Psychological intervention for acute mental health inpatient care: A meta-analysis and feasibility study

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by

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Abstract

Psychological intervention has been recommended to address some of the common problems reported in acute psychiatric inpatient services, such as having nontherapeutic environments, minimal provision of therapeutic interactions and activities and high readmission rates. There is a small evidence base investigating the effectiveness of acute inpatient psychological therapy, however, this has never been reviewed or synthesised. Robust investigation of cross-diagnostic inpatient psychological intervention is also absent, and whether this is feasible is unknown.

Informed by the Medical Research Council (MRC) framework, this thesis examined and synthesised the current evidence base of controlled trials of psychological therapy for acute psychiatric inpatients for the first time. It also tested the feasibility of implementing and evaluating cross-diagnostic psychologically informed acute mental health care in comparison to treatment as usual. The latter was largely based on the Woodhaven Approach, which is theory-driven psychological model of care. The model offers psychological intervention for acute inpatients and targets mechanisms of psychological dysfunction identified by the Interacting Cognitive Subsystems model (ICS). This thesis, therefore, comprises two main studies: 1) a meta-analysis, and 2) a feasibility study.

The meta-analysis focused on the effectiveness of brief inpatient psychological therapy on psychotic symptoms, risk of readmissions, and emotional distress (depression and anxiety). Results showed that in randomised and single-blind studies psychological intervention had little effect on psychotic symptoms. Other outcomes, however, showed more promising results. For example, although not significant, robust evidence suggests that brief psychological therapy may reduce emotional distress and risk of readmission for some acute inpatients.

The feasibility study aimed to test the feasibility of implementing and evaluating a cross-diagnostic psychological model of acute inpatient care, and gather preliminary clinical outcome data. Using a framework of methodological issues, the feasibility study showed that some aspects of the trial processes were run successfully, i.e. some clinical outcomes

had good completion rates, some intervention components were successfully implemented and some outcomes produced effects which favoured the intervention group over the control group. However, other aspects of the trial processes were problematic and required amendment before progressing to a full trial. Key issues identified by the feasibility study include problematic eligibility criteria, poor implementation of some intervention components, poor engagement, poor completion of follow-up questionnaires and therefore poor trial retention. The feasibility study also highlighted methodological issues which have not yet been addressed, but are important in planning a future definitive trial, i.e. randomisation and assessor blinding.

This thesis has provided the first study to test the feasibility of evaluating the effectiveness of this psychological model, in comparison to treatment as usual, and it was the first time the impact of this psychological model has been investigated in relation to readmissions. Overall, this thesis indicates that a cross-diagnostic approach to acute psychiatric inpatient psychological therapy is feasible, however further work is needed to fully implement the model into routine practice.

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1 Introduction to the thesis

This thesis presents the work completed within a three-year PhD. Overall this thesis has drawn on a scientific framework for developing and evaluating complex interventions and provided a novel contribution to the literature that examines psychological intervention delivered in acute mental health inpatient settings in two ways. First, it reviews and synthesises the existing literature, and second it investigates the feasibility of delivering cross-diagnostic psychological therapy in a National Health Service (NHS) acute mental health inpatient service. This chapter introduces the scientific framework for the development and evaluation of complex interventions used to guide this thesis. This chapter then briefly summarises the aims and original contributions of the thesis, provides an overview of the thesis structure and locates each chapter within the scientific framework.

1.1 A scientific framework for developing and evaluating complex interventions

Complex interventions, such as acute psychiatric inpatient care, have been defined by the Medical Research Council (MRC) as interventions which comprise of a number of separate, but interacting, elements or components (Craig et al., 2008). Evaluating such interventions is challenging. The MRC have published an updated framework to provide guidance on developing and evaluating complex interventions (Campbell et al., 2000; Craig et al., 2013). The aim of the MRC framework is to encourage systematic development and evaluation of complex interventions in a phased approach, although it should be noted that phases may not always be conducted in a linear manner (Craig et al., 2013), i.e. phase two or three may reinform phase one (phases described below). This methodical approach is now considered best practice and includes four phases: development, feasibility/piloting, evaluation and implementation (Craig et al., 2013), which are described in the remainder of this chapter.

1.1.1 Phase 1: development

The first step identified by the MRC framework involves developing appropriate interventions which are expected to have the desired effect. First, this includes identifying

the existing evidence base through existing systematic reviews and meta-analyses, or conducting a systematic review or meta-analysis where one does not exist. Based on such evidence, phase one also includes identifying and developing theories which highlight rationale for the intervention and related changes. Modelling these processes and outcomes is also considered important in developing the intervention, and in designing an appropriate intervention evaluation. This may involve multiple studies which gradually refine the design of both the intervention and the evaluation. Qualitative work, specifically, is recommended to inform how and why interventions (and associated evaluations) work or not. Such work may also be included in the feasibility/pilot phase.

1.1.2 Phase 2: feasibility/piloting

This phase involves testing the feasibility of the intervention and the proposed methods to evaluate it. Often, this can involve assessing recruitment, retention, acceptability, delivery, safety, adverse events and estimating parameters to inform a main definitive trial. Without testing and assessing such processes, larger intervention evaluations can be weakened by unforeseen problems with trial processes such as recruitment and retention (Lancaster, Dodd, & Williamson, 2004). Outcomes proposed for a main trial may also be assessed during the feasibility/piloting phase, however it is recommended that formal hypothesis testing is not the purpose of doing so. Rather, testing the acceptability of the measures (i.e. proportion of completed outcomes) and estimating effects (size and direction) and precision should be the aim of including outcome measures in the feasibility/piloting phase (Eldridge et al., 2016).

1.1.3 Phase 3: evaluation

Phase three of the MRC framework involves intervention evaluation using the best and most appropriate designs. The aim of the evaluation phase is to determine the effectiveness or efficacy of the intervention. Researchers must decide which primary and secondary outcomes are most suitable to measure effectiveness. Such decisions should be informed by prior development and pilot/feasibility work. Researchers are also advised to conduct a process evaluation which explores how the intervention is delivered within the study, e.g. assessing treatment fidelity, and identifying influential contextual factors or causal mechanisms (Craig et al., 2013; Moore et al., 2015). This is important in

understanding intervention adaptations that may be required to implement the intervention in different contexts (Moore et al., 2015).

1.1.4 Phase 4: Implementation

Phase four involves intervention implementation. Wide-spread implementation should be informed by the work carried out in all previous phases. Findings from prior process evaluations are of particular importance in this phase as they should inform required adaptations necessary to implement the intervention in different context (Moore et al., 2015). Implementation also requires surveillance, monitoring of the intervention and long term follow-up (Craig et al., 2013).

1.2 Aims and original contributions of the thesis

The overall objective of the thesis was to contribute to the development and evaluation of a cross-diagnostic psychological intervention for an acute mental health inpatient setting. To do so, the thesis had two main aims and novel contributions to research which aimed to inform a future definitive trial.

The first stage of this thesis aimed to review and synthesise the existing acute inpatient psychotherapy evidence base, for the first time, using meta-analysis. This maps onto phase one of the MRC framework (Craig et al., 2008, 2013). Specifically, the meta-analysis aimed to assess the benefit of acute inpatient psychotherapy in relation to psychotic symptoms, readmissions and emotional distress in controlled trials.

The second stage of this thesis draws on phase two of the MRC framework (Craig et al., 2008, 2013) as the aim was to pragmatically test the feasibility of implementing and evaluating a cross-diagnostic, psychological intervention for acute inpatients (largely based on the Woodhaven Approach (Clarke & Wilson, 2009)), in preparation for progression to a full definitive trial. The main objectives were to assess the feasibility of implementing the intervention, to test the feasibility of the trial processes, and to test whether the psychological intervention, compared to treatment as usual (TAU), could produce effects which favour the intervention on relevant outcomes (i.e. readmissions, psychological distress and mental health related self-efficacy).

1.3 Structure of the thesis

Chapter two of the thesis provides a brief historical background of the development of inpatient care and describes modern acute mental health inpatient services in the UK. Chapter two also reviews different psychological approaches to severe mental illness and presents the psychological model, and associated theoretical underpinning, of the intervention relevant to feasibility trial reported Chapters four, five and six. Chapter three presents the first study of the thesis which reviews and synthesises the current acute inpatient psychotherapy evidence base. It therefore addresses phase one of the MRC framework (described above). The second study of this thesis is addressed in the remainder of the thesis. In line with the MRC framework (Craig et al., 2008, 2013), chapter four provides an in-depth and transparent description of the chosen methods used for the feasibility study and provides an extensive justification for the methods that were used (including protocol amendments). Chapter five reports data from the feasibility study using Shanyinde, Pickering and Weatherall's (2011) methodological issues as an analytical framework. Guided by the ADePT process (A process for Decision-making after Pilot and feasibility Trials) (Bugge et al., 2013), Chapter 6 provides a detailed discussion of the feasibility study findings with a particular focus on progressing to a future definitive trial. Chapter 6 therefore contributes to the preparation of phase 3 of the MRC framework (Craig et al., 2008, 2013), i.e. intervention evaluation.

2 General introduction

This chapter aims to introduce and summarise the development of psychiatric inpatient services, define the role of modern acute inpatient psychiatric services and highlight the problems currently associated with acute inpatient care. This chapter also intends to provide a brief overview of different therapeutic approaches to serious mental illness (SMI) relevant to this thesis, and the associated evidence, and highlight the challenges of providing psychological intervention in acute inpatient settings. Finally, this chapter describes and reviews different models of acute inpatient psychosocial care, with a particular focus on the Woodhaven Approach (Clarke & Wilson, 2009).

2.1 Background

2.1.1 A brief history of inpatient psychiatric care

Bethlem Hospital, London, was the first of many mental health inpatient facilities to open in the UK (Chambers, 2009). These were typically large asylums, originally designed to provide care and shelter for vulnerable people, such as people with mental health problems, physical disabilities or homeless people. Such hospitals were initially small services, however the number patients grew, despite limited access to adequate space and resources. To cope with the influx of patients many of the original values, centred on 'moral treatment', were lost (Fakhoury & Priebe, 2007). Instead, structured and efficient care became a priority. Consequently, hospitals such as Bethlem were criticised for providing inhumane care, poor hygiene, poor living conditions and overcrowding (Fakhoury & Priebe, 2007). Such criticism provoked a reform of both values and logistics, leading to deinstitutionalization: a process that continues today. The Mental Treatment Act of 1930 helped to improve conditions of the remaining inpatient units, however, it also brought the amalgamation of mental and physical illness and therefore approval of the medical model in management and treatment of mental health problems (Moncrieff, 2003). This saw the introduction of treatments such as electro-compulsive therapy and frontal lobotomy, which aimed to physically correct mental health problems, followed by medications for sedation, antidepressants or antipsychotics (Moncrieff, 2003). In the 1950s mental health hospitals were integrated into the National Health Service (NHS) in

the UK with the medical model being the primary approach to treatment of mental health problems.

2.1.2 The medical approach and the anti-psychiatry movement

The medical model is the traditional approach to treating both physical and mental illness and remains dominant in modern acute psychiatric inpatient services. In treating mental illness it applies the process of identifying, diagnosing and treating problems with emotion, thought, behaviour and interpersonal relationships with the assumption that the problem derives from a physical or biological cause (Engel, 1977). Therefore, treatment is primarily physical or biological and recovery from mental illness is defined by a reduction or resolution of symptoms, which are used to identify a specific disorder. However, this approach is often criticised for adopting a reductionistic and paternalistic manner which promotes the notion of 'normal' (British Psychological Society, 2014). In response to such criticisms, an anti-psychiatry movement emerged in the 1960s, which emphasised the role of non-biological factors in understanding and treating mental illness. This saw the opening of inpatient treatment centres such as Kingsley Hall, followed by Soteria House, which prioritised non-pharmacological treatment. Kingsley Hall was a London based residential treatment centre, developed by Dr Robert D. Laing, where, unlike inpatient units in the NHS, doors were unlocked, antipsychotics were not used and labels such as 'patient' and 'professional' were discouraged (Torn, 2012). This approach to treat severe mental illnesses such as psychosis was considered radical, however Laing was also praised for his compassionate understanding of mental illness which was that symptoms are a rational response to horrible experiences (Torn, 2012). Inspired by Kingsley Hall, Loren Mosher developed The Soteria House Project in America (Mosher, Vallone, & Menn, 1995). Again, a psychosocial approach to intervention was adopted which aimed to resolve patients' emotional crisis by focussing largely on personal or interpersonal problems. The intention was to create a therapeutic milieu in which anti-psychotic medication was used minimally (Mosher et al., 1995). The ultimate aim of Soteria House was to reduce the number of early-episode patients becoming long-term mental health service users. A systematic review of controlled trials of the Soteria Paradigm (k=3) was carried out (Calton, Ferriter, Huband, & Spandler, 2008). Results show that patients who received treatment under the Soteria Paradigm, i.e. received only non-pharmacological treatment, had significantly greater reductions in global psychopathology and the number of readmissions when compared to patients who were hospitalisation as usual (Calton, et al., 2008). These results are promising, however, as

the reviewers point out, most studies included only participants who provided end-point or data or completed treatment in the analysis and the randomisation methods used by the included studies, where they were implemented (k=2), were questionable or unclear (Calton, et al., 2008). Such promising results may therefore be biased (Sedgwick, 2015).

More recently, the effect of cognitive therapy for people diagnosed with schizophrenia not taking medication has again been evaluated in a randomised, single-blind controlled trial (RCT) (Morrison et al., 2014). The results showed little group differences on some outcomes, for example, negative psychotic symptoms, depression and symptom related distress. However, the findings also showed that patients receiving cognitive therapy had significantly larger reductions in psychiatric symptoms (specifically positive and general psychotic symptoms, as measured by the positive and negative symptoms scale (Kay, Fiszbein, & Opler, 1987)) and significantly larger improvements in social and personal functioning compared to those receiving just usual treatment (Morrison et al., 2014). Such results provide initial evidence to suggest that some patients can benefit from cognitive therapy, whether receiving parallel pharmacotherapeutic treatment or not.

Psychological treatment in the absence of medication was, and still is, considered radical and has been criticised. It has been argued that withholding or discouraging evidence-based treatment, such as anti-psychotic drugs, on the basis of a psychosocial ideology, is inappropriate and unethical practice (Carpenter & Buchanan, 2002; Shah & Mountain, 2007). However, treatment centres such as Soteria House and Kingsley Road have had a positive impact on mental health treatment as they have marked the first exploration into alternative treatment options, and encouraged investigation of psychosocial cause and treatment of severe mental illness.

2.2 Modern acute psychiatric inpatient services

Acute psychiatric inpatient services now make up one component of the network of care available to patients in crisis. NICE (National Institute for Health and Care Excellence, 2014) recommends a specialised system of both inpatient and outpatient services for individuals experiencing an acute episode of mental illness. This includes community crisis teams (Intensive Home Treatment Teams (IHTT) or Crisis Resolution Teams (CRT) and acute hospital admissions. Community crisis teams offer regular nursing visits at home and access to crisis houses which are designed to provide rest bite and a safe place away from home. Acute inpatient care typically provides medication as the primary

treatment option. It aims to 'provide treatment when a person's illness cannot be managed in the community, and where the situation is so severe that specialist care is required in a safe and therapeutic space. Admissions should be purposeful, integrated with other services, as open and transparent as possible and as local and as short as possible' (The Commission on Acute Adult Psychiatric Care, 2015).

Like other forms of crisis care, described above, acute psychiatric inpatient services in the NHS provide care for people with a variety of diagnoses at different stages of recovery. Diagnoses commonly found in acute psychiatric inpatient services include psychosis, schizophrenia, bipolar disorder, major depression, borderline personality disorder and people who have experienced trauma (British Psychological Society, 2012). Although deliberate self-harm or suicidality is not a diagnosis, it is also a common problem resulting in brief hospital admission. A brief description of the prevalence and typical symptomology of such diagnoses is provided in the following paragraph.

Psychotic disorders are serious mental illnesses that are characterised by symptoms such as delusions, hallucinations and thought disorder. They include a range of diagnoses such as schizophrenia, major depressive disorder with psychotic symptoms, bipolar disorder with psychotic symptoms, and substance induced psychosis (Kirkbride et al., 2012). In a systematic review carried out by the department of health policy research, it was reported that 1 in every 1000 people in England have an active psychotic disorder (Kirkbride et al., 2012). Major depressive disorder is also considered a serious mental illness. It includes a range of symptoms but is broadly characterised by low mood and loss of pleasure (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008). As previously mentioned, in more severe cases, patients may also experience psychotic symptoms. The prevalence of depression in England ranges between 29 to 42 in every 1000 people (McCrone et al., 2008). Borderline personality disorder is another diagnosis which is common in acute inpatient services. It is thought to affect around 0.7% of people in the United Kingdom (UK) (National Collaborating Centre for Mental Health, 2009) and is characterised by a range of emotional challenges which often result in difficulties creating and maintaining good relationships, impulsive behaviour and self-harm.

Due to the variety of patients using acute inpatient services, they are distinctly different from other psychiatric inpatient services. For example, unlike specialist inpatient services that select patients based on their diagnosis and appropriateness for the service (e.g.

borderline personality disorder inpatient services), acute inpatient services must respond to the diverse patient group they receive, sometimes with little notice and on an as-needed basis. Acute inpatient services also differ from personality disorder services, and rehabilitation inpatient services, in that admissions are short in length, and the usual length of stay is often unpredictable. Acute services must therefore be responsive and flexible to treat acute inpatients accordingly.

2.2.1 The need for change

While admission to hospital was once considered the only choice of care (discussed earlier in this chapter), it is now considered the last resort, in part due to the high cost of inpatient beds (Sainsbury Centre for Mental Health, 2005). In a population size of one million, it is calculated that the cost of providing acute psychiatric inpatient care ranges between £4,321,170 and £24,654,930, depending on the number of beds provided for the population (Bowers & Flood, 2008). Financial resources allocated to mental health services are, however, increasingly limited, with around 40% of mental health trusts in England reporting reduced funding between 2013/14 and 2014/15 (King's Fund, 2015). The government have continuously focused on improving community crisis services to reduce inpatient costs (Department of Health, 1999). Consequently, in the last few decades the number of inpatient beds has reduced. Between 1955 and 2012 the number of inpatient beds has reduced from 150,000 to 22, 300 (The Commission on Acute Adult Psychiatric Care, 2015). In Scotland alone, the number of acute beds has decreased by 34% from 2004 to 2013 (ISD, 2013).

Despite continuous reductions, the demand for psychiatric beds remains (King's Fund, 2015), and the number of people being detained under the Mental Health Act continues to increase (NHS Digital, 2016). Consequently, the threshold for admission has increased (Brooker, Ricketts, Bennett, & Lemme, 2007), suggesting the acute inpatient population now consists of patients who are more severely ill (British Psychological Society, 2012). Furthermore, the vast majority of wards currently run at overcapacity with few adequately trained staff (The Commission on Acute Adult Psychiatric Care, 2015). Little has been done to address such changes, which has consequently negatively impacted those using and working in psychiatric inpatient services (Mind, 2004). The quality of psychiatric inpatient care, for example, is continuously criticised (Care Quality Commission [CQC], 2016; MIND, 2013; Royal College of Psychiatrists, 2009; Royal College of Psychiatrists Centre for Quality Improvement, 2010; Sainsbury Centre for Mental Health., 1998;

Schizophrenia Commission, 2012; The Commission on Acute Adult Psychiatric Care, 2015), despite the development of guidelines which aim to improve the standard of care (Royal College of Psychiatrists, 2010; Royal College of Psychiatrists Centre for Quality Improvement, 2014). Specifically, inpatient services are reported to be particularly unsafe and nontherapeutic environments (Mind, 2004; Schizophrenia Commission, 2012), which are lacking in therapeutic activities and interactions (British Psychological Society, 2015; Mind, 2004). According to a recent qualitative comparison of nurse and service users' views of acute services, patients found interactions with staff were 'non-therapeutic' and focused mainly on medication and administration duties (Rose, Evans, Laker, & Wykes, 2015). Staff also expressed a need to spend more time with patients but felt powerless in their ability to do so due to administration duties and lack of qualified staff on shift (Rose et al., 2015).

The number of readmissions are also a problem in psychiatric inpatient services at a national and regional level. In the UK, 13% of people detained under section 136 of the Mental Health Act in 2012/13 had also been detained in the previous 90 days (Care Quality Commission, 2015). In Scotland, the ISD (Information Services Division Scotland, 2012) found 55% of those admitted to psychiatric hospitals were readmissions. And in NHS Lanarkshire, approximately 20% of all acute inpatient admissions, and approximately 24% of all psychiatric beds occupied, were 'revolving door' patients (Cogan, Shajahan, & Pethe-kulkarni, 2012). This data demonstrates the strain on psychiatric inpatient services at a national and regional level and suggests patients are either prematurely discharged or are not receiving sufficient support during their admission. Improving the quality of care, and thus outcomes for patients and acute inpatient services, is clearly important.

2.2.2 A solution

Treatment offered in routine clinical practice in acute psychiatric inpatient services primarily consists of medication (Sainsbury Centre for Mental Health, 2005). Such services have been described as 'the last bastion of the medical model in its pure form' (Clarke & Wilson, 2009, pp. 2). However, it has been suggested that providing psychological therapy in this context may address some of the key problems (Bright, 2008) described earlier in this chapter, i.e. nontherapeutic environment, poor patient outcomes and the high risk of readmission. Some clinicians, for example, argue that it may create an opportunity to engage patients at a critical point, who may otherwise be

difficult to engage, and that opportunity may be used to identify problematic thoughts, feelings and behaviours leading to the current crisis (Clarke, 2015; Jacobsen, Peters, & Chadwick, 2016). Access to psychological therapies, that are appropriate for severe mental illness, is now recommended during acute psychiatric admissions by a number of inpatient initiatives and regulatory bodies (Bright, 2014; British Psychological Society, 2012, 2015; Joint Commissioning Panel for Mental Health, 2013; Royal College of Psychiatrists Centre for Quality Improvement, 2014). Such recommendations are largely based on clinical expertise (Clarke & Wilson, 2009) and the development of psychological therapies for severe mental illness.

2.2.3 The development of psychological intervention for severe mental illness

The National Institute for Health and Care Excellence (NICE) recommend that a variety of psychological interventions, such as cognitive behavioural therapy (CBT) and family intervention, are available for patients with diagnoses of severe mental illnesses which are common in acute psychiatric settings (British Psychological Society, 2012, 2015): psychosis and schizophrenia (National Institute for Health and Care Excellence, 2014), personality disorder (National Institute for Health and Care Excellence, 2009), bipolar disorder and depression (National Excellence Institute for Health and Care, 2016). Such recommendations are based on the continued development and evaluation of psychological therapies, over the last 20 years, for people who were once thought to be too ill to engage in therapy. Although multiple therapies have been developed, such as family therapy and CBT, the following sections will focus only on therapies relevant to this thesis, i.e. CBT and relevant third wave therapies.

2.2.3.1 CBT

The development of CBT has occurred in stages, or 'waves'. The first wave of evidence based therapies, known as behavioural therapies, were originally developed from Pavlovian conditioning as a desensitising treatment for anxiety disorders and phobias (Öst, 2008). Later, in the 1970s, cognitive therapies were developed by Beck (1976), which were soon integrated with behavioural therapies, consequently developing one of the most commonly used and researched therapies today: CBT. CBT is a talking therapy in which therapists and clients work together to identify, understand and alter unhelpful thoughts, feelings and behaviours. While initially developed for depression, many cognitive behavioural psychological models of psychosis have also been developed in the last 20 years (Bentall, Corcoran, Howard, Blackwood, & Kinderman, 2001; Chadwick &

Birchwood, 1994; Garety, Kuipers, Fowler, Freeman, & Bebbington, 2001; Kingdon & Turkington, 1994; Morrison, Haddock, & Tarrier, 1995). Similar to cognitive behavioural models for depression, unhelpful automatic appraisals, beliefs and safety seeking behaviours are thought to sustain symptoms of psychosis and related distress, and are therefore a target of CBT for psychosis (CBTp). The ultimate aim of therapy is to monitor and question problematic thoughts and feelings in order to adapt these into new strategies of coping with symptoms, which in theory will reduce distress and improve functioning and wellbeing (Hutton, 2016).

The CBT evidence base covers a range of diagnoses, with a particular focus on CBTp in recent years. Many meta-analyses have been conducted which show that in high quality evidence CBTp is effective in reducing symptoms of psychosis with a small effect (Jauhar et al., 2014; Turner, Van Der Gaag, Karyotaki, & Cuijpers, 2014; Van der Gaag, Valmaggia, & Smit, 2014; Wykes, Steel, Everitt, & Tarrier, 2008) and it is now a growing opinion that patients with psychotic symptoms should have a choice of treatments which includes CBT, or other psychological therapies (Morrison et al., 2014; Morrison, Hutton, Shiers, & Turkington, 2012).

Meta-analysis has also investigated the effectiveness of CBT for other severe mental illness diagnoses that are commonly found in acute inpatient services, i.e. bipolar disorder and major depression. Lynch et al (2010), for example, investigated the effectiveness of CBT for major psychiatric disorders in general using meta-analysis, in which nine studies included participants with major depressive disorder. Results suggested CBT was effective in reducing symptoms of depression and in reducing relapse for people diagnosed with major depressive disorder. Four studies looking at CBT for the prevention of relapse in patients with bipolar disorder were also included (Lynch et al., 2010). The overall treatment effect, however, was not statistically significant, from which the authors concluded that CBT is ineffective in preventing relapse of bipolar disorder (Lynch et al., 2010). However since publication, this meta-analysis has been heavily criticised for reasons such as using inconsistent and questionable inclusion/exclusion criteria (Hutton, Wood, Taylor, Irving, & Morrison, 2014). More recently, a systematic review investigating the effect of psychotherapy on symptoms of anxiety in bipolar disorder has been conducted (Stratford, Cooper, Di Simplicio, Blackwell, & Holmes, 2015). Fourteen of the 22 included studies investigated CBT. The results suggest that CBT, including a component that specifically targets anxiety, reduces symptoms of anxiety, cyclothymic,

refractory and rapid cycling when compared to usual treatment, and therefore concluded that CBT for anxiety may result in improved outcomes for people diagnosed with bipolar disorder (Stratford, et al., 2015).

2.2.3.2 'Third wave' cognitive behavioural therapies

Over the last 10 to 15 years third wave therapies have emerged as an extension of CBT. They are thought to differ, or expand (Hofmann, Sawyer, & Fang, 2010), from CBT in that the focus of therapy is the inner experience rather than the content. Therapy emphasises validation, acceptance and attentional control rather than simply thought and behaviour change (Hofmann, et al., 2010). Third wave therapies are therefore thought to bridge the gap that traditional CBT cannot, i.e. achieving rational cognition and emotional conviction of that rationale (Clarke, 2009a, 2015). Such therapies include, but are not limited to, Mindfulness, Compassion-Focused Therapy (Gilbert, 2005, 2009), Acceptance and Commitment Therapy (Hayes, 2004), Dialectical Behavior Therapy (Linehan, 1993), and Mentalization Based Therapy (Bateman & Fonagy, 2010). Different third wave therapies relevant to this thesis are briefly described below.

Mindfulness

Mindfulness has become a popular therapeutic technique which is integrated into various therapies for depression and anxiety, personality disorder and psychosis (Chadwick et al., 2016; Linehan, Cochran, Kehrer, & Barlow, 2001; Segal, Williams, & Teasdale, 2002). The primary aim is to direct attention away from rumination or intolerable emotion, which may lead to unhelpful coping mechanisms (e.g. taking drugs, self-harm, dissociation from reality), and redirect attention to the present moment (e.g. breath and bodily sensations or an object such as a pebble). The initial evidence base for mindfulness for severe mental illness is promising. One meta-analysis of 6 RCTs, for example, has shown that mindfulness-based cognitive therapy reduces relapse of major depression by around 34% compared to controls (Piet & Hougaard, 2011). Additionally, another meta-analysis of the effectiveness of mindfulness-based therapy for psychosis has provided evidence which suggests that patients may benefit from learning mindfulness techniques in terms of reducing negative symptoms and rehospitalisation with small to moderate effects (Khoury, Lecomte, Gaudiano, & Paquin, 2013). However, of the thirteen studies included in this meta-analysis, only 7 were controlled trials, with the remaining 6 making a pre-post comparison. Due to the varied quality of the included studies, the meta-analysis results should be interpreted with caution.

Compassion focused therapy (CFT)

Compassion focused therapy (CFT) refers to therapy in which a compassion model is applied, while compassionate mind training (CMT) is concerned with exercises that improve compassion related skills (Gilbert, 2009). Both therapy and training are underpinned by a biopsychosocial philosophy (see Gilbert (2009) for further detail), in which self-soothing techniques are taught to individuals with feelings of shame, low self-esteem and are highly self-critical (Gilbert, 2005). High self-criticism and low self-esteem are associated with a variety of mental health problems, particularly psychosis, in relation to relapse or readmission to hospital (Gumley & Schwannauer, 2006), and early life trauma (Gilbert, 2005, 2009). The aim of CFT or CMT is to acknowledge negative automatic reactions, accept that these are difficult to control and realise they occur because of learned defences (Gilbert, 2006). Metacognitive awareness (i.e. awareness of one's cognitions), acceptance of acknowledged thoughts and compassionate skills are therefore key learning outcomes of CFT. One randomised control trial, including a sample with mental health problems (i.e. psychotic symptoms), has been conducted (Braehler et al., 2013). Results showed that those who received group compassion focused therapy had larger improvement in terms of clinical global improvement and compassion, when compared to treatment as usual, and improvements in compassion were associated with reduced depression (Braehler et al., 2013). A systematic review of compassion focused therapy demonstrates that the current evidence base for compassion based therapies is still small and mostly of limited quality (Leaviss & Uttley, 2015). However, the authors conclude that initial evidence shows encouraging results, specifically in terms of reducing symptoms of depression for people receiving treatment for trauma (Leaviss & Uttley, 2015). Clearly more rigorous evaluation is necessary, however the evidence base, in its current form, does suggest that compassion focused therapy maybe beneficial for people experiencing different mental health problems, e.g. schizophrenia, depression, bipolar affective disorder, personality disorder and deliberate self-harm (Leaviss & Uttley, 2015).

Dialetical behaviour therapy (DBT)

DBT is an evidence-based, emotion focussed treatment originally developed by Marsha Linehan (Linehan, 1993) for borderline personality disorder. Acceptance and validation of emotions and emotion regulation are the key aspects of therapy which set it apart from more traditional CBT. The aim of DBT is to improve patients' emotion regulation,

mindfulness skills, interpersonal skills and distress tolerance. Typical DBT comprises of individual therapy, group skills training and multidisciplinary work.

The benefit of DBT for borderline personality disorder has been widely researched with promising results. Meta-analysis of 16 studies of the effectiveness of DBT for borderline personality disorder showed moderate overall improvements in all studies (Kliem, Kröger, & Kosfelder, 2010). In just RCTs (k=8), results showed small or small to moderate improvements in suicidal and self-injury behaviour and general outcomes, respectively (Kliem, et al., 2010). In another meta-analysis including just two studies, DBT has also been shown to reduce symptoms of anger, parasuicidality and overall mental health when compared to usual treatment with moderate to large effects (Stoffers et al., 2012). However, as pointed out by Chapman (2006), the evidence primarily supports application of the entire DBT package, while different settings (i.e. acute inpatient settings) are likely to require treatment adaptations. For example, an acute inpatient setting may require a more flexible approach to address the chaotic nature of the ward, unpredictable discharges and the mostly short length of stays. Consequently, the evidence base does not currently apply to an acute inpatient environment (discussed further in this chapter), despite regular care for people diagnosed with personality disorder in acute inpatient services.

Mentalization based therapy (MBT)

Like DBT, MBT was originally developed for patients with personality disorder (Bateman & Fonagy, 2010). Mentalization is defined as the ability to make sense of ourselves and others, both implicitly and explicitly. Therefore, the aim of MBT is to improve such skills which in turn should have a positive impact on ones' relationship with themselves and others. Poor mentalization skills have primarily been associated with personality disorder, however some recent evidence suggests patients with first episode psychosis who present with negative symptoms also have difficulty mentalizing (MacBeth et al., 2016) and research to investigate the effectiveness of mentalization-based therapy for psychosis is currently being planned (Weijers et al., 2016).

2.3 The challenges of providing psychological intervention in acute inpatient settings

While developments in psychotherapeutic approaches have undoubtedly had a positive impact on treatments offered to people with severe mental illness, there are a number of

challenges associated with providing psychological intervention in the acute psychiatric inpatient context. Firstly, as pointed out by Clarke and Wilson (2009), there may be a fundamental clash of cultures' between psychological interventions and the acute inpatient environment. Key principles of many psychological therapies, for example, are collaboration between patient and therapist and normalising patients' unusual or distressing experiences, which are not inherent to the medical model that dominates most acute inpatient services.

Other challenges of providing psychological intervention in such settings include the high levels of distress and arousal associated with an acute crisis, the diagnostic diversity and uncertainty that are characteristic of the acute inpatient population (Clarke & Wilson, 2009), and the typically short admission lengths (Mental Health Network, 2012) coupled with unpredictable discharges that are common in acute inpatient services. To address these challenges, therapy may need to be flexible in length, and the content should be accessible to patients who are highly distressed (discussed in the 'Woodhaven Approach' section). Given that this population includes a range of diagnoses, co-morbidities and diagnostic uncertainty, it is also reasonable to argue that a cross-diagnostic approach to therapy may be efficient in an acute inpatient service.

2.3.1 The cross-diagnostic approach

While many psychological interventions have been developed to address specific diagnoses, the concept that common processes exist across diagnoses has grown momentum (Mansell, Harvey, Watkins, & Shafran, 2009). The key principle of the cross-diagnostic approach (also referred to as the trans-diagnostic approach) is that while symptoms of different diagnostic categories manifest in different ways, they are driven by shared dysfunctional processes. Theoretically, treatment of common pathologies should benefit people with different disorders, such as depression or schizophrenia (Larsen-Barr, 2009). While not considered to be unique treatments, cross-diagnostic therapies utilise treatments whose effectiveness are already evidenced in diagnostically diverse groups (Larsen-Barr, 2009; Mansell et al., 2009), for example CBT and third wave therapies (discussed earlier in this chapter).

Three main advantages of the cross-diagnostic approach to CBT have been identified by Mansell et al. (2009). First, theories of shared processes are likely to be more theoretically parsimonious than multiple theories underpinning different diagnoses. The second

advantage is that cross-diagnostic research may prove more fruitful in understanding the working mechanisms of therapies. And the third reason is that cross-diagnostic psychological intervention may prove to be more pragmatic for services (Mansell et al., 2009), particularly in time and resource restricted services, such as the acute inpatient wards. For example, services which focus on common processes, as opposed to diagnostic specificity, within staff training, patient assessment and delivery of psychological interventions, could potentially increase the provision of staff training and therapeutic intervention with a lower cost (Mansell et al., 2009).

Overall, while interventions targeting single diagnoses may be beneficial for some acute inpatients, a cross diagnostic approach may address some key problems highlighted in acute inpatient services: limited provision of therapeutic intervention and lack of sufficiently trained staff (Royal College of Psychiatrists, 2009; Royal College of Psychiatrists Centre for Quality Improvement, 2010, 2014).

2.4 Psychotherapeutic initiatives for acute psychiatric inpatient services

As previously mentioned, although psychological intervention has been recommended for acute psychiatric inpatient services (British Psychological Society, 2012, 2015) (discussed earlier in this chapter), medication remains the primary treatment during admission, and access to therapeutic activity is limited (British Psychological Society, 2012; Joint Commissioning Panel for Mental Health, 2013). It has been reported that less than 20% of inpatients are offered CBT while in hospital (Sainsbury Centre for Mental Health, 2005). This may be due to the challenges of delivering psychological intervention in this environment (discussed earlier in this chapter, section 2.3). Although not routinely offered in clinical practice, in the last decade four notable psychosocial therapeutic initiatives have been developed for acute inpatient settings: the Tidal Model, the Refocusing Model, Star Wards and the Woodhaven Approach. These approaches will now be discussed.

2.4.1 The Tidal Model

The Tidal Model, developed by Barker (2001), is a nurse led initiative which aims to improve the quality of staff-patient interactions and ward milieu. The model is based on a philosophical approach to nursing (interpersonal relations in nursing) which is a conceptual reference for psychodynamic nursing. It is recovery focused in that person-

centred care is advocated and less importance is placed on medical diagnoses. It aims to help patients understand their difficulties, reduce distress and develop therapeutic relationships with staff through patients telling their unique stories, through writing, in a one-to-one session or in a group setting (Barker, 2001). Evaluations of the model, including pre- and post-implementation comparisons, have shown that incidents on the ward (from 32% to 14%) and mean length of stay has either reduced or remained the same post-implementation (depending on the study) (Gordon, 2005). Furthermore, nurses rated the Tidal Model as 'better' or 'much better' than previous ways of working (Gordon, 2005) and patient outcomes improved after implementation of the intervention (Stevenson, Barker, & Fletcher, 2002). Such evaluations, however are not rigorous, and there has been no RCT conducted to evaluate the benefit of this initiative (Barker, 2001). Furthermore, unlike other psychologically informed inpatient initiatives (Clarke & Wilson, 2009) (discussed later in this chapter), the Tidal Model (Barker, 2001) is lacking guidance from an empirical evidence base, and is lacking psychological support for staff (e.g. clinical supervision).

2.4.2 Refocusing Model

Also developed in the UK, the Refocusing Model aims to increase and improve staff-patient interactions (Dodds & Bowles, 2001). Key aspects of the model include increased one-to-one sessions and group activities for patients. Nurses also have increased responsibility in terms of practical decision-making regarding patients. To evaluate the impact of implementing this initiative, an interrupted times series study was carried out, in which audit data collected at pre- and post- implementation was compared (Dodds & Bowles, 2001). The data shows that after implementation there were fewer incidents of self-harm on the ward, absence without leave, violent incidents and hours lost to staff sickness were recorded when compared to pre-implementation. This suggests that the intervention is associated with a positive impact on both staff and patients, however no other research has investigated this model and more scientifically robust evidence is necessary to confirm such conclusions.

2.4.3 Star Wards

Another recovery focussed project, called Star Wards, has been developed to improve acute inpatient care (Bright, 2008; Janner, 2007). Designed by Marion Janner, a psychiatric inpatient service user, Star Wards aims to create a ward culture that is actively

therapeutic and thus improve patient outcomes. This is done through providing ideas for various psychosocial activities, ranging from recreational activities to talking therapies. Star Wards has proved popular in uptake, with a reported 300 wards becoming members of the project (Bright, 2008). However, the development of psychotherapeutic activity, in particular, is reported to be slow (Bright, 2008). Janner, (2007) argues that talking therapies should have equal presence to medication in inpatient wards, and it is acknowledged that offering medication alone to psychiatric inpatients is 'completely unacceptable' (Bright, 2008). However, it is noted that there is an absence of workable service models that promote continuous psychological training, supervision and patient care, and it is suggested that structured guidance regarding therapy type, format and delivery is required (Bright, 2008). Poor uptake is also thought to be due to a lack of resource, trained personnel and time (Bright, 2008).

Although this project is likely to have improved many inpatient services in the UK, no RCT has been conducted to definitively and rigorously evaluate it. There is therefore still work to be done in terms of impact evaluation and identification or development of a working psychological model of care with a theoretical basis.

2.4.4 The Woodhaven Approach

One notable model of psychologically informed acute inpatient care is the Woodhaven approach, developed by Isabel Clarke and colleague (Clarke & Wilson, 2009). It is a cross-diagnostic model of acute inpatient psychological intervention guided by evidence based therapy (i.e. CBT), and underpinned by a theoretical framework of cognition (Barnard & Teasdale, 1991). Like early models of psychological intervention for psychiatric inpatients (e.g. 'Soteria House' and Kingsley Hall (described earlier in this chapter)) and modern inpatient initiatives described above, the Woodhaven Approach aims to create a more therapeutic environment for both staff and patients and ultimately improve outcomes for patients. The Woodhaven Approach, the Tidal Model and Star Wards, however, differ from older psychological models of inpatient care because they are cross-diagnostic, and are applied in addition to treatment as usual, i.e. they do not discourage pharmacotherapy.

The Woodhaven Approach extends the inpatient initiatives described above, in two ways. First, unlike Star Wards, the psychological intervention is manualised and is adapted from evidence based psychological therapy, such as CBT. Second, unlike Star Wards and the

Tidal Model, the Woodhaven Approach is underpinned by a theoretical framework of cognitive processing – the Interacting Cognitive Subsystems model (ICS) (Barnard & Teasdale, 1991) (described in the following section). This framework conceptualises the mechanisms responsible for dysfunctional processing, which lead to symptom development and maintenance of symptoms, or an acute crisis, which are relevant to a variety of mental health problem (Clarke, 1999; Gumley, White, & Power, 1999). However, similar to the acute inpatient approaches discussed above, the evidence base for the Woodhaven Approach is small and does not currently include a definitive RCT to evaluate effectiveness or efficacy (a review of the evidence base is provided later in this chapter, p27).

The main aims of the Woodhaven Approach are: 1) to improve patient outcomes by providing access to psychological interventions and facilitating therapeutic engagement with staff, 2) to improve staff morale and facilitate a psychologically minded and compassionate inpatient staff team, and 3) to create a therapeutic milieu via aims one and two. The intervention includes different components for both staff (psychological training, clinical supervision and reflective practice) and patients (individual formulation and brief CBT-based and third-wave-based group therapies). In line with guidance from the British Psychological Society (2012), the Woodhaven Approach is a recovery focused, skills-based approach to therapy, in that hospital admission is considered a critical turning point in which self-management skills are taught to improve outcomes for patients.

2.4.4.1 The interactive cognitive subsystems model

As previously mentioned the Woodhaven Approach is underpinned by a theoretical framework of cognition – the ICS (Barnard & Teasdale, 1991). The ICS is a model of information processing (Barnard & Teasdale, 1991) which is used as a theoretical framework to explain shared cognitive processes of different mental illnesses and lends itself well to understanding the beneficial processes of third wave therapies for a variety of diagnoses. The model proposes that different types of information are processed in different subsystems. Two subsystems of relevance are the propositional and the implicational. These are conceptually similar to Linehan's rational and emotional mind (Linehan et al., 2001). The propositional subsystem processes verbal information and, like the rational mind (Linehan et al., 2001), is associated with conceptual meaning that can be validated using logic and evidence (Walz & Rapee, 2003). In contrast, the

implicational subsystem processes sensory and body state information and, like the emotional mind (Linehan et al., 2001), is associated with meaning that is described as schematic (Walz & Rapee, 2003). Information with implicational meaning is abstract in nature and is related to emotion (Gumley et al., 1999), for example a personal feeling or sense such as the feeling of being Scottish (Gillanders & Fleming, 2006). Such meaning is created through reoccurring experiences of interactions with others, cultural norms, values and traditions (Gillanders & Fleming, 2006). Implicational processing is automatic and immediate, and only the implicational subsystem can directly generate emotional meaning. However, the body state subsystem is closely connected and in a high state of arousal can trigger the implication subsystem to generate emotion. For example, tense muscles and a fast heartbeat can pass from the body state subsystem to the implicational subsystem to induce negative emotions such as stress or worry.

The hypothesis that information is processed in different subsystems, depending on the meaning, has been empirically tested. Walz and Rapee (2003) did this by using a Stroop-type decision task which included emotionally and neutrally expressed (i.e. spoken) words, which had either an emotional or neutral content (i.e. 'fury' or 'jury'). Such stimuli were used to separately manipulate expression and content, therefore eliciting implicational and propositional processing, respectively. Participants were asked to quickly determine whether the word expression was emotional or neutral (expression task). The authors hypothesised that, according to the ICS, emotionally expressed words would decrease reaction times in the expression task, because emotional expression would prime direct processing of implicational meaning (Walz & Rapee, 2003). Furthermore, they hypothesised that the content of the word would have no impact on decision times in the expression task because, according to the ICS, content has propositional meaning and the propositional subsystem is not used to identify expression. The results supported these hypotheses, thus providing initial evidence that information with implicational and propositional meaning is processing in separate subsystems (Walz & Rapee, 2003).

Information processing is thought to occur dynamically in both the propositional and implication subsystems, and like the wise mind (Linehan et al., 2001), optimal processing (and functioning) occurs when they interact fluidly (Clarke, 2009b). However, this balance can be disrupted where by one subsystem becomes dominant. For example, when arousal is high or overwhelming emotions occur, implicational processing becomes

dominant, leading to reduced or complete loss of rational processing of information in the propositional subsystem. Acute episodes of mental illness, often characterised by overwhelming emotional distress and high states of arousal, are hypothesised to result from such disruption (Clarke, 1999; Teasdale, 1993). Symptoms of various, or all, mental health problems are also hypothesised to result from such dysfunctional processing. When implicational processing prevails and emotions are too overwhelming, or are overwhelming for an extended period of time, symptoms such as dissociation (psychosis), hopelessness (depression), misplaced worry (anxiety) and drug and alcohol use become ways of coping with this negative emotion (Clarke, 2009a, 2015). The ICS may, therefore, provide a framework for understanding shared dysfunctional processing across diagnoses, and has implications for psychological therapy designed for acute crisis. For example, theoretically, acute inpatient psychological work needs to address disconnected processing, and it needs to be accessible at the implicational level of processing.

The ICS and early life adverse events

Trauma and other adverse childhood experiences are now widely acknowledged as risk factors of mental illness (Read & Bentall, 2012) and the ICS provides a framework which underpins this. As previously mentioned, the implicational subsystem is related to processing sensory and body state information to form abstract meaning about the self. Such meaning develops throughout life and is largely influenced by key relationships and events in early life (Clarke, 1999). This concept is not new and has been previously recognised by developmental theories, e.g. attachment theory (see Bowlby, (1969) for detail). There is a now general consensus that, as a result of adverse life experiences or trauma, negative self-constructs are likely to be formed (Read & Bentall, 2012).

The ICS extends this concept, in that the implicational subsystem (storing and processing abstract information about the self) has a close and automatic communication with the body state subsystem (storing and processing arousal related information).Therefore, the construction of the self in early life is thought to develop in parallel with the development of arousal patterns (Clarke, 2009b). This automatic connection is designed to protect the self against threat, i.e. to prepare the body to respond to threat (fight, flight or freeze). Where constant exposure to threat is experienced in early life, negative constructs about the self (e.g. shame and worthlessness) are developed and automatic responses (i.e. increased arousal leading to fight, flight or freeze) are reinforced and stored, therefore creating hyper-vigilance to perceived threat (either external or internal). This pattern of

processing is not considered to be diagnostic specific, therefore such experiences which create dysfunctional processing can increase the risk of developing a variety of mental illnesses in adult life. The following examples describe how this may lead to depression or psychosis.

Continuous exposure to a negative implicational understanding of the self (due to adverse experiences) leads to embedded negative propositional understanding of the self and an automatic response to threat, i.e. giving up (Gillanders & Fleming, 2006). This creates a feedback loop which reinforces and maintains negative beliefs about the self, thus preserving a negative mood and the associated automatic response. This pattern of information processing is considered involuntary and has been termed the 'depressive interlock' (Teasdale, 1993). There is initial empirical support for this concept. Gillanders and Fleming (2006) tested the hypothesis that information processing becomes 'stuck', or repetitive, for people diagnosed with depression, and that such processing is negatively inclined (characteristics of the 'depressive interlock'). This was done by comparing clinically depressed and non-depressed participants on a task which tests the effect of emotional stimuli on information processing. The authors hypothesised that depressed participants would respond more repetitively than non-depressed participants, and this would be more evident for emotionally related stimuli (Gillanders & Fleming, 2006). Results supported both hypotheses, and therefore the depressive interlock. The depressive interlock therefore provides a theoretical understanding of sustained depressive moods supported by initial empirical evidence and it offers a theoretical understanding of the potential influence of adverse childhood experiences in adult mental health problems.

Another hypothesis derived from the ICS is that negative information stored about the self may lie dormant due to effective interaction between implicational and propositional processing (Clarke, 1999; Gumley, White, & Power, 1999). Then, implicational stores, and associated arousal stores, are triggered by later life events (e.g. a traumatic experience) or circumstance (i.e. extreme or constant stress) which mimic negative or threatening early life events, or circumstance. This interrupts processing that is usually balanced (i.e. the implicational subsystem becomes dominant or disconnected from the propositional subsystem), resulting in an acute episode of mental illness or relapse. Gumley et al. (1999) argue that this process can lead to the onset and relapse of psychosis – and that access to implicational and arousal information stored in early life may evolve

and become faster with each episode or relapse. Such hypotheses, however, are yet to be empirically tested.

It is important to note that when someone has not experienced trauma in early life, the perceived self may still be disrupted. Losing self-defining roles and relationships or experiencing transitions in life (e.g. divorce, losing a job, or moving to a new city), for example, can also lead to extreme distressing emotions, such as fear, anger or pain (Clarke, 2009a). However, in each of these scenarios, the ICS continues to support the notion that mental illness (whether severe and enduring or short-term and acute) is a result of dominant implicational processing, therefore creating automatic, and overwhelming, emotional and physical arousal for an extended period of time.

Symptomatic coping

In line with the recovery approach and Laing's early conception of severe mental illness (discussed earlier in this chapter), The Woodhaven Approach considers symptoms of severe mental illness to be a reasonable reaction to overwhelming negative emotion, which is explained by dominant implicational processing (described in previous sections). For example, symptoms of depression, such a hopelessness and giving up, have been attributed to a reasonable reaction of continued overwhelming emotion and high arousal (i.e. dominant implicational processing) (Gilbert, 1992). Individuals may also attempt to escape overwhelming negative emotion using various learned and unhelpful behaviours, such as drug or alcohol use (addiction), withdrawal or submission (depression), worry and hyper-vigilance (anxiety), compulsions or displaced anxiety (i.e. obsessive compulsive behaviours or eating disorders) or dissociation (e.g. psychotic experiences) (Clarke, 2009b). Although these responses differ in presentation, Clarke (2009b) argues that the common feature is that they act as coping strategies which people have learned as a form of short term relief from adverse feelings which have resulted in dysfunctional processing (described in previous sections). Unfortunately, such coping strategies are unhelpful in the long-term, thus resulting in poor mental health and sometimes hospital admission. The ICS therefore provides a conceptual understanding of shared dysfunctional processing, leading to overwhelming emotion and extreme distress, which may underlie acute crisis presenting in a variety of way. This has several implications for psychological therapy for the acute inpatient population

2.4.4.2 Therapeutic components of the Woodhaven Approach

The ICS provides a theoretical framework of cross-diagnostic dysfunctional processing that underlies symptoms of severe mental illness and acute crisis. The Woodhaven Approach has drawn on this to link mechanisms of change to third-wave and CBT based techniques. The importance of acknowledging and managing emotion and closely related physicality within therapeutic work is emphasised, and a recovery orientated response by means of CBT- and 'Third-wave'-based therapies is promoted. The overall aim of therapy is to help patients' make sense of their current situation and improve their ability to help themselves. In keeping with the person-centred approach, individual formulation is at the heart of this process.

Emotion focused crisis formulation

As pointed out by Clarke (2009a), individual therapy provided during an acute hospital admission differs in a number of ways from a community setting. For example, the time from referral to appointment is considerably shorter in hospital due to generally short admissions, the exact length of admissions is often unpredictable (previously discussed in this chapter) and prior knowledge of the client may be limited in comparison to community settings (Clarke & Wilson, 2009). However, according to the Woodhaven Approach, exploring a patients' complex history is not advised in this context due to the highly emotive state the individual is likely to be in (Clarke & Wilson, 2009). Instead, and in keeping with the person-centred approach, it is advised that therapy aims to validate and make sense of each individuals' unique experience by determining past (briefly) and current factors which trigger and maintain imbalanced processing (i.e. dominant processing of implicational (emotional) information with associated high arousal) that have led to the current admission (Clarke, 2009a). Also in accordance with the recovery approach, patients are encouraged to take control of their crisis through identifying resolutions for unbalanced or disconnected processing. Such resolutions are likely to include appropriate third-wave and CBT based therapeutic approaches, which provide alternative skills-based coping strategies that help break self-defeating patterns of behaviour (Clarke, 2009a).

The process of emotion focused crisis formulation centres around 'spiky diagram' (see Figure 1) (Clarke, 2009b, 2015). Similar to CBT formulation, the spiky diagram aims to provide validation of negative feelings and behaviours via acknowledgement of past adverse experience, although, unlike outpatient CBT, exploration of such experiences is

not recommended at this stage. Then, recent stress or adverse events are identified, along with patterns of current (unhelpful) coping strategies that maintain problems and overwhelming distress. Such patterns are named 'vicious cycles'. With the aim of giving each individual full responsibility of their own situation, new ways of coping are identified. Central to this process is mindfulness (described earlier in this chapter). Mindfulness based techniques are taught to allow patients to become more tolerable of overwhelming negative emotion and control physiological responses (associated with implicational processing), thus allowing time to choose a helpful coping strategy before automatically resorting to learned unhelpful patterns of behaviour (e.g. self-harm or taking drugs) (Clarke, 2015). Figure 1 demonstrates a typical formulation for someone experiencing symptoms associated with psychosis. Individual formulation, in this form, is considered central to acute inpatient psychological intervention.

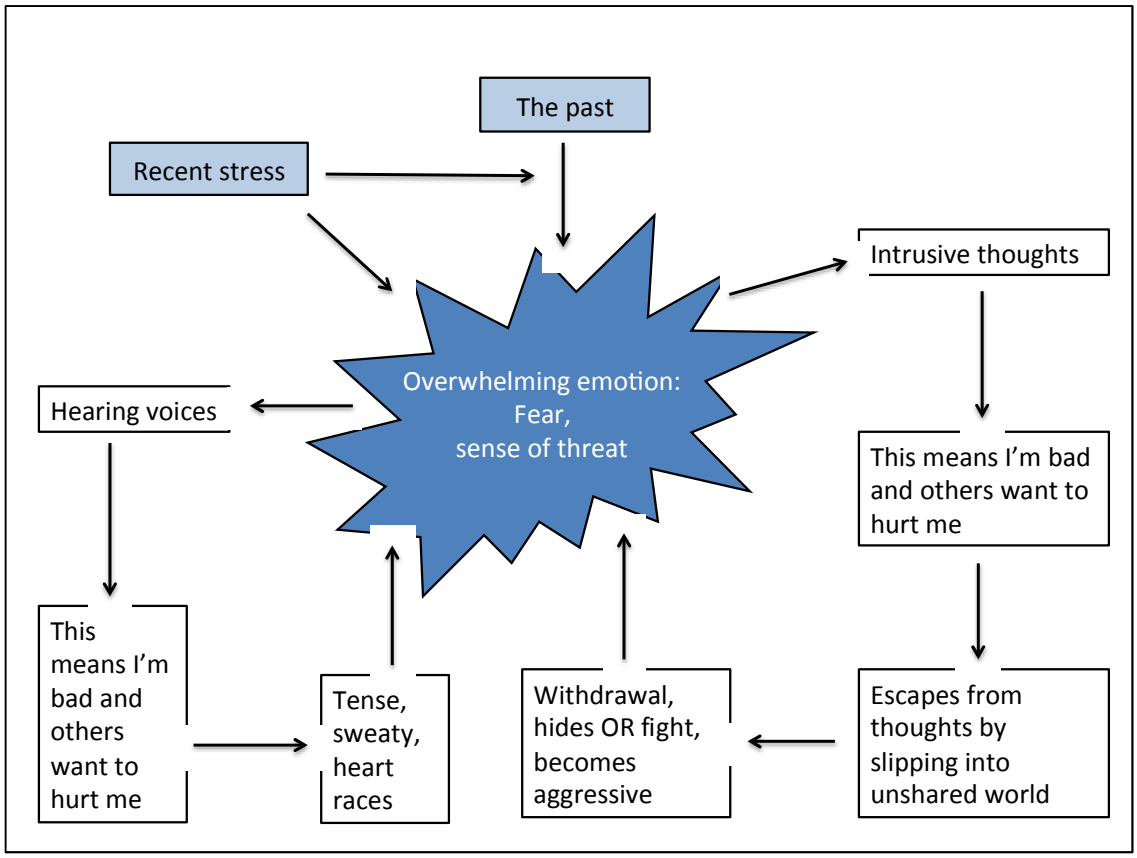

Figure 1 *Emotion focused formulation example for psychosis (Clarke, 2009b).*

Group therapy components

All group components of the Woodhaven approach (Clarke & Wilson, 2009) are drawn from CBT-based and third-wave-based approaches (e.g. mindfulness, compassion and DBT), and have the common aim to interrupt unhelpful coping strategies which maintain distress, as identified by individual formulation. This is done through managing the

threshold between the two detached/disconnected subsystems related to current acute distress. One group draws on mindfulness techniques and aims to manage high states of arousal ('Stress and Anxiety Management'), one draws on compassion focused therapy (Gilbert, 2009) and aims to increase self-esteem ('Making Friends with Yourself'), one group aims to normalise unshared experiences ('What is Real and What is Not') and one group draws on DBT and is designed to improve distress tolerance and emotion regulation ('Coping With Emotions'). Group therapy is considered to be a cost-effective approach to address limited resource in acute inpatient services and is advocated by inpatient initiatives such as Star Wards (Bright, 2008). Unlike Star Wards, Woodhaven psychological group interventions are manualised to allow ward staff to co-facilitate and facilitate sessions (further detail of group components is provided in chapter four).

2.4.4.3 A brief review of the evidence

A small evidence base has emerged which aims to evaluate some components of the Woodhaven Approach. The studies are small in size and are not controlled, however encouraging results have come from a total of five studies. First, an informal evaluation (n=11) of the compassion focused group intervention was conducted, in which inpatients were subjectively judged by an independent researcher to find the group acceptable (Hill, Clarke, & Wilson, 2009). The evaluation also showed that measures of self-reported mental health related self-efficacy indicated patterns of improvement in most patients following the intervention (n=7), however there were too few participants to allow for statistical analysis. Another small study (n=31) was carried out which aimed to evaluate the effectiveness of the 'What is Real and What is Not?' group ([WRWN] psychosis group) (Wilson, Clarke, & Phillips, 2009). The results showed increased self-reported locus of control (in relation to mental health) at post-treatment compared to pre-treatment. Additionally, a trend of reduced psychological distress was reported by the authors, however statistical significance was not reached on this outcome (Wilson et al., 2009). Again, these initial results are promising, however it is difficult to attribute improvements directly to the intervention without a control group. More recently, a larger, non-randomised, non-blind controlled trial (n=113) of the WRWN group (n=71) found improved self-efficacy at post-intervention and follow-up, when compared to treatment as usual (Owen, Sellwood, Kan, Murray, & Sarsam, 2015). Again, patterns of decreasing distress emerged in the intervention group at follow-up, however authors report that the data collected was inadequate to allow for statistical comparisons to be made between groups. Together, these studies provide initial results which are promising, however they

are lacking in quality and they focus on evaluating the impact of specific intervention components rather than the entire intervention. Only two studies have aimed to evaluated the whole intervention (Araci & Clarke, 2016; Durrant, Clarke, Tolland, & Wilson, 2007) to date, and have produced results which are in keeping with the findings described above (Hill et al., 2009; Owen, Sellwood, et al., 2015; Wilson et al., 2009). Results indicate that the intervention, as a whole, was associated with benefits for inpatients in terms of increasing self-reported self-efficacy and confidence in expressing emotions and perceived locus of control (n=14) at post-treatment when compared to pre-treatment (Durrant, et al., 2007). This study, however, also lacked a control condition, therefore limiting the conclusions that can be drawn from the results. A more recent, and larger, study (n=131) including patients from four acute services (both inpatient and outpatient) also aimed to evaluated the benefit of the whole service with similar results (Araci & Clarke, 2016). Again, findings indicated reduced distress and increased self-efficacy, in relation to mental health, at post-treatment in comparison to pre-treatment assessment. However, similar limitations apply due to the absence of a comparison group, and therefore randomisation and assessor blinding. Despite such limitations, the study also reported the feasibility of embedding the model within four acute services (inpatient and outpatient). The authors reported extensive implementation of the model: providing over 200 multidisciplinary staff with introductory training and 340 referrals to the model. However, it is unclear what time span this has been recorded and the latter may be inaccurate as the authors report potential incomplete recording of data. A two-week snap shot of clinical activity is also reported in this study (Araci & Clarke, 2016). From four acute services, 25 referrals were made, 36 one to one emotion focused formulation sessions were delivered, 52 patients attended group intervention components and 21 staff were involved in intervention delivery (including psychologists, nurses and occupational therapists). This data suggests implementation is feasible and acceptable across disciplines, however further good quality research is necessary (Araci & Clarke, 2016)

Summary and conclusion

Overall, the current literature provides initial promising evidence to suggest that components of the Woodhaven Approach, and the model as a whole may be beneficial for patients in terms of improving mental health related self-efficacy and perceived locus of control. However, the evidence consists mostly of studies of limited size and quality, and as pointed out by Araci and Clarke (2016), more rigorous evaluation is needed. To date no controlled trial has evaluated this cross-diagnostic psychological intervention as

whole, specifically assessing the impact on readmissions. To determine whether this psychological model can address some of the problems associated with acute inpatient services (i.e. high levels of readmissions) and improve outcomes for patients, a scientifically robust definitive trial is needed. The Medical Research Council (MRC) considers a phased approach as best practice to systematically develop and evaluate complex interventions (see Chapter 1) (Craig et al., 2008, 2013). This includes both development and feasibility/piloting of an intervention before definitive evaluation. This thesis, therefore, aims to address both these phases in preparation for a future definitive trial.

2.5 Implications for the thesis

The arguments made in this chapter have two main implications for the thesis. First, this chapter has highlighted that there is evidence to support the effectiveness of CBT and third-wave therapies for a variety of SMIs. This evidence suggests that the cross-diagnostic application of such therapies may be feasible. However, previous meta-analyses have included both inpatient and outpatient populations with severe mental illnesses, therefore such evidence is not easily generalised to an acute inpatient setting. Additionally, studies examining the effectiveness of psychological intervention specifically for acute inpatients are often small and therefore lack power (see chapter three). A comprehensive synthesis of controlled trials of psychological intervention delivered in acute inpatient settings would address these issues and is currently lacking. The current thesis aims to address this gap.

The second implication for the thesis is that, given the diagnostic variability of inpatients in acute services, it might be useful to take a cross-diagnostic approach to psychological intervention, in this context. Some acute inpatient psychological initiatives advocate such an approach but lack formal guidance on a working psychological approach with a theoretical basis (Bright, 2008), with one notable exception: the Woodhaven Approach (Clarke & Wilson, 2009). Initial evaluation of the Woodhaven Approach is promising but contains small studies which lack power. And whether such an intervention benefits acute inpatients with regards to emotional distress or benefits acute inpatient services with regards to the number of readmissions has not yet been tested. A definitive randomised controlled trial is needed to address these issues. Initial development and pilot/feasibility work is recommended to inform the design of a full trial (Craig et al., 2008, 2013). This thesis therefore aims to address these gaps. Chapter 3 contributes to the development of

inpatient psychological intervention in reviewing and synthesising the initial evidence base. Chapters 4, 5 and 6 contribute to determining the feasibility of conducting a definitive trial of a cross-diagnostic psychological intervention for acute inpatients.

3 Meta-analysis of trials of the effectiveness of brief psychotherapy for acute mental health inpatients

This chapter presents a meta-analysis of brief psychotherapy for acute psychiatric inpatients. It aims to identify, review and synthesise the current evidence base of controlled trials reporting the effectiveness of brief inpatient psychological intervention for acute mental health inpatients for the first time. This maps onto the primary stages of developing and evaluating complex interventions (i.e. reviewing and meta-analysing the existing evidence base), as recommended by the Medical Research Council (MRC) framework (Craig et al., 2013).

3.1 Justification for meta-analysis

Psychiatric inpatient services have continuously been criticised for having particularly nontherapeutic environments (Mind, 2004; Schizophrenia Commission, 2012), minimal provision of therapeutic activities (British Psychological Society, 2015; Mind, 2004) and a high rate of readmissions (Care Quality Commission, 2015; Information Services Division Scotland, 2012) (see Chapter 2). To address some of these problems, it has been recommended that acute psychiatric inpatients should have access to psychological intervention during their admission (British Psychological Society, 2012, 2015; Royal College of Psychiatrists Centre for Quality Improvement, 2014). In the past 20 years, psychological therapies have been developed for severe mental illnesses which are common in acute inpatient services (e.g. psychosis, schizophrenia, bipolar disorder, personality disorder and major depressive disorder), and there is a growing evidence base which has provided some encouraging results (see Chapter 2). However, much of this evidence base either focuses on patients who are not in the acute phase of illness or includes both inpatients and outpatients (see Jauhar et al., 2014; Khoury, Lecomte, Gaudiano, & Paquin, 2013; Leaviss & Uttley, 2015; Stoffers et al., 2012; Turner, Van Der Gaag, Karyotaki, & Cuijpers, 2014; Van der Gaag, Valmaggia, & Smit, 2014). Many participants are therefore likely to be less severely ill than the acute inpatient population. The evidence base also evaluates interventions which are longer than a typical acute admission (Mental Health Network, 2012; NHS Confederation, 2014), therefore such therapies are not appropriate for application in acute inpatient services. Consequently, it is difficult to generalise this evidence base to an acute inpatient setting.

Recently, some evidence has emerged which suggests brief psychological intervention is effective for outpatients with some severe mental health problems (i.e. presenting with suicidality and psychotic symptoms) (Husain et al., 2014; Johns et al., 2016; Naeem et al., 2015). However, the acute ward environment is not always considered to be therapeutic, safe or conducive to emotional disclosure (Bowers et al., 2002; Jones et al., 2010; Schizophrenia Commission, 2012), therefore it is possible that treatment outcomes of psychotherapy are moderated by the milieu of an acute ward. Some guidelines even recommend that therapy begin after discharge (National Institute for Health and Care Excellence, 2014). However, there is increasing demand for inpatient therapeutic interaction and activities (Csipke et al., 2014; Rose et al., 2015), and professional bodies continue to recommend that acute inpatient services provide some form of psychotherapeutic activity (British Psychological Society, 2015; Department of Health, 2002; Royal College of Psychiatrists Centre for Quality Improvement, 2014). Determining the effectiveness of brief psychological intervention for acute psychiatric inpatients is therefore important.

Recently, a review of the entire evidence base for group cognitive behavioural therapy for psychosis (CBTp) in acute care was published (Owen, Speight, Sarsam, & Sellwood, 2015). Results suggest that CBTp, in addition to usual care, has the potential to reduce patients' distress and affective symptoms, and to increase patients' knowledge of symptoms. Additionally, the intervention was associated with reduced readmissions. However, this review only synthesised results from studies which target patients with psychosis, and only two of the ten studies included in the review were randomised controlled trials (RCTs), while the rest adopted either a pre- post- experimental design or were cohort studies. Therefore, conclusions drawn from the review are not definitive, and can only be generalised to acute inpatients with psychosis.

At present, an up-to-date cross-diagnostic systematic review and meta-analysis of controlled trials is lacking. The current systematic review and meta-analysis endeavoured to identify and synthesis the current evidence base. The aim was to establish the effect of therapy delivered in an acute inpatient setting on psychotic symptoms, risk of readmission and emotional/psychological distress.

3.2 Methods

3.2.1 Protocol registration

A review protocol was developed and registered online (PROSPERO CRD42015026732). Subsequent changes include specification of additional subgroup analyses, i.e. contact with a therapist in the control group, therapy type and diagnosis.

3.2.2 Inclusion/Exclusion Criteria

All randomised and non-randomised trials of talking psychological therapies for adult receiving acute inpatient care, where the comparator was usual care, usual care plus waiting list, or usual care plus 'inactive' psychological intervention (e.g. non-directive' interventions such as befriending or supportive counselling) (see Table 1, page 37, for included therapies and control) and that were conducted after 1980 were included, if a published or unpublished report was available in English. Given the broad focus of the review, i.e. to identify the benefit of any talking psychological therapy, studies in which two talking therapies were compared were excluded. Given that this was the first cross-diagnostic review of acute inpatient psychotherapy and the limited number of studies, inclusion of non-randomised trials was planned largely to obtain a broad overview of current evidence base. The extent to which this led to a reduction in internal validity was determined by subgroup analysis of trials which are, and are not, randomised and single-blinded (i.e. assessors were blind). Uncontrolled studies, including case studies and case series were excluded due to associated risks of bias (Higgins & Green, 2011).

For the purpose of this meta-analysis, psychotherapy was defined as: "meeting with a therapist (..) to talk about feelings and thoughts and how these affect behaviour and wellbeing" (National Institute for Health and Care Excellence, 2014, para. 1); "Any group of therapies, used to treat psychological disorders, that focus on changing faulty behaviours, thoughts, perceptions, and emotions that may be associated with specific disorders" (Gerrig, Zimbardo, Campbell, & Cumming, 2011, p. 575) where therapy is delivered verbally. Examples of interventions fitting this description include, but was not limited to, cognitive behavioural therapy (CBT), psychodynamic therapy (PT), acceptance and commitment therapy (ACT) and meta-cognitive therapy (MCT). Interventions were included regardless of delivery format (e.g. group or individual). Interventions not satisfying the definition are those primarily aiming to reduce substance misuse, to aid reintegration into the community (reintegration therapy), increase

compliance with medication (compliance therapy), increase knowledge of mental illness (psychoeducation), decrease muscle tension (muscle relaxation training, Progressive Muscle Relaxation Therapy), improve employability (vocational rehabilitation), improve neurocognitive functioning (Cognitive Remediation or Cognitive Rehabilitation). Trials where interventions were delivered via art, music or computers also did not meet the working definition of psychological therapies and were therefore excluded. Additionally, therapies considered 'non-directive' or 'less sophisticated', e.g. psychoeducation, supportive counselling or befriending, were not categorised as 'directive' or 'sophisticated' psychological therapy for the purpose of this review.

This review was primarily concerned with the effect of therapy for patients in a specific setting (i.e. acute psychiatric inpatient settings) therefore no restriction was placed on the diagnosis of participants. However, trials where less than 50% of participants were inpatients (and where data for inpatients could not be separated from data for outpatients) were excluded. Only studies where usable data relating to either severity of psychotic symptoms, depression, anxiety or number of readmissions were included. Criteria developed by The Mental Health Network (Mental Health Network, 2012) were used to define acute inpatient mental health care leading to the exclusion of wards for adolescents, older adult wards, specialist wards (e.g. for eating disorder, learning disability, national obsessive compulsive disorder (OCD), anxiety disorders, mother and baby unit beds for perinatal psychiatry, residential psychotherapy for personality disorder, autistic spectrum), forensic wards, rehabilitation wards, crisis houses or respite beds and inpatient substance misuse units. While length of stay in an acute inpatient ward can vary, in order to specifically evaluate acute inpatient therapy a limit was placed on length of stay in this meta-analysis. According to the NHS Confederation (2012), the average length of stay in acute inpatient mental health care is 90 days, therefore studies where the average length of stay of participants was longer than this were not considered to be studies of acute treatment and were therefore excluded.

3.2.3 Outcomes

Psychotic symptoms are often encountered in acute inpatient settings, occur over a range of diagnoses and are commonly measured in intervention trials, therefore overall psychotic symptoms were chosen as the primary outcome. This was defined by group differences in mean post-treatment Positive and Negative Symptom Scale (PANSS) (Kay et al., 1987) total scores but where this was not available, group difference in mean change

was used. If neither were available, the nearest post intervention mean was used, as per previous meta-analyses (Jauhar et al., 2014). If no PANSS total scores were reported but subscale scores were reported, then these were combined using the method specified by Jauhar et al., (2014). If PANSS was not used, the Brief Psychiatric Rating Scale ([BPRS], Overall & Gorham, 1962) or the Global Assessment of Functioning ([GAF], (Hall, 1995) mean scores were converted to PANSS scores using conversion tables provided by Leucht and colleagues (Leucht, Rothe, Davis, & Engel, 2013) and Samara and colleagues (Samara et al., 2014). Further details on the process of data conversion can be found in Appendix 1.

Secondary outcomes included follow-up PANSS total score, number of readmissions, symptoms of depression and symptoms of anxiety. Depression and anxiety were thought to be useful indicators of emotional distress (Derogatis, 2001), which is often the target of psychological interventions and is considered by some researchers to contribute to the onset and maintenance of a variety of SMIs (Birchwood, Shiers, & Smith, 2014; Clarke, 1999). If available, Beck Depression Inventory ([BDI], Beck, Steer, & Carbin, 1988) or BDI-2 (Beck, Steer, & Brown, 1996) data was extracted for the depression outcome. If unavailable, Hamilton rating Scale of Depression ([HMRD], Hamilton, 1960) data was used. If neither were available other measures reported by the authors were used if adequate reliability and validity were reported (see Appendix 2). For example, the anxiety outcome included a combination of data from the anxiety subscale of the Hospital Anxiety and Depression Scale ([HADS], Zigmond & Snaith, 1983), Hamilton Anxiety Rating Scale ([HAMA], Hamilton, 1959) and the Symptom Checklist – 90 – Revised ([SCL-90-R], van der Laan, Van Spaendonck, Horstink, & Goris, 1999).

3.2.4 Search Strategy

As suggested by Lipsey and Wilson (2001) three methods were used to search the literature thoroughly: (i) the use of two or more computerised databases, (ii) manually searching the reference lists of related meta-analyses and reviews, (iii) making contact with researchers for relevant material. The electronic databases ASSIA, Embase, Cinahl, Cochrane, Medline and PsycINFO were searched in October 2014 and again in February 2016, with the following search strategy: ((SU.EXACT.EXPLODE("Cognitive behavioural psychotherapy") OR SU.EXACT("Cognitive psychotherapy") OR SU.EXACT("Individual psychotherapy") OR SU.EXACT("Group psychotherapy") OR SU.EXACT("Behavioural psychotherapy")) OR (cognitive therap* OR behavio?r*

therap* OR cognitive behavio?r* therap* OR CBT OR psychological therap* OR group therap* OR individual therap* OR dialectical behavio?r* therap* OR DBT OR compassion focus?ed therap* OR compassionate mind training OR CMT OR psychological treatment OR psychological intervention OR mindfulness OR emotion regulation OR acceptance commitment therap* OR ACT OR mindfulness based OR third wave therap* OR third wave cognitive therap*)) AND (((psychiatric inpatient care) OR (acute inpatient mental health care)) OR (mental health AND inpatient care)) AND (acute psychosis OR psychosis OR psychotic OR schizo* OR personality disorder OR PD OR borderline personality disorder OR BPD OR severe mental illness) AND (inpatient OR acute). Clinical trial registries were also searched for potential unpublished trials (clinicaltrials.gov; ISRCTN). Titles and abstracts were screened first and studies obviously not meeting inclusion exclusion criteria were removed. Full texts of the remaining papers were then accessed and reviewed.

3.2.5 Data Extraction

One reviewer (CP) extracted data from each study specifically for this review. Any uncertainties were discussed with other reviewers. Attempts to obtain missing or unclear data were made by contacting trial authors. In keeping with recommendations from Lipsey and Wilson (2001), a variety of study features were extracted and grouped. For each study, information on a number of design, treatment, and outcome related variables were extracted. This included method of randomisation, use of assessor blinding, length of follow-up, diagnosis of participants, equivalence of groups, overall sample size, type of intervention and control, likely contact with therapist in control group, sample for analysis (see Appendix 3 for further detail) and duration of therapy (including number of sessions and total therapy time in minutes) (reported later in this chapter). Finally, reported outcome measures were extracted and grouped under general concepts (see Appendix 4 for more detail).

3.2.6 Data conversion and analysis

Procedures outlined in the Cochrane Handbook (Higgins & Green, 2011) were used to combine groups where studies had more than two relevant treatment or control arms. Where multiple follow-up data was reported, the longest was included. Meta-analysis was carried out using Comprehensive Meta-Analysis (CMA, version 2.0) (Borenstein & Rothstein, 2004). For continuous outcomes, pooled standardised mean differences (SMD)

and 95% confidence intervals were calculated, with Hedge's g adjustment for small samples. Using the SMD allows multiple continuous measures of the same construct to be combined. All SMDs were interpreted using Cohen's (1988) guidelines: 0.2 signifies a small effect, 0.5 a medium effect and 0.8 a large effect. Odds ratios and 95% confidence intervals were used to quantify group differences in dichotomous outcomes. A random-effects model was applied in all analyses due to the variation between studies (Borenstein, 2009) (i.e. therapy type, length, diagnosis, control group).

Table 1

Grouping of therapies and comparators

Therapy/comparator groups	Therapies/Comparators Included
Psychological therapies	CBT; ACT; CT; MCT; DBT; SST; EMDR; IPP; 'Psychological approach'
Control group with extra therapist contact	Relaxation therapies; PMR; Psycho-education; Supportive counselling; Befriending; TAUP
Usual Treatment	TAU; Waiting list; Newspaper reading group; TAUP; ETAU
All controls	TAU; TAUP; Waiting list; Newspaper reading group; Medication; Relaxation therapies; PMR; Psycho-education; Supportive counselling; Befriending

Acceptance and Commitment Therapy, ACT; Cognitive Behavioural Therapy, CBT; Cognitive Therapy, CT; Dialectical Behaviour Therapy, DBT; Eye-Movement Desensitisation Reprocessing, EMDR; Interpersonal psychotherapy, IPP; Meta-Cognitive Therapy, MCT; Progressive Muscle Relaxation, PMR; Social Skills Training, SST; Treatment as Usual with Psychotherapy, TAUP; Treatment as Usual, TAU.

3.2.7 Assessment of study and outcome quality

One author (CP) assessed study-level risk of bias with the Cochrane Collaboration risk of bias tool (Higgins et al., 2011). This tool measures the potential risk of bias associated specifically with randomisation, allocation, blinding, incomplete data and selective reporting. Outcome quality was also measured using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt et al., 2008). For each outcome, this approach assesses the type of evidence included, the quality of the included studies, the consistency among study results, the generalisability of the result, the precision of the estimated treatment effect and the risk of publication bias. Any uncertainties were discussed at review meetings with other authors. Further details of ratings and rationale are provided in the appendices (see Appendices 7 and 8).

3.2.8 Subgroup analysis

Subgroup analyses were carried out on all outcomes where there were at least 4 studies to investigate the effect of randomisation and assessor blinding. Studies were categorised as either randomised and single-blind (i.e. assessors were blind) (Aghotor, Pfueller, Moritz, Weisbrod, & Roesch-Ely, 2010; Bechdolf et al., 2004; Bowers, 1990; Habib, Dawood, Kingdon, & Naeem, 2015; Haddock et al., 1999; Kim, Choi, & Kim, 2010; Lewis et al., 2002; Moritz, Veckenstedt, Randjbar, Vitzthum, & Woodward, 2011; Schramm et al., 2007) or not randomised and single-blind (Bach & Hayes, 2002; Gaudiano, 2006; Gibson, Booth, Davenport, Keogh, & Owens, 2014; Hall & Tarrier, 2003; Hayashi, Yamashina, Igarashi, & Kazamatsuri, 2001; Kumar et al., 2010; Miller, Norman, Keitner, Bishop, & Dow, 1989; Mortan, Sutcu, & Kose, 2011; Shelley, Battaglia, Lucey, & Opler, 2001; Startup, Jackson, & Bendix, 2004; Veltro et al., 2006). Additional subgroup analyses were carried out on the primary outcome to examine the effect of therapy type and the nature of control groups (i.e. extra contact with a therapist in the control group). Studies were categorised into three groups to look at differences in therapy types: CBT and cognitive therapies (Bechdolf et al., 2004; Habib et al., 2015; Haddock et al., 1999; Hall & Tarrier, 2003; Hayashi et al., 2001; Lewis et al., 2002; Shelley et al., 2001; Startup et al., 2004), third-wave therapies (Aghotor et al., 2010; Bach & Hayes, 2002; Gaudiano & Herbert, 2006; Kumar et al., 2010; Moritz et al., 2011) and other therapies (Kim et al., 2010; Schramm et al., 2007). Additionally, some studies included control groups that had more contact with a therapist than usual treatment. This is thought to mediate the summary effect (Button & Munafò, 2015; Wykes et al., 2008), therefore all studies were categorised into two groups: probable extra contact with a therapist in the control group (Bach & Hayes, 2002; Bechdolf et al., 2004; Gaudiano & Herbert, 2006; Haddock et al., 1999; Kim et al., 2010; Lewis et al., 2002; Moritz et al., 2011; Schramm et al., 2007) and no probable extra contact with a therapist in the control group (Aghotor et al., 2010; Habib et al., 2015; Hall & Tarrier, 2003; Hayashi et al., 2001; Kumar et al., 2010; Shelley et al., 2001; Startup et al., 2004). Details of therapies and control group categories can be found in Table 1, Table 3 and Table 4 (page 37, 45 and 47). Additional subgroup analysis was conducted to explore the moderating role of diagnosis in the depression symptom outcome. Three diagnostic groups were identified: depression (Bowers, 1990; Miller et al., 1989; Schramm et al., 2007), psychosis (Habib et al., 2015; Hall & Tarrier, 2003; Mortan et al., 2011) and 'other' which included one study which evaluated the effectiveness of therapy for behaviours of self-harm (Gibson

et al., 2014). As only one study was included in the 'other' group it was excluded from this subgroup analysis.

3.2.9 Sensitivity Analyses

Startup et al. (2004) only reported 6- and 12-month follow-up data, therefore 6-month data was used in the post treatment analysis and 12-month data was used as follow-up data. Sensitivity analysis was carried out to investigate the effect of excluding Startup et al. (2004) from post PANSS total score and follow-up PANSS total score.

3.2.10 Analysis of homogeneity and publication bias

The I-squared statistic was calculated to determine the proportion of homogeneity in outcome estimates (Lipsey & Wilson, 2001). Heterogeneity was investigated further if the proportion was judged to be at least moderate, defined as an I-squared value of 40% or more (Higgins & Green, 2011). Duval and Tweedie's Trim and Fill method (Duval & Tweedie, 2000) was used to look for missing studies due to publication bias where ten or more studies were included in the analysis (see Appendix 5 for Trim and Fill results).

3.3 Results

A total of 512 studies were retrieved from searching online databases, 13 were retrieved from searching reference lists of included studies and meta-analyses, reviews and other relevant studies (Jauhar et al., 2014; Lynch et al., 2010; Mehl, Werner, & Lincoln, 2015; Turner, et al., 2014) and one unpublished study was found from emailing relevant authors. Of the 526 reports that were examined, 20 individual studies (described in 27 separate reports) were identified for inclusion in one or more of the meta-analyses (Aghotor, et al., 2010; Bach & Hayes, 2002; Bechdolf et al., 2004; Bowers, 1990; Gaudiano & Herbert, 2006; Gibson,et al., 2014; Habib, et al., 2015; Haddock et al., 1999; Hall & Tarrier, 2003; Hayashi, et al., 2001; Kim, et al., 2010; Kumar et al., 2010; Lewis et al., 2002; Miller, et al., 1989; Moritz, et al., 2011; Mortan, et al., 2011; Schramm et al., 2007; Shelley, et al., 2001; Startup, et al., 2004; Veltro et al., 2006). The process of study selection is summarised in the PRISMA flow diagram (Figure 2, page 40) and a list of studies excluded after inspection of the full-text is provided in the appendices (Appendix 6).

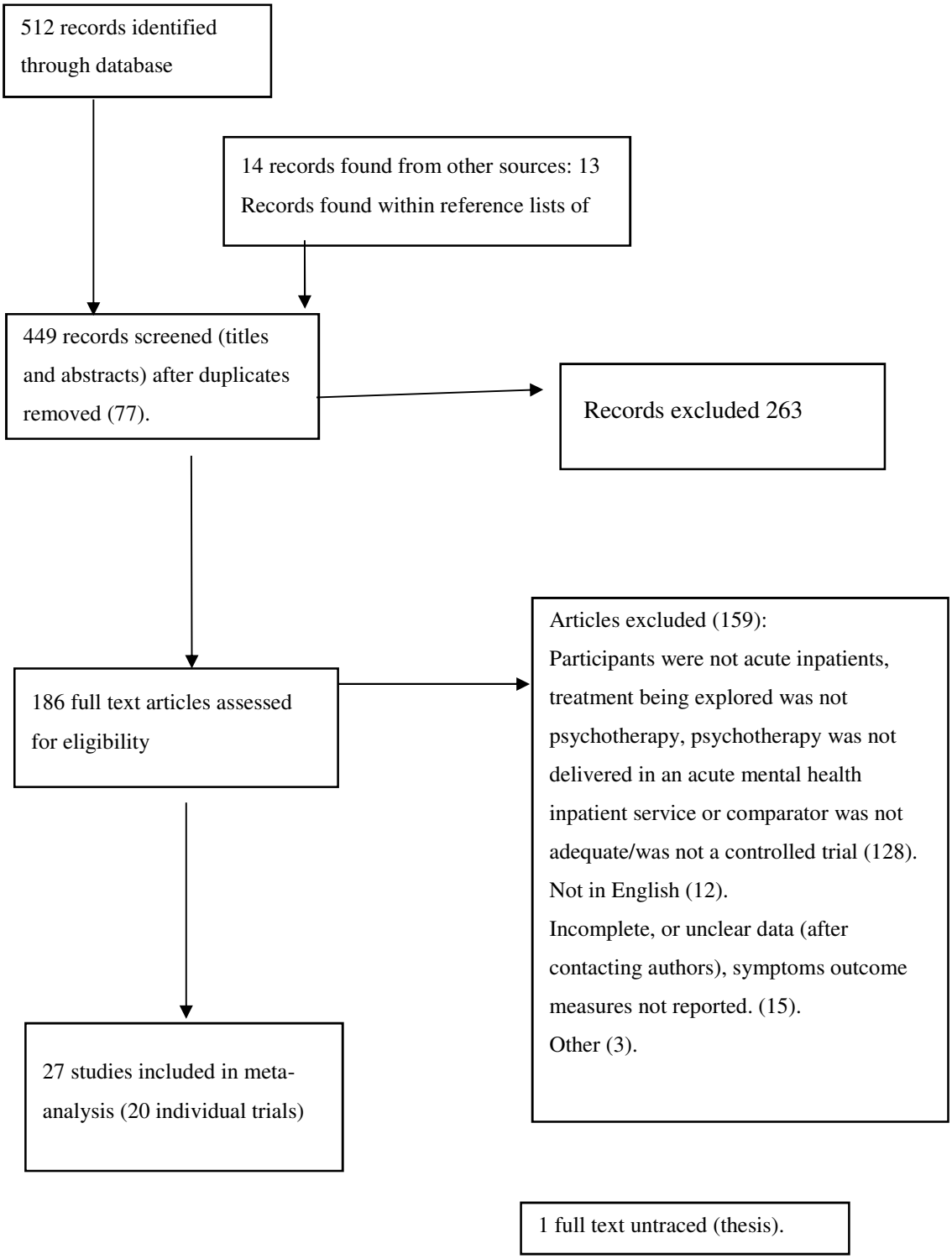

Figure 2 PRISMA flow diagram

3.3.1 Treatment characteristics

Eleven trials examined CBT (Bechdolf et al., 2004; Bowers, 1990; Habib, et al., 2015; Haddock et al., 1999; Hall & Tarrier, 2003; Lewis et al., 2002; Miller, et al., 1989; Mortan, Set al., 2011; Shelley, et al., 2001; Startup, et al., 2004; Veltro et al., 2006), and the remaining examined MCT (k=3) (Aghotor et al., 2010; Kumar et al., 2010; Moritz et al., 2011), ACT (k=2) (Bach & Hayes, 2002; Gaudiano & Herbert, 2006), dialectical behaviour therapy (DBT; k=1) (Gibson et al., 2014), eye-movement desensitisation and reprocessing (EMDR; k=1) (Kim et al., 2010), interpersonal psychotherapy (IPT; k=1) (Schramm et al., 2007) or social skills training (SST; k=1) (Miller et al., 1989) (see Table 4, page 47, for therapy descriptions). One trial investigated the effectiveness of a 'psychological approach', which in content appeared to be similar to CBT and was therefore included in the CBT category for subgroup analysis (Hayashi et al., 2001). Seven studies used a group format to deliver treatment, eleven used an individual format and two used a mixture of both. The period between baseline and post treatment assessment ranged between 2 and 12 weeks. The total number of sessions available ranged between 3 and 54, and the number of sessions available per week was between 1 and 7. The actual number of hours of therapy available ranged widely, between 3 and 133 (see Table 2, p43).

3.3.2 Comparator Characteristics

Sixteen trials compared psychological therapy to TAU alone (k=13) or to TAU plus a comparator intervention (i.e. relaxation therapy (k=2), and supportive counselling (k=1)). The remaining trials compared psychological therapy to psychoeducation (k=2), cognitive remediation (k=1) and supportive counselling (k=1). See Table 3 (page 45) for a description of comparators.

3.3.3 Risk of Bias

As shown in Table 5 (page 51) the studies tended to perform well with regards to random sequence generation, with a minority (k=4) judged to have a high risk of bias in this area, due to non-randomisation. However, the studies performed very poorly in relation to selective reporting bias, with all but two being judged to have a high risk of bias due to a lack of preregistration (k=18). Attrition bias was also judged to be high, with over half of the studies being judged to have a high risk of this bias (k=11-14). Almost all studies

were judged to have a high risk of performance bias due to an unavoidable lack of blinding of personnel and participants, due to the nature of the interventions. Over half of the studies had a high risk of detection bias because assessors were aware of groups that participants were allocated to. Risk of bias ratings for individual studies can be found in the Table 5 (page 51) and further detail and justification for these ratings can be found in Appendix 7.

A summary of outcome quality ratings can be found in the Table 6 (page 57). Of the 20 outcomes (including subgroup outcomes), 12 were rated as very low quality, 8 were rated low and none were rated as moderate or high. Further detail of these ratings can be found in table 5 and justification for ratings can be found in Appendix 8.

Table 2

Summary of study interventions

Name	Intervention type	Extra therapy info	Format	Duration (weeks)	Number of sessions (total)	No. sessions (per week)	Length of session (mins)	Total offered (mins)
Aghotor (Aghotor et al., 2010)	MCT	Focus on schizophrenia	Group	4	8	2	60	480
Bach (Bach & Hayes, 2002)	ACT	Focus on psychosis	Individual	2	4	1-4	50	200
Bechdolf (Bechdolf et al., 2004)	CBT	Focus on schizophrenia	Group	8	16	2	90	1440
Bowers (Bowers, 1990)	CT	Focus on depression	Individual	Unclear	12	7	50	600
Gaudiano (Gaudiano & Herbert, 2006)	ACT	Focus on psychosis	Individual	Unclear	3	Unclear	60	180
Gibson (Gibson et al., 2014)	DBT	Focus on DSH	Group	6	24	4	60	1440
Habib (Habib et al., 2015)	CBT	Focus on psychosis	Individual	8	16	2	60	960
Haddock (Haddock et al., 1999)	CBT	Focus on early psychosis	Individual	5	17.5 (+4 booster outpatient)	4	50	875
Hall (Hall & Tarrier, 2003)	CBT	Focus on low self-esteem in psychosis	Individual	7	7	1	Unclear	Unclear
Hayashi (Hayashi et al., 2001)	Psychological approach	Focus on schizophrenia	Individual	8	8	1	50	400
Kim (Kim et al., 2010)	EMDR	Focus on schizophrenia	Individual	3	3	1	90	270

Table 2

Summary of study interventions

Name	Intervention type	Extra therapy info	Format	Duration (weeks)	Number of sessions (total)	No. sessions (per week)	Length of session (mins)	Total offered (mins)
Kumar (Kumar et al., 2010)	MCT	Focus on schizophrenia	Group	4	8	2	60	480
Lewis (Lewis et al., 2002)	CBT	Focus on early schizophrenia	Individual	5	17.5 (+4 booster outpatient)	4	50	875
Miller (Miller et al., 1989)	CT + SST	Focus on depression	Individual	Unclear	Unclear	7	50	Unclear
Moritz (Moritz et al., 2011)	MCT	Focus on delusional symptoms in schizophrenia	Group + individual	Unclear	8	Unclear	60	480
Mortan (Mortan et al., 2011)	CBT	Focus on coping with auditory hallucinations	Group	5	10	2	80	8000
Schramm (Schramm et al., 2007)	IPP	Focus on depression	Group + individual	5	15	3	50	750
Shelley (Shelley et al., 2001)	CBT	Symptom specific	Group	12	54	5	Unclear	Unclear
Startup (Startup et al., 2004)	CBT	Focus on acute schizophrenia	Individual	Unclear	25	Unclear	90	2250
Veltro (Veltro et al., 2006)	CBT	Focus on group for inpatients	Group	Unclear	Unclear	Unclear	90	Unclear

ACT, Acceptance and Commitment Therapy; CBT, Cognitive Behavioural Therapy; CT, Cognitive Therapy; DBT, Dialectical Behaviour Therapy; DSH, Deliberate Self Harm; EMDR, Eye Movement Desensitisation Reprocessing; IPP, Interpersonal Psychotherapy; MCT, Metacognitive Therapy/Training; SST, Social Skills Training.

Table 3

Characteristics of control conditions

Control	Definition	N of studies	N of participants receiving intervention	Studies
Usual Treatment				
Newspaper discussion group (grouped as TAU)	Described in the study as a group discussion of issues in a current newspaper. Participants were also asked to discuss and summarise these topics and received usual treatment such as medication.	1	14	Aghotor (Aghotor et al., 2010)
TAU [a]	TAU refers to usual treatment received by inpatients. This varies between studies, however all participants in these studies received just usual treatment.	12	410	Bowers (Bowers, 1990); Gibson (Gibson et al., 2014); Habib (Habib et al., 2015); Hall (Hall & Tarrier, 2003); Hayashi (Hayashi et al., 2001); Kumar (Kumar et al., 2010); Lewis (Lewis et al., 2002); Miller (Miller et al., 1989); Mortan (Mortan et al., 2011); Shelley (Shelley et al., 2001); Startup (Startup et al., 2004); Veltro (Veltro et al., 2006)
TAU including psychotherapy (TAUP)[b]	This varied between studies but includes some form of individual therapy (described as individual psychotherapy sessions with a psychologist or psychoeducation) with a focus on psychoeducation, stress management, mood management, anxiety management, exercise groups, craft groups, and symptom identification. All participants in these studies (control and intervention) received TAUP.	3	60	Bach (Bach & Hayes, 2002); Gaudiano (Gaudiano & Herbert, 2006); Kim (Kim et al., 2010)
Total		16	514	

Table 3

Characteristics of control conditions

Control	Definition	N of studies	N of participants receiving intervention	Studies
Less sophisticated control interventions				
Supportive Counselling	A talking therapy described as delivering basic assessment, psycho-education and counselling in a supportive and empathetic unstructured style. Often used as an active comparator to psychological therapy to control for therapy time.	2	117	Haddock (Haddock et al., 1999); Lewis (Lewis et al., 2002)
Psycho-education[c]	Provision of information relating to patients' mental health diagnosis to aid understanding and coping. This intervention is commonly delivered in a group setting. Substantial variations exist within this intervention as it can act as a means to provide information or teaching coping skills.	2	109	Bechdolf (Bechdolf et al., 2004); Schramm (Schramm et al., 2007)
PMR/Relaxation Therapy	PMR is led by a therapist. It is used to monitor and control the tension of muscles with the aim to relax.	2	19	Bowers (Bowers, 1990); Kim (Kim et al., 2010)
Cognitive Remediation [d]	Neuropsychological therapy consisting of exercises that aim to improve cognitive processing and functioning such as memory, attention and problem solving.	1	24	Moritz (Moritz et al., 2011)
Total		7	239	

Table 3

Characteristics of control conditions

Control	Definition	N of studies	N of participants receiving intervention	Studies

TAU, Treatment as Usual; TAUP, Treatment as Usual with Psychotherapy; PMR, Progressive Muscle Relaxation.

a. medication alone (MA) (Miller et al., 1989) and waiting list (Gibson et al., 2014) also used to describe TAU.

b. Enhanced treatment as usual (ETAU) also used to describe TAUP

c. Clinical management also used to describe psycho-education.

d. Cognitive Remediation is a psychologically active therapy, however differs from psychotherapies included in this analysis as it targets cognitive processes rather than cognition and behaviour and can therefore be used as a control.

Table 4

Characteristics of included therapies

Treatment	Definition	N of studies	N of participants receiving intervention	Studies
Metacognitive Training/Therapy	Encourages thinking about thinking. Aims to identify typically negative cognitive bias such as dysfunctional attribution styles, jumping to conclusions, over confidence in errors, negative schemata. Therapy aims to address these and challenge them.	3	46	Aghotor (Aghotor et al., 2010); Kumar (Kumar et al., 2010); Moritz (Moritz et al., 2011)

Table 4

Characteristics of included therapies

Treatment	Definition	N of studies	N of participants receiving intervention	Studies
Cognitive Behavioural Therapy	Uses techniques such as formulation, problem solving, guided discovery, reality testing, distraction techniques, exposure, rational responding and more. It aims to increase awareness of connections between thoughts, behaviours and mood in order begin change.	10	868	Bechdolf (Bechdolf et al., 2004); Bowers (Bowers, 1990); Habib (Habib et al., 2015); Haddock (Haddock et al., 1999); Hall (Hall & Tarrier, 2003); Lewis (Lewis et al., 2002); Miller (Miller et al., 1989); Mortan (Moritz et al., 2011); Startup (Startup et al., 2004); Veltro (Veltro et al., 2006)
Acceptance and Commitment Therapy	Mindfulness and acceptance exercises are used to address and decrease avoidance and difficult internal experiences (e.g. disturbing thoughts and emotions).	2	52	Bach (Bach & Hayes, 2002); Gaudiano (Gaudiano & Herbert, 2006)
Dialectical Behaviour Therapy	Derives from CBT. It aims to change harmful behaviours with a particular focus on regulating and reducing intense emotional distress. Often targets behaviours such as deliberate self-harm, eating problems and substance abuse. Acceptance is a key focus of therapy.	1	58	Gibson (Gibson et al., 2014)

Table 4

Characteristics of included therapies

Treatment	Definition	N of studies	N of participants receiving intervention	Studies
Psychological Approach	Described as creating a collaborative approach with a focus on self-esteem. Patients' attitudes and understanding of their illness are discussed and new perspectives are encouraged. Psycho-educational techniques are also used. Content described similarly to CBT therefore grouped as CBT for analysis.	1	25	Hayashi (Hayashi et al., 2001)
Eye Movement Desensitization & Reprocessing	A psychological therapy used to release blocked traumatic memories with continuous sounds, taps or eye movements. Stressful life event, trauma experienced during childhood or adulthood, distressing psychotic symptoms or adversities related to treatment were key focuses.	1	11	Kim (Kim et al., 2010)
Interpersonal Psychotherapy	IPP primarily focuses on the way our relationships affect us and also how other mental health difficulties can affect our relationships.	1	63	Schramm (Schramm et al., 2007)
Rational Emotive Behaviour Therapy	Described as a specific type of CBT. It focuses on resolving emotional and behavioural disturbances. Grouped as CBT.	1	25	Shelley (Shelley et al., 2001)
Social Skills Training	A psychotherapy used to improve social skills. Primarily behavioural, however can involve some cognitive elements.	1	10	Miller (Miller et al., 1989)

Table 4

Characteristics of included therapies

Treatment	Definition	N of studies	N of participants receiving intervention	Studies

CBT, Cognitive Behavioural Therapy; IPP, Interpersonal Psychotherapy.

Table 5

Summary of risk of bias ratings

Study	Random sequence	Allocation concealment	Blinding of participants and personnel	Blinding of assessor (symptom outcomes)	Blinding of assessor (readmissions outcome) (N/A: study does not report readmission data)	Incomplete data (attrition bias)	Selective outcome reporting
Aghotor et al. (2010)	Low	High	High	Low	N/A	High	High
Bach & Hayes (2002)	Low	Unclear	Low	High	Low	High	High
Bach et al. (2013)[a]	Low	High	High	High	Low	Low	High
Bechdolf et al. (2004)	Low	Low	High	Low	Low	High	High
Bowers (Bowers, 1990)	Low	Unclear	High	Low	N/A	High	High
Gaudiano (Gaudiano & Herbert, 2006)	Low	High	High	High	Low	Low	High
Gibson (Gibson et al., 2014)	High	Unclear	High	Unclear	N/A	High	High
Habib (Habib et al., 2015)	Low	Unclear	High	Low	N/A	High	High
Haddock (Haddock et al., 1999)	Low	Unclear	Low	Low	Low	Low	High
Hall (P. L. Hall & Tarrier, 2003)	Low	Low	High	High	N/A	High	High
Hayashi (Hayashi et al., 2001)	Low	Unclear	High	High	N/A	High	High

Table 5

Summary of risk of bias ratings

Study	Random sequence	Allocation concealment	Blinding of participants and personnel	Blinding of assessor (symptom outcomes)	Blinding of assessor (readmissions outcome) (N/A: study does not report readmission data)	Incomplete data (attrition bias)		Selective outcome reporting
Kim (Kim et al., 2010)	Low	Unclear	High	Low	Unclear	Low[b]	High[b]	Low
Kumar (Kumar et al., 2010)	Low	Low	High	Unclear	N/A	High		High
Lewis (S. Lewis et al., 2002)	Low	Low	High	Low	N/A	Low[a]	High[a]	High
Miller (I. W. Miller et al., 1989)	Low	Unclear	High	High	N/A	High		High
Moritz (Moritz et al., 2011)	Low	Low	Low	Low	N/A	Low		Low
Mortan (Mortan et al., 2011)	High	Unclear	High	Unclear	N/A	High		High
Schramm (Schramm et al., 2007)	Low	Unclear	High	Low	Unclear	High[b]	Low[b]	High
Shelley (Shelley et al., 2001)	High	Unclear	High	High	Unclear	High		High
Startup (M Startup et al., 2004)	Low	Low	High	High	N/A	High		High
Veltro (Veltro et al., 2006)	High	High	High	N/A	Unclear	N/A		High

H, high risk of bias; L, low risk of bias; N/A, not applicable; Unclear, unclear risk of bias.

a. Bach (Bach et al., 2013) carries out an intention to treat analysis using data from Bach (Bach & Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006), therefore data from Bach (Bach et al., 2013) was used in outcomes where Bach (Bach & Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006) were both included.

Table 5

Summary of risk of bias ratings

Study	Random sequence	Allocation concealment	Blinding of participants and personnel	Blinding of assessor (symptom outcomes)	Blinding of assessor (readmissions outcome) (N/A: study does not report readmission data)	Incomplete data (attrition bias)	Selective outcome reporting

b. Complete data at post intervention but incomplete data at follow-up.

3.3.4 Outcomes

The results of all meta-analyses and subgroup analyses are reported below and in Table 6 (page 57). Forest plots for subgroup analyses are available in the supplement.

3.3.4.1 Psychotic symptoms (primary outcome)

Fifteen studies reported post-intervention symptom data, and the pooled estimate suggested psychological therapy was associated with a small to medium benefit over comparators (SMD -0.39; CI -0.64, -0.14; p=0.00) (see Figure 4, page 55). Heterogeneity was high (I^2=68%) but there was no clear evidence of publication bias. The quality of the evidence was downgraded due to the majority of included studies having been judged as having a high risk of bias on more than one domain, including selective reporting, incomplete data and non-blinding of assessors. Six studies were included in the analysis for follow-up PANSS total scores. The overall effect was small (SMD -0.21) and not significant (CI -0.52 to 0.09) (see Figure 5, page 55). Moderate heterogeneity (I^2=59%), wide confidence intervals (including both a moderate effect favouring intervention and a small effect favouring control) and high risk of bias meant the evidence was judged to be very low in quality. There were too few studies to assess publication bias. Startup, et al. (2004) did not report end of treatment data (Startup et al., 2004), but inclusion of their 6-month follow-up data in the end of treatment meta-analysis and their 12-month follow-up data in the follow-up meta-analysis had no effect on these estimates.

3.3.4.2 Depression and anxiety (secondary outcomes)

Data from six studies suggested psychological therapy had a moderate effect on depression when compared to comparators (k=7, SMD -0.49, CI -0.83 to -0.15, p = 0.01) (see Figure 6, page 56). Inclusion of follow-up data from Startup et al. (2004) had no effect on estimates. Four studies provided data on anxiety. The pooled estimate suggested psychological therapy had a moderate to large benefit at end of treatment (k=4, SMD -0.68, CI -1.29 to -0.07, p = 0.03) (see Figure 7, page 56). Imprecision and risk of detection bias, selective reporting bias and attrition bias meant the evidence was judged to be very low in quality. Some heterogeneity was observed (depression I^2=50%; anxiety I^2=60%), however there was a clear direction of effect for both estimates. There were too few studies to assess publication bias.

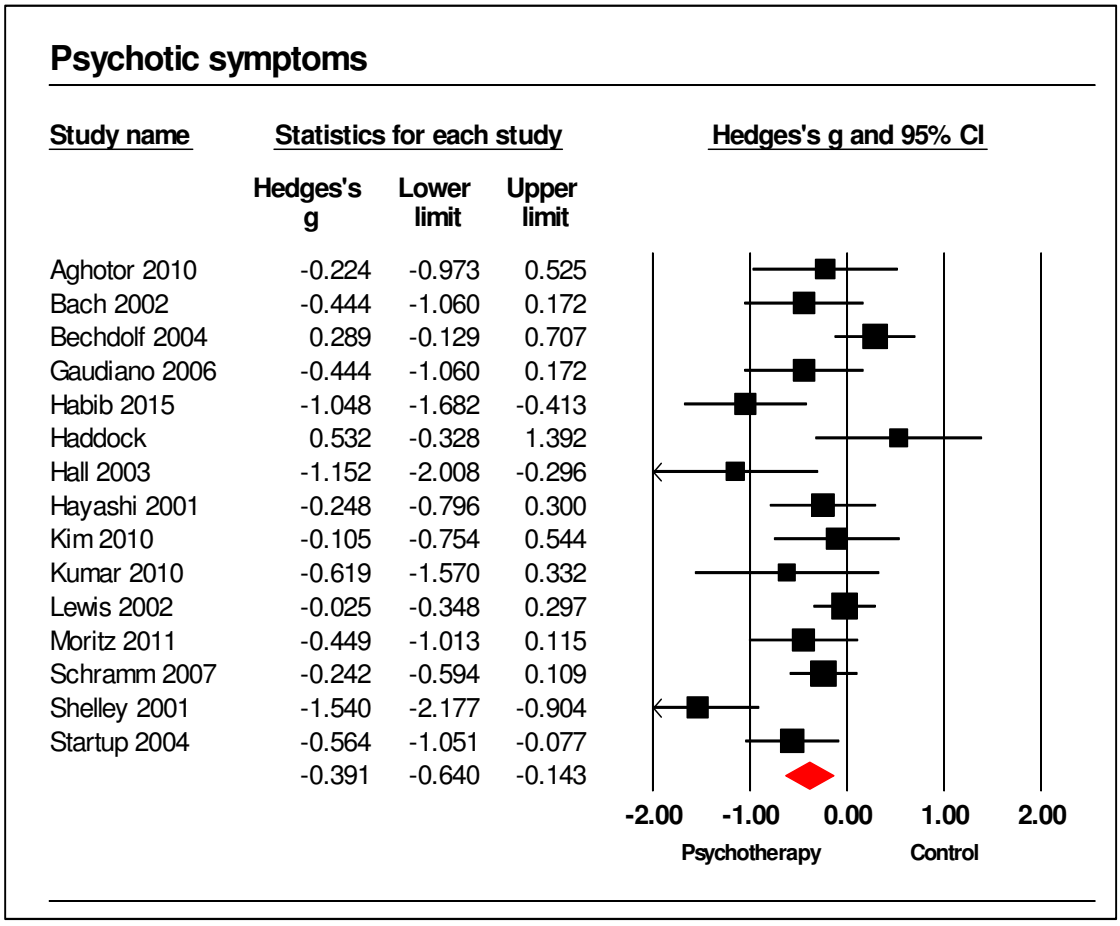

Figure 3 Forest plot showing SMD of psychotic symptoms at post-intervention

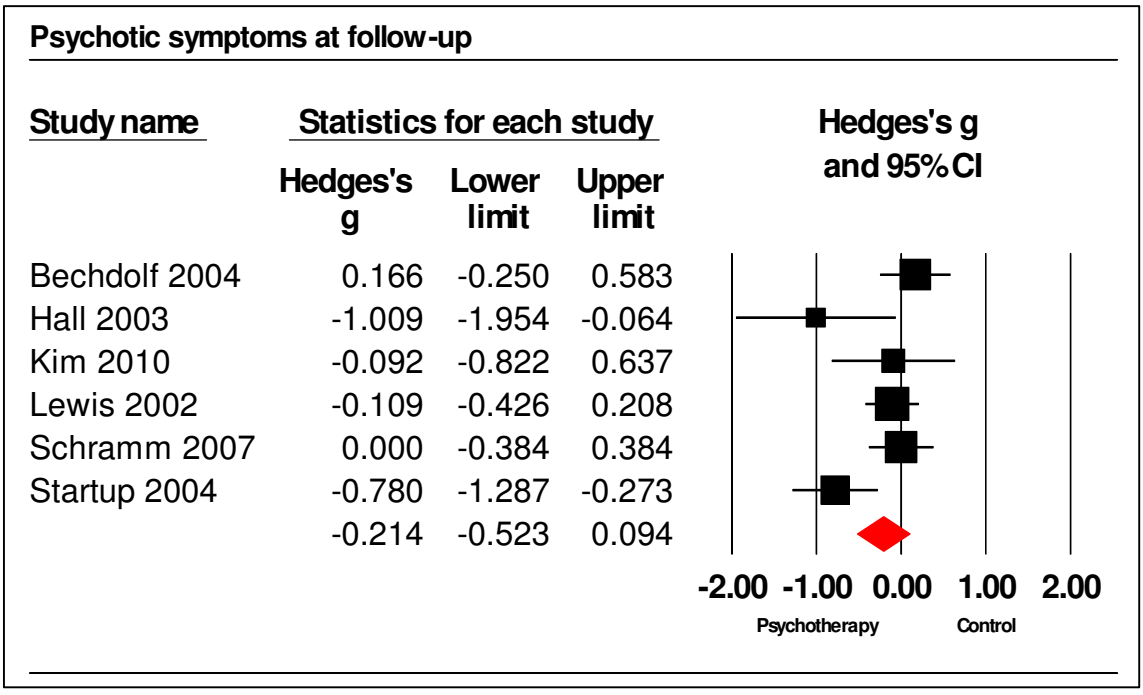

Figure 5 Forest plot showing SMD of psychotic symptoms at follow-up

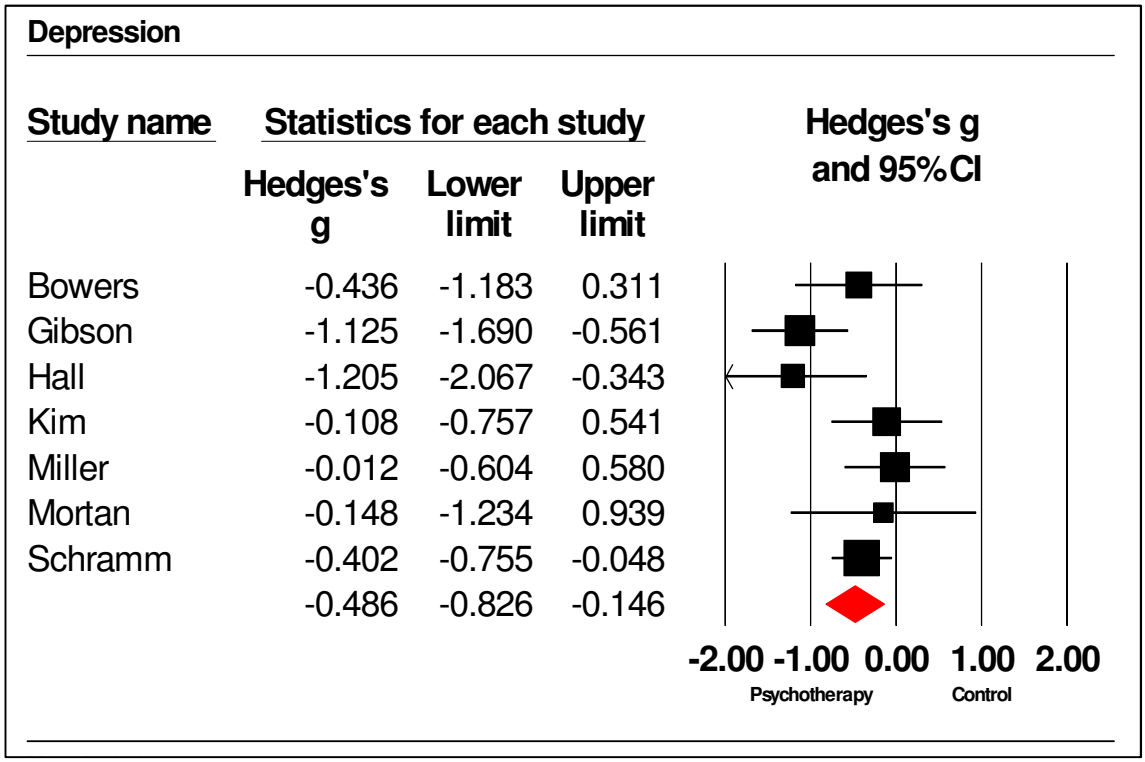

Figure 6 Forest plot showing SMD of symptoms of depression

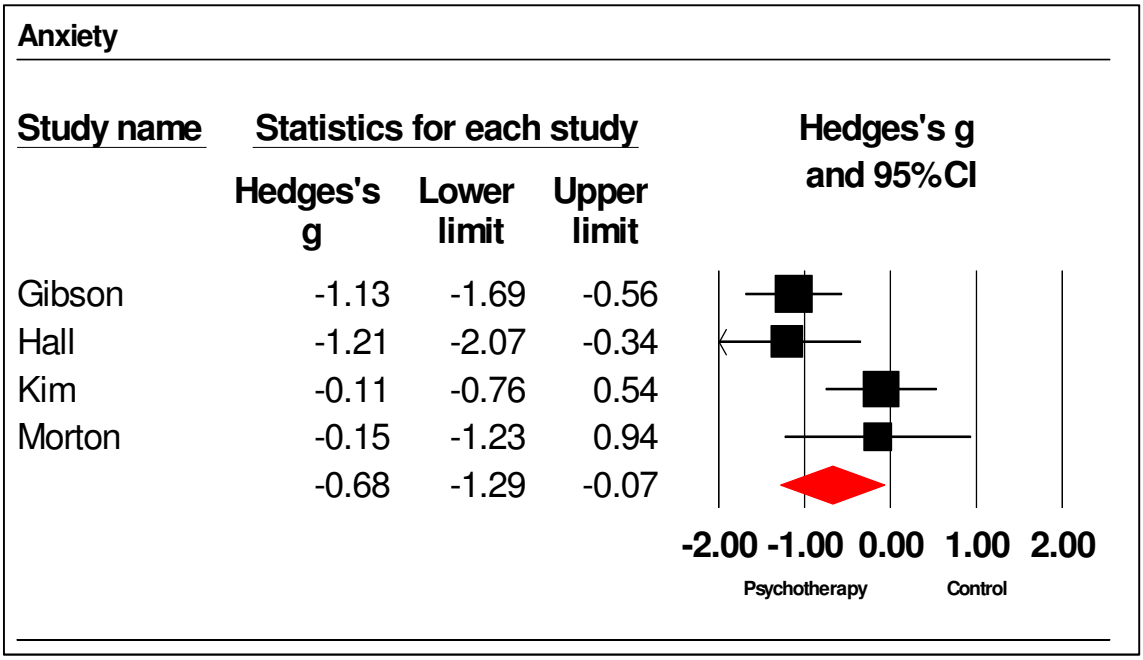

Figure 7 Forest plot showing SMD of symptoms of anxiety

Table 6

Summary of results of meta-analyses and subgroup analyses

Outcomes (k studies)	N	SMD or OR	95% CI	P	Z-Score	I^2 (%)	Tau	T^2	Quality rating
Post PANSS total (15)	993	-0.39	-0.64, -0.14	0.00	-3.44	67.86	0.41	0.17	VL
Post PANSS total (randomised and single-blind studies) (8)	686	-0.16	-0.45, 0.13	0.28	-1.08	56.10	0.30	0.09	VL
Post PANSS total (non-randomised and non-blind studies) (7)	307	-0.68	-1.02, -0.35	0.00	-3.44	49.79	0.33	0.11	VL
Post PANSS total (probable contact with therapist in control group) (8)	520	-0.12	-0.38, 0.13	0.35	-0.94	30.68	0.17	0.03	L
Post PANSS total (no probable contact with therapist in control group) (7)	295	-0.75	-1.06, -0.44	0.00	-4.67	55.04	0.38	0.14	VL
Post PANSS total CBT (8)	670	-0.44	-0.80, -0.07	0.02	-2.33	82.06	0.59	0.34	VL
Post PANSS total third-wave (5)	170	-0.43	-0.92, 0.06	0.09	-1.72	0.00	0.00	0.00	VL
Post PANSS total other (2)	153	-0.18	-0.89, 0.52	0.61	-0.51	0.00	0.00	0.00	L
Follow-up PANSS total (6)	501	-0.21	-0.52, 0.09	0.18	-1.35	58.50	0.29	0.08	VL
Follow-up PANSS total (randomised and single-blind studies) (4)	420	-0.01	-0.22, 0.19	0.91	-0.12	0.00	0.00	0.00	VL
Follow-up PANSS total (non-randomised and non-blind studies) (2)	81	-0.83	-1.28, -0.38	0.00	-3.64	0.00	0.00	0.00	VL

Readmissions (7)	1376	0.62 (OR)	0.46, 0.84	0.00	-3.05	11.34	0.14	0.02	L
Readmissions (randomised and single-blind studies) (4)	523	0.83 (OR)	0.54, 1.28	0.40	-0.85	0.00	0.00	0.00	L
Readmissions (non-randomised and non-blind studies) (3)	853	0.52 (OR)	0.37, 0.73	0.00	-3.77	0.00	0.00	0.00	L
Depression (7)	338	-0.49	-0.83, -0.15	0.01	-2.80	49.65	0.32	0.10	VL
Depression (randomised and single-blind studies) (3)	183	-0.32	-0.83, 0.18	0.21	-1.26	0.00	0.00	0.00	L
Depression (non-randomised and non-blind studies) (4)	155	-0.65	-1.14, -0.15	0.01	-2.56	68.33	0.56	0.32	VL
Depression (psychosis) (3)	74	-0.46	-0.99, 0.08	0.09	-1.84	53.63	0.49	0.00	L
Depression (depression) (3)	199	-0.30	-0.69, 0.09	0.14	-2.23	0.00	0.00	0.00	L
Anxiety (4)	149	-0.68	-1.29, -0.07	0.03	-2.22	59.98	0.48	0.23	VL

H (high); L, low; M, moderate; OR, odd ratio; PANSS, Positive and Negative Symptom Scale;SMD, Standardised mean difference; VL, very low.

3.3.4.3 Readmissions (secondary outcome)

Six studies provided readmission data, and together these suggested that active psychological therapy reduced the odds of readmission by just over a third (OR 0.62, CI 0.46, 0.84, z=-3.05, p=0.00) (see Figure). No heterogeneity was observed (I^2=0%), however the relative weight was not evenly distributed between studies with one study (Veltro et al., 2006) contributing approximately 50%. Excluding this study did not change the magnitude or the significance of the effect (OR=0.68, CI 0.47 to 0.99). The quality of evidence was judged to be low because of a high risk of detection bias, attrition bias and selective reporting bias. There were too few studies to assess publication bias.

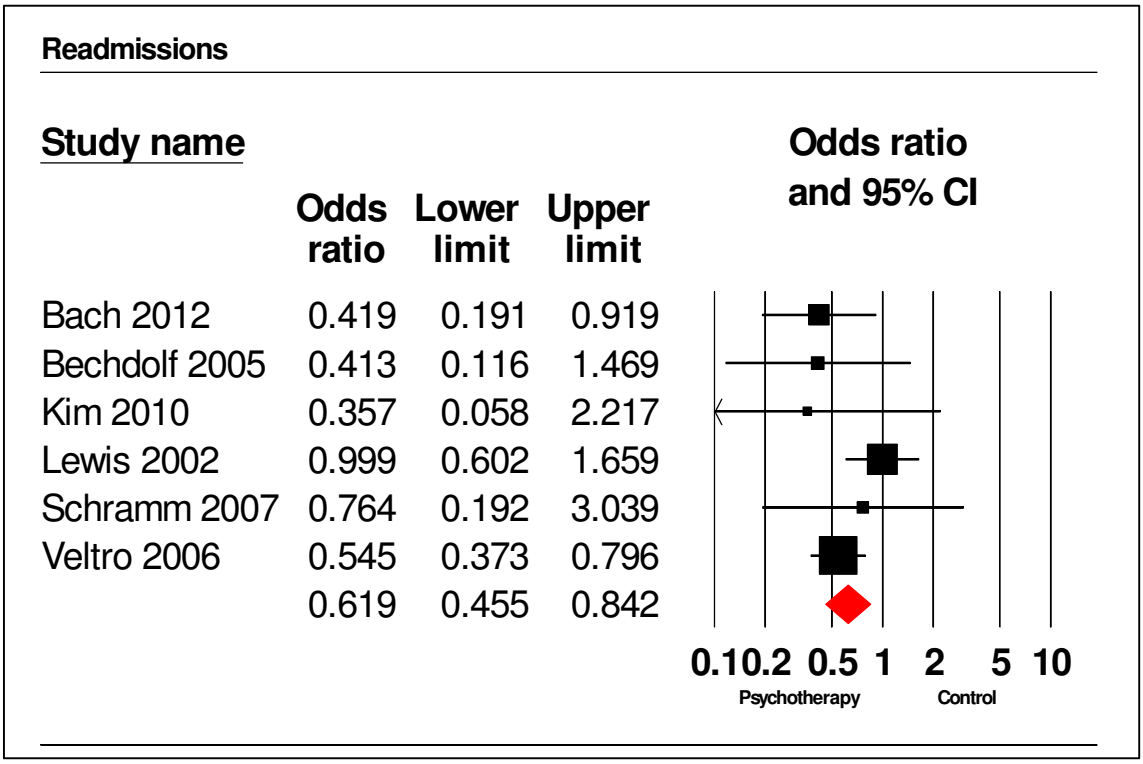

Figure 7 Forest plot showing OR of readmissions (Bach, 2012 includes data from Bach & Hayes, 2002 and Guadiano, et al., 2006).

3.3.5 Moderator analyses

3.3.5.1 Randomisation and single blinding

Eight studies were randomised and single-blind in the primary outcome (Aghotor et al., 2010; Bechdolf et al., 2004; Habib et al., 2015; Haddock et al., 1999; Kim et al., 2010; Lewis et al., 2002; Moritz et al., 2011; Schramm et al., 2007), while seven studies were not (Bach & Hayes, 2002; Gaudiano & Herbert, 2006; Hall & Tarrier, 2003; Hayashi et al., 2001; Kumar et al., 2010; Shelley et al., 2001; Startup et al., 2004). The overall effect

of treatment on psychotic symptoms at post treatment increased when randomised single-blind studies were excluded (SMD -0.68, CI=-1.02, -0.35; p=0.00), and decreased when studies without randomisation and single-blinding were excluded (SMD -0.16, CI=-0.45, 0.13; p=0.28). This difference was significant (Q=5.47, df=1, p=0.02), suggesting that study quality was significantly and inversely associated with estimates of effectiveness in this domain. However, both overall estimates were judged to be very low quality, partly because dividing the data like this introduced imprecision to both estimates. At follow-up, randomised studies with single-blinding (k=4) suggested there was no effect of therapy on symptoms (SMD -0.01, CI-0.22, 0.19; p=0.91; very low quality evidence), whereas non-randomised studies with no single-blinding (k=2) suggested there was a large effect (SMD -0.83, CI -1.28, -0.38; p=0.00; very low-quality evidence). Again, this difference was significant (Q=10.71, df=1, p=0.00).

Randomisation and single-blinding did not emerge as a significant moderator of readmission (Q=2.78, df=1, p=0.10). However, the overall effect size in four randomised and single-blind studies was small and non-significant compared to control (0.83; CI 0.54, 1.28; p=0.40; low quality evidence). The evidence was rated as low quality because included studies were judged to have a high risk of bias and because the confidence intervals for the estimate were very wide. The overall effect size for three studies without randomisation and single-blinding compared to all controls was larger and significant -0.52 (CI 0.37, 0.73; p=0.00; low quality evidence). Psychological therapy had a small non-significant effect on depression in randomised and single-blind studies (SMD -0.32 CI-0.83, 0.18; p=0.21) and a moderate to large effect in non-randomised studies that were not single-blind (SMD -0.65 (CI -1.14, -0.15; p=0.01), however this difference was not significant (Q=0.84, df=1, p=0.36). These outcomes were judged to be low and very low in quality, respectively, in part because of the risk of bias in the individual studies and in part because the estimate was imprecise. There were too few studies to examine the relationship between study quality and the effect of therapy on anxiety.

3.3.5.2 Therapy type

The overall effect of treatment on psychotic symptoms at end of treatment was not significantly moderate by therapy type (Q=0.43, df=2, p=0.81). CBT (k=8) had an overall moderate effect (SMD -0.44, CI -0.80, -0.07; p=0.02; very low quality evidence). 'Third-Wave' approaches (k=5) had an effect of similar size (SMD, -0.43, CI -0.92, 0.06; p=0.09;

very low quality evidence) and 'other' approaches (k=2) combined had a small, non-significant effect (SMD -0.18 (CI -0.89, 0.52; p=0.61; low quality evidence).

3.3.5.3 Contact with a therapist in the control group

Probable contact with a therapist in the control group emerged as a significant moderator of treatment effect on psychotic symptoms at end of treatment. The effect of active therapy in trials where there was no probable therapist contact in the control group (k=7) was large (SMD -0.75, CI=-1.06, -0.44; p=0.00; very low quality evidence), and significantly higher (Q=9.46, DF=1, p=0.00) than the effect size for studies with probable therapist contact in the control group (k=8; SMD = -0.12, CI=-0.38, 0.13; p=0.35; low quality evidence).

3.3.5.4 Diagnosis (post hoc analysis)

A post hoc analysis found no evidence that participant diagnosis moderated the effect of therapy on depression (Q=4.05, df=2, p=0.13). The effect of psychological therapy on depression was moderate but non-significant in trials where participants also had psychosis (k=3; SMD -0.46, CI -0.99, 0.08; p=0.09; low quality evidence), and small but non-significant where participants had depression only (k=3; SMD -0.30, CI -0.69, 0.09; p=0.14; low quality evidence), however these estimates were not significantly different.

3.4 Discussion

This review provided the first meta-analytical assessment of findings from controlled trials of brief psychological intervention for acute psychiatric inpatients. The review focused on clinician and patient important outcomes: psychotic symptoms, risk of readmission, and emotional distress (depression and anxiety). Overall, psychological therapy was significantly more effective than control groups in reducing psychotic symptoms at post treatment, risk of readmissions and emotional distress. However, like other meta-analyses of psychological intervention for severe mental illness (Turner et al., 2014; Wykes et al., 2008), randomisation and assessor blinding, together, emerged as a significant mediator of effect for some outcomes. Findings from randomised and single-blind studies suggest that brief psychological intervention is not effective in reducing psychotic symptoms for acute inpatients. Although not significant, there is also some promising evidence that suggests brief psychological intervention may reduce emotional distress (depression and anxiety) and the risk of readmission for some acute inpatients in

studies which are randomised and single-blind. Each outcome will now be examined, followed by a discussion of strengths and limitations of this study.

3.4.1 Main findings

Psychotic symptoms

A total of 14 studies reported psychotic symptoms and included mostly participants with a diagnosis of psychosis. Meta-analysis of these produced a small to medium effect (-0.39), which is consistent with previous trials and meta-analyses of psychotherapy for psychosis (Turner et al., 2014; Wykes et al., 2008) and of antipsychotics such as quetiapine (Hutton, Taylor, Mulligan, Tully, & Moncrieff, 2015) and clozapine (Moncrieff, 2003). A high degree of heterogeneity was identified across studies which was explored using subgroup analyses of therapy type, contact with a therapist in the control group, and the use of randomisation and assessor blinding. Therapy type was not a significant moderator of treatment effect of overall psychotic symptoms, however CBT (-0.44) and third-wave therapies (-0.43) had larger effects than other therapies (-0.18). Previous meta-analyses, of mostly outpatients with psychotic symptoms, have shown different therapies have varying effects, depending on the type of psychotic symptoms targeted (Turner et al., 2014; Zimmermann, Favrod, Trieu, & Pomini, 2005). Perhaps taking this approach to investigate psychological interventions for acute inpatient with psychosis in future studies would be informative.

Extra contact with a therapist in the control group (i.e. psycho-education, supportive counselling or unstructured therapy time) significantly moderated the overall treatment effect. Similar patterns of effect have previously been acknowledged (Button & Munafò, 2015). However, it is important to note that some of the included trials (Haddock et al., 1999; Bechdolf, et al., 2004; Lewis, et al., 2002), one of which had a large sample size (Lewis et al., 2002), used less sophisticated control interventions (labelled by the authors as psycho-education or supportive counselling) which contained components that resemble CBTp: formulation, relapse prevention and guided discovery (Morrison & Barratt, 2010). It is possible that treatment in the control group was too similar to the intervention of interest to produce a difference in effect. Alternatively, it may simply be that time with a therapist during an acute hospital admission is particularly beneficial for inpatients, despite therapy type. However further work is necessary to investigate whether this is true, and if it is, exactly why therapist time is important for inpatients and whether therapy type is important. Given that few acute psychiatric inpatient services routinely

offer time with a therapist (British Psychological Society, 2012; Joint Commissioning Panel for Mental Health, 2013; Sainsbury Centre for Mental Health, 2005), the implications for service design are clear.

As expected, randomisation and single-blinding also significantly moderated treatment effects. Excluding randomised and single-blind studies inflated the effect size (-0.68), while excluding studies that were not randomised or single-blinded decreased the effect (-0.16). The direction of this effect is to be expected, as trials lacking randomisation and assessor blinding are well known to inflate the overall effect (Higgins & Green, 2011). These findings suggest that brief psychological intervention is not beneficial for acute inpatient in terms of reducing psychotic symptoms, despite much of the psychotherapy evidence base having focussed on this treatment outcome. It is possible that outcomes other than psychotic symptoms should be the focus of treatment and associated treatment evaluations in future (Birchwood & Trower, 2006).

Readmissions

Findings showed that psychological intervention was more effective than control in reducing risk of readmission. The results suggest that the odds of readmission are reduced by approximately 38% after receiving brief inpatient psychotherapy, compared to control. This is a substantial reduction. Although the effect of randomisation and single-blinding did not emerge as a significant moderator, it is important to note that the overall treatment effect reduced when studies that were not randomised or single-blind were excluded, and significance was lost. Despite this, the effect suggests that for some people, the odds of readmission are reduced by approximately 17% if they receive brief inpatient psychological intervention, compared to control. It is possible that significance was lost in this outcome due to the small number of studies that were randomised and single-blind (k=4) resulting in limited power. Confidence intervals around the treatment effect, remained wide, suggesting that only some patients benefit from inpatient psychotherapy. However, given that the number of readmissions is a major problem for acute psychiatric inpatient services (Care Quality Commission, 2015; Cogan et al., 2012; Information Services Division Scotland, 2012), this result may be considered a meaningful difference in readmissions that warrants further investigation. Future work should aim to confirm such promising results and identify exactly who benefits from psychological therapy, as clearly not everyone does.

Emotional distress

Promising results were also found in relation to emotional distress (depression and anxiety). Psychological intervention was significantly more effective than controls in reducing depression (-0.49) and anxiety (-0.68). However, similar to outcomes of psychotic symptoms and readmissions, significance was lost when non-randomised studies with no assessor blinding were excluded from the depression outcome. Despite this lack of statistical significance, the magnitude of effect survived (-0.33), suggesting that brief psychological intervention may be beneficial for some acute inpatients in terms of reducing depression. Only three studies that were randomised and single-blinded reported depression, therefore it is possible that the small sample size resulted in inadequate power to detect significant group differences. Furthermore, the effect of randomisation and single-blinding on estimated treatment outcome was not significant, however again, this may be due to limited power. Future research is needed to investigate these uncertainties further. There were too few randomised, single-blind studies that reported anxiety to explore the effect of randomisation and assessor blinding, therefore whether this positive result would survive in more rigorous studies is unknown. Further research is necessary to confirm the promising results found in this outcome, however this initial evidence suggests that therapies which target emotional distress, such as those advocated in the Woodhaven approach (described in chapter two), may be appropriate for an acute inpatient environment.

Overall, the results of this meta-analysis suggest that while brief psychological therapy has little benefit for acute inpatients in terms of reducing psychotic symptoms, it may reduce the risk of readmission and emotional distress for some acute inpatients.

3.4.2 Strengths and limitations

A strength of this study is that, using the MRC framework (Craig et al., 2008, 2013), it has informed the primary stages of developing and evaluating complex interventions. Another strength of the study is that, for the first time, the evidence base of controlled trials of brief acute psychiatric inpatient psychotherapy has been identified, reviewed and synthesised using meta-analysis. While this study makes an original contribution to the field, a number of limitations should be acknowledged and are discussed below.

The definition of psychological therapy adopted in this review focused on ‘directive’ psychotherapies, therefore excluding ‘non-directive’ or ‘less sophisticated’ psychosocial

therapies such as befriending and supportive counselling. Whether 'non-directive' therapies improve outcomes for acute inpatients compared to usual treatment, and whether 'directive' therapies improve outcomes more than 'non-directive' therapies is unknown. Given that extra contact with a therapist in the control condition significantly decreased the treatment effect in the primary outcome, such uncertainties warrant further investigation.

Consistent with the pragmatic aim of the review, there was no restriction on diagnosis or therapy type. The diversity of the included studies can be considered both a strength and a weakness. While this approach is likely to produce findings of greater relevance to the entire (diagnostically diverse) acute inpatient population, it is also likely to produce more heterogeneous estimates of effect, therefore conclusions that can be drawn are less definitive. A variety of therapies were also included in the meta-analysis, although a large proportion were CBT based. This is to be expected given the attention CBT has received in recent years, particularly for psychosis. Although effect of therapy type on psychotic symptoms was explored, unfortunately there were too few studies to explore this within other outcomes. This review is therefore unable to inform which types of therapies are most effective in acute psychiatric inpatient services. This study was also unable to shed light on an acceptable and effective duration and intensity of therapy due to the small sample size. Future work is needed to explore what characteristics of therapy, i.e. type, duration, format and intensity, are acceptable and effective for inpatients and is feasible to deliver in acute inpatient services.

A potential concern with this meta-analysis is that non-randomised controlled trials were included. This increases the possible risk of bias; for example, there is an increased risk of selection bias and unbalanced confounding factors between groups in non-randomised trials (Higgins & Green, 2011). However, without including these trials, initial evidence regarding the effect of brief inpatient psychological intervention on anxiety would not have been synthesised, and initial investigation of therapy and control type would not have been conducted. Furthermore, study quality was considered throughout this review and the moderating effect of randomisation (and assessor blinding) was investigated empirically, thus avoiding overstated conclusions drawn from the results.

Another limitation is that effect sizes for continuous data (i.e. all outcomes but readmissions) were interpreted using Cohen's guidance of effect magnitude (Cohen,

1988). This interpretation is widely used, therefore allowing for easy comparison between studies, however the importance of such effects, in relation to patients and services, are context dependent. Therefore although 0.2 is considered a small effect when interpreted using Cohen's terms, it may be a significant effect to someone who is experiencing extreme emotional distress or acute psychotic symptoms. However, factors such as time and effort involved in receiving therapy, and the potential risk of adverse effects must also be taken into consideration.

Although the primary outcome (psychotic symptoms) was observer rated, depression and anxiety measures were self-report. It can be argued that self-report measures increase risk of bias (Higgins & Green, 2011). However, measures that ask patients directly for their perspective can also be considered important and are, in turn, more consistent with the person-centred approach (Crawford et al., 2011). With increasing importance placed on person centred care, outcomes that are important to patients (e.g. self-rated quality of life, self-efficacy and self-esteem) are recommended in mental (and physical) healthcare evaluation (Crawford et al., 2011; Guyatt, Oxman, Kunz, Atkins, et al., 2011). Unfortunately, due to a lack of reporting, the current review was unable to include such outcomes. This was also the case for adverse events. Recording adverse events is considered important to assess the potential harm associated with intervention (Duggan, Parry, McMurran, Davidson, & Dennis, 2014). Whether brief inpatient psychological intervention has positive effects on 'patient important' outcomes, or causes adverse effects is therefore currently unknown. Future research should aim to include such outcomes.

3.4.3 General recommendations for research

This review and meta-analysis has identified gaps in the current evidence base that may be fruitful for future research. For example, further examination of 'what works for whom' would be useful. Specifically, identification of patient characteristics that predict therapy response and non-response would be particularly informative. Additionally, investigation of what duration, format and intensity of therapy is acceptable and effective for inpatients, and is feasible for inpatient services, is necessary to inform future practice. As more evidence emerges, a network meta-analysis comparing all psychosocial interventions, 'directive' and 'non-directive', for acute inpatients would be very informative. Network meta-analysis allows for the effectiveness of interventions to be compared against each other in the absence of direct comparison in the literature (Mills,

Thorlund, & Ioannidis, 2013). However, until then, rigorous, adequately powered, definitive trials are recommended to investigate these issues. Specifically, randomisation (individual or cluster) and assessor blinding should be implemented in definitive trials, and all studies should pre-register the trial protocol in a public domain. This will allow more definitive conclusions to be drawn, therefore allowing more specific recommendations for practice to be made.

It is recommended that a definitive trial adopts a pragmatic approach that has no restriction on diagnosis. A cross-diagnostic sample, as opposed to a diagnostic specific sample, will represent the diagnostic variability, diagnostic uncertainty and comorbidities often found in acute inpatient services. The results will therefore be more generalisable to the acute inpatient population. It is also recommended that an intervention which targets emotional distress is first evaluated using outcomes that focus on emotional distress, as opposed to psychotic symptoms. Not only has the important role of emotions been recognised in serious mental illnesses, particularly during an acute episode of illness (Clarke, 2015) (see Chapter 2), but this may be conducive to a cross-diagnostic approach, i.e. therapy that targets shared dysfunctional processes leading to emotional distress may be beneficial to more acute inpatients with a variety of diagnoses. Finally, it is recommended that a definitive trial include outcomes which are important to patients, and that adverse events are recorded. As highlighted in this meta-analysis, there was minimal reporting of such outcomes and adverse events in the current evidence base. However, there is increasing pressure to adopt a person-centred approach in mental health inpatient services (The Commission on Acute Adult Psychiatric Care, 2015), and the importance of identifying potential risk associated with receiving treatment has been recognised (Duggan, et al., 2014). Future research should therefore include outcomes that are important to patients (such as quality of life, self-efficacy and self-esteem) and record adverse events to establish whether brief inpatient therapy has benefits on such outcomes, and whether it is harmful to patients.

It is important to note that preliminary work is recommended before undertaking a large RCT, therefore pilot/feasibility work is more appropriate at this stage (Craig et al., 2013). During the feasibility stage, it may be beneficial to compare characteristics of those who do and do not want to engage in psychological therapy in this environment and to qualitatively investigate which components of therapy patients find most beneficial and why. This would allow identification of therapies, or components of therapies, that are

the most acceptable. Additionally, understanding why patients feel benefit from specific components can inform the adaptation of therapies for acute inpatient application with the hope to provide more value. However, first it is recommended that a feasibility trial be undertaken to assess the feasibility of implementing and evaluating a cross-diagnostic psychological therapy.

3.4.4 Recommendations for practice

Results from this review have been suggestive but not conclusive, therefore recommendation for practice cannot be definitive based on the current evidence. As previously mentioned acceptable and effective therapy type, duration, and intensity cannot yet be advised as meta-analysis does not allow for investigation of these characteristics. However, the current analysis provides initial evidence to suggest that some inpatients may benefit from some form of brief inpatient psychotherapy in terms of reducing emotional distress and acute inpatient services may benefit in terms of reducing the risk of readmission for some patients. It is therefore recommended that brief therapy, perhaps targeting distressing emotions (e.g. emotion focussed formulation and distress management (see Chapter two)), be offered to acute inpatients that wish to receive it. This is a pragmatic approach that allows psychological intervention to be utilised by a variety of inpatients, despite diagnosis.

3.4.5 Conclusion

In attempting to answer the question of whether brief inpatient psychotherapy is beneficial for acute inpatients, the current meta-analysis has drawn on the small evidence base and provided initial insight. Overall, it has produced initial evidence which indicates that psychotherapy may be beneficial for some acute inpatients in terms of reducing self-reported depression and anxiety and the risk of readmission. However, many of the included studies are of low quality and many of the therapies are diagnostic specific, therefore cannot be generalised to an entire acute inpatient population. The recommended type, duration and intensity of therapy has yet to be determined, and for whom exactly inpatient psychotherapy is most beneficial is still unknown. Future high quality work is needed to strengthen the evidence base and enable more specific recommendations to be made. Prior feasibility work is necessary in preparation for a large definitive RCT.

3.5 Implications for the thesis

Findings from this meta-analysis have suggested that while brief inpatient psychological therapy may not be effective in reducing psychotic symptoms it may be effective in reducing risk of readmissions and emotional distress (i.e. depression and anxiety) for some acute inpatients with a variety of diagnoses. However, clearly further work is needed to identify exactly who benefits from inpatient psychotherapy, and what type and dose of therapy is most effective. As discussed in Chapter 2, a cross-diagnostic approach to inpatient therapy and related evaluation is pragmatic approach to investigate these issues further. For example, cross-diagnostic psychological intervention, in theory, should benefit patients with a number of diagnoses which characterise the acute inpatient population. One notable model of cross-diagnostic psychologically informed acute psychiatric inpatient care is the Woodhaven Approach (described in Chapter 2). Understanding and addressing patients' extreme emotional distress is central in the Woodhaven Approach, and is supported by the results of this meta-analysis. The evidence base evaluating this model of care, as it stands, remains scarce (see Chapter 2 for a brief review). To date, no trial using a control group, has evaluated the impact of this cross-diagnostic psychological intervention, as a whole, on outcomes of both readmissions and emotional distress. Whether this is feasible is currently unknown. The remainder of this thesis aims to address this.

4 Feasibility study: methods

4.1 Introduction

This chapter describes the design of a pragmatic, parallel, non-randomised, cluster feasibility trial of cross-diagnostic psychological intervention applied in an acute mental health inpatient context. The intervention investigated in this study was largely based on the Woodhaven approach (discussed in Chapter 2): a cross-diagnostic psychological intervention which has been successfully implemented in acute services (inpatient and outpatient) in the New Forest (Araci & Clarke, 2016; Clarke & Wilson, 2009). Initial evaluation of the Woodhaven Approach has produced promising results (see chapter two for a brief review of evidence), however more robust evidence is needed.

According to the MRC, psychologically informed acute mental health care is a complex intervention, i.e. it is 'made up of various interconnecting parts' (Campbell et al., 2000; Craig, 2012). For example, acute inpatient care involves contact with multiple healthcare professionals and the psychological intervention of interest consists of multiple components which target both staff and patients. Evaluation should therefore be phased, including development, feasibility/piloting, implementation and evaluation (Craig, 2012; Craig et al., 2008, 2013) (see Chapter 1 for more detail). Development of the psychological intervention in the current study, i.e. identifying underlying theory for acute inpatient psychotherapy and reviewing the current acute inpatient psychological evidence base, has been addressed in preceding chapters. However, whether it is feasible to implement and evaluate this cross-diagnostic psychological intervention in an RCT is currently unknown. This chapter describes a feasibility study aiming to inform a future definitive trial which rigorously evaluates this intervention (Lancaster, 2015; Moore et al., 2015).

4.2 Aims

After receiving ethical approval (REC No: 15/SS/0093) and trial registration (researchregistry509) the main aims of this study changed. Detail of amendments can be found in the 'Protocol amendments' section of this chapter (page 110). The remainder of this section (and chapter) describes the amended aims (and the amended trial protocol).

This study has two primary aims as they were considered to be of equal importance to inform a future definitive trial (Lancaster, 2015; Moore et al., 2015). The primary study aims were to test the feasibility of implementing and evaluating a cross-diagnostic, psychological intervention in an acute mental health inpatient setting in order to inform a future definitive trial of effectiveness. The secondary study aim was to gather exploratory clinical outcome data, likely to be used in a larger trial, and estimate treatment effects.

4.2.1 Specific aims

1. Pilot and test the feasibility of implementing a cross-diagnostic psychological intervention in an acute inpatient context (primary study outcome):
    a. To investigate the number of sessions of each component successfully delivered overall.
    b. To examine the number of inpatients engaged in the intervention.
2. To pilot and test the feasibility of chosen trial process in an acute inpatient context (primary study outcome):
    a. To investigate the number of inpatients approached, screened, consented, recruited and retained.
    b. To investigate reasons for refusal where possible.
    c. To examine the completion rate at post-intervention and follow-up to provide information on the appropriateness of chosen outcomes and the acceptability of self-report clinical outcome measures and a predictor outcome measure.
    d. To investigate reasons for attrition where possible.
3. To gather preliminary clinical outcome data likely to be used to test the psychological model compared to treatment as usual (TAU) (secondary study outcomes):
    a. To describe the potential effect on the expected future definitive trial primary outcome (i.e. readmissions) data using descriptive statistics.
    b. To describe chosen clinical outcome data using descriptive statistics.
    c. To investigate whether clinical outcomes can produce adequate effects in the right direction.
    d. To record adverse events.
4. To summarise and assess the findings of this feasibility study using the data collected for the above aims:
    a. To investigate the extent to which key methodological issues, defined by Shanyinde, Pickering and Weatherall (2011), were addressed by this study.

Further detail of the study aims and rationale are described throughout the remainder of this chapter.

4.3 Trial design

The current trial is considered exploratory as it encompasses characteristics of feasibility/pilot trials, as defined by Eldridge, Chan, et al. (2016) and Lancaster (2015), which are considered by the MRC to be in phase 2 (piloting/feasibility) of the framework for developing and evaluating complex interventions (Craig et al., 2013). It also adopted a primarily pragmatic approach according to criteria identified by (Loudon et al., 2015) (see 'Pragmatic and explanatory trials' section). The current study was also a cluster, non-randomised, feasibility trial of a psychological intervention for acute mental health inpatiens. The psychological intervention (as piloted in one acute inpatient ward) plus TAU was compared with TAU delivered in another acute inpatient ward. A longitudinal design was adopted to allow for multiple data collection points: baseline, post treatment and 6-month post discharge follow-up (referred to from now on as follow-up).

Where applicable, this trial was reported in accordance with a combination of the Consolidated Standards for Reporting of Trials (CONSORT) statement for randomised controlled trials (RCTs) (Schulz, Altman, Moher, & Group, 2010), the extension to randomised pilot and feasibility trials (Eldridge, Chan, et al., 2016), the extension to non-pharmacological treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008) and the extension to pragmatic trials (Zwarentein et al., 2009).

4.3.1 Justification of trial design

The current study was a pragmatic, non-randomised, non-blind feasibility cluster trial. Rationale for and implications of the trial design characteristics are discussed at length below.

Pilot and feasibility studies

The current study characterised a feasibility design according to recently published guidelines and recommendations for pilot and feasibility trials (Eldridge, Chan, et al., 2016). As previously mentioned, the aims were to determine the feasibility of implementing and evaluating a psychological intervention for acute mental health

inpatients. Additionally, preliminary clinical outcome data was gathered to establish whether adequate effects in the right direction can be produced, even in the absence of any attempt of formal testing for statistical significance. The current trial is not adequately powered to detect significant differences on any chosen outcomes measures. It is important to note that conclusions drawn from such effects will be made with consideration of design (i.e. no assessor blinding or randomisation) and sample size limitations (Thabane et al., 2010), and that such effects will be interpreted as a guidance of treatment effect rather than definitive (Lancaster et al., 2004).

Although the distinction between pilot and feasibility trials is ambiguous (Lancaster, 2015), the UK National Institute for Health Research (NIHR) provide definitions which clearly differentiate between pilot and feasibility studies. Feasibility studies are defined as trials which aim to test whether a larger study can be done via estimation of parameters needed for a main study of effectiveness or efficacy (e.g. estimation of standard deviation of outcome measures, follow-up rates, time needed to collect data, willingness of participants to be recruited, etc.). Alternatively, pilot trials are considered smaller versions of the main trial which aim to pilot key processes of the main trial when implemented together (e.g. randomisation, treatment, assessment, follow-up) (National Institute for Health Research, 2015). Therefore, it is recommended that feasibility studies are completed first.

The terminology regarding pilot and feasibility trials, however, are not concrete. A new framework for defining pilot and feasibility trials and reporting guidelines considers them to overlap (Eldridge, Chan, et al., 2016; Eldridge, Lancaster, et al., 2016) because they both aim to inform large definitive trials. In keeping with the NIHR's definition, the new framework considers pilot studies to be conducted as a small version of the future definitive RCT, however rather than a conceptually different design, they are also considered a subgroup of feasibility studies (Eldridge, Chan, et al., 2016). According to Eldridge, Lancaster, et al. (2016), the current study is in line with the umbrella term of 'feasibility studies'. Additionally, as some evaluation processes of a larger trial were also implemented, e.g. gathering preliminary clinical outcome data and implementing the intervention, this study may also fall into Eldridge, Lancaster, et al.'s (2016) subcategory of non-randomised pilot trials. However, given that the primary aims of the trial are to determine the feasibility of implementing the intervention and the feasibility of evaluating it in a future larger trial, this study is referred to as a feasibility study, therefore mapping

onto phase two of the MRC framework for developing and evaluating complex interventions (Craig et al., 2008).

The MRC recommends initial pilot or feasibility trials be carried out to inform larger definitive RCTs (Craig et al., 2008, 2013). While a definitive trial aims to establish the efficacy or effectiveness of an intervention, reasons for conducting a pilot/feasibility study have been categorised as 1) process: to assess the feasibility of the main stages of a future study, e.g. recruitment rate, retention rate, etc., 2) resource: to determine the time and resource needed to complete aspects of the study, e.g. the time taken to complete outcome measures, 3) management: to identify potential problems related to personnel and data management, 4) scientific: to determine dose levels and response and to estimate treatment effect and direction, and variance (Thabane et al., 2010). This study addressed reasons one and four. The feasibility of implementing and evaluating the psychological intervention was considered important to determine in order to guide future definitive evaluation of the intervention (Eldridge, Lancaster, et al., 2016; Lancaster, 2015; Thabane et al., 2010).

Pragmatic and explanatory studies

Whether definitive or feasibility, trials can be classed as pragmatic or explanatory, which are considered to be at either end of a spectrum and are associated with different aims, advantages and limitations (Loudon et al., 2015). The current trial adopts a largely pragmatic approach. Justifications and implications are discussed in this section.

According to Schwartz & Lellouch (2009), explanatory trials are concerned with the efficacy of a treatment and are carried out in controlled conditions with specific inclusion/exclusion criteria that define a homogeneous sample. The aim is usually to test a causal research hypothesis therefore internal validity is important. On the other hand, pragmatic trials aim to evaluate the effectiveness of treatment in usual conditions (Schwartz & Lellouch, 2009; Thorpe et al., 2009). Heterogeneity of participants, of adherence to intervention and of intervention delivery is expected (Dunn, 2013), and is likely necessary to successfully achieve the aims of a pragmatic trial. It is more important for pragmatic trials to have external validity as they try to answer the question of whether an intervention can work in the 'real world'. This would be the case for a future definitive trial of the psychological intervention of interest.

There are both advantages and disadvantages associated with these approaches which result in each design suiting different trial aims and settings (Loudon et al., 2015). Controlled conditions, i.e. a homogeneous sample, standardised treatment, etc., increase internal validity in a trial and is characteristic of an explanatory trial. Internal validity refers to the extent to which a trial measures what it set out to (Dunn, 2013). However, such controlled conditions also decrease external validity, i.e. the extent to which findings can be generalised to other settings and people (Dunn, 2013). A pragmatic approach, on the other hand, allows for more heterogeneity in terms of population, treatment adherence and delivery, and therefore asks the question of whether an intervention works in the 'real world' (Dunn, 2013). Consequently, a pragmatic approach was considered appropriate for evaluating interventions in an acute inpatient setting because the population and treatment is likely to be heterogeneous. Patients are typically diagnostically diverse, often including multiple diagnoses and comorbidities. Additionally, an acute inpatient ward is often chaotic in nature and discharges can be quick and unpredictable, therefore delivering structured therapies (i.e. a specified number of sessions is delivered over a specific amount of time) is unfeasible in this environment (Clarke & Wilson, 2009). If an explanatory approach was used to determine the efficacy of psychological treatment in this environment then this could result in approval and delivery of ineffective or unfeasible therapies which may have previously produced promising results in well-designed RCTs evaluating inflexible therapy for a homogenous group. Furthermore, the intervention of interest (the Woodhaven Approach, Clarke & Wilson, 2009) is designed for cross-diagnostic application, therefore a pragmatic approach is more fitting. For these reasons a pragmatic approach was taken for the current study and should be taken for future definitive trials.

As previously mentioned, characteristics of the current study differ from an explanatory trial in that the intervention was not standardised between participants (i.e. patients attend different therapeutic components of the model, in a different order, a different number of times) and participants consisted of a heterogeneous group. As recognised by the new MRC guidance, complex interventions can work best when tailored for specific local services and are flexible for patients (Craig et al., 2013). This is true of the psychological intervention investigated in the current study, which is considered a strength and a limitation. The pragmatic approach of this study is advantageous because the evaluation considers feasibility of intervention delivery, trial design and outcomes when the complex intervention is applied in an NHS Lothian acute inpatient service. Additionally, this

approach is in keeping with the flexible nature of the intervention (see 'Intervention' section for details of the intervention). However, evaluating non-standardised interventions can also be considered problematic as it reduces generalisability of the intervention across all acute services. Nevertheless, it has been suggested that careful consideration of how to tailor the intervention to other similar services (i.e. other acute inpatient services) would allow implementation on a wider basis (Craig et al., 2013; Moore et al., 2015). Furthermore, documentation of contextual factors in both the intervention and control condition are important to allow generalisability of the trial results (Zwarentein et al., 2009).

It has been argued that trials of complex psychological interventions may (or should) adopt both pragmatic and explanatory aims (Dunn, 2013), and there are now criteria published to help researchers position a study design on the continuum[1] (Loudon et al., 2015). The current trial adopted a primarily pragmatic approach according the following criteria (Loudon et al., 2015):

1. Participant eligibility: limited inclusion criteria were implemented beyond that of being admitted to the acute inpatient ward at time of recruitment (see inclusion/exclusion criteria section) (very pragmatic).
2. Recruitment: participants are only recruited if they are admitted to the included acute inpatient wards (very pragmatic).
3. Settings: trial conducted in identical setting to which the results will be applied (very pragmatic).
4. Organisation: intervention took place in the same organisation as usual care. Practitioners were required to have appropriate therapeutic training to provide therapy, however they differed in experience. All individuals with sufficient therapeutic training could deliver the intervention. Additional therapeutic training was provided for organisation staff in order to implement the intervention (very explanatory)
5. Flexibility of the experimental intervention (delivery): delivery of the intervention was flexible, i.e. although each group included a specific number of sessions according to the manual, patients could attend as many or as few as they like. The trial was not concerned with how practitioners varied the intervention as

[1] Each domain is scored on a 5-point Likert scale: 1) very explanatory, 2) rather explanatory, 3) equally pragmatic and explanatory, 4) rather pragmatic, and 5) very pragmatic (Loudon et al., 2015).

flexibility was a key characteristic of the intervention. Additionally, individual sessions were delivered flexibly depending on each patient, and other interventions were permitted, e.g. occupational therapy (very pragmatic).

6. Flexibility (adherence): psychological intervention was not mandatory in the intervention group, therefore adherence was measured indirectly (number of sessions attended) for the purposes of the trial with no strategy to improve or enforce engagement (very pragmatic).
7. Follow-up intensity: follow-up assessments were longer term than patients' hospital admissions (follow-up at 6-months post discharge) and required patient contact (via phone or in person) (rather pragmatic).
8. The proportion of readmissions at 6-months post discharge is the planned primary outcome of a future definitive trial (see outcomes section). Therefore, events were monitored following discharge to establish whether the proportion of readmissions reduced following the experimental intervention. This outcome is more relevant to some patients (i.e. 'revolving door patients) than others (rather pragmatic).
9. Analysis of the expected primary outcome in a future definitive trial: non-adherence to intervention was not considered in the initial analysis, characterising an intention to treat analysis. However, a sensitivity analysis excluding participants in the intervention group who did not directly engage with psychological intervention (see analysis section) was also carried out (per treatment protocol analysis). This trial, therefore, characterises both pragmatic and explanatory trials (equally pragmatic and explanatory).

Superiority, non-inferiority and equivalence

One aim of the current study was to determine whether the psychological intervention can provide evidence of a group difference in the expected direction, in comparison to usual treatment. Detecting this difference as part of feasibility work is an essential characteristic ahead of undertaking a definitive superiority trial. A psychological intervention, as part of a definitive future trial, would be hypothesised to be more effective, rather than inferior or equivalent to usual treatment. Implications of this design are discussed in this section.

Trials can be categorised as testing superiority, non-inferiority or equivalence depending on the objectives. A superiority trial, for example, aims to show a new treatment is more effective than current treatment. However, if the null hypothesis (i.e. there will be no difference between treatments) is not rejected equivalence should not be assumed (Sedgwick, 2013a). Equivalence trials aim to show a new treatment has a similar effect to another treatment (usual current standard treatment). This is useful to develop new treatments which are therapeutically similar but may have fewer adverse effects or be cheaper. Non-inferiority trials are similar to equivalence trials in that they aim to determine whether a new treatment is not less effective than another treatment (Piaggio, Elbourne, Pocock, & Evans, 2012), therefore the hypothesis would be that the control treatment is similar or less effective than the new treatment. Where superiority trials use statistical significance to determine whether the null hypothesis can be rejected, equivalence and non-inferiority trials base analysis and conclusions on confidence intervals, i.e. in relation to a pre-specified non-inferiority boundary (Sedgwick, 2013a). As the current study is a feasibility trial the focus is on effect estimations along with precision of estimated intervals which will be used to inform a future larger trial (Lancaster et al., 2004). However, the estimated effects are expected in favour of the intervention, which would also be true of a future definitive trial. Therefore, the current study is considered a feasibility study in preparation of a future, larger superiority trial.

Cluster trials

The current feasibility study was based on a cluster trial design. Rationale for adopting this design will be discussed in this section.

As in the current study, allocation of individuals to trial groups is not always possible or preferable due to context, resulting in randomisation or allocation of clusters (i.e. a group of individuals nested in a social unit, e.g. a household, a town or an institution) (Campbell, Piaggio, Elbourne, & Altman, 2012). As the psychological intervention in this trial was piloted in one acute inpatient ward in NHS Lothian, allocation of individual participants was not possible without incurring considerable contamination bias (discussed below). Instead, whole wards were allocated to trial groups. Therefore, the wards were the unit of group allocation and the unit of intervention, the unit of observation was the participants and the unit of analysis was the wards.

Cluster trials differ from regular trials and therefore require some methodological considerations. For example, there can be substantial contamination effects within clusters, where participants and/or staff will discuss with each other the aspects of the intervention or trial. As a result, participants from the same cluster are likely to be correlated, therefore producing homogeneity of outcomes within a cluster compared to a random sample (Eldridge & Kerry, 2012). To account for this, sample size is often required to be larger than other individually randomised definitive trial designs, the extent of which is decided by the strength of correlations within clusters: the intra-cluster correlation coefficient (ICC) (Campbell et al., 2012). Analysis should also account for the correlation within clusters to avoid inflated precision of estimated effects, and interpretation of the results must consider influences of clusters and individual participants (Campbell et al., 2012). As no formal sample size calculation informed this feasibility study, no ICC was calculated for the current trial.

Consent also needs to be considered in cluster RCTs. As clusters are randomised to trial groups, individuals are not always able to consent to randomisation to a group. Such a circumstance instead requires consent to be sought from individuals to receive the intervention associated with their group, and to be follow-up, therefore ethical concerns should be addressed (Campbell et al., 2012; Eldridge & Kerry, 2012). In the current trial, verbal consent was provided by each cluster (i.e. from the charge nurse of each ward), and written consent was obtained from individual participants.

Randomisation and blinding

Two trial design characteristics considered key to ensuring methodological rigour in intervention evaluation are randomisation (of either clusters or individuals) and blinding. Neither were employed in the current study. Reasons and implications are discussed in this section.

Randomisation

Randomisation of individuals was not possible in the current study. Reasons for failing to randomise and associated limitations are discussed in the remainder of this section. Randomisation aims to reduce selection bias and, where randomisation occurs at participant level, ensures confounders are controlled for, i.e. unknown influencing variables are evenly distributed between groups. As a result the internal validity of

statistical tests is preserved (Dunn, 2013). However, as was the case for the current trial, randomisation is not always possible in health care research, due to organisational restrictions or intervention and service complexities (Craig et al., 2013; Habicht, Victora, & Vaughan, 1999). As previously mentioned, the intervention investigated in this study was implemented within a whole acute inpatient ward to which patients were admitted based on their residential location. Individuals were, therefore, not randomised as everyone in the ward was expected to be exposed to the intervention. Randomisation of clusters (wards) was not possible due to organisational constraints, i.e. implementation was already underway in the intervention ward. Non-randomisation is associated with limitations such as selection bias (Higgins & Green, 2011); these are acknowledged in the interpretation of the findings from the current study. Additionally, as non-randomisation of individual participants can lead to baseline differences between groups, even in the presence of randomised clusters (Eldridge & Kerry, 2012), participant characteristics, e.g. diagnosis, ages, length of stay, previous admissions, were investigated descriptively to identify potential differences.

Blinding

Blinding of assessors, personnel and participants to treatment group was not possible in this study. Justification for the lack of blinding and associated limitations are discussed in this section.

Blinding of assessors and personnel to treatment groups reduces detection bias (i.e. assessors/researchers wanting a desired effect) and blinding of participants to trial groups reduces performance bias (i.e. participants self-reporting outcomes that are considered desirable to clinicians or researchers) (Button & Munafò, 2015). Due to the nature of treatment in psychotherapy trials it is difficult to blind participants, staff and therapists to group allocation, therefore more importance is placed on assessor blinding. It is argued by some that non-blinding of participants and clinicians is pragmatic in design because in routine clinical practice both staff and patients are aware of treatment received (Hotopf, 2002). However, non-blinding of assessors is known to increase the risk of bias in trials (Button & Munafo, 2015), therefore assessor blinding is expected to be implemented where possible. In the current study blinding of personnel and participants could not occur due to the nature of the intervention, and assessors were not blind due to limited resource. In order to blind assessors in the current study, an independent researcher or volunteer, responsible for data collection only, could have been needed. Due to limited resources

the PI was involved in management of the trial and data collection therefore assessor blinding was not feasible. Alternatively, the researcher could have met participants outside of the ward to maintain allocation concealment. However, this method is sometimes unreliable as participants may tell the researcher what treatment they have received. Furthermore, given that all inpatient wards were locked, some participants would likely need escorted by ward staff to multiple data collection meetings off the ward. Given the high bed occupancy levels, the staff shortages (The Commission on Acute Adult Psychiatric Care, 2015) and the busy nature of acute inpatient services (Clarke & Wilson, 2009), this option was also not feasible. Limitations associated with failure to blind assessors are considered in the interpretation of results (see Chapter 6).

4.4 Recruitment, participants and sample size

Cluster recruitment and inclusion/exclusion

Clusters were inpatient wards recruited from the Royal Edinburgh Hospital, NHS Lothian. Potential clusters were identified and approached by a member of the psychological team (SH). Potential clusters were considered appropriate if they were not in receipt of psychological input at the time of recruitment.

Participant recruitment

Participants were recruited from two acute inpatient wards at the Royal Edinburgh Hospital (REH), NHS Lothian, between October 2015 and October 2016. As part of usual clinical service, patients were allocated to acute wards by their residential location. According to the Scottish Index of Multiple Deprivation (SMID), 5% (Scottish Government, 2016a) and 14% (Scottish Government, 2016b) of the areas which the control and intervention ward (respectively) provide care for are in the 20% most deprived areas in Scotland. Such characteristics of residential location are considered later in the thesis (see Chapter 6).

All patients who consented provided written informed consent. All patients were recruited via poster advertisement on the ward or by the researcher. Recruitment rate estimation was challenging, as on request, there was no data available with regards to patient turnover in relevant acute services. Recruitment was expected to be challenging due to the nature of acute inpatient services and the severity of patients using such services (i.e. a high percentage of participants were expected to decline participation or

were expected to be lost to follow-up after initial consent). Originally, six months were allocated to recruitment and agreed with Senior Charge Nurses. However, recruitment was extended to 12 months to enable recruitment of the planned sample size (see 'Protocol amendments' section, page 110). Recruitment of clusters is described in the Control section (page 81 and 83).

Participant inclusion/exclusion

In order to take a pragmatic approach to recruitment, as few eligibility criteria as possible were used (Godwin et al., 2003; Loudon et al., 2015). Inpatients were considered eligible to participate if they were a current inpatient in either the intervention ward or the control ward, with no restriction on diagnosis. People were included if they were aged between 16 and 65, deemed able to give informed consent (decided by nursing or medical staff), admitted to one of the acute wards at time of first data collection point, were classed as 'stabilised' by medical staff or nursing staff (i.e. unlikely to find questionnaires too distressing, thoughts were not too chaotic) and were likely to be admitted for more than 3 days (as judged by ward staff). Participants were excluded if they had received a diagnosis of moderate or severe and profound learning disability, dementia or organic mental disorder, were unable to understand self-report questionnaires due to impaired cognitive processes, concentration, had severe cognitive difficulties which may hinder engagement in talking therapy interventions, did not speak English, presented unsafe behaviour, i.e. severe hostility/aggression or sexually uninhibited behaviour towards staff or were discharged or moved to a different ward within 2 days of completing the first assessment. Inclusion/exclusion criteria for clusters is described in the 'Control' section (page 81 and 83).

Sample size

Sample size was based primarily on published recommendations using simulated data for feasibility trials with binary outcomes. A sample size of 60 per group has been recommended for pilot trials with binary outcomes (Teare et al., 2014). Therefore, as the proposed primary clinical outcome for future trials is a binary outcome (i.e. proportion readmitted) (see 'Clinical outcomes' section, page 95) the target sample size was 120. Teare et al. (2014) simulated a feasibility study at least 10, 000 times each for a range of sample sizes, in steps of five subjects, for proportions in the range up to 0.5 in increments of 0.05. Results showed that for binary outcomes anything greater than n=60 in the

intervention arm did not provide any relative gain in precision, i.e. estimates predicted to be within the 95% confidence interval. Although this is larger than traditional feasibility studies, it is now deemed more efficient to use large external pilot studies to reduce variation around statistical power for future definitive trials (Eldridge, Costelloe, Kahan, Lancaster, & Kerry, 2015). A sample of 120 between groups is deemed more than sufficient to identify potential problems on a range of other outcomes which have a 5% probability of occurring (Viechtbauer et al., 2015). These are namely the feasibility of conducting a trial in an acute inpatient context, e.g. eligibility rate, consent rate; secondly, to inform the feasibility of collecting data on an acute inpatient ward, and to inform the feasibility of implementing the intervention, e.g. number of sessions delivered and average number of sessions per person. In addition, 120 participants was deemed sufficient as it is larger than the sample recruited in previous acute inpatient pilot trials (range=12-40) (Gaudiano & Herbert, 2006; Haddock et al., 1999; Hall & Tarrier, 2003; Kim et al., 2010; Mortan et al., 2011). However, as is frequently the case with PhD studies, the ideal aspirations of this sort of work are restricted by the time restrictions of the PhD, and therefore a maximum of one year had to be allocated to data collection, in part as a direct consequence of the extended recruitment period.

Although 120 was the desired recruited number, attrition and drop-outs during the feasibility study was also accounted for. Allowing for 20% attrition (base on similar studies (Bechdolf et al., 2004; Lewis et al., 2002)), means an overall number of 150 participants were required for the study. It should be noted that this sample size was calculated after the study began, due to protocol amendments (see 'Protocol amendments' section for detail, page 110).

4.5 Control

Treatment as usual (TAU) was chosen as the control condition. This choice is advantageous as results from the current study will inform a larger future trial which will aim to show that psychological therapy plus TAU is more effective than TAU alone. However, comparing interventions to TAU has been associated with inflated treatment effects due to a failure to control for non-specific effects of treatment (Button & Munafò, 2015). Less sophisticated control interventions (e.g. befriending) can be used to counter this limitation, although this was not possible in the current study due to limited resource. A second option is to use an active treatment as a comparator. However again, this study did not have enough resource to deliver another active treatment. Furthermore, use of an

active treatment asks the question of which treatment is most effective, rather than whether the novel treatment of interest is more effective than current usual treatment. Given that psychological therapy is not currently routinely offered in acute inpatient settings comparing a new approach with another active treatment was not deemed appropriate at this point in time (Thompson & Schoenfeld, 2007). Another option might be to compare the new intervention to an intervention which mimics the format of the new intervention but is missing the active ingredient, i.e. offering individual sessions and groups which are not psychologically orientated. Due to restricted resource, this option was also not feasible in the current study.

The choice of the control ward was determined by one main factor: no inpatient access to psychological therapies. Two eligible wards were identified within the same national health board, one of which met eligibility criteria[2]. The chosen control ward was a low security, 25 bed, mixed sex ward for acute inpatients residing in Midlothian and East Lothian. TAU in this ward included, at the time of recruitment, initial consultation with a psychiatrist on admission, followed by weekly or 'as-required' reviews, formation of a care plan, patient involvement in care planning, occupational therapy input, pharmacotherapy input and assignment of a key worker (staff nurse). No psychological intervention was routinely available or provided.

The control ward differed from the intervention ward in that Consultant Psychiatrists are not resident to the ward. Instead, they work between community and inpatient services, therefore patients maintain contact with the same psychiatrist while admitted to hospital. Similar to the intervention ward, there is a constant flow of medical students and one senior charge nurse, a charge nurse and a team of resident nurses and nursing assistants. In addition to a medical team there is also an Occupational Therapist and an in-house Recreation Officer. Differences between the intervention and control ward are discussed later in this thesis (see Chapter 6).

4.6 Intervention

Setting

The intervention ward was a low security 40 bed acute mental health inpatient ward for people residing in North West Edinburgh and is divided into two separately secure

[2] One ward had input from an art therapist therefore was excluded.

sections: male and female. At the time of recruitment, the ward had three resident consultant psychiatrists, four junior doctors and a continuous flow of medical students. Additionally, two senior charge nurses (one for each section), two charge nurses (one for each section) and a team of nurses and nursing assistants (each section had dedicated staff teams) were employed during data collection. Outside the medical team, the ward also had an Occupational Therapist, a Recreation Officer and psychological input. Psychological input was provided specifically for this study and was additional to usual treatment. This included a Consultant Clinical Psychologist who provided three hours of individual sessions per week and a Clinical Psychologist/Advance Nurse Practitioner (17.5 hours per week) who was responsible for running groups, providing individual sessions for patients, providing clinical supervision to ward staff delivering components of the psychological intervention and facilitating group reflective practice. All participants in the intervention ward received TAU, like the control group described above. They also had access to the psychological intervention (described in the following section).

4.6.1 Cross-diagnostic, psychological intervention

The meta-analysis in chapter three highlighted the need for evaluation of cross-diagnostic inpatient psychological therapy. Additionally, it provided evidence which suggests inpatient therapy may be beneficial in terms of reducing emotional distress (see Chapter 3). This study investigated a cross-diagnostic, psychological intervention which aims to reduce overwhelming emotion (i.e. depression and anxiety) for acute inpatients. The intervention is largely based on the Woodhaven Approach (Clarke & Wilson, 2009). The Woodhaven Approach addresses some notable problems experienced in acute inpatient services (e.g. limited access to psychological therapy, poor therapeutic milieu, poor quality of care and frequent staff burnout and poor patient outcomes leading to readmission) (see chapter 2 for further discussion). The main aims of the Woodhaven Approach are as follows, however it should be noted that the current study primarily investigated the feasibility of implementing patient components of the intervention and evaluating outcomes related to patient benefit (see specific aims section):

1. Provide acute inpatients with an opportunity to make sense of their admission using psychological formulation and encourage patients to take responsibility for maintaining good mental wellbeing by teaching them skills to cope with overwhelming emotion. This should lead reduced emotional distress and increased self-efficacy in relation to coping with their mental health (see patient

components, below). In turn, the risk of future admissions, and other contact with other crisis services (see 'Clinical outcomes' section, page 95) should be reduced.

2. To facilitate staff members psychological and empathic understanding of patients so as to improve therapeutic engagement.
3. As a product of 1 and 2, the Woodhaven Approach also aims to enhance therapeutic milieu, staff morale, quality of care and patient experience (Clarke & Wilson, 2009).

People in the intervention group had access to individual and group psychological intervention on the ward. Individual sessions were offered to patients identified by staff or to patients who self-identified. Groups were advertised on the wards through posters and staff in both the male and female ward, however all groups were delivered on the female ward for practical reasons.

According to the Woodhaven Approach (Clarke & Wilson, 2009), patients should receive individual therapy to identify current problems and 'exit strategies' via emotion focussed formulation (described in the following section) of the current acute crisis (see Chapter two for formulation example). Patients should then be directed to appropriate CBT-based and 'third-wave'-based group therapies. However, to suit the unpredictable nature of an acute inpatient environment the intervention remains flexible, therefore patients can attend groups without first attending individual sessions and patients can attend as few or as many groups as they wished, and they could leave therapeutic sessions early if necessary. Group therapies for patients, adopted from the Woodhaven Approach, included 'Anxiety and Stress Management', 'Making Friends with Yourself', 'What is Real and What is Not?' (described in the following sections). An additional emotion regulation group, called 'Living Well with Emotions', was offered to patients. These therapeutic components were brought together to target dual and uncertain diagnoses and high levels of distress which are characteristic of acute inpatients (Durrant & Tolland, 2009).

The model of intervention also included training for staff. Mentalisation Based Therapy (MBT) skills training and basic CBT skills training was available for staff, in addition to weekly group reflective practice and Clinical supervision for staff facilitating groups. Staff components of the intervention aimed to support staff in their work in what can often be a chaotic and stressful environment. As a result, staff should be better equipped

for the demands of this environment and feel more supported. Additionally, the overall environment of the ward should become more therapeutic thus improving the service users experience (Clarke & Wilson, 2009). Components of the psychological intervention piloted in the current study are described below and summarised in Table 7 (page 92).

Patient components

Emotion focused formulation (individual therapy)

As suggested by Clarke and Wilson (2009) weekly one hour individual therapy sessions were offered to patients once admitted and stabilised. Two clinical psychologist and one specialist nurse therapist delivered individual sessions. These typically involved assessment of inpatients' acute crisis to allow the development of emotion focussed formulation. Formulation aims to provide a new perspective on the individuals' distress for both the patient and the multidisciplinary team working with them (Kinderman, 2009), leading to increased confidence in coping with such distress for patients. Formulation in this context specifically aims to identify current problems leading to the index admission and introduces potential 'exit strategies' for inpatients (see Chapter two for an example of formulation). Previous qualitative analysis of staff and patient perspectives of the effects of team formulation delivered in psychiatric inpatient settings highlighted that staff felt formulation increased their understanding of patients, improved team collaboration and improved interpersonal awareness (Berry et al., 2016).

Group therapies

Group therapies were initially delivered by a clinical psychologist or an advanced nurse practitioner. However, ward staff were expected to co-facilitate group sessions until they felt confident in facilitating them alone. All group therapies are manualised (see Table 7, page 92), allowing staff to easily co-facilitate and facilitate groups. Although staff did not receive training specifically for facilitating group therapies, those who did facilitate or co-facilitated groups received clinical supervision from either a clinical psychologist or a specialist nurse practitioner. This was thought to be key to sustaining the delivery, and quality of delivery, of the intervention long term. Patients could attend all or any group sessions and could drop in and out as they wished. Due to this flexibility, participation was monitored.

Only three ('Anxiety and Stress Management', 'Living Well with Emotions' and 'Being Friends with Yourself') of the intended four group therapies were delivered during the study period, due to implementation challenges (see 'Protocol amendments' section, page 110). All intended group therapy components are described below.

Anxiety and Stress Management

The anxiety and stress management group was adopted from the Woodhaven approach (Clarke & Wilson, 2009). It is a two-session group delivered once weekly and lasts approximately an hour. The aim is to introduce the concept of the physiological safety system, i.e. the flight or fight reaction to threat situations, and teach mindfulness and arousal management skills to reduce distress (i.e. anxiety) and distress related arousal (i.e. somatization), and increase patients' confidence in coping with anxiety and stress.

Mindfulness and arousal management are core coping mechanism of the Woodhaven Approach (Clarke, 2015). Overwhelming emotion is closely linked with high states of arousal, largely due to the fight flight response (i.e. the body physically prepares to combat threat). It is argued that acute inpatients often find themselves admitted to acute inpatient services due to behaviours or reactions which are a response to overwhelming emotion (Clarke & Wilson, 2009). When emotion becomes overwhelming, different levels of processing - implicational (emotional) and propositional (rational) - become disconnected or unbalanced (see 'ICS' section in Chapter two for further discussion). Mindfulness and arousal management techniques provide the opportunity to reconnect rational and emotional processing. Management of high arousal is essential to begin rational processing and appraisal again (Clarke, 2015).

This group psychological intervention primarily comprised of psycho-education and mindfulness techniques. Patients are taught to identify factors which maintain or trigger threat reactions, and to identify associated physical feelings that lead to panic, avoidance or other unhelpful coping strategies (i.e. self-harm or taking drugs). Once these factors and feelings can be recognised coping techniques (i.e. controlled breathing and mindfulness techniques) can be implemented to manage arousal, therefore allowing time to employ rational processing and more useful coping strategies. As a result, distress should decrease while self-efficacy related to coping with mental health should increase.

Making friends with yourself (compassion based group)

The making friends with yourself group is three-session group also adopted from the Woodhaven approach (Clarke & Wilson, 2009; Hill, Clarke, & Wilson, 2009). It draws on elements of compassionate mind training and compassion focused therapy (see Gilbert & Procter, 2006) and is designed for inpatients with low self-esteem that results in self-criticism and feelings of shame. The group teaches skills to cope with and improve negative internal relationships with the aim to decrease negative emotions (i.e. depression) and improve patients' confidence in managing such feelings. The following topics are covered: i) identifying what influences actions and feelings/mood; ii) recognition that thoughts about the self can affect feelings about the self; iii) understanding the role of core beliefs; iv) teaching alternative ways to think about themselves; v) practice of alternative techniques with support from other group members; vi) practice in real life situations.

What is real and what is not? (WRWN)

This group was also adopted from the Woodhaven approach (Clarke & Wilson, 2009; Hill et al., 2009) and is designed for inpatients who have encountered unusual perceptual experiences such as hearing voices or sensory/visual hallucinations. It aims to normalise the phenomena of hearing voices and other unusual perceptual experiences (Romme & Escher, 1989) in order to help patients make sense of and gain control of such experiences, consequently improving self-esteem. As a result, confidence in coping with unusual experiences should improve and distress should decrease. This weekly group lasts approximately one hour and includes four sessions with the following topics: i) introduction to openness and normalising unusual experiences, ii) different states of mind (and factors that influence it, e.g. stress and life events) and different sorts of reality, iii) coping strategies including distraction, relaxation, arousal management, mindfulness and education.; iv) identifying what is real and what is not.

Living Well with Emotions

Living Well with Emotions is a manualised (see Appendix 10) emotion regulation group developed for an acute inpatient setting (Lennon, 2015). It comprises of six sessions delivered twice weekly. It is an open, rolling group, therefore participants can join and leave as needed. This level of flexibility is suitable for the unpredictable nature of an acute inpatient environment. Similar to the emotion regulation group developed by Clarke

and colleagues (Rendle & Wilson, 2009), this group primarily draws on Dialectical Behaviour Therapy (DBT) (Linehan, 1993) but also incorporates mindfulness based exercises (see Chapter two for detail of DBT and mindfulness). In contrast to Linehan's work, the group is designed for brief admissions and is applied cross-diagnostically. Emotion dysregulation is seen as central to all pathology under the ICS framework, therefore all inpatients who want to attend the group are encouraged to (Clarke, 1999; Teasdale, 1993).

Key elements covered in the six sessions are labelling emotions, identifying the function of emotions, learning effective and ineffective expression of emotions, reducing vulnerability to emotions, learning self-soothing techniques and increasing positive emotions and learning how to act opposite to difficult emotions (Lennon, 2015). Clarke (2015) proposes that once mindfulness skills are achieved (i.e. reduced arousal and disconnection from overwhelming emotion) patients can reflect on and make sense of emotions associated with their current crisis. The overall goal of this group is for patients to become aware of, recognise, understand and cope with emotions that have been previously avoided. In turn, mental health related self-efficacy and emotional distress should improve.

Staff components

All staff were encouraged to attend all training where possible, however due to staff shortages, which are common in acute inpatient wards (The Commission on Acute Adult Psychiatric Care, 2015), attendance was not guaranteed and was ultimately decided by charge nurses.

Introduction to the model and CBT based skills training

This one day training session was delivered by a consultant clinical psychologist and a clinical psychologist or advanced nurse practitioner for all available ward staff. The aim was to teach the underpinning values and rationale of the intervention being implemented (see Chapter two for detail of the underpinning values and theoretical rationale) and improve integration of the psychological approach within the service. This covered the following topics: i) philosophy of the model (validation, control and change), ii) introducing the aims of the model, iii) detail of training and support available to staff and

detail of therapeutic interventions available to patients, iv) detail of implementation logistics and feedback from staff.

MBT Skills Training

Drawn from mentalisation based therapy (MBT) (Bateman & Fonagy, 2010), two days of MBT-based skills training were provided by a psychiatrist/psychotherapist and a clinical psychologist. This was available to all ward staff able to attend. The aim was to teach mentalisation-based skills in order to facilitate more effective communication with acutely distressed, and often challenging, patients. Techniques include learning to think about thinking, becoming aware of one's own thoughts and beliefs and evaluating whether these are useful, truthful and based on reality.

Group Reflective Practice

Group reflective practice was offered once fortnightly to provide time for ward staff to discuss challenging situations with colleagues and reflect on the use of MBT and CBT skills on the ward. The aim of the group is to provide time for nurses to share and formulate their experiences and promote personal and professional development.

Table 7

Summary of intervention components

Name	Component type	Recipient	Therapeutic alliance	Origin	Aim	Number of sessions	Delivery
Emotion focused formulation	Individual therapy	Patient	N/A	Woodhaven approach[1]	Identify emotional distress and unhelpful coping mechanisms	Flexible	1 hour, weekly, flexible delivery
Anxiety and stress management	Group therapy	Patients	Psycho-education, mindfulness, arousal management	Woodhaven approach[1]	Teach concept of physiological safety system in relation to stress and anxiety and teaches mindfulness and arousal management skills to cope	2	1 hour, weekly, manualised [2]
Making friends with yourself	Group therapy	Patients	Compassion focused therapy, DBT, CBT, mindfulness	Woodhaven approach[1]	Increase self-esteem and decrease self-criticism	3	1 hour, weekly, manualised [2]
What is real and what is not?	Group therapy	Patients	CBTp, mindfulness, arousal management	Woodhaven approach[1]	Normalise non-shared experiences, identify triggers, recognise and reduce arousal	4	1 hour, weekly, manualised [2]
Living well with emotions	Group therapy	Patients	ACT, DBT, mindfulness	Developed for current model	Emotion regulation	6	1 hour, twice weekly, manualised [3]

Induction	Staff training	Staff	CBT	Developed for current model	To introduce staff to philosophy of the model and introduce CBT based skills such as formulation	1	1 full day
MBT skills training	Staff training	Staff	MBT	Developed for current model	To improve quality of staff-patient interaction	2	2 full days
Clinical supervision	Staff component	Staff	N/A	Routine component of psychological practice	Provides a forum to problem solve with a clinical supervisor	Flexible – only offered to staff who co-facilitate or facilitate groups	1 hour, frequency is flexible
Reflective Practice	Staff component	Staff	N/A	Routine component of psychological practice	Provides a group forum to problem solve	Rolling	1 hour, weekly

Acceptance and commitment therapy (ACT); Cognitive behavioural therapy (CBT); Cognitive behavioural therapy for psychosis (CBTp); Dialectal behaviour therapy (DBT); Mentalization based therapy (MBT); Not applicable, (N/A).

1. (Clarke & Wilson, 2009).
2. (Clarke, n.d.)
3. See appendices.

4.7 Assessment

A variety of data were collected to achieve the aims of the study (see 'Specific aims' section, page 71). Data relating to feasibility of implementing and evaluating the intervention were collected for the primary outcomes of the study, in order to inform development of the intervention and future definitive evaluation. Detail of the feasibility data recorded can be found in the 'Analysis plan' section, presented later in this chapter (page 111). The secondary outcome of the study was to gather clinical outcome data relating to effect and data on adverse events. Clinical outcomes were collected in the current study to acquire preliminary evidence of the direction of any treatment effect and to estimate completion rates of the chosen clinical outcomes (Lancaster et al., 2004; Thabane et al., 2010). The remainder of this section describes and justifies the chosen clinical outcomes proposed for future trials.

Clinical outcome data collected for this feasibility study included questionnaires, readmission data and data on adverse events. All questionnaires were collected at baseline, post-treatment and 6-month follow-up (see Table 8). They were primarily collected in person where possible. Alternatively, participants were contacted by telephone, by post or via their clinical psychiatric nurse (CPN). All other data (readmission and adverse events data) were extracted from NHS Lothian electronic medical records.

Table 8

Timeline of clinical outcome data collection

Baseline measures	Post-treatment Measures	6-month follow-up Measures
MHCS	MHCS	MHCS
CORE 10	CORE 10	CORE 10
BSI-18	BSI-18	BSI-18
	CTQ-SF	Readmission data
	LOS	Adverse events data

Brief Symptom Inventory Scale-18 (BSI-18), Clinical Outcome of Routine Evaluatio-10 (CORE-10), Childhood Trauma Questionnaire-Short Form (CTQ-SF), length of stay (LOS), Mental Health Confidence Scale (MHCS).

4.7.1 Clinical outcomes

Proposed primary outcomes for main trial

The proportion of readmissions at 6-months following discharge of the index admission is the proposed primary outcome measure for a future trial. The number of readmissions, or 'revolving door patients' is a significant problem for acute inpatient services in the UK (Cogan et al., 2012) and worldwide (Loch, 2014). Readmissions are expensive for services (Personal Social Services Research Unit [PSSRU], 2010) and may have a negative effect on patient outcome, i.e. a predictor of readmissions is the number of previous admissions (Information Services Division Scotland, 2009). One aim of the psychological intervention is to use acute admissions as a turning point for patients, which involves identify problems resulting in the current admission and teaching patients' new ways of coping in future (Clarke & Wilson, 2009). Consequently, patients are supported to take responsibility for maintaining their mental health which may have implications for future service use, specifically readmission. Understanding whether this cross-diagnostic psychological intervention can reduce the risk of readmissions is valuable to both patients and services, however is currently unknown.

Although informative, there are also limitations associated with recording only the proportion of readmissions (Fischer et al., 2014). For example, individuals who have not been discharged at follow-up may not be considered readmitted. Additionally, the proportion of individuals discharged from the index admission may influence the proportion of people readmitted during the follow-up period. Additional information would need to be gathered to address this in a full trial. To address these limitations in the current study, the number of days admitted to an acute inpatient ward within 6-months of the index discharge was also recorded for each participant to further inform service use following discharge.

Although the proportion of readmissions at 12-months was pre-specified, the proportion of readmissions was recorded at 6-months instead (see 'Protocol amendments' section, page 110). The length of follow-up was reduced due to slow recruitment and time restrictions, therefore 6 months was the longest follow-up possible. Previous research of psychological intervention in acute inpatient settings has used between three- and 24-month follow-up (Bach & Hayes, 2002; Bechdolf, Köhn, Knost, Pukrop, & Klosterkötter,

2005; Gaudiano & Herbert, 2006; Schramm et al., 2007; Tarrier et al., 2004), therefore six months was considered acceptable for the current feasibility trial.

Proposed secondary outcomes for main trial

Three other clinical outcomes measures were pre-specified and collected. These included two self-report measures of emotional/psychological distress and one self-report measure of self-efficacy in relation to coping with metal health (see Appendix 11). Self-report measures have previously been rated as more acceptable measures, than clinician rated measures, to those with lived experiences of psychosis and affective disorder (Crawford et al., 2011), therefore only self-report questionnaires were used in this feasibility trial.

Questionnaires

Psychological/emotional distress

In line with the aims of the intervention, psychological (or emotional) distress was considered an important outcome to include in evaluating the psychological intervention. The influential and maintaining role of emotional/psychological distress in severe mental illnesses (SMI) and acute exacerbation of symptoms has been recognised (Birchwood & Trower, 2006; Clarke, 2015; Linehan, 1993). Additionally, results from the meta-analysis reported in Chapter three suggest that brief psychological therapy delivered during an acute psychiatric admission may reduce inpatients emotional distress (i.e. depression and anxiety) at post-intervention. Two measures of psychological distress were collected, one of which has been used in previous evaluation of the Woodhaven approach, therefore allowing for easy comparison. The second measure of psychological distress was included because it specifically measures physical symptoms of psychological distress (somatization). Details of these measures are described below.

The Clinical Outcomes in Routine Evaluation (CORE) 10 (Connell & Barkham, 2007) was one questionnaire used to measure psychological distress. It is a 10-item questionnaire measuring total psychological distress and three domains of distress: 'problems' largely relating to anxiety and depression (6 items), general and social 'functioning' (3 items) and 'risk' to self (1 item). Each item is measured on a 5-point scale ranging from 0 (not at all) to 4 (most or all of the time) with a higher score indicating higher severity. The 10 items have been taken from the 34-item CORE-OM. Although the CORE-OM is recommended where possible, the CORE 10 lends itself better to an

acute inpatient environment as it requires less time to complete. The CORE 10 has shown to have good internal reliability (.90) (Barkham et al., 2013), good internal consistency (0.82) in a primary care clinical sample (Connell & Barkham, 2007). Furthermore, it has previously been used by Clarke and colleagues to evaluate the Woodhaven Approach (Durrant & Tolland, 2009) (see Chapter 2).

According to the theory underpinning the psychological intervention (see intervention section), high states of arousal are associated with emotional distress experienced by acute inpatients (Clarke, 1999; Teasdale, 1993). The intervention, therefore, predominantly focuses on teaching or improving skills to cope with and tolerate such arousal (see intervention section and introduction). Consequently, reduced arousal was considered an important outcome of treatment. The Brief Symptom Inventory Scale (BSI-18) (Derogatis, 2001) was chosen to capture this. The BSI-18 is a shortened version (18 items) of the BSI (Derogatis & Melisaratos, 1983) which is a 57-item self-report measure of psychological distress with nine dimensions. (Derogatis, 2001). Each item is scored on a 5 point Likert scale (0='not at all' to 4='extremely') with a higher score indicating higher severity. The BSI-18 was developed to include the most prevalent psychiatric symptoms of psychological distress: somatisation (6 items), depression (6 items) and anxiety (6 items), therefore the questionnaire was considered suitable to measure psychological distress in a cross-diagnostic population. Specifically, questions within the somatization subscale, such as 'how much were you distressed by pains in your heart or chest, trouble getting your breath, spells of terror or panic, etc.', were thought appropriate to capture changes in physical arousal targeted by the intervention. Furthermore, the BSI-18 is quick to administer, therefore suiting an acute inpatient population. The BSI-18 has shown good reliability for the global symptom index (GSI), somatization, depression and anxiety (.90, .68, .84, and .79 respectively) and good internal consistency (.89, .74, .84, and .79, respectively) (Derogatis, 2001).

Self-efficacy

There is strong support for the notion that self-efficacy mediates the relationship between coping, and positive and negative outcomes (Salanova, Grau, & Martinez, 2006). In line with the person-centred approach, an aim of treatment was to increase patients' feeling of control in terms of their symptoms, as opposed to just reducing presentation of symptoms. According to Clarke and colleagues (Durrant & Tolland, 2009), improvements in self-efficacy should be expected following recovery based interventions

that incorporate a coping strategy (e.g. attention control, self-compassion, distress tolerance and emotion regulation). Self-efficacy should therefore indicate intervention effectiveness. The Mental Health Confidence Scale (MHCS) was used to measure self-efficacy (Carpinello, Knight, Markowitz, & Pease, 2000). This measure was developed by a group involving mental health researchers, recipients of mental health services and individuals who have recovered from mental illness (Carpinello et al., 2000). It can therefore be considered a patient important outcome. The MHCS has also been identified as a recovery-related measure, therefore is in keeping with the recovery approach (Ralph, Kidder, Edmund, & Phillips, 2000). This measure was thought to be acceptable to participants as it contains 'positive' items which is an important feature of outcome measures identified by service user (Crawford et al., 2011). The MHCS measures self-efficacy in relation to mental health using 16 items that are rated on a six point Likert scale that ranges from 1 (very non-confident) to 6 (very confident) with a higher score indicating higher levels of self-efficacy. The 16 items include three domains: optimism, coping and advocacy. A total score is made up of the total of all items. Construct validity of this scale is high and error variance is low, therefore the measure is considered by the authors to be reliable (Carpinello et al., 2000).

Adverse events

Trials of psychological intervention have been criticized for failing to measure adverse events (Duggan et al., 2014). Therefore, as recommended, adverse events are reported in the current study (Duggan et al., 2014). The number of people who made contact with intensive home treatment teams (IHTT), the number of people who made contact with A&E services (in relation to mental health), the number of deaths related to mental health (e.g. suicide) and the number of participants not discharged at follow-up were recorded.

Proposed predictor of treatment outcome for main trial

Theoretically, the role of childhood adversity has been highlighted as a contributing factor of adulthood mental health problems (Clarke, 2002; Teasdale & Barnard, 1995); and in the last decade, supporting evidence has emerged. For example, a meta-analysis of 18 case controls, 10 prospective and quasi-experimental studies and 8 population based cross-sectional studies suggests childhood trauma is strongly associated with increased risk of developing psychosis in later life (Varese et al., 2012). Furthermore, a recent study, including 251 participants, has shown a positive correlation between the number of

experienced adverse childhood events and number of psychotic symptoms (Longden, Sampson, & Read, 2016). A recent meta-analysis has also suggested that childhood adversity is strongly associated with bipolar disorder compared to non-clinical controls (Palmier-Claus, Berry, Bucci, Mansell, & Varese, 2016). Given that acute psychiatric inpatient services commonly provide care for people with the diagnoses previously mentioned, it is possible that trauma may be a predicting factor of treatment outcome of psychological interventions delivered in acute inpatient settings. However, whether this is the case is currently unknown. To investigate this issue in a future definitive trial, an outcome of childhood trauma may be collected. However, some patients may find completing outcomes which measures childhood trauma unacceptable, given the sensitive nature of the questions. In order to determine the feasibility of exploring childhood trauma as a predictor of outcome of acute inpatient psychological intervention, a measure of childhood trauma was collected during the current study. The aim was to determine the feasibility of collecting a measure of childhood trauma as a predictor of treatment outcome in future definitive trials, based on the completion rate.

The Childhood Trauma Questionnaire Short Form (CTQ-SF) (Bernstein et al., 2003) is a retrospective self-report measure of childhood abuse and neglect. It consists of 28 items that focus on constructs of adverse childhood experiences such as emotional abuse, physical abuse, neglect and sexual abuse. Each item is rated on a 5-point scale from 'Never true' to 'Very often true', where a higher score indicates higher constructs of trauma. This measure includes five types of maltreatment: emotion abuse, physical abuse, sexual abuse, emotional neglect and physical neglect. It also includes a denial scale to detect false negative trauma. The scale is a valid measure in both clinical and non-clinical samples and has good criterion-related validity (Bernstein et al., 2003).

4.8 Trial procedures

Once ethical approval was obtained (see Appendix 14) both potential participating wards (clusters) were identified and verbal consent was sought from ward psychiatrists and charge nurses to participate in the study. Once cluster consent was obtained, electronic medical databases were checked daily by the primary researcher to identify newly admitted patients and check available eligibility criteria. For the intervention ward this occurred between October 2015 and October 2016 and for the control ward this occurred between October 2015 and June 2016 (due to other therapeutic work beginning, i.e. art therapy). Once potential participants were identified, the researcher then met with ward

staff (nursing or medical) to check remaining eligibility criteria. Once approved by medical or nursing staff, patients were approached in the ward by the primary researcher, were given the information sheet (see Appendices 12 and 13) and invited to take part in the study. In addition, posters advertising group therapies (in the intervention ward) and study details (see Appendix 15) were presented on ward notice boards with contact details for the primary researcher, although no participants were recruited using this method.

If patients agreed to take part in the study written consent was obtained and the first assessment (baseline) was completed. Patients then either received TAU (control ward) or TAU plus psychological input (intervention ward). Patients in the intervention ward were advised which therapy they may benefit most from, however all patients allocated to intervention had access to all group therapies. The number and type of therapy components attended while in hospital and length of stay (LOS) were recorded. The researcher aimed to approach participants again before discharge to complete the second clinical outcome measures. Unfortunately, this was not always possible, due to the busy nature of the ward, or due to unexpected discharges. If unable to meet participants on the ward for the post-intervention assessment the researcher made contact with participants where possible via telephone, or through their clinical psychiatric nurse (CPN) in order to complete assessments over the phone, by post or to arrange an assessment appointment within a week of being discharged. If participants preferred to make an assessment appointment this was organised either at the hospital (REH), during a CPN meeting or in a community mental health centre of convenience to the participant. Participants were contacted again, via telephone or through contact with their clinical psychiatric nurse (CPN) after 6-month following discharge and asked to complete the final assessment. Readmission and adverse event data were also obtained from hospital records at 6-month follow-up.

4.9 Analysis plan

Statistical analyses were performed using IBM SPSS 23 (IBM, 2016). Analysis plans for each aim of the study are reported below in the following order: feasibility of evaluating the intervention, feasibility of implementing the intervention, treatment effects on chosen clinical outcomes and assessing the findings from this feasibility study.

4.9.1 Aim 1: feasibility of evaluating the intervention (primary outcome)

Descriptive summaries are reported to investigate the feasibility of the trial. These outcomes were not pre-registered (see 'Protocol amendments' section for detail, page 110). The following data is reported to address recruitment, retention and the acceptability of the clinical outcome measures chosen for a definitive trial:

1. Eligibility rate: proportion of those who were eligible to participate as a percentage of those screened (i.e. fulfilled eligibility criteria of the study).
2. Consent rate: proportion of those who consented to participate as a percentage of those who were approached to participate.
3. Trial entry rate: proportion of those who consented that officially entered the trial as a percentage of those that consented and completed baseline measures, and had not been discharged or moved wards within two days of doing so.
4. Completion rate:
    a) Proportion of clinical outcome questionnaires (CORE-10, BSI-18 and MHCS) completed at each time point (baseline, post-intervention and follow-up) as a percentage of those who entered the trial, with reasons for attrition where possible and assumed missing data mechanisms. This also provided an inverted measure of trial attrition.
    b) Proportion of readmission data successfully collected as a proportion of those who entered the trial, with reasons for missingness were possible and assumed missing data mechanism.
    c) Proportion of predictor outcome questionnaires completed in total (CTQ-SF) as a proportion of those who entered the trial.

4.9.2 Aim 2: feasibility of implementing the intervention (primary outcome)

Additional descriptive summaries (together with any relevant estimates of variability) are reported to investigate the feasibility of implementing the patient components of the psychological model. The following data addresses feasibility of implementing patient components of the intervention:

1. Number of components delivered.
2. Number of components not delivered, with reasons where possible.
3. Number of sessions (of each component) delivered.
4. Average number of overall sessions received by participants
5. Average number of group sessions received by participants.

6. Average number of individual sessions received by participants.
7. Proportion of participants who self-referred and were referred by ward staff to individual sessions.
8. Number and proportion of participants who engaged.
9. Number and proportion of participants who did not engage (with reasons where possible).

4.9.3 Aim 3: preliminary clinical outcome data

As this study was a feasibility trial and not adequately powered for effective hypothesis testing, no inferential statistical analyses were conducted using the clinical outcome data collected (Arain, Campbell, Cooper, & Lancaster, 2010; Eldridge, Chan, et al., 2016). Underpowered studies can result in biased conclusions because the distribution of the sample estimates is too wide (i.e. estimates are not precise) and replication is unlikely to yield the same estimates (Eldridge, Chan, et al., 2016). Therefore, all analyses were descriptive and exploratory, as opposed to definitive. Descriptive statistics, assessment of whether estimated treatment effects were in the expected direction, and confidence intervals were therefore the main focus of this study, while no formal statistical significance testing was conducted (Eldridge, Chan, et al., 2016; Lancaster, 2015; Lancaster et al., 2004). Specifically, means, standard deviations (SD), change in mean scores (SD) and standardised mean difference (SMD) are presented for continuous outcomes of effect, or medians and interquartile ranges where appropriate. All SMDs were interpreted using Cohen's (1988) guidelines: 0.2 signifies a small effect, 0.5 a medium effect and 0.8 a large effect. Count data, percentages and absolute risk differences are presented for dichotomous outcomes of effect. There is no standardised interpretation of risk difference magnitude. The Scottish Government (2010), however, has previously identified a 10% reduction in readmissions in one year as a meaningful difference, therefore this guided interpretation of risk difference. Additionally, descriptive summaries are reported for adverse event data.

4.9.3.1 Approaches to intervention non-engagement and trial noncompliance

Clinical trials are often burdened with intervention noncompliance and missing outcomes (Dunn, 2013), both of which can result in biased results, and interpretation. In the current study, both exist in the form of non-engaging participants in the intervention group and

loss to follow-up in both groups. Methods used to deal with both are described in the remainder of this section.

Non-adherence

There are two main approaches to the analysis of clinical outcome data: intention to treat (ITT) and per protocol (PP). An intention to treat analysis includes all recruited participants who are compared on the basis of their originally allocated group. It is therefore considered the least biased approach, in that confounding factors remain balanced between groups (Sedgwick, 2015). It is also considered the most pragmatic approach, in that treatment effects reflect real world clinical practice, e.g. treatment non-compliance (Sedgwick, 2015), therefore such analyses are often used in pragmatic trials. In contrast, per protocol analyses include participants who have completed the treatment protocol (i.e. received minimum dose) and the trial protocol (i.e. provided outcome data). This analysis is often used in explanatory trials because the treatment effect is measured more directly, in that the results reflect the effect of the intervention, unaffected by non-adherence and protocol deviations (Dunn, 2013). Nevertheless, per protocol analyses may be biased, as the balance of confounding factors, achieved through randomisation, may no longer be balanced and group differences may be a result of this imbalance, rather than the treatment of interest (Sedgwick, 2015). Furthermore, treatment effects derived from per protocol analyses may not remain when applied in real life.

As this is a pragmatic trial, an intention to treat analysis is suitable. However, after the trial began, an additional exclusion criterion was added (see 'Protocol amendments', page 110): patients were excluded if they were discharged or moved wards within two day of consenting and completing baseline measures. This was included to increase the chances of patients actually receiving the intervention. This is characteristic of an intention to treat analysis as all participants are included according to original groups, regardless of treatment received (Higgins & Green, 2011). However, to maintain transparency of reporting, this analysis is referred to as a modified intention to treat analysis for the purpose of this study because some participants were excluded after giving consent (see 'Protocol amendments' and 'Inclusion/exclusion criteria'). Although modified intention to treat analyses can overestimate the treatment effect (Abraha et al., 2015), this is dependent on the type of modifications made and can be accounted for in the design of a future trial. The **modified intention to treat analysis,** in this trial, aims to descriptively

summarise data and estimate treatment effects, with confidence intervals, for all participants who officially entered the trial.

Although this was a pragmatic trial, a large proportion of participants in the intervention group did not receive the psychological intervention, partly due to unavailability, and little change in ward culture was observed (see consort diagram in Chapter 5 and the 'Protocol amendments' section later in this chapter, page 110, for more detail). This had clear implications for the clinical outcomes collected in the present study, i.e. those who did not directly receive the intervention are unlikely to have benefited. To address non-engaging participants in the intervention group in the current trial, a **per treatment protocol analysis** was conducted to supplement the **modified intention to treat analysis** on all clinical outcome data (i.e. readmission data, questionnaires and adverse event data) in an attempt to directly estimate intervention effects of those who received the intervention as well as the effect of treatment decisions (Dunn, 2013). The **per treatment protocol analysis** aims to descriptively summarise and estimate treatment effects, with confidence intervals, for all participants who officially entered the trial and received the intervention. Therefore, participants in the intervention group who did not receive at least one session of the intervention (non-engaging intervention group) were excluded from the per treatment protocol analysis. The excluded group of non-engaging participants was also not included in the control group for analysis because it is also possible that, being in the intervention ward, they received some benefit from a therapeutically enhanced environment, therefore potentially diluting any effect of treatment.

Analysis of only participants who adhered to treatment (or in this case received at least one session of intervention) is sometimes criticised as the results are likely to reflect the maximum treatment benefit and confounding factors addressed with randomisation may influence treatment outcomes (Sedgwick, 2013c; Dunn, 2013). However, given that this trial was not randomised and did not aim to estimate definitive treatment effects, such limitations were less concerning. Therefore, the addition of per treatment protocol analysis was thought to supplement the modified intention to treat analysis, in that both analyses are more informative for intervention development and designing a future trial. Furthermore, the results of the current study will be interpreted with consideration of these limitations.

To conduct both a modified intention to treat analysis and a per treatment protocol analysis, descriptive summaries of clinical outcome data (i.e. questionnaire data and readmission data) and adverse event data are reported for two intervention groups (one as a subset of the other), and the control group as follows:

1. Intervention modified intention to treat group (i.e. all participants who entered the trial and were in the intervention group).
2. Control group (i.e. all participants who entered the trial and were in the control group)[3].
3. Intervention per treatment protocol group (i.e. participants in the intervention group who received at least one session of psychological intervention, as a subset of 1).

Additionally, the following analyses estimate treatment effects, with 95% confidence intervals for all clinical outcome data (i.e. questionnaire data and readmission data):

1. Primary analysis: control group versus intervention modified intention to treat group.
2. Supplementary analysis: control group versus intervention per treatment protocol group.

Dealing with missing data

Missing data are common in clinical trials, and includes either missing outcomes, e.g. due to non-compliance, drop-out, loss to follow-up, etc., or missing responses within outcomes, e.g. due to patients finding some questions unacceptable or difficulty understanding some questions. Missing data can be problematic because, if ignored, sample size reduces, therefore decreasing the study power, and the benefit of randomisation in RCTs, i.e. balanced confounders, is reduced. Inferences made from the available data cannot be generalised to the entire target population, and the robustness of an intention to treat analysis may be compromised (Dunn, 2013). Investigating patterns of missing data can help identify what group of participants is likely to have missing data or whether particular responses are likely to be missing (Dziura, Post, Zhao, Fu, & Peduzzi, 2013). Three categories are used to identify how data has come to be missing (Little & Rubin, 2002) which have implications for the chosen analysis (Graham, 2009):

[3] As all participants in the control group received treatment, the control modified intention to treat group includes the same participants as the control per treatment protocol group. For ease, this group will only be labelled 'control group'.

Missing Completely at Random (MCAR), Missing at Random (MAR) and Missing Not at Random (MNAR). MCAR is the mechanism where by missing data is assumed to be completely unrelated to any observed or unobserved variables, therefore the chance of missingness is equal between individuals and groups and the complete cases represent all cases originally included (Dziura et al., 2013). Furthermore, where a trial is randomised, the benefit of randomisation, i.e. equally balanced confounders between groups, is not compromised by missingness that is completely random, therefore missingness does not introduce bias in the analysis (Dziura et al., 2013). Such missing data is considered ignorable (Graham, 2009), but is rare. When data are considered to be MAR, recorded variables are accountable for differences in the distribution of missing variables for observed and missing cases, i.e. missingness is related to observed variables but not unobserved or missing variables (Dziura et al., 2013), therefore missingness is conditional (Graham, 2009). Depending on the amount of missing data, this mechanism is considered ignorable as unbiased estimates can be obtained (Graham, 2009). Methods to handle data that are MAR, however, are recommended to minimise bias in estimated parameters and maintain study power (Graham, 2009). MNAR refers to missing data where missingness is related to unobserved variables (Dziura et al., 2013). Such missingness is non-ignorable because it is likely to produce biased estimates if not dealt with appropriately in the analysis (Graham, 2009). To produce unbiased results, statistical modelling is required to relate outcomes of interest and the probability of non-response (Dziura et al., 2013). These techniques may be considered beyond the scope of a feasibility trial, because the aim of this type of trial is not to provide a definitive assessment of treatment effects, and is unlikely to have sufficient power to allow these analyses.

Imputing missing values in questionnaires

Associated guidelines were used to impute missing questionnaire values where possible. Such guidelines, and methods used where guidelines were not available, are now described. Missing values of the BSI-18 were imputed as recommended by the scoring manual (Derogatis, 2001). Each participant's subscale score can be computed if four or more items have been answered (i.e. 2 missing values per subscale). Therefore, the BSI 18 can be computed with up to 6 missing values across 3 subscales. Where a participant's questionnaire has missing values within these specified limits all subscales and overall score can be calculated. To do so the values for all items responded to were summed and divided by the number of answers completed. This value was then rounded to the nearest

whole number and substituted for each of the missing items (<0.5 round down; > or equal to 0.5 round up). Missing values of the CORE-10 were also imputed as recommended by the user manual (Connell & Barkham, 2007). Where one value is missing the clinical score (i.e. total score) can be calculated using the total mean score (i.e. the total score is divided by the number of completed items). These methods of imputation were considered appropriate for the current study because 1) they are parsimonious, 2) they allow for complete case analysis to be carried out, whilst maintaining sample size and power, 3) they minimise disadvantages associated with mean-imputation and last observation carried forward such as underestimated variability (Dziura et al., 2013), because imputed values are participant specific (and subscale specific for the BSI-18). Furthermore, this follows the scale recommendations and enables standardization of use of the scale across all experiments.

No guidelines for handling missing values were provided by the MHCS, therefore mean individual imputation was also used to impute missing values. Mean individual imputation has been shown to be a reliable method of imputation in self-report measures of depression but a simpler method than others, e.g. multiple imputation (Shrive, Stuart, Quan, & Ghali, 2006) and was therefore considered an appropriate method.

Missing outcomes

Preliminary outcome data for this study was collected via questionnaires or from electronic medical files, both of which had missing data. To maintain sample size, missing data were imputed using multiple imputation in SPSS 23 (IBM, 2016) and the imputed dataset was descriptively analysed under the assumption that data are missing at random (MAR) (Little & Rubin, 2002). Reasons for assuming MAR are described in the Chapter 5. Multiple imputation uses all available data to obtain multiple possible values for each missing observation, and then combines all possible values (Graham, 2009). This method has been shown to produce unbiased estimates of treatment effects under the assumption that data are MAR (Dziura et al., 2013), and was therefore considered suitable for the current study. The multiple imputation model included the following variables: total inpatient days (during follow-up), number of intensive home treatment team episodes, number of A&E episodes, length of index admission stay, gender, diagnosis, readmissions during follow-up, all questionnaire questions and group allocation. Some of these were auxiliary variables (i.e. they inform estimations of incomplete data but are not part of the main analysis) and some were outcome variables. As per recent

recommendations, 50 imputations were used to match the percentage of missing data (Lee, Roberts, Doyle, Anderson, & Carlin, 2016) and non-normal variables were entered unmodified (von Hippel, 2013).

Where a large percentage (approximately 50%) of data was missing, a sensitivity analysis was conducted to assess the robustness of the missing data assumption. The sensitivity analysis excluded imputed data under the assumption that data were missing completely at random (MCAR) (i.e. complete case analysis) (Dziura et al., 2013).

Although no data were thought likely to be missing as a result of the intervention, sensitivity analysis to investigate the robustness of the results when data were analysed under the assumption that data were missing not at random (MNAR) was judged to be beneficial. However, to obtain unbiased results under the assumption that data are MNAR, advanced statistical methods are recommended (Dziura et al., 2013; Little et al., 2012). The current study was not adequately powered for such statistical methods. Detail of analyses planned for all preliminary clinical outcome data are described below.

4.9.3.2 Effect

Readmission data

Descriptive summaries (n (%)) and estimated treatment effect and 95% CI for number of readmissions, were reported. Additionally, descriptive summaries (median (IQR)) and estimated treatment effect and 95% CI were reported for total number of inpatient days during the follow-up period will. These results were used to investigate whether these outcomes indicated change in the predicted direction, i.e. favouring the intervention.

Questionnaire data: psychological distress and mental health related self-efficacy

Descriptive summaries (means (SD)) were reported at pre-intervention, post-intervention and 6-month follow-up. Additionally, to estimate treatment effect and 95% Cis, mean change was calculated from baseline to post-intervention and from baseline to 6-month follow-up between groups. Mean change was used, rather than post-intervention, to account for pre-intervention differences. This was used to investigate whether the chosen outcome measures produce change in the expected direction and will be used to inform clinical outcomes for a future definitive trial.

4.9.3.3 Adverse events

Descriptive summaries (n (%)) are reported for each measure of safety (i.e. contact with the Intensive Home Treatment Team (IHTT), contact with A&E, not discharged from index admission at follow-up and deaths (related to mental health). It should be noted that IHTT contact relating to initial discharge was not included as this is often routine practice. If a participant was readmitted and received input from IHTT again following discharge, the readmission itself was recorded but not the contact with IHTT as this would count the adverse event twice.

4.9.4 Aim 4: summarise and assess the findings of this feasibility study

As recommended by Bugge et al. (2013), data collected for aims one to three were presented using Shanyinde, Pickering and Weatherall (2011) as an analytical framework to highlight the extent to which this study addressed each issue, and to examine the type of problems encountered during the trial, i.e. relating to the trial, the real world or both. This maps onto stage one (of three) of the ADePT (a process for decision-making after pilot and feasibility trials) process (Bugge et al., 2013). Stages two and three of the ADePT process are addressed in Chapter 6.

4.10 Intracluster correlation coefficient (ICC)

Similarities between patients within each ward are expected, therefore variability of treatment effects within each cluster (ward) is reduced (Eldridge & Kerry, 2012; Medical Research Council, 2000). An ICC is sometimes estimated from a feasibility trial when there is sufficient data. This calculation compares within-group variance to between-group variance and is used to account for the effect of clusters in sample size calculations and analysis of trial data (Eldridge & Kerry, 2012). However, ICC estimations can often be imprecise, especially when calculated using pilot/feasibility data (due to the small size of pilot/feasibility studies and non-randomised sample of clusters). Data from the current feasibility trial were not used because few clusters were included (k=2), and clusters were not randomised. The included clusters are unlikely to represent a random sample of the population of clusters, and ICCs calculated using data from such clusters are unlikely to represent the true variation of the cluster population (Eldridge & Kerry, 2012). No ICC has previously been published for an acute mental health inpatient environment with a binary outcome (i.e. number of readmissions), therefore a relevant ICC was calculated in this study using other sources (Eldridge & Kerry, 2012). There is evidence to suggest that

ICC calculations vary depending on outcome, setting, prevalence (of event in a binary outcome), size of a cluster (based on the context) and type of measurement (Campbell, Fayers, & Grimshaw, 2005). Relevant, existing ICC estimates were used to calculate an appropriate ICC for a future definitive trial and are reported in section 5.1 in Chapter 5.

4.11 Sample size calculation for a definition trial

Clinical outcome data collected during pilot/feasibility studies are often used to calculate the sample size for a larger main trial, however this is not recommended if the study is underpowered to accurately estimate such parameters (Eldridge et al., 2016). As this study was not adequately powered to accurately estimate treatment effects, the required sample size for a future definitive trial could not be confidently calculated based on these parameters. Instead, this calculation was based on a meaningful change in readmissions identified by the Scottish Government: 10% reduction in one year (Scottish Government, 2010), using G-Power (version 3.1.9.2) (Faul, Erdfelder, Lang, & Buchner, 2007). The effect of cluster randomisation was also accounted for in the calculation (see ICC section above) (Eldridge & Kerry, 2012, section 7.2). The only data from the current feasibility trial used to calculate sample size was related to attrition. The calculation is reported in section 5.1 in Chapter 5.

4.12 Ethical approval

Ethical approval was provided by Edinburgh Napier University and NHS Lothian (REC No: 15/SS/0093) (see appendices).

4.13 Registration

The trial protocol was registered, before recruitment began, on a publically accessible database (researchregistry509). Amendments made after original ethical approval and registration of the trial protocol are detailed in the 'Protocol amendments' section (below).

4.14 Protocol amendments

After original ethical approval and registration of the trial protocol (researchregistry509), amendments were made to the study. Important changes are discussed at length in this section, followed by a list of other amendments.

The first important amendment was made to the aims of the study. The original aims of the thesis were to assess whether the addition of psychological intervention to TAU was more effective than TAU alone with regards to reducing readmissions, reducing psychological distress and increasing mental health related self-efficacy. An additional aim was to investigate the role of childhood trauma as a predictor of treatment outcome. However, in light of newly developed conceptual frameworks that define and guide reporting of pilot and feasibility trials (Eldridge, Chan, et al., 2016; Eldridge, Lancaster, et al., 2016; Lancaster, 2015) it became clear, during the course of this PhD research, that the original aims and proposed methodology were ambitious and beyond the scope of this study. According to Eldridge, Lancaster, et al., (2016), the current study fitted under the umbrella term of 'feasibility studies'. As some aspects of a larger trial were also implemented in this study, e.g. gathering preliminary clinical outcome data (and predictor outcome data) and implementing the intervention, it may also fall into Eldridge, Lancaster, et al.'s (2016) subcategory of non-randomised pilot trials. However, as the primary aims are to determine the feasibility of implementing the intervention and the feasibility of evaluating it in a future larger trial, the current study is referred to as a feasibility study, therefore mapping onto phase two of the MRC framework for developing and evaluating complex interventions (Craig, 2012; Craig et al., 2008). Roll-out of the psychological intervention as planned was challenging, suggesting that the model is in early stages of development and evaluation. Consequently, the aims and outcomes of the trial were re-specified (see 'Specific aims' section, page 71) according to the CONSORT guidelines for pilot and feasibility trials (Eldridge, Chan, et al., 2016) prior to analysis. Redefining the aims was deemed important and informative to guide a future, adequately powered, definitive trial of this intervention (Lancaster, 2015). Changing the aims, and therefore the outcomes, of a study is often considered a concern as it increases the risk of bias, for example due to selective reporting (Higgins & Green, 2011). However, in reporting all amendments in the current study, the decision to make changes remains transparent and is therefore in keeping with the open science framework.

A limitation related to changing the current design from a proposed effectiveness trial to a feasibility trial during the study period is that important feasibility data may not have been recorded. For example, it is recommended that data such as recruitment rates, retention rates, refusal rates, etc. (see Thabane et al., (2010) for more examples) should be recorded during the feasibility phase. Accordingly, a variety of feasibility data were

recorded throughout the study, however it became apparent during the study that other useful data was not, i.e. reasons for not participating in the study or engaging with the intervention and acceptability of the intervention and trial processes. These issue will be discussed further later in the thesis (Chapter 6).

The second important post registration amendment was the addition of per treatment protocol analyses (i.e. excluding participants in the intervention group who did not receive the intervention), with the following rationale. A large proportion of participants in the intervention group did not receive the psychological intervention (see consort diagram in results and amendments to trial section for more detail). Additionally, through direct observation, it was evident that ward staff involvement in co-facilitating and facilitating the groups was slow and in some cases absent. The ward psychologist facilitated group sessions where possible, however due to other commitments (i.e. individual sessions) delivery relied heavily on ward staff. Unfortunately, there was no protected time for ward staff to deliver groups, therefore given the busy nature of an acute inpatient ward staff few group therapies were delivered: only three group rolled out (rather than four), and some weeks no groups were delivered. Furthermore, a number of staff who attended relevant psychological training (i.e. CBT and MBT staff training, see intervention section for more detail) left the ward and were replaced by staff who had not attended psychological training. The absence of ward staff involvement in group delivery, along with few psychologically trained staff suggested culture change had not taken place yet and it was likely that a psychological milieu had not yet been adopted. This had clear implications for the clinical outcomes collected in the present study. For example, under the assumption that ward culture and environment had not changed (i.e. become more therapeutic) it is unlikely that inpatients who did not attend psychological groups or individual sessions would have benefited from the intervention. Thus, although pragmatic, an intention to treat analysis is likely to underestimate treatment effects (Dunn, 2013). For this reason, it was decided that the descriptive analysis in which all participants who formally entered the study are included, should be supplemented by a descriptive analysis in which participants in the intervention group who did not engage with the intervention are excluded (see ‘Analysis plan’ section for details, page 100).

Other post-registration amendments include:

1. Withdrawal of secondary outcome measures, including locus of control (LCB) and mindfulness (FFMQ) questionnaires, to reduce patient burden and increase

recruitment. This amendment was put in place before recruitment after discussions with charge nurses on the ward, who advised that less questionnaires were likely to be more manageable for patients, therefore improving recruitment.

2. 6-month follow-up instead of 12-month follow-up assessment was carried out due to time limitations. This decision was driven by slow recruitment. Recruitment time was extended in order to increase sample size.
3. Although aiming to keep the study as pragmatic as possible, additional inclusion/exclusion criteria were added after recruitment began. First, in order to maintain safety in the conduct of the study, patients were not deemed eligible for participation if presenting unsafe behaviour, i.e. severe hostility/aggression or sexually uninhibited behaviour towards staff. Second, participants were excluded from study if discharged or moved wards (to either the other participating ward or a non-participating ward) within 2 days of giving consent and completing baseline questionnaires in order to reduce the effect of participants not receiving the intended intervention. This will be considered in the design of a larger definitive trial to avoid exclusions after randomisation.
4. Only three groups ('Anxiety and Stress Management', 'Living Well with Emotions' and 'Being Friends with Yourself'), rather than four groups, were run when possible due to limited resource for group delivery (see discussion above).
5. In order to account for limitations associated with number of readmissions between groups as an outcome (see 'Clinical outcomes' section for more detail), additional planned data collection to estimate the number of readmission days (median number of days with IQR) between groups were also added as outcomes related to readmission, after registration of the trial.
6. In accordance with the change in study aims (described above) the sample size required for the current study was recalculated after the study began. The target sample size changed from 160 to 150 participants.

5 Feasibility study findings

The aim of this chapter is to present data from the feasibility study and to highlight the extent to which key methodological issues, defined by Shanyinde, Pickering and Weatherall (2011), were addressed by this study. The results are reported in accordance with such methodological issues and are summarised in Table 24 (page 139).

5.1 Sample

Sample size of current study

The CONSORT diagram (Figure , page 116) presents the flow of participants through the study and the intervention received. The target sample size for this feasibility study was 150. Due to the time restrictions of this PhD and a lower than anticipated consent rate, only 96 participants were able to be recruited.

Sample size calculation of a future definitive trial

The intracluster correlation coefficient (ICC) was calculated using ICCs previously calculated for a number of relevant outcomes and settings. The median ICC for secondary care settings (e.g. acute psychiatric services) has previously been calculated as 0.061, for clinical or participant related outcomes as 0.030, for binary outcomes with a prevalence of 29-63.4% as 0.089, for a sub-unit in a hospital (e.g. one ward in a hospital service) as 0.080 and for objectively measured outcomes (such as readmissions) is 0.053 (Campbell et al., 2005). The average ICC for a cluster RCT with these characteristics and with a binary primary outcome (i.e. proportion of readmissions) was therefore calculated as 0.063.

The Scottish Government identified a meaningful reduction in readmissions as 10% in one year (Scottish Government, 2010). Based on this target, an individually randomised definitive trial would require recruitment of 808 participants (404 in each group, 80% power, 5% significance level, two-tailed) to detect a 10% change in the primary outcome measure (proportion of readmissions). The design effect was calculated as 4.528, based on an intra-class correlation coefficient of 0.063 (see ICC section) and an average cluster size of 56.5 (i.e. 57) (based on the average number of participants recruited to each cluster in this trial (allowing 12 months for recruitment)). The total sample size calculated was 1829, with an average of 32 clusters. To account for 10% attrition in the primary outcome,

observed in this feasibility study (see attrition section later in this chapter), 2012 participants should be recruited between 36 clusters within 12 months. In any future definitive trial, the services of a registered Clinical Trials Unit would be engaged and a dedicated statistician would check and advise further.

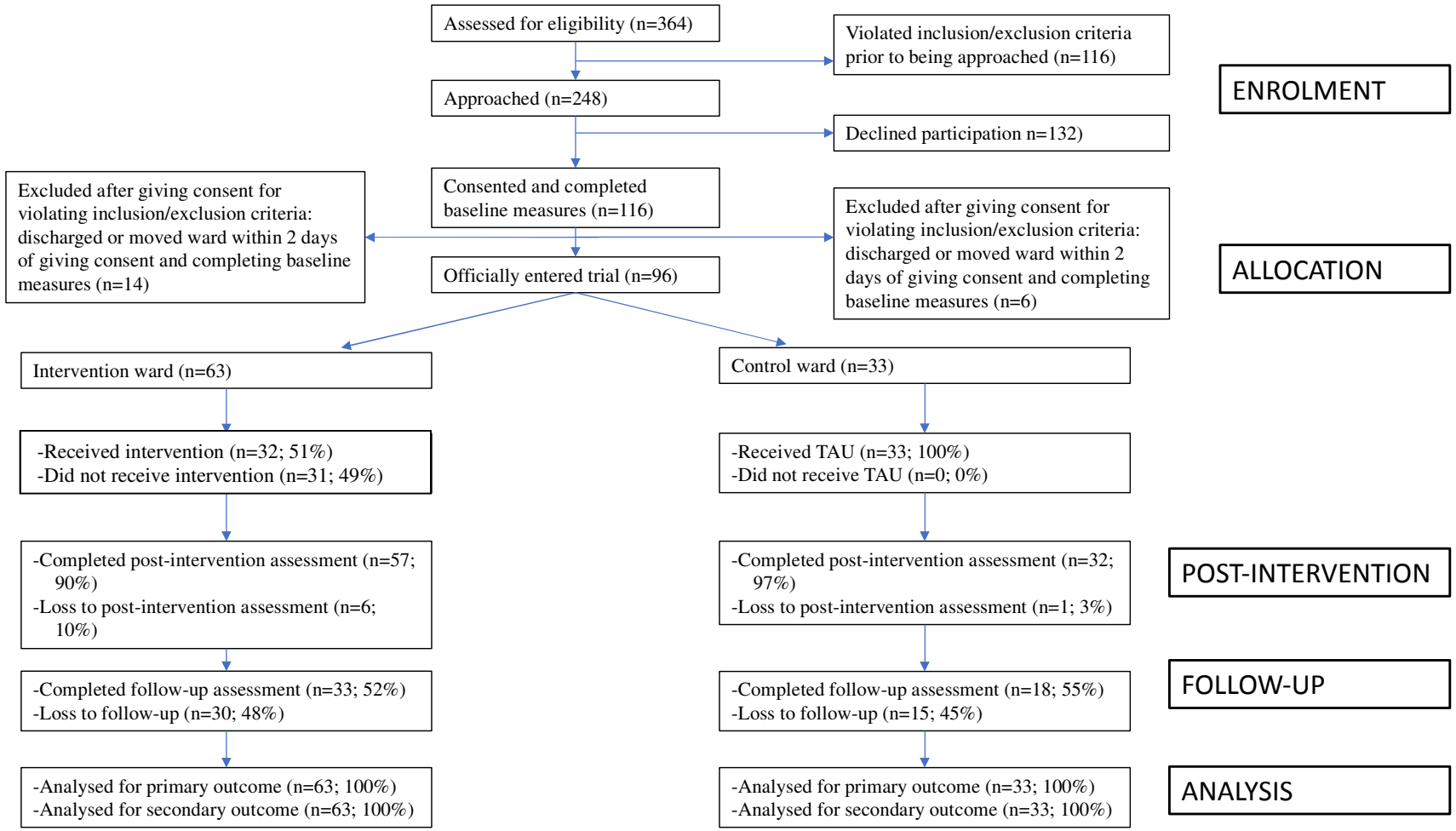

Figure 8 CONSORT flowchart through feasibility study

5.2 Eligibility

Participants

Between October 2015 and October 2016 364 people were screened for eligibility and 248 initially met eligibility criteria. The initial eligibility rate was 68%. As seen in Figure 8, a further 20 people were excluded after consenting to participate and completing baseline measures, therefore the overall eligibility rate was 63%. Reasons for ineligibility are presented in Table 9 (below). 27% of participants were excluded because staff anticipated their admission to the study ward would be less than three days. However, when staff misjudged admission length or where anticipated length of stay changed due to unforeseen circumstances, some initially eligible patients were excluded. The proportion of participants wrongly excluded was not directly measured. Participants were also excluded after consenting to participate and completing baseline measures (15%) if they moved wards or were discharged within two days of doing so.

Table 9
Reasons for ineligibility (as judged by ward staff)

Criteria for exclusion	**n %**
Not classed as 'stabilised' by ward staff (i.e. too distressed/unwell or likely to find questionnaires too distressing)	27 (20%)
Not able to complete questionnaires (e.g. due to impaired attention/distracted)	12 (9%)
Unlikely to be admitted for more than 3 days (discharged or moving wards)/discharged before able to meet for baseline assessment	36 (27%)
Diagnosis of moderate to severe learning disability, dementia or organic mental disorder	6 (4%)
Presented unsafe behaviour (violent or sexually inappropriate)	12 (9%)
Did not speak English	3 (2%)
Not available to meet on ward (i.e. in medical hospital/on pass/sleeping and asked not to be disturbed, with visitors, with medical team, with occupational therapist)	18 (13%)

Delayed discharge[1]	2 (1%)
Excluded after consenting to participate and completing baseline measures due to being discharge or moving wards within 2 days of doing so	20 (15%)
Total	136 (100%)

1. Delayed discharge refers to patients who are admitted but are considered well, e.g. waiting for appropriate accommodation on discharge, or waiting for available bed in another service.

Clusters

As the main aim of this study was to pilot and test the feasibility of implementing and evaluating the intervention, few clusters (i.e. acute psychiatric inpatient wards) were considered for inclusion (k=3). Initially, two clusters were considered and asked to participate, both of which agreed. However, one was then excluded due to other therapeutic input. A third cluster was invited and agreed to participate. Cluster inclusion/exclusion criteria remained broad, which resulted in clinical context differences between included wards. For example, patient care pathways differed between wards in that psychiatrists in the control ward worked consistently with patients, whether treated in hospital or in the community, while psychiatrists in the intervention ward were resident psychiatrists, therefore patients in the intervention group received input from different psychiatrists, depending on whether they were admitted or not.

5.3 Recruitment

A reasonable number of participants were recruited for the trial, but recruitment was labour intensive and slower than anticipated. Six months were initially allocated to recruitment, however due to slow recruitment this period was extended to 12 months to increase the sample recruited for this study. Participants were recruited between October 2015 to October 2016 from the control ward and between October 2015 and October 2016 from the intervention ward. All participants were recruited by one full time researcher. Of the 116 participants who consented and completed baseline measures, 96 officially entered the study (83%): 63 were recruited from the intervention group and 33 from the control group. The other 17% did not officially enter the trial because they violated post hoc inclusion/exclusion criteria after consenting and completing baseline measures (see eligibility section and Figure 8). It should be noted that the difference in sample size between groups reflects the time spent recruiting each group rather than more acceptability in either group. The average number of participants recruited from one ward

per month was four. No participants responded to the poster advertisement. All participants were recruited in person.

5.4 Consent

Participants

A proportion of 47% of patients deemed eligible to participate consented to participate in the study. No participants withdrew consent after this point. Reasons for not consenting were recorded where possible, however this trial did not have ethical approval to formally ask patients for reasons. Although not formally measured, anecdotal evidence regarding refusal to participate was recorded where possible. One patient felt that participating in the study would be 'too much', one patient refused participation because they felt 'uncomfortable being part of a study', two patients had concerns that if they completed questionnaires medical staff may think they were ill, one patient told the researcher that their concentration was too poor to complete questionnaires, one participant reported they were 'not the right person', one patient refused because their experience was too personal to share, one patient refused because they were 'not just an experiment' and one patient felt that 'ticking boxes doesn't explain how I feel'.

Clusters

All ward charge nurses (i.e. of each cluster) asked to take part in this trial gave consent.

5.5 Randomisation procedures

Neither participants nor clusters were randomised.

5.6 Blinding procedures

Participant and personnel blinding was not possible in this study due to the nature of the intervention. Assessors were also not blind to trial arm due to limited resource of the study, namely there were no funds available to employ an independent outcome assessor.

5.7 Implementation of and engagement with the intervention

5.7.1 Implementation

Some components of the intervention were well implemented, while others were not. Over the study period a total of 133 therapy sessions (group and individual) were

delivered to 32 participants. Participants received a median of 3 sessions in total (IQR=4). Individual sessions were implemented well in this trial. A total of 105 individual sessions ('Emotion focused formulation') were delivered to 16 participants. Participants received a median of 3.5 sessions (IQR=4). Of the 16 participants who received individual sessions, 5 (31%) self-referred and 11 (69%) were referred by ward staff.

Group components were poorly implemented in this study. According to the intervention, four different group therapies should be delivered to patients each week. If implemented as planned, approximately 208 group sessions should have been delivered during the study period (12 months). In practice, only three of the four group sessions were implemented, and a total of 28 group sessions were delivered overall. 20 participants received a median of 2 group sessions (IQR=2). 15 emotion regulation groups ('Living well with emotions'), 4 anxiety management groups ('anxiety and stress management') and 9 compassionate mind groups ('Making friends with yourself') were delivered. The hearing voices group was not implemented during the study period due to limited resource for delivery. Resource from the clinical psychologist and advanced nurse practitioner was primarily used for individual sessions, and nursing staff reported having little time for group delivery after completing usual ward tasks.

5.7.2 Engagement with the intervention

Patient engagement

Patient adherence to the intervention and treatment attrition was challenging to measure due to the flexible nature of the intervention (i.e. patients could attend as many or as few sessions as they wish). Instead, participant engagement was recorded and defined as attending at least one group or individual session. Of the 63 participants in the intervention group, only 32 (51%) engaged with the psychological intervention. Reasons for not engaging in the intervention were not directly and systematically recorded, however reasons were recorded where possible and are reported in Table 10 (below). Ten (16%) participants in the intervention group expressed interest but were unable to engage in the intervention due to limited resource or unexpected discharge. Comparison of engaging and non-engaging participant characteristics is reported in the 'Baseline symptom severity and sample characteristics' section.

Table 10
Number of participants not engaged in the intervention with reasons where possible

Reason for not engaging in psychological therapy		**N (%)**
Did not provide a reason		20 (31%)
Made appointment but did not attend		1 (1%)
Did not think it would help		1 (1%)
Expressed interest but did not attend	Discharged while on waiting list for individual session	5 (8%)
	Discharged before next scheduled group session	5 (8%)
Total number of participants not engaging in the intervention		31 (49%)

Staff engagement

Staff engagement was not directly investigated in this study. However, poor group implementation suggests poor staff engagement. According to the intervention, once appropriately trained, staff should facilitate group components. Although not directly measured, few staff did so. Reasons for not engaging were not formally recorded, however it was observed that staff lacked confidence and time during shifts to deliver groups. Furthermore, many staff who had received the relevant psychological training left the ward during the study period, resulting in fewer staff who were able to facilitate groups. Lack of adequately trained staff was a barrier to consistent group implementation in combination with staff sickness and inflexible rotating staff rotas (i.e. shift patterns tended to be a block of day shifts followed by a block of night shifts). Future steps to address staff adherence in a future trial are considered in Chapter 6.

5.8 Acceptability of intervention

Acceptability of the intervention was not formally measured in this study. However, 16% of participants in the intervention group expressed an interest in receiving it, but did were unable to due to being discharged while on a waiting list. This data suggests that there is some demand for the intervention. Further investigation of intervention acceptability is considered in Chapter six.

Table 11

Completion rate of each outcome measure at each time point (n (%))

Group	Pre-intervention			Post-intervention			6-month follow-up			Readmissions (dichotomous and continuous)	CTQ-SF
	CORE-10	BSI-18	MHCS	CORE-10	BSI-18	MHCS	CORE-10	BSI-18	MHCS		
Intervention (n=63)	63 (100%)	62 (98%)	63 (100%)	57 (90%)	56 (89%)	57 (90%)	33 (52%)	32 (51%)	33 (52%)	58 (92%)	38 (60%)
Control (n=33)	33 (100%)	33 (100%)	33 (100%)	32 (97%)	32 (97%)	32 (97%)	18 (55%)	18 (55%)	18 (55%)	30 (91%)	23 (70%)
Total (n=96)	96 (100%)	95 (99%)	96 (100%)	89 (93%)	88 (92%)	89 (93%)	51 (53%)	50 (52%)	51 (53%)	88 (92%)	61 (64%)

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

5.9 Cost of intervention

No economic evaluation was carried out with this study.

5.10 Completion of outcome measures

Outcomes measured in this study included questionnaires, regarding patient psychological distress and mental health related self-efficacy, and electronic medical data regarding acute inpatient readmissions. Completion rates and associated missing data mechanisms of all outcomes are as follows.

Completion rates of pre- and post-intervention were very good (92-100%). Overall, seven participants (7%) provided no questionnaires at post-intervention. Four of the participants (4%) were discharged quickly and were unable to be met before, or contacted after, and were lost to follow-up. This represents the unpredictable nature of an acute inpatient ward and the related challenges of data collection within this environment. Such missing data was assumed to be MCAR. Three participants (3%) declined assessment without giving a reason. There was no reason to think this was due to the intervention, as the intervention was well received, therefore such data was assumed to be MAR. One participant in the intervention group also chose not to complete the BSI-18 due to its similarities to the CORE-10 and was assumed to be MAR. While patterns of missing values in questionnaires were investigated, no patterns of missingness emerged in pre- or post-intervention questionnaire data. One notable pattern, however, was identified in follow-up questionnaire data: a large proportion of participants failed to complete all questionnaires at follow-up (51-55%, depending on the questionnaire and group) (see Table 11, above). Missingness was of even proportions across groups and questionnaires, therefore supporting the assumption that data were MAR. Reasons for missing questionnaires at follow-up and assumed missing data mechanisms are reported in Table 12 (below).

Readmission data were available for 92% of participants (n=88). Reasons for missing readmission data and related missing data assumptions are presented in Table 13 (page 125).

Completion rate of the predictor outcome (CTQ-SF) was calculated overall and for each group at 6-month follow-up. A proportion of 64% of participants completed the CTQ-SF. Reasons for non-completion were not recorded.

While the chosen outcomes are relevant to the aims of the intervention, other relevant outcomes were not measured in the current study, but could be considered in a future definitive trial. For example, the intervention also aims to improve outcomes for staff, e.g. staff burnout and staff understanding of patient problems, and it aims to improve the milieu. Appropriate tools could be used to measure such outcomes in future.

Table 12

Number and proportion of participants missing all follow-up questionnaires per group (n (%)) with reasons

Reason	Group		Total (n=96)	Assumed missing data mechanism
	Intervention (n=63)	Control (n=33)		
No contact number recorded/no CPN	5 (8%)	1 (3%)	6 (6%)	MAR
Number available but could not contact[1]	8 (13%)	5 (15%)	16 (17%)	MAR
Successfully contacted but unable to contact again[2]	4 (6%)	1 (3%)	5 (5%)	MAR
Declined	10 (16%)[3]	5 (15%)[4]	15 (16%)	MAR
Moved out of country/area	4 (6%)	1 (3%)	5 (5%)	MCAR
Died	0 (0%)	2 (6%)	2 (2%)	MCAR/MAR
Total	31 (49%)	15 (45%)	46 (48%)	MCAR/MAR

Community psychiatric nurse (CPN); Missing at random (MAR); Missing completely at random (MCAR).

1. Unable to contact via recorded contact number, via contact number given by participant or via CPN or other healthcare professional.
2. Successfully contacted and organised meeting for follow-up assessment (in person or via telephone) however participant was unable to be contacted again, e.g. at time of arranged telephone meeting or otherwise.
3. Reasons given for decline in intervention group: did not want to be reminded of admission (n=2), CPN said no on participants' behalf (n=2), too busy (n=1), no reason given (n=2), not feeling well (n=1), family member said no on participants' behalf (n=1), too physically unwell (n=1).
4. Reasons given for decline in control group: did not want to be reminded of admission (n=1), too busy (n=1), no reason given (n=2), too unwell (n=1).

Table 13

Number of participants missing readmission data per group (n (%)) with reasons

Reason		Group: Intervention N=63	Group: Control N=33	Total N=96	Assumed missing data mechanism
Moved to an area or country linked to a different health board		4 (6%)	1 (3%)	5 (5%)	MCAR
Died	Relating to mental health	0 (0%)	1 (3%)	1 (1%)	MAR
	Not relating to mental health	0 (0%)	1 (3%)	1 (1%)	MCAR
Not discharged from index admission		1 (2%)	0 (0%)	1 (1%)	MAR
Total		5 (8%)	3 (9%)	8 (8%)	MCAR/MAR

Missing at random (MAR); Missing completely at random (MCAR).

5.11 Outcome assessments (clinical outcome results)

In this section, baseline symptom severity and sample characteristics are presented (Table 14 and Table 15, page 126 and 127). Descriptive statistics are reported for all between group outcomes such as mean change (SD) and frequencies (%). Hedge's g and absolute risk difference with 95% confidence intervals were calculated for between group differences. All data were analysed in SPSS (version 23). The main analysis of between group differences was done under modified intention to treat (mITT) principles. A per treatment protocol (PtP) analysis is also reported to supplement the main analysis (see Chapter 4 for further detail). As data MCAR can be treated as MAR (Dziura et al., 2013) all data were analysed under the assumption that data are MAR. However, a large percentage of questionnaire data was missing at follow-up (see section 5.10). Sensitivity analysis was conducted to assess the robustness of missing data assumptions. All outcomes including follow-up questionnaires were reanalysed under the assumption that data is MCAR, therefore missing data was ignored (i.e. a complete case analysis). Sensitivity analysis was not conducted on outcomes not including follow-up questionnaire data because missingness was minimal (see section 5.10).

Table 14

Summary of sample characteristics

Characteristic		Intervention (mITT) (n=63)	Control[1] (n=33)	Total (n=96)	Intervention (PtP) (n=32)[2]	Intervention non-engagers (n=31)[2]
Gender (n (%))	Male	35 (56%)	12 (36%)	47 (49%)	17 (53%)	18 (58%)
	Female	28 (44%)	21 (64%)	49 (51%)	15 (47%)	13 (42%)
	Total	63 (100%)	33 (100%)	96 (100%)	32 (100%)	31 (100%)
Diagnosis (n (%))	Bipolar (manic)	13 (21%)	10 (30%)	23 (24%)	6 (19%)	7 (23%)
	Bipolar (depression)	4 (6%)	2 (6%)	6 (6%)	2 (6%)	2 (6%)
	Personality disorder	6 (10%)	5 (15%)	11 (12%)	2 (6%)	4 (13%)
	Depression	11 (18%)	8 (24%)	19 (20%)	6 (19%)	5 (16%)
	Schizophrenia and psychosis	29 (46%)	8 (24%)	37 (39%)	16 (50%)	13 (42%)
	Total	63 100%	33 (100%)	96 (100%)	32 (100%)	31 (100%)
Age (M, SD)		43.03 (12.34)	44.03 (9.59)	43.38 (11.43)	40.75 (13.17)	45.38 (11.15)
Previous admission (n, %)		37 (59%)	20 (61%)	57 (59%)	17 (53%)	20 (65%)
LOS (median, IQR)		34.50 (48.75)	24.00 (29.50)	28.00 (44.00)	35.00 (63.00)	33.00 (38.00)

Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

1. As all participants in the control group received treatment, the control group includes the same participants whether mITT ot PtP. For ease, this group will only be referred to as control group.
2. As a subgroup of intervention (mITT).

Table 15

Summary of baseline symptom severity

Outcome measure		Intervention (mITT) (n=63)	Control[1] (n=33)	Total (n=96)	Intervention (PtP) (n=32)[2]	Intervention non-engagers (n=31)[2]
Baseline CORE-10 (M, SD)	Total score	21.63 (10.44)	22.27 (10.56)	21.85 (10.43)	22.72 (9.65)	20.52 (11.25)
	Problems	14.40 (6.95)	15.12 (7.25)	14.65 (7.02)	15.09 (6.58)	13.68 (7.34)
	Functions	5.70 (3.31)	5.45 (3.04)	5.6 (3.21)	6.16 (3.04)	5.23 (3.56)
Baseline BSI (M, SD)	Total	34.56 (20.69)[3]	37.88 (19.76)	35.37 (20.30)[4]	37.06 (20.39)[5]	32.06 (21.01)
	Somatization	8.76 (6.94)[3]	9.33 (6.70)	8.96 (6.83)[4]	10.03 (7.45)[5]	7.48 (6.24)
	Depression	12.61(8.17)[3]	13.94 (8.48)	13.07 (8.26)[4]	13.29 (8.06)[5]	11.94 (8.35)
	Anxiety	13.21 (8.28)[3]	13.88 (6.97)	13.44 (7.82)[4]	13.84 (7.83)[5]	12.58 (8.80)
MHCS[6] (M, SD)	Total	54.63 (23.60)	58.94 (24.82)	56.11 (23.98)	52.84 (22.06)	56.48 (25.32)
	Optimism	21.41 (9.23)	23.06 (9.63)	21.98 (9.35)	21.78 (8.35)	21.03 (10.18)
	Coping	22.16 (10.94)	22.15 (11.69)	22.16 (11.14)	22.09 (10.46)	22.23 (11.59)
	Advocacy	12.14 (4.83)	13.09 (4.72)	12.47 (4.79)	11.16 (4.68)	13.16 (4.85)

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

1. As all participants in the control group received treatment, the control group includes the same participants whether mITT ot PtP. For ease, this group will only be referred to as control group.
2. As subgroup of intervention (mITT).
3. N=62 (one participant chose not to complete the BSI-18 due to similarities with the CORE-10).
4. N=95 (see 3).
5. N=31 (see 3).
6. Lower score indicates higher severity.

5.11.1 Baseline symptom severity and sample characteristics

Table 14 and Table 15 (page 126 and 127) present baseline symptom severity and sample characteristics for the intervention group, the control group and the total sample. As seen in table 14, psychosis and schizophrenia was slightly more prevalent in the intervention group, however why this way the case is unknown. Symptom severity appears to be slightly worse in the intervention group (PtP) compared to the intervention non-engagers group (see table 15). This may be due to a small bias towards more severely ill patients to receive treatment, however, the difference is small. There were little group differences on other measures of baselines symptom severity and sample characteristics.

5.11.2 Outcomes

5.11.2.1 Readmissions

Within the modified intention to treat analysis, readmissions were slightly lower in the intervention group (18/63 (29%)) compared to the control group (11/33 (33%)). This corresponds with an absolute risk difference of -5% (95% CI: -24%, 14%), indicative of a direction of effect (if weak) necessary to take forward feasibility work to a future trial. However, a smaller, and more precise, difference is observed between the intervention group and the control group when data is analysed under per treatment protocol principles (10/32 (31%), 11/33 (33%), respectively), relating to an absolute risk difference of -2% (95% CI: -24%, 0%).

When analysed as modified intention to treat, the mean days spent readmitted was similar in the intervention group (m=11.34, SD=14.55) and the control group (m=11.46, SD=15.02). This similarity corresponds with no treatment effect (Hedge's g=-0.01, 95% CI -0.43, 0.41). Within the per treatment protocol analysis the intervention group (m=13.57, SD=18.59) spent marginally more days readmitted than the control (m=11.46, SD=15.02), corresponding to a negligible estimated treatment effect (Hedge's g = 0.12, 95% CI -0.36, 0.61).

5.11.2.2 Psychological distress and mental health related self-efficacy

Means and standard deviations are presented in Table 16 (page 131) by time point and group (i.e. intervention group (mITT), control group and the intervention group as per treatment protocol principles). Mean change and effect sizes are also presented for pre-to post-intervention change (Table 17, page 132) and pre-intervention to follow-up change

(Table 18, page 133). All SMDs were interpreted using Cohen's (1988) guidelines: 0.2 signifies a small effect, 0.5 a medium effect and 0.8 a large effect.

Change at post-intervention

As seen in Table 17 (page 132), when analysed as modified intention to treat, group differences in change at post-intervention all favoured the intervention, however with varying degrees, depending on the outcome. Many of these were either trivial or small to moderate. Treatment effects were smaller on outcomes of psychological distress, while the largest effect was on the MHCS advocacy subscale (SMD=0.37; CI -0.05, 0.79).

All group differences also favoured the intervention when analysed as per treatment protocol. Most group differences increased when analysed as per treatment protocol, with the exception of coping in relation to mental health (MHCS coping) and overall mental health related self-efficacy. The largest group differences were mainly observed on outcomes of psychological distress, specifically, overall psychological distress (BSI-18 total score, SMD=-0.48, CI -0.97, 0.06; and CORE-10 total score, SMD=-0.48, CI -0.97, 0.01) and somatization (BSI-18 somatization subscale, SMD=-0.47, CI -0.97, 0.02) and were all of medium magnitudes. Mental health related advocacy also produced a medium effect (MHCS advocacy, SMD=0.48, CI -0.02, 0.97 (positive effect favours intervention)). These results suggest that measures of psychological distress are most sensitive at post-intervention and could be used in a main trial.

Change at follow-up

As seen in Table 18 (page 133), when analysed as modified intention to treat, group differences in change at follow-up favoured the intervention on most outcomes, with the exception of CORE-10 problems subscale (SMD=-0.01, CI -0.43, 0.41) and the BSI-18 total score (SMD=0.02, CI -0.40, 0.44), which had no effect, and the BSI-18 somatization subscale (SMD=0.04, CI -0.38, 0.47) and the BSI-18 depression subscale (SMD=0.11, -0.31, 0.54) which favoured control but to a marginal degree.

When analysed as per treatment protocol, group differences favoured the intervention on all outcomes but depression (BSI-18 depression subscale). Again, the magnitude of effects was larger on most outcomes of mental health related self-efficacy, however the largest effect was observed on the CORE-10 functioning subscale, (SMD=-0.60, CI-1.10, -0.10) which includes questions of general and social functioning. These results suggest

that measures of self-efficacy and functioning are most sensitive at follow-up and could be used in a main trial.

Table 16

Descriptive summary of questionnaire data by group and assessment point

	mITT intervention group (n=63)			Control group(n=33)			PtP intervention group (n=32)		
Outcome	**Baseline (mean SD)**	**Post-intervention (mean SD)**	**Follow-up (mean SD)**	**Baseline (mean SD)**	**Post-intervention (mean SD)**	**Follow-up (mean SD)**	**Baseline (mean SD)**	**Post-intervention (mean SD)**	**Follow-up (mean SD)**
CORE-10 Total	22.08 11.51	14.78 9.45	15.70 7.38	22.33 10.51	16.56 9.31	17.59 8.56	23.59 11.65	13.44 7.41	15.44 7.47
CORE-10 Problems	14.67 7.38	9.44 6.35	10.30 5.24	15.12 7.24	10.67 7.30	10.82 5.34	15.63 7.47	8.59 5.15	10.52 5.32
CORE-10 Functioning	5.98 3.97	4.70 3.10	4.78 3.02	5.52 3.04	4.77 2.76	5.81 2.93	6.59 4.36	4.26 2.43	4.33 2.83
BSI-18 Total	34.58 20.40	21.78 16.11	24.05 12.06	37.33 19.82	27.06 18.84	26.30 14.02	37.26 19.97	19.03 12.28	24.59 12.95
BSI-18 Somatization	8.68 6.91	4.96 4.76	4.88 3.89	9.42 6.72	6.56 6.09	5.30 4.02	9.84 7.35	4.04 3.79	4.96 4.19
BSI-18 Depression	12.78 8.02	8.51 6.59	10.14 5.56	14.03 8.50	9.85 7.64	10.29 6.72	13.60 7.64	7.21 5.37	10.20 5.83
BSI-18 Anxiety	13.12 8.02	8.31 6.43	9.03 5.56	13.88 6.89	10.65 7.35	10.71 6.03	13.83 7.75	7.78 5.26	9.44 5.76
MHCS Total	55.18 22.62	64.27 18.18	59.24 12.62	58.88 24.59	63.54 19.53	54.18 15.05	55.98 21.10	64.42 13.35	59.78 11.82
MHCS Optimism	21.19 9.29	24.48 7.62	22.17 5.64	23.06 9.59	25.23 8.04	20.17 6.38	21.09 8.37	25.07 5.66	22.64 4.98
MHCS Coping	22.29 11.03	26.29 8.89	24.30 7.14	22.72 12.12	25.00 9.19	22.06 6.78	21.95 10.52	26.14 7.24	24.56 6.84
MHCS Advocacy	11.70 4.76	13.50 3.49	12.77 3.41	13.09 4.71	13.31 3.96	11.95 3.85	10.94 4.75	13.21 2.88	12.59 3.62

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

Table 17

Summary of pre- to post-intervention change scores as per mITT and PtP analyses

		Primary analysis of pre- to post-intervention mean change (mITT analysis)					Supplementary analysis of pre- to post-intervention mean change (PtP analysis)				
Outcome	**Group**	**n**	**Mean change**	**SD**	**g (95% CI)**	**Summary[1]**	**n**	**Mean change**	**SD**	**g (95% CI)**	**Summary[1]**
CORE-10 Total	**Intervention**	63	-7.30	9.52	-0.17	Favouring intervention	32	-10.15	9.84	-0.48	Favouring intervention
	Control	33	-5.78	8.16	-0.59, 0.26	Very small	33	-5.78	8.16	-0.97, 0.01	Medium
CORE-10 Problems	**Intervention**	63	-5.23	6.91	-0.12	Favouring intervention	32	-7.03	6.79	-0.40	Favouring intervention
	Control	33	-4.45	5.97	-0.54, 0.30	Very small	33	-4.45	5.97	-0.89, 0.09	Small to medium
CORE-10 Functioning	**Intervention**	63	-1.28	3.65	-0.15	Favouring intervention	32	-2.33	4.13	-0.43	Favouring intervention
	Control	33	-0.75	3.10	-0.57, 0.27	Very small	33	-0.75	3.10	-0.92, 0.06	Small to medium
BSI-18 Total	**Intervention**	63	-12.80	18.81	-0.14	Favouring intervention	32	-18.24	18.10	-0.48	Favouring intervention
	Control	33	-10.31	14.71	-0.56, 0.28	Very small	33	-10.31	14.71	-0.97, 0.02	Medium
BSI-18 Somatization	**Intervention**	63	-3.72	7.06	-0.13	Favouring intervention	32	-5.80	6.84	-0.47	Favouring intervention
	Control	33	-2.87	5.34	-0.55, 0.29	Very small	33	-2.87	5.34	-0.97, 0.02	Medium
BSI-18 Depression	**Intervention**	63	-4.27	6.75	-0.01	No effect	32	-6.39	6.68	-0.34	Favouring intervention
	Control	33	-4.18	6.03	-0.43, 0.41		33	-4.18	6.03	-0.83, 0.15	Small to medium
BSI-18 Anxiety	**Intervention**	63	-4.81	7.06	-0.23	Favouring intervention	32	-6.05	7.01	-0.42	Favouring intervention
	Control	33	-3.22	6.32	-0.65, 0.19	Small	33	-3.22	6.32	-0.91, 0.07	Small to medium
MHCS Total	**Intervention**	63	9.09	17.07	0.28[2]	Favouring intervention	32	10.44	24.49	0.29[2]	Favouring intervention
	Control	33	4.66	13.44	-0.15, 0.70	Small	33	4.66	13.44	-0.20, 0.78	Small
MHCS Optimism	**Intervention**	63	3.28	7.14	0.17[2]	Favouring intervention	32	3.98	7.30	0.29[2]	Favouring intervention
	Control	33	2.18	4.83	-0.25, 0.59	Very small	33	2.18	4.83	-0.20, 0.78	Small
MHCS Coping	**Intervention**	63	4.00	9.13	0.20[2]	Favouring intervention	32	4.19	16.74	0.15[2]	Very small effect
	Control	33	2.26	6.95	-0.22, 0.63	Small	33	2.27	6.95	-0.34, 0.64	
MHCS Advocacy	**Intervention**	63	1.80	4.44	0.37[2]	Favouring intervention	32	2.27	4.70	0.48[2]	Favouring intervention
	Control	33	0.22	3.79	-0.05, 0.79	Small to medium	33	0.22	3.79	-0.02, 0.97	Medium

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

1. Summary is based on Cohen's (1988) benchmarks.
2. Positive effect favours intervention.

Table 18
Summary of pre-intervnetion to follow-up change scores as per mITT and PtP analyses

		Primary analysis of pre-intervention to follow-up mean change (mITT analysis)					Supplementary analysis of pre-intervention to follow-up mean change (PtP analysis)				
Outcome	**Group**	**n**	**Mean change**	**SD**	**g (95% CI)**	**Summary[1]**	**n**	**Mean change**	**SD**	**g (95% CI)**	**Summary[1]**
CORE-10 Total	**Intervention**	63	-6.38	11.35	-0.14	Favouring intervention	32	-8.15	11.37	-0.30	Favouring intervention
	Control	33	-4.74	11.37	-0.56, 0.28	Very small effect	33	-4.74	11.37	-0.79, 0.19	Small to medium
CORE-10 Problems	**Intervention**	63	-4.37	7.86	-0.01	No effect	32	-5.11	7.64	-0.10	Favouring intervention
	Control	33	-4.30	7.87	-0.43, 0.41		33	-4.30	7.87	-0.59, 0.38	Very small
CORE-10 Functioning	**Intervention**	63	-1.21	4.37	-0.36	Favouring intervention	32	-2.27	4.58	-0.60	Favouring intervention
	Control	33	0.30	3.85	-0.78, 0.07	Small to medium	33	0.23	3.85	-1.10, -0.10	Medium to large
BSI-18 Total	**Intervention**	63	-10.53	21.75	0.02	No effect	32	-12.76	22.74	-0.07	Favouring intervention
	Control	33	-11.00	20.68	-0.40 ,0.44		33	-11.00	20.68	-0.56, 0.41	Very small
BSI-18 Somatization	**Intervention**	63	-3.84	7.62	0.04	No effect	32	-4.88	7.92	-0.10	Favouring intervention
	Control	33	-4.13	6.72	-0.38, 0.47		33	-4.13	6.72	-0.59, 0.39	Very small
BSI-18 Depression	**Intervention**	63	-2.65	8.97	0.11	Favouring control	32	-3.40	9.90	0.03	No effect
	Control	33	-3.74	10.40	-0.31, 0.54	Very small	33	-3.74	10.40	-0.45, 0.52	
BSI-18 Anxiety	**Intervention**	63	-4.09	8.73	-0.11	Favouring intervention	32	-4.39	8.77	-0.15	Favouring intervention
	Control	33	-3.17	7.35	-0.53, 0.31	Very small	33	-3.17	7.35	-0.64, 0.34	Very small
MHCS Total[2]	**Intervention**	63	4.05	23.34	0.35	Favouring intervention	32	5.80	24.38	0.40	Favouring intervention
	Control	33	-4.70	27.57	-0.08, 0.77	Small to medium	33	-4.70	27.57	-0.09, 0.89	Small to medium
MHCS Optimism[2]	**Intervention**	63	0.98	9.68	0.37	Favouring intervention	32	1.54	9.90	0.41	Favouring intervention
	Control	33	-2.89	11.43	-0.05, 0.80	Small to medium	33	-2.89	11.43	-0.08, 0.90	Small to medium
MHCS Coping[2]	**Intervention**	63	2.00	11.51	0.21	Favouring intervention	32	0.65	18.27	0.20	Favouring intervention
	Control	33	-0.66	13.73	-0.21, 0.64	Small	33	-0.66	13.73	-0.29, 0.69	Small effect
MHCS Advocacy[2]	**Intervention**	63	1.07	6.11	0.38	Favouring intervention	32	1.65	6.45	0.47	Favouring intervention
	Control	33	-1.14	5.17	-0.05, 0.80	Small to medium	33	-1.14	5.17	-0.02, 0.97	Medium

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

1. Summary is based on Cohen's (1988) benchmarks.
2. Positive effect favours intervention.

Comparison of participants with completed and missing follow-up questionnaire data

As seen in Table 19 (below), there is little difference in most baseline symptom severity or sample characteristics between participants who completed follow-up questionnaires and those that did not.

Table 19

Summary of symptom severity and sample characteristics of participants who did and did not provide follow-up questionnaires

Characteristic		Follow-up completers (n=51)	Follow-up non-completers (n=45)	Total (n=96)
Gender (n (%))	Male	24 (47%)	23 (51%)	47 (49%)
	Female	27 (53%)	22 (49%)	49 (51%)
	Total	51 (100%)	45 (100%)	96 (100%)
Diagnosis (n (%))	Bipolar (manic)	13 (25%)	10 (22%)	23 (24%)
	Bipolar (depression)	3 (6%)	3 (7%)	6 (6%)
	Personality disorder	6 (12%)	5 (11%)	11 (11%)
	Depressions	10 (20%)	9 (20%)	19 (20%)
	Schizophrenia and psychosis	19 (37%)	18 (40%)	37 (39%)
	Total	51 (100%)	45 (100%)	96 (100%)
Age (M (SD))		42.60 (11.57)	44.20 (11.47)	43.38(11.43)
Previous admission (n (%))		29 (57%)	28 (62%)	57 (59.4%)
LOS (median (IQR))		27 (42.25)	33 (44.50)	28.00 (44.00)
Baseline CORE-10 M (SD)	Total score	23.48 (10.08)	20.22 (10.71)	21.85 (10.43)
	Problems	15.48 (6.76)	13.76 (7.34)	14.65 (7.02)
	Functions	6.26 (3.19)	5.00 (3.09)	5.6 (3.21)
Baseline BSI (M (SD))	Total	38.28 (19.71)	32.13 (20.67)	35.37 (20.30)
	Somatization	9.48 (6.69)	8.38 (7.00)	8.96 (6.83)
	Depression	14.46 (8.16)	11.53 (8.17)	13.07 (8.26)
	Anxiety	14.34 (7.69)	12.44 (7.93)	13.44 (7.82)
Baseline MHCS[1] (M (SD))	Total	53.4 (23.15)	59.02 (25.13)	56.11 (23.98)
	Optimism	21.40 (8.93)	22.60 (9.96)	21.98 (9.35)
	Coping	21.08 (10.51)	23.49 (12.20)	22.16 (11.14)
	Advocacy	12.14 (4.64)	12.84 (5.02)	12.47 (4.79)

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS)

1. Lower scores indicate greater severity.

Sensitivity analysis

As seen in Table 20 (below), only marginal differences exist between descriptive statistics (i.e. means and standard deviations) of follow-up questionnaires when missing data is

ignored and imputed. As seen in Table 21 (page 136), when analysed as modified intention to treat, group differences in change on all outcomes at follow-up increased when missing data was not imputed, compared to when missing data was imputed. This was also the case for most outcomes when analysed as per treatment protocol, except for BSI-18 depression, CORE-10 problems and CORE-10 total. However more importantly, group differences favoured the intervention on all outcomes.

Table 20

Descriptive summary of follow-up questionnaire data by group where data is imputed and not imputed

	No imputed data			**Imputed**		
Outcome	**mITT intervention group (mean SD) (n=33)**	**Control group (mean SD) (n=18)**	**PtP intervention group (mean SD) (n=19)**	**mITT intervention group (mean SD) (n=63)**	**Control group (mean SD) (n=33)**	**PtP intervention group (mean SD) (n=32)**
CORE-10	15.64	17.50	15.38	15.70	17.59	15.44
Total	7.38	8.56	7.58	7.38	8.56	7.47
CORE-10	10.25	10.78	10.48	10.30	10.82	10.52
Problems	5.32	5.40	5.43	5.24	5.34	5.32
CORE-10	4.78	5.74	4.30	4.78	5.81	4.33
Functioning	2.86	2.93	2.83	3.02	2.93	2.83
BSI-18 Total	24.04	26.17	24.52	24.05	26.30	24.59
	11.99	14.02	12.84	12.06	14.02	12.95
BSI-18	4.86	5.32	4.92	4.88	5.30	4.96
Somatization	3.89	4.08	4.19	3.89	4.02	4.19
BSI-18	10.19	10.21	10.28	10.14	10.29	10.20
Depression	5.48	6.78	5.77	5.56	6.72	5.83
BSI-18	9.00	10.64	9.33	9.03	10.71	9.44
Anxiety	5.64	5.97	5.66	5.56	6.03	5.76
MHCS Total	59.23	54.20	59.69	59.24	54.18	59.78
	12.86	15.22	11.88	12.62	15.05	11.82
MHCS	22.21	20.16	22.70	22.17	20.17	22.64
Optimism	5.71	6.55	5.09	5.64	6.38	4.98
MHCS	24.35	22.16	24.49	24.30	22.06	24.56
Coping	7.14	6.83	6.84	7.14	6.78	6.84
MHCS	12.67	11.88	12.50	12.77	11.95	12.59
Advocacy	3.25	3.91	3.51	3.41	3.85	3.62

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

Table 21

Summary of pre-intervention to follow-up change in questionnaire scores where no data is imputed

Outcome	Group	Pre to follow-up mean change (mITT analysis)					Pre to follow-up mean change (PtP completer analysis)				
		n	Mean	SD	g (95% CI)	Summary[1]	n	Mean	SD	g (95% CI)	Summary[1]
CORE-10 Total	Intervention	33	-8.25	9.32	-0.31	Favouring intervention	19	-8.89	9.92	-0.35	Favouring intervention
	Control	18	-5.00	11.77	(-0.89, 0.27)	Small to medium effect	18	-5.00	11.77	(-1.00, 0.30)	Small to medium effect
CORE-10 Problems	Intervention	33	-5.09	7.17	-0.05	No effect	19	-4.95	6.78	-0.03	No effect
	Control	18	-4.72	7.78	(-0.63, 0.53)		18	-4.72	7.78	(-0.68, 0.61)	
CORE-10 Functioning	Intervention	33	-1.88	3.67	-0.64	Favouring intervention	19	-2.84	3.39	-0.92	Favouring intervention
	Control	18	0.50	3.70	(-1.23, -0.05)	Medium to large effect	18	0.50	3.70	(-1.60, -0.24)	Large effect
BSI-18 Total	Intervention	33	-15.19	21.91	-0.15	Favouring intervention	19	-16.00	24.18	-0.18	Favouring intervention
	Control	13	-11.89	19.99	(-0.73, 0.43)	Very small effect	18	-11.89	19.99	(-0.83, 0.47)	Small effect
BSI-18 Somatization	Intervention	32	-5.41	7.76	-0.20	Favouring intervention	19	-6.11	7.80	-0.31	Favouring intervention
	Control	18	-3.94	5.76	(-0.78, 0.38)	Small effect	18	-3.94	5.76	(-0.96, 0.34)	Small effect
BSI-18 Depression	Intervention	33	-4.41	9.16	-0.01	No effect	19	-5.11)	10.59	-0.07	Favouring intervention
	Control	18	-4.33	10.59	(-0.59, 0.57)		18	-4.33	10.59	(-0.72, 0.56)	No to very small effect
BSI-18 Anxiety	Intervention	33	-5.94	9.08	-0.28	Favouring intervention	19	-5.21	8.87	-0.20	Favouring intervention
	Control	18	-3.56	7.04	(-0.86, 0.30)	Small effect	18	-3.56	7.04	(-0.85, 0.45)	Small effect
MHCS Total[2]	Intervention	33	9.03	21.39	0.61	Favouring intervention	19	14.16	23.45	0.75	Favouring intervention
	Control	18	-5.83	28.43	(0.02, 1.20)	Medium to large effect	18	-5.83	28.43	(0.09, 1.42)	Large effect
MHCS Optimism[2]	Intervention	33	1.84	9.10	0.54	Favouring intervention	19	3.11	10.55	0.59	Favouring intervention
	Control	18	-3.72	11.99	(-0.05, 1.12)	Medium effect	18	-3.72	11.99	(-0.07, 1.25)	Medium effect
MHCS Coping[2]	Intervention	33	3.91	10.37	0.42	Favouring intervention	19	5.32	11.11	0.51	Favouring intervention
	Control	18	-1.00	13.11	(-0.16, 1.00)	Small to medium effect	18	-1.00	13.11	(-0.07, 1.25)	Medium effect
MHCS Advocacy[2]	Intervention	33	1.13	6.14	0.36	Favouring intervention	19	2.16	6.59	0.57	Favouring intervention
	Control	18	-1.00	5.40	(-0.23, 0.94)	Small to medium effect	18	-1.00	5.40	(-0.13, 1.17)	Medium effect

Brief Symptom Inventory Scale (BSI); Clinical Outcomes Routine Evaluation (CORE); Mental Health Confidence Scale (MHCS); Modified intention to treat (mITT); Per treatment protocol (PtP); Standard deviation (SD).

1. Summary is based on Cohen's (1988) benchmarks.
2. Positive effect favours intervention.

5.11.2.3 Adverse events

When analysed as modified intention to treat or as per treatment protocol, more people died in the control group (n=2) compared to the intervention group (n=0). People in the control group also had more A&E episodes and contact with IHTT, within 6 months of discharge, compared with the intervention group (see Table 22 and Table 23, below). One person in the intervention group, in comparison to no people in the control group, had not been discharged at follow-up, however this difference is negligible.

Table 22

Summary of the proportion of participants who had A&E episodes during 6-month follow-up

		Number participants who had x number of A&E episodes					
Group	**n**	**Participants that had 1 episodes (n (%))**	**Participants that had 2 episodes (n (%))**	**Participants that had 3 episodes (n (%))**	**Participants that had 4 episodes (n (%))**	**Participants that had 5 episodes (n (%))**	**Participants that had at least 1 episode (n (%))**
Intervention (mITT)	63	7 (11%)	3 (5%)	1 (2%)	0	0	11 (17%)
Control	33	5 (15%)	2 (6%)	1 (3%)	0	1 (3%)	9 (27%)
Intervention (PtP)	32	3 (9%)	1 (3%)	0	0	0	4 (13%)

Intensive home treatment team (IHTT);Modified intention to treat (mITT); per protocol (PtP)

1. IHTT is the home crisis resolution team in NHS Lothian.

Table 23

Summary of the proportion of participants who had intensive home treatment team (IHTT)[1] episodes during 6-month follow-up

		Number of IHTT episodes					
Group	**n**	**Participants that had 1 episode (n (%))**	**Participants that had 2 episodes (n (%))**	**Participants that had 3 episodes (n (%))**	**Participants that had 4 episodes (n (%))**	**Participants that had 5 episodes 5 (n (%))**	**Participants that had at least 1 episode (n (%))**
mITT intervention	63	6 (10%)	2 (3%)	0	0	0	8 (13%)
Control	33	5 (15%)	2 (6%)	1 (3%)	0	1 (3%)	9 (27%)

PtP intervention	32	3 (9%)	1 (3%)	0	0	0	4 (13%)

Intensive home treatment team (IHTT);Modified intention to treat (mITT); per protocol (PtP)

1. IHTT is the home crisis resolution team in NHS Lothian.

5.12 Retention (trial attrition rate)

Treatment retention/attrition could not be recorded given the flexible nature of the intervention (i.e. patients were encouraged to attend as many or as few therapy sessions as they chose). Instead, intervention engagement was recorded and has been discussed in section 5.7. Trial retention/attrition was calculated as the number of participants who provided no questionnaires, therefore has been described in the section 5.10.

5.13 Logistics of multicentre trial

The logistics of running a multicentre trial could not be assessed in this study as multiple centres were not recruited.

5.14 Summary of all components of the protocol working together

As seen in Table 24 (below), while some components of the protocol worked well, data from this feasibility study revealed problems existing in other components. The main problems identified were that some eligible participants were excluded from the study and ineligible patients were initially recruited, some components of the intervention protocol were poorly implemented, questionnaires were poorly completed at follow-up and no staff related outcomes were included. Adaptations to both clinical context and the trial protocol are necessary to progress to a full definitive trial. Methodological issues not addressed by the current feasibility study include the logistics of running a multi-centre trial, the cost-effectiveness of the intervention, the acceptability of the intervention for patients and staff, assessor blinding and cluster randomisation.

Table 24

Summary of findings against key methodological issues in feasibility research[1]

Methodological Issue	Findings and evidence
1. Was target sample size recruited? Did the feasibility study allow a sample size calculation for the main trial?	• Target sample size was not successfully recruited. o Target sample size (n=150); actual sample recruited (n=96). • Sample size for a future definitive trial has been calculated, although only attrition data from this trial was used. • 2012 participants should be recruited between 36 clusters.

2. What factors influenced eligibility?	Participant
	• 63% of those 248 screened were eligible.
	• Main reasons for ineligibility were as follows:
	  • Anticipation that patients would be discharged or moved wards within three days of completing baseline measures (27%) or participants excluded after completing baseline measures and consenting if discharged or moved wards within 2 days of doing so (15%).
	  • Patients were considered too distressed or unwell by ward staff (20%).
	Cluster
	  • All clusters that were approached agreed to participate.
	  • One cluster was excluded due to external therapeutic input.

3. Was recruitment successful?	• Recruitment was reasonable, but slower than expected and labour intensive. • 96 participants were recruited over 12 months from 2 wards. Therefore, average number of participants recruited from one ward per month is 4.
4. Did eligible participants consent?	• 47% of those who were eligible consented. • Reasons for not consenting were not formally measured but some anecdotal evidence was recorded where possible (see consent section).
5. Were participants successfully randomised and did randomisation result in equality between groups?	• No randomisation procedure used.

Table 24

Summary of findings against key methodological issues in feasibility research[1]

Methodological Issue	Findings and evidence
6. Were blinding procedures adequate?	• Neither assessors nor participants were blind to trial group.
7. (i) Was the intervention implemented as planned?[2]	• Some intervention components were well implemented (individual sessions) while others were not (groups). • Individual sessions were consistently delivered during the study period (k=105), while groups were not (k=28).
7 (ii) Did participants and staff engage with the intervention?	Patient engagement • Approximately half of the intervention group engaged with the intervention (51%). Staff engagement • Not directly measured but poor implementation of groups suggests poor staff engagement. • Not directly measured but observed that, despite encouragement, no management staff or psychiatrists attended psychological training, suggesting little commitment to implementing the model.
8. Was the intervention acceptable to participants	• This was not formally measured, however 16% participants in the intervention group expressed interest in receiving the intervention but could not (see section 5.7 and 5.8).
9. Was it possible to calculate intervention costs and duration?	• Not calculated in this study.
10. Were outcome measures completed?	• All outcomes had good completion rates at baseline and post-intervention, however there was poor completion of questionnaires at follow-up and of the CTQ-SF. Baseline completion rates: CORE-10: 100%; BSI-18: 99%; MHCS: 100% Post-intervention completion rates: CORE-10: 93%; BSI-18: 92%; MHCS: 93% 6-month follow-up completion rates: CORE-10: 53%; BSI-18:52%; MHCS: 53% • Readmission rate at 6 months: 92% • CTQ-SF completion rate: 64%
11. Were outcome measures those that were the most important?	• Chosen outcomes assessed areas of interest (see outcome assessments section). • No staff or milieu related outcomes measured.

Table 24

Summary of findings against key methodological issues in feasibility research[1]

Methodological Issue	Findings and evidence
12. Was retention to the study good?	Treatment retention • Treatment retention/attrition measured as patient engagement (see number 7). Study retention/attrition • No participants explicitly dropped out, therefore retention was based on available outcome data (see number 10).
13. Were the logistics of running a multicentre trial assessed?	• Not formally assessed.
14. Did all components of the protocol work?	Some components worked well while others did not. Components that did not work include: • Issues with eligibility criteria. • Poor intervention implementation. • Poor completion of questionnaires at follow-up. • No staff or milieu outcomes were included.

1. Table adapted from Bugge et al. (2013)
2. Extra methodological issue not included by Shanyinde, Pickering and Weatherall (2011)

6 Discussion

The previous chapter presented results of the feasibility study using Shanyinde, Pickering and Weatherall (2011) as an analytical framework to highlight the extent to which this study addressed each issue, and to identify problems encountered during the study. This chapter aims to summarise the thesis and then discusses key findings, interpretation of the findings and strengths and limitations of the feasibility study.

6.1 Summary of the thesis

This thesis investigated the role of brief psychological intervention for acute mental health inpatients. The process was guided by the Medical Research Council (MRC) framework for developing and evaluating complex interventions (see Chapter 1) (Craig et al., 2008, 2013).

The first aim of the thesis was to systematically-review and meta-analyse controlled trials of brief psychological intervention delivered in acute inpatient settings (reported in Chapter 3), therefore mapping onto phase one of the MRC framework (Craig et al., 2008, 2013). Specifically, the meta-analysis aimed to evaluate the benefit of psychological therapy in this context with regards to psychotic symptoms, readmissions and emotional distress. Results showed that in randomised and single-blind studies psychological intervention had little effect on psychotic symptoms, however, other outcomes showed more promising results. For example, although not statistically significant, there is some evidence to suggest that brief psychological therapy may reduce emotional distress and risk of readmission for some acute inpatients.

The second aim of the thesis was to conduct a feasibility study to pilot and test the feasibility of implementing and evaluating a cross-diagnostic, psychologically informed acute mental health care intervention versus treatment as usual (TAU), and to collect some preliminary outcome data relating to any potential treatment effect and adverse events. This study maps onto phase two of the MRC framework.

The results relating to the first aim were discussed in Chapter 3 of the thesis. The remainder of this chapter focuses on the findings from the feasibility study and considers how progression

to a full sized definitive trial of cross-diagnostic, psychologically informed model of acute mental health inpatient care versus TAU could be achieved.

6.2 Discussion of feasibility trial

6.2.1 Main findings

This trial piloted and tested the feasibility of implementing and evaluating a cross-diagnostic psychological intervention for acute psychiatric inpatients and assessed whether the intervention demonstrated evidence for the desired direction of effect, in comparison to TAU. Overall, this trial has provided valuable insight into implementing a psychological intervention, and running a trial, in an acute psychiatric inpatient context. The data collected shows that some aspects of the trial were successful, i.e. clinical outcomes had good completion rates at pre- and post-intervention, some intervention components were successfully implemented (e.g. individual therapy) and some promising group differences were observed on some outcomes (e.g. overall psychological distress and somatization at post-intervention, and functioning and self-efficacy at follow-up). However, other aspects of the trial were problematic and need refinement to fully implement the intervention in real world settings and progress to a full trial. Key issues identified in this study include problematic eligibility criteria, poor implementation of some intervention components, poor engagement, poor completion of follow-up questionnaires, and therefore poor trial retention, and no staff or milieu related outcomes were included. Furthermore, the intervention was not associated with clear group differences in the primary outcome, namely a reduction in the proportion of those readmitted. This study did not address some important methodological issues, such as randomisation and blinding procedures, acceptability and cost effectiveness of the intervention and the logistics of running a multicentre trial.

6.2.2 Interpretation of the findings

6.2.2.1 Challenges of implementing the intervention

Implementing complex interventions in any healthcare setting is well known to be challenging (Craig et al., 2008; Moore et al., 2015). Although the intervention piloted in this study has been implemented in other acute psychiatric services in the UK (Araci & Clarke, 2016; Durrant & Tolland, 2009), some components, i.e. groups, were poorly implemented in this feasibility trial, while others, i.e. individual sessions, were implemented well. Few group sessions were

successfully delivered during the study period, and those that were, were done so infrequently, inconsistently and with little notice for patients. It is possible that challenges were faced in implementing group sessions, and not individual sessions, because individual sessions were delivered by staff from the psychological team, i.e. not ward staff. Group sessions on the other hand, relied largely on consistent input from staff nurses. Individual sessions, therefore, ran independently of day to day ward activity, while group sessions required the intervention to be integrated into routine practice. Many barriers to routine delivery of group therapies were observed. Such barriers included staff shortages, staff sickness, inflexible rotas (i.e. rotational night shifts), many relevantly trained ward staff left during the study period and other duties were prioritised over therapeutic work in the presence of a busy workload. In a time of austerity, many of these challenges, e.g. staff shortages, are common in acute inpatient services, and may be a consequence of service cuts (King's Fund, 2015). However, high stress working environments have also long been associated with staff burnout, high staff turnover and staff shortages (Cronin-Stubbs & Brophy, 1985; Price & Mueller, 1981). Further consideration of how to integrate group therapies into routine practice in a high stress, resource restricted service is necessary (discussed later in this chapter). Some staff also expressed a lack of confidence in their ability to facilitate groups. Given that key aims of offering therapies in a group format is to create a therapeutic milieu through increased awareness of CBT knowledge and skills within different staff groups and increased access to psychological therapy for more patients, this has major implications for the reach of the intervention to both service users and staff. Similar challenges have previously been acknowledged in establishing routine psychological group session in acute psychiatric inpatient services (Clarke & Wilson, 2009; Bright, 2008). One solution is to ensure the members of staff interested in facilitating groups works one nine-to-five day once a week on a specific day for a fixed period of time (Hill et al., 2009). This time should be used to facilitate and co-facilitate groups (Hill et al., 2009). Furthermore, additional staff training should be offered to ensure staff feel well equipped to deliver specific group therapies. Together, these solutions may facilitate the integration of group sessions into routine practice, improve staff psychological knowledge and therefore improve the therapeutic milieu.

In the current study, it was also observed that, despite invitation, managerial staff and psychiatrists did not attend the relevant psychological training, suggesting a lack of support for the intervention. This was considered another barrier to achieving full implementation because support from staff in such positions is likely to have a profound effect on the success or failure of a new intervention. It is possible that this affected the routine delivery of group therapies.

Recent studies have shown that nursing staff, charge nurses and psychiatrists find psychological therapy acceptable and beneficial in rehabilitation and acute psychiatric inpatient units (Berry et al., 2016; Donaghay-Spire, McGowan, Griffiths, & Barazzone, 2016). Therefore, perhaps low levels of attendance at training observed in the current study, was due to time and resource restrictions. Alternatively, it may be that the intervention was not promoted well enough or that it was not akin to their disciplinary model of mental illness. This study lacked information on staff (at all levels) perceptions of the intervention and on facilitators and barriers to implementation, therefore definitive reasons are unknown. However, as identified in previous studies and in the current trial, successful implementation and evaluation of new interventions rely heavily on agreement and commitment from the organisation and staff at all levels (Berry et al., 2016; Berry & Haddock, 2008; Ince, Haddock, & Tai, 2016), therefore further investigation of these issues is warranted, e.g. using qualitative methods.

Another major problem identified in this study was that only half of the participants in the intervention group engaged with the intervention, i.e. attended at least one group or individual session. This was lower than expected and lower than that reported in other trials of acute inpatient psychotherapy (Bechdolf et al., 2004; Haddock et al., 1999: 97%, 95%, respectively). This suggests that the intervention piloted in the current study was less acceptable or that not everyone wanted to receive psychological intervention during an acute admission. However, 16% of participants in the intervention group (or 32% of non-engaging participants in the intervention group) expressed an interest in receiving it, but were unable to due to being discharged while waiting for the next available individual session or the next scheduled group session. This suggests that while it is likely that some patients simply did not want to receive the intervention, others were unable to due to limited provision. It is also possible that some patients did not receive the intervention because they were not offered it. This may have implications for the results of the current study and of future trials. It is recognised that failure to implement an intervention properly may result in misleading conclusions regarding its impact (Moore et al., 2015). However, whether this was the case in the current study is unknown. Due to ethical restrictions and poor planning, participants were not asked why they did not receive psychological intervention in the current study, therefore such conclusions are speculative. In a future trial, it is important to record reasons for engagement and non-engagement, as this will provide valuable insight into the interventions demand, acceptability

and reach, and will better inform conclusions that can be made based on the estimated treatment effects.

Based on the clinical outcome data collected in this study, the impact of the intervention varied, depending on the outcome and analysis. When analysed as intention to treat (i.e. including all participants who officially entered the trial, despite treatment received), few group differences were observed on most outcomes compared to per treatment protocol analyses, with the exception of some outcomes of self-efficacy. In contrast, when analysed under principles of per treatment protocol, the intervention was favoured on a range of outcomes, specifically outcomes of change in psychological distress at post-intervention and change in outcomes of self-efficacy and functioning at follow-up. Estimated treatment effects also tended to be more precise under per treatment protocol principles. However, the 95% confidence interval all overlapped zero which, like the results in the meta-analysis (see Chapter 3), demonstrates that the sample was likely too small to detect significant group differences. This is to be expected given that this was a feasibility study. The differences in results observed between the intention to treat and per treatment protocol analyses reflects the large proportion of participants in the intervention group not engaging with the intervention. This suggests that, in terms of the milieu, there was no clear change as a result of the intervention.

Minimal group differences were observed on the primary outcome (proportion of readmissions and number of days spent readmitted) whether analysed under intention to treat or per treatment protocol principles. It is possible that the intervention simply had little impact on readmissions, however it is also possible that poor implementation diluted the impact of the intervention (Moore et al., 2015). Another explanation for the lack of clear differences on the primary outcome is that the intervention group was more severely ill at baseline. Participants in the intervention group reported slightly worse distress and slightly worse mental health related self-efficacy at baseline compared to the non-engaging intervention group and the control group. Those who received the intervention were primarily referred by ward staff. Therefore, although this difference was slight, it is possible that participants perceived to be more ill were more readily referred to, or encouraged to attend, psychological therapy during their admission by ward staff. Allocation bias is a well-known risk associated with non-randomised trials (Sedgwick, 2013b), and may be a limitation of the current study (discussed later is in this chapter).

6.2.2.2 Challenges of conducting the trial

Although recruiting patients with severe mental illness to trials is known to be difficult, the number of participants recruited to the current trial was considered reasonable, given the available resource and time. However, adequate time should be allocated for recruitment in a future trial. In contrast, the eligibility rate in this trial was considerably lower than that reported in other trials conducted in acute psychiatric inpatient settings: 94% (Schramm et al., 2007), 85% (Lewis et al., 2002) and 91% (Gaudiano & Herbert, 2006). Such differences may be due to problems identified with the eligibility criteria in the current study. For example, some patients were excluded if ward staff anticipated that their admission would be three days or less (26%). This exclusion criterion aimed to minimise recruitment of patients who received almost no treatment from either the control or intervention group. However, although not formally recorded, it was observed that some patients who were predicted to have short admissions were admitted for longer than expected. Therefore, some patients who were initially deemed ineligible and excluded from the trial may have indeed been eligible, had the short admission criteria not been in place from the outset. The eligibility criteria were also problematic in this trial in that 15% of patients were excluded after consenting to participate and completing baseline measures because they moved to a different ward or were discharged within two days of doing so. This demonstrates the challenges of conducting research in a service which moves at a fast pace and has a quick turnover of patients. This criterion was added after the study began in order to reduce the number of participants who did not receive the allocated treatment, i.e. to measure the effect of treatment more directly, and it aimed to reduce contamination between trial arms. However, in doing so the principles of an intention to treat analysis were violated. Deviating from an intention to treat analysis for such reasons has been referred to as modified intention to treat and is common in medical literature (Abraha et al., 2015). However, modified intention to treat analysis is associated with inflated estimates of treatment effect (Abraha et al., 2015), therefore excluding participants after consenting to enter a main trial may raise questions about the validity of the analysis. To address this issue, amendments must be made to the current trial protocol to progress to a full trial (discussed later in this chapter).

Completion rates for some of the clinical outcomes collected in this study also threaten the validity of an intention to treat analysis. While completion of questionnaires was good at pre- and post-intervention, 48% of participants were lost to follow-up, therefore a large proportion

of follow-up questionnaires were missing. This highlights the challenges of collecting data from a population with severe mental illness. Furthermore, in comparison to the proportion of drop-out or loss to follow-up in other trials of psychological intervention for acute psychiatric inpatients that follow-up up patients to collect outcome data, 48% is at the higher end of the range: 63% (Owen, Sellwood, et al., 2015); 19% (Bechdolf et al., 2004); 18% (Lewis et al., 2002). This pattern of missing questionnaire data is to be expected as meta-analysis has shown that inpatient settings are associated with higher outcome completion rates, or lower drop-out, compared to outpatient settings (Villeneuve, Potvin, Lesage, & Nicole, 2010). Missing outcomes are extremely problematic for accurate parameter estimations, because it is unlikely that missingness is completely random (Dunn, 2013). The benefit of randomisation is therefore lost, thus exposing parameter estimations to a risk of bias. In order to increase confidence in the conclusions drawn from a main trial, further consideration of how to improve contact with participants as outpatients (i.e. to complete follow-up questionnaires) is needed, or more appropriate outcomes should be considered prior to progression.

Completion of the childhood trauma questionnaire (CTQ-SF) was also low in this trial (64%). While this may indicate that participants found this questionnaire unacceptable, it is also likely that failure to contact participants for follow-up assessment is associated with poor completion of the CTQ-SF. Therefore, improving contact with participants at follow-up in a main trial should also improve completion of the CTQ-SF.

6.2.3 Strengths and limitations of the trial

Using a framework for developing and evaluating complex interventions (Craig et al., 2008, 2013), the aim of this feasibility trial was to test the intervention of interest in a real-world setting. As recommended by Bugge et al. (2013), this study has also benefited from the use of Shanyinde, Pickering and Weatherall (2011) methodological issues as an analytical framework. The study provided insight into the extent to which each issue was addressed and highlighted problems with the trial, intervention and clinical context.

Another strength of the trial is that it tested a theoretically driven intervention (Clarke, 2009), which has produced promising treatment outcomes for patients in initial exploratory studies (Araci & Clarke, 2016; Durrant, Clarke, Tolland, & Wilson, 2007; Durrant & Tolland, 2009; Wilson, Clarke, & Phillips, 2009). However, such studies are small and have either not

included a control group (Araci & Clarke, 2016; Durrant & Tolland, 2009) or have tested a single component of the intervention (Owen, Sellwood, et al., 2015). Therefore, the current trial builds on this previous work, in that it is the first study to test this intervention as a whole and use a control group. It is also the first study of this intervention to include service related outcomes (i.e. readmissions) and record adverse events. More serious adverse events were recorded in the control group, compared with no evidence of serious adverse effects in the intervention group during the follow-up period (i.e. deaths). This preliminary result may have important implications for the design of a future definitive trial of acute psychiatric inpatient services, in terms of carefully capturing adverse event information, including thoughtful consideration of trial stopping rules.

Two major issues identified in this trial were poor implementation of some intervention components within the clinical context and poor staff engagement. Consequently, the intervention was poorly integrated into the service. It is possible that the intervention had little impact on the therapeutic milieu, however this trial did not directly measure change in milieu therefore further research investigating this is required. Staff related outcomes, of effect (e.g. burnout) or process (i.e. average number of relevantly trained staff, number of sessions facilitated by staff, etc.), were also not collected (discussed later in this chapter). However, given that the intervention sought to achieve change at all organisational levels, these outcomes are important to measure in future trials (Craig et al., 2008).

Other limitations of this study are that clusters and participants were not randomised, and assessors were not blind to the treatment arm. Both methodological features are fundamental in the design of a main trial. Lack of randomisation in non-cluster trials is well known to increase the risk of selection bias and allocation bias, and introduce bias associated with unbalanced sample characteristics, such that estimated parameters may not reflect the true treatment effectiveness or efficacy (Eldridge & Kerry, 2012). In cluster trials, the issue of randomisation is more complex in that possible bias can be introduced at cluster level, e.g. allocation bias, and at individual participant level, e.g. selection bias, if randomisation is not implemented, therefore it is imperative that a future definitive trial employs both design features, and with sufficient randomised clusters to adequately control for bias.

Contextual factors should also be recorded in a future trial. There were two notable contextual differences between the control and intervention ward. First is that the control and intervention

ward provided acute inpatient care for patients residing in rural or urban areas, respectively. The second difference is that patients in the intervention ward received different psychiatric care, depending on whether they were an outpatient or inpatient. In contrast, psychiatric care for patients in the control ward was consistent, despite hospitalisation. Such contextual differences may have implications for treatment outcomes, therefore contextual factors like these should be considered in a process evaluation in a main trial to increase confidence in the conclusions drawn from it (Moore et al., 2015). Cluster randomisation designs, such as stratification or minimisation, should account for such differences to ensure groups are equally balanced and improve the external validity of the trial (Eldridge & Kerry, 2012).

A further limitation of the current feasibility study is that, due to insufficient planning (see 'Protocol amendments' in Chapter 5), some feasibility outcomes were not included. For example, no information on the acceptability of the intervention (i.e. content, format, logistics of delivering it in routine practice) was formally gathered. As recommended by the MRC, qualitative investigation of such issues, i.e. staff and patient experience of the intervention, should be conducted to develop and refine the intervention further before progressing to a main trial (Craig et al., 2008, 2013; Lancaster et al., 2010). Quantitative methods, e.g. a questionnaire, would also inform the acceptability of the intervention. Reasons for non-engagement in the intervention group were also not recorded in the current trial, due to ethical restrictions. However, investigating of such issues could further inform the design of the intervention, with the view to increase its acceptability, and should therefore be considered in the design of future research (discussed later in this chapter).

Other limitations of this trial are that participants were followed up at six months, rather than the pre-specified 12 months, and the specified sample size was not recruited. This was unavoidable, due to the time restrictions of the PhD. However, a future trial should ensure adequate time is allocated for recruitment and follow-up assessment.

6.2.4 Implications for future research and practice

It is clear that conducting a full trial of the intervention would have problems without modifying the trial protocol, the clinical context and the intervention. Using the ADePT process (Bugge et al., 2013), various amendments have been identified and considered (see Appendix 16 for all identified amendments) to address the problems discussed in the previous section.

Required amendments to progress to a full trial are discussed in the following sections and summarised in Table 24 (page 156). Key design features of a main trial are summarised in Table 25 (page 156).

6.2.4.1 Changes to the trial design

From the results of this trial, it is clear that the eligibility criteria and the process of collecting follow-up questionnaires need refinement. The first possible change to the eligibility criteria is that patients who do not want to receive the intervention could be excluded. This could reduce the number of non-engaging participants in the intervention group, therefore allowing for an intention to treat analysis which measures the effects of the intervention on patient level outcomes more directly (Dunn, 2013). One way to achieve this is by asking patients to rate their interest in receiving the intervention before entering the trial. Although increasingly restrictive eligibility may be a sign of a less pragmatic trial and reduce external validity (Loudon et al., 2015), asking participants whether they want to receive the intervention is common in routine clinical practice and, if the intervention were to be fully implemented, could improve the quality of an intention to treat analysis on patient level outcomes. Furthermore, such information will quantify demand for the intervention, and characteristics of those who do and do not want to receive psychological intervention during their acute admission could be identified. Second, patients should not be excluded based on anticipation of a short admission. Instead, different options should be considered, for example patients could continue to be excluded if they are discharged within two days of completing baseline measures, however to avoid excluding eligible patients and excluding participants after entering the trial, baseline measures could be collected from everyone who provides initial consent to do so, and consent could be sought from participants twice; once when completing baseline measures and once three days after doing so to enter the trial. This would avoid exclusion of patients who have officially entered the trial but ensure data is collected for those who stay longer than expected, and for those who have a very short admission (i.e. three days). This method, however, should be carefully considered with a dedicated clinical trials unit before progressing to a full trial. Another option to avoid excluding participants based on a short-term admission is to continue to provide therapy after discharge. This is likely to reduce the number of participants being excluded based on this criterion, however the logistics of offering therapy in this way would require consideration.

Various solutions should be considered to improve the completion of follow-up questionnaires in a main trial. One solution is to identify characteristics of patients who are unlikely to provide follow-up data and exclude them (Eldridge & Kerry, 2012). This is likely to reduce the risk of bias associated with large proportions of missing outcome data. However, in doing so, the trial results may not apply to a proportion of patients who have such characteristics but may benefit from the intervention. This has implications for the external validity of the trial and the generalisability of the results. Given that a future trial should remain as pragmatic as possible to evaluate the effectiveness of the intervention in real life (see Table 24, page 156), a combination of other solutions would therefore be preferred. More suitable changes include collecting contact details directly from patients, arranging follow-up meeting with patients at the point of discharge assessment, increasing contact with patients between discharge and follow-up (Jacobsen et al., 2016) and offering incentives for completion of follow-up assessments which compensate for time taken to complete measures (Brueton et al., 2014; Royal College of Physicians, 2007), e.g. a £10 shopping voucher. A combination of these modifications is likely to improve completion of follow-up questionnaires in a main trial, however support from a research assistant will be required. While the changes described above are likely to be effective, given that loss to follow-up is common in clinical trials of complex interventions, and that major problems are associated with missing data (Dunn, 2013), it is recommended that the primary outcome of a main trial is not reliant on patients completing questionnaires, as in the current study.

Other recommended changes, or additions, to the trial design are the inclusion of outcomes which address staff and ward level outcomes, i.e. staff burnout and potential change in milieu: two key outcomes of the intervention (Clarke & Wilson, 2009). A validated measure of burnout, for example the Maslach Burnout Inventory (Maslach & Jackson, 1981), is recommended to assess intervention impact on staff outcomes. The impact of treatment on milieu, however, is more difficult to measure directly. Multiple factors, such as communication between staff and patients, decision-making procedures, organisational hierarchy and power structures, morale and the handling of conflict (Lewis, Beck, King, & Stephen, 1971) contribute to a successful therapeutic milieu. Therefore, while an outcome of general ward atmosphere should be included, for example the Ward Atmosphere Scale (Moos, 1974), more specific outcomes relating to milieu would also be informative. A specific aim of the intervention investigated in this study was to improve the quality of staff-patient interactions (i.e. facilitate more therapeutic interactions) (Clarke & Wilson, 2009). Therefore, a validated

measure of the quality of such interactions, for example the Working Alliance Inventory (Tracey & Kokotovic, 1989), could also be included in the design on a future trial, to provide an indication of change in milieu. Further consideration of other indicators or milieu targeted by this intervention should also be considered before progressing to a main trial. In addition, although the current study recorded some data regarding intervention implementation, a formal process evaluation which targets intervention fidelity should be included in future research. For example, thorough documentation and audio recordings of sessions will make clear the extent to which the intervention is delivered, and how this impacts treatment outcomes (Moore et al., 2015)

6.2.4.2 Changes to the clinical context and intervention

This trial highlighted that either the intervention or the clinical context, or both, need modifications to work in harmony. To improve implementation of the group components of the intervention, a protocol which focusses on fewer than four group therapy types may be more feasible because less staff time is required to fully implement the intervention and staff may feel more confident in their knowledge of the therapy. However, negotiations with management will still be essential to protect time for delivery and the aims of the intervention, and its reach, may need to be reconsidered. Another solution is to increase psychological resource to facilitate groups. There is evidence that consistent delivery of groups is achievable when delivered by a member of the psychological team and co-facilitated by member of ward staff (Owen, Sellwood, et al., 2015). Furthermore, increased psychological resource will increase time for staff training, which is recommended in psychiatric inpatient services to promote staff awareness of therapeutic principles because staff play a key role in encouraging and enabling participant attendance (Jacobsen, Morris, Johns, & Hodkinson, 2011). Therefore, increasing psychological resource may also have a positive effect of patient engagement. The recommended optimum ratio of full time clinical psychologist to inpatients is 1:20 (Sainsbury Centre for Mental Health, 2005). However, given that the recommended minimum is half a day per week (Royal College of Psychiatrists Centre for Quality Improvement, 2014), this seems unfeasible. Discussions at organisational level are necessary if the intervention is to be implemented in its current form.

An alternative solution to improve group implementation is to employ a designated member of staff as group facilitator. However, this is not conducive to integrating the intervention into the whole service, which is a key aim of the intervention. Consideration of available funding is

also necessary for this solution. Amendments that are more akin to the aims of the intervention are to improve the flexibility of nursing staff rotas, to ensure nursing staff have protected time for group facilitation, and to increase the psychological resource to support nurse engagement. Identifying staff who are interested in facilitating groups and are willing to work one day a week, at the same time, on the same day, for a fixed period of time may also be useful. This time can be used to facilitate and co-facilitate groups with a psychologist (Hill et al., 2009). To achieve this, managerial staff must allow a degree of flexibility in rotas. Furthermore, an assigned project 'champion' who is influential (e.g. a senior staff member) and responsible for supporting implementation of the intervention is also likely to be beneficial (Shaw et al., 2012). These approaches may be effective in terms of improving implementation of group therapies, however this study lacks knowledge of whether managerial staff will support nursing staff to routinely delivery groups. Discussion with managerial and nursing staff is needed to identify the most feasible option before progressing to a full trial.

This trial clearly shows that further work is needed to better understand and improve the process of service redesign, implementation and multi-level culture change in acute psychiatric inpatient services. The field of implementation science has recently grown and recent literature (e.g. Pfadenhauer et al., 2017) should be consulted to seek guidance for successful implementation of the intervention into routine acute psychiatric inpatient practice, if it is shown to be effective, safe and cost-effective. Formal process evaluation should be used to inform how this intervention works in this context and why. This is also important to inform how the intervention may need altered for implementation in different contexts (Moore et al., 2015).

6.2.4.3 Consideration of methodological issues not addressed in the current study

Some methodological issues, which are considered important to address in pilot/feasibility trials (Shanyinde et al., 2011), were not tested in this study but require careful consideration before progressing to a main trial. Such issues include cluster randomisation and blinding procedures, acceptability and cost-effectiveness of the intervention and the logistics of running a multicentre trial.

Given the nature of the intervention, cluster randomisation should be used in a main trial, and should ideally take place after receiving consent from clusters to minimise potential bias (Eldridge & Kerry, 2012). However, to ensure a future trial is successful, agreement from ward

managers (i.e. charge nurses) should be sought to ensure ward staff are able to attend relevant training and deliver group therapies, irrespective of being in the intervention or TAU arm as allocation to treatment should not be known until after cluster level consent is given (Eldridge & Kerry, 2012). Furthermore, as seen in this feasibility trial, acute psychiatric inpatient units can vary, for example in terms of the care pathway (i.e. continuity of inpatient and outpatient psychiatric care) or in size (i.e. the number of patients cared for per ward). The patients within each service may also differ, for example, in terms of their residential location (i.e. rural or urban) or diagnosis. To avoid imbalance between trial arms, methods such as stratification or minimisation could be employed, depending on the number of factors and clusters included (Eldridge & Kerry, 2012). Another possibility is to use a stepped wedge design, where by all clusters (wards) begin receiving TAU and then all clusters are added to the intervention arm at different, pre-specified time-points. Like stratification and minimisation, this approach avoids imbalanced influential factors between treatment arms. It is also beneficial in that psychological input would not be withheld from any ward, which has previously been deemed unethical by some clinicians (Clarke & Wilson, 2009).

Due to restricted resource, the assessor in the current study was not blind to treatment allocation. Lack of assessor blinding, however, is known be associated with inflated estimates of treatment effects (Eldridge & Kerry, 2012). Indeed the results of the meta-analysis reported in chapter three are consistant with this. Blinding of assessors is therefore imperative to progress to a main trial to improve scientific rigor and increase confidence in the conclusions drawn from it. Eldridge & Kerry (2012) highlight the risk of bias associated with identifying and recruiting participants after treatment has been allocated to clusters. However, given the high turnover and fast pace of an acute psychiatric inpatient unit, and the time needed to implement the intervention, patients cannot be recruited before treatment is randomly allocated to clusters. To avoid potential bias, a research assistant who is blind to allocation could be used to recruit participants and collect data. While this would reduce the risk of bias associated with lack of assessor blinding (e.g. at post-intervention and follow-up), a research assistant would still need to consult a member of ward staff to identify appropriate patients to participate, therefore an unavoidable risk of bias (i.e. selection bias) will remain (Eldridge & Kerry, 2012).

This study lacks information regarding the cost-effectiveness of the intervention and logistics of running a multi-centre trial. However, given the preparation involved in implementing the intervention and the cost and organisation of conducting a multisite trial, such issues should be

considered before progressing to a definitive trial. Furthermore, in a time of austerity, information regarding the expense of introducing and sustaining new interventions is extremely important for decision-makers. Therefore, as recommended by the MRC (Craig, 2012), a full economic evaluation is recommended alongside an investigation of effectiveness in order to determine the cost-effectiveness of the intervention, provide a more comprehensive overall evaluation and highlight potential savings for the NHS.

Table 24

Summary of changes and additional feasibility research required for progression to a full trial

Type of change	Change
Changes to the clinical context	Discussions with managerial staff in participating wards is necessary to ensure ward staff have adequate support and resources to facilitate groups.
	Designated project 'champion'.
	Increase psychological resource to full time clinical psychologist to inpatient ratio of 1:20, to achieve this, discussions at an organisational level are necessary.
	Guidance should be sought from the implementation science literature on implementing complex interventions in routine practice.
Changes to the intervention	Consider reducing number of group therapy types offered.
	Consider offering access to group therapies after discharge.
Changes to the trial design	Refine eligibility criteria to exclude patients who do not want to receive the intervention.
	Possible introduction of two consent points.
	Increase contact between discharge assessment and follow-up assessment.
	Inclusion of staff and ward level outcomes, e.g. burnout and change in milieu.
Additional feasibility research	Process evaluation including qualitative investigation of staff and patient experience of the intervention
	Full economic evaluation
	Formal assessment of intervention fidelity

Table 25

Example of main trial design

Aim: To determine the effectiveness of cross-diagnostic psychologically informed acute psychiatric inpatient care.

Clusters: 36 UK National Health Service acute psychiatric inpatient units. Matching using stratification of the following factors should be considered: residency (rural/urban), size (small/large), continuity of care (yes/no).

Consent (cluster level): Verbal consent from clusters (i.e. ward managers) before allocation.

Participants: 2012 acute psychiatric inpatients who express an interest in receiving psychological intervention. Adjust for matching if used.

Recruitment: Participants are recruited after clusters are randomised and recruiters will not be blind to allocation due to the nature of the intervention.

Consent (participant level): Initial consent and baseline measures obtained from participants and second consent to officially enter the trial is obtained after three days of initial consent.

Intervention: CBT based intervention (Clarke & Wilson, 2009) (see Methods chapter). Should be fully implemented before data collection begins.

Primary outcome: Readmission at 12-month follow-up (proportion of readmissions and total number of readmitted days during follow-up); possibly in preference, number of days to first readmission using a survival analysis approach (requires discussion with clinical trials unit statistician).

Secondary outcomes (patient related): Psychological distress, self-efficacy, adverse events.

Secondary outcomes (staff related): Burnout

Secondary outcomes (ward related): Milieu

6.3 Concluding remarks

With guidance from the MRC framework (Craig et al., 2008, 2013), the findings of this thesis have contributed to the development and evaluation of cross-diagnostic psychological intervention for acute mental health inpatients and has provided direction for future evaluation.

This thesis has done so using two main studies. First, it has provided the first systematic review and meta-analytical synthesis of controlled trials of the effectiveness of psychological intervention delivered in acute psychiatric inpatient settings (Chapter 3). Second, it has carried out the first study which has assessed the feasibility of conducting a definitive RCT to investigate the impact of a cross-diagnostic psychological intervention, with a specific focus on readmissions (Chapter 4, 5 and 6). This thesis has therefore contributed to phase one (i.e. development) and phase two (i.e. feasibility/piloting) of the MRC framework (Craig et al., 2008, 2013) (see Chapter 1). It has also made detailed consideration of progressing to phase three (i.e. evaluation) of the MRC framework (Craig et al., 2008, 2013).

The systematic review and meta-analysis focused on the effectiveness brief inpatient psychological therapy in terms of reducing psychotic symptoms, emotional distress and risk of readmissions. The findings indicate that in randomised, single-blind trials brief inpatient psychological intervention is not effective in reducing psychotic symptoms. However more promising findings were observed on other outcomes. The results also suggest that therapy may reduce emotional distress and risk of readmissions for patients with a variety of diagnoses. This is an important finding, given that psychological therapy is not currently routinely offered in acute inpatient services (British Psychological Society, 2012; Joint Commissioning Panel for Mental Health, 2013). This study has also highlighted that many of the studies contributing to the current evidence base are of low quality and that minimal work has investigated the benefit of psychological intervention applied cross-diagnostically. Good quality studies, e.g. RCTs, are necessary to strengthen the evidence base, definitively determine the effectiveness of cross-diagnostic psychological intervention for acute inpatients and make specific recommendations for practice. It is recommended by the MRC that large definitive trials are informed by initial feasibility work (Craig et al., 2008, 2013). The feasibility study in this thesis has contributed to the preparation required for a definitive trial of cross-diagnostic psychological care for acute inpatients.

The feasibility study aimed to investigate the feasibility of implementing and evaluating cross-diagnostic psychological intervention, largely based on the Woodhaven Approach (Clarke & Wilson, 2009). With guidance from a methodological framework (Shanyinde et al., 2011), the results of the feasibility study demonstrated that some trial processes were conducted effectively, i.e. good completion of some clinical outcomes, some components of the intervention were well implemented and some clinical outcomes produced effects which

favoured the intervention group. However, some aspects of conducting the trial and implementing the intervention were challenging. These included problematic eligibility criteria, poor completion of clinical outcomes at follow-up, poor engagement with the intervention and poor implementation of some intervention components. Using the ADePT process (Bugge et al., 2013), such problems were assessed, potential solutions were considered in detail and further feasibility work thought to be informative to future evaluation and implementation of the intervention was identified. This feasibility study has also highlighted methodological issues which have not yet been address, but are imperative to the design of a future definitive trial, e.g. randomisation and assessor blinding. Methods to implement such methodological features were also considered in this study.

Overall, this thesis has indicated that cross-diagnostic psychological therapy may be feasible for delivery in acute psychiatric inpatient settings, however further work is required to refine the intervention and fully implement and evaluate it in routine practice.

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Appendices

Appendix 1

Justification of outcomes, detail of data conversion and linked studies

The primary outcome was post intervention means measured by Positive and Negative Symptom Scale (PANSS) total scores (Hall & Tarrier, 2003; Kim et al., 2010; Moritz et al., 2011; Shelley et al., 2001). Where PANSS total scores were not reported the PANSS subscale scores were combined to create the total score which was calculated using Jauhur's (Jauhar et al., 2014) method (Bechdolf et al., 2004; Habib et al., 2015; Hayashi et al., 2001; Kumar et al., 2010). Where PANSS was not available the Brief Psychiatric Rating Scale (BPRS) or the Global Assessment of Functioning (GAF) mean scores were converted into PANSS using Leucht, and colleague's (Leucht et al., 2013) and Samara and colleague's (Samara et al., 2014) conversion (Bach & Hayes, 2002; Gaudiano & Herbert, 2006; Haddock et al., 1999; Schramm et al., 2007; Startup et al., 2004). Leucht et al.'s (Leucht et al., 2013) total score conversion table was used to convert BPRS standard deviations into PANSS standard deviations (10 point difference on BPRS converted to 19 point difference on PANSS).

Other outcomes included symptoms of depressions and anxiety at post intervention. 7 studies measured symptoms of depression (Bowers, 1990; Gibson et al., 2014; Hall & Tarrier, 2003; Kim et al., 2010; Miller et al., 1989; Mortan et al., 2011; Schramm et al., 2007). Within these 7 studies 6 measures of depression were used (BDI, DAS, HAD-D, HMRD, M-HMRD, SCL-90-R-D). HMRD and BDI are the most commonly used measures of depression in these studies, therefore where a study used either of these measures and another measure of depression, the BDI or HMRD was chosen. In a previous meta-analysis (Belvederi Murri et al., 2015) the BDI was found to be used more in research in the area of depression in schizophrenia, therefore if both the BDI and HMRD were reported the BDI was chosen. Other included measures used by studies that did not use the BDI or HMRD were the HAD-D (Hall & Tarrier, 2003) and the SCL-90-R-D (Gibson et al., 2014). Therefore, a total of 4 measures of depression were included (BDI, HAD-D, HMRD, and SCL-90-R-D). Psychometric properties of all measures were explored and found to be sufficient (see Appendix 2). Of the 22 identified studies 4 measured symptoms of anxiety (Gibson et al., 2014; Hall & Tarrier,

2003; Kim et al., 2010; Mortan et al., 2011). Within these studies 3 measures were used (HAD-A, HAMA, SCL-90-R-A). All these measures were included in order to increase the number of studies included in the meta-analysis.

Some studies were linked as multiple publications had been produced from the same research. It is vital that the studies are independent, therefore the following studies were coded once: Bechdolf et al., (2004); linked with (Bechdolf, Köhn, Knost, Pukrop, & Klosterkötter, 2005; Bechdolf et al., 2010), Startup, Jackson, & Bendix, (2004); linked with Startup, Jackson, Evans, & Bendix, (2005), and Veltro et al., (2006); linked with Veltro et al. (2008), Lewis et al., (2002)linked with Tarrier et al. (2004). Bach et al., (2013) combined readmission datasets from Bach & Hayes, (2002) and Gaudiano and Herbert (2006) in order to use an ITT analysis. This combined dataset was used for readmission outcomes only. This left 20 independent studies for meta-analysis.

Appendix 2

Properties of depression and anxiety measures

Table summarising properties of measures of depression							
Measure	**Reference**	**Reporting style**	**Items**	**Properties of scale**	**Concepts aimed to be measured**	**Previously validated (psychometric properties)**	**Included studies using measure**
Beck depression inventory	(Beck, Steer, & Brown, 1996)	Patient reported outcomes	21	-continuous. -each question 0-3. -total score between 0-63. -High score indicate higher severity.	Aims to measures characteristic attitudes and symptoms of depression	Internal consistency found to be high in psychiatric patients (.86) (Beck, Steer, & Carbin, 1988). Construct validity found to be high in relation to clinical ratings (0.72) and HMRD (0.73).	Bowers Miller Mortan Schramm
Hospital Anxiety and Depression Scale-Depression	(Zigmond & Snaith, 1983)	Patient reported outcomes	7	-continuous. -each question 0-3. -total score between 0-21. -High score indicate higher severity.	To detect states of depression	In Norwegian population the depression subscale found to: share 30% variance with anxiety subscale, have to be internally consistent Internal consistency: good in mental health population (Cronbach's alpha was 0.83) (Mykletun, Stordal, & Dahl, 2001).	Hall
Hamilton Rating Scale for Depression	(Hamilton, 1960)	Observer rated	21 but scoring based on first 17	-higher scores indicate higher severity. -8 items scored 0-4. -9 items scored 0-2. -total score between 0-50.	Depression severity among patients	Internal consistency: extremely varied as it ranges between 0.48 and 0.92 because 2 patients identical scores have different meanings (i.e. high rating on 1 item can produce same score as low ratings on a few items) Validity: found to range between 0.65 and 0.90 . Limitations: i. excludes some symptom domains of MDD, ii. Some items measure different constructs (e.g. irritability and anxiety), iii. Symptom domains are weighted differently (Cusin, Yang, Yeung, & Fava, 2009).	Bowers Kim Mortan Schramm

Modified Hamilton Rating Scale of Depression	(Miller, Bishop, Norman, & Maddever, 1985)	Observer rated	25	25 item score: -reflects total of all symptoms assessed. Same properties as HMRD. 17 item score: Same as HMRD	Severity of depression. HMRD with the following modifications: i. items were added to include greater depressive symptoms, ii. Rating points were altered to increase specificity and linearity, iii. Prompt questions added with each item so paraprofessionals could administer also.	Interrater reliability in paraprofessionals was high (Miller, Bishop, Norman, & Maddever, 1985). Relationship between clinician ratings on MHRSD and HRSD were high (Miller, Bishop, Norman, & Maddever, 1985).	Miller
Hamilton (HMRD)							

Table summarising properties of measures of depression					
Measure	**Reporting style**	**Items**	**Properties of scale**	**Concepts aimed to be measured**	**Previously validated (psychometric properties)**
HAD-A	PRO	7	-continuous. -each question 0-3. -total score between 0-21. -High score indicate higher severity.	To detect states of anxiety	In Norwegian population the anxiety subscale found to have: 30% variance with the depression subscale, internal consistency Internal consistency: good in mental health population (Cronbach's alpha was 0.85) (Mykletun et al., 2001)
HAMA **(Hamilton, 1960)**	Clinician rated	14	-continuous. -each question 0-4. -total score 0-54. -higher score indicates higher severity.	Measures anxiety symptoms (e.g. tension, insomnia, respiratory)	Internal consistency: ranges from adequate to excellent (.77 (Moras, Nardo & Barlow, 1992) to .92 (Kobak, Reynolds & Greist, 1993).
SCL-90-R-A (Derogatis, 1994)	PRO	10	-continuous -each question 0-4 (not at all to extremely). -total score 0-40.	Symptoms of anxiety and related distress	High internal consistency (alpha=.88) and high test-retest reliability (Horowitz, et al., 1988, cited in Derogatis, 1994). Cronbach's alpha coefficient found to be .88 by Gibson et al.

			-high score indicates higher severity.		

Appendix 3

Summary of selected study characteristics of included studies

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Aghotor (Aghotor et al., 2010)	Schizophrenia spectrum disorder (ICD-10 criteria, diagnoses F2.x)	UC	1. MCT 2. NRG	26	MCT	NRG	N	1. pre 2. post	N/A	C	Y	Y	H
Bach et al 2002	Psychotic disorder (DSM-IV)	10.7	1. ACT 2. ETAU	40	ACT	ETAU	Y	1. pre 2. FU	4	ITT	Y	N	L

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Bach 2012	Psychotic disorder (DSM-IV)	10.7	1. ACT 2. ETAU	120	ACT	ETAU	Y	1. pre 2. post 3. FU	4	ITT	Y	N	L
Bechdolf et al 2004	Schizophrenia and related disorders (ICD-10 criteria, diagnoses F20, F23, F25)	UC	1. Brief GCBT 2. PE	88	GCBT	PE	Y	1. pre 2. post 3. FU	6	ITT	Y	Y	H
Bowers 1990	DSM-III unipolar depression	29.43	1. CT&M 2. RT&M 3. M	30	CT&M	1. RT&M 2. M	Y	1. pre 2. post	N/A	ITT	Y	Y	H

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Gaudiano & Herbert 2006	DSM-IV diagnosis of psychotic disorder or affective disorder	10.7	1. Brief GCBT 2. PE	40	ACT	ETAU	Y	1. pre 2. post 3. FU	4	ITT	Y	N	L
Gibson et al 2014	Engaged in DSH or meet diagnostic criteria for BPD	UC	1. LTD 2. TAU	103	LTD	TAU	N	1. pre 2. post	N/A	ITT	N	N	L
Habib et al 2015	DSM-IV-TR diagnosis of schizophrenia	UC	1. CaCBTp 2. TAU	42	CaCBTp	TAU	N	1. pre 2. post	N/A	ITT	Y	Y	H
Haddock et al 1999	DSM-IV diagnosis of schizophrenia or schizo-affective disorder	46.49	1. CBT 2. SC+PE	21	CBT	SC	Y	1. pre 2. post 3. F/U	24	C	Y	Y	H

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Hall et al 2003	Diagnosis of psychotic disorder and low self esteem (as scored by RSCQ)	UC	1. CBT for self esteem. 2. TAU	25	CBT for self esteem	TAU	N	1. pre 2. post 3. F/U	3	C	Y	N	L
Hayashi et al 2001	DSM-IV diagnosis of schizophrenia	78.3	1. CBT[a] 2. TAU	58	CBT	TAU	N	1. pre 2. post	N/A	C	Y	N	L
Kim et al 2010	DMS-(V axis 1 disorders	UC	1. EMDR 2. PMR 3. TAU	45	EMDR	1. PMR 2. TAU	Y	1. pre 2. post 3. F/U	3/ 24	C	Y	Y	H
Kumar et al 2010	ICD-10 diagnosis of paranoid schizophrenia	UC	1. MCT 2. TAU		MCT	TAU	N	1. pre 2. post	N/A	UC	Y	UC	L

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Lewis et al 2002	1st or 2nd admission and meets criteria for DSM-IV diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder or Delusional disorder	UC	1. CBT for early acute schizophrenia 2. SC 3. TAU	309	CBT	1. SC 2. TAU	Y	1. pre 2. post 3. F/U	24	ITT	Y	Y	H
Miller et al 1989	Diagnosis of Major Depressive Disorder	25.35	1. CBT 2. SST 3. TAU	45	1. CBT 2. SST	TAU	N	1. pre 2. post 3. F/U	6/12	ITT	Y	N	L
Moritz et al 2011	Fulfilled criteria for schizophrenia diagnosis.	UC	1. MCT 2. CR	48	MCT	CR	Y	1. pre 2. post	N/A	ITT	Y	Y	H

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
Mortan et al 2011	Diagnosis of schizophrenia or schizoaffective disorder (DSM-IV)	UC	1. GCBT 2. TAU	12	GCBT	TAU	N	1. pre 2. post	N/A	C	N	UC	L
Schramm et al 2007	Diagnosis of MDD (DSM-IV)	UC	1. IPP 2. TAU	124	IPP	TAU	N	1. pre 2. post 3. F/U	6/12	ITT/C[b]	Y	Y	H
Shelley et al 2001	Diagnosis of schizophrenia or schizo-affective disorder	UC	1. CBT 2. TAU	48	CBT	TAU	N	1. pre 2. post	N/A	ITT	N	N	L
Startup et al 2004	Diagnosis of schizophrenia or schizo-affective disorder and	UC	1. CBT 2. TAU	90	CBT	TAU	N	1. pre 2. F/U	6/12	ITT	Y	N	L

Study characteristics of included studies.													
Study	**Target Group**	**Average length of stay (days)**	**Conditions**	**N**	**Intervention**	**Control**	**Contact with therapist in control**	**Assessment points**	**Follow-up length (months)**	**Sample for analysis**	**Randomisation**	**Assessor blinding**	**Quality (randomisation and blinding)**
	experiencing an acute psychotic episode (DSM-IV)												
Veltro et al 2006	All inpatients	12.2	1. GCBT 2. TAU	733	GCBT	TAU	N	1. F/U	48	ITT	N	N/A	L

BPD, Borderline Personality Disorder; CBT, CR, Cognitive Remediation; Cognitive behavioural therapy; CBTp, CBT for psychosis; C, Completer analysis; CT, Cognitive Therapy; CaCBTp , Culturally adapted CBT for psychosis; DSH, Deliberate self harm; EMDR, Eye Movement Desensitisation & Reprocessing; ETAU, Enhanced treatment as usual; F/U, Follow-up; GCBT, Group CBT; H, High quality; ICD-10, International Classification of Diseases; IPP, Interpersonal Psychotherapy; ITT, Intention to treat; LTD, Living through distress; L, Low quality; LOS, length of stay; MDD, Major Depressive Disorder; M, Medication; MCT, Metacognitive training; N/A, Not Applicable; N, No; NRG, Newspaper reading group; PE, Psychoeducation; Post, Post-intervention assessment; Pre, Pre-intervention assessment; PMR, Progressive Muscle Relaxation; RM, Relaxation therapy; RSCQ, Robson Self Concept Questionnaire; SC, Supportive Counselling; UC, Unclear; Y, Yes.

a. Intervention described as psychological approach, however considered CBT for the purpose of this meta-analysis.
b. ITT analysis for pre-post analysis but Completer analysis for follow-up.

Appendix 4

Summary of outcomes reported in included studies grouped by concept

Outcomes in included studies grouped by concept				
	Construct	**Measure**	**Studies using measure**	**Total No. studies reporting measure**
0	**Global Functioning**	GAF	Schramm, Startup	2
		GAS	Haas [a]	1
		RPTS	Haas [a]	1
		CGI	Gaudiano	1
		SDS	Bach, Gaudiano	2
1	**Psychiatric symptom severity**	PANSS (total)	Aghotor, Bechdolf, Habib, Hall, Hayashi, Kim, Kumar, Lewis, Moritz, Shelley	10
		BPRS	Bach, Gaudiano, Haddock, Startup	4
		PAS	Drury [a]	1
		PEF	Haas [a]	1
		PSE	Drury [a]	1
		SCL-90-G	Miller	1
		PSYRATS	Habib, Haddock, Lewis, Owen [a], Moritz	5
		Symptom Checklist	Mortan,	1
2	**Distress related to symptoms**	**Distress Total: 5**		
		H-distress	Bach, Gaudiano	2
		Symptomology-D	Haas [a]	1
		Problem Distress	Mortan	1
		CORE-10	Owen	1
3	**Negative symptoms severity**	**Negative General Total: 10**		
		PANSS (negative subscale	Bechdolf, Habib, Hall, Hayashi, Kim, Kumar, Lewis , Shelley	8
		SANS	Mortan, Startup	2
4	**Positive symptoms severity**	**Positive General Total: 12**		
		SAPS	Mortan, Startup	2
		PANSS (positive subscale);	Aghotor, Bechdolf, Habib, Hall, Hayashi, Kim, Kumar, Lewis, Moritz, Shelley,	10
		Specific:		

		SCL-90-Pos	Miller	1
		BCS	Drury [a]	1
		BABS	Kumar	1
		H-frequency	Bach, Gaudiano	2
5	**Depressive symptoms severity**	**Depression General Total: 7**		
		BDI	Bowers, Miller, Mortan, Schramm	4
		HRSD	Bowers, Kim, Miller, Schramm	4
		HAD (D-scale)	Hall	1
		HDI	Mortan	1
		SCL-90-R-D	Gibson	1
		Specific:		
		DAS	Bowers	1
		ATQ	Bowers	1
		HS	Bowers	1
		BHS	Mortan	1
		BADE (JTC)	Aghotor, Moritz	2
6	**Anxiety Symptoms severity**	**Anxiety Total: 4**		
		HAMA	Kim	1
		HAI	Mortan	1
		SCL-90-R-A	Gibson	1
		HAD (A-scale)	Hall	1
7	**Coping/self efficacy**	SCQ	Hall	1
		Problem Coping	Mortan	1
		MHSC	Owen [a]	1
8	**Service use**	Readmission (%)	Bach, Bechdolf, Gaudiano, Haddock, Kim, Lewis, Schramm, Veltro	7
		Days in hospital	Bach, Veltro	2
		Mean no. of total readmissions	Drury [a]	1
		Median time in acute care	Drury [a]	1
9	**Social functioning**	SFS	Hall, Startup	2
		SAS	Miller	1
		IPDC	Miller	1
10	**Deliberate Self Harm/Suicide**	DSI	Gibson	1
		MSSI	Miller	1
11	**Emotion Regulation**	DERS,	Gibson	1
		CERQ-short	Gibson	1
12	**Self Esteem**	RSES	Mortan	1
13	**Insight**	PANSS G12 (judgement and insight subscale)	Hayashi	1
		ABPS	Hayashi	1
		H-believability	Bach	1

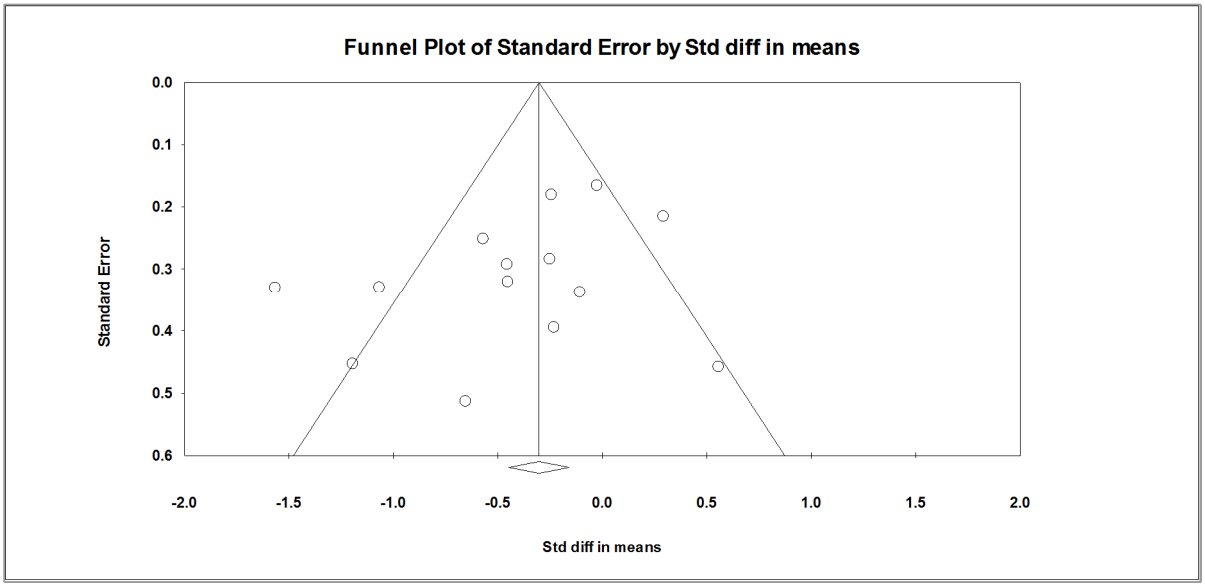
		SAI	Habib	1
14	**Personality**	MPI	Hayashi	1
15	**Quality of Life**	MSQoL	Bechdolf	1

ABPS, Awareness of Being a Patient Scale; A-Scale, Anxiety Scale; ATQ, Automatic Thoughts Questionnaire; BABS, Brown Assessment of Beliefs Scale; BCS, Belief and Conviction Scale; BDI, Beck Depression Inventory; BHS, Becks Hopelessness Scale; BPRS, Brief Psychiatric Rating Scale; CERQ-Short, Cognitive Emotion Regulation Questionnaire- Short Form; CGI, Clinical Global Impression Scale; CORE-10, Clinical Outcome Routine Evaluation-10; DAS, Dysfunctional Attitudes Scale; DERS, Difficulties in Emotion Regulation Scale; D-Scale, Depression Subscale; DSI, Deliberate Self Harm Inventory; GAF, Global Assessment of Psychological Functioning; GAS, Global Assessment Scale; HAD, Hospital Anxiety and Depression Scale; HAI, Hamilton Anxiety Inventory; HAMA, Hamilton Anxiety Rating Scale; H-believability, Hallucinations- believability; H-distress, Hallucination-distress; HDI, Hamilton Depression Inventory; H-frequency, Hallucinations frequency; HRSD, Hamilton Rating Scale of Depression; HS, Hopelessness Scale; IPDC, Interpersonal Dependency Scale; JTC, Jumping to Conclusions; MHCS, Mental Health Confidence Scale; MPI, Maudsley Personality Inventory; MSQoL, Modular System of Quality of Life; MSSI, Modified Scale of Suicide Ideation; PANSS, Positive and Negative Symptom Scale; PANSS G12, PANSS judgement and insight subscale; PAS, Psychiatric Assessment Scale; PEF, Psychiatric Evaluation Form; PSE, Present State Examination; PSYRATS, Psychotic Symptom Rating Scale; RPTS, Role Performance Treatment Scale; RSES, Rosenberg Self-Esteem Scale; SAI, Schedule for Assessment of Insight; SANS, Scale for the Assessment of Negative Symptoms; SAPS, Scale for the Assessment of Positive Symptoms; SAS, Social Adjustment Scale; SCL-90-A, Symptom Checklist 90 anxiety symptoms; SCL-90-D, Symptom Checklist 90 depression symptoms; SCL-90-G, Symptom Checklist 90 General Symptom Index; SCL-90-P, Symptom Checklist 90 Positive Symptoms; SCQ, Stress Coping Questionnaire; SDS, Sheenan Disability Scale; Symptomology-D, Symptomology-distress; SFS, Social Functioning Scale.

a. Studies excluded due to outcome measures used (Drury, Birchwood, & Cochrane, 2000; Drury, Birchwood, Cochrane, & Macmillan, 1996a, 1996b; Haas et al., 1988; Owen, Sellwood, et al., 2015).

Appendix 5

Trim and fill results for primary outcome



Funnel plot showing publication bias in primary outcome

Appendix 6

List of excluded studies

Excluded studies with rationale		
Study (first author and date)	**Reason for exclusion**	**Reason Code [a]**
Andres (1998)	Full text not in English	1
Andres (2000)	No access to required data	2
Andres (2003)	No access to required data	2
Arnevik (2010)	Therapy specialised for PD	3
Ascher-Svanum (1999)	Comparing 2 psycho-education styles.	3
Bartak (2011a)	Study is a comparison of locations of psychotherapy, therefore same psychotherapy in both groups.	3
Bartak (2011b)	Study is a comparison of locations of psychotherapy, therefore same psychotherapy in both groups.	3
Bateman (1999)	Service specialised for PD	3
Bateman (2001)	Service specialised for PD	3
Bateman (2008)	Service specialised for PD	3
Beecham (2006)	Service specialised for PD	3
Bellack (2006)	Treatment targets drug abuse	3
Berglund (2003)	Psycho-education	3
Bertelsen (2008)	Community treatment	3
Bertolin-Colilla (2011)	Review/meta-analysis (including mixed patient group)	3
Bertolin-Guillen (2011)	Conference paper. Emailed authors for more information but no response.	4
Bohus (2000)	Treatment specialised for PD/no comparator	3
Bohus (2004)	Treatment specialised for PD/waiting list control group in community	3
Bout (2008)	Centre specifically designed for couples therapy therefore not acute service	3
Brady (1984)	Outdated review	4
Candini (2013)	Outpatients	3
Carter (2010)	Outpatient/treatment specialised for PD	3
Chien (2004)	Outpatient service	3
Chien (2013)	Outpatient treatment	3
Clarke (2013)	Outpatients	3
Clarkin (1990)	Does not include chosen outcomes	2
Colom (2003)	Outpatients/psychoeducation	3
Colom (2004)	Outpatients	3
Comtois (2010)	Treatment focus on reintegration	3
Crameri (2009)	Not in English	1
Davidson (2006)	Not inpatient	3
Davidson (2010_	Not inpatient	3
Durham (2003)	Long term treatment (9 months)	3
Drury (1996i)	Not correct outcome measures	2
Drury (1996ii)	Not correct outcome measures	2

Drury (2000)	Not correct outcome measures	2
Dyck (2002)	Outpatients	3
Falloon (1985)	Community treatment	3
Feldmann (2002)	Outpatients	3
Fisher (1996)	Therapy tailored for substance abused/outpatients and inpatients included but not separated.	3
Fox (2015)	Within subjects design	3
Frank (1990)	No control group	3
Frank (2005)	Participants recruited from inpatient and outpatient services. Emailed author and author responded that 17.5% patients began as inpatients.	3
Gaudiano (2005)	Outpatients/all participants received same treatment	3
Giron (2010)	Not inpatient; long term treatment	3
Glick (1985)	Does not include chosen outcomes	2
Glick (1990)	Does not include chosen outcomes	2
Glick (1991)	Does not include chosen outcomes	2
Glick (1993)	Does not include chosen outcomes	2
Glynn (2010)	Therapy targets substance abuse/not inpatients	3
Gratz (2014)	Community treatment	3
Grawe (2006)	Not inpatients	3
Grawe (2013)	Not inpatients	3
Haller (2009)	Article in German	1
Haas (1988)	Does not include chosen outcomes	2
Haas (1990)	Does not include chosen outcomes	2
Healey (1998)	Compliance therapy	3
Herz (2000)	Outpatients	3
Herz (1979)	Comparison of hospital length not effectiveness of psychotherapy/before 1980	3
Huang (2005)	Not typical acute inpatients (all soldiers)	3
Isasi (2010)	Refractory bipolar disorder therefore not acute	3
Jackson (2008)	57% participants were outpatients.	3
Jacob (2010)	Outpatients	3
James (2004)	Therapy aims to reduce drug use.	3
Javadpour (2013)	Outpatients	3
Kanas (1980)	US airforce teaching hospital-not typical acute inpatients	3
Kessing (2011)	Outpatient	3
Kessing (2014)	Outpatients	3
Kim (2005)	Rehabilitation service- longer term and not acute.	3
Kleindienst (2011)	Inpatient service specifically for PD	3
Kliem (2010)	Specifically for PD	3
Kohler (2014)	Not a controlled trial (within design)	3
Kopelowicz (1998)	Community re-entry	3
Kopelowicz (2012)	Treatment aimed at adherence	3
Kopinke (2007)	Within group	3
Kroger (2006)	No control group.	3
Kuipers (1998)	Community treatment	3

Lam (2003)	Not inpatient treatment	3
Lana (2015)	Outpatients	3
Lee (2013)	Community	3
Leerer (1997)	Thesis. No access	4
Li (1994)	Long term hospitalisations	3
Liang (2004)	Published in Chinese	1
Liberman (1981)	Psychoeducation rather than psychotherapy	3
Linehan (1991)	Control= TAU in community; 1 year of treatment; service specifically for PD	3
Linehan (1993)	Control in community; service for PD	3
Linehan (2006)	Outpatient and community clinic	3
Linehan (2015)	Community setting	3
Links (2013)	Within group; long treatment; treatment for PD	3
Linszen (1996)	Outpatient intervention evaluation	3
Lipton (1988)	Not acute inpatient setting	3
Liu (1999)	Not psychological therapy	3
Lukoff (1986)	Not an acute inpatient environment. Holistic programme	3
Lykke (2010)	Therapy for substance abuse	3
Malik (2009)	Community treatment	3
Manning (1997)	Not controlled trial	3
Marois (2011)	Not acute inpatients	3
Marziali (1995)	Service specific for PD	3
McFarlane (1995)	2 year treatment; outpatient treatment	3
Miklowitz (2003)	Therapy began after acute hospitalisation	3
Millson (1993)	Treatment aimed at increasing water intake	3
Min (2001)	Published in Chinese	1
Monroe-Blum (1995)	Treatment specific to BPD	3
Mueser (2008)	Community treatment; treatment specific for PTSD	3
Naoki (2003)	Community re-entry therapy	3
Newton (2007)	Cognitive remediation therapy	3
Ng (2006)	Rehabilitation ward (long term)	3
Norman (2002)	Not inpatient	3
Norrie (2013)	Treatment in community	3
Novakovic (2011)	Not controlled trial	3
O'Donnell (2003)	Compliance therapy; not psychological	3
Ohlenschlaeger (2007)	Community as comparison	3
Ojeda (2012)	Rehabilitation ward	3
Owen (2015)	Does not include chosen outcomes	2
Pabst (2014)	Therapy for PTSD	3
Penn (2009)	Community and outpatient clinical	3
Penn (2011)	Community and outpatient clinical	3
Pereira (1994)	Published in Spanish	1
Petersen (2008)	Day hospital treatment; service for PD	3
Phillips (2007)	Not relevant patient group/context	3
Puschner (2011)	Not psychological therapy	3

Qu (2007)	Cognitive remediation	3
Quee (2014)	Outpatients	3
Rabovsky (2012)	Psychoeducation	3
Rea (2003)	Treatment began after hospitalisation	3
Reker (1997)	Work therapy	3
Roder (2006/2011)	Meta-analysis about psychiatric rehabilitation therefore not acute. Mixed inpatients and outpatients (not separated in analysis)	3
Roder (2006)	Vocational rehabilitation is aim of therapy and in German	1
Rodriguez (2007)	Case study	3
Ruggeri (2015)	Community service	3
Salkever (2014)	Community and rehabilitation treatment	3
Schilling (2015)	BDI data not presented – emailed author but no response	2
Schmidt-Kraeplin (2009)	Participants recruited on discharge from hospital	3
Scott (2001)	Not inpatient	3
Scott (2009)	No psychological therapy	3
Sellwood (2007)	Not inpatient	3
Sieftert (2012)	Not controlled trial	3
Sigrunarson (2013)	Not directly accessing addition of psychological therapy to TAU (also included home based crisis management, etc).	3
Silverstein (2006)	Long term inpatients (1-7 years)	3
Soloman (2008)	Outpatient and long term treatment	3
Spencer (1988)	Does not include chosen outcomes	2
Srihari (2015)	Community treatment	3
Stevenson (1999)	Outpatients	3
Styla (2012)	Residential ward therefore not acute setting. 66 participants in day-treatment setting and 39 participants in residential ward.	3
Svensson (1999)	Long term stay (average 230 days)	3
Tao (2015)	Cognitive rehabilitation	3
Tarrier (1998)	Outpatient treatment	3
Tarrier (1999)	Outpatient treatment	3
Thekiso (2015)	Treatment for substance abuse	3
Thunnissen (2008)	Assessing continued community treatment following hospitalisation	3
Turner (2000)	Not acute inpatient (recruited from emergency room and treated in community)	3
Valencia (2010)	Outpatients	3
Valmaggia (2005)	22 weeks of therapy (over 90 days).	3
Van den Bosch (2014)	Service for PD	3
Van der Gaag (2011)	Community treatment	3

Van Wel (2009)	Published in Dutch	1
Vancampfort (2011)	Not psychotherapy (PMR)	3
Van Meerten (2013)	Therapy in community (counting how many inpatient admissions following this)	3
Vaslamatzis (2014)	Comparing presence or absence of medication (psychological therapy in both groups)	3
Vauth (2005)	Rehab ward (not acute)	3
Vauth (2001)	Published in German	1
Veltro (2006)	Community; not in English?	3
Wang (2000)	Published in Chinese	1
Wang (2000)	Psychoeducation; Published in Chinese	1
Wykes (1999)	Cognitive Remediation	
Wykes (2003)	Cognitive Remediation	
Wykes (2007)	Cognitive Remediation	3
Xiang (2007)	Community re-entry (not psychological therapy). For clinically stable inpatients and outpatients.	3
Xiong (1994)	Therapy adapted specifically for complex family situation in China. Not relevant for typical acute setting.	3
Zaretsky (2008)	Patients in remission. Therefore assumed not acute.	3
Zhou (2005)	Published in Chinese; long term hospitalisation	1
Zieba (1996)	All participants received psychotherapy	3

BDI, Beck Depression Inventory; PD, Personality Disorder; PMR, Progressive Muscle Relaxation; PTSD, Post Traumatic Stress Disorder; TAU, Treatment as Usual.
a. The following codes were given for exclusion reasons: 1) Not in English, 2) Adequate data not presented/does not present data for chosen outcomes, 3) Not acute inpatient setting/appropriate psychotherapy/controlled trial, and 4) Other.

Appendix 7

Risk of bias methods and assessment

Appendix 7.1: Risk of bias methods

Selection Bias: randomisation

Low risk rating given if randomisation is reported (even is method not specified). Unclear risk rating given if randomisation is not reported. High risk rating given if non-randomisation is specified.

Selection Bias: allocation concealment

If unreported an unclear rating was given. If method for concealment was reported a low risk rating was given. If non-concealment was reported or it seemed unlikely that concealment was possible a high risk rating was given.

Performance Bias: blinding of participants and personnel

Blinding of participants and personnel is uncommon in trials of psychotherapy (Slade & Priebe, 2001) and unrealistic in an acute inpatient environment, however where unreported bias was rated as high.

Detection Bias: blinding of subjective outcomes; self and observer reported

Where non-blinding was reported a high risk of bias rating was given. If blinding was reported a low risk of bias was reported. If unreported an unclear risk of bias rating was given.

Detection Bias: blinding of objective outcomes (readmission)

Where applicable, a low risk of bias rating was given if the decision of readmission was separate from the researchers. An unclear risk rating was given if unreported. A high risk rating was given is researchers were involved in the decision of readmission.

Attrition Bias: incomplete outcome data

A high risk rating was given if ≥ 25% of those who entered the trial did not complete it (Xia et al., 2009) or if attrition was not reported (or not clearly reported) and a completer analysis was carried out. If attrition was low (≥ 25%) and completer analysis was used risk of bias was rated as low.

Reporting Bias: selective outcome reporting

If outcomes are pre-specified and reported a low risk of bias rating was given. However, if no protocol is reported a high risk of bias rating was given. If subgroup analysis is reported but not pre-specified a high risk rating was given.

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
Aghotor (Aghotor et al., 2010)	'non-stratified randomisation method' established by statistician. Randomisation used.	'Predetermined random plan'. Group assignment was previously planned.	Not reported.	Observer rater blinding.	N/A	Attrition not reported clearly. Completer analysis.	All outcomes pre-specified and reported but no protocol
	Low risk	High risk	High risk	Low risk	N/A	High risk	High risk
Bach (Bach & Hayes, 2002)	States randomisation but method not reported	Unreported	Staff were blind to treatment allocation.	Subjective measures presented orally. Assessor not blind.	Readmission data taken from hospital records.	Completer analysis	No protocol. Scores from one outcome not reported.
	Low risk	Unclear risk	Low risk	High risk	Low risk	High risk	High risk
Bach (Bach et al., 2013)[a]	Randomisation reported	Unreported (Bach) No concealment (Gaudiano).	Staff blind to treatment allocation (Bach)/staff not blind to treatment allocation (Gaudiano)	Subjective measures presented orally. Assessor not blind (Bach). Observer raters unblind to group allocation. Self report measures	Readmission data taken from hospital records (Bach). Readmission determined independently of study (Gaudiano).	About 6% missing data. ITT analysis.	All pre-specified outcomes reported. No protocol

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
				also used (Gaudiano).			
	Low risk	High risk	High risk	High risk	Low risk	Low risk	High risk
Bechdolf (A Bechdolf et al., 2004)	'Randomization conducted by computer-generated random numbers' Blocks of 8.	'results were placed in sealed envelopes'	Not reported	Psychopathology and compliance measures mostly done by independent rater. Secondary outcomes were self-report.	Readmission decided independent of study.	24% lost to 6-month follow-up and around 50% lost to 24 month follow-up. ITT used.	ITT reported. All pre-specified outcomes were reported. But no protocol.
	Low risk	Low risk	High risk	Low risk	Low Risk	High risk	High risk
Bowers (W. A. Bowers, 1990)	'Assignment to one of three groups was done on a rotating basis.'	Unreported	Unreported	Self-report measures used. But observer rated measures were blind.	N/A	Attrition not reported.	All pre-specified outcomes reported but no protocol
	Low risk	Unclear risk	High risk	Low risk	N/A	High risk	High risk
Gaudiano (Gaudiano & Herbert, 2006)	'Simple randomisation without blocking or stratification	'…without concealment.'	'Staff were not blinded to treatment allocation'.	Observer ratersnot blind to group allocation. Self-	Readmission determined independently of study.	Around 24% missing data.	All outcomes said to be reported were. But no protocol

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
	based on a computer generated list was used'			report measures also used.		Completer and ITT data analysed.	
	Low risk	High risk	High risk	High risk	Low Risk	Low risk	High risk
Gibson (Gibson et al., 2014)	Non-randomised. Assigned by timing of referrals.	Not reported	Not reported.	Assessor blinding not reported.	N/A	27% missing data. Completer analysis used where entire measures missing.	No protocol. Although pre-specified outcomes were reported.
	High risk	Unclear risk	High risk	Unclear risk	N/A	High risk	High risk
Habib (Habib et al., 2015)	Randomised using online programme	Unreported	Not reported	Blind assessors	N/A	Percentage of missing data not reported.	Previously specified outcomes were reported. Means and SDs not reported but available through contact with author.

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
							No protocol reported.
	Low risk	Unclear risk	High risk	Low risk	N/A	High risk	High risk
Haddock (Haddock et al., 1999)	Reported randomisation but no detail.	Not reported	Staff blind to treatment allocation.	Blinding of assessors reported.	Blind independent assessor using case notes.	10% attrition. Analysis unclear (likely to be completer analysis).	Subscales of measures reported-not previously specified. Follow-up data not presented due to missing data. No protocol
	Low risk	Unclear risk	Low risk	Low risk	Low risk	Low risk	High risk
Hall (P. L. Hall & Tarrier, 2003)	Reported clearly. 'Sealed envelope technique'	'Neither participants nor investigator knew which condition had been assigned until baseline	Blinding not reported. Assume staff are not blinded as they were consulted before	Assessor not blind. Inter-rater reliability checked by blind assessor.	N/A	8% attrition at post-treatment. 28% attrition at follow-up. Unclear what analysis was used.	All data pre-specified was reported with means and variance. No protocol.

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
		assessments were complete'.	assessor approached.				
	Low risk	Low risk	High risk	High risk	N/A	High risk	High risk
Hayashi (Hayashi et al., 2001)	States randomisation.	Not reported	Not reported	Assessors not blind.	N/A	Attrition not reported.	Subscale analyses carried out which were not pre-specified. No protocol reported.
	Low risk	Unclear	High risk	High risk	N/A	High risk	High
Kim (Kim et al., 2010)	Reports randomisation.	Not reported	Unreported	All observer rated. Blind assessor.	Unreported	12% attrition at post-treatment. 25% attrition at follow-up. Analysis type unknown.	'Study protocol was approved by the institutional research board of this institution'
	Low risk	Unclear	High risk	Low risk	Unclear risk	Low/High risk	Low risk
	'names of patients were shuffled and	Participants were aware of	Participants were aware of	Observer reported measures used.	N/A	Attrition not reported and	All pre-specified outcomes

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
Kumar (Kumar et al., 2010)	given numbers sequentially. Once numbers were assigned, each even numbered patient was included in the experimental group….'	allocation after randomisation.	allocation after randomisation. Blinding of staff not reported.	Blinding unreported		analysis type not specified.	reported adequately. No protocol
	Low risk	Low risk	High risk	Unclear risk	N/A	High risk	High risk
Lewis (S. Lewis et al., 2002)	Randomised	Allocation concealed	Not reported	Raters were blind	N/A	18% missing data post-treatment.28% missing data at follow-up .ITT analysis.	All outcomes reported, however subscales also reported but not previously specified. No prospective protocol reported.
	Low risk	Low risk	High risk	Low risk	N/A	Low/high risk	High risk

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
Miller (I. W. Miller et al., 1989)	Reports randomisation.	Not reported	Not reported	Assessor not blind but some interviews taped and check by blind independent raters.	N/A	ITT and completer data analysed. 33% dropout.	All means and variance reported for pre-specified outcomes. No protocol
	Low risk	Unclear risk	High risk	High risk	N/A	High risk	High risk
Moritz (Moritz et al., 2011)	Randomization plan created by statistician.	Patient informed of allocation by independent person	Patients were asked not to reveal group allocation therefore unlikely staff would know.	Observer reported measures blind to groups.	N/A	8% missing data at post-intervention. ITT used.	All pre-specified outcomes reported. Protocol registered.
	Low risk.	Low risk	Low risk	Low risk	N/A	Low risk	Low risk
Mortan (Mortan et al., 2011)	Not randomised-based on number of psychotic patients admitted at one time	Unreported	Unreported	Unreported	N/A	14% dropout at post intervention and 50% missing data at follow-up. Only completers analysed.	Mean and variance reported for only completers. No protocol

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
	High risk	Unclear risk	High risk	Unclear risk	N/A	High risk	High risk
Schramm (Schramm et al., 2007)	'dynamic allocation using minimisation method'	Unreported	Unreported	'assessments were performed by blind and independent raters'.	Unreported who decides readmission.	15% missing data at post intervention. 22% missing data at follow-up. Only ITT for post analysis. Completer analysis at both post and follow-up.	All pre-specified outcomes reported.No protocol reported.
	Low risk	Unclear risk	High risk	Low risk	Unclear risk	Low/high risk (depending on outcome)	High risk
Shelley (Shelley et al., 2001)	Not randomised. Allocated depending on ward.	Not reported	Unreported	Rated by group leader. Not blinded	Not reported	Not reported but ITT used.	No protocol
	High risk	Unclear risk	High risk	High risk	Unclear risk	High risk	High risk
	Coin toss	Coin tossed at allocation	Unreported	Assessor not blind, however 12 blind	N/A	45% dropout from	All pre-specified outcomes are

Appendix 7.2: Risk of bias assessment of included studies							
Study	**Selection Bias: random sequence generation**	**Selection Bias: allocation concealment**	**Performance Bias: blinding of participants and personnel**	**Detection Bias: blinding of subjective outcomes: self and observer reported**	**Detection Bias: blinding of objective outcomes (readmission)**	**Attrition Bias: incomplete outcome data**	**Reporting Bias: selective outcome reporting**
Startup (M Startup et al., 2004)				re-ratings showed inter-rater reliability.		intervention group during treatment. No control group drop out. Methods for missing data not reported.	reported with adequate data. However sample divided by disorganisation score and reanalysed-not pre-specified. No protocol
	Low risk	Low risk	High risk	High risk	N/A	High risk	High risk
Veltro (Veltro et al., 2006)	Not randomised. Retrospective control	No concealment as retrospective design	Blinding to group allocation not possible due to retrospective design	N/A	Unclear who assessors of readmission were	N/A	Pre-specified outcomes were reported adequately. No protocol
	High risk	High risk	High risk	N/A	Unclear risk	N/A	High risk

N/A, Not applicable.

a. Bach (Bach et al., 2013) carries out an intention to treat analysis using data from Bach (Bach & Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006), therefore data from Bach (Bach et al., 2013) was used in outcomes where Bach (Bach & Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006) were both included.

Appendix 8

GRADE assessment methods and results

Appendix 8.1

GRADE Assessment Methods

While observational studies increase the risk of bias included in an outcome, the current available literature specifically involved in evaluating psychotherapy in acute inpatient settings is limited and some of that literature is not randomised. Therefore, despite the known limitations of such inclusions, the current meta-analysis included both randomised and non-randomised trials. However, if an outcome included less than 50% RCTs the quality rating of the evidence started as moderate instead of the recommended high for RCTs or low for observational studies.

4=high; 3=moderate; 2=low; 1=very low

Risk of bias

If >50% of studies included 2 high risk of bias ratings, according to the Cochrane Risk of Bias assessment that was conducted, the quality of the outcome was downgraded (-2). If >50% of studies included 1 or more high risk of bias rating the quality of the outcome was downgraded (-1). A 'high' risk rating for non-randomisation or performance bias was excluded as one of the two ratings because non-randomisation has already been addressed (see above) and blinding of personnel and participants is uncommon and near impossible in psychotherapy trials (Slade & Priebe, 2001). If the risk of bias was not related to the outcome being assessed, the quality was not downgraded. For example, if the study was rated 'high risk' for missing data that did not relate to the outcome of interest it was not noted for that outcome.

Inconsistency

Quality was downgraded by 1 point if the I-squared statistic was >40% in the context of an unclear direction of effect or >75% in the context of a clear direction of effect. 2 points were deducted if the I-squared statistic was >75% in the context of an unclear direction of effect. An unclear direction of effect was identified by an outcome including studies which favoured both intervention and control.

Indirectness

Study population, intervention and outcome measures were considered in the rating outcomes for indirectness.

Imprecision

Precision was downgraded by 1 if "a recommendation or clinical course of action would differ if the upper versus the lower boundary of the CI represented the truth", for example if the confidence intervals include no effect and a large effect (Guyatt, Oxman, Kunz, Brozek, et al., 2011). Therefore clinical, over statistical, significance was considered. In addition to or instead of clinical significance, precision was also downgraded if the OIS (i.e. sample size or number of events) was not reached. Optimum information size (OIS) was generated using G-Power to judge imprecision. If the OIS (i.e. sample size or number of events) was not reached the outcome was downgraded (-1). Guyatt's (Guyatt, Oxman, Kunz, Brozek, et al., 2011) recommendations were used to calculate OIS of continuous outcomes: alpha was 0.05, beta was 0.20 and the effect size used was 0.2 therefore recommending OIS of 400 (n=200 in each arm). The OIS for readmission outcomes was calculated using http://www.stat.ubc.ca/~rollin/stats/ssize/ b2.html. Proportions entered into the programme were taken for all included studies reporting number of readmissions (intervention (p1)=0.24; control (p2)=0.37). The calculated OIS was n=392 (n=196 in each arm).

Publication Bias

Quality was downgraded by one level if, for outcomes including over 10 studies, funnel-plots showed asymmetry. Quality was not downgraded if less than 10 studies were included in the analysis as no evidence was available although publication bias may exist.

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
Is end of treatment PANSS total score in psychological therapy statistically superior to control?	4 All but 1 of the included studies were randomised	-2 9 of 13 studies had 2 high risk of bias ratings	-1 High heterogeneity (67.86%) and unclear effect.	0	0	0	1	Very low	Aghotor (Aghotor et al., 2010); Bechdolf (Bechdolf et al., 2004); Gaudiano (Gaudiano & Herbert, 2006); Habib (Habib et al., 2015); Haddock (Haddock et al., 1999); Hall (Hall & Tarrier, 2003); Hayashi (Hayashi et al., 2001); Kim (Kim et al., 2010); Kumar (Kumar et al., 2010); Lewis (Lewis et al., 2002); Moritz (Moritz et al., 2011); Schramm (Schramm et al., 2007); Shelley

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
									(Shelley et al., 2001); Startup (M Startup et al., 2004).
Is end of treatment PANSS total score in psychological therapy statistically superior to control in randomised and single-blind studies?	4 All studies randomised	-1 >50% studies had 1 or more high risk of bias ratings.	-1 >40% heterogeneity and unclear direction of effect.	0	-1 N exceeded OIS but wide confidence intervals (-0.46, 0.14).	N/A	1	Very low	Aghotor (Aghotor et al., 2010); Bechdolf (Bechdolf et al., 2004); Habib (Habib et al., 2015); Haddock (Haddock et al., 1999); Kim (Kim et al., 2010); Lewis (Lewis et al., 2002); Moritz (Moritz et al., 2011); Schramm (Schramm et al., 2007).
Is end of treatment PANSS total	4	-2 >50% of	0	0	-1	N/A	1	Very low	Gaudiano (Gaudiano & Herbert, 2006);

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
score in psychological therapy statistically superior to control in non-randomised and non-blind studies?	All but 1 study was randomised	studies had 2 or more high risk of bias ratings	>40% but has clear direction of effect.		N not exceeded OIS				Hall (Hall & Tarrier, 2003); Hayashi (Hayashi et al., 2001); Kumar (Kumar et al., 2010); Shelley (Shelley et al., 2001); Startup (Startup et al., 2004).
Is end of treatment PANSS total score in CBT and cognitive therapy group statistically superior to control?	4 All but 1 study was randomised	-2 >50% of studies had 2 or more high risk of bias ratings	-2 >75% heterogeneity and unclear direction of effect.	0	-1 N exceeded OIS but wide CI (-0.82, -0.07)	N/A	-1	Very low	Bechdolf (Bechdolf et al., 2004); Habib (Habib et al., 2015); Haddock (Haddock et al., 1999); Hayashi (Hayashi et al., 2001); Lewis (Lewis et al., 2002); Shelley (Shelley et al., 2001); Startup

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
									(Startup et al., 2004).
Is end of treatment PANSS total score in third wave therapy group statistically superior to control?	4 All studies were randomised	-2 >50% of studies had 2 or more high risk of bias ratings	0 0% heterogeneity and clear direction of effect	0	-1 N not exceeded OIS and wide CI (-0.95, 0.06)	N/A	1	Very low	Aghotor (Aghotor et al., 2010); Gaudiano (Gaudiano & Herbert, 2006); Kumar (Kumar et al., 2010); Moritz (Moritz et al., 2011).
Is end of treatment PANSS total score in other therapies group statistically superior to control?	4 All studies were randomised	-1 50% of studies had 1 or more high risk of bias rating	0 0% heterogeneity and clear direction of effect.	0	-1 N not exceeded OIS and very wide CI (-0.90, 0.53).	N/A	2	Low	Kim (Kim et al., 2010); Schramm (Schramm et al., 2007)
Is end of treatment	4	-1	0	0	-1	N/A	2	Low	Bechdolf (Bechdolf et al.,

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
PANSS total score in psychological therapy statistically superior to control group that had increased contact with a therapist?	All studies were randomised	50% of studies had 1 or more high risk of bias ratings	Heterogeneity did not exceed 40%		N exceeded -1 OIS but wide CI (-0.38, 0.13).				2004); Gaudiano (Gaudiano & Herbert, 2006); Haddock (Haddock et al., 1999); Kim (Kim et al., 2010); Lewis (Lewis et al., 2002); Moritz (Moritz et al., 2011); Schramm (Schramm et al., 2007)
Is end of treatment PANSS total score in psychological therapy statistically superior to control groups that	4 All but one study was randomised	-2 >50% studies had 2 or more high risk ratings.	0 >40% heterogeneity but clear direction of effect.	0	-1 N not exceeded OIS	N/A	1	Very low	Aghotor (Aghotor et al., 2010) Habib (Habib et al., 2015) Hall (Hall & Tarrier, 2003) Hayashi (Hayashi et al., 2001) Kumar (Kumar et al., 2010)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
did not have increased contact with a therapist?									Shelley (Shelley et al., 2001) Startup (M Startup et al., 2004)
Is follow-up PANSS total score in psychological therapy statistically superior compared to control?	4 All included studies randomised	-2 >50% studies had 2 or more high risk ratings	-1 >40% heterogeneity but unclear direction of effect	0	-1 N exceeded OIS but wide CI (-0.53, 0.10)	N/A	0	Very low	Bechdolf (Bechdolf et al., 2004) Hall (Hall & Tarrier, 2003) Kim (Kim et al., 2010) Lewis (Lewis et al., 2002) Startup (Startup et al., 2004)
Is follow-up PANSS total score in psychological therapy statistically	4 All studies randomised	-2 >50% have 2 or more high risk of	0 No heterogeneity (I^2=0.00)	0	-1 N exceeded OIS but wide CI (-0.22, 0.19).	N/A	1	Very low	Bechdolf (Bechdolf et al., 2004) Kim (Kim et al., 2010)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
superior compared to control in randomised and single-blind studies?		bias ratings.							Lewis (Lewis et al., 2002) Schramm (Schramm et al., 2007)
Is follow-up PANSS total score in psychological therapy statistically superior compared to control in non-randomised and non-blind studies?	4 All studies randomised	-2 >50% have 2 or more high risk of bias ratings.	0 No heterogeneity (I^2=0.00)	0	-1 N did not exceed OIS.	N/A	1	Very low	Hall (Hall & Tarrier, 2003) Startup (Startup et al., 2004)
Is there a significant difference in	4 ¾ studies randomised	-2 >50% have 2	0 Heterogeneity <40%	0	0	0	2	Low	Bach (Bach et al., 2013) (including Bach (Bach &

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
number of readmissions during follow-up period between psychological therapy and control group?		or more high risk of bias ratings.							Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006); Bechdolf (Bechdolf et al., 2004); Kim (Kim et al., 2010); Lewis (Lewis et al., 2002); Schramm (Schramm et al., 2007); Veltro (Veltro et al., 2006);
Is there a significant difference in number of readmissions during	4 All studies randomised	-1 > 50% studies have 1 or more high	0 Heterogeneity <40%	0	-1 N exceeded OIS but wide CI (OR: 0.54, 1.28)	N/A	2	Low	Bechdolf (Bechdolf et al., 2004) Kim (Kim et al., 2010)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
follow-up period between psychological therapy and control group in randomised and single-blind studies?		risk of bias ratings.							Lewis (Lewis et al., 2002) Schramm (Schramm et al., 2007)
Is there a significant difference in number of readmissions during follow-up period between psychological therapy and control group in non-	4 All but 1 study randomised	-2 All studies have 2 or more high risk of bias ratings.	0 Heterogeneity <40%	0	0	N/A	2	Low	Bach (Bach et al., 2013) (including Bach (Bach & Hayes, 2002) and Gaudiano (Gaudiano & Herbert, 2006); Veltro (Veltro et al., 2006)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
randomised and non-blind studies?									
Is there a significant difference in depression between psychological therapy and control group?	4 5/7 included studies are randomised	-2 All studies have 2 or more high risk of bias ratings.	0 Heterogeneity >40% with clear direction of effect	0	-1 N does not reach OIS	0	1	Very low	Bowers (Bowers, 1990) Gibson (Gibson et al., 2014) Hall (Hall & Tarrier, 2003) Kim (Kim et al., 2010) Miller (Miller et al., 1989) Mortan (Mortan et al., 2011) Schramm (Schramm et al., 2007)
Is there a significant difference in depression	4 All studies are randomised	-1 Over 50% of studies	0 0% heterogeneity	0	-1 N does not reach OIS and wide CI	N/A	2	Low	Bowers (Bowers, 1990) Kim (Kim et al., 2010)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
between psychological therapy and control group in randomised and single-blind studies?		included at least one high risk of bias rating			(-0.84, 0.18).				Schramm (Schramm et al., 2007)
Is there a significant difference in depression between psychological therapy and control group in non-randomised and non-blind studies?	3 50% of studies were not randomised	-2 Over 50 % of studies included as least 2 risk of bias ratings.	0 >40% heterogeneity but clear direction of effect.	0	-1 N does not reach OIS and wide CI (-1.18, 0.18).	N/A	1	Very low	Gibson (Gibson et al., 2014) Hall (Hall & Tarrier, 2003) Miller (Miller et al., 1989) Mortan (Mortan et al., 2011)
Is there a significant difference in	4 50% if included	-2 Over 50 % of	0 heterogeneity >40% with	0	-1 N does not reach OIS	N/A	1	Low	Hall (Hall & Tarrier, 2003)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
depression between psychological therapy and control group in patients diagnosed with psychosis?	studies are randomised	studies included as least 2 risk of bias ratings.	clear direction of effect		and wide CI (-1.18, 0.16).				Kim (Kim et al., 2010) Mortan (Mortan et al., 2011)
Is there a significant difference in depression between psychological therapy and control group in patients diagnosed with depression?	4 50% if included studies are randomised	-2 Over 50 % of studies included as least 2 risk of bias ratings..	0 no heterogeneity.	0	-1 N does not reach OIS and wide CI (-1.03, 0.08).	N/A	1	Low	Bowers (Bowers, 1990) Miller (Miller et al., 1989) Schramm (Schramm et al., 2007)
Does psychological	4	-2	0	0	-1	N/A	0	Very low	Gibson (Gibson et al., 2014)

Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
therapy have a significant effect on symptoms of anxiety at post intervention compared to control?	50% of included studies are randomised	Over 50 % of studies included as least 2 risk of bias ratings.	Heterogeneity >40% with clear direction of effect.		N does not reach OIS and wide CI (-0.70, 0.10).				Hall (Hall & Tarrier, 2003) Kim (Kim et al., 2010) Mortan (Mortan et al., 2011)
Does psychological therapy have a significant effect on 'coping' at post intervention compared to control?	N/A	N/A	N/A	0	N/A	N/A	N/A	Important outcome for patients however too few report this outcome (k=3)	
Does psychological therapy have a significant	N/A	N/A	N/A	0	N/A	N/A	N/A	Important outcome for patients however	

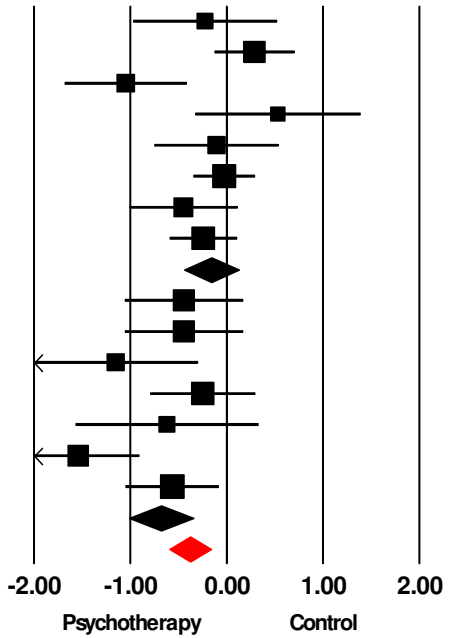
Appendix 8.2 Summary of GRADE assessment results									
Outcomes and questions	**Starter number (what % of studies are randomised)**	**Quality (risk of bias)**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall**	**Comments**	**Included studies**
effect on quality of life at post intervention compared to control?								too few studies directly report this outcome (k=1)	
CBT, Cognitive Behavioural Therapy; OIS, Optimal Information Size; PANSS, Positive and Negative Symptom Scale.									

Appendix 9

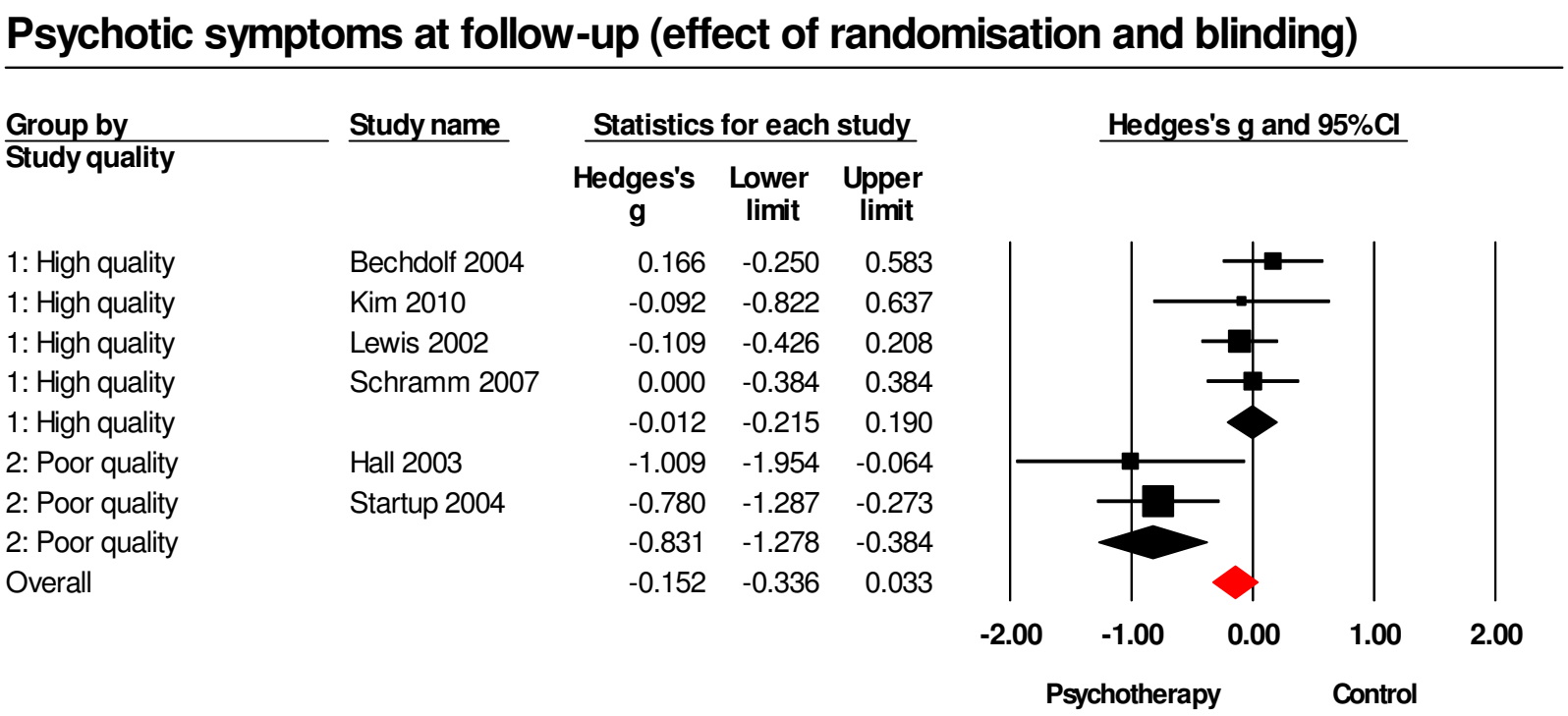
Subgroup analyses forest plots

Psychotic symptoms (effect of randomisation and blinding)

Group by Quality	Study name	Hedges's g	Lower limit	Upper limit
1=high quality	Aghotor 2010	-0.224	-0.973	0.525
1=high quality	Bechdolf 2004	0.289	-0.129	0.707
1=high quality	Habib 2015	-1.048	-1.682	-0.413
1=high quality	Haddock	0.532	-0.328	1.392
1=high quality	Kim 2010	-0.105	-0.754	0.544
1=high quality	Lewis 2002	-0.025	-0.348	0.297
1=high quality	Moritz 2011	-0.449	-1.013	0.115
1=high quality	Schramm 2007	-0.242	-0.594	0.109
1=high quality		-0.160	-0.445	0.125
2=low quality	Bach 2002	-0.444	-1.060	0.172
2=low quality	Gaudiano 2006	-0.444	-1.060	0.172
2=low quality	Hall 2003	-1.152	-2.008	-0.296
2=low quality	Hayashi 2001	-0.248	-0.796	0.300
2=low quality	Kumar 2010	-0.619	-1.570	0.332
2=low quality	Shelley 2001	-1.540	-2.177	-0.904
2=low quality	Startup 2004	-0.564	-1.051	-0.077
2=low quality		-0.682	-1.015	-0.349
Overall		-0.380	-0.597	-0.164

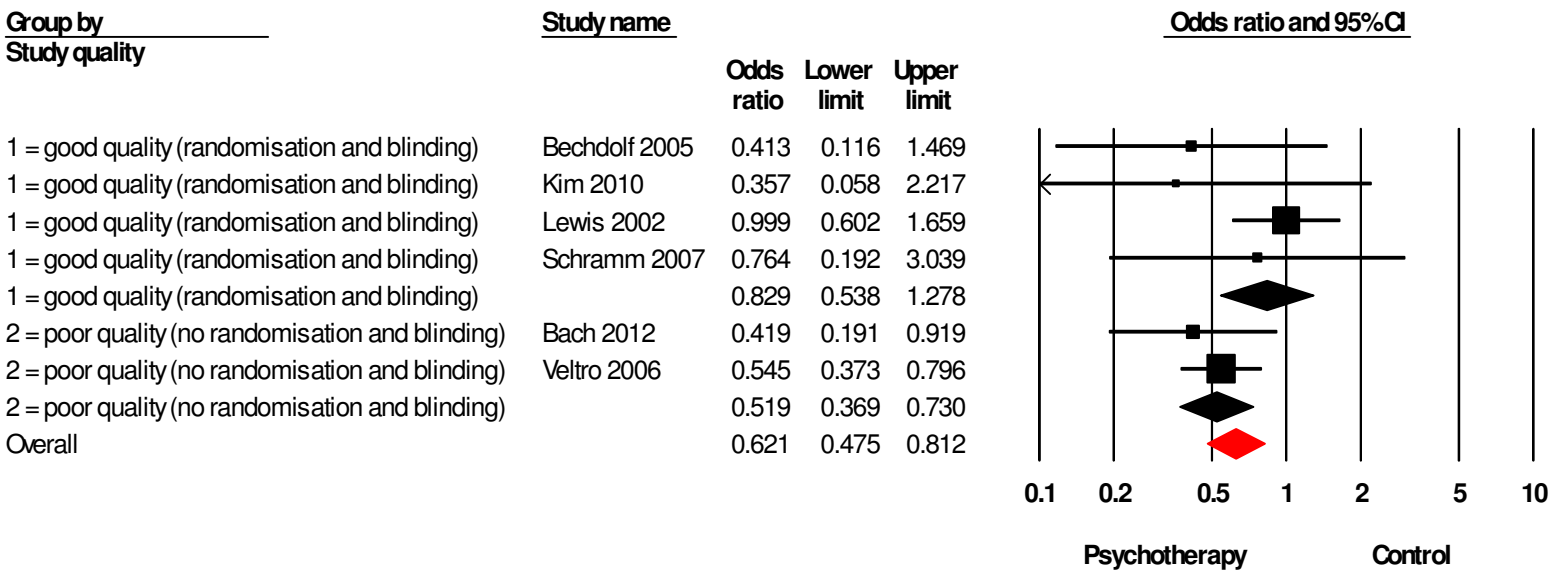


Appendix 9.1 Forest plot showing effect of randomisation and assessor blinding on psychotic symptoms at post-intervention



Appendix 9.2 Forest plot for effect of study quality on symptoms at follow-up

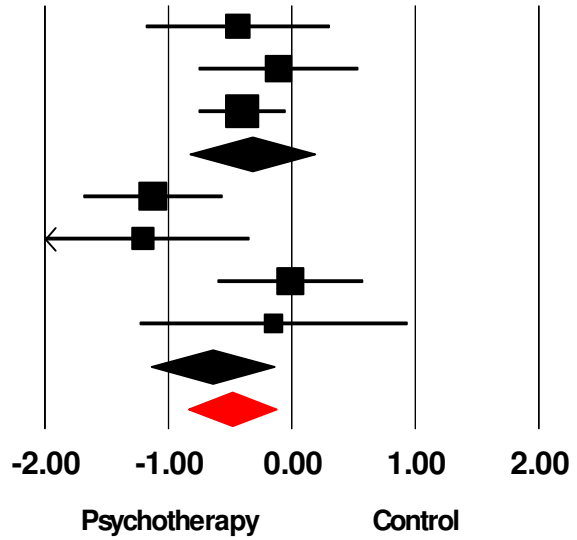
Readmissions (effect of randomisation and blinding)



Appendix 9.3 Forest plot for effect of study quality on readmission

Depression (effect of randomisation and blinding)

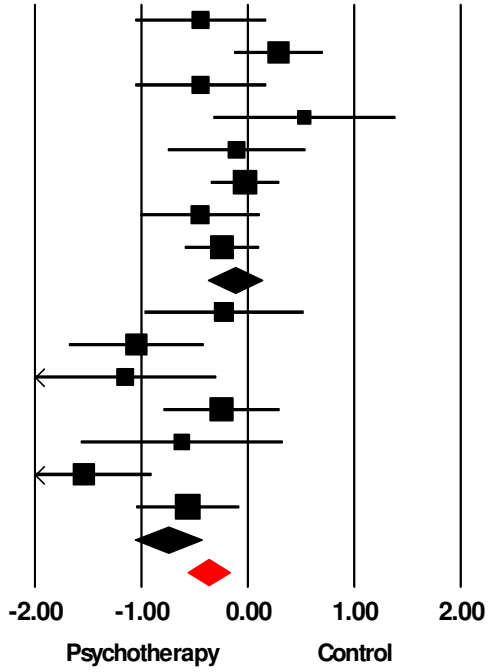
Group by Study quality	Study name	Hedges's g	Lower limit	Upper limit
1 = good quality	Bowers	-0.436	-1.183	0.311
1 = good quality	Kim	-0.108	-0.757	0.541
1 = good quality	Schramm	-0.402	-0.755	-0.048
1 = good quality		-0.324	-0.829	0.182
2 = poor quality	Gibson	-1.125	-1.690	-0.561
2 = poor quality	Hall	-1.205	-2.067	-0.343
2 = poor quality	Miller	-0.012	-0.604	0.580
2 = poor quality	Mortan	-0.148	-1.234	0.939
2 = poor quality		-0.645	-1.143	-0.147
Overall		-0.487	-0.842	-0.132



Appendix 9.4 Forest plot for effect of study quality on depression

Psychotic symptoms (effect of control)

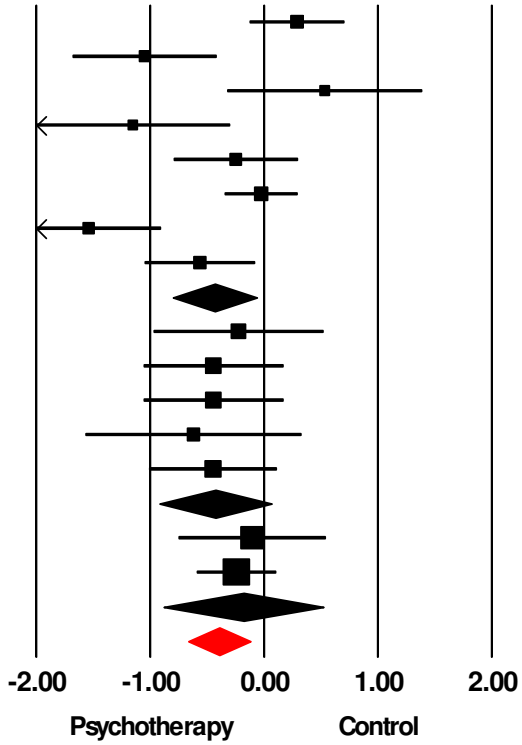
Group by Therapist Contact	Study name	Hedges's g	Lower limit	Upper limit
1=probable contact	Bach 2002	-0.444	-1.060	0.172
1=probable contact	Bechdolf 2004	0.289	-0.129	0.707
1=probable contact	Gaudiano 2006	-0.444	-1.060	0.172
1=probable contact	Haddock	0.532	-0.328	1.392
1=probable contact	Kim 2010	-0.105	-0.754	0.544
1=probable contact	Lewis 2002	-0.025	-0.348	0.297
1=probable contact	Moritz 2011	-0.449	-1.013	0.115
1=probable contact	Schramm 2007	-0.242	-0.594	0.109
1=probable contact		-0.121	-0.375	0.132
2=no probable contact	Aghotor 2010	-0.224	-0.973	0.525
2=no probable contact	Habib 2015	-1.048	-1.682	-0.413
2=no probable contact	Hall 2003	-1.152	-2.008	-0.296
2=no probable contact	Hayashi 2001	-0.248	-0.796	0.300
2=no probable contact	Kumar 2010	-0.619	-1.570	0.332
2=no probable contact	Shelley 2001	-1.540	-2.177	-0.904
2=no probable contact	Startup 2004	-0.564	-1.051	-0.077
2=no probable contact		-0.751	-1.064	-0.438
Overall		-0.370	-0.567	-0.173



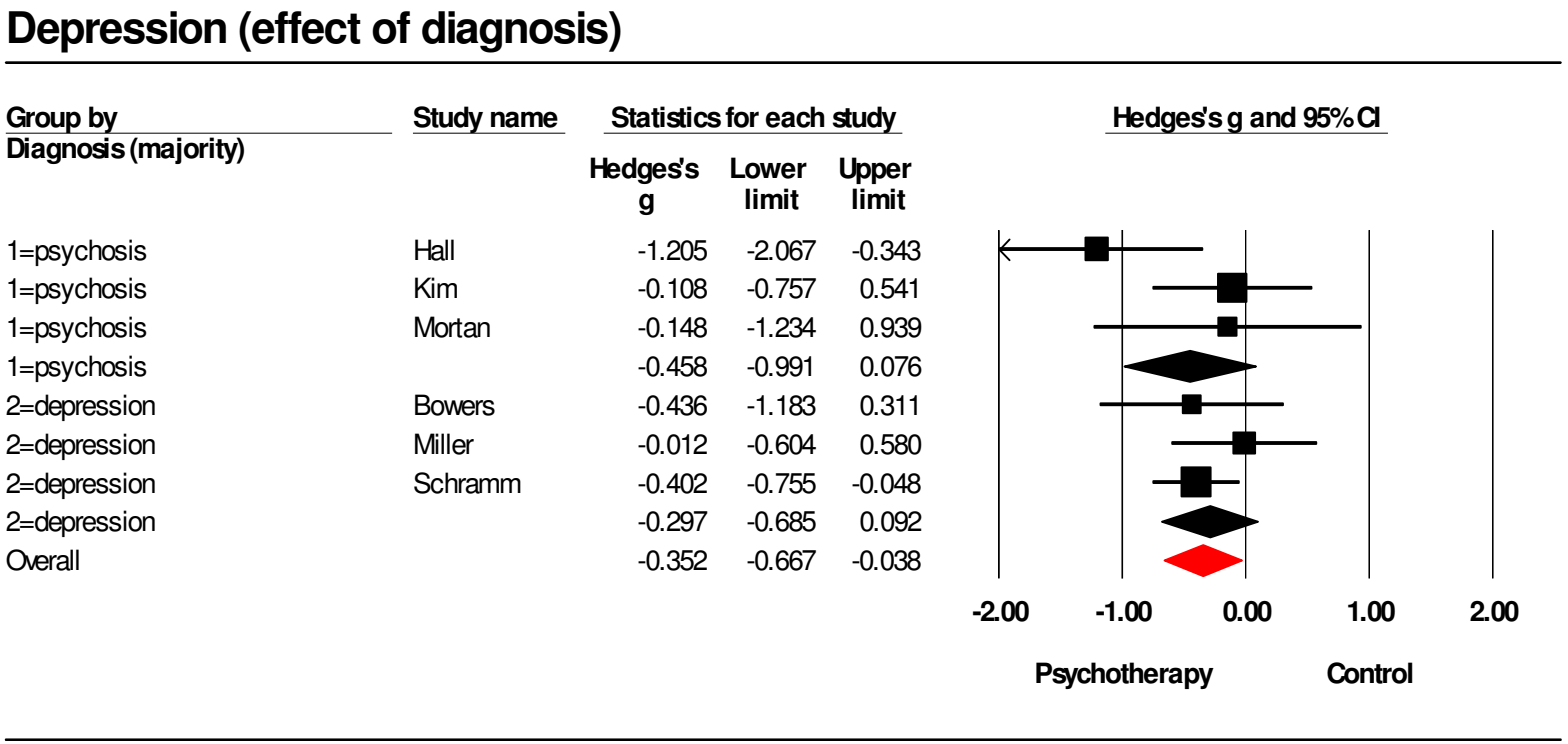
Appendix 9.5 Forest plot for effect of 'contact with therapist in control group' on overall psychotic symptoms at end of treatment

Psychotic symptoms (effect of therapy type)

Group by Therapy type	Study name	Hedges's g	Lower limit	Upper limit
1=CBT/CT	Bechdolf 2004	0.289	-0.129	0.707
1=CBT/CT	Habib 2015	-1.048	-1.682	-0.413
1=CBT/CT	Haddock	0.532	-0.328	1.392
1=CBT/CT	Hall 2003	-1.152	-2.008	-0.296
1=CBT/CT	Hayashi 2001	-0.248	-0.796	0.300
1=CBT/CT	Lewis 2002	-0.025	-0.348	0.297
1=CBT/CT	Shelley 2001	-1.540	-2.177	-0.904
1=CBT/CT	Startup 2004	-0.564	-1.051	-0.077
1=CBT/CT		-0.436	-0.803	-0.069
2=Third Wave	Aghotor 2010	-0.224	-0.973	0.525
2=Third Wave	Bach 2002	-0.444	-1.060	0.172
2=Third Wave	Gaudiano 2006	-0.444	-1.060	0.172
2=Third Wave	Kumar 2010	-0.619	-1.570	0.332
2=Third Wave	Moritz 2011	-0.449	-1.013	0.115
2=Third Wave		-0.430	-0.922	0.062
3=Other	Kim 2010	-0.105	-0.754	0.544
3=Other	Schramm 2007	-0.242	-0.594	0.109
3=Other		-0.184	-0.885	0.517
Overall		-0.396	-0.668	-0.125



Appendix 9.6 Forest plot for effect of therapy type on overall psychotic symptoms at end of treatment



Appendix 9.7 Forest plot for effect of diagnosis on depression

Appendix 10

Manual for 'Living Well with Emotions'

Living Well with Emotions

6 Session Group program

Facilitators Guide

Adapted from DBT skills training manual (Linehan 1993).
Resources from The Happiness TRAP - ACT (Harris, 2008);
WISE choices manual (Spectrum & Harris 2009).

Living Well with Emotions

Session 1.

Introduction – names

Introduction to the group:
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:

- Exploring our feelings or "emotions".
- Learning how to understand our emotions.
- Learn skills to manage our emotions, instead of them managing us.

***Group Rules** – Review with Flip Chart
Respect others, confidentiality, being aware that discussion about trauma/self harm can be a trigger for other people in the group.

*Introduce the Point - To learn how to cope with emotions we first need to become aware of which emotions we are experiencing and when we are experiencing them. This is a bit like the idea that: "It is hard to come up with a solution if we don't really know what the problem is". Being aware of our emotions can be tricky because a lot of the time we try to ignore or avoid our painful emotions. This seems to be a normal response that most of us try from time to time – but when we do it all the time it can start to be unhelpful.

*Group Discussion (use flip chart if necessary)
What kind of ways do we try to ignore our painful emotions, or push them away? What happens when we do this? Do the painful emotions go away?

Point
Analogy of holding an inflatable ball under the water – It takes a lot of effort to try and push these emotions away, we can't push them away forever, and when we do stop pushing them away they can jump right back

into our faces. How would it be different if instead of trying to push the plastic ball under the water, we just let it float on the water around us? The plastic ball would still be the same (i.e.: the emotion would still be the same), but you would not be involved in such a struggle. When we are so focused on pushing away the negative emotion, we might not have any space left to pay attention to the more positive emotions. In this group the goal is not about getting rid of all emotions – it is about learning how to cope with the more painful emotions, so that you are not struggling and fighting against them all the time.

*Flip chart –Identifying and labelling emotions – Ask group members to see if they can identify and label any emotions that they have experienced in past 24 hours. Provide your own responses to model for the group members if needed. Prompt for different names for emotions, and body experiences that accompany different emotions. Prompt for positive emotions.

*Discussion - It can be hard to identify or be aware of our emotions. It can also be difficult because we can experience numerous emotions at the same time.

Reflect on how it can be difficult to see the positive experiences. It can be like we are wearing blinkers, which are making us focus on the painful experiences, and block out any of the positive experiences. It can also be difficult because we can experience numerous emotions at the same time.

*Discussion – Emotions involve body changes such as tensing or relaxing muscles, change in blood vessels, change in heart rate and temperature, changes in facial muscles. What body changes have people in the group noticed?

Mindfulness Practice–
Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath.

Be aware as you breathe in…and be aware as you breathe out…... Notice your breath without trying to change it. Just acknowledge it as it is.

Focusing on your stomach as you breathe in... and as you breathe out …. Notice if your mind wanders, just acknowledge this, and gently bring your focus back to your breath.

Notice any physical sensations in your body; notice how your body feels against the chair – your back against the chair, the air against your skin, your feet against the soles of your shoes. Notice any tension or tightness in your body – just notice without any judgement.

Now gently bring your focus to your feelings or emotions. Notice any sense of emotions, unpleasant feelings, pleasant feelings, discomfort. Just notice their presence without any judgment. Acknowledge their presence.

Gently bring your focus back to your breath. Noticing as you breathe in… and noticing as you breathe out…
being aware as you breathe in.. and aware as you breathe out… Noticing how your stomach may rise and fall as you breathe in…and out ….

And when you are ready return your focus to the room, opening your eyes when you feel ready, and stretching to wake your body up if you need to.

*Enquiry
What did people notice during that exercise?

Homework –
Practice mindfulness exercise – stopping and noticing feelings.
Practice exercise of labelling different emotions that you experience.

Session 2.
Introduction – names, welcome new group members.

Introduction to the group (for new group members):
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:

- *Exploring our feelings or "emotions".*
- *Learning how to understand our emotions.*
- *Learn skills to manage our emotions, instead of them managing us.*

**Recap of group rules – Respect, confidentiality, aware that discussion about trauma/self harm can be a trigger for other people in the group.*

OPEN WITH A BRIEF FOCUS ON BREATH EXERCISE

*Recap on homework from last session – labelling different emotions experienced. Mindfulness exercise – awareness of emotion experienced.

*Introduce Point – Painful and traumatizing experiences can lead us to have very intense emotions. Our emotions can be reactions to events, or reactions to thoughts/memories. Fighting against these emotions or trying to ignore them sometimes makes them worse. Sometimes we can keep emotions going by fighting against them.

- Group discussion – (use flip chart as needed)

Ask group of they can think of any times they have done something to try to get rid of a painful emotion, but it just ended up keeping that emotion around for longer? (model answers as needed - alcohol, arguments, medication etc).

POINT - Sometimes it can be helpful to think of emotions as "waves in the sea". Some waves can be bigger than others. But all emotions will pass like all waves pass. Emotions will pass if we don't struggle with them or try to get rid of them.

***Point** – **So why we do experience emotions?**
Emotions have a purpose. And because they have a purpose they can be hard to change.

1. Emotions communicate to others. Our facial expressions communicate to others how we are feeling without words. When we really want someone else to know how we are feeling it can be hard for us to change the emotion until this happens. Some people can mask their facial expressions (both consciously and subconsciously) – what do you think happens to the emotion in these cases?

2. Emotions organise us and get us ready for action. For example they motivate us. If we feel really passionately about a certain charity the emotion might motivate us to get involved and do some volunteer work. Emotions can be helpful in certain situations – fear motivates us to leave a dangerous situation without having to think about it. It can be a hard wired response (leaving a building that is on fire). Strong emotions can help us overcome obstacles (in our mind or the environment). EG: Woman lifting a heavy object that her pet dog was trapped under, motivated by love/fear.

3. Emotions can be self validating - Our emotional reactions to certain situations can be a signal about that situation (or person). For example –if we are feeling excited it may give us information that we are looking forward to the situation, if we are feeling love it may give us information that the person we are near is important to us. But sometimes we can get this wrong. If we treat emotions as facts we can run into difficulty, for example "If I'm afraid I might automatically assume that what I'm afraid of it threatening". So treating the emotion as a fact, even when this is not the case.

***Group brainstorm** – Can people think of an emotion that they recently experienced. What do you think was purpose of that emotion? Highlight that sometimes it is not clear. People can have emotions related to painful memories – maybe the emotion is highlighting to the person that the painful experience from the past was difficult – self validating, signalling

that it was awful. However that signal can get stuck in the "on" position, even though the experience was in the past.

<u>*Point</u> - So what can we do to cope with emotions?
The key to remember, it is not about doing "what is right" – it is about doing what **works**. There is no right way to feel, and there is no wrong way to feel. In the same way, there is not right or wrong way to cope with our emotions. What we need to do is figure out what is an **effective** way for us to cope with our emotions. What do we mean by **effective**? (Doing what works, coping with the emotion without causing harm to ourselves/others).

<u>Group brainstorm</u> – write suggestions on flip board (give group members the associated handout so they can write some of these coping ideas down on their own sheet).
What effective ways to cope with emotions have people come across? So, ways to cope with emotions that aren't harmful to yourself or others, and don't make the painful emotion worse.

E.G.: when feeling sad – notice feeling that way – be kind to myself. Wrap up in a nice duvet and watch favourite comedy show. Provide other examples for the group if needed, going for a walk, listening to music, having a bath, talking to a friend.

<u>Mindfulness Exercise –</u>
Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath. Be aware as you breathe in and be aware as you breathe out. Notice your breath without trying to change it. Just acknowledge it as it is. Focusing on your stomach as you breathe in...and as you breathe out..... Notice if your mind wanders, just acknowledge this, and gently bring your focus back to your breath.

Be aware that the mind likes to wander, that is what it does. It is completely normal for the mind to wander. Just notice when this happens and try to gently bring your focus back to your breath. Being aware as you are breathing in... and aware as you are breathing out.....

Sometimes we can have difficult thoughts or memories in our mind. We can acknowledge that these thoughts or memories are there, but then gently return our focus to our breath. Being aware as we breathe in..... and being aware as we breathe out..... Noticing how your stomach may rise and fall as you breathe in and out. Each time we return our focus to the breath you can allow the difficult thoughts or memories to fall into the background, noticing that their volume is reducing.

Each time it wanders, bringing your focus back to your breath. Noticing as you breathe in and noticing as you breathe out... being aware as you breathe in and aware as you breathe out. Noticing how your stomach may rise and fall as you breathe in and out.

And when you are ready return your focus to the room, opening your eye when you feel ready, and stretching to wake your body up if you need to.

*Enquiry
What did people notice during that exercise?

Homework
Practice the mindfulness exercise – returning focus to the breath.
Try out a different ("effective") way of coping with your emotions.

Session 3.
Introduction – names, welcome new group members.

Introduction to the group (for new group members):
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:

- *Exploring our feelings or "emotions".*
- *Learning how to understand our emotions.*
- *Learn skills to manage our emotions, instead of them managing us.*

**Recap of group rules – Respect, confidentiality, aware that discussion about trauma/self harm can be a trigger for other people in the group.*

OPEN WITH A BRIEF FOCUS ON BREATH EXERCISE

*Recap on homework
1. Mindfulness practice – returning focus to the breath.
2. Trying out a different (or "effective") ways to cope with your emotions.
*Use flip chart with effective ways of coping ideas from last session to review homework. In this way people who are new to the group will have an opportunity to think about some strategies they could try, and provide any suggestions that they have.

*Point - Learning to be aware of your emotions can make it easier to see that they are not *who* you are but that they are something you are experiencing. It can sometimes be difficult to focus on our emotions, particularly if they are very painful emotions. As humans we can have a tendency to try to ignore them or push them away. But if we can learn to be aware of our emotions, and label what we are feeling, we can sometimes create a bit of distance from the difficult emotion (labelling "I am feeling depressed" creates more distance rather than thinking "I am depressed").

Point - For some people emotions can be like a fog – it can be hard to pinpoint what they are feeling. Does anyone identify with this experience? In these situations it is good to start with what you notice you are feeling in your body physically. Can people thing of some physical sensations they notice in their body when they experience different emotions?

Point - Remember the idea that emotions are like waves, they come and go. If we can learn not to fight against them or try not to push them away or avoid them they are more likely to pass like a wave.

*Point – One of the reasons we have emotions is as a way to communicate to others. We can express our emotions in different ways.

***Discussion point - How do we express our emotions?**

1. Body Language – posture, facial expression. Some facial expressions are hard wired and easier to understand, for example a smile when someone is feeling joy.

2. Words – "I am sad" "I'm sorry" "I hate you" "I love you".

3. Actions – hitting, running towards someone, withdrawing, kissing.

***Group Discussion Use flip chart and ask group members for feedback.**

- Do you have any experience of expressing an emotion and it being misread? (E.G. – saying I'm fine… but body language displaying something else)

- Are there certain ways that we express our emotions that can leave us feeling worse? Eg: arguments, harmful actions, shouting.

- What do you think the problem is with trying not to show any emotion at all – so shutting down – trying not to show any expression etc? Does it help you to feel different when you do this? (Prompt - It might keep the emotion going)

***Group brainstorm – write suggestions on flip board.**
What have you noticed to be **effective** ways to express your emotions? So ways of expressing emotion that works for you. Ways to express

emotions which help you to communicate how you are feeling in a way that has not resulted in making things more difficult for you?

Intro to Mindfulness exercise

Mindfulness can help up to observe our emotions, and step back from them giving us some distance from them. The distance can give us the chance to problem-solve things. It can help us to experience our emotions, but not act on them.

Mindfulness exercise –

Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath. Be aware as you breathe in and be aware as you breathe out. Notice your breath without trying to change it. Just acknowledge it as it is. Focusing on any movement in your stomach as you breathe in...and as you breathe out.....

Gently shift your attention to any body sensations you are experiencing. See if you can notice any physical sensations in your body, any tension or tightness in your muscles, just notice without judgment. Are there other physical sensations that you are experiencing in your body, any tingling or warmth in your body? Do you notice any pain or discomfort? Do you notice any muscles that feel more relaxed? Just see if you can label what you notice without any judgment, just acknowledging these sensations as they are.

Now can you gently bring your focus to any emotions that you are experiencing? Try to just observe any of these emotions, without any judgement. See if you can become aware of them, as if you are just an observer. Can you label the emotion, and give them a name. Just acknowledge the emotions, noticing the emotion just as it is. Being aware that you can experience the emotion, without having to act on it. You can acknowledge its presence.

And now gently return your focus to your breath, being aware as you breathe in and aware as you breathe out. Noticing that the emotion can fall into the background as you return your focus to your breath. Bringing your attention back to the rise and fall of your stomach as you breathe in and as you breathe out. Noticing if your mind wanders, acknowledging what it has wandered to, and then gently bringing your

focus back to you breathe. Following your in breath, and following as you breathe out. Breathing in...and breathing out .....

And when you are ready return your focus to the room, opening your eye when you feel ready, and stretching to wake your body up if you need to.

*Enquiry
What did people notice during that exercise?

Homework
Practice the mindfulness exercise – labelling body sensations and emotions.
Try out a different ("effective") ways of expressing your emotions.

Session 4.
Introduction – names, welcome new group members.

Introduction to the group (for new group members):
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:
- *Exploring our feelings or "emotions".*
- *Learning how to understand our emotions.*
- *Learn skills to manage our emotions, instead of them managing us.*

**Recap of group rules – Respect, confidentiality, aware that discussion about trauma/self harm can be a trigger for other people in the group.*

OPEN WITH A BRIEF FOCUS ON BREATH EXERCISE

*Recap on homework
- Mindfulness exercise – labelling body sensations and emotions.
- Trying out effective ways of expressing your emotions. (*Use flip chart to write up the groups ideas of: effective ways of expressing ideas from last session as a review of homework. In this way people who are new to the group will have an opportunity to think about some strategies they could try, and provide any suggestions that they have).

*Point – Painful emotions can be difficult to experience. Sometimes as humans we try to push these emotions away or avoid them. However this usually just results in the painful emotions staying around for longer. If we can stop fighting against the painful emotions we can see that the emotions will come and go. We can think of them like waves. If we can label our emotions and learn how to observe our emotions, it can give us some distance or breathing space from them. The emotions might still be painful but by observing them without any judgment, we can stop them from feeling over-whelming. We can learn to experience our emotions without feeling like we have to act on them.

*Group Discussion – Have people had the experience of having painful/difficult emotions, and been able to sit back and observe the emotion? Or label the emotion without acting on it?

*Group Brainstorm – (use flip chart to write up ideas).
There are certain times when we are more likely to feel our emotions more intensely. For example when we are very tired. Can people think of other times/situations when you notice you can experience your emotions more intensely?

*Point - There are some strategies that we can use to reduce our vulnerability to experiencing overwhelming emotions. A lot of these strategies are things that we might already know, but sometimes it can be hard to put these things into practice.

POINT - How to reduce our vulnerability to overwhelming emotions

1. Treat Physical Illness

Being sick can make you more vulnerable to painful/difficult emotions. Do the group have any examples of this?
What stops us from looking after our physical health, can we problem solve any of these barriers?

2. Balanced eating

When we are hungry we are more vulnerable to difficult/painful emotions. What foods do people notice makes them feel better (e.g. chocolate). Thinking about having a balanced diet, eating things in moderation.

3. Avoid mood altering drugs (that are not prescribed for you)

Alcohol and drugs can make us more vulnerable to experiencing painful emotions. Discuss with group what they have noticed. Discuss any difficulties with staying off/away from mood altering drugs – how to problem solve this.

4. Balanced Sleep

When we are not sleeping, or tired we are more vulnerable to over whelming emotions. Have people experience of this? What kinds of things have people noticed that have helped with their sleep?

5. Get Exercise

Doing exercise that gets your heart beating faster, such as walking at a brisk pace or climbing a flight of stairs, can help improve mood. Discuss- What sort of things stop us from doing exercise? Any group members have suggestions on how to problem solve this?

6. Doing things that give you a sense of achievement

When we do things that make us feel good, or give us a sense of achievement it can have a positive impact on our mood. Examples might be getting dressed that day, or registering at the GP, or playing a musical instrument. These things will be different for everyone. Does anyone have any examples?

*The key is to do things that might be a bit challenging, but once you have done them you feel good or have a sense of achievement.

Mindfulness exercise – Making room for emotions.

Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath. Be aware as you breathe in...and be aware as you breathe out..... Notice your breath without trying to change it. Just acknowledge it as it is. Focusing on any movement in your stomach as you breathe in...and as you breathe out .....

Bring your awareness to any emotions you are experiencing in your body. See if you can label that emotion, without any judgement.

Sometimes our emotions can have uncomfortable physical sensations, such as tightness in the chest when we are anxious, or a lump in our throat when we are feeling sad. Focus on the emotion or the associated physical sensation, and see if you can pinpoint exactly where in the body you are feeling it. What shape does this sensation have? Can you trace the outline of the sensation in your mind? Are the edges rough or smooth? Does the sensation have a colour? What temperature is the sensation? How would you describe the texture of the sensation, rough, smooth? Is it close to the surface of your skin or is it closer to the centre of your body?

Now I want you to use your breath, and breathe into the sensation. Notice that as you are breathing in, your breath is surrounded the

sensation. Each time you breathe in your breath surrounds the sensation, and with each breath you are creating more room for the sensation. Each breath creates more and more room, giving space for the sensation to be present. Each in breath creates more space for the sensation, making it easier to allow the sensation to be there. Continue breathing in, noticing your breath surround the sensation, creating space for it.

And when you are ready return your focus to the room, opening your eye when you feel ready, and stretching to wake your body up if you need to.

*Enquiry
What did people notice during that exercise?

Homework
Practice the mindfulness exercise – creating space for emotions/sensations.
Think about the strategies that can reduce your vulnerability to over whelming emotions.

Session 5
Introduction – names, welcome new group members.

Introduction to the group (for new group members):
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:
- *Exploring our feelings or "emotions".*
- *Learning how to understand our emotions.*
- *Learn skills to manage our emotions, instead of them managing us.*

**Recap of group rules – Respect, confidentiality, aware that discussion about trauma/self harm can be a trigger for other people in the group.*

OPEN WITH A BRIEF FOCUS ON BREATH EXERCISE

*Recap on homework
Mindfulness exercise – creating space for sensations and emotions.
Trying out strategies that can reduce your vulnerability to over whelming emotions.

*Point – People who have had painful experiences in their past can experience difficult emotions more intensely. One of the ways we try to deal with these intense emotions can be to push the emotion away or try to avoid them. However this usually just makes the emotion stay around for longer. If we can learn to be aware of our emotions, and label them it can make it easier to cope with them. This can give us some distance from the emotions, so that they don't feel quite so overwhelming.

Analogy – painful emotion as table tennis ball (use a table tennis ball, and a small glass and a large glass to illustrate point).
When you try to fit the ball into a small glass, it fills the whole thing. The painful emotion can fill your whole life. Mindfulness can help us make room for the painful emotion, illustrate with putting the ball into larger pint glass. The painful emotion does not change, but by learning how to

allow the emotion to be there and create more room for it, your life can change.

***Group brainstorm** – Use Flip chart to write up group ideas.
It is important to try and bring in a balance of positive emotions/experiences into your life. What type of pleasurable experiences do people have in their lives? What types of things give you positive emotions? Think about the small things (e.g. seeing a rabbit outside).

*Point - One of the ways to increase positive emotions can be through learning to be kind to ourselves. Sometimes we can find that this is a difficult thing to do. What stops us from looking after ourselves and being kind to ourselves?

Point - One strategy to develop kindness to ourselves can be learning how to self sooth. We can sooth each of our senses. (Use self soothing box to illustrate point below).

Self Soothing
Vision: light a candle and watch the flame, visit a museum and look at the wonderful art, watch the stars at night.

Hearing: Try listening to some music, pay attention to natural sounds such as the chirping of the birds, sounds of the waves.

Smell: use some smelly oils or your favourite perfume, Walk in a wooded area and be aware of all the natural smells.

Taste: Have a delicious meal, or your favourite drink. Eat your food mindfully, slowly and taste every bite.

Touch: Take a bubble bath, put clean sheets on your bed. Stroke your pet. Hug someone.

*Point – It is important to have positive experiences in our lives in order to feel happy. Sometimes we need to work hard to make changes so that we can have positive events more frequently. Sometimes we can find it difficult to focus on the positive events in our life, we might notice that our mind drifts to thinking about negative things, or worrying about when the positive event might end. Has anyone experienced this?

We need to work on being mindful of the positive events, and unmindful of the worries. If we can learn to stay focused in the present it can be easier to enjoy the positive events, without worrying about the future or getting caught up in thoughts or memories from the past.

Be mindful of positive experiences

- FOCUS attention on positive events that happen
- REFOCUS when your mind wanders to the negative

Be unmindful of worries

Distract from:

- Thinking about when the positive experiences WILL END
- Thinking about whether you DESERVE this positive experience
- Thinking about how much more might be EXPECTED of you now

Mindfulness exercise – Mindfulness of positive experiences (ask group members to choose an object from the self soothing box that they find pleasant/soothing).

Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath. Be aware as you breathe in… and be aware as you breathe out…….. Notice your breath without trying to change it. Just acknowledge it as it is. Focusing on any movement in your stomach as you breathe in… and as you breathe out…….

Bring your attention to the object that you have chosen. Hold it in your hand, notice how it feels to touch it. Be aware of the texture, is it rough or smooth? Notice the shape; trace the outline of the object with your eyes. Notice the weight of the object in your hand.

Can you notice any pleasant feeling in your body? Is there any warmth, any sense of relaxation, any pleasant sensations in your body? Notice

these sensations. Can you pinpoint where in your body you are feeling them?

Notice if your focus is drifting away to any worries or thoughts. Just acknowledge this has happened and gently bring your focus back to your soothing object. Gently returning your focus back to any pleasant sensations in your body.

Again notice if your mind has drifted away to worries about when the pleasant experience will end, or other worries of thoughts you might be having. Just notice if this has happened, acknowledge it without any judgement. Then gently guide your focus back to the soothing object, noticing how it feels to hold. Noticing any pleasant sensations that you are experiencing in your body, notice is there a sense of relaxation or calm? And just continue to guide your focus back to these positive experiences.

And now gently return your focus to your breath, being aware as you breathe in and aware as you breathe out. Bringing your attention back to the rise and fall of your stomach as you breathe in and as you breathe out. Following your in breath, and following as you breathe out. Breathing in...and breathing out.....

And when you are ready return your focus to the room, opening your eye when you feel ready, and stretching to wake your body up if you need to.

*Enquiry
What did people notice during that exercise?

Homework
Practice the mindfulness exercise – being mindful of positive events. Think about introducing some activities/events that increase positive emotions.

Session 6
Introduction – names, welcome new group members.

Introduction to the group (for new group members):
This is a group that will explore how our emotions can affect us. Everyone experiences a whole range of emotions from happiness to excitement to anger to shame to guilt. This range of emotions is normal, and part of life. Sometimes when we have had painful or traumatizing experiences in our past our difficult emotions can be very intense. The group will look at how to cope with these "intense" or "overwhelming" emotions, so that you can feel more in control.

Goals of the group:
- *Exploring our feelings or "emotions".*
- *Learning how to understand our emotions.*
- *Learn skills to manage our emotions, instead of them managing us.*

**Recap of group rules – Respect, confidentiality, aware that discussion about trauma/self harm can be a trigger for other people in the group.*

OPEN WITH A BRIEF FOCUS ON BREATH EXERCISE

*Recap on homework
- Mindfulness exercise – being mindful of positive experiences.
- Introducing some activities/events that increase positive emotions (*Use flip chart to review activities/events that increase positive emotions. In this way people who are new to the group will have an opportunity to think about some strategies they could try, and provide any suggestions that they have).

Point - People who have experienced painful events in their past can experience painful emotions. As humans we can try to avoid these emotions, or fight against them to try and get rid of them. However fighting against them usually makes them worse. It can be helpful to think about our emotions as waves, if we stop struggling against them we can notice that they come and go by themselves.

*Group discussion - What ways have people tried to fight against their painful emotions, or try to get rid of them? (e.g. alcohol, running away, shouting). Do these strategies work?

Point - One of the ways we can reduce our emotional suffering is learning to allow the painful emotion to be there, but to give ourselves some distance from it. We can sometimes become fearful of our painful emotions, and worry about having them around. When we are fearful, we can try to push away our painful emotion. In these situations we then have to deal with fear on top of the painful emotion. If we can allow ourselves to notice the painful emotion we will probably notice that while the painful emotion might be the same, the fear might reduce. This is a bit like the idea of "facing what we are afraid of". If we can face these painful emotions, our fear might reduce.

***Discussion Point – write up on Flip chart**
Different painful emotions can create different urges. So for example when we are:

Fearful	- urge is avoid or run away	- keeps the fear present
Depressed	- urge to withdraw/isolate	-keeps depression around
Anger	-urge to attack	-keeps anger around

When we act on these urges, we can notice that it just keeps the emotion going. We can learn to change or reduce these painful emotions by acting opposite to the emotion urges.

Acting Opposite

Fearful – face what you are afraid of (if safe)	- fear reduces
Depressed – be active/around others	-depression reduces
Anger – gently avoid person/situation	- anger reduces
- do something nice for person	- anger reduces

*Group brainstorm - Do people have examples of how the could act opposite to anger, fear, and depression? Share on flip chart.

Mindfulness Exercise – Mindfulness of Painful Emotions
Find a comfortable position, sitting upright but not too rigid. Hands resting comfortably in your lap or on the arm rest. Feet grounded on the floor. Gently bring your focus to your breath. Be aware as you breathe in...and be aware as you breathe out..... Notice your breath without trying to change it. Just acknowledge it as it is. Focusing on any movement in your stomach as you breathe in...and as you breathe out.....

Bring your awareness to any emotions you are experiencing in your body. Sometimes our emotions can have uncomfortable physical sensations, such as tightness in the chest when we are anxious, or a lump in our throat when we are feeling sad. Focus on the emotion or the associated physical sensation, and see if you can pinpoint exactly where in the body you are feeling it.

See if you can label that emotion, without any judgement. Just step back from the emotion and observe it, as if you are just watching it.

Be aware that you can experience this emotion without needing to act on it. Notice any urges that you have to act on the emotion and just acknowledge them. Holding the awareness that you don't need to react to the emotion. You can let it be there without doing anything.

Hold in mind the idea that this emotion is like a wave, coming and going. You don't need to ignore it, you can be aware of it without needing to pay any extra attention to it. Notice that you can experience it in the background. You can allow it to be there. Continue to notice this emotion, being aware that you can experience it without needing to react to it. Notice the emotion as if it is a wave, coming and going.

And now gently return your focus to your breath, being aware as you breathe in and aware as you breathe out. Bringing your attention back to the rise and fall of your stomach as you breathe in and as you breathe out. Following your in breath, and following as you breathe out. Breathing in...and breathing out.....

And when you are ready return your focus to the room, opening your eye when you feel ready, and stretching to wake your body up if you need to.

<u>*Enquiry</u>
What did people notice during that exercise?

<u>Homework</u>
Practice the mindfulness exercise – mindfulness of painful emotions
Try out acting opposite.
Below is a story which can be helpful in explaining the idea of learning to accept emotions (allow emotions to be present).

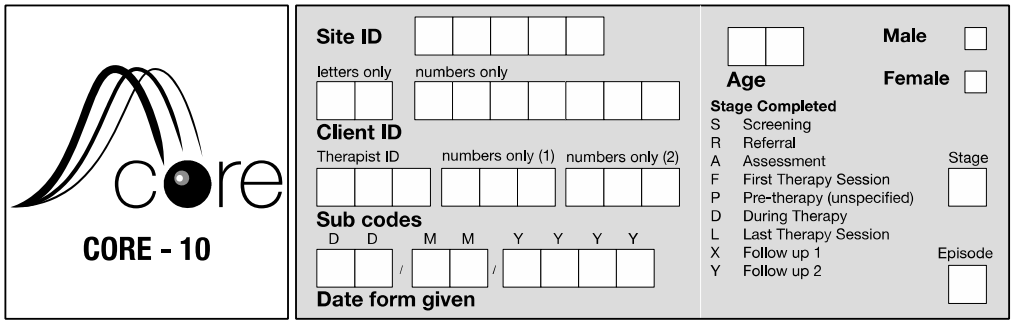
Dandelions

Story Adapted from Anthony de Mello

A man bought a new house and decided that he was going to have a very beautiful lawn. He worked on it every week, doing everything the gardening books told him to do. His biggest problem was that the lawn always seemed to have dandelions growing where he didn't want them. The first time he found dandelions, he pulled them out. But they grew back. He went to his local gardening shop and bought weed killer. This worked for some time but after summer rain the dandelions grew back. He worked and pulled and killed dandelions all summer long. The next summer he thought he would have no dandelions at all, since none have grown over winter. But then all of a sudden he had dandelions again. This time he decided the problem was with the type of grass. So he spent a fortune putting down new sods of grass. The worked for some time and was very happy. Just as he had started to relax, a dandelion came up. A friend told him it was due to the dandelions in the lawns of his neighbours. So he went on a campaign to get all his neighbours to kill all their dandelions. By the third year he was exasperated. He still had dandelions. So after consulting every local expert and garden book he decided to write to the department of agriculture for advice. Surely the government could help him. After waiting several months he finally got a letter back. He was so exciting, help at long last! He tore open the letter and read the following:
"Dear Sir: We have considered your problem and have consulted all of our experts. After careful consideration, we think we can give you very good advice. Sire, our advice is that you learn to love those dandelions"

Appendix 11

Questionnaires used in feasibility study



IMPORTANT – PLEASE READ THIS FIRST

This form has 10 statements about how you have been OVER THE LAST WEEK.
Please read each statement and think how often you felt that way last week.
Then tick the box which is closest to this.
Please use a dark pen (not pencil) and tick clearly within the boxes.

Over the last week		Not at all	Only Occasionally	Sometimes	Often	Most or all the time
1	I have felt tense, anxious or nervous	0	1	2	3	4
2	I have felt I have someone to turn to for support when needed	4	3	2	1	0
3	I have felt able to cope when things go wrong	4	3	2	1	0
4	Talking to people has felt too much for me	0	1	2	3	4
5	I have felt panic or terror	0	1	2	3	4
6	I made plans to end my life	0	1	2	3	4
7	I have had difficulty getting to sleep or staying asleep	0	1	2	3	4
8	I have felt despairing or hopeless	0	1	2	3	4
9	I have felt unhappy	0	1	2	3	4
10	Unwanted images or memories have been distressing me	0	1	2	3	4

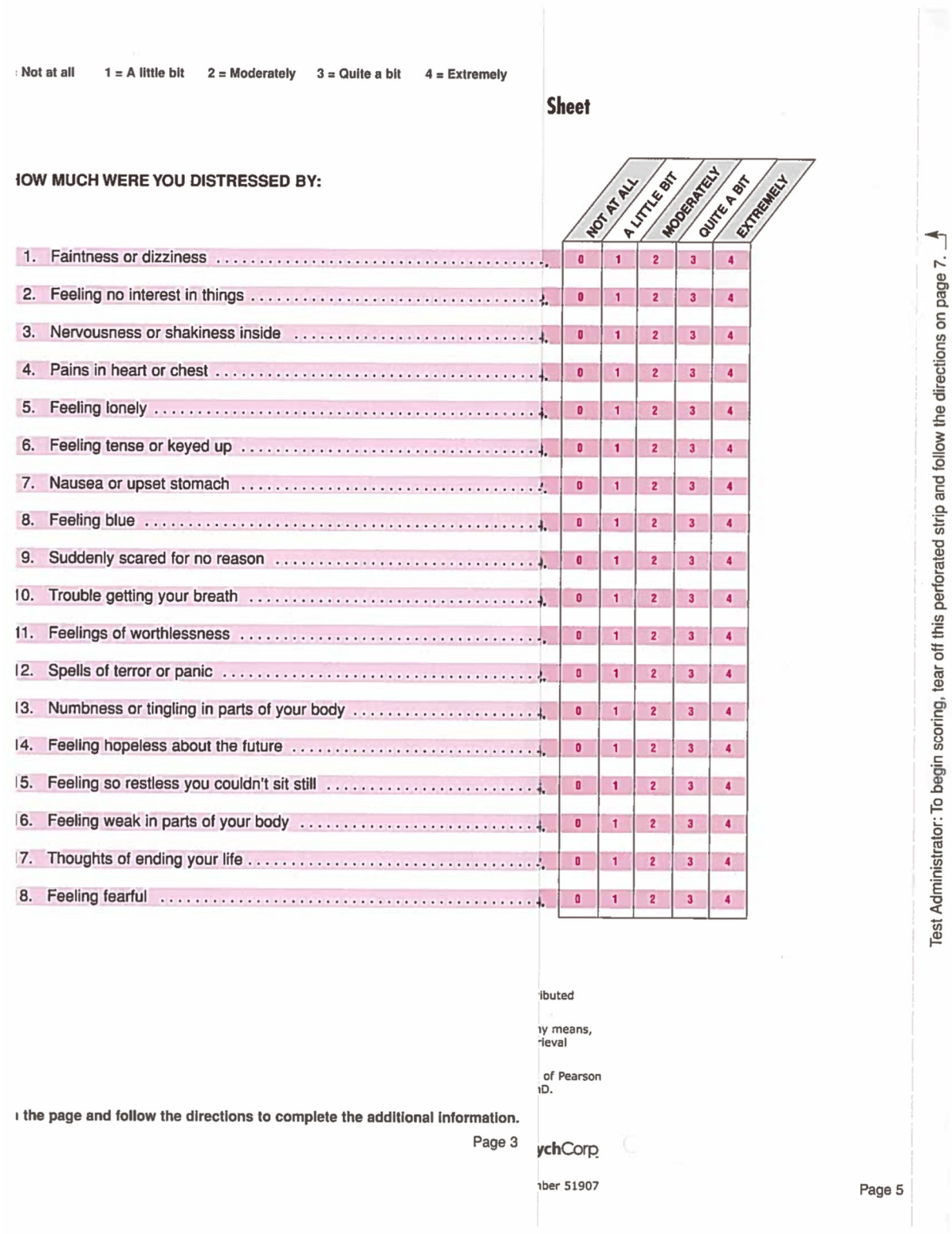
Total (Clinical Score*)

* **Procedure**: Add together the item scores, then divide by the number of questions completed to get the mean score, then multiply by 10 to get the Clinical Score.

Quick method for the CORE-10 (if all items completed): Add together the item scores to get the Clinical Score.

THANK YOU FOR YOUR TIME IN COMPLETING THIS QUESTIONNAIRE

Appendix 11.1 Clinical outcome routine evaluation (CORE)-10



Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

Sheet

OW MUCH WERE YOU DISTRESSED BY:

	NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1. Faintness or dizziness	0	1	2	3	4
2. Feeling no interest in things	0	1	2	3	4
3. Nervousness or shakiness inside	0	1	2	3	4
4. Pains in heart or chest	0	1	2	3	4
5. Feeling lonely	0	1	2	3	4
6. Feeling tense or keyed up	0	1	2	3	4
7. Nausea or upset stomach	0	1	2	3	4
8. Feeling blue	0	1	2	3	4
9. Suddenly scared for no reason	0	1	2	3	4
10. Trouble getting your breath	0	1	2	3	4
11. Feelings of worthlessness	0	1	2	3	4
12. Spells of terror or panic	0	1	2	3	4
13. Numbness or tingling in parts of your body	0	1	2	3	4
14. Feeling hopeless about the future	0	1	2	3	4
15. Feeling so restless you couldn't sit still	0	1	2	3	4
16. Feeling weak in parts of your body	0	1	2	3	4
17. Thoughts of ending your life	0	1	2	3	4
18. Feeling fearful	0	1	2	3	4

Test Administrator: To begin scoring, tear off this perforated strip and follow the directions on page 7.

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the page and follow the directions to complete the additional information.

Page 3

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Page 5

Appendix 11.2 Brief symptom inventory (BSI) 18

Table 2—Mental Health Confidence Scale

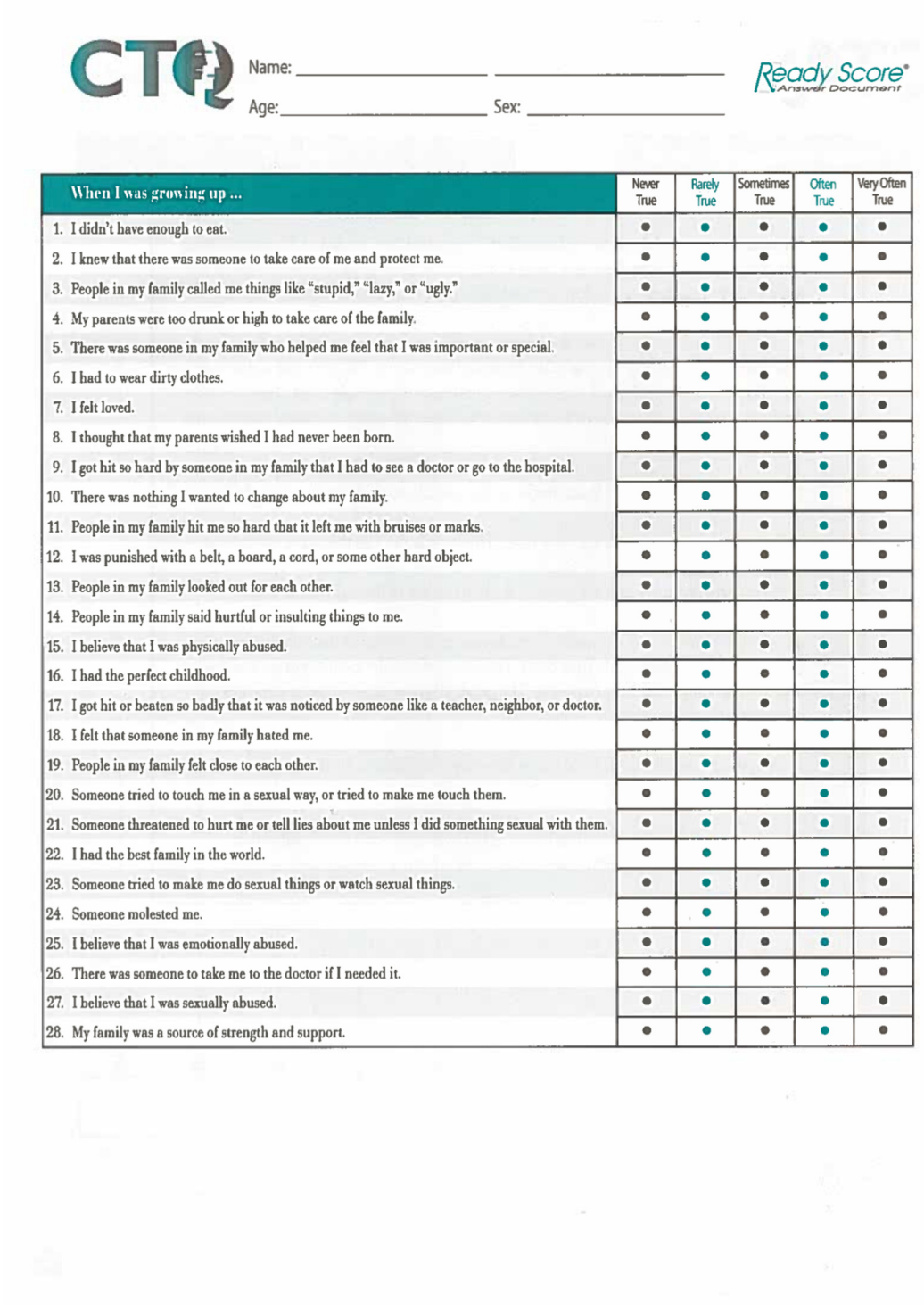
We would like to know how confident you are about your ability to help yourself deal with those things that commonly influence our lives. For each item, indicate *how confident you are that you could do something to help yourself right now.*

Directions: Rate the degree of your confidence by circling a number from 1 to 6, where 1 = very nonconfident and 6 = very confident.

HOW CONFIDENT ARE YOU RIGHT NOW THAT YOU CAN:

	VERY NONCONFIDENT	NONCONFIDENT	SLIGHTLY NONCONFIDENT	SLIGHTLY CONFIDENT	CONFIDENT	VERY CONFIDENT
1. Be happy	1	2	3	4	5	6
2. Feel hopeful about the future	1	2	3	4	5	6
3. Set goals for yourself	1	2	3	4	5	6
4. Get support when you need it	1	2	3	4	5	6
5. Boost your self-esteem	1	2	3	4	5	6
6. Make friends	1	2	3	4	5	6
7. Stay out of the hospital	1	2	3	4	5	6
8. Face a bad day	1	2	3	4	5	6
9. Deal with losing someone close to you	1	2	3	4	5	6
10. Deal with feeling depressed	1	2	3	4	5	6
11. Deal with feeling lonely	1	2	3	4	5	6
12. Deal with nervous feelings	1	2	3	4	5	6
13. Deal with symptoms related to your mental illness diagnosis	1	2	3	4	5	6
14. Say no to a person abusing you	1	2	3	4	5	6
15. Use your right to accept or reject mental health treatment	1	2	3	4	5	6
16. Advocate for your needs	1	2	3	4	5	6

Appendix 11.3 Mental health confidence scale (MHCS)



CTQ

Name: _____ _____ Ready Score® Answer Document

Age: _____ Sex: _____

When I was growing up ...	Never True	Rarely True	Sometimes True	Often True	Very Often True
1. I didn't have enough to eat.	●	●	●	●	●
2. I knew that there was someone to take care of me and protect me.	●	●	●	●	●
3. People in my family called me things like "stupid," "lazy," or "ugly."	●	●	●	●	●
4. My parents were too drunk or high to take care of the family.	●	●	●	●	●
5. There was someone in my family who helped me feel that I was important or special.	●	●	●	●	●
6. I had to wear dirty clothes.	●	●	●	●	●
7. I felt loved.	●	●	●	●	●
8. I thought that my parents wished I had never been born.	●	●	●	●	●
9. I got hit so hard by someone in my family that I had to see a doctor or go to the hospital.	●	●	●	●	●
10. There was nothing I wanted to change about my family.	●	●	●	●	●
11. People in my family hit me so hard that it left me with bruises or marks.	●	●	●	●	●
12. I was punished with a belt, a board, a cord, or some other hard object.	●	●	●	●	●
13. People in my family looked out for each other.	●	●	●	●	●
14. People in my family said hurtful or insulting things to me.	●	●	●	●	●
15. I believe that I was physically abused.	●	●	●	●	●
16. I had the perfect childhood.	●	●	●	●	●
17. I got hit or beaten so badly that it was noticed by someone like a teacher, neighbor, or doctor.	●	●	●	●	●
18. I felt that someone in my family hated me.	●	●	●	●	●
19. People in my family felt close to each other.	●	●	●	●	●
20. Someone tried to touch me in a sexual way, or tried to make me touch them.	●	●	●	●	●
21. Someone threatened to hurt me or tell lies about me unless I did something sexual with them.	●	●	●	●	●
22. I had the best family in the world.	●	●	●	●	●
23. Someone tried to make me do sexual things or watch sexual things.	●	●	●	●	●
24. Someone molested me.	●	●	●	●	●
25. I believe that I was emotionally abused.	●	●	●	●	●
26. There was someone to take me to the doctor if I needed it.	●	●	●	●	●
27. I believe that I was sexually abused.	●	●	●	●	●
28. My family was a source of strength and support.	●	●	●	●	●

2

Appendix 11.4 Childhood trauma questionnaire- short form

Appendix 12

Patient information sheet and consent form for intervention group

Participant Information Sheet and Consent Form for Intervention Group
Psychologically Informed Acute Mental Healthcare

You are being invited to take part in a research study. Before you decide whether or not to take part, 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 sheet carefully. Talk to others about the study if you wish. Contact 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?
The purpose of the study is to investigate whether psychological input within an acute mental health service is beneficial when applied along side treatment as usual. Psychological input refers to offering inpatients individual and group therapy during hospital admission and providing psychologically based training for staff working in the service.

Why have I been asked to take part?
You have been asked to take part as you are currently an inpatient within an acute mental health service.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?
During your admission you will receive standard care from the acute mental health service (e.g. typically involving contact with ward staff and a psychiatrist). You will have a routine meeting with healthcare staff on admission to the ward. After you are settled in a research student will approach you to explain the study and answer any questions you may have. You will have up to 24 hours to decide if you would like to take part. The research student will approach you again after this time. If you choose to take part, she will ask you to read and sign a consent form. This will give the research student permission to look at your medical files and inform your GP of your participation. She will also ask you to fill out four questionnaires before attending any psychological sessions (please see details of questionnaires in table 1.). If you do not wish to take part in the study you will not be asked to fill out any questionnaires and your treatment/care will not be affected. You may be offered individual therapy with a Psychologist or Nurse Therapist which will involve identification of current problems being experienced and possible 'exit strategies'. Ward staff, the Psychologist or the Nurse Therapist may recommend certain group therapies that could benefit you, however you will have access to all group therapies running on the ward and you are able to leave these group sessions at any point. Details of these group therapies are as follows:

Anxiety and Stress Management
This group includes 2 sessions (once a week), each lasting approximately 1 hour. You will learn how anxiety and stress can occur and effect individuals. You will also learn coping strategies to help recognise and handle anxiety and stress.

Making Friends with Yourself (MFY)
This group includes 3 sessions (once a week). It is based on a therapy approach called Compassionate Mind Training (CMT). This group is designed for those with low self-esteem and promotes acknowledgment of negative automatic thoughts and reactions, and helps patients learn how to be kinder to themselves.

What is real and what is not?
This group includes 4 sessions (once a week), each lasting approximately 1 hour. It is designed for individuals who have encountered unusual perceptual experiences such as hearing voices or sensory/visual hallucinations. The aim is to help patients normalise the phenomena of these experiences, help gain control of these experiences and increase self-esteem.

Mindfulness
This group includes just 1 session. It is designed to teach the ability to become aware of internal and external experiences while maintaining an accepting and non-judgemental attitude.

Before discharge, the research student will approach you again and ask you to fill three of the same questionnaires and a feedback form (see table 1 for detail). Following discharge, you will continue to have access to group therapies if you wish to attend. Six months and twelve months following discharge the research student will contact you via telephone to arrange a convenient time to meet. This could be at the hospital or in a private room at a local community centre. She will ask you to fill out the same three questionnaires.

After the study has finished you will have access routine mental health care and continue to have access to the group therapies if you wish to attend.

Table 1. Details of questionnaires

Questionnaire	**Administered (after admission/before discharge/follow-up)**	**Description**
CORE-10	Admission, discharge, follow-up	10 questions about feelings of distress
Brief Symptom Inventory-18	Admission, discharge, follow-up	18 questions about psychological symptoms
Mental Health Confidence Scale	Admission, discharge, follow-up	16 questions about your self-efficacy in relation to mental health
Childhood Trauma Questionnaire Short Form	admission	28 questions about adverse childhood experience

What are the possible benefits of taking part in the study?
The psychological intervention offered in this study may be beneficial to you, however if you decline participation you will still have access to this psychological intervention. The results from this study might also inform future healthcare of other patients.

What are the possible disadvantages and risks of taking part?
It is not thought that there are many disadvantages, however one questionnaire in the first batch of questionnaires includes questions of a sensitive nature (e.g. adverse childhood experiences). Ward staff will be accessible for support if necessary.

Additionally, approximately 20 minutes of your time will be required on four occasions (after admission, before discharge, 6 month follow-up and 12 month follow-up).

What if there is a problem?
If you have a concern about any aspect of this study please contact Charlotte Paterson (40188096@live.napier.ac.uk) who will do their best to answer your questions.

In the unlikely event that you feel distressed due to questionnaires you will be urged to discuss this with ward staff, your community care team or the ward Clinical Psychologist, Dr. Sean Harper (0131 6932).

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay for legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What happens when the study is finished?
At the end of the research we will securely hold the data for a maximum of three years. You will still have access to group therapies running on the ward following your discharge.

Will my taking part in the study be kept confidential?
All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. Hard copies of your questionnaires will be coded in order to protect your identity. These will be kept in a locked cabinet in a locked room within NHS grounds. Your questionnaires will be stored electronically in NHS computers which are password protected. Consent forms containing personal information (e.g. name, contact detail, identifying code) will be locked in a separate cabinet in a locked room in NHS grounds. Your GP will be informed of your participation. In the event that your responses indicate risk to yourself or others, your GP or an appropriate member of your healthcare team will be informed. All information gathered during the study (questionnaires, consent forms, information from medical records, etc.) will be responsibly disposed of after three years.

To ensure that the study is being run correctly we will ask your consent for responsible representatives from the Sponsor (Edinburgh Napier University) and NHS Institution to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

Identifiers (i.e. any information that can identify you personally such as initials) will be removed from all data.

What will happen to the results of the study?

The study will be written up as part of a PhD Thesis. You will not be identifiable in any published results.

This, or a general summary of findings, will be available to you if you contact Charlotte Paterson (40188096@live.napier.ac.uk).

Who is organising the research and why?
This study is being sponsored and funded by Edinburgh Napier University.

Who has reviewed the study?
The study proposal has been reviewed by Edinburgh Napier University. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland REC. NHS management approval has also been obtained.

If you have any further questions about the study please email Charlotte Paterson: 40188096@live.napier.ac.uk

If you would like to discuss the study with someone independent of the study please contact Dr. Barabara Neades (b.neades@napier.ac.uk).
If you wish to make a complaint about the study please contact NHS Lothian:
NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708
craft@nhslothian.scot.nhs.uk

Thank you for taking the time to read this information sheet.

Appendix 13

Patient information sheet and consent form for control group

Participant Information Sheet and Consent Form for Control Group
Psychologically Informed Acute Mental Healthcare

You are being invited to take part in a research study. Before you decide whether or not to take part, 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 sheet carefully. Talk to others about the study if you wish. Contact 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?
The purpose of the study is to investigate whether psychological input within an acute mental health service is beneficial when applied alongside treatment as usual.

Why have I been asked to take part?
You have been asked to take part in this study as part of the control group (i.e. you will receive treatment as usual which does not involve psychological input), as you are currently an inpatient within an acute mental health service.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?
During your admission you will receive standard care from the acute mental health service (e.g. typically involving contact with ward staff and a psychiatrist). Choosing not to take part in the study will not affect the healthcare you receive. You will have a routine meeting with healthcare staff following admission to the ward. After you are settled in a research student will approach you to explain the study and answer any questions you may have. You will have up to 24 hours to decide if you would like to take part. If you would like to take part in the study a research student will ask you to read and sign a consent form. This will give the research student permission to look at your medical files and inform your GP of your participation. She will also ask you to fill out four questionnaires (details of questionnaires are below in table 1). You will then receive acute mental health treatment as usual. If you so not wish to take part in the study you will not be asked to fill in any questionnaires. Your treatment will not be effected in any way if you do not wish to take part in the study.

Table 1. Details of questionnaires

Questionnaire	**Time of administration (after admission, before discharge, at follow-up)**	**Description**
CORE-10	Admission, discharge, follow-up	10 questions about feelings of distress
Brief Symptom Inventory-18	Admission, discharge, follow-up	18 questions about psychological symptoms

Mental Health Confidence Scale	Admission, discharge, follow-up	16 questions about your self-efficacy in relation to mental health
Childhood Trauma Questionnaire Short Form	Admission	28 questions about adverse childhood experience

Before discharge, the research student will approach you again and ask you to fill three of the same questionnaires and a feedback questionnaire. Six months and twelve months following discharge the research student will contact you via telephone to arrange a convenient time to meet. This could be arranged at the hospital or in a private room at a local community centre. She will ask you to fill out the same three questionnaires.

What are the possible benefits of taking part in the study?
Choosing not to take part in the study will not affect the healthcare you receive therefore there are no additional benefits of taking part in the study. However, the results from this study might inform future healthcare of other patients.

What are the possible disadvantages and risks of taking part?
It is not thought that there are many disadvantages, however one questionnaire in the first batch of questionnaires includes questions of a sensitive nature (e.g. adverse childhood experiences). Ward staff will be accessible for support if necessary.

Additionally, approximately 30 minutes of your time will be required on four occasions (after admission, before discharge, 6 month follow-up and 12 month follow-up).

What if there is a problem?
If you have a concern about any aspect of this study please contact Charlotte Paterson (40188096@live.napier.ac.uk) who will do her best to answer your questions. In the unlikely event that you feel distressed due to questionnaires you will be urged to discuss this with ward staff, your community care team or the ward Clinical Psychologist, Dr. Sean Harper (0131 537 6932).

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay for legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What happens when the study is finished?
At the end of the research we will securely hold the data for a maximum of three years. You will receive routine community care appropriate to you and you will continue to have access to group therapies on the ward if you wish to attend.

Will my taking part in the study be kept confidential?
All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. Hard copies of your questionnaires will be coded in order to protect your identity. These will be kept in a locked cabinet in a locked room within NHS grounds. Your questionnaires will be stored electronically in NHS computers which are password protected. Consent forms containing personal information (e.g. name, contact details, identifying code) will be locked in a separate cabinet in a locked room

in NHS grounds. Your GP will be informed of your participation. In the event that your responses indicate risk to yourself or others, your GP or an appropriate member of your healthcare team will be informed. All information gathered during the study (questionnaires, consent forms, information from medical records, etc.) will be responsibly disposed of after three years.

To ensure that the study is being run correctly we will ask your consent for responsible representatives from the Sponsor (Edinburgh Napier University) and NHS Institution to access your medical records and data collected during the study, where it is relevant to your taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity.

Identifiers (i.e. any information that can identify you personally such as initials) will be removed from all data.

What will happen to the results of the study?
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If you have any further questions about the study please email Charlotte Paterson: 40188096@live.napier.ac.uk

If you would like to discuss the study with someone independent of the study please contact Dr. Barabara Neades (b.neades@napier.ac.uk).
If you wish to make a complaint about the study please contact NHS Lothian:
NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708
craft@nhslothian.scot.nhs.uk

Thank you for taking the time to read this information sheet.

CONSENT FORM
Psychologically Informed Acute Mental Healthcare

Participant ID:
Contact Details:

Please initial box

1. I confirm that I have read and understood the information sheet (as specified in this document header) for the above study and have had the opportunity to consider the information and ask questions.	
2. 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.	
3. I understand that [relevant sections of my medical notes and] data collected during the study may be looked at by individuals from Edinburgh Napier University, from the NHS organisation, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree that my GP will be informed of my participation in this study.	
5. I agree to my anonymised data being used for future ethically approved studies.	
6. I agree to take part in the above study.	

_____ _____ _____
Name of Participant Da te S ignature

_____ _____ _____
Name of Person taking consent Da te S ignature

Appendix 14

Letter of ethical approval

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
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FM/CK/approval

14 August 2015

Miss Charlotte Paterson
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Director: Professor David E Newby

Dear Miss Paterson

Lothian R&D Project No: 2015/0292

Title of Research: Psychologically Informed Acute Mental Health Inpatients Care Plus Treatment as Usual versus Treatment as Usual Alone.

REC No: 15/SS/0093

Participant Information Sheet:
Version 4.0, 20 July 2015

Consent Form:
Version 4.0, 20 July 2015

Protocol:
Version 2.0, 9 July 2015

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Fiona McArdle.

Ms Fiona McArdle
Deputy R&D Director

Cc: Tim Montgomery, Director of Operations, REH

A034

Appendix 15

Recruitment posters for feasibility study

Research in Hermitage Ward

Who am I?
Hi, my name's Charlotte Paterson and I am a research student.

What am I doing?
I'm looking at how people feel while in hospital. If you'd like to take part in this research I would ask you to fill out some questionnaires shortly after your admission and again just before or after your discharge.

Who can take part?
Anyone currently admitted to the ward.

Where?
I will come to meet you on the ward to tell you about the study, show you the questionnaires and see if you'd like to take part. If you decide to take part we can sit somewhere quiet while you complete them or I can leave them with you to fill out in your own time. If you'd like help with the questionnaires I can also help out.

How long will it take?
Approximately 15-20 minutes in total. This can also be broken down into smaller time frames (e.g. 10 minutes and 10 minutes).

What will happen to your questionnaires?
The answers in your questionnaires will be collected and written up in a study, however all data will be anonymous.

Interested?
Taking part in the research is entirely voluntary. Choosing not to take part will not affect your routine healthcare. If you'd like to be involved or would like some more information feel free to come and chat to me! You can also contact me on 0131 537 6916. Thanks for your cooperation!

Research in Balcarres Ward

Who am I?
Hi, my name's Charlotte Paterson and I am a research student.

What am I doing?
I'm looking at how people feel while in hospital. If you choose to take part in this research I would ask you to fill out some questionnaires shortly after your admission and again just before or after your discharge.

Who can take part?
Anyone currently admitted to the ward.

Where?
I will come to meet you on the ward to tell you about the study, show you the questionnaires and see if you'd like to take part. If you decide to take part we can sit somewhere quiet while you complete them or I can leave them with you to fill out in your own time. If you'd like help with the questionnaires I can also help out.

How long will it take?
Approximately 15-20 minutes in total. This can be broken down into smaller time frames (e.g. 10 minutes and 10 minutes).

What will happen to your questionnaires?
The answers from your questionnaires will be collected and written up in a study, however all data will be anonymous.

Interested?
Taking part in the research is entirely voluntary. Choosing not to take part will not affect your routine healthcare and you will still have access to group and individual therapy sessions. If you'd like to be involved or would like some more information feel free to come and chat to me while I'm around! You can also contact me on 0131 537 6916. Thanks for your cooperation!

Appendix 16

ADePT process

ADePT Process

Using the ADePT process (Bugge et al., 2013), solutions to address problems identified by this trial are assessed. In addition to changes to the intervention, trial design and the clinical context, a fourth option was included where additional feasibility research was deemed necessary or informative before progressing to a full trial. As this option includes solutions which inform a future trial, rather than directly influence the trial or real world, no assessment of solutions in this category were carried out.

Problem B1

Type B: Poor implementation of some components of the intervention (i.e. groups).

Evidence

- Few group therapies delivered overall and only 3 of 4 possible groups delivered during study period.
- Due to lack of staff engagement -> no time, staff sickness, many staff with relevant psychological training left during study period, inflexible rotas and some staff did not feel confident in their ability to deliver groups.
- May have been influenced by poor integration of the intervention into the whole service.
    - Influenced by above points and lack of support from managerial staff and psychiatrists.

All of the above may influence a trial and the real world.

Solutions

Change aspects of:

a) Intervention

1. Alter intervention, i.e. focus on fewer group types.
2. More thorough staff training.

b) Trial design

None

c) Clinical context

1. Increase psychological resource to increase psychological presence on the ward, psychological training and supervision for ward staff.

2. Flexible rotas, protected time for therapeutic work to ensure more consistent and frequent group interventions are delivered.
3. Hire staff specifically for group facilitator role.
4. Assign designated project 'champion'

d) Additional feasibility research

1. Qualitative work to investigate staff (from all levels) perception intervention acceptability and of barriers and facilitators to intervention implementation.

Assessment of solutions

A1: Alter intervention, i.e. focus on fewer group types.

Could a1 be effective in trial setting?

Yes, likely to be less burden for service to release staff and may improve quality of delivery as fewer therapeutic approaches for staff to learn. However, dependent on C1 and C2 but the aims of the intervention should be reconsidered and the impact of the intervention may be diluted.

Could a1 be feasible in trial setting?

Likely to be more feasible than current protocol. However, dependent on C1 and support from management. Aims of the intervention will need to be reconsidered.

Could a1 be effective in real world?

Likely to be less burden for staff and improve quality of delivery. However, dependent on C1 and C2.

Could a1 be feasible in real world?

Likely to be more feasible than current protocol. However, dependent on C1 and support from management. Aims of the intervention will need to be reconsidered.

A2: More thorough staff training.

Could a1 be effective in trial setting?

Yes, likely to increase staff confidence in their ability to deliver groups, however dependent on C1.

Could a1 be feasible in trial setting?

Dependent on C1.

Could a1 be effective in real world?

Yes, likely to increase staff confidence in their ability to deliver groups, however dependent on C1.

Could a1 be feasible in real world?

Dependent on C1.

C1 Increase psychological resource to increase psychological presence on the ward, psychological training and supervision for ward staff.

Could the solution be effective in trial setting?

Yes, evidence of consistent delivery of groups when delivered by psychological team and co-facilitated by member of ward staff (Owen, Sellwood, et al., 2015) but dependent on C2. 1:20 full time clinical psychologist to inpatient ratio is recommended by the Sainsbury Centre for Mental Health (2005). Additional time to co-facilitate more complex groups with staff will improve staff members' confidence in delivery.

Could the solution be feasible in trial setting?

Only if resource is available. Also dependent on C2.

Could solution be effective in real world?

Yes, evidence of consistent delivery of groups when delivered by psychological team and co-facilitated by member of ward staff (Owen, Sellwood, et al., 2015) but dependent on C2. Additional time to co-facilitate more complex groups with staff will improve staff members' confidence in delivery.

Could solution be feasible in real world?

Yes, if cost-effective and psychological resource available. Also dependent on C2.

C2 Flexible rotas, protected time for therapeutic work to ensure consistently delivered groups

Could the solution be effective in trial setting?

Staff interested in facilitating groups should work 9-5 one day a week, additional to shifts, on the same day for a fixed period. This time can be used to facilitate and co-facilitate groups with psychologist (Hill et al., 2009).

Could the solution be feasible in trial setting?

Discussions with management required to establish this. Agreement from managerial staff to support staff to develop skills and facilitate groups. Management support has been identified as a facilitator to successful implementation of new interventions in similar contexts (Berry et al., 2016; Berry & Haddock, 2008).

Could solution be effective in real world?

Staff interested in facilitating groups should work 9-5 one day a week, additional to shifts, on the same day for a fixed period. This time can be used to facilitate and co-facilitate groups with psychologist (Hill et al., 2009).

Could solution be feasible in real world?

Yes, but dependent on organisational level factors, i.e. management and resource. Agreement from managerial staff to support staff to facilitate. Staff will need enthusiasm to agree to work an additional day.

C3 Hire staff specifically for group facilitator role.

Could the solution be effective in trial setting?

Yes, would ensure groups are delivered but does not conduce integration of the intervention into the whole service, therefore aims of the intervention should be reconsidered.

Could the solution be feasible in trial setting?

Unlikely that resource is available.

Could solution be effective in real world?

Yes, but does not conduce whole service approach, therefore aims of the intervention should be reconsidered.

Could solution be feasible in real world?

Unlikely that resource is available.

C4 Assign designated project 'champion'

Could the solution be effective in trial setting?

Yes, there is evidence that this technique is successfully used to improve intervention implementation (Shaw et al., 2012).

Could the solution be feasible in trial setting?

Dependant on the support received from staff members who are likely to be influential.

Could solution be effective in real world?

Yes, there is evidence that this technique is successfully used to improve intervention implementation (Shaw et al., 2012).

Could solution be feasible in real world?

Dependant on the support received from staff members who are likely to be influential. Discussions with management staff are required.

Assessment of options and tolerance of trade-off between explanatory and pragmatic trial

To improve implementation of the group components of the intervention, it may be more feasible to focus on fewer than four types of therapy initially. However, negotiations with management will still be required to protect time for delivery of even one group and the aims and reach of the intervention may need reconsideration. Alternatively, a designated member of staff might be employed as group facilitator, however it is unlikely that resource would be available and this solution is not conducive to integrating the intervention into the whole service, therefore the aims will, again, need to be reconsidered. Solutions that are more akin to the aims of intervention, i.e. to improve staff knowledge and skills in relation to CBT and increasing the reach of psychological therapy within service users and staff, are to improve the flexibility of nursing staff rotas and ensure they have protected time for group facilitation and to increase the psychological resource for more thorough staff training. The former involves identifying staff who are interested in facilitating groups and are willing to work one nine-five day a week on the same day for a fixed period. This time can be used to facilitate and co-facilitate groups with psychologist (Hill et al., 2009). To achieve this, either staff must work this in addition to shifts, or managerial staff must allow a degree of flexibility in rotas. Both options are likely to be effective in terms of improving implementation of groups therapies, however knowledge of whether staff are willing to work additional hours to develop their skills or whether managerial staff will support routine delivery of groups by staff is lacking.

Problem B2

Type B: Problem with patient engagement with the intervention.

Evidence

- Only half the participants engaged.
- Only 1.7 patients per group.
- Engagement may have been influenced by poor implementation of some components of the intervention (see poor implementation section).

- May have been influenced by poor integration of the intervention into the whole service.
- Engagement may have been influenced by broad inclusion criteria, i.e. including patients who do not want to receive the intervention.

All of the above may influence a trial and the real world.

Solutions

Change aspects of:

a) Intervention

None

b) Trial design

1. Alter eligibility criteria to exclude patients that do not want to receive psychological intervention during their admission.

c) Clinical context

1. Increase psychological resource to make intervention more available, increase psychological presence on the ward and increase psychological training and supervision for ward staff (see solution C1 of problem B1).
2. Improve staff engagement with intervention (see poor implementation section).

d) Additional feasibility research

1. Qualitative work to investigate intervention acceptability and why patients do and do not want to receive psychological input during acute admission.

Assessment of solutions

B1 Alter eligibility criteria to exclude patients that do not want to receive psychological intervention during their admission. Use a rating scale in initial consent meeting.

Could the solution be effective in trial setting?

Yes. Likely to reduce number of participants included in the trial who do not want to receive the intervention.

Could the solution be feasible in trial setting?

Yes. Researcher would ask patients whether they want to receive psychological therapy during admission when patient is initially approached for the study.

Could solution be effective in real world?

Yes, if psychological therapy was routinely offered patients would have the option to receive it.

Could solution be feasible in real world?

Yes, if psychological therapy was routinely offered patients would have the option to receive it.

C1 Increase psychological resource to make intervention more available, increase psychological presence on the ward and increase psychological training and supervision for ward staff.

Could the solution be effective in trial setting?

Yes, 1:20 full time clinical psychologist to inpatient ratio recommended by (Sainsbury Centre for Mental Health, 2005). More time for staff training: staff education recommended to promote awareness of therapeutic principles as staff play a key role in encouraging and enabling participant attendance (Jacobsen et al., 2011).

Could the solution be feasible in trial setting?

Unlikely in a financially restricted service. Recognised by The British Psychological Society (2012) that 1:20 ratio is unrealistic but argue that 0.5 per ward (as recommended by (Royal College of Psychiatrists, 2010) is too little.

Could solution be effective in real world?

Staff education recommended to promote awareness of therapeutic principles as staff play a key role in encouraging and enabling patient attendance (Jacobsen et al., 2011).

Could solution be feasible in real world?

Unlikely in a financially restricted service. Recognised by The British Psychological Society (2012) that 1:20 ratio is unrealistic but argue that 0.5 per ward (as recommended by (Royal College of Psychiatrists, 2010) is too little.

<u>Assessment of options and tolerance of trade-off between explanatory and pragmatic trial</u>

Patients expressing an interest in the intervention when asked if they want to receive it should be added to eligibility criteria. This option will reduce the proportion of non-engaging participants recruited to the trial and will mimic routine practice, if the intervention is implemented. Such data can also be used to identify characteristics of those who do and do not want to receive psychological intervention during their acute

admission. In addition, increasing psychological resource should be effective in improving patient engagement for both the trial and the real world. Increased psychological resource will allow increased staff training. Increased staff training is recommended in psychiatric inpatient services to promote awareness of therapeutic principles as staff play a key role in encouraging and enabling participant attendance (Jacobsen et al., 2011), however financial restrictions may be a barrier.

Problem A1

Type A: Problem with excluding eligible patients and initially including non-eligible patients.

Evidence

- 26% excluded if ward staff anticipated admission should be short.
- 15% patients excluded after consenting and completing baseline measures.

The above issues may influence a trial.

Solutions

Change aspects of:

a) Intervention

1. Provide therapy on an outpatient basis.

b) Trial design

1. Introduce two consent points. 1 to obtain initial consent and complete baseline measures. 2 to obtain consent to officially enter the trial 2 days after initial consent.

c) Clinical context

None

Assessment of Solutions

A1 Provide therapy on an outpatient basis

Could the solution be effective in trial setting?

Yes, short admissions would be less of a concern if patients could continue therapy after discharge.

Could the solution be feasible in trial setting?

The time of the end-point or post-intervention data collection point would need consideration for the control group. Logistics of doing so also needs consideration, e.g. whether resources are available to extend therapy to outpatients.

Could solution be effective in real world?

Yes, patients who have short admissions would still be eligible for therapy.

Could solution be feasible in real world?

The time of the end-point or post-intervention data collection point would need consideration for the control group. Logistics of doing so also needs consideration, e.g. whether resources are available to extend therapy to outpatients.

B1 Introduce two consent points. 1 to obtain initial consent and complete baseline measures. 2 to obtain consent to officially enter the trial 2 days after initial consent.

Could the solution be effective in trial setting?

Yes, likely to reduce the number of eligible patients who are not recruited. Data obtained at first consent point and if patient is still admitted at second consent point and give consent they officially enter the trial. If patient is being discharged on the day of the second consent point then post-intervention outcomes should be collected. If the patient has been discharged by the second consent point they do not enter the trial.

Could the solution be feasible in trial setting?

Yes, if ethical approval obtained and trial has resource to introduce an extra meeting with participants. Recruitment is labour intensive.

Could solution be effective in real world?

N/A

Could solution be feasible in real world?

N/A

Assessment of options and tolerance of trade-off between explanatory and pragmatic trial

Introducing two consent points would be effective in reducing the number of eligible patients that are excluded and ineligible patients that are included. Additional consent will need ethical approval and will require more time from research assistants. Alternatively, therapy could continue to be received if patients were discharged quickly.

However, given the limited resource already allocated to such services, therefore whether resources are available to extend therapy to outpatients needs careful consideration.

Problem A2

Type A: **Poor completion of follow-up questionnaires**.

Evidence

- 52-53% of follow-up questionnaires completed.
- 20% of participants with missing follow-up questionnaires could not be contacted.
- 64% of trauma questionnaires completed.

The above issues may influence a trial.

Solutions

Change aspects of:

a) *Intervention*
   None

b) *Trial design*
   1. At point of discharge, collect all contact details, alternative contact number and arrange appointment with participants.
   2. Increase contact with participant between discharge and follow-up, i.e. reminder letter/phone call.
   3. Offer incentive.
   4. Primary outcome should not rely on contacting participants at follow-up.
   5. Create profile for individuals unlikely to complete follow-up assessments and develop more stringent eligibility criteria on that basis.

c) *Clinical context*
   None

Assessment of solutions

B1: At point of discharge, collect all contact details and arrange appointment with participants.

Could the solution be effective in trial setting?

Yes, all current details are available to researcher therefore contacts lacking in medical files are no longer a problem.

Could the solution be feasible in trial setting?

Yes, can be stipulated in trial protocol. If patients can be met at post intervention this solution will be feasible. Completion of post-intervention assessments was good in this trial.

Could solution be effective in real world?

N/A

Could solution be feasible in real world?

N/A

B2: Increase contact with participant between discharge and follow-up, i.e. reminder letter/phone call.

Could the solution be effective in trial setting?

Technique used in other trials including acute inpatients (Jacobsen et al., 2016). Some evidence that increased phone calls improves completion in difficult to reach population (Kleschinsky, Bosworth, Nelson, Walsh, & Shaffer, 2009)

Could the solution be feasible in trial setting?

Will require support from a research assistant per site.

Could solution be effective in real world?

N/A does not affect real world. Patient will not be contacted at follow-up in real world.

Could solution be feasible in real world?

N/A does not affect real world. Patient will not be contacted at follow-up in real world.

B3: Offer incentive.

Could the solution be effective in trial setting?

Some evidence to suggest monetary incentive improve completion of questionnaires (Brueton et al., 2014).

Could the solution be feasible in trial setting?

Payment offered to take part in research rather than receive clinical treatment is in line with guidance (Royal College of Physicians, 2007) but must have ethical approval.

Could solution be effective in real world?

Patient will not be contacted at follow-up in real world.

Could solution be feasible in real world?

Patient will not be contacted at follow-up in real world.

B4: Primary outcome should not rely on contacting participants at follow-up.

Could the solution be effective in trial setting?

Good completion of outcomes collected via electronic database in this trial.

Could the solution be feasible in trial setting?

Easy and efficient method of data collection.

Could solution be effective in real world?

Patient will not be contacted at follow-up in real world.

Could solution be feasible in real world?

Patient will not be contacted at follow-up in real world.

B5: Exclude patients on basis of meeting profile of participants likely to be lost to follow-up.

Could the solution be effective in trial setting?

Likely to reduce missing data at follow-up (Sandra. Eldridge & Kerry, 2012).

Could the solution be feasible in trial setting?

Work to be done before trial to identify characteristics of those likely to be lost to follow-up.

Could solution be effective in real world?

Will compromise external validity in a main trial. No follow-up in real world, therefore may exclude participants that may benefit from intervention.

Could solution be feasible in real world?

Results may not apply to those likely to be missing follow-up data.

Assessment of options and tolerance of trade-off between explanatory and pragmatic trial

This is a pragmatic trial, therefore while excluding patients based on whether they are unlikely to provide follow-up data may reduce risk of bias associated with large proportions of missing data, it is not an option as trial results may not apply to a proportion of patients who may well benefit from the intervention (Eldridge & Kerry, 2012).

Participants already met at discharge for assessment, therefore collecting additional information (i.e. best contact details) will fit with current protocol. Increased contact between discharge and follow-up will be useful and is a technique used in other trials including acute psychiatric inpatients (Jacobsen et al., 2016) and there is some evidence that increasing contact with patients improves outcome completion of difficult to reach participants (Kleschinsky et al., 2009). However, this solution will require research assistant report and may be time consuming. As incentives are commonly used and are effective in healthcare trials (Brueton et al., 2014; Royal College of Physicians, 2007) this also seems a helpful solution.