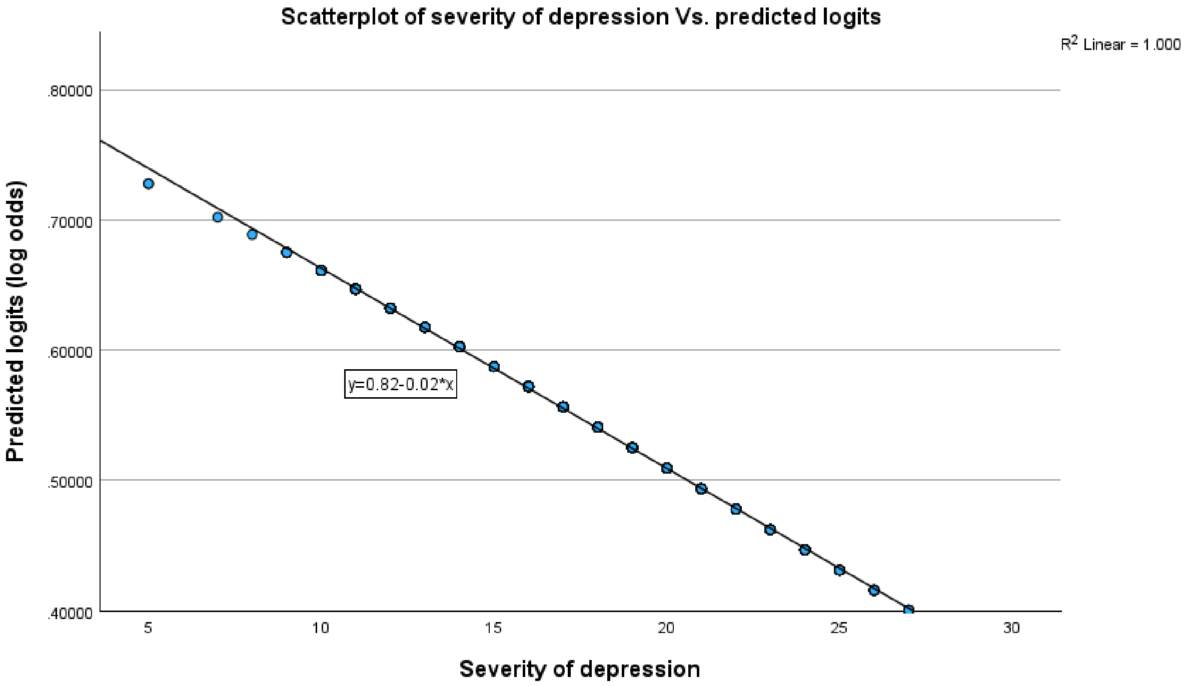
NHS Confirmation of Capacity and Capability for the above research has been granted on the basis described in the HRA approval application. The documents received are:

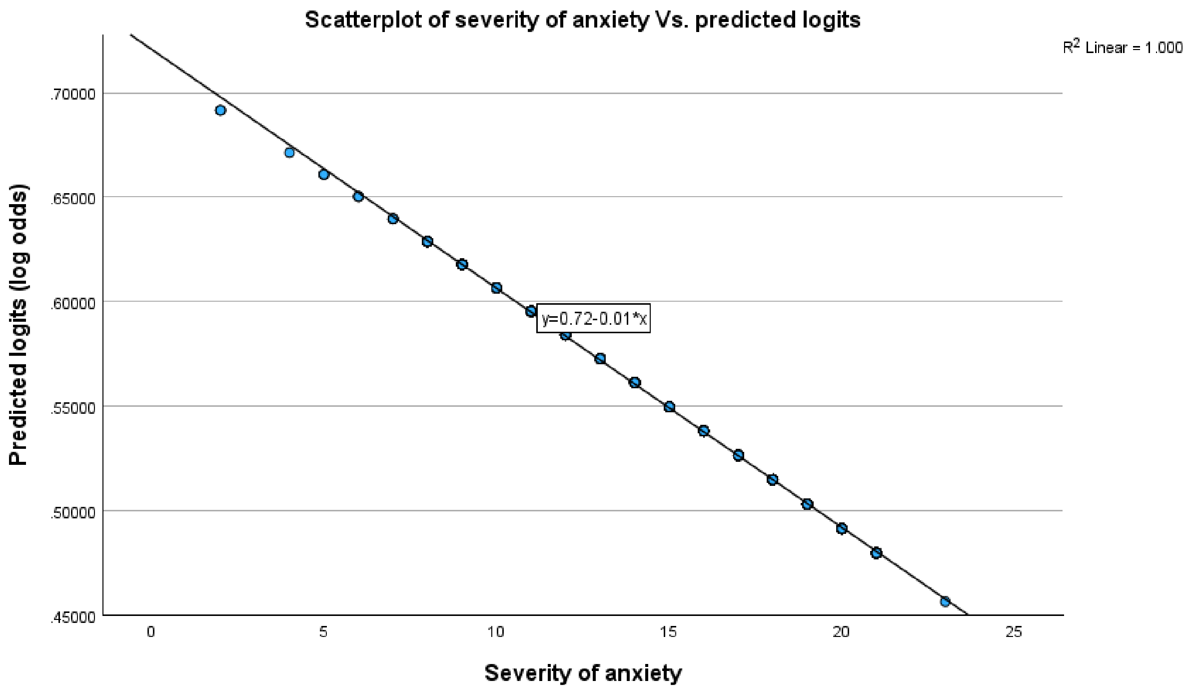
Document	**Version**	**Date**
Protocol	1	08/05/2019
Data Collection Flowchart	1	25/11/2019
HRA Approval Letter		27/01/2020
Keele REC Letter		19/06/2019
Sponsorship Letter		03/01/2020
Insurance Certificate		31/07/2019
Organisation Information Document	1	03/01/2020
Schedule of Events	1	27/01/2020
CI / Supervisor CV		25/11/2019
PI / Student CV		25/10/2019
PI GCP Certificate		25/05/2019
IRAS form		21/01/2020

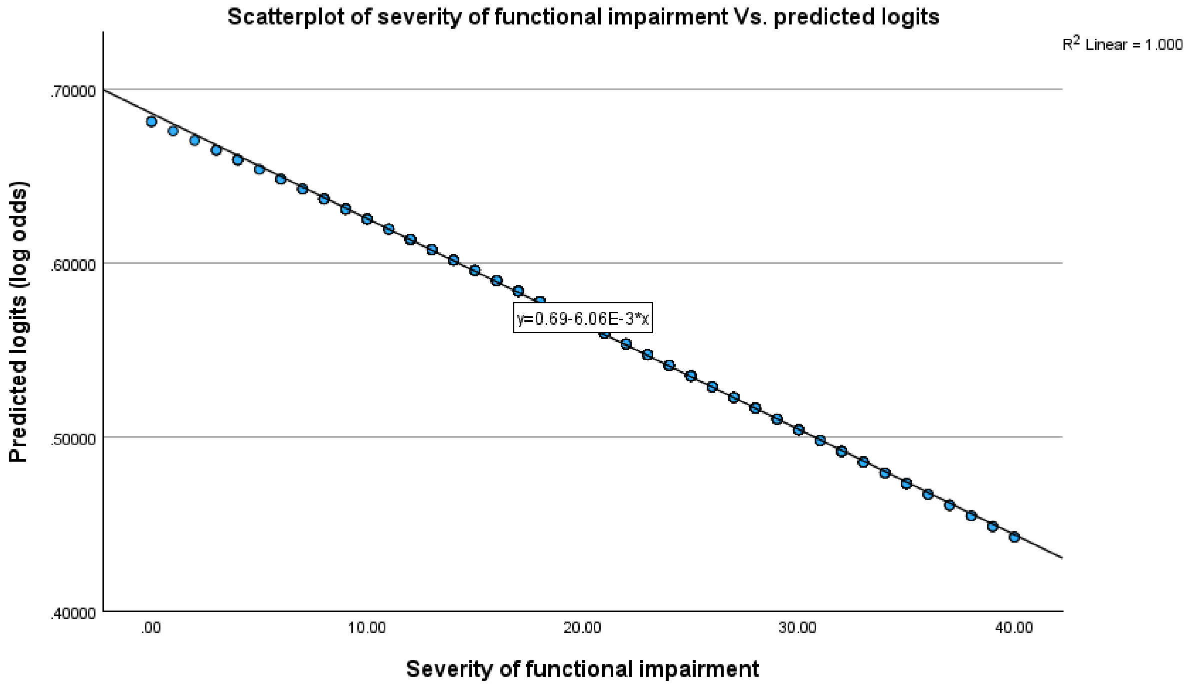
Appendix XVII

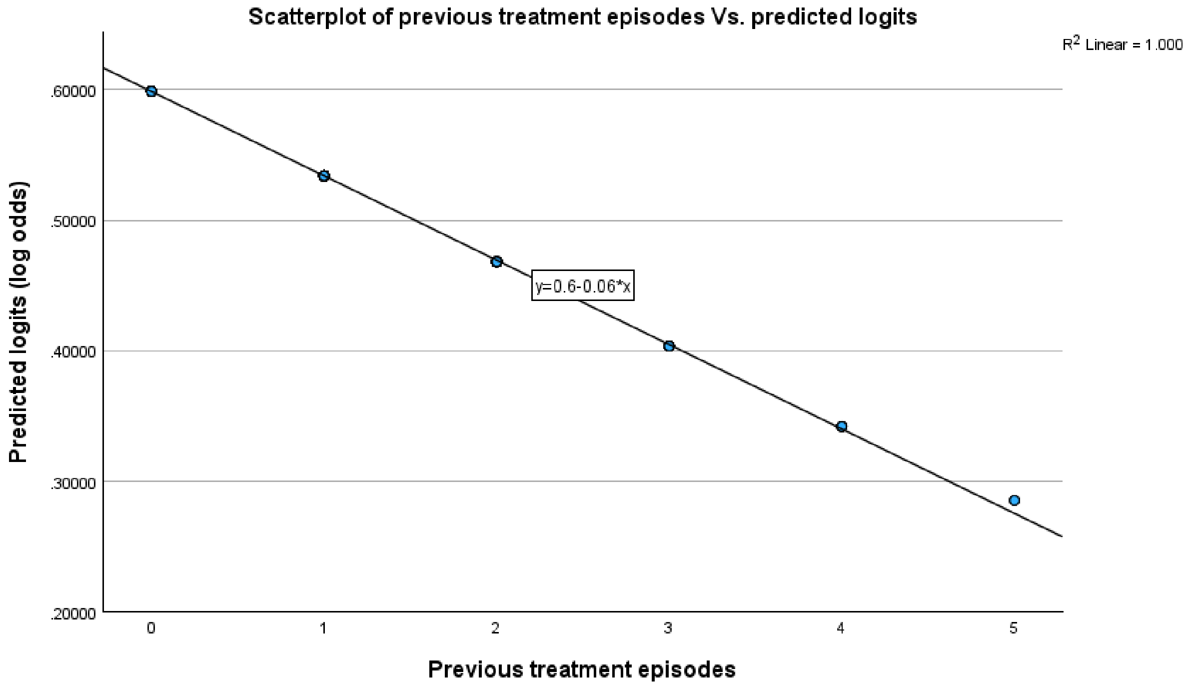
Scatterplots of linearity for significant continuous predictor variables

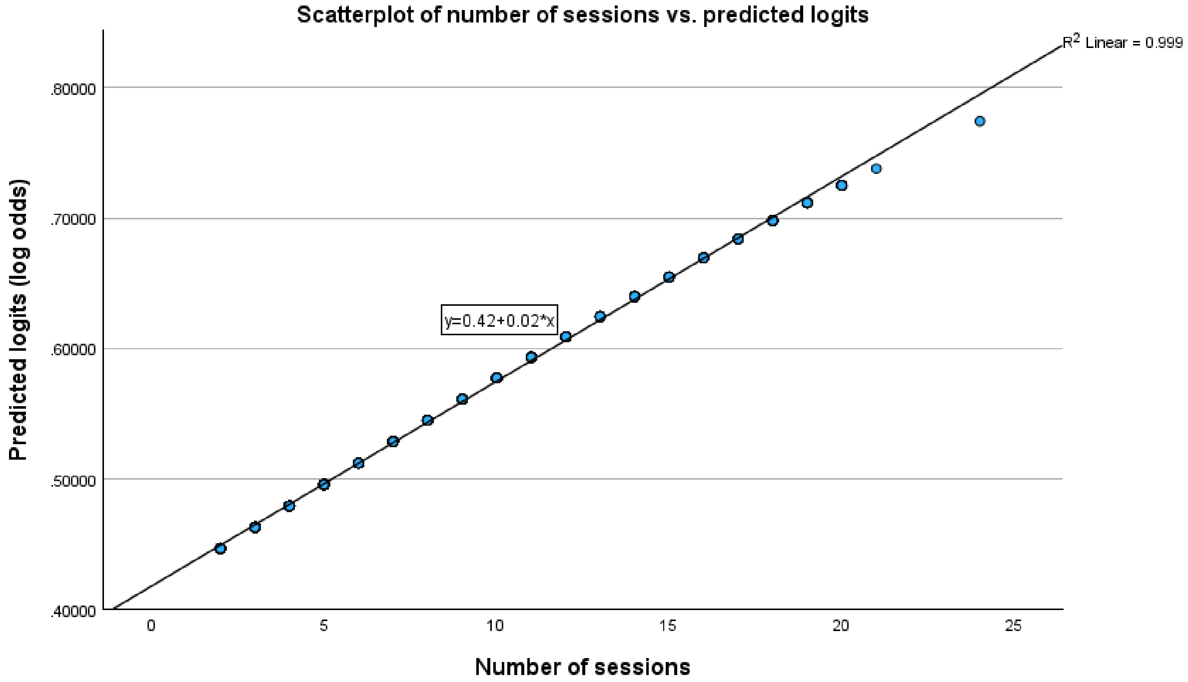

Scatterplot of age Vs predicted logits
R^2 Linear = 1.000
y=0.38+3.44E-3*x
.70000
.60000
.50000
.40000
Predicted logits (log odds)
20
40
60
80
Age


Scatterplot of severity of depression Vs. predicted logits
R^2 Linear = 1.000
y=0.82-0.02*x
.80000
.70000
.60000
.50000
.40000
Predicted logits (log odds)
5
10
15
20
25
30
Severity of depression


Scatterplot of severity of anxiety Vs. predicted logits
R2 Linear = 1.000
Predicted logits (log odds)
.70000
.65000
.60000
.55000
.50000
.45000
y=0.72-0.01*x
0
5
10
15
20
25
Severity of anxiety


Scatterplot of severity of functional impairment Vs. predicted logits
R2 Linear = 1.000
Predicted logits (log odds)
.70000
.60000
.50000
.40000
y=0.69-6.06E-3*x
.00
10.00
20.00
30.00
40.00
Severity of functional impairment


Scatterplot of previous treatment episodes Vs. predicted logits
R^2 Linear = 1.000
y=0.6-0.06*x
Predicted logits (log odds)
.60000
.50000
.40000
.30000
.20000
0
1
2
3
4
5
Previous treatment episodes


Scatterplot of number of sessions vs. predicted logits
R^2 Linear = 0.999
y=0.42+0.02*x
Predicted logits (log odds)
.80000
.70000
.60000
.50000
.40000
0
5
10
15
20
25
Number of sessions

Appendix XVIII

Binary logistic regression SPSS output for all predictor variables

Variables in the Equation

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Age	.014	.005	7.071	1	.008	1.014	1.004	1.025
	Constant	-.509	.288	3.118	1	.077	.601		

Binary regression model of age and reliable recovery

a. Variable(s) entered on step 1: age.

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Gender(1)	-.268	.183	2.133	1	.144	.765	.534	1.096
	Constant	.415	.154	7.259	1	.007	1.514		

Binary regression model of gender and reliable recovery

a. Variable(s) entered on step 1: gender.

b. Reference category 1 was male

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	Marital status(1)	-.274	.171	2.589	1	.108	.760	.544	1.062
	Constant	.336	.108	9.714	1	.002	1.399		

Binary regression model of marital status and reliable recovery

a. Variable(s) entered on step 1: marital status. b. Reference category 1 was married/co-habiting

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1[a]	employment status			17.852	3	<.001			
	employment status(1)	.508	.202	6.352	1	.012	1.663	1.120	2.469
	employment status(2)	.770	.450	2.924	1	.087	2.160	.894	5.220
	employment status(3)	.996	.240	17.150	1	<.001	2.707	1.690	4.336
	Constant	-.259	.158	2.690	1	.101	.772		

a. Variable(s) entered on step 1: employment status.

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1^a	Socioeconomic status			.006	2	.997			
	socioeconomic status(1)	.016	.193	.006	1	.936	1.016	.696	1.482
	socioeconomic status(2)	20.983	40192.969	.000	1	1.000	1296368701.053	.000	.
	Constant	.220	.096	5.239	1	.022	1.246		

Binary regression model of socioeconomic status and reliable recovery

a. Variable(s) entered on step 1: socioeconomic status.

b. Category 1 was area A

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1^a	Type of CMHP(1)	.130	.168	.603	1	.437	1.139	.820	1.582
	Constant	.169	.112	2.266	1	.132	1.184		

Binary regression model of type of common mental health problem and reliable recovery

a. Variable(s) entered on step 1: Type of CMHP. b. Category 1 was depression

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1^a	Multimorbidity (1)	-.671	.177	14.347	1	<.001	.511	.361	.723
	Constant	.457	.104	19.221	1	<.001	1.580		

binary regression model of presence of multimorbidity and reliable recovery

a. Variable(s) entered on step 1: multiple ltc diagnosis.

b. Category 1 was the presence of multimorbidity

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1^a	PHQ-9 baseline	-.063	.018	12.230	1	<.001	.939	.906	.973
	Constant	1.298	.319	16.570	1	<.001	3.664		

Binary regression model of baseline severity of depression and reliable recovery

a. Variable(s) entered on step 1: PHQ-9 baseline.

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1ᵃ	GAD-7 baseline	-.047	.020	5.717	1	.017	.954	.918	.992
	Constant	.901	.295	9.323	1	.002	2.462		

Binary regression model of baseline severity of anxiety and reliable recovery.
a. Variable(s) entered on step 1: GAD-7 baseline.

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1ᵃ	Functional impairment	-.025	.010	6.456	1	.011	.975	.957	.994
	Constant	.761	.227	11.218	1	<.001	2.140		

Binary regression model of baseline severity of functional impairment and reliable recovery

a. Variable(s) entered on step 1: work and social adjustment.

								95% C.I.for EXP(B)	
		B	S.E.	Wald	Df	Sig.	Exp(B)	Lower	Upper
Step 1ᵃ	Personality disorder	-.078	.049	2.498	1	.114	.925	.839	1.019
	Constant	.494	.191	6.707	1	.010	1.639		

Binary regression model of the presence of personality disorder and reliable recovery

a. Variable(s) entered on step 1: sapas .

								95% C.I.for EXP(B)	
		B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
Step 1ᵃ	Previous treatment episodes	-.264	.089	8.774	1	.003	.768	.645	.915
	Constant	.400	.102	15.343	1	<.001	1.492		

Binary regression model of number of previous treatment episodes and reliable recovery

a. Variable(s) entered on step 1: previous treatment episodes.

		B	S.E.	Wald	Df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Treatment type			1.302	2	.521			
	treatment type(1)	.077	.216	.129	1	.720	1.080	.708	1.649
	treatment type(2)	.284	.251	1.281	1	.258	1.328	.812	2.172
	Constant	.174	.101	2.942	1	.086	1.190		

Binary regression model of type of treatment and reliable recovery

a. Variable(s) entered on step 1: treatment type.

b. Reference category 1 was high intensity CBT

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Number of sessions	.066	.017	14.598	1	<.001	1.068	1.033	1.105
	Constant	-.348	.170	4.164	1	.041	.706		

Binary regression model of number of session and reliable recovery

a. Variable(s) entered on step 1: number of sessions.

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Early reliable improvement (1)	2.416	.258	87.655	1	<.001	11.204	6.756	18.581
	Constant	-1.683	.238	50.152	1	<.001	.186		

Binary regression model of early reliable improvement and reliable recovery

a. Variable(s) entered on step 1: early reliable improvement.

b. Reference category 1 was achieved reliable improvement