

Stepped Care for Depression:  
A Systematic Review and Feasibility Study

Submitted by Jacqueline Janet Hill to the University of Exeter  
as a thesis for the degree of  
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*Declaration*

I certify that all material in this thesis which is not my own work has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

Signature:

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke at the bottom.



## **Dedication**

To our beautiful girls, Emma and Claudia.

## **Acknowledgements**

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## **Abstract**

**Background.** Stepped care is widely implemented as a means to organise depression treatment. However, it is unclear how this system and the system it was designed to replace – long-term intensive psychotherapy for all – compare.

**Aim.** To further the development and evaluation of stepped care. Specifically, assess the clinical effectiveness of stepped care and prepare for a fully-powered evaluation of stepped care vs. high-intensity psychotherapy alone for depressed adults.

**Design.** A systematic review and mixed methods feasibility study encompassing a pilot randomised controlled trial and semi-structured interviews.

**Results of the systematic review.** Fourteen randomised controlled trials involving 4580 participants were included. Relative to controls, there was significantly greater improvement in depression for adults treated with stepped care ( $d=0.34$  at six months; 95% CI 0.20 to 0.48). The quality of included studies was good and there was little evidence of publication bias. All comparisons were with usual care.

**Results of the feasibility study.** 66 patients were recruited to the pilot trial. The recruitment rate was 2.9% and follow-up data was obtained from 90.9% of participants. A third of stepped care patients stepped up to high-intensity therapy. Patients improved in both groups: the mean reduction in depressive symptoms was 13.4 in the stepped care group and 13.6 in the high-intensity therapy alone group. Recruitment methods were appropriate to patients and therapists but only somewhat appropriate to IAPT staff. Although the stepped care intervention was broadly acceptable to therapists, patient experience varied and some patients who demonstrated a low level of self-efficacy declined any therapy or dropped out of treatment.

**Conclusions.** The effectiveness of stepped care compared with long-term intensive psychological therapy for all has not yet been established. A fully-powered trial of stepped care vs. high-intensity therapy alone is feasible although pilot trial methods and procedures should be modified to improve recruitment and acceptability.

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## List of Abbreviations

AccEPT	Accessing Evidence Based Psychological Therapies Clinic
ADM	Antidepressant Medication
BDI-I	Beck Depression Inventory (version I)
CBT	Cognitive Behaviour Therapy
CIS-R	Clinical Interview Schedule – Revised
CLAHRC	Collaboration for Leadership in Applied Healthcare Research
CONSORT	Consolidated Standards of Reporting Trials
DSM-V	Diagnostic and Statistical Manual of Mental Disorders (version 5)
EBM	Evidence-Based Medicine
EBP	Evidence-Based Practice
GAD-7	Generalised Anxiety Disorder – seven item questionnaire
GSH	Guided Self-Help
GP	General Practitioner
IAPT	Improving Access to Psychological Therapies
ICD-10	International Classification of Diseases (version 10)
LEG	Lived Experience Group
MDD	Major Depressive Disorder
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PCS	Physical Component Scale
PCP	Primary Care Practitioner
PHQ-9	Patient Health Questionnaire – nine items
PWP	Psychological Wellbeing Practitioner
MCS	Mental Component Scale
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
STEPS	Stepped care vs. high-intensity therapy feasibility study
WB	Wellbeing

## **CHAPTER 1. INTRODUCTION**

This thesis will help develop and prepare to evaluate stepped care for the treatment of depression in adults. As a system for the organisation of depression treatment, stepped care requires that almost all patients start with an evidence-based therapy of low-intensity; progress is monitored systematically and patients who do not respond adequately go on to receive high-intensity treatment (Davison, 2000). Compared with the provision of long-term, intensive psychotherapy for all, stepped care is assumed to achieve equivalent clinical outcomes at reduced cost (Bower & Gilbody, 2005b); implemented in a publicly funded health care system, it is expected to increase access to depression treatment (Richards, 2012). For these reasons, many clinical guidelines worldwide endorse stepped care for depression (Andrews & World Health Organisation Collaborating Centre for Classification in Mental Health, 2006; National Collaborating Centre for Mental Health, 2010; Spijker, van Vliet, Meeuwissen, & van Balkom, 2010). In England stepped care has become the dominant model of treatment organisation as implemented by Improving Access to Psychological Therapies (IAPT) services. Yet around a decade ago, Bower and Gilbody (2005b) cautioned that the acceptability of stepped care and the clinical and cost-effectiveness of this system vs. high-intensity psychological treatment were untested. To establish equivalence and efficiency with certainty, a fully-powered randomised controlled trial of stepped care compared with intensive psychological therapy alone will be required. Several trials of stepped care have been undertaken (Ell et al., 2008; Oosterbaan et al., 2013; Unutzer et al., 2002). However, the strength of evidence on the effectiveness of stepped care vs. high-intensity psychological therapy alone has not been systematically appraised; patients' and therapists' views of stepped care remain important to establish.

### **1.1 Thesis overview**

The aim of this thesis is to further the development and evaluation of stepped care treatment for depression in adults. Two studies are presented which have been conducted in line with the Medical Research Council framework for the development and evaluation of complex interventions: (1) a systematic review of the effectiveness of stepped care treatment for depression in adults and (2) a

mixed methods feasibility study to prepare for a large randomised controlled trial of stepped care compared with intensive psychological therapy alone. Techniques for integrated mixed methods analysis are included in the feasibility study. The potential for these techniques in the field of Health Services Research going forward is considered.

## **1.2 Thesis structure and content**

This thesis is structured as follows: Chapter 2 provides a summary of depressive symptomatology, prevalence and impact followed by a description and discussion of evidence on (a) the origin and definition of stepped care; (b) the acceptability of this system and (c) effects of stepped care implemented in routine clinical practice.

Chapter 3 describes the methodological framework and philosophy underpinning my programme of research. The thesis is situated in the context of evidence-based medicine, the development and evaluation of complex interventions and the appropriateness of mixed methods for health services research.

Chapter 4 identifies and assesses existing evidence on the effectiveness of stepped care treatment for depression in adults through a systematic review and meta-analysis (study 1). The results of the review are used to determine, with confidence, whether current evidence is sufficient to conclude that stepped care is equivalent to long-term, intensive psychological therapy for all.

Chapters 5 & 6 describe and report the methods and results of a feasibility study (study 2) to prepare for a fully-powered evaluation of stepped care vs. high-intensity psychological therapy. Key clinical, methodological and procedural uncertainties associated with the conduct of a large trial are addressed. The results of integrated mixed methods analysis are presented.

Chapter 7 concludes this thesis with: (i) a summary of results in relation to the aim and objectives the systematic review and each of five research questions addressed in the mixed methods feasibility study, (ii) a discussion of the findings from each study comprising strengths and limitations, clinical implications and directions for future research, and (iii) a summary of key conclusions. The value of integrated mixed methods analysis is considered.

### **1.3 Aims and objectives**

**Study 1** - The aim of the systematic review of stepped care will be to assess the clinical effectiveness of stepped care treatment for depression in adults. Specific objectives are to: (1) determine whether existing evidence is sufficient to conclude, with confidence, that stepped care is equivalent to high-intensity psychological therapy for all; (2) investigate heterogeneity in the findings of relevant randomised controlled trials by exploring aspects of study design and elements of the intervention that are associated with more or less effect.

**Study 2** – The aim of the feasibility study will be to provide information to inform the design of a large randomised controlled trial that will evaluate the clinical and cost-effectiveness of stepped care vs. high-intensity psychotherapy alone for the treatment of depression in adults. Specific objectives will be to: (1) gather enough information on recruitment, retention, the proportion of patients who step up from low- to high-intensity therapy and treatment effects to design a fully-powered clinical trial or to determine that such a trial is not feasible; (2) explore patients' and therapists' views of stepped care and the ways in which patients' views relate to how much they engage in therapy to inform a stepped care clinical protocol for the large trial.

## **CHAPTER 2. BACKGROUND**

The purpose of this chapter is to demonstrate the requirement for a programme of research on stepped care for the treatment of depression in adults.

The chapter provides an overview of depressive symptomology, prevalence and impact followed by a summary of effective treatment for depression. Work on improving care for depressed patients is described. This is followed by a review of literature on (a) the origin and definition of stepped care, (b) a critique of this system and (c) how stepped care has been implemented in the UK. Current evidence on the acceptability of stepped care, how patients' views of this system might relate to attendance and the effects of stepped care in routine clinical practice is presented. The key limitations of studies on the effects of stepped care in clinical practice are described; implications for future research are presented. Chapter two culminates in a summary of my PhD programme of work; the aim and specific objectives of my thesis are provided.

Material is organised into several sections. Sections one to six are: (2.1) depression – symptoms, prevalence & impact; (2.2) treating depression; (2.3) improving access; (2.4) stepped care; (2.5) a critique of stepped care (2.6) the implementation of stepped care. Sections 2.7 to 2.10 summarise existing research on acceptability, the relationship between acceptability and therapeutic attendance and the effect of stepped care in routine clinical practice.

Limitations of the evidence on effect are presented in section 2.11. Sections 2.12 and 2.13 comprise 'implications for future research' and my 'PhD programme of work'.

### **2.1 Depression – symptoms, prevalence and impact**

Major depression is a common, recurrent and debilitating disorder which, for many, is a lifelong and chronic illness (Richards, 2011). Two systems are predominantly used for the diagnosis of depression: the ICD-10 (World Health Organization, 1992) in Europe and DSM-V (American Psychiatric Association, 2013) in the USA. In both systems, diagnosis is primarily based on the presence of depressed mood or loss of interest or pleasure; other symptoms include insomnia, low self-esteem, reduced concentration and feelings of hopelessness.

Internationally, the World Health Organisation predicts that by 2030 depression will become the third leading cause of the global burden of disease (Mathers, Boerma, & Ma Fat, 2008). In the UK, epidemiological studies demonstrate that depression is highly prevalent with the National Psychiatric Comorbidity Survey estimating a point prevalence rate of 8.8% for mixed anxiety and depression and 2.3% for depression (McManus, Meltzer, Brugha, Bebbington, & Jenkins, 2009). Lifetime and twelve month prevalence rates for depression, as estimated in the US, are higher at 16.6% and 6.7%, respectively (Kessler, Berglund, et al., 2005).

For individuals, depression is often recurrent. Between 40% and 60% of people who experience a first depressive episode will go on to have another where the risk of recurrence subsequently increases with successive episodes (Eaton et al., 2008; Moffitt et al., 2010; Solomon et al., 2000). Rates of psychiatric comorbidity and risk for suicide are also high (Fava et al., 1997; Kasper, Schindler, & Neumeister, 1996; Kessler, Berglund, et al., 2005; Robins, Locke, & Regier, 1991) and comorbidity has been established between depression and physical conditions (Angst, Gamma, Rossler, Ajdacic, & Klein, 2009; Rosenthal, 2003). In the UK, the cost of depression and anxiety is significant at £17bn in lost output and direct health care costs to the economy annually and a £9bn impact on the Exchequer through benefit payments and lost tax receipts (The Centre for Economic Performance Mental Health Policy Group, 2006).

## **2.2 Treating depression**

Effective pharmacological and psychological treatments for depression are available. Different types of psychotherapy are efficacious including Cognitive Behaviour Therapy (CBT), Interpersonal Psychotherapy (IPT), Problem-Solving Therapy (PST) and Behavioural Activation (BA) with only small differences in effect between them (Cuijpers, Andersson, Donker, & van Straten, 2011). Psychological treatments have also been found to have an important role to play in the primary prevention of depression (Cuijpers, van Straten, Smit, Mihalopoulos, & Beekman, 2008). For patients with mild to moderate depression, the efficacy of psychological treatments is about the same as the efficacy of pharmacotherapy (Cuijpers, van Straten, van Oppen, & Andersson, 2008). However, there may be advantages of psychotherapy over

pharmacological treatments in terms of relapse prevention (Cuijpers, Hollon, et al., 2013; Vittengl, Clark, Dunn, & Jarrett, 2007). For example, patients who receive acute phase CBT are less likely to relapse than those who are withdrawn from pharmacotherapy (Cuijpers, Hollon, et al., 2013); although rates of relapse after acute phase CBT and continuation of pharmacotherapy following remission are similar (Cuijpers, Hollon, et al., 2013), advantages of acute phase CBT include an absence of medication side-effects.

### **2.2.1 Problems in the detection and treatment of depression**

Despite the availability of effective pharmacological and psychological treatments, in the 1990s problems in the detection and treatment of depression were convincingly demonstrated through empirical research. Data from the United States indicated that only half of depressed patients were accurately diagnosed in primary care (Public Health Service Agency for Healthcare Policy and Research, 1993). Worldwide, approximately half of people presenting with psychiatric problems in primary care went unrecognised; one third of cases were misdiagnosed (Lecrubier, 2001). More broadly, access to treatment, irrespective of setting, was poor (Katz et al., 1997; Robins et al., 1991). Several studies found that only one in three patients with depressive disorders received treatment (Kessler, Demler, et al., 2005; Young, Klap, Sherbourne, & Wells, 2001). Among patients who were accurately diagnosed, 25% to 50% received guideline-level antidepressant medication however many patients treated with antidepressant medications in primary care had persistent symptoms (Katon et al., 1999). With respect to psychological treatment, fewer than 10% of those diagnosed with depression received an evidence-based psychological therapy (Wells, Katon, Rogers, & Camp, 1994). In these ways, care for depression was associated with problems in detection and recognition, unsatisfactory pharmacotherapy and a lack of access to any treatment, most notably evidence based psychotherapy.

### **2.2.2 Problems in the organisation of treatment**

Reflecting on such problems, academics, clinical researchers and those responsible for the design and delivery of treatment for depression began to recognise that the structure and delivery of mental health services, as traditionally configured, prohibited high quality care for depression. In the US,

Wagner and colleagues (2001) observed that care systems which had been designed for the efficient and effective treatment of acute illness were poorly suited to care for chronic illness including depression. Failures of primary care to meet the growing demand from rises in chronic disease were attributed to poorly organised treatment and system level change was recommended (Institute of Medicine, 2001b; Wagner et al., 2001).

### **2.2.3 Problems in the organisation of psychological therapies in the UK**

In the UK, the efficacy of CBT for common mental health problems was well established by the end of the 1990's (Lovell & Richards, 2000). The National Service Framework for Mental Health (Department of Health, 1999) had identified CBT as a major component of primary and secondary mental health care and CBT was central to government plans for modernising mental health services (Department of Health, 1997). However, in the same way that health care for chronic illness was deemed inadequate in the US, Lovell and Richards (2000) argued that traditional systems for the delivery of CBT were inadequate: access to care was limited by the structure and supply of services.

Traditional systems for the provision of CBT required patients to consult with their GP or a mental health specialist to secure a place on a waiting list; therapists then typically offered patients around six to twelve sessions of 45-60 minutes face to face therapy. However, the supply of trained CBT therapists was inadequate for the number of people estimated to be suffering from most of the major disorders for which CBT had been shown to be effective; as such, services were often characterised by lengthy waiting lists and wait times (Lovell & Richards, 2000).

Importantly, Lovell and Richards (2000) also argued that CBT could be delivered more efficiently. They contended that the typical duration of CBT sessions of between 45 and 60 minutes had been determined by tradition and convenience rather than evidence (Lovell & Richards, 2000). The authors also cited research to suggest that a large number of people could and would respond to treatment in a relatively small number of sessions (Howard, Kopta, Krause, & Orlinsky, 1986); people improve more quickly when limits on the numbers of sessions are imposed (Barkham et al., 1996); although patients who receive 16 sessions ultimately improve more than those who receive eight,



gains are small in comparison to the additional effort from both the therapist and patient (Barkham et al., 1996). Thus it was suggested that problems in access to CBT due to the structure of care and a lack of CBT therapists were compounded by inefficiencies in the treatment provided – ‘long term’, intensive CBT for all.

### **2.3 Improving access**

Drawing on studies that had been designed to (i) explore elements of CBT that may be associated with good effect and (ii) compare CBT involving multiple components with less complex forms, Lovell & Richards (2000) proposed that the use of brief (or ‘low-intensity’) versions of CBT had potential to greatly improve access to evidence-based treatment for a wide range of disorders, including depression. Since then, others have highlighted the potential for low-intensity psychological therapies in general (including but not limited to low-intensity CBT) to significantly increase access to depression treatment (Bilsker, Goldner, & Anderson, 2012; Bower & Gilbody, 2005a; Clarke, Lynch, Spofford, & DeBar, 2006).

Low-intensity psychological therapies are typically defined as psychotherapies that require less time from a health care professional than conventional, or high-intensity, psychological treatments (Bennett-Levy, Richards, & Farrand, 2010). However, intensity might also refer to the time required of patients and therapists’ level of expertise and it is possible for treatments to differ in one but not all of these dimensions (van Straten, Hill, Richards, & Cuijpers, 2014). Patients, for example, may spend similar amounts of time undertaking high- or low-intensity psychotherapies which require a different amount of time from a professional.

In practice, low-intensity psychological treatment can be delivered in a very wide range of formats, including self-help, group therapy, and book- or internet-based courses with support provided over the internet, by phone, email or face-to-face (Bennett-Levy et al., 2010). Key to the potential for low-intensity psychological treatments to increase access to psychological therapies is that, compared with conventional psychotherapies, low-intensity treatments cost less and are less reliant on scarce therapeutic resource. In a publicly funded

healthcare system, the offer of such low-intensity psychotherapy can increase the number of people accessing psychological therapy for depression.

### **2.3.1 Possible issue with low-intensity psychotherapy**

In the last decade, the effectiveness of low-intensity psychological therapies for depression, delivered in a variety of ways, has been demonstrated convincingly (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Cuijpers, Donker, van Straten, Li, & Andersson, 2010; Gellatly et al., 2007; Richards & Richardson, 2012). However, a potential shortcoming of such treatments is that they may be inappropriate and insufficient for some. Low-intensity psychological treatments may not be acceptable to all; some patients might require more robust psychotherapy (K. E. Green & Iverson, 2009; Richards, 2012) and not everyone will require the same treatment (Patten, Bilsker, & Goldner, 2008).

Access to healthcare can be conceived as more than the supply of services; for services to be truly accessible they must also be used by and effective for the population for whom they are provided (Gulliford et al., 2002). Against this definition, the provision of low-intensity psychological treatments may be insufficient. The challenge may be to retain the benefits of low-intensity psychotherapies but incorporate them within a system for the allocation of psychological therapies that is sensitive to the different needs of different patients.

## **2.4 Stepped care**

Stepped care represents one such attempt to titrate the provision of psychological (and pharmacological) treatment to need. In 2000, Haaga introduced a series of papers in the *Journal of Consulting and Clinical Psychology* on the potential for and implementation of stepped care for common mental health disorders (Haaga, 2000). In this series, the authors reflected on how to define and implement stepped care as a system for the organisation of treatment for a variety of mental health problems - Generalised Anxiety Disorder (Newman, 2000), Panic Disorder (Otto, Pollack, & Maki, 2000), Eating Disorders (G. T. Wilson, Vitousek, & Loeb, 2000), and alcohol problems (Sobell & Sobell, 2000). In the fifth paper, Davison appraised all four articles and the core principles of his description of stepped care have come to define this

system of treatment: almost all patients start with an evidence-based treatment of low intensity; only patients who require further treatment 'step up' to a treatment of higher intensity (Davison, 2000). In practice, low-intensity psychotherapies delivered in the variety of forms described above are often used as a first step in stepped care treatment for depression and for patients who do not respond, high-intensity psychological therapies delivered in a more conventional form can follow.

Integral to the definition of stepped care is the requirement for patient progress to be assessed to inform next treatment step. This is an element of stepped care that has been made more explicit by other authors (Bower & Gilbody, 2005b). To determine which patients 'step up', response to treatment is systematically evaluated; patient progress is assessed using validated symptom checklists and the decision to end or continue treatment after low-intensity therapy is made using set criteria appraised at a pre-specified time interval (van Straten et al., 2014).

Defined and implemented in this way, compared with offering almost all patients long-term intensive psychological therapies, stepped care as a system for the allocation of depression treatment has potential to improve access whilst reassuring those who may be concerned about the appropriateness and effectiveness of low-intensity psychological therapy for all (Scogin, Hanson, & Welsh, 2003).

#### **2.4.1 The role for clinical judgment**

The core principles of stepped care are arguably simple – offer patients the least intensive treatment first, monitor, and only 'step up' if required. Yet the more detailed description by Davison (2000) and colleagues (Newman, 2000; Otto et al., 2000; Sobell & Sobell, 2000; G. T. Wilson et al., 2000) incorporates a role for clinical judgment. Davison argues that stepped care should be sufficiently flexible to offer patients non-validated treatment where it makes sense to do so, moreover that clinical judgment should be applied to identify the least intensive / intrusive treatment to which a patient is likely to respond favourably (Davison, 2000). Hence whilst advising that, wherever possible, clinical work is informed by empirical evidence (Davison, 2000), the finer detail of Davison's description supports a definition of stepped care that is flexible

enough to allow patients to begin with high-intensity treatment and be offered non-validated treatment if judged appropriate by a suitably qualified health care professional (2000). Others share this position (Katon, Von Korff, Lin, & Simon, 2001; Von Korff & Tiemens, 2000).

#### **2.4.2 Progressive vs. stratified stepped care**

Whilst Davison and others support the role for clinical judgment in stepped care, their model is still one of 'progression': almost all patients start with low intensity treatment and move on to more intensive treatment if needed (Ekers & Webster, 2013). By comparison, Newman (2000) and G. T. Wilson et al. (2000) describe 'stratified' models of stepped care (Ekers & Webster, 2013). In this form of stepped care, prior to treatment, patients are assessed and allocated to different treatment intensities; some patients begin with low intensity treatment, others 'jump' straight to high intensity treatment. Initial allocation or 'matching' of patients therefore requires some judgment to be made as to the likely response individual patients will make to the treatments available (Richards et al., 2010). In this way, there is overlap between stratified stepped care and 'personalised medicine' where treatment choice is determined by individual patients' characteristics that are (ideally) known to predict response to treatment (Simon & Perlis, 2010).

#### **2.4.3 Stepped care involving a change in the type or modality of treatment**

In one other respect, the definition of stepped care is varied: authors use the term to describe sequential treatments that are not organised in terms of increasing intensity. Writing on stepped care for the treatment of alcohol problems, Sobell and Sobell (2000) suggest that 'stepping up' need not be limited to increasing the intensity of treatment – changing 'type' might also be justified where 'type' refers to treatments of different modalities (pharmacological, psychological etc.) but also qualitatively different treatments of the same modality and intensity (Sobell & Sobell, 2000). Similarly, Otto et al. (2000) investigated the cost-effectiveness of CBT and medication for Panic Disorder: CBT was recommended as a first line treatment in a stepped care model; subsequent treatment could involve a combination of CBT and medication or medication alone (Otto et al., 2000). Given that it is difficult to characterise pharmacological treatments as intensive or otherwise, stepped

care involving medication and psychological treatment cannot be easily defined in this way. In these examples, the term stepped care is used to describe treatment that is organised in steps characterised by a switch in treatment or the augmentation of one treatment with another.

There are several examples of stepped care for depression defined by no clear intensity order. Joffe and Levitt (1995) describe stepped care for patients with 'treatment resistant' depression involving substitution, combination or augmentation of an antidepressant agent with a second agent. For the same population, Sharan and Saxena (1998) refer to stepped care treatment that involved augmentation of and switching antidepressant agents; this could be combined with psychological therapy. Stepped care for women with depression has encompassed pharmacological treatment followed by high intensity psychological therapy, if required (Katon & Ludman, 2003).

Considering the widespread use of pharmacotherapy alongside psychological treatment for depression, it is perhaps unsurprising that the term stepped care has been used to describe treatment that is organised in steps defined by switching or adding treatments of different modalities (van Straten et al., 2014). This version of stepped care substantially departs from the model described by Davison (2000) but has a place in the literature.

#### **2.4.4 Stepped care as an 'adaptive treatment'**

Broadly defined, stepped care has been described as an example of 'adaptive treatment' (Murphy, Collins, & Rush, 2007). Such strategies are based on decision rules that recommend when and for whom treatment should change; often they incorporate a sequence of treatments and patient characteristics, adherence and response to treatment are used to inform treatment recommendations (Murphy et al., 2007). Progressive models of stepped care, stepped care involving initial stratification and allocation and stepped care defined by a change in treatment are captured by this umbrella term.

#### **2.4.5 Stepped and collaborative care**

Stepped care is also compatible with other systems that aim to improve care quality and within the literature stepped care is often combined with collaborative care in a single intervention. Collaborative care is defined by

enhanced communication between primary and specialist care providers, a structured patient management plan and scheduled patient follow-ups provided by a dedicated 'case manager' working in primary care but supervised by a mental health specialist (Gunn, Diggins, Hegarty, & Blashki, 2006). It is also deemed to be compatible with stepped care because the need for specialist involvement is often determined by a lack of response to first- and second-line treatments (Von Korff, Katon, Unutzer, Wells, & Wagner, 2001). Combined, stepped care and collaborative care is labelled in a variety of ways: as collaborative care, stepped care or collaborative stepped care, for example. For this reason, it can be difficult to identify as stepped care but nonetheless meets criteria for a definition of this system.

## **2.5 Critique of stepped care**

The variety of ways in which stepped care has been defined and implemented can, in part, be thought of as a response to key criticisms of this way of organising treatment. Concerns with stepped care have been highlighted by several authors and cover four themes: the appropriateness of low-intensity treatment; consequences of unsuccessful low-intensity treatment; reduced patient choice; monitoring and stepping.

### **2.5.1 Inappropriate low-intensity treatment**

Despite credible evidence that low- and high-intensity psychological therapies have comparable effects (Cuijpers, Donker, et al., 2010), there is an assumption implicit in the language of stepped care that high-intensity treatment (of any kind) is in some way superior to low-intensity treatment (Williams & Martinez, 2008). With respect to depression treatment, patients and professionals may feel that the provision of low-intensity psychological therapy is inappropriate (Bilsker et al., 2012; Scogin et al., 2003). Some people may be particularly committed to the view that low-intensity psychological treatments are inappropriate for those with more severe depression (Landreville, Landry, Baillargeon, Guérette, & Matteau, 2001). Meta-analysis of individual patient data has found that patients with more severe depression show at least as much clinical benefit from low-intensity psychotherapies as less severely depressed patients (Bower et al., 2013). However, treatment guidelines that clearly recommend stratified stepped care involving low-intensity psychological

therapy for patients with mild and moderate depression but more intensive psychotherapy for those with more severe symptoms (Spijker et al., 2010; Van Weel-Baumgarten et al., 2012) are likely to reinforce the belief that low-intensity psychological interventions are unsuitable for patients with more severe symptoms.

### **2.5.2 Unsuccessful low-intensity treatment**

A second cause of concern with stepped care focuses on the consequences of unsuccessful low-intensity treatment in a stepped care framework.

Paradoxically, assuming that high-intensity treatment alone may have led to improvement, the treatment of patients who receive unsuccessful low-intensity treatment followed by a high-intensity intervention may be unnecessarily burdensome and prolonged (Richards et al., 2010). There is also a concern that patients who do not respond to minimal interventions may develop negative attitudes towards treatment and ultimately be deterred from further treatment (Kellett & Matthews, 2008; Scogin et al., 2003). In addition, in terms of depression treatment, if severe depressive symptoms, including suicide ideation, are not promptly addressed with high-intensity psychotherapy, Scogin et al. (2003) worry that serious consequences could occur.

### **2.5.3 Restricted patient choice**

Another issue of concern is the scope for patient choice in stepped care. The importance of a health care service that offers patients more choice, personalised care and genuine empowerment has been at the forefront of the National Health Service agenda (Lovell & Bee, 2008). Although patient attitudes to choice in the NHS are equivocal and complex (Ipsos MORI, 2006), the opportunity to select one's own treatment may be important, at least for some patients (Bromley & Hewton, 2005). The efficiency of stepped care services for depression may, to a degree, be determined by constraints on choice; allowing patients to choose between low- and high-intensity psychological treatment could negate the benefits of this system if most expect and would prefer the latter (Bower & Gilbody, 2005b; Richards et al., 2010). Whilst patients may be provided with a choice of treatment within steps even if the choice between steps is more constrained, the stepped care model could be

perceived as limiting, directing patients towards low intensity options and thus restricting choice (Lovell & Bee, 2008).

#### **2.5.4 Monitoring and stepping criteria**

The fourth criticism of stepped care concerns monitoring patients who are in receipt of a low intensity intervention to determine their next treatment step. In the same way that the efficiency of stepped care is, in part, determined by a lack of patient choice, the cost of stepped care is also influenced by timely decisions to step up patients without any clear therapeutic gains to the next level of treatment (Delgadoillo, Gellatly, & Stephenson-Bellwood, 2015).

Qualitative evidence has suggested that the decision to step up depressed patients does not happen consistently or in line with clinical guidelines (Gellatly, 2011). Central to the difficulty faced by clinicians is a tension between the desire to tailor or individualise psychological treatment which is perceived to conflict with standardised measures and guidelines for deciding which patients have high intensity psychotherapy and when (Gellatly, 2011). Congruent with the findings of Gellatly (2011), analysis of questionnaire data from 82 clinicians on factors associated with the decision to step up or refer patients for further treatment has demonstrated that a range of idiosyncratic assumptions, perceptions and attitudes influence clinicians' decision making processes (Delgadoillo et al., 2015). The use of clinical outcome measures and algorithms in order to reach timely decisions about who should remain in low-intensity psychological treatment or step up may not be wholly acceptable to professionals – or patients.

#### **2.6 The implementation of stepped care**

Notwithstanding commentators' concerns about stepped care, many authors have remained focused on its potential to improve access to depression treatment (Gjerdingen, Katon, & Rich, 2008; Katon & Ludman, 2003; Richards, 2012). For this reason, several authors have recommended that stepped care should be widely adopted (Ormel, Bartel, & Nolen, 2003; ten Have, de Graaf, Vollebergh, & Beekman, 2004). In practice, many depression treatment guidelines worldwide have endorsed this system for the treatment of depression in adults (Andrews & World Health Organisation Collaborating Centre for Classification in Mental Health, 2006; Spijker et al., 2010; Van Weel-



Baumgarten et al., 2012). In the UK, the National Institute for Health and Care Excellence (NICE) recommends that psychological therapies for depression are delivered using stratified stepped care (National Collaborating Centre for Mental Health, 2010; National Institute for Health and Care Excellence, 2009a, 2009b, 2011). Low-intensity psychological treatment is recommended for patients with mild to moderate depression – followed by high-intensity psychotherapy only if required; patients with moderate to severe depression can start with high-intensity psychological therapy (National Institute for Health and Care Excellence, 2009b, 2011).

A little over a decade ago, economists and clinical researchers in the UK also argued strongly that increased access to psychological therapies would largely pay for itself (Clark, 2011). The UK Government was receptive to these arguments (and to the recommendation of NICE) but also recognised that the English NHS could not possibly implement NICE guidelines without fundamental reform of therapy provision (Richards, 2012). A political commitment to increase the availability of evidence-based psychological therapies was secured in 2005 (Clark, 2011) and the government set out to reform traditional services for depression (and anxiety) into new Improving Access to Psychological Therapies (IAPT) services ([www.iapt.nhs.uk](http://www.iapt.nhs.uk)) that operated on stepped care principles in accordance with NICE guidelines.

Two pilot projects (termed 'Demonstration Sites' – one each in Doncaster and Newham) were established to test the viability of such services and whether expected outcomes could be achieved (Clark, 2011, 2013). Following the success of these sites (Clark et al., 2009; Richards & Suckling, 2009), in 2007 the UK government announced funding for a phased national rollout of the IAPT initiative in the English NHS (Clark, 2013). A national implementation plan was published in early 2008 (Department of Health, 2008) and funding for the first three years was allocated to train up to 3,600 new psychological therapists (Clark, 2011). In February 2011, the UK government announced further investment to complete and extend the IAPT programme over the period 2011 to 2015 and by Summer 2012, IAPT services had been established in 99% of the then Primary Care Trusts across England (Clark, 2013).

## **2.7 Research on stepped care**

In support of the significant investment in IAPT, several studies were conducted to evaluate services and inform national roll-out (Clark et al., 2009; Department of Health, 2012; Department of Health Mental Health Division Improving Access to Psychological Therapies Programme, 2008; Glover, Webb, & Evison, 2010; Gyani, Shafran, Layard, & Clark, 2013; Parry et al., 2011; Richards & Borglin, 2011; Richards et al., 2012; Richards & Suckling, 2009; Richards et al., 2010). Studies were able to utilise the minimum data set on patient related outcomes which all IAPT services are required to collect (Department of Health, 2009). This included patient data on the nine item Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001). Two studies also evaluated patients' and therapists' views of IAPT services (Parry et al., 2011; Richards et al., 2010). Other studies have investigated what patients and healthcare professionals think of stepped care delivered outside of IAPT (Franx, Oud, de Lange, Wensing, & Grol, 2012; Hermens, Muntingh, Franx, van Splunteren, & Nuyen, 2014; Mitchell, Dwyer, Hagan, & Mathers, 2011; van Beljouw et al., 2014). Collectively, this body of research provides evidence on: (i) the acceptability of stepped care, (ii) a possible relationship between acceptability and therapeutic attendance and (iii) the effects of stepped care in routine clinical practice.

## **2.8 Evidence on the acceptability of stepped care**

Data are available on each of the four key concerns with stepped care described above: (a) the degree to which low-intensity psychological therapy is considered appropriate; (b) views and experiences of unsuccessful low-intensity psychotherapy; (c) patient choice; (d) monitoring and stepping.

### **2.8.1 The appropriateness of low-intensity psychological therapy**

Qualitative studies suggest that low-intensity psychological therapy may indeed be perceived as inappropriate by some. From semi-structured interviews conducted with 77 patients who had completed stepped care treatment at the newly established Doncaster and Newham IAPT services, Parry et al. (2011) reported a perception that low-intensity psychotherapy was too difficult given how unwell people felt; patients struggled to engage in treatment with relatively little therapeutic support (Parry et al., 2011). Research by Franx et al. (2012)

also provides evidence to suggest that low-intensity psychological interventions delivered as part of stepped care is considered inappropriate by some healthcare professionals. Semi-structured group interviews were conducted with 79 professionals including Primary Care Physicians (PCPs), mental health specialists, psychologists and mental health nurses working in The Netherlands. Among interviewees there was a perception that treatment for depression was difficult to standardise and several PCPs mistrusted the effectiveness of low-intensity psychotherapies (Franx et al., 2012). Similarly in a UK study, Farrand, Duncan, and Byng (2007) found that GPs and managers of Graduate Mental Health Workers (GMHW) felt that low-intensity psychological therapy was unsuitable for patients with more severe difficulties. Together, these studies provide a small amount of evidence to suggest that some patients and healthcare professionals consider low-intensity psychotherapies inappropriate.

Although low-intensity psychological therapy might sometimes be seen as inappropriate, it is possible that the mistrust expressed in the above research might not be shared by patients and professionals receiving and delivering stepped care in different contexts. All three studies interviewed participants at a time when stepped care incorporating low-intensity psychotherapy for depression was uncommon; views may have changed as the use of low-intensity psychological therapies has become more widespread. In addition, studies did not obtain or clearly report the views of therapists who were responsible for the delivery of low-intensity treatment and whose opinion may be influenced by direct experience of the success or otherwise of low-intensity psychotherapy for patients with more and less severe depressive symptoms. Rather, negative views of the appropriateness of low-intensity psychotherapy were often expressed by Primary Care Physicians and GPs who may, consciously or otherwise, be motivated to defend their involvement in the treatment of patients with depression, and whose perspective may not be shared by other healthcare professionals.

### ***Other aspects of low-intensity psychological therapy***

It is also notable that although some patients and professionals might be concerned with the appropriateness of low-intensity psychotherapy for depression, patients' dissatisfaction but also satisfaction with low-intensity

psychological treatment appears to be shaped by a wide range of other elements of that care. Richards et al. (2010) conducted interviews with 14 patients attending four services that had recently implemented stepped care as part of IAPT. This study and that of Parry et al. (2011) identified a large number of elements of low-intensity psychotherapy (besides appropriateness) with which patients were unhappy. They included phone calls, the duration of treatment, content that is too simple or superficial, patients' ability to apply and use material, the therapeutic relationship and the qualifications and experience of low-intensity therapists (Parry et al., 2011; Richards et al., 2010).

In the same studies, elements of low-intensity psychotherapy with which patients were satisfied included phone calls - for their anonymity, convenience and flexibility - and the structure of low-intensity therapy (Parry et al., 2011; Richards et al., 2010). Farrand et al. (2007) also found a positive perception among twelve patients who were interviewed about the role of Graduate Mental Health Workers (employed, at the time of the research, to deliver low-intensity psychotherapy) that low-intensity psychological treatment helped you take control and be responsible for your own recovery. Patients evidently hold different and perhaps mixed views of low-intensity psychotherapy that are shaped by a host of factors, not only the degree to which it is considered appropriate.

A limitation of data on factors shaping patients' views of low-intensity psychological therapy is that it is not possible to interpret what patients thought about different aspects of therapy in relation to the specific treatment that they received. Parry et al. (2011) and Richards et al. (2010) recruited patients from several services; services differed in the form of stepped care provided and the treatment received by individual participants was not reported. Negative views on low-intensity psychotherapy delivered in one form may not be a good guide to patients' views of another. Without more information it is not possible to appreciate which components or exactly what about those components was liked or caused most difficulty. The views of patients in response to other forms of low-intensity psychotherapy may be somewhat difficult to gauge based on existing research.

## **2.8.2 Unsuccessful low-intensity psychological therapy**

Patients' and professionals' views of the consequences of unsuccessful low-intensity psychotherapy have been explored in several studies. Following interviews with 14 patients but also 18 members of IAPT staff (graduate workers, mental health practitioners / nurses, psychologists, a GP and counsellor), Richards et al. (2010) found that some patients experienced negative consequences following unsuccessful low-intensity psychological treatment; patients described feeling disillusioned. Furthermore, some staff worried about the possibility of such consequences; there was a perception that patients might drop out of treatment following a lack of response to low-intensity psychotherapy (Richards et al., 2010).

However, in a larger cohort of patients, Parry et al. (2011) found no evidence that negative consequences arose. Following unsuccessful low-intensity psychotherapy, patients had been relieved and reassured to be offered further support; some patients who dropped out of therapy viewed this decision positively although it is unclear whether such views were expressed by patients who had dropped out following unsuccessful low-intensity psychotherapy. Among the small number of other qualitative studies of stepped care conducted with healthcare professionals (Farrand et al., 2007; Franx et al., 2012; Hermens et al., 2014; Mitchell et al., 2011; van Beljouw et al., 2014), there is no evidence that staff were particularly concerned for patients who did not respond to low-intensity psychological treatment.

Reasons for the discrepancies in findings are unclear. It is possible that professionals' views of unsuccessful low-intensity psychotherapy may not have been explored in studies conducted by Farrand et al. (2007), Franx et al. (2012), Hermens et al. (2014), and Mitchell et al. (2011). Alternatively, it may not have been an issue about which staff felt strongly. With respect to patients, although people might respond both negatively and positively to unsuccessful low-intensity psychotherapy, studies by Parry et al. (2011) and Richards et al. (2010) shed no light on features of treatment that could make patients' transition into high-intensity psychotherapy easier. From existing research, it is not possible to conclude with any degree of certainty that patients who receive stepped care delivered in other ways will respond positively to unsuccessful

low-intensity psychotherapy. Nor is it possible to anticipate the views of healthcare professionals.

### **2.8.3 Patient choice**

Concerns regarding a lack of choice in stepped care have focused on the acceptability of directing patients to low-intensity treatment as a first line intervention. In this context, it is noteworthy that patients and health care professionals have endorsed stepped care for providing an alternative to antidepressant medication (Mitchell et al., 2011; Parry et al., 2011). Concerns about directing patients to low-intensity psychotherapy could be attenuated where patients and healthcare professionals are focused on the increased choice available to patients compared with offering antidepressant medication alone.

On the other hand, Parry et al. (2011) also found that patients were dissatisfied with the lack of choice in psychological therapies at Doncaster and Newham. A key difficulty with the interpretation of this finding, however, is that it is unclear what patients objected to: being directed to low-intensity psychotherapy, a lack of alternative forms of low-intensity psychological therapies from which to choose or the similarity of low- and high-intensity psychotherapies on offer. Indeed, given that at the time of the study approximately half of all patients in Newham were allocated straight to high-intensity treatment (Parry et al., 2011), it is possible that some patients may have expressed dissatisfaction with the lack of choice of high-intensity psychological therapies or with being 'denied' low-intensity psychotherapy.

It is also difficult to interpret qualitative research on the degree to which healthcare professionals dislike directing patients to low-intensity psychological therapy. Franx et al. (2012) and Richards et al. (2010) both found that some staff were uncomfortable 'forcing' patients to conform to a stepped care model but it is unclear whether reservations related to perceptions regarding the clinical effectiveness of such a system, the lack of patient choice, or both. Practitioners may have been concerned less about patient choice but more the reduced role for clinical judgment.

The degree to which the above findings apply to stepped care delivered in other ways is also uncertain. Franx et al. (2012) studied patients' response to stratified stepped care; all four sites from which participants were recruited by Richards et al. (2010) implemented systems incorporating an element of stratification and in the study by Parry et al. (2011), only Doncaster operated stepped care in which the majority of patients received low-intensity psychological therapy. The views of patients and healthcare professionals on patient choice in stepped care defined by increasing intensity have not been clearly established.

#### **2.8.4 Monitoring and stepping**

In addition to the research by Delgado et al. (2015) and Gellatly (2011) summarised in section 2.5.4, information on views of monitoring is available from a small number of other studies. Patient feedback was obtained by Parry et al. (2011); health care professionals' views are described in research by Franx et al. (2012) and Hermens et al. (2014). Studies by Franx et al. (2012) and Hermens et al. (2014) provide feedback on the use of symptom checklists by Primary Care Physicians (PCPs) implementing stratified stepped care in The Netherlands; Hermens et al. (2014) also conducted group interviews involving other healthcare practitioners e.g. mental health nurses, psychologists, social workers and physiotherapists.

In all three studies patients and professionals held mixed views of monitoring. Being monitored was sometimes useful to patients (Parry et al., 2011); PCPs reported that it legitimised treatment decisions and gave structure and focus to patient consultations (Franx et al., 2012). However, patients and professionals also distrusted scores (Franx et al., 2012; Parry et al., 2011) and had issue with the time taken to complete measures (Hermens et al., 2014; Parry et al., 2011). Some patients were uncomfortable being monitored (Parry et al., 2011) and, consistent with the findings of Delgado et al. (2015) and Gellatly (2011), PCPs rated their own judgement of patients' wellbeing over scores on a symptom checklist (Franx et al., 2012). There was also a perception that asking patients to complete a checklist was not in accordance with a PCP's role, albeit more appropriate for others (Franx et al., 2012).

With respect to the decision to end or continue treatment following low-intensity psychotherapy, although Delgado et al. (2015) and Gellatly (2011) provide data to suggest that therapists might struggle to apply pre-defined stepping criteria, healthcare professionals' views of specific criteria have not been explored. Likewise, no data are available for patients. Parry et al. (2011) and Richards et al. (2010) describe patients' views of ending treatment but the point at which patients ended treatment (following low- or high-intensity psychotherapy) is unclear and patients' views of how the decision was made to end treatment are not reported. Other limitations of the data on monitoring and stepping are that: results are based on one study with patients; Hermens et al. (2014) did not specify the measure(s) used; none of the studies conducted by Franx et al. (2012), Hermens et al. (2014) or Parry et al. (2011) clarified exactly how and when checklists were administered. Thus, the extent to which findings will apply to monitoring conducted in other ways is unclear.

### **2.8.5 Evidence on acceptability – summary**

Although a number of studies provide data on what people think of stepped care, the degree to which this system is acceptable to patients and professionals has not yet been fully understood. Studies suggest that low-intensity psychotherapy may indeed be perceived as inappropriate yet some patients also rate minimal interventions positively; negative consequences of unsuccessful low-intensity treatment might occur and be of concern to some professionals; choice may be an issue although exactly how is unclear; views of monitoring are mixed. Data are limited in that findings may not apply to stepped care delivered at the current time and in different ways. Results are also somewhat difficult to interpret and extrapolate and patients' and healthcare professionals' views of key elements of this system e.g. stepping criteria, have not yet been established.

### **2.9 Evidence on how acceptability and attendance might relate**

In addition to research on the acceptability of stepped care, data are available from two studies which allow for the possibility that patients' views of this system might relate to attendance at therapy.



IAPT data reveal that between 14% and 30% of patients who are referred do not attend an assessment and around a quarter of those assessed, offered or who commence treatment drop out or decline further contact (Parry et al., 2011; Richards & Borglin, 2011; Richards & Suckling, 2009). In an investigation of differences between patients who had been referred to the Doncaster and Newham services and subsequently attended vs. not, Di Bona, Saxon, Barkham, Dent-Brown, and Parry (2014) found that people referred to Newham were more likely to attend than those referred to Doncaster. Logistic regression revealed 'site' to be a statistically significant predictor of attendance and the authors concluded that patients' views and opinions of stepped care in the different sites may have had a bearing on attendance (Di Bona et al., 2014).

A key limitation of this work is that analyses were observational with results that are subject to confounding: differences in the attendance of patients at Doncaster and Newham might readily be explained by a variety of factors, unknown or known, such as the socio-demographic or clinical characteristics of sites' local populations and other features of care. Nonetheless it is possible that views of stepped care delivered in different ways might have influenced attendance.

Qualitative research by van Beljouw et al. (2014) also allows for a possible relationship between the acceptability of stepped care and attendance. Qualitative and quantitative data were used to explore barriers and facilitators to the engagement of older adults who scored six or more on the PHQ-9 in a stepped care programme for the treatment of depression. Perceptions of the appropriateness of high-intensity psychological therapy were an important influence on patients' decision to step up; many people did not define themselves as depressed rather emotional distress was viewed as a normal part of ageing. Patients' lack of self-perceived depressive symptoms was decisive to refuse more intensive treatment (van Beljouw et al., 2014). Negative views of intensive psychological therapy appear to have influenced patients' decision to drop-out of stepped care.

Although patient decisions to drop out stemmed from views of high-intensity psychological therapy and not unique features of stepped care such as monitoring, stepping criteria or the offer of low-intensity psychotherapy prior to

the option of high-intensity treatment, results nonetheless suggest that objections to a component of this system could influence patients' decision to end therapy. For other patients and in other settings, it is possible that views of some of the unique features of stepped care might influence patients' attendance. However, to date, no research has focused on the relationship between the acceptability of stepped care and attendance.

Evaluations of IAPT report better clinical outcomes for patients who complete stepped care treatment (Clark et al., 2009; Parry et al., 2011). Thus, if patients' views of stepped care have a bearing on attendance, what people think of this system could have important clinical implications. From an increased understanding of how attendance and acceptability relate, it might be possible to deliver stepped care in ways that anticipate patients' concerns and perhaps help retain patients in treatment. In addition, research on the relationship between acceptability and attendance may help identify patients likely to decline treatment or who are at increased risk of dropping out and might benefit from a different system of treatment allocation.

## **2.10 Evidence on the effect of stepped care in routine clinical practice**

Besides research on the acceptability of stepped care and how acceptability and attendance might relate, several studies provide data on the effects of stepped care in IAPT. Studies report clinical and work-related outcomes for IAPT patients. There has also been a small amount of work to benchmark clinical outcomes with the effects of high-intensity psychological therapy alone.

### **2.10.1 Clinical outcomes**

Clinical outcomes associated with stepped care have been evaluated in Doncaster and Newham – IAPT 'demonstration' sites (Clark et al., 2009; Parry et al., 2011; Richards & Borglin, 2011; Richards & Suckling, 2009) as well as a broader cohort of IAPT services (Department of Health, 2012; Department of Health Mental Health Division Improving Access to Psychological Therapies Programme, 2008; Glover et al., 2010; Gyani et al., 2013).

### ***Doncaster and Newham***

An analysis of the Doncaster and Newham services at the end of their first full year of operation (2006-07) indicated that stepped care is associated with reasonable effect. Among patients who completed treatment, uncontrolled, pre-post treatment effect sizes in terms of depressive symptoms were large: 1.26 (Clark et al., 2009) and 1.39 (Richards & Suckling, 2009) in Doncaster and 1.09 in Newham (Clark et al., 2009). Recovery rates at both sites were also in excess of 50% (Clark et al., 2009).

Favourable effects were also observed based on data collected over two years and using a more stringent assessment of clinical improvement: 41% of patients treated at Doncaster, studied to the point of exit from that service, achieved reliable and clinically significant change; uncontrolled pre-post treatment effect sizes were 1.07 in terms of depressive symptoms (Richards & Borglin, 2011).

Similarly, based on an analysis of Doncaster and Newham over three years (2006-2009), Parry et al. (2011) found that 40% of patients who received treatment achieved reliable and clinically significant change although this proportion fell to 36% among all patients accepted for treatment i.e. assessed and offered treatment but who may or not have received therapy. For patients who completed treatment, recovery rates reported by Parry et al. (2011) of 56% in Doncaster and 66% in Newham, were at least as good as those reported by Clark et al. (2009) for the same sites during year one. Thus, it appears that the clinical effects of stepped care at Doncaster and Newham observed during their first year of operation were maintained.

### ***Other services***

Data on the performance of a broader cohort of IAPT services indicates that stepped care implemented elsewhere has been associated with a similar level of clinical benefit to that observed in Doncaster and Newham. Among eleven 'Pathfinder' sites, uncontrolled pre-post treatment effect sizes for patients treated for depression were 1.25 (Department of Health Mental Health Division Improving Access to Psychological Therapies Programme, 2008) and during the first year of IAPT operation, across 32 services, the recovery rate among

patients treated for depression was 47% (Glover et al., 2010). A report on the first three years of IAPT published by the Department of Health (2012) reported an overall recovery rate for the fourth quarter of 2011-12 of 46%.

Whilst average levels of the effectiveness of stepped care delivered in a larger number of services pointed to good clinical outcomes, data also obscured considerable differences across sites (Glover et al., 2010; Gyani et al., 2013). Among 30 of the 32 services for which effects could be estimated, individual sites' uncontrolled pre-post treatment effect sizes in terms of depressive symptoms ranged from 0.38 to 0.95 (Gyani et al., 2013) and whilst Gyani et al. (2013) identified a small number of service-level characteristics that predicted higher reliable recovery rates (e.g. the use of treatments recommended by NICE and higher rates of stepping) features of stepped care that are associated with more or less effect are not generally well understood.

### **2.10.2 Employment-related benefits**

In addition to the clinical outcomes associated with stepped care delivered in routine practice, four studies provided an indication of effects on employment. Among patients attending Doncaster and Newham in year one, there was a 4% net increase in the number at work and a 10% net decrease in the number of patients receiving Statutory Sick Pay (Clark et al., 2009). Across Pathfinder sites, the number of patients returning to work and off Statutory Sick Pay increased by 16% (Department of Health Mental Health Division Improving Access to Psychological Therapies Programme, 2008). Effects on employment were evident but smaller among the 32 services established in year one of IAPT (Glover et al., 2010). Data published by the Department of Health (2012) on the first three years of IAPT appeared to show an increase, quarter on quarter, in the number of IAPT patients off Statutory Sick Pay and other benefits. Across different services, to a greater or lesser extent, it appears that stepped care has been associated with employment-related patient benefit.

### **2.10.3 Effect in routine clinical practice vs. high-intensity psychological therapy alone**

Whilst clinical and employment-related data indicate that stepped care implemented in routine clinical practice has been associated with good effect, in

no way does this information reveal whether stepped care is as clinically or cost-effective compared with offering patients high-intensity psychological therapy alone.

### ***Stepped care in routine practice vs. trial data on the effectiveness of high-intensity CBT alone***

To help address this question, two IAPT evaluations cited published research on the effectiveness of high-intensity CBT as estimated in randomised controlled trials alongside their primary data on the effectiveness of stepped care in IAPT. Richards and Suckling (2009) reported that the magnitude of the uncontrolled, pre-post-treatment effect size in Doncaster (1.38) was smaller than the effect of high-intensity CBT for depression (1.46) stated in a non-systematic review of CBT trials conducted by Pilling and Burbeck (2006). Likewise, across the first three years of operation, Parry et al. (2011) reported that uncontrolled, pre-post treatment effect sizes in Doncaster and Newham (in the region of 1.3) were smaller than the effect of high-intensity CBT alone (1.49) identified from a non-systematic review of RCTs conducted by the authors.

Findings appeared to indicate that high-intensity CBT alone could be more effective than stepped care however Parry et al. (2011) argued that the modest differences provided very little support for the contention that stepped care is less effective; the magnitude of difference was consistent with the effects of psychological therapies estimated from randomised controlled trials vs. practice-based studies more generally (Barkham et al., 2008).

### ***Stepped care vs. high-intensity psychotherapy alone in routine clinical practice***

The same studies also cited published data on the effectiveness of high-intensity psychological therapy that had been delivered in routine clinical practice. Richards and Suckling (2009) reported that the uncontrolled pre-post treatment effect size in Doncaster following its first year of operation (1.38) was similar to that of high-intensity psychological therapy alone (1.34) in a review of cognitive-behavioural, person-centred and psychodynamic therapies delivered in UK primary care by Stiles, Barkham, Mellor-Clark, and Connell (2008). Similarly, Parry et al. (2011) cited data to suggest that recovery rates for

Doncaster and Newham in their first three years of operation fell within the 95% confidence interval of rates for patients with similar symptom severity seen at 24 NHS sites delivering pre-IAPT primary care services. Together, these studies provide a small amount of evidence to suggest that stepped care and intensive psychological therapies implemented in routine clinical practice might achieve similar effects.

***The cost-effectiveness of stepped care and high-intensity psychological therapy alone in routine practice***

In terms of the cost-effectiveness of stepped care compared with intensive psychological treatment alone, Parry et al. (2011) reported data on the cost of treatment and clinical outcomes for patients recruited from General Practices in Doncaster vs. patients recruited from GP practices in matched comparator sites - Wakefield and Barnsley. Although details of the treatments offered and received in Wakefield and Barnsley were not described, it may be reasonable to assume that they operated traditionally configured psychological therapy services. If this is correct, data on Doncaster, Wakefield and Barnsley represent data on the cost-effectiveness of stepped care and high-intensity psychological therapy alone in routine clinical practice.

When Doncaster was compared to Wakefield and Barnsley, the incremental cost effectiveness ratio (ICER) was £37,571 per QALY. This was calculated using the Short Form-6 dimensions (SF-6D) (Ware & Sherbourne, 1992). In a sensitivity analysis based on 'predicted' EQ-5D values – a metric preferred by NICE for measuring health states – the ICER was £20,230 per QALY gained (Parry et al., 2011). The latter ICER falls within a decision-maker willingness to pay threshold of £20,000-£30,000 adopted by NICE (Parry et al., 2011) indicating that stepped care may be cost-effective compared with 'traditional care'.

However, limitations of the analysis include that it was substantially under-powered. Moreover, comparisons between participants' PHQ-9 scores collected for this study and post-treatment scores in the larger cohort of Doncaster patients used by Parry et al. (2011) indicated that improvements for the cost-effectiveness evaluation may have been underestimated by up to 20% (Parry et al., 2011). As such, results do not provide credible evidence on the

cost-effectiveness of stepped care and that of high-intensity psychological therapy alone in routine clinical practice.

#### **2.10.4 Effect in routine clinical practice – summary**

IAPT service evaluations provide evidence of the ‘real life’ effectiveness of stepped care that has been implemented in routine clinical practice (Richards & Suckling, 2009). Collectively, they have found that stepped care is associated with favourable clinical and employment-related outcomes across a range of services and over a number of years. However, services have varied in their performance and, despite a small amount of research on elements of stepped care that may be associated with more or less effect, optimal and sub-optimal components of this system are not yet well understood. In terms of how stepped care and high-intensity psychological therapy alone compare, data is available to suggest that both are associated with good outcomes delivered in routine clinical practice but no credible evidence has been collected on the cost-effectiveness of stepped care and more high-intensity psychotherapy.

#### **2.11 Key limitations of evidence on the effect of stepped care in IAPT**

IAPT service evaluations provide a large body of data on the effects of stepped care in routine clinical practice. They are also an example of observational cohort studies: using routinely collected outcome data, authors observed how depressive symptoms changed among patients who received stepped care in IAPT. A key limitation of such studies is that they do not establish causality. Although the evaluations might provide an indication of the effects of stepped care delivered in routine clinical practice, outcomes cannot be reliably attributed to that system; the direction and magnitude of effects may be due to other factors (confounders).

The presence of confounding undermines the degree to which the data can be thought of as a valid estimate of the effect of stepped care on the patients under study. Moreover, where confounders influence pre- and / or post-test data in ways that result in an under- or over-estimate of the difference between the two, outcomes are biased. Sources of bias are commonly classified in terms of: (i) selection, (ii) performance, (iii) attrition, and (iv) measurement (Higgins & Altman, 2008). Together with the role for ‘spontaneous remission’ and

'regression to the mean', risk of bias threatens the internal validity of observational cohort studies such that the effects of stepped care on IAPT study participants cannot be reliably attributed to stepped care.

### **2.11.1 Spontaneous remission**

Many illnesses, including depression, tend to be self-limiting and left un-treated a proportion of patients will recover from any one episode. From meta-regression incorporating the results of 19 studies, it has been estimated that without intervention 23% of patients will remit within three months, 32% within six months and 53% within 12 months (Whiteford et al., 2013). Across all of the IAPT evaluations, the role for natural recovery will have influenced outcomes and, in observational cohort studies, it is not possible to disentangle these temporal effects from that of the intervention.

### **2.11.2 Regression to the mean**

The role for natural recovery can be exaggerated by the statistical phenomenon of regression to the mean which occurs when there is measurement error. When a group of people is assessed on a dimension and then re-assessed, individuals with 'extreme' scores on the first assessment will tend to score closer to the mean on the second (Torgerson & Torgerson, 2008). This is because high levels of error in the measurement of extreme scores mean that, by chance, when someone is re-assessed, their second score will move closer towards his or her 'true' state. In a group of people purposively selected for their high (or low) scores, this phenomenon will produce apparent improvement without any intervention. In studies of IAPT patients, most of whom are likely to have presented with relatively high scores on the PHQ-9 (or GAD-7) that is itself, to a degree, unreliable (McMillan, Gilbody, & Richards, 2010), regression to the mean will confound estimates of the effect of stepped care.

### **2.11.3 Selection bias**

In a study of two groups, selection bias refers to systematic differences in the baseline characteristics of each group that could help to explain differences in the effects of treatment (Higgins & Altman, 2008). In an observational cohort study, threats to internal validity might arise if participants' characteristics differ systematically before and after treatment. Circumstances in which this might



apply may not be obvious or thought likely and, perhaps for this reason, authors of IAPT evaluations have tended to focus on threats to external validity in terms of selection i.e. the degree to which participants' characteristics mean that results generalise.

However, sources of confounding can be 'known' and 'unknown' and it is possible that the circumstances of IAPT patients may have changed during treatment in ways that could have a bearing on outcome but that may not be thought important. Prognostic and prescriptive variables predict differential treatment outcomes for individuals with depression. Some of the predictor variables are (potentially) transient e.g. marriage, employment and number of recent life events (Fournier et al., 2009). Moreover, combinations of those variables (rather than any single predictor) are likely to have a bearing on treatment outcomes (DeRubeis et al., 2014). Yet our understanding of how variables combine is in its infancy and we have a limited understanding of individual patient characteristics that predict treatment response (Cuijpers, Reynolds, et al., 2012). As such, it may not be possible for us to spot potentially important changes in people's circumstances which, if experienced by 'enough' participants, could confound treatment outcomes for the sample as a whole, yet confounding would still occur. In the IAPT evaluations, selection bias remains a threat to internal validity although we may not be able to identify how.

#### **2.11.4 Performance bias**

Performance bias is defined as a threat to validity that arises from the way in which care is delivered to patients other than as part of the intervention (Higgins & Altman, 2008). Sources of performance bias are also not discussed by the authors of IAPT evaluations but could include the prescription of antidepressant medication, other care provided by patients' GPs and alternative forms of support or therapy accessed by patients - via employers or paid for privately, for example. IAPT patients' clinical and employment-related outcomes could be affected by any additional care that they may have received.

### **2.11.5 Attrition bias**

The significance of missing data (levels of attrition) on estimates of the effect in IAPT was explored by Clark et al. (2009). By comparing clinical outcomes in different sub-samples, Clark et al. (2009) found that effect sizes for patients with complete pre- and post-treatment data were larger than for patients with partially complete data. Moreover, patients with complete data received more therapy than those without (Clark et al., 2009). The authors therefore concluded that patients without post-treatment data would probably have worse outcomes than patients with post-treatment data. Accepting this, levels of attrition are likely to bias estimates of the effect of stepped care in IAPT.

### **2.11.6 Measurement bias**

The way in which treatment-related outcomes are assessed is another source of potential bias. None of the IAPT evaluations used standardised diagnostic interviews to establish the presence or absence of depression. Studies varied in the degree to which the metrics used took account of inherent unreliability of symptom measurement on the PHQ-9. Clark et al. (2009) and Richards and Suckling (2009) reported recovery rates; other studies utilised reliable and clinically significant change criteria (Parry et al., 2011; Richards & Borglin, 2011). Moreover, a risk of measurement bias arose from the collection of outcome data by staff as part of their everyday clinical work rather than by independent assessors – a point noted by Richards and Borglin (2011). Estimates of the effect of stepped care in IAPT may have been biased by the way in which treatment outcomes were assessed.

### **2.11.7 Comparison of stepped care vs. high-intensity therapy alone**

For being at high risk of bias, evaluations of IAPT do not prove, categorically, that stepped care delivers favourable outcomes. In this regard, the data are limited. In one other key respect, the data are also limited: none of the evaluations directly compared stepped care with high-intensity psychological therapy alone. Parry et al. (2011) and Richards and Suckling (2009) cited published data on the effects of high-intensity psychotherapy from randomised controlled trials and routine clinical practice. However, differences or similarities between the published data and the results of their primary data analysis are

not a robust indication of the difference between stepped care and high-intensity psychotherapy. In the same way that observational cohort studies are at risk of confounding, differences between studies might be explained by many factors other than treatment received e.g. sample characteristics, how outcomes were assessed and levels of attrition. Without a direct comparison of the effect of stepped care vs. high-intensity psychological therapy alone that is at low risk of bias and therefore internally valid, we cannot conclude, with certainty, whether stepped care achieves similar patient benefit for less cost than traditionally configured systems of depression treatment.

## **2.12 Implications for future research**

Over a decade ago, Bower and Gilbody (2005b) argued that a randomised controlled trial (RCT) of stepped care compared with high-intensity psychological therapy alone was required to establish the relative clinical and cost-effectiveness of these systems.

### **2.12.1 The need for a randomised controlled trial**

The essence of an RCT is the *random allocation* of individuals (or groups) of people into two (or more) groups. The major strength of random allocation is that it is the best method available for dealing with selection bias, regression to the mean and temporal changes (Torgerson & Torgerson, 2008). In a large enough trial, provided that investigators enrolling participants cannot see the sequence in which participants will be allocated to different groups, random allocation will produce groups that, on average, have the same characteristics as each other (Schulz, Chalmers, Grimes, & Altman, 1994; Schulz, Chalmers, Hayes, & Altman, 1995). Known characteristics of patients that could affect outcome will be present in both groups without bias and unknown characteristics that could affect outcome will also be unbiasedly present in both groups. The equal presence of all patient characteristics that could affect outcome in both groups will cancel out their effects in analysis. Likewise, through random allocation, the role for temporal change and regression to the mean will also be equally present in each group and their effects will similarly cancel out in analysis. Thus, in a large enough RCT, we can be confident that any differences observed between groups are due to the effect of the

intervention or, depending on the nature of the control group, the relative difference in the effect of two interventions.

Based on a well-conducted RCT to compare patients randomly allocated to stepped care vs. high-intensity psychological therapy alone, we could be confident that differences in the outcomes associated with each were due to the effect of the interventions. A large RCT would establish the clinical effectiveness of stepped care vs. high-intensity psychological therapy alone, with certainty, and by incorporating established methods for the estimation of the relative costs and benefits of complex interventions (Drummond, Sculpher, Torrance, O'Brien, & Stoddart, 2005), it would also be possible to understand whether stepped care offers added value, and hence potential to genuinely increase access to treatment, relative to the system it was designed to replace.

### **2.12.2 The need for a systematic review**

The most reliable means to establish whether an RCT of stepped care vs. high-intensity psychological therapy alone has already been undertaken is a systematic review. A systematic review attempts to collate all of the relevant empirical evidence on an intervention and, by using explicit, systematic methods, provides a reliable estimate of its effects on which to base defensible conclusions and make decisions (Antman, Lau, Kupelnick, Mosteller, & Chalmers, 1992; Oxman & Guyatt, 1993). Five key features of a systematic review (S. Green et al., 2008) are:

- A clearly stated set of objectives with pre-defined eligibility criteria for including studies
- An explicit and reproducible methodology
- A systematic search that attempts to identify all studies that would meet eligibility criteria
- An assessment of the internal validity of the included studies
- A systematic presentation and synthesis of the included studies' characteristics and results

Bower and Gilbody's (2005b) recommendation to undertake an RCT of stepped care compared with high-intensity psychological therapy alone was based on a narrative review of the literature conducted over ten years ago. Since then,

several RCTs of stepped care have been undertaken (Davidson et al., 2013; Ell et al., 2010; Seekles, van Straten, Beekman, van Marwijk, & Cuijpers, 2011; van Dijk et al., 2013). Yet an initial search in the *Cochrane Database of Systematic Reviews* (CDSR) and *Database of Abstracts of Reviews of Effectiveness* (DARE) found no systematic review of stepped care as the primary intervention against which other systems for the allocation of depression treatment were compared. Without a systematic review, we cannot establish, with confidence, whether a large trial of stepped care vs. high intensity therapy alone has been conducted.

Performing a systematic review of RCTs on the effectiveness of stepped care treatment for depression in adults would clarify if such a trial exists but would also provide an opportunity to appraise and synthesise all of the relevant RCTs on stepped care. Although randomised controlled trials represent the 'gold standard' method for drawing causal inference, individual RCTs can be methodologically flawed, time and context dependent, inadequately reported and biased (Moher et al., 2010; P. Wilson, Petticrew, Calnan, & Nazareth, 2008). Individual studies can also reach conflicting conclusions, sometimes simply by chance (Centre for Reviews and Dissemination, 2008). If appropriate, combining the results of studies on stepped care in a meta-analysis as part of a systematic review and doing so using methods that reflect the quality of included studies will provide a more reliable and precise estimate of the effectiveness of this system than would be possible from any one study alone (L'Abbe, Detsky, & O'Rourke, 1987; Oxman, 1993; Sacks, Berrier, Reitman, Ancona-Berk, & Chalmers, 1987). A systematic review and meta-analysis of stepped care can establish if the existing evidence base as a whole is sufficient to determine whether stepped care is equivalent to long term, high-intensity psychological therapy for all.

Meta-analysis would also facilitate an exploration of differences across studies (Deeks, Higgins, & Altman, 2008; S. Green et al., 2008). If a sufficient number of studies were available, by looking at the results of different groups of those studies, it would be possible to explore ways in which stepped care has been implemented that may be associated with more or less effect.

### **2.12.3 The need for a mixed methods feasibility study**

If the results of a systematic review reveal that the effectiveness of stepped care compared with high-intensity psychological therapy alone has not been established, a fully-powered RCT of stepped care vs. high-intensity psychological therapy will be required. However, to maximise the success of such a trial and help ensure resource is not wasted on an evaluation which produces an invalid result, it would first be important to conduct a feasibility study (Giangregorio & Thabane, 2015; Thabane et al., 2010).

Feasibility studies are an opportunity to gather information on potential problems that might compromise the success of a main evaluation and to collect information to inform study design (Giangregorio & Thabane, 2015). The terms 'feasibility study' and 'pilot study' are often used synonymously. Where they are defined as distinct entities (Arain, Campbell, Cooper, & Lancaster, 2010), feasibility studies refer to research done before a main study that is used to gather key pieces of information needed to design the main study. Feasibility research questions usually centre around discrete study processes for example on recruitment or retention although feasibility studies need not involve a randomised controlled trial (Arain et al., 2010). On the other hand, the term 'pilot study' is used to refer to a mini version of the main study to test whether all of the components of that study will work together; conducted in anticipation of a large RCT, it will employ the same design as the main trial (Arain et al., 2010). Together, these types of studies have a similar aim to inform the development and conduct of a planned research project.

Feasibility and pilot studies can be very useful to prepare for trials of complex interventions that present additional complexity in design and procedures compared with the evaluation of a sole pharmacological agent (Giangregorio & Thabane, 2015). In support of the importance of this phase of work, the UK Medical Research Council guidance on the development and evaluation of complex interventions recommends a stage of 'feasibility and piloting' prior to full evaluation (Craig et al., 2008). Undertaken in anticipation of a large trial of a complex intervention, areas of uncertainty that feasibility studies can address include clinical, methodological and procedural (Giangregorio & Thabane, 2015).

In terms of a feasibility study on stepped care, this chapter has highlighted our lack of understanding of the acceptability of this system but also its relationship with therapeutic attendance. Thus, alongside methodological and procedural aspects of a large stepped care trial about which we may be uncertain, it will be important to test the acceptability of the intervention and how this might relate to the number of therapy sessions trial participants attend. In this regard, qualitative but also mixed methods can be used to make an important contribution to addressing clinical uncertainties. Moreover, by successfully completing a feasibility study that involves a pilot trial of stepped care vs. high-intensity psychological therapy alone, it will be possible to determine if a fully-powered evaluation of the same can be done. A mixed methods feasibility study will provide all of the information required to design a large trial and improve the chances that the main trial will achieve its objectives so that valid inferences can be made about the clinical and cost-effectiveness of stepped care compared with traditionally configured systems for the provision of psychological therapies.

### **2.13 PhD programme of work**

In response to the need for research on stepped care, the purpose of my PhD has been to pursue a programme of work that will advance our understanding of the effectiveness and acceptability of this system for the treatment of depression in adults.

This programme of work has comprised: (1) a systematic review of existing evidence on the effectiveness of stepped care treatment for depression and (2) a mixed methods feasibility study incorporating a pilot trial of stepped care vs. high-intensity psychological therapy alone for the treatment of depression in adults plus in-depth, semi-structured interviews to explore what trial participants think of stepped care. Techniques for integrated mixed methods analysis have also been used to investigate how patients' views of the intervention and therapeutic attendance might relate.

### **2.13.1 Systematic review**

The aim of the systematic review of stepped care was to assess the clinical effectiveness of stepped care for the treatment for depression in adults.

Specific objectives were to:

- (1) determine whether existing evidence is sufficient to conclude, with confidence, that stepped care is equivalent to high-intensity psychological therapy for all;
- (2) investigate heterogeneity in trial findings by exploring aspects of study design and elements of the intervention that may be associated with more or less effect.

From a non-systematic reading of the available literature, it was thought unlikely that the effectiveness of stepped care compared with high-intensity psychological therapy alone for depression had been reliably established.

Whilst a systematic review and meta-analysis was required to establish this with certainty, a mixed methods feasibility study was planned (and subsequently undertaken) to prepare for a fully-powered randomised controlled trial of stepped care vs. high-intensity psychological therapy alone.

### **2.13.2 Feasibility study**

The aim of the mixed methods feasibility study was to provide information to inform the design of a large randomised controlled trial that will evaluate the clinical and cost-effectiveness of stepped care vs. high-intensity psychotherapy alone for the treatment of depression in adults. Specific objectives of the mixed methods feasibility study were to:

- (1) gather enough information on recruitment, retention, the proportion of patients who step up from low- to high-intensity psychological therapy and treatment effects to design a fully-powered clinical trial or to determine that such a trial is not feasible;
- (2) explore patients' and therapists' views of stepped care and the ways in which patients' views relate to how much they engage in therapy to inform a stepped care clinical protocol for the main study.



### **2.13.3 A brief summary of anticipated impact**

Together, the results of the systematic review and mixed methods feasibility study will provide new knowledge on stepped care and its evidence base that will inform future programmatic research on this system. Results are also likely to be of immediate interest to those involved in the design and delivery of current stepped care services for depression treatment. If used successfully, the innovative application of techniques for integrated mixed methods analysis will demonstrate new and systematic ways in which such techniques can be used to combine quantitative and qualitative data with rigour to address important research questions in the development and evaluation of complex interventions.

## **CHAPTER 3. METHODOLOGICAL FRAMEWORK**

Chapter Two set out the need for a programme of research on stepped care treatment for depression and ended with an outline of my doctoral studies, specifically, a systematic review and mixed methods feasibility study. Before describing these studies in full (see Chapters Four to Six) this chapter sets out the methodological framework and philosophy that underpin my doctoral research.

The chapter is organised into four main sections. Evidence-based medicine and the need for experimental research are described in section 3.1. This is followed by a summary of the Medical Research Council framework for the development and evaluation of complex interventions in section 3.2. In the third section (3.3), I consider the value of mixed methods in health services research. The chapter finishes with a description of the philosophy of pragmatism that underpins my doctoral studies (section 3.4).

### **3.1 Evidence-based medicine**

By the beginning of the 20<sup>th</sup> century, medicine had started to differentiate between successful interventions (e.g. vaccination and antiseptic surgery) and those of less certain benefit (Spring, 2007). Based on this differentiation, the concept of evidence-based medicine (EBM) began to take shape (Spring, 2007). Initial attention focused on increasing advocacy for and control over medical training. Several decades later, towards the end of the 1900's, a faculty group was established at McMaster University, Canada, with significant interest in clinical epidemiology - the study of the determinants and consequences of health care decisions. This group has been credited with a pivotal role in the modern development of EBM (Spring, 2007).

#### **3.1.1 Defining evidence-based medicine**

David Sackett, a key member of the McMaster group, defined evidence-based medicine as:

*“The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual*

*patients,*” (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996) p 71.

Based on this definition, clinical decision making involves integrating individual healthcare professionals’ expertise with the best available evidence from systematic research (Sackett et al., 1996). ‘Clinical expertise’ is described as the “proficiency and judgment” (p 71) that clinicians acquire from experience and clinical practice; ‘best available evidence’ entails clinically relevant research, especially research into diagnostic tests, prognostic indicators and the efficacy and safety of health care interventions (Sackett et al., 1996). Sackett, Richardson, Rosenberg, and Haynes (1997) also advocated that the practice of EBM should involve clinicians acquiring skills that allow them to convert their information needs into answerable questions; to find, as efficiently as possible, the best evidence with which to address them; and to critically appraise and apply that evidence before evaluating the outcome. Defined as such, EBM represents a way of practising medicine for which clinicians were encouraged to acquire skills that would allow them to change their way of working for the duration of their careers.

Although the role of patients was not obviously demarcated in Sackett et al.’s (1996) definition of EBM, in their description of what it entailed, the authors emphasised the need to consider patients. Clinical expertise was said to manifest in the, “Thoughtful identification and compassionate use of individual patients’ predicaments, rights and preferences in making clinical decisions,” (p 71); patient-centred research was given credence as a source of ‘best available evidence’ (Sackett et al., 1996). In 2001, the U.S. Institute of Medicine adopted a modified definition that gave more prominence to patients. EBM was defined as, “The integration of best research evidence with clinical expertise and patients values,” (Institute of Medicine, 2001a) (p 147). Similarly, in a statement by the American Psychological Association (APA), evidence-based practice (EBP) was defined as, “The integration of the best available research with clinical expertise in the context of patient characteristics, culture and preferences (A. P. A. Presidential Task Force on Evidence-Based Practice, 2006) (p 273).

Thus, today, in recognition of the role of patients alongside that of evidence and clinical experience, EBP is typically denoted by three overlapping circles (Figure 1). Clinical decision making is made by tying together or integrating information from each (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2013; Spring, 2007).

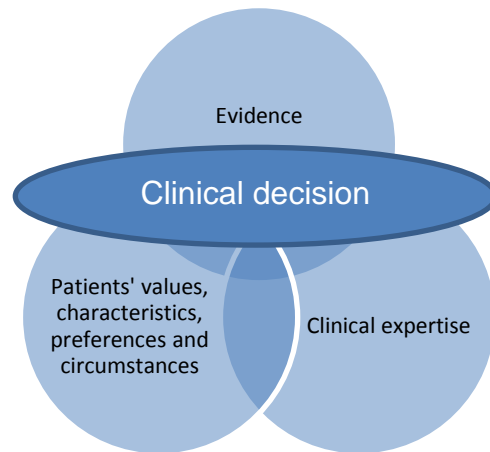


Figure 1. The 'three-legged stool' of evidence based practice – adapted from Spring (2007)

### 3.1.2 The evolving role of patients in evidence-based medicine

Although changing definitions of EBM have made the role of patients more explicit, other recent developments in how patients utilise and are involved in research also shape the meaning of EBP. In 1996, Sackett et al. described clinicians as responsible for sensitively enquiring about and coming to understand individual patients' circumstances and preferences which they should allow for when reaching a clinical decision (Sackett et al., 1996). In contrast, in *'Testing treatments'*, Evans, Thornton, Chalmers, and Glasziou (2011) strongly encourage patients to proactively, "Raise concerns, questions and what's important to them; recognise that they have a right to be equal participants in their care; seek and use high quality health information" (p159). The description of patient involvement in EBP in these two statements is representative of a move away from a model of 'medical paternalism', where a doctor (or other healthcare professional) ultimately remains responsible for evidence-based clinical decision making albeit considering and encouraging patients to share their needs, to a model of shared decision making (Thornton, 2009) in which patients as well as clinicians track down, discuss and use evidence to help make decisions together. Thus, the interface between patients

and clinicians but also patients and evidence is altering in ways that are significant and see patients as well as clinicians using research for mutually agreed benefit.

Patient involvement in EBP has also evolved in one other key respect. The critical importance of actively involving patients (and the public) in research has been recognised and supported by the emergence of relatively new infrastructure and guidance. The James Lind Alliance (<http://www.lindalliance.org>) brings patients, carers and clinicians together on an equal footing to jointly identify priorities for research (Partridge & Scadding, 2004); how to involve lay members and good practices for doing so is the subject of helpful guidance from INVOLVE (<http://www.invo.org.uk>); in the UK, the National Institute for Health Research will not grant funding for research unless there is a programme of patient and public involvement (PPI) built into the research programme (National Institute for Health Research, 2016; Richards, 2015b). New methods for patients and researchers to work together are developing across the whole spectrum of research activities including formulating research questions, study design and the analysis and interpretation of research findings (Evans et al., 2011). In these ways, not only are patients seeking out and using evidence to help inform healthcare decisions made in conjunction with their clinician, they are also involved in the generation of evidence.

### **3.1.3 Why evidence matters**

The need for research to inform clinical decision-making stems from uncertainty that arises in the absence of robust evidence regarding which treatments are effective or which treatments might be best for which patients. Without research, rarely are benefits and harms of a potential intervention so clear that there is no room for doubt; most treatments do not have dramatic effects (Evans et al., 2011). Rather, the degree to which an intervention is effective and for whom it may work is usually uncertain.

Furthermore, as noted in chapter two (section 2.11) in the absence of robust research, patients' apparent response to treatment cannot be reliably attributed to an intervention. Diseases improve or resolve without intervention; people get better by believing in their treatment; other temporal changes occur (Evans et

al., 2011; Lilienfeld et al., 2013; Torgerson & Torgerson, 2008) e.g. children acquire new skills and understanding through maturity (Torgerson & Torgerson, 2008). Other factors, that may be unrelated to treatment, such as increased social support, can also generate gains (Lilienfeld et al., 2013). Without sufficient evidence, it is not possible therefore to disentangle the effects of an intervention from other explanations of why people improve: positive gains in patients' health and wellbeing are liable to be misattributed to treatment.

Difficulty making sense of the effects of treatments in the absence of robust research is evident in the use of treatments which are believed to be both safe and beneficial but that cause harm or are ineffective. Evans et al. (2011) provide a number of examples. Following World War II, an epidemic of 'blindness' among premature babies was found to be associated with the way supplemental oxygen had come to be used in their management (Silverman, 1985); in the 1950s, a form of synthetic oestrogen called diethylstilboestrol (DES) that had been prescribed to help pregnant women who had previously had miscarriages and stillbirths, was found to be ineffective (Chalmers, 1989) – twenty years later, evidence emerged of an increased frequency of rare cancers in both men and women who had been exposed to DES before they were born (Ulfelder, 1980). In each example, treatments for which there was insufficient research caused harm or were ineffective.

Taken together, errors in the attribution of cause and effect and the cost to individuals and societies when interventions are implemented without good quality research on their benefits and harms, speak to the need for high quality evidence to inform clinical decision making.

### **3.1.4 The need for experimental research**

Descriptions of EBP emphasise that it involves drawing on the most appropriate evidence to address a given uncertainty (A. P. A. Presidential Task Force on Evidence-Based Practice, 2006; Sackett et al., 1996; Spring, 2007). Qualitative studies are used to elicit people's views and opinions of a disease and / or treatment; public health and ethnographic research can track the availability and utilisation of treatments; process evaluations can help to identify mechanisms and moderators of treatment effects (A. P. A. Presidential Task Force on Evidence-Based Practice, 2006). However, to answer questions about

treatment efficacy (the ability of a treatment to work in ideal circumstances) and effectiveness (the degree to which a treatment works in practice), experimental research is needed that has the potential to provide credible information which can be trusted to inform clinical decision-making.

As described in chapter two, the key benefit of experimental research - in which one or more factors is deliberately (or experimentally) manipulated - is that, relative to other forms of research, it has potential to establish causality with greater certainty. Observational cohort studies that compare similar groups of patients who have received different treatments in the same timeframe and historical comparisons which investigate outcomes for patients who have received different treatments over different timeframes are more susceptible to selection and other biases (see section 2.11).

In terms of different experimental approaches, randomised controlled trials (RCTs) comprise our most robust method for assessing treatment effects (Collins & MacMahon, 2001; Eccles, Grimshaw, Campbell, & Ramsay, 2003; Torgerson & Torgerson, 2008). As previously argued (in section 2.12.1) in a large and well conducted RCT, allocation of individuals to two or more groups at random will produce groups that have, on average, the same characteristics as each other (Torgerson & Torgerson, 2008). Known but also unknown and therefore unmeasured patient characteristics that might rival treatment as an explanation of effect, will be evenly distributed across groups (Torgerson & Torgerson, 2008). The presence of all such variables that could affect outcome (including people's experience of spontaneous remission, placebo effects and other temporal changes) will be present without bias in all groups and the effects of such characteristics will be cancelled out in analysis (Torgerson & Torgerson, 2008). In this way, large and well conducted RCTs make it possible to arrive at healthcare decisions based on information that can be trusted to represent the effect of treatment.

### **3.2 The development and evaluation of complex interventions**

In the last fifteen years, EBP encompassing a recognition of the requirement for experimental research, has gained increasing traction outside of medicine in fields including education, social work, psychology, and public health (Lilienfeld

et al., 2013). Across all fields, options for intervening in people's lives for better health and quality of life are examples of so called 'complex interventions'.

Interventions can be complex in terms of different parameters (Richards, 2015a). The Medical Research Council (Campbell et al., 2000; Craig et al., 2008) emphasise characteristics of the intervention itself by suggesting that complex interventions comprise a number of components that may act dependently and / or inter-dependently to achieve effect; the greater the difficulty defining what the 'active ingredients' are and how they relate, the greater the likelihood that the intervention is complex (Campbell et al., 2000). Others define complexity with respect to the context in which an intervention is implemented and how an intervention might be implemented (Anderson et al., 2013; Datta & Petticrew, 2013). On whichever respect definitions focus, complex interventions present a number of challenges in terms of generating high quality research to inform decision-making (Craig et al., 2008; Richards, 2015a).

### **3.2.1 The MRC framework**

In response to such challenges, in 2000, the UK Medical Research Council (MRC) published a framework for researchers on how to investigate the effects of complex interventions (Campbell et al., 2000). This document was subsequently updated (Craig et al., 2008) and the MRC framework has been widely used as tool for helping the research community improve the quality and value of complex interventions' research. Guidance covers four stages of research: develop, test, evaluate and implement.

#### **Develop**

The goal of the first stage of the MRC framework is to develop an intervention to the point where it can be reasonably expected to be effective (Craig et al., 2008). This involves acquiring a secure knowledge of the existing evidence for the intervention, becoming clear about its theoretical base, being able to describe how it will be implemented, and modelling in order to be sufficiently convinced that, should the intervention be proven effective, it will be adopted by those for whom it is intended. At this stage, there is also an ethical and scientific imperative to establish whether further research is required at all and,



for this, relevant prior research must be properly identified (Robinson & Goodman, 2011).

## **Test**

Once adequate development work has been undertaken, an intervention can then be evaluated. However there may be a number of uncertainties that have the potential to undermine the success of the evaluation if they are not addressed (Richards, 2015a) – see Chapter Two, section 2.12.3. These uncertainties often concern the feasibility of potential research methods and procedures and the degree to which an intervention is acceptable to the people who will deliver and receive it (Richards, 2015a). Conducted prior to the main evaluation, feasibility testing and piloting encourages methodological rigour (Lancaster, Dodd, & Williamson, 2004) and can enhance the likelihood of success of the main evaluation (Thabane et al., 2010).

## **Evaluate**

In the evaluation stage of the MRC framework, the main aim is to establish *causality* i.e. the link between the intervention and effect (Richards, 2015a). Minimising bias is critical and possible to achieve through randomisation. Nonetheless, in circumstances where randomisation may not be possible, criteria are available to help researchers consider other methods by which they can establish causality beyond reasonable doubt (A. B. Hill, 1965; Howick, Glasziou, & Aronson, 2009). In parallel to the main evaluation, the 2008 guidance also recommends that two other forms of investigation are conducted – process and economic evaluations (Craig et al., 2008). A process evaluation is designed to identify for whom, in what circumstances and how an intervention ‘works’ (Moore et al., 2014); health economists have developed ways of estimating the economic value of treatments to individuals so that the benefits and costs of different interventions can be compared (Bowling, 2005; Elliot & Payne, 2005).

## **Implement**

In the last phase of the MRC framework, three forms of activity are suggested to help the results of evaluative studies translate into routine practice: (1) active dissemination of research findings; (2) ‘implementation research’ - focused on

how to successfully embed an intervention in routine practice; and (3) long-term follow-up and monitoring to identify the actual effects of an intervention in practice plus any unanticipated consequences (Craig et al., 2008). In the last decade or so, the implementation of complex interventions and with it, the need for implementation research, has received increasing attention (van Achterberg, 2015). Strategic and systematic approaches to the identification of factors that facilitate and hinder the adoption of interventions have been developed (Helfrich, Li, Sharp, & Sales, 2009; May et al., 2009; McCormack, McCarthy, Wright, Slater, & Coffey, 2009). In addition, methods for implementing interventions have themselves become the subject of a scientific approach (Boaz, Baeza, Fraser, & for the European Implementation Score Collaborative Group (EIS), 2011).

In practice, developing, testing, evaluating and conducting implementation research into complex interventions can take a very wide range of different forms. Moreover, despite the linear description of the MRC framework provided above, the order in which different stages of the process is undertaken is flexible and the stages, as summarised, are not necessarily discrete. Nonetheless, implemented in a variety of ways, by providing guidance to help researchers, the MRC framework has potential to support a better standard of research on the development and evaluation of complex interventions.

### **3.2.2 Implications for research on stepped care**

Stepped care typifies a complex intervention. As a system for the organisation of depression treatment, it contains several interacting components. At the 'highest' level these include low-intensity psychological therapy, a means to decide who 'steps up', high-intensity psychological therapy and the contribution of one or more therapists. Stepped care is also implemented in diverse ways for different patient groups (Glover et al., 2010; Richards et al., 2012; Richards et al., 2010) and it is probable that the anticipated effects of stepped care will be modified by patient characteristics. Thus, as a complex intervention, the MRC framework is available to inform the development and evaluation of this system for the allocation of depression treatment and, in response to the need for research described in chapter two, the MRC framework was used to guide my PhD programme of work

This programme of work covered two stages of the MRC framework: development and testing. With respect to development, study one entailed a systematic review of the effectiveness of stepped care. This was designed to avoid research waste and un-necessary burden on patients by ascertaining the need for further research on stepped care, specifically, whether a fully-powered RCT of this system vs. high-intensity psychological therapy alone was required. Other development work (e.g. to establish, as far as possible, whether the intervention was likely to be effective and modelling to help ensure that, if proven effective, the intervention could be implemented) was not undertaken for two main reasons: (1) at the beginning of my PhD, various forms of stepped care were already widely implemented; (2) the favourable effects of low- and high-intensity variants of Cognitive Behaviour Therapy (CBT) that would comprise the key therapeutic components of the stepped care intervention to be tested in study two had been convincingly demonstrated (Cuijpers, Berking, et al., 2013; Cuijpers, Hollon, et al., 2013; National Institute for Health and Care Excellence, 2009b). With finite resource available, study two was therefore designed to test key methodological, procedural and clinical uncertainties associated with the conduct of a fully-powered evaluation of stepped care vs. high-intensity CBT. Given the existing evidence base for and widespread use of high-intensity CBT for depression, this work did not include research to enhance the control intervention.

### **3.3 Mixed methods for complex interventions**

As noted, my PhD studies comprised: (1) a systematic review of the effectiveness of stepped care and (2) a mixed methods feasibility study to prepare for a large RCT. The mixed methods study incorporated a pilot trial and semi-structured interviews.

#### **3.3.1 Defining mixed methods research**

Studies that incorporate more than one type of method have been published from the late 1950's. However, in the late 1980s, there was a more systematic attempt to develop 'mixed methods' as a distinct approach to research (Creswell & Plano Clark, 2011). Authors from different disciplines considered how to link, combine and integrate quantitative and qualitative data and several definitions of mixed methods research were proposed.

Tashakkori and Teddlie (1998) provided an early and straightforward definition of mixed methods as the combination of, “Qualitative and quantitative approaches in the methodology of a study,” (p ix). Others have similarly focused on the use of both quantitative and qualitative methods but also emphasise how different data types might be combined (‘mixed’ or ‘folded together’) as well as the world view or philosophy that underpins data collection and analysis. This is illustrated by Creswell and Plano Clark (2007) who have defined mixed methods as, “A research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches... As a method, it focuses on collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies...” (p 5).

### **3.3.2 Types of mixed methods research**

In practice mixed methods are employed in a range of different forms and alongside attempts to define mixed methods, several approaches have been developed for characterising or classifying the design of mixed methods studies (Creswell, Plano Clark, Gutmann, & Hanson, 2003). One such approach by Creswell and Plano Clark (2011) offers six prototypes which differ according to: the order in which qualitative and quantitative elements of work are undertaken; the relative priority of each – which, if either, of the qualitative or quantitative strand is given precedence; and for what purpose and at what point the quantitative and qualitative elements are integrated – during data collection, analysis or the interpretation of results only. Two of the prototypes are the ‘embedded’ and ‘multi-phase’ designs.

In the embedded design, one type of data is given priority while the other is used mainly in a supportive capacity. Qualitative and quantitative elements are mixed from the outset in that the research is purposefully designed so that the supplemental data can inform what the major component may entail or be used to better understand or explain the results obtained from it; the collection of the supporting strand of data can occur before, during or after the major component (Creswell & Plano Clark, 2011). In this design, mixed methods are employed within a single study.

The multi-phase design involves a series of connected studies. Studies may be undertaken concurrently or sequentially; each study will comprise quantitative, qualitative or mixed methods; across all studies, both quantitative and qualitative methods are employed (Creswell & Plano Clark, 2011). Importantly, successive studies build on what has already been learned and equal priority is afforded to the quantitative, qualitative (and mixed methods) elements (Creswell & Plano Clark, 2011).

At the current time, multi-phase designs are most common in large funded studies where the purpose is to advance one programmatic objective by addressing a series of incremental research questions (Creswell & Plano Clark, 2011). In respect of my PhD, a systematic review followed by a mixed method feasibility study can be considered to comprise two stages (development and testing) of a multi-phase design that has been organised in line with the MRC complex interventions framework (2008). The mixed methods feasibility study employs an embedded design.

### **3.3.3 The value of mixed methods in the development and evaluation of complex interventions**

From the description of the multi-phase and embedded designs, it is possible to appreciate ways in which mixed methods are suited to the development and evaluation of complex interventions.

#### **Mixed methods and complexity**

For research on complex interventions to be of value to patients, professionals and others who deal with multiple uncertainties when making decisions about service provision or healthcare for individuals, researchers also need to address multiple uncertainties (Borglin, 2015; Griffiths & Norman, 2013). In this respect, there is growing recognition that mixed methods may be 'fit for purpose' (Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). Quantitative or qualitative research alone may not be appropriate to address different research questions. Indeed, by describing a phased and potentially iterative approach to researching complex interventions and by providing examples of good practice involving both qualitative and quantitative methods, the MRC framework (2008) highlights the potential of different methods. The multi-phase design described

by Creswell and Plano Clark (2011) is particularly suited to the 'develop, test, evaluate, implement' stages of complex interventions research. Mixed methods designs that capitalise on the strengths of both methodologies by combining them in a single study to increase breadth and depth of understanding (Johnson, Onwuegbuzie, & Turner, 2007) offer potential at all stages of the MRC framework (Borglin, 2015).

### **Advantages of gathering quantitative and qualitative information**

Collecting quantitative and qualitative data in single study or programme of research in the development and evaluation of complex interventions offers potential to offset the limitations of both types of information (Borglin, 2015; Creswell, 2003; Creswell & Plano Clark, 2011). Moreover, the use of different data types may strengthen the credibility of research (Creswell, 2003). Where the results of quantitative and qualitative analysis concur, data might be considered more trustworthy; where different data types conflict, this might raise important questions warranting further investigation. Mixed methods also offer potential to help answer research questions that lend themselves to the integration of quantitative and qualitative data.

In this regard, Creswell and Plano Clark (2011) advise researchers to identify separate research questions for quantitative and qualitative methods and a mixed methods question that frames the integration of the results from both. This approach raises the possibility of answering specific questions relating to the 'mixing' of the quantitative and qualitative data. Examples of mixed methods questions include, "In what ways do the qualitative data help explain the quantitative results?" and, "To what extent do the quantitative and qualitative results converge?" (Creswell & Plano Clark, 2011) (p 166).

Such questions require researchers to explore the relationship between quantitative and qualitative phenomena. At present, the most well-known form of mixed methods comprises the simultaneous collection of quantitative and qualitative data that are integrated only at the point of discussion (Kettles, Creswell, & Zhang, 2011). In contrast, mixed methods can also be used to address mixed methods research questions by 'merging' quantitative and qualitative data at the point of analysis (Creswell & Plano Clark, 2011). In this way, it is possible that mixed methods might support a novel, potentially deeper

understanding of phenomena than may be possible from quantitative or qualitative analysis alone.

### **Helping avoid research waste**

One other advantage of mixed methods is advanced by Creswell (2003) which also applies to their use in the development and evaluation of complex interventions. Specifically, mixed methods support an incremental or stepwise increase of knowledge. By conducting mixed methods, sequentially or concurrently, it is possible to build in 'feedback loops': knowledge from one strand of research can inform another (Cresswell 2003). By providing such opportunities, the use of mixed methods may help to reduce levels of avoidable waste in studies that fail to provide appropriate, credible and useful information due to correctable problems e.g. in the formulation of research questions and study design (Chalmers & Glasziou, 2009). For example, in a multi-phase design, results from a systematic review might determine what, if any, qualitative research is required to help develop a new intervention; in an embedded mixed methods study, feedback from qualitative interviews set in a pilot trial might provide important insights regarding the acceptability of an intervention – the interviews may suggest that a main evaluation is not warranted. By using what has been learnt from one methodological strand of research to inform another, mixed methods can help minimise unnecessary research waste in the development and evaluation of complex interventions.

### **3.4 Philosophical assumptions**

All forms of research, mixed methods included, are underpinned by a set of implicit or explicit beliefs and assumptions about the nature of our world and our ability to know it (Greene & Caracelli, 1997). Collectively, those assumptions, variably called a paradigm (Greene & Caracelli, 1997) philosophy or worldview (Creswell & Plano Clark, 2011) warrant different types of methods. Two such philosophies, constructivism and positivism, are typically associated with qualitative and quantitative methods. For purists, these worldviews are incompatible: they encompass different assumptions that cannot be reconciled with the logical result that it is not possible to combine mixed methods in a single study or programme of work. For researchers who employ mixed methods, a different perspective is required.

### **3.4.1 The pragmatic perspective**

From a pragmatic perspective, different philosophies can be upheld. Those who support this philosophy argue that, in the real world, studies rarely exemplify a paradigm in full but embody different worldviews in how they are conducted; moreover, contradictions between different paradigms do not need to be resolved (Patton, 1988). Thus, researchers who adopt a pragmatic philosophy reject the need to choose between positivism and constructivism; methods which are typically associated with each of these worldviews can be combined (Borglin, 2015). Pragmatism is also characterised by one other key feature: the primary importance given to the research question (Creswell & Plano Clark, 2011). When deciding on and planning how to approach an investigation, the research question is more important than a philosophy or method in determining how that inquiry takes shape. The emphasis is on the objective or purpose of the research and ultimately doing ‘what works’ to address it. At this time, pragmatism is commonly associated with mixed methods research (Creswell & Plano Clark, 2011; Johnson & Onwuegbuzie, 2004; Johnson et al., 2007). It also underpins my PhD programme of research.

### **3.4.2 Pragmatism and my PhD**

In conducting elements of a multi-phase programme of research on stepped care, I have afforded highest priority to the research questions to be addressed. For example, starting with the question, ‘What is the existing evidence on the effectiveness of stepped care treatment for depression in adults?’, I selected the most appropriate method (a systematic review) to address this question. Similarly, to prepare for a fully-powered trial of stepped care vs. high-intensity psychological therapy alone, a mixed methods design was chosen to address key methodological, procedural and clinical uncertainties associated with the conduct of that trial. By attaching primary importance to the research questions, my approach is consistent with a pragmatic worldview.

Congruent with pragmatism, my research also embodies multiple philosophies. In conducting a pilot RCT, I have upheld a positivist paradigm: I have sought, for example, to measure the effect of stepped care compared with CBT alone on symptoms of depression to inform the sample size calculation required for a main evaluation. This is illustrative of the ‘determinism’ or ‘cause and effect’



thinking which characterises positivism. I have also subscribed to a constructivist worldview: the results of qualitative interviews on the acceptability of stepped care have been analysed allowing for multiple participant meanings, accepting that those meanings are shaped by social interaction with others, including myself as the researcher, and participants' own personal histories. By upholding positivism and constructivism, but also by attaching primary importance to the research questions to be addressed, I have illustrated how my doctoral thesis embodies a pragmatic perspective.

## **CHAPTER 4. SYSTEMATIC REVIEW OF STEPPED CARE FOR DEPRESSION**

Earlier in this thesis, several observational cohort studies were described which found that stepped care implemented in routine clinical practice is associated with favourable patient outcomes (see Chapter Two). Although the results of such studies assess the 'real life' effectiveness of this system, they do not establish causality: outcomes cannot be reliably attributed to stepped care. Moreover, whilst two of the observational studies cited published findings on the effects of high-intensity psychological therapy alongside their primary data on the effect of stepped care in routine clinical practice (Parry et al., 2011; Richards & Suckling, 2009), none directly compared these systems.

To determine the relative effectiveness of stepped care vs. high-intensity psychological therapy alone with greater certainty requires a fully-powered RCT. Although several large trials of stepped care have been conducted (Davidson et al., 2010; Katon et al., 2004; Unutzer et al., 2002), a systematic review is needed to determine, with confidence, if this body of work provides sufficient evidence to determine whether stepped care is equivalent to high-intensity psychological therapy for all – the system it was designed to replace. As such, this chapter reports a systematic review encompassing a meta-analysis of randomised controlled trials of stepped care; meta-analyses also allowed for an exploration of the features of this intervention that may be associated with more or less effect.

### **4.1 Chapter structure**

This chapter is organised into three main sections. Section one summarises the methods, results and conclusions of a systematic review and meta-analysis of stepped care conducted between September 2012 and March 2013. The results of this work have been published and the article is reproduced in section one with additional information provided:

van Straten A, Hill J, Richards DA, Cuijpers P. (2014) Stepped care treatment delivery for depression: a systematic review and meta-analysis. *Psychological Medicine*, 45 (2): 231-246.

Section two comprises an update of the original review conducted between November and December 2015. The method underpinning the update is described; results reported are those combined with data from the original review. Section three comprises a succinct description of key conclusions. (Results are discussed in full in Chapter Seven.)

## **4.2 Part I - Original systematic review and meta-analysis**

The original review (undertaken from September 2012 to March 2013) was conducted by myself (JJH) in collaboration with Professors van Straten (AVS), Richards (DR) and Cuijpers (PC). The study team were responsible for different activities: the scope of the review, search strategy and study inclusion criteria were defined by AVS, DR and PC; JJH and AVS were jointly responsible for study identification and data extraction – DR acted as a third reviewer. Risk of bias assessment and narrative synthesis of included studies were produced by JJH. Meta-analyses were performed by AVS. Methods are described further in section 4.2.2.

### **4.2.1 Aim and specific objectives**

The aim of the original systematic review of stepped care was to assess the clinical effectiveness of stepped care for the treatment for depression in adults. Specific objectives were to: (1) determine whether existing evidence is sufficient to conclude that stepped care is equivalent to long term, intensive psychological therapy for all; (2) investigate heterogeneity in trial findings by exploring aspects of study design and elements of the intervention that may be associated with more or less effect.

### **4.2.2 Method**

#### **Search strategy**

A comprehensive literature search was conducted in PubMed, PsycINFO, EMBASE, and the Cochrane Central Register of Controlled Trials. Terms indicative of depression were combined with those of stepped care (Box 1). Literature was searched up to April 2012 without any language restrictions. Identified protocol papers published before April 2012 were followed up to determine if the researchers had subsequently published their findings before

May 2013. Two researchers (AVS and JJH) reviewed all of the abstracts and titles of retrieved references for eligibility. Full papers were retrieved for all of the references that had been judged as potentially eligible and were examined independently by two of AVS, DR and JJH. In case of disagreement the paper was discussed with the third reviewer until a consensus was achieved. Reference lists of the included papers and a recent meta-analysis on collaborative care (Archer et al., 2012) were checked.

#### Box 1. Systematic review search terms

**Cochrane Central Register of Controlled Trials**

MeSH descriptor: Depression OR Mood Disorders OR Depressive Disorder  
*AND*

Free text in title, abstract and keywords: stepped *AND* care

**Embase**

Major descriptor: Depression OR Major Affective Disorder (search terms exploded)  
*AND*

Free text: stepped *AND* care

**PsycINFO**

From the thesaurus: Depression OR Major Depression OR Affective Disorders (search terms exploded)  
*AND*

Free text: stepped *AND* care

**PubMed**

MeSH descriptor: depression OR depressive disorder OR mood disorders  
*AND*

Free text search in all fields: stepped *AND* care

#### **Inclusion criteria**

Inclusion criteria were as follows: (1) the study had to be a randomised controlled trial (2) aimed at adults (3) with a recognised depressive disorder (meeting criteria set by the World Health Organization or American Psychiatric Association) identified through a diagnostic interview, or with depressive symptoms established by scoring above a cut-off on a depression questionnaire and, (4) investigating 'stepped care' as one of the randomised trial arms.

Randomised controlled trials could be of any type e.g. cluster, stepped wedge. The definition of stepped care was developed to reflect the widespread use of

pharmacotherapy alongside psychological treatment and the use of the term to refer to both the organisation of psychological therapies in order of intensity but also treatment where at each 'step' patients switch or add treatments of different modalities (pharmacological, psychological). Stepped care was defined accordingly i.e. as the availability of more than one psychological treatment of different intensities and / or the availability of more than one treatment modality (pharmacological and psychological treatments). Treatment had to include psychological therapy. The intensity of psychological treatments was defined with respect to the time to deliver; non-psychological (pharmacological) treatments were not characterised in this regard. We did not require treatments to be organised in a hierarchy of low- to high-intensity. Decisions about stepping up had to be based on a systematic clinical evaluation undertaken by a clinician or through questionnaire assessment, performed at a pre-specified time interval and with an explicit aim to determine the next treatment step. Studies were included in which only a proportion of patients were depressed, for example studies including patients with a common mental health disorder and a subgroup of patients specifically diagnosed with depression. Physical and psychiatric comorbidity with other disorders was allowed. Studies were included regardless of their setting or control group.

### **Data extraction**

General characteristics of the studies were extracted as follows: year of publication, country, randomisation level (patient or cluster), number of trial arms, features of the control group (e.g. treatment as usual, waiting list), setting, how depression or depressive symptoms were established (e.g. diagnostic interview or scoring above a cut-off on a questionnaire), participants' diagnosis / symptom profile in terms of depression and anxiety as an inclusion criteria, possible comorbidity as an inclusion criterion (e.g. cancer patients, diabetes), age, total number of patients included in the study. Features of the stepped care interventions that were coded were: number of steps, the content of the interventions in each step, stepping criteria, treatment providers (e.g. mental health nurses, psychologists) and total duration of the programme. Extracted outcome data were: primary and secondary outcome measures relevant to the review, continuous (e.g. means, standard deviations) and / or dichotomous (e.g. proportion 'recovered') data for each measure at each time point. Two

independent assessors coded each study; differences were discussed by JJH, DR and AVS until consensus was reached.

### **Risk of bias assessment**

The internal validity of studies was assessed using criteria as suggested by the Cochrane Handbook (The Cochrane Collaboration, 2011): adequate sequence generation; concealment of allocation; blinding of participants, study personnel and outcome assessors; intention to treat (defined as whether participants were analysed in the groups to which they had been allocated) and handling incomplete outcome data; selective outcome reporting; other potential threats to internal validity. Two reviewers conducted the quality assessment independently of each other. Summary assessments were made for individual studies by counting the number of domains in which the study was considered at low and high risk of bias.

### **Meta-analyses**

Between-group effect sizes (Cohen's  $d$ ) were calculated for all individual studies. The effect size represents the difference between two groups in number of standard deviations (Cooper & Hedges, 1994; Hedges & Olkin, 1985; Lipsey & Wilson, 1993). Available statistics as published in the papers (means and standard deviations, mean difference score and 95% confidence interval, or proportions of patients improved or recovered) were used to calculate between-group effect sizes. Effects were subsequently pooled across treatment trials; data from prevention trials and treatment trials reporting insufficient outcome data for meta-analyses were excluded. Missing data were not imputed. When more than one outcome was reported (e.g. more than one depression questionnaire or more than one cut-off score) sensitivity analyses of post-test effects were performed: effects were pooled using (a) the highest reported post-test effect size for each study, (b) the lowest reported post-test effect size for each study and (c) the combined post-test effect size for each study. (The combined effect size averaged the between-group differences from the various measures used in a given study.)

Individual effect sizes as well as the pooled effects were calculated using the computer program Comprehensive Meta-analysis version 2.2.046 for Windows,

developed for support in meta-analysis ([www.metaanalysis.com](http://www.metaanalysis.com)). Statistical heterogeneity i.e. variability in the intervention effects being evaluated in the different studies (The Cochrane Collaboration, 2011) was tested under the fixed-effect model using the statistics  $I^2$  and  $Q$ . This model assumes that there is one true effect size underlying all of the studies included in the analysis (Borenstein, Hedges, Higgins, & Rothstein, 2009). Pooled effects are hence interpreted as an estimate of that true effect (Deeks et al., 2008).  $I^2$  describes the proportion of variance between studies that is due to heterogeneity rather than sampling error (The Cochrane Collaboration, 2011): a value of 0% indicates no observed heterogeneity; larger values were interpreted as evidence of heterogeneity - 25% suggested a low degree of heterogeneity, 50% moderate and 75% high. The statistical significance of the heterogeneity was tested with the  $Q$  statistic. A significant  $Q$  value rejects the null hypothesis that observed differences between studies are compatible with chance alone (The Cochrane Collaboration, 2011). All results in which the p-value was less than 0.05 were marked. In the presence of statistical heterogeneity, pooled effect sizes were calculated using the random effects model. In contrast to the fixed-effect model, under this model the true effect of the intervention is assumed to vary from study to study (Borenstein et al., 2009). Pooled effects represent an 'average' of systematically different intervention effects (Deeks et al., 2008). Formulae for the basic meta-analyses (i.e. calculation of Cohen's  $d$ , pooled effects using the random effects model, the  $Q$  statistic and  $I$  statistic) are provided at Appendix I.

Sub-group analyses investigated heterogeneity and were performed to explore characteristics of the stepped care interventions and study design that may be associated with more or less effect. Significant differences between the effect sizes in different categories of studies were tested. The mixed effects model was used which pooled studies within subgroups using the random effects model but tested for significant differences between them using the fixed effects model. Publication bias was tested by inspecting the funnel plot, and by Duval and Tweedie's trim and fill procedure that yields an estimate of the effect size after publication bias has been taken into account - as implemented in Comprehensive Meta-Analysis (Duval & Tweedie, 2000).

## **Summary of outcomes among studies excluded from meta-analysis**

The effects of stepped care as reported in prevention studies and treatment trials with insufficient data to include in meta-analyses were summarised. Between-group effect sizes (Cohen's *d*) were calculated for individual treatment trials; incidence rate ratios were derived from published data on the prevalence of depression in the prevention studies. A pooled incidence rate ratio was calculated for indicated prevention trials.

### **4.2.3 Results**

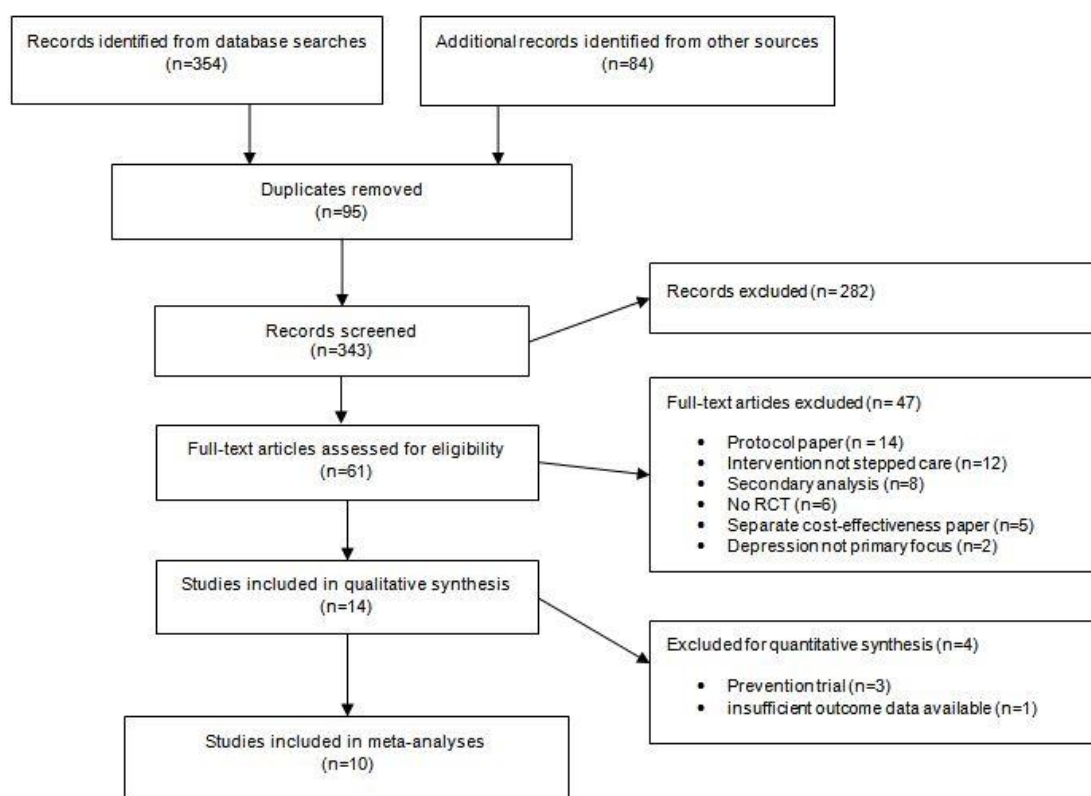
#### **Inclusion of studies**

A total of 343 unique records were identified from electronic databases and other sources (Figure 2). After screening, 61 full text papers were retrieved and reviewed; 47 did not fulfil study inclusion criteria and were excluded. Fourteen studies on stepped care treatment for depression were included: Unutzer et al. (2002) [study number 13]; Araya et al. (2003) [2]; Katon et al. (2004) [10]; Ell et al. (2008) [7]; van't Veer-Tazelaar et al. (2009) [14]; Bot, Pouwer, Ormel, Slaets, and de Jonge (2010) [3]; Davidson et al. (2010) [4]; Ell et al. (2010) [8]; Patel et al. (2010) [11]; Seekles et al. (2011) [12]; Apil, Hoencamp, Haffmans, and Spinhoven (2012) [1]; Dozeman et al. (2012) [6]; Davidson et al. (2013) [5]; Huijbregts et al. (2013) [9]. The results of one trial [3] were not published in full: post-test data were only available for the intervention and control arms combined; data was not reported at each time point. The authors were contacted to obtain the (unpublished) research protocol and additional results.

Ten of the 14 studies were included in quantitative meta-analyses on the treatment of depression in which outcomes were expressed as the reduction of depressive symptoms. One treatment trial [3] was excluded because the authors did not provide post-test results but long-term follow-up data only. The three remaining trials were aimed at prevention of depression either as indicated prevention [6, 14] or relapse prevention [1] with the incidence of depressive disorders as the main outcomes.



Figure 2. Study identification and selection for meta-analyses



### Characteristics of the included studies

The 14 studies included a total of 5194 patients of whom 2560 were randomised to stepped care and 2634 to a control condition. For the ten studies included in the quantitative meta-analyses, the total number of included patients was 4580 with 2243 in the stepped care arms and 2337 in the control (Table 1).

Twelve of the included trials were patient-randomised [studies 1-8, 10, 12-14]; two were cluster-randomised [9, 11]. Six trials were conducted in the US [4-5, 7-8, 10, 13], six in The Netherlands [1, 3, 6, 9, 12, 14], one in Chile [2] and one in India [11]. Participants were recruited mainly from primary care [2, 9-11, 12-14] or secondary care [3-5, 7]. All studies compared stepped care to usual care, either standard [1-6, 9-10, 12-14] or 'enhanced' [7-8, 11].

Of the eleven treatment trials, six [3-5, 7-8, 10] included patients scoring above a cut-off on a self-rated depression questionnaire only; two of those [7, 8] also used the core symptoms of Major Depressive Disorder (MDD). Five others [2,

9, 11-13] performed diagnostic interviews to include patients with MDD; one study [12] also included patients with minor depression and two [12, 13] also included patients with dysthymia. The three prevention trials [1, 6, 14] used a diagnostic interview to exclude patients with existing MDD. Six of the studies were aimed at depressive symptoms among patients with either co-morbid acute coronary syndrome [4-5], cancer [7] or diabetes mellitus [3, 8, 10]. Five trials, including the three prevention studies, were specifically aimed at older adults [1, 3, 6, 13, 14].

***Table 1 overleaf***

Table 1. Characteristics of included studies (continued overleaf)

ID	Author	Year	Country	Random level	Target of the trial	Control condition	Depression criteria	Comorbid disorder	Age (years)	IMPACT based	Total N (EXP / CTRL)
1	Apil	2012	Netherlands	Patient	Prevention	Usual care: depressive symptoms monitored.	Not depressed (MINI)	-	55+	No	136 <sup>1</sup> (74/62)
2	Araya	2003	Chile	Patient	Treatment	Usual care: GPs given guidelines on depression treatment.	MDD (MINI)	-	18-70	No	240 (120/120)
3	Bot	2010	Netherlands	Patient	Treatment	Usual care: ADs or psychotherapy were available.	Depressive symptoms (CES-D $\geq$ 16)	Diabetes	55+	No	123 <sup>1</sup> (64 / 59)
4	Davidson	2010	USA	Patient	Treatment	Usual care: physicians informed of patients' depressive symptoms/ MDD criteria.	Persistent depressive symptoms (BDI $\geq$ 10 and < 45 at week 1 and 13)	Acute Coronary Syndrome	NS <sup>3</sup>	Yes	157 (80/77)
5	Davidson	2013	USA	Patient	Treatment	Usual care: PCPs and/or cardiologists informed of patients' depressive symptoms.	Depressive symptoms (BDI $\geq$ 10 on 2 occasions or $\geq$ 15 on 1 occasion, 2 to 6 months after hospitalization for ACS)	Acute Coronary Syndrome	35+	Yes	150 (73/77)
6	Dozeman	2012	Netherlands	Patient	Prevention	Usual care <sup>4</sup>	Depressive symptoms (CES-D $\geq$ 8), no MDD (MINI)	-	Elderly in residential homes	No	185 <sup>1</sup> (93/92)
7	Ell	2008	USA	Patient	Treatment	Enhanced usual care: patient/family depression and cancer educational pamphlets + resource list. <sup>5</sup>	1 or 2 core depressive symptoms, and PHQ $\geq$ 10, and/or 2 questions from the SCID indicating dysthymia	Cancer	18+	Yes	472 (242/230)

Table 1. Characteristics of included studies (continued from previous page)

ID	Author	Year	Country	Random level	Target of the trial	Control condition	Depression criteria	Comorbid disorder	Age (years)	IMPACT based	Total N (EXP / CTRL)
8	Elli	2010	USA	Patient	Treatment	Enhanced usual care: depression educational pamphlets + resource list; PCPs informed of patient depression diagnoses.	Depressive symptoms (PHQ $\geq$ 10 and 1 or 2 core symptoms)	Diabetes	18+	Yes	387 (193/194)
9	Huijbregts	2013	Netherlands	Cluster	Treatment	Usual care: patients informed of diagnosis and advised to consult GP.	MDD (MINI) and PHQ $\geq$ 10	-	18+	Yes	150 (101/49)
10	Katon	2004	USA	Patient	Treatment	Usual care: patients advised to consult PCP.	Persistent depressive symptoms (PHQ $\geq$ 10 and mean SCL $\geq$ 1.1 at 2 weeks)	Diabetes	NS <sup>3</sup>	Yes	329 (164/165)
11	Patel	2010	India	Cluster	Treatment	Enhanced usual care: physicians & patients given screening results and a treatment manual.	MDD (CIS-R) and GHQ > 5	-	18+	No	774 <sup>2</sup> (304/470)
12	Seekles	2011	Netherlands	Patient	Treatment	Usual care: patients advised to consult GP	Persistent depressive symptoms (K10 $\geq$ 21 at week 1 and 4), MDD, dysthymia, minor depression (CIDI)	-	18-65	No	120 (60/60)
13	Unutzer	2002	USA	Patient	Treatment	Usual care <sup>4</sup>	MDD or dysthymia (SCID)	-	60+	Yes	1801 (906/895)
14	Van 't Veer	2009	Netherlands	Patient	Prevention	Usual care <sup>4</sup>	Persistent depressive symptoms (CES-D $\geq$ 16 at week 1 and 13), no MDD or anxiety disorder (MINI)	-	75+	No	170 <sup>1</sup> (86/84)

Notes: <sup>1</sup> not included in quantitative meta-analysis; <sup>2</sup> total N in this trial is 2796 but only results from the depressed subsample were included in meta-analyses; <sup>3</sup> age in- and exclusion criteria 'not specified'; <sup>4</sup> no particular feature of usual care described; <sup>5</sup> oncologists may have attended a depression treatment didactic session by the study psychiatrist at the start of the study and yearly thereafter and have been informed of patients' depression status although it is unclear whether these features applied to patients in the Enhanced Usual Care group.

Abbreviations: GP – General Practitioner; PCP - Primary Care Physician; MDD – Major Depressive Disorder; ACS – Acute Coronary Syndrome; GHQ – General Health Questionnaire; other abbreviations refer to depressive symptom checklists (CES-D, BDI, PHQ, SCL) and diagnostic interviews for depression (MINI, CIS-R, SCID, CIDI)

***Continued overleaf***

## **Characteristics of the stepped care interventions**

There were considerable differences between studies in numbers of steps (two, three or four), types of treatments offered at each step and duration of the total intervention (between three and 12 months; Table 2).

### ***IMPACT vs. progressive intensity***

The stepped care interventions in seven studies [4, 5, 7-10, 13] (six of which were undertaken in the U.S.) were based on the 'IMPACT' model and used Problem Solving Treatment (PST) and antidepressant medication (ADM) as the core of the intervention. The IMPACT intervention is primarily a collaborative intervention in which a dedicated team works together to provide optimal depression care, meeting inclusion criteria as a stepped care approach because patients were evaluated at pre-determined time intervals according to defined improvement criteria and care was adjusted or augmented if the patient did not improve sufficiently. Treatments were provided according to patients' needs and preferences. In all seven 'IMPACT' studies and one other [study 22] involving both psychological treatment (psycho-education) and ADM, there was no progression of increasing therapeutic intensity.

In contrast, care was delivered in the other six trials [1, 3, 6, 11-12, 14] through steps of increasing intensity. Five of these studies started with watchful waiting although two [12, 14] only included patients after the watchful waiting period while the other three [1, 3, 6] included watchful waiting as part of their stepped care model. The first therapeutic component included psycho-education or bibliotherapy alone or combined, offered either as self-help (with online, telephone or face-to-face support), in a group, or as individual sessions. The next step in these six studies varied widely and included psychological therapy (CBT, life review, IPT, PST, Coping with Depression Course) [1, 3, 6, 12, 14] or a psychological therapy (IPT) combined with ADM [11]. The last step typically consisted of referral to specialists, a GP or mental health services. Only two [11, 12] of the six studies which used steps of increasing intensity were included in the quantitative meta-analysis. As described above (see Inclusion of Studies) one study was excluded because of unavailability of post-test data [3] and three were excluded for being aimed at prevention [1, 6, 14].

### ***Healthcare providers***

In twelve studies [1-2, 4-13] more than one healthcare professional was involved in stepped care including nurses [1-2, 4-6, 10, 12-13], psychiatrists [4-5, 7-11, 13], General Practitioners [2, 5, 8, 9, 11, 13], social workers [2, 4, 7-8], psychologists [4-5, 12-13] and relatively less qualified staff (residential home staff [6], an assistant patient navigator [8], lay health counsellor [11] and study researcher [1]). In two studies, treatment was provided by one healthcare professional: a nurse or psychologist [3] or a nurse only [14]. No details are available for external professionals providing treatment after referral outside the core stepped care team.

### ***Stepping criteria***

Patient progress was assessed using one [1-7, 9-11, 13-14], two [8] or three [12] self-rated instruments. In five studies the decision to 'step up' was contingent on patients' score relative to a specific cut-off on the HDRS [2], CES-D [1, 14], PHQ-9 [7] or HADS, IDS and WSAS [12]. In five studies the decision to 'step up' was dependent on improvement (relative to baseline or the last assessment) on the PHQ-9 [4-5, 10, 13] or CES-D [6]. Three studies used a combination of improvement and a specific cut-off on the CES-D [3], PHQ-9 [9] or PHQ-9 and SCL [8]. In one study [11] improvement was assessed by health counsellors following application of the GHQ with no further detail specified.

***Table 2 overleaf***

Table 2. Characteristics of the stepped care interventions for depression

ID	Author	N step	Step 1	Step 2	Step 3	Step 4	Providers <sup>1</sup>	Stepping up rules	Total duration
1	Apil	4	Watchful waiting (1 phone call)	Bibliotherapy based on CWD (3 phone calls)	Individual CWD course (12 sessions)	Referral to a GP or psychotherapist	Nurse, Researcher	CES-D $\geq$ 16 at 6 weeks, 3 months and 6 months	6 months
2	Araya	2	PE group (9 sessions) + self-help book. If HDRS > 19 also structured ADs	Initiating or adjusting ADs	-	-	Social workers, nurses, GP	HDRS > 12 at 6 weeks	3 months
3	Bot	4	Watchful waiting + 3 phone	Bibliotherapy based on CWD (3 phone calls)	CBT: 4 modules of CWD course (5 sessions)	Referral to psychiatrist	Prevention worker (nurse or psychologist)	CES-D improvement < 5 or CES-D $\geq$ 16 at 6, 12 & 24 weeks	36 weeks $\approx$ 8 months
4	Davidson 2010	3	PST (no predetermined number of sessions) or ADs (patient preference)	Switching treatments, adding treatments, intensifying original treatment (patient preference)	Referral to usual care provider	-	nurse, psychologist, social worker, psychiatrist	Initial PHQ9 5-10 and improvement < 30%; initial PHQ9 11-20 and improvement < 50%; initial PHQ-9 > 20 and improvement < 60%. Assessed every 8 weeks.	6 months
5	Davidson 2013	4	PST (number of sessions not specified) and/or ADs, or neither	Switching treatments, adding treatments (patient preference)	Switching treatments, adding treatments (patient preference)	Switching treatments, adding treatments (patient preference)	PST therapist, psychiatrist, clinical psychologist, GP or advanced practice nurse	See Davidson 2010. Assessed every 6-8 weeks.	6 months
6	Dozeman	4	Watchful waiting	Bibliotherapy based on CWD (face-to-face guidance; no predetermined number of sessions)	Individual face-to-face Life Review (no predetermined number of sessions) + advise to consult GP	If CESD $\geq$ 16: advised to consult GP or referral to mental health specialist	Residential home staff, mental health nurses	CES-D improvement < 5 at 1 & then every 3 months.	10 months
7	Eil 2008	3	1 visit CDCS then PST (8 to 12 sessions) and/or ADs (patient preference)	ADs and additional psychotropic medications	Referral to usual care provider / public safety net clinic	-	Social workers (Cancer Depression Clinical Specialist), psychiatrist	PHQ9 $\geq$ 10. Timing unclear.	12 months



Table 2. Characteristics of the stepped care interventions for depression (continued from previous)

ID	Author	N step	Step 1	Step 2	Step 3	Step 4	Providers <sup>a</sup>	Stepping up rules	Total duration
8	Elli 2010	3	PST (number of sessions in this step not specified) or ADs (patient preference)	PST in step 1: addition of pharmacotherapy; ADs in step 1: change of ADs or adding PST (patient preference)	Additional PST, adding insomnia medication, referral to specialty mental health care.	-	Social work diabetes depression clinical specialists, GP, psychiatrist, assistant patient navigator	Partial or non-response: clinical improvement = SCL or PHQ-9 50% reduction of symptoms; remission = PHQ < 5 or SCL < 0.5. Assessed at 8 & 12 weeks.	12 months
9	Huibregts	3	Self-help book (all patients) plus PST (6 or 12 sessions) or PST + ADM (patient preference)	Self-help book, also switching treatments (PST / ADs, patient preference)	Referral to specialty mental health care	-	Depression Care Manager, GP, consultant psychiatrist	PHQ-9 reduction < 5 and/or PHQ-9 score $\geq$ 5 at 6 & 12 weeks.	18 weeks $\approx$ 4.5 months
10	Katon	3	1 visit + PST (6 sessions) or ADs (patient preference)	Switching treatments, adding treatments, changing ADs and psychiatric consultation	Referral to specialty mental health care	-	Nurses, psychiatrist	PHQ-9 reduction < 50% at 10-12 weeks then + 8-12 weeks.	6 months
11	Patel	4	Face-to-face PE	ADs or IPT (6 to 12 sessions) + adherence management	ADs + IPT (6 to 12 sessions) + adherence management	Continue all treatments + referral to clinical specialist	Lay health counselor (non-medical graduate), GP, psychiatrist	Routine clinical assessment by the health counsellor. Time point not reported.	6 months
12	Seekles	3	PE (1 face-to-face session) + bibliotherapy (content depending on diagnosis, online/telephone support on request)	PST (5 sessions)	Contact with Care Manager (1 session): referral to GP or specialist mental health setting	-	Mental health nurse, junior psychologist	IDS $\geq$ 14 or HADS-A $\geq$ 8 or WSAS $\geq$ 6 every 8 weeks.	18-24 weeks $\approx$ 6 months
13	Unutzer	3	Videotape + booklet + 1 DCM visit then PST (6 to 8 sessions) or ADs (patient preference)	Switching treatments, adding treatments, changing ADs (patient preference)	Team considered alternative treatment for each patient individually (e.g. hospitalisation)	-	Depression Care Manager (nurses, psychologist), psychiatrist, GP	PHQ9 reduction < 50% and more than 2 out of the 9 symptoms of MDD. Assessed end step 1 (precise timing not reported) & after 10 weeks step 2 treatment.	12 months
14	Van 't Veer	3	Bibliotherapy (based on CWD; support by telephone calls or face-to-face visits, no predetermined number)	PST (7 sessions)	Referral to GP	-	Home care / community mental health nurse	CES-D $\geq$ 16 every 3 months.	12 months

Notes: <sup>1</sup> 'Providers' includes the role of all health care professionals involved in the stepped care intervention except for professionals who cared for patients 'on referral'.

Abbreviations: ADs =antidepressants; CBT = cognitive behavioral therapy; CDCS = cancer depression clinical specialist; CES-D = Center for Epidemiological Studies Depression Scale; CGI-S= Clinical Global Impression Severity Scale; CWD = Coping With Depression; HADS-A = Hospital Anxiety and Depression Scale-Anxiety; HDRS = Hamilton Depression Rating Scale; IPT = interpersonal psychotherapy; MDD = major depressive disorder; PST = problem solving treatment; PE = psycho-education; WSAS = Work and Social Adjustment Scale

***Please see over***

## Risk of bias

In one study [3] all criteria were rated as either unclear or at high risk of bias and in a second [1], five of the six criteria were rated as unclear or at high risk of bias (Table 3). For the remaining twelve studies, risk of bias on most criteria was low. Across these trials, the description of the randomisation sequence generation was adequate although four studies [4, 10, 11 & 14] did not clearly report methods of allocation concealment. None of the 12 studies were able to blind patients or clinicians but all studies used assessors to measure outcomes who were unaware of the randomisation status of the patients or collected data using measures that were self-report. Post-intervention study drop-out ranged between 8.0% [5] and 49.6% [3] and one study [9] was rated at high risk of bias with respect to handling incomplete outcome data. All twelve studies used intention-to-treat analyses. None of the twelve were considered at high (or unclear) risk of bias from selective reporting. Three were at high risk of other biases because of the potential for contamination between trial arms [6, 8, 13] or because patients were recruited in different ways in the intervention and control groups [9].

Table 3. Risk of bias in included studies

Study no.	Author	Risk of Bias						N low (N high)
		Generation of random sequence	Allocation concealment	Blinding <sup>1</sup>	Incomplete outcome data	Selective reporting	Other potential bias	
1	<a href="#">Apil</a>	Unclear	Unclear	Unclear	High	High	Low	1 (2)
2	<a href="#">Araya</a>	Low	Low	Low	Low	Low	Low	6 (0)
3	<a href="#">Bot</a>	Unclear	Unclear	Unclear	High	High	High	0 (3)
4	<a href="#">Davidson (2010)</a>	Low	Unclear	Low	Low	Low	Low	5 (0)
5	<a href="#">Davidson (2013)</a>	Low	Low	Low	Unclear	Low	Low	5 (0)
6	<a href="#">Dozeman</a>	Low	Low	Low	Low	Low	High	5 (1)
7	<a href="#">Ell (2008)</a>	Low	Low	Low	Low	Low	Low	6 (0)
8	<a href="#">Ell (2010)</a>	Low	Low	Low	Low	Low	High	5 (1)
9	<a href="#">Huibregts</a>	Low	Low	Low	High	Low	High	4 (2)
10	<a href="#">Katon</a>	Low	Unclear	Low	Low	Low	Low	5 (0)
11	<a href="#">Patel</a>	Low	Unclear	Low	Low	Low	Low	5 (0)
12	<a href="#">Seekles</a>	Low	Low	Low	Low	Low	Low	6 (0)
13	<a href="#">Unutzer</a>	Low	Low	Low	Low	Low	High	5 (1)
14	<a href="#">van't Veer-Tazelaar</a>	Low	Unclear	Low	Low	Low	Low	5 (0)
<b>N Low</b>		12	8	12	10	12	9	63
<b>N Unclear</b>		2	6	2	1	0	0	11
<b>N High</b>		0	0	0	3	2	5	10

Notes: <sup>1</sup>Blinding of participants and personnel was not possible in any study; included ratings are with respect to the blinding of outcome assessors

## **Effects of stepped care**

### ***Post-intervention effect sizes***

The overall (pooled) post-intervention effect size calculated from the combined effect size in each individual study was  $d = 0.38$  (95% confidence interval 0.18 to 0.57; Table 4). Sensitivity analyses estimating overall effects using the measure in each study with the highest and lowest post-test effect size produced pooled effect sizes of  $d = 0.42$  (95% CI 0.22 to 0.62) and  $d = 0.33$  (95% CI 0.13 to 0.52), respectively. All of the pooled effect sizes were significantly in favour of stepped care.

### ***Effect sizes at various time points***

The stepped care interventions varied in duration between three and 12 months. Overall effect sizes at different time points estimated using the combined effect size in individual studies were as follows:  $d=0.57$  at two to four months (95% confidence interval 0.21 to 0.94);  $d=0.34$  at six months (95% CI 0.20 to 0.48);  $d=0.43$  at nine to 12 months (95% CI 0.20 to 0.65);  $d=0.26$  at 18 months (one study only; Table 4). All effects were significantly in favour of the stepped care intervention with the exception of the 18 month result.

***Table 4 overleaf***

Table 4. Pooled effect sizes (Cohen's d) across treatment trials examining the effects of stepped care treatment for depression compared with usual care

	$N_{comp}$ <sup>1</sup>	$d$	95% CI	$I^2$
<b>Post intervention effect sizes</b>				
• Outcomes combined	10	0.38	0.18 to 0.57	81.53* <sup>2</sup>
• Outcomes with highest ES	10	0.42	0.22 to 0.62	81.33*
• Outcomes with lowest ES	10	0.33	0.13 to 0.52	84.81*
<b>Effect sizes for different time points<sup>3</sup></b>				
• 2-4 months	4	0.57	0.21 to 0.94	83.61*
• 6 months	10	0.34	0.20 to 0.48	68.11*
• 9-12 months	5	0.43	0.20 to 0.65	74.81*
• 18 months	1	0.26	< -0.01 to 0.53	-

Notes: <sup>1</sup>  $N_{comp}$  = number of comparisons; <sup>2</sup> \* =  $p < 0.01$ ; <sup>3</sup> pooled effect sizes for different time points were calculated using the combined outcomes effect sizes for individual studies

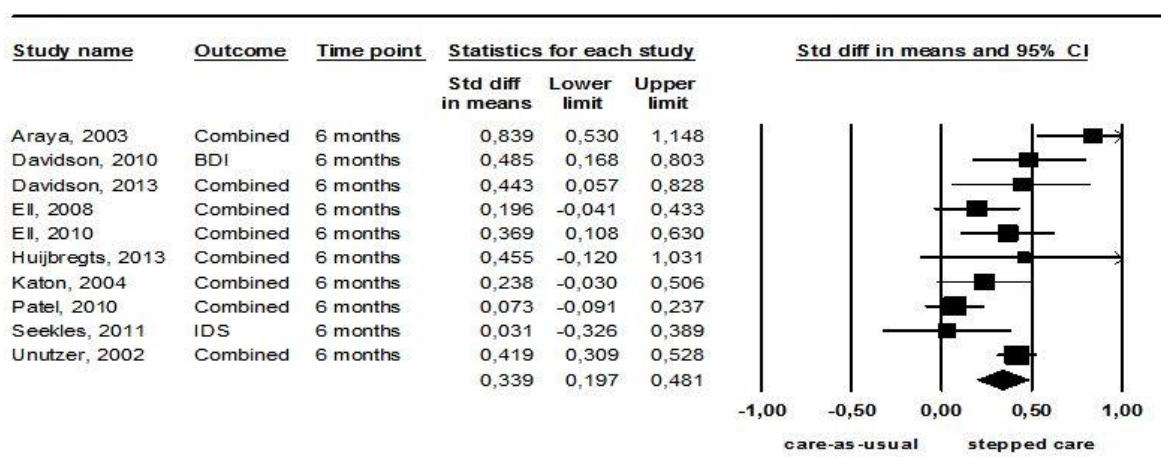
Abbreviations: 95% CI = 95% confidence interval; ES = Effect Size

### **Statistical heterogeneity**

Heterogeneity, as indicated by  $I^2$ , was high for the post-intervention effect sizes as well as for the effect sizes at the different time points (Table 4). From Figure 3 it can be observed how the six month effect sizes varied between the different studies.

**Figure 3 overleaf**

Figure 3. Effects of stepped care vs. care as usual at six months



### Sub-group analysis and publication bias

The association of the six months outcomes estimated using combined effect sizes (overall  $d=0.34$ ; Table 5) with the following variables was explored: country in which the study was undertaken (USA, Netherlands, or other), treatment based on IMPACT protocol (yes or no), stepped care treatment using progressive intensity (yes or no), physical health comorbidity (present or absent), and diagnostic status at inclusion (diagnosis assessed or not). The overall effect of the eight studies on stepped care models without progressive intensity ( $d=0.41$ ) was significantly higher than the effect of the two studies examining stepped care models with progressive intensity ( $d=0.07$ ;  $p < 0.01$ ). None of the remaining variables were significantly related to the effect size. There was no indication of publication bias in the funnel plot of the six month outcomes or in Duval and Tweedie's trim and fill procedure.

**Table 5 overleaf**

Table 5. Sub-group analyses on overall effect of stepped care compared with usual care at six months (calculated using combined outcomes; effect size  $d=0.34$ ; 95% CI 0.20 to 0.48)

	$N_{comp}$ <sup>1</sup>	$d$	95% CI	$I^2$	p value
Country					
• USA	6	0.38	0.29 to 0.46	0.00	0.63
• Netherlands	2	0.18	-0.22 to 0.58	33.54	
• other	2	0.44	-0.31 to 1.19	94.57* <sup>2</sup>	
IMPACT based					0.79
• yes	7	0.38	0.30 to 0.46	0.00	89.78*
• no	3	0.31	-0.18 to 0.80		
Progressive treatment intensity					< 0.01
• yes	2	0.07	-0.08 to 0.22	0.00	44.03
• no	8	0.41	0.33 to 0.49		
Physical co-morbidity					0.82
• Present	5	0.32	0.19 to 0.44	0.00	84.11*
• Absent	5	0.35	0.09 to 0.62		
Inclusion based on diagnosis					0.82
• yes	5	0.35	0.09 to 0.62	84.11*	0.00
• no	5	0.32	0.19 to 0.44		

Notes: <sup>1</sup>  $N_{comp}$  = number of comparisons; <sup>2</sup> \* =  $p < 0.01$

Abbreviations:  $d$  = Cohen's  $d$ ; 95% CI = 95% confidence interval

### Effect of stepped care in studies excluded from meta-analysis

The treatment study by Bot et al. (2010) [3] only provided two year follow-up data for the complete cases (49.6%) and reported no difference between the groups ( $d=-0.12$ ; 95% CI -0.62 to 0.39). Both of the trials on indicated prevention [6, 14] showed results in favour of stepped care. One [6] demonstrated 12 month MDD rates of 6.5% in the intervention group and 14.1% in the control group (Incidence Rate Ratio = 0.46; 95% CI 0.17 to 1.21). The other [14] demonstrated 12 month prevalence rates of combined MDD and anxiety disorders of 11.6% in the intervention group and 23.8% in the control group (Incidence Rate Ratio = 0.49; 95% CI 0.24 to 0.98). The pooled rate ratio of the two studies was 0.48 (95% CI 0.27 to 0.83;  $I^2 = 0$ ). The study on relapse prevention [1] reported no difference in the 12 month MDD incidence rate between stepped care and care-as-usual.

#### **4.2.4 Summary of key findings from the original review and meta-analysis**

Fourteen trials on stepped care for depression were identified, ten of which could be used in meta-analyses of treatment outcomes. Stepped care had a moderate effect on depression ( $d=0.34$  at six months and  $d=0.38$  post-intervention). Stepped care interventions based on progressive treatment intensity performed worse ( $n=2$ ;  $d=0.07$ ) than those without a clear intensity order ( $n=8$ ;  $d=0.41$ ;  $p < 0.01$ ). In most trials, risk of bias on the majority of criteria was low. There was no indication of publication bias. The stepped care interventions were extremely heterogeneous with different numbers of steps, different treatment components, different duration of the steps, different rules about stepping up and different professionals involved. All of the included studies compared stepped care with care as usual.



### **4.3 Part II – Updated systematic review and meta-analysis**

The original systematic review and meta-analyses were completed by June 2013. Work to update the review was undertaken from November to December 2015 by myself with the assistance of Professors Richards and van Straten. Responsibilities were as follows: study identification, data extraction, narrative synthesis and meta-analysis were undertaken by JJH; DR and JJH appraised the full text of potential papers for in- or exclusion; AVS provided a third opinion where JJH and DR did not agree. Methods are described further in section 4.3.2.

#### **4.3.1 Aims and objectives**

The aim and specific objectives of the review update were as for the original i.e. to assess the clinical effectiveness of stepped care treatment for depression in adults and thus: (1) determine whether existing evidence is sufficient to conclude that stepped care is equivalent to long-term, intensive psychological therapy for all; (2) explore aspects of study design and elements of the intervention that may be associated with more or less effect.

#### **4.3.2 Method**

Methods for updating the review replicated those of the original. A comprehensive literature search was performed in PubMed, PsycINFO, Embase and the Cochrane Central Register of Controlled Trials using the search terms described in Box 1, section 4.2.2. Searches were limited to studies published from January 2012 onwards. JJH reviewed all abstracts and titles of retrieved references; full text papers were examined by JJH and DAR. In case of disagreement, the paper was discussed with AVS. Reference lists of included papers were checked and JJH contacted the authors of protocol papers that met study inclusion criteria but for which there were no published results to request available data. In-and exclusion criteria were identical to those used previously. As per the original review, studies were included in which only a proportion of patients were depressed, for example studies including patients with a common mental health disorder and a sub-group of patients specifically diagnosed with depression. Data on the characteristics of the included studies and the stepped care interventions were extracted by JJH.

Risk of bias was assessed using the criteria as suggested by the Cochrane Handbook (The Cochrane Collaboration, 2011). Summary assessments were made for individual studies by counting the number of domains in which the study was considered to be at low and high risk.

### **Meta-analyses**

Meta-analyses were performed using data from all of the eligible and included studies i.e. studies identified in the original review and update. Pooled effects of stepped care in the sub-set of new studies alone were not estimated.

### ***Individual study effects***

Between-group effect sizes (Cohen's *d*) were calculated for all individual studies included in analyses using the available data as published in the papers (means and standard deviations, proportions of patients improved etc.). For studies in which only a proportion of patients were depressed and where the publication of results allowed, individual study effect sizes were also calculated for the depressed sub-sample.

### ***Pooled effects – primary and secondary analyses***

Effects were subsequently pooled across treatment trials. Data from prevention studies, treatment trials reporting insufficient outcome data and trials comparing two active treatments were excluded. Primary analyses estimated the effect of stepped care on patients with depression: effects were pooled across studies that only included patients with depression and, when available, from the estimate of the effect of stepped care in the depressed sub-sample in studies in which only a proportion of patients were depressed. Secondary analyses estimated the effects of stepped care on depressive symptoms in patients with depression and other common mental health problems: effects were pooled across studies that included patients with depression only and studies that included patients with common mental health problems, including but not limited to depression.

In primary and secondary analyses, pooled post-intervention effects were calculated using the highest reported effect size in each study, the lowest and the average or combined; pooled intervention effects at a variety of other time

points were calculated using the combined effect in each study. Statistical heterogeneity was tested under the fixed-effects model using the statistics  $I^2$  and  $Q^2$ . Pooled effects were calculated with the random-effects model. Missing data were not imputed. Computational formulae for basic meta-analyses are provided at Appendix I.

### ***Sub-group analyses***

Planned sub-group analyses investigated heterogeneity in the effects of stepped care across studies that included patients with depression only and the depressed sub-samples in studies in which only a proportion of patients were depressed. As per the original review, analyses tested whether there were significant differences between the effect sizes in different categories of studies, specifically studies: set in different countries; adopting an IMPACT based stepped care clinical protocol (yes/no); that organised stepped care using progressive treatment intensity (yes/no); that recruited patients with a co-morbid physical health condition (yes/no); and that in- or excluded potentially eligible patients by assessing their diagnostic status using a diagnostic interview (yes/no).

### ***Publication bias***

Publication bias was tested by inspecting the funnel plot and Duval and Tweedie's trim-and-fill procedure (Duval & Tweedie, 2000) for primary and secondary analyses of the effects of stepped care immediately after treatment and at six to nine months estimated using the average (combined) effect in individual studies.

## **4.3.3 Results**

### **Inclusion of studies**

Two hundred unique records were identified from electronic databases and other sources (Figure 4). After screening, 48 full text papers were reviewed; 28 did not fulfil study inclusion criteria and were excluded. Seven new studies were included: J. J. Hill, Kuyken, and Richards (2014) [study number 15]; Krebber et al. (2015) [16]; Oladeji et al. (2015b) [17]; Oosterbaan et al. (2013) [18]; Stoop, Nefs, Pommer, Pop, and Pouwer (2015) [19]; van der Aa et al.

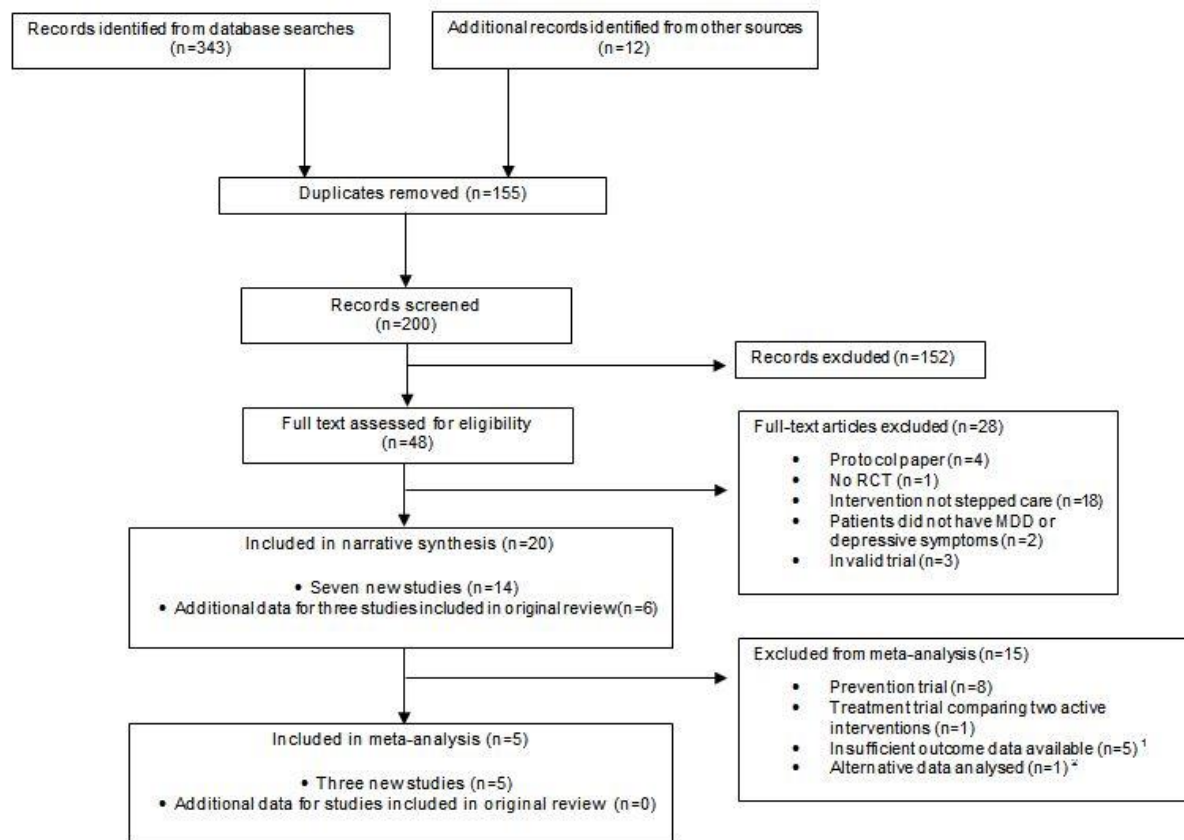
(2015) [20]; D. X. Zhang et al. (2014) [21]. One other study met inclusion criteria (Van Beljouw et al., 2015) but was excluded from the review due to problems which rendered the study invalid: part-way through the trial and in response to high drop-out rates, the intervention was substantially altered such that more than half of participants did not receive stepped care; in their results, the authors did not distinguish between participants who had stepped care vs. the modified intervention. Three of the new studies were included in quantitative meta-analyses. One treatment trial [19] was excluded because the authors did not report outcome data with sufficient clarity for results to be useable; one study [15] (conducted by myself as part of my doctoral studies) was excluded for comparing two active treatments - stepped care and high-intensity psychological therapy alone; the two remaining trials [20, 21] were aimed at the indicated prevention of depression.

***Papers providing supplementary information and data for studies already included in the review***

Six papers were also included that provided supplementary information or data for three studies that were included in the original review. Apil, Spinhoven, Haffmans, and Hoencamp (2014) reported 24 month outcomes for Apil et al. (2012) [study no. 1]. Bosmans et al. (2014) and van Schaik et al. (2014) reported cost-effectiveness data, ten and 22 month outcomes for Dozeman et al. (2012) [study 6]. Three papers provided additional information for the IMPACT study by Unutzer et al. (2002) [13]: Hunkeler et al. (2006) reported 18 & 24 month outcomes; Tang, Song, Belin, and Unutzer (2005) described a comparison of imputation methods using the 12 month IMPACT data; Unutzer et al. (2008) published the results of cost-effectiveness analyses.

None of the six papers were included in meta-analyses. Three papers (Apil et al., 2014; Bosmans et al., 2014; van Schaik et al., 2014) provided additional data or supplementary information for prevention trials [1, 6]. The cost-effectiveness analysis by Unutzer et al. (2008) did not report new clinical outcome data; longer-term outcome data reported by Hunkeler et al. (2006) was not reported in a format suitable for meta-analysis; 12 month outcome data (using all available data) that had been extracted for the original review was incorporated in the update.

Figure 4. Review update: study identification and selection for meta-analyses



Notes: <sup>1</sup> n=5 refers to (i) three papers reporting the study design and results of a trial by Stoop et al. where the results were not provided in a format suitable for analysis, (ii) results of a cost-effectiveness analysis and longer-term outcome data for Unutzer et al. (2002) where the cost-effectiveness paper included no new clinical data and longer term outcome data was not reported in a format suitable for meta-analysis; <sup>2</sup> n=1 refers to imputed 12 month outcome data for Unutzer et al. 2002 – 12 month outcomes using 'all available cases' were included as per the original review.

## Characteristics of the included studies

Characteristics of the seven new studies are summarised in Table 6.

Combined with the 14 studies included in the original review, the 21 studies encompassed a total of 6364 patients of whom 3202 were randomised to stepped care and 3157 to a control condition. For the 13 studies included in the quantitative meta-analyses, the total number of included patients was 5133 with 2577 in the stepped care arms and 2551 in the control conditions. (The allocation of five patients in one study [18] was not reported. For this reason, the number of patients randomised to stepped care and the control condition do

not equal the total number of participants included in the review or meta-analysis.)

Of the 21 included trials, 17 were patient randomised [studies 1-8, 12-16 and 19-21] and four were cluster randomised [ 9, 11, 17-18]; six were conducted in the USA [4, 5, 7, 8, 10 and 13], eleven in Europe, specifically The Netherlands [1, 3, 6, 9, 12, 14, 16, 18, 19], The Netherlands and Belgium [20] and the UK [15]; four were conducted in other countries (Chile [2], India [11], Nigeria [17] and Hong Kong [21]). Participants were mainly recruited from primary care [studies 2, 9-11, 12-15, 17-19, 21] or secondary care [3-5, 7, 16 & 20]. All studies bar one compared stepped care with usual care, either standard [ 1-6, 9, 10, 12-14, 16, 18-21] or 'enhanced' [ 7, 8, 11, 17]; one study compared stepped care with high-intensity psychological therapy alone [15].

Of the 16 treatment trials, eight included patients scoring above a cut-off on a self-rated depression questionnaire [3-5, 7, 8, 10, 16 and 19]; two also used the core symptoms of MDD [7 & 8] while eight others performed diagnostic interviews to include patients with MDD [6, 9, 11-13, 15, 17, 18]. Two also included minor depression [12, 18] and three also included dysthymia [12, 13, 18]. The five prevention trials [1, 6, 14, 20 and 21] used a diagnostic interview to exclude patients with existing MDD.

Nine studies included patients with a common mental health problem that could include but was not limited to depression. Of those, eight included patients with anxiety [6, 11, 12, 14, 16, 18-21] and one study included patients with stress [18] alongside depressed sub-samples. Nine studies were aimed at depressive symptoms among patients with co-morbid acute coronary syndrome [4 & 5], cancer [7 & 16], diabetes [3, 8, 10, 19] or visual impairment [20]. Six trials, including four of the prevention studies, were specifically aimed at older adults [1, 3, 6, 13, 14 and 20].

***Table 6 overleaf***

Table 6. Characteristics of the new studies (n=7)

ID	Author	Year	Country	Random level	Target of the trial	Control condition	Depression criteria	Comorbid disorder	Age (years)	IMPACT based	Total N (EXP / CTRL)
15	Hill	2014	UK	Patient	Treatment	CBT alone	MDD (CIS-R)	-	18+	No	66 (33/33)
16	Krebber <sup>3</sup>	2015	NL	Patient	Treatment	Usual care: typically interview with nurse or specialist intervention	Depressive symptoms (HADS-D > 7)	Lung or Head & Neck Cancer	NS <sup>4</sup>	No	156 (75/81)
17	Oladeji	2015	Nigeria	Cluster	Treatment	Enhanced usual care: PCPs trained in depression recognition + management; patients advised to share PHQ-9 scores with PCP	MDD (CID-I)	-	18+	No	234 (165/69)
18	Oosterbaan	2013	NL	Cluster	Treatment	Usual care <sup>5</sup>	MDD, minor depression or dysthymia (MINI)	-	18+	No	163 (94/64) <sup>1,2</sup>
19	Stoop	2015	NL	Patient	Treatment	Usual care: GP notified if patient's PHQ-9 scores >=15 at two consecutive research assessments	Depressive symptoms (PHQ-9 ≥ 7)	Diabetes or Lung Disease (asthma, COPD)	18+	No	46 (23/23)
20	van der Aa	2015	NL, Belgium	Patient	Prevention	Usual care <sup>5</sup>	Depressive symptoms (CES-D ≥ 16), not MDD (MINI)	Visual Impairment	50+	No	265 (131/134)
21	Zhang	2014	Hong Kong	Patient	Prevention	Usual care: patients with high levels of depression / anxiety at or following end treatment advised to contact GP; patients with MDD/GAD referred to family doctor	Depressive symptoms (CES-D ≥ 16), not MDD (SCID)	-	18+	No	240 (121/119)

Notes: <sup>1</sup> The allocation of five patients who did not complete baseline questionnaires was not specified – numbers of intervention and control participants do not equal the total; <sup>2</sup> Response and remission data were reported for a subset of patients who presented with a primary diagnosis of depression; the sub-set of data (comprising information on response and remission for n=71 (I:46/C:25) and n=69 (I45/C:24) patients, respectively) were included in primary meta-analyses – data from all participants (numbers as reported in the table) were included in secondary meta-analyses; <sup>3</sup> The protocol paper for this study was published in 2012 – outcome data were extracted from a manuscript currently under review provided to JJH by the authors; <sup>4</sup> age in- and exclusion criteria ‘not specified’; <sup>5</sup> no particular features of usual care described

Abbreviations: CBT – Cognitive Behaviour Therapy; GP – General Practitioner; PCP - Primary Care Physician; MDD – Major Depressive Disorder; GAD – Generalised Anxiety Disorder; COPD – Chronic Obstructive Pulmonary Disease; other abbreviations refer to depressive symptom checklists (HADS-D, PHQ-9, CES-D) and diagnostic interviews for depression (MINI, CIS-R, SCID, CIDI)

***Continued overleaf***



## **Characteristics of the stepped care interventions**

Consistent with the original review, with respect to the seven new studies, there was considerable between-study heterogeneity in numbers of steps (two, three or four), types of treatments offered at each step and duration of the total intervention (between 14 weeks and 12 months; Table 7). In six of the seven, the stepped care intervention was offered in steps of increasing intensity [15, 16, 18-21]. Three studies started with watchful waiting [16, 20, 21]; the first therapeutic component included psycho-education [19], counselling [21] or bibliotherapy alone [20, 21] or combined with one session of counselling [16] or medication [18] and offered as self-help with email, telephone or face to face support. The next step typically comprised CBT or PST either alone [15, 16, 20, 21] or combined with ADM [18]. The last step often consisted of referral to a GP [16, 20, 21]. In one other study psycho-education was followed by bibliotherapy (based on the Coping With Depression / Anxiety course); thereafter patients received six booster sessions of the same and were advised to discuss medication with their GP [19]. There was no progression of increasing therapeutic intensity in one study predominantly involving PST and ADM [17]. None of the new studies implemented stepped care based on the IMPACT model.

### ***All included studies***

Combining data from the update and original review, care was delivered in steps of increasing intensity in 12 studies [1, 3, 6, 11, 12, 15, 16, 18-21]. There was no progression of increasing therapeutic intensity in nine studies [2, 4, 5, 7-10, 13, 17], seven of which were based on the IMPACT model [4, 5, 7-10, 13]. Consistent with studies' inclusion criteria, in twelve studies the stepped care intervention was aimed at depression alone [1-5, 7-10, 13, 15, 17] whereas nine studies sought to treat or prevent both depression and anxiety [6, 11, 12, 14, 16, 18-21] and one study also treated stress [18].

In 19 studies, more than one healthcare professional was involved in delivering stepped care. Professionals included nurses [1, 2, 4-6, 10, 12, 13, 15-19], psychologists [4, 5, 12, 13, 15, 19, 20], psychiatrists [4, 5, 7-11, 13], GPs [2, 5, 8, 9, 11, 13, 15, 17, 19, 21], social workers [2, 4, 7, 8, 20, 21], an occupational therapist [20] and relatively less qualified staff (study researcher [1], residential

home staff [6], an assistant patient navigator [8], lay health counsellor [11], care co-ordinator / trained coach [16], and community mental health workers and officers [17]). In two studies treatment was provided by one healthcare professional: a nurse or psychologist [3] or nurse [14]. No details were available in any study for external professionals providing treatment on referral outside the core stepped care team.

Across all studies, patient progress was assessed using one [1-7, 9-11, 13-15, 17, 18], two [8, 16, 19-21] or exceptionally three [12] self-rated instruments. In four of the six studies using more than one instrument, stepped care was aimed at anxiety in addition to depression and progress was monitored using symptom checklists for each condition [12, 16, 19-21]. In the study using three instruments, progress was monitored using checklists for anxiety, depression and a measure of social function and function at work [12]. In the sixth study, stepped care was aimed at the treatment of depression only; patient progress was assessed using two depressive symptom checklists [8].

In ten studies, the decision to step up was contingent on patients' score relative to a specific cut-off on a symptom checklist [1, 2, 7, 12, 14, 16, 18, 19-21]; in five studies the decision to step up was dependent on improvement on a checklist (relative to baseline or last assessment) [4, 5, 6, 10, 13]; five studies used a combination of improvement and a specific cut-off [3, 8, 9, 15, 17]. In one study, improvement was assessed by health counsellors following application of the General Health Questionnaire with no further detail specified [11].

Checklists typically used to assess progress were the Patient Health Questionnaire-9 [used in studies 4, 5, 7-10, 13, 15, 17, 19], the Centre for Epidemiological Studies Depression Scale [1, 3, 6, 14, 20, 21] and the Hospital Anxiety and Depression Scale [12, 16, 20 and 21]. Other less utilised measures were: the Hamilton Depression Rating Scale [2], Symptom Checklist [8], Inventory of Depressive Symptomatology [12], Work and Social Adjustment Scale [12], Clinical Global Impression – Severity scale [18] and the Generalised Anxiety Disorder questionnaire [19].

Table 7. Characteristics of the stepped care interventions for depression in the new studies (n=7)

ID	Author	N step	Step 1	Step 2	Step 3	Step 4	Providers <sup>1</sup>	Stepping up rules	Total duration
15	Hill	2	WB course (CBT based); support by 1 face to face and 5 telephone contacts	Individual face-to-face CBT (8-20 sessions)	-	-	Nurse, Psychologist, GP	PHQ9 $\geq$ 10 & < 50% improvement at 6 weeks	6 months
16	Krebbber	4	Watchful waiting (2 weeks)	Counselling (1 session) + PST based "Allesondercontrole" course, email / telephone support (5 sessions)	Individual, face to face PST (6 sessions)	Referral to physician for ADs or to speciality mental health care for psychotherapy	Care-coordinator, "trained coach", nurse	HADS-A and/or HADS-D > 7 at 2, 7 and 14 weeks	$\approx$ 14 weeks (steps 1 to 3)
17	Oladeji	3	PE, activity scheduling, PST (8 sessions) if PHQ-9 = 8 to 14. (If PHQ-9 $\geq$ 15, start with step 2)	PST (8 sessions) + ADs. (If started with step 2 and no response on end treatment (see rules) repeat step 2.)	Assessed by GP for referral or consultation with psychiatrist	-	Community health workers & officers, nurse, GP	PHQ-9 $\geq$ 5 & / or < 50% improvement	16 weeks $\approx$ 4 months
18	Oosterbaan	2	GSH (using CWD or Sresspac course, 5 sessions). If depression or anxiety is moderate also ADs.	CBT (no pre-specified number of sessions) + ADs. (If depression or anxiety severe, start with step 2.)	-	-	Nurse, specialist mental health service <sup>2</sup>	CGI-S $\geq$ 3 at 4 months	Up to 8 months
19	Stoop	3	PE (4 sessions)	CWD/A course + face to face coaching (10 sessions)	Advised to discuss meds with GP + CWD/A booster sessions (n=6)	-	Nurse, psychologist, GP	PHQ-9 $\geq$ 7 & / or GAD-7 $\geq$ 8 at 4 & 14 weeks; PHQ-9 or GAD-7 $\geq$ 15 at 9 weeks	38 weeks $\approx$ 9.5 months
20	van der Aa	4	Watchful waiting (3 months)	'Glance At Your Dip' course supported by 1 initial face to face session & several telephone calls + optional extra face to face)	PST (1 phone call + 7 face to face sessions)	Referral to GP to discuss ADs / more intensive treatment	Occupational therapist, social worker, psychologist, GP	CES-D $\geq$ 16 or HADS-A $\geq$ 7 at 3 months, end step 2 & 3	12 months
21	Zhang	4	Watchful waiting (3 months)	Telephone counselling (6 sessions)	Face to face PST (6 sessions)	Referral to family doctor for treatment (ADs if required) / onward referral to psychiatrist	Social worker, GP	CES-D $\geq$ 16 or HADS-A $\geq$ 6 at 3, 6 & 9 months	12 months

Notes: <sup>1</sup> 'Providers' includes the role of all health care professionals involved in the stepped care intervention except for professionals who cared for patients 'on referral'; <sup>2</sup> the professional group of persons involved in the delivery of specialist mental health services was not specified.

Abbreviations: ADs =antidepressants; CBT = cognitive behavioral therapy; CES-D = Center for Epidemiological Studies Depression Scale; CGI-S= Clinical Global Impression - Severity Scale; CWD/A = Coping With Depression / Anxiety; GAD-7 = General Anxiety Disorder questionnaire; GP = General Practitioner; HADS-A / HADS-D = Hospital Anxiety and Depression Scale-Anxiety / -Depression; PHQ-9 = Patient Health Questionnaire-9; PST = problem solving therapy; PE = psycho-education; WB = Wellbeing Course

***Please see over***

## **Risk of bias**

In one study [3], all criteria were rated as either at unclear or high risk of bias; in a second [1] five of the six criteria were rated at unclear or high risk of bias. In two of the new studies, three criteria were rated at high or unclear risk of bias [17, 18] (Table 8). Across the remaining 17 trials, most criteria were rated at low risk of bias.

The description of the randomisation sequence generation was adequate except for in four studies where methods were not clearly reported [1, 3, 18, 21]; seven studies did not clearly report methods of allocation concealment [1, 3, 4, 10, 11, 14, 17). No studies were able to blind patients or study personnel (clinicians) but the large majority (n=19) used self-report data and / or assessors to measure outcomes who were unaware of the randomisation status of their patients; two studies did not clearly report blinding [1, 3]. With respect to handling incomplete outcome data, three studies were rated at high risk of bias [1, 3, 9] and another at unclear risk [18]. All studies used intention to treat analyses i.e. analysed patients according to the group to which they had been allocated. In terms of selective reporting, five studies were rated at high risk of bias [1, 3, 17-19] and one at unclear risk [21]. Three studies were rated at high risk of other biases because of the potential for contamination between trial arms [6, 8, 13], because patients were recruited differently in the intervention and control groups [9] and because data collection in the intervention and control groups occurred at different time points post baseline – the authors did not allow for this in their analysis [16]. One study was rated at high risk of other biases because a sub-set of analyses had not been undertaken according to protocol and was therefore not reported [3].

***Table 8 overleaf***

Table 8. Risk of bias in the new studies (n=7)

Study no.	Author	Risk of Bias						N low (N high)
		Generation of random sequence	Allocation concealment	Blinding <sup>1</sup>	Incomplete outcome data	Selective reporting	Other potential bias	
15	Hill	Low	Low	Low	Low	Low	Low	6 (0)
16	<a href="#">Krebber</a>	Low	Low	Low	Low	Low	High	5 (1)
17	<a href="#">Oladeji</a>	Low	Unclear	Low	High	High	Low	3 (2)
18	<a href="#">Oosterbaan</a>	Unclear	Low	Low	Unclear	High	Low	3 (1)
19	Stoop	Low	Low	Low	Low	High	Low	5 (1)
20	van der Aa	Low	Low	Low	Low	Low	Low	6 (0)
21	Zhang	Unclear	Low	Low	Low	Unclear	Low	4 (0)
<b>N Low</b>		5	6	7	5	3	6	32
<b>N Unclear</b>		2	1	0	1	1	0	5
<b>N High</b>		0	0	0	1	3	1	5

Notes: <sup>1</sup>Blinding of participants and personnel was not possible in any study; included ratings are with respect to the blinding of outcome assessors.

## Effects of stepped care

### Primary analyses

Eleven comparisons reported post-intervention outcomes for patients with depression. The pooled post-intervention effect size from the combined effect size in each individual study was  $d=0.40$  (95% confidence interval 0.22 to 0.57; Table 9). Sensitivity analyses estimating overall effects using the measure in each study with the highest and lowest post-test effect size produced pooled effect sizes of  $d=0.45$  (95% CI 0.27 to 0.63) and  $d=0.33$  (95% CI 0.15 to 0.52), respectively. Levels of heterogeneity (indicated by  $I^2$ ) were high. All of the pooled effect sizes were significantly in favour of stepped care. Corresponding forest plots are provided in Figure 5.

**Table 9 & Figure 5 overleaf**

Table 9. Pooled post-intervention effects (Cohen's d) across treatment trials examining the effects of stepped care compared with usual care in patients with depression

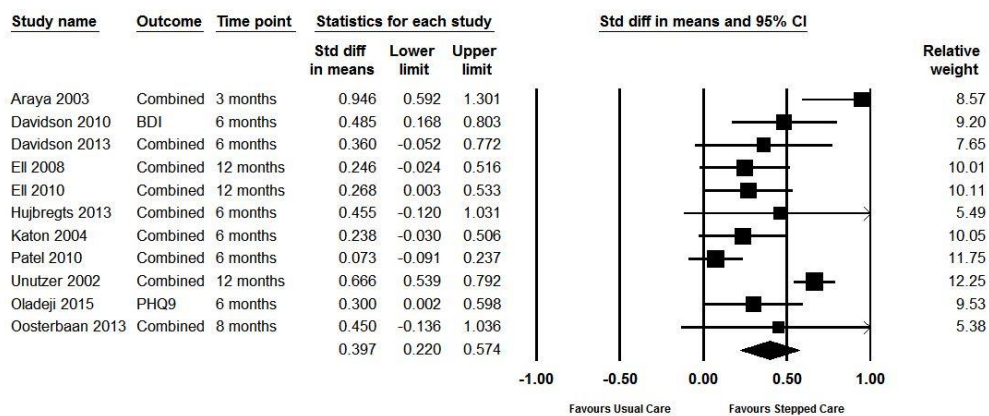
Post intervention effect sizes	N <sub>comp</sub> <sup>1</sup>	d	95% CI	I <sup>2</sup>
• Outcomes combined	11	0.40	0.22 to 0.57	78.09* <sup>2</sup>
• Outcomes with highest ES	11	0.45	0.27 to 0.63	74.88*
• Outcomes with lowest ES	11	0.33	0.15 to 0.52	82.49*

Notes: <sup>1</sup> N<sub>comp</sub> = number of comparisons; <sup>2</sup> \* = p < 0.01.

Abbreviations: d = Cohen's d; 95% CI = 95% confidence interval; ES = Effect Size

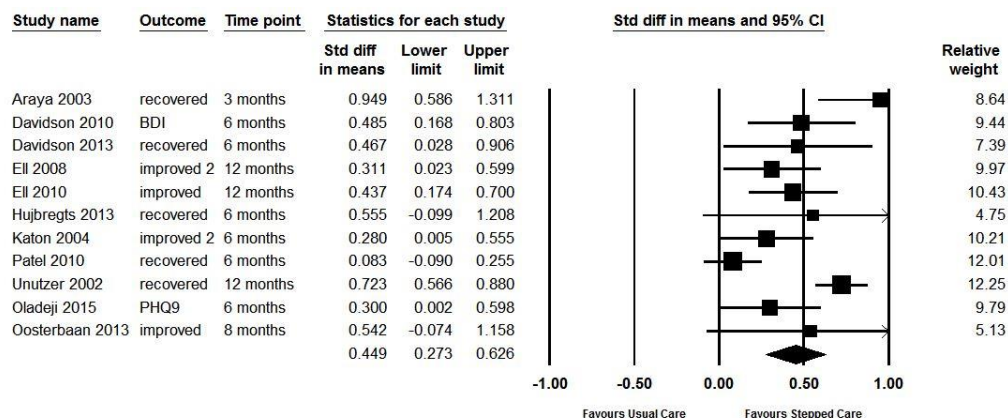
Figure 5. Forest plots of stepped care vs. usual care: post-intervention improvement among patients with depression calculated using the combined, highest and lowest effect size in individual studies.

**i) Multiple outcomes in individual studies combined:**

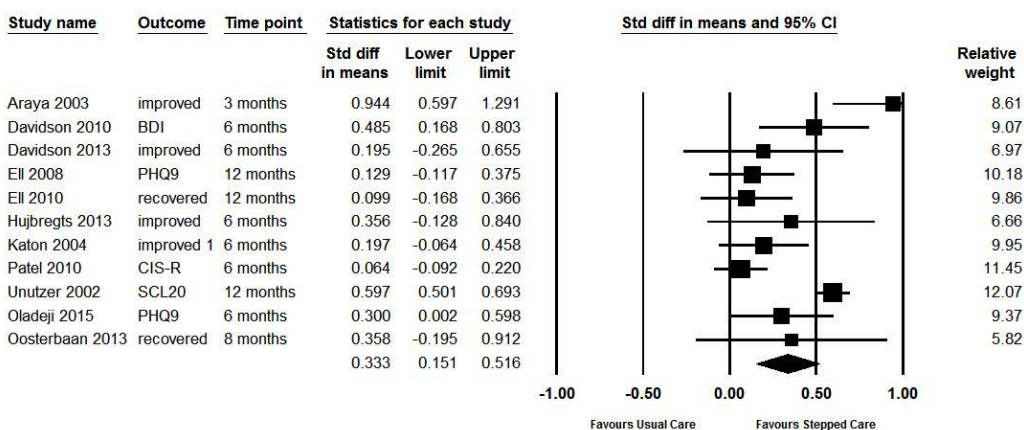


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## ii) Highest effect size in individual studies:



## iii) Lowest effect size in individual studies:



### ***The effect of stepped care on patients with depression at different time points***

The stepped care interventions varied in duration between three and 12 months. Overall effect sizes at different time points estimated using the combined effect size in individual studies were as follows:  $d=0.69$  at three to four months (95% confidence interval 0.46 to 0.93);  $d=0.36$  at six to nine months (95% CI 0.23 to 0.49);  $d=0.40$  at 12 to 18 months (95% CI 0.20 to 0.61;

Table 10). Levels of heterogeneity (indicated by  $I^2$ ) were high except for in the analysis of improvement at three to four months. All effects were significantly in favour of the stepped care intervention. Forest plots of the analysis at each time point are provided in Figure 6.



Table 10. The pooled effect (Cohen's *d*) of stepped care vs. usual care at different time points among patients with depression

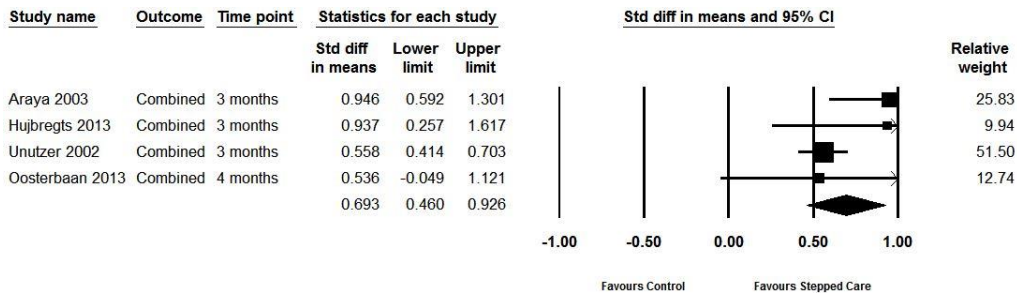
	N <sub>comp</sub> <sup>1</sup>	<i>d</i>	95% CI	I <sup>2</sup>
<b>Effect sizes for different time points</b> <sup>3</sup>				
• 3-4 months	4	0.69	0.46 to 0.93	38.30
• 6-9 months	11	0.36	0.23 to 0.49	61.22*
• 12-18 months	6	0.40	0.20 to 0.61	67.75*

Notes: <sup>1</sup> N<sub>comp</sub> = number of comparisons; <sup>2</sup> \* = *p* < 0.01; <sup>3</sup> pooled effect sizes for different time points were calculated using the combined outcomes effect sizes for individual studies

Abbreviations: *d* = Cohen's *d*; 95% CI = 95% confidence interval; ES = Effect Size

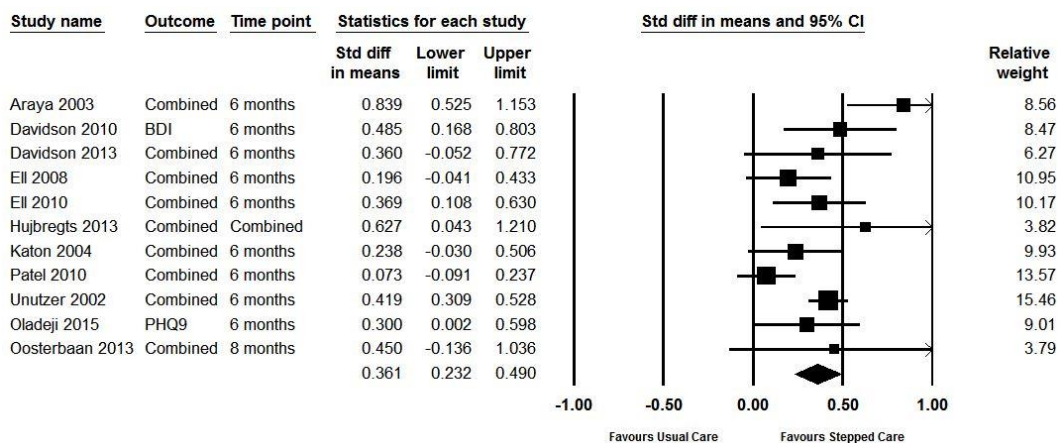
Figure 6. Forest plots of stepped care vs. usual care: improvement among patients with depression at three to four, six to nine and 12-18 months - effect sizes estimated using the combined effect in each study

**i) Effects of stepped care at three to four months:**

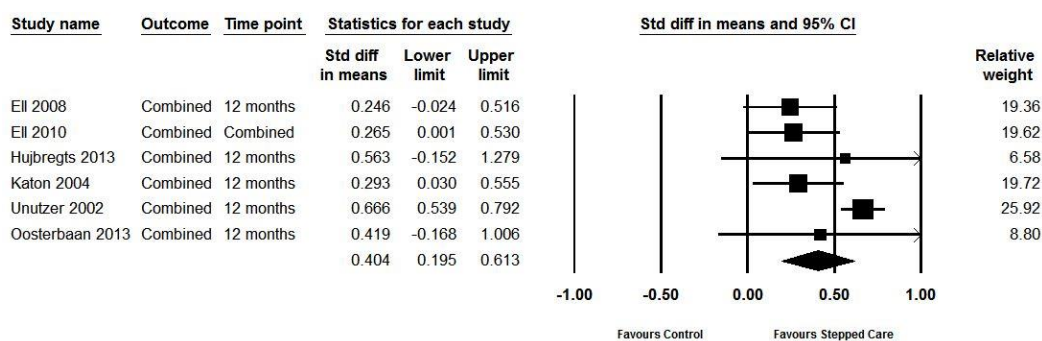


**Figure continued overleaf**

## ii) Effects of stepped care at six to nine months:



## iii) Effects of stepped care at 12 to 18 months:



## Secondary analyses

Thirteen studies reported effects of stepped care on depressive symptoms in patients with a common mental health disorder that could include but was not limited to depression. The pooled post-intervention effect size from the combined effect size in each individual study was  $d=0.37$  (95% confidence interval 0.20 to 0.54; Table 11). Sensitivity analyses estimating overall effects using the measure in each study with the highest and lowest post-test effect size produced pooled effect sizes of  $d=0.41$  (95% CI 0.23 to 0.59) and  $d=0.32$  (95% CI 0.15 to 0.49), respectively. Levels of heterogeneity (indicated by  $I^2$ ) were high. All of the pooled effect sizes were significantly in favour of stepped care but smaller than the equivalent effects estimated for patients with depression only. Forest plots of improvement immediately after stepped care relative to usual care are provided in Figure 7.

Table 11. The pooled post-intervention effect (Cohen's *d*) of stepped care vs. usual care on patients with common mental health problems including depression

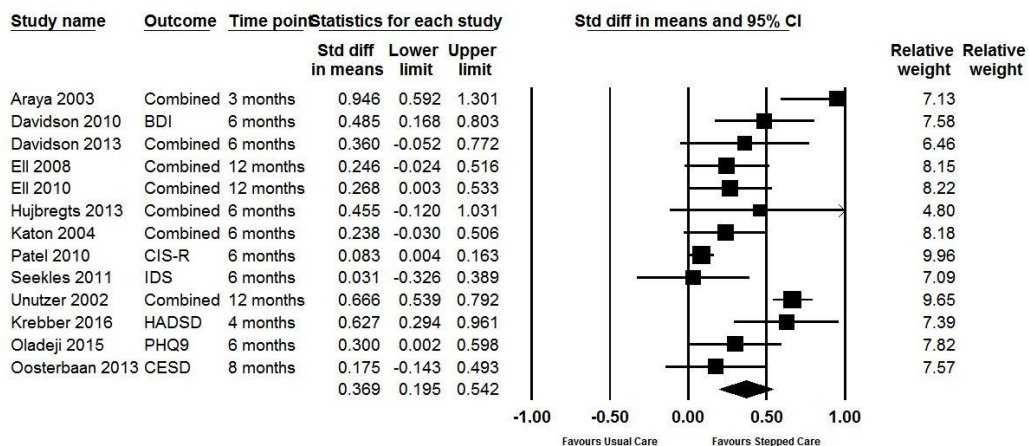
	N <sub>comp</sub> <sup>1</sup>	<i>d</i>	95% CI	I <sup>2</sup>
<b>Post intervention effect sizes</b>				
• Outcomes combined	13	0.37	0.20 to 0.54	85.29* <sup>2</sup>
• Outcomes with highest ES	13	0.41	0.23 to 0.59	84.59*
• Outcomes with lowest ES	13	0.32	0.15 to 0.49	86.87*

Notes: <sup>1</sup> N<sub>comp</sub> = number of comparisons; <sup>2</sup> \* = p < 0.01.

Abbreviations: *d* = Cohen's *d*; 95% CI = 95% confidence interval; ES = Effect Size

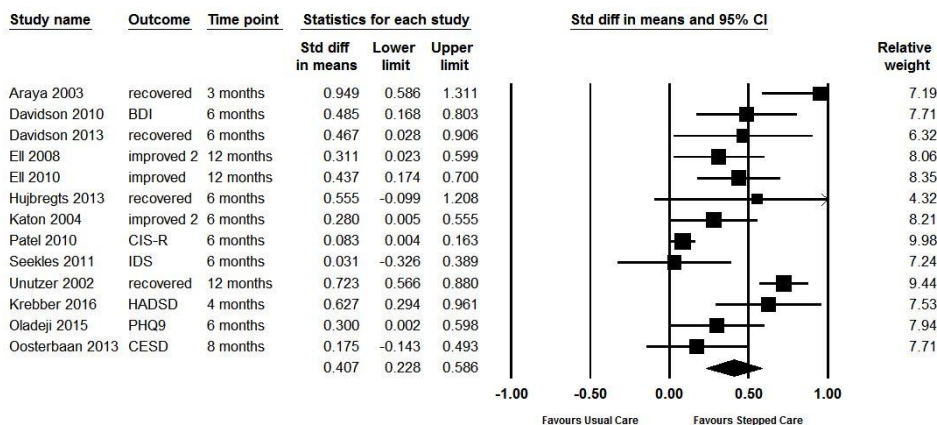
Figure 7. Forest plots of stepped care vs. usual care: post-intervention improvement in depressive symptoms among patients with common mental health problems including depression - calculated using the combined, highest and lowest effect size in individual studies

**i) Multiple outcomes in individual studies combined:**

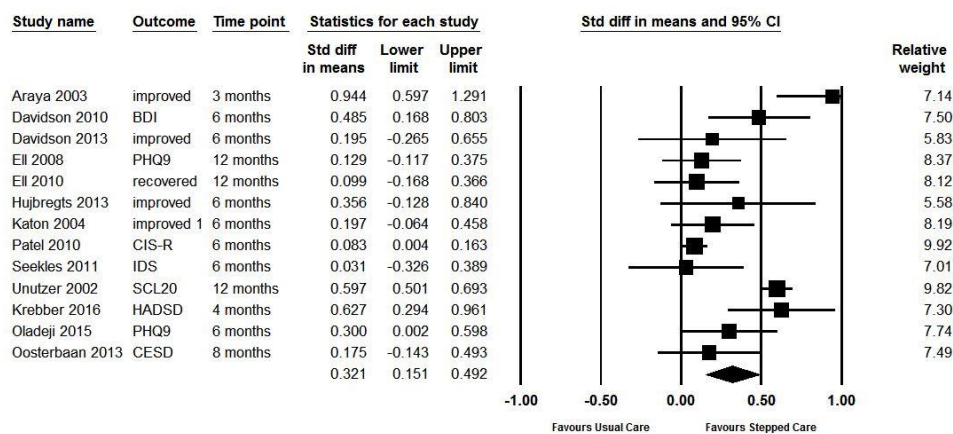


**Figure 7 continued overleaf**

## ii) Highest effect size in individual studies:



## iii) Lowest effect size in individual studies:



## ***The effect of stepped care on patients with common mental health problems at different time points***

Six comparisons reported outcomes at two to four months for patients with a common mental health problem that could include but was not limited to depression; 13 comparisons reported six to ten month outcomes and seven comparisons reported effects at 12 to 18 months. Overall effect sizes at different time points estimated using the combined effect size in individual studies were as follows:  $d=0.55$  at two to four months (95% confidence interval 0.34 to 0.77);  $d=0.32$  at six to ten months (95% CI 0.19 to 0.45);  $d=0.35$  at 12 to 18 months (95% CI 0.15 to 0.55; Table 12). Levels of heterogeneity (indicated by  $I^2$ ) were high. All effect sizes were significantly in favour of the stepped care

intervention but smaller than the equivalent estimates for patients with depression only. Corresponding forest plots are provided in Figure 8.

Table 12. The pooled effect (Cohen's d) of stepped care vs. usual care at different time points among patients with common mental health problems including depression

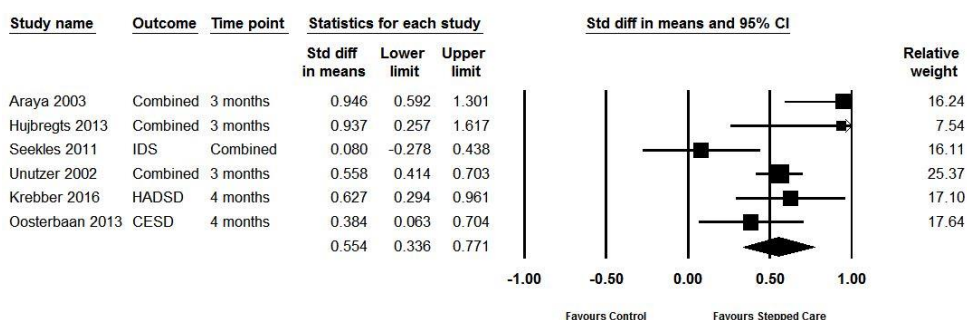
	N <sub>comp</sub> <sup>1</sup>	d	95% CI	I <sup>2</sup>
<b>Effect sizes for different time points</b> <sup>3</sup>				
• 2-4 months	6	0.55	0.34 to 0.77	64.05* <sup>2</sup>
• 6-10 months	13	0.32	0.19 to 0.45	73.93*
• 12-18 months	7	0.35	0.15 to 0.55	71.41*

Notes: <sup>1</sup> N<sub>comp</sub> = number of comparisons; <sup>2</sup> \* = p < 0.05; <sup>3</sup> pooled effect sizes for different time points were calculated using the combined outcomes effect sizes for individual studies

Abbreviations: d = Cohen's d; 95% CI = 95% confidence interval; ES = Effect Size

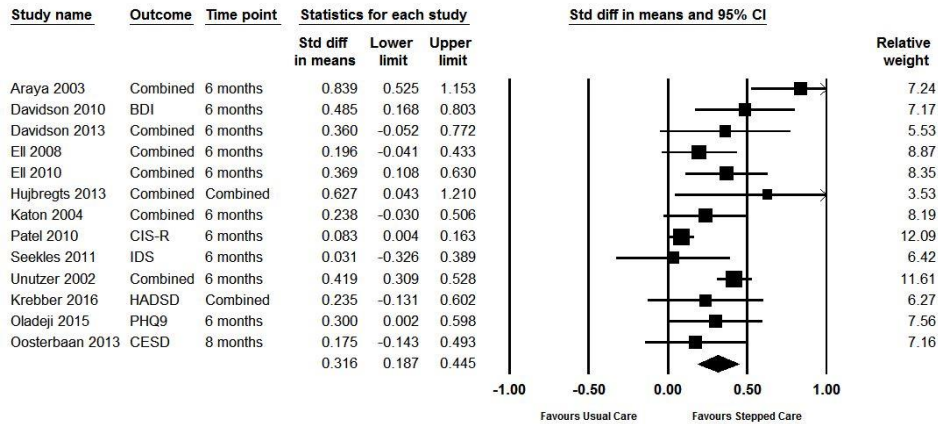
Figure 8. Forest plots of stepped care vs. usual care: improvement among patients with common mental health problems, including depression, at two to four, six to ten and 12-18 months - effect sizes estimated using the combined effect in each study

**i) Effects of stepped care at two to four months:**

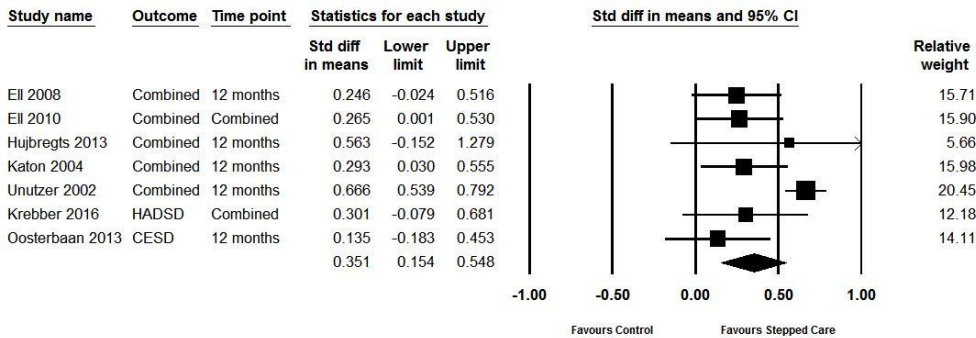


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## ii) Effects of stepped care at six to ten months:



## iii) Effects of stepped care at 12 to 18 months:

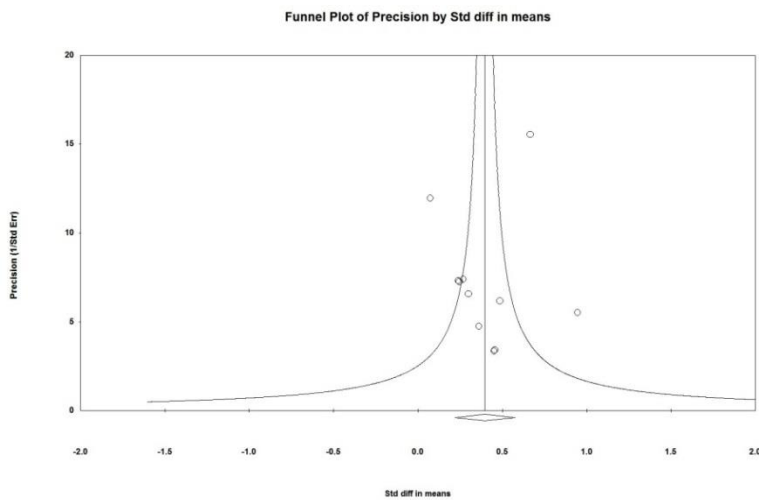


## Publication bias

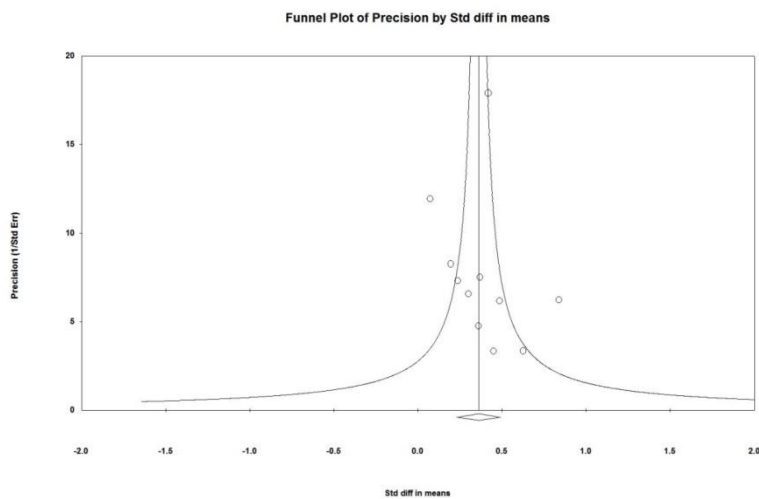
Although there was no marked evidence of asymmetry in funnel plots of the effect of stepped care vs. usual care immediately after treatment or at six to nine months on patients with depression (Figure 9 – primary analyses) Duval and Tweedie's *Trim and Fill* procedure removed three studies from the estimate of the pooled effect at six to nine months. The adjusted effect size was  $d=0.28$  (95% CI 0.15 to 0.42); the magnitude of the observed effect was  $d=0.36$  (95% CI 0.23 to 0.49). With respect to secondary analyses, there was some evidence of asymmetry in funnel plots of the effect of stepped vs. usual care immediately after treatment and at six to ten months on patients with common mental health problems that included but were not limited to depression (Figure 9). However, in both cases, Duval and Tweedie's *Trim and Fill* procedure did not remove any study from analysis; observed and adjusted estimates of effects were identical.

Figure 9. Funnel plots for the primary and secondary analyses of the effects of stepped care immediately after treatment and at six to nine months estimated using the average (or combined) effect in each study

**i) Primary analysis – post-intervention effects on patients with depression:**

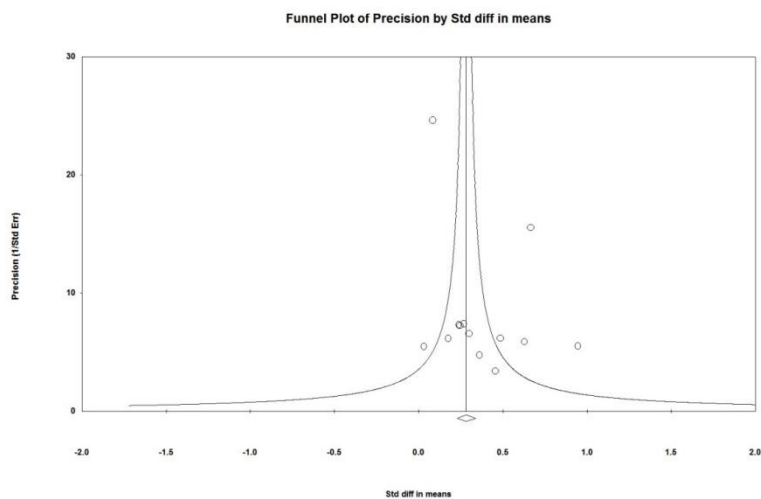


**ii) Primary analysis – effects on patients with depression at six to nine months:**

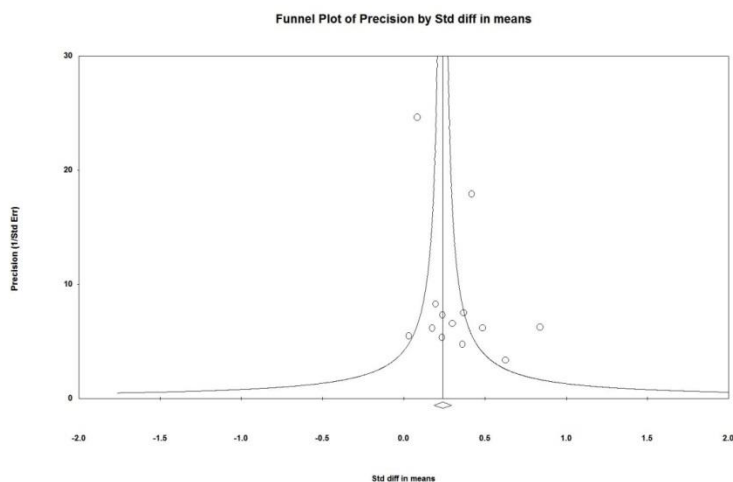


**Figure 9 continued overleaf**

**iii) Secondary analysis – post-intervention effects on patients with common mental health problems:**



**iv) Secondary analysis – effects on patients with common mental health problems at six to ten months:**



**Sub-group analysis**

The effect of stepped care at six to nine months among patients with depression (overall  $d = 0.36$ , 95% CI 0.23 to 0.49) was significantly higher in nine studies [2, 4, 5, 7-10, 13, 17] examining models of no clear intensity order ( $d = 0.40$ ) than in two studies [11, 18] on stepped care of increasing intensity ( $d = 0.15$ ; Table 13). None of the other analysed variables (country, stepped care treatment based on IMPACT protocol, physical health comorbidity and patients' diagnostic status at inclusion) were significantly related to effect size.



Table 13. Sub-group analyses on overall effects of stepped care compared with controls at six to nine months among patients with depression - pooled effects calculated using combined outcomes; effect size  $d = 0.35$ ; 95% CI 0.22 to 0.47

<i>Effects at six to nine months by:</i>	$N_{\text{comp}}^1$	$d$	95% CI	$I^2$	p value
Country					
• USA	6	0.37	0.29 to 0.45	0.00	0.19
• Europe	2	0.54	0.13 to 0.95	0.00	
• other	3	0.39	-0.05 to 0.83	88.94* <sup>2</sup>	
IMPACT based					
• yes	7	0.38	0.29 to 0.46	0.00	0.13
• no	4	0.40	0.03 to 0.77	83.78*	
Progressive treatment intensity					
• yes	2	0.15	-0.15 to 0.45	32.20	< 0.01
• no	9	0.40	0.28 to 0.51	39.56	
Physical co-morbidity					
• present	5	0.31	0.18 to 0.44	0.00	0.53
• absent	6	0.41	0.19 to 0.64	78.07*	
Inclusion based on diagnosis					
• yes	6	0.41	0.19 to 0.64	78.07*	0.53
• no	5	0.31	0.18 to 0.44	0.00	

Notes: <sup>1</sup>  $N_{\text{comp}}$  = number of comparisons; <sup>2</sup> \* =  $p < 0.01$

Abbreviations:  $d$  = Cohen's  $d$ ; 95% CI = 95% confidence interval

### Effect of stepped care in studies excluded from meta-analysis

In all, eight studies were excluded from primary and secondary meta-analyses including one on relapse prevention [1], four indicated prevention trials [6, 14, 20, 21] and three treatment trials [3, 15, 19]. The treatment study by Stoop et al. (2015) [19] appeared to show results in favour of stepped care but did not report outcome data with sufficient clarity for results to be useable. In another treatment study, Bot et al. (2010) [3] only provided two-year follow-up data for complete cases (49.6% of participants) and reported no difference between the groups ( $d=-0.12$ ; 95% CI -0.62 to 0.39). The treatment study by J. J. Hill et al. (2014) [15] (presented in full in Chapters Five and Six) comprised a pilot trial of

stepped care compared with high-intensity psychological therapy alone. For patients allocated to receive stepped care, the mean difference in depressive symptoms from baseline to follow-up measured using the Beck Depression Inventory version 1.0 (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) was -13.4 points; for patients allocated to CBT alone, the mean difference was -13.6.

Three of the four indicated prevention studies showed results that were in favour of stepped care. As reported in section 4.2.3, one study [6] reported 12-month MDD rates of 6.5% in the intervention and 14.1% in the control group; the second study [14] demonstrated 12-month prevalence rates of combined MDD and anxiety disorders of 11.6% in the intervention and 23.8% in the control. The pooled rate ratio of the two studies was 0.48 (95% CI 0.27 to 0.83,  $I^2 = 0$ ). The third study [20] reported 24-month MDD, dysthymia and anxiety rates of 29% in the intervention and 46% in the control (incidence rate ratio = 0.63, 95% confidence interval 0.45 to 0.87). The other prevention trial [21] found no difference between stepped care and care as usual: 12 month MDD and GAD rates were 6.4% in the intervention and 6.5% in the control (incidence rate ratio = 0.99, 95% confidence interval 0.30 to 3.27). The study on relapse prevention [1] reported no difference in the 12 month MDD incidence rate between stepped care and care as usual.

#### **4.3.4 Summary of key findings from the updated review and meta-analysis**

Twenty-one trials on stepped care for depression were identified, eleven of which were used in primary meta-analyses and 13 of which were used in secondary meta-analyses. All of the included studies except for one compared stepped care with care as usual. The results of primary analyses showed that stepped care had a moderate effect on depressive symptoms among patients with depression ( $d=0.36$  at six to nine months and  $d=0.40$  post-intervention). Secondary analyses found that stepped care had a moderate effect on depressive symptoms in patients with common mental health problems that included but were not limited to depression ( $d=0.32$  at six to ten months and  $d=0.37$  post-intervention). Interventions were extremely heterogeneous; those based on progressive treatment intensity performed worse ( $n=2$ ;  $d=0.15$ ) than those without ( $n=9$ ;  $d=0.40$ ;  $p < 0.01$ ). In most trials, risk of bias on the majority of criteria was low. There was little evidence of publication bias.

#### **4.4 Key conclusions**

This study involved a systematic review undertaken and updated with the aim to assess existing evidence on the effectiveness of stepped care treatment for depression in adults. The results of the original and updated review were consistent. Relative to care as usual, stepped care was found to be efficacious. Sub-group analyses indicated that interventions without a clear intensity order may produce greater gains than those defined by progressive intensity. However, the review did not find sufficient evidence to establish whether stepped care is equivalent to long-term intensive psychological therapy for all.

All of the studies in the original review compared stepped care with treatment as usual. Meta-analyses incorporated trials of stepped care with treatment as usual only; it was not possible to estimate the relative effectiveness of stepped care vs. high-intensity psychological therapy. Although the systematic review update included a pilot trial of stepped care vs. intensive psychotherapy it also confirmed that a definitive evaluation of the same has not yet been undertaken. In the absence of at least one well conducted fully-powered RCT comparing stepped care vs. high-intensity psychological therapy for all, there remains insufficient evidence to determine the relative effectiveness of these systems.

At this time, it is not possible to determine whether the assumption underpinning the widespread implementation of stepped in the UK and elsewhere holds. Commensurate with MRC guidance for the development and evaluation of complex interventions (Craig et al., 2008), prior to a fully-powered evaluation, preparatory work is needed to determine feasibility and inform trial design. On completion of the original systematic review, it was concluded that a feasibility study to inform a fully-powered evaluation of stepped care compared with intensive psychological therapy alone was required. The resulting study, 'STEPS', is now described: methods are summarised in Chapter Five; results in Chapter Six. The findings of the systematic review are discussed in full in Chapter Seven.

## **CHAPTER 5. THE STEPPED CARE VS. HIGH-INTENSITY THERAPY (STEPS) FEASIBILITY STUDY: METHODS**

This chapter describes the methods of a feasibility study undertaken to prepare for a fully-powered randomised controlled trial of stepped care compared with high intensity psychological therapy alone for the treatment of depression in adults. Study results are described in Chapter Six. The need for the study was established following a systematic review of randomised controlled trials on the effectiveness of stepped care (see Chapter Four). Feasibility study methods have been reported in J. J. Hill et al. (2014). This chapter is based on the published article; additional information is provided.

The chapter is organised into eight main sections: aim, objectives and research questions (5.1); study overview (5.2); pilot randomised controlled trial of stepped care (5.3); embedded semi-structured interviews (5.4); analysis - quantitative, qualitative and mixed methods (5.5); ethical issues (5.6); patient and public involvement (5.7); study set-up and management including execution dates (5.8).

### **5.1 Aim, objectives and research questions**

The aim of the feasibility study was to test the feasibility of and provide information to inform the design of a large clinical trial that will investigate the effectiveness and efficiency of stepped care treatment of depression in adults. Specific objectives were to: (1) gather enough information on recruitment, retention, step ups and treatment effects to design a fully-powered clinical trial or to determine that such a trial is not feasible; (2) explore patients' and therapists' views of stepped care and the ways in which patients' views relate to how much they engage in therapy to inform a stepped care clinical protocol for a proposed randomised trial.

There were five related research questions:

1. What is the quantifiable performance of recruitment and retention methods which may be used in a fully powered trial? (Objective 1)
2. What proportion of people who receive stepped care step up from low-intensity to high-intensity treatment or are discharged following low-intensity psychological therapy? (Objective 1)

3. What is the variability in patient-related outcomes following stepped care or intensive psychological therapy alone and how do they correlate with patients' baseline scores? (Objective 1)
4. To what extent are potential recruitment methods considered appropriate by trial participants (patients), study therapists and other health professionals and how do people's views combine with numeric data on the performance of trial recruitment methods? (Objective 1)
5. How acceptable is stepped care to patients and therapists and how do patients' views explain variability in the number of treatment sessions they attend? (Objective 2)

## **5.2 Study design**

The study employed a mixed methods embedded design (Creswell & Plano Clark, 2011) in which semi-structured interviews with patients, therapists and IAPT staff were embedded in a pilot randomised controlled trial of stepped care versus intensive psychological therapy alone for adults with depression. Quantitative data were used to assess the feasibility of trial recruitment, retention and clinical procedures and to inform the sample size calculation that is required for a full-scale evaluation. Semi-structured interviews with patients, therapists and other IAPT staff were embedded in the pilot trial and undertaken concurrently to explore what interviewees thought of (i) trial methods and procedures and (ii) the acceptability of the stepped care intervention. Quantitative and qualitative data on trial methods and procedures were combined so that one type of data could be interpreted in the context of the other for a more informed understanding of feasibility and appropriateness. By integrating qualitative and quantitative data on the acceptability of stepped care I sought to generate hypotheses regarding how acceptability and treatment adherence might relate.

## **5.3 Pilot randomised controlled trial**

### **5.3.1 Setting and participants**

Participants were recruited from an Improving Access to Psychological Therapies (IAPT) service serving a city population. Eligible participants were aged 18 years and older with DSM Major Depressive Disorder identified by

standard clinical interview (Clinical Interview Schedule – Revised, CIS-R) (Lewis, Pelosi, Araya, & Dunn, 1992). In line with the current operating criteria for IAPT services to determine who they treat and to reflect the pragmatic nature of this trial (and the fully-powered evaluation), at interview patients were excluded who were alcohol or drug dependent, acutely suicidal or cognitively impaired, had bipolar disorder or psychosis/psychotic symptoms. Participants were eligible whether they were in receipt of antidepressant medication or not.

Patients were subsequently treated at the Mood Disorders Centre AccEPT Clinic facilities (<http://www.exeter.ac.uk/mooddisorders/acceptclinic/>). The AccEPT Clinic is part of the School of Psychology at the University of Exeter. It provides psychological therapies as part of the Mood Disorders Centre's mission to develop, test and make accessible effective treatments for depression and other disorders. Although the AccEPT Clinic has been commissioned by the NHS, it is separate to and not an IAPT Service.

### **5.3.2 Randomisation, allocation concealment and blinding**

Participants were allocated in a 1:1 ratio to either the stepped care or intensive psychological therapy arms stratified according to their symptom severity on the Beck Depression Inventory – version I (BDI-I: minimal (0-9), mild (10-18), moderate (19-29), severe (30-63)) (Beck et al., 1961). Allocation was minimised to maximise the likelihood of balance in stratification variables across the two study arms. Concealment was ensured by use of an externally administered, password-protected randomisation website and retaining a stochastic element to the minimisation algorithm. The computer-based allocation and website were developed and maintained by the accredited Peninsula Clinical Trials Unit, independent of the trial. Participants' details were sent to the AccEPT Clinic Administrator to alert them to assign the patient a study therapist and contact the patient to arrange treatment.

All research measures were applied equally to both groups of participants. At baseline, the study researcher (JJH) was blind to group allocation which occurred after this assessment. At follow-up, I was un-blinded to allow me to interview patients who had been allocated to receive stepped care; interviews were conducted prior to follow-up. Follow-up and baseline data were self-reported.

### **5.3.3 Recruitment**

The Increasing Access to Psychological Therapies (IAPT) service from which participants were recruited wrote to all patients who were offered an initial assessment appointment to invite them to take part. Letters were sent out by the Administrative Team and were an amended version of the service's standard appointment letter. A study summary sheet and 'permission for researcher to contact' form accompanied each letter - see Appendix II. Interested patients were asked to bring their completed 'permission to contact' form to their initial assessment and hand it to their therapist. Therapists placed completed forms in a clearly marked box in the IAPT service reception for the study researcher to collect. When a therapist met with patients at a local GP practice, completed forms were placed in the box on return to the IAPT service. In the interim, therapists were asked to send form information to the IAPT Admin Team via secure email.

#### **Assessing eligibility**

Patients who completed and returned a form were telephoned by the study researcher who used a standard two-question case-finding instrument for depression (Whooley, Avins, Miranda, & Browner, 1997) to assess possible eligibility. Baseline interviews were arranged with potentially eligible and willing participants. Interviewees were sent a full study information sheet and flow-chart (provided at Appendix II). At interview, the study was explained in full and eligibility was assessed using the Mini-Cog (Borson, Scanlan, Brush, Vitaliano, & Dokmak, 2000) to screen for cognitive impairment and the CIS-R (Lewis et al., 1992) to establish a diagnosis of depression. Self-report data was used to establish if patients were alcohol or drug dependent, had been diagnosed with Bipolar Disorder, Schizophrenia or had psychotic symptoms. Patients who were acutely suicidal were identified by self-report; good clinical practice was employed in monitoring risk (see section 5.6.3).

#### **Action on end of interview**

Ineligible and / or unwilling patients continued with usual care at IAPT. If eligible, fully informed and consenting, patients entered into the study. For each new participant, the study researcher completed an 'Information for Clinic' form

(see Appendix II). This comprised a description of the participant's diagnosis on the CIS-R (Lewis et al., 1992), demographics, risk status and other relevant clinical information. Forms were passed to the AcCEPT therapists via the Clinic Administrator. The study researcher also contacted the IAPT Admin Team to let them know if patients were 'in' or 'out' of the study. The IAPT Admin Team wrote to patients who were no longer in their care to confirm that they had been discharged; returning patients were contacted by their IAPT therapist to schedule their first treatment session. Towards the end of the study, this procedure was revised. At initial assessment, IAPT therapists scheduled a telephone call with their patient for two weeks forth i.e. when the outcome of recruitment would be known. The purpose of the call was to acknowledge that the patient had joined the study and wish them well or to arrange the patient's first IAPT treatment session.

### **Treatment delay**

Two procedures were implemented so that patients' treatment was not delayed and to enable the IAPT service to meet a key performance target to commence treatment within 28 days of patients' initial assessment: the study researcher completed recruitment procedures within five working days of an individual's IAPT assessment appointment; for people who returned a permission form, the IAPT service activated a 'patient delay'. This delay remained in place until the outcome of recruitment was known. The period of delay did not count towards the 28 days from assessment to first treatment session.

### **Logging study involvement**

Patients' involvement in the study was logged by the IAPT service as follows. Individuals' entry on IAPT-us ([www.iaptus.co.uk](http://www.iaptus.co.uk)), an electronic patient record keeping system, was updated to record when people were sent study information. The Admin Team and study researcher maintained a list of patients who completed and returned permission forms; individuals' interest was noted on IAPT-us. When a patient joined the study or continued treatment with IAPT, both the list and IAPT-us entry were updated; the date on which the decision had been communicated was recorded on the list. Systems allowed the IAPT service to monitor whether recruitment had been completed within five working days and to avoid sending patients study information twice - this could



happen when patients had been invited to take part, received and completed treatment at IAPT or the AccEPT Clinic and returned to IAPT for further treatment whilst recruitment was ongoing.

### **5.3.4 Trial interventions**

Clinical procedures in both arms of the feasibility trial were Cognitive Behaviour Therapy (CBT) in both low- and high-intensity variants.

#### ***Stepped care***

Stepped care involved initial low-intensity CBT in the form of Guided Self Help and subsequently, dependent on treatment response, high-intensity CBT. Guided Self Help (GSH) encompassed delivery of an off-line version of the internet delivered Wellbeing Course developed by the Centre for Emotional Health at Macquarie University, Sydney, Australia (<http://www.ecentreclinic.org/>). For some patients, the Centre for Emotional Health supplies course material by post and patients are supported by a therapist via the internet or by phone. The Wellbeing Course was utilised in this study for two main reasons: course effectiveness has been established (Titov et al., 2013; Titov et al., 2014; Titov, Dear, Johnston, & Terides, 2012); the course content is highly structured and relatively prescribed such that all patients receive similar treatment.

With the permission of Macquarie, Wellbeing Course material was adapted for UK patients. Culturally specific information and references were replaced with equivalent for the UK. Course material was otherwise unchanged. Weekly delivery of the course material was replicated in how patients were provided with pdf or paper documents. Each week for five weeks, the AccEPT Clinic Coordinator emailed or posted patients a Lesson, Do It Yourself (DIY) Guide, Stories and Additional Resources.

Lessons were 'core reading'. The first lesson comprised material about anxiety, low mood and depression. Lessons two to four covered unhelpful thoughts (lesson two), physical symptoms of depression and anxiety (lesson three) and unhelpful behaviours (lesson four). The fifth lesson encompassed information on relapse prevention. DIY Guides provided patients with the opportunity to further their understanding of and begin to implement key concepts which were

covered in the Lessons. Stories provided examples of how two people who had read the Wellbeing Course material learnt and practised concepts therein. Additional Resources were optional reading; they provided further information on specific topics that may have been helpful to patients e.g. sleep, communication skills.

Patients were supported in their reading and application of the Wellbeing Course material by weekly contact with their therapist involving up to six 30-minute consultations. The first consultation was face to face; the remainder were by phone although patients' request for some or all of these to be face to face could be accommodated.

Stepped care participants' progress was monitored using the nine item Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001). At session six of low-intensity therapy, the decision to discharge patients or offer high-intensity psychological treatment was informed by a clinical algorithm (Table 14) that was designed to reflect the degree to which the PHQ-9 has been found to correctly identify depressed patients (sensitivity) and distinguish between depressed and non-depressed individuals (specificity) using different thresholds for recovery (Gilbody, Richards, & Barkham, 2007). Patients who unambiguously scored below the accepted PHQ-9 threshold for recovery ( $\leq 9$ ) (Kroenke et al., 2001) were discharged. This score has a 94.4% sensitivity for depression (highly sensitive) and a 73.3% specificity (reasonable although subject to some false positives) (Gilbody et al., 2007).

Compared with a threshold for recovery of  $\leq 9$ , cut-off scores of between 10 and 12 are associated with slightly reduced sensitivity (91.7% for all scores) albeit each additional point in the scale confers increased specificity (10=78.3%, 11=81.7%, 12=85.0%) (Gilbody et al., 2007). These three scores, therefore, represent a certain amount of ambiguity in terms of recovery from depression. For this reason, the decision to step up or discharge patients who scored 10-12 at week six of GSH was guided both by their PHQ-9 score at follow up and by their progress from baseline. Discharge was suggested to patients who had made around 50% improvement on the PHQ-9 from week one to six. For patients who had made less than 50% improvement, therapists suggested

progression to high-intensity therapy. Patients who scored unambiguously above the cut-off i.e. 13-27 were offered high-intensity therapy.

Table 14. Stepping criteria

Pre-treatment score	Score at six weeks	Criteria	Action	Decision
Any	0-9	Patient is unambiguously below diagnostic cut off	Inform participant that treatment is ended as a consequence of them no longer meeting diagnostic criteria	Discharge
19-27	10-12	Patient is within suggested diagnostic cut off range and has made around 50% improvement	Discuss with participant and <b>suggest discharge</b> due to good rate of progress	Step up or discharge depending on participant's wishes
<19	10-12	Patient is within suggested diagnostic cut off range and has made less than 50% improvement	Discuss with participant and <b>suggest stepping up</b> to increase progress further	Step up or discharge depending on participant's wishes
Any	13-27	Patient is unambiguously above diagnostic cut off	Offer CBT to participant	Step up

In almost all cases, high-intensity psychological therapy was delivered by a different therapist to the person who had provided low-intensity treatment. High-intensity CBT was delivered by therapists following a treatment protocol based on the standard manuals published by Beck et al. (Beck, Rush, Shaw, & Emery, 1979) and used in two other recent trials led by or in which the study researcher's supervisors were involved (Rhodes et al., 2014; Wiles et al., 2013). Early sessions focused on agreeing problems to be addressed, therapeutic goals and learning about the CBT model and techniques for behaviour change. Patients subsequently worked on negative automatic thoughts, maladaptive beliefs and, where indicated, underlying core beliefs. Later sessions helped patients anticipate and practice managing their response to stressors which could lead to future relapse. Specific CBT techniques available for the therapists to use included scheduling activity and mastery behaviours and the

use of thought records. All sessions were face to face and consistent with NICE recommendations for duration and frequency i.e. between eight and 20, 50 minute consultations over a maximum of 16 weeks (National Institute for Health and Care Excellence, 2009b). Patients could be offered up to two 'booster' sessions.

### ***Intensive psychological therapy alone***

High-intensity psychological therapy for participants in the control arm of the trial was identical to the high-intensity treatment for patients in stepped care except that patients only had intensive CBT; they were not offered Guided Self Help first.

The decision to offer control patients high-intensity psychological therapy alone was made for the following reasons. Although the National Institute for Health and Care Excellence (NICE) has made a specific recommendation to conduct a fully-powered trial of stepped care versus matched care (National Institute for Health and Care Excellence, 2009b), prior to the conduct of this study, there were no published prognostic indicators, including severity of depression itself, with sufficient power to predict response to treatment and therefore the specific treatment required for matched care (Fournier et al., 2009). In terms of severity, a recent Individual Patient Data meta-analysis of 2470 patients with depression receiving low-intensity treatment found that patients with severe symptoms show at least as good clinical benefit from low-intensity interventions as less severely ill ones (Bower et al., 2013). Moreover, as described in Chapter Two (sections 2.3 and 2.4) stepped care was conceived and implemented as an alternative to long-term, high-intensity psychological therapy for all. High-intensity CBT has been found effective against a number of comparators, in patients with a range of severity of depressive symptoms, in group and individual settings and for both relapse prevention and treatment of a current episode (National Institute for Health and Care Excellence, 2009b). Compared with matched care, there are fewer uncertainties associated with it. Thus, prior to the conduct of the study, it was logically decided that the most appropriate and robust test of the equivalence and efficiency of stepped care would be a fully-powered RCT against high-intensity CBT alone; the pilot trial comparator was selected accordingly.

All trial treatments were delivered by Mood Disorders Centre AccEPT Clinic therapists with considerable experience of CBT. Two of the therapists (a Clinical Psychologist and specialist mental health nurse) were accredited by the British Association of Behavioural and Cognitive Psychotherapy. The Clinical Psychologist, who had no prior experience of stepped care, had previously been employed as a CBT therapist for over ten years; the specialist mental health nurse had previously worked in IAPT as a low-intensity therapist. The third therapist had received expert training in high-intensity CBT as part of his doctoral studies in Clinical Psychology at the University of Calgary, Canada, of which he was in his final year and on placement at the Mood Disorders Centre. All three therapists delivered both low- and high-intensity CBT for the current study. Prior to the start of recruitment, the study researcher organised a Trial Orientation Day for AccEPT staff. Therapists were briefed on: the background to the study; trial treatments and related clinic procedures; patients' transition into therapy on randomisation; risk and adverse / serious adverse event protocols (see sections 5.6.3 & 5.6.4); embedded qualitative interviews. Supervision and training in the delivery of clinical treatments was provided by senior academic and clinically qualified experts in high-intensity Cognitive Behaviour Therapy and mental health.

### **5.3.5 Outcomes**

As this was a feasibility study with a range of different aims to inform a fully-powered evaluation of stepped care, there was no single primary outcome measure. Rather a variety of patient-related data were collected at baseline and six months post randomisation: severity of depressive symptoms (BDI-I) (Beck et al., 1961), worry and anxiety (Generalised Anxiety Disorder-7; GAD-7) (Spitzer, Kroenke, Williams, & Lowe, 2006) and health related quality of life (Short Form Health Survey-36 version 2.0; SF-36 v2) (Ware et al., 2007). A copy of the baseline Case Report Form is provided at Appendix III. At six months post randomisation, it was expected that patients' treatment, including for people randomised to stepped care and stepped up to CBT, would be complete. However, for a sub-set of participants, the actual duration of treatment was greater than six months and follow-up data was consequently obtained prior to the end of patients' treatment.

Data were also collected on: trial participants' baseline demographic and clinical characteristics including age, sex, ethnic group, employment, history of depression and use of anti-depressant medication; the flow of participants through the trial i.e. numbers of patients at each step; the number and proportion of people who stepped up and were discharged from stepped care following low-intensity psychological therapy. For the duration of recruitment, the IAPT Admin Team recorded the number of patients to whom they sent study information; this data was collated and sent to the study researcher weekly. Numbers of patients who had been offered and then attended IAPT assessments was provided by the mental health trust responsible for the IAPT service. With the help of a University of Exeter colleague (see Acknowledgements), a trial database was developed in which the details of all patients who completed and returned a permission form were entered. Patients' recruitment status e.g. declined telephone screen, ineligible at baseline was recorded therein. Patient-related outcome data was entered in the same database.

Therapists collected data on treatment adherence and content: patient contacts were recorded on a Participant Contact Log; key themes covered at each treatment session were recorded using semi-structured Session Record Forms (see Appendix III). Patients' PHQ-9 scores at each treatment session were recorded on the Participant Contact Log and Session Record Form for Guided Self-Help.

### **5.3.6 Sample Size**

A conventional power calculation is inappropriate for a pilot RCT (Arain et al., 2010; Thabane et al., 2010). As such, the sample size required was calculated (with the assistance of a University of Exeter Medical School statistician – see Acknowledgements) based on the margins of error associated with the key parameters of interest, specifically: recruitment and retention rates; the standard deviation of the primary outcome (and other continuous outcomes); the correlation between baseline and six month follow-up outcome scores – which can be used to refine the sample size calculation for the fully-powered evaluation to take into account the added precision gained from adjusting for

baseline scores when comparing the follow-up outcome scores between the trial arms.

It was expected that a total of 1500 patients would need to be approached to participate in the pilot trial. This was large enough to estimate a participation rate (as percentage of subjects approached) of 5% with a margin of error of +/- 1.1% or to estimate a participation rate of 10% with a margin of error of +/- 1.5% based on 95% confidence intervals. However, if it was necessary to approach a higher number of potential participants (2000) and a lower participation rate of 2% was achieved, it was calculated that the associated margin of error would be +/- 0.7% based on 95% confidence intervals.

Assuming the participation rate would be 5% of 1500 people approached, the feasibility trial would recruit 75 participants. It was calculated that this would be sufficient to: (i) estimate a follow-up rate (as percentage of participants recruited) of 80% with a margin of error of +/- 9%; (ii) estimate the standard deviation of the continuous primary outcome to within 22% of its true value based on the upper limit of the 95% confidence interval; (iii) estimate the correlation between the baseline and follow-up outcome scores with a margin of error of 0.12 (based on the lower limit of the 95% confidence interval) if the true correlation was 0.8. Assuming a participation rate of 2% of 2000 people approached, this would be sufficient to: (i) estimate a follow-up rate of 80% with a margin of error of +/- 10.1% and (ii) estimate the correlation between the baseline and follow-up outcome scores with a margin of error no greater than 0.13 (based on the lower limit of the 95% confidence interval).

The margins of error associated with the recruitment of 75/1500 people and 60/2000 approached were considered to be acceptable. A range of between 60 and 75 was therefore selected as the target sample size.

#### **5.4 Semi-structured interviews**

Semi-structured interviews were embedded in the pilot trial to explore what patients, therapists and IAPT staff thought of (i) trial methods and procedures, (ii) the acceptability of stepped care.

### **5.4.1 Sample and setting**

Recommendations by qualitative methodologists on the number of interviews required for qualitative research vary (Bertaux, 1981; Corbin & Strauss, 2008; Morse, 1994). Numbers differ by type of inquiry (e.g. six for phenomenological studies (Morse, 1994); 20 to 30 for Grounded Theory (Creswell, 2013)) and in ways that are unexplained; there is almost no evidence to substantiate recommendations. Prior research on stepped care provides limited guidance on what may be an appropriate number of interviews for the current study. For example, Parry et al. (2011) interviewed 77 patients. However, the authors did not provide a rationale for their sample size; benefits were not described. Sample sizes for qualitative studies of other systems of care also differ (Coupe et al., 2014; Gask, 2005; Johnston et al., 2007). The number of interviews for the current study was therefore selected with thought to the purpose of the current research, the degree to which the population of interest was homogenous, researcher experience and resource constraints.

#### **Number of patient interviews**

The aim of the patient interviews was, in part, to help understand what people thought of the stepped care intervention and how this might relate to treatment adherence. Data was not required to test this relationship, provide definitive evidence of acceptability or (necessarily) represent the views of patients who may have experience of other forms of stepped care. Very large numbers of interviews were not therefore required. However, the population of interest (trial participants) was non-homogenous; it was anticipated that patients would have different treatment (GSH alone or GSH and CBT) and vary in the number of treatment sessions they would attend. Thus, the researcher aimed to interview all of the trial participants who had been allocated stepped care. A minimum sample size of 24 was selected to include patients with varied receipt of and adherence to low- and high-intensity therapy within the stepped care protocol. (See section 5.5.2 for a related explanation of numbers of patient interviews analysed.)



## **Number of therapist and IAPT interviews**

The number of therapist interviews was limited to the number who had provided stepped care treatment in the pilot RCT i.e. three. The IAPT Team Manager, a Psychological Wellbeing Practitioner (PWP) and Team Administrator were also interviewed. The Team Manager and Administrator had been closely involved in the set-up and design of recruitment procedures; the Administrator and PWP had good experience of how procedures worked in practice. It was considered that this number of IAPT interviews would provide reasonable and informed feedback on the feasibility and appropriateness of recruitment methods and procedures.

Patient interviews were undertaken at AccEPT Clinic facilities or by phone depending on interviewees' preference. Therapist interviews were held at the Mood Disorders Centre. Interviews with IAPT staff were conducted at IAPT facilities.

### **5.4.2 Recruitment**

Patients' informed consent to be interviewed was determined at trial participants' baseline interview. On completion of stepped care treatment, patients were telephoned to establish that they were still willing to be interviewed; patients were reminded what an interview would involve and questions were answered. For patients who remained willing, interviews were arranged no sooner than 48 hours later and confirmation of arrangements was sent in writing. The opportunity to rearrange or cancel the interview was mentioned in the letter. Therapists were given details of the therapist interviews at the Trial Orientation Day when their willingness to be interviewed was established. Therapists' interviews were arranged shortly before the end of their involvement in the pilot RCT. IAPT personnel were invited for interview shortly before the end of the trial recruitment period; interviews were arranged on end recruitment.

### **5.4.3 Interview process and questions**

Semi-structured interviews were employed to enable the interviewer to explore the meaning of participants' responses and elicit more detail on themes that arose during the interviews as well as explore what people thought of pre-

defined topics of interest (Taylor, 2011). Individual semi-structured interviews were also utilised as they allowed participants to describe their views in confidence.

### **Topic guides**

Interview schedules were developed for patients, therapists and IAPT staff. (Final versions are available at Appendix III). People were asked for their views and experience of stepped care and trial methods and procedures in relation to their study involvement. Questions about the acceptability of stepped care were designed to explore what people thought of its underpinning principles and implementation. Questions on the feasibility and appropriateness of trial procedures aimed to identify procedures which facilitated the efficient running of the trial but also any that were perceived to be problematic.

### **Patients**

Patient interview schedules were structured as follows. Interviewees were asked why they had sought treatment, how they felt on being offered stepped care, what they thought of GSH and CBT and their symptoms of depression being monitored. Interviews also explored patients' views of stepping 'up' or 'out' of treatment following GSH, ending treatment and the extent to which therapy helped. The latter (and smaller) part of the interview focused on what people thought about trial methods and procedures specifically recruitment, the transition to therapy and the administration of treatment (scheduling appointments and receipt of the Wellbeing Course material for example). Patients were invited to suggest what, if anything, could have been done to improve how the study was run. At the end of the interview, patients could share views and opinions not already discussed.

An early version of patient interview schedule was shared with two members of the Mood Disorders Centre Lived Experience Group (LEG) for review and comment. (Members of the group have direct or indirect experience of living with depression and are available to advise on all research activity at the Centre – see section 5.7.) Changes were consequently made to the schedule to help make the interview feel more personal. Consistent with standard practice in qualitative fieldwork (Arthur, Mitchell, Lewis, & McNaughton Nicholls, 2014),

successive versions of the topic guide were also amended to help participants provide more relevant information and to facilitate the smooth running of the interview; new questions were included based on what had been discussed at previous interviews.

### **Therapists**

The therapist interview schedule was predominantly focused on what people thought of stepped care. Interviewees were asked for their definition of this system of treatment, their view of GSH, monitoring patients, stepping criteria and high-intensity therapy. The interviewer tried to elicit how the option to offer patients CBT influenced therapists' delivery and views of GSH and similarly, how patients' prior experience of GSH impacted delivery of CBT. Questions on the feasibility and appropriateness of trial procedures sought feedback on study set up, patients' transition to therapy on randomisation, the administration of treatment, record-keeping and clinic procedures for managing risk, reporting Serious Adverse Events and supervision.

### **IAPT staff**

Interviews with IAPT staff were tailored depending on how the interviewee had been involved in recruitment. The Team Manager, Administrator and PWP were all asked what they thought of research in general and the role for the NHS / their service. Interviews with the Team Administrator and PWP subsequently explored their initial reaction to the prospect of being involved in this study, how patients were invited to take part, receiving and passing on completed permission forms, logging patients' involvement in the study and continuing care for people who were ineligible / unwilling to take part. The IAPT Team Manager was asked for her views and opinions of negotiation to agree recruitment procedures as well as how well they had worked in practise. Interviewees were asked to consider what had worked well or caused difficulty from their own and patients' perspectives.

### **Process**

Interviews lasted between forty-five and sixty minutes and were audio-recorded with participant's permission. Prior to the start of the interview, the therapists

and IAPT staff were reminded that they were one of three people interviewed hence their anonymity could not be guaranteed.

### **Field notes**

Field notes were made on completion of each patient interview. (See Appendix IIIV for an example.) Notes included the study researcher's summary of: what the patient thought of stepped care; main themes arising on trial methods and procedures; thoughts or new hypotheses on the acceptability of stepped care; potential questions for future interviews. Field notes were primarily used to help inform changes to the patient topic guide (see above) and select interviews for analysis (see section 5.5.2, below).

## **5.5 Analysis**

There were three strands of analysis: quantitative, qualitative and mixed methods. First, quantitative trial data and the qualitative data from the semi-structured interviews were analysed separately. Next, quantitative and qualitative data were integrated in a mixed methods analysis (Creswell & Plano Clark, 2011).

### **5.5.1 Quantitative analysis**

Recruitment and outcome data were downloaded from the trial database in a format suitable for import into STATA v.13, STATA, StataCorp LP, 4905 Lakeway Drive, College Station, Texas 77845-4512, USA. To check for inaccuracies, outcome data were double-data entered by an undergraduate Psychology student as part of a six month internship. Treatment data (participant contact logs and session records) were collated and entered into an Excel spreadsheet (Microsoft 2010, Microsoft Excel, Redmond, Washington: Microsoft). All data were imported into STATA v.13. Following published guidance (Ware et al., 2007), Physical and Mental Health Component Scores were calculated from raw scores on the SF-36v2. All of the variables to be analysed were cleaned by generating descriptive statistics and frequency data.

### **Recruitment and retention**

To address the first research question, "What is the quantifiable performance of recruitment and retention methods which may be used in a fully powered trial?"

count data were used to enumerate the flow of the participants through the trial. Data were expressed both as a percentage of the total number of participants approached and in relation to the preceding step in recruitment. Margins of error were estimated for each parameter. For each of the interventions, the number of participants who withdrew, could not be contacted or did not provide six month follow up data for another reason was quantified. Numbers were expressed as a percentage of the total number of participants in each of the stepped care or high-intensity group. CONSORT guidelines (Schulz, Altman, & Moher, 2010) on reporting the number of participants who exit the trial at each step of recruitment and from whom it was not possible to collect follow up data were followed.

### **Baseline characteristics**

Descriptive statistics were calculated to describe trial participants' baseline demographic and clinical characteristics. Frequency and percentage information was calculated from categorical data on patients' sex, ethnic group, education, marital status, employment, home ownership, diagnostic status, history of depression and use of antidepressant medication. Means and standard deviations were estimated to describe continuous data on patients' age and CIS-R total score at baseline.

### **Receipt of the intervention**

The number and proportion of people who received stepped care and stepped up from low- to high-intensity treatment or were discharged following low-intensity therapy (Question Two) was quantified. Quantitative data on patients' therapeutic attendance (Question Five) was analysed as follows. For each of the interventions descriptive statistics were generated to describe the number and proportion of total available sessions attended where the total number of available sessions was six for patients who had GSH alone, 20 for patients who had CBT alone and 26 for patients who had GSH and CBT. The number and proportion of participants who declined any treatment, dropped out early or completed treatment was quantified. For stepped care participants, the number and proportion that dropped out prior to low-intensity therapy, before high-intensity therapy having been stepped up, and during each treatment step was quantified. The total number of hours in treatment was estimated assuming that

each GSH and CBT session lasted 30 and fifty minutes respectively. Dates of patients' first and last treatment sessions were used to calculate the number of weeks in therapy.

### **Outcomes**

To measure the variability in patient-related outcomes following stepped care or intensive psychological therapy alone and the correlation with patients' baseline scores (Question Three) estimates were made of the standard deviation around mean BDI-I, GAD-7 and SF-36 scores at baseline and six months for both groups. Estimates were then made of the correlation between participants' scores on the BDI-I, GAD-7 and SF-36 at baseline and at six months.

### **Sensitivity analyses**

The effect of six month follow up data that had been obtained prior to the completion of patients' therapy was analysed in sensitivity analyses by excluding this data from estimates of the variability in patient-related outcomes and correlations between participants' scores at baseline and six months.

### **Planned sub-group analyses**

Several additional exploratory analyses were undertaken. Analyses did not address the study research questions but were undertaken in anticipation of broader interest in the outcome data and in response to a specific concern with the stepping criteria for patients who had a relatively high pre-treatment PHQ-9 score of 19-27, scored 10-12 at the end of low-intensity treatment and were subsequently discharged due to good progress. Given that the severity of patients' first / index episode of depression has consistently been found to relate to rates of recurrence, although a causal relationship has not been established (Burcusa & Iacono, 2007), it is possible that discharging patients with relatively high levels of depressive symptoms before treatment who were not unambiguously below cut-off on end GSH, was premature.

Thus, to explore the impact of the stepping criteria on patients with more severe pre-treatment depressive symptoms, six month outcome data was described for patients with a mild to moderate versus severe diagnosis of mental health problems on the CIS-R at baseline. Other analyses described: levels of 50%

improvement on the BDI-I and GAD-7 from baseline to six months and associated margins of error; six month treatment outcomes for stepped care patients who were discharged on end GSH versus progressed to CBT.

### **Underpinning principles**

All analyses were undertaken on an intention to treat basis i.e. participants were analysed in their original assigned groups. Emphasis was on quantification and estimation rather than hypothesis testing. Missing data was reported but not imputed; as far as possible reasons for missing outcomes were stated. All analyses were conducted using STATA v.13.

### **5.5.2 Qualitative analysis**

Interviews on the acceptability of stepped care and the appropriateness of trial recruitment were analysed to inform answers to Research Questions Four & Five. Interviews were transcribed verbatim by the study researcher, University of Exeter colleagues and a specialist in qualitative research. Transcribers were briefed by the study researcher and used a common template for transcription (see Appendix IV). Transcripts were checked for consistency of style and accuracy.

### **Analytic sample**

All of the IAPT and therapist interviews were analysed. A sub-set of the patient interviews was purposively selected for analysis. Transcripts were chosen to include patients with a range of treatment experience (GSH alone and GSH + CBT). Compared with the proportion of trial patients who were offered stepped care and had progressed to high-intensity therapy, a larger proportion of the analytic sample (50%) had GSH and CBT. The experiences of this group were considered particularly important. To facilitate the mixed methods analysis (see section 5.5.3), all of the interviews completed with patients who had declined any treatment or dropped out early were included. The remainder of the analysed interviews were conducted with patients who had completed treatment. Given the potential for what people think of stepped care to be confounded by the degree to which they improved, patients who had stepped up and completed treatment were selected to include a range of treatment outcomes. (All of the patients who had GSH alone had responded to therapy.)

The study researcher's record of the quality of the interview and whether the interviewee expressed notable (potentially distinctive) views was also considered.

In total, 18 interviews were analysed, 12 with patients, three with the study therapists and three with IAPT staff. This number was chosen for two main reasons: to ensure that all of the qualitative analysis could be completed by the study researcher in the period planned (the time available was limited within the context of a three year programme of work and needed to allow good time for the mixed methods analysis) and for the potential to achieve saturation.

Although saturation (the point at which no new information are observed in the data (Glaser & Strauss, 1967; Schensul & Le Compte, 2010)) has become the gold standard by which the size of purposive sample sizes is determined (Guest, Bunce, & Johnson, 2006), there are no practical guidelines or tests of adequacy for estimating what this means in practice (Guest et al., 2006; Morse, 1995).

In response, Guest et al. (2006) systematically documented the degree of data saturation achieved over the course of analysis of sixty in-depth interviews with women from two countries on their sexual behaviours. Seventy-three percent of the thematic codes generated from analysis of all thirty interviews with women in one of the countries were identified in the first six transcripts; 92% of the codes were identified from twelve. The authors therefore posited that data saturation had, for the most part, been achieved from the analysis of twelve interviews (Guest et al., 2006). Whilst it is hard to say how generalizable this finding might be (Guest et al., 2006), it suggests that analysis of twelve patient interviews on stepped care could provide a largely 'complete' understanding of what trial participants think of this system; the analysis of six interviews with patients who had GSH alone and six interviews with patients who had GSH+CBT might provide a reasonable insight into the experiences of these different patient groups.

## **Framework**

A series of framework analyses (Spencer, Ritchie, Ormston, O'Connor, & Barnard, 2014) were conducted using an abductive approach. Analyses explored the acceptability of stepped care to patients and therapists, the



feasibility and appropriateness of trial methods and procedures to patients and therapists, the feasibility and appropriateness of recruitment to IAPT staff.

Transcripts were coded at the level of individual participants but analysed thematically across datasets as well as in the context of each participant's interview, using a constant comparison approach (Miles & Huberman, 1994). Thematic frameworks were developed from a combination of interview topics and data collected from participants. Data were indexed (applied to the thematic frameworks) and reviewed. Initial thematic frameworks were modified; themes were merged, split or re-defined. Data were re-coded (indexed) accordingly. Coded data were subsequently charted, abstracted and interpreted to distil, structure and make sense of what people said (Spencer, Ritchie, O'Connor, Morrell, & Ormston, 2014), the original transcripts being frequently revisited to check and clarify contextual meaning. Examples of thematic frameworks, charts and abstraction are provided at Appendix IV. Frameworks were comprised of themes and sub-themes that were very descriptive. Interviewees' views and experiences of stepped care and trial recruitment were captured in detail. A small number of (cross-cutting) interpretive themes on the acceptability of stepped care to patients were also derived (see below).

### **Framework applied to acceptability**

Data on the acceptability of stepped care to patients was summarised in a number of charts. Two charts were developed to capture what patients said across all of the major themes in the modified thematic framework. This information was used to help develop typologies of the acceptability of stepped care to patients. Additional charts were generated to summarise in more detail what interviewees said on each major theme: a chart was created for each theme; therein data were summarised by sub-theme. For each sub-theme, common elements across all patients were identified and abstracted into dimensions and where appropriate higher order classifications. This information was used to write summaries of patients' views and experiences of stepped care in relation to each sub-theme. Emergent cross-cutting themes that seemed to shape patients' views and experiences of more than one component of stepped care were identified. At the end of analysis, mini-summaries were

written (in the first person but not using quotes) of what each interviewee thought of stepped care as a whole; analogous summaries were written to encapsulate what each patient thought of GSH and CBT. Summaries were presented in tables on patients' views and experiences of low-intensity therapy, high-intensity therapy and the stepped care intervention as a whole.

Data on the acceptability of stepped care to therapists was similarly analysed: a chart was developed for each major theme; therein data was summarised by sub-theme; for each sub-theme, common elements across all therapists were identified and abstracted; this information was incorporated in a summary of therapists' views on each sub-theme.

### **Framework applied to recruitment**

Compared with data on the acceptability of stepped care, less (complex) data was gathered on the feasibility and appropriateness of recruitment. Data was consequently analysed using a modified framework approach. Indexed data were charted by sub-theme and case. Where helpful, common elements were abstracted and organised into dimensions; this information was used to write summaries of what patients, therapists and IAPT staff thought of recruitment. However, where it was possible to distil meaning without this level of abstraction, summaries were written directly from charts; within charts, summaries of what people thought of each sub-theme were sometimes organised by dimensions.

### **Software**

NVivo version 9.0 ([www.qsrinternational.com/products\\_nvivo.aspx](http://www.qsrinternational.com/products_nvivo.aspx)) was used to organise the data and help ensure systematic analysis.

### **Patient and public involvement**

Prior to analysis, six patient interview transcripts were sent to two members of The University of Exeter Mood Disorders Centre Lived Experience Group. Members were asked for their 'first impressions' of how the interviewees had found stepped care. Each member returned a short description of what each interviewee had said about being offered stepped care, GSH, CBT, being monitored and ending treatment. The study researcher compared her

interpretation with LEG members'. Where discrepancies arose, the study researcher returned to the original transcripts to check her understanding of the interview. If needed, summaries of patients' views (entered in Framework charts) were updated. The study researcher was alert to any 'type' of discrepancy that was common to more than one transcript so that she could be mindful of this in her interpretation of interviews that were not shared with the LEG.

### **5.5.3 Mixed methods analysis**

Mixed methods analysis was undertaken to integrate qualitative and quantitative data. The choice of specific techniques was guided by the nature of the quantitative and qualitative data that was ultimately obtained and the inferences that arose from the separate analysis of both. Techniques were developed based on three methods for merged data analysis summarised by Creswell and Plano Clark (2011). Specifically: (1) a side-by-side comparison of quantitative and qualitative data presented in a summary table or as part of a discussion; (2) a joint display of quantitative and qualitative findings whereby qualitative data are presented for categories of people defined on a quantitative dimension (a category/theme display) or the presentation of quantitative data for typologies of people defined using qualitative information (a typology/statistics display); (3) a case-oriented display that positions cases (individuals) on a quantitative scale along with qualitative data about those cases (Creswell & Plano Clark, 2011). Techniques were also developed with reference to examples of the use of such methods (Li, Marquart, & Zercher, 2000; McEntarffer, 2003; Mendlinger & Cwikel, 2008; Wittink, Barg, & Gallo, 2006) cited by Creswell and Plano Clark (2011).

### **Acceptability and attendance**

To investigate how patients' views on the acceptability of stepped care might help explain variability in the number of treatment sessions they attend (Research Question Five), data were merged in three ways. Two approaches – (1) & (2) below – examined how patients' views of stepped care as a whole might relate to the total number of therapy sessions people attend. The third approach (3) was used to explore how patients' views of low-intensity treatment might relate to the number of GSH sessions they attend and how what people

thought of high-intensity therapy might relate to the number CBT sessions attended.

**(1) Typology / statistics display.** Categories of patients were defined using the typologies of patients' views on stepped care. Categories therefore represented groups of people for whom stepped care was more and less acceptable. For each patient in each category, data were presented on the total number of therapy sessions attended and the number of low- and high-intensity sessions received.

**(2) Category / theme display.** Groups of patients were identified by the percentage of total available sessions attended - groups were defined to demarcate clusters of people who had more or less therapy. For each group, treatment adherence data and mini-summaries of what people thought of stepped care were displayed jointly. Mini-summary statements were highlighted to illustrate how patients' views of stepped care were shaped by the cross-cutting themes identified from qualitative analysis. Data were examined for similar and different views on acceptability within and between attendance categories and how cross-cutting themes might relate to attendance.

**(3) Case-oriented display.** Cases (patients) were positioned on two scales of treatment adherence (number of low- and high-intensity sessions attended). Corresponding qualitative data (mini-summaries) were presented on the acceptability of GSH and CBT. Qualitative data on the acceptability of low- and high-intensity treatment were reviewed for similarities and differences across the number of GSH and CBT sessions attended.

Given the potential for what people think of their treatment to be confounded by its success or otherwise, outcome data (change in and improvement on the PHQ-9 pre- to post-treatment) were incorporated in the display of results from (1) to (3). (Analyses were not designed to explore how what people thought of stepped care and treatment outcome relate.) The results of (1) to (3) were ultimately used to develop hypotheses on the relationship between acceptability and treatment attendance for testing in a fully-powered evaluation of stepped care.

## **Recruitment**

For an improved understanding of the feasibility and appropriateness of recruitment (Research Question Four), qualitative data on appropriateness and numeric data on the performance of recruitment methods and procedures was presented in a side-by-side summary table so that one type data could be compared to the other. Included data were a sub-set of all the available quantitative and qualitative information on recruitment: qualitative data were key findings from the patient, therapist and IAPT staff interviews considered helpful to interpret the quantitative data; numeric data (from STEPS' CONSORT diagram) was included that was thought helpful to place what people thought of recruitment in context.

Data were organised by stage of recruitment e.g. initial approach to patients, handling permission forms and telephone screening. Synergy and disparity between quantitative and qualitative data were highlighted. In terms of a fully-powered evaluation of stepped care, it was suggested that procedures which elicited positive feedback and appeared to perform well could remain unchanged; procedures which elicited negative feedback and did not perform well according to numeric data, could be modified, and; procedures for which there was disparity between quantitative and qualitative data e.g. positive patient feedback and numeric data to suggest poor performance, required further thought.

### **5.6 Ethical issues**

The pilot trial and embedded interviews were conducted in such a way to protect the human rights and dignity of the participants as reflected in the Helsinki Declaration (World Medical Association General Assembly, 2013). Participants were not paid to participate. The study was approved by the National Research Ethics Service South West – Frenchay (reference 13/SW/0140). National Health Service Research and Development permission was obtained from Devon Partnership Trust (reference DPT 0258) to identify and recruit patients. The School of Psychology Ethics Committee at the University of Exeter approved the study (reference 2012/500). Copies of

approval letters are provided at Appendix V. To conform to data protection and freedom of information acts, all data was stored securely and anonymised wherever possible. No published material contained (or will contain) identifiable patient information.

### **5.6.1 Obtaining informed consent from patients**

Patients' informed consent was determined in two stages. As described in section 5.3.3, potential participants were sent a one page study summary sheet and a form seeking their permission to be contacted by a member of the study team, not at this stage to give consent to taking part. Patients who were interested in taking part returned their form to the study team (via IAPT staff). Interested patients could also telephone the study researcher. Potential participants were telephoned by the study researcher to assess their possible eligibility and to answer any questions. For those who were willing and possibly eligible, the study researcher sent a Patient Information Sheet and arranged a baseline interview. The study summary and information leaflets were produced using the current guidelines for researchers on writing information sheets and consent forms, posted on the UK ethics website ([www.nres.nhs.uk/applications/guidance/consent-guidance-and-forms/](http://www.nres.nhs.uk/applications/guidance/consent-guidance-and-forms/)) and informed by consumer/lived experience user representatives. Full informed consent was only obtained at interview by the study researcher. She assessed eligibility in full, fully explained the study and answered outstanding questions. The opportunity to participate in a semi-structured interview was optional; patients could consent to participate in the pilot RCT only. It was explained that a decision not to be interviewed would not affect patients' participation in the trial. Consent to record and transcribe interviews was established. The opportunity to withdraw from the pilot trial and / or interview was explained. The study researcher was fully trained and supervised by senior academic and clinically qualified staff. Communication and recording systems enabled the study team to monitor and act on participants' wishes to withdraw.

### **5.6.2 Risks and benefits**

No treatment was withheld from participants taking part in this study. Interventions comprised active psychological treatments with previously demonstrated efficacy and no known iatrogenic effects. By participating in the

study, participants received an intensive level of monitoring such that any participants worsening or at suicidal risk were identified and directed to appropriate care. The participant information leaflet provided potential participants with information about the possible benefits and risks of taking part in the trial. Participants were given the opportunity to discuss this with the study researcher prior to consenting. The study researcher committed to inform the participants if new information came to light that may affect persons' willingness to participate; information did not arise.

### **5.6.3 Managing risk of suicide**

Good clinical practice in monitoring the risk of suicide to patients was adhered to during all clinical and research appointments with study participants. Where any risk to participants due to expressed thoughts of suicide was encountered, this was reported directly to the patient's General Practitioner (GP) (with the participant's expressed permission) or, if an acute risk was present, immediate advice was sought from the GP. All of the study therapists and members of the research team were familiar with established protocols for if a participant indicates that they are having thoughts of self-harm or suicide. A copy of the Risk Protocol for Researchers is provided at Appendix V. Clinicians and researchers were specifically trained in risk assessment and management and supervised by experienced clinicians. Senior academic and clinically qualified members of the study team were notified on detection of any risk to patients' safety.

### **5.6.4 Serious Adverse Events**

Following instruction by the National Research Ethics Service South West – Frenchay, Serious Adverse Events (SAEs) were defined as any untoward or unintended medical occurrence, related to the trial treatments or not, that could be further classified as: fatal; life threatening; requiring hospitalisation or prolonging existing hospitalisation; resulting in significant, persistent disability or incapacity; resulting in congenital abnormality or birth defect; leading to any other condition judged significant by a clinician. Serious Adverse Events were reported to the study sponsor (University of Exeter) within 24 hours of coming to light. Within 15 days and consistent with the SAE standard operating procedure (see Appendix V) a more detailed report was reviewed by an external advisor

(academic psychiatrist) and sent to the National Research Ethics Service South West – Frenchay Committee.

### **5.7 Patient and public involvement**

The proposal for this study arose from a research prioritisation process in the NIHR CLAHRC South West Peninsula (PenCLAHRC, <http://clahrc-peninsula.nihr.ac.uk/>). PenCLAHRC has a well-developed patient and public involvement process through a funded group of representatives – the Peninsula Public Involvement Group (PenPIG). PenPIG members are involved in research topic identification and prioritisation. Patient and public representatives from both PenPIG and the University of Exeter Mood Disorder Centre’s Lived Experience Group (LEG) were involved at all stages in identification and preparation of the proposal for this study and in the early work conducted to underpin it. As described above (see 5.4.3 and 5.5.2) two LEG members were subsequently involved in the design and analysis of the semi-structured patient interviews. National good practice guidance for researchers on public involvement in research and the paying of PPI representatives at [www.invo.org.uk](http://www.invo.org.uk) was followed.

### **5.8 Study set up and management**

The study researcher was responsible for study design, set-up and management and was the named Principal Investigator in all communications with the National Research Ethics Service South West – Frenchay committee. IAPT and AccEPT Clinic Handbooks were developed on recruitment, clinic and research procedures. Handbooks were circulated, updated and available throughout the trial. Prior to the start of recruitment, the study researcher organised a Trial Orientation Day for AccEPT staff (see section 5.3.4). Senior and appropriately qualified academics provided clinical supervision; the study researcher handled all other study related questions, was in regular communication with the AccEPT Clinic therapists and attended monthly AccEPT Clinic meetings. Recruitment procedures were agreed in close communication with senior IAPT staff. The researcher attended several IAPT team meetings to brief therapists on their study involvement, answer questions and provide an update on progress. Outside of meetings, regular contact was maintained with the IAPT Team Administrator and Team Manager.



**Execution dates**

The preparatory period for this study started in April 2013. Recruitment ran from September 2013 for a period of approximately one year. Follow-up and qualitative data were collected from April 2014 to March 2015. Data analysis was conducted from April 2015 for six months. The study protocol paper (J. J. Hill et al., 2014) was published following submission in June 2014.

## **CHAPTER 6. THE STEPPED CARE VS. HIGH-INTENSITY THERAPY (STEPS) FEASIBILITY STUDY: RESULTS**

This chapter describes the results of STEPS - a mixed method feasibility study encompassing a pilot RCT and embedded qualitative interviews undertaken to prepare for a fully-powered trial of stepped care compared with high intensity psychological therapy alone for the treatment of depression in adults. The requirement for this study was described in Chapters Two and Four; Chapter Five set out study design, methods and procedures.

### **Research questions**

STEPS addressed two specific objectives and five related research questions. Specific objectives were to: (1) gather enough information on recruitment, retention, step ups and treatment effects to design a fully-powered clinical trial or to determine that such a trial is not feasible; (2) explore patients' and therapists' views of stepped care and the ways in which patients' views relate to how much they engage in therapy to inform a stepped care clinical protocol for a proposed randomised trial.

Research questions were: (1) What is the quantifiable performance of recruitment and retention methods which may be used in a fully powered trial?; (2) What proportion of people who receive stepped care step up from low-intensity to high-intensity treatment or are discharged following low-intensity psychological therapy?; (3) What is the variability in patient-related outcomes following stepped care or intensive psychological therapy alone and how do they correlate with patients' baseline scores?; (4) To what extent are potential recruitment methods considered appropriate by trial participants (patients), study therapists and other health professionals and administrators and how do people's views combine with numeric data on the performance of trial recruitment methods?; (5) How acceptable is stepped care to patients and therapists and how do patients' views explain variability in the number of treatment sessions they attend?

This chapter describes the results obtained in response to each question as well as the results of several exploratory and planned sub-group analyses that

were undertaken in anticipation of broader interest in the outcome data (see Chapter Five, section 5.5.1).

### **Chapter structure**

The chapter is divided into four parts. Part I presents the results of the quantitative analysis of pilot trial data. Part II encompasses qualitative and mixed methods data on recruitment. The results of qualitative and mixed methods analysis on the acceptability of stepped care are presented in Part III. Part IV summarises key results in relation to each research question.

Across Part I to IV, material is further organised into fourteen sections: patient flow and retention (6.1); baseline characteristics (6.2); receipt of the intervention and control (6.3); treatment outcomes (6.4); the appropriateness of recruitment (6.5) – to patients (6.6), therapists (6.7) and IAPT personnel (6.8); comparing quantitative and qualitative data on recruitment (6.9); the acceptability of stepped care (6.10) – to patients (6.11) and therapists (6.12), and; the relationship between acceptability and attendance (6.13). Section 6.14 provides a brief summary of key findings.

## **Chapter 6. PART I**

### **Quantitative analysis of pilot trial data**

Comprising sections:

6.1 Patient flow and retention

6.2 Baseline characteristics

6.3 Receipt of the intervention and control

6.4 Treatment outcomes

## **6.1 Patient flow and retention**

### **6.1.1 Recruitment**

Over an eleven month period, 2299 IAPT patients were approached via written invitation to participate in STEPS (Figure 10). Of those approached, 7.8% (179/2299) 'opted in' i.e. completed and returned a 'permission for researcher to contact' form. Nine percent (179/1980<sup>1</sup>) of patients who attended an initial IAPT assessment appointment returned a form. The potential eligibility of 67.6% (121/179) of patients who returned a form was assessed via a telephone screen; baseline interviews were completed with 46.9% (84/179) – or 69.4% (84/121) of patients screened. A total of 63.1% (113/179) of patients who opted in did not join the study. Reasons for attrition were that: it was not possible to recruit 21.8% (39/179) of patients who returned a permission form due to limited therapist capacity at the AccEPT Clinic – therapists were unable to take on new patients; recruitment procedures could not be completed in five days with 15.1%% (27/179) of persons; 12.8% (23/179) of patients were ineligible; 12.2% (22/179) of patients declined or did not attend a telephone screen or baseline interview; 1.1% (2/179) were randomised in error. Overall, 2.9% (66/2299) of patients invited to take part, were recruited.

Based on the 95% confidence interval for the recruitment rate, it is estimated that in a future trial the proportion of patients invited who were willing, eligible and randomised without error would be between 2.2% and 3.5%; the proportion invited who returned a permission form would be between 6.7% and 9.0%.

### **6.1.2 Retention**

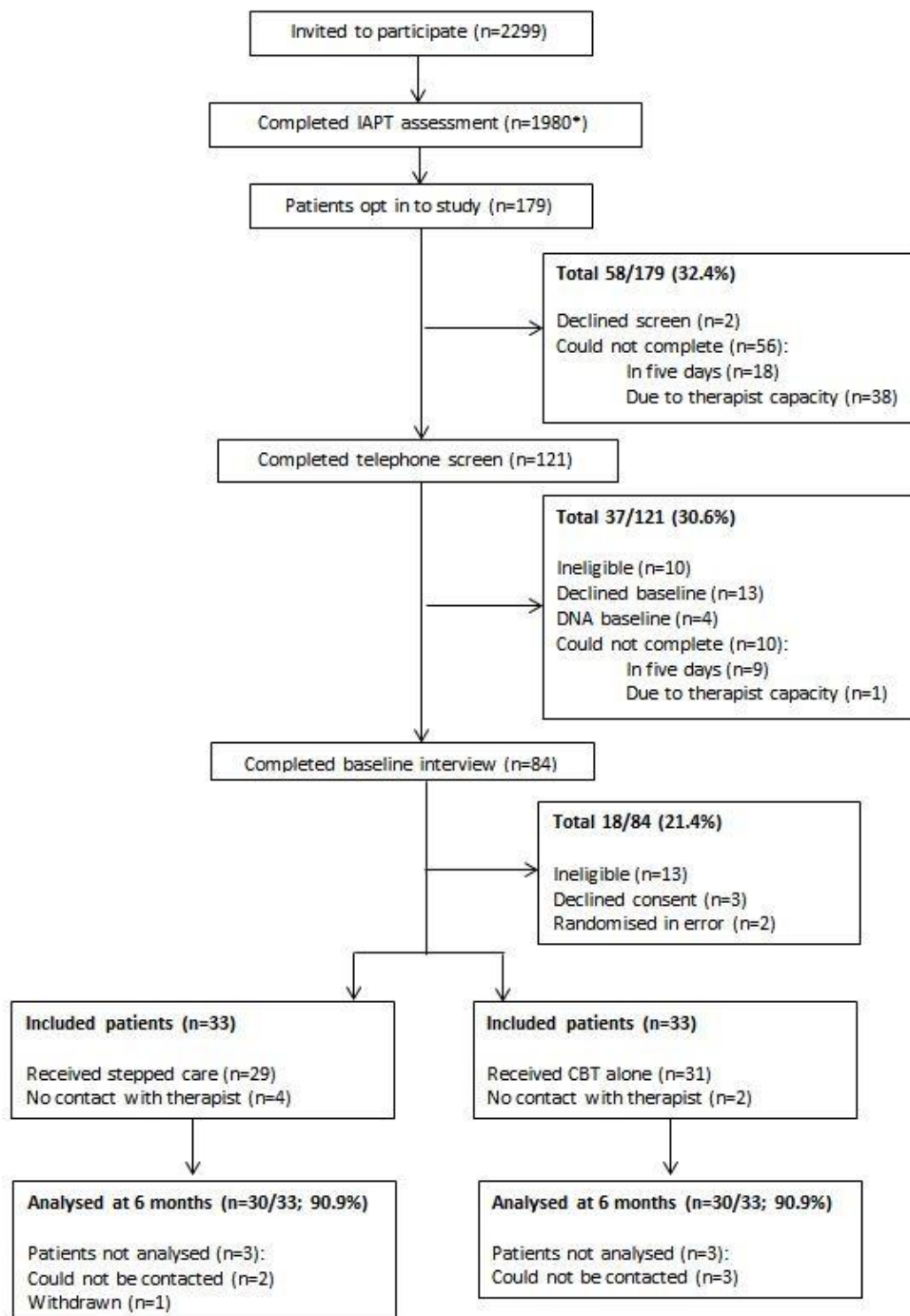
STEPS' six month retention rate was 91%; 60 of the 66 patients randomised without error completed a six month follow-up assessment. The same number and proportion of participants were retained in each of the control and intervention arms: 91% (30/33). Across groups, five patients were lost to follow up because they could not be contacted; one patient (randomised to receive

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<sup>1</sup> The figure of 1980 was an estimate based on data supplied by IAPT on the number of patients (i) invited to book and (ii) who subsequently attended an initial assessment appointment. The proportion of patients invited to book who attended the assessment was calculated. This percentage was applied to the number of patients sent study information to obtain an estimate of the number who subsequently attended an IAPT assessment appointment.

stepped care) withdrew from the study. From the 95% confidence interval around the retention rate, it can be inferred that in a future trial the proportion of randomised participants who would complete a six month follow-up assessment would be between 83.8% and 97.8%.

Figure 10. CONSORT diagram



Notes: The number of patients who were sent study information and completed an IAPT assessment (1980) has been estimated – see footnote, section 6.1.1.

## **6.2 Baseline characteristics**

Participants' baseline characteristics are summarised in Table 15. Prior to treatment, half (50.0%) met criteria for a moderately severe depressive episode, with a further 41% meeting criteria for severe depression, 9% mild depression, and 67% having had depression in the past. The majority of participants (64%) were in full or part time paid employment, the mean age was 43.3 years (standard deviation 12.8) and 62% were women. A small minority of participants (3%) had no educational qualification, 24% were qualified at GCSE or O' Level, 46% post GCSE or O' Level, and 27% had a degree or higher. Less than half (46%) were married or cohabiting. Most participants (74%) had a secondary diagnosis of an anxiety disorder, the most common being generalised anxiety disorder. Half (50.0%) of participants reported a longstanding illness or disability. At baseline, 53% of participants had been prescribed antidepressant drugs by their primary care doctor.

***Table 15 overleaf***

Table 15. Participant baseline characteristics

	StC (n=33)	CBT alone (n=33)	Total (n=66)
<b>Sex</b>			
Female	22 (66.7)	19 (57.6)	41 (62.1)
Male	11 (33.3)	14 (42.4)	23 (34.8)
<b>Age (years)</b>			
Means (SD)	42.5 (13.6)	44.1 (12.1)	43.3 (12.8)
<b>Ethnic origin</b>			
White British	30 (91.0)	32 (97.0)	62 (93.9)
White Other	3 (9.1)	1 (3.0)	4 (6.1)
<b>Education</b>			
No qualifications	0 (0.0)	2 (6.1)	2 (3.0)
GCSE or O Level	9 (27.3)	7 (21.2)	16 (24.2)
Post GCSE or O Level	16 (48.5)	14 (42.4)	30 (45.5)
Degree or higher	8 (24.2)	10 (30.3)	18 (27.3)
<b>Employment</b>			
Employed or self-employed	22 (66.7)	20 (60.6)	42 (63.6)
Student	5 (15.2)	2 (6.1)	4 (6.1)
Not working	6 (18.2)	11 (33.3)	17 (25.8)
<b>Home ownership</b>			
Home owner	15 (45.5)	14 (42.4)	29 (43.9)
<b>Marital status</b>			
Married or cohabiting	14 (42.4)	16 (48.5)	30 (45.5)
<b>Revised CIS-R total score</b>			
Means (SD)	26.2 (4.8)	26.8 (5.9)	26.5 (5.4)
<b>ICD-10 diagnosis</b>			
Mild	2 (6.1)	4 (12.1)	6 (9.1)
Moderate	19 (57.6)	14 (42.4)	33 (50.0)
Severe	12 (36.4)	15 (45.5)	27 (40.9)
<b>History of depression</b>			
Previous episode	20 (60.6)	24 (72.7)	44 (66.7)
<b>Secondary Diagnosis</b>			
Any anxiety disorder	23 (69.7)	26 (78.8)	49 (74.2)
Longstanding illness or disability	14 (42.4)	19 (57.6)	33 (50.0)
<b>Antidepressant treatment</b>			
Prescribed antidepressants	14 (42.4)	21 (63.6)	35 (53.0)

Notes: data are number (%) unless stated otherwise; SD=standard deviation; percentages may not always total 100 due to rounding.

## 6.3 Receipt of the intervention and control

### 6.3.1 Receipt of stepped care

#### Proportion of step ups

The proportion of stepped care participants who progressed to high-intensity therapy following low-intensity treatment was 33.3% (11/33; Table 16). Based on the 95% confidence interval for this percentage, it is estimated that in a future trial, the percentage of patients who would step up from low- to high-intensity treatment would be between 17.9% and 51.8%.



Table 16. Progression through stepped care

Stepped care participants' next treatment step following Guided Self Help (n=33) – n (%)	
Discharged	22 (66.67%) – 95% confidence interval 48.1% to 82.0%
High-intensity CBT	11 (33.3%) – 95% confidence interval 17.9% to 51.8%

### Number and proportion of available sessions received

Stepped care patients received a mean number of 9.0 therapy sessions (standard deviation 7.8, range 0 to 27; Table 17); figures encompass the number of sessions attended by patients who had GSH alone and those who received both GSH and CBT. The mean number of GSH sessions received by all stepped care patients (irrespective of next treatment step) was 4.6 (SD 2.2, range 0 to 6). Stepped care patients who had low-intensity therapy alone received a mean number of 4.4 (standard deviation 2.5, range 0 to 6) GSH sessions. Patients who progressed to high-intensity therapy received a mean number of 5.9 GSH sessions (0.3, range 5 to 6). The mean number of CBT sessions received by stepped care patients who had high-intensity treatment after GSH was 12.9 (standard deviation 4.5, range 5 to 21).

Of the maximum number of sessions available (n=26, 6 GSH and up to 20 CBT), the mean proportion attended was 34% (standard deviation 30%, range 0% to 100%). On average, stepped care patients attended 78% (37%, range 0% to 100%) of available GSH sessions and 65% (23%, range 25% to 100%) of the maximum number of CBT sessions.

### Treatment adherence

Twelve percent (4/33) of stepped care participants declined to attend GSH and thus did not receive any therapy; none of the stepped care patients who stepped up declined CBT (Table 17). Twelve percent (4/33) of patients started but subsequently ended treatment prior to the point at which their therapist believed they were ready; three such patients dropped out of therapy during GSH and one whilst in receipt of CBT.

## **Duration of treatment**

The mean total time in stepped care was estimated to be 5.9 hours (standard deviation 6.1) over a period of 12 weeks (SD 11.8; Table 17) and among patients who attended at least one session, the mean total time in treatment was 6.7 hours (SD 6.0) over a period of 13.5 weeks (SD 11.7). (All of the preceding figures reflect the total time in treatment among stepped care patients who had GSH alone and GSH plus CBT.) The mean total time in low-intensity therapy was 2.3 hours (SD 1.1) over a period of 4.9 weeks (SD 2.7) irrespective of next treatment step. Among patients who progressed to CBT, the mean total time in high-intensity therapy was 10.8 hours (SD 3.8) over 19.3 weeks (SD 6.5).

### **6.3.2 Receipt of CBT alone**

Patients randomised to receive high-intensity therapy alone attended a mean number of 8.8 therapy sessions (standard deviation 5.4, range 0 to 20) - 44% of the maximum number (n=20) available (standard deviation 27%, range 0% to 100%); Table 17). Six percent (2/33) of patients declined any treatment; 42% (14/33) started but subsequently dropped out of therapy. The mean total time in treatment was estimated to be 7.3 hours (standard deviation 4.5) over a period of 13 weeks (SD 9.8).

***Table 17 overleaf***

Table 17. Receipt of the intervention and control

	Stepped Care			CBT alone
	All (n=33)	GSH (n=33)	CBT (n=11)	All (n=33)
<b>N sessions attended – mean (SD)</b>	9.0 (7.8)	4.6 (2.2)	12.9 (4.5)	8.8 (5.4)
<b>% of available sessions attended – mean (SD)<sup>1</sup></b>	34% (30%)	78% (37%)	65% (23%)	44% (27%)
<b>Treatment status – n (%)</b>				
Declined any	4 (12%)	4 (12%)	0	2 (6%)
Dropped out <sup>2</sup>	4 (12%)	3 (9%)	1 (9%)	14 (42%)
Completed	25 (76%)	26 (79%)	10 (91%)	17 (52%)
<b>Total time in treatment – mean (SD)<sup>3</sup></b>				
Hours (all patients)	5.9 (6.1)	2.3 (1.1)	10.8 (3.8)	7.3 (4.5)
Hours (receiving 1+ session)	6.7 (6.0)	2.7 (0.7)	10.8 (3.8)	7.8 (4.2)
Weeks (all patients)	11.9 (11.8)	4.9 (2.7)	19.3 (6.5)	12.7 (9.8)
Weeks (receiving 1+ session)	13.5 (11.7)	5.5 (2.2)	19.3 (6.5)	13.5 (9.5)

Notes: <sup>1</sup> Percentage of available sessions attended has been calculated based on a total of six available GSH sessions, 20 CBT and 26 stepped care. <sup>2</sup> 'Dropped out' is defined as ending treatment prior to a point at which the therapist believed the patient was ready to do so; <sup>3</sup> 'Hours' spent in treatment has been estimated assuming 0.5 hrs per GSH contact and 0.83 hours per CBT session as detailed in Chapter Five, section 5.5.1.

## 6.4 Treatment outcomes

This study was not powered to detect clinically meaningful differences in the effectiveness of stepped care vs. high-intensity psychological therapy alone. Similarly, it was not powered to detect differences in outcomes between stepped care patients who were discharged from treatment following GSH vs. 'stepped up' or those with a mild to moderate vs. severe level of baseline depression. Inferences regarding the relative effectiveness of stepped care and CBT alone cannot be drawn. The study does not provide robust evidence on the effectiveness of stepped care for different patient groups.

### 6.4.1 Variability in outcomes

The pooled standard deviation around the mean BDI-I score for all patients at baseline was 6.9; equivalent figures for the intervention and control groups were 6.4 and 7.4 (Table 18). At follow-up, the pooled standard deviation around mean BDI-I scores across groups was 10.0; the standard deviation around

mean six month depression scores for stepped care patients and patients who had CBT alone was 9.6 and 10.5, respectively.

Ninety-five percent confidence intervals indicate that, in a future trial, the pooled standard deviation around the mean BDI-I score at baseline for all patients would be between 5.9 and 8.3; standard deviations around mean baseline depression scores for the intervention and control groups would be from 5.1 to 8.5 and from 5.9 to 9.8, respectively. At follow-up, it can be inferred that the standard deviation around the mean BDI-score for all patients would be 8.0 to 12.2; standard deviation around the mean BDI-I score for patients in the stepped care arm would be 7.6 to 12.9. Equivalent six month figures for the control group would be between 8.3 and 14.2.

Standard deviations around mean scores on the GAD-7 and physical and mental component scales (PCS, MCS) of the SF-36 at baseline and six months are provided in Table 18. Ninety-five percent confidence intervals around the standard deviations are also provided.

Table 18. Variability in outcomes at baseline and six month follow up

Outcome	All patients				Stepped Care				CBT alone			
	n	Mean	SD <sup>1</sup>	95% CI <sup>2</sup>	n	Mean	SD	95% CI	n	Mean	SD	95% CI
BDI at baseline	66	27.4	6.9	5.9 to 8.3	33	26.9	6.4	5.1 to 8.5	33	27.9	7.4	5.9 to 9.8
BDI at 6 months	59	13.9	10.0	8.0 to 12.2	30	13.7	9.6	7.6 to 12.9	29	14.2	10.5	8.3 to 14.2
GAD-7 at baseline	66	13.8	4.3	3.7 to 5.2	33	14.1	4.2	3.4 to 5.6	33	13.5	4.5	3.6 to 6.0
GAD-7 at 6 months	60	6.6	5.2	4.3 to 6.4	30	7.2	5.2	4.1 to 7.0	30	6.0	5.3	4.2 to 7.1
SF-36 PCS at baseline	66	51.5	10.3	8.8 to 12.4	33	52.4	11.1	8.9 to 14.7	33	50.7	9.5	7.6 to 12.6
SF-36 PCS at 6 months	59	49.4	10.7	8.6 to 13.1	29	50.9	8.7	6.9 to 11.8	30	47.9	12.3	9.8 to 16.6
SF-36 MCS at baseline	66	18.6	9.5	8.1 to 11.5	33	16.8	9.0	7.3 to 11.9	33	20.5	9.7	7.8 to 12.8
SF-36 MCS at 6 months	59	40.4	14.0	11.3 to 17.0	29	38.7	13.0	10.3 to 17.6	30	42.0	14.9	11.8 to 20.0

Notes: <sup>1</sup> SD = standard deviation of the mean; <sup>2</sup> 95% CI = 95% confidence intervals around the standard deviation.

#### 6.4.2 Correlation between baseline and six month scores

The size of the correlations between stepped care participants' BDI-I, GAD-7, PCS and MCS scores at baseline and six months ranged from small (Spearman's Rho 0.19) to large (Rho 0.59) according to commonly used

guidelines (Cohen, 1988); Table 19. For patients who were randomised to receive CBT alone, correlations in depression, anxiety, physical and mental health scores were medium to large (Spearman's Rho 0.39 to 0.52). The margin of error (based on the lower limit of the 95% confidence interval) associated with each correlation is provided in Table 19.

Table 19. Correlation between participant scores at baseline and six months

Association	Participants	N	Rho <sup>1</sup>	Margin of error <sup>2</sup>	P
BDI-I at baseline and six months	All	59	0.49	0.22	<0.001
	Stepped Care	30	0.44	0.35	0.014
	CBT alone	29	0.52	0.33	0.004
GAD-7 at baseline and six months	All	60	0.33	0.25	0.011
	Stepped Care	30	0.19	0.37	0.313
	CBT alone	30	0.42	0.35	0.021
SF-36 PCS at baseline and six months	All	59	0.49	0.22	0.001
	Stepped Care	29	0.47	0.34	0.011
	CBT alone	30	0.48	0.20	0.007
SF-36 MCS at baseline and six months	All	59	0.49	0.22	<0.001
	Stepped Care	29	0.59	0.30	0.001
	CBT alone	30	0.39	0.36	0.035

Notes: <sup>1</sup> Rho = Spearman's Rho; <sup>2</sup> margins of error associated with Rho have been estimated based on the lower limit of the 95% confidence interval.

### 6.4.3 Reduction in depressive symptoms

From baseline to six months, symptoms of depression reduced in both groups: the mean reduction in depression scores for patients in the stepped care arm was 13.4 points (standard deviation 8.6); the mean reduction for patients who had CBT alone was 13.6 points (standard deviation 9.1; Table 20). Patients' symptoms of anxiety and mental health function (as measured on the mental component scale, MCS, of the SF-36) also improved in both arms. The mean reduction in GAD-7 scores from baseline to six months was 7.2 points (standard deviation 5.6) among stepped care patients and 7.3 points (SD 5.9) among those who had CBT alone. The mean increase in stepped care participants' MCS scores was 21.2 points (SD 10.7); for patients who had CBT alone the

mean increase was 21.3 points (SD 14.2). (Higher scores on the MCS and Physical Component Scale, PCS, represent better function (Ware et al., 2007).) From baseline to six months, patients' physical health function did not improve. The mean reduction in stepped care participants' PCS scores was -1.4 (SD 10.7); the mean reduction in PCS scores among patients who had CBT alone was -2.6 (SD 11.6).

Table 20. Treatment outcomes at baseline and six month follow-up

	All			Stepped Care			CBT alone		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
BDI at baseline	66	27.4	6.9	33	26.9	6.4	33	27.9	7.4
BDI at 6 months	59	13.9	10.0	30	13.7	9.6	29	14.2	10.5
<b>BDI difference from 0 to 6 m</b>	<b>59</b>	<b>-13.5</b>	<b>8.8</b>	<b>30</b>	<b>-13.4</b>	<b>8.6</b>	<b>29</b>	<b>-13.6</b>	<b>9.1</b>
GAD-7 at baseline	66	13.8	4.3	33	14.1	4.2	33	13.5	4.5
GAD-7 at 6 months	60	6.6	5.2	30	7.2	5.2	30	6.0	5.3
<b>GAD-7 difference from 0 to 6 m</b>	<b>60</b>	<b>-7.3</b>	<b>5.7</b>	<b>30</b>	<b>-7.2</b>	<b>5.6</b>	<b>30</b>	<b>-7.3</b>	<b>5.9</b>
SF-36 PCS at baseline	66	51.5	10.3	33	52.4	11.1	33	50.7	9.5
SF-36 PCS at 6 months	59	49.4	10.7	29	50.9	8.7	30	47.9	12.3
<b>SF-36 PCS difference from 0 to 6 m</b>	<b>59</b>	<b>-2.0</b>	<b>11.1</b>	<b>29</b>	<b>-1.4</b>	<b>10.7</b>	<b>30</b>	<b>-2.6</b>	<b>11.6</b>
SF-36 MCS at baseline	66	18.6	9.5	33	16.8	9.0	33	20.5	9.7
SF-36 MCS at 6 months	59	40.4	14.0	29	38.7	13.0	30	42.0	14.9
<b>SF-36 difference from 0 to 6 m</b>	<b>59</b>	<b>21.3</b>	<b>12.5</b>	<b>29</b>	<b>21.2</b>	<b>10.7</b>	<b>30</b>	<b>21.3</b>	<b>14.2</b>

#### 6.4.4 Improvement in depression and anxiety

Participants' depressive symptoms reduced by 50% or more from baseline to six months for 63% (19/30) of stepped care patients and 44.8% (13/29) of patients receiving CBT alone (Table 21). The majority of patients in both trial arms experienced a reduction in symptoms of anxiety of at least 50%: this was true for 60.0% (18/30) of stepped care patients and 80.0% (24/30) of patients who had CBT alone.

Table 21. Treatment response ( $\geq 50\%$  reduction in symptoms from baseline to six months)

Measure	Participants	No. of participants	No. (%) responded
BDI-I	All	59	32 (54.2)
	Stepped Care	30	19 (63.3)
	CBT alone	29	13 (44.8)
GAD-7	All	60	42 (70.0)
	Stepped Care	30	18 (60.0)
	CBT alone	30	24 (80.0)

#### 6.4.5 Outcomes for patients discharged vs. stepped up

Relative to baseline, at six months symptoms of depression among stepped care patients who were either discharged following GSH or who subsequently had CBT, were reduced: the mean reduction in symptoms of depression for patients who were discharged was 15.4 points (standard deviation 9.5); the mean reduction in depressive symptoms for patients who stepped up was 10.1 points (standard deviation 5.8; Table 22). Levels of anxiety and mental health function improved for both groups. At six months, the mean reduction in anxiety symptoms was 8.2 points (SD 5.8) for stepped care patients who had GSH alone and 5.6 points (SD 5.1) among patients who had GSH and CBT. The mean increase in MCS scores was 22.3 (SD 10.5) for stepped care patients who had GSH alone and 19.5 (SD 11.2) among those who 'stepped up'. Physical health function did not improve in either group: relative to baseline, the mean decrease in PCS scores was 0.1 points (SD 10.6) at six months for patients who had GSH alone and -3.4 points (SD 11.0) among patients who progressed to CBT.

**Table 22 overleaf**

Table 22. Outcomes for stepped care patients who were discharged or 'stepped up' following GSH

Outcome	Discharged			Stepped Up		
	n	Mean	SD	n	Mean	SD
BDI at baseline	22	25.7	6.2	11	29.4	6.4
BDI at 6 months	19	10.4	8.0	11	19.2	9.8
<b>BDI difference from 0 to 6 m</b>	<b>19</b>	<b>-15.4</b>	<b>9.5</b>	<b>11</b>	<b>-10.1</b>	<b>5.8</b>
GAD-7 at baseline	22	14.0	4.9	11	14.4	2.6
GAD-7 at 6 months	19	6.4	5.5	11	8.7	4.5
<b>GAD-7 difference from 0 to 6 m</b>	<b>19</b>	<b>-8.2</b>	<b>5.8</b>	<b>11</b>	<b>-5.6</b>	<b>5.1</b>
SF-36 PCS at baseline	22	52.1	10.6	11	52.9	12.5
SF-36 PCS at 6 months	18	51.8	8.0	11	49.5	10.0
<b>SF-36 PCS difference from 0 to 6 m</b>	<b>18</b>	<b>-0.1</b>	<b>10.6</b>	<b>11</b>	<b>-3.4</b>	<b>11.0</b>
SF-36 MCS at baseline	22	17.6	8.7	11	15.1	9.8
SF-36 MCS at 6 months	18	41.2	13.0	11	34.7	12.5
<b>SF-36 difference from 0 to 6 m</b>	<b>18</b>	<b>22.3</b>	<b>10.5</b>	<b>11</b>	<b>19.5</b>	<b>11.2</b>

#### 6.4.6 Outcomes for patients with mild to moderate vs. severe depression

Relative to baseline and across groups, at six months there was a reduction in symptoms of depression for patients who had a mild to moderate episode of depression at baseline and for patients who had a severe level of baseline depression (Table 23). The mean reduction in symptoms of depression among patients who had a mild to moderate depressive episode was 12.3 points (standard deviation 6.5) in the stepped care arm and 14.1 points (standard deviation 7.9) among patients randomised to receive CBT alone. The mean reduction in symptoms of depression among patients who had a severe depressive episode at baseline was 15.4 points (SD 11.5) in the stepped care group and 13.1 points (SD 10.9) in the CBT alone arm.

Across groups and relative to baseline, at six months there was also a reduction in anxiety symptoms for patients with a mild to moderate level of baseline depression and for those with a severe depressive episode (Table 23). The mean reduction in GAD-7 scores among patients who had a mild to moderate episode was 6.4 points (SD 4.9) in the stepped care group and 7.9 points (SD 3.9) in the CBT alone arm. Among patients who had a severe depressive episode at baseline, the mean reduction in symptoms of anxiety at six months



was 8.6 points (SD 6.5) for stepped care participants and 6.6 points (SD 7.8) among those who had CBT alone.

Table 23. Depression and anxiety at baseline and six months for participants with a mild to moderate vs. severe depressive episode

Baseline level of depression	Outcome	ALL			Stepped Care			CBT alone		
		n	Mean	SD	n	Mean	SD	N	Mean	SD
Mild to Moderate	BDI at baseline	39	25.5	6.8	21	26.5	7.1	18	24.3	6.5
	BDI at six months	35	12.2	8.0	19	14.3	8.9	16	9.7	6.1
	<b>BDI difference</b>	<b>35</b>	<b>-13.1</b>	<b>7.1</b>	<b>19</b>	<b>-12.3</b>	<b>6.5</b>	<b>16</b>	<b>-14.1</b>	<b>7.9</b>
Severe	BDI at baseline	27	30.1	6.1	12	27.7	5.2	15	32.1	6.1
	BDI at six months	24	16.5	12.1	11	12.6	11.1	13	19.8	12.3
	<b>BDI difference</b>	<b>24</b>	<b>-14.1</b>	<b>10.9</b>	<b>11</b>	<b>-15.4</b>	<b>11.5</b>	<b>13</b>	<b>-13.1</b>	<b>10.9</b>
Mild to moderate	GAD-7 at baseline	39	12.4	4.2	21	13.2	4.5	18	11.4	3.8
	GAD-7 at six months	35	5.5	3.8	19	7.4	4.0	16	3.4	1.9
	<b>GAD-7 difference</b>	<b>35</b>	<b>-7.1</b>	<b>4.5</b>	<b>19</b>	<b>-6.4</b>	<b>4.9</b>	<b>16</b>	<b>-7.9</b>	<b>3.9</b>
Severe	GAD-7 at baseline	27	15.8	3.7	12	15.7	3.4	15	15.9	4.1
	GAD-7 at six months	25	8.1	6.6	11	7.0	7.0	14	8.9	6.4
	<b>GAD-7 difference</b>	<b>25</b>	<b>-7.5</b>	<b>7.2</b>	<b>11</b>	<b>-8.6</b>	<b>6.5</b>	<b>14</b>	<b>-6.6</b>	<b>7.8</b>

#### 6.4.7 Sensitivity analyses

Six month outcome data was collected from 15% (10/66) of patients prior to the end of their treatment. Sensitivity analyses excluding this data produced estimates of the variability in treatment outcomes (standard deviation around mean scores on the BDI-I, GAD-7, PCS and MCS) at six months that were similar to those estimated from all of the available data (Table 24). The strength of correlations between patients' baseline and six month data estimated using all of the available data vs. excluding follow up data collected from patients prior to the end of treatment, were also similar: the strength of the correlations estimated using all available data ranged from 0.19 to 0.59; the size of correlations estimated excluding data ranged from 0.24 to 0.59 (Table 25).

Table 24. Means and standard deviations estimated using all available data and excluding data collected from (n=10) patients prior to the end of treatment

Six month outcome	All patients				Stepped Care				CBT alone			
	Available <sup>1</sup>		Excluding <sup>2</sup>		Available		Excluding		Available		Excluding	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
BDI	59	13.9 (10.0)	49	12.9 (9.6)	30	13.7 (9.6)	22	11.2 (8.7)	29	14.2 (10.5)	27	14.2 (10.9)
GAD-7	60	6.6 (5.2)	50	6.1 (5.3)	30	7.2 (5.2)	22	6.4 (5.2)	30	6.0 (5.3)	28	5.9 (5.4)
SF-36 PCS	59	49.4 (10.7)	49	49.0 (11.0)	29	50.9 (8.7)	21	51.2 (8.3)	30	47.9 (12.3)	28	47.5 (12.6)
SF-36 MCS	59	40.4 (14.0)	49	42.1 (13.8)	29	38.7 (13.0)	21	41.6 (12.6)	30	42.0 (14.9)	28	42.4 (14.8)

Notes: <sup>1</sup> Means and standard deviations (SD) estimated using all available data; <sup>2</sup> Means and standard deviations estimated excluding six month outcome data collected from ten patients (eight in stepped care, two CBT alone) prior to the end of treatment.

Table 25. Correlation between baseline and six month scores estimated using all available data and excluding data from patients with whom a six month follow-up was conducted prior to end treatment

Correlation	Group	Available data <sup>1</sup>			Excluded data <sup>2</sup>		
		n	Rho <sup>3</sup>	P	n	Rho	P
BDI-I at baseline and six months	All	59	0.49	<0.001	49	0.41	0.003
	Stepped Care	30	0.44	0.014	22	0.24	0.281
	CBT alone	29	0.52	0.004	27	0.52	0.006
GAD-7 at baseline and six months	All	60	0.33	0.011	50	0.37	0.009
	Stepped Care	30	0.19	0.313	22	0.29	0.198
	CBT alone	30	0.42	0.021	28	0.44	0.019
SF-36 PCS at baseline and six months	All	59	0.49	0.001	49	0.44	0.001
	Stepped Care	29	0.47	0.011	21	0.38	0.087
	CBT alone	30	0.48	0.007	28	0.47	0.011
SF-36 MCS at baseline and six months	All	59	0.49	<0.001	49	0.45	0.001
	Stepped Care	29	0.59	0.001	21	0.59	0.005
	CBT alone	30	0.39	0.035	28	0.37	0.052

Notes: <sup>1</sup> n, Spearman's Rho and p estimated using all available data; <sup>2</sup> n, Spearman's Rho and p estimated excluding data from patients with whom a six month follow up was conducted prior to end treatment; <sup>3</sup> Spearman's Rho

## **Chapter 6. PART II**

### **Qualitative and mixed methods analysis on recruitment**

Comprising sections:

6.5 Appropriateness of recruitment

6.6 Appropriateness of recruitment to patients

6.7 Appropriateness of recruitment to therapists

6.8 Appropriateness of recruitment to IAPT personnel

6.9 Comparing quantitative and qualitative recruitment data

## **6.5 Appropriateness of recruitment**

Interviews were conducted with 30 trial participants (patients), three study therapists and three IAPT personnel. All of those approached consented to be interviewed. Data from 12 patient interviews and all of the therapist and IAPT personnel interviews were analysed. A description of the patient sample is provided in Part II, section 6.10. Qualitative analysis aimed to describe the degree to which recruitment methods and procedures were considered appropriate. It covered patients' views and experiences of each stage of recruitment as well as what therapists and IAPT staff thought of the elements in which they had been involved. The results of the qualitative analysis of the patient data are presented first (section 6.6) followed by the views of the therapists (section 6.7) and IAPT personnel (section 6.8). The results of mixed methods analysis to compare interviewees' views of recruitment with numeric data on the performance of recruitment methods and procedures are presented in section 6.9. The aim of the mixed methods analysis was to help understand the implications of combining quantitative and qualitative data on recruitment in terms of a future trial.

## 6.6 Appropriateness of recruitment to patients

Qualitative analysis showed patients' views of recruitment methods and procedures could be understood in terms of three themes: 'initial approach and further information', 'pace of recruitment' and the 'baseline interview'.

### 6.6.1 Theme one - initial approach and further information

The theme 'initial approach and further information' describes what patients thought of how they were first contacted about the study and the written information that they received. It covers patients' views of being sent a study summary sheet with their initial IAPT assessment appointment letter, returning a 'permission for researcher to contact' form and the Patient Information Sheet.

In terms of what patients thought about being sent a study summary sheet, people responded to it in the context of what was important to them and recollections of the experience were mixed. Some patients could recall the summary and received it positively: it represented a source of much needed help, was clear and interesting and the location of the study was convenient. A few patients decided to take part directly on reading the summary. Other patients could not (much) remember the summary and were uncertain whether they had received it at or prior to their assessment. Patients were sometimes critical of layout and content.

I read the short summary and thought sounded quite interesting and fascinating and was happy with that [laugh]. (Patient 027)

*Interviewer: At what point did you decide to take part?*

Pretty much, I mean, as soon - so once I saw the leaflet. (Patient 028)

I think I remember feeling like there was quite a lot of information, so maybe a little bit too much at the top of the sheet. (Patient 039)

There was also a small amount of feedback to suggest that patients were not troubled by being asked about their interest in STEPS at assessment. Some patients decided to take part at this appointment.

I just said yes to [my therapist] when she said, 'Might you be interested?'... That was fine, nothing wrong with that at all. (Patient 007)

Responses to the Patient Information Sheet (PIS) were similar to the study summary sheet: people responded to the PIS in the context of what was important to them and experiences were mixed. Some of the interviewees read and found the PIS useful. It was thorough; nothing stood out as missing; included information was appropriate and informative. Reading the PIS also reinforced patients' decision to get involved in the study and that STEPS was a means to access help. In contrast, other patients did not read or only skimmed the PIS. There was a perception that it was too long and dense; a leaflet may have been more accessible.

[The PIS was] absolutely fine really, just, you know, appropriate and informative... what more do I want from information like this? (Patient 023)

It gave a lot more of the background and allowed me to understand what it entailed... It helped reinforce ... if I'm selected, this would be a good thing for me to do.' (Patient 053)

If somebody knows they need help and then they get these thick pages and think, 'Oh God I've got to read through these now!' it might, like, feel a bit too much. You know, they know they need help but then they've got to get through all these pages. (Patient 039)

### ***Summary – initial approach and further information***

Views on being sent study information were mixed. Some patients could recall the study summary sheet and received it positively. Likewise, some patients read and found the PIS useful. Other patients could not remember the summary sheet and some of the interviewees thought that the summary sheet and PIS contained too much information. Data indicated that patients were not troubled by being asked about STEPS at their IAPT assessment.

## 6.6.2 Theme two – pace of recruitment

In the theme 'pace of recruitment' patients described their views and experiences of how long it took the research team to make contact once they had returned their 'permission for researcher to contact' form. Patients also described how they felt about the length of time between their telephone screen and baseline interview and their views of the length of time for treatment to commence post-baseline.

With respect to how long it took the study researcher to make contact, patients responded positively. The speed of contact impressed on people that the research was well organised and that their problems were recognised as such; it maintained a sense of momentum (once people had decided to seek help) and for one person, was important in retaining her in treatment.

Oh it was very good, it was perfect, if it had been any longer I probably wouldn't have carried on. (Patient 014)

Had it been, you know, a month before I had heard anything, then you'd suddenly start to think, 'Oh,' – because I think, you know, having reached the point where you want to... Thinking, 'I just want to get on with it now!' you know, the importance of maintaining momentum and actually feel that you're moving forward towards some help and therapy is, naturally, is useful. (Patient 053)

Fewer people commented on the length of time to pass from when the research team made first contact to their baseline interview but those that did predominantly felt that it had not been long and were pleased with this. Patients were also pleased with the length of time between their baseline interview and the start of treatment. At a time when they were low, confirmation that they would start treatment quickly was welcome; patients expressed a sense that when you ask for support (which can be difficult) it is important that help soon follows. The treatment of one patient (who was deaf and required an interpreter) took longer than average to arrange; this person had found the wait difficult but acceptable.

It was just you know, nice to- well actually because you know, having been seen by [IAPT Service] previously, and then it takes them, you

know, three weeks to do anything pretty much. I guess because of staffing and- and- and busy-ness. It was, you know, yeah. It was nice to know, you know to- to, get quick responses. (Patient 023)

### ***Summary – pace of recruitment***

The speed of recruitment was very well received. Patients welcomed how quickly the study researcher made contact and arranged their baseline interview. Patients were also pleased to begin treatment shortly after meeting with the study researcher.

### **6.6.3 Theme three – the baseline interview**

The theme 'baseline interview' encompassed patients' views on attending a baseline interview shortly after an initial assessment appointment at IAPT as well as experiences of the interview itself.

Views on attending a baseline interview shortly after meeting with a DAS therapist for an assessment varied. For some patients having two assessments (an initial IAPT appointment and baseline interview) close together was acceptable, without issue. The baseline interview was seen as part of a due research process and the need for it was understood. One patient described it as a good opportunity to better phrase thoughts, feelings and experiences that they had not put across very well at their initial IAPT assessment.

It was, it was good because I think the first time I went away thinking, Oh, I could have phrased that better or I could have answered that better,' and it was basically getting a do-over umm opportunity ... Yeah, to have like a practice, yeah to have a practice one... and then have time to think about it... personally I thought that was good.  
(Patient 027)

Other patients described difficulty having their baseline after an IAPT assessment. After a difficult experience at IAPT, one patient was nervous about her baseline interview; this person had been grateful for the opportunity to complete it by phone. Another interviewee had been disheartened at the prospect of going over thoughts, feelings and experiences already discussed at IAPT although, in practice, the patient found that she was not bothered by this



at interview. In these ways, difficulties for patients around scheduling baseline interviews shortly after an IAPT assessment were resolved or did not materialise as feared.

I think I did feel a bit, kind of like 'Oh I've got to go through it all again!', 'cause I had already been through all the information with the DAS Service, so I think it was a bit like, 'Oh, I've got to go through it again'... But then when I was here it didn't really bother me.

(Patient 039)

Patients expressed a range of views about the baseline interview itself. Direct comparison between the baseline interview and IAPT assessment sometimes reflected less favourably on the baseline. One patient found the baseline less personal. Another patient thought that it was harder to complete for being more in-depth than the IAPT assessment although the same patient also viewed this positively.

Well in many ways it [sighs] this was a lot more in depth, particularly completing the questionnaires... it was a lot more intensive, a lot more soul searching and in a lot more depth in the way that we went through the process here than the relatively superficial level of interview that I had through the NHS. So yes, it was a bit harder, but – it made me look at things a lot more, a lot more soul-searching and actually looking at some of the issues and was the start of the process from my point of view. (Patient 053)

Other negative feedback about the baseline interview was mainly focused on the CIS-R: closed questions were disliked; the CIS-R was found to be repetitive and difficult to understand; the CIS-R failed to include questions about gambling (a problem that was perceived to be widespread and had affected one patient personally). An older person observed that questions did not take into account people's life stage / age. In contrast, positive opinions of the baseline interview were that it was more personal than the IAPT assessment; at interview, treatment was very well explained; a patient had been reassured about starting therapy having met with the researcher. Some patients decided to take part in the study at their interview.

### ***Summary – the baseline interview***

Patients' views on attending a baseline interview shortly after their IAPT assessment were mixed: for some patients it presented no issue; other patients felt nervous about the interview and did not want to go over what had already been discussed at IAPT. The option to complete the baseline by phone helped. Views of the baseline interview itself were also mixed. Some patients were critical of the CIS-R and found the interview less personal than their IAPT assessment. Other patients thought that the baseline was more personal than their IAPT assessment and that treatment had been very well explained.

#### **6.6.4 A summary of the appropriateness of recruitment to patients**

Patients shared their views and experiences of being sent study information, the pace of recruitment and the baseline interview. The study summary sheet and PIS were well received by some patients but not very memorable and thought to contain too much information by others. A small amount of feedback suggested that patients were happy to be asked about STEPS at their IAPT assessment appointment. The speed of recruitment was very well received although some patients found the prospect of attending a baseline interview after their IAPT assessment, difficult. This had been helped by the offer to complete the baseline by phone. In terms of the baseline interview itself, some patients were critical of some elements e.g. the CIS-R. Others viewed the same features, positively.

## **6.7 Appropriateness of recruitment to therapists**

The study therapists were relatively uninvolved in recruitment. Their views on its appropriateness were encapsulated in two themes: 'study inclusion criteria' and 'patients' transition into therapy'.

### **6.7.1 Theme one – study inclusion criteria**

One therapist deliberated whether the criteria by which the eligibility of patients was determined should have been more closely defined. One of his patients had bulimia; another was dependent on alcohol. The therapist speculated that had he known of their problems prior to the start of therapy, he would not have accepted them into his care. He suggested that stricter inclusion criteria may be required to help make sure that patients presenting with problems which may be more appropriate to treat in other services, did not join the study.

'Cause I wouldn't have taken the bulimic into the CBT if I'd known she was bulimic... and I certainly wouldn't have had an alcoholic at that level had it not sort of been diagnosed earlier on... So I suppose that goes to inclusion and I suppose when other things, if it was a [fully-powered] randomised controlled trial would the inclusion have been stricter? (Therapist 02)

#### ***Summary – study inclusion criteria***

Study inclusion criteria may need to be more closely defined or implemented to exclude patients who are unsuitable for treatment.

### **6.7.2 Theme two – patient transition to therapy**

Therapists were pleased with how quickly patients entered treatment after their baseline interviews. There was a perception that the transition was handled efficiently and represented good care. However, there was a concern that relevant information from a patient's baseline which had been summarised for clinical use was not always reliably passed on via the AccEPT Clinic Administrator. One of the therapists wanted more information from the baseline interview. This additional information would be used to avoid asking patients the same questions at baseline and the start of treatment; it would also

be used to inform conversations with patients about the nature of their difficulties.

When you assess people [at baseline] you clearly get a whole wealth of information from them that seems somehow a bit of a waste if we don't have that, because then a). there's a risk of total repetition a lot of the time, as in a person may come in for a CBT assessment and they'll be having to recount the same material over again... [And] I suppose, for me, if I had more detail of what you'd gathered, I would be taking my lines of enquiry perhaps to unpack some of this or, you know, what does that anxiety look like? Is it kind of generalised across all areas of life? Is it more specific? (Therapist 03)

Another therapist thought that it would be useful to have an idea of what had been learned about the patient from their IAPT assessment. However, he cautioned against sharing this information for patients who were randomised to stepped care as it may make it harder for the GSH therapist to work as an 'educator' rather than a therapist.

### ***Summary – patients' transition to therapy***

Therapists thought that patients' transition to therapy worked well and represented good care. However clinical information that had been summarised by the study researcher for the therapists was not always reliably passed on. One therapist thought that it may have been helpful to receive more information; another warned that this may make it difficult for them to perform their role in low-intensity therapy.

### **6.7.3 A summary of the appropriateness of recruitment to therapists**

Therapists described what they thought of the study inclusion criteria and patients' transition into therapy. There was a perception that study inclusion criteria may need to be more closely defined or carefully implemented. The transition into therapy worked well although clinical information from patients' baseline interview was not always reliably passed on. One therapist thought that it may have been helpful to receive more information although another felt that this may not be beneficial.

## 6.8 Appropriateness of recruitment to IAPT personnel

Analysis of the interviews conducted with IAPT personnel found that their views of recruitment could be described by five themes: 'views of research and research in the NHS', 'initial approach to patients', 'handling permission forms', 'post-baseline' and 'administrative systems, workload and support'. Four of the five themes comprised several sub-themes. Themes and sub-themes were descriptive and are summarised in Box 2.

Box 2. Key themes (numbered 1 to 5) and sub-themes describing the appropriateness of recruitment to IAPT personnel

<b>1. Views of research and research in the NHS</b>
<b>2. Initial approach to patients</b> Booking an assessment Written approach to patients
<b>3. Handling permission forms</b> Changing the format of an assessment appointment Asking for permission forms Responding to patient questions Handling forms for potentially ineligible patients
<b>4. Post-baseline</b> Joining STEPS Returning to IAPT Therapist capacity
<b>5. Administrative systems, workload and support</b> Record-keeping Workload Staff briefing and support

### 6.8.1 Theme one - views of research and research in the NHS

The theme 'views of research and research in the NHS', describes what the IAPT interviewees thought of research and the role of the NHS in research. It also covers interviewees' views of the role for research in their service.

All of the IAPT interviewees were supportive of research and believed that research should be undertaken in the NHS. The IAPT Manager felt that the involvement of her service in research was very important.

If you didn't have research then you'd sort of fall behind all other health authorities around the world, wouldn't you really? You've got to be sort of leading your way in new ideas, new ventures and – else you'd just get left behind really. (IAPT Administrator)

I'd see it as being very important, and we're obviously a service that's driven by the evidence base, so actually adding to the evidence base is a really valuable thing to do, otherwise it's static isn't it? So I'd get the value of that, I would think it a really important thing to do. (IAPT Manager)

However, support for research was tempered. The Administrator and Service Manager foresaw difficulty when the needs of research and those of an IAPT service driven by performance targets were different. The Administrator was clear that involvement in research should not compromise patient care. The IAPT Manager's views of the current study were also influenced by her team's involvement in another (larger) trial. Although the larger trial was seen as important, she felt that it had left the IAPT service somewhat depleted of therapists. There was a perception that this may have made it harder to negotiate and implement STEPS' recruitment method and procedures.

I guess the negatives are that services are under quite a lot of pressure to meet their own performance targets and research hasn't necessarily got the same agenda, so those things sometimes can feel a little bit competing. (IAPT Manager)

I would think of them [the larger trial and current study] as both being really good, valid bits of research. The fact that they've come along

at the same time is probably not great, because they're both completely different, and obviously [this study] has not taken any resource out of the team in terms of therapists, but [the larger trial] has... So I suppose that makes me feel a bit depleted then, as the manager, and... it can make you feel a little bit overwhelmed by research requests, demands etc. So I'd see them as both really valid and valuable, but quite intensive in terms of effort, resource, I suppose, from our point of view. (IAPT Manager)

### ***Summary – views of research and research in the NHS***

Although all of the IAPT interviewees were supportive of research this was tempered. There was a perception that research should not compromise patient care and the IAPT Manager and Administrator foresaw difficulty when the needs of research conflicted with IAPT service performance targets. Involvement in another trial affected how staff felt about STEPS.

#### **6.8.2 Theme two - initial approach to patients**

In this theme, the IAPT interviewees described their views and experiences of the initial approach to patients. The theme covered what the interviewees thought of a member of the Admin Team mentioning STEPS to patients when they rang to book their initial IAPT assessment appointment. It encompassed interviewees' views of subsequently referring to STEPS in the letter to confirm patients' appointment and including a study summary sheet alongside other standard information sent to patients with their letter.

#### ***Booking an assessment appointment***

The Admin Team's mention of STEPS when patients rang to book their initial assessment was endorsed by the IAPT Manager who felt that this helped patients. The Administrator was also comfortable with this procedure. In response to queries (e.g. 'what's the study about?') the IAPT Administrator referred patients to the study summary sheet and contact telephone number therein. This was viewed as entirely appropriate. Interviewees' main concern had been to avoid confusing patients and there was a sense that the Admin Team was successful in this. The IAPT Administrator mentioned STEPS briefly and sometimes not at all. Only a handful of people declined to receive study

information.

The script was such that, 'Sent you out a questionnaire – erm, the letter, confirming the appointment, there will be a questionnaire that you need to fill in from the DAS Service, there'll also be information about the STEPS project that's taking place', so we would mention that in the letter. We had a few, very few, a handful of people who said, 'Don't bother sending me out that information'. But that is, you know, a handful at most. (IAPT Administrator)

I think... if you went into [describing STEPS] at a very early stage, you would have just got people even more confused because a lot of people will phone us up saying, 'My doctor's told me to phone this number, I need to see a counsellor.' So we don't even go into whether it's counselling or whatever, 'cause they don't know, they just want to come and see someone and then decide when they see someone. So if you then went on to explain a bit more about the project and stepped care and – it would have just confused them even more. (IAPT Administrator)

### ***Written confirmation and information***

In terms of sending patients the study summary sheet with the letter to confirm their initial assessment plus other IAPT information, one of the interviewees observed that this did not overcome difficulty recruiting patients with poor literacy skills and / or for whom English was not their first language. Moreover, all of the IAPT interviewees felt that patients may have been overwhelmed by the amount of material sent. The Administrator felt that the majority of people would have ignored the study information. The PWP suggested that, at assessment, patients were sometimes stressed and may not have understood all of the paperwork that they had received; at assessment patients sometimes changed their mind about returning a completed permission form. The PWP wondered if the accompanying appointment letter could be clearer that patients were not required to fill in the form.

For patients, I think we send them an overwhelming amount of information in the post already, so more information I think was



probably a bit of information overload for them. I think it's really good that we amalgamated it into the letter and that we got the admin staff to tell people on the telephone... So that was helpful, gave a little clarity to patients, but still an overwhelming amount of information that people get landing on their doorstep. They're anxious about coming to the appointment. Hard to know, really, what you could do about that, because we did streamline the information down as much as we could. (IAPT Manager)

### ***Summary – initial approach to patients***

The IAPT Admin Team mentioned STEPS when patients rang to book their initial assessment appointment. This was seen as helpful to patients and was competently handled by the Admin Team who had been comfortable with this procedure. On the other hand IAPT personnel were uncomfortable sending patients study information. Information was included with a letter to confirm patients' assessment appointment that also enclosed a large amount of paperwork sent as standard by the IAPT service. Interviewees felt that this may have overwhelmed and confused patients.

### **6.8.3 Theme three – handling permission forms**

The theme 'handling permission forms' describes interviewees' views and experiences of IAPT therapists receiving completed 'permission for researcher to contact' forms at patients' initial assessment appointment. The theme covers four ways in which the procedure caused difficulty or uncertainty: changing the format of the assessment appointment; the degree to which PWPs were proactive in asking patients for forms; responding to patients' questions; passing on forms for patients who were potentially ineligible for STEPS.

#### ***Changing the format of an assessment appointment***

Receiving permission forms required PWPs to change how they handled patients' initial assessment appointments. Outside of the study, it was usual for therapists to conclude the appointment with a discussion about IAPT treatment options and to give patients a booklet about treatment. Receiving the booklet was defined as initiating IAPT treatment. For this reason, therapists were asked

not to give the booklet to patients who returned a permission form. They were also asked not to discuss IAPT treatment options with patients who were interested in the current study. Changing the format of assessment appointments to accommodate these differences was difficult. Whilst most patients presented their form at the start of an appointment, sometimes it was only mentioned at the end, perhaps when IAPT treatment options had already been discussed. When forms were presented at the end of appointments, the PWP described how there was little time to prepare not to discuss IAPT treatment; remembering not to talk about treatment options was very much 'out of habit'.

We do quite a lot of high volume work and we get used to our habits around, perhaps assessments and just remembering not to discuss treatment options if a patient's interested in the trial... that took a little bit of getting used to. (IAPT PWP)

When we do introductions assessment, we would say, 'The assessment will take around about thirty five, forty minutes. After the assessment I'll talk to you a little bit about what we offer from our service.' Now, there were instances when – I... said that and then had to [renege]... 'cause actually at the end I then realised that the patient's presented me with a STEPS form, so I'd have to then retract what I'd said by saying, 'I said I was going to talk to you about treatment options from our service, but actually I notice that you're interested in the STEPS research so I'm deliberately not going to talk about treatment options at this stage.' (IAPT PWP)

### ***Asking for permission forms***

There was a perception that therapists varied (and hence may have been uncertain) regarding how proactive they were required to be in asking for permission forms. At the start of the study, the IAPT Manager asked her team to accept forms when they were returned but not to enquire about patients' interest in STEPS if forms were not readily presented. Nonetheless, the PWP interviewee routinely asked people for their questionnaires (to include IAPT and STEPS' forms) at the start of their assessment appointments. Furthermore, the IAPT Manager described a variety of reasons why some PWPs may be more

proactive in asking for permission forms than others: some therapists may be more organised, oriented to research, motivated to reduce their workload; PWPs may have got better at asking for forms as the trial progressed – it became more routine to do so.

I encouraged them to not be overly proactive, so if people come with a form, to accept that form and then do the thing, you know, the process, but if people didn't readily come with the form I did not ask the PWPs to proactively check whether they wanted to be involved in the study. (IAPT Manager)

Some of the PWPs may have been more clued in to the study and therefore the permission forms... I would think some PWPs may have said about the study, 'Did you get the form?' and other ones wouldn't have, so I think some people could have been more active than others about it. (IAPT Manager)

### ***Responding to patient questions***

PWPs may not have been entirely comfortable with how they responded to patients' questions and concerns about STEPS. As well as asking therapists not to ask patients for their forms, early on in the study, the IAPT Manager reminded the therapists not to dissuade patients from taking part. This communication followed feedback from one patient to suggest that her therapist had said she should not take part in the current study as it would 'cut her off' from IAPT treatment. As such, PWPs were minded to be 'neutral' in how they handled permission forms. This instruction may have influenced how the PWPs responded to queries about STEPS. At interview, the PWP described how he said very little in response to questions. He queried whether this was the right approach and whether he should have had more information to share with patients.

I felt very conscious about not influencing, like having any influence over, you know, encouraging the patient to take part or not. And I suppose I was fairly reticent to actually give too much information. Whether that's helpful or whether, you know, I should have been

more primed to be more specific or have more information about how the research worked or -? (IAPT PWP)

### ***Handling forms for potentially ineligible patients***

Passing on forms for patients who PWPs did not believe would be accepted onto the trial caused considerable difficulty. Such patients included people who were not depressed or who did not present with depression as their primary problem but also patients who may have difficulty engaging in any treatment as well as those for whom the PWP perceived CBT may be less helpful. PWPs passed on the permission forms for people who they did not think would be accepted but to do so was frustrating and seen as a waste of time. This frustration may have been compounded by experience: most of the people who the PWP interviewee anticipated would be ineligible for the study returned to IAPT. A potential solution proposed by the PWP was to be given more information such that when it was very clear that patients were ineligible, he could let them know. Indeed, he felt that he had a duty to do so.

Patients who I felt maybe there was some complexity with problems they were presenting with and I just felt fairly certain they were not gonna meet the criteria, but it wasn't my place to say, 'You're not gonna be – I don't think you're gonna be taken on for this research.' And I guess I had some misgivings about that because I felt actually, the likelihood is that this patient is not going to be taken on and that's wasting time, 'cause actually they're probably not going to be taken on. (IAPT PWP)

Reflecting on the same issue, the IAPT Manager surmised that high-intensity therapists would not follow the recruitment procedure. Rather, she thought that they would more likely take an independent decision not to pass on permission forms for such patients.

I think the PWPs would have done that, because they're fairly black and white in their practice, so if they're kind of told to do something they would then generally then carry that out. I think it would be really interesting to ask the high intensive therapists when they were doing... assessments, which they will do sometimes, how they would

have handled the form, because they will be more likely to make an independent clinical decision. (IAPT Manager)

### ***Summary – handling permission forms***

Handling permission forms presented several difficulties for IAPT therapists. When a patient returned a form, it was hard for PWP to remember not to give the patient a booklet about treatment or to discuss treatment options. Moreover PWP felt very uncomfortable passing on forms for patients who they anticipated would be unsuitable or ineligible for STEPS, specifically, patients who were not depressed, did not present with depression as their primary problem, had difficulty engaging in treatment or would not benefit from CBT. To pass on forms for patients who would not be accepted was seen as a waste of time; the IAPT Manager thought that high-intensity therapists may not return forms. The PWP interviewee also wanted to give patients more information in response to study-related questions. Therapists varied in the degree to which they were proactive in asking people for their form.

### **6.8.4 Theme four – post-baseline**

The theme 'post-baseline' encompassed what IAPT personnel thought of patients joining STEPS, remaining under the care of IAPT and returning to IAPT due to a lack of therapist capacity at the AcCePT Clinic.

#### ***Joining STEPS***

The prospect of discharging patients from IAPT to join STEPS was initially met with some enthusiasm by the PWP who, somewhat jokingly, described it as an opportunity to reduce his caseload. The PWP also commented that the Admin Team worked very well to let therapists know when a patient joined (or was ineligible for) STEPS. However, the IAPT Manager described a conflict of interest for her service and the study when patients joined STEPS. At the time of the study, the service had not met a key performance target to treat 15% of the local population estimated to have depression and anxiety. Patients who joined STEPS did not count towards the target. Although this did not pose a substantial problem given the small number of people involved, it was anticipated that the same issue would affect a large stepped care trial and be

more problematic. The same problem had arisen around the service's support of another large mental health trial. For trial patients to count towards the service's performance target people would be required to complete the same measures necessary of all patients who enter IAPT services - to date, this had not been possible.

Your trial did not impact much, because it was small but there is a competing demand for us to increase our prevalence... we have fifteen percent of the prevalence target that we have to see. So whilst on the one hand I'd think research really important to be doing this, to find out what we're doing, I've also got a competing demand that actually do I want our patients to go elsewhere because I've got to increase my prevalence of people entering treatment. (IAPT Manager)

### ***Returning to IAPT***

In terms of the interviewees' views of the experience of patients with whom recruitment procedures could not be completed or who were ultimately ineligible for STEPS and thus returned to IAPT, these were mixed. Positive views were that recruitment procedures enabled the IAPT service to meet another of its key performance targets i.e. to see patients for their first treatment appointment within 28 days of their initial assessment. By determining whether patients were in or out of STEPS within five working days of their assessment and by enacting a 'patient delay' (a mechanism by which days spent waiting for treatment do not count towards the 28 days), the target was not compromised. On the other hand, the IAPT Manager's description of how she handled patients' questions about STEPS indicated that, in her experience, the treatment of patients who were interested in the study and came back to IAPT was still delayed compared with the treatment of patients who were not interested. She had not felt able to tell patients otherwise. There was also a perception that, despite best efforts to explain the recruitment procedure to patients, it was confusing for people to attend an IAPT assessment, meet elsewhere with the STEPS team and (potentially) return to IAPT.

I can't say it [interest in STEPS] won't delay it, because there is a delay. So it's short, but there is a delay, so ordinarily, if we see

someone we'd see them the next week for treatment at Step Two to start, so there is a very short inbuilt delay, isn't there? If they come across, find that they're not coming into the trial and then come back, potentially there's a couple of weeks' delay built into that: a bit from you and a bit from us then fitting them back into our diaries. (IAPT Manager)

The confusion, complexity for patients, I'm still not quite sure we resolved that throughout the trial, I still think patients felt quite confused by -the process to us was very clear, but I think if you're a depressed person coming into the service then even though we all try to make it really clear, I still think it's quite confusing for people to come to one place, to go to another, to potentially come back to the place that you started off from. (IAPT Manager)

Another issue caused considerable concern: a worry that patients who returned to IAPT would not commence treatment. This was thought possible for two reasons. Patients who were unsuitable for STEPS may feel 'rejected' and hence disinclined to continue treatment at IAPT. Second, it took more PWP resource and time to book patients into their first treatment session on return to IAPT than usual; returning patients might 'slip off' therapists' radar. This worry was significant enough to warrant a change to recruitment procedures: at the outset of the trial, arrangements for future therapy were left open at the end of the IAPT assessment appointment; during the second half of STEPS, on end assessment therapists arranged a telephone call with patients for in two weeks. The purpose of the call was to discuss and schedule treatment if the patient was returned to IAPT or to wish them well if they were not. This was seen as a good but imperfect solution. Interviewees still feared that some patients would drop out of therapy on return to IAPT.

When people came back, because they're out of the flow of the normal PWP work, so they'd normally see somebody and book an appointment, for second appointment, but they weren't doing that, so that could mean that the person would then come back, and the PWP would get an email and it would slip off their radar, because it's not in their normal working practice, so for that reason I suspect some

people will have then missed their second twenty eight day appointment. (IAPT Manager)

It also makes sense, that people who come to us, then go to you and then come back, if people are struggling with – I mean it's hard to engage with the Mental Health Service, isn't it – that, that process of coming to one place and going to another and coming back, inevitably, people will drop out because of that. (IAPT Manager)

I'd at least a couple of patients who, when they were not taken on for STEPS I wasn't then able to re-engage with them and that, so I'll never really know whether they dropped out, whether they would have dropped out of treatment if STEPS wasn't offered anyway, or whether they dropped out of treatment because of how they felt about not being taken on for the research or whether it was just difficulties with engagement anyway. And was sort of a question mark which, you know, was quite frustrating really. (IAPT PWP)

### ***Therapist capacity***

Continuing to send patients study information, collect forms and pass patients to STEPS whilst recruitment was 'slow' or 'on hold' because of a lack of capacity at the AccEPT Clinic also raised questions. During this period the Administrator and PWP implemented recruitment procedures as usual. However, to do so had felt a 'bit of a waste'. There was also a concern that patients who returned to IAPT due to a lack of AccEPT capacity might feel rejected and be at increased risk of drop out. The PWP wondered if patients could be forewarned (perhaps in the Patient Information Sheet) that they may not be 'taken on'.

Us kind of sending people over even though the trial's full, so knowing that they're going to come back. So that bit of the process created some question marks, I think. (IAPT Manager)

I mean, I understood there were some instances where I think the patient had expressed interest in STEPS and the reason they weren't taken on was because there weren't researchers available at the time. I think I've got that right.... I just wonder whether, perhaps, with the information the research for patients, whether, you know, whether



that's something which can happen, so there's not – just so a patient has an understanding of the nature of research, about how, you know, there has to be certain time constraints, this could happen to them. (IAPT PWP)

### ***Summary – post-baseline***

The experiences of patients following the baseline interview raised several concerns for IAPT personnel: patients who joined STEPS did not count towards a service target to treat 15% of the local population estimated to have depression and anxiety; although patients who returned to IAPT were seen for their first treatment session within 28 days of their initial assessment, their treatment was still delayed compared with that of patients who did not return a permission form; some patients may have been confused by attending an IAPT assessment, meeting with the study researcher and then returning to IAPT. A fourth issue was particularly troubling. Therapists could fail to re-engage patients who returned to IAPT in treatment and patients may drop out of therapy. In addition, sending out and collecting permission forms when recruitment was 'on hold' had seemed wasteful.

### **6.8.5 Theme five – administrative systems, workload and support**

The theme 'administrative systems, workload and support' reflected IAPT interviewees' views and experiences of systems for recording patients' interest and involvement in STEPS. It also covered what the IAPT personnel thought of the workload STEPS entailed and the support they were given.

#### ***Record-keeping***

The IAPT Administrator was confident in the method used to record how many patients were sent a study summary sheet. Procedures for keeping track of patients who returned a permission form worked well. Maintaining a paper list of the names of patients who returned a permission form together with the date of their IAPT assessment was particularly helpful. The list was simple to complete and from it, the Admin Team knew at a glance which patients the research team had yet to confirm were in or out of STEPS.

The yellow [permission for researcher to contact] forms were put in a box once they'd erm, the therapist would bring them down or they would email us about them if they were based at a different location and weren't able to get into the service and then one of your colleagues would come over, get the information and write it down on a list. And I think that list really worked well, we then knew, could tell how many people had yet to – you needed to inform us about, really, as to whether they were in or out of the project. (IAPT Admin)

Problems arose only for a time half way through the study when the Administrator had been on sick leave and several admin staff left. Temporary personnel were employed. The Admin Team stopped recording on IAPT-us (an electronic database of patient records – see Chapter Five, section 5.3.3) when a patient was invited to take part and whether the patient joined STEPS. Potential consequences included that patients who returned to IAPT for a second time could be sent study information twice despite a lack of interest. The Administrator thought that a 'step by step guide' to recruitment could have been written for new / temporary staff but she was uncertain if the Admin Team would have had time to read it. Administrative systems were re-introduced when the IAPT Administrator returned to work.

I was off sick and then people were just having to mend and make-do with whatever they could, because bank staff were being brought in, they were just covering the bare bones. So that is when we stopped recording that people had been invited... That was just about our staff resources and lack of training on new people coming because we didn't have the staff to train them. (IAPT Administrator)

Whether we should have written sort of an idiot's guide to what we needed to do, a step-by-step approach, but then would they have had time to have read that? (IAPT Administrator)

### ***Workload***

All of the interviewees felt that the workload created by STEPS was relatively small. Nonetheless, the IAPT Manager was concerned for the Admin Team on whom the burden of work fell. There was a perception that they coped well but

were frustrated by their involvement in STEPS alongside all else they had to do. The IAPT Administrator's initial reaction to supporting STEPS was consistent with this view: she had been concerned at the prospect of more work. However, once procedures were up and running, although the Admin Team noticed the additional work, at no time did the Administrator feel that it was unmanageable.

I think probably [the IAPT Administrator] has done the most towards the trial in terms of holding the process around it, and that's quite a lot. The amount of work around the STEPS trial is not huge, it's not massive, it's that their overall work volume is so massive and their fairly stretched, and it's like 'another thing'. (IAPT Manager)

It's just another ball, really [laughs]. You just sort of think 'Oh' because the role in our office is so, quite manic and there's so many things going on, you get approached by a therapist and this, that and the other. You just sort of take it in your stride, really, it's just something else to, er, it didn't affect me at all, it was just another process we had to deal with and get on with it, really. (IAPT Administrator)

The IAPT Manager also thought that the therapists may have reacted a little negatively to STEPS given that it was 'something else to do'. The IAPT PWP felt that difficulties mainly arose around changing practices. For herself, the IAPT Manager described how STEPS similarly felt like 'another thing to juggle'. During the period of staff illness in the Admin Team, the IAPT Manager took on some of STEPS' administrative responsibilities which had been difficult. The IAPT Manager suggested that, ideally, the trial would have provided some additional financial, administrative support.

I guess the only thing you can do is to provide some additional admin support, which would have been, I guess, would have been financial, wouldn't it, in terms of money to increase our admin capacity. (IAPT Manager)

### ***Staff briefing and support***

IAPT interviewees generally felt well supported by the study researcher. There was a perception that therapists' involvement in the study had been clearly explained at the outset and the study researcher's presence at team meetings was welcome. The IAPT Administrator also felt that day to day liaison with the researcher worked well. The researcher was endorsed for being easy to contact and quick to respond, persistent and open. The IAPT Manager also let her team know what was required of them for STEPS. This happened via email, staff meetings and a more direct approach with the IAPT Administrator. The IAPT Manager's involvement in negotiation between the IAPT Administrator and study researcher, as required, did not present any problems.

I mean, yeah, it was helpful to get an update on the last meeting you came to just about how many people had been taken on and the quotas. I thought that was quite helpful. (IAPT PWP)

I think we've kept dialogue going on, we've kept, I think we've spoken quite a lot if there was a problem either end I think we were fairly open and sort of said 'Well, this isn't working I can't do this, I can't do that' and I think that's why it seemed to work quite smoothly really. (IAPT Administrator)

I think you communicated really well with us, it was quite easy to get hold of you by email, you know, you responded pretty quickly, you know, just some concerns we had about the process like contacting the patient to see if they'd been taken on, that was really helpful to have that dialogue with you. (IAPT PWP)

### ***Summary – administrative systems, workload and support***

Administrative systems for recording when patients were sent study information and tracking those who returned a permission form were manageable and worked well. However, they represented more work for an Admin Team that was already very busy. Ideally, STEPS would have provided financial support to assist. STEPS also represented additional work for the IAPT Manager and, to a degree, therapists although the main challenge for PWPs had been to change working practices (see Theme

three – Handling permission forms). Interviewees felt well supported by the study researcher.

#### **6.8.6 A summary of the appropriateness of recruitment to IAPT personnel**

The appropriateness of STEPS' recruitment methods and procedures to IAPT personnel has been described by five themes covering what staff thought of research, STEPS initial approach to patients, handling permission forms, the experience of patients after a baseline interview and administrative systems, workload and support. In terms of interviewees' views of research, IAPT personnel were wary of the potential for conflict with patient care and service targets but still felt that research was important to support. Moreover, the service supported STEPS despite being involved in another trial which had depleted clinic resource.

Feedback on STEPS methods and procedures indicated that one aspect worked very well, specifically, the Administrative Team's involvement in recruitment. Systems for recording when patients were sent study information and monitoring their involvement the study were effective. There was also a perception that patients benefited from the Admin Team mentioning STEPS when they rang to book an assessment appointment. However, most of the workload associated with STEPS fell on the administrators who were already very busy and extra financial support to assist would have been welcome.

Qualitative analysis also highlighted problems with recruitment methods and procedures. Two were particularly troubling for IAPT personnel and may represent key barriers to the success of recruitment in a future trial. They are (1) a concern that patients who return a permission form but ultimately remain under the care of IAPT could drop out of therapy or might not be contacted by their PWP and (2) a reluctance to pass on permission forms for patients who may be unsuitable or ineligible to take part. A third problem was also identified that could affect the degree to which IAPT services may be willing to support a future trial: patients who joined STEPS did not count towards a key performance target to treat 15% of the local population estimated to have depression and anxiety.

Other ways in which recruitment was considered less appropriate were similarly motivated by a concern for patient wellbeing i.e. the view that sending patients study information may have overwhelmed and confused people and that some patients may have been confused by attending an IAPT assessment, meeting with the study researcher and then returning to IAPT. The PWP interviewee also identified several issues around handling patient permission forms for which it may be possible to offer more support in a future trial: changing the format of an assessment to collect forms, responding to patient questions, the degree to which therapists should be proactive in asking people for their form.

## 6.9 Comparing quantitative and qualitative recruitment data

Table 26 presents quantitative and qualitative data on recruitment. Numeric information on the performance of pilot trial recruitment methods is displayed next to a summary of the views of patients, therapists and IAPT personnel. Data are organised according to each main stage of recruitment. Synergy and conflict between the different data types is highlighted as follows (Box 3):

Box 3. Key to disparity and synergy between quantitative and qualitative recruitment data

<p><b>Quantitative and qualitative data highlighted green:</b> synergy – numeric and qualitative data are mostly positive indicating an element of recruitment that might remain unchanged in a fully-powered evaluation</p> <p><b>Quantitative and qualitative data highlighted red:</b> synergy – numeric and qualitative data are fairly negative indicating a recruitment procedure that could be modified for a fully-powered evaluation</p> <p><b>Quantitative and qualitative data highlighted yellow:</b> disparity – numeric and qualitative data hold different valence with implications for a fully-powered evaluation that may require further thought</p>
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Key findings with respect to congruence or divergence are noted in the final column. Results are described in section 6.9.1

***Table 26 overleaf***

Table 26. Quantitative and qualitative data on the appropriateness and performance of recruitment methods and procedures

Theme	Qualitative data from semi-structured interviews	Numeric data	Key finding
<p>Sending study information with patients' initial IAPT assessment appointment letter</p>	<p><b>Sending study information with patients' appointment letter is appropriate</b></p> <ul style="list-style-type: none"> <li>Patients generally liked the study summary sheet</li> <li>The IAPT Manager and Administrator endorsed and were happy for the Admin Team to mention STEPS during telephone calls to arrange patients' assessment appointments</li> <li>The Administrator felt that patients were not confused when told they would receive study info</li> <li>Only a handful of patients declined to receive study info</li> </ul> <p><b>Being sent study info need not deter people from assessment</b></p> <ul style="list-style-type: none"> <li>Patients did not always recall receiving study info with their IAPT appointment letter</li> <li>Some were uncertain when they had received it or thought that they had received it at their assessment appointment</li> </ul> <p><b>Being sent study info with an appointment letter is less appropriate</b></p> <p><i>IAPT personnel were concerned that patients:</i></p> <ul style="list-style-type: none"> <li>May have been overwhelmed by the amount of information they received</li> <li>Did not always understand all of the paperwork</li> <li>Were sometimes unclear what they were signing up to</li> <li>With poor literacy skills &amp; / or for whom English was not their first language may have been excluded</li> </ul>	<p>1980/2299 (86.1%) of patients sent study info attended an assessment</p>	<p><i>Sending study information with patients' appointment letter is acceptable enough to most patients and did not obviously deter patients from attending an IAPT assessment</i></p>
<p>Handling permission forms at assessment</p>	<p><b>Receiving and passing on forms is less appropriate</b></p> <ul style="list-style-type: none"> <li>Passing on forms for patients whom therapists did not believe would be eligible / suitable caused considerable tension</li> <li>IAPT personnel were uncomfortable referring patients to STEPS knowing recruitment was slow or on hold.</li> </ul> <p><b>There may be scope to improve the number of patients returning forms</b></p> <ul style="list-style-type: none"> <li>Therapists were asked not to enquire about people's forms if patients did not readily present them</li> <li>Therapists varied in how proactive they were in asking patients for their forms</li> <li>The PWP was uncomfortable with his response to patients' questions: he felt that he should offer little information in reply but was not happy with this.</li> <li>When asked if interest in STEPS would delay someone's treatment, the Team Manager did not feel that she could tell patients there would be no delay</li> </ul> <p><b>Receiving and passing on permission forms is appropriate</b></p> <ul style="list-style-type: none"> <li>Patients were happy to be asked if they were interested in STEPS</li> <li>The PWP was not precious about 'referring' patients</li> <li>The PWP had initially seen the study as an opportunity to reduce his caseload</li> <li>Completed permission forms were usually passed to the Admin Team without delay</li> <li>Procedures for logging when patients returned a form worked well</li> </ul>	<p>179/2299 (7.8%) of patients returned a permission form</p>	<p><i>Handling permission forms at assessment caused some difficulty for IAPT staff – but not patients – and may have contributed to the relatively low number of forms received</i></p>



<p>Telephone screens – first contact with a researcher</p>	<p><b>The brief amount of time between patients returning a permission form and the telephone screen was appropriate</b></p> <ul style="list-style-type: none"> <li>• Patients welcomed how quickly they were contacted</li> <li>• It impressed patients that the research was well organised and their problems were taken seriously; it maintained a sense of momentum once people decided to seek help. For one person, it kept her in treatment following a difficult experience at IAPT.</li> <li>• Successful implementation of the five day turnaround (along with use of a ‘patient delay’) enabled the IAPT service to meet its 28 day target from assessment to first treatment appointment for patients who were returned to its care.</li> </ul>	<p>Telephone screens could not be completed with a total of 58/179 (32.4%) patients who returned a permission form.</p> <p>Of those, it was not possible to screen 18/58 (31.0%) patients in five days.</p>	<p><i>The brief amount of time between returning a permission form was appreciated but led to a loss of potential participants</i></p>
<p>Baseline interviews</p>	<p><b>Attending a baseline interview - after initial assessment at IAPT - is acceptable</b></p> <ul style="list-style-type: none"> <li>• When asked how they felt about attending a baseline interview after their initial assessment at IAPT, some patients said this was not a problem</li> <li>• Patients were pleased by how quickly their baseline interview had taken place</li> <li>• Positive views about the baseline were that treatment had been well explained; having met with a researcher, a patient had been reassured about starting therapy; the baseline provided a welcome opportunity to reflect.</li> </ul> <p><b>Attending a baseline interview - after initial assessment at IAPT - is less acceptable</b></p> <ul style="list-style-type: none"> <li>• One patient had been disheartened at the prospect of discussing thoughts and feelings that had already been voiced at IAPT</li> <li>• Compared with their initial assessment, the baseline interview sometimes felt impersonal (although patients understood why)</li> </ul>	<p>84/121 (69.4%) patients screened completed a baseline interview</p> <p>17/121 (14.0%) patients declined or did not attend a baseline interview</p>	<p><i>Baseline interviews were seemingly acceptable enough to the majority.</i></p> <p><i>However, difficulties associated with the baseline interview may have contributed to the decision by a minority of patients not to attend.</i></p>
<p>Joining STEPS / returning to IAPT</p>	<p><b>‘Losing’ patients to STEPS was not considered entirely appropriate by IAPT staff</b></p> <ul style="list-style-type: none"> <li>• The IAPT service had a key performance target to treat 15% of the local population with depression and anxiety; at the time of the study, the target had not been met; patients who joined STEPS did not count towards the target</li> </ul> <p><b>Returning patients to IAPT was not considered wholly appropriate by IAPT personnel</b></p> <ul style="list-style-type: none"> <li>• The IAPT Manager felt that it was confusing for people to attend an initial assessment, go to another location to meet with the researcher and return to IAPT.</li> <li>• Staff were worried that patients who came back to IAPT would be more likely to drop out of therapy</li> <li>• Compared with patients who were not interested in STEPS, it took more PWP resource and time to book in people’s first treatment session</li> </ul>	<p>68/2299 (3.0%) patients invited to take part were randomised, two in error</p> <p>111/179 (62.0%) patients who completed a permission form continued treatment with IAPT</p>	<p><i>Target numbers were recruited but this was somewhat problematic for the IAPT service.</i></p> <p><i>A large number of patients who completed forms remained under the care of IAPT which presented some difficulty.</i></p>
<p>Transition to STEPS therapy</p>	<p><b>Patients’ transition from baseline into therapy was managed appropriately</b></p> <ul style="list-style-type: none"> <li>• Patients and STEPS therapists were very pleased with how soon people began treatment</li> <li>• Discharging people from DAS on joining STEPS did not seemingly confuse or concern patients</li> </ul> <p><b>Elements of the transition were found to be less appropriate</b></p> <ul style="list-style-type: none"> <li>• One patient was disappointed to learn that he would not see the researcher for therapy</li> </ul>	<p>62/68 (91.1%) randomised patients attended treatment.</p>	<p><i>Patients transition into therapy following their baseline interview appeared to work well</i></p>

## **6.9.1 Combined data at each main stage of recruitment**

### **Sending patients study information with their IAPT assessment appointment letter**

The majority of patients (1980/2299, 86.1%) who were sent study information with their IAPT assessment appointment letter attended an initial assessment appointment indicating that receiving a study summary sheet did not deter the majority from pursuing therapy. This interpretation of the numeric data is consistent with positive patient feedback on the study summary sheet and IAPT interviewees' views that mentioning STEPS during telephone calls to arrange patients' assessment was helpful. Concerns that patients may have been overwhelmed by information, did not understand all of the paperwork or had not fully understood what they were signing up were not obviously problems enough to deter most patients from pursuing therapy. Indeed, qualitative data suggest that for some (even patients who join the research), receiving study information with an assessment letter may be fairly irrelevant in their decision to attend an assessment; patients did not (much) remember the study summary sheet or recall when it had been received. Implications are that, with respect to a fully-powered evaluation of stepped care, the procedure of sending study information with patients' initial IAPT appointment letter could remain unchanged.

### **Receiving and passing on permission forms**

Qualitative data on therapists' handling of permission forms suggests that, at assessment, patients were happy to be asked about STEPS and PWP did not obviously obstruct their interest in the study. Procedures for passing on forms to the Admin Team worked. Nonetheless, the number of patients who completed and returned a form was relatively small (179/2299 (7.8%) of those sent study information). Interviews with IAPT staff also indicated that it may be possible to increase the number of permission forms received as well as the degree to which handling forms is considered appropriate. Implications for a large trial are that it may be advantageous to modify procedures: IAPT personnel might be encouraged to routinely ask patients for forms; it may be desirable to offer PWPs more support to help them respond to patients' questions.

## **Telephone screening**

Telephone screens were not completed with 58/179 (32.4%) of patients who returned a permission form and, of those, 18/58 (31.0%) patients could not be contacted within five working days of their initial IAPT assessment. In this way, the limit of five working days contributed to attrition in recruitment. On the other hand, patients welcomed how quickly they were contacted. Moreover, successful implementation of the five day turnaround enabled the IAPT service to meet a key performance target. Implications for a fully-powered evaluation are that allowing more time to complete telephone screens could increase the participation rate but may be unpopular with patients and IAPT services. Whether to modify this procedure may require further thought.

## **Baseline interviews**

Baseline interviews were completed with the majority of patients screened (84/121; 69.4%) indicating that completing an interview was broadly acceptable to most patients. This interpretation is consistent with patients' positive views of the baseline including that attending an interview shortly after a similar (initial) assessment at IAPT was generally not a problem. However, qualitative data also revealed that scheduling the interview after an IAPT assessment caused some difficulty for some people and a minority of patients screened, declined a baseline or did not attend (17/121; 14.0%). With respect to a large trial, it would be possible to leave procedures for the baseline interview unchanged but it might also be helpful to reflect on what further could be done to offset difficulties associated with arranging an interview after patients' IAPT assessment.

## **Joining STEPS or returning to IAPT**

In terms of patients 'joining' STEPS, although target numbers of participants were recruited, patients who were successfully recruited did not count towards the IAPT service target to treat 15% of the local population with depression and anxiety. Whilst this was not a problem in the current study (due to the small number of people taking part), the IAPT manager anticipated that the same issue could threaten services' willingness to be involved in a fully-powered evaluation. Whether and how to address this conflict may require further consideration.

Qualitative analysis also found that returning patients who expressed an interest in STEPS to IAPT was not considered wholly appropriate. A key concern was that patients who returned to IAPT would be less likely to attend their first treatment session although no data was available to help establish the degree to which the concern was justified. The number of patients returning to IAPT was large; 111/179 (62.0%) of patients who completed a permission form ultimately continued treatment with IAPT. In terms of a large trial, it may be advantageous to reduce the number of patients who returned to IAPT and obtain data on the number who returned a permission form but continued treatment with IAPT and subsequently dropped out.

### **Trial participants' transition to therapy**

Post baseline, only a minority of patients randomised (6/68; 8.8%) declined or did not attend any treatment. Qualitative data also suggest that patients' reasons for declining treatment are unlikely to be related to trial procedures: patients and therapists were very pleased with how quickly patients began therapy following their baseline interview and patients were not confused when they were discharged from IAPT. On this basis, in terms of a large trial, it would be possible to leave procedures for patients' transition from baseline into therapy unchanged.

### **6.9.2 A summary of combined quantitative and qualitative recruitment data**

A side-by-side summary table was used to compare quantitative and qualitative data on each main stage of recruitment. Synergy and disparity between different data types pointed to elements of recruitment that might remain unchanged in a large trial, be modified or require further consideration. Procedures that could remain unchanged are sending study information with patients' initial IAPT appointment letter, the administration of the baseline interview and patients' transition to therapy on randomisation. Aspects that could be refined include support for IAPT staff handling permission forms, offsetting difficulties associated with scheduling a baseline interview following an IAPT assessment appointment and collecting data on the treatment received by patients who are interested in taking part but ultimately remain under the care of IAPT. The brief amount of time (five working days) to complete

recruitment and the potential conflict between recruitment and IAPT services' target to treat 15% of the local population with depression and anxiety may require further consideration.

## **Chapter 6. PART III**

### **Qualitative and mixed methods analysis on the acceptability of stepped care**

Comprising sections:

6.10 Acceptability of stepped care

6.11 Acceptability of stepped care to patients

6.12 Acceptability of stepped care to therapists

6.13 The relationship between acceptability and attendance

## 6.10 Acceptability of stepped care

Qualitative data on the acceptability of stepped care was collected from interviews with 30 stepped care patients and three therapists. All of the patients and therapists who were asked to participate consented to be interviewed. Data from 12 patient interviews were analysed. Six patients received GSH alone of whom two declined any treatment, one ended therapy prior to the point at which her therapist believed she was ready ('dropped out') and three completed treatment; six patients received low-and high-intensity therapy of whom one dropped out (of intensive CBT) and five completed treatment (Table 27). From patients' first to last treatment session, levels of depressive symptoms improved by at least 50% for half of the patients who received GSH alone and half of the interviewees who had progressed to CBT.

Table 27. Treatment offered, adherence to therapy and outcomes for patients interviewed and analysed

ID	Treatment <sup>1</sup>	Adherence <sup>2</sup>	n GSH	n CBT	Change in PHQ-9 <sup>3</sup>	50% improvement <sup>4</sup>
007	GSH alone	Declined any	0	NA <sup>5</sup>	NA	NA
023	GSH alone	Declined any	0	NA	NA	NA
031	GSH alone	Dropped out	1	NA	0	No
039	GSH alone	Completed	6	NA	-10	Yes
058	GSH alone	Completed	6	NA	-4	Yes
063	GSH alone	Completed	6	NA	-7	Yes
014	GSH + CBT	Completed	5	9	-8	Yes
027	GSH + CBT	Dropped out	6	5	-10	Yes
028	GSH + CBT	Completed	6	14	-8	No
047	GSH + CBT	Completed	6	15	-4	No
051	GSH + CBT	Completed	6	10	-14	Yes
062	GSH + CBT	Completed	6	21	-4	No

Notes: <sup>1</sup> Therapy offered to stepped care patients; <sup>2</sup> Patients' adherence to treatment; <sup>3</sup> difference in PHQ-9 scores between patients' first and last treatment session; <sup>4</sup> whether patients' PHQ-9 scores between their first and last treatment reduced by 50% or more – yes / no; <sup>5</sup> Not Applicable.

Analysis of the qualitative data on stepped care aimed to describe the degree to which the intervention was acceptable to patients and therapists. It covered interviewees' views of key components of the intervention including e.g. low-

intensity therapy (Guided Self-Help; GSH), monitoring and stepping, high-intensity therapy (Cognitive Behaviour Therapy; CBT). Interviewees' views were described by several themes and sub-themes.

The results of the patient data analysis are presented first (section 6.11). Patients' views were understood in terms of six major themes described in sub-sections 6.11.1 to 6.11.6; results on each theme are summarised at the end of each sub-section.

The summary of patients' views of low-intensity therapy incorporates mini-summaries of what each patient thought of GSH (see 6.11.2). Similarly, the summary of patients' views of high-intensity therapy incorporates mini-summaries of what each patient thought of CBT (see 6.11.5). Individual summaries of what each patient thought of stepped care as a whole are provided in section 6.11.7 and patients' views of stepped care are also depicted in a number of typologies. Ways in which patients talked about a variety of different elements of the intervention that appeared to influence the degree to which it was acceptable to them are described in the form of three 'cross cutting themes' (see 6.11.8).

Patient data is followed by a description of what the therapists thought of stepped care (section 6.12). Therapists' views were understood in terms of four themes described in sub-sections 6.12.1 to 6.12.4; results on each theme are summarised at the end of each sub-section. An overview of what the therapists thought of stepped care as a whole is provided in section 6.12.5.

Section 6.13 presents the results of mixed methods analysis on the relationship between acceptability and therapeutic attendance. Results include a description of findings based on: (1) a joint typologies / statistics display of treatment adherence data for patients for whom stepped care is more and less acceptable (see section 6.13.1); (2) a case-oriented display of the number of GSH and CBT sessions attended and patients' views of low- and high-intensity therapy (6.13.2); (3) a joint categories / themes display of views of stepped care among patients who attended more and less therapy (6.13.3). A summary of the results of the mixed methods analysis on acceptability and attendance is provided in section 6.12.4.



## 6.11 Acceptability of stepped care to patients

Analysis of the patient interviews found that trial participants' views of stepped care could be described by six descriptive themes: 'thoughts and feelings before treatment'; 'Guided Self-Help'; 'monitoring'; 'stepping'; 'Cognitive Behaviour Therapy' and 'ending therapy'. Five themes comprised several sub-themes. Themes and sub-themes are summarised in Box 4.

Box 4. Key themes (numbered 1 to 6) and sub-themes describing the acceptability of stepped care to patients

<b>1. Thoughts and feelings before treatment</b>
<b>2. Guided Self-Help</b> Wellbeing Course material Reading and using material Phone calls Therapeutic support Timings Influence of the option to have CBT
<b>3. Monitoring</b> Being monitored and the use of information to inform stepping decisions Responding to and using scores Critique of the PHQ-9
<b>4. Stepping</b> Thoughts and feelings following unsuccessful GSH Going on to CBT The transition
<b>5. Cognitive Behaviour Therapy</b> CBT as a whole Therapy in person and the therapeutic relationship Timings
<b>6. Ending therapy</b> Feelings about ending treatment Benefits of treatment and residual difficulties Reasons for dropping out

### 6.11.1 Theme one – thoughts and feelings before treatment

The theme ‘thoughts and feelings before treatment’ describes patients’ response to being offered stepped care treatment for depression. It describes how patients felt at the prospect of beginning therapy with GSH knowing CBT could follow.

Views on starting treatment with GSH were divided. For some patients, it hadn’t at all been what they wanted - they would have (much) preferred CBT.

However, the contrasting view was much more positive; patients viewed GSH as good opportunity, useful in its own right (e.g. as a means to acquire tools that patients could apply) but also favourable knowing that CBT could follow if needed.

I was generally happy that I was given the self-guided, the GSH first, knowing the back-up, CBT, could follow. I mean hoping it wouldn’t at that point. (Patient 027)

More moderate views were also expressed. They entailed some reservation(s) or uncertainties about starting treatment with GSH or a more open-minded stance. Patients who held a more negative view of starting with GSH were both prepared to try it and anticipated that they would probably decline treatment.

[Chuckles] Maybe at first I was thinking, ‘Really? Is that going to be enough for me? Maybe I do need the in depth CBT.’ I remember sort of thinking, ‘Hold on, I don’t know which one’s best,’ then I thought, ‘I’ll just give it a go’. (Patient 039)

I think I knew then [at baseline] that if it was going to be step one, I probably wouldn’t do it. (Patient 007)

Reasons for feeling negative or cautious about starting therapy with GSH were a lack of knowledge of GSH compared with an understanding of CBT, having an interest in CBT and prior experience of unsuccessful low-intensity / successful high-intensity treatment. Some aspects of the GSH course (principally the idea of ‘homework’) did not appeal and some people expressed a preference for face to face therapy. Patients were also worried about ‘relying on oneself’ and were

concerned that GSH may not be enough given how they were feeling or because they thought that they were already quite self-aware.

When you said 'self-help' I was probably slightly, again, put off by the fact that it might have felt like the emphasis was only on me, I don't know, I don't know. And maybe I felt I needed that face-to-face or whatever it was, someone external to really help me, that's how vulnerable I was feeling at the time, that maybe I thought that wouldn't quite be enough, just to be getting a few things through the post. (Patient 063)

### ***Summary – thoughts and feelings before treatment***

Views on starting therapy with GSH were mixed. Some patients wanted CBT; others were content to start treatment with GSH and, in this regard, patients were reassured that CBT could follow. Elements of GSH that did not appeal included homework and phone calls; patients thought that they may need more support and were uncertain about relying on themselves.

#### **6.11.2 Theme two – Guided Self-Help**

In the theme 'Guided Self Help' patients reflected on their actual experience of low-intensity treatment. Patients described what they thought of the Wellbeing Course material, how they found reading and using course material, therapy by phone, therapeutic support and the timings of low intensity treatment (session duration (30 mins), pace (weekly) and the total length of treatment (six weeks)). The theme also encompassed patients' description of how the option to have CBT influenced their experience of low-intensity treatment.

#### ***Wellbeing Course material***

Views of the Wellbeing Course material varied. One view was that it was very good. Those who spoke positively gave generic feedback e.g. the course was brilliant. Patients also said that the course material was well-structured and laid out, materials worked well together and they had been given the right amount of material each week. Patients felt that they knew where they were with the Wellbeing Course, knew what they were doing; repetition in the material helped. For some patients, selected elements of the course stood out as 'spot on' e.g.

the stories, lessons & DIY guides, material on unhelpful thoughts and thought-challenging.

The couple of bits that really stood out for me were the stories about other people that have umm had you know like periods in their life when they've been depressed or really low. Umm. And that was... like, wow, I'm not the only one out there that has like these you know, sort of, like weird thoughts or feelings n, n things like that. And it was, I suppose it was just a bit of an awakening really that. I don't know, I suppose when you're feeling a bit low you just think it's all about you.  
(Patient 031)

The contrasting view was that the course material was poor. Material was patronising; patients did not relate to it or it did not relate to them; material was inadequate for their needs. In particular, stories were mentioned as something patients did not relate to and, for a similar reason, case studies were disliked.

I mean, I do remember the people's stories and I just thought both those people's stories, for me they were – I think they were both married, they both had families, and because of that I couldn't relate really, as a single person, having relationship difficulties and, you know, huge abandonment issues and all the rest of it. I couldn't really relate... I don't think it affected my understanding of the material but it just made me feel [sighs] different, that I needed something else.  
(Patient 062)

### ***Reading and using material***

Patients' experience of reading and using course material ranged from engaging with the material very little (if at all) to reading quite intensively. In general, the more acceptable patients found reading and using material, the more they read. However, some people who found reading and using material much less acceptable nonetheless described reading and applying what they had learnt.

Those for whom reading was more acceptable felt motivated to apply what they were learning and were able to read in a way to suit themselves e.g. by focussing on elements of the course that particularly resonated. Patients also

reported that they had received material in good time prior to their forthcoming therapy session and being able to read before speaking with a therapist helped patients to work with material and prepare to meet with their therapist.

Well I actually had a really positive reaction to the materials because I think I'm quite a, I think I'm more the thinking type as well, so sometimes I actually benefit from thinking things over and I suppose the only downside of the sort of face-to-face, unless you're given materials to take away, which I suppose is an option, is that, you know, everything's said and then you go home and think, 'Oh, I wish I'd talked about that or that,' whereas maybe with materials to work through for a week I was able to think what I wanted to get out of the next session by working through the materials and maybe prepping for it, almost. (Patient 063)

In contrast, patients who found reading and using course material less acceptable were not motivated to read. Participants perceived that they were too poorly and did not want to do 'homework'. There was also a perception that there was not enough time to read. Practical issues sometimes made reading difficult including patients' reading ability and lack of organisational skills. For some, reading the course material elicited a negative emotional response that deterred them from remaining in therapy.

'Cause every time you picked it up it brought something back that I was ill, you know, and it was like, although I don't ever, ever regret doing what I did, it was still in the back of your mind that I did let people down, I did let myself down, and I was an ill person and it was like, 'I can't be bothered with it... and I was thinking 'I don't need this work. I can get through this myself.' (Patient 058)

### ***Phone calls***

In the same way that views of the Wellbeing Course material and the degree to which patients read and used material varied, there was a range of opinion about receiving therapy by phone. This encompassed a strong dislike for calls, a dislike but tolerance of therapy by phone and finding calls really useful, completely normal and without issue. Opinions could change over the course of

treatment: some respondents settled into calls after some uncertainty or found that they did not mind phone calls after disliking therapy by phone.

Patients were unhappy with phone calls in three respects: therapy by phone was thought to be unsuitable or at least less helpful for the individual given their needs; practical issues arose with calls including problems with reception; participants felt less cared for.

I think it's mostly sort of, I mean, particularly for me who – I have problems with disconnecting from things. If, you know, there's a face to the voice... then it actually can be a lot more useful. (Patient 028)

The other thing was I've got one of these phones that the battery wants to suddenly die on, so I had to get home, charge it up and sometimes I was speaking to her while – so that was limiting me from where I could reach from the plug to the phone. In the early days, you know, in the first two, three weeks, that used to really rattle me that, and I'd find myself getting sweaty and thinking, you know, I'd be having a conversation and we'd lose contact and me thinking, 'What the hell, why am I doing this?' and then she'd phone back and in the mean time I'd be thinking, 'Well, at least she's phoning me, it's not costing me money'... but every time it happened I just thought, 'Why can't we just have a one-to-one? Why can't they just come into the office and have a one-to-one?' (Patient 058)

I guess it's a question of distance really with the whole, you know, the - the material being generalised and the conversations happening on the phone. It just seemed slightly sort of removed, you know, compared to meeting first face to face and then getting, what I presume to be tailored materials, and then meeting face to face again. (Patient 023)

The main benefit of calls was perceived to be their convenience. Having an element of face to face therapy at the start of low-intensity treatment (session one was in person) and sending people course material in advance helped.

### ***Therapeutic support***

The therapeutic support that people had received in low-intensity therapy was viewed negatively and positively. A small number of criticisms were not obviously related to GSH e.g. preferring a female therapist. Others were and included that the support was impersonal, as if the therapist had done their job but had not been there for the patient. Patients wondered if there was scope to 'move away from the material and there was a desire for 'closer' support – more involvement on the part of a therapist.

Sometimes I wanted to talk more about one particular subject and it was as though, like, she had a list in front of her that she has to ask, and it was like, 'No, we've got to go on to the next question, we've got to go on to the next stage' and it was like, 'Oh right, if you can't be bothered, then why should I be bothered.' (Patient 058)

Positive views of therapeutic support in GSH were that it had a clear purpose, helped people to use, understand and engage with the course material, supported patients' own learning and in direct contradiction to others' opinion, that it had never felt impersonal.

You've got the support in the background and you've got the support on paper but you're doing it alone, but you're not alone... It didn't feel like a business but actually it was important that everything was talked about and that the time for me it was important what I was going through and what was happening and that was, that was the main feeling of it. (Patient 027)

### ***Timings***

With respect to session duration, there was a perception that contacts were (sometimes) too brief, felt rushed and prevented patients sharing important thoughts and feelings. For one interviewee, this had led to adverse behaviour following a session. Patients also reported that sessions sometimes over ran and that this was helpful. The contrasting view was that 30 minutes was sufficient and had been appropriate for the type of therapy involved (where you were not encouraged to 'open up'). This amount of time was also perceived to help people focus. Views on the total length of the course also varied. At one

extreme, patients felt that the course had been too long; others wanted it to be longer or implied that six weeks may have been too brief without the option to proceed to individual CBT. Patients liked the pace of treatment. Interviewees remarked that scheduling sessions weekly gave them time to think, reflect and try out ideas that they had discussed with their therapist and that, in these ways, they had been encouraged to help themselves. However, people also commented that it was (sometimes) difficult to read all of the material they had been sent within one week.

### ***Influence of the option to have CBT***

Most of the ways in which patients described how the option to have CBT influenced GSH appeared to make stepped care more acceptable: it took the pressure off the need to get well in just six weeks; people felt reassured / happier to start treatment with GSH; they were pleased not to be left without another option if low-intensity therapy failed. This compared with a fear that if they had been offered intensive CBT alone, should this 'gold standard' treatment option fail, they would not know what else to do. The option to have CBT also became a motivation to continue GSH and it avoided difficulty around choosing between treatments where there was a risk that the patient might want whatever they didn't have (choose).

It took a lot of pressure off, to be honest... I was definitely happy that I was having a lot of available weeks. If someone had told me it was only five weeks, I would have thought, 'Ugh, that's not going to be enough for me.' So to know that it would be five weeks, an assessment and then possibly another ten weeks and then it would be face-to-face (which is obviously something I wanted at the time) that was reassuring. (Patient 063)

I mean, if it had just been CBT alone and without the Self-Help, I mean, CBT always sort of feels like it's fairly comprehensive because it is individual and you are - it is tailored to you - so my feeling was always that if that doesn't work then you're a bit stuck. (Patient 028)



If the course had been you're, you know, doing just the coursework or you're doing CBT then I would have been like, 'Oh I don't want to do this, I want to do that.' (Patient 031)

A more exceptional view was that, as a consequence of the option to have CBT, GSH became instrumental, necessary to complete in order to access CBT.

I knew kind of what I felt that I needed was the CBT, so I kind of went through the process with the - [Guided Self Help]. (Patient 062)

### ***Summary – Guided Self Help***

Views of the Wellbeing Course material, reading and using material, therapy by phone, therapeutic support and how the option to have CBT influenced GSH combined to determine the degree to which low-intensity therapy was acceptable to patients. Acceptability varied. Views of GSH ranged from wholly negative to positive; in-between patients expressed opinions that were predominantly but not completely negative, or predominantly positive (Table 28). The views of patients who had a negative or cautious view of GSH prior to treatment were sometimes but not always confirmed during therapy: some patients found that they disliked GSH; others came to view it more positively. For patients who had a negative view of GSH both prior to and after treatment, the option to have CBT sometimes meant that GSH became a 'means to an end'; for others it both reassured and motivated.

***Table 28 overleaf***

Table 28. Summary – patient experience of low-intensity therapy

ID	Mini-summary	Feelings about starting with GSH	Views and experiences of GSH treatment	Influence of option to have CBT
007	<b>Negative.</b> I did not like the idea or experience of GSH. The WB course material was not at all relevant to me - I hardly read or used it. I do not like phone calls.	<b>Anti</b> – probably won't do it	<b>Disliked</b>	Not discussed
023	<b>Negative.</b> I thought I would need CBT but was prepared to try GSH. However, I did not at all relate to the WB course material or like the idea of phone calls.	<b>Cautious</b> – prepared to try	<b>Disliked</b>	GSH instrumental
014	<b>Negative.</b> Although I was pleased to be offered GSH, I did not rate the WB course material. I was too unwell to read and phone calls felt a bit impersonal. I wanted more support – therapy did not feel like therapy. Sessions felt like a chore when I wasn't improving although the pace was fine.	<b>Pro</b>	<b>Disliked</b>	Not discussed
047	<b>Negative.</b> I was open to the offer of GSH but did not rate it. I did not like the WB course material (it was patronising). I tolerated phone calls but disliked them. I did not feel well supported. Sessions were too short.	<b>Open-minded</b>	<b>Disliked</b>	Not discussed
031	<b>Mostly negative.</b> I did not like the idea of GSH although I did like the WB course material. However, I had difficulty reading and using material. I did not feel well supported by my therapist.	<b>Anti</b> – prepared to try	<b>Disliked</b> – except for course material	Reassurance Meant 'didn't want what didn't have'
058	<b>Mostly negative.</b> I didn't like the idea of GSH although I rated the WB course material. However, it was difficult for me to read and use material. Phone calls were very difficult. I did not feel well supported. Sessions were too short and the course dragged at the end.	<b>Anti</b>	<b>Disliked</b> – except for course material	Reassurance Motivation to start GSH
062	<b>Mostly negative.</b> I was unhappy to be offered GSH and I didn't relate to the WB course material. I had difficulty reading. Phone calls were convenient but I did not feel well supported. The duration of sessions kept me focused but did not allow me to open up.	<b>Anti</b>	<b>Disliked</b> – except for phone calls	GSH instrumental

Table 28. Summary – patient views and experiences of low-intensity therapy (continued from previous)

ID	Mini-summary	Feelings about starting with GSH	Views and experiences of GSH treatment	Influence of option to have CBT
028	<b>Quite positive.</b> I was initially a little uncertain about the offer of GSH. I didn't like the WB course material (it was patronising) but I still read around sessions. I didn't like phone calls to start but then found them OK. I felt well supported. The pace of sessions was mainly OK.	<b>Cautious</b>	<b>Liked –</b> except for course material	Reassurance Motivation to start GSH
039	<b>Mostly positive.</b> Although I was unsure about GSH I gave it a go. I found that I liked the WB course material. I read around sessions and got used to mind mapping. Sessions were a bit short but having six in total, one a week was fine.	<b>Cautious</b>	<b>Liked</b>	Not discussed
063	<b>Mostly positive.</b> Although I was unsure about GSH, the WB course material was good and I read and used it. Phone calls were good. Sessions were sometimes too short. The pace of therapy and having six sessions in total was fine.	<b>Anti</b>	<b>Liked</b>	Took pressure off GSH
051	<b>Mostly positive.</b> I liked the idea of GSH. The WB course material was mostly good. I read material to suit me and was well supported. However, I did not like phone calls. The duration of sessions was mostly fine as was the pace.	<b>Pro</b>	<b>Liked –</b> except for phone calls	Not discussed
027	<b>Positive.</b> I was really pleased to be offered GSH. I liked the WB course material and read it (more than once). To start I was unsure about phone calls but I found them completely normal. I was well supported. The length of sessions was fine and well-paced although I wanted more than six.	<b>Pro</b>	<b>Liked</b>	Not discussed

### **6.11.3 Theme three – monitoring**

The theme of 'monitoring' describes what patients thought about their symptoms of depression being systematically assessed throughout treatment. It covers their views of being monitored and this information being used to inform stepping decisions. It also encompasses patients' description of how they responded to and used their scores as well as their critique of the PHQ-9.

#### ***Being monitored and the use of information to inform stepping decisions***

When asked how they felt about their symptoms of depression being assessed at each therapy session and this information being used to inform stepping decisions, patients said that the process made sense and was useful. However, difficulties sometimes arose around being honest. Patients described how they had downplayed their symptoms of depression believing that it was important not to waste therapists' time; a patient had contemplated lying in order to receive CBT and one interviewee wondered if patients would want to please their therapist with lower scores.

An exceptional view was that monitoring was wholly unacceptable. This view was upheld for two reasons: using numbers and boxes to capture emotions felt completely inappropriate; there was a concern that information on 'risk to self' identified using the PHQ-9 and consequently shared with the patient's GP would become known to the local community. One patient raised a very specific criticism: whilst symptoms of depression had been assessed, anxiety was not. This had caused confusion and raised an important issue about the design of the current study: STEPS was described as an evaluation of stepped care treatment for depression; symptoms of depression were used to make stepping decisions yet the Wellbeing Course supported patients with depression and anxiety.

I remember you saying it's mainly aimed at depression, and again, you know, this is a bit of a question mark about all this for me is how much is this mainly aimed at depression and how much is it depression and anxiety? And I felt the stepped care [low-intensity therapy] was very much both, but I was under the impression, I think, that after that it [high-intensity] would be mainly focused on

depression, and of course, the week by week scores were only based on depression, not on anxiety. So that, for me, remains a little bit of an issue about this whole treatment. (Patient 063)

### ***Responding to and using scores***

Descriptions of how people responded to and used their PHQ-9 scores were positive. Scores were often trusted e.g. made sense to patients and mattered, sometimes a great deal.

It was the clarification. 'Cause you could just say, 'Right, well you've had your nine session, well done, you've done very well, you look and sound a lot better, thanks very much.' But, like I say, it was almost like getting good marks in an exam, not just that you'd passed, but you got an A! (Patient 014)

When scores came down, people felt good; when they went up, patients commented that this was useful, if not heartening. On occasion when scores did not tally with how people felt, scores were sometimes dismissed or ignored. This did not necessarily undermine the acceptability of being monitored; patients continued to trust scores with which they agreed. An example of how patients used scores was to identify specific difficulties rather than persist in seeing all aspects of themselves and their lives as awful.

[Completing the PHQ-9] was helpful in helping me to identify the areas where I might need help, as well, because, you know, when you generally feel rubbish, well, fine, how do you feel rubbish, what should you be doing, what should you be targeting to make you feel less rubbish as opposed to just going, 'Well, I feel rubbish.' [Laughter] It forced me to start defining some of the things, some of the ways in which I felt bad, as opposed to just, as I said, going 'I feel bad.'  
(Patient 028)

Other patients responded to their scores in ways that were more negative. Some patients had been sceptical about their scores i.e. thought they were inaccurate; patients described feeling frustrated when their scores did not come down or dropped a little only. For one patient, facing a difficult set of family

circumstances, being monitored was especially problematic: the patient felt that their scores were both irrelevant and misleading given the situation they faced.

It felt irrelevant to be filling out forms in comparison to how I felt the week before or the two weeks before when considering how something so serious and life-changing had happened between when I saw him and when I filled out the form before. It was just like he just wanted to get a comparison but I didn't think that the comparison would be fair to how my mental state really is. (Patient 031)

### ***Critique of the PHQ-9***

Although the use of symptom checklists to monitor symptoms of depression was generally endorsed, the PHQ-9 was heavily criticised. Comments included that it failed to fully capture patients' experience of living with depression; questions and response options lacked detail; some items were a poor measure of depression and more likely reflected patients' broader circumstances and difficulties; some difficulties were over-emphasised, others omitted. When completing the PHQ-9 patients also found it difficult to remember how things had been and there was a perception that scores were overly influenced by what had happened on the day the measure was administered.

### ***Summary – monitoring***

Monitoring symptoms of depression made sense and was useful to most patients. Patients felt good when their scores came down albeit frustrated when their scores went up or stayed the same. The PHQ-9 was heavily criticised but the acceptability of monitoring was not necessarily undermined when scores did not tally with how people felt: scores were sometimes ignored. One patient raised an important issue, specifically, why monitor symptoms of depression but not anxiety.

#### **6.11.4 Theme four – stepping**

The theme of 'stepping' covered patients' views and experiences following unsuccessful low-intensity treatment. It describes patients' response to unsuccessful GSH; how they felt about going on to CBT; how the transition worked in practice and what patients thought about changing therapists.

### ***Thoughts and feelings following unsuccessful GSH***

Patients' thoughts and feelings following unsuccessful GSH were predominantly negative. Interviewees felt fed up, frustrated, and that GSH had become a chore. There was an element of self-recrimination; some patients felt that they had failed – they should have been able to succeed - and were worried that they had not responded to GSH because there was something wrong with them. Not responding to GSH also compounded a loss of faith in trained professionals and there was a concern that if those trained to do so had been unable to help, who could?

You do start to lose faith, and you're thinking, OK, so professionals have designed this, and you start to lose faith in the professionals and think – do they actually know what they're talking about, and then you think, 'Oh God! Well, if they don't know what they're talking about, who's going to help me?' [Laughs] It's like, 'Is anyone going to be able to help me?' Or maybe it's me, you know maybe it's', 'cause I've been told that it's worked for other people, so maybe there's something wrong with me. (Patient 047)

A more exceptional response to unsuccessful low-intensity therapy was to be more objective. Non-response was seen as simply that, viewed without emotion.

It was kind of like OK, I've done that now, got that out of the way, I can move on to what I really need. (Patient 062)

### ***Going on to CBT***

Patients' views about going on to high-intensity CBT varied. At one extreme, patients were excited, keen and positive at the prospect of having CBT. In contrast, others felt frustrated, defensive and dubious about how effective it would be. Doubts either focused on oneself (*am I the right person for CBT*) or therapy (*will CBT help*). However, doubts were ultimately replaced by more positive feelings. In this transition, patients described a role for therapists. By giving patients time and space, patients were able to reflect on the chance to have CBT and speak with family and friends. Therapists also provided helpful information about what CBT would entail and its potential benefits. Patients

came to see CBT as an opportunity or at least something they were prepared to try.

He [my therapist] said that, you know, if I obviously, if I went into the CBT I could still stop at any point, and I figured 'Well', you know, 'Give it a try, give it a few sessions', I don't have to have, you know, twenty sessions if I don't feel I'm getting anywhere, but let's at least give it a spin and see. (Patient 028)

In terms of the 'link' between how patients' felt about unsuccessful GSH and having CBT, feelings about the former did not predict the latter: despite negative thoughts, patients were to a greater or lesser degree, keen to have CBT – albeit after a time and following discussion with family and friends.

### ***The transition***

The practical transition from GSH to CBT was criticised in a small number of ways. On occasion patients were unhappy with the length of time from low- to high-intensity treatment although this was, in part, attributed to how awful the patient felt and less to do with the actual amount of time passed. There was also a suggestion that it would help to provide more information about CBT at the end of unsuccessful GSH.

### ***Changing therapist***

Changing therapists from GSH to CBT was generally not a problem. Patients tended to speak of this positively even when they described a lack of rapport with their new CBT therapist. Advantages of having a new therapist were that patients did not feel pre-judged and that this person could provide a fresh start.

I think it's good in a way to have that sort of fresh, refresher point, to sort of go, 'Oh all right, well, we tried one thing and it didn't go anywhere, so let's start again in some ways,' and actually have someone come in who doesn't know you and doesn't know how you've, what you've said or what you've done about the previous things you've seen. (Patient 028)



### ***Summary – stepping***

Patients' thoughts and feelings following unsuccessful GSH were often negative e.g. some patients lost faith in health care professionals and felt that they had failed. However, negative feelings did not determine how people felt about having CBT. Some patients felt excited at the prospect of high-intensity therapy. For others, helped by therapists, friends and family, doubts were replaced with a more positive outlook. Changing therapists from low- to high-intensity therapy was not a problem.

#### **6.11.5 Theme five – Cognitive Behaviour Therapy**

The theme 'Cognitive Behaviour Therapy' describes what patients thought of high-intensity treatment delivered as part of the stepped care intervention. It includes patients' reflections on CBT as a whole, therapy in person and the therapeutic relationship, and how they found the length of sessions and the total length of CBT.

##### ***CBT as a whole***

Views and experiences of Cognitive Behaviour Therapy divided patients who had stepped up into three groups: patients who had predominantly negative, predominantly positive and mixed opinions. Criticisms of CBT held by those who had a negative or mixed opinion were that it did not contain anything new and that patients had been unable to understand what it was. CBT had a negative impact on self-esteem; sessions felt as if they perpetually highlighted one's weaknesses. Other criticisms were that it did not address long-standing, difficult issues and that (from a patient who did not step up but reflected on what CBT would entail) that it was mainly focused on depression whereas help with anxiety was very important too.

Someone says 'So what do you do in CBT?' and I don't know! I talk about how horrible I've been during the week and then get told to do something nice for myself or breathe. (Patient 047)

Positive descriptions of CBT were around what the therapy entailed e.g. being taught how to deal with the here and now, benefits to individual patients such as increased self-awareness and generic statements – CBT was enjoyed.

### ***Therapy in person and the therapeutic relationship***

Views and experiences of therapy in person and the therapeutic relationship in CBT also divided patients. One group found therapy in person positive, they liked their therapist and had a good rapport with them; a second group criticised the therapeutic relationship heavily, felt unsupported, and wanted more empathy, understanding and guidance. Some patients who stepped up explicitly said that they preferred the face to face delivery of CBT to phone calls. However, patients who preferred face to face did not always rate the therapeutic relationship positively. Benefits of CBT that were directly attributed to it being in person included that face to face therapy was a welcome opportunity for patients to 'get away' from their home surroundings and everyday environments and that, face to face, a therapist could tell when the patient avoided things which was not always possible by phone.

Being one-to-one, being face-to-face, being away from my home and my situation, you know, actively going – actually getting a break from work, to be honest, as well... Just having a break, change, different situation, different person, it just felt a positive, so much more positive in a way and helped by the physical action of moving out of the situation, I felt freer, felt literally like I had more control, (Patient 062)

[My therapist] pretty quickly caught up on the fact that I avoid things if I don't like doing them. If you see someone and talk to them it's a lot easier to call up on than if it's done over a phone call... So that was quite, that was quite comforting to have someone there look at you and go, like, 'So you're avoiding again.' (Patient 027)

### ***Timings***

In terms of the duration of CBT sessions and the total length of time patients spent in high-intensity therapy, patients held different views. One view was that the duration of sessions was good and, together with how individual sessions had been planned, helped patients avoid trawling over difficulties in a way that

was unconstructive. On the other hand, sessions were found to be too short and when they did over run (beyond the allotted 50 minutes) this was considered useful. The total length of CBT did not necessarily feel too long, especially in the context of how long people had lived with depression; conversely, sessions seemed as if they went on and on.

### ***Summary – Cognitive Behaviour Therapy***

Patients' views of CBT delivered as part of stepped care varied. Some patients did not understand CBT and had a poor relationship with their therapist. There was also a perception that sessions were too brief and the total number more than required. Other patients enjoyed CBT, including face to face therapy; the length of individual sessions and the total duration of CBT were perceived as appropriate. Patients who preferred face to face therapy did not always rate the relationship with their CBT therapist, positively. Patients' views of CBT and stepping (theme four) are combined in Table 29. The table illustrates that some patients who experienced negative feelings following unsuccessful low-intensity treatment nonetheless liked CBT.

Table 29. Summary – patient experience of high-intensity therapy as part of the stepped care intervention

ID	Mini-summary of CBT	Response to unsuccessful GSH	View of going on to CBT	Actual experience of CBT
027	<b>Positive.</b> I felt that I had failed at GSH and I did not want CBT at first. However, I came to see it as an opportunity. I liked changing therapists and having therapy in person. The length of sessions worked well. Ultimately, I enjoyed CBT – it was better than I expected.	Felt had failed	Doubtful at first but positive after discussing with family and friends	Liked
014	<b>Positive.</b> I felt that I had failed STEPS by not getting better in GSH. However, I looked forward to CBT and found that I liked it. Having therapy in person was good and I felt well supported. Fifty minutes for sessions worked well.	Had failed research GSH had become pointless, a chore	Keen, positive	Liked
051	<b>Negative.</b> I knew I wasn't ready to stop therapy after GSH but I did not like CBT – I didn't 'get it'. Although I thought changing therapists was positive, I did not have a good relationship with my CBT therapist. I did not feel well supported. It was difficult to schedule sessions. GSH was more useful.	Not discussed	Knew not ready to stop treatment	Disliked
028	<b>Mixed feelings.</b> I was fed up after GSH and felt annoyed and dubious about having CBT. However, I was willing to give it a go. I preferred therapy in person to by phone. Elements of CBT were useful but it didn't offer me anything new or help with some of my long standing problems.	Felt fed up and frustrated	Annoyed and dubious at first but ultimately willing to give it a go	Mixed opinion
047	<b>Negative.</b> After I did not get better in GSH, I was worried that there was something wrong with me and it compounded my loss of faith in professionals. However, I was excited to have CBT. I liked therapy in person but I did not feel well supported. I did not 'get' CBT – it did not offer me anything new / useful. Sessions made me feel bad about <i>myself</i> .	Self-recrimination, compounded a loss of faith in professionals	Positive, hopeful, excited	Disliked
062	<b>Positive.</b> I was matter of fact about not responding to GSH and positive about having CBT. I preferred therapy in person and felt well supported by my therapist. I liked being given tools for changing things. Sessions were sometimes too short and we had difficult scheduling them.	Objective, matter of fact	Positive, viewed as starting afresh	Liked

### **6.11.6 Theme six – ending therapy**

The theme ‘ending therapy’ covered how patients felt about ending treatment (following GSH alone or GSH + CBT), benefits of treatment and any residual difficulties and, for patients who ended a treatment before their therapist believed they were ‘ready’, why patients ‘dropped out’.

#### ***Feelings about ending treatment***

Faced with the prospect of ending treatment, patients had mixed feelings. This was true for patients who ended treatment following GSH alone and GSH plus CBT. Patients at once understood and accepted that treatment had to end but also felt uncertain about doing so. Negative feelings about ending therapy included worries around the loss of support and coping with ongoing difficulties. Patients who had high-intensity treatment following GSH did not always feel ready or expect to stop CBT. Patients were sometimes reassured knowing they could return to their local IAPT service if they required more treatment. However, patients did not normally want such support directly on ending therapy – one GSH patient wanted to be ‘checked up on’ at a later date.

#### ***Benefits of treatment and residual difficulties***

When reflecting on the benefits of therapy, patients who had GSH alone but also those who stepped up described how low-intensity therapy helped them with the way they were thinking and feeling.

I think it’s changed my mind set, the literature has, quite considerably, and, which is really positive, it’s really good. (Patient 051)

It was bringing me to terms with life again. You know, these people in the book, they’d gone through worse, you know, losing their wife, having a car crash, losing a limb, and they got up and got on with it and it was like ‘You know what, someone up there’s looking over me, they’ve given me another chance and I [knew that]... nobody could do that for me, there was only me that could do that. (Patient 058)

I think it [GSH] made me give myself a bit more slack. Because a lot of the time I would kind of berate myself with ‘Oh, you’re so lazy’ and it’s like, well, no, I’m tired for a reason. (Patient 047)

Interviewees described benefits of having the GSH material to return to when needed. This was important for patients who had GSH alone and those who had GSH and CBT. Patients varied in the degree to which they actually used the material: some suggested that they had re-read it; others were reassured to know it was there but had not actually picked it up since ending therapy.

I... love, think it's amazingly useful that I have... all the paperwork from the self-guided work. That was one of the first things I packed and make sure I got it handy, so if I feel like I need it, I can have it. Umm. And knowing that I have this material and if I ever feel like I need to read it, I can. I thought that was just, I think that was brilliant. (Patient 027)

I have sort of put the course to one side, for the time being, but I've still got it mulling over in the back of my mind, but I haven't actually looked at the stuff, I've just left that to the side. (Patient 039)

The self-help literature was brilliant, is brilliant, because I still have referred to it. (Patient 051)

Both patients who had GSH alone and low- and high-intensity therapy described residual difficulties or problems in their lives which they anticipated would continue to be difficult beyond therapy and which treatment may not have addressed.

### ***Reasons for 'dropping out'***

For patients who had declined any treatment or 'dropped out early, reasons given for doing so were both treatment related and not. Two patients had declined any GSH. The prospect of 'homework', a strong preference for face to face therapy or CBT and a belief that the Wellbeing Course material was not appropriate or relevant to them contributed to this decision; one of the patients also understood that he could access high-intensity CBT without first being referred for low-intensity treatment, on return to his local IAPT service. A third patient who had significant difficulty with the idea of homework and being monitored and who had ended GSH treatment after one session, attributed her decision to end treatment primarily to a family crisis combined with work-related

demands. A fourth stepped care patient ended CBT when she moved location for employment.

### ***Summary – ending therapy***

Patients who had GSH alone and GSH + CBT described ways in which treatment had helped but also residual problems at the end of therapy. Both groups of patients had mixed feelings about ending treatment. Patients who had CBT after GSH did not always expect or feel ready to end high-intensity therapy. Both those who responded and did not respond to GSH were pleased to have GSH material at the end of treatment and said that they referred to it. Patients declined or dropped out of low-intensity therapy because of treatment and for other reasons.

### **6.11.7 A summary of the acceptability of stepped care to patients**

Patients' views and experiences of being offered stepped care, low-intensity treatment and (where applicable) unsuccessful GSH, going on to CBT and actual CBT as well as ending treatment combine to determine the degree to which the intervention was acceptable. In this regard, patients divided into three groups: those for whom stepped care was wholly or largely unacceptable; patients who found stepped care somewhat acceptable and a group for whom stepped care was acceptable (Table 30). The views of patients for whom stepped care was unacceptable were often based on their response to GSH alone but could also reflect a dislike for both low- and high-intensity treatment. Some patients who found stepped care somewhat acceptable disliked GSH and liked CBT; others rated GSH positively but did not like or held a mixed opinion of high-intensity treatment. Positive views of stepped care reflected a good experience of GSH alone but were also held in relation to GSH that had not 'worked' but was nonetheless viewed positively followed by CBT that was enjoyed.

Table 30. Summary – patient experience of the stepped care intervention

ID	Mini-summary of stepped care	Starting with GSH	Actual GSH	Prospect of CBT	Actual CBT
007	<b>Unacceptable.</b> I did not want GSH. I disliked the idea of homework and phone calls. I did not relate to the WB course material which was inappropriate for someone my age. I was too poorly to read. I found being monitored unacceptable – I cannot put my emotions into boxes.	<b>Anti</b> – probably won't do it	<b>Disliked</b>	NA	NA
023	<b>Unacceptable.</b> I thought I would need CBT but was prepared to try GSH. I did not relate to the WB course material (it was too 'generic' and therefore not relevant to me). The idea of therapy by phone was unappealing – it felt impersonal. I knew I could get CBT elsewhere.	<b>Cautious</b> – prepared to try	<b>Disliked</b>	NA	NA
031	<b>Largely unacceptable.</b> I was put off GSH by the idea of homework but prepared to give it a go. Although I liked the WB course material I found it difficult to read and use. My mum became seriously ill. It did not feel relevant to measure my symptoms of depression. My therapist did not understand. I dropped out due to my mum and work commitments.	<b>Anti</b> – Prepared to try	<b>Disliked</b> – except for course material	NA	NA
058	<b>Largely unacceptable.</b> I was disappointed and irritated to be offered GSH. However, I liked the WB course material although I found it difficult to read and use. Phone calls were very problematic. Sessions were too short. I did not feel well supported. The option of CBT kept me in treatment. I had difficulties being completely honest when filling in the PHQ9 but I responded well to my scores. On end treatment, I go back to course material.	<b>Anti</b>	<b>Disliked</b> – except for course material	NA	NA
047	<b>Largely unacceptable.</b> I had no opinion about starting therapy with GSH but found that I did not relate to the WB course material (it was inadequate and patronising). I tolerated phone calls but disliked them. Sessions were too short. I was unhappy with my therapist. I responded constructively to my depressive symptoms being measured although I was critical of the PHQ9. When I did not respond to GSH, I worried that there was something wrong with me. It compounded my loss of faith in professionals. Nonetheless I was positive about going on to CBT. I found that I preferred therapy face to face but I did not feel well supported. I did not 'get it' – CBT did not offer me anything useful and made me feel bad about myself.	<b>Open-minded</b>	<b>Disliked</b>	<b>Positive</b> Hopeful, excited	<b>Disliked</b>
062	<b>Somewhat acceptable.</b> I did not particularly want GSH. I did not relate to the WB course material and had difficulty reading. Phone calls were convenient and OK. Sessions were too short to allow me to open up. I wanted more therapeutic support. I was critical of the PHQ9 but responded well to my scores. I saw GSH as a means to access CBT. I felt matter of fact about not getting better and looked forward to CBT. Therapy in person was good and I was well supported. Sessions were sometimes too short. Some elements of CBT were particularly helpful and on end treatment I felt that I had tools to retrain my brain. I would benefit from ongoing support e.g. a personal coach for 2 years.	<b>Anti</b>	<b>Disliked</b> – except for phone calls	<b>Positive</b> Viewed as starting afresh	<b>Liked</b>
014	<b>Somewhat acceptable.</b> I was pleased to be offered GSH but did not really like it. The WB course material was too simplistic; I was too poorly to read at home. Phone calls did not feel very personal and I was not well supported by my therapist. I did not mind my symptoms of depression being monitored although I was	<b>Pro</b>	<b>Disliked</b>	<b>Positive</b> Keen	<b>Liked</b>



Table 30. Summary – patient experience of the stepped care intervention (continued from previous)

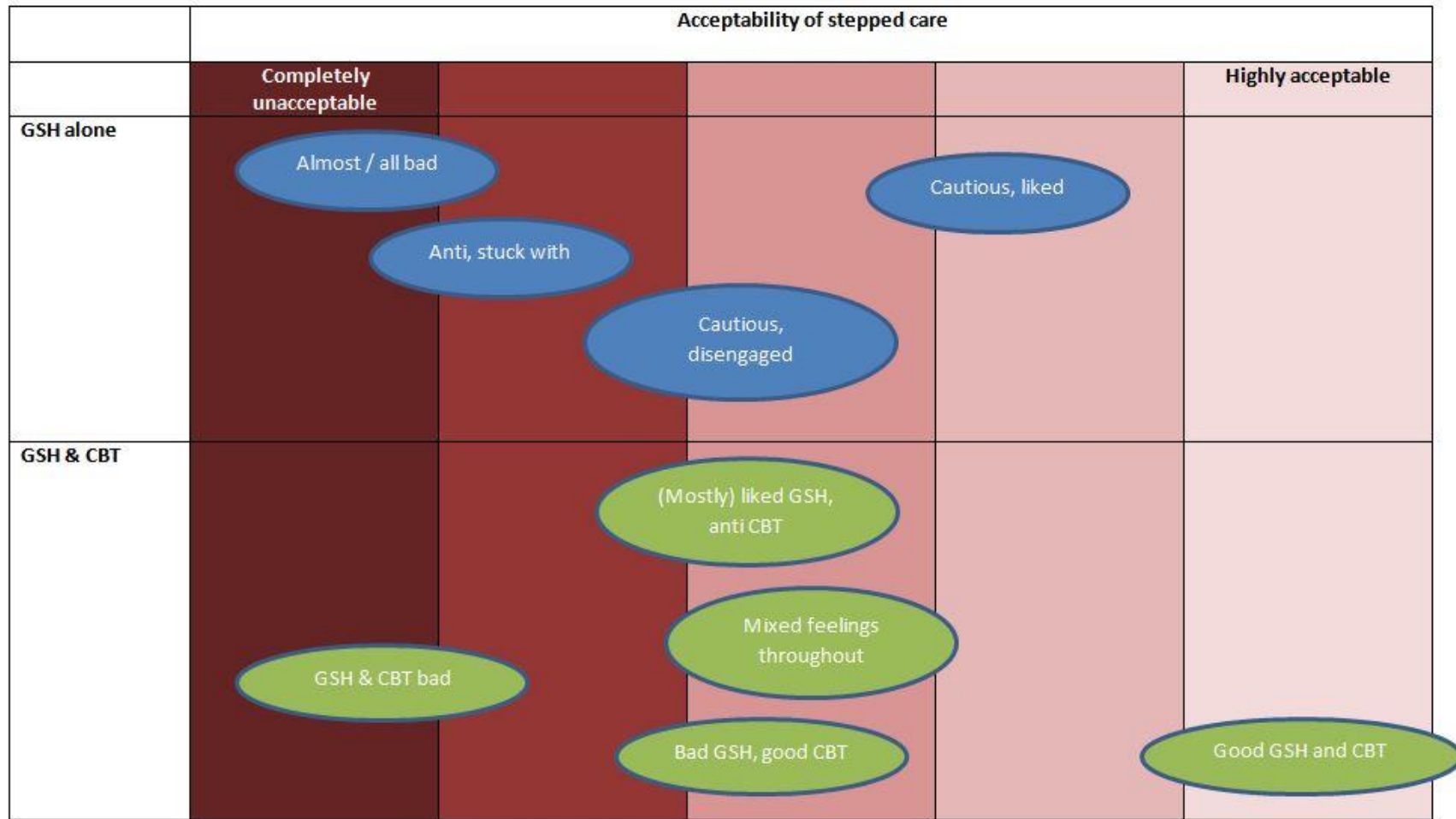
	critical of the PHQ9. When I did not get better after GSH, I felt I had failed STEPS. I was still keen to have CBT and I found that therapy in person was good; I had a good relationship with my therapist. What I learnt in CBT helped.				
051	<b>Somewhat acceptable.</b> I was pleased to be offered GSH. I mostly liked the WB course material and I read it in a way that suited me. I did not like phone calls but tolerated them. I had good therapeutic support. Sessions were the right length. It was helpful to monitor my depressive symptoms. When I did not get better after GSH, I was not ready to stop. I was happy to change therapists but did not have a good relationship with the person who took over. I 'didn't get' CBT and was uncertain about its benefits. On end treatment, I refer to the GSH material.	<b>Pro</b>	<b>Liked – except for phone calls</b>	<b>Knew not ready to stop treatment</b>	<b>Disliked</b>
028	<b>Somewhat acceptable.</b> I was a little cautious about starting therapy with GSH but willing to try. I didn't relate to the WB course material – it was patronising. All the same, I read around sessions in a way to suit me. I initially disliked phone calls but found them OK. I had good therapeutic support. I understood why my symptoms of depression were monitored and responded constructively although I was critical of the PHQ9. When I did not get better after GSH, I was fed up and frustrated. I felt annoyed and dubious about going on to CBT although I was happy to change therapists. I found that I preferred therapy in person. Elements of CBT were useful but it didn't offer me anything new or help with some of my long standing problems. On ending therapy, I felt better equipped to deal with the day to day.	<b>Cautious</b>	<b>Liked – except for course material</b>	<b>Annoyed and dubious at first then willing to give CBT a go</b>	<b>Mixed opinion</b>
039	<b>Largely acceptable.</b> I was unsure about how I would get on with GSH but found that I liked it. Some elements of the WB course material were particularly useful. I read around sessions and benefited from that. Sessions were a bit short. I understood why my depressive symptoms were monitored and responded well to my PHQ9 scores although I was critical of that measure. On ending GSH, I reflect on the course material. I have residual difficulties but GSH helped me with specific problems.	<b>Cautious</b>	<b>Liked</b>	NA	NA
063	<b>Largely acceptable.</b> I was disappointed to be offered GSH but found that I liked the WB course material. I read around sessions in a way that suited me and I was motivated to apply what I learnt. Phone calls were OK. Sessions were sometimes too short although six in total was fine. I was concerned that symptoms of anxiety were not monitored alongside depression but I responded well to my PHQ9 scores. I made definite gains as a result of GSH.	<b>Anti</b>	<b>Liked</b>	NA	NA
027	<b>Highly acceptable.</b> I was pleased to be offered GSH – I wanted to help myself. I liked the WB course material and read around sessions. Although I was initially unsure about phone calls they felt OK. I had good therapeutic support. I responded constructively to my PHQ9 scores. When I did not get better after GSH, I felt a failure and did not want CBT but my family and friends helped me see it as an opportunity. I enjoyed CBT. Changing therapists was good. I finished therapy when I moved location. On ending treatment, I was really pleased to have the GSH material and felt confident that I could begin to help myself.	<b>Pro</b>	<b>Liked</b>	<b>Doubtful then positive</b>	<b>Liked</b>

### ***Typologies of the degree of acceptability to patients***

The degree to which stepped care was acceptable to patients was also summarised using typologies (Figure 11). Nine typologies were derived from the experiences of stepped care among the twelve patients analysed and are displayed along a continuum of acceptability. Typologies that appear to the left of the figure represent the views of patients for whom stepped care was completely unacceptable; typologies that appear to the right represent the views of patients for whom stepped care was highly acceptable. The derivation of nine typologies from twelve patients analysed is further evidence of the heterogeneity in patients' views of stepped care. Stepped care was both highly acceptable and completely unacceptable with a range of opinion in-between.

***Figure 11 overleaf***

Figure 11. Typologies of patient attitude to stepped care arrayed by acceptability



### **6.11.8 Cross-cutting themes shaping patient acceptability**

Across all of how patients felt before treatment, on ending therapy, about GSH, being monitored and (where applicable) stepping up and CBT, three 'cross-cutting' themes were derived from inferential analysis that appeared to influence the degree to which the intervention was acceptable to patients. The themes were: 'needing something more', 'you're on your own' and 'self-efficacy'.

#### ***'Needing something more'***

The theme 'needing something more' was often but not exclusively evident in patients' response to starting therapy with low-intensity treatment. It describes a sense that the treatment offered was somehow inadequate or unsuitable. Patients felt that high-intensity treatment was more appropriate either because of how unwell they felt (the severity of their symptoms) or because of specific problems that they wanted to address for which they believed low-intensity therapy would be less effective. Features of high-intensity treatment were perceived to be more appropriate: greater support and the increased length of therapy.

At first I didn't think it was for me, I would have preferred to have had the other one because it was a case of I was possessive. The problem that I thought I had was with being jealous and possessive, not trusting people or not trusting the person I was in the relationship with. So I felt at the time it would have been better me going on to the second course straight away. (Patient 058)

Well it was a step in the right direction, literally, if I can use the words, 'step in the right direction.' So I wanted to give it a go but I just felt it didn't go into enough depth... I wasn't at a stage where I could actually help myself. I would say you have to be quite well to be able to help yourself, and at that point I don't think I was that well. (Patient 062)

Maybe I felt I needed that face-to-face or whatever it was, someone external to really help me, that's how vulnerable I was feeling at the time, that maybe I thought that wouldn't quite be enough, just to be getting a few things through the post... And I thought I would need

it, at the beginning, because I thought I was really down in the, you know, really down, and would need that extra ten weeks. (Patient 063)

Once in low-intensity treatment, the same sentiment was expressed. Patients felt that they were too poorly to read or do 'homework' or that they required more than 'simplistic' GSH.

It does surprise me that anyone who's really anxious and depressed would want to do all that homework. (Patient 007)

I was in too bad a state, I think, to just do something as simple as Guided Self Help at the time... It really ended up not being for me. I wasn't in a state of mind to do homework every week. (Patient 014)

A more exceptional view was that high-intensity therapy was inadequate given specific needs. One patient felt that it was unable to help with her long-standing issues around bereavement.

### ***'You're on your own'***

The second cross-cutting theme, 'you're on your own', describes patients' feelings of not being well understood or supported throughout therapy but rather of being 'on their own' with their problems, distant to and perhaps different from others. Again, this sentiment was typically evident in how patients described low-intensity treatment. Patients did not relate to the Wellbeing Course material or felt that it was not relevant to them, disliked phone calls and were unhappy with the nature of the therapeutic support that was 'confined' to thirty minutes, aimed to get people through the course but only with reference to that material.

I mean, no disrespect, I've forgotten his name, I think it was [therapist name] I used to speak to, I mean, he was doing his job, he wasn't, as far as I understand, a therapist of any kind, if he was I apologise, but that's the way I understood it at the time, but I did feel it was all a little bit like it was being read off a sheet. (Patient 014)

Other people may want to be more independent and do it all themselves - but I kind of felt I needed somebody alongside me. (Patient 062)

Feelings of being 'on your own' were also evident in how patients talked about the shortcomings of being monitored. Perceived inaccuracies in scores or a lack of detailed assessment or feedback in areas that were important to patients contributed to a sense that the patient was not as well supported as they might be.

### **'Self-efficacy'**

The third cross-cutting theme that appeared to shape the degree to which stepped care was acceptable to patients was 'self-efficacy'. This theme was associated with higher levels of acceptance of low-intensity therapy. It describes how patients felt good about and wanted to be responsible for helping themselves. The sentiment applied to how they felt about therapy but also their hopes for what could be achieved once treatment had finished.

In treatment, patients wanted to learn how they could help themselves and put this into practice. Scores on the PHQ-9 were used by patients to identify areas for individual improvement. The theme also included examples of how patients took initiative in (or responsibility for) their own learning in the ways they described adapting, using and applying Wellbeing Course material to suit. Under this theme, therapeutic support was viewed as an aid to enable one's own learning. One patient for whom stepped care was highly acceptable exemplified how self-efficacy shaped her very positive views of GSH:

I think having, having, knowing that I was giving, was given umm material, I was given tools I can use pretty much for the rest of my life with the help of someone else there but it's me doing it. I thought that was brilliant. (Patient 027)

Being able to see you're making progress [on the PHQ-9] or you don't so what do I have to change, I found that quite helpful for myself. (Patient 027)

I know I can tackle it [my depression]. I might not be successful on my own but I know I can at least be starting to tackle if it comes back again, on my own. And learning that by reading it - that was important... It was still helpful for me to see that I can make the start by myself and I can... use the methods I've been given. (Patient 027)

### ***Summary – cross-cutting themes***

Three cross-cutting themes were identified that appeared to shape the degree to which stepped care was acceptable to patients. Negative views of low-intensity therapy were associated with a sense of ‘needing something more’ and ‘you’re on your own’. Patients felt that low-intensity therapy was inappropriate because of how unwell they were or because of specific problems they wanted to address. Feeling poorly supported and different to patients whose experiences were described in the Wellbeing Course material, contributed to a sense of isolation. On the other hand, positive views of low-intensity treatment were associated with ‘self-efficacy’ – the degree to which patients assumed responsibility for getting better. Self-efficacy was evident in how people engaged with GSH and their thoughts and feelings about ending treatment.

***Section 6.12 overleaf***

## 6.12 Acceptability of stepped care to therapists

As well as patient data on acceptability, therapists' views of stepped care were analysed. Analysis indicated that therapists' views of stepped care could be described by four themes: 'low-intensity therapy', 'monitoring', 'stepping', and 'high-intensity therapy'. All of themes comprised several sub-themes. Themes and sub-themes were descriptive and are listed in Box 5.

Box 5. Key themes (numbered 1 to 4) and sub-themes describing the acceptability of stepped care to therapists

<p><b>1. Low-intensity therapy</b></p> <ul style="list-style-type: none"><li>Appropriateness</li><li>Anticipated benefits of treatment</li><li>Wellbeing Course material</li><li>Therapeutic support</li><li>Timings</li><li>Option to have CBT following GSH</li></ul>
<p><b>2. Monitoring</b></p> <ul style="list-style-type: none"><li>The PHQ-9</li><li>Using patients' scores</li><li>Monitoring depression but not anxiety</li></ul>
<p><b>3. Stepping</b></p> <ul style="list-style-type: none"><li>Stepping criteria</li><li>When to apply the criteria</li><li>Discharging patients following low-intensity therapy</li><li>Stepping up</li><li>Changing therapists</li></ul>
<p><b>4. Cognitive Behaviour Therapy</b></p> <ul style="list-style-type: none"><li>Connections between GSH and CBT</li><li>Ending CBT</li></ul>



### **6.12.1 Theme one – low-intensity therapy**

The theme ‘low-intensity therapy’ describes therapists’ views and experiences of delivering GSH as part of the stepped care intervention. The theme encompassed interviewees’ views of the appropriateness of GSH, the anticipated benefits of low-intensity treatment for patients, views of the Wellbeing Course material, the nature of the support therapists offered and the timings of therapy i.e. session duration (30 mins), pace (weekly) and total length (six weeks). It also covered therapists’ description of how the option to have CBT influenced their delivery of GSH.

#### ***Appropriateness***

At the beginning of the study, therapists’ views of the appropriateness of low-intensity therapy were divided. One therapist viewed GSH as appropriate for all patients. Others (with no previous experience of stepped care) viewed GSH as inappropriate for people with severe depression as well as patients who presented with more complicated, multiple and entrenched difficulties.

Guided Self Help... means they have to help themselves. And I think part of my understanding of depression is it's very difficult to be self-disciplined. So when you're tasked with helping yourself essentially, I get nervous about how much pressure that puts on people. These were some of my concerns when people showed up with severe, or what we'd call a severe level of depression. (Therapist 01)

However, views of the appropriateness of low-intensity treatment changed in response to positive experiences of GSH for patients with severe depression. Low-intensity therapy came to be seen as a useful first step for people with entrenched and complex problems although there remained a concern that GSH would be less effective for patients with severe depression particularly where they lacked motivation. For the same reason, the effectiveness of high-intensity CBT for severely depressed patients was also doubted.

I think I was, yeah, surprisingly all right with it, really... I started to see the Guided Self-Help, if there was a sense that a person was more complex or had more entrenched difficulties that it could be a useful first step in terms of psychoeducation. (Therapist 03)

So I see motivation, you know, as kind of negatively or inversely correlated with depression scores - so the higher your depression score the lower your level of motivation. And yes, that was a bit of a concern for me, going through the Guided Self-Help course. But as I'm saying that, I'm thinking about the type of commitment needed from a – within high intensity CBT and it is really quite intense as well... I think the dilemma's the same, or presents itself in both low intensity and high intensity, people that need this stuff the most probably find it more difficult to do, unfortunately. (Therapist 01)

The therapists were also uncertain about the appropriateness of GSH for other groups of patients: who, from around the second session, did not understand or engage with the cognitive element of the Wellbeing Course; who said that they found the Course too basic; patients with a strong preference for CBT; those who did not respond week on week; a patient with bulimia; a patient with dyslexia and drinking problems who had entered a period of crisis whilst in treatment.

### ***Anticipated benefits of treatment***

Despite concerns regarding the appropriateness of GSH, therapists expected (at least some) patients to benefit from low-intensity therapy. It was anticipated that gains might be limited by the nature of therapy. There was a perception that the Wellbeing Course would expose people to a good number of evidence-based strategies, techniques etc. for depression and anxiety; patients would learn something useful but would not benefit from everything covered. Compared with CBT, one therapist thought that patients would pick up fewer skills and techniques and that for this reason, GSH would bring about less symptom reduction. However, in practise, the therapist who held this belief was surprised by the amount of improvement shown by GSH patients.

I was expecting that [in GSH] people would get some sort of psycho-education, that they would pick up some skills, but they may not pick up the spectrum of skills that were offered, that they might kind of find one or two tools that were of value to them. But that over that duration, I probably hadn't anticipated such symptom reduction. (Therapist 03)

## ***Wellbeing Course material***

Therapists' views of the Wellbeing Course material were largely positive: it was perceived as well written and researched; course material was judged suitable for a wide range of people with different abilities. However, there was a concern that there was too much material, too much repetition therein and for some, the material may be patronising - one therapist wondered if it was targeted at a lower level than required.

'Do It Yourself Guides' were rated as particularly helpful; the therapists thought that patients sometimes referred to them because they were a useful summary of material covered elsewhere and could save time reading. There was a suggestion that more examples (stories, case studies) might be included to help people with interpersonal difficulties. Of all of the course components, the therapists were most critical of the additional resources. There was a perception that they were valued less and used less by patients; therapists found it difficult to incorporate the resources into sessions.

What I didn't get a huge sense of was that people made a huge amount or attached much value to the additional resources. They came up a lot less. I would sort of signpost people to them if there were particular issues so, for example, with sleep or – but I do wonder whether those additional resources could potentially be slightly surplus. (Therapist 03)

The therapists also queried the order in which the Wellbeing Course material was delivered. There was a feeling that a different order may have been useful for some as would flexibility to adapt the order for individual patients although the therapist who made this suggestion wondered if changes would influence effectiveness and therefore undermine the basis on which the WB course was administered as a first treatment step.

One other means to improve how the course material was delivered was proposed. One of the therapists wondered if the content could be more explicitly linked to patients' therapeutic goals.

I'm wondering if a more explicit link with goals would have been helpful. We didn't routinely do this, it wasn't required of us, but I

would actually ask people to tell me what they would like to achieve as a result of doing the course... having a little bit more of a motivational framework whereby you could actually link [GSH] to a value or an activity or to something they really wanted to do, get a better job, whatever, may have been helpful. (Therapist 02)

### ***Therapeutic support***

Before the start of the trial, therapists' held different views about conducting therapy by phone. One therapist felt uncertain about supporting patients by phone; for another, phone calls presented no significant problem. Views also changed. Once STEPS was underway, the therapist who had been unsure about phone calls came to view them as sufficient for the type of support she was required to give.

I guess I was kind of, by the time I came to actually start doing the therapy, so we'd had a kind of lead-up, we'd had quite a lot of preparation, so in that time I might have been 'Mmn, I'm not sure about providing therapy by phone'. By the time it actually came to start I was open, curious and willing, and quite happy to have different modes. (Therapist 03)

However, all of the therapists identified limitations of therapy by phone: the absence of non-verbal communication (although this was perceived to be less of a problem in low-intensity CBT than it might have been in other therapies) and the potential for a loss of rapport between the patient and their therapist. Likewise, all of the therapists described benefits: phone calls helped one therapist to distinguish her role as a GSH therapist from that of a CBT therapist; calls were perceived to fit patients' lifestyles; outside of the current study, therapy could be delivered without a physical location (premises) for business.

There's something about it being over the phone that I think, conceptually, was quite helpful for me as I came predominantly from a CBT, face-to-face therapist, that made this distinction, so you aren't a CBT therapist, you're on the end of the phone, you're a Guided Self-Helper. So there was a conceptual thing that was quite helpful,

probably, for me around, 'This is a different form of therapy'.

(Therapist 03)

A small number of factors were described that helped to facilitate calls and thus make them more acceptable to therapists: meeting with the patient face to face at session one; the development of a typical format for calls which meant that they were straightforward to manage; having a limited amount of information about the patient prior to therapy.

With regard to the type of support that therapists were required to deliver by phone, this was perceived to be different to that required in high-intensity CBT. The 'Guided Self Help-er' did not have to gather and interpret information about the patient but was required to help people use and engage with their reading / reflection on that. This had sometimes caused frustration. A therapist who was used to delivering high-intensity therapy had sometimes wanted to cover cognitive techniques in more depth, find out more about people and personalise their treatment.

I found it sometimes, for the more severe individuals, I found it a little bit restricting, frustrating, that I couldn't find out a little bit more, couldn't talk to them a little bit more about, you know, more in depth about some of these techniques that they were learning through Guided Self-Help, but also a little bit more about themselves and how to tailor the programme for them. But I say that as a therapist.

(Therapist 01)

### ***Timings***

Opinions on the length of sessions (thirty minutes) were divided. Some therapists felt that 30 minutes was usually sufficient; others that it was too brief. Therapists mentioned several disadvantages of the brief contact with patients: it did not allow them to incorporate use of the additional resources; difficulties arose around the balance of time spent on how things had been in the last week and looking ahead; clock-watching may have affected therapeutic rapport.

I think the difficulty was how much retro and how much forward planning, you know... how much time do you spend on what they did,

particularly if it was a difficulty or a barrier, versus, I've got to move you on to this week's [material]. (Therapist 02)

I was, in fact, clock watching for some clients, like 'Oh God! Errgh, it's now 23 minutes and this woman's telling me a story'. So yes, I found it a little bit restricting on that end. Not that there's like a, you know, like something's gonna go off and the thirty minutes mark, but obviously yeah, you wanna to keep to the thirty minutes, otherwise if you're going on for forty five, an hour, it's pretty high intensity.

(Therapist 01)

To help limit the impact of such difficulties, there was a feeling that it was very important to set out ground rules regarding the length and nature of sessions so that patients knew what to expect. There was also a sense that once patients got used to the format of sessions, they were straightforward to manage.

The pace of GSH (being sent course material each week) could also be challenging: when patients missed a session, had a difficult week, or found it difficult to do homework this put pressure on the therapist. There was a belief that this was impossible to resolve without greater flexibility. One therapist was initially negative about the total length of GSH; it was assumed that people would need more than six sessions. However this view was ultimately replaced with a perception that six weeks was sufficient. Advantages of the relatively short timeframe described by therapists were: six weeks gave people permission to get what they could out of GSH as well as a sense that they had done well if they could learn and apply something (rather than everything); the total length of GSH was used as an incentive to keep people in treatment when they did not engage in therapy.

The fear if you just don't have that buy-in, you're just not gonna try, we're gonna send you the material, you're just not gonna read it, you're not gonna do the DIY guide etc. So what I've attempted to do when somebody comes in and tells me that is keep encouraging them to try it out, just try it out and we can talk after six sessions or after a few sessions, we'll talk and see what your other options are at that point. (Therapist 01)

One of the therapists doubted the requirement for session six at least for some patients: it wasn't modularised and was short; the purpose of session six was unclear; patients sometimes indicated that they felt ready to end therapy at session five.

### ***Option to have CBT following GSH***

The option to offer patients CBT at the end of unsuccessful GSH helped make stepped care more acceptable to therapists. Therapists were reassured knowing CBT could follow unsuccessful GSH and they felt more comfortable about encouraging patients to stick with GSH. One of the therapists said that it had made him more open-minded to delivering low intensity treatment and less risk-averse knowing CBT could follow; he could be more experimental with patients.

It also gives you, as a therapist, a bit of a cushion, because 'You know what', you say to yourself, 'If they don't do very well on Guided Self-Help, yes, I can stand by the idea that there are other options and this is not something that I'm just saying. This is actually true that there are other options and they can step up and that's fine.' So yeah, so it made me a little bit more – I guess it made me a little bit... less risk-averse I think about just trying out what Guided Self-Help has to offer. (Therapist 01)

### ***Summary – low-intensity therapy***

Therapists' views of low-intensity therapy were described by six sub-themes: appropriateness, anticipated benefits of treatment, the Wellbeing Course material, therapeutic support, timings and the option for patients to have CBT following GSH.

Two therapists initially considered low-intensity treatment inappropriate for some patients but came to see GSH as a useful first step for patients with complex and entrenched difficulties. For patients with severe depression, there remained a concern that GSH would be less effective. The Wellbeing Course material was regarded positively although there was a perception that the Additional Resources may not have been very useful and the therapists wondered if the order of material could be changed; one

of the therapists queried if course content could be more explicitly linked to patients' therapeutic goals. Phone calls presented no major problems. The length of GSH sessions (30 minutes) caused some difficulty but was felt to be manageable and there was a perception that the total number of sessions (six) helped motivate patients although one of the therapists doubted the need for session six for some patients. The pace of sessions (one a week) could sometimes be challenging. The option for CBT to follow GSH made low-intensity therapy more acceptable.

### **6.12.2 Theme two – monitoring**

The theme of 'monitoring' describes therapists' views and opinions of routinely assessing patients' symptoms of depression. It encompasses what therapists thought of the PHQ-9, how scores were used and a specific issue around monitoring anxiety.

#### ***The PHQ-9***

Views of the PHQ-9 were divided. Whilst all of the therapists were comfortable using a symptom checklist to monitor symptoms of depression, two of the interviewees were critical of the PHQ-9. Criticisms included that it asks patients on how many days they have experienced a given symptom in the last fortnight but does not reflect the intensity of symptoms or capture for how long symptoms are experienced on a given day. There was also uncertainty about how well the PHQ-9 would detect change over a seven day period. In addition, the PHQ-9 was thought to be subject to recall bias and insensitive to change because of a lack of range of scores. Practical problems arose in that one therapist found the PHQ-9 repetitive and time-consuming to administer. However, this difficulty was successfully addressed: the PHQ-9 was sent out with Wellbeing Course material for patients to complete prior to phone calls.

I was getting some feedback from people about, you know - 'I still do worry in the evening but it's not four hours any more'. The PHQ-9's not going to pick that up because it's still happening every day. Or, yeah, 'I still have times when I feel worthless, but not half as bad, not half as intensely as I used to.' You won't pick that up with a PHQ-9



'cause it doesn't measure intensity, it's only frequency. (Therapist 03)

Although it's quick and dirty, right, you just – there are nine items... I don't think the range – there's something about seeing your scores really drop versus drop one or two points. (Therapist 01)

Despite finding ways to administer the PHQ-9 that made it more acceptable, one of the interviewees was sufficiently concerned by its limitations to query whether it should be used to decide if patients required further treatment on end GSH. Another therapist advised that he would have chosen an alternative checklist for monitoring.

### ***Using patients' scores***

All of the interviewees were able to describe ways in which they had used patients' scores. Patients' response to item nine was used to help detect risk of suicide and one of the therapists described how he used scores to signpost patients to the additional resources of the Wellbeing Course. More generally, scores were used to mark patients' progress, reinforce success and flag specific problems when symptoms got worse. There was a perception that sharing scores with patients was very important.

### ***Monitoring depression but not anxiety***

Therapists thought that it may have been important to administer the GAD-7 (Spitzer et al., 2006) as well as the PHQ-9. Indeed, one therapist sometimes asked patients to complete both measures. Suggested reasons for monitoring anxiety as well as depression were that patients presented with both disorders; the Wellbeing Course addressed anxiety and depression; information on anxiety and depression was useful to help determine the order in which GSH material should be delivered.

Whilst we're on the questionnaires, though, what I was aware of is the PHQ-9 clocks symptoms of depression and the Wellbeing course very much equally targets anxiety and depression, and I wonder whether actually it would be important to include the GAD, because I

had a lot of people presenting with concurrent anxiety that was a big as or as much of an issue as low mood. (Therapist 03)

### ***Summary – monitoring***

All of the therapists were comfortable using a symptom checklist to monitor patients' symptoms of depression and scores were used in therapy.

However, two of the therapists were highly critical of the PHQ-9. One therapist queried whether it should be used to determine patients' next treatment step following GSH. The therapists also felt that we should monitor symptoms of anxiety as well as depression.

### **6.12.3 Theme three – stepping**

The theme 'stepping' covered what therapist thought of the stepping criteria, how they had applied the criteria in practice and feelings about ending patients' treatment after GSH as well as stepping up patients to CBT. The theme also encompassed views of changing patients' therapist from low- to high-intensity treatment.

#### ***Stepping criteria***

Views of the stepping criteria were largely positive albeit with scope to improve. Therapists thought that the criteria 'got people in the right ballpark' for discharge or step up and that they worked for the majority (around 70%) of patients. However, the criteria were perceived to work less well for one group: patients with low pre-treatment scores (less than 10) on the PHQ9 who were eligible for discharge at the end of GSH without having made much, if any, improvement.

I did face a couple of people, as I was saying earlier that had come in with an initial very low score and didn't really move too much. And I'm like 'OK, is this progress or is this -? I'm thinking of a client, two clients, that showed up with a nine and she ended up with, like, a seven. Which is a clear discharge, but in terms of treatment progress, how much is that? (Therapist 01)

Suggested ways to improve the criteria were: requiring patients with low pre-treatment scores to reduce their scores further; amending the criteria for all to give priority to progress over cut-off; lowering the cut-off at which patients were

recommended for discharge from less than ten to less than five to reduce risk of relapse.

One of the therapists noted that the stepping criteria did not offer guidance on when to step patients 'out' of treatment prior to the end of therapy e.g. where problems were uncovered that may be more appropriate to address in a different service or using a different treatment.

It could well be that actually you see this and you think 'Oh no, this needs, this definitely needs Dialectical Behaviour Therapy, there's sort of personality disorder issues here, why are we doing the Beckian CBT model with them? ... Once they're randomised it's so hard to get them out, you know, you'd rather sort of like keep them in than get them out, then they're in! (Therapist 02)

### ***When to apply the criteria***

One of therapists had felt uncertain about when to apply the stepping criteria. He described how patients' progress and the outcome of treatment were often discussed at the fifth session of GSH as part of relapse prevention planning. Indeed, for patients who responded to GSH, it was often clear by session five that they had made good progress and some patients said that they were ready to end therapy at this point. In such circumstances, the need to wait to apply the stepping criteria was unclear. On the other hand, the same therapist observed that it could sometimes be helpful to administer the stepping criteria at session six. Patients' PHQ-9 scores could sometimes increase between sessions five and six; the decision to step up became clearer.

### ***Discharging patients following low-intensity therapy***

In circumstances where the stepping criteria were applied and led to patients being discharged at the end of GSH, therapists generally felt comfortable with this decision. They observed that patients themselves were often very positive about the progress they had made. However, the therapists were unsure about ending treatment for patients who were at or just below cut-off at session six (and might, therefore, be at increased risk of relapse) and for patients with low pre-treatment scores. The therapists wanted to offer (all) patients follow-up on

end GSH. Offering follow-up was perceived as good practice for any therapy but a priority for GSH.

It's the same sort of thing that I was telling you about earlier, I think, for seventy five percent of the people that I saw it made perfect sense, whatever at the end of treatment, yeah, because they're scoring at a three or a two. For the other people, especially that one case that I'm thinking of, the woman showing up at a nine, discharging at a seven, then I go, 'Oh, I don't know', yeah.

(Therapist 01)

No, I think, yeah, yes, I think it makes more sense at this stage of the game to, especially, if you only had resources to do it [offer follow-up] for one of those people I would do it for the Guided Self-Help people, because we don't know much about it at this stage in terms of relapse. (Therapist 01)

### ***Stepping up***

When patients did not respond to GSH, all of the therapists worried that this would negatively affect patients. Interviewees were concerned that at least some patients would feel upset and as if they had failed. The therapists themselves were also disappointed that GSH had not 'worked' although one therapist observed that he felt less responsible for patients' 'failure' than he might do having delivered other therapies.

There's not so much pressure on the therapist to feel I really didn't work 100% on this because you're reactive as a coach... if you've got someone who you're coaching and, for a football team, but they really aren't a very fast runner, they're not going to make the team, but you don't feel personally responsible for the fact that they don't run very fast! So that lessens the pressure on the therapist or the practitioner, to actually in some way take that responsibility, burden, so much, you know, it's either, well, the course wasn't right for them. (Therapist 02)

Therapists' main concern with stepping up patients was with regard to how they might respond to CBT. There was a suggestion that some patients who stepped up may approach CBT with unhelpful preconceptions. They may not

see the onus being on them to actively engage in treatment or they may not believe in particular skills, for example. Patients who did not engage or do well in GSH were of particular concern given that CBT involved a commitment to 'more of the same' offered more intensively. There was also an assumption that patients who did not engage in GSH might include those with severe symptoms of depression who were vulnerable to a lack of motivation and would therefore be likely to fail in CBT just as they had failed to engage in GSH. The option to provide an alternative to CBT was considered.

Yeah, so if they make a big improvement, but not good enough, within a low intensity treatment may be this person can actually benefit from high intensity, because it's just giving them that extra push. Whereas if somebody is just, you know, kind of hanging around and moderately severe, no change throughout the six weeks, they're doing the work, still no change, I don't know, I don't know if high intensity is the way to go. (Therapist 02)

Often I would say things like, 'What you'll find is that it's exactly – you'll be doing the same sort of Cognitive Behaviour Therapy format, it will be much more intense, it will be more in depth, you'll have to turn up more regularly, there'll be a lot of homework.' And sometimes I would be saying that for them to make another determination whether they wanted it, because if they hadn't done homework very well doing this, what was the point? (Therapist 02)

### ***Changing therapists***

Changing patients' therapist from GSH to CBT was perceived to work well. Therapists identified a number of advantages including that it brought a fresh pair of eyes to someone's problems, patients could make a fresh start, the CBT therapist was not affected by how much the patient did or did not do in GSH, staying with the same therapist would still have required a more detailed patient assessment at the start of CBT which may have felt artificial. A disadvantage of changing therapists was seen as the potential for a loss of rapport.

### ***Summary – stepping***

Although the therapists thought that the stepping criteria worked for the majority of patients, the clinical algorithm was criticised for patients with low pre-treatment scores who made little progress during therapy. The therapists also suggested that the cut-off score at which patients were recommended for discharge might be lowered to less than five to reduce risk of relapse. There was some uncertainty about when to administer the criteria (session five or six) and one of the therapists wanted more guidance on when to end the treatment of patients who may be better served by an alternative. The therapists also wanted to offer a follow-up appointment to all patients who were discharged at the end of GSH. Therapists were concerned that some patients who progressed to CBT may not respond because they did not engage with a low-intensity form of the same treatment. Changing therapists from low- to high-intensity therapy was seen as positive.

#### **6.12.4 Theme four – Cognitive Behaviour Therapy**

The theme ‘Cognitive Behaviour Therapy’ described therapists’ views and experiences of delivering CBT as part of stepped care. It comprised what therapists thought of the connection between GSH and CBT and how they felt about patients ending CBT.

##### ***Connections between GSH and CBT***

In terms of the link between GSH and CBT, therapists felt that neither they nor their patients connected the two treatments. Therapists described how patients saw GSH and CBT as separate and different. There was a view that how STEPS was explained to patients contributed to the lack of connection made between low- and high-intensity therapies.

Patients that are stepping up, it was a little bit strange at some points because, although you think that you can just, you know, refer back to course material because they just kind of know this stuff from the low intensity, I think there’s a bit of a disconnect between this type of treatment and the other type of treatment, so it’s not as seamless as you think it might be. It’s a completely different type of treatment I

think, as it is, you know, it's not advertised to be – more of the same.

(Therapist 01)

Similarly, therapists' own delivery of CBT was not much, if at all, influenced by patients' prior experience of low-intensity therapy. One therapist felt that she had started CBT from scratch; another described asking patients at the start of high-intensity treatment what they had found most engaging in GSH for an idea of what he needed to work on in CBT and how patients might approach it. He did not, however, refer back to patients' GSH relapse prevention plan or to the content of the Wellbeing Course. All of the therapists were interested in the potential to make more and better use of patients' prior experience of GSH.

### ***Ending CBT***

What to do for patients who made little progress in low- and high-intensity treatment evoked different opinions. Where such patients consistently failed to do much work between sessions, one of the therapists was not inclined to keep them in treatment. Based on a Beckian approach to CBT, he had understood eight sessions to constitute an adequate dose of therapy after which other options should be considered.

I'm not sure there is much sense in keeping them in, but under the protocol conditions we actually felt that we had to... Particularly if supervision is saying, you know, you've got to try and get them down to a lower score on the symptom checklist, you'll keep going. And that was one of my confusions. (Therapist 02)

On the other hand, another therapist felt uncomfortable about discharging patients who had made little progress in CBT yet met criteria for discharge. As for GSH, it was suggested that follow up after CBT would be useful though not essential; one therapist felt that booster sessions were sufficient.

### ***Summary – Cognitive Behaviour Therapy***

Therapists felt that neither they nor their patients connected Guided Self-Help and CBT and all of the therapists wanted to make more use of patients' prior experience of GSH in CBT. Views of what to do for patients who made little progress in CBT varied. One therapist felt that it may have been appropriate to

discharge them soon after session eight; another therapist did not feel comfortable about discharging such patients who met criteria for ending CBT.

#### **6.12.5 A summary of the acceptability of stepped care to therapists**

Therapists' views of low-intensity therapy, monitoring, stepping and the delivery of high-intensity treatment in stepped care combine to determine the acceptability of the intervention to therapists. Across all themes, the therapists were supportive but identified ways in which stepped care was less acceptable and could be improved; views and opinions are summarised in Table 31.

***Table 31 overleaf***



Table 31. Summary – the acceptability of stepped care to therapists

Theme	Ways in which stepped care was broadly supported	Ways in which stepped care was less acceptable and could be improved
<b>Low-intensity therapy</b>	<ul style="list-style-type: none"> <li>• Low intensity therapy was seen as appropriate for most patients</li> <li>• Therapists were broadly happy with the Wellbeing Course material and therapy by phone</li> <li>• The duration of individual sessions (30 mins) was manageable</li> <li>• The total length of the course (six weeks) was viewed positively</li> <li>• Offering patients CBT after GSH made GSH more acceptable</li> </ul>	<ul style="list-style-type: none"> <li>• Low-intensity therapy was seen as less appropriate for patients with severe depression and complex problems</li> <li>• Changing the order in which Wellbeing Course material was delivered and the use of Additional Resources may be helpful</li> <li>• Course material could be linked to patients' therapeutic goals</li> <li>• Session six may not be needed</li> <li>• Scheduling a session a week caused difficulty that would not be possible to resolve without greater flexibility</li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>• The use of a symptom checklist to monitor depressive symptoms was acceptable</li> <li>• Therapists used patients' PHQ-9 scores constructively</li> </ul>	<ul style="list-style-type: none"> <li>• The PHQ-9 was heavily criticised</li> <li>• Anxiety should have been monitored alongside depression</li> </ul>
<b>Stepping</b>	<ul style="list-style-type: none"> <li>• Stepping criteria worked for the majority of patients</li> <li>• Changing therapists from low- to high-intensity therapy was viewed positively</li> </ul>	<ul style="list-style-type: none"> <li>• There was some uncertainty about when to apply criteria: session five or six</li> <li>• Stepping criteria did not work well for patients with low pre-treatment scores who made limited progress during GSH</li> <li>• The cut-off score at which patients were discharged could be lowered to &lt;5 to reduce risk of relapse</li> <li>• More guidance would be useful on when to end the treatment of patients who might benefit from alternative support</li> <li>• High-intensity CBT may be unsuitable for patients who did not engage with low-intensity CBT i.e. GSH</li> <li>• Follow-up appointments should be offered to all patients discharged at the end of GSH</li> </ul>
<b>High-intensity therapy</b>		<ul style="list-style-type: none"> <li>• Therapists wanted to make more use of patients' experience of GSH in CBT</li> <li>• There was some uncertainty about how best to support patients who made little progress in CBT: discharge them soon after session eight vs. retain them in treatment</li> </ul>

## **6.13 The relationship between acceptability and attendance**

The results of integrated mixed methods analysis exploring how patients' views of stepped care might help explain variability in the number of treatment sessions they attend are described in sections 6.13.1 to 6.13.3. The analyses provided information on how treatment adherence data varied among patients for whom stepped care was more or less acceptable; the relationship between patients' views of low- and high-intensity treatment and the number of GSH and CBT sessions they attended; how the cross-cutting themes that were identified from the qualitative analysis and that appeared to shape people's views of stepped related to attendance.

### **6.13.1 Attendance and opinion of stepped care**

Table 32 is a joint typologies / statistics display of the number of treatment sessions attended by patients for whom stepped care was more and less acceptable. Data is organised by typologies of the degree to which stepped care was acceptable: the number of sessions attended by patients for whom stepped care was completely unacceptable are presented at the top of the table; the number of sessions attended by patients for whom stepped care was highly acceptable appear at the bottom. Data from patients who described stepped care as less acceptable are presented in rows of a darker shade. Treatment outcome data are included to help appreciate the extent to which views of stepped care and outcomes are confounded but are not referred to in the following interpretation of how acceptability and attendance were related.

The results of this analysis indicate that some patients for whom stepped care was highly unacceptable attended little or no treatment [ID 007 & 023]. Their reasons for declining or dropping out of therapy were treatment-related [007] or treatment-related in part [023]. However, other patients for whom stepped care was highly unacceptable also completed low-intensity treatment [047, 058] and, in one case [047], attended more than the minimum number of eight CBT sessions recommended by the National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2009b).

Some patients for whom stepped care was more acceptable attended a reasonable or very high number of therapy sessions. This was true for a patient

who had mixed feelings about stepped care [028], another patient who enjoyed GSH but not CBT [051], patients who did not like GSH but rated CBT positively [014, 062] and patients who were initially cautious about GSH but ultimately enjoyed it [039, 063]. One other patient for whom stepped care was highly acceptable attended fewer than eight CBT sessions following a complete course of GSH [027]; the patient's decision to drop out of CBT was unrelated to her views of treatment.

***Table 32 overleaf***

Table 32. Joint typologies / statistics display: treatment adherence data for patients for whom stepped care is more and less acceptable

Patient ID	Treatment received	Typology of views	n sessions of GSH	n sessions of CBT	n sessions in total	Reason for dropping out	Change in PHQ-9 <sup>1</sup>	50% improvement <sup>2</sup>
007	GSH alone	Almost / all bad	0	NA	0	Treatment related	NA <sup>3</sup>	NA
023	GSH alone	Almost / all bad	0	NA	0	Treatment related <sup>4</sup>	NA	NA
047	GSH + CBT	GSH & CBT bad	6	15	21	NA	-4	No
058	GSH alone	Anti, stuck with	6	NA	6	NA	-4	Yes
031	GSH alone	Cautious, disengaged	1	NA	1	Treatment / personal	0	No
051	GSH + CBT	(Mostly) liked GSH, anti CBT	6	10	16	NA	-14	Yes
028	GSH + CBT	Mixed feelings throughout	6	14	20	NA	-8	Yes
014	GSH + CBT	Bad GSH, good CBT	5	9	14	NA	-8	Yes
062	GSH + CBT	Bad GSH, good CBT	6	21	27	NA	-4	No
039	GSH alone	Cautious, liked	6	NA	6	NA	-10	Yes
063	GSH alone	Cautious, liked	6	NA	6	NA	-7	Yes
027	GSH + CBT	Good GSH & CBT	6	5	11	Moved location	-10	Yes

Notes: rows are coloured coded by the degree to which stepped care was acceptable to patients – darker shades indicate that stepped care was less acceptable (see Figure 11); <sup>1</sup> 'Change in PHQ-9' is the difference between patients' pre- and post-treatment PHQ-9 scores; <sup>2</sup> '50% improvement' refers to the reduction in depressive symptoms pre- to post-treatment – 'Yes' indicates that scores fell by 50% or more; <sup>3</sup> NA = not applicable; <sup>4</sup> Patient 023 believed that he could return to IAPT for high intensity therapy alone.

### **6.13.2 Attendance and opinion of low- and high-intensity therapy**

The relationship between what patients thought of low- and high-intensity therapy and levels of attendance at each is apparent from the case-oriented display in Table 33. Mini-summaries of what patients thought of GSH and CBT are displayed alongside a plot of the number of high- and low-intensity sessions attended by each patient. The upper half of the table displays data for patients who had GSH alone; the lower half of the table displays data for patients who had GSH and CBT. Patient-related outcome data are included but are not referred to in the following interpretation.

In terms of the relationship between views of low-intensity therapy and attendance at GSH, some patients viewed GSH negatively. Of those, three patients did not attend or attended very few sessions [ID 007, 023, 031; others completed five or six therapy sessions [058, 014, 047, 062]. There was no evidence that the negative views of GSH held by patients who attended more vs. less treatment were markedly different. For example, patients who disliked GSH and attended more but also less therapy were unhappy with phone calls and the Wellbeing Course.

With respect to attendance at high-intensity therapy and views of CBT, patients who had a positive [014, 062], negative [051, 047] and mixed [028] opinion of high-intensity treatment attended more than the minimum number of sessions recommended by NICE (National Institute for Health and Care Excellence, 2009b). Moreover, some patients with a negative or mixed view [051, 028, 047] attended a higher number of CBT sessions than other patients who rated high-intensity therapy positively [027, 014]. One patient [047] attended 15 CBT sessions despite a negative view of both low- and high-intensity treatment. Following unsuccessful GSH, this person had been excited by the prospect of CBT. By comparison, other patients who had a fairly positive view of GSH but disliked CBT [051, 028] attended a smaller number of CBT sessions; they had not been excited at the prospect of CBT.

Table 33. Case-oriented display of number of GSH & CBT therapy sessions attended and patient experience of each treatment

GSH alone patients

ID	Views of GSH	No. of GSH sessions							Views of CBT	Change in PHQ-9 <sup>1</sup>	50% improvement <sup>2</sup>
		0	1	2	3	4	5	6			
007	Negative, I did not like the idea or experience of GSH. The WB course material was not at all relevant to me - I hardly read or used it. I do not like phone calls.	●							NA <sup>3</sup>	NA	NA
023	Negative, I thought I would need CBT but was prepared to try GSH. However, I did not relate to the WB course material or like the idea of phone calls.	●							NA	NA	NA
031	Mostly negative. I did not like the idea of GSH. However, I liked the WB course material although I found it difficult to read and apply. I did not feel well supported by my therapist.		●						NA	0	No
039	Mostly positive. Although I was unsure about GSH I gave it a go. I found that I liked the WB course material. I read around sessions and got used to mind mapping. Sessions were a bit short but having six in total, one a week was fine.							●	NA	-10	Yes
058	Mostly negative, I didn't like the idea of GSH. However, I liked the WB course material although it was difficult for me to read and apply. Phone calls were very difficult. I did not feel well supported. Sessions were too short and the course dragged at the end.							●	NA	-4	Yes
063	Mostly positive. Although I was unsure about GSH, the WB course content was good and I read and used material. Phone calls were good. Sessions were sometimes too short. The pace of therapy and having six sessions in total was fine.							●	NA	-7	Yes
		0			10			20			
		No. of CBT sessions									

Notes: <sup>1</sup> 'Change in PHQ-9' is the difference between patients' pre- and post-treatment PHQ-9 scores; <sup>2</sup> '50% improvement' refers to the reduction in depressive symptoms pre- to post-treatment – 'Yes' indicates that scores fell by 50% or more; <sup>3</sup> NA = not applicable

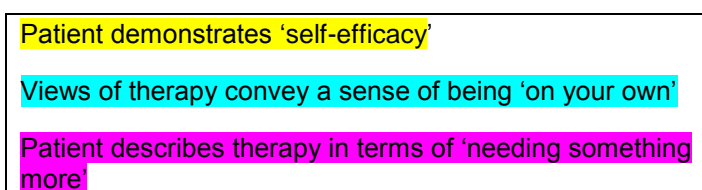
## Patients who had GSH and CBT

ID	Views of GSH	No. of GSH sessions							Views of CBT	Change in PHQ-9	50% improvement	
		0	1	2	3	4	5	6				
(27)	Positive, I was pleased to be offered GSH. I liked the WB course content and read material (more than once). To start I was unsure about phone calls but I found them completely normal. I was well supported. The length of sessions was fine and well-paced although I wanted more than six.			●					●	Positive. I felt that I had failed at GSH and I did not want CBT at first. However, I came to see it as an opportunity. I liked changing therapists and having therapy in person. The length of sessions worked well. Ultimately, I enjoyed CBT – it was better than I expected.	-10	Y
(14)	Negative, although I was pleased to be offered GSH, I did not rate the WB course material. I was too unwell to read and phone calls felt a bit impersonal. I wanted more support – therapy did not feel like therapy. Sessions felt like a chore when I wasn't improving although the pace was fine.				●			●	Positive. I felt that I had failed STEPS by not getting better in GSH. However, I looked forward to CBT and found that I liked it. Having therapy in person was good and I felt well supported. Fifty minutes for sessions worked well.	-8	Y	
(51)	Mostly positive, I liked the idea of GSH. The WB course material was mostly good. I read material to suit me and was well supported. However, I did not like phone calls. The duration of sessions was mostly fine as was the pace.				●			●	Negative. I knew I wasn't ready to stop therapy after GSH but I did not like CBT – I didn't 'get it'. Although I thought changing therapists was positive, I did not have a good relationship with my CBT therapist. I did not feel well supported. It was difficult to schedule sessions. GSH was more useful.	-14	Y	
(28)	Quite positive. I was initially a little uncertain about the offer of GSH. I didn't like the WB course material (it was patronising) but I still read around sessions. I didn't like phone calls to start but then found them OK. I felt well supported. The pace of sessions was mainly OK.					●		●	Mixed feelings. I was fed up after GSH and felt annoyed and dubious about having CBT. However, I was willing to give it a go. I preferred therapy in person to by phone. Elements of CBT were useful but it didn't offer me anything new or help with some of my long standing problems.	-8	Y	
(47)	Negative. I was open to the offer of GSH but did not rate it. I did not like the WB course material (it was patronising). I tolerated phone calls but disliked them. I did not feel well supported. Sessions were too short.						●	●	Negative. After I did not get better in GSH, I was worried that there was something wrong with me and it compounded my loss of faith in professionals. However, I was excited to have CBT. I liked therapy in person but I did not feel well supported. I did not 'get' CBT – it did not offer me anything new / useful. Sessions made me feel bad about myself.	-4	N	
(62)	Mainly negative. I was unhappy to be offered GSH and I disliked the WB course material – I didn't relate to it. I had difficulty reading. Phone calls were convenient but I did not feel well supported. The duration of sessions kept me focused but did not allow me to open up.							●	●	Positive. I was matter of fact about not responding to GSH and positive about having CBT. I preferred therapy in person and felt well supported by my therapist. I liked being given tools for changing things. Sessions were sometimes too short and we had difficult scheduling them.	-4	N
		0			10				20			
		No. of CBT sessions										

### 6.13.3 Cross-cutting themes and attendance

Table 34 is a joint categories / themes display of views of stepped care among groups of patients who attended more vs. less therapy. Views are incorporated with the cross-cutting themes identified from qualitative analysis highlighted (see Box 6 below).

Box 6. Colour coding of cross-cutting themes in the joint categories / theme display



Patient demonstrates 'self-efficacy'  
Views of therapy convey a sense of being 'on your own'  
Patient describes therapy in terms of 'needing something more'

The display illustrates that patients in all but the lowest category of attendance (category A) described ways of thinking about and approaching stepped care that demonstrated 'self-efficacy'. None of the patients in the lowest category of attendance [ID 007, 023, 031] spoke about GSH in a way to suggest that feelings of being responsible for getting better, wanting to help themselves and to be in control of how to do that were uppermost in shaping their views of therapy; responses to GSH were dominated by feeling 'on your own' and (to a lesser extent) 'needing something more'. All of the patients in the lowest attendance category were offered GSH alone and had either declined any treatment or attended one session.

Among patients who completed five or six sessions of GSH (classified in categories B to E) some described ways of thinking about and engaging in stepped care that demonstrated 'self-efficacy' [027, 051, 028, 058, 063, 062]. Others did not [014, 047, 039] suggesting that 'self-efficacy' may have helped to retain some patients in low-intensity treatment but was not necessary for patients to complete all or the majority of GSH sessions.

With respect to high-intensity CBT, two patients with a positive view of treatment attended nine [014] and twenty-one [062] sessions. The views of



patient 062 but not patient 014 demonstrated a degree of 'self-efficacy'. Two patients with a negative view of treatment attended ten [051] and fifteen [047] sessions. A degree of 'self-efficacy' was evident in the approach to treatment by patient 051 but not patient 047. For patients with a positive view of CBT, 'self-efficacy' was associated with increased attendance; for patients with a negative view, 'self-efficacy' was associated with decreased attendance.

***Table 34 overleaf***

Table 34. Treatment adherence data and views of stepped care with cross-cutting themes highlighted arrayed in categories of attendance

Category	ID	Treatment	% sessions attended <sup>1</sup>	n GSH	n CBT	The acceptability of stepped care	View of GSH / CBT
A 0-20% of sessions attended	007	GSH alone	0	0	NA <sup>2</sup>	<b>Unacceptable.</b> I did not want GSH. I disliked the idea of homework and phone calls. I did not relate to the WB course material which was inappropriate for someone my age. I was too poorly to read. I found being monitored unacceptable – I cannot put my emotions into boxes. (007)	<b>Negative GSH</b>
	023	GSH alone	0	0	NA	<b>Unacceptable.</b> I thought I would need CBT but was prepared to try GSH. I did not relate to the WB course material (it was too 'generic' and was not relevant to me). The idea of therapy by phone was unappealing – it felt impersonal. I knew I could get CBT elsewhere. (023)	<b>Negative GSH</b>
	031	GSH alone	16.6	1	NA	<b>Largely unacceptable.</b> I was put off GSH by the idea of homework but prepared to give it a go. Although I liked the WB course content I found it difficult to read and use material. My mum became seriously ill. It did not feel relevant to measure my symptoms of depression. My therapist did not understand. I dropped out due to my mum and work commitments. (031)	<b>Negative GSH</b>
B 21-45% of sessions attended	027	GSH + CBT	42.3	6	5	<b>Highly acceptable.</b> I was pleased to be offered GSH – I wanted to help myself and I liked the idea that I could help myself. The WB course material was good and I read around sessions in a way to suit me. Although I was initially unsure about phone calls they felt OK. I had good therapeutic support – my therapist helped me to use material. I used my PHQ9 scores constructively. When I did not get better after GSH, I felt a failure and did not want CBT but my family and friends helped me see it as an opportunity. I enjoyed CBT. Changing therapists was good. I finished therapy when I moved location. On ending treatment, I was really pleased to have the GSH material and felt confident that I could begin to help myself. (027)	<b>Positive GSH &amp; CBT</b>
C 46-65% of sessions attended	014	GSH + CBT	53.8	5	9	<b>Somewhat acceptable.</b> I was pleased to be offered GSH but did not really like it. The WB course was inadequate given what I needed; I was too poorly to read at home. Phone calls did not feel very personal and I was not well supported by my therapist. I did not mind my symptoms of depression being monitored although I was critical of the PHQ9. When I did not get better after GSH, I felt I had failed STEPS. I was still keen to have CBT and I found that therapy in person was good; I had a good relationship with my therapist. What I learnt in CBT helped. (014)	<b>Negative GSH</b> <b>Positive CBT</b>
	051	GSH + CBT	61.5	6	10	<b>Somewhat acceptable.</b> I was pleased to be offered GSH. I mostly liked the WB course. I read material in a way that suited me. I did not like phone calls but tolerated them. I had good therapeutic support. Sessions were the right length. It was helpful to monitor my depressive symptoms. When I did not get better after GSH, I was not ready to stop. I was happy to change therapists but I did not have a good relationship with the person who took over. I 'didn't get' CBT and was uncertain about its benefits. On end treatment, I refer to the WB course material. (051)	<b>Positive GSH</b> <b>Negative CBT</b>

Notes: <sup>1</sup> % sessions attended = percentage of maximum number of sessions available (6 in GSH, 20 in CBT, 26 for patients who stepped up), attended; <sup>2</sup> NA = not applicable

Category	ID	Treatment	% sessions attended	n GSH	n CBT	The acceptability of stepped care	View of GSH / CBT																				
D 66-85% of sessions attended	028	GSH + CBT	76.9	6	14	<p><b>Somewhat acceptable.</b> I was a little cautious about starting therapy with GSH but willing to try. I didn't relate to the WB course material – it was patronising. All the same, I read around sessions in a way to suit me. I initially disliked phone calls (I thought face to face would be more appropriate) but found them OK. I had good therapeutic support. My therapist helped me to use the material. I understood why my symptoms of depression were monitored and I used my scores constructively although I was critical of the PHQ9. When I did not get better after GSH, I was fed up and frustrated. I felt annoyed and dubious about going on to CBT although I was happy to change therapists. I found that I preferred therapy in person. Elements of CBT were useful but it didn't offer me anything new that could help with my long standing bereavement issues. On ending therapy, I felt better equipped to deal with the day to day. (028)</p> <p><b>Largely unacceptable.</b> I had no opinion about starting therapy with GSH but found that I did not relate to the WB course material (it was inadequate and patronising). I tolerated phone calls but disliked them. Sessions were too short. I was unhappy with my therapist. I responded constructively to my depressive symptoms being measured although I was critical of the PHQ9. When I did not respond to GSH, I worried that there was something wrong with me. It compounded my loss of faith in professionals. Nonetheless I was positive about going on to CBT. I found that I preferred therapy face to face but I did not feel well supported. I did not 'get it' – CBT did not offer me anything new / useful and made me feel bad about myself. (047)</p>	<p>Mixed GSH &amp; CBT</p> <p>Negative GSH &amp; CBT</p>																				
	047	GSH + CBT	80.8	6	15			E 86-100% of sessions attended	039	GSH alone	100	6	NA	<p><b>Largely acceptable.</b> I wasn't sure that GSH would be enough for me (I felt that I needed to off load) but I found I liked it. Some elements of the course material were particularly useful. I read around sessions and benefited from that. Sessions were a bit short. I understood why my depressive symptoms were monitored and responded well to my PHQ9 scores although I was critical of that measure. On ending GSH, I reflect on the WB course material. I have residual difficulties but GSH helped me with specific problems. (039)</p> <p><b>Largely unacceptable.</b> I was disappointed and irritated to be offered GSH (I wanted face to face therapy and thought it would help me more with my problems) but I liked the WB course material. I found it difficult to read. I used material in a way to suit me. Phone calls were very problematic; they weren't enough for me in my state. Sessions were too short. I did not feel well supported. The option of CBT kept me in treatment. I had difficulties being completely honest when filling in the PHQ9 but I responded well to my scores. On end treatment, I go back to course material. (058)</p> <p><b>Largely acceptable.</b> I was disappointed to be offered GSH (I thought I would need face to face therapy and was unsure about relying on myself) but found that I liked the WB course material. I read around sessions in a way that suited me and I was motivated to apply what I learnt. Phone calls were OK. I sometimes wanted a bit more flexibility to focus on my difficulties. Sessions were sometimes too short although six in total was fine. I was concerned that symptoms of anxiety were not monitored alongside depression but I used my PHQ9 scores constructively. I made definite gains as a result of GSH. (063)</p> <p><b>Somewhat acceptable.</b> I did not particularly want GSH; I thought I needed CBT. I did not relate to the WB course material and had difficulty reading. Phone calls were convenient and OK. Sessions were too short to allow me to open up. I wanted more therapeutic support. I was critical of the PHQ9 but responded well to my scores. I saw GSH as a means to access CBT. I felt matter of fact about not getting better and looked forward to CBT. Therapy in person was good and I was well supported. Sessions were sometimes too short. Some elements of CBT were particularly helpful and on end treatment I felt that I had tools to retrain my brain. I would benefit from ongoing support e.g. a personal coach for 2 years. (62)</p>	<p>Positive GSH</p> <p>Negative GSH</p> <p>Positive GSH</p> <p>Negative GSH Positive CBT</p>	058	GSH alone	100	6	NA	063	GSH alone	100	6	NA	062	GSH + CBT
E 86-100% of sessions attended	039	GSH alone	100	6	NA	<p><b>Largely acceptable.</b> I wasn't sure that GSH would be enough for me (I felt that I needed to off load) but I found I liked it. Some elements of the course material were particularly useful. I read around sessions and benefited from that. Sessions were a bit short. I understood why my depressive symptoms were monitored and responded well to my PHQ9 scores although I was critical of that measure. On ending GSH, I reflect on the WB course material. I have residual difficulties but GSH helped me with specific problems. (039)</p> <p><b>Largely unacceptable.</b> I was disappointed and irritated to be offered GSH (I wanted face to face therapy and thought it would help me more with my problems) but I liked the WB course material. I found it difficult to read. I used material in a way to suit me. Phone calls were very problematic; they weren't enough for me in my state. Sessions were too short. I did not feel well supported. The option of CBT kept me in treatment. I had difficulties being completely honest when filling in the PHQ9 but I responded well to my scores. On end treatment, I go back to course material. (058)</p> <p><b>Largely acceptable.</b> I was disappointed to be offered GSH (I thought I would need face to face therapy and was unsure about relying on myself) but found that I liked the WB course material. I read around sessions in a way that suited me and I was motivated to apply what I learnt. Phone calls were OK. I sometimes wanted a bit more flexibility to focus on my difficulties. Sessions were sometimes too short although six in total was fine. I was concerned that symptoms of anxiety were not monitored alongside depression but I used my PHQ9 scores constructively. I made definite gains as a result of GSH. (063)</p> <p><b>Somewhat acceptable.</b> I did not particularly want GSH; I thought I needed CBT. I did not relate to the WB course material and had difficulty reading. Phone calls were convenient and OK. Sessions were too short to allow me to open up. I wanted more therapeutic support. I was critical of the PHQ9 but responded well to my scores. I saw GSH as a means to access CBT. I felt matter of fact about not getting better and looked forward to CBT. Therapy in person was good and I was well supported. Sessions were sometimes too short. Some elements of CBT were particularly helpful and on end treatment I felt that I had tools to retrain my brain. I would benefit from ongoing support e.g. a personal coach for 2 years. (62)</p>	<p>Positive GSH</p> <p>Negative GSH</p> <p>Positive GSH</p> <p>Negative GSH Positive CBT</p>																				
	058	GSH alone	100	6	NA																						
	063	GSH alone	100	6	NA																						
	062	GSH + CBT	100	6	21																						

#### **6.13.4 A summary of the relationship between acceptability and attendance**

Two types of mixed methods analysis were used to explore the relationship between what patients thought of stepped care and therapeutic attendance: a joint display (of typologies / statistics and categories / themes) and a case-oriented display. Key results were that among patients for whom stepped care was highly unacceptable, some attended very few or no therapy sessions whereas others completed treatment. Likewise, in terms of low-intensity therapy, among patients with a negative view of GSH, some declined or dropped out of therapy; others completed treatment. For patients who declined GSH or dropped out early there was no sense of self-efficacy in how they talked about stepped care. Once in high-intensity treatment, patients tended to remain in therapy regardless of their views of CBT; one patient remained in treatment despite a negative view of both GSH and CBT. For patients with a positive view of CBT, self-efficacy was associated with increased therapeutic attendance. However, for patients with a negative view, self-efficacy was associated with decreased attendance.

## **Chapter 6. PART IV**

### **Summary of study findings**

Comprising section:

6.14 A summary of STEPS feasibility study results

## **6.14 A summary of STEPS feasibility study results**

The STEPS study was designed to address five research questions:

(1) What is the quantifiable performance of recruitment and retention methods which may be used in a fully powered trial?; (2) What proportion of people who receive stepped care step up from low-intensity to high-intensity treatment or are discharged following low-intensity psychological therapy?; (3) What is the variability in patient outcomes following stepped care or intensive psychological therapy alone and how do they correlate with patients' baseline scores?; (4) To what extent are potential recruitment methods considered appropriate by trial participants (patients), study therapists and other health professionals and administrators and how do people's views combine with numeric data on the performance of trial recruitment methods?; (5) How acceptable is stepped care to patients and therapists and how do patients' views explain variability in the number of treatment sessions they attend?

Study results were described in Parts I to III of this chapter. Results are summarised in sections 6.14.1 to 6.14.5 with respect to each research question. Implications of the results are discussed in full in Chapter Seven, sections 7.14 and 7.15.

### **6.14.1 The quantifiable performance of recruitment and retention methods (Q1)**

Quantitative data indicated that trial recruitment methods and procedures performed reasonably well. The total number of participants was within the target range and 2.9% of patients approached were recruited. Moreover, the performance of retention procedures was strong. Based on the 95% confidence intervals for the recruitment and retention rates, it is estimated that in a future trial, the randomisation rate would be between 2.2% and 3.5% and the retention rate would be between 83.8% and 97.8%. In terms of a future trial, it may also be possible to obtain a higher participation rate: pilot trial recruitment was negatively affected by finite therapist capacity and a higher recruitment rate may be achieved by increasing the limit of five working days from when patients return a permission form to complete recruitment procedures.

#### **6.14.2 The proportion of stepped care patients who were discharged vs. stepped up (Q2)**

Quantitative data on patient progress through stepped care was collected to help estimate the clinic resource required in a future trial. A third (11/33; 33.3%) of patients received high-intensity CBT; the remainder (22/33, 66.7%) were discharged from treatment following GSH. Based on the 95% confidence interval for the percentage of patients who received CBT, it can be inferred that in a fully-powered evaluation the percentage of patients who would step up from low- to high-intensity treatment would be between 17.9% and 51.8%.

#### **6.14.3 Variability in patient outcomes and how they correlate with baseline scores (Q3)**

The standard deviation of patient scores on the BDI-I (the primary outcome in a future trial) and other continuous outcomes was calculated to inform the sample size calculation for a fully-powered evaluation of stepped care vs. high-intensity CBT alone. An estimate of the correlation between patients' baseline and six-month follow-up scores was made to allow the sample size calculation to be refined to take account of the added precision gained from adjusting for baseline scores when comparing treatment outcomes between the intervention and control groups.

At six months' follow-up, the pooled standard deviation on the BDI-I was 10.0 and the standard deviation on the BDI-I for the stepped care and CBT alone groups was 9.6 and 10.5, respectively. The magnitude of the correlation (calculated using Spearman's Rho) between patients' baseline and follow-up scores on the BDI-I was 0.49 for all patients, 0.44 in the stepped care group and 0.52 in the CBT alone group.

#### **6.14.4 The appropriateness of recruitment methods and procedures (Q4)**

Data on the appropriateness of recruitment was collected from patients, therapists and IAPT staff. Mixed methods analysis was subsequently used to compare qualitative and quantitative recruitment data and point to procedures that could remain unchanged or might be modified in a future trial.

### ***The appropriateness of recruitment to patients and therapists***

Qualitative analysis suggested that recruitment methods and procedures were mostly appropriate to patients and therapists. Although some patients were critical of STEPS study information and had found the prospect of attending a baseline interview after their IAPT assessment difficult, analysis did not reveal any major problem with recruitment. On the other hand, there were a small number of aspects that were considered less appropriate by patients and / or therapists that could be modified in a future trial. Of those, mixed methods analysis underlined that it may be advantageous to respond to patient concerns about the prospect of a baseline interview following an IAPT assessment. Mixed methods analysis also indicated that allowing more than five days from when patients return a permission form to complete recruitment procedures could increase the participation rate but may be unpopular with patients and therapists (as well as IAPT staff).

### ***The appropriateness of recruitment to IAPT personnel***

Although IAPT personnel were supportive of research in general and STEPS in particular, recruitment caused several difficulties for staff and was therefore considered somewhat inappropriate. Difficulties arose out of a concern that some methods and procedures could harm patients whilst others had been practically challenging to implement.

With respect to the potential to harm patients, two issues were particularly troubling: the possibility that patients who were interested in STEPS but returned to IAPT might drop out of treatment and passing on permission forms for patients who may be unsuitable or ineligible to take part. The need to address the concern of IAPT staff regarding patients who return to IAPT was underlined by the results of the mixed methods analysis. In terms of procedures that were practically challenging to implement, several issues were identified around handling patient permission forms. Mixed methods analysis highlighted that it may be advantageous to provide more support around asking patients for their form as this may improve the recruitment rate in a future trial.



#### **6.14.5 The acceptability of stepped care and its relationship with attendance (Q5)**

A large amount of qualitative data was obtained on the acceptability of the stepped care intervention to patients and therapists. In addition, mixed methods analysis was conducted to explore the relationship between the acceptability of the intervention to patients and their attendance at therapy.

##### ***The acceptability of stepped care to patients***

Qualitative analysis of the patient data revealed that there was no single experience or pattern of experiences of stepped care from which it was possible to define acceptability. Stepped care was both highly unacceptable and acceptable to patients with a wide range of opinion in between. Consistent with this interpretation, patients had different views of the high- and low-intensity components and there was no single experience in response to unsuccessful GSH. It was not possible to identify ways in which the stepped care clinical protocol might be modified that would reliably improve patient experience.

##### ***The acceptability of stepped care to therapists***

Despite reservations about the appropriateness of the intervention for some patients, therapists found the stepped care clinical protocol broadly acceptable. Interviewees were largely happy with the Wellbeing Course material, therapy by phone and the timings of GSH; the use of a symptom checklist for monitoring was also acceptable and the stepping criteria were perceived to have worked for most patients. Changing patients' therapist from low- to high-intensity therapy was viewed positively.

Nonetheless therapist experience highlighted several ways in which each core component of the intervention (low-intensity therapy, high-intensity therapy, monitoring and stepping) might be modified. Potential modifications to low-intensity therapy include the option to drop session six of GSH, change the order in which Wellbeing Course material was delivered and reconsider the use of Additional Resources. In terms of monitoring, the use of the PHQ-9 was heavily criticised and it may be advantageous to monitor anxiety alongside depression. The therapists also wondered if the stepping criteria might be modified for patients who met criteria for discharge but had made relatively little

progress and to reduce risk of relapse. All of the therapists wanted to increase the use of patient experience of GSH in CBT.

***The relationship between acceptability and attendance***

Mixed methods analysis of patient data found that there was no simple relationship between the acceptability of stepped care and therapeutic attendance. However, self-efficacy (feeling good about and wanting to be responsible for getting better) had a role in patient engagement. Groups of patients were identified for whom low-intensity therapy was less acceptable that declined or dropped out of therapy vs. remained in treatment. Self-efficacy was also related to patient commitment to high-intensity therapy.

## **CHAPTER 7. DISCUSSION AND CONCLUSIONS**

This thesis aimed to further the development and evaluation of stepped care by conducting a systematic review (Chapter Four) and mixed methods feasibility study (Chapters Five and Six) to prepare for a fully-powered RCT of stepped care vs. high-intensity psychological therapy alone for the treatment of depression in adults.

Specific objectives of the systematic review were to: (1) determine whether existing evidence is sufficient to conclude that stepped care is equivalent to long term, intensive psychological therapy for all; (2) investigate heterogeneity in trial findings by exploring aspects of study design and elements of the intervention that may be associated with more or less effect. Specific objectives of the feasibility study were to: (1) gather enough information on recruitment, retention, step ups and treatment effects to design a fully-powered clinical trial or to determine that such a trial is not feasible; (2) explore patients' and therapists' views of stepped care and the ways in which patients' views relate to how much they engage in therapy to inform a stepped care clinical protocol for a proposed randomised trial. There were five related feasibility study research questions (Chapter Five, section 5.1).

In line with the underpinning methodological framework for this programme of work (Chapter Three) and to conclude, findings from both studies are now discussed in a single chapter. The general discussion is organised as follows. First the reader is oriented to the purpose of the PhD programme of research, what was done and found (section 7.1). Study results are then described with respect to the aim and objectives of the systematic review and each of the five feasibility study research questions (section 7.2). The strengths and limitations of the systematic review are considered in section 7.3, followed by clinical implications (section 7.4) and directions for future research (section 7.5). The strengths and limitations of STEPS feasibility study, directions for future research and clinical implications are subsequently described in sections 7.6 to 7.8. The chapter ends with a brief description of the key conclusions that have arisen from my doctoral programme of work (section 7.9).

Sections 7.3 to 7.5 incorporate material that has previously been published in the report of the original systematic review (van Straten et al., 2014).

## **7.1 Overview of thesis**

This thesis assessed evidence on the effectiveness of stepped care for the treatment of depression in adults. Relative to care as usual, stepped care was found to improve depression in the short and medium term however there was insufficient evidence to establish whether stepped care is equivalent to high-intensity psychotherapy for all. This led to a mixed methods feasibility study in preparation for a fully-powered RCT of stepped care vs. high-intensity psychological therapy alone. Data were collected to assess the feasibility and appropriateness of pilot trial recruitment and retention, the acceptability of the stepped care intervention and how patient experience related to attendance. Data were also collected to estimate the sample size and clinic resource needed in a future trial.

The performance of retention procedures was strong and recruitment methods and procedures worked reasonably well with scope to improve the participation rate and the appropriateness of recruitment to IAPT staff. The stepped care intervention was broadly acceptable to therapists and, although no single experience defined patient acceptability, self-efficacy was found to have a role in patient engagement. Several ways to modify the clinical protocol were apparent from therapist experience. Data on the variability in patient outcomes, the correlation between patient baseline and follow-up scores and the proportion of stepped care patients who step up (33%) are now available to estimate the sample size and clinic resource needed in a future trial.

## **7.2 Summary of results**

### ***The effectiveness of stepped care***

The aim of the systematic review was to assess the clinical effectiveness of stepped care treatment for depression in adults. Twenty-one RCTs involving 6364 patients were included. The results of primary analyses demonstrated that stepped care is more effective than usual care for the treatment of depression immediately after treatment (Cohen's  $d=0.40$ ) and in the medium term ( $d=0.36$  at six to nine months). The quality of included studies was good and there was little evidence of publication bias.

### ***Stepped care vs. high-intensity therapy alone***

The systematic review also addressed a specific objective to determine whether there is sufficient evidence to establish the equivalence of stepped care and high-intensity psychological therapy alone. Meta-analyses exclusively compared stepped care and care as usual. There was insufficient evidence to establish whether stepped care is equivalent to long-term intensive psychological therapy for all.

### ***Extent of heterogeneity***

The second objective of the review was to assess heterogeneity by exploring aspects of study design and elements of the intervention that may be associated with more or less effect. Considerable clinical and methodological heterogeneity was observed in terms of participants, interventions and study design. Sub-group analyses found that the effect of stepped care treatment based on no clear intensity order ( $d=0.40$ ) was significantly greater than the effect of stepped care defined by increasing intensity ( $d = 0.15$ ,  $p<0.01$ ).

### ***Performance of recruitment and retention methods***

The results of the systematic review led to a mixed methods feasibility study to prepare for a fully-powered trial of stepped care vs. high-intensity psychological therapy alone. As part of this study, quantitative data were collected to evaluate the performance of pilot trial recruitment and retention methods. Recruitment methods performed reasonably well. The target number of participants was recruited and the participation rate was 2.9%. Based on the 95% confidence

interval for this parameter, it was estimated that in a future trial the randomisation rate would be between 2.2% and 3.5%. Although this level of recruitment may be acceptable, numeric data also indicated that it may be possible to obtain a higher recruitment rate. The performance of retention procedures was strong.

### ***Stepping rate***

The feasibility study also addressed a specific research question to establish what proportion of people who receive stepped care step up from low- to high-intensity treatment. A third of patients who were offered stepped care progressed from low- to high-intensity therapy. Based on the 95% confidence interval, it was estimated that between 17.9% and 51.8% of participants in a future trial would step up.

### ***Variability in outcome and correlation with baseline data***

A separate feasibility study question concerned the variability in patient-related outcomes following stepped care or intensive psychological therapy alone and the correlation between patient baseline and follow up data. The pooled standard deviation of patient scores on the BDI-I (the primary outcome in a future trial) at six months was 10.0. Equivalent figures for patients in the stepped care and CBT alone groups were 9.6 and 10.5. The magnitude of the correlation between baseline and follow-up BDI-I data was 0.49 for all patients, 0.44 in the stepped care group and 0.52 in the CBT alone group. This information can now inform the sample size calculation for a future trial.

### ***Appropriateness of recruitment***

As part of the feasibility study, semi-structured interviews were conducted to assess the appropriateness of pilot trial recruitment methods and procedures. Analysis revealed that methods were largely appropriate to patients and therapists but much less appropriate to IAPT staff. Difficulties for IAPT staff arose out of a concern that some procedures could harm patients whilst others had been practically challenging to implement. Qualitative and mixed methods analysis highlighted ways in which recruitment could be modified to improve appropriateness to IAPT staff and to counter a smaller number of patient and therapist concerns.

### ***Acceptability of stepped care***

Semi-structured interviews also explored the acceptability of the stepped care intervention to patients and therapists. There was no single experience or pattern of experiences to define acceptability to patients and, consistent with this interpretation, it was not possible to identify ways in which the intervention could be modified that would reliably improve how it was received. On the other hand, despite reservations about the suitability of stepped care for some patients, therapists found the intervention broadly acceptable. In addition, therapist experience identified several ways in which each of the core components of the stepped care clinical protocol (low- intensity, high-intensity treatment, monitoring and stepping) could be modified that might improve the degree to which it is considered acceptable.

### ***Acceptability and attendance***

STEPS feasibility study addressed a specific mixed methods question on the relationship between patient experience and attendance. There was no simple relationship between acceptability and attendance however self-efficacy had a role in patient engagement. Groups of patients were identified for whom low-intensity therapy was less acceptable than either declined or dropped out of therapy vs. remained in treatment. Self-efficacy was also related to patient attendance at high-intensity therapy.

### **7.3 Strengths and limitations of the systematic review**

A key strength of the original systematic review was that it was the first to describe all available RCTs on stepped care treatment for depression in adults. However, the included number of studies was small (n=14). Although the updated review included a larger number of studies (n=21), only two thirds were suitable for meta-analysis. Other system-level interventions for improving mental health in primary care have been evaluated a good deal more; a recent Cochrane review of collaborative care for depression and anxiety included 79 RCTs (Archer et al., 2012). The small number of studies made it difficult to perform sub-group analyses and, combined with substantial levels of clinical and methodological heterogeneity, might limit the degree to which results can be considered to generalise.

#### **7.3.1 Setting and participants**

The majority of the included studies were conducted in the US and the Netherlands; three were conducted in developing countries (Araya et al., 2003; Oladeji et al., 2015a; Patel et al., 2010). One of the three (Araya et al., 2003) had a very high effect size (0.9). Although the results of sub-group analyses found no significant difference in the effect of stepped care delivered in different countries, given the limited evidence base and the influence of one study with a high effect size, the main findings of meta-analyses on the effectiveness of stepped care for the treatment of depression in adults may need to be interpreted with more caution when considering less developed nations.

Research into stepped care has been conducted on patients with diverse disorders. In addition to depression, some of the included studies recruited participants with other mental health problems (typically anxiety) and physical health conditions (Acute Coronary Syndrome, diabetes, cancer or visual impairment). Clinical diagnosis of depression was not necessary and a wide range of depressive symptoms and/or disorders (sub-threshold, minor and major depression) were included.

To apply an argument made by Archer et al. (2012) in the review of collaborative care, studies of patients that use diagnostic criteria to determine eligibility are often prioritised over those that use self-report outcome measures



or clinician judgement, particularly as evidence-based guidelines often exclude the latter from their reviews of the literature. However, whilst positive effects may be more likely when interventions target a specific diagnostic group (Roth & Fonaghy, 2005), studies where interventions are offered based on levels of symptoms rather than clinical diagnosis may be more representative of routine practice (Archer et al., 2012).

### **7.3.2 Definition and implementation of stepped care**

As originally defined, stepped care refers to the organisation of successive treatments in terms of increasing intensity (Davison, 2000). Whilst the concept of intensity readily applies to psychological therapies, it is difficult to characterise pharmacological (and perhaps physical treatments) as intensive or otherwise. Nonetheless studies of stepped care, explicitly labelled as such, frequently encompass medication and implement a version of this system that is not organised by progressive intensity: at each step, patients switch or add treatments of different modalities (pharmacological, psychological); patients may start with intensive psychotherapy (Araya et al., 2003; Ell et al., 2008; Katon et al., 2004).

Given the importance pharmacotherapy in the treatment of depression and the number of trials of stepped care defined in this way, inclusion criteria were set to permit studies of stepped care defined by progressive intensity and more than one treatment modality. Although this was considered the most comprehensive definition of stepped care reflecting current clinical practice, it led to substantial variation in what was delivered as part of the intervention. Several studies were included that evaluated stepped care combined with collaborative care [studies 2, 7, 8, 10, 11]. Among the fourteen studies included in meta-analyses, five evaluated stepped care defined by progressive intensity [11, 12, 15, 16, 18] and nine evaluated stepped care that was in no clear intensity order [2, 4, 5, 7-10, 13, 17]. Our decision to include studies of stepped care defined by different treatment modalities is debateable: findings based on one definition of stepped care may not generalise to the other; in studies of stepped and collaborative care it is impossible to assess the value of each intervention; other researchers may choose to review or conduct future research on stepped care in line with how it was originally conceived.

The delivery of stepped care also varied in many other respects. In terms of providers, some studies included just one or two healthcare professionals whilst others included a team of three, four or five personnel. Treatment was provided by less and more qualified staff: residential home staff, study researchers, lay health counsellors vs. psychiatrists, GPs and psychologists. There was variation in the number of treatment steps (between two and four), duration (14 weeks to 12 months), stepping criteria (measures, cut-off scores and reference to improvement) and in the delivery of the same treatments across different studies e.g. a watchful waiting period that ranged from two weeks to three months. Variation in the delivery of stepped care complicates the interpretation of results.

### **7.3.3 Stepped care for the prevention of depression**

Five of the included studies evaluated stepped care for the prevention of depression; four evaluated stepped care for indicated prevention, one for relapse prevention. Results were mixed. Promising results reported in three studies conducted in the US and Europe were not replicated elsewhere (De Xing Zhang et al., 2014). Although it has been argued that prevention has potential to contribute most in reducing the global burden of depression (Cuijpers, Beekman, & Reynolds, 2012), the size of the evidence base currently precludes a conclusive interpretation of the potential benefits of stepped care for the prevention of depression - in any country.

### **7.3.4 Usual care comparator**

All of the included studies except for one compared stepped care with treatment as usual. A limitation of this review is that the implementation of usual care varies and included studies did not clearly describe key elements. Usual care sometimes included a level of enhancement (training and education of primary care physicians, informing patients of their depression scores, distribution of treatment guidelines for practitioners and educational material for patients). Evidence for these interventions delivered in isolation is limited (Bower & Gilbody, 2005a) but they could result in a lower treatment effect (Archer et al., 2012).

### **7.3.5 The design of included studies**

Although most studies were patient randomised, four used cluster randomisation, all of which were included in meta-analyses. Cluster trials are recommended for testing system-level interventions (Ukoumunne, Gulliford, Chinn, Sterne, & Burney, 1999) avoiding 'contamination' across the control and intervention groups when patients are managed in the same setting. However, one of the main consequences of a cluster design is that participants in any one cluster tend to respond in a similar manner. As a result, their data can no longer be considered independent. Many cluster trials fail to allow for this in their analysis and studies in which clustering is ignored result in artificially narrow confidence intervals that, in the context of a meta-analysis, afford them more weight than is appropriate (Higgins, Deeks, & Altman, 2010).

All of the cluster trials in the review provided an estimate of effect from an analysis that was reported to properly account for the study design. However, cluster trials also generally require larger patient samples and may be vulnerable to other sources of bias (selective patient recruitment after cluster randomisation, baseline imbalance, loss of clusters) (Higgins et al., 2010). As such, effect sizes may have been over- or underestimated. Sensitivity analyses to explore the pooled effects of stepped care excluding cluster trials were not performed but will be included in the published update of the original review.

### **7.3.6 Quality of the evidence**

Data from a relatively small number of studies were included in the review, producing estimates of the effects of stepped care that lacked precision. Ninety-five percent confidence intervals around estimates of the effect at all points were wide, most notably in the short- (2-4 months) and long-term (18 months).

There was also substantial statistical heterogeneity. In the review update, the value of the  $I^2$  statistic for the effect of stepped care immediately after treatment estimated using the average (combined) effect in each individual study was 77%; 'substantial' according to recommended criteria (Deeks et al., 2008). At six to nine months it was 59% indicating 'moderate' heterogeneity (Deeks et al., 2008). Random-effects models were used in all analyses as, in contrast to

fixed-effects models, random-effects meta-analysis does not assume that all studies are estimating the same intervention effect (see also Chapter Four, section 4.2.2).

Risk of bias assessment identified two studies [that were at high or unclear risk on the majority of criteria suggested by the Cochrane Handbook (Higgins & Altman, 2008)]. Both studies were excluded from meta-analysis. In the remaining trials, most criteria were rated at low risk of bias indicating that the large majority of studies were of good quality. Estimates of effect from high-quality studies of psychotherapy for adult depression have been found to be smaller than estimates obtained from lower-quality studies (Cuijpers, van Straten, Bohlmeijer, Hollon, & Andersson, 2010).

Although studies were unable to blind patients or study personnel (clinicians) and may be susceptible to bias in this regard, this reflects the reality of conducting complex intervention trials in practice; blinding is not always possible (Centre for Reviews and Dissemination, 2008; Higgins & Altman, 2008). Risk of bias with respect to blinding of outcome assessors was rated as low; the majority of studies used self-report outcome data. As estimates of the effect of psychotherapy on depression in adults from self-report data have been found to be lower than those calculated using data obtained from clinician rated instruments (Cuijpers, Li, Hofmann, & Andersson, 2010), this may have led to a relatively conservative estimate of effect in the current review.

There was little evidence of publication bias from funnel plots and Duval and Tweedie's trim and fill procedure (Duval & Tweedie, 2000). However, we did not search 'grey literature'. Adding unpublished studies to published studies of psychological treatment for depression has been found to reduce effects (Driessen, Hollon, Bockting, Cuijpers, & Turner, 2015). It is possible that a more comprehensive search of the literature would result in a reduced estimate of the effect of stepped care.

### **7.3.7 Other potential biases in the review methods and procedures**

Sub-group analyses investigated differences in the effectiveness of stepped care by country, type of stepped care (IMPACT based, yes / no; progressive intensity, yes / no), physical health comorbidity and diagnostic status at

inclusion. Sub-group analyses were not conducted for other methodological and clinical factors that may have had a bearing on outcome and for which data were extracted e.g. randomisation (cluster / individual), control (enhanced usual care vs. usual care) or for which we were unable to extract data (e.g. proportion of patients who stepped up).

Exploration of the impact of different variables on the effects of stepped care would benefit from a multivariate approach such as a meta-regression analysis. Unlike sub-group analyses, this could assess the relative importance of a series of factors on the effect of stepped care but would require extensive imputation of missing data. However, the results of a meta-regression would still need to be interpreted with caution. Meta-regression and sub-group analyses are entirely observational in nature. Results are subject to confounding and susceptible to aggregation bias (where differences on a factor of interest that are observed within a single study are no longer apparent by looking at effects associated with the 'average' of that factor across several studies) (Deeks et al., 2008).

The effects of stepped care were studied at different time points using time from randomisation. Included interventions were sometimes delivered over several months (up to one year). Long term effects (at 12 months and beyond) do not entirely reflect persistent effects of the intervention but will encompass the short-term effects of longer interventions. In the original review, the estimate of the effect of stepped care at 18 months was based on one comparison. Estimates of the long term effect of stepped care need to be interpreted with caution.

### **7.3.8 Agreement and disagreement with other reviews**

Only one other published review has examined the effectiveness of stepped care treatment for depression in adults (Firth, Barkham, & Kellett, 2015). Unlike the current review, this review was not limited to RCTs; included studies were both controlled and uncontrolled. Estimates of the effect of stepped care in the current review obtained from randomised controlled trials alone are at lower risk of confounding and thus more trustworthy.

Although Firth et al mainly used a narrative synthesis to examine outcomes, the standardised mean difference between stepped and usual care was estimated for five RCTs: Araya et al. (2003), Davidson et al. (2010), Ell et al. (2008), Patel et al. (2010), Seekles et al. (2011). Across studies, the median effect size was  $d=0.41$ . This figure was similar to estimates of effect immediately after treatment and at six months in the current review. As all five of the studies for which Firth et al. calculated an effect size were included in meta-analyses in the current review, this might be expected.

## **7.4 Clinical implications of the review**

### **7.4.1 Magnitude of effect**

Although this review has provided reasonable evidence of the effectiveness of stepped care treatment vs. usual care for improving depression outcomes, the clinical relevance of the magnitude of the effects is more difficult to interpret. The size of the effect immediately after treatment ( $d = 0.38$ ) and at six to nine months ( $d = 0.35$ ) was modest according to current conventions (Cohen, 1988; Lipsey, 1990). Moreover, to draw on an argument developed by Archer et al. (2012), although there is a lack of consensus on 'minimally clinically important differences' in mental health, a standardised mean difference of 0.5 has previously been adopted as a criteria in the UK; effects observed in the current review are less than this.

However, the benefits of stepped care treatment for adult depression are similar to those reported for collaborative care (effect size 0.34 from 30 comparisons) (Archer et al., 2012), psychological therapies in general (provided in both low and high intensity forms; effect size 0.42 from 175 comparisons) and for individual CBT (excluding GSH; effect size 0.41 from 41 comparisons) (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010). The majority of meta-analyses of low-intensity psychotherapy also demonstrate comparable effects (range 0.42 to 0.56) (Bower et al., 2013; Gellatly et al., 2007; Richards & Richardson, 2012).

One meta-analysis of low-intensity treatment reported a greater effect size (0.88 across 22 studies) (Andrews et al., 2010). Included trials were limited to those of patients who met diagnostic criteria for depression and / or anxiety. Results

of individual patient-data meta-analysis have found that patients in receipt of low-intensity treatment who are more severely depressed demonstrate larger effects than those who are less severely depressed (although the magnitude of the interaction is small) (Bower et al., 2013). Greater effects of self-help treatment have also been demonstrated in patients with an existing problem compared with those at risk for depression (Gellatly et al., 2007). The higher effect size reported by Andrews et al. (2010) may reflect the patient population included in that study.

#### **7.4.2 Progressive intensity vs. no clear intensity order**

The National Institute for Health and Care Excellence (NICE) currently recommends a stepped care framework for the management of depression in adults that is defined by increasing intensity (National Collaborating Centre for Mental Health, 2010), albeit with the option to stratify patient care initially. In this review, greater effects were demonstrated for stepped care of no clear intensity order ( $d = 0.40$ ) than for models of increasing intensity ( $d = 0.15$ ). In models of no clear intensity order, at each step, patients switched or added treatments of different modalities (psychological, pharmacological). The result implies that it may be more effective to treat depression using a clinical algorithm that explicitly encompasses medication and psychotherapy than by offering patients low- and then high-intensity psychological therapy.

Evidence to support this conclusion is weak. As noted above, sub-group analyses are observational in nature and at risk of aggregation bias. Moreover, in the updated review, only three studies evaluated stepped care of progressive intensity and seven of the nine studies that evaluated stepped care of no clear intensity order were based on the IMPACT model. The effects of stepped care in studies that were IMPACT and non-IMPACT based were similar. This means that the difference in the results between the two sub-group analyses (IMPACT - yes/no; increasing intensity - yes/no) was based on two studies [IDs 2 & 17], one of which had a very large effect size (0.84 at six to nine months). At present, there is insufficient evidence to conclude with any degree of certainty that stepped care models of no clear intensity order are more effective than stepped care defined by increasing intensity.

### **7.4.3 Combined pharmacotherapy and psychotherapy in stepped care**

The majority of studies in the systematic review, including trials that evaluated stepped care models of psychological therapies organised by increasing intensity, incorporated medication alongside psychotherapy as part of the stepped care intervention. However, fewer studies implemented a version of stepped care where patients received pharmacotherapy and psychological treatment at the same time; combined treatment was not often incorporated in step one. Meta-analysis has demonstrated superior effects for combined pharmacotherapy and psychological treatment vs. pharmacotherapy alone where the magnitude of the difference was moderately large and clinically meaningful in favour of combined treatment (Cuijpers et al., 2014). Results also suggested that the effects of psychotherapy and pharmacotherapy were largely independent of each other, with both contributing about equally to the effects of combined treatment (Cuijpers et al., 2014). Based on these results, it is suggested that the role for pharmacotherapy and psychotherapy in stepped care may yet require further consideration. Patients are likely to be interested in the advantages of combined treatment when considering how they engage in stepped care.

## **7.5 Directions for future research following the systematic review**

### **7.5.1 A fully-powered evaluation**

Evidence for the effectiveness of stepped care treatment for depression relative to usual care is increasing. Seven new studies were included in the updated review, six of which compared stepped care with usual care. Yet comparisons of stepped care and usual care do not establish the effectiveness of stepped care compared with the system that it was designed to replace: long-term, intensive psychological therapy alone.

The clinical effects of CBT in the treatment of adult depression are well established, if over-estimated (Cuijpers, Berking, et al., 2013; Cuijpers, Hollon, et al., 2013; Cuijpers, Smit, et al., 2010). However, providers of publicly-funded and private healthcare systems must balance clinical effects with costs of treatment. To repeat an argument introduced in Chapter Two, as an alternative to long-term intensive CBT, stepped care is assumed to deliver similar patient



benefit for less cost. In a publicly funded healthcare system, providing high-quality depression treatment at less cost may enable more people to access care. Although stepped care has been widely implemented on this basis, the results of the systematic review confirm that the equivalence and efficiency of stepped care vs. high-intensity therapy alone have not been tested.

To determine if stepped care delivers treatment that is equivalent in clinical effect but more efficient compared with the traditional provision of psychological therapies, a rigorous evaluation of the effectiveness of stepped care vs. intensive psychological therapy alone is still required. An appropriately powered, non-inferiority randomised controlled trial of stepped care encompassing psychotherapies of increasing intensity compared with intensive CBT alone is recommended; cost-effectiveness analyses should be incorporated.

### **7.5.2 Other areas for future research**

#### ***Reporting standards***

The central tenet of stepped care on which the assumption of increased efficiency rests is that for many patients, low-intensity treatment is sufficient. In the current review, a limited number of trials provided data on the proportion of patients recovered after step one treatment. Data that were available were difficult to interpret. Stepping criteria varied between studies as well as the number of patients who dropped out of treatment. The number of patients who met criteria for progression and the actual percentage who accepted additional treatment were not reported. This is important information within stepped care as there is a risk that some patients choose not to start a second high-intensity treatment after failure of the first. Minimum reporting standards for stepped care trials are recommended. Data to include in the report of a clinical trial on stepped care for depression are listed in Box 7.

#### ***Box 7 overleaf***

## Box 7. Recommended reporting standards on stepped care

<p><b>Data to include in the report of a clinical trial on stepped care for depression</b></p> <p>Number of patients in stepped care and control group(s) Drop out prior to step one and between steps (n, %) Number, % of people discharged from treatment at each step Number, % of people stepping up to subsequent steps</p> <p><b>For each step:</b> N treated Health care professionals involved Training and education provided to deliver clinical protocols Treatment received</p> <ul style="list-style-type: none"><li>• n patients in receipt</li><li>• dose e.g. n sessions of psychological therapy (mean, SD)</li><li>• duration e.g. n weeks (mean, SD)</li></ul> <p>Drop out of treatment during specific step (n, %) Patient outcomes on end of each treatment step</p> <ul style="list-style-type: none"><li>• n patients' health status assessed</li><li>• depressive symptoms (mean, SD, n in analysis)</li><li>• n, % recovered or improved with definition of recovery / improvement specified</li></ul> <p><b>Stepping criteria:</b> Measure Frequency and timeframe of assessment Definition of improvement / recovery required to end treatment or to step</p> <p><b>For the control group:</b> Number treated Treatment received (detail as above) Treatment drop out (n, %)</p>
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### ***Further research to identify elements of stepped care associated with more and less effect***

Exploration of the moderators and mediators of stepped care (Kraemer, Wilson, Fairburn, & Agras, 2002) could provide a better understanding of who is most likely to benefit from stepped care and the elements of the model associated with more and less effect. A process evaluation should be incorporated in a fully-powered trial of stepped care compared with high-intensity psychological therapy alone. Prior to a fully-powered evaluation, meta-regression analysis might be undertaken to assess the relative importance of a series of factors with potential to influence the effectiveness of stepped care.

### ***Testing stepped care defined by increasing intensity vs. stepped care of no clear intensity order***

Sub-group analyses indicated that stepped care of no clear intensity order may be favourable compared with stepped care of increasing intensity but results

were in no way conclusive. Going forward, stepped care involving pharmacological and psychological treatments will remain important. The advantages of combined anti-depressant medication and psychotherapy may not yet have been realised in stepped care clinical protocols. An appropriately powered, non-inferiority RCT of stepped care for depression defined by increasing intensity versus stepped care involving different treatment modalities is recommended that should also consider the role for combined treatment in both.

### ***Evaluation of stepped care for the prevention of depression***

As already noted, five of the twenty-one studies included in the current review evaluated the effectiveness of stepped care for the prevention of depression. Given the potential importance of prevention in reducing the global burden of depression (Cuijpers, Beekman, et al., 2012), additional RCTs to compare stepped care with other treatment for the prevention of depression are also recommended.

### ***A randomised controlled trial of stepped vs. matched care***

A large RCT of stepped care vs. CBT alone would establish the effectiveness of stepped care treatment compared with the system that it was designed to replace however NICE (2010) has recommended the conduct of a fully-powered trial of stepped vs. matched care. Also referred to as *personalised medicine*, matched care involves selecting the best treatment available treatment for a given individual (Simon & Perlis, 2010). As such, it requires that individual differences that predict differential response to different treatments are known and can be combined for clinical decision making (Huibers et al., 2015).

At the time of the original systematic review of stepped care, the development of personalised medicine for the treatment of depression had only just begun (Cuijpers, Reynolds, et al., 2012). Yet within the last two years, DeRubeis et al. (2014) developed a method for integrating predictive information that, applied retrospectively, was able to identify an optimal treatment for patients that when received would have led to superior clinical outcomes (DeRubeis et al., 2014; Huibers et al., 2015). This method, known as the *Personalised Advantage Index (PAI)*, holds great promise for matched care but will need to be tested

prospectively (DeRubeis et al., 2014; Huibers et al., 2015). If the results of prospective research yield similar effects to that obtained from the retrospective application of the PAI, this method could rival and potentially out-perform stepped care as a system for the organisation of treatment for depression. Once the results of prospective studies are known, a non-inferiority randomised controlled trial of stepped care for depression compared with a matched care control utilising the PAI should be undertaken to determine the relative clinical and cost-effectiveness of both.

***Section 7.6 overleaf***

## **7.6 Strengths and limitations of the feasibility study**

Following the results of the systematic review, STEPS provided robust and relevant evidence on the feasibility of a fully-powered RCT of stepped care compared with intensive psychological therapy alone. The strengths and weaknesses of this study are now described followed by directions for future research and clinical implications.

### **7.6.1 Study design**

The aim, specific objectives and research questions of STEPS were commensurate with the definition of a feasibility study provided by the National Institute for Health Research Trials and Studies (2015) and endorsed by Arain and colleagues (Arain et al., 2010). Key clinical, methodological and procedural uncertainties associated with the conduct of a large trial were addressed using appropriate quantitative, qualitative and mixed methods. Results support inferences about the suitability of a stepped care clinical protocol and pilot trial methods and procedures for a fully-powered evaluation. Findings have been described in line with guidelines for reporting the results of feasibility studies (Thabane et al., 2010).

### **7.6.2 Methodological framework**

A key strength of the feasibility study is its clear and explicit commitment to mixed methods. The study has been described in line with recommendations for Good Reporting of a Mixed Methods Study (O'Cathain, Murphy, & Nicholl, 2008). Key decisions on the level of interaction, priority, timing and mixing of the quantitative and qualitative strands were reached. This was reflected in the implementation of an embedded mixed methods study design (Creswell & Plano Clark, 2011). Techniques for integrated mixed methods analysis were also incorporated in new ways that have the potential to extend and strengthen how mixed methods are typically utilised in Health Services Research (see also section 7.7.5).

### **7.6.3 Quantitative components**

#### ***Precision of key parameters of interest***

Quantitative data were collected on recruitment, retention and treatment. Margins of error associated with the recruitment rate, retention rate and the variability in the primary outcome (for a future trial i.e. BDI-I) were similar to or less than the margins of error for the same parameters associated with the recruitment of 75/1500 and 60/2000 people. Margins of error associated with the recruitment of 75/1500 and 60/2000 people were considered acceptable for the purpose of this study (J. J. Hill et al., 2014). Key parameters have thus been calculated with an acceptable level of precision to help determine feasibility and the sample size required for a fully-powered evaluation.

#### ***Primary outcome in large trial***

Quantitative outcome data were collected at six months post-baseline. Treatment was designed to last up to 24 weeks. However, 15% (10/66) of patients provided follow-up data prior to the completion of treatment. Of those, one patient completed treatment at 11 months post-baseline; the remainder completed treatment within nine months of randomisation. In a fully-powered evaluation, the primary outcome may need to be collected at 12 months post-baseline to ensure that all patients had completed treatment although data collection at nine months may obtain post-treatment data from the large majority of interviewees. Data on retention, variability in treatment outcomes and the correlation between baseline and follow-up scores collected at six months may not be an accurate estimate of retention, variability and correlations at a later time point.

#### ***IAPT treatment received by non-participants***

IAPT personnel were concerned that patients who were sent study information and returned a 'permission' form but did not join STEPS would subsequently drop out of IAPT treatment. Although IAPT routinely collect data on the treatment received by patients who are referred to their service, we did not have ethical approval to obtain and analyse this information. We do not know, therefore, how many patients dropped out of IAPT therapy after they did not

take part in STEPS. This information is not available to help respond to the concerns of IAPT staff.

#### **7.6.4 Qualitative components**

##### ***Number of patient interviews***

Qualitative data were analysed from twelve patients. Six of the analysed patients had been offered or received low-intensity therapy alone and six had received both low- and high-intensity treatment. Four of the analysed patients had declined any treatment or dropped out early; the remainder completed treatment. As noted in Chapter Five (section 5.5.2), data suggest that the majority of themes developed in a qualitative analysis can be obtained from the analysis of six transcripts (Guest et al., 2006). On this basis it is suggested that the analysis of twelve patient interviews had potential to generate a good understanding of the degree to which the stepped care intervention and recruitment procedures were acceptable to STEPS patients.

##### ***Patient experience of stepped care***

Although the analysis of patient data incorporated an adequate number of interviews, the degree to which patients' views of stepped care in the pilot trial might reflect the views of patients in a fully powered evaluation could be debated. Patients' views of stepped care in this study were generated in response to therapy delivered by three trial therapists working at the University of Exeter Mood Disorders Centre AccEPT Clinic. In a fully-powered evaluation, trial treatments would likely be delivered by IAPT therapists working mainly from IAPT premises and GP surgeries. Differences in the delivery of stepped care in different settings by different therapists might shape how it is received by patients.

However, stepped care as delivered in the feasibility study was highly protocolised. Patients received a standard set of GSH material; stepping criteria were closely defined; therapists utilised a detailed clinical protocol for high-intensity CBT and were supervised by highly qualified and experienced senior academic clinicians. By providing expert supervision and using the same (or a similar) highly protocolised form of stepped care in a future trial, opportunities for the delivery of stepped care to vary greatly from the feasibility

study would be constrained. Qualitative data revealed that feasibility study patients endorsed or were concerned by some elements of stepped care that were not overly susceptible to the influence of different therapists or settings e.g. the use of the PHQ-9. Provided the stepped care clinical protocol for a fully-powered evaluation was not very different to the protocol for the feasibility study, it is reasonable to expect that patient experience of both would be similar.

### ***Patient data on recruitment***

Qualitative patient data on recruitment may need to be interpreted with caution. Views on recruitment were obtained from trial participants yet a large majority of patients (92%) who were sent study information did not respond and around two thirds of patients who returned a permission form did not take part. IAPT personnel were concerned that patients who were sent study information with their IAPT assessment appointment letter may be overwhelmed or confused by the material that they received. Qualitative patient data suggested that study information was well received but we do not know if this was true for people who did not respond. If participants' views of recruitment are different to those of non-participants, modifying recruitment procedures in a future trial in ways that respond to the results of the patient interviews may not increase the appeal of those procedures to all potential participants.

### ***Therapist experience and number of interviews***

Three AccEPT Clinic therapists were interviewed. This comprised all of the AccEPT Clinic therapists who delivered stepped care. Involving a larger number of therapists may have generated new and different results on the acceptability of stepped care but this was not possible with the resource available.

In addition, we did not employ therapists who will deliver the intervention in a large trial. Trial therapists were a dedicated team of three research clinicians: a specialist mental health nurse who had previously been employed as a Psychological Wellbeing Practitioner; a trainee Clinical Psychologist with a strong clinical and research interest in adult CBT; a qualified Clinical Psychologist, accredited by the British Association of Behavioural and Cognitive



Psychotherapy and with over ten years' experience of high-intensity CBT. In a fully-powered RCT, it is likely that trial treatments would be delivered by low- and perhaps high-intensity IAPT therapists. Therapists in this study and those in a fully-powered evaluation may differ in terms of their interest in research and their prior knowledge, experience and understanding of stepped care, depression and the efficacy of CBT. The views of therapists in the current study may not reflect the views of therapists in a large trial.

However, this conclusion may not be wholly justified. Pilot trial therapists varied in their opinion of stepped care: a therapist who had previously worked in an IAPT service as a Psychological Wellbeing Practitioner strongly endorsed low-intensity therapy; the Clinical Psychologists were more sceptical about the benefits of GSH for some patients. In the same way, low- and high-intensity IAPT therapists might vary in their opinion of the intervention. Variation in therapists' views in this study may help to anticipate aspects of stepped care that could be more and less acceptable to different IAPT therapists in a large trial.

### ***IAPT staff experience***

The views of IAPT staff on recruitment were from three employees: a manager, Psychological Wellbeing Practitioner and Administrator. Although the range of views expressed by these individuals might be limited by their small number, personnel were purposively selected who had different roles in recruitment and were well placed to provide a good understanding of the degree to which procedures were considered appropriate to the wider staff. Interviews generated a large amount of qualitative data on a wide range of relevant topics to inform a fully-powered evaluation.

### ***Framework analysis***

All of the in-depth interviews with patients, therapists and IAPT staff were analysed using a framework approach (Pope, Ziebland, & Mays, 2000; Spencer, Ritchie, O'Connor, et al., 2014). Their views of recruitment and the stepped care intervention were described by a number of themes; themes sometimes comprised multiple sub-themes. In this way, framework analysis handled data on a very large number of related topics and the derivation of

each theme and sub-theme could be readily traced. By coding and analysing the results of the patient, therapist and IAPT staff interviews separately, it was possible to develop a detailed description of the ways in which recruitment and the stepped care intervention were more and less appropriate / acceptable to different groups of people who will be involved in a fully-powered evaluation.

However, there were potential limitations to framework analysis applied in this way. By indexing, sorting, charting and then engaging in a process of abstraction and interpretation, the context and meaning of individual narratives may have sometimes been lost. Contradictions and inconsistencies in individual's recount of their experiences may not have been captured well; the analysis may not have readily reflected how patients' views of acceptability changed over time.

### **7.6.5 Strengths and limitations of mixed methods analysis**

Three forms of analysis were undertaken in the current study: quantitative, qualitative and integrated mixed methods. A key strength of the integrated mixed methods analysis is that it combined different data types in ways that were rigorous and transparent. Quantitative and qualitative data on recruitment were compared methodically; the results of mixed methods analysis to explore how attendance and acceptability might relate were robust for being systematic and clear. In this way, mixed methods analysis supported a set of conclusions that can be easily understood and readily interrogated. Compared with studies where mixed data types are reflected on in the Discussion, the risk of reaching selective, spurious or biased conclusions about what one type of data mean in relation to the other is likely to be reduced.

#### ***Comparing mixed data on recruitment***

Comparing different data types in a side-by-side summary table of recruitment produced mixed results. Although qualitative and quantitative recruitment were systematically compared and clearly pointed to aspects of trial design that could be modified or remain unchanged in a future trial, it was sometimes difficult to interpret the level of synergy and disparity between interviewees' views of recruitment and numeric data from the STEPS CONSORT diagram. What one type of data meant in relation to the other was not always immediately clear.

A possible reason for this is that quantitative data on attrition were compared with qualitative data from trial participants only. The views of non-respondents and those who were interested in taking part but did not complete recruitment and join STEPS were unavailable to include in the side-by-side summary table. Thus, it was sometimes necessary to make inferences about the behaviour of non-trial participants based on participants' views of recruitment and, as a result, it was not always possible to make strong conclusions about what the quantitative data meant in relation to the qualitative.

Another limitation of the mixed methods analysis on recruitment that may have led to difficulty interpreting synergy and conflict was that the included data were aggregated. Statistics for the sample as a whole were compared with summary statements on recruitment experience. From this information, it was sometimes difficult to make sense of the complexity and variation in people's views in relation to the number of people completing (or exiting) each step of recruitment. By combining quantitative and qualitative recruitment data in a side by side summary table at the level of the individual participant it may have been possible to generate stronger and perhaps more meaningful conclusions about synergy and disparity which may have led to a deeper understanding of the feasibility and appropriateness of recruitment.

### ***Integrating data on acceptability and attendance***

Although combining different types of information on recruitment led to mixed results, mixed methods analysis on the relationship between acceptability and attendance readily generated insights that may not have been possible from a less rigorous integration or, indeed, a more straightforward comparison of quantitative and qualitative information. A key part of the success of this analysis, and an aspect that differentiated it from the mixed methods analysis on recruitment was that, in integrating quantitative and qualitative data, information was manipulated. Individuals were grouped into categories; patient experience was represented using typologies; data were also ordered - as in the case-oriented display. By folding together data that had been manipulated in some way, it became possible to spot new relationships between attendance and acceptability. Changes in how quantitative and qualitative data was

presented helped identify new and different patterns in the relationship between these two factors.

A limitation of the mixed methods analysis on attendance and acceptability arose with respect to the number and range of cases included in the analysis. In the same way that very few authors have tried to operationalise the number of interviews to include in a qualitative analysis, as yet, there is no practical guidance on how much data is appropriate to include in integrated mixed methods analysis. Moreover, whilst qualitative analysis typically aims to achieve 'saturation' (Morse, 1995), an equivalent concept has not yet been proposed for mixed methods analysis. Sample size requirements are, however, likely to be influenced by the purpose of analysis and, related, the degree to which it is important to understand heterogeneity.

In the STEPS study, quantitative and qualitative data were analysed for twelve patients. Of those, six patients had received low-intensity therapy alone and six had low- and high-intensity treatment. In addition, only four of the analysed patients had declined any therapy or dropped out of treatment, three of whom had GSH alone and one who had low- and high-intensity treatment. As such, the results on how views of stepped care might relate to attendance were based on a limited amount of data from people who did not complete therapy and, in particular, the results on how views of each of low- and high-intensity therapy might relate to attendance at GSH and CBT drew on the experience of very few people who did not engage in treatment. Results may not generalise or reflect the relationship between acceptability and attendance in full. Whilst discrete groups of patients were identified for whom acceptability and attendance related in different ways, other relationships are possible.

#### **7.6.6 Other potential limitations**

##### ***Generalisability of the stepped care clinical protocol***

A stepped care clinical protocol was developed for the current study that was true to stepped care principles. However, we do not know how the effectiveness of this intervention compares with stepped care implemented in other ways. The feasibility trial may have prepared to evaluate a 'sub-optimal' form of stepped care.

The basis for this conclusion is weak. The intervention included treatments for which there is strong evidence of effect (Titov et al., 2013; Titov et al., 2014; Titov et al., 2012). High-intensity CBT was delivered by experienced therapists following a treatment protocol based on the standard manuals published by Beck and colleagues (Beck et al., 1979) and used in two other recent mental health trials (Rhodes et al., 2014; Wiles et al., 2013). The systematic review of stepped care found considerable variety in the implementation of stepped care but only one significant difference between sub-groups of studies requiring further investigation. Differences in the implementation of stepped care are not necessarily associated with (statistically significant) differences in effects. On this basis, there is no 'good reason' to anticipate that the stepped care clinical protocol tested in the feasibility study would necessarily be less effective than stepped care implemented in other ways.

## **7.7 Directions for future research following the feasibility study**

The mixed methods feasibility study addressed key clinical, methodological and procedural uncertainties concerning the feasibility and conduct of a fully-powered randomised controlled trial of stepped care vs. intensive psychological therapy alone. Data have implications for a future trial in terms of: (i) recruitment, (ii) the clinic resource and sample size and, (iii) the stepped care clinical protocol. Findings also point to the potential for a programme of work on mixed methods as well as research that could be embedded in a future trial of stepped care vs. high-intensity therapy alone.

### **7.7.1 Recruitment in a future trial**

#### ***Feasibility of recruitment in a large trial***

Although it was possible to recruit to target in the current study, the participation rate of 2.9% was lower than expected and could only be achieved by extending the recruitment period albeit by two months only. However, several investigations underline that the recruitment of patients into RCTs can be extremely difficult (Charlson & Horwitz, 1984; Haidich & Ioannidis, 2001; McDonald et al., 2006). In a study of 114 trials supported by the UK Medical Research Council and the Health Technology Assessment Programme, less than a third achieved their original recruitment target and half were awarded an

extension (McDonald et al., 2006). Other stepped care trials set in primary care report participation rates that are similar to or less than that observed in the current study (Huijbregts et al., 2013; Seekles et al., 2011; Stoop et al., 2015; Unutzer et al., 2002). In this context, the performance of STEPS recruitment methods and procedures may be considered more acceptable.

### ***Opportunities to improve the recruitment rate***

Yet for procedures to be used in a future trial with greater confidence, it might still be important to refine them in ways that could improve the participation rate. A number of systematic reviews have focused on strategies to enhance recruitment (Caldwell, Hamilton, Tan, & Craig, 2010; Treweek et al., 2013; Watson & Torgerson, 2006). Interventions that could help to improve recruitment include telephone contact on patient non-response to written invitation and the use of opt-out rather than opt-in procedures whereby patients are contacted unless they withdraw the use of their details (Treweek et al., 2013). However, the application of such techniques in a large stepped care trial would need careful consideration. The use of such strategies may present methodological and ethical challenges (Bower et al., 2014; Treweek et al., 2013) and data on the feasibility of recruitment incorporating the use of these techniques was not collected as part of the current study.

### ***Opportunities to improve recruitment evident from STEPS feasibility study data***

On the other hand, STEPS feasibility study data also highlighted ways to improve the participation rate. Two opportunities were identified by quantifying the performance of trial methods and procedures: (1) increase the limit of five working days from when patients return a permission form to complete procedures; (2) secure adequate clinical resource to treat trial participants. In addition, based on previous examples of the use of qualitative research to identify and overcome barriers to recruitment and the promise of such methods for improving recruitment rates (Bower et al., 2014; Fletcher, Gheorghe, Moore, Wilson, & Damery, 2012), there might also be potential to improve the randomisation rate in a future trial by addressing ways in which STEPS methods and procedures were considered less appropriate to IAPT staff.

Difficulties for IAPT personnel arose out of a concern that some methods and procedures could harm patients whilst others had been practically challenging to implement. These difficulties map onto two high level themes ('perceived patient barriers' and 'effects on clinical practice') that have been found to influence clinicians' support for recruitment in several other studies (Fletcher et al., 2012). Although there is very little evidence on how best to overcome such concerns, two studies have investigated the use of qualitative methods to improve recruitment in a prostate cancer trial and implemented several strategies that subsequently corresponded with improvement in the number of patients recruited: presentation of study design to recruiters, initiation for new staff, regular training for all staff involved in recruitment, documents providing tips and advice and personalised individual feedback to recruiters (Donovan et al., 2009; Donovan et al., 2002). The same strategies, deployed to address the concerns of IAPT staff, can be considered for a future stepped care trial and may help to improve the randomisation rate.

Possible modifications to STEPS recruitment methods and procedures that incorporate some of these strategies are summarised in Box 8. Options for increasing the recruitment rate that arose from the quantitative data analysis (as noted above) are also included. Suggested changes mostly address ways in which recruitment was less appropriate to IAPT staff. However, other modifications are proposed that respond to a smaller number of concerns raised by patients and therapists.

***Box 8 overleaf***

Box 8. Possible modifications to pilot trial recruitment methods and procedures in response to patient, therapist and IAPT staff concerns

Problem with recruitment	Suggested action
<b>Ways to increase the participation rate evident from quantitative data</b>	
<p>Insufficient therapist resource</p> <p>Attrition associated with limit of five working days from when patients return their form to complete recruitment</p>	<p>Secure adequate clinic resource in a future trial</p> <ul style="list-style-type: none"> <li>Use STEPS data on the clinic resource required for stepped care to support a funding application for a future trial that would employ a sufficient number of therapists for the target number of patients to be recruited and treated in a reasonable timeframe</li> </ul> <p>Consider raising the limit of five working days to complete recruitment procedures</p> <ul style="list-style-type: none"> <li>Discuss potential impact on IAPT services (re 28 day performance target to start treatment after assessment) and patients who welcomed the pace of recruitment</li> </ul>
<b>Ways to improve the appropriateness of recruitment to IAPT staff - addressing perceived patient harms</b>	
<p>Patients may drop out of therapy on return to IAPT</p> <p>IAPT therapists were reluctant to pass on permission forms for patients who may be ineligible / unsuitable</p>	<p>Obtain STEPS data on treatment outcomes for patients who returned to IAPT. Alternatively, in a future trial, monitor patient treatment on return to IAPT; provide feedback to recruiters</p> <p>Reconsider IAPT therapist involvement in recruitment; present study design to recruiters and provide more information on study recruitment via training and guidance documents</p>
<b>Ways to improve the appropriateness of recruitment to IAPT staff – addressing effects on clinical practice</b>	
<p>Impact of recruitment on format of IAPT assessment appointment</p> <p>Responding to patient questions</p> <p>Variation in the degree to which recruiters were proactive in asking patients for their permission forms</p> <p>Administrative Team workload</p> <p>Trial participants did not count towards service performance target to treat 15% of depressed / anxious population</p>	<p>Initial and regular training for all staff involved in recruitment and documents providing tips and advice. Training and documents to include guidance on changing the format of an IAPT assessment appointment, responding to questions and asking patients for their permission forms</p> <p>Personalised individual feedback to recruiters / recruitment teams on number patients recruited</p> <p>Consider securing financial support for administrative work on recruitment as part of a funding application for a future trial</p> <p>Review ways in which trial participants might count towards 15% target. Discuss potential target conflict with IAPT services who may be involved in future trial.</p>
<b>Ways to improve the appropriateness of recruitment to therapists</b>	
<p>Trial participants included a patient with bulimia and another patient who was dependent on alcohol</p> <p>Unreliable communication of clinic info from baseline interview</p>	<p>Review study inclusion criteria and how they are implemented</p> <ul style="list-style-type: none"> <li>Also review criteria for when to discharge patients from treatment (see Box 9)</li> </ul> <p>Review procedures for summarising and passing on relevant clinic information from patient baseline interviews with therapists</p>



<b>Ways to improve the appropriateness of recruitment to patients</b>	
Study documents contained too much information	Modify the content and format of the Patient Information Sheet (PIS) and Study Summary Sheet
Difficulty attending a baseline interview after an IAPT assessment	Offer patients the opportunity to complete a baseline interview by phone in PIS

### ***Possible modifications to study inclusion criteria***

One of the concerns included in Box 8 was raised by therapists and focused on STEPS' study inclusion criteria. Although criteria excluded patients who were alcohol or drug dependent, once in treatment it became clear that one participant was alcohol dependent. Another participant had bulimia. Study inclusion criteria were not designed to exclude patients with bulimia however there was a concern that it may have been more appropriate for this person to receive specialist care. To optimise recruitment in a large trial, it will be important to critically reflect on and potentially modify feasibility study inclusion criteria and / or how they are implemented.

With respect to which patients to include, feasibility study data speak to a general tension in the design of RCTs involving depressed adults: whether and in what circumstances to include depressed persons with comorbid mental health problems. Although it may be important for the internal validity of a future trial to recruit a tightly defined sample, this may reduce external validity as many depressed adults present with comorbid mental health problems (McManus et al., 2009). Clinically, it may be difficult to determine for whom trial treatment is appropriate: a comorbid condition may require priority treatment; on the other hand it may be sufficient for some patients to access treatment for a comorbid condition alongside depression trial treatment. To help determine study inclusion criteria for a large trial, treatment guidelines for other mental health disorders and the evidence to support them should be appraised and in deciding on criteria, equipoise (genuine uncertainty over which of the intervention and control will be more effective) should be maintained for all participants.

In terms of the implementation of inclusion criteria in a large trial, to help reliably exclude patients who are alcohol or drug dependent, the SCID-5 – Structured

Clinical Interview for DSM-V (First, Williams, Karg, & Spitzer, 2015) – could be used as an alternative to the CIS-R (Lewis et al., 1992). The CIS-R is a relatively brief diagnostic interview that can be administered by a non-clinically qualified professional for the diagnosis of depression. Likewise, the SCID-5 is a recognised diagnostic interview schedule that can be used by a non-clinically qualified professional to diagnose depression but from which selected modules can also be used to identify patients with other comorbid conditions. Use of the SCID-5 in a future trial may help reliably identify patients who do not meet inclusion criteria and thereby minimise randomisations in error.

### ***Use of an alternative recruitment method***

The suggested modifications to recruitment in Box 8 represent one means to improve the acceptability of recruitment in a large trial and perhaps increase the recruitment rate. However, given the modest pilot trial recruitment rate, the level of dissatisfaction with recruitment among IAPT staff and the work that may be required to address concerns, the use of an alternative recruitment method in a large trial should also be considered.

Case-note screening in which patients are recruited by searching the electronic case records of general practices (or other services) for patients with depression, identifying potential participants from depression classification codes, has been successfully used in other large depression trials (Richards et al., 2016; Richards et al., 2013). Use of this method in a future stepped care trial would avoid the need to involve IAPT staff but would rely on the willingness of General Practitioners and other practice staff to assist. A relatively large number of GP surgeries would need to be engaged and, in an area where surgeries were already involved in other (potentially large) research projects, support for a fully-powered stepped care trial may be reduced.

By recruiting via IAPT, STEPS minimised burden on local General Practices known to be involved in other projects. This recruitment method also accessed a patient sample that was considered reasonably representative of people who utilise stepped care services in routine clinical practice. This advantage would extend to a large trial adopting a similar recruitment method. Recruitment via IAPT would also be appropriate for a future trial given that the fully-powered evaluation would involve an active treatment control. Thus, patients who had

been referred for psychological therapy would be offered a suitable form of CBT. When deciding on the recruitment method for a future trial, the merits of recruitment via IAPT should be considered alongside difficulties involving IAPT staff and the pros and cons of case-note screening.

### **7.7.2 Sample size in a future trial**

Pilot trial data were collected on the variability in patient outcomes and the correlation between baseline and follow-up scores. This information was obtained to inform an estimate of the sample size required for a fully-powered evaluation. From baseline to six month follow-up, the mean reduction in STEPS patients' depressive symptoms (on the BDI-I – the primary outcome in a future trial) was 13.4 in the stepped care group and 13.6 in the high-intensity therapy alone group. At follow-up, the standard deviation in patients' depressive symptoms was 10.0 across groups, 9.6 in the stepped care group and 10.5 in the high-intensity therapy alone group. Based on the assumption that stepped care is equivalent to offering all patients long-term, intensive psychological therapy alone, a two-arm non-inferiority trial is recommended to evaluate the relative effectiveness of these systems. Accordingly, this trial should be powered on the basis of clinical non-inferiority (Jones, Jarvis, Lewis, & Ebbutt, 1996).

Specific methods have been proposed for the calculation of non-inferiority margins i.e. the number of score units by which an intervention can perform worse than a control and not be considered inferior (European Medicines Agency Committee for Medicinal Products for Human Use (CHMP), 2005; Snappin, 2000). By applying such methods, it is possible to calculate the non-inferiority margin for a fully-powered evaluation of stepped care vs. high-intensity therapy alone using the effect size of historical trials comparing stepped care versus controls. Based on the (updated) systematic review of stepped care reported in this thesis, stepped care was superior to care as usual by a mean of 0.4 standard deviation units (95% confidence interval 0.22 to 0.57) or a mean of 5.1 (2.8 to 7.3) BDI-I units (assuming an SD of 12.8 from Beck and colleagues (Beck, Steer, & Brown, 1996). Non-inferiority margins can be calculated as 0.5 x mean control effect size (that is,  $0.5 \times 5.1 = 2.55$ ) or as the lower limit of the 95% confidence interval for the effect (that is, 2.8) (European

Medicines Agency Committee for Medicinal Products for Human Use (CHMP), 2005; Snappin, 2000).

Additional calculations can also be performed that acknowledge the unreliability of the estimate of the relative effect of stepped care in the systematic review. Excluding the results of one trial (Araya et al., 2003) with a very large effect size, stepped care was superior to care as usual by a mean of 0.35 standard deviation units (95% confidence interval 0.17 to 0.52) – or 4.5 (2.2 to 6.7) BDI-I units, assuming a SD of 12.8 (Beck et al., 1996). Based on this sensitivity analysis, the non-inferiority margin can be calculated as 2.25 (that is  $0.5 \times 4.5$ ) or 2.2, the lower limit of the associated 95% confidence interval.

It is also possible to estimate the non-inferiority margin using the published minimal clinically important difference (MCID) for the BDI. Button et al. (2015) have found that the BDI-II MCID is dependent on initial (pre-treatment) depression severity. For a sample of patients with 'more typical' (rather than treatment resistant) depression, they estimated a MCID of a 17.5% reduction in BDI-II scores from baseline. Assuming that the 17.5% reduction is a valid percentage with which to estimate the MCID between trial arms at follow-up, the non-inferiority margin for a large stepped care trial can be calculated as 17.5% of the STEPS' six month mean control group score on the BDI-I. That is 17.5% of 14 i.e. 2.5 BDI-I units. To help ensure an adequate test of the non-inferiority of stepped care vs. high-intensity therapy alone, a number of scenarios have subsequently been used to estimate the sample size required in a future trial that allow for the potential uncertainty in the non-inferiority margin (

Table 35). Based on STEPS pilot trial data on the variability in patient outcomes all of the scenarios use a standard deviation of 10.0 in the primary outcome. In addition, although STEPS study data suggested that the retention rate will be between 83.8% and 97.8%, scenarios allow for 20% attrition.

Table 35. Sample size estimation for a future trial

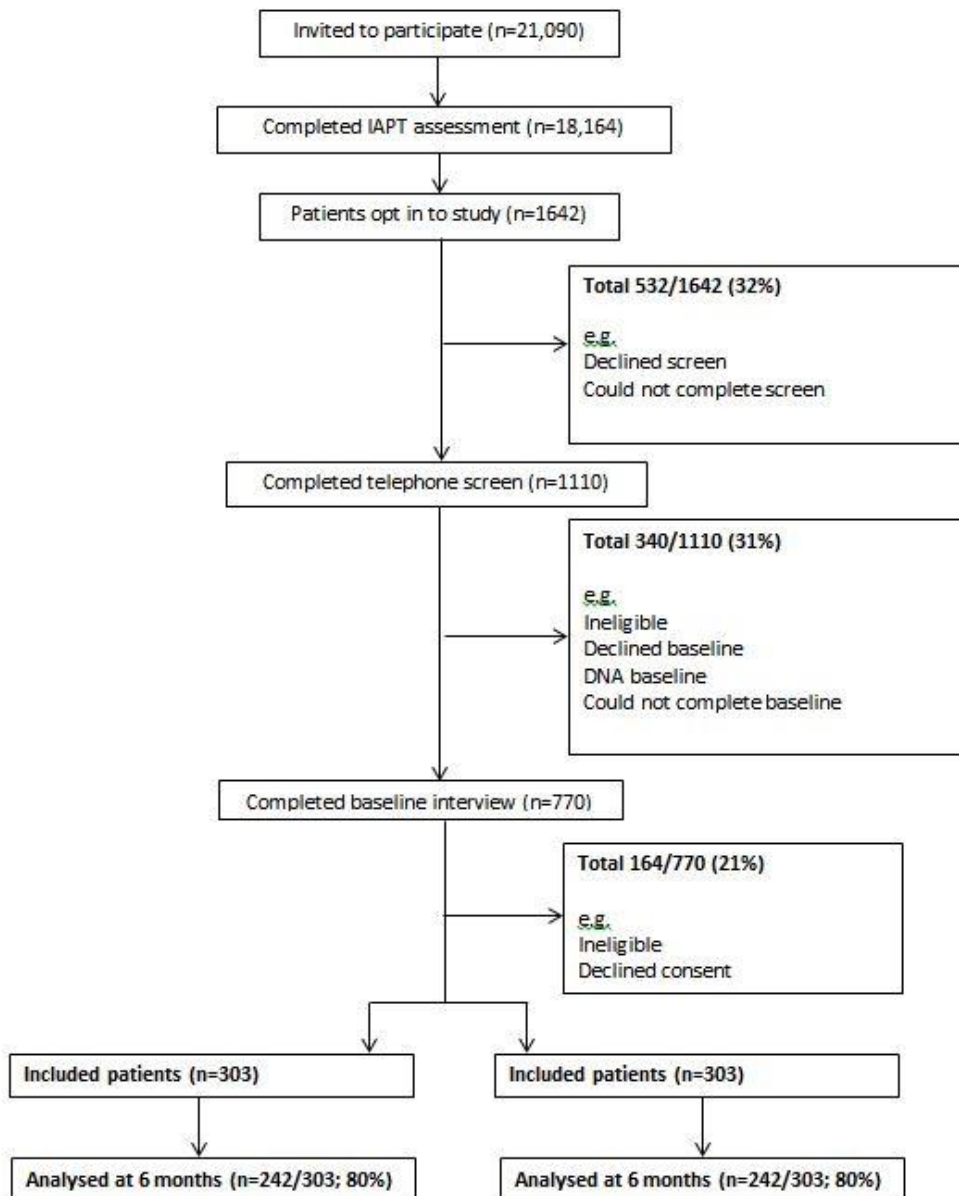
<b>Approach</b>	<b>MCID</b> 1	<b>Power</b>	<b>Sample size per group after 20% attrition</b>
LCI StC – UC effect size <sup>2</sup>	2.8	90%	337
50% StC – UC effect size	2.55	90%	405
BDI-II MCID	2.5	90%	421
50% StC – UC ES, Araya omitted	2.25	90%	520
LCI StC - UC ES, Araya omitted	2.2	90%	544
LCI StC – UC effect size	2.8	80%	252
50% StC – UC effect size	2.55	80%	303
BDI-II MCID	2.5	80%	315
50% StC - UC ES, Araya omitted	2.25	80%	389
LCI StC - UC ES, Araya omitted	2.2	80%	406

Notes. <sup>1</sup> MCID= Minimal Clinically Important Difference (non-inferiority margin) - calculated using BDI-I SD of 12.8 from Beck et al 1996; <sup>2</sup> LCI=Lowest confidence interval limit of the stepped care vs. usual care effect size.

Selecting a relatively conservative non-inferiority margin and power of 80%, a total of 606 participants would need to be recruited in a future trial to detect a between group non-inferiority margin of 2.55 in BDI-I units at a one-sided alpha, allowing for 20% attrition. Applying the level of attrition observed at each stage of pilot trial recruitment (Figure 10), it is subsequently estimated that, in a fully-powered evaluation, a total of 21,090 patients would need to be invited to participate in order to recruit to target (Figure 12). Equivalent data could be estimated based on the alternative scenarios in

Table 35 and combined with the estimates provided here, should be used to select a target sample size for a future trial.

Figure 12. Estimated recruitment and retention in a fully-powered non-inferiority trial of stepped care vs. high-intensity therapy alone to achieve a target sample size of n=606



### **7.7.3 Resource required in a future trial**

Pilot trial data on the clinic and research resource required to conduct STEPS can be used to estimate the resource required for a fully-powered RCT with a target sample size of 606 participants. Sixty-six STEPS participants were recruited in 11 months via one IAPT service; patients were subsequently treated by 1.5 Full Time Equivalent (FTE) therapists. The total treatment period was 1.75 years. Based on this data, it is estimated that to recruit 606 patients in approximately one year would require nine IAPT services of a similar size; patient treatment could be completed in 1.75 years by 13.5 FTE therapists.

The exact number of therapist hours required in a future trial will, in part, depend on the proportion of stepped care patients who step up. Pilot trial data revealed that a third of STEPS patients progressed from low- to high-intensity treatment. Based on the 95% confidence interval for this percentage it was inferred that in a future trial, the percentage of patients who would step up would be between 17.9% and 51.8%. Additional therapist hours would be needed to accommodate a higher step up rate. Given that pilot trial recruitment was negatively affected by a lack of therapist resource (a higher number of potential participants were available than the AccEPT Clinic had capacity to treat) it is suggested that engaging more than 13.5 FTE therapists in a large trial would help to avoid difficulties in recruitment, reduce the recruitment (and treatment) period and ensure adequate clinic resource to accommodate a higher step up rate.

In terms of the research resource required in a large RCT, STEPS engaged one full-time researcher to recruit 66 participants and collect six month follow-up data from 91% of patients; recruitment and data collection were complete within 1.5 years. Based on this data, it can be inferred that a large trial would require nine FTE researchers to recruit and follow-up 606 participants. If primary outcome data was collected at twelve instead of six months (see section 7.6.3), researchers would need to be employed for at least two years.

### **7.7.4 Stepped care clinical protocol in a future trial**

Qualitative analysis on acceptability found that although the stepped care intervention was broadly acceptable to therapists, there was no single



experience or pattern of experiences to define patient acceptability. Across the small number of other qualitative studies that have been completed on stepped care, heterogeneity is not atypical: attitudes towards stepped care in routine clinical practice have been found to vary (Parry et al., 2011; Richards et al., 2010); another stepped care trial reported variation in the level of patient satisfaction with the intervention (Shinde et al., 2013). In this context, it is suggested that heterogeneity alone should not prevent the conduct of a large RCT using the STEPS clinical protocol. However, in terms of the suitability of the stepped care clinical protocol for use in a large trial, it is also relevant to appraise patients' and therapists' views of the intervention in relation to the four possible problems with stepped care that have been highlighted by a number of authors (Chapter Two, section 2.5.).

### ***(1) The appropriateness of low-intensity therapy***

Consistent with authors' suggestion that patients and professionals may feel that the provision of low-intensity therapy is inappropriate (Bilsker et al., 2012; Scogin et al., 2003), some STEPS patients doubted the suitability of low-intensity therapy given the severity of their symptoms and / or the nature of their difficulties. Therapists also expressed reservations regarding the suitability of low-intensity treatment for patients with severe depression and complex or entrenched difficulties. However, other patients viewed low-intensity therapy positively and were not greatly troubled by the degree to which it might be suitable. Furthermore, patient views of low-intensity treatment could change; those who were cautious about the appropriateness of GSH sometimes came to view it positively. In addition, despite their reservations, STEPS therapists viewed the intervention as appropriate for the majority of patients. It is therefore suggested that concerns regarding the suitability of low-intensity therapy were not so strong or entrenched to prevent the conduct of a future trial incorporating the use of low-intensity therapy as tested in STEPS.

### ***(2) Unsuccessful low-intensity treatment and (3) patient choice***

Other features of stepped care thought to be problematic include the consequences of unsuccessful low-intensity treatment (Kellest & Matthews, 2008; Scogin et al., 2003) and restricted patient choice (Lovell & Bee, 2008). With respect to unsuccessful low-intensity treatment, although some patients

experienced difficult and negative feelings when they did not respond to GSH, it is noteworthy that, despite this experience, unsuccessful low-intensity therapy did not deter patients from high-intensity CBT. Rather, with support from family, friends and therapists, patients who had negative feelings came to view the option to have high-intensity therapy, positively. Furthermore, in terms of patient choice, this did not emerge as a significant concern. Whilst some people expressed a preference for high-intensity treatment, most patients did not object strongly to the prospect of low-intensity therapy and although therapists were sometimes uncertain about the suitability of high-intensity CBT for patients who did not engage in low-intensity CBT, patients did not ask for a wider choice of high-intensity therapies after unsuccessful GSH. Patient experience of unsuccessful low-intensity therapy and restricted choice offer no reason to modify or decide against using the stepped care intervention in a large trial.

#### ***(4) Stepping criteria***

Gellatly (2011) proposed that inconsistency around therapists' decision to step patients up or out of treatment following low-intensity therapy may stem from a tension between the desire to tailor or individualise treatment and standardised guidelines for deciding which patients have high-intensity therapy and when. Although STEPS therapist experience highlighted uncertainties about the stepping criteria, concern did not obviously reflect a desire to tailor patient treatment. Rather, therapists queried how well the criteria worked for all patients or a distinct group, specifically, (i) the appropriateness of criteria for patients with low pre-treatment scores, (ii) whether criteria were sufficient to help prevent risk of relapse and recurrence, and (iii) the focus on symptoms of depression but not anxiety. For this reason, although it might still be important to address therapist questions (see below) it is not obvious that greater freedom in how criteria are applied is needed for decision making to be more acceptable. The stepped care clinical protocol can be used in a future trial without changes to address a tension between the desire to tailor treatment and standardised guidelines.

### ***Possible changes to a stepped care clinical protocol for a large trial***

Based on patient data, it was not possible to identify ways in which the stepped care clinical protocol could be modified that would reliably improve acceptability. Only one aspect generated reasonable consensus: patients and therapists raised issue with use of the PHQ-9 for monitoring symptoms of depression. As such, it may be possible to address this issue in a future trial (see Box 9). However, modifying other aspects of stepped care might improve the intervention for some patients but make it less acceptable to others. Patient experience does not offer a clear basis for changes to the stepped care intervention in a large trial.

In contrast, although the stepped care intervention was broadly acceptable to therapists, therapist experience highlighted elements of each of high- and low-intensity treatment, monitoring and stepping that could be modified in a large trial - or that at least require further consideration. In terms of how to respond to one particular aspect of therapist experience – stepping criteria – due to a lack of evidence on the performance of different criteria, changes that would reliably improve patient outcomes and therefore acceptability to therapists, cannot be identified. Long-term outcomes for patients who begin treatment with low PHQ-9 scores and are discharged despite relatively little progress are unclear. Although the presence of residual symptoms has been implicated in the risk of relapse and recurrence of depression (Beevers, Keitner, Ryan, & Miller, 2003; Bockting, Spinhoven, Koeter, Wouters, & Schene, 2006; Faravelli, Ambonetti, Pallanti, & Pazzagli, 1986), the relationship between residual symptoms and relapse is also unclear (Burcusa & Iacono, 2007). Rather than modify stepping criteria, it may be sufficient to discuss related uncertainties with trial therapists to help promote their understanding and acceptance of existing criteria for use in a large trial. This and other suggestions for how to respond to therapist experience are outlined in Box 9. Several ways in which the stepped care clinical protocol might be modified are proposed.

Box 9. Possible modifications to the stepped care clinical protocol and other action in response to therapist experience

Therapist experience	Suggested modification / action
<b>Low-intensity therapy</b>	
<p>A different order to the WB course may have been helpful for some patients as would flexibility to tailor the order for individuals</p> <p>Patients did not use or value Additional Resources; there was not enough time to talk about the resources in therapy</p> <p><i>No particular issue prompted this suggested modification</i></p> <p>Session six was not modularised and was not needed by some patients</p> <p>When patients missed sessions, had a difficult week or did not do homework this was difficult for the therapist to accommodate</p>	<p>Review the order in which Wellbeing Course material is delivered and the option for therapists to vary the order for individual patients</p> <p>Reconsider how best to incorporate the use of Additional Resources</p> <p>Consider linking course material to patients' therapeutic goals</p> <p>Review the need for session six; revisit its structure and content (see also 'monitoring and stepping', point three)</p> <p>Consider flexibility for therapists to defer patient sessions; agree circumstances in which this may be appropriate</p>

**Box 9 continued overleaf**

Therapist experience	Suggested modification / action
<b>Monitoring and stepping</b>	
<p>The PHQ-9 was time-consuming to deliver and did not always accurately reflect patient experience</p> <p>Patients presented with anxiety as well as depression which may have been important to monitor</p> <p>Patient progress was often discussed at session five; the need apply stepping criteria in session six was unclear</p> <p>The suitability of stepping criteria for patients with low pre-treatment scores who made little progress and in terms of preventing relapse and recurrence was unclear</p> <p>Trial participants included a patient with bulimia and another patient who was dependent on alcohol</p> <p>High-intensity CBT may be unsuitable for patients who did not engage with low-intensity CBT</p> <p>Uncertainty re long-term outcomes for patients discharged from low-intensity therapy</p>	<p>Administer the PHQ-9 with course material for patients to complete prior to phone calls. Consider additional measures and other ways of recording patient progress alongside the PHQ-9 plus how this information may or not be used to inform stepping decisions</p> <p>Consider monitoring anxiety alongside depression and how this information may or not be used to inform stepping decisions</p> <p>Subject to a review session six (see 'low-intensity therapy, point four), continue to administer stepping criteria at session six but allow flexibility to apply criteria at session five</p> <p>Present stepping criteria to therapists as part of trial orientation and provide more information via supervision and guidance documents</p> <p>Review criteria for when to discharge patients from therapy</p> <p>Consider presenting feasibility study data on acceptability and role of self-efficacy in patient engagement to illustrate different patient experience</p> <p>Consider offering follow-up appointments to all patients discharged at the end of GSH</p>
<b>High-intensity therapy</b>	
<p>Patient experience of GSH was not used in high-intensity CBT</p> <p>Uncertainty re how best to support patients who made little progress in high-intensity CBT</p>	<p>Develop a pro-forma / separate forms for patients and therapists that capture patient experience of GSH and how this might influence CBT. Discuss other options for making more use of GSH in CBT, with STEPS therapists</p> <p>Consider presenting feasibility study data on acceptability of high-intensity therapy to illustrate different patient experience of stepped care among those for whom high-intensity therapy is less acceptable</p>

### 7.7.5 Research that could be embedded in a future trial

In addition to changes to the stepped care clinical protocol, directions for future research are recommended that could be embedded in a fully-powered RCT of stepped care vs. high-intensity psychological therapy alone for the treatment of depression in adults.

### ***Testing the relationship between acceptability and attendance***

STEPS found that self-efficacy had a role in patient engagement. The role for self-efficacy in low-intensity therapy is also evident in other qualitative research (Farrand et al., 2007) and the concept can be likened to that of self-liberation which has been used by Critis-Christoph and Connolly Gibbons (2002) to describe a belief held by patients as they prepare to modify their behaviour that they, “Have the personal determinism to change... and the commitment and recommitment to act on this belief,” (p306). However, although others may have captured the role for self-efficacy (or a related concept) in patient attitude to treatment and its implications for behaviour change, our understanding of the role of self-efficacy in therapeutic attendance, or indeed patient outcomes, is at an early stage. STEPS feasibility study data offered insight into how patient engagement and self-efficacy may relate among a small number of participants who received stepped care yet findings are in no way conclusive.

To improve our understanding of the role for self-efficacy in patient experience, self-efficacy data should be collected as part of a fully-powered RCT of stepped care vs. high-intensity therapy alone. In addition, the trial should incorporate a process evaluation to investigate mechanisms of change in stepped care and the influence of context on patient outcomes. As part of the process evaluation, analyses should investigate the relationship between self-efficacy, therapeutic attendance and patient outcomes.

### ***Generating evidence on effective strategies for improving recruitment***

Given the dearth of evidence available to inform the development of effective recruitment methods and procedures, there may be an opportunity for a large trial of stepped care to include an embedded trial to test the effectiveness of an adapted recruitment strategy. An adapted strategy could respond to the barriers to recruitment identified from qualitative research. The Systematic Techniques for Assisting Recruitment to Trials (START) programme has been funded by the UK Medical Research Council to support the routine adoption of embedded trials to test recruitment interventions in host trials (Rick et al., 2014). Health services researchers involved in planning a large stepped care trial should refer to the outputs of that programme which are expected to include

guidelines for the design, analysis and reporting of embedded recruitment studies.

#### **7.7.6 Improving the use of mixed methods in health services research**

Although the use of mixed methods may be reasonably common in health services research, STEPS is unusual for conducting mixed methods analysis. Mixed methods studies typically employ multiple methods but undertake quantitative and qualitative strands of work in parallel; data is only integrated at the point of discussion (Borglin, 2015). In contrast, STEPS demonstrated how different data types can be combined with rigour at the point of analysis and, in response to a mixed methods question, generate new insights that may not have been possible from a more straightforward comparison of quantitative and qualitative data. In this regard, STEPS provides an original example of how it is possible to formulate a mixed methods research question and take full advantage of existing techniques that truly integrate data in the development and evaluation of complex interventions.

Yet more generally, very little guidance is available for the health service research community to follow on how to integrate data throughout study designs, including during analysis. In addition, standards for the reporting of mixed methods studies and how to assess the quality of published studies have only fairly recently received attention (Borglin, 2015) and despite attempts to improve reporting (O'Cathain et al., 2008), the quality of published articles on mixed methods research is often sub-optimal (Wisdom et al., 2012). The shortage of guidance to assist researchers, those responsible for reviewing grant applications as well as studies that have been written up for publication, means that current limitations in the quality and conduct of mixed methods may be more likely to persist. Without the transfer of knowledge, it is possible that mixed methods studies will continue to be undertaken that fail to maximise the potential of integrated mixed methods analysis.

To improve the use and utility, therefore, of mixed methods research, a programme of work is recommended to provide the health services research community with practical guidance and information in the design, conduct and appraisal of mixed methods studies. Consistent with an approach that has previously been used to develop process evaluation guidance (Moore et al.,

2014), this programme of work might encompass a workshop of participants with a strong interest and experience in mixed methods, literature review and the identification of and detailed reflection on high-quality case studies of mixed methods research.

## **7.8 Clinical implications of the feasibility study**

STEPS feasibility study was undertaken to inform the conduct, design and development of a fully-powered evaluation of stepped care compared with high-intensity psychological therapy alone. However, results on acceptability may be of immediate interest to patients, clinicians and health service providers. Pilot trial findings on the resource saving associated with the delivery of stepped care vs. high-intensity CBT alone may also be of interest.

### ***Clinical implications of data on acceptability***

The three cross-cutting themes on the acceptability of stepped care, one of which may have a role in patient engagement, provide a way of exploring what people think of this system. Likewise, the themes and sub-themes used to describe STEPS patient experience offer a framework for patients and therapists to consider how people might feel about each core component of this intervention (see Box 10).

Box 10. A framework for exploring patient views of stepped care

#### **1. Guided Self-Help**

How does the person feel about the idea of starting with low-intensity therapy knowing high-intensity therapy could follow?

To what extent might the patient relate to any written material

How do they feel about reading and using material on their own?

- What is the person's reading ability / organisational skills?
- How much time do they have?
- Is the person likely to approach reading in a way to suit themselves?

How does the patient feel about therapy by phone?

What is the person hoping for from their therapist?

How do they feel about the length and pace of sessions and the total duration of low-intensity therapy?

***Box 10. continued overleaf***



## **2. Monitoring**

What does the patient think about their symptoms of depression (and anxiety) being routinely monitored using a checklist?  
How might they use their scores?  
How might the person react if a score did not tally with how they were feeling?  
What do they make of the specific questionnaire(s) for monitoring?

## **3. Stepping**

How does the patient think they might respond to unsuccessful low-intensity therapy?  
And then feel about going on to high-intensity therapy?  
If applicable, what does the patient think about the prospect of changing therapist?

## **4. Cognitive Behaviour Therapy**

How does the person feel about meeting with their therapist face to face?  
What would be important from the therapeutic relationship?  
What does the patient think about the length and pace of sessions and the possible duration of high-intensity therapy?

By using this framework and exploring the degree to which patients demonstrate a sense self-efficacy, being 'on their own' and 'needing something more' before treatment, it may be possible to anticipate patients for whom stepped care may be less acceptable. Based on this information (and perhaps the results of further research on the role of self-efficacy in patient engagement and treatment outcomes) it may also be possible to develop a clinical algorithm for stratifying stepped care such that patients for whom low-intensity therapy is least acceptable (and who may be less likely to accept and remain in treatment) are immediately allocated high-intensity psychological therapy. Moreover, if the results of further research confirm a relationship between self-efficacy and patient outcomes, it may ultimately be possible to incorporate an assessment of self-efficacy alongside other factors that are currently being considered as part of a clinical algorithm to personalise the care of patients with depression (DeRubeis et al., 2014; Huibers et al., 2015).

In the immediate future, clinicians may want to consider how the findings on acceptability reported in this study, might apply to their own clinical practice. In this regard, the data may apply to a greater or less extent depending on the level of similarity and difference between the form of stepped care implemented in STEPS and that implemented elsewhere. By supplying a detailed description

of the feasibility study intervention, information is available to help clinicians interpret how findings on acceptability might relate to their work.

***Possible resource saving associated with the delivery of stepped care vs. high-intensity CBT alone***

As concluded earlier in this chapter (see 7.5.1) a fully-powered RCT incorporating cost-effectiveness analyses is required to establish, with certainty, if stepped care delivers treatment that is equivalent in clinical effect but more efficient compared with the traditional provision of psychological therapies. STEPS was not powered to detect clinically meaningful differences in the effectiveness of stepped care vs high-intensity CBT alone; it does not provide robust evidence on the clinic resource required to deliver stepped care. However, pilot trial data on receipt of the intervention and control (Table 17) can be used to estimate the therapist time that was required to deliver stepped care and high-intensity CBT alone and the patient journeys undertaken to attend treatment.

Per patient, participants randomised to receive high-intensity CBT alone spent an average of 7.3 hours in treatment; on average, stepped care participants spent 5.9 hours in therapy. Assuming that an hour of patient contact required an additional hour of therapist 'admin' time, the total therapist time to deliver therapy was 14.6 hours per CBT alone patient and 11.8 hours per stepped care participant. Relative to CBT alone, per stepped care patient this represented an average saving of 2.8 therapist hours – or approximately 20% (2.8 / 14.6).

With respect to patient journeys, pilot trial data on the number of CBT sessions attended (all of which were delivered in person at the MDC AccEPT Clinic) and the number of GSH patient contacts (one of which was routinely conducted face to face at the MDC) can be used to estimate patient travel. Per participant, patients randomised to CBT alone attended a mean number of 8.8 therapy sessions for which they made 17.6 journeys to or from the AccEPT Clinic. Per participant, stepped care patients attended a mean number of 4.3 high-intensity CBT sessions and 0.9 GSH sessions at the AccEPT Clinic – 5.2 sessions in total. The mean number of journeys to or from stepped care was therefore estimated to be 10.4. Compared with travel for patients who received CBT

alone, per stepped care participant, this represented an average saving of 7.2 journeys – or approximately 40% (7.2 / 17.6) of the travel involved.

***Continued overleaf***

## **7.9 Conclusions**

This thesis has encompassed a systematic review of stepped care treatment for depression and a mixed methods feasibility study to prepare for a fully-powered evaluation of stepped care compared with high-intensity psychological treatment alone.

### ***Key conclusions from the systematic review***

The systematic review found that, relative to usual care, stepped care is associated with significant improvements in depression outcomes. However, there is a dearth of evidence on the effectiveness of this system compared with the provision of long-term intensive psychological therapies for all. In the absence of robust, empirical research on the effect of stepped care vs. high-intensity therapy alone it is not possible to conclude, with certainty, that stepped care should remain the dominant model of treatment organisation in the UK and elsewhere. A non-inferiority randomised controlled trial should be undertaken to establish whether stepped care is not substantially inferior to high-intensity CBT in terms of clinical effect. Cost-effectiveness analyses should be incorporated to determine the relative efficiency of both systems.

### ***Key conclusions from STEPS feasibility study***

Data from STEPS feasibility study suggests that a fully-powered evaluation of stepped care vs. high-intensity therapy alone is feasible albeit with scope to improve the performance of pilot trial recruitment methods and procedures and the acceptability of the stepped care intervention. Recruitment methods and procedures should be modified in ways that address perceived patient barriers and effects on clinical practice reported by IAPT staff. Changes to the intervention should reflect therapist experience of each key component of stepped care. A funding application for a fully-powered evaluation of stepped care vs. high-intensity CBT alone can subsequently be prepared that should plan to recruit upwards of 600 participants and obtain adequate therapist resource to treat all patients. Trial design should combine the definitive evaluation of stepped care with a process evaluation to investigate the role of self-efficacy in patient engagement and outcome.

### ***Key conclusions from the mixed methods analysis***

By applying mixed methods analysis, STEPS provided an example of how it is possible to take full advantage of existing techniques that truly integrate data in the development and evaluation of complex interventions. To help improve the use and utility of mixed methods going forward, a programme of work is recommended that will provide the health services research community with practical guidance and information on mixed methods research.

## Appendices

- Appendix I: Meta-analysis computational formulae
- Appendix II: Feasibility study recruitment
- Appendix III: Feasibility study data collection
- Appendix IV: Qualitative analysis of semi-structured interviews
- Appendix V: Feasibility study management

## Appendix I: Meta-analysis computational formulae

### 1. Standardised Mean Difference (Cohen's $d$ )

- (i) Given mean, SD and  $n$  in each group

Raw difference in means (RawDiff) = Mean1 - Mean2

Pooled (within groups) standard deviation (SDP) =  $\text{Sqr}(((N1 - 1) * SD1^2 + (N2 - 1) * SD2^2) / (N1 + N2 - 2))$

Standardized difference in means = RawDiff / SDP

- (ii) Given a 2 x 2 table of events

Nomenclature for 2 x 2 table of events:

	Events	Non-Events	N
Intervention	A	B	$n_1$
Control	C	D	$n_2$

Compute the Log Odds Ratio and then convert to  $d$

Odds Ratio =  $A * D / B * C$

Log Odds Ratio =  $\ln(\text{Odds Ratio})$

$d = \text{Sqr}(3) * \text{Log Odds Ratio} / \text{PI}$

(PI (mathematical constant) = 3.142)

- (iii) Given difference in means between independent groups,  $n$  in each group and  $p$

$p_{\text{Obs}} = p_{\text{Entered}} / \text{tails}$

$df = N1 + N2 - 2$

$t = \text{Abs}(t \text{ for } p, df)$

HarmonicN =  $(2 * N1 * N2) / (N1 + N2)$

$d = t / (\text{Sqr}(\text{HarmonicN}) / \text{Sqr}(2))$

- (iv) Given difference in means between independent groups and associated CI

Compute the SD of the (raw) difference in means (RawDiff SD) and then convert the raw difference (RawDiff) to  $d$

RawDiff SD =  $\text{Sqr}((N1 * N2) / (N1 + N2)) * \text{RawDiffSE}$

$d = \text{RawDiff} / \text{RawDiffSD}$

### 2. Pooled effect using random effects model

Pooled effect = weighted average of the intervention effects (Cohen's  $d$ ) estimated in each individual study

Compute a weight for each study ( $W_i$ ) and then the pooled effect

$W_i = 1 / V^*_{y_i}$

( $V^*_{y_i}$  = within-study variance for each study + between studies variance)

Weighted average = sum of (estimate x weight) / sum of weights i.e.  $\sum d_i W_i / \sum W_i$

### 3. Q statistic

Q = sum of (the difference between each study effect and the pooled effect, squared x the weight for each study)

$Q = \sum W_i (d_i - M)^2$

$W_i$  = study weight ;  $d_i$  = individual study effect;  $M$  = pooled effect

### 4. $I^2$ statistic

$I^2 = (Q - df / Q) * 100\%$

## **Appendix II: Feasibility study recruitment**

This appendix provides a copy of supporting documents used for feasibility study recruitment, specifically:

- Study summary sheet
- 'Permission for researcher to contact' form
- Patient Information Sheet
- 'Information for Clinic' form





### **Patient Summary Information Leaflet**

**STEPS** (Development and Evaluation of **St**opped Care: A Mixed Methods Feasibility Study)

This is a very short summary of our study. **It asks you to consider taking part in our research and for your permission for a researcher to contact you.**

**Introduction.** We are carrying out a study to help develop a large trial of ways to organise depression treatment. We are writing to you because your local IAPT service has agreed to help us with this by sending information to you when you were referred for treatment.

**What is the treatment that is being tested?** This study will provide us with the information we need to investigate the effects of two ways to **organise** depression treatment. Ultimately, we would like to carry out a large trial to find out whether a system called 'stepped care', which is widely used in the UK, is more efficient than offering patients 'Cognitive Behavioural Therapy' (CBT) alone. Before we can do this, we need to carry out a small trial to develop and test our methods and procedures. We also want to know if stepped care is acceptable to patients and to clinicians.

**What will happen to me if I take part?** We are asking people who are referred for IAPT services in this area if they would like to take part. If you would like to do this, a researcher will speak with you to see if you are eligible for the study and to explain it in more detail. If you are eligible and agree to take part you will receive stepped care or CBT at the University of Exeter Mood Disorder Centre AccePT Clinic. Taking part would not delay your treatment.

Stepped care will involve up to two psychological treatments for depression (guided self-help and CBT) over a maximum period of six months; CBT will involve from eight to 20 appointments over a four month period. All treatments will be delivered by a trained therapist. We would also want to meet with you at the start of your treatment and again six months later to fill in some questionnaires.

This study is a randomised controlled trial which means that the decision about which treatment you would receive is made completely by chance. Half of our participants will receive stepped care and half will be treated by CBT alone. At the end of the trial, we will look at how many people took part and filled in our questionnaires. We will also use the information people provide to work out how big a large trial needs to be.

**Will my taking part in this study be kept confidential?** We will keep all of the information that we collect about during the course of the research strictly confidential.

#### **What should I do now?**

If you are interested in the study and are happy for a researcher to contact you to discuss whether or not you would like to take part, you should **complete the enclosed 'Permission for Researcher to Contact' form and bring it with you to your Devon DAS Assessment Appointment.**

Someone working on the study will then contact you with more information about this study and arrange a time to meet you and answer any questions you may have. Meanwhile, if you would like to find out more, you can call the STEPS study researcher on 01392 725273.

**Thank you for reading this and for considering taking part in this study.**



'Permission for researcher to contact' form



**'Permission for Researcher to Contact' Form**

**Study Title: STEPS** (Development and Evaluation of **Stepped Care: A Mixed Methods Feasibility Study**)

I confirm that I have read and understand the summary sheet for the above study and I am happy for a researcher to contact me to discuss whether or not I would like to take part.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

Name.....  
(Please print name)

Address.....  
.....  
.....

Signature.....

**Telephone contact details:**

Day.....

Evening.....

Mobile.....

The best day(s) and time(s) for the study team to call me are .....

**Email address:** .....

**Date of your DAS Assessment Appointment:** .....

***Please bring this form to your DAS Assessment Appointment and give it to your therapist.***





## **Participant Information Sheet**

### **STEPS (Development and Evaluation of Stepped Care: A Mixed Method Feasibility Study)**

You are being invited to take part in a research study. Before you decide whether you want to take part or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### **What is the purpose of the study?**

Depression causes misery to many people and is a major health problem in the UK. Although drug and psychological treatments are effective, we are less certain about how to organize these. A system for depression treatment called 'stepped care' requires that almost all patients receive a 'low intensity' psychological treatment such as guided self-help and only those patients who do not respond are given more intensive treatment such as cognitive behaviour therapy (CBT). Although this way of organising treatment is widely used in the UK, we do not know if it is acceptable to patients and to clinicians and whether it is more efficient than alternatives. By carrying out a large clinical trial to compare the cost and outcome of stepped care with offering almost all patients intensive psychological therapy, we hope to find out which system is most effective for depression treatment. However, before we can do this, we need to test our methods and procedures in a small trial. We also need to speak with patients and clinicians to find out what they think about stepped care.

#### **Why have I been invited?**

Your local IAPT service is taking part in this study and you have recently been referred to them for treatment. The letter from the service asks you to consider taking part in the research because you may have some of the depression symptoms we are treating in this study. If you decide to take part one of our

research team will go through this information sheet with you and answer any questions you have. You will also be asked some questions by the researcher to see if you are eligible to be included for the treatments being tested. If you are already taking medication for depression you would still be eligible however if you are already receiving psychological treatment ('talking therapy') for depression then you would not. Although you would need to be excluded from taking part in this specific study, you will still be treated by the IAPT service and your treatment with them would not be delayed.

### **Do I have to take part?**

No. It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will still be still free to withdraw at any time and without giving a reason. A decision to withdraw or not to take part will not affect the care you receive in any way.

### **What is being tested?**

We are running a small clinical trial to compare two systems used to organize depression treatment – stepped care and offering patients intensive talking therapy (psychological therapy). Stepped care will involve two psychological therapies for depression – guided self-help and CBT which are recommended by the UK National Institute for Health and Clinical Excellence (NICE) for the treatment of depression. Intensive psychological therapy will involve CBT only. NICE has recommended that a large trial be carried out to test stepped care but before we can do this, we need to find out how big such a trial needs to be and how many people we need to approach to take part. We also need to know what patients and clinicians think about stepped care. A small trial will allow us to develop our trial methods and we will use qualitative interviews to find out if stepped care is acceptable to people.

**Guided self help** is based on the idea that it can sometimes be easier and helpful for people to learn about depression and how they can manage its symptoms by reading useful material whilst being supported by a therapist. The therapist aims to be available to you and encourage you to read. The treatment involves learning about the symptoms of depression, how to challenge unhelpful thoughts, and managing physical symptoms and behaviours that can maintain the symptoms of depression.

**Cognitive Behaviour Therapy (CBT)** is based on the idea that certain ways of thinking can trigger, or fuel, certain mental health problems such as depression. The therapist helps you to understand your thought patterns. In particular, to identify any harmful or unhelpful ideas or thoughts which you have that can make you depressed. The aim is then to change your ways of thinking to avoid these ideas and to help your thought patterns to be more realistic and helpful, to achieve changes in the way that you think, feel and behave.

### **What will happen to me if I take part?**

If you decide you might like to take part and return your 'Permission for Researcher to Contact' form, a researcher will telephone you and ask some questions to see if you are potentially eligible and to explain the study in more detail, but only after you have agreed to be contacted by us and we have allowed you time to think about whether you want to take part or not. If you are potentially eligible to take part, we will then arrange to speak with you on the phone or meet with you at your home to ask you some more questions that will tell us if you are eligible. Alternatively, if we cannot speak on the phone or meet at your home, we will arrange to meet with you at the University of Exeter. You can ask us about the study at any time. If we confirm that you are eligible and you agree to take part you will receive stepped care or CBT alone. However, if after you have spoken with the researcher and answered some questions it is found that you are not eligible to take part, we are really sorry if it causes you disappointment and thank you for your interest and time that you have given. If you are not eligible to take part we would refer you back to your local IAPT service to continue treatment in the normal way.

If you are eligible to take part we need to explain that this study is a randomised controlled trial which means that once you have been interviewed by a researcher and have decided you would like to take part, the decision about whether you receive stepped care or CBT alone is made completely by chance. In this trial half of our participants will receive stepped care and half CBT alone. We will allocate you to either stepped care or CBT by assigning you a personal identification number, known only to the research team, which will be entered into a secure computer system that picks the numbers at random and allocates

them to one of the treatments at random. We will let your local IAPT service know that you are participating in this study.

If you are allocated to stepped care, you will receive a minimum of six sessions of 30 minutes duration with a trained therapist once a week, spread over 6 weeks. The therapist will see you face to face or speak with you over the phone and help you read material about depression and what you can do to reduce and manage depressive symptoms. If at the end of the six week period, you require more intensive therapy, you will go on to receive between eight and twenty sessions of CBT with a trained therapist who will deliver your treatment in the same way as for people who only receive CBT. If you are allocated to CBT alone, you will receive between eight and twenty sessions of 50 minutes duration with a therapist, spread over up to four months. You will receive face to face sessions, with the option of the session being conducted up to twice weekly over the first two months and then weekly thereafter.

Once you have been allocated to stepped care or CBT alone and receive all of the treatment sessions, you will be seen again for a follow-up appointment with a researcher at six months to complete a number of questionnaires. Overall, your involvement in the study will be for a maximum of six months although the research study will last for two years.

### **What information do you need from me?**

If you agree to take part in the research the first thing we will want to do is find out about you. We will need to ask about your current and past mental health as well as your life more generally. We will ask you some questions about how you have been feeling recently and there will be a few questionnaires that we would like you to fill out. You will also be able to ask any questions you may have about the study. This meeting will take about two hours. We expect that the follow-up appointment will take no more than around 45 minutes and we will collect some more questionnaires from you at this appointment.

We are also interested in finding out about people's experiences of taking part in the trial and what they think of stepped care and will be giving a small number of people the opportunity to describe their experiences. We will ask some of the participants who are allocated to stepped care to attend a longer interview of up

to 60 minutes after they have completed treatment and we would like to audio or video record this. The interview would be conducted over the phone or face to face at your home. Alternatively, if you cannot speak on the phone or meet a study researcher at your home, we will arrange to meet with you at the University of Exeter. There is a separate part to the consent form to allow for the interview and you do not have to agree to it if you do not want to. If you choose not to take part in the interview, you can still take part in the trial and it will not affect the standard of care you receive. If you agree, the recordings will be given a code and securely stored for a maximum of nine years before being destroyed. We will also make typed copies of the recorded conversations. We will ensure all information in these copies is anonymous by removing all named references to you or your family and friends.

So that we can select people for interview depending on how much therapy they receive, we would like to keep track of how many and which therapy sessions you attend. This information will be recorded by your therapist and will be shared with the research team. The number of sessions you attend will not affect your care or your on-going involvement in the trial.

**Will I have to do anything differently?**

No, there are no restrictions in your lifestyle from taking part in this research. You should continue to follow the advice of your GP if they remain involved in your care.

**Will I be paid to take part?**

No. We cannot pay people to attend appointments with their therapist and we will not reimburse travel expenses for these. Occasionally, it may be necessary for people to attend additional interviews with a study researcher at the University of Exeter for which we will pay travel expenses.

**Are there any side effects, disadvantages and risks of taking part?**

We are not aware of any side effects, disadvantages or risks to you of taking part in this research.

### **What are the possible benefits of taking part?**

Many people find that guided self-help and/or CBT are helpful as both have been shown to have a positive effect for some people with depression. We hope that you will find the treatment you are given will help you. However, we cannot guarantee that you will benefit from the treatments. The information we get from this study may help us to treat future patients with depression better.

### **What happens when the research study stops?**

We will encourage you to continue to see your GP who will treat you as s/he feels is best for you and with your agreement. We may also encourage you to re-contact your local IAPT service who will treat you in the usual way.

### **What if something goes wrong or I have a complaint?**

We do not expect any harm coming to you from being in this study. However, if you wished to complain, or had any concerns about any aspect of the way you have been approached or were treated during the course of this study, the normal National Health Service complaints mechanisms are available to you through the Patient Advice and Liaison Service (PALS) on 0800 0730741. Alternatively, you may prefer to raise the matter with the Mood Disorder Centre AccEPT Clinic. Written complaints should be sent to the AccEPT clinic complaints manager, Holly Sugg, AccEPT Clinic Administrator, at: Washington Singer Laboratories, School of Psychology, University of Exeter, Perry Road, Exeter, EX4 4QG. If you are eligible, agree to take part and are unhappy with the care or treatment you receive, you can also raise the matter (in writing or by speaking) with your clinic therapist.

### **Will my taking part in this study be kept confidential?**

All information collected about you during the course of the research will be kept strictly confidential. Any information about you that is collected from the questionnaires or interviews will have your name and address removed so that you cannot be recognised from it. As your GP may be involved in your treatment, s/he will be informed of your progress as part of the research study, with your permission. Should your condition worsen to a point where it is felt by either a researcher or a clinician that you may be a danger to yourself or others,



your GP will be informed of this; with or without your permission. However, this is the only time we would ever break confidentiality.

### **Who is organising and funding the research?**

The study researcher is funded by the University of Exeter who also sponsor this research. This is not a commercially funded industry study. This means that the IAPT service which invited you to express your interest and the research team will not receive any extra money for conducting this study.

### **Who has reviewed the study?**

All research involving NHS patients is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights well-being and dignity. The study has been reviewed and given a favourable opinion by the South West - Frenchay Research Ethics Committee.

### **Further Information – Next Steps**

Please look at the 'Participant Flow Chart' which sets out the assessment and treatment process in a way which we hope you find helpful. If you would like to know more about the study you should complete your 'Permission for Researcher to Contact' form and bring it with you to your DAS Assessment Appointment. We will then contact you and invite you to ask us any questions you may have. If you want to take part and are potentially eligible, an appointment will be arranged at a time to suit you, for you to come and see Jacqueline Hill who is the study researcher. During this meeting you will also have the chance to ask questions and we will ask you for more information to find out if you are eligible. Last, if you are eligible and want to take part, we will ask you to sign a form to say so and then get you to fill out some questionnaires about yourself. We will complete this process within five working days of your Assessment Appointment.

If you need further information to help you decide, please contact Jacqueline Hill at the address below.

***Thank you for reading this and for considering taking part in this study.***

### **Contact for Further Information**

If you need further information about this study please contact:

Jacqueline J. Hill, STEPS Study Researcher  
Sir Henry Wellcome Building for Mood Disorders Research  
University of Exeter, The Queen's Drive  
Exeter, EX4 4QQ

Email: [j.j.hill@exeter.ac.uk](mailto:j.j.hill@exeter.ac.uk)

Office telephone: 01392 725273



**STEPS Participant Information for Clinic Form**

*To be completed at end baseline for eligible and willing patients*

**TRIAL ID:**

**Date Randomised:**

**PREFERRED DAY(S) / TIME(S) FOR THERAPY:**

**Demographics**

Marital Status:

Number of Children:

Ethnic Group:

Level of Education:

Age:

Housing:

Employment:

**CIS-R results**

Probable primary diagnosis:

Probable secondary diagnosis:

Total Score:

### **History of Depression and Treatment**

Previously diagnosed with depression in the past:

If YES, number of previous episodes:

Duration of current episode:

Currently prescribed anti-depressant medication:

### **Questionnaire Data**

BDI-I Total Score:

BDI-I Level of Depression:

GAD-7 Total Score:

GAD-7 Level of Difficulty:

### **Risk**

Risk Protocol Enacted:

If YES:

Date:

Time point:

Level of Risk:

Previous suicide attempt: YES/NO

### **Other Useful Information**


### **Appendix III: Feasibility study data collection**

This appendix provides a copy of feasibility study questionnaires, therapy session record forms and interview topic guides used to collect data:

- Baseline Case Report Form
- Guided Self-Help session record
- Cognitive Behaviour Therapy session record
- Patient Health Questionnaire (PHQ-9)
- Patient topic guide
- Therapist topic guide
- IAPT manager topic guide \*\*

*\*\* Administrator and PWP guides not included - available on request*

Baseline Case Report Form (CRF)

Date: _____	Participant Number: _____	Section A
 <b>STEPS</b> Stepped Care Trial		
<b>The Development and Evaluation of Stepped Care:</b> A Mixed Method Feasibility Study		
<b>BASELINE</b> <b>CASE REPORT FORM</b>		
BASELINE CRF v1.2_16 OCT 2013		1

Date: \_\_\_\_\_ Participant Number: \_\_\_\_\_

Section A

Recruitment Number: \_\_\_\_\_

Date of Birth: \_\_\_/\_\_\_/\_\_\_\_\_

Gender: Male  Female

### Consent

Has the participant given their consent? Yes  No   
Date of consent: \_\_\_/\_\_\_/\_\_\_\_\_

### Exclusion Criteria



1. Is the participant 18 or over?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Is the participant currently receiving psychological treatment from a provider other than Devon DAS?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Ensure patient is aware that they cannot take part in STEPS whilst receiving psychological treatment in DAS or elsewhere.		
Does patient wish to take part in STEPS?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. Is the patient alcohol or drug dependent?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Yes, has the patient been diagnosed with a substance abuse disorder?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4. Has the patient been diagnosed with Bipolar Disorder, Schizophrenia or psychotic symptoms?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5. Is the patient acutely suicidal? (complete at end of interview)	Yes <input type="checkbox"/>	No <input type="checkbox"/>

### Exclusion Criteria: Mini-Cog

#### Administration

The test is administered as follows:

1. Instruct the participant to listen carefully to and remember the following three words, and then to repeat the words:  
     APPLE            WATCH            PENNY
2. Instruct the participant to draw the face of a clock (on page 4), and then ask them to draw the hands of the clock to represent the time “forty five minutes past ten o’clock”.
3. Ask the participant to repeat the three previously stated words.

#### Scoring

Please circle the scores given for each question below and then tick if the participant is or is not cognitively impaired.

Question

2. (circle one)

Abnormal

Normal

3. (circle one)



Cognitively impaired

Not cognitively impaired

(tick one)



#### Additional Scoring Information

- Q2 Clock Drawing Test (CDT) – score the CDT ‘Normal’ or ‘Abnormal’. The CDT is considered normal if all numbers are present in the correct sequence and position, and the hands readably display the requested time.
- Q3 Word recall – give 1 point for each recalled word.

Q3 = 0 + any CDT	Cognitively impaired
Q3 = 1 or 2 + CDT Abnormal	Cognitively impaired
Q3 = 1 or 2 + CDT Normal	Not cognitively impaired
Q3 = 3 + any CDT	Not cognitively impaired



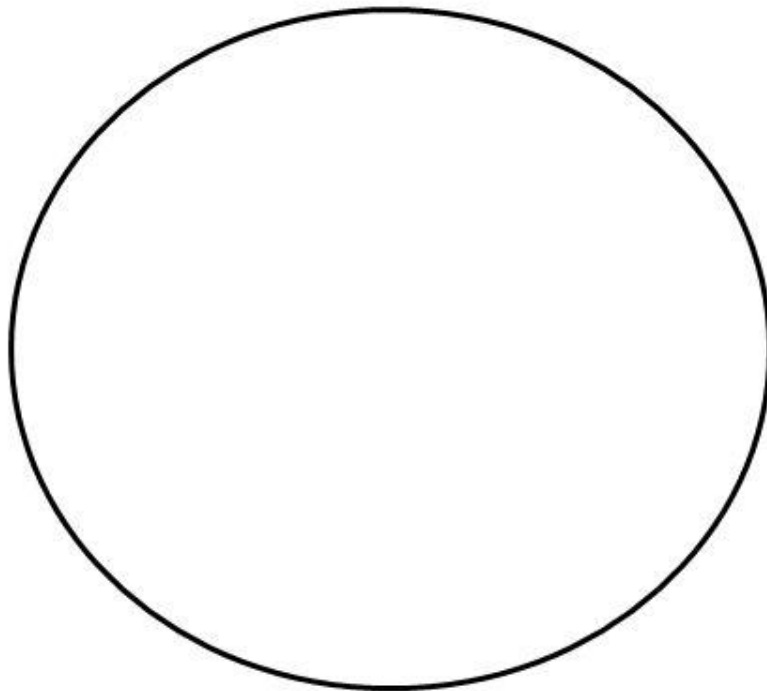
Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section A

**Instructions:**

Inside the circle please draw the face of a clock. Then place the hands of the clock to represent the time "forty five minutes past ten o'clock".



Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section A

### Exclusion Criteria: CIS-R

Probable primary ICD-10 diagnosis \_\_\_\_\_

Probable secondary ICD-10 diagnosis \_\_\_\_\_

CIS-R Total Score \_\_\_\_\_

Does the patient have a current diagnosis of Major Depressive Disorder: YES/ NO

### Exclusion Criteria: SUMMARY

Is participant excluded from study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b><i>If 'Yes', please specify reason for exclusion:</i></b>		
Under 18	<input type="checkbox"/>	
Intends to continue with DAS therapy	<input type="checkbox"/>	
Currently receiving psychological therapy elsewhere	<input type="checkbox"/>	
Diagnosed with Substance Abuse Disorder, Bipolar Disorder and / or Psychosis	<input type="checkbox"/>	
Cognitively impaired	<input type="checkbox"/>	
Does not have current Major Depressive Episode	<input type="checkbox"/>	
Acute risk <i>(please complete at end of interview)</i>	<input type="checkbox"/>	

Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section B

**Demographics**

<b>Marital Status: (from CIS-R)</b> Single Married / Living as Married Divorced / Separated Widowed	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Number of Children:</b> 0 1 2 3 4+	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Ethnicity:</b> White: British White: Irish White: Other White Mixed: White and Black Caribbean Mixed: White and Black African Mixed: White and Asian Mixed: Other Mixed Asian: Indian Asian: Pakistani Asian: Bangladeshi Other Asian Black Caribbean Black African Other Black Chinese Other Prefer not to say	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Level of Education:</b> No qualifications GCSEs/O-Levels AS/A-Levels NVQ or other vocational qualification Undergraduate degree Postgraduate degree Doctoral degree Professional degree (e.g. MD)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section B

**Demographics**

<b>Age (from CIS-R):</b>		<b>Housing situation (from CIS-R):</b>	
19 yrs or under	<input type="checkbox"/>	Home owner	<input type="checkbox"/>
20-29 yrs	<input type="checkbox"/>	Tenant	<input type="checkbox"/>
30-39	<input type="checkbox"/>	Living with relative / friend	<input type="checkbox"/>
40-49	<input type="checkbox"/>	Hostel / Care Home	<input type="checkbox"/>
50-59	<input type="checkbox"/>	Homeless	<input type="checkbox"/>
60-69	<input type="checkbox"/>	Other	<input type="checkbox"/>
70-79	<input type="checkbox"/>		
80 yrs or over	<input type="checkbox"/>		
<b>Employment Status (from CIS-R):</b>			
Working Full Time	<input type="checkbox"/>		
Working Part Time	<input type="checkbox"/>		
Student	<input type="checkbox"/>		
Retired	<input type="checkbox"/>		
Houseperson	<input type="checkbox"/>		
Unemployed job seeker	<input type="checkbox"/>		
Unemployed due to ill health	<input type="checkbox"/>		

Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section B

### History of Depression and Previous Treatment

#### Preferred day and time for therapy

Have you been previously diagnosed with depression? Yes  No

How many previous episodes of depression have you had?

Number of previous episodes: \_\_\_\_\_

For how long have you had your current episode of depression

Number of weeks: \_\_\_\_\_

Are you currently being prescribed anti-depressant medication? Yes  No

Have you received psychological therapy in the past? Yes  No

Number of courses of GSH: \_\_\_\_\_

Number of courses of CBT: \_\_\_\_\_

Number of courses of other therapy: \_\_\_\_\_

Have you attempted suicide in the past? Yes  No

Number of times: \_\_\_\_\_

Date of most recent attempt: \_\_\_\_\_ (month/year)

**What day or time would you prefer for therapy as part of this research?** Although we will consider this information when we arrange your treatment we may not be able to offer you an appointment at your preferred time.

Day(s) \_\_\_\_\_

Time(s) \_\_\_\_\_

**BDI-I**

Please read each group of statements carefully, then pick out the **one** statement in each group which best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked.

If several statements in the group seem to apply equally well, simply circle the statement which has the largest number. Be sure that you do **not** circle more than one statement for any item.

**A Mood**

- 0 I do not feel sad
- 1 I feel blue or sad
- 2a I am blue or sad all the time and I can't snap out of it
- 2b I am so sad or unhappy that it is very painful
- 3 I am so sad or unhappy that I can't stand it

**B Pessimism**

- 0 I am not particularly pessimistic or discouraged about the future
- 1a I feel discouraged about the future
- 2a I feel I have nothing to look forward to
- 2b I feel that I won't ever get over my troubles
- 3 I feel that the future is hopeless and that things cannot improve

**C Sense of Failure**

- 0 I do not feel like a failure
- 1 I feel like I have failed more than the average person
- 2a I feel I have accomplished very little that is worthwhile or that means anything
- 2b As I look back on my life all I can see is a lot of failures
- 3 I feel I am a complete failure as a person (parent, husband, wife)

**D Lack of Satisfaction**

- 0 I am not particularly dissatisfied
- 1a I feel bored most of the time
- 1b I don't enjoy things the way I used to
- 2 I don't get satisfaction out of anything any more
- 3 I am dissatisfied with everything

**E Guilty Feeling**

- 0 I don't feel particularly guilty
- 1 I feel bad or unworthy a good part of the time
- 2a I feel quite guilty
- 2b I feel bad or unworthy practically all the time now
- 3 I feel as though I am very bad or worthless

**F Sense of Punishment**

- 0 I don't feel I am being punished
- 1 I have a feeling that something bad may happen to me
- 2 I feel I am being punished or will be punished
- 3a I feel I deserve to be punished
- 3b I want to be punished

**G Self Hate**

- 0 I don't feel disappointed in myself
- 1a I am disappointed in myself
- 1b I don't like myself
- 2 I am disgusted with myself
- 3 I hate myself

**H Self Accusations**

- 0 I don't feel I am any worse than anybody else
- 1 I am very critical of myself for my weaknesses or mistakes
- 2a I blame myself for everything that goes wrong
- 2b I feel I have many bad faults

**I Self-punitive Wishes**

- 0 I don't have any thoughts of harming myself
- 1 I have thoughts of harming myself but I would not carry them out
- 2a I feel I would be better off dead
- 2b I have definite plans about committing suicide
- 2c I feel my family would be better off if I were dead
- 3 I would kill myself if I could

**J Crying Spells**

- 0 I don't cry any more than usual
- 1 I cry more now than I used to
- 2 I cry all the time now. I can't stop it
- 3 I used to be able to cry but now I can't cry at all even though I want to

**K Irritability**

- 0 I am no more irritated now than I ever am
- 1 I get annoyed or irritated more easily than I used to
- 2 I feel irritated all the time
- 3 I don't get irritated at all at the things that used to irritate me

**L Social Withdrawal**

- 0 I have not lost interest in other people
- 1 I am less interested in other people now than I used to be
- 2 I have lost most of my interest in other people and have little feeling for them
- 3 I have lost all my interest in other people and don't care about them at all

**M Indecisiveness**

- 0 I make decisions about as well as ever
- 1 I am less sure of myself now and try to put off making decisions
- 2 I can't make decisions any more without help
- 3 I can't make any decisions at all any more

**N Body Image**

- 0 I don't feel I look any worse than I used to
- 1 I am worried that I am looking old or unattractive
- 2 I feel that there are permanent changes in my appearance and they make me look unattractive
- 3 I feel that I am ugly or repulsive looking

**O Work Inhibition**

- 0 I can work about as well as before
- 1a It takes extra effort to get started at doing something
- 1b I don't work as well as I used to
- 2 I have to push myself very hard to do anything
- 3 I can't do any work at all

**P Sleep Disturbance**

- 0 I can sleep as well as usual
- 1 I wake up more tired in the morning than I used to
- 2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep
- 3 I wake up early every day and can't get more than 5 hours sleep

**Q Fatigability**

- 0 I don't get any more tired than usual
- 1 I get tired more easily than I used to
- 2 I get tired from doing anything
- 3 I get too tired to do anything

**R Loss of Appetite**

- 0 My appetite is no worse than usual
- 1 My appetite is not as good as it used to be
- 2 My appetite is much worse now
- 3 I have no appetite at all any more

**S Weight Loss**

- 0 I haven't lost much weight, if any, lately
- 1 I have lost more than 5 pounds
- 2 I have lost more than 10 pounds
- 3 I have lost more than 15 pounds

**T Somatic Preoccupation**

- 0 I am no more concerned about my health than usual
- 1 I am concerned about aches and pains or upset stomach or constipation or other unpleasant feelings in my body
- 2 I am so concerned with how I feel or what I feel that it's hard to think of much else
- 3 I am completely absorbed in what I feel

**U Loss of Libido**

- 0 I have not noticed any recent change in my interest in sex
- 1 I am less interested in sex than I used to be
- 2 I am much less interested in sex now
- 3 I have lost interest in sex completely

PTO

10

Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section B

**GAD-7**

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Not being able to stop or control worrying	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Worrying too much about different things	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Trouble relaxing	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Being so restless that it is hard to sit still	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Becoming easily annoyed or irritable	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Feeling afraid as if something awful might happen	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

Total \_\_\_\_\_ = Add \_\_\_\_\_ + \_\_\_\_\_ + \_\_\_\_\_  
Score Columns

If you checked off any problems, how difficult have these problems made it for you to do your  work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

□

The GAD-7 was developed by Drs. Robert L. Spitzer, Kurt Kroenke, Janet B.W. Williams, and Bernd Löwe. For research information, contact Dr. Spitzer at [rls8@columbia.edu](mailto:rls8@columbia.edu). Copyright© 2005 Pfizer Inc. All rights reserved. Reproduced with permission



Date: \_\_\_\_\_

Participant Number: \_\_\_\_\_

Section B

## SF-36 v2

### HEALTH STATUS QUESTIONNAIRE

The following questions ask you about your health, how you feel and how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

#### OVERALL HEALTH

1. In general, would you say your health is:

*(Please circle one number only)*

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

*(Please circle one number only)*

+	Much better now than one year ago	1
	Somewhat better now than one year ago	2
	About the same as one year ago	3
	Somewhat worse now than one year ago	4
	Much worse now than one year ago	5

***Please turn the page and continue***

**HEALTH AND DAILY ACTIVITIES**

- 3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**

*(Please circle one number on each line)*

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. <b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing <b>several</b> flights of stairs	1	2	3
e. Climbing <b>one</b> flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking <b>more than a mile</b>	1	2	3
h. Walking <b>several hundred yards</b>	1	2	3
i. Walking <b>one hundred yards</b>	1	2	3
j. Bathing or dressing yourself	1	2	3

***Please turn the page and continue***

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(Please circle one number on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <b>amount of time</b> you spent on work or other activities	1	2	3	4	5
b. <b>Accomplished less</b> than you would like	1	2	3	4	5
c. Were limited in the <b>kind</b> of work or other activities	1	2	3	4	5
d. Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(Please circle one number on each line)

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the <b>amount of time</b> you spent on work or other activities	1	2	3	4	5
b. <b>Accomplished less</b> than you would like	1	2	3	4	5
c. Did work or other activities <b>less carefully than usual</b>	1	2	3	4	5

***Please turn the page and continue***

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

*(Please circle one number)*

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much **bodily pain** have you had during **the past 4 weeks**?

*(Please circle one number)*

None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

*(Please circle one number)*

Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

***Please turn the page and continue***

**YOUR FEELINGS**

- 9. These questions are about how you feel and how things have been with you during the past 4 weeks. (For each question, please give the one answer that comes closest to the way you have been feeling.)**

*(Please circle one number on each line)*

How much of the time during the <u>past 4 weeks</u> :	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5
b. Have you been very nervous?	1	2	3	4	5
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
d. Have you felt calm and peaceful?	1	2	3	4	5
e. Did you have a lot of energy?	1	2	3	4	5
f. Have you felt down-hearted and depressed?	1	2	3	4	5
g. Did you feel worn-out?	1	2	3	4	5
h. Have you been happy?	1	2	3	4	5
j. Did you feel tired?	1	2	3	4	5

***Please turn the page and continue***

**HEALTH IN GENERAL**

- 10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives etc.)?**

*(Please circle one number)*

All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

- 11. How TRUE or FALSE is each of the following statements for you?**

*(Please circle one number on each line)*

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

**THANK YOU FOR COMPLETING THIS QUESTIONNAIRE**

**FOR RESEARCHERS ONLY**

Researcher Name:	
Researcher Signature:	
Date:	

## Participant Session Record

### Guided Self-Help

<b>Participant ID:</b>	<b>Date of contact:</b>	<b>Session number:</b>	<b>PHQ9 Score:</b>	<b>Adverse Event:</b> <i>Circle all that apply</i>  <b>YES / NO</b> <b>Serious</b>
<i>Against the appropriate lesson, indicate key themes covered</i>				
<b>Lesson One</b>				
<b>Lesson Two</b>				
<b>Lesson Three</b>				
<b>Lesson four</b>				
<b>Lesson Five</b>				
<b>Action Following (including summary of any GP contact):</b>				

**Participant Session Record**  
**Cognitive Behaviour Therapy**

Participant ID: \_\_\_\_\_

Therapist: \_\_\_\_\_

Date of session: \_\_\_\_\_

Session number: \_\_\_\_\_

**Adverse Event** (please circle all that apply): YES  
/ NO / Serious

<b>Themes covered - please tick all that apply</b>	
Assessment/rationale	<input type="checkbox"/>
Descriptive conceptualisation	<input type="checkbox"/>
Goal setting & first interventions	<input type="checkbox"/>
Behavioural experiments	<input type="checkbox"/>
Behavioural intervention: activity and mastery	<input type="checkbox"/>
Behavioural intervention: activity scheduling	<input type="checkbox"/>
Identifying and responding to negative thoughts	<input type="checkbox"/>
Cross-sectional case formulation	<input type="checkbox"/>
Session summary	<input type="checkbox"/>
Patient feedback on session	<input type="checkbox"/>



## PHQ-9

Over the last 2 weeks, 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: Total Score \_\_\_\_\_ = \_\_\_\_ + \_\_\_\_ + \_\_\_\_ )

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult  
at all

Somewhat  
difficult

Very  
difficult

Extremely  
difficult

From the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD PHQ). The PHQ was developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues. For research information, contact Dr. Spitzer at [rls8@columbia.edu](mailto:rls8@columbia.edu). PRIME-MD® is a trademark of Pfizer Inc. Copyright© 1999 Pfizer Inc. All rights reserved. Reproduced with permission



<b>TRIAL ID</b>
<b>DATE</b>
<b>LOCATION</b>

The development of **stepped** care: a mixed method feasibility **study**

## **Views and experiences of stepped care: Qualitative interview topic guide**

### **PATIENTS**

- **What are patients' views about the acceptability of stepped care?**
- **What did people think of the Wellbeing Course?**
- **What were people's reactions to our trial methods and procedures?**

## Introduction

Thank you very much for meeting with me today. We really appreciate your time.

You may remember that we'd like to know what you think about the treatment you've received as part of this study. We'd also like to hear your views of how we have set up and run the study so I'll be asking you some questions about that, too.

Compared with when I last met with you, this interview will be a bit different. We'd like to know what you think about things. This means that I will ask you questions for you to tell me your views and opinions – how things have been from your perspective. Sometimes, I might follow up something you say with a few more questions to make sure that I fully understand it.

Before we begin, are you still happy for our interview to be audio-recorded? I'll let you know when I start recording.

You may remember that everything you say is kept strictly confidential with one exception and that's if you tell me anything which makes me think you may be at risk of harming yourself or someone else. Is that OK?

Is there anything that you would like to ask before we begin?

As we go through the questions, if anything is unclear, please do ask me to explain.

Ready to begin?

I'm going to start recording now.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

## ACCEPTABILITY OF STEPPED CARE

### Thoughts and feelings before treatment

I'm interested in why you sought treatment for depression / anxiety. What led you to seek help?

What did you expect from treatment?

**Were there any problems with which you particularly wanted help? What were they?**

How did you feel when you were offered stepped care?

### Experiences of therapy

What did you think about **Guided Self Help**?

- Of the material you received?
- About meeting with your therapist
  - Face to face or by phone
  - How often you met or spoke
  - The length of each session
- The total length of time you were in therapy – received GSH (max 6 weeks)

What did you think about **CBT**?

- The course content?
- About meeting with your therapist
  - Face to face for all / most sessions
  - How often you met
  - The length of each session
- The length of time you were in therapy – received CBT (max 4 months)

What was useful / not useful about your treatment?

**How well did the therapy help you with the problems you wanted to work on?**

Why did you decline any treatment / stop early?

How could your treatment have been improved?

## **Experiences of stepped care**

What do you understand by the term stepped care?

What did you think about starting with Guided Self Help?

- Knowing you may get CBT – or not?
- Compared with only having CBT?

How did you feel about going on to CBT?

- What did you think about changing therapists?

How did you feel about your symptoms of depression being assessed?

- How often this happened
- Using a symptom checklist
- How the information was used (to decide if you stop treatment after GSH or go on to CBT)

How did you feel when your treatment ended?

- What, if anything, further should be done to help people who respond well to GSH and do not have CBT?

## **FEASIBILITY AND APPROPRIATENESS OF TRIAL PROCEDURES**

Your views and opinions of how this study has been set up and run are also important to us.

### **Recruitment**

First, I'd like you to think about how you came to join this study so what happened before you started treatment...

When did you decide to take part?

What did you think about the written information you received (summary sheet and PIS)?

How did you feel about how long it took for me to contact you after you returned your form?

What did you think about meeting with your DAS therapist and then with me?

- How did you find talking about your feelings / reasons for seeking treatment again?

### **In study support**

Now I would like to know about how things were once you joined the study...

What did you think of how long it took the clinic team to contact you after we met for your baseline interview?

How easy was it to schedule therapy appointments?

Did you receive all of the GSH material? If not, what went wrong?

How well have we addressed any questions or concerns you may have had since starting therapy?

### **General**

What, if anything, could have been done differently to improve the running of the study?

### **FINISH**

Finally, are there any other comments that you would like to make about taking part?

***Thank you.***

Stop recording and tell the patient that the recorder has been switched off.

Explain that the patient will receive a short summary of the results of the interviews once completed plus a feedback form for their comment.

Remind the patient that the research team will be in touch to arrange their six month follow up appointment.

## PATIENT INTERVIEW CHECKLIST

INTERVIEW NOTES		TRIAL ID	
		DATE	
		LOCATION	
<p><b>Before treatment</b></p> <p><input type="radio"/> How they came to treatment</p> <p><input type="radio"/> Expectations <b>and problems to be addressed</b></p> <p><input type="radio"/> View of being offered stepped care</p>	<p><b>Recruitment</b></p> <p><input type="radio"/> When decided to take part</p> <p><input type="radio"/> Summary and PIS</p> <p><input type="radio"/> Five day turnaround</p> <p><input type="radio"/> Meeting DAS therapist and then me</p>		
<p><b>Experience of therapy</b></p> <p><input type="radio"/> <i>Guided Self Help</i> Material Meeting mode, frequency and length of each contact Total time in therapy</p> <p><input type="radio"/> <i>CBT</i> Course content Meeting mode, frequency and length of each contact Total time in therapy</p> <p><input type="radio"/> What was useful / not about therapy</p> <p><input type="radio"/> <b>How well were problems addressed</b></p> <p><input type="radio"/> Reasons for declining / stopping treatment How to improve therapy</p>	<p><b>In study</b></p> <p><input type="radio"/> Time for clinic to contact after baseline</p> <p><input type="radio"/> Arranging therapy</p> <p><input type="radio"/> Being sent GSH material</p> <p><input type="radio"/> Addressing questions / concerns</p> <p><b>General</b></p> <p><input type="radio"/> How could we improve how the study is run?</p> <p><b>END</b></p> <p><input type="radio"/> Any other comments on taking part?</p>		
<p><b>Experiences of stepped care</b></p> <p><input type="radio"/> What's meant by stepped care</p> <p><input type="radio"/> Starting with GSH</p> <p><input type="radio"/> Going on to CBT</p> <p><input type="radio"/> <i>Being monitored</i> How often Check list How the info was used</p> <p><input type="radio"/> <i>Ending treatment</i> Additional support for patients who do not have CBT</p>	<p><b>OTHER</b></p> <p><i>Arising from interview...</i></p>		



<b>THERAPIST ID</b>
<b>DATE</b>
<b>LOCATION</b>

The development of **stepped** care: a mixed method feasibility **study**

## **Views and experiences of stepped care: Qualitative interview topic guide**

### **THERAPISTS**

- **What are therapists' views about the acceptability of stepped care?**
- **What do therapists think of the Wellbeing Course?**
- **What were their reactions to our trial methods and procedures?**



## **Introduction**

Thank you very much for meeting with me today. I really appreciate your time. As you know, I would like to find out what you think about the stepped care you've delivered as part of this study. I'd also like to hear your views of how we have set up and run STEPS so I'll be asking you some questions about that too. I have broad questions that will help structure the interview but I will also be led by what you say. Sometimes I might follow up something you tell me with more questions to help me understand it in full.

Is that OK?

Before we begin, I would like to acknowledge that it may sometimes be difficult for you to provide honest feedback. However, it is important for me to understand what did and didn't work well. The information you provide will be used to help develop a large clinical trial on stepped care. Everything you say is kept strictly confidential. This means that if I quoted something you said in a report or paper, I would not attribute the quote to you. Nor will I, without your permission, include a quote that would directly identify you by something you said. However, because a very small number of therapists have been involved in STEPS, it may be possible for a reader who is familiar with the project to attribute quotes and/or views, to you or your colleagues.

Do you have any concerns?

I will now ask you to complete a consent form. By signing it you will give me permission to speak with you and to use the information you provide. Run through consent form and invite questions.

Is there anything that you would like to ask before we begin?

As we go through the interview, if any of my questions are unclear, please do ask me to explain.

Ready to begin?

I'm going to start recording now.

Switch on recorder and introduce the recording by stating the **date** and **time** of the interview and the interviewee's **first name**.

## **1. UNDERSTANDING OF STEPPED CARE**

**To help me understand what you think of stepped care, I would like to know how you define it. Please describe stepped care to me.**

Explore:

*Definition of low and high intensity therapy*

*The role of systematic monitoring to inform next treatment step*

*Previous experience of stepped care*

## **2. LOW INTENSITY THERAPY**

**I would now like to ask you about the stepped care you have implemented as part of this study. First, please tell me what you thought of the Wellbeing Course.**

Explore:

*What they thought about the course material*

*How they felt about conducting sessions by phone*

*The frequency and length of each session and the total duration of the course*

*How they expected patients to benefit from GSH*

*Views on starting every StC patient with GSH - knowing patients may (or not) get CBT*

*By comparison, what they thought of giving patients CBT alone*

*Any patients or circumstances where it felt inappropriate to begin with GSH and how they handled that*

*Reasons why patients declined GSH or dropped out early and how they felt about this*

*Ways in which the WB course and how it was delivered could be improved*

### 3. MONITORING

**You monitored stepped care patients' symptoms of depression and used this information to help decide if people ended treatment or 'stepped up' following GSH. What were your views and experience of this?**

Explore:

*How they felt about monitoring patients every week / session and how they used this information*

*Their views on using a symptom checklist to monitor progress*

*What they thought of the stepping criteria and how criteria were applied in practice*

*The extent to which patients were involved in deciding to end treatment / step up*

*Any patients for whom or circumstances in which the criteria felt wrong or were difficult to implement and how they handled this*

*How they felt when patients ended treatment following GSH and what, if any, additional support they wanted to offer*

### 4. HIGH INTENSITY THERAPY

**About one third of patients 'stepped up' following GSH. Please tell me what you thought about patients going on to CBT and the therapy they received.**

Explore:

*How they felt about patients stepping up and any concerns this raised*

*Views on patients changing therapists and how they facilitated this transition*

*What they thought of the frequency, length of sessions and total duration of CBT treatment - given that patients had already completed the WB course*

*Views on patients' total time in treatment following step up i.e. 6 to 8 months*

*Any reasons patients gave for declining CBT or dropping out early after completing GSH*

*How they felt when patients who had stepped up ended CBT and how this was influenced by patients' progress*

*What more, if any, support they wanted to offer on end CBT*

**Please tell me about anything else that feels important to feedback on your experience of stepped care.**

*Patients for whom stepped care worked especially well or not and why*

*How (else) we could improve how stepped care is delivered*

## **5. FEASIBILITY AND APPROPRIATENESS OF TRIAL PROCEDURES**

**Your views and opinions of how this study has been set up and run are also important to us...**

Explore:

*What they thought of the STEPS orientation day [SHOW AGENDA].*

*Views on the Clinic handbook [SHOW HANDBOOK] including how much and what ways it was used*

*How well we coordinated patients' care on randomisation (allocated therapists and arranged first treatment sessions)*

*Problems scheduling therapy sessions or sending patients GSH material*

*Views and experiences of record keeping and file management including how they found filling in session records and patient contact logs*

*How they felt about SAE and risk procedures*

*Views on STEPS' DNA protocol and letters to people who withdrew from therapy*

*How they felt about clinical supervision*

**Please tell me about anything else that feels important to feedback on the set up and running of STEPS**

*What might be done to improve how the study is run*  
*Any other comments about the research*

## **THANK YOU**

Stop recording and tell the therapist that the recorder has been switched off.

Explain that the therapist will receive a short summary of the interview to check for accuracy.

Then, once the results of all of the interviews with the therapists are combined, they will receive a brief summary and feedback form for comment. This will be in a few months' time.

## THERAPIST INTERVIEW CHECKLIST

THERAPIST ID; DATE AND LOCATION OF INTERVIEW:	
<p><b>Stepped Care</b></p> <p><input type="radio"/> <i>Understanding of stepped care</i></p> <p><input type="radio"/> <i>Wellbeing Course</i> Material Session mode, frequency and length Total time in GSH Any improvements</p> <p><input type="radio"/> <i>Starting with GSH</i> Knowing patients may (or not) have CBT Compared with only giving CBT Patients for whom this felt inappropriate How they expected patients to benefit Why people dropped out</p> <p><input type="radio"/> <i>Monitoring</i> How they felt about weekly monitoring Using a check list How info was used</p> <p><input type="radio"/> <i>Stepping criteria</i> Implementation in practice Patient involvement Patients for whom criteria felt wrong Circumstances where criteria felt wrong</p> <p><input type="radio"/> <i>Ending treatment after GSH</i> Additional support</p> <p><input type="radio"/> <i>Stepping up</i> Views on stepping up patients Changing therapists</p> <p><input type="radio"/> <i>CBT</i> Meeting mode, frequency and length of each contact Total time in CBT Total time in StC for patients who step up Why patients dropped out</p> <p><input type="radio"/> <i>Ending treatment after CBT</i> Additional support</p>	<p><b>Study methods / procedures</b></p> <p><input type="radio"/> <i>Set up</i> Orientation day Clinic handbook</p> <p><input type="radio"/> <i>In study</i> Patient care on randomisation Arranging therapy Sending GSH material Record keeping / file management SAEs Risk DNA protocol and with-drawls Clinical Supervision</p> <p><b>END</b></p> <p><input type="radio"/> <i>Any other comments</i> On stepped care About study</p> <p><b>OTHER</b></p> <p><input type="radio"/> <i>Arising from interview</i></p>



<b>INTERVIEWEE</b>
<b>DATE</b>
<b>LOCATION</b>

The development of **stepped** care: a mixed method feasibility **study**

## **Feasibility and appropriateness of recruitment Qualitative interview topic guide**

### **IAPT MANAGER**

- **To what extent were recruitment procedures implemented**
- **What facilitated / hindered recruitment**

## INTRODUCTION

Thank you very much for meeting with me today. I really appreciate your time. As you know, I would like to find out what you think about STEPS. Specifically, what you think about recruitment and how it involved DAS. I have some broad questions that will help structure the interview but I will also be led by what you say. Sometimes I might follow up something you tell me with more questions to help me understand it in full.

Is that OK?

Before we get going I would like to acknowledge that it may sometimes be awkward for you to share your views. However, it is important for me to understand what did and didn't work well. The information you provide will be used to help develop a large clinical trial on stepped care. I would also like to share a summary of what I learn from today with my colleagues: your views would be combined with those of other interviewees; I would not pass on confidential patient information; I would not attribute a specific view or quote to you. However, because I will interview a small number of DAS personnel, it may be possible for someone who is familiar with STEPS and Exeter DAS to attribute what is said, to you. Nonetheless, your feedback and that of your colleagues will be very useful.

Please can you tell me if you have any concerns?

I will now ask you to complete a consent form. This will give me permission to speak with you and to use the information you provide.

Run through the consent form; invite questions. On completion, explain that we are ready to proceed.

Is there anything that you would like to ask me before we begin?

If any of my questions are unclear during the interview, please do ask me to explain.

I am going to start recording now.



Switch on recorder and introduce the recording by stating the **date, time** and the **interviewee's first name**.

### **1. RESEARCH AND THE ROLE OF THE NHS**

**To help me understand what you think about STEPS, I would like to know what you think about research in general.**

Explore:

*Positive and negative views*

*The role of the NHS / DAS and research*

*Previous experience of research – negative or positive*

### **2. SET UP**

**I would now like to ask you about STEPS - first our work to agree how to recruit patients. This involved a number of meetings. We considered at what point to approach patients and a number of other concerns were raised. Please tell me what you thought about this process.**

Explore:

*To what extent were concerns raised addressed*

*Any other concerns*

*What she thought about interaction with the research team*

*How she felt about the agreed procedures*

### **3. IMPLEMENTATION**

**We are also interested in how the agreed procedures worked in practice. Please can you tell me about your experiences of this?**

Explore:

*How did she communicate what was required of her team – therapists, admin – how did they react*

*Any problems*

*What worked well*

*What facilitated or hindered recruitment*

*How she felt about interaction with the research team*

#### **4. THERAPIST REACTION**

**Please can you tell me (a bit more) about your and others' experience of handling permission forms?**

Explore:

*What it felt like asking people for forms*

*Anyone who did not ask patients about STEPS*

*Types of patient or situations where people were not asked about STEPS*

#### **5. PATIENT REACTION**

**Drawing on your own and others' experience, please tell us how patients responded when being asked if they wanted to return a permission form.**

Explore:

*What patients asked – any concerns*

*How did therapists feel about and respond to these questions*

*Reasons patients gave for deciding not to return a permission form*

*Views on the IAPT letter and STEPS summary sheet*

#### **6. END**

**Please tell me about anything else which has been important in your experience of STEPS that we have not already discussed.**

Any other comments

What, if anything, would you have liked to have done differently?

THANK YOU

Stop recording and tell the interviewee that the recorder has been switched off.

Explain that within a few weeks or so she will receive a short summary of the interview to check.

Then, once all of the interviews with DAS have been completed, a summary of what we have learnt, again for feedback and comment. This will be in a few months' time.

At the end of the study (end 2015) we will share what we have learnt from STEPS as a whole.

## **Appendix IV: Qualitative analysis**

This appendix provides a copy of material related to the qualitative analysis of feasibility study interview data, specifically:

- Sample patient interview field note
- Transcription template
- Example thematic framework
- Example chart
- Sample of abstraction

## Sample Patient Interview Field Note

INTERVIEW NOTES	TRIAL ID	trial 62
	DATE	6 Mar 2015
	LOCATION	patient's home
<b>Respondent characteristics (therapy received; pre and post PHQ-9 scores; demographics)</b> Baseline: severe dep Treatment: GSH 6 sessions PHQ-9 16 to 19 CBT 20 sessions PHQ-9 19 to 20.		
<b>Main themes on stepped care (starting with GSH; session length, mode, number &amp; total time in therapy; monitoring; stepping up; ending treatment)</b> GSH viewed as 'to be done' to get CBT - but seen as worthwhile albeit likely insufficient. CBT preferred for being personal, 1:1 and with a f. therapist whom he had known. Little notice paid to or use made of scale; did not call discussion 'stepping up' total time in therapy 'nothing' in context of life of illness.		
<b>Main themes on Wellbeing Course (material)</b> like a job! too much paperwork. Stories led to 2 probs & families & was unable to relate to them.		
<b>Main themes on trial methods and procedures</b> - rec'd course material for wrong week, once. - unable to readily get hold of clinic contact details / contact for Jo.		
<b>Anything not asked that would have liked to in hindsight</b> no.		
<b>Thoughts, new hypotheses</b> no.		
<b>Directions / questions for next interview</b> no. 'last ever interview!' miranda 😊		
<b>Comments about the contact</b> How did it go? How did I feel during? Rapport? Anything about the environment or events before or during the interview which may have influenced how it went? Interview interrupted couple of times by car recording in 2 parts following phone call for patient. Good rapport.		

## STEPS Qualitative Interview Transcript Template

Participant	Trial XX
Interviewer	Jacqueline J Hill
Date of interview	XX/XX/XXXX
Mode of interview	In person / By phone (delete as appropriate)
Transcribed by	Insert full name
Date last modified	XX/XX/XXXX
Transcript checked by	Insert name of person who checked transcript and date check completed

### Transcription conventions:

{} Interviewer and participant talk at same time  
 [] non-verbal utterances e.g. laughter  
 Xxx unintelligible  
 (...) pause  
 Hyphen indicates an abrupt cut off or self-interruption  
 Underlining indicates emphasis on the word

**Formatting:** Trial transcripts have been formatted so that each exchange of conversation is labelled by the identifier for the person (patient, interviewer) who is speaking. Insert what the person says on the line below their identifier. Interviewer and patient identifiers have been formatted as 'heading levels'; what people say must be formatted as 'normal' text. Insert a line break after what someone says and the next identifier. The start of the transcript is labelled by the interviewee's identifier – this label is formatted as normal text. The end of the transcript is demarcated by, "END OF TRANSCRIPT" – this has been written as normal text. All formatting should be left as is.

**Identifiers:** The interviewer will always be Jacqueline J Hill. Her identifier is I-JJ. Patient identifiers contain three pieces of information and they are written in the form: PAT-XXX-XXX. 'PAT' stands for patient. Next, insert the patient's Trial ID. Last denote whether the patient has had GSH only or both GSH and CBT - insert 'GSH' or 'ALL', respectively. (JJ will let you know what treatment

the patient has received.) As an example, the identifier for participant Trial01 who has received GSH and CBT would be 'PAT-001-ALL'.

**File labels:** Please save transcripts in the form: Trial ID\_ 'Transcriber's initials' 'date last modified'.

E.G. Trial 01\_JJ 12 Jan 2014. Replace (delete / save over) old versions of the transcript with the latest version; ensure that file is labelled by the date on which the document was last modified. Please save transcripts here:

N:\PSY\projects\Stepped Care\B. STEPS\7. Data\3.

Interviews\Patients\Transcripts\2. Originals

**[PATIENT IDENTIFIER]**

**I-JJ**

Insert text here and continue on a new line as required.  
Insert a blank line between the end of this text and the patient's identifier.  
Ensure that the blank line is formatted as normal text.

**PAT-XXX-XXX**

Insert text here and continue on a new line as required.  
Insert a blank line between the end of this text and the interviewer's identifier.  
Ensure that the blank line is formatted as normal text.

**I-JJ**

**PAT-XXX-XXX**

**I-JJ**

**PAT-XXX-XXX**

**I-JJ**

**PAT-XXX-XXX**

**I-JJ**

**PAT-XXX-XXX**

**I-JJ**

**END OF INTERVIEW**



## **IAPT – Recruitment: Development of Initial Thematic Framework**

### **1. Detected elements, 3-4 September 2015**

Feelings about research

Feelings about STEPS

Impact of other research on STEPS

Benefit – caseload

Passing over patients

Non-interest

### **Recruitment challenges**

Initial approach / DAS letter

28 day target

Five day turnaround

Returning to DAS – keeping people in treatment

Workload

Complexity for patients

Patient complexity

Handling forms / assessment

Record keeping

Handling risk

Risk / PTSD

Literacy

Non-depressed patients

Potentially ineligible patients

Potentially unsuitable patients

STEPS therapist capacity

Patients' questions – how STEPS would help

Handling patient questions

Patients' questions – treatment delay

Patients' questions – getting treatment

Patient queries – scheduling treatment

Patient queries – focus of treatment

Prevalence target

Returning to DAS

Treatment delay

Therapist capacity

Keeping people in treatment

Receiving treatment at DAS and STEPS

Staff briefing / interaction

Staff support

## ***IAPT Recruitment: development of initial thematic framework continued***

### **2. Elements organised into Initial Thematic Framework, 4 September 2015**

#### **1. Context**

Feelings about research  
Impact of other research on STEPS  
Feelings about STEPS

#### **2. Administration**

Record keeping

#### **3. Initial approach**

Initial approach  
Complexity for patients  
Literacy

#### **4. At Assessment**

Handling forms  
Patient questions and how they were handled  
Risk / PTSD  
Potentially ineligible or unsuitable patients  
Non-interest

#### **5. Post assessment**

Five day turnaround  
Passing over patients  
Caseload benefit  
Prevalence target  
Receiving treatment at DAS and STEPS  
Therapist capacity  
Returning to DAS (keeping people in treatment / 28 day target)  
Treatment delay

#### **6. Other**

Workload  
Staff briefing and support

## ***Development of initial thematic framework continued***

### **3. Elements re-organised into modified Initial Thematic Framework (following review of coded material), 6 Sep 2015**

#### **1. Context**

Feelings about research  
Impact of other research on STEPS  
Feelings about STEPS

#### **2. Initial approach**

Appointment booking  
Appointment letter

#### **3. At Assessment**

Handling forms  
Patient questions  
Risk / PTSD  
Other potentially ineligible / unsuitable patients  
Non-interest

#### **4. Post assessment**

Returning to DAS  
Therapist capacity  
Discharging from DAS  
Other

#### **5. Other**

Record keeping  
Workload  
Staff briefing and support

## Example Chart: Therapist GSH elements

	A	B	C	D	E	F	G	H
		A : 2.5 Wellbeing course	B : 2.6 Phone calls	C : 2.7 Material mode of delivery	D : 2.8 Therapeutic role	E : 2.9 Session duration	F : 2.10 Pace	G : 2.11 Length of GSH
1		Rated course highly (with the implication that had not expected to). Thought it was well written and suitable for people with a range of abilities. Might have had a sense that there was too much material and repetition but patients valued it. More examples (stories, case illustrations) to help with interpersonal difficulties would be useful and could benefit clients who have "heavy interpersonal issues" as part of a more complex presentation. Compared with the other material, additional resources were valued less and felt a bit surplus.	Was unsure about providing therapy by phone (that did not provide the non-verbal information available face to face) but felt willing to give it a go after trial preparation. Found that calls helped her distinguish her role in GSH from that of a CBT therapist. Also came to perceive that calls were sufficient given how she was required to support people (help them read and engage with written material). It helped to meet patients face to face in session one – you could see what their problems were, how they were affected by them and how well they could use the course material.	Being able to email or post material to people was important.	Thought that her role in GSH was different to that in CBT. She was not required to gather as much information and interpret it; she had to support people to use and engage with their reading / reflection on that.	Thirty minutes normally felt sufficient. On the odd occasion it didn't, this may have been with more complex people who presented with high levels of distress but she could not accurately recall.	ND	Had assumed that people may need longer but found that six weeks was sufficient for people to engage with the course and use / practise elements of it. Thought that the total length of the course gave people permission to get what they could out of it and a sense that they would have done well if they could learn and apply some (but not necessarily all) of what they were taught. This perception may have been shaped by how the therapist talked about the course but also the course itself.
2	1 : THERAPIST 03	Rated the course highly for being evidence based and easy to read - the colour coding was useful. Over time, he was more able to explain why we used the course. Found the DfY guides especially helpful and that some patients used them because they were a useful summary of material repeated elsewhere and could therefore save them time. He wondered if delivery of the course could have been improved by a more explicit link with goals. A different order to the material may have helped some people – more behaviour at the front, then cognitions. Found it difficult to incorporate use of the additional resources (there was not enough time and no flexibility to give more time; it was tricky to provide resources in response to what patients said). He also felt that he did not know how much the resources were used. Implied that if patients were going to be given all of the resources, how therapists should help them use the material needs more thought.	Had no real problem with calls (the length of the session was more of a challenge) – they readily fitted people's lifestyle and were more convenient than F2F. However he would have liked to see one patient who had problems with drinking and eating. There were sometimes difficulties around patients not being able to take calls at the planned time and then chasing them to rearrange but this was seen as inevitable. He developed a typical format / pattern to the calls (start with homework, move on to current week's material and work in DfY guide) that was straightforward to manage. Calls went more smoothly for having a limited amount of information about the patient.	ND	Felt that it was vital for therapists to help patients not only to read but to apply and use material.	Thirty mins is tight (and did not easily allow the therapist to incorporate use of additional resources) but was straightforward to manage once patients got used to the session format. Felt that it presented difficulty around how much time you gave to how things had been and this week / looking ahead.	Carrying out a session per week had an impact when patients missed a session, had a difficult week or issue doing homework. E.g. the therapist had to decide if it would be helpful to focus on how to help the patient try the homework again or move on; it was not possible to spend time on two sets of material where patients had missed a week but issues might arise when briefly discussing the first set of material that warranted more attention. This put pressure on the therapist which was not possible to resolve given that there was no flexibility to complete the course in a longer time period.	Implied that extending the period over which the course could be completed may have helped deal with pressure when patients missed a session, had a difficult week or did not do homework (see 2.10).
3	2 : THERAPIST 01	Felt that the course was very well written, researched and, for the most part, good for a wide range of people, although he recalled that some patients had found it a bit patronising. He wondered if it may have been targeted at a lower level than was required. On the other hand, some of the additional resources were way too complicated e.g. on the risk / coping calculator. More generally, he had seen lots of patients benefit from the course and be able to identify helpful elements. He queried the order in which material was presented. It may have been helpful to have more flexibility but he thought that it would be difficult to know how to sequence material without a case formulation and wondered if we could be sure of the effectiveness of the course delivered in a different order to that tested. Nonetheless, were he to implement the course outside of STEPS he would offer patients the opportunity to select which lessons to deliver first; he could also envisage using feedback on patients' symptoms of depression and anxiety to help order material.	Thought that phone calls made therapy more accessible to patients who found it difficult to attend in person and because therapists could deliver treatment even if they did not have suitable premises. On the downside, felt that the rapport between patient and therapist may be compromised although he did not know if this was true. Therapists certainly miss out on non-verbal communication but this would be less of a problem in (content oriented) CBT than other therapies. Observed that phone calls were helped by carrying out session one in person.	Wondered what difference it would make to deliver the course online (as in Australia). Realised that some people really liked having hard copies.	As a CBT therapist was sometimes frustrated when couldn't cover cognitive techniques in more depth, find out more about people and personalise treatment. Identified an important role for therapists to encourage people to keep trying out techniques even when people don't see the point.	Limiting sessions to thirty minutes can be restricting. He ended up clock-watching and wondered if his relationship with patients was compromised when he hurried them along. However he thought people had understood. He considered that setting up ground rules so patients knew what to expect was very important.	Delivering one session per week had not been problem except for one client who had a lot going on in her life and needed more time between lessons. If he were to implement the course outside of STEPS he would offer people the option to schedule sessions every fortnight.	For patients who do not rate GSH and find it difficult to engage with and apply material, he encouraged them to keep trying out techniques by saying that he would talk with them about other options after six or just a few sessions. Felt that a six week course was very short in the context of people's lives and especially where people had been depressed for a long time, years.
4	3 : THERAPIST 02							

**Example of abstraction:** therapist experience of stepping criteria

*Detected elements (from chart) organised into dimensions*

Elements (criteria / appropriateness)	Dimensions
<p>Criteria got people in the right ballpark (03)</p> <p>Could not recall patients who met criteria for discharge for whom that felt wrong although might have been instances where bit more ongoing support would be valuable (03)</p> <p>Did not step up people where thought further treatment was not required (03)</p> <p>Criteria worked brilliantly for majority (around 70%) people (02)</p> <p>Criteria worked really well – with patients who were mainly clear cut step ups (01)</p>	<p><b>Summary</b></p>
<p>Wondered about lowering cut off to &lt;5 to reduce risk of relapse (03)</p>	<p><b>Reducing risk of relapse</b></p>
<p>Queried aiming for people who present with &lt;10 to reduce their scores further e.g. to 2 (03)</p> <p>Criteria did not work well for patients at or below cut-off on start GSH – they may have remained at a similar level throughout treatment and eligible for progress without having made much if any gain. (02)</p> <p>Wondered about changing criteria to give priority to progress over cut-off tho any criteria based on arbitrary cut points (how much progress = satisfactory) would likely not work for minority (02)</p>	<p><b>Discharging patients who present with low scores on start treatment</b></p>
<p>Criteria did not deal with probs uncovered at assessment / during tx (except risk) where it may be appropriate to step patients 'out' / onto a different service (01)</p>	<p><b>Stepping 'out'</b></p>

## **Appendix V: Feasibility study management**

This appendix provides a copy of selected material related to the management of STEPS feasibility study, specifically:

- Ethics approval letters
  - National Research Ethics Committee South West – Frenchay
  - Devon Partnership NHS Trust
  - University of Exeter, School of Psychology
- Risk protocol
- Serious Adverse Event standard operating procedure



**Health Research Authority**

**NRES Committee South West - Frenchay**

Bristol Research Ethics Committee Centre  
Level 3, Block B  
Whitefriars  
Lewins Mead,  
Bristol  
BS1 2NT

Telephone: 01173421334  
Facsimile: 01173420445

24 July 2013

Ms Jacqueline Hill  
Exeter Graduate Fellow, Health Services Research  
University of Exeter  
Sir Henry Wellcome Building for Mood Disorders Research  
The Queen's Drive  
Exeter  
EX4 4QQ

Dear Ms Hill

**Study title:** The development and evaluation of stepped care: a mixed-methods feasibility study.  
**REC reference:** 13/SW/0140  
**IRAS project ID:** 128979

Thank you for your letter of 09 July 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Christine Hobson, [nrescommittee.london-camberwellstgiles.southwest-frenchay@nhs.net](mailto:nrescommittee.london-camberwellstgiles.southwest-frenchay@nhs.net).

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**



## Ethics approval letter: NRES Committee South West – Frenchay (page 2/4)

### NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

### Non-NHS sites

Notification(s) of no objection have been received from local assessors for the non-NHS site(s) listed in the table below, following site-specific assessment (SSA).

I am pleased to confirm that the favourable opinion applies to the following research site(s), subject to site management permission being obtained prior to the start of the study at the site (see under 'Conditions of the favourable opinion below').

Research Site	Principal Investigator / Local Collaborator
University of Exeter, Mood Disorders Centre: Accessing Evidenced Based Psychological Therapies (AccEPT) Clinic	Ms Jacqueline Hill

### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The Committee request the REC is named South West - Frenchay and not just Frenchay.
2. The Committee request in the addition to response to Point 2 (page 1 of PIS) is made clearer. The requirement is that it is made clear that if a patient is taking medication then this will not exclude him/her from the study. The Committee felt that this is inferred rather stated clearly. The Committee felt it would be more helpful to the patient if there was a sentence stating clearly that if he/she is taking medication then this would not exclude them from the study.

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.**

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential*

## Ethics approval letter: NRES Committee South West – Frenchay (page 3/4)

*participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		10 May 2013
Covering Letter		09 July 2013
Evidence of insurance or indemnity		13 July 2012
Interview Schedules/Topic Guides	1	24 April 2013
Interview Schedules/Topic Guides	1	25 April 2013
Investigator CV		
Other: Supervisor DR CV		
Other: Supervisor WK CV		
Other: Phase 2 and 3 - letter from IAPT	1	22 April 2013
Other: Phase 1 - initial tel contact script	1	24 April 2013
Other: Phase 1 - letter confirming interview	1	24 April 2013
Other: Patient summary sheet	1	23 April 2013
Other: Permission to contact researcher form	1	22 April 2013
Other: Tel screen record	1	23 April 2013
Other: Letter confirming baseline interview	1	24 April 2013
Other: Phase 3 - post trial tel contact script	1	25 April 2013
Other: Phase 3 - letter confirming interview	1	25 April 2013
Other: List of Appendices		
Other: Validated : Mini COG		
Other: Validated : CIS- R		
Participant Consent Form: Phase 2 and 3 - participant	1	03 May 2013
Participant Consent Form: Clinical	1	09 July 2013
Participant Consent Form	1.1	09 July 2013
Participant Information Sheet: Phase 2 and 3	1	07 May 2013
Participant Information Sheet: Clinical	1	09 July 2013
Participant Information Sheet	1.1	09 July 2013
Protocol	1	09 May 2013
Questionnaire: Validated: BDI -I		

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Questionnaire: Validated: GAD -7		
Questionnaire: Validated: SF-36		
REC application		09 May 2013
Response to Request for Further Information		09 July 2013
Summary/Synopsis	1	03 May 2013

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

#### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

<b>13/SW/0140</b>	<b>Please quote this number on all correspondence</b>
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We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



**Dr Robert Beetham**  
Chair

**Ethics approval letter: Devon Partnership NHS Trust**

**Devon Partnership**   
NHS Trust

Research and Development  
Wonford House Hospital  
Dryden Road  
Exeter  
EX2 5AF

Tel: 01392 674112  
[jayneclarke@nhs.net](mailto:jayneclarke@nhs.net)

Ms Jacqueline Hill  
Exeter Graduate Research Fellow, Health Services Research  
University of Exeter  
Sir Henry Wellcome Building for Mood Disorders Research  
The Queen's Drive  
Exeter  
EX4 4QQ

Date: 06/08/2013

Dear Jacqueline

**Study Title:** The development and evaluation of stepped care: a mixed-methods feasibility study.  
**REC reference:** 13/SW/0140  
**DPT reference:** DPT 0258

I have reviewed the file for the above project and am happy to give approval for Devon Partnership Trust to be used as a Participant Identification Centre.

The study may be advertised at Trust premises, subject to the agreement of local teams. Trust staff may identify potential participants and inform them of the study and how to contact the research team. They may also, with the permission of the people concerned, pass on contact details of potential participants.

If any other activity is to take place at the Trust, please get back in touch with this office as a further approval process may be needed.

With best wishes for a successful study,



Dr Peter Aitken  
Director of Research and Development

## Ethics approval letter: University of Exeter, School of Psychology



Psychology Research Ethics  
Committee

Psychology, College of Life  
& Environmental Sciences

Washington Singer Laboratories  
Perry Road  
Exeter  
EX4 4QG

Telephone +44 (0)1392 724611  
Fax +44 (0)1392 724623  
Email Marilyn.evans@exeter.ac.uk

**To:** Jacqueline Hill  
**From:** Cris Burgess  
**CC:** David Richards  
**Re:** Application 2012/500 Ethics Committee  
**Date:** April 2, 2016

The School of Psychology Ethics Committee has now discussed your application, *2012/500 – The development & evaluation of stepped care*. The project has been approved in principle for the duration of your study.

The agreement of the Committee is subject to your compliance with the British Psychological Society Code of Conduct and the University of Exeter procedures for data protection (<http://www.ex.ac.uk/admin/academic/datapro/>). In any correspondence with the Ethics Committee about this application, please quote the reference number above.

I wish you every success with your research.

A handwritten signature in black ink, appearing to read 'Cris Burgess', with a horizontal line underneath.

Cris Burgess  
Chair of Psychology Research Ethics Committee

## Exploring Risk in Research Assessments

*“These are thoughts that people suffering from depression often have but it’s important to make sure that you are receiving the right kind of support so I will now ask you some questions that will explore these feelings in a little more depth.”*

<b>PLANS</b>	
1. Do you know how you would kill yourself?  If <b>yes</b> – details	Yes / No
2. Have you made any actual plans to end your life?  If <b>yes</b> – details	Yes / No

<b>ACTIONS</b>	
3. Have you made any actual preparations to kill yourself?  If <b>yes</b> – details	Yes / No
4. Have you ever attempted suicide in the past?  If <b>yes</b> – details	Yes / No

<b>PREVENTION</b>	
5. Is there anything stopping you killing or harming yourself at the moment?  If <b>yes</b> – details	Yes / No
6. Do you feel that there is any immediate danger that you will harm or kill yourself?  If <b>yes</b> – details	Yes / No

Response	Action	Tell Participant
<p>All 'no' apart from Q5 'yes'</p> <p><i>No plans or actions, preventive factors</i></p> <p><b>A</b></p>	<p>Advise speak with GP</p>	<p>I can see that things have been very difficult for you but it seems to me that these thoughts about death are not ones you would act on. Would this be how you see things? (If 'yes')</p> <p><b>I would advise you to make an appointment to see your GP to talk about these feelings.</b></p>
<p>'Yes' for any <b>one</b> of Q1-4 and 'yes' for Q5 but 'no' for Q6</p> <p><i>Some plan / action but preventive factor and no immediate danger</i></p> <p><b>B1</b></p>	<p>Advise speak with GP</p> <p>Write to GP</p>	<p>Things seem to be very hard for you right now and I think it would be helpful if you were to speak with your GP about these feelings.</p> <p><b>I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I'd also advise you to make an appointment to see your GP to talk about these feelings.</b></p>
<p>'Yes' for any <b>one</b> of Q1-4 and 'yes' for Q5 but 'no' for Q6</p> <p><i>AND the same at last assessment but patient has not spoken with GP since</i></p> <p><b>B2</b></p>	<p>Advise speak with GP</p> <p>Telephone GP</p> <p>Follow up by letter – include the statement, "The clinical management of this patient remains your responsibility but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan."</p>	<p>I think it's important that your GP knows how difficult things are for you right now.</p> <p><b>I will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings.</b></p>
<p>'No' to Q5 or 'yes' to Q6</p>	<p>Keep patient with you</p>	<p>I am very concerned about your safety at this</p>

<p><i>Acute risk</i></p> <p><i>No preventive factors or in immediate danger</i></p> <p><b>C</b></p>	<p>Contact supervisor</p> <p>Involve GP or other appropriate clinician</p>	<p>moment. I'm not a clinician but I would like you to talk to one right now.</p> <p><b>I am going to call your GP (other) to let them know how you are feeling and to arrange for you to receive immediate help.</b></p>
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**For patients who remain in IAPT or who have been discharged but are at acute risk of suicide – “I will also tell IAPT that you have been having some troubling thoughts. This will include a description of the action I have suggested or taken to help support you.”**

**If the patient is at acute risk of suicide, contact the first or second supervisor for STEPS:**

Professor David Richards	[Telephone Number]	[Telephone Number]
Professor Willem Kuyken	[Telephone Number]	[Telephone Number]

**Other MDC staff qualified to cover risk are:**

Barney Dunn	[Telephone Number]	[Telephone Number]
Anke Karl	[Telephone Number]	[Telephone Number]
Natalia Lawrence	[Telephone Number]	[Telephone Number]
Heather O'Mahen	[Telephone Number]	[Telephone Number]
Kim Wright	[Telephone Number]	[Telephone Number]
Ed Watkins	[Telephone Number]	[Telephone Number]

**Use the emergency numbers below, in order of preference:**

<b>GP – ask for a home visit or get an appointment (If out of hours call Devon Doctors on 0845 6710270)</b>	<b>Ask participant for GP details</b>
<b>DPT Mental Wellbeing &amp; Access - offer specialist assessment, consultation and advice between 8am –</b>	<b>01392 823172</b>



<p>6pm (Mon-Fri) and links with other network function teams to respond outside of these hours.</p>	
<p><b>Crisis Resolution Home Treatment Team</b> - this number is to make urgent referral to the Crisis Team and should not be given out to participants / members of the public under any circumstances. The participant's GP can also make an urgent referral to the Crisis Team and should be the first port of call.</p>	<p><b>[Telephone Number]</b></p>
<p><b>Ambulance / A&amp;E, Exeter</b> Royal Devon &amp; Exeter Hospital, Barrack Road, Exeter, EX2 5DW</p>	<p><b>999</b></p>

**As soon as possible after identification of risk and action following, complete a report using the template following.**

**STEPS Risk Assessment Form:** A significant risk has been identified for the participant below and the STEPS Risk Protocol has been enacted.

<b>Date risk protocol enacted:</b>		<b>Participant ID:</b>
<b>Time Point:</b> Telephone screen / Baseline / 6 month / other, please specify:		
<b>Risk protocol has identified level of risk as:</b> <b>A</b> <b>B1</b> <b>B2</b> <b>C</b>		
<b>Suicide Risk Information:</b> Report which questionnaire and the score that gave cause for concern and attach copy of risk assessment. Include whether the participant has reported any of the following:		
<ul style="list-style-type: none"> <li>• Current suicidal ideation</li> <li>• Suicide plans</li> <li>• Active preparations to commit suicide</li> <li>• Protective factors or lack of them</li> <li>• Regular contact with GP?</li> </ul>		
<b>Clinical supervisor contacted:</b> Y / N		<b>Date:</b>
<b>Name of supervisor:</b>		
<b>Actions taken:</b>		
<b>Additional relevant information:</b>		
Researcher Name:	Date:	Signature:
Clinical Supervisor Name:	Date:	Signature:

## **STEPS Adverse & Serious Adverse Event SOP**

### **Adverse Event**

An **Adverse Event (AE)** is any untoward or unintended medical occurrence or response, whether it is causally related to the trial treatments or not.

Adverse Events may be disclosed by a participant, their GP, next of kin or another person involved in the patient's care.

### **Serious Adverse Event**

An adverse event can be further classified as a **Serious Adverse Event (SAE)** if the event is:

- Fatal
- Life threatening
- Requires hospitalisation or prolongs existing hospitalisation
- Results in significant or persistent disability or incapacity
- Results in congenital abnormality or birth defect
- Leads to any other condition, judged significant by a clinician.

### **Immediate Action for Reporting an SAE**

If you are alerted to an **SAE** please contact Jacqueline J Hill (JJ) immediately.

An immediate report (within 24 hours of a **SAE** coming to light) must be made orally or in writing to the research sponsor (University of Exeter). Therefore, telephone JJ (01392 725273) immediately. If you are unable to speak to her and have left answer phone messages, it is important that you also email and text her.

Complete an **Adverse & Serious Adverse Event Recording Form** and email ([j.j.hill@exeter.ac.uk](mailto:j.j.hill@exeter.ac.uk)) or hand a copy to JJ immediately. If you do not receive a response, please call or find JJ in person to confirm receipt. If you are unable to contact JJ, please email a copy of the completed form to Professor David Richards ([d.a.richards@exeter.ac.uk](mailto:d.a.richards@exeter.ac.uk)); please call or find Dave in person to confirm receipt.

The immediate report must be followed by a detailed written report of the event. This report must be sent to the Frenchay National Research Ethics Service Committee – South West and the STEPS External Adviser (Professor Chris Dickens) within 15 days of JJ becoming aware of the event. This will be handled by JJ.

### **General guidelines for completing an Adverse & Serious Adverse Event Recording Form**

Ask the participant (or person disclosing the event) the start and end date/time of the event. If they cannot remember then enter as accurate an estimate as possible. Document the outcome of the event and any actions taken.

Please do not write the participant's name on the form; identify the participant using their Trial ID.

As STEPS is a non-CTIMP (Clinical Trial of an Investigational Medicinal Product) we are not required to log non-serious AE's, however the Adverse Event & Serious Adverse Event Recording Form allows researchers to record AE's when it is not immediately clear if it falls into the SAE category. Hence, if you are uncertain whether an AE meets criteria for an SAE, please complete the Adverse & Serious Adverse Event Recording Form and follow the procedure for reporting an SAE.

Routine hospitalisations and planned surgery involving a hospital stay are classified as SAEs. This would include, for example, hospitalisation for a cataract operation, hip replacement or cancer treatment.

At 6 month follow-up assessments, any SAE that might have occurred since the previous visit should be elicited from the participant.

### **SAE's and risk**

Risk issues may sometimes meet criteria for a SAE and should be handled as such. *ALL instances where the risk protocol is enacted must be recorded in the usual manner on the Risk Form and countersigned by the site lead or a nominated deputy.*



## Serious Adverse Event (SAE) Report Form

The Chief Investigator should report any SAE to the sponsor within 24 hours, orally or in writing. The immediate report must be followed by a detailed written report on the event, using the form below. A copy of this form must also be sent to the Frenchay NRES Committee – South West and STEPS' External Adviser within 15 days of the CI becoming aware of the event.

### 1. Details of Chief Investigator

Name:	Prof David A Richards
Address:	University of Exeter Medical School Highton Building University of Exeter St Luke's Campus Heavitree Exeter EX1 2LU
Telephone:	01392 724615
Email:	<a href="mailto:D.A.Richards@exeter.ac.uk">D.A.Richards@exeter.ac.uk</a>

### 2. Details of Study

Full title of study:	STEPS (The development and evaluation of stepped care treatment for depression: a mixed method feasibility study)
Name of main REC:	Frenchay National Research Ethics Service Committee – South West
REC reference:	12/SW/0140
Research sponsor:	University of Exeter
Sponsor's reference for this report (if applicable):	

### 3. Type of Event

Please categorise this event, ticking all appropriate options:

Fatality:	Life threatening:	Hospitalisation or Pro- longation of hospitalisation: <input type="checkbox"/>
Persistent or significant disability <input type="checkbox"/> or incapacity:	Congenital anomaly or birth defect: <input type="checkbox"/>	Other: <input type="checkbox"/>

### 4. Circumstances of the Event

Date of event:	
Location of event:	
Describe the circumstances of the event (attach further details if required):	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

### 5. Declaration

Name of Chief Investigator: (BLOCK CAPITALS)	
Date of submission:	
Signature:	

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**6. Acknowledgement of Receipt by REC**

The Frenchay NRES Committee – South West acknowledges receipt of the above.

Name: (BLOCK CAPITALS)	
Position on REC:	
Date:	
Signature:	

Signed original to be sent back to the Chief Investigator; copy to be kept for information by REC.



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