Mindfulness-Based Crisis Interventions (MBCI) for psychosis within acute inpatient psychiatric settings

A feasibility randomised controlled trial

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Mindfulness-Based Crisis Interventions (MBCI) for psychosis within acute inpatient psychiatric settings; A feasibility randomised controlled trial

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Finally, I am dedicating this thesis to my Mum, Joan, who made all things possible for me.

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Abstract

Background: Inpatient psychiatric care is a scarce and expensive resource in the National Health Service (NHS), with chronic bed shortages being partly driven by high re-admission rates. People often need to go into hospital when they have a mental health crisis due to overwhelming distressing psychotic symptoms, such as hearing voices (hallucinations) or experiencing unusual beliefs (delusions). Brief talking therapies may be helpful for people during an acute inpatient admission as an adjunct to medication in reducing re-admission rates, and despite promising findings from trials in the USA, there have not yet been any clinical trials on this kind of intervention within NHS settings.

Objectives: The primary objective of the study was to find out whether it was possible to carry out this kind of trial successfully within UK inpatient settings in terms of successfully recruiting and retaining patients in the trial. The secondary objective was to collect pilot data on clinical outcome measures, including re-admission rates at 6-month follow-up.

Method: The amBITION study (BrIef Talking therapIes ON wards; ISRCTN376253384) was a parallel groups, feasibility randomised controlled trial (RCT) of a manualised brief talking therapy (Mindfulness-Based Crisis Intervention; MBCI). Inpatients on acute psychiatric wards were eligible for the study if they reported at least one positive psychotic symptom, and were willing and able to engage in a talking therapy. In addition to treatment as usual (TAU), participants were randomly allocated to receive either MBCI or a control intervention (Social Activity Therapy; SAT) which involved doing activities on the ward with the therapist.

Results: Fifty participants were recruited to the trial (26 MBCI; 24 TAU). No participants dropped-out during the therapy phase, and everyone in the trial received at least one therapy session. The average number of sessions per participant was 3 in both arms of the trial. Retention in the trial was excellent, and exceeded the pre-set benchmark of no more than 20% loss to follow-up at trial end-point (6-month follow-up after discharge). The follow-up rate at 6-month follow-up was 98% for service use data extracted from clinical notes, and 86% for self-report questionnaire measures. Three participants experienced adverse events, but none of these were considered to be related to their participation in the trial.

Conclusions: It is feasible to recruit and retain participants in the trial. The therapy was acceptable to patients, and satisfaction ratings with therapy was high. Progression to a further trial is warranted based on these encouraging feasibility outcomes.

Chapter 1: Acute inpatient care, CBT for psychosis and impact on reducing risk of relapse

1.1 Overview

Acute inpatient care for mental health in the National Health Service (NHS) is a scarce and expensive resource. Bed occupancy is too high and length of admission is increasing. Service user satisfaction with inpatient care is generally low. A common source of dissatisfaction with acute inpatient care is the lack of access to talking therapies. The Schizophrenia Commission Report suggested that greater access to talking therapies during hospitalisation might be helpful in reducing short-term readmission rates. However, the current gold-standard psychological therapy, Cognitive-Behavioural Therapy for psychosis (CBTp), whilst effective in reducing psychotic and affective symptoms, has not generally proven effective in reducing relapse. There have been some randomised controlled trials (RCTs) of CBTp within acute inpatient settings, however they also failed to show a convincing effect in reducing relapse. Furthermore, interventions tested in the 3 largest in-patient RCTs comprised many treatment sessions (16-20), however, most participants did not complete a set minimum of sessions, let alone the full therapy course. Given that the average length of an inpatient admission is around 4 weeks, what is required is a briefer intervention which is tailored to fit the setting. This is preferable to trying to implement a standard CBTp protocol, which has been primarily designed and evaluated in community settings for people with residual psychotic symptoms, rather than for people experiencing a mental health crisis. There have been 2 promising pilot trials in the United States (US) of a mindfulness-based intervention (Acceptance and Commitment Therapy; ACT), specifically adapted to be delivered within inpatient settings. It is a brief therapy (1-5 sessions), with stand-alone sessions to accommodate unpredictable lengths of stay, and targets the underlying psychological processes implicated in crisis. Pilot trial results suggest that the ACT intervention reduced the risk of re-admission by 50% at 4-month follow-up, compared to treatment as usual. It is not yet known whether such an approach would also be effective within NHS acute inpatient settings for people with psychosis.

1.2 Acute inpatient care: Expensive, inadequate and in short supply

> *"The reduction in acute hospital beds might be viewed as a tremendous success for deinstitutionalization in the UK, were it not that the demand for inpatient care now grossly outstrips supply, accompanied by a rising tide of demoralization and dissatisfaction with care among hospital staff and patients"* p. 91 (Craig, 2016)

There is a crisis in acute inpatient care in the United Kingdom (UK). Bed occupancy in the NHS is too high (>85% safety threshold), length of stay is increasing, and costs are rising (Figure 1). The rising tide of demoralization and dissatisfaction, which Craig refers to in the quote above, is all too apparent in the findings of service user surveys and studies (Csipke *et al.*, 2014, Csipke *et al.*, 2016, Rose *et al.*, 2015). A frequent complaint amongst service users is that there is inadequate access to psychological therapies during inpatient admissions (Wood and Alsawy, 2016).

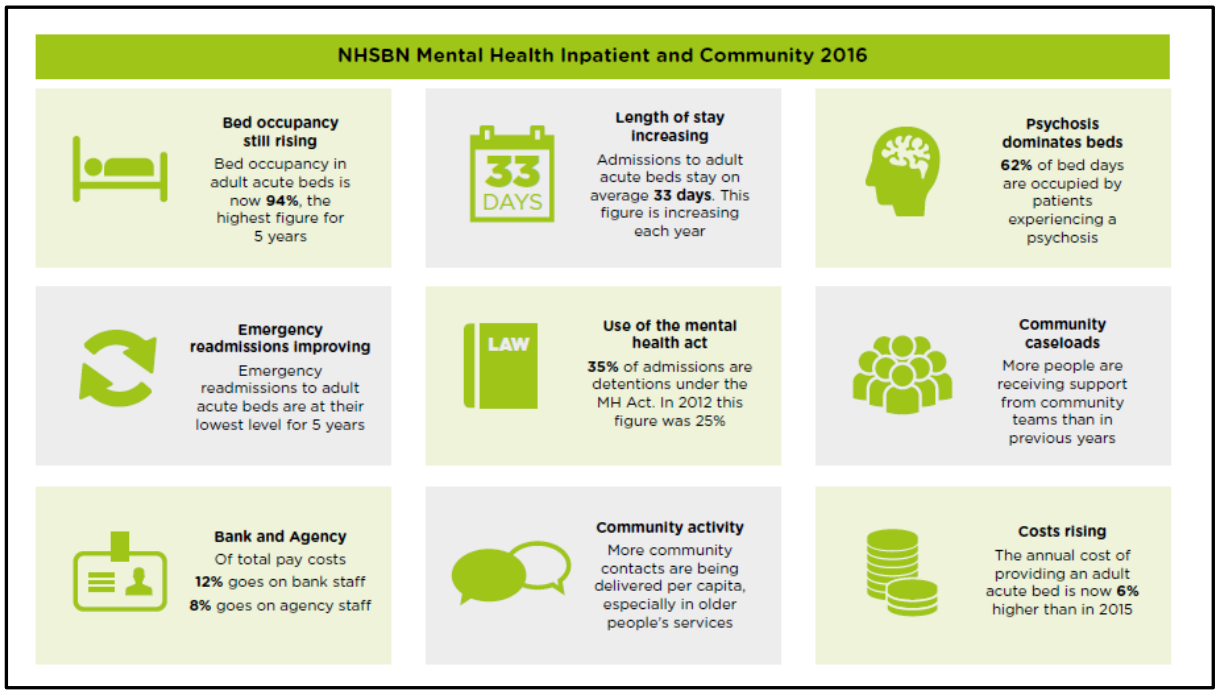


Figure 1 NHS Mental Health Benchmarking Summary (Network, 2017)

In addition to the academic literature, charity reports have also played a vital role in giving a voice to service user concerns. For example, a report from the mental health charity Mind (2011) high-lighted concerns about a therapeutically impoverished environment on wards and an undue emphasis on a medical model of care (Figure 2).

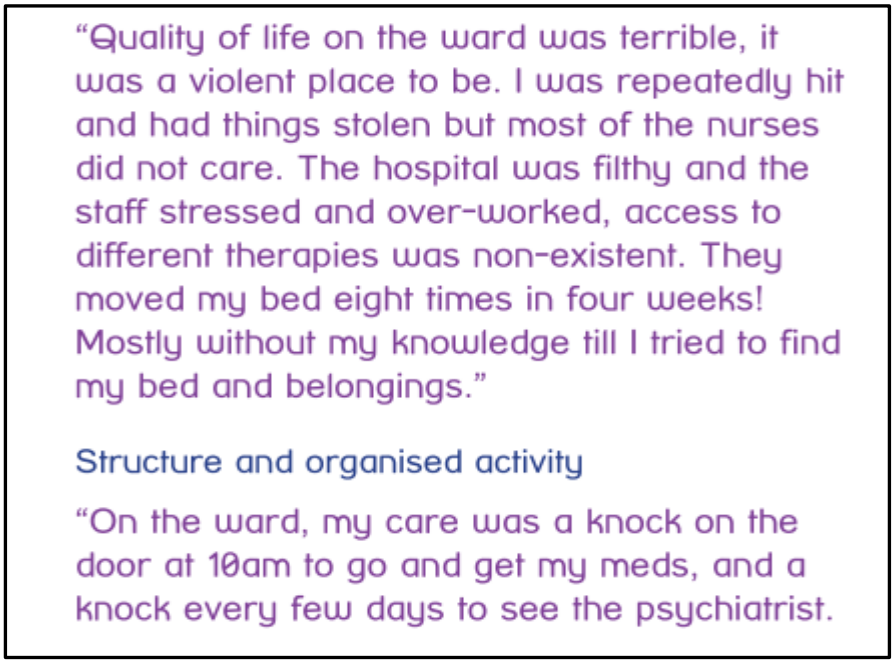


Figure 1 Service user quotes from Mind report (2011)

These findings were later mirrored in the Schizophrenia Commission Report (2012), which noted:- "*We were particularly concerned about the lack of access to CBT and other psychological therapies which are recommended in the NICE guidelines and can be very valuable in helping people deal with the impact of symptoms and in keeping them out of hospital.*" (p. 33). This quote draws attention to another critical issue, which is intrinsically linked to the bed-shortage crisis; high re-admission rates. Sometimes people are successfully stabilised in hospital, only to relapse again in the community shortly after discharge, leading to another admission. This sometimes attracts the stigmatising label of being a "revolving-door" patient. Frequent hospital admissions are distressing and disruptive to service users and their families, as well as placing a high economic burden on NHS services (Lloyd-Evans *et al.*, 2010). The Schizophrenia Commission is correct of course in its assertion that CBTp is recommended in clinical guidelines (NICE, 2014). However, does the evidence support its role in keeping people out of hospital for longer?

1.3 CBTp; Effective in symptomatic reduction but not for reducing risk of relapse

NICE clinical guidelines (2014) recommend both CBTp and Family Intervention (FI) as evidence-based psychological therapies which should be widely available to service users (CG178 – Psychosis and Schizophrenia in adults: prevention and management). The guidelines further stipulate that CBTp should be delivered as an individual therapy, of at least 16 planned sessions, and should focus on helping people to establish links between thoughts, emotions and behaviours, and to promote alternative ways of coping with the target symptom. The aims of the intervention should include reducing distress and improving functioning. CBT can be started "*either during the acute phase or later, including in inpatient settings*" (recommendation 1.4.4.1). Although the evidence reviewed for the 2014 NICE guidelines clearly showed CBTp to be an effective treatment, this was based on evidence that it helped reduce psychotic symptoms, and associated affective symptoms such as depression and anxiety e.g. (Wykes *et al.*, 2004). There is no specific recommendation for the provision of CBTp as an effective treatment to keep people out of hospital for longer, or to reduce overall admission rates.

There has been a proliferation of meta-analyses for CBTp over the 15 years, however only CBTp meta-analyses that report data relating to impact on hospital admissions will be discussed here. This is also a timely point to note the distinction that is made between *relapse* and *readmission* in the literature. A person may relapse, in that there is a recurrence or exacerbation of symptoms, but this will not necessarily always lead to an admission. Given the acute shortage of inpatient beds, admissions are often driven by additional factors such as the presence of a perceived risk to self or others. Conversely, readmission can occur in the absence of a relapse of psychotic symptoms. For example, admissions may be to re-start or stabilise people on medication regimes, particularly with the introduction of Community Treatment Orders (CTOs), which allow a person to be recalled to hospital if they do not comply with medication in the community even in the absence of a relapse in mental state. For this reason, some trials have defined relapse only in relation to a deterioration in mental state, or a recurrence of psychotic symptoms. This can either be assessed by using scores on symptom rating scales to define a significant deterioration over a defined period, or systematically reviewing clinical notes for indications of re-emergence of psychotic symptoms, and subsequent changes to clinical management such as increased keyworker

visits (e.g. Bebbington *et al.* (2006)). Readmission (for whatever reason) is then usually reported as a separate outcome. Some trials have used a composite definition, such as defining relapse in terms of admission to hospital, but only in the context of a worsening of psychotic symptoms (Drury *et al.*, 2000).

An early meta-analysis of 8 RCTs of CBTp concluded there was no evidence that CBTp prevented relapse or readmission during treatment, but trials with longer follow-up periods were lacking at the time (Pilling *et al.*, 2002). A later review by Lynch and colleagues argued that if only well-controlled trials were included in a meta-analysis, CBTp was not effective in reducing symptoms or in preventing relapse (Lynch *et al.*, 2010). Specifically, in relation to relapse, this review included 8 RCTs with follow-up periods of 6 months to 3 years, and reported a pooled odds ratio (OR) of 1.17 (95% CI 0.88-1.55, p=0.29). Finally, a Cochrane review of CBTp compared to other psychological therapies also concluded that there was no evidence that it reduced risk of relapse, or readmission (Jones *et al.*, 2012). Only 5 RCTs were found eligible for their review, and they included studies with follow-up periods of up to 5 years. They reported a non-significant risk ratio (RR) of 0.91 (95% CI 0.63-1.32, n=183) for relapse over the long-term, and 0.86 for re-admission over the long-term (95% CI 0.62-1.21, n=294). Comparable results were found for RRs over the short- and medium-term. It is important to note at this point that the field of CBTp meta-analyses is not without its controversies, mainly relating to how the inclusion/exclusion criteria for studies is set, and how risk of bias is assessed and accounted for in the results (Thomas, 2015). However, the overall picture relating to reducing risk of relapse/readmission is clear; CBTp is not effective.

Exploring one of the key studies in the area may be helpful at this stage in helping us to understand why this might be, from an individual trial perspective. The Psychological Prevention of Relapse in Psychosis trial (PRP) was the first large-scale (n=301) and robustly designed RCT to explicitly focus on relapse as key outcome. The aim was to test the effectiveness of CBT and FI in reducing relapse in people who had recently relapsed (whether or not this had led to a hospital admission). This contrasted with many of the previous trials which had focused mainly on people with chronic distressing psychotic symptoms in the community. The trial had 2 pathways within the study, for service users with and without carers (as people without carers could not be randomised to FI). CBTp in the trial was delivered over the course of 9 months, and had a minimum of 12 and a

maximum of 20 planned therapy sessions. The primary outcomes were relapse (rated using case-note review), and hospital admission (collected through hospital notes). They found that neither CBT nor FI reduced the risk of relapse or hospital admission at 12 or 24-month follow-up (Garety *et al.*, 2008). This was a somewhat unexpected finding, as one of the key hopes for CBTp was that it might help keep people well for longer, or reduce the number of relapses, as well as improving symptoms over the course of treatment. To explore this finding further, the PRP team later published a subsequent sub-group analysis (Dunn *et al.*, 2012). They looked at 102 participants with sufficient therapy rating data, and divided them into 3 groups. The 'No Therapy' group were defined as having received <5 sessions (n=21). The 'Partial Therapy' group (n=39) were defined not by the number of sessions they received, but rather by the content of the sessions. Partial therapy was defined as only including the initial stages of a manualised CBTp approach (i.e. engagement and assessment). The 'Complete Therapy' group (n=42) were defined as having also progressed to the later stages of therapy, including specific work on relapse prevention, reinterpreting the meaning of delusional beliefs and hallucinations and schema work. They found that the people who had completed therapy showed statistically significant increases in the number of months in remission, and also showed significant improvements in psychotic and affective symptoms. By contrast, partial or no therapy was found not to be effective in reducing relapse or improving symptoms. Furthermore, these sub-groups in the treatment arm were compared to three comparable groups in the TAU group, controlling for key demographic and clinical variables in the analysis of outcomes. Although this is an interesting finding, the sub-group analysis was carried out post-hoc, and so should be interpreted with an appropriate degree of caution. It also leads to further questions about why only 40% in this sub-group analysis met the criteria for having completed therapy, even with CBTp delivered to a high standard by highly trained therapists in the trial.

1.4 CBTp within inpatient settings also does not show any evidence of impact on risk of relapse/readmission

Although the NICE guidelines state that CBTp may be started in hospital, and carried on seamlessly post-discharge in the community, there are relatively few trials which evaluate therapy started in the acute phase in hospital. It is also important to note that most services in the NHS have a clear division between inpatient and community psychology provision, although there are variations in service models across the country. The meta-analyses

discussed above have included inpatient trials, including trials set in long-stay wards (Valmaggia *et al.*, 2005) and trials with a mixture of participants in inpatient and outpatient settings (Haddock *et al.*, 2009, Pinto *et al.*, 1999). In addition to these, there are also some RCTs conducted in the UK that have investigated delivering CBTp within an acute inpatient setting, with a focus on working with people with psychotic symptoms in the acute phase (Drury *et al.*, 1996a, b, Lewis *et al.*, 2002, Startup *et al.*, 2004). Although there were reported benefits in the remission of psychotic symptoms, again there was no evidence that CBTp in the acute phase provided benefits in reducing risk of relapse over the longer-term.

Drury and colleagues conducted a trial of cognitive therapy for acute psychosis in an inner city psychiatric hospital in Birmingham. The strengths of this study are that it was set in a typical acute ward, and it had a credible control arm (ATY; recreational therapy) which was matched for therapy hours with the active treatment arm (CT; cognitive therapy). New admissions to the ward were screened within a week, and people with positive psychotic symptoms (hallucinations and/or delusions) in the context of a psychosis diagnosis were eligible to participate. Although 62 people in total were randomised into the trial, a third of the sample were excluded after randomisation (10 in CT arm; 12 in ATY) for several reasons including not admitting to symptoms, inadequate medication compliance and refusal to engage in therapy. Only the remaining 40 participants (20 in each arm) were included in the analysis, meaning that the analysis was effectively per protocol rather intention-to-treat (ITT). The package of care in the CT arm was complex and intense. It included not only individual CT sessions, but also group and family work. The aim was to provide an average of 8 hours of total therapy time a week, for a maximum of 6 months. The authors do not report the actual number of sessions participants completed, or the average therapy time (although people who did not engage at all were excluded from the analysis as outlined above). The aim of the study was to investigate the effectiveness of CT in hastening the resolution of positive symptoms, and reducing residual symptoms. The results indicated a relatively greater decline in positive psychotic symptoms in the CT compared to the control group, with only 5% of people in the CT group showing moderate or severe symptoms at 9-month follow-up, compared to 56% in the control group (Drury *et al.*, 1996a). They also found that there was a significant reduction in time to recovery at 6-month follow-up in the CT group compared to the control group (Drury *et al.*, 1996b). Although risk of relapse/readmission was not a primary outcome measure for the trial, participants were

followed up 5 years later to examine any longer-term impact of the intervention (Drury *et al.*, 2000). Readmission data were collected through hospital records and were available for 37/40 participants (18 in CT group; 19 in ATY group). In addition to looking at hospital admissions, the research team also rated rates of relapse, which was defined as i) admission to hospital or home treatment team, with an exacerbation of acute psychotic symptoms, or ii) documentation of early relapse followed by an increase in medication and/or increased keyworker visits. The results showed no significant difference between the CT and control group in terms of relapse rate, positive symptoms or insight at 5-year follow-up. In fact, the mean number of admissions was 1.2 in both the CT and control group, and the mean number of relapses was also virtually identical between the groups (1.4 in CT group vs. 1.2 in ATY group). In summary, the intensive CT intervention in this trial was found to be effective in its primary aims of symptom reduction in the acute phase, but had no longer-term positive impact on risk of relapse/readmission. However, the results should be interpreted with caution due to the small sample size and lack of ITT analysis.

Drury's study demonstrated the feasibility of running a CBTp trial in an acute inpatient setting, despite some methodological limitations. A subsequent inpatient study by Haddock and colleagues in Manchester extended this work by focusing only on people with a more recent diagnosis of psychosis, who had been first treated for psychosis less than 5 years ago (Haddock *et al.*, 1999c) . Although in the Drury study, 2/3 participants were described as experiencing their first or second episode of psychosis, the sample also included some people with more chronic difficulties. It is of course possible that inpatient CBTp may have a more positive impact in the early stages of psychosis, and would fit in with the general early intervention model of trying to prevent longer-term disability and the development of secondary difficulties over time. The Haddock trial was designed as a pilot study, so the sample size was small. There were 10 people in the CBTp arm, and 12 people in the control arm, which was supportive counselling (SC). The treatment protocol was simpler than the Drury study, as it only included individual therapy sessions, and not additional group and family sessions. They designated a therapy envelope of 5 weeks, to fit in with a typical length of admission, with 4 booster sessions offered at monthly intervals post-discharge. The mean average of sessions completed was 10 in the CBTp arm and 9 in the SC arm during the inpatient phase. However, the authors noted there was considerable variability in the number of therapy sessions people received, with a range of 3-18 sessions over the inpatient phase.

Take-up of the post-discharge booster sessions was generally poor. People in the CBTp group attended an average of 1.67 booster sessions, but only 2/10 attended all 4 sessions, and 3/10 did not attend any booster sessions at all. Similarly, in the SC group, the average number of booster sessions attended was 0.91, no-one attended all 4 sessions, and 7/12 did not attend any at all. The primary outcome for the trial was reduction of psychotic symptoms at 4 months post-discharge. Data on the main outcome measure (Brief Psychiatric Rating Scale; BPRS; Overall and Gorham (1962)) was only available for 8 people in the CBTp group and 10 in the SC group, so group comparisons should be treated with caution due to the small sample size. The results showed a significant reduction on the BPRS in both groups, but no significant differences between groups. Although not a primary outcome, the researchers also looked at relapse/readmission data at 2-year follow-up. Relapse was defined as a change in clinical management resulting from an increase in psychotic symptoms. They found that the mean number of relapses in the CBT group was lower than the SC group (44% vs. 73% respectively), but that the time to 1st readmission was shorter in the CBTp group (mean 316 days vs. 639 days in the SC group). These differences were not found to be statistically significant, probably due to the small sample size.

Given that this pilot study indicated that a larger trial would be feasible, and the therapy was acceptable to an inpatient population, the research team progressed onto a larger efficacy trial (SoCRATES; Study of Cognitive Realignment Therapy in Early Schizophrenia, Lewis *et al.* (2002)). There was a similar focus on an early intervention population, in that the trial recruited people who were mostly in their first admission (83%), with the remainder only having had 1 other previous admission (which had to be within the past 2 years). The study again tested CBTp vs. SC as the active control arm, but also added in an additional treatment as usual arm (TAU). The aim of the study focused on whether CBTp would speed up remission of acute psychotic symptoms, with prevention of future relapse as a secondary aim. This was a much larger multi-site trial, with 101 participants randomised into the CBTp arm, 106 in the SC arm, and 102 in the TAU arm. They used the same therapy envelope of 5 weeks as in the pilot trial, aiming to provide 15-20 hours of intervention within this time, with booster sessions offered at 2, 4 and 8 weeks post-discharge. The findings showed that the mean number of sessions attended were comparable in the CBTp (16.1) and SC groups (15.7), although the CBTp group received significantly longer therapy time overall (8.6 hours) compared to the SC group (7.1 hours). Interestingly, the average number of therapy

hours (as opposed to therapy sessions) was still only about 50% of the target number of hours stated in the protocol. This may reflect the clinical setting, in that people in acute crisis may only be able to engage with therapy sessions of shorter duration than the standard therapy hour. This therefore calls into question how realistic it is to aim to deliver 15-20 therapy hours within an acute inpatient setting. Acute phase outcomes showed a similar picture to the pilot trial, in that people in all 3 groups showed significant improvement in psychotic symptoms over the course of the trial, with a trend to faster improvement in the CBTp compared to the TAU group, although this was not statistically significant (Lewis *et al.*, 2002). There was no evidence of faster improvement in the CBTp compared to the SC group. At 18-month follow-up, they found that both the CBTp and SC groups scored lower on symptom measures compared to TAU, but there was no group difference on relapse or re-hospitalisation (Tarrier *et al.*, 2004). Hospital admission data was available for 99% of the original sample, and clinical notes for 95% of the sample. Relapse was defined as change in clinical management in response to a worsening of psychotic symptoms lasting at least a week. In the CBTp group, 33% had at least one re-admission, and 55% had at least one relapse. The figures were similar in the SC group (29% readmission; 52% relapse) and the TAU group (36% re-admission; 51% relapse). The higher rates of relapse compared to re-admission in each group validates the approach of using both a case-note review as well as looking at hospital admission alone, as clearly not all relapses in the community lead to an admission.

The most recent large inpatient RCT was the North Wales trial of CBTp for acute psychosis (Startup *et al.*, 2004). The authors noted that the SoCRATES trial found less positive outcomes for CBTp over the acute-phase compared to the Drury trial, which could probably be explained by a larger sample size and the use of an ITT analysis in the SoCRATES trial. However, Startup and colleagues also noted the intensity of the therapy intervention in previous trials, and questioned the generalisability of such an approach in routine clinical practice given that therapist time is a highly scarce resource. They therefore took a slightly different approach to treatment delivery, and offered participants in the trial up to a maximum of 25 weekly sessions, with participants being asked to commit to at least 12 sessions. In contrast to the previous trials, they also explicitly stated that therapy could be continued without interruption following discharge. They recruited people with acute psychotic symptoms within the first 28 days of their admission, but did not limit the inclusion criteria to

only people experiencing their first-or second episode of psychosis. In contrast to the Drury and Lewis trials, they did not use an active control condition, just TAU. In total, 47 people were randomised to CBTp and 43 to TAU. The primary outcomes were positive and negative symptoms and social functioning, at 6 and 12-month follow-up. The mean average number of therapy sessions of CBTp was 12.9, however, there was an interesting pattern of engagement in therapy (for people who attended at least 1 session) which the authors described as trimodal (like the findings of the PRP study; Garety et al, 2008). There was a bottom group of participants who only had 2-3 sessions, a middle group who completed approximately the minimum agreed of 12 sessions, and a top group who continued up to the maximum of 25 sessions. Treatment was prematurely terminated in 21/47 (45%) of the participants in the CBTp arm for various reasons including not attending sessions, and discharging themselves early from hospital. In summary, a minimum therapy dose was conservatively defined as 50% of the maximum allowed sessions, but only just over half of participants met this threshold. Although therapy could be continued in the community after discharge without interruption, the trial paper does not report how many sessions on average were completed pre- or post-discharge for each participant, or the proportion of participants who carried on with therapy after discharge. Therefore, it is not possible to know whether most therapy sessions were in fact conducted in the inpatient or outpatient setting (or if it was fairly balanced between settings).

At 12-month follow-up, a significantly larger proportion of people in the CBTp group showed reliable and clinically important change as assessed by the Global Assessment of Functioning Scale (GAF; American Psychiatric Association (1994)), and the CBTp group showed greater improvement on psychotic symptom scales compared to the TAU group. However, these findings should be interpreted with caution, as there was no active control group for non-specific therapy factors such as therapist time and attention, and the follow-up assessments were not blind rated. At 2-year follow-up, there was no significant difference in the average number of admissions between the CBTp and TAU groups (0.4 vs. 0.7 respectively), proportion of people with at least 1 re-admission (0.61 vs. 0.7) or total number of days in hospital (Startup *et al.*, 2005). They did not rate relapse separately from hospital admission.

In summary, although these inpatient trials have some mixed findings, they tell a consistent story in terms of the impact of CBTp delivered during the acute phase within an inpatient setting. There is no evidence of benefit in terms of reducing the risk of relapse or readmission, up to 5 years post-treatment. Startup and colleagues (2005) note: -

"The fact that 61% of the CBT group were readmitted to hospital at least once (70% of the TAU group) shows that CBT was not effective in maintaining patients in the community once treatment was terminated, despite the large improvement in symptoms and social functioning that were obtained during treatment." (p. 1314)

This echoes the comments of Garety and colleagues, who concluded from the results of the PRP trial that they could not recommend CBTp for routine prevention of relapse, and "*CBT targeted at this acute population requires development"* (Garety et al, 2008, p. 412). What might this development be? To re-cap, NICE guidelines recommend CBTp should consist of at least 16 planned sessions, and the inpatient trials to date have tried implementing this within various therapy envelopes, ranging from 5-25 weeks. However, given that the average length of an acute inpatient admission in the UK is now 33 days (NHS Benchmarking Network, 2017), what if a different kind of approach was needed; a brief, crisis-focused intervention that was tailored to an inpatient setting, and specifically targeted the underlying psychological processes that bring people into crisis, to reduce future risk of relapse.

1.5 Brief Acceptance and Commitment Therapy (ACT) for acute psychosis shown to reduce risk of relapse in US pilot trials

In recent years there have also been promising findings in applying mindfulness-based interventions to psychosis (see Chapter 3). These therapeutic approaches all share a common goal in focussing on reducing distress and disability associated with psychotic symptoms. However, mindfulness-based interventions differ from conventional cognitive therapies in that they focus exclusively on changing people's relationship to their thoughts and feelings, and do not aim to modify content directly. This focus makes them ideally suited to brief interventions, as they do not attempt any cognitive restructuring that typically requires a longer period of engagement and building therapeutic rapport. Furthermore, patients in a mental health crisis are experiencing high levels of suffering. The core principles of a

.mindfulness-based approach (e.g. compassion, non-judgement, acceptance, here-and-now focus) are particularly relevant in meeting this suffering during a crisis.

Mindfulness-based brief crisis-focused interventions are also ideally placed to reduce the risk of future relapse and re-admission, as they can help a person understand how their maladaptive coping strategies have brought them into crisis, and to develop skills in alternative coping strategies. Two pilot RCTs (Bach and Hayes, 2002, Gaudiano and Herbert, 2006) have been conducted in the USA evaluating a type of mindfulness-based intervention known as Acceptance and Commitment Therapy (ACT). The core ACT principle is that much maladaptive behaviour is the result of unsuccessful attempts to suppress or avoid unwanted thoughts, feelings or bodily sensations (Hayes *et al.*, 2011). This is particularly relevant to understanding what brings people into crisis culminating in an inpatient admission. For example, people may cope with unpleasant voices (auditory hallucinations) by drinking alcohol or using illicit drugs to block them out. Someone experiencing persecutory delusions may choose to avoid the anxiety they feel when they go out in public by isolating themselves at home. These behaviours not only stop the person from being able to function normally in their everyday life, they also increase the risk of serious self-neglect and possible risk to self and others under the influence of drugs and alcohol. Once people stop taking care of themselves, their compliance with their anti-psychotic medication regime also tends to deteriorate along with everything else, leading to a spiral of increased symptoms and a decreased capacity to cope effectively.

Bach & Hayes (2002) and Gaudiano & Herbert (2006) both conducted RCTs of ACT vs. TAU for inpatients with distressing psychotic symptoms in the USA. The need for brief interventions is even more urgent in the USA, where there is no national health service, and acute inpatient admissions are generally only funded for up to 7 days. The aim of the ACT intervention was to help people:-

a) *to identify and abandon internally oriented control strategies*
b) *to accept the presence of difficult thoughts or feelings*
c) *to learn to "just notice" the occurrence of these private experiences, without struggling with them, arguing with them, or taking them to be literally true*
d) *to focus on overt behaviours that produce valued outcomes*

- (Bach & Hayes, 2002, p. 1130)

Bach & Hayes (2002) used a manualised 4-session treatment, with the last session occasionally being delivered post-discharge in the case of early or unexpected discharge. Gaudiano & Herbert (2006) used a slightly different approach, to take into account that length of stay is often variable and unpredictable, by offering people between 1 and 5 sessions, all of which followed a single-session, self-contained format. The median number of sessions people completed was 3. In contrast to the UK trials reviewed in the previous section, these ACT trials were specifically targeted at reducing relapse/readmission rather than symptom reduction over the acute phase.

Bach & Hayes (2002) randomised 40 people each to the ACT and TAU arms respectively. The trial was open to all participants admitted with psychotic symptoms, and most participants had previous admissions (80%), rather than being a predominantly early intervention population. They reported that the re-hospitalisation rate at 4-month follow-up for the ACT group was half that of the TAU group (20% vs. 40% respectively), a statistically significant difference. This significant advantage for ACT over TAU in reducing readmission rates was also maintained at 1 year follow-up (Bach *et al.*, 2012). Gaudiano & Herbert (2006) report the same trend of results (28% ACT vs. 45% TAU respectively), but this did not reach statistical significance. This could partly be accounted for by a smaller sample size in this later study (n=19 ACT; n=21 TAU), meaning it was likely to be underpowered. Bach & Hayes additionally reported self-report psychotic symptom measures at baseline and 4-month follow-up, and Gaudiano & Herbert reported the same measures at baseline and post-treatment (discharge), but not at follow-up. They asked people to identify their most distressing psychotic symptom (either voices or beliefs) and then to rate it on frequency, distress and believability. Believability as a dimension is not common within CBTp trials, and is sometimes confused with conviction, e.g. as measured in the PSYRATS (Psychotic Symptom Rating Scales; (Haddock *et al.*, 1999b). However, ACT researchers conceptualise believability as a slightly different concept to conviction, more related to cognitive defusion, i.e. how much people are 'buying into' their experiences, or to what degree they can step back and view them as mental events. This idea of being able to step back from internal experiences and 'de-fuse' is also covered in the curriculum of a standard mindfulness-based cognitive therapy course (MBCT) in week 6, which refers to this theme as 'Thoughts are not Facts' (Segal *et al.*, 2013). The data from the two trials were later combined for the purposes of a mediation analysis, and it was found that the reduction in readmission rate at 4-month

follow-up was mediated by symptom 'believability', but not symptom-related distress (Bach *et al.*, 2013). This finding was in line with the underlying model of the intervention, in that the key target is a person's relationship with their experience, rather than the content or form of the experience itself. Given that distressing psychotic symptoms are likely to reoccur frequently for people who have required hospital admission in the past, perhaps the most important thing is not to try to get rid of symptoms faster, but to change the behavioural impact of such experiences when they arise in the future. Finally, brief, crisis-focused interventions such as those trialled by Bach and colleagues may also be successful because they specifically target the problematic behaviours which have brought people into crisis (e.g. maladaptive attempts to block out distressing experiences) at a time when people are willing to explore them. This window of opportunity may be lost as the crisis resolves, particularly for people with a "sealing over" recovery style who prefer not to think about their psychotic experiences after admission (Mcglashan *et al.*, 1975).

A 50% reduction in readmission is an encouraging result in a field which so far has singularly failed to demonstrate any positive impact of psychological therapies on reducing the risk of relapse. These results have not yet been replicated in other countries though, or in a larger multi-site trial in the US. Results such as these, which seem almost too good to be true, are often treated cautiously and with an understandable degree of scepticism. Öst (2008) published a systematic review and meta-analysis of so-called 'third-wave' behavioural therapies, an umbrella terms for therapy approaches including acceptance and commitment therapy (ACT). The findings were rather critical of the methodological quality of studies in the review in general. In fact, Öst concludes by stating that "none of the third wave therapies fulfilled the criteria for empirically supported treatments" (p. 296). A subsequent update of the review reached similar conclusions (Öst, 2014). He singles out the Bach/Gaudiano inpatient trials as being examples of trials with limited generalisability as all therapy was delivered by a single therapist, and there was a limited description of the 'enhanced' TAU condition used as the comparator. However, prominent researchers in the ACT field later published a robust response to the review, which was critical of its methods (Atkins *et al.*, 2017). Almost 10 years on from the first Öst review the controversy continues. Are these unreliable findings arising from studies with significant methodological limitations; or whether in fact, these are credible brief therapies for inpatient settings, warranting further investigation within a UK NHS setting.

1.6 Summary

Current clinical guidelines in the UK recommend CBTp, but there is little evidence on which to recommend treatment within inpatient settings. Inpatient trials have suggested that few people complete a full course of CBTp even when it is offered, and the intensity and cost of such an approach is unlikely to be generalisable to routine clinical practice. Furthermore, although CBTp provided during an inpatient admission may be helpful for speeding up symptom remission, there is no evidence it reduces the risk of relapse of readmission, either in the short or longer-term. Briefer interventions, which are designed to be crisis-focused, rather than condensed versions of a full CBTp intervention, may be more feasible and effective at reducing relapse. Two pilot trials from the USA have tested out brief, mindfulness-based interventions which reduced re-admission rates by 50% at 4-month follow-up. Such approaches have not yet been tested in the UK. The next chapter will put these findings into a broader context by way of a systematic scoping review of psychological therapies for psychosis delivered within acute inpatient settings, both in the UK and internationally. This review includes all study designs, and all therapy models, to give a better overall picture of the state of the evidence base for inpatient therapies for psychosis.

Chapter 2: A Systematic Review of Psychological Therapies for Psychosis within Acute Psychiatric Inpatient Settings

2.1 Overview

The provision of psychological therapies on acute wards is recommended by good practice guidelines, and welcomed by service users. However, provision varies widely both nationally and internationally. This chapter describes a systematic review which was designed to scope out the current evidence base for psychological therapies for psychosis delivered within acute inpatient settings. All study designs, and therapy models, were eligible for inclusion in the review. A total of 65 studies were included in the final review. The search strategy and review protocol is described. The results are reported according to the 5 main review questions, which were set in advance. The findings are discussed with regards to implication for clinical practice, challenges in conducting research within inpatient settings, and suggestions for future research.

2.2 Introduction

As discussed in Chapter 1, the Schizophrenia Commission Report highlighted concerns that people often did not have access to talking therapies during acute inpatient admissions. These concerns are mirrored in a report by the Care Quality Commission (CQC) which found that less than a third of respondents reported having access to any kind of talking therapy during inpatient admissions, and the majority of people who wanted to access a talking therapy during an admission were unable to (CQC, 2009). First-person accounts of inpatient care frequently highlight boredom on wards, and the detrimental impact of not having access to therapies e.g. (Antoniou, 2007).

Good practice guidelines for inpatient wards all make reference to the importance of the provision of regular activities and therapies. This includes the Royal College of Psychiatry's Accreditation for Inpatient Mental Health Services framework (AIMS-AT; RCPsych (2014)) and the service-user led initiative StarWards (www.starwards.org.uk). The AIMS-AT standards for example recommend "*all patients are offered specific psychosocial interventions appropriate to their presenting needs and in accordance with national clinical guidelines (e.g. NICE and SIGN)"* (section 53.6) and that "*at least one staff member based on the ward/unit is trained and supervised to deliver one basic, low intensity evidence-based psychological intervention (U53.7) AND/OR one problem-specific, high intensity evidence-based psychological interventions (U53.8)*".

However, if we examine further this suggestion that ward staff should be delivering "evidence-based interventions", a key question arises; to what evidence base should we refer? The NICE guidelines for psychosis recommend CBT for psychosis (CBTp) and Family Interventions (FI) (NICE, 2014). However, these recommendations are largely based on trials conducted in community settings. Furthermore, when CBTp has been evaluated within inpatient settings, the large number of sessions, and the intensity of delivery required, does not fit well with the constraints of an admission which may only last up to 30 days, and the limited number of staff available to provide such therapies within routine acute care. There are other key differences between the delivery of psychological therapies within inpatient and community settings. For example, CBTp may be more likely to be delivered as a group, rather than an individual intervention, within inpatient settings. However, a recent systematic

review of group therapy for psychosis in acute care highlighted the small number of studies published overall in this area, and in particular the paucity of randomised controlled trials in the literature (Owen *et al.*, 2015b).

At the time of writing the review protocol, there were no existing systematic reviews or meta-analyses focusing solely on psychological interventions for psychosis within inpatient settings. There were also no protocols of reviews underway according to the PROSPERO database, the international prospective register of systematic reviews (https://www.crd.york.ac.uk/PROSPERO/). Given the lack of existing reviews in the area, the aim of this review was intended mainly as a 'scoping' review. This kind of review is used to find out what the potential size and scope is of the available research literature, and may include ongoing or planned research (Grant and Booth, 2009). Scoping reviews are particularly relevant to areas of healthcare where it is not clear whether the evidence exists to answer a more precise question, such as the effectiveness of a particular therapy for a particular population. Scoping reviews are therefore *"useful for examining emerging evidence when it is still unclear what other, more specific questions can be posed and valuably addressed"* - pg. 6, Joanna Briggs Institute Reviewer's Manual (2015).

The aim of this review was therefore to explore and map out the evidence base for psychological therapies for psychosis within acute inpatient settings. Five review questions were set in advance: -

1) What is the current state of the evidence base for psychological therapies for psychosis within acute psychiatric inpatient settings? **(Primary)**
2) What study designs are used to evaluate psychological therapies for psychosis within acute inpatient settings?
3) How are psychological therapies for psychosis within acute psychiatric inpatient settings evaluated, and what are considered to be the key outcome measures?
4) What health care professionals are involved in delivering psychological therapies for psychosis, and in which roles (e.g. sole therapist, group co-facilitator, clinical supervisor)?
5) How are psychological therapies for psychosis adapted for use within acute psychiatric inpatient settings?

2.3 Method

2.3.1 Search Strategy

A review protocol was written and registered in the public domain before searching and data extraction began (PROSPERO Registration: CRD 42015025623). The review team was as follows:-

Dr. Pamela Jacobsen, IOPPN, King's College London **(Primary reviewer)**
Dr. Kathleen Hodkinson, Webster University, Vienna **(Secondary reviewer)**
Professor Paul Chadwick, IoPPN, King's College London
Dr. Emmanuelle Peters, IoPPN, King's College London

We included only studies published in English, with no date restrictions on searches. Searches were initially run in September 2015, and updated in December 2016. We planned to include a wide range of different study types to address the main review question as to the current state of the evidence base. We anticipated that there would be relatively few eligible randomised controlled trials (RCTs), and the majority of studies would be small-scale, uncontrolled, non-randomised studies. Eligible studies therefore included:-

- Randomised Controlled Trials (RCT)
- Non-RCT study designs (e.g. uncontrolled studies, observational studies)
- Case studies
- Study protocols for future studies
- Reviews/meta-analyses
- Qualitative studies
- Book chapters
- Dissertations/theses
- Conference abstracts

Electronic databases PubMed and PsychINFO were used to search for peer-reviewed journal articles, and EThOS and ProQuest for theses or dissertations. Clinical Psychology Forum

(professional body publication of the British Psychological Society) was hand-searched. The Conference Proceedings Citation Index - Science (CPCI-S) was searched for conference abstracts. Trials were searched for on 3 different trial registries (ISRCTN registry; clinicaltrials.gov; Cochrane Central Register of Controlled Trials). Existing reviews in the area were searched for in the Cochrane Library. Finally, the Trip database (www.tripdatabase.com) and Open Gray database (www.opengray.eu) were searched for grey literature. We also checked the reference lists of eligible studies for further possible studies which had not already been identified. We contacted experts in the field to ask for information on any other potentially eligible studies. This was done by contacting the corresponding author on all relevant papers from the past 10 years.

Eligible studies were identified by the primary (PJ) and secondary (KH) reviewer. In the 1st stage, PJ independently screened all titles and abstracts identified from searches to determine which met the inclusion criteria. In the 2nd stage, PJ and KH both independently screened full text articles for inclusion or exclusion, with discrepancies resolved by discussion. For included studies, we linked multiple reports from the same study, so that each study (rather than each report) was the unit of interest in the review. The search strategy and search terms for each resource is outlined in Table 1.

2.3.2 Condition or domain being studied

Psychological therapies for psychotic symptoms within acute psychiatric inpatient care.

2.3.3 Definition of acute care

The recent Commission on Acute Adult Psychiatric Care provides a helpful definition of acute care (CAAPC, 2015):- '*Acute psychiatric inpatient services provide treatment and care in a safe and therapeutic setting for patients in the most acute and vulnerable stage of mental illness, and whose circumstances or acute care needs are such that they cannot, at that time, be treated and supported appropriately at home or in an alternative, less restrictive setting*.' In line with this definition, we defined acute psychiatric care as including triage/acute assessment wards, general acute wards and psychiatric intensive care units (PICU). Non-acute inpatient care settings were excluded (e.g. rehabilitation wards, specialist units,

residential therapy units). Non-inpatient acute services were also excluded (e.g. day hospitals, crisis/home treatment teams). There were some challenges in defining acute care for the purposes of this review, as care settings vary from country to country, and also over time within the same country. We therefore adopted a liberal definition of acute care, and erred on the side of being over-, rather than under-inclusive. In circumstances where the care setting was unclear, or did not easily fit into standard categories of inpatient care, we focused on assessing the eligibility of the intervention itself, and included interventions which seemed feasible to deliver within an average 30-day admission.

2.3.4 Participants/ population

Inclusion:

1) People experiencing an acute mental health crisis (defined by having been admitted to an acute psychiatric ward)
2) People taking part in a psychological therapy for psychosis regardless of their diagnosis (or whether they have received a psychiatric diagnosis)
3) Adults only (defined as receiving treatment on an adult ward)
4) Under a section of the Mental Health Act (MHA) or admitted informally

Exclusion:

1) People not experiencing an acute mental health crisis (defined as receiving care in settings other than an acute psychiatric ward)
2) Children or adolescents

2.3.5 Intervention

Any psychological intervention/therapy aimed at alleviating distress or impairment to functioning arising from psychotic symptoms (e.g. voices, delusions) or aimed at emotional difficulties commonly associated with psychotic symptoms (e.g. anxiety, depression). We included individual, family and group therapies, delivered by any health care professional, of any length, frequency or duration. We included CBT-based psychological therapies, broadly defined as a talking therapy based on an underlying theoretical model of the relationship between thoughts, emotions and behaviours. Third-wave cognitive therapies including mindfulness, acceptance and commitment therapy (ACT), meta-cognitive therapy (MCT),

dialectical-behavioural therapy (DBT) and compassion-focused therapy were included and classified as sub-types of CBT. Non-CBT based therapies such as psychodynamic therapy were also included. Cognitive-remediation therapy (CRT) was excluded on the basis that it is aimed primarily at remediating cognitive deficits rather than emotional difficulties associated with psychotic symptoms (likewise any intervention such as social skills training which is focussed solely on the remediation of functioning). We also excluded compliance therapy, any intervention focused primarily on improving psychiatric 'insight', staff-based interventions, therapeutic community or milieu therapy. Arts therapies including art, drama and movement therapy were also excluded. Any therapies started within the acute inpatient setting were included, whether or not the therapies continued post-discharge. Therapies initiated outside of acute inpatient settings were excluded (even if the therapy was continued during an inpatient admission for an individual).

2.3.6 Comparator(s)/ control

Studies with any, or no control conditions, were included. Possible control conditions included treatment as usual (TAU), waiting list control, plus other psychosocial interventions.

Table 1 Search Terms

Category	Database/resource searched	Search Terms	Stage 2 (Full Text Review)	Retained for inclusion in review
1. Electronic Databases Combination of searches with 3 concepts: - Concept 1 – PSYCHOTHERAPY (includes all sub-types of therapy) *AND* Concept 2 – SCHIZOPHRENIA (includes psychosis) *AND* Concept 3 – ACUTE/INPATIENT psychiatric setting	PsychINFO	Keyword searches: - • brief psychotherapy • hospital admission • psychiatric hospital admission • psychiatric hospitalization • psychiatric hospitals • psychiatric units • psychotherapy • schizophrenia (.tw.) qualifier used to search following terms in title and/or abstract:- • acute • hospita* • inpatient? • psychosis • psychotic • psychoses • schizo* • therap*	227	
	PubMed	((inpatient) AND psychosis) AND (psychotherapy OR therapy)	18	
Total (without duplicates)			241	69
2. Theses/Dissertations	EThOS	(any word)=psychosis OR schizophrenia AND (acute OR inpatient)		
	ProQuest			

Total (without duplicates)			3	2
3. Professional Body Publication	Clinical Psychology Forum	Hand-searched	1	1
4. Conference abstracts	Conference Proceedings Citation Index - Science (CPCI-S)	(Topic Heading=(psychosis OR psychotic OR schizo*) AND TS=(acute OR hospita* OR inpatient*) AND TS=therap*)	3	1
5. Trial Registries	ISRCTN registry	Condition=psychosis OR schizophrenia Inclusion criteria=inpatient OR acute Interventions=therapy OR behavioral		
	Clinicaltrials.gov			
	Cochrane Central Register of Controlled Trials			
Total (without duplicates)			10	8
6. Existing Reviews	Cochrane Library	TOPIC=mental health OR schizophrenia/psychosis AND therapy	7	0
7. Grey Literature	Trip Database	(Area of Clinical Practice = Medicine OR Psychology OR Psychiatry OR Mental Health) AND (Psychotherapy OR Psychological therapies) AND (Inpatient OR Hospital)	5	0
	Open Gray		0	0
8. Misc Sources			24	21
TOTAL			294	102
TOTAL (after linking records)				65

2.3.7 Data Extraction

A standard data extraction template was used to record relevant information from each included study (see Appendix 1). Data for each study was extracted by either PJ or KH, with each reviewer cross-checking each of the other reviewer's forms to ensure consistency and accuracy of data extraction. We assessed the quality of eligible studies using the Mixed Methods Appraisal Tool (MMAT; Pluye (2013)). The MMAT is designed to assess quantitative, qualitative and mixed methods studies using a single integrated tool which also incorporates criteria for assessing RCTs in line with the Cochrane criteria (Higgins *et al.*, 2011). Each study was assessed using the MMAT by either PJ or KH, then cross-checked by the other reviewer, with any discrepancies agreed by discussion to reach a consensus score. We did not conduct a meta-analysis due to the wide variety of outcome measures used by different studies and the small number of eligible RCTs which were anticipated. A narrative approach was taken in synthesising and describing the findings in line with the aims of the review.

2.4 **Results**

2.4.1 Search Results

As shown in Figure 3, we identified 65 studies for inclusion in the narrative synthesis. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in summarising the search results (Moher *et al.*, 2009). Fourteen of the 65 studies were linked to at least one other record (e.g. Drury et al (1996b) was published as 3 peer-reviewed journal articles as well as a PhD thesis). In this case, where at least one of the records was a peer-reviewed journal article, this was taken as the 'primary' reference. In the case of RCTs which often published acute-phase and follow-up data in separate journal articles, the paper which had been published first was designated as the primary paper. However, the data extraction form was completed using all relevant information across all linked studies. Overall, 58 out of the 65 studies had a peer-reviewed journal article designated as the primary paper. Of the remaining studies, 4 were published solely as book chapters, 1 was published as a PhD thesis and we could not find any subsequent published journal articles (Cholet, 1984) and the remaining 2 existed only as trial registry records. One of

these had not yet been published in a peer-reviewed journal because the trial was still on-going (Gaudiano, 2015), and the remaining reported results on the trial registry website but we could not find evidence of subsequent publication in a peer-reviewed journal (Boden, 2013) .

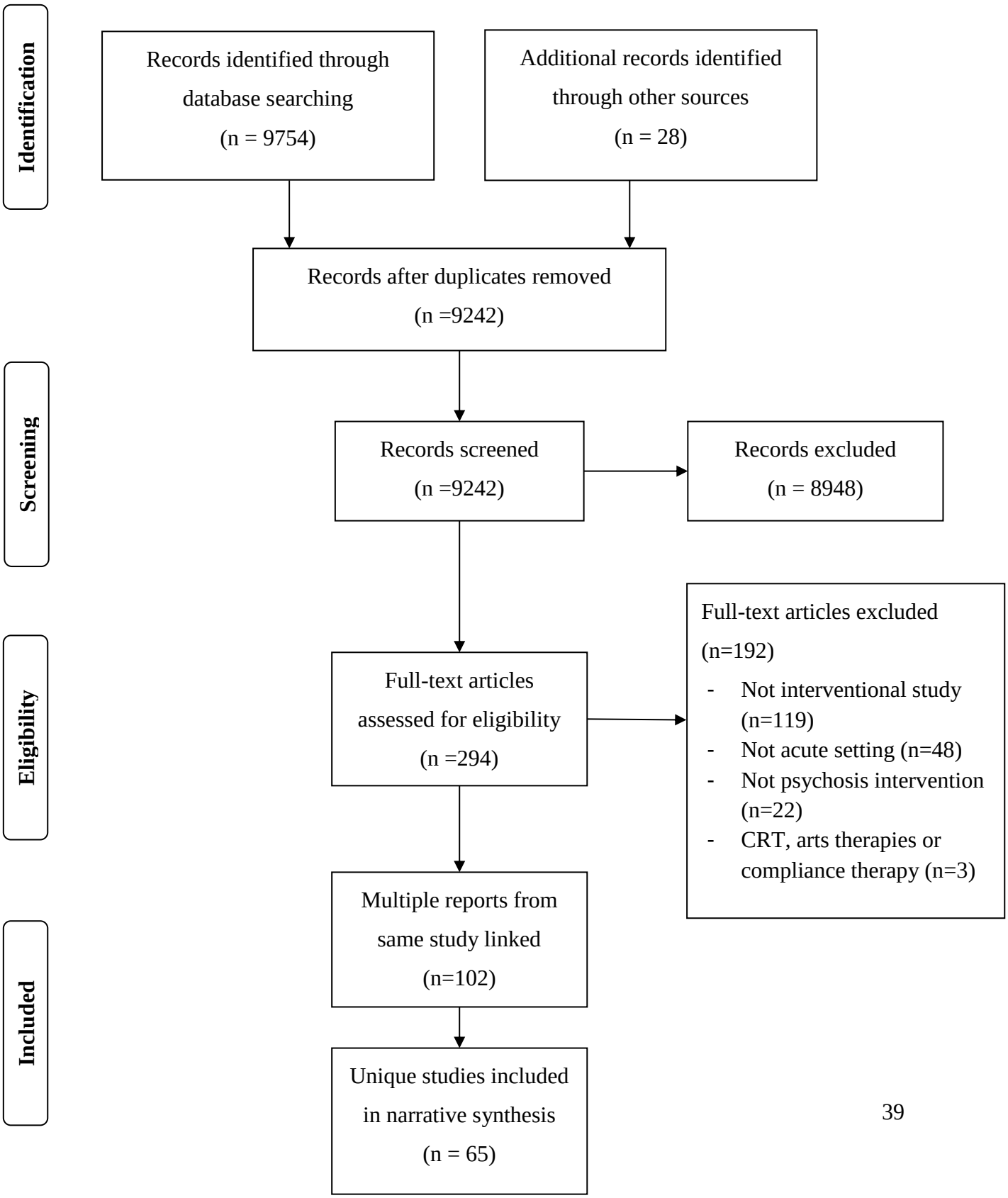


Figure 2 PRISMA Flowchart

2.4.2 Review Question 1: Current state of evidence base

The sixty-five studies included in the review are summarised in Table 2. The most common type of studies were RCTs (N=21), service evaluation projects (i.e. descriptions or evaluations of therapies offered within routine clinical practice, not requiring ethical approval; N=18) and non-randomised controlled trials (N=14). There were a minority of case series (N=5), single case studies (N=4) and studies reporting only qualitative data (N=3). Quality assessment using the MMAT involved two stages. The initial stage involved assessing each study according to two screening questions, which can be answered 'yes', 'no' or 'can't tell':-

- Are there clear qualitative and quantitative research questions (or objectives), or a clear mixed methods question (or objective)?
- Do the collected data address the research question (objective)? E.g. consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components)

The instructions for the MMAT state that further appraisal may not be feasible or appropriate when the answer is 'no' or 'can't tell' to one or both of the screening questions. Any studies which did not report any outcomes (whether quantitative or qualitative) automatically failed the screening, and could not be assessed further with the MMAT. Studies which did report some kind of outcome data, but failed both the screening questions were also not assessed further. For other studies which reported outcome data, and only failed 1 of the screening questions, we used our discretion as to whether we felt we could make a meaningful quality assessment with the MMAT. The second stage of the MMAT involves assessment under one of the following categories: -

1. Qualitative
2. Quantitative randomised controlled trials (RCTs)
3. Quantitative non-randomised
4. Quantitative descriptive
5. Mixed methods (studies are assessed under section 1, then either 2,3 or 4 depending on how the quantitative component of the study is best categorised).

Each category has 4 sub-items which are assessed in the same way as the screening questions (yes/no/can't tell). A summary score may be calculated by dividing the number of criteria definitely met (i.e. scored as a 'yes') divided by 4, and expressed as a percentage. Quality scores therefore ranged from 0%, 25%, 50%, 75% to 100%. For ease of interpretation, MMAT scores are colour-coded in Table 2, with low quality scores (0%-25%) in red, medium scores (50%) in orange and high scores (75%-100%) in green.

Table 2 Studies included in review (with quality assessment)

RANDOMISED CONTROLLED TRIALS (N=21)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Kanas et al. (1980)** n=86 USA	RCT[1] (JA)[2]	Non-CBT[3] (Psychodynamic)	Group	Yes	2. RCT	0%
2	**Beutler (1984)** n=176 USA	RCT (JA)	CBT	Group	Yes	2. RCT	25%
3	**Cholet (1984)** n=40 USA	RCT (Thesis)	Non-CBT (Humanistic-Existential)	Individual	Yes	2. RCT	50%
4	**Glick *et al.* (1985)** n=144 USA	RCT (JA)	CBT (Family Intervention)	Family	Yes	2. RCT	50%
5	**Youssef (1987)** n=30 USA	RCT (JA)	Non-CBT (Psychoeducation only)	Family	Yes	2. RCT	0%
6	**Drury *et al.* (1996a)** n=62 UK	RCT (JA)	CBT	Individual + Group + Family	Yes	2. RCT	0%
7	**Wahass and Kent (1997)** n=6 Saudi Arabia	RCT (JA)	CBT (Culturally adapted)	Individual	Yes – but failed MMAT screening stage		
8	**Haddock *et al.* (1999c)** n=21 UK	RCT (JA)	CBT	Individual	Yes	2. RCT	25%

[1] RCT=Randomised Controlled Trial
[2] JA=Journal article
[3] CBT=Cognitive-Behavioural Therapy

9	**Bach and Hayes (2002)** n=80 USA	RCT (JA)	CBT (Third-wave)	Individual	Yes	2. RCT	50%
10	**Lewis *et al.* (2002)** n=309 UK	RCT (JA)	CBT	Individual	Yes	2. RCT	100%
11	**Hall and Tarrier (2003)** n=25 UK	RCT (JA)	CBT	Individual	Yes	2. RCT	100%
12	**Bechdolf *et al.* (2004)** n=88 Germany	RCT (JA)	CBT	Group	Yes	2. RCT	100%
13	**Startup *et al.* (2004)** n=90 UK	RCT (JA)	CBT	Individual	Yes	2. RCT	25%
14	**Gaudiano and Herbert (2006)** n=40 USA	RCT (JA)	CBT (Third-wave)	Individual	Yes	2. RCT	50%
15	**Klingberg *et al.* (2010)** n=169 Germany	RCT (JA)	CBT	Individual + Group + Family	Yes	2. RCT	50%
16	**Moritz *et al.* (2011)** n=48 Germany	RCT (JA)	CBT	Individual + Group	Yes	2. RCT	100%
17	**Boden (2013)** n=18 USA	RCT (TR)[4]	CBT (Third-wave)	Individual	Yes	2. RCT	0%

[4] TR=Trial Registry

18	**Gaudiano (2015)** n=60 (target) USA	RCT (TR)	CBT (Third-wave)	Individual	No (trial protocol only)		
19	**Habib *et al.* (2015)** n=42 Pakistan	RCT (JA)	CBT (Culturally adapted)	Individual	Yes	2. RCT	50%
20	**Jacobsen *et al.* (2016)** n=60 (target) UK	RCT (JA)	CBT (Third-wave)	Individual	No (trial protocol only)		
21	**Tyrberg *et al.* (2016)** n=21 Sweden	RCT (JA)	CBT (Third-wave)	Individual	Yes	2. RCT	75%
NON-RANDOMISED CONTROLLED TRIALS (N=14)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Feifel and Schwartz (1953)** n=68 USA	Non-randomised CT[5] (JA)	Non-CBT (Psychodynamic)	Group	Yes	3. QNR[6]	50%
2	**Walker and Kelley (1960)** n=82 USA	Non-randomised CT (JA)	Non-CBT (Psychodynamic)	Individual	Yes	3. QNR	25%
3	**Bookhammer *et al.* (1966)** n=51 USA	Non-randomised CT (JA)	Non-CBT (Psychodynamic)	Unclear	Yes	3. QNR	0%
4	**Stern *et al.* (1972)** n=75 USA	Non-randomised CT (JA)	Non-CBT (Psychodynamic)	Individual	Yes	3. QNR	50%

[5] CT=Controlled Trial
[6] QNR=Quantitative Non-Randomised

5	**Gould *et al.* (1975)** n=17 USA	Non-randomised CT (JA)	Non-CBT (Psychodynamic)	Group	Yes	3. QNR	75%
6	**Serok and Zemet (1983)** n=31 Israel	Non-randomised CT (JA)	Non-CBT (Gestalt)	Group	Yes	3. QNR	75%
7	**Levene *et al.* (1989)** n=10 Canada	Non-randomised CT (JA)	Non-CBT (Family Therapy)	Family	Yes	3. QNR	25%
8	**Hodel *et al.* (1998)** n=19 Switzerland	Non-randomised CT (JA)	CBT (Emotional Management Therapy)	Individual	Yes	3. QNR	75%
9	**Hauff *et al.* (2002)** n=96 Norway	Non-randomised CT (JA)	Non-CBT (Psychodynamic)	Individual	Yes	3. QNR	50%
10	**Veltro *et al.* (2006)** n=502 Italy	Non-randomised CT (JA)	CBT	Group	Yes	3. QNR	0%
11	**Schmid and Wanderer (2007)** n=320 Switzerland	Non-randomised CT (JA)	Non-CBT (Phantasy therapy)	Group	Yes – but failed MMAT screening stage		
12	**Mortan *et al.* (2011)** n=12 Turkey	Non-randomised CT (JA)	CBT	Group	Yes	3. QNR	50%
13	**Owen *et al.* (2015a)** n=112 UK	Non-randomised CT (JA)	CBT (Third-wave)	Group	Yes	5. MM	50%
14	**Witkowska (2015)** n=60 Poland	Non-randomised CT (JA)	Non-CBT (Psychoeducation only)	Individual	Yes – but failed MMAT screening stage		

SERVICE EVALUATION (N=18)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Coffey (1954)** n=not stated USA	Service Evaluation (BC)[7]	Non-CBT (Psychodynamic)	Group	No		
2	**Goldberg *et al.* (1955)** n=not stated USA	Service Evaluation (JA)	Non-CBT (Psychodynamic)	Group	No		
3	**Canter (1956)** n=60 USA	Service Evaluation (JA)	Non-CBT (Psychodynamic)	Group	No		
4	**Chazan (1974)** n=not stated Israel	Service Evaluation (JA)	Non-CBT (Psychodynamic)	Family (Group)	No		
5	**Birckhead (1984)** n=not stated USA	Service Evaluation (JA)	Non-CBT (Psychodynamic)	Group	No		
6	**Cole and Greene ((1988)** n=20 USA	Service Evaluation (JA)	Non-CBT (Psychodynamic)	Group	Yes	4. QD[8]	0%
7	**Kelly *et al.* (1990)** n=not stated UK	Service Evaluation (JA)	Non-CBT (Supportive Counselling)	Group	No		
8	**Aviera (1996)** n=not stated USA	Service Evaluation (JA)	No clear therapy model	Group	No		

[7] BC= Book chapter
[8] QD= Quantitative Descriptive

CASE SERIES (N=5)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Boyd (1979)** n=3 USA	Case Series (JA)	Non-CBT (Psychodynamic)	Individual + Group	No		
2	**Cole (1993)** n=3 USA	Case Series (BC)	CBT (Family Intervention)	Family	No		
3	**Ahmed *et al.* (1997)** n=3 USA	Case Series (JA)	No clear therapy model	Individual	Yes – but failed MMAT screening stage		
4	**Kerr (2001)** n=4 UK	Case Series (JA)	Non-CBT (CAT)[9]	Individual	No		
5	**Freemantle and Clarke (2009)** n=2 UK	Case Series (BC)	CBT (Third-wave)	Individual	No		

[9] CAT= Cognitive-Analytical Therapy

SINGLE CASE STUDIES (N=4)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Dublin (1973)** n=1 USA	Case Study (JA)	Non-CBT (Gestalt)	Individual	No		
2	**Ginsburg (2000)** n=1 USA	Case Study (JA)	Non-CBT (Supportive Counselling)	Individual	No		
3	**Mansell and Fadden (2009)** n=1 UK	Case Study (BC)	CBT (Family Intervention)	Family	No		
4	**Cooper (2014)** n=1 UK	Case Study (JA)	Non-CBT (Psychodynamic)	Group	Yes – but failed MMAT screening stage		
QUALITATIVE ONLY (N=3)							
No.	**Author (year)** n=total no. of participants Country	**Study Design (Record type)**	**Therapy Model (Sub-type)**	**Mode of Delivery**	**Outcome Data Reported?**	**MMAT Section assessed under**	**MMAT score**
1	**Holma and Aaltonen (1997)** n=15 Finland	Qualitative (JA)	Non-CBT (Family Therapy)	Family	Qualitative data only	1. Qual	50%
2	**Gonzalez de Chavez *et al.* (2000)** n=32 Spain	Qualitative (JA)	Non-CBT (Psychodynamic)	Group	Qualitative data only	1. Qual	75%
3	**York (2007)** n=8 UK	Qualitative (JA)	CBT (Third-wave)	Group	Qualitative data only	1. Qual	75%

Overall, 40% of studies failed the initial MMAT screening stage (26/65). Of the remaining 60% which were assessed further, 21.5% were rated as high quality, 20% were medium quality and 18.5% were low-quality. We broadly categorised therapies into CBT, and non-CBT models, with sub-types of therapy noted where appropriate. Overall, we found there were slightly more CBT studies (N=35) than non-CBT therapies (N=28). We took a broad definition of therapy models, but even so were unable to categorise 2 studies into a recognisable therapy model (Dichos therapy (Aviera, 1996) & Computer-facilitated therapy (Ahmed *et al.*, 1997)). Among the CBT studies, there was a noticeable increase in so-called third wave cognitive therapies in recent years, with 12 studies categorised as either mindfulness, compassion-focused, or acceptance and commitment therapy (ACT). The majority of the non-CBT studies were psychodynamic (N=17). A clear difference emerged between countries in their dominant therapy models. For the UK studies, over 75% were CBT based (16/20). However, the reverse was true for the USA studies, with 62% of studies being non-CBT based (16/26). For other countries (which were predominantly European), CBT and non-CBT studies were more evenly balanced (11 CBT and 8 non-CBT). The first CBT studies did not emerge until the 1980s, but they represent the majority of studies included in the review published since 2000.

To provide a broad overview of the main findings of the studies in the review, relevant studies were identified according to four criteria. These were 1) the stated aim of the study was described as evaluating efficacy/effectiveness 2) the study reported at least one outcome measure 3) the study stated which was the primary outcome measure, where multiple outcomes were reported and 4) the study passed MMAT screening stage. Twelve studies in total met all these criteria and are summarised in Table 3, in chronological order from oldest to most recent. No exclusions were made based on study quality; the findings should therefore be interpreted with great caution, and in the context of the associated MMAT quality scores shown in Table 2.

Table 3 Summary of main findings (efficacy studies with primary outcomes only)

Author (year) Study Design **Country**	**Treatment** **n=no. of participants**	**Control condition(s)** **n=no. of participants**	**Primary Outcome Measure**	**Main Findings**
Bookhammer et al (1966) Non-randomised CT **USA**	Rosen's Direct Analysis n=14	Treatment as Usual (TAU) n=37	Binary outcome of improved/unimproved as rated by treating clinician at 5-year follow-up	No difference in rates of improvement between the Direct Analysis and TAU groups
Serok and Zemet (1983) Non-randomised CT **Israel**	Gestalt group therapy n=16	Treatment as usual (TAU) n=15	Neuropsychological reality perception test	Gestalt group showed evidence of improvement in perception of self and others
Beutler (1984) RCT **USA**	1) Behavioural/task (BT) 2) Expressive-experiential (EE) 3) Process-oriented (PO) Number of participants in each group not stated (Total n=176 including controls)	Treatment as usual (TAU)	Composite symptom measure (including symptom check-list, nurse assessment, and group facilitator ratings)	Compared to TAU control group: - 1) no change in BT group, 2) deterioration in EE group 3) improvement in PO group
Cholet (1984) RCT **USA**	Humanistic-existential (HE) psychotherapy n=20	Equivalent time as in treatment condition spent with college student n=20	Behavioural adjustment scale (staff rated)	No difference between groups on mood, co-operation or communication sub-scale but significant improvement on social contact scale in HE group compared to control
Cole and Greene (1988) Service Evaluation **USA**	Unstructured psychodynamic group n=20 (repeated measures design –all patients did both groups)	Structured occupational therapy group n=20 (repeated measures design –all patients did both groups)	Patient self-report of which group they preferred	Patients preferred the occupational therapy group to the psychodynamic group
Bach and Hayes (2002) RCT **USA**	Acceptance and Commitment Therapy (ACT) n=40	Enhanced Treatment as Usual (ETAU) n=40	Re-admission to hospital at 4-month post-discharge	Re-admission to hospital was significantly lower in the ACT group (20%) compared to the ETAU group (40%)

Hauff et al (2002) Non-randomised CT **Norway**	Specialist therapy ward with individual psychotherapy + psychodynamic milieu n=25	Standard care on acute ward n=71	Global mental health status at 7-year follow-up	No difference between outcomes for patients treated on the specialist therapy ward compared to the standard care ward
Lewis et al (2002) RCT **UK**	Cognitive-behaviour therapy (CBT) n=101	Supportive counselling n=106 Treatment as usual (TAU) n=102	Psychotic symptoms at 70-day follow-up	All patients improved significantly over time, with a trend to faster improvement in the CBT group
Startup et al (2004) RCT **UK**	Cognitive-behaviour therapy (CBT) n=47	Treatment as usual (TAU) n=43	Psychotic symptoms at 12-month follow-up	The CBT group showed significantly greater improvement compared to the TAU group
Veltro et al (2006) Non-randomised CT **Italy**	Cognitive-behaviour group therapy (CBT) as part of ward routine care n=352	Ward routine care before introduction of CBT programme (pre-post design) n=150	Total re-admissions up to 4-year follow-up	The re-admission rate was significantly lower in the 4 years following the introduction of CBT (24%) compared to the year before its introduction (38%)
Klingberg et al (2010) RCT **Germany**	Cognitive Behaviorally Oriented Service (CBOS) – individual, group and family sessions n=84	Individual supportive treatment – individual and group sessions based on practical and non-directive emotional support n=85	Mean time to relapse (defined by deterioration on psychotic symptom rating scale)	Mean time to relapse was significantly longer in the CBOS group (168 days) compared to the control group (157 days)
Moritz et al (2011) RCT **Germany**	Meta-Cognitive Therapy (MCT) n=24	Cogpak (computerised cognitive remediation therapy) n=24	Delusions severity at end of treatment	Significantly greater decline in delusion severity in the MCT group compared to control group

2.4.3 Review Question 2: Types of study design

As expected, a full range of study designs were included in the review, from single case studies to large-scale RCTs. RCTS were much more likely to describe CBT, rather than non-CBT interventions, and the converse was true for non-randomised controlled trials. Service evaluation, case series/studies and qualitative studies were more evenly matched between CBT and non-CBT models (Table 4).

Table 4 Study design by therapy model

	Therapy model			Total
	CBT	**Non-CBT**	**No clear therapy model**	
RCT	18	3	0	21
Non-randomised controlled trial	4	10	0	14
Service Evaluation	9	8	1	18
Case Series/Case study	3	5	1	9
Qualitative only	1	2	0	3
Total	35	28	2	65

Quality assessment scores were variable across different categories of study designs. For the RCTs (N=21), there was evidence of an improvement in quality over time, as all studies published pre-2000 were rated as low-medium quality (0-50%), but post-2000 included at least 5 studies rated as high quality (75-100%). This probably reflects improvements in trial reporting guidelines arising from the first publication of the CONSORT statement in the 1990s (Begg *et al.*, 1996), and its subsequent adoption by most major journals.

In addition to the MMAT, we also assessed RCTs using the Cochrane Risk of Bias. As can be seen from Table 5 and Figure 4, randomisation methods, allocation concealment and blinding were causes for concern. Only two of the RCTs clearly stated using the 'gold standard' of an independent randomisation service with randomly varying block sizes, with a large number of studies not specifying the randomisation method at all (N=10). A minority

of studies mentioned blinding of outcome assessors, and blinding of the inpatient and/or community teams potentially involved in treatment decisions. Size of trials was also a concern – out of the 19 RCTs with published results, over half (N=10) had fewer than 25 people in the treatment arm. Finally, most of the RCTs used TAU (or 'enhanced' TAU in the Gaudiano trials) as the control arm (N=11), and therefore did not control for non-specific therapy factors such as time and attention from a warm, empathic therapist. A minority of trials did use an active control arm. One of the largest trials had a strong design in this respect, and included both a supportive counselling and TAU condition, with over 100 participants in each arm (Lewis *et al.*, 2002).

Table 5 Risk of bias summary for RCTs only using Cochrane Tool

		Selection Bias		Performance Bias	Detection Bias	Attrition Bias	Reporting Bias	Other Bias
		Random sequence generation	**Allocation concealment**	**Blinding (participants and personnel)**	**Blinding of outcome assessment**	**Incomplete outcome data**	**Selective reporting**	
1	**Kanas et al.(1980)** USA							No ITT analysis
2	**Beutler (1984)** USA							No ITT analysis
3	**Cholet (1984)** USA							Unclear if ITT analysis Small N (N=20 in treatment arm)
4	**Glick *et al.* (1985)** USA							Unclear if ITT analysis
5	**Youssef (1987)** USA							No ITT Analysis Small N (N=15 in treatment arm)
6	**Drury *et al.* (1996a)** UK							No ITT analysis
7	**Wahass and Kent (1997)** Saudi Arabia							Small N (N=3 in treatment arm)
8	**Haddock *et al.* (1999c)** UK							Unclear if ITT analysis Small N (N=10 in treatment arm)
9	**Bach and Hayes (2002)** USA							No ITT analysis
10	**Lewis *et al.* (2002)** UK							None

11	Hall and Tarrier (2003) **UK**							**No ITT Analysis Small N (N=12 in treatment arm)**
12	**Bechdolf *et al.* (2004)** Germany							None
13	**Startup *et al.* (2004)** **UK**							None
14	**Gaudiano and Herbert (2006)** USA							Small N (N=19 in treatment arm)
15	**Klingberg *et al.* (2010)** Germany							Unclear if ITT analysis
16	**Moritz *et al.* (2011)** Germany							Small N (N=24 in treatment arm)
17	**Boden (2013)** USA							Unclear if ITT analysis Small N (N=12 in treatment arm)
18	**Gaudiano (2015)** USA	**NOT ASSESSED – TRIAL PROTOCOL ONLY**						
19	**Habib *et al.* (2015)** Pakistan							No ITT analysis Small N (N=21 in treatment arm)
20	**Jacobsen *et al.* (2016)** UK	**NOT ASSESSED – TRIAL PROTOCOL ONLY**						
21	**Tyrberg *et al.* (2016)** Sweden							Small N (N=11 in treatment arm)

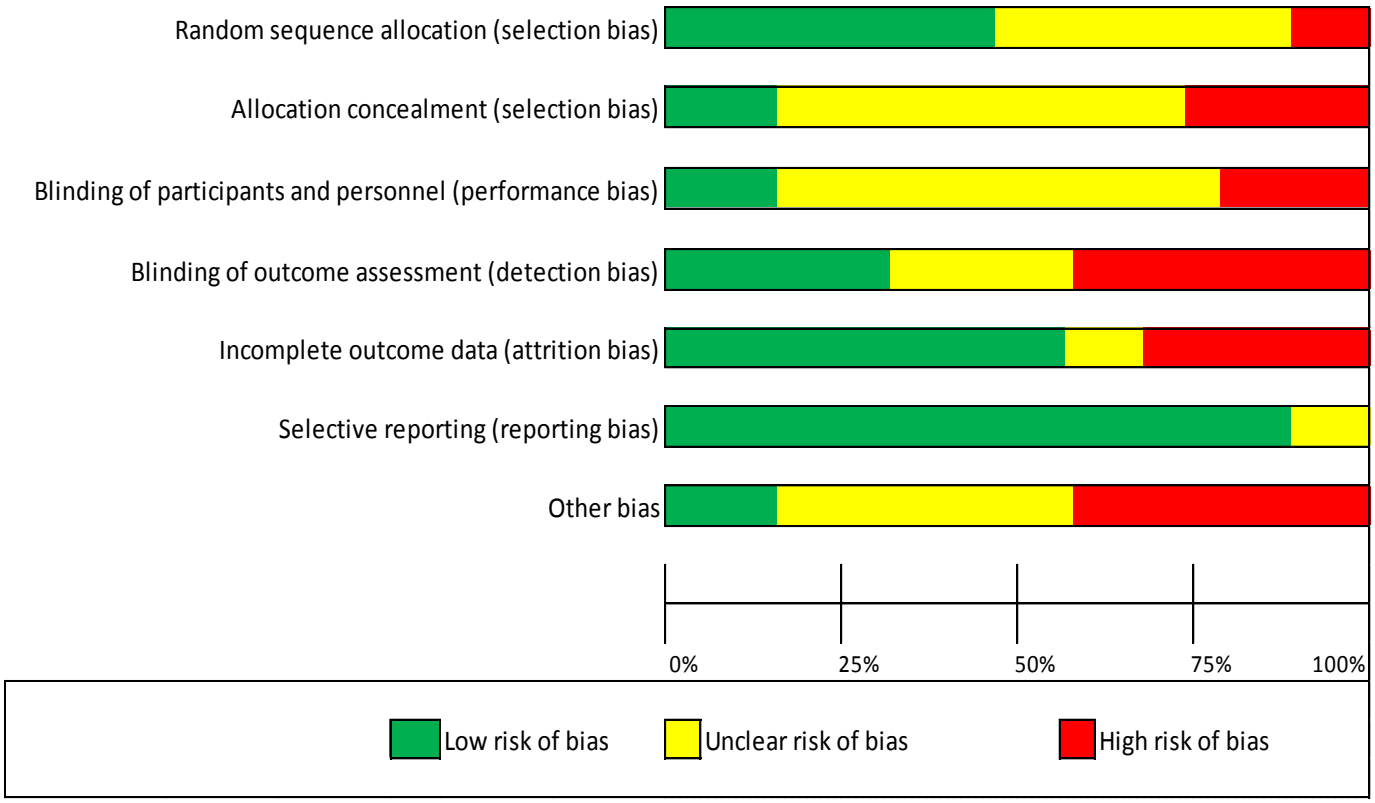


Figure 4 Risk of Bias Summary for RCTs

2.4.4 Review Question 3: Evaluation and Outcome measures

Most of the studies included in the review reported collecting some kind of outcome measure (N=48). We categorised the outcome measures used into 4 main categories (psychotic symptoms, affective symptoms, general/clinical functioning, and readmission/relapse). The results are summarised in Table 6. Where outcome measures were reported, these were usually focused on assessing psychotic symptoms and/or general functioning. There were relatively few studies that reported assessing affective symptoms, such as depression or anxiety. Only 3 of the 65 studies used self-report recovery measures. Even though they were not usually the primary outcome measure, many studies reported readmission/relapse data. The timing of outcome assessments was variable, and usually included a combination of different time points (e.g. baseline, discharge and 6-month follow-up). The assessment schedule was not specified in 2 studies. For the remaining 46 studies, 32 reported data at baseline, 12 reported outcomes session by session, 4 at mid-therapy and 26 at discharge/end of therapy. Twenty-one studies reported follow-up data beyond the end of therapy. The longest follow-up point was 6 months or less for 10 studies, and longer than 6 months for the remaining 11 studies.

Table 6 Summary of outcome measures

	INCLUDED?	
DOMAIN (No. of studies including each scale in parentheses) [10] N=48 studies (21 RCTs)	**Yes (RCTs only)**	**No (RCTs only)**
1) Psychotic symptoms - UNPUBLISHED SCALES (4) - PANSS (7) - PSYRATS (5) - BPRS (5) - PAS (2) - SAPS/SANS (2) - SAHI (1)	21 (16)	27 (5)
2) Affective symptoms - UNPUBLISHED SCALES (3) - BAI/BDI (2) - HADS (1) - DASS (1) - HDI (1)	7 (2)	41 (19)
3) General/Clinical Functioning - GAF (3) - HSRS (1) - GAS (3) - ADL (1) - CORE (34 OR 10 ITEM) (2) - CGI-S (1) - SFS (3) - NOISE (1) - OQ-45 (1)	14 (7)	34 (14)
4) Recovery - Self-rating of goals (1) - MHCS (2) - QPR (1)	3 (1)	45 (20)
5) Readmission Relapse (defined other than just readmission e.g. exacerbation in symptoms)	13 (10) 6 (4)	35 (11) 42(17)

[10] Some studies included more than 1 scale within the same domain

Key to abbreviations: PANSS=Positive and Negative Syndrome Scale (Kay *et al.*, 1987); PSYRATS= Psychotic Symptom Rating Scales (Haddock *et al.*, 1999a); BPRS=Brief Psychiatric Rating Scale (Overall and Gorham, 1962); PAS=Psychiatric Assessment Scale (Krawiecka *et al.*, 1977); SAPS=Scale for the Assessment of Positive Symptoms (Andreasen, 1984b); SANS=Scale for the Assessment of Negative Symptoms (Andreasen, 1984a); SAHI=Structured Auditory Hallucinations Interview (Kent and Wahass, 1996); BDI=Beck Depression Inventory (Beck *et al.*, 1996); BAI=Beck Anxiety Inventory (Beck and Steer, 1993); HADS=Hospital and Anxiety Depression Scale (Zigmond and Snaith, 1983); DASS=Depression, Anxiety & Stress Scales (Lovibond and Lovibond, 1995); HDI=Hamilton Depression Inventory (Reynolds and Kobak, 1995); GAF=Global Assessment of Functioning (APA, 1994); HSRS=Health Sickness Rating Scale (Luborsky and Bachrach, 1974); GAS=Global Assessment Scale (Endicott *et al.*, 1976); ADL=Activities of Daily Living; CORE=Clinical Outcomes in Routine Evaluation(Evans *et al.*, 2000); CGI-S=Clinical Global Impression Scale (NIMH, 1985); SFS=Social Functioning Scale (Birchwood *et al.*, 1990); NOISE=Nurses' Observation Scale for Inpatient Evaluation (Honigfeld and Klett, 1965); OQ-45=Outcome Questionnaire-45 (Lambert *et al.*, 1996); MHCS=Mental Health Confidence Scale (Carpinello *et al.*, 2000); QPR=Questionnaire about the Process of Recovery (Neil *et al.*, 2009)

2.4.5 Review Question 4: Delivery of therapies

The most common mode of delivery was group therapy (N=27), followed by individual therapy (N=19). There was a notable difference in the types of trial design between group and individual treatment modalities. The majority of the studies describing individual therapies were RCTs (12/19), compared to 3/27 of the group therapy studies.
As anticipated, a variety of staff groups were involved with delivering psychological therapies within inpatient settings, including psychologists, psychiatrists, nurses, occupational therapists, social workers, family therapists, CBT therapists and clinical trainees from different disciplines. It was notable however that almost a third of the studies included in the review failed to specify the professional group delivering the intervention. This limits the interpretation and replicability of such studies. The primary, or sole, therapist was described as a Clinical Psychologist in the majority of studies where the profession was specified (N=14).

Training, supervision and checks on treatment fidelity were generally poorly described or entirely absent. Over 50% of studies included in the review gave no details about training and supervision of therapists. For the 21 RCTs in the review, only a third of studies (N=7) clearly reported that the staff delivering the intervention were both trained and supervised. An additional third reported either staff training or supervision, but not both. The final third gave no details on either. The majority of RCTs gave no details on checking treatment fidelity. Only 8 studies reported fidelity checks – this was usually done by an independent rater reviewing a sample of audiotapes of therapy sessions (N=6), but the use of direct observation (N=1) and videotapes (N=1) was also reported.

2.4.6 Review Question 5: Adaptations to delivery within acute settings

After an initial review of the included studies, we identified and categorised studies according to 5 main adaptations. These were 1) increased frequency of sessions (≥2 sessions a week), 2) briefer interventions (≤5 sessions), 3) shorter sessions (<50 minute standard length of sessions), 4) use of single session format (i.e. each session is stand-alone, although therapy may include more than one session) and 5) continuing therapy post-discharge. The most common adaptation was an increased frequency of sessions. An increased frequency of sessions sometimes reflected an attempt to deliver a larger number of sessions within a shorter period of time to fit the typical length of an inpatient admission. Other studies aimed to deliver a smaller number of sessions, but still had an increased frequency of sessions to fit in with short lengths of admissions (Bach and Hayes, 2002, Gaudiano and Herbert, 2006). Only a quarter of studies reported briefer interventions (15/65), with 5 or fewer planned sessions. This is perhaps surprising given concerns that acute admissions are short, and so there is limited time to provide psychological therapies. However, the number of planned sessions, or the average number of sessions delivered per patient, was often not stated, and we were unable to extract this information for many studies. We found that the use of the standard therapy 'hour' (i.e. around 50 minutes) was in fact the most commonly reported length of session (41/65). Over a third of studies reported using a single-session format (24/65). This may be particularly helpful in settings when length of admission is unpredictable, and discharges may occur unexpectedly in the middle of treatment. Single-session formats may be particularly useful in groups, in meeting the needs of people who may attend only 1 session, but also in allowing people to flexibly 'drop in' over the course of an admission. In relation to group interventions, the use of single-session formats is of course closely linked to whether the group is open (people can join and leave at any session) or closed (people can join only at the beginning and are encouraged to stay for the full course). We found that open groups were the most common format reported (N=17), with only 2 studies explicitly reporting a closed group format (Cooper, 2014, Owen *et al.*, 2015a). It was not always clear whether group formats were open or closed. There was some reference to continuing therapy post-discharge in 13 studies. This was sometimes to allow people to complete a set number of sessions, for a group (Bechdolf *et al.*, 2004) or individual intervention (Bach and Hayes, 2002). Some studies offered booster sessions post-discharge, but take-up of these was generally low (Haddock *et al.*, 1999c, Lewis *et al.*, 2002).

2.5 Discussion

2.5.1 Summary of main findings

We conducted a systematic scoping review of psychological therapies for psychosis within acute inpatient settings. We found that there were a broad range of therapies in the published literature, delivered in many ways, by different groups of professionals, and evaluated using a wide range of approaches. This makes a coherent synthesis of current evidence challenging. For example, out of the 12 efficacy studies with well-defined primary outcome measures, no two of them in fact used the same outcome with the same end-point (Table 3). Quality was varied across different study types and over time, but we found significant methodological weaknesses in many studies, including in RCTs. Such a high degree of heterogeneity surely provides a challenge to any quantitative synthesis of findings by means of a meta-analysis. Reporting of diagnosis or symptom profile is also inconsistent in the literature – and indeed, in practice often there is no clear diagnosis for inpatients. For this reason, the present review took the pragmatic step of selecting studies on the basis of setting (acute inpatient) and type of psychological therapy (e.g. CBT for psychosis). We would recommend all future inpatient research on psychological therapy for psychosis report diagnostic information on participants where available, in addition to symptom profiles using established assessment tools.

Evaluating therapies within inpatient settings is undoubtedly challenging. It is not possible, or indeed ethical, to control or keep constant all other elements of treatment each person is receiving, such as medication, nursing care or occupational therapy. Attributing change, whether it be improvement or deterioration, to any single component of treatment is therefore not normally possible. There is also the problem of accounting for 'natural' recovery after a mental health crisis. The added value of any psychological intervention should therefore always be carefully assessed.

2.5.2 Outcome assessment

The present study focussed on patient outcomes – as opposed for example to change in ward milieu or in staff well-being. Direct patient outcomes can relate to well-being during admission (e.g. psychotic symptoms, length of admission), or after (e.g. subsequent relapse or readmission rates), or both. The studies reviewed included a wide range of primary and secondary outcomes and assessment tools, making it difficult to draw conclusions. The field may therefore benefit from the development of an agreed standardised set of outcomes, known as 'core outcome sets' (COS). A COS can be used as the minimum to be reported for any study or trial, and makes it easier to combine and compare the results of studies, over time, and from different countries. The urgent need for a COS in psychosis can be no better demonstrated than by the findings of a recent review of schizophrenia intervention trials (both drug and psychological therapy trials) which found 2194 different scales were used to measure outcomes, with every fifth study introducing a new rating instrument (Miyar and Adams, 2013). We would encourage development of COS for inpatient research that address core outcomes both during and post admission.

2.5.3 Therapy delivery

Only 3/27 evaluations of group therapies used an RCT design, which may reflect methodological challenges in evaluating inpatient groups – in-patient group therapies are normally open to everyone on a ward, for ethical and practical reasons, and there is also increased risk of treatment "contamination" between conditions on inpatient wards where patients are in close proximity. One potential solution is to use a cluster randomised design, where individual wards are randomised to a particular intervention, rather than individual patients, although there are often important differences between wards (e.g. catchment area, therapeutic milieu) and larger sample sizes are needed, which is often a barrier to conducting this kind of study in routine clinical practice (Torgerson, 2001).

2.5.4 Adapting therapy protocols for in-patient settings.

Most studies reported having adapted psychological therapy for delivery within inpatient settings. Commonly this meant offering traditional numbers of sessions but more frequently,

or offering fewer sessions, or developing a single-session format. We would recommend that future research describe more clearly the process of adapting therapies and protocols: for example, giving a clear rationale for the need to adapt a therapy; a clear rationale for the chosen adaptations; a clear statement about if and how the adaptations were piloted (e.g. a small case series); being clear about the degree of service user consultation and participation throughout the process. Furthermore, future research might examine, perhaps through mixed methods, the impact of the specific adaptations made.

2.5.5 Strengths and limitations

As this review was planned as a scoping review, we designed the strategy accordingly, and published our search strategy and review questions in advance on the PROSPERO database. A particular strength of this review is that we searched for literature from a wide variety of sources, including those not readily available (e.g. non-digitised book chapters, unpublished PhD theses). However, work not published in academic journals has not been subject to the same degree of peer review or scrutiny, and therefore should be interpreted with caution. We also attempted to search for studies underway as well as completed, by searching trial registries for planned or ongoing research, and by contacting experts in the field. However, despite increasing calls for all trials to be pre-registered on a public registry, compliance is still variable. Therefore, we cannot exclude the possibility that there is work underway that we would not have found from registry searches. There were some challenges in defining acute care for the purposes of this review, as care settings vary from country to country, and over time within the same country. We therefore adopted a liberal definition of acute care, and erred on the side of being over-, rather than under-inclusive. In circumstances where the care setting was unclear, or did not easily fit into standard categories of inpatient care, we focused on assessing the eligibility of the intervention itself, and included interventions which seemed feasible to deliver within an average 30-day admission. However, difficulties in defining key terms in the search strategy may have led to relevant studies being excluded, or less relevant studies being included in the final review.

2.5.6 Conclusions and implications for practice

A systematic approach is now clearly needed to develop the evidence base for inpatient psychological interventions, and to progress from promising pilot studies to larger, well-designed RCTs in line with guidelines for developing complex interventions (MRC, 2006). Qualitative research (including pre-trial assessment) also has a role to play, for example in optimising use of interventions within RCTs and in informing future choice of interventions (O'Cathain *et al.*, 2013). Core outcome sets are required to establish common, minimum outcomes both during and post admission, and the process of adapting therapies for in-patient settings needs greater methodological rigour and clarity.

2.6 Summary

The evidence base for inpatient interventions is mixed, and difficult to interpret in its totality. A minority of studies have specifically focused on evaluating impact on readmission/relapse. As reviewed in Chapter 1, the most promising intervention in this respect are brief, mindfulness-based interventions which are specifically crisis-focused, and have been successfully piloted in the US (Bach and Hayes, 2002, Gaudiano and Herbert, 2006). The next chapter will set out the development of mindfulness for psychosis, from its theoretical underpinnings, to the first feasibility trials to later RCTs and meta-analyses.

Chapter 3: Mindfulness for Psychosis

3.1 Overview

Mindfulness has a rapidly expanding evidence-based across a wide range of physical and mental health conditions, in addition to the promotion of well-being in the general population. Historically, there were concerns about whether meditation was safe for people experiencing psychotic symptoms, despite little hard evidence to support such concerns. Chadwick developed a theoretical model of mindfulness for psychosis, which proposed that people are often caught up in a pattern of reacting to psychotic symptoms that perpetuates distress. This is characterised by experiential avoidance, judgement, and struggling or fighting against experiences when they enter awareness. A mindfulness response style is an alternative way of relating to experiences, which involves deliberately turning towards difficulty, acceptance of what is present in the moment, and letting experiences come and go in their own time without reactive engagement. This model of mindfulness for psychosis is consistent with studies linking avoidance-based coping strategies to increased distress associated with psychotic symptoms. Meditation practises in mindfulness for psychosis are adapted by making them shorter in length, providing more frequent guidance (including reference to the psychotic experience), and using concrete, everyday language in the guidance. Early pilot trials by Chadwick and colleagues confirmed that these adapted mindfulness practises were safe and acceptable to service users, and there was no indication of any harmful effects. There is now increasing interest in the effectiveness of mindfulness for psychosis, including the recent publication of several meta-analyses and systematic reviews. However, the number of trials in the area remains low, and the quality of such trials is variable. There are no published controlled trials of mindfulness for psychosis within UK inpatient settings.

3.2 Development of mindfulness for psychosis

3.2.1 Theoretical model

The popularity of mindfulness-based interventions has grown exponentially over recent years. Studies have proliferated in mindfulness for both physical (Carlson, 2012, Gotink *et al.*, 2015) and mental health conditions (Strauss *et al.*, 2014), and for promoting general well-being in healthy populations (Khoury *et al.*, 2015). Mindfulness could be considered as having reached the mainstream of NHS provision when Mindfulness-Based Cognitive Therapy (MBCT) was recommended in clinical guidelines to reduce risk of depressive relapse for the first time in 2009 (guideline updated (2016)).

However, there are historical concerns about using mediation techniques with people experiencing current psychotic symptoms, or who might be vulnerable to developing them. For example, as far back as the 1970s, a pilot study reported positive benefits of mindfulness meditation with people with mood symptoms including depression and anxiety but cautioned against their use in with people experiencing "*hallucinations, delusions, thinking disorders, and severe withdrawal*" - (p.331, Deatherage (1975). Subsequent case studies have reported people, both with and without a previous history of psychosis, experiencing psychotic or manic episodes associated with meditation (Kuijpers *et al.*, 2007, Sethi and Bhargava, 2003, Walsh and Roche, 1979, Yorston, 2001). However, the precipitating events to these episodes are often described as particularly intensive bouts of meditation (of varying schools of meditation), usually in the context of a retreat. None of the meditation practises described would be typical of a mindfulness-based intervention; and additional complex factors associated with retreats such as the effects of sleep deprivation and food restriction were likely to have played a significant role (Shonin *et al.*, 2014, Walsh and Roche, 1979). Ongoing concerns additionally arise from a misunderstanding of the intentions or practice of mindfulness. There is often a misguided idea that somehow encouraging people to focus on voices or difficult thoughts could make things worse, or even that due to the cognitive difficulties that people with psychosis sometimes also experience, they are simply unable to concentrate or to direct the focus of their attention in any way (Lavin, 2015). This is of course not the case. Mindfulness is not about inducing or creating any kind of internal experience, whether that is a paranoid thought, voice, emotion or bodily sensation. In a

mindfulness practice, the intention is to simply turn towards whatever is already present, and developing an alternative response style to constant avoidance or struggle.

Despite the scant evidence on harm, and growing evidence of benefit across a wide range of mental health conditions, Chadwick's model of mindfulness for psychosis was still a radical development in the field when it was first published (Chadwick *et al.*, 2005). Chadwick noted that the aim of conventional CBTp was to alleviate distress associated with psychotic symptoms, rather than to attempt to directly eliminate the symptoms themselves. Mindfulness based approaches are therefore theoretically consistent with this approach, in that they aim to alleviate distress and suffering, through modification of the relationship we have with our internal experiences, rather than changing the form or content of the experiences themselves. Chadwick further noted that people with distressing psychosis often struggle to cope with distressing voices or beliefs, and frequently get trapped in cycles of either trying to avoid their experiences or getting lost in battling against them. Mindfulness offers an alternative way of being with psychotic experiences; bringing non-judgemental awareness, acceptance of the present moment and the letting go of struggling or fighting against experiences (Figure 5).

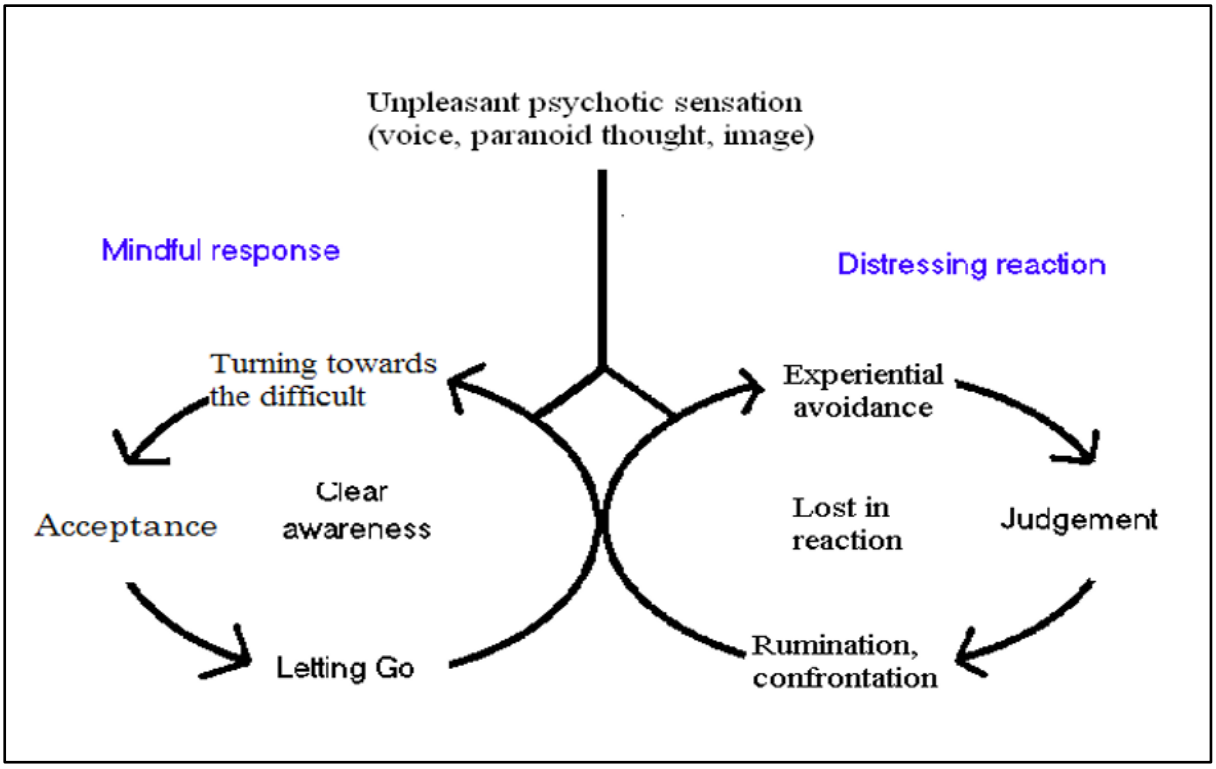


Figure 5 Theoretical model of Mindfulness for psychosis; Chadwick (2005)

As with other cognitive therapies, the basis for mindfulness for psychosis is an idiosyncratic formulation, developed collaboratively between therapist and client, which explicitly identifies processes that maintain distress. It is important to normalise wanting to block out or avoid our difficult experiences at times; or at the other end of the spectrum, to get caught up in struggling or fighting against them. For example, a study of 40 people with chronic voices found that the most common cognitive coping strategies they reported was trying to block voices out, telling them to go away, or trying to debate with them (Falloon and Talbot, 1981). However, a sole reliance on these response styles can often perpetuate distress and disruption to everyday activities as they are usually ineffective over the longer-term (Howard *et al.*, 2013, Johns *et al.*, 2002, Rassin and van der Heiden, 2007). The rationale for a mindfulness-based intervention is therefore to help people develop an alternative way of relating to their experiences, which involves deliberately turning towards the difficult, practising acceptance of what is present just in the moment, and letting experiences come and go in their own time.

Experiential avoidance is therefore a key process that is targeted in mindfulness for psychosis. Experiential avoidance (EA) is defined as occurring when a person is unwilling to remain in contact with internal events or sensations, and takes steps to alter the form or frequency of those events and the context in which they arise (Hayes *et al.*, 2011). So for example, someone may use drugs or alcohol to block voices out, or use cognitive strategies to suppress their thoughts as outlined above. Self-initiated coping strategies are commonly reported for people who hear voices, in both clinical and non-clinical populations (Farhall *et al.*, 2007). However, people who report coping poorly with their voices are more likely to use avoidance-based, distraction techniques, and to feel less in control of their voices compared to people who cope well with voices (Romme and Escher, 1989). Consistent with Chadwick's model, a cross-sectional study of 50 people who heard voices found that people who scored highly on a measure of EA (Acceptance and Action Questionnaire-II (AAQ-II); Bond *et al.* (2011)) were more likely to report behavioural and emotional attempts to resist voices (Morris *et al.*, 2014). Similarly, Varese *et al.* (2016) surveyed 101 clinical voice-hearers and found that EA was associated with high levels of voice-related distress, but was not related to voice frequency or duration. Not only is EA linked to less effective coping strategies and increased distress in relation to voices, there is also evidence it plays a mediating role in the relationship between life hassles and delusional distress. Goldstone *et al.* (2011) did a questionnaire survey comparing a non-clinical (n=133) and clinical

(schizophrenia diagnosis; n=100) sample of people, and measured life hassles (Survey of Recent Life Experiences; (Kohn and Macdonald, 1992), delusional ideas (Peters Delusions Inventory (PDI); Peters *et al.* (2004)) , and EA (AAQ-II). They found that both life hassles and EA were significantly correlated with both overall delusion score on the PDI, as well as the distress sub-scale, and the relationship was strongest between EA and delusional distress. They went on to perform a mediation analysis and found that EA mediated the relationship between life hassles and delusions, and delusional distress, in both the clinical and non-clinical group. The authors concluded that *"the findings suggest that individual (irrespective of their diagnostic status) with a tendency to suppress or avoid unwanted thoughts are significantly more likely to experience distressing delusions in response to stressful life occurrences"* - p.260. The findings should be interpreted with caution because the study was cross-sectional, and we therefore cannot infer the direction of causality. In order to overcome some of the limitations of cross-sectional data, Udachina *et al.* (2014) later conducted an experience sampling method (ESM) study, which is a structured diary technique. They recruited people experiencing paranoia in the context of a schizophrenia-spectrum diagnosis (n=41) who were asked to rate paranoia, self-esteem and EA, 10 times a day over 6 consecutive days. They found that EA partially mediated the relationship between low self-esteem and paranoia. The authors suggest this would be consistent with a model in which "*persecutory delusions arise as a result of dysfunctional attempts to avoid unpleasant thoughts about the self*" – p.442. They further found that EA was also independently associated with low self-esteem, and this was more pronounced at times when participants reported feeling under stress related to their daily activities. Both these cross-sectional (Goldstone *et al.*, 2011) and contextual data (Udachina *et al.*, 2014) would therefore be consistent with a model of crisis in which people who used EA to cope at times of stress might be more likely to experience a subsequent exacerbation of psychotic symptoms.

3.2.2 Adaptations in mindfulness for psychosis

Crane and colleagues recently wrote a timely paper on what defines mindfulness-based programs (Crane *et al.*, 2016). The paper discusses the importance of understanding the commonalities between different mindfulness based approaches, as well as the specific adaptations required for different populations, or settings. They use an inventive visual metaphor for this, of the warp thread and the weft threat on a weaving loom. The warp

thread is a fixed thread which runs vertically through the cloth, whereas the weft is the transverse thread which makes every tapestry unique. They propose that if something is defined as a mindfulness-based therapy, it should contain certain commonalities with other approaches (the warp thread), whilst also being explicit about what makes the intervention unique (weft thread).

Warp threads for Mindfulness-Based Interventions (Crane *et al.*, 2016)

1. **Is informed by theories and practices that draw from a confluence of contemplative traditions, science, and the major disciplines of medicine, psychology and education.**
2. **Is underpinned by a model of human experience which addresses the causes of human distress and the pathways to relieving it**
3. **Develops a new relationship with experience characterized by present moment focus, decentering and an approach orientation**
4. **Supports the development of greater attentional, emotional and behavioural self-regulation, as well as positive qualities such as compassion, wisdom, equanimity**
5. **Engages the participant in a sustained intensive training in mindfulness meditation practice, in an experiential inquiry-based learning process and in exercises to develop insight and understanding**

As outlined in the previous section, all these central 'warp threads' are present within mindfulness for psychosis. It is based on a well-defined psychological model, and this includes proposed mechanisms for what causes and maintains human distress and suffering. The aim of the intervention is not to get rid of symptoms, or eliminate any kind of internal experiences, but rather to help people come into a new relationship with their experience. This is done by developing skills in self-regulation of attention, emotions and behaviours and cultivating attitudinal qualities of kindness, compassion and curiosity when turning towards the difficult. The approach is based in experiential-learning, and involves an iterative process between meditation practice and teacher-led enquiry.

So what of the weft - what are the particular components that make mindfulness for psychosis unique, and suited to the needs of people with distressing psychotic experiences? Whilst

emphasising that mindfulness meditation can be appropriate for people with psychosis, Chadwick and colleagues have also been keen to acknowledge the particular challenges this population may face. People may be experiencing intense symptoms such as distressing voices or paranoid thoughts, and people's concentration levels and attentional flexibility may further be affected by cognitive difficulties and the sedating effects of psychiatric medication. Chadwick *et al.* (2005) therefore recommend the following: -

- Limit meditation practices to 10 minutes
- Avoid prolonged silences, and provide frequent anchors in the guidance
- Use concrete, everyday language in guidance
- Give prior permission for the person to stop the practice at any time if needed

For example, a typical 10-minute mindfulness practice may begin with grounding in the body through a brief body scan, beginning in the soles of the feet. The invitation is to just tune into whatever bodily sensations are present, with no sense of a right or wrong way to be feeling, and taking up a decentred stance of awareness, letting sensations come and go in their own time. The entire practice can be guided as 'choiceless awareness', meaning people are encouraged to notice and accept whatever is coming up in awareness, moment by moment; whether this is a thought, voice, or emotion, and letting things come and go in their own time. The level of concentration or focus in the practice can also be adjusted as necessary for the individual or group. For example, the breath can be introduced as an anchor for the awareness, so inviting people to come to an awareness of the bodily sensations of breathing, whether this is at the nostrils, in the chest or down in the stomach. If appropriate, guidance can also be offered on working with mind-wandering, so simply noticing when the mind has wandered away from the breath, whether to voices, thoughts or images in the mind, and to gently disengage from struggling or fighting with experience, and to come back to the sensations of breathing in the body as a way of re-connecting with the present moment. As for any mindfulness of the breath practice, it is emphasised that the intention is not to force the attention to stay on the breath, and not to view mind-wandering as any kind of failure, or getting it wrong in some way. Mind-wandering is emphasised as a normal and healthy part of having a human mind, but what is being cultivated is a greater awareness of noticing when the mind has wandered, and what it has wandered away to. Overtime, this can lead to greater awareness and familiarity with the habits of the mind; for example, when a critical voice

arises in awareness, noticing if there is a tendency to get caught up in pushing the voice away or getting caught up in struggling against it.

3.2.3 Early pilot trials of mindfulness for psychosis

The first published study of mindfulness for psychosis was an uncontrolled pilot trial published by Chadwick *et al.* (2005). They delivered mindfulness for psychosis in a group consisting of 6 sessions, with a maximum group size of 6 people. Each group session included 2 x 10-minute mindfulness of the breath meditation, followed by facilitator-led inquiry and group discussion. All participants had been experiencing distressing psychosis for at least 2 years (including voices and paranoia), and were current users of secondary mental health services. Fifteen people completed one of 4 groups, and outcome data were available from 10 people. The main outcome used was a general measure of clinical functioning (Clinical Outcomes in Routine Evaluation (CORE); Evans *et al.* (2000)). The results showed a significant improvement on the CORE from pre-post group, and there were no adverse effects arising from the meditation practises.

Given these encouraging results, Chadwick and colleagues (2009) went on to conduct a randomised controlled trial. People were eligible for the trial if they had been experiencing distressing voices for at least 6 months, and were receiving treatment for a psychotic disorder from secondary mental health services. Twenty-two people were randomised into the study (n=11 allocated to mindfulness group intervention, n=11 allocated to wait-list control). Most of the participants experienced distressing paranoid thoughts in addition to voices, all were taking anti-psychotic medication, and the mean duration of illness was 17 years. It is therefore important to note that this was a group of people with complex, chronic difficulties who were generally representative of people receiving care within secondary services (Chadwick, 2014). The intervention consisted of twice-weekly group sessions for 5 weeks plus home practice, followed by 5 further weeks of home practice. Home practice was not formally measured, but all participants reported at least some home practice during the group intervention, which they then maintained in the following weeks. The primary outcome measure was again the CORE, and a mindfulness measure, validated for use in psychosis, was additionally included as a process measure (Southampton Mindfulness Questionnaire (SMQ); Chadwick *et al.* (2008). Measures were taken at baseline, and at post-treatment (10

weeks). Data were available on 18 participants, and the primary analysis showed no significant difference between the intervention and control group on the CORE. A secondary analysis of all group completers (n=15) indicated significant pre-post improvements on both the CORE and mindfulness of thoughts and images (Southampton Mindfulness Questionnaire; SMQ).

Chadwick and colleagues later expanded this work into an intervention for distressing voices called Group Person Based Cognitive Therapy (PBCT), which integrates CBTp and mindfulness. The therapy included mindfulness practice, guided discovery and behavioural experiments. Data from nine pilot groups indicated a positive benefit for 50 voice-hearers who completed pre- and post measures of well-being, distress, control and dependence upon the voice (Dannahy *et al.*, 2011). This led on to a larger randomised controlled trial of 108 participants who had been hearing voices for at least a year (Chadwick *et al.*, 2016). Participants were randomly allocated to received either PBCT in addition to treatment as usual (TAU) (n=54), or TAU only (n=54). The intervention consisted of 12 weekly 90-minute sessions of group PBCT. There was no significant difference at post-treatment (4 months post-randomisation) between the PBCT and TAU groups on the primary outcome measure of general psychological distress (CORE). However, they did find evidence of a significant benefit in the PBCT group for depression (HADS; (Zigmond and Snaith, 1983) and intensity of distress associated with voices (PSYRATS; (Haddock *et al.*, 1999b). This benefit was only maintained for depression at follow-up (10 months post-randomisation). There was more than 20% loss to follow-up at the 10 months time-point however, so this latter finding should be interpreted with caution.

Overall, these trials have focused on the acceptability, safety and feasibility of the approach. This is a vital first step in any treatment development, particular in an area as contentious and controversial as using meditation techniques in psychosis. There are some methodological limitations to these trials, which could be addressed in further trials. For example, rather than using TAU alone as the control condition, an active control could be used to better match for non-specific therapy factors such as the general benefits of attending a supportive group for several weeks. The findings also indicate that the most appropriate primary outcome measure for future trials is likely to be a more symptom-specific measure (i.e. distress associated with

voices/delusions) rather than a general measure of well-being or clinical functioning such as the CORE.

3.2.4 Qualitative studies of service user experiences of mindfulness for psychosis

In addition to clinical outcome measures, another important source of information from mindfulness for psychosis trials is qualitative data, arising from a study of people's experiences within the group. An exploration of the phenomenology of people's experiences in undertaking a mindfulness intervention has much to contribute to our understanding of the processes involved, and whether this is consistent with the underlying theoretical model. With the aim of investigating the psychological processes involved, Abba *et al.* (2008) conducted interviews (both in groups, and individually) with 16 people who had completed at least 4 sessions of a mindfulness group (as outlined in Chadwick *et al.* (2005)). Interviews were conducted using a semi-structured interview schedule, and were audio-taped and transcribed verbatim. They were analysed using grounded theory (Glaser and Strauss, 1967), with emergent themes grouped into categories of increasing abstraction, which were then hierarchically organised resulting in the creation of higher-order categories (Figure 6).

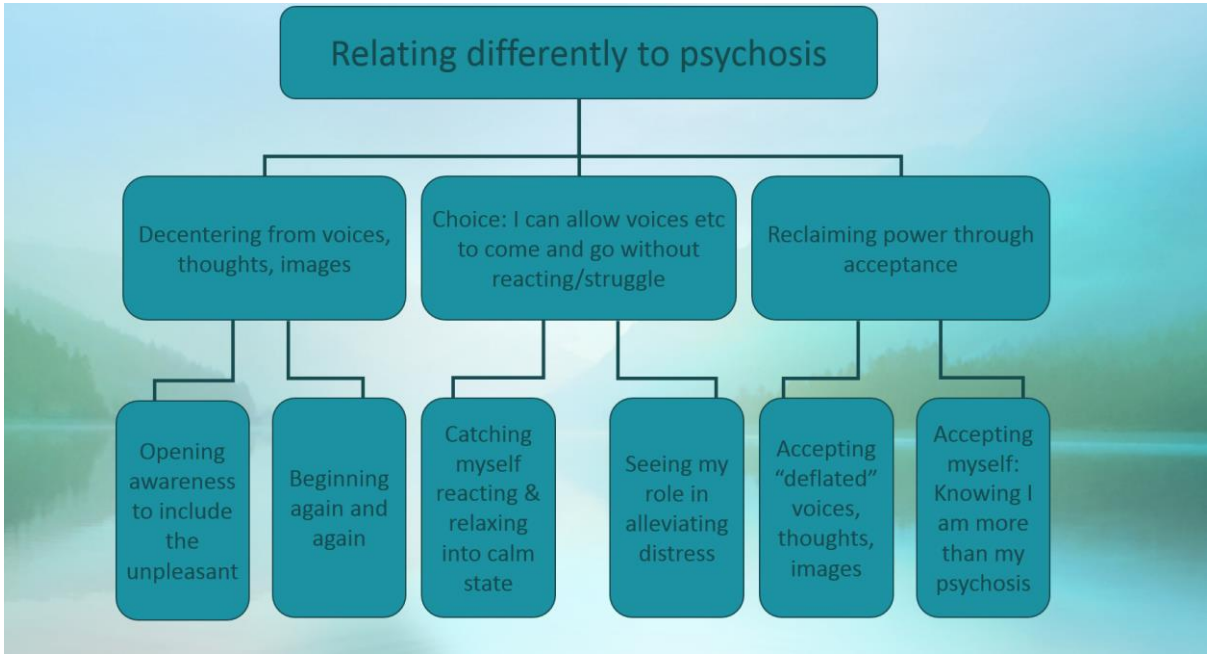


Figure 6 Grounded theory model of mindfulness for psychosis (Abba et al., 2008)

The core theme was identified as "relating differently to psychosis", with three sub-themes describing the key processes involved. The first describes the process of decentering, and opening towards experience, even when it is unpleasant or unwanted. The second describes a

realisation that there is a choice available in responding to voices, thoughts or images, and avoiding or struggling against them are not the only possibilities. Finally, this wider choice of responses provides a vital opportunity to reclaim power through acceptance of psychotic symptoms, and building a "sense of self" independent of psychotic symptoms. The authors noted that the findings fitted well not only with Chadwick's model of mindfulness for psychosis (Figure 5), but also with the broader literature on how people without psychosis describe learning mindfulness skills (e.g. Allen *et al.* (2009)). However, they did note the particular importance of reclaiming power for people with psychosis, given people often feel bullied or denigrated by voices and other perceived persecutors, and this sense of subordination and marginalisation is often mirrored in their other social relationships (Birchwood *et al.*, 2000).

Other qualitative studies of mindfulness for psychosis have been conducted within community, inpatient and early intervention settings and are summarised in Table 7. All the studies produce slightly different resulting themes, given the different methods and clinical samples used. However, there is an interesting convergence in the results. Participants describe the process of deliberately turning towards difficulty, and in doing so, coming to a powerful realisation that they can make an active choice in how to respond to their experiences, on a moment-by-moment basis, and this leads to a greater acceptance of themselves, and a sense of identity which is no longer dominated by psychosis.

> *"It's like, being mindful wipes the fog from your glasses, you know, on a steamy day or something, you know, on a rainy day"*
>
> - Participant quoted in Dennick *et al.* (2013)

Table 7 Qualitative studies of participants' experiences of taking part in a mindfulness for psychosis group

Authors	Setting	Intervention	Participants	Qualitative method	Key themes
York (2007)	Acute inpatient	Weekly open group, 60mins duration, included mindfulness of the breath, & walking meditation	n=8 (attended at least 2 sessions) Mixed diagnostic group (including psychosis)	Thematic analysis	1) Cognitive changes 2) Concentration 3) Sense of peace/relaxation 4) Acceptance 5) Exposure to problems 6) Awareness 7) Self-management 8) After discharge 9) Negative experiences & misunderstandings 10) Medication
Ashcroft *et al.* (2012)	Early intervention for psychosis service (EIP)	Weekly rolling group, 60 mins duration, format followed Chadwick (2005)	n=9 (attended at least 6 sessions, commenced at least 20 weeks ago)	Grounded theory	1) Using mindfulness 2) Making sense and coping 3) Relating to people differently 4) Understanding and accepting myself
Dennick *et al.* (2013)	Community (day centre)	Weekly group for 6 sessions, 90 mins duration, format followed Chadwick (2005)	n=3 (attended all 6 sessions) all were experiencing distressing psychotic symptoms (voices)	Interpretative Phenomenological Analysis (IPA)	1) Experiencing distress 2) Group as beneficial 3) Mindfulness as beneficial 4) Mindfulness groups as part of the process of recovery

3.2.5 Meta-analyses and systematic reviews

Since the early pilot trials, there has been significant interest in the efficacy of mindfulness as a treatment for psychosis. This is reflected in the large number of reviews and meta-analyses of mindfulness for psychosis, which have proliferated over recent years (Table 8). These include meta-analyses (Cramer *et al.*, 2016, Khoury *et al.*, 2013, Louise *et al.*, 2017), systematic reviews (Aust and Bradshaw, 2017, Lam and Chien, 2016, Strauss *et al.*, 2015) and a narrative review (Shonin *et al.*, 2014). A closer look at the first meta-analysis by Khoury *et al.* (2013) reveals the state of the evidence base and the challenges inherent in trying to produce a coherent synthesis of the data. One considerable source of heterogeneity in this review was the type of mindfulness intervention used. Interventions included Acceptance and Commitment Therapy (ACT; (Bach and Hayes, 2002, Gaudiano and Herbert, 2006, Shawyer *et al.*, 2012, White *et al.*, 2011), Compassionate Mind Training (CMT; (Laithwaite *et al.*, 2009), Person Based Cognitive Therapy (PBCT; (Dannahy *et al.*, 2011), loving-kindness meditation (Johnson *et al.*, 2011) and mindfulness-based psychoeducation (Chien and Lee, 2013). There was also variation in the therapeutic target within each sub-type of therapy. For example, the ACT studies were variously focused on reducing risk of hospital readmission for acute inpatients (Bach and Hayes, 2002, Gaudiano and Herbert, 2006), treating post-psychosis depression (White *et al.*, 2011) and reducing compliance with harmful command hallucinations (Shawyer *et al.*, 2012). In terms of the quality of the studies, only 7/13 studies were RCTs, with the remainder reporting only pre-post outcomes for the intervention group. There was wide variation in the primary outcome measures used, which included general clinical functioning, psychotic symptoms, mood symptoms and hospital re-admission. It is perhaps not surprising that I^2 (a measure of heterogeneity) was above 75% for the end of treatment effect across all studies, which would be categorised as a high degree of heterogeneity (Higgins *et al.*, 2003). Indeed, the later review by Lam and Chien (2016) explicitly stated they did not perform a meta-analysis on the studies they found, due to the wide variation in study designs, interventions and outcome measures.

Table 8 Reviews of mindfulness for psychosis studies

Author	Type of review	Inclusion criteria	Number of studies (no. of participants)	Quality assessment	Conclusions
Khoury *et al.* (2013)	Meta-analysis	Any study reporting outcome data (symptoms and/or psychosocial functioning)	**13 (n=468)** 7 RCTs 6 uncontrolled trials	A composite quality scale was devised (average score was 5/10). 4 studies included blinded assessments. Only 1 RCT had an active control group.	Mindfulness moderately effective in pre-post studies (smaller effect sizes in controlled studies)
Shonin *et al.* (2014)	Narrative	Any mindfulness study reporting quantitative or qualitative data (ACT excluded as mindfulness considered only component of treatment)	**11 (n=221)** 3 RCTs 3 uncontrolled trials 1 case series 4 qualitative	No formal quality assessment	Mindfulness appears to have a beneficial role, but data not yet sufficient to demonstrate clear treatment effects for psychosis
Strauss *et al.* (2015)	Systematic review	Mindfulness for people who hear voices (either treatment studies or cross-sectional studies of mindfulness constructs)	**15 (n=479)** 3 RCTs 2 uncontrolled studies 1 case study 4 qualitative 5 cross-sectional	No formal quality assessment	Mindfulness is acceptable and safe, but there are no adequately powered RCTs to provide sufficient data on efficacy
Lam and Chien (2016)	Systematic review	RCTs of mindfulness (ACT excluded as mindfulness considered only component of treatment)	**6 (n=407)**	Cochrane Risk of Bias Tool. Most studies had high risk of bias for selection, performance and detection bias due to unclear description of randomisation procedures and non-blinded assessors	Insufficient evidence to demonstrate promising effects based on existing studies
Cramer *et al.* (2016)	Meta-analysis	RCTs of mindfulness or acceptance-based therapy	**8 (n=434)**	Cochrane Risk of Bias Tool. 6 RCTs had low risk of bias, 2 had high risk. Only 3	No serious adverse events reported. Mindfulness and acceptance-based

				studies used ITT analysis.	treatments can be recommended in psychosis in addition to standard care
Louise *et al.* (2017)	Meta-analysis	RCTs, including mindfulness, acceptance and compassion-based interventions	**10 (n=572)**	Clinical Trial Assessment Measure (CTAM). Four studies rated as high risk of bias (score <65)	Overall findings indicate that mindfulness and acceptance-based therapies show beneficial effects on symptoms in psychosis
Aust and Bradshaw (2017)	Systematic review	RCTs, including mindfulness, acceptance and compassion-based interventions	**11 (n=549)**	Clinical Trial Assessment Measure (CTAM). Three studies rated as high risk of bias (score <65)	Mindfulness is safe and appears to have therapeutic benefits. Larger trials are now needed.

Given that the number of studies included in these reviews ranges from only 6-15, the evidence base is still sparse, and it is always problematic when the number of reviews begins to outpace the number of primary research studies. The number of RCTs included in the first published meta-analysis was 7 (Khoury *et al.*, 2013), and this only increased to 10 in the latest meta-analysis (Louise *et al.*, 2017). The strongest conclusion to be drawn from the state of the evidence base so far is that more randomised controlled trials need to be conducted, particularly with the inclusion of active control arms, rather than just TAU or wait-list control. Only 2 of the RCTs used an active control (befriending) to account for non-specific therapy factors (Shawyer *et al.*, 2012, Shawyer *et al.*, 2016). There are no RCTs of mindfulness for psychosis within UK inpatient settings in the published literature. The 2 ACT for psychosis studies from the US ((Bach and Hayes, 2002, Gaudiano and Herbert, 2006) have been replicated in a small-scale feasibility study in Sweden (n=22; Tyrberg *et al.* (2016)), however this later study was not included in either the Louise *et al.* (2017) or Aust and Bradshaw (2017) reviews. Accounting for significant levels of heterogeneity remains a challenge; future reviews may have to be more specific about the type of interventions included, the clinical setting and the patient population. Although the reviews summarised in Table 8 do vary in terms of whether they included just RCTs, or included other study designs as well, and whether they considered acceptance and compassion-focused studies eligible, a

clear pattern does appear to emerge. Mindfulness for psychosis is feasible, acceptable and safe. However, as for establishing clear treatment effects, there is more work to be done.

3.3 Summary and objectives of study

Mindfulness for psychosis is based on a clearly defined theory of how experiential avoidance perpetuates distress associated with psychotic symptoms. The first uncontrolled of trial of mindfulness for psychosis was published over 10 years ago. Pilot randomised trials in several different countries followed, which established mindfulness for psychosis as a safe and acceptable intervention. The evidence base is still in an early stage of development in terms of establishing efficacy. A major challenge to interpreting the current evidence base arises from the wide range of interventions, clinical settings, and outcome measures used. The role of mindfulness for psychosis in reducing risk of readmission for people admitted to hospital with acute distressing symptoms warrants further study, given promising results from pilot trials conducted in the US.

In line with the MRC guidelines for developing and evaluating complex interventions (updated (2006)), the focus of this preliminary trial was on establishing feasibility. This includes gathering data relevant to testing procedures, estimating recruitment/retention and determining sample size. The primary objective of this study was therefore to find out whether it is possible to carry out this kind of trial successfully within inpatient settings and to find out whether patients and staff find it an acceptable intervention. The secondary objective was to collect pilot data on clinical outcome measures. The trial protocol is set out in Chapter 4, and the statistical and data management plan in Chapter 5.

Chapter 4: Method

4.1 Overview

This chapter gives an overview of the method for the study. The trial protocol was written using a standard template provided by King's Clinical Trials Unit, which conforms to the SPIRIT 2013 Statement recommendations for clinical trial protocols (Chan *et al.*, 2013). In line with good practice guidelines (MHRA, 2012), the trial was pre-registered prior to the start of recruitment on the ISRCTN registry (DOI 10.1186/ISRCTN37625384). The trial protocol was also published in *Pilot and Feasibility Trials*, a peer-reviewed open-access journal (Appendix 2).

The trial design was a single-centre, parallel-groups, feasibility randomised controlled trial. Consecutive new admissions to acute wards at the Maudsley Hospital were screened for eligibility over the recruitment period. A full screening log of all admissions was kept, including recording the reasons for any patients not entering the trial. Eligible patients were randomly allocated to receive either the intervention or control treatment, both of which consisted of between 1-5 sessions of intervention, all within the duration of the inpatient admission. Participants completed self-report measures at baseline, post-therapy and 3- and 6-month post-discharge follow-up. Outcome measures included service use data, collected by clinical note review and blind-rated, and clinical measures from self-report questionnaires.

4.2 Trial identifiers

Title of Trial: Mindfulness-Based Crisis Interventions (MBCI) for psychosis within acute inpatient psychiatric settings; A feasibility randomised controlled trial
Trial Acronym: BrIef Talking therapies ON wards (amBITION study)
ISRCTN: 376253384
REC Number: 15/LO/1338
UKCRN Number: 19490
Lead Sponsor: King's College London
Co-Sponsor: South London and Maudsley NHS Foundation Trust

4.3 Primary and secondary objectives

The primary objective of the study was to find out whether it is possible to carry out this kind of trial successfully within inpatient settings and to find out whether patients and staff find it an acceptable intervention. The secondary objective was to collect pilot data on service use and clinical outcomes.

4.4 Study design and timeline

This study was a single-centre, parallel-groups, feasibility randomised controlled trial. Trial procedures and the assessment schedule are shown in the study plan (Figure 7). End of therapy was defined as EITHER i) completing 5 sessions of therapy OR ii) discharge from acute ward, whichever came first. Post-therapy measures were taken either at i) discharge OR ii) 5 weeks post-randomisation, whichever occurred first. The first follow-up occurred 3 months (90 days) after discharge, and the second follow-up occurred 6 months (180 days) after discharge. The end of the study for each participant was when the 6-month follow-up was completed. The 3-month mid-point follow-up was included to minimise missing data arising from loss to follow-up, and to provide more detailed information on symptom change in the short-term after discharge.

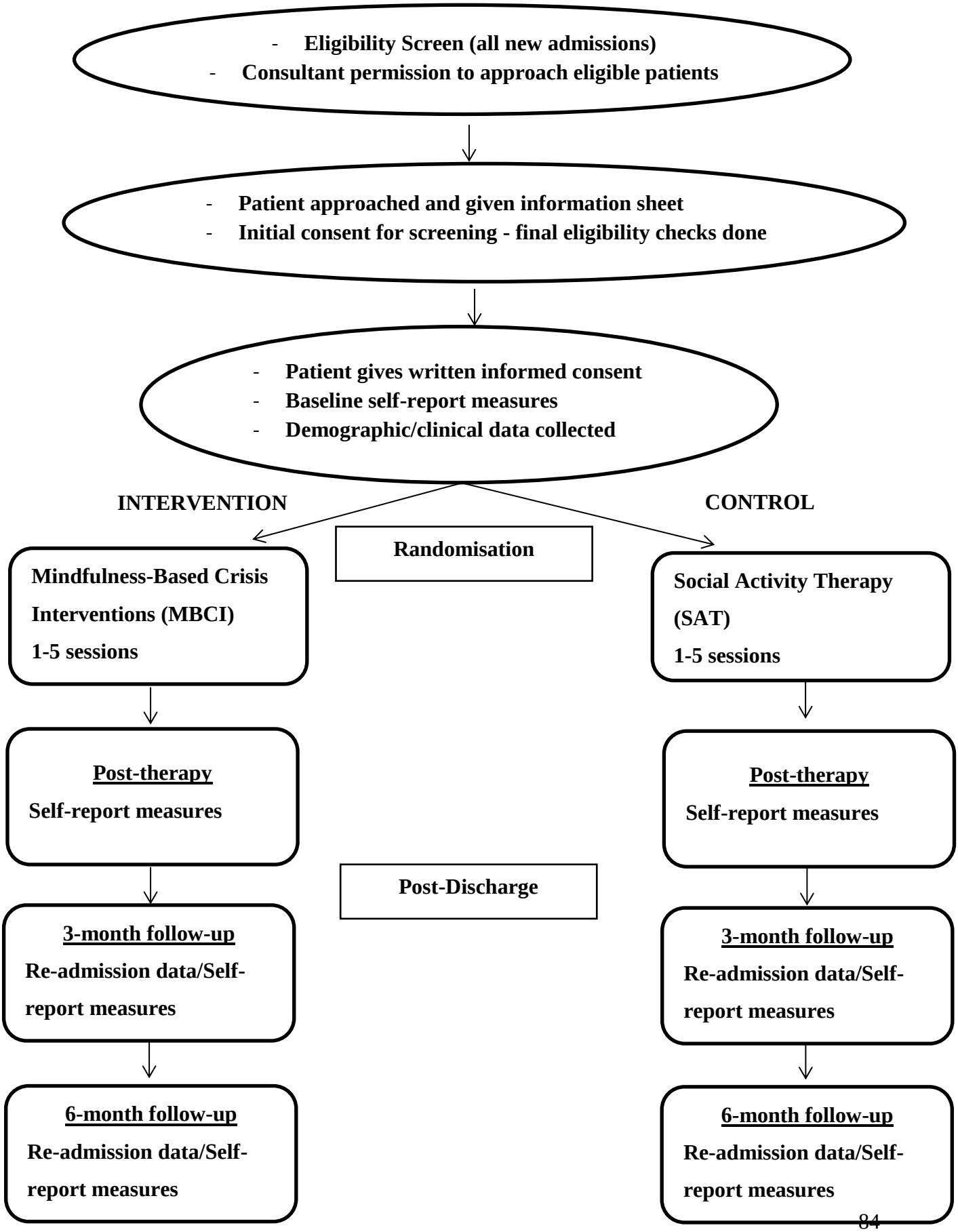


Figure 3 Study Plan

4.5 Ethical approval

Ethical approval for the study was given by the London -Camberwell St Giles Research Ethics Committee (REC reference number: 15/LO/1338). See Trial Master File for confirmation of favourable opinion letter (dated 29/09/15).

4.6 Participants

4.6.1 Inclusion/Exclusion Criteria

Inclusion Criteria

i) Aged 18 or above

ii) Current psychiatric inpatient on a working-age adult ward

iii) Diagnosis of schizophrenia-spectrum disorder or psychotic symptoms in the context of an affective disorder (ICD-10 codes F20-39; (WHO, 2010)

iv) Reports at least one current positive psychotic symptom (scores >1 on frequency on self-report symptom scale)

v) Able to give informed consent to participate in trial, as assessed by consultant psychiatrist/responsible clinician and researcher

vi) Willing and able to engage in psychological therapy

Exclusion Criteria

i) established diagnosis of learning disability, or major cognitive impairment arising from any underlying medical condition (e.g. head injury, neurological disorder) resulting in significant functional impairment

ii) unable to engage in a talking therapy in English, or to complete simple written questionnaires in English

iii) primary diagnosis of substance misuse

v) lacks capacity to consent to participation in research trial

vi) unable to take part in individual therapy due to risk of aggression/violence

vii) mental state precludes possibility of engaging in a talking therapy, e.g. significant thought disorder, as assessed by clinical team and researcher

4.6.2 Recruitment, randomisation and blinding

Participants were recruited from 4 acute inpatient psychiatric wards at the Maudsley Hospital. All consecutive new admissions were screened for eligibility by consultation with the inpatient care team. The initial screening criteria were patients presenting with positive psychotic symptoms in the context of a psychosis or mood disorder. Potentially eligible patients were then approached to take part with permission of their inpatient Consultant Psychiatrist and the nurse in charge of the shift, if it was agreed that they were deemed to have capacity to consent to take part in research, and there was no risk to the researcher in approaching the person. Patients could take part in the trial if they were admitted under a section of the Mental Health Act (MHA) so long as they were deemed to have retained capacity to consent to participation in research. The researcher asked patients for permission to speak to them about the research (with any refusals at this stage recorded on the screening log), and provided them with a copy of the brief information sheet to introduce them to the main aims of the study. Further eligibility screening by reference to electronic clinical notes was conducted with written consent from patients who had been approached and were potentially interested in participating. Once the researcher had confirmed the patient's eligibility, they approached the patient again to give them a copy of the full patient information sheet and to talk it over with them and explain the study further. If for any reason the patient was found to be not eligible, for example they did not self-report any psychotic symptoms on interview with the researcher, or they had an ineligible diagnosis, then the reason was explained to them, and was recorded on the screening log. Eligible patients were given at least until the next day to read over the full information sheet, think it over, ask questions and to discuss their participation with anyone they may wish to (e.g. primary nurse or family member). Screening and recruitment was overseen by PJ who completed all the screening logs. Patients on the wards were approached either by PJ herself, a Clinical Studies Officer (CSO) from the local Clinical Research Network (CRN), or a psychologist on a short-term CRN secondment.

After giving informed consent, eligible participants completed baseline measures. They were then randomised using an online computerised service at the Kings Clinical Trials Unit (KCTU). Block randomisation was used, with randomly varying block sizes to ensure allocation concealment. The randomisation sequence was not stratified. Each participant

was randomised at the beginning of their first therapy session, using a laptop computer, and participants were shown the process on-screen. This was done for 2 reasons. Firstly, it kept the time between randomisation and the beginning of the intervention to a minimum, which reduced the risk of participants being randomised into the trial, but not receiving any intervention. This is a particularly pertinent issue within acute settings, where unpredictable discharges occur frequently. Secondly, it made the randomisation process as transparent and open as possible, with the intention of increasing participants' sense of trust in the process and mitigating against the possibility of any concerns arising from the randomisation process.

As with all psychological therapy trials, both the therapist and participant were aware of the treatment condition they were randomised to. However, the 2 therapies were referred to by neutral labels in all participant and staff literature (therapy 1 vs. therapy 2) with the aim of promoting equal treatment credibility between the conditions. The participant's inpatient and community care team were however blinded to treatment allocation, as far as could be achieved with conservative measures. This included not referring to any content of the therapy sessions in clinical notes or standard trial letters, and conducting all therapy sessions in a private room on the ward. Key members of the inpatient and community team (e.g. inpatient and community consultant psychiatrist, care co-ordinator, psychologist/therapist) and GP were notified of the patient's participation in the trial at i) randomisation and ii) end of intervention. They were informed of how many sessions were attended, and any goals arising from the intervention that the participant was happy to be shared. Participants were not explicitly advised against sharing any details of their therapy or treatment allocation with other staff. This was done to assess what, if any, were the major threats to blinding of inpatient and community teams that might occur, so these could be mitigated against in the planning of any future trials. The service use data, which included relapse and re-admission assessed at 6-month follow-up, were blind rated by an appropriately trained researcher who was not otherwise involved in the trial. Clinical outcome measures were all self-report, rather than clinician-rated, to reduce the risk of assessor bias – though risk of demand characteristics of course remains. All questionnaire measures were collected by PJ.

4.6.3 Withdrawal of Participants

Participants had the right to withdraw from the study at any time for any reason. It was decided in advance, and documented in the trial protocol, that the researcher may also withdraw any participants who i) lose capacity to consent ii) no longer wish to take part in therapy iii) their mental state deteriorates to the extent they can no longer engage with therapy or iv) there is a risk of harm to self or others arising from their participation in therapy. All reasons for withdrawal were recorded. The trial protocol stipulated that participants who wished to withdraw from the study, or who were withdrawn by the researcher, would be asked to confirm whether they were still willing to provide clinical self-report measures at follow-up, and qualitative feedback at the end of the trial. Data on relapse/readmission for people who dropped-out were gathered from the clinical note system as normal, as this did not require any further contact with the participant. This was made clear on the participant information sheet and the consent form.

4.7 Description of therapies

Therapy sessions in both conditions were delivered on an individual basis in a private room on the inpatient wards. PJ was the trial therapist in both conditions. PJ is a Clinical Psychologist registered with the UK Health & Care Professions Council (HCPC) with expertise in cognitive behavioural therapy for psychosis (CBTp) and mindfulness interventions as well as experience of working in acute settings. Therapy sessions in both conditions ranged from 1-5 sessions, depending on variables such as length of admission, with the frequency of sessions adjusted as needed between a minimum of weekly and maximum of daily. All sessions followed a stand-alone, self-contained format, to accommodate unpredictable lengths of stay and unexpected discharges. The treatment phase was restricted to the duration of the inpatient admission. However, treatment did continue if a participant was transferred from one acute ward to another (as can frequently happen due to bed shortages and other factors).

All participants in the trial continued to receive treatment as usual (TAU) both during their inpatient admission and post-discharge. In theory, this could have included medication, attendance at activity and/or therapy groups, individual therapy sessions and family therapy

sessions. Information relating to TAU was recorded on each participant's Case Report Form (CRF).

4.7.1 Mindfulness-Based Crisis Interventions (MBCI) – Experimental Intervention

MBCI was developed in line with the ACT trials conducted in the US and the model of mindfulness for psychosis proposed by Chadwick (Chadwick, 2006a). The treatment protocol for the current trial was adapted for use within an acute crisis setting, following Bach and Hayes (2002) and Gaudiano and Herbert (2006). The full therapy manual developed for the trial is included in the Trial Master File. In brief, each session included 3 key components to be included in each session, with varying amounts of emphasis placed on each component depending on the session number and the stage of therapy. These were: -

i. **Developing mindfulness skills (guided practice)**
ii. **Making sense of crisis using mindfulness model**
iii. **Identifying values and setting goals**

The guided practice was always done at the beginning of each session. The first session focused primarily on the development of a crisis-focused formulation, using a standard template, which formed the basis of a shared understanding of what brought the person into hospital on this occasion. This formulation then informed any future sessions, focusing on key processes that had been identified in the run-up to the crisis, such as experiential avoidance. The therapist also worked with the participant to identify their values (e.g. family, work, health, society), and discuss specific behavioural goals consistent with these values. Participants were then helped to set a small, achievable goal for homework at the end of each session that could be reviewed at the beginning of next session, where possible. In preparation for discharge, longer-term goals were also identified (e.g. starting a college course) and were shared with the community care team at the end of therapy in the end of therapy letter, to act as a bridge to carrying on the recovery process in the community.

4.7.2 Social Activity Therapy (SAT) – Control Intervention

The control condition was taken from the PICASSO trial of CBTp for people with psychosis and a history of violence, which was conducted partly on inpatient wards (Haddock *et al.*, 2009). SAT involved working collaboratively with the participant to identify activities they enjoyed and which they could engage in during and between sessions as they wished (e.g. board games, puzzles). The aim was to provide a supportive environment with a therapist using non-specific aspects of therapy (e.g. collaboration, feedback, empathy). The aim was to keep the sessions activity focussed, and to be supportive, collaborative and empathic without employing any therapy techniques specific to any model of therapy, including CBTp or mindfulness-based therapies.

4.7.3 Treatment Fidelity

All participants were asked their permission to audio-tape sessions for the purposes of clinical supervision and fidelity checks. The proportion of people who agreed was recorded, as this is important data for assessing the feasibility of audio-recording as the primary method of fidelity checking for future trials. Participants were offered copies of the recordings if they so wished. A sample of therapy sessions was randomly selected for fidelity checking by an experienced clinician, who was blind to treatment allocation, and had not been otherwise involved in the trial. Fidelity checks were completed using the adherence and competency scale developed for the trial (see Trial Master File). In brief, this comprised 4 sub-scales: -

A: Non-specific Cognitive Therapy Scale (essential to MBCI & SAT)

From Cognitive Therapy Scale for Psychosis (CTS-PSY; Haddock *et al.* (2001))

1) Agenda
2) Feedback
3) Understanding
4) Interpersonal Effectiveness
5) Collaboration
6) Homework

B: MBCI-specific Therapy Scale (unique to MBCI)

Following Chadwick (2006b)

1) Making sense of crisis using mindfulness model
2) Developing mindfulness skills
3) Identifying values and committed action

C: SAT-specific Therapy Scale (unique to SAT)

From PICASSO study (Haddock *et al.*, 2009)

1) Within-session activities
2) Response to emotion distress

D: CBT for psychosis Therapy Scale (proscribed for both MBCI & SAT)

From Revised Cognitive Therapy for Psychosis Adherence Scale (R-CTPAS; Rollinson *et al.* (2008))

1) Columbo style
2) Evidence for delusional beliefs
3) Verbal challenge of delusions
4) Validity testing
5) Schemas

Within each sub-scale, each key component was rated for adherence (0=absent, 1=present), and then where relevant, further assessed on a 6-point competence scale (0=poor, 3=satisfactory, 6=excellent). To maintain a high-level of treatment fidelity over the course of the trial, PJ received regular supervision from an independent clinical supervisor with expertise in acute care, and mindfulness-based approaches. Clinical supervision included the use of audio recordings from therapy sessions and presentation of case formulations.

4.8 Outcome measures

4.8.1 Primary objective – Feasibility/acceptability data

1) Number of eligible participants identified over study period
2) Total numbers recruited into trial and recruitment rate (benchmark of 80% of target)
3) Proportion of participants who dropped out during the intervention stage
4) Range and average number of sessions completed (including number of sessions attended as a proportion of those offered)
5) Reasons for participants dropping out during the intervention stage
6) Number lost to follow-up and reasons (benchmark of less than 20% to be set in line with previous studies)
7) Any unexpected adverse effects of participating in the trial

4.8.2 Qualitative data on acceptability

1) Participant feedback on trial procedures, randomisation, credibility of two therapies
2) Staff feedback on trial procedures, recruitment strategies, blinding procedures

At the end of the study, all participants were asked for some brief feedback on a questionnaire that was completed with PJ at their 6-month follow-up (see Trial Master File for topic guide). They were also asked if they would be willing to give additional feedback around the same topics, via either a follow-up interview or focus group, which would be conducted by one of the service user researchers working on the trial. All service user researchers were part of the advisory group for the trial, and were recruited from the Trust Involvement Register, and had appropriate training. Staff from the in-patient units where patients were recruited were also invited to give feedback on the trial via an individual interview or focus group. Staff interviews were conducted by two assistant psychologists who had not otherwise been involved in the trial. The assistant psychologists were working for the Trust in the Corporate Directorate, and had previous experience of conducting staff interviews and focus groups. Interviews and focus groups were audio-recorded, with written consent from all participants.

4.8.3 Secondary objective - Pilot data

Pilot outcome measures were collected, as detailed in Table 9 (service use data) and Table 10 (clinical measures).

Table 9 Service use outcome data

Outcome	Method	Time period
Main outcome: -		
1) Re-hospitalisation (≥1 OBD[11])	Clinical notes	Discharge – 3 & 6 mth follow-up
Additional outcomes: -		
2) Time to re-admission (days)	Clinical notes	Discharge – 3 & 6 mth follow-up
3) Total number of OBDs	Clinical notes	Discharge – 3 & 6 mth follow-up
4) Episodes of care with crisis/home treatment team (HTT)	Clinical notes	Discharge – 3 & 6 mth follow-up
5) Contact with CMHT[12] (number of meetings/contact with CMHT including care co-ordinator)	Clinical notes	Discharge – 3 & 6 mth follow-up
6) Reference to therapy goal which was shared with team	Clinical notes (free text search for goal as defined in end of therapy letter shared with team)	Discharge – 3 & 6 mth follow-up
7) Relapse rate **Defined as a documented exacerbation in psychotic symptoms, in addition to a subsequent change in clinical management (change in meds/increase frequency of visits/referral for admission or mental health act assessment/admission to HTT or inpatient ward)**	Clinical notes	Discharge – 3 & 6 mth follow-up

[11] OBD=occupied bed day
[12] CMHT=community mental health team

Table 10 Clinical measures outcome data

Construct assessed	Questionnaire	Method	Time points
Credibility of therapy	**1) Therapy credibility**	Self-report	Baseline only (immediately post-randomisation)
In the moment rating of stress and interference from symptoms, and hope for the future	**2) Stress bubbles**	Self-report	At the beginning and end of every therapy session
Frequency, distress & believability of beliefs and/or voices	**3) Self-ratings of psychotic symptoms** (Based on Bach & Hayes, 2002; Gaudiano & Herbert, 2006)	Self-report	Baseline, end of therapy, 3 mth mid-point and 6 mth follow-up
Mood – depression, anxiety and stress	**4) DASS-21** (Depression, anxiety & stress scale; Lovibond & Lovibond, 1995)	Self-report	Baseline, end of therapy, 3 mth mid-point and 6 mth follow-up
Self-defined recovery	**5) QPR** (Questionnaire about the Process of Recovery; Neil et al 2009)	Self-report	Baseline, end of therapy, 3 mth mid-point and 6 mth follow-up
Voices (incl. frequency, distress, interference & compliance)	**6) HPSVQ** (Hamilton Program for Schizophrenia Voices Questionnaire; Van Lieshout & Goldberg, 2007)	Self-report	Baseline, end of therapy, 3 mth mid-point and 6 mth follow-up
Mindfulness	**7) SMQ** (Southampton Mindfulness Questionnaire; Chadwick et al, 2008)	Self-report	Baseline, end of therapy, 3 mth mid-point and 6 mth follow-up

4.8.4 Description of clinical measures

1) Therapy Credibility

Immediately after randomisation, participants were read a brief description of the therapy they had been assigned to. They were then asked to rate on a scale from 0 (not helpful at all) to 10 (extremely helpful) how helpful they thought the therapy sounded.

2) Stress Bubbles

The use of within-session measures can be helpful in measuring change in brief interventions, by capturing small shifts in key processes that may occur over the course of a therapy session. Stress bubbles are a form of visual analogue scale, with 6 bubbles gradually increasing in size from "not at all" (1) to "extremely" (6). Participants rated 3 items (stress, interference from symptoms, and hope for the future) at the beginning and end of every session. These unpublished scales have been successfully used in a previous study of mindfulness interventions for psychosis (Jacobsen *et al.*, 2011).

3) Self-ratings of psychotic symptoms

This is a self-report scale that asks respondents to rate their psychotic symptoms (voices and/or distressing beliefs) on a scale of 1-7 (frequency) and 0-10 (distress and believability). These scales were used in the ACT inpatient trials (Bach and Hayes, 2002, Gaudiano and Herbert, 2006), and were found to be easy for participants to complete, and showed sensitivity to change over time.

4) Depression, anxiety and stress scales; (DASS-21) (Lovibond and Lovibond, 1995)

The DASS-21 is a short-form version of the original 42-item DASS comprising 7 items on each of the 3 sub-scales for depression, anxiety and stress. It is a self-report scale with respondents scoring each item on a four-point scale from 0 (never) to 3 (almost always). The DASS-21 has been well-validated in both clinical (Antony *et al.*, 1998) and non-clinical

samples (Henry and Crawford, 2005). The DASS-21 is particularly suitable for this study, being relatively quick and easy to complete, and has been shown to have good internal consistency and convergent validity in an acute psychiatric population (Weiss *et al.*, 2015) and is suitable for use with people experiencing psychotic symptoms (Samson and Mallindine, 2014).

5) Questionnaire about the Process of Recovery; QPR (Neil *et al.*, 2009)

The QPR is a 22-item self-report measure based on service user accounts of the process of recovery from psychosis. It has 2 sub-scales assessing both intrapersonal and interpersonal processes in recovery. Each item is rated on a 5-point scale from 0 (disagree strongly) to 4 (agree strongly). Neil et al. (2009) report that the scale has good internal consistency, construct validity and reliability.

6) Hamilton Program for Schizophrenia Voices Questionnaire; (HPSVQ) (Van Lieshout and Goldberg, 2007)

The HPSVQ is a 13-item self-report measure in which respondents rate the first 9 items on a five-point Likert scale from zero (lowest severity) to four (highest severity). The total score of these 9 items is intended to indicate the severity of auditory verbal hallucinations, and includes items on frequency, distress and interference with daily activities. There are an additional 4 qualitative items, not included for the purposes of this study. Kim et al. (Kim *et al.*, 2010) reported high test-retest reliability and good convergent validity with established clinician-rated scales (PSYRATS-AH (Haddock *et al.*, 1999b); PANSS (Kay *et al.*, 1987)) when used in a clinical sample of people with a diagnosis of schizophrenia.

7) Southampton Mindfulness Questionnaire; SMQ (Chadwick *et al.*, 2008)

The SMQ is a 16-item self-report measure designed to assess mindfulness of difficult thoughts and images. Each item is scored on a 7-point scale ranging from 0 (totally agree) to 6 (disagree totally). The SMQ has been validated in a clinical sample of people experiencing distressing psychotic symptoms. Chadwick et al. (Chadwick *et al.*, 2008) report that the

SMQ has good internal reliability, and shows convergent reliability with other established mindfulness scales (e.g. MAAS; (Brown and Ryan, 2003)).

4.9 Procedures for Recording and Reporting Adverse Events

Procedures for adverse event recording were detailed in the trial protocol. In brief, all adverse events were recorded for each participant from randomisation, to completion of the trial at 6-month follow-up. In addition to standard adverse events (death, hospitalisation, disability, birth defect), several additional adverse events were identified in advance, and specified in the trial protocol, which were of particular relevance to this patient group and clinical setting. This is in line with an approach previously successfully applied by Horigian and colleagues (2010), who defined additional adverse events of particular relevance to a trial of a behavioural intervention for adolescent drug abuse, including arrests and school suspensions. Taking this approach can be helpful in making adverse event reporting guidelines more relevant to psychological therapy trials. Standard definitions of adverse events are focussed on occurrences of physical harms, because the criteria for defining an adverse event were designed primarily for drug trials (Duggan *et al.*, 2014). However, other events, such as emotional harms, or occurrences of potentially risky behaviour, are often more relevant to monitoring harm for psychological therapy trials. Additional adverse events were therefore identified in the trial protocol for this study, which consisted of self-harm, absconsion from the ward, and harm to or from others (e.g. assault). All adverse events were reported to the independent chair of the Trial Steering Committee, who ratified the project team's assessment of whether they could be related to trial participation and would require reporting to the ethics committee and Trust R&D department.

4.10 Stopping Rules

Stopping rules were defined in advance in the trial protocol, and were as follows. The trial could have been prematurely discontinued by the Sponsor or Chief Investigator based on new safety information or for other reasons given by the Ethics Committee, Trial Steering Committee or other regulatory authority concerned. The trial could also have been prematurely discontinued due to lack of recruitment or upon advice from the Trial Steering Committee, who would advise on whether to continue or discontinue the study and make a

recommendation to the sponsor. If the study were to have been prematurely discontinued, active participants would have been informed and no further participant data would have been collected.

4.11 Trial Steering Committee (TSC)

Membership of the TSC: -

- Katherine Berry – Independent Chair
- Pamela Jacobsen – Chief Investigator
- Paul Chadwick – Co-Investigator
- Emmanuelle Peters – Co-Investigator
- Service User Representatives
- Emily Robinson - Trial Statistician (representing King's Clinical Trials Unit)

The TSC met 3 times over the course of the study (28/04/16, 13/03/17, & 02/11/17). The minutes for each meeting are included in the Trial Master File.

Chapter 5: Statistical Analysis and Data Management Plan

5.1 Overview

This chapter details the statistical analysis and data management plan for the trial. A statistical analysis plan was written in advance, using a King's Clinical Trials Unit (KCTU) template. The analysis plan was written by PJ, with support from the advising statistician from KCTU, Emily Robinson. A data management plan was written using DMPonline, an online service provided by the Digital Curation Centre, which provides template plans according to both funder and institutional requirements (see Trial Master File).

The focus of the analysis plan was on data description for the main feasibility outcomes, and description of participant flow through the trial using a standard CONSORT diagram. The data management plan outlined what data would be collected as part of the trial, and how it would be stored, backed-up and archived according to the requirements of the funder, sponsor and NHS ethics committee. Finally, strategies for ensuring high quality data, and maintaining good data 'hygiene' throughout the trial are outlined.

5.2 Duration of the treatment period

The treatment phase was restricted to the period of time the participant spent as an inpatient. End of therapy was defined as EITHER i) completing 5 sessions of therapy OR ii) discharge from acute ward, whichever came first.

5.3 Frequency and duration of follow-up

Participants completed follow up measures at 3- and 6-month post-discharge from hospital. The due date for the 3-month follow-up was calculated as discharge date +90 days, and the due date for the 6-month follow-up was calculated as discharge date +180 days. This definition was used to make the study consistent with the previous inpatient trials conducted in the US which also used re-admission as a primary outcome, and calculated the follow-up period from discharge date rather than randomisation date (Bach and Hayes, 2002, Gaudiano and Herbert, 2006) This was to accommodate the fact that trial participants had varying lengths of admission, and the duration of treatment window would be more variable compared to trials conducted in community settings. For example, it would be theoretically possible for a participant to still be in hospital 6 months post-randomisation therefore reducing the probability of them being re-admitted to 0, if randomisation was used as the anchor date rather than discharge.

5.4 Visit windows

The assessment window was defined as +/- 28 days from the due date of the 3- and 6-month follow-up. Outcomes were treated as missing for any time-point if no data had been collected within the 28-day window.

5.5 Sample size estimation

A power calculation to determine a sample size is not appropriate for a feasibility trial such as this one, as the purpose of the trial is not to establish efficacy. However, the data from this trial could be used to inform a sample size calculation for a later efficacy pilot trial. The target recruitment for this feasibility trial was set at N=60 (30 in each arm). This was

determined with reference to existing studies in the field, and is consistent with good practice recommendations for feasibility studies (Lancaster *et al.*, 2004).

5.6 Data analysis plan – data description

5.6.1 Recruitment and representativeness of recruited patients

Flow through the trial was presented in a standard CONSORT diagram (Schulz *et al.*, 2010), showing total number of new admissions screened, number meeting initial eligibility criteria, reasons for potentially eligible participants being excluded, number randomised, drop-outs before the end of treatment, and numbers retained in the trial at 3- and 6-month follow-up. Descriptive statistics were presented for key feasibility outcomes, including proportion of target sample size achieved (≥80% benchmark), proportion of initially eligible patients who were randomised, and proportion of participants lost to follow-up (≤20% benchmark).

5.6.2 Baseline comparability of randomised groups

Descriptive statistics were reported for the baseline clinical and demographic characteristics of participants, by treatment group, with means, standard deviations, or numbers and proportions reported as appropriate.

5.6.3 Adherence to allocated treatment and treatment fidelity

A minimum 'dose' of therapy was defined as 1 therapy session. The proportion of participants in each arm receiving at least 1 therapy session was reported, with reasons given for any participants who were randomised into the trial, but who did not receive any intervention. Any reasons for withdrawals from treatments were summarised. A random sample of 20% of recorded therapy sessions (evenly split between treatment and control arms) were checked for treatment fidelity by an independent rater using the trial adherence and competency scale (see Trial Master File). Fidelity data were summarised, including proportion of sessions which were correctly identified as coming from the intervention or control arm.

5.6.4 Loss to follow-up and other missing data

The proportions of participants missing each variable were summarised in each arm and at each time point. The baseline characteristics of those missing follow up were compared to those with complete follow up. The reasons for withdrawal from the trial were summarised.

5.6.5 Adverse event reporting

Adverse events (AE), adverse reactions (AR), serious adverse events (SAE) and serious adverse reactions (SAR) were summarised. AEs were monitored and recorded from randomisation to final follow-up (6 months post-discharge).

5.6.6 Assessment of outcome measures (unblinding)

PJ, as the trial therapist, was not blind to treatment allocation, nor were the trial participants, as would be normal for a psychological therapy trial. The service use outcome data, including re-admission and relapse rate at 6-month follow-up, which was blind-rated by an independent researcher using clinical note data, extracted and anonymised in advance by PJ. Complete notes were extracted for review without further editing, other than that necessary to anonymise names. Any unanticipated threats to 'unblinding' using this method were reported. Follow-up interviews were conducted with ward staff to explore the feasibility of keeping them blinded to treatment condition. For example, they were asked if they could easily guess which condition participants were in, or whether trial participants discussed any details of their therapy sessions with them, which could lead them to infer which treatment condition they were in.

5.7 Data analysis plan – inferential analysis

5.7.1 Main analysis of treatment differences

All analyses were conducted on an intention-to-treat (ITT) basis, analysing participants as randomised, regardless of actual treatment received. The main statistical analyses estimated the difference in mean outcomes between patients randomised to MBCI and SAT by ITT at the various post-treatment observation time points. Group difference estimates and associated confidence intervals were reported.

5.7.2 Analysis of service use outcomes

Pilot data on re-hospitalisation at 6-month follow-up were analysed using survival analysis. The proportion n (%) with odds ratio (95% CI) of patients readmitted were reported in separate contingency tables for data at 3- and 6-month follow-up, with the difference in time to re-admission between intervention and control groups being formally compared using Kaplan-Meier / Log rank survival analysis.

A secondary analysis on the re-admission data was planned in advance, using randomisation date as the anchor date for the follow-up period, rather than the discharge date. This was to allow for a comparison of the two approaches, to see if there was a difference in results between using randomisation or discharge date. This was to help inform whether to use randomisation or discharge date as the anchor for defining the follow-up window in subsequent trials.

5.7.3 Analysis of clinical outcome measures (questionnaires)

Pilot data on clinical measures, which were all continuous outcomes, were analysed using a general linear model on an intention-to-treat (ITT) basis, co-varying for baseline score and treatment condition. As this was a feasibility study, no adjustment was made for any difference in demographic characteristics at baseline.

5.7.4 Stratification and clustering

There was no stratification or clustering in the randomisation. The data collected in this trial would be helpful in planning a stratification strategy for a subsequent larger trial however: For example, whether there should be stratification for demographic factors (e.g. gender), or clinical factors (e.g. number of previous admissions), which might be predictor variables for risk of re-admission at 6-month follow-up.

5.7.5 Missing items in scales and subscales

The number (%) with complete data was reported. If any of the self-report measures had missing items, the missing value guidance published for each scale was followed. Where scales did not have published guidance to deal with missing items, scales were pro-rated for an individual if 20% or fewer items were missing. For example, in a scale with 10 items, prorating was applied to individuals with 1 or 2 items missing. The average value for the 8 or 9 complete items was calculated for that individual and used to replace the missing values. The scale score was calculated based on the complete values and these replacements.

5.7.6 Missing baseline data

It was not anticipated that missing baseline data would be an issue for the primary analysis. In the case of any extensions to this analysis using other baseline variables, if these contained missing data, the number with complete data was reported and an appropriate method of imputation was used.

5.7.7 Missing outcome data

Where there were two or more outcome time points, missing post-randomisation assessments were dealt with by fitting linear mixed models to all the available data using maximum likelihood methods. Such an approach provides valid inferences under the assumption that the missing data mechanism is ignorable (or MAR; missing at random).

5.7.8 Method for handling multiple comparisons

There was no correction for multiple comparisons as this was a feasibility study and therefore it was not powered to test for efficacy based on a specified outcome. However, care should be given to the interpretation of inference in group differences on primary or secondary outcome measures on this basis.

5.7.9 Model assumption checks

The models assume normally distributed outcomes; this was checked when describing the data and where substantial departures from normality occurred, transformations were considered. Residuals were plotted to check for normality and inspected for outliers.

5.8 Data management plan

The full data management plan can be found in the Trial Master File. The main points are summarised below.

The primary data for each trial participant was recorded on individual Case Report Forms (CRFs), in Microsoft Word format. Weekly screening logs from each ward were saved in Microsoft Excel format. The main trial database was created and saved using IBM SPSS (version 24). Audio recordings, of therapy sessions and feedback interviews, were saved in mp3 format and saved securely. A Trial Master File (TMF) was compiled, which was indexed and organised according to a standard format. PJ took responsibility for keeping the TMF up-to-date over the course of the trial. In terms of general file management, file names were generated in a standard format, and organised into clearly labelled folders, to ensure a consistent approach, and to make key files easy to locate and identify. For example, the CRFs were labelled using a standard format so that the participant ID number was clearly identifiable at the beginning of each file name. All electronic data were saved on the secure networked server at King's College London (KCL). KCL file servers are managed by IT and provide regular backups. In addition to the on-site and off-site back-ups provided by KCL IT, study files were also backed up using OneDrive for Business (remote cloud storage) on a weekly basis.

The storage of data containing sensitive or confidential information was kept to a minimum. The only file for the whole trial containing personally identifiable information (the ID key that linked names to participant identification numbers) was password-protected and stored only on the secure KCL network drive. Audio-recordings of therapy sessions and feedback interviews were downloaded (and then deleted) from the digital recorder as soon as possible (usually on the same day) and were saved as digital files with anonymous identification codes. The paper files for each participant containing hard copies of questionnaires and therapy session records were identified only by anonymous identification code and were stored securely in a locked filing cabinet in a locked office. They were not taken out of the office or stored elsewhere under any circumstances.

The funder of this trial, NIHR, does not specify when and for how long data should be archived. However, NIHR guidelines do stipulate that "Data generated through participation of patients and the public should be put to maximum use by the research community and, whenever possible, translated to deliver patient benefit." It was therefore planned to deposit any data that supported published research or had long-term value with the King's RDM system, after consultation with the NIHR. King's is committed to preserving research data for a minimum of 10 years since last use of the data.

5.9 Data quality control

Ensuring the quality of data and documentation in a clinical trial is a key part of adherence to Good Clinical Practice (MHRA, 2012). The general approach taken was to try to ensure good data 'hygiene' from the very start, to minimise the need for data cleaning at a later stage due to missing or inaccurate data. Some of the key steps that were taken are outlined below.

- Use of a standard KCTU template for the CRF, and careful piloting to identify and rectify any potential problems early in the trial. For example, pre-defined categories and corresponding check-boxes were used, in order to eliminate "free-text" as much as possible. This made it easier to later generate and code the variables on the trial database on SPSS, and aided faster and more accurate data-entry from CRF to database.

- Use of checklists on CRFs to ensure that all relevant data were collected at each assessment point (or where data were missing, or incomplete, this was also recorded accurately).
- Minimising the potential for transcription errors by keeping the data chain to a minimum. Data were entered directly into the electronic CRFs wherever possible, and from there entered onto the SPSS database.
- Paper questionnaires were checked for completeness and accuracy at the time of completion, and any discrepancies rectified immediately with the participant wherever possible (for example, participants occasionally missed out items by accident, or circled 2 responses by mistake on the same item).
- Raw data for each questionnaire were entered onto scoring templates, created using excel spreadsheets. The scoring spreadsheets included safe-guards against data entry mistakes such as setting maximum and minimum value limits for relevant cells. The use of standard formulas guarded against simple calculation mistakes, particularly those that can arise from mistakes in reverse-scoring items.
- All questionnaire scores were double-scored, so that any mistakes in entry or scoring could be easily identified and rectified. In addition to scoring using excel spreadsheets, all raw questionnaire data were also entered onto SPSS. The calculate function on SPSS was then used as a double-check of questionnaire scores, and any discrepancies were corrected and resolved by reference back to the hard copies.

Chapter 6: Results: Feasibility Outcomes

6.1 Overview

This chapter reports feasibility outcomes for the trial. Participants were recruited from 4 acute wards over a 15-month period. Approximately 50% of new admissions met the initial eligibility criteria for the trial (302/590). Of these, 175 were assessed further, and 65 were eligible to participate. Fifty participants were randomised into the trial (83% of pre-set target). All participants received at least one therapy session, and no-one dropped out during the intervention stage. The average number of sessions completed was 3 (range 1-5) in both arms of the trial. Overall, 76% of offered appointments were attended (146/191 sessions). At 6-month trial end-point, only one participant was lost to follow-up as they moved abroad immediately upon discharge. Data on hospital re-admission were available for the remaining 49 participants (98% follow-up). Follow-up rate for self-report questionnaire measures was 86%, which exceeded the 80% benchmark set in the trial protocol. Three participants experienced adverse events, none of which was judged to be related to their participation in the trial.

6.2 Screening and Recruitment

Participants were recruited for the trial from 4 acute inpatient wards at one hospital site in South London. At the time of the study, there were 3 male wards and 1 female ward at the hospital. Each ward had 18-22 beds open at any one time, and bed occupancy was always high (95-100%). Recruitment started on Ward A in November 2015, then expanded to subsequent wards in approximately 3-month intervals (Table 11). Recruitment was gradually rolled out in this way to try and achieve an average recruitment rate of 5 participants per month (Figure 8). The admission rate was fairly consistent on the male wards, at between 3 and 4 admissions a week, however it was considerably higher on the female ward at over 6 admissions a week on average.

Table 11 Recruitment on participating wards

	Gender	First week of recruitment	Last week of recruitment	Total number of weeks recruitment open	Number of admissions screened	Average admission rate/week
Ward A	Male	16/11/15	16/01/17	56	207	3.70
Ward B	Female	22/02/16	09/01/17	45	274	6.09
Ward C	Male	23/05/16	16/01/17	31	106	3.42
Ward B	Male	08/08/16	16/01/17	24	89	3.71

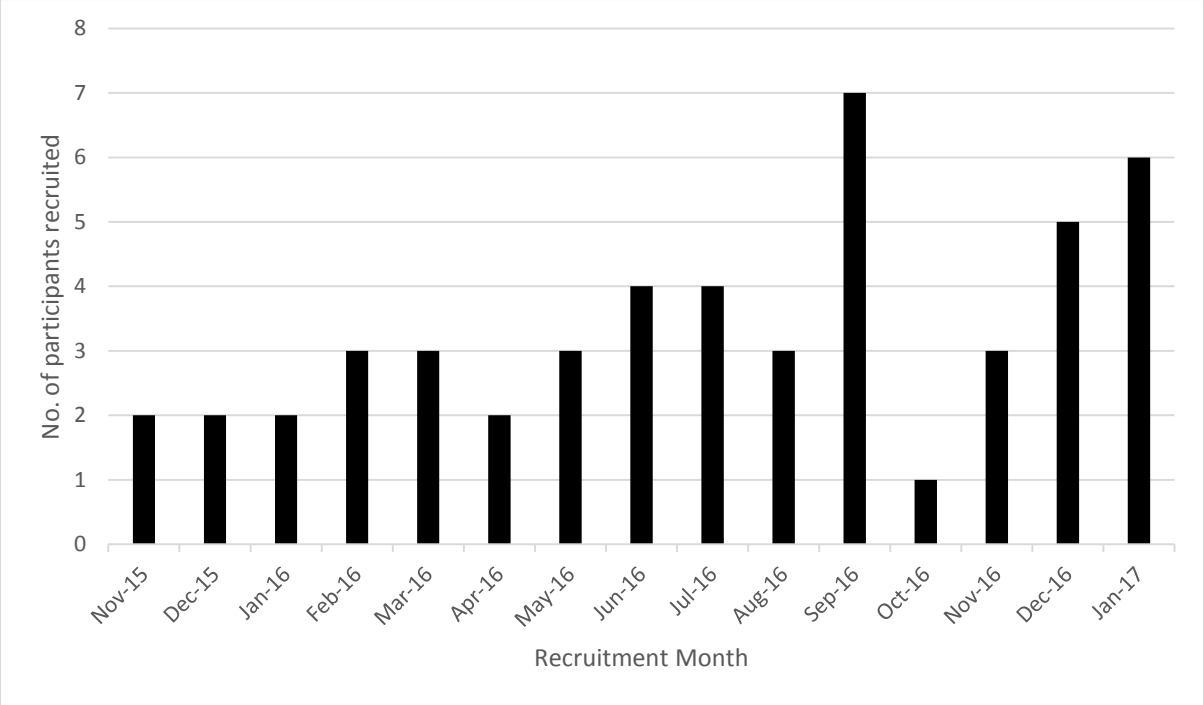
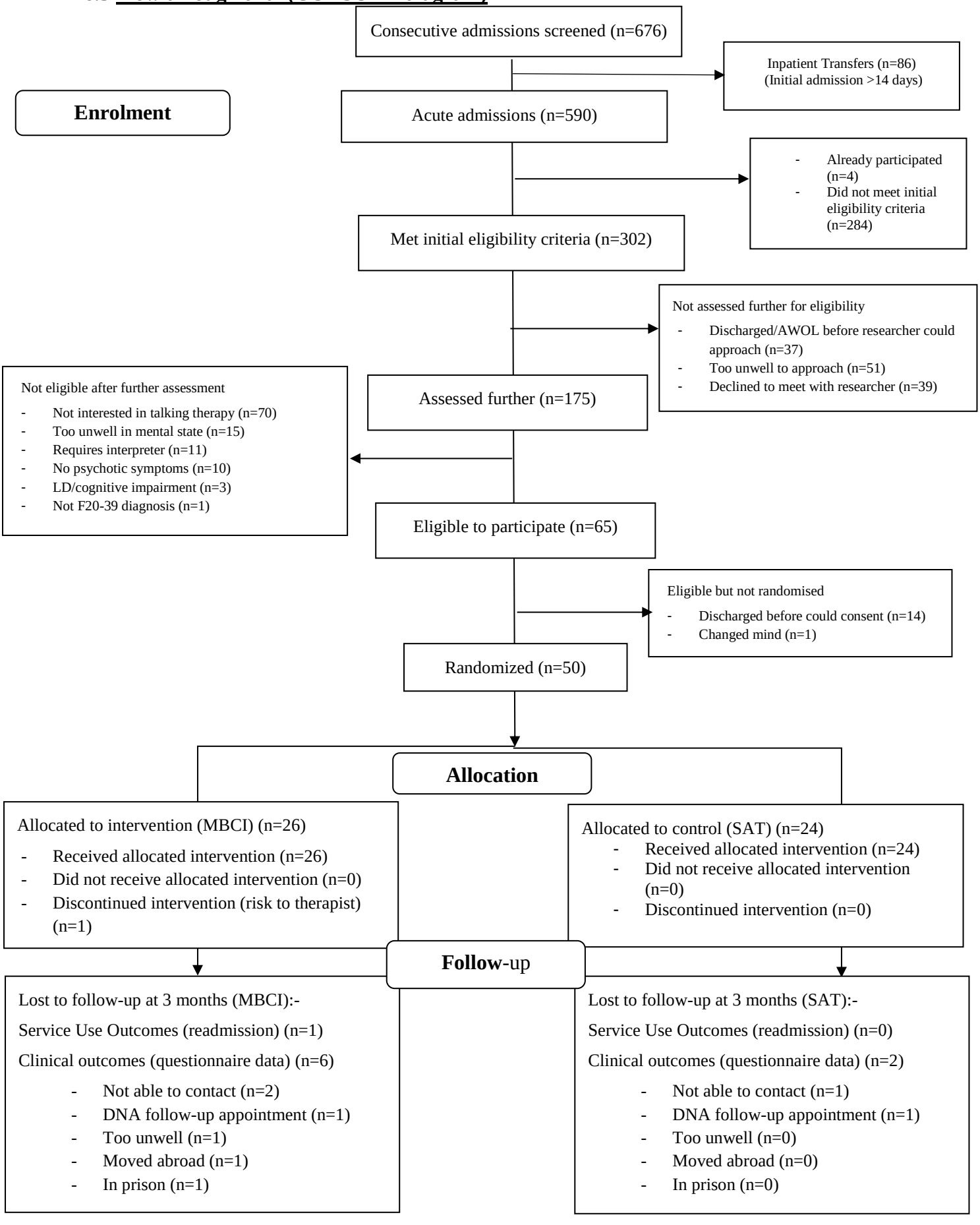


Figure 8 Recruitment rate by month

Figure 9 (CONSORT diagram) presents patient flow through the study. Each ward had its own Consultant Psychiatrist, who was the leader of the multi-disciplinary inpatient team that included junior doctors, nurses, health-care assistants and occupational therapists. In line with the trial protocol, consecutive admissions were screened with the consultant psychiatrist and clinical team for eligibility for the trial. As the aim was to screen all potential participants in the acute phase of their admission, a 'new' admission was defined as someone within the first 14 days of their admission. People who had been transferred from other wards or hospitals, and were no longer in the first 14 days of their admission, were excluded and not assessed further for eligibility (13% of all admissions screened; see Figure 9). The initial eligibility criteria for the trial were defined as people presenting with positive psychotic symptoms in the context of a F20-39 diagnosis. Just over 50% of all acute admissions were identified by the clinical team as meeting these criteria (302/590). People who were identified by the clinical team as lacking capacity, being too unwell in mental state, or posing a risk to the researcher were not assessed further. Some potentially eligible participants were not assessed further as they were discharged from the ward or went absent without leave (AWOL) before they could be approached.

Once identified as eligible, there was a 2-stage consent process to the study. Participants who were initially approached about the study were asked if they were interested in having a talking therapy on the ward, given a brief information leaflet and asked to give written permission for the researcher to check their clinical notes to further assess eligibility for the study (stage 1). The main reason people did not want to take part at this stage was because they were not interested in a talking therapy (n=70). People who were interested in taking part, and confirmed as eligible from a clinical notes check, were then given the full information sheet. Everyone was given the opportunity to ask questions, discuss the study with the ward team, and to think it over before making a final decision to participate. Participants then signed the full consent form (stage 2), and completed the baseline questionnaires. Overall, 65 out of the 175 people assessed further (37%) were confirmed as eligible for the trial. Fourteen of these did not go on to participate further as they were discharged from hospital before they could give consent and be randomised. Additionally, one person changed their mind about taking part at this stage. This resulted in 50 people being randomised into the trial, 26 in the MBCI arm and 24 in the SAT arm. Participants were randomly allocated to treatment condition at the beginning of their first therapy session, to try to minimise any drop-out between randomisation and the start of therapy. This was a highly successful strategy, as everyone randomised into the trial (100%) ended up receiving at least one session of intervention, which was pre-defined as the 'minimum' dose.

6.3 Flow through trial (CONSORT diagram)



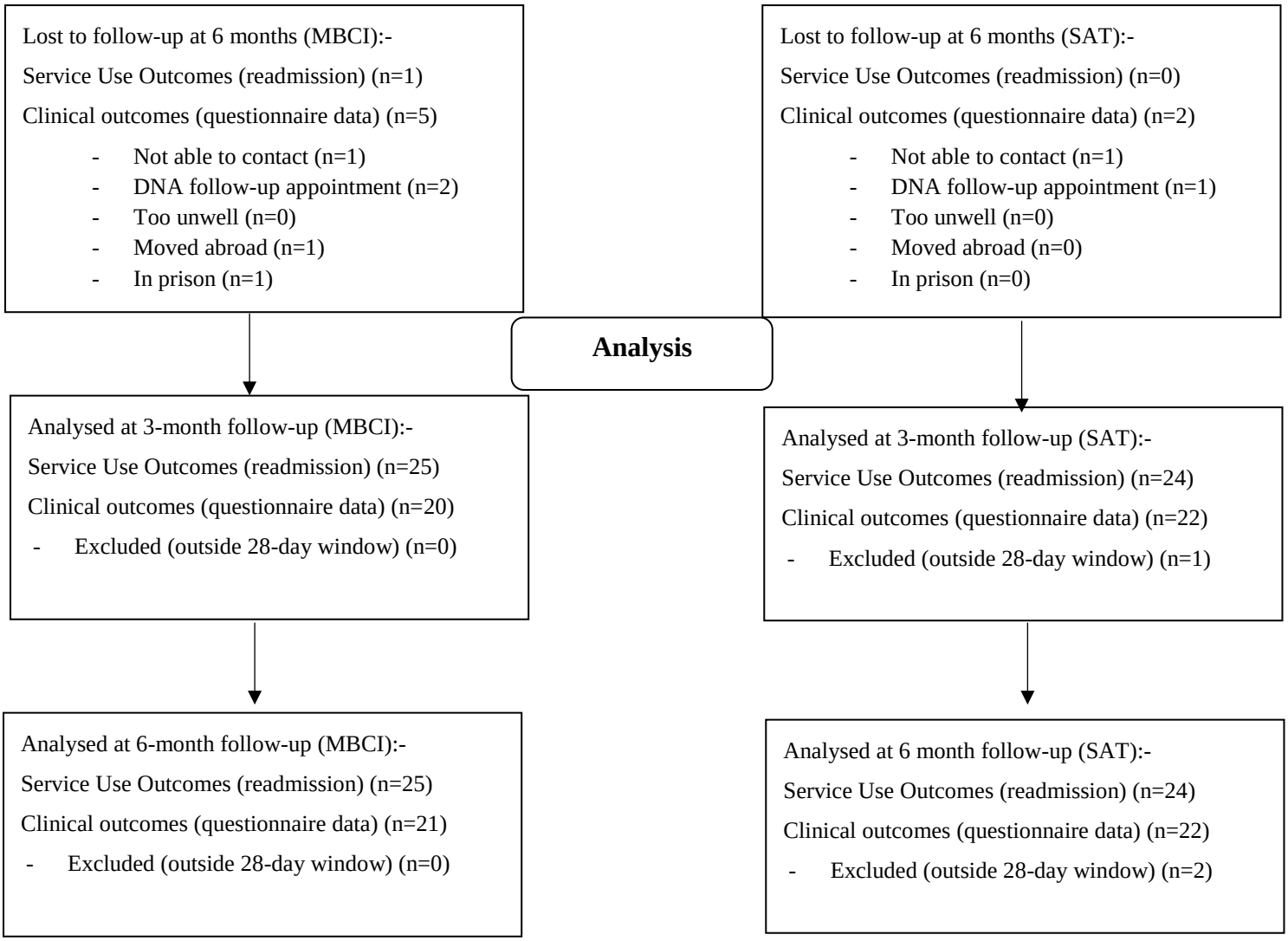


Figure 4 CONSORT diagram

6.4 Loss to follow-up

Loss to follow-up at both 3 and 6 months follow-up was low, and did not exceed the 20% predefined benchmark (Table 12). Only one person was lost to follow-up, as they left the country immediately upon discharge from hospital. One person was taken into police custody immediately on discharge, and subsequently was sent to prison. Information on hospital admissions was obtained from the prison healthcare team for this participant. In Table 12, follow-up rates are reported separately for the service use outcomes (readmission), which could be obtained from clinical notes, and clinical measure outcomes, which required direct contact with participants to complete questionnaires. Most clinical measures were completed face to face with the participant, although three participants also returned questionnaires via post (at their own request). Participants were usually seen for follow-up at their community mental health team, at the hospital outpatient department, or on the ward for people who were inpatients at the time of their follow-up. One person did not want to be seen within a NHS setting, and so the follow-up was done in the local library at their request.

Table 12 Follow-up rates

	Service use (Readmission) N (%)	**Clinical measures (Self-report questionnaires) N (%)**
3-month follow-up (F1)	49 (98%)	42 (84%)
6-month follow-up (F2)	49 (98%)	43 (86%)
Participants completing both F1 + F2	49 (98%)	39 (78%)
Participants completing at least 1 follow-up	49 (98%)	46 (92%)
Participants not completing any follow-ups	1 (2%)	4 (8%)

The assessment window was pre-defined as +/- 28 days from the due date of the 3- and 6-month follow-up. A generous visit window is helpful with this clinical population, who can be challenging to follow-up. It frequently took several attempts to contact people, and sometimes appointments had to be re-scheduled several times. Despite this, only 2 participants had follow-ups outside the 28-day window. One participant completed their 3-month follow-up 29 days after the due date, and completed their 6-month follow-up 47 days

after the due date. Another participant completed their 6-month follow-up 51 days after the due date. In line with the statistical analysis plan, these 3 data points were excluded from the analysis. For those follow-ups completed within the visit window, the average number of days between the due date and completed date was +4 for 3-month follow-up, and +3 for 6-month follow-up.

6.5 Baseline Data

Baseline data for participants are shown in Table 13 (demographic characteristics) and Table 14 (clinical characteristics). No statistical significance tests or confidence intervals were calculated for the difference between randomised groups on any baseline variables. The randomisation of intervention groups to participants should have ensured that any imbalance over all measured and unmeasured baseline characteristics is due to chance (Altman and Dore, 1991). Characteristics that varied between group, and which might be hypothesised to predict a greater risk of readmission in the follow-up period (e.g. prior history of hospitalisations), were entered as predictor variables in the Cox regression analysis (Chapter 7).

Table 13 Demographic Characteristics of Participants at Baseline

	SAT (N=24)	MBCI (N=26)	OVERALL (N=50)
DEMOGRAPHIC CHARACTERISTICS			
Age			
- Mean (range)	33 years (19-65)	35 years (18-52)	34 years (18-65)
Gender			
- Male	17 (71%)	17 (65%)	34 (68%)
- Female	7 (29%)	9 (35%)	16 (32%)
Ethnicity			
- White	8 (33%)	8 (30%)	16 (32%)
- Asian	3 (13%)	3 (12%)	6 (12%)
- Black	9 (37%)	12 (46%)	21 (42%)
- Mixed Race	3 (13%)	3 (12%)	6 (12%)
- Other	1 (4%)	0 (0%)	1 (2%)
Highest educational qualification			
- No formal qualifications	3 (13%)	5 (18%)	8 (16%)
- GCSE (or equivalent)	6 (25%)	8 (31%)	14 (28%)
- A-Levels (or equivalent)	7 (29%)	8 (31%)	15 (30%)
- Graduate	6 (25%)	2 (8%)	8 (16%)
- Post-Graduate	1 (4%)	1 (4%)	2 (4%)
- Vocational Qualification	1 (4%)	1 (4%)	2 (4%)
- Not known	0 (0%)	1 (4%)	1 (2%)
Employment status			
- Working (full/part-time)	7 (29%)	2 (8%)	9 (18%)
- Studying	3 (13%)	4 (15%)	7 (14%)
- Retired	1 (4%)	0 (0%)	1 (2%)
- Looking after family	1 (4%)	0 (0%)	1 (2%)
- Unemployed	2 (8%)	6 (23%)	8 (16%)
- Disability benefits	10 (42%)	14 (54%)	24 (48%)
Currently in a relationship			
- Yes	5 (21%)	1 (4%)	6 (12%)
- No	19 (79%)	25 (96%)	44 (88%)

Accommodation status			
- Council tenant	10 (41%)	11 (42%)	21 (42%)
- Private tenant	3 (13%)	0 (0%)	3 (6%)
- Own property	2 (8%)	0 (0%)	2 (4%)
- Living in family home	5 (21%)	11 (42%)	16 (32%)
- Supported accommodation	3 (13%)	2 (8%)	5 (10%)
- Temporary accommodation/homeless	1 (4%)	2 (8%)	3 (6%)
Live alone			
- Yes	11 (46%)	15 (58%)	26 (52%)
- No	13 (54%)	12 (42%)	24 (48%)

The acute wards were general working-adult age services, and the age range of participants in the study reflects this, spanning the full range from 18-65 years old. As noted earlier, there was only 1 female ward open at the hospital during the recruitment period, which led to a two-thirds majority of men in the final sample (68%). The participants reflected the diverse and multi-cultural nature of the local community. Around a third of participants (15/50) had migrated to the UK from other countries, and almost a quarter spoke English as an additional language (11/50). It is well-documented that people from black and minority ethnic backgrounds (BME) are over-represented within inpatient populations at a national level, particularly for those being treated under a section of the Mental Health Act (Bhui *et al.*, 2003). Data for the London borough in which recruitment took place confirmed this was also the case at a local level (Figure 10). Figure 10 shows the latest available census data from 2011 for the borough where recruitment took place, alongside the figures from the most recent equality and diversity report, which provides a snapshot of all admissions over a selected month (September 2016). As can be seen in the graph, people from a BME background represent 42% of people living in the borough, but represent 64% of acute psychiatric admissions. However, Figure 10 also shows that the ethnic backgrounds of participants in the current study were representative of the population on the ward in general, with 68% of people coming from a BME background. There was therefore no indication of over-or under-representation of any particular ethnic group in the final sample, using the general ward population as a comparator.

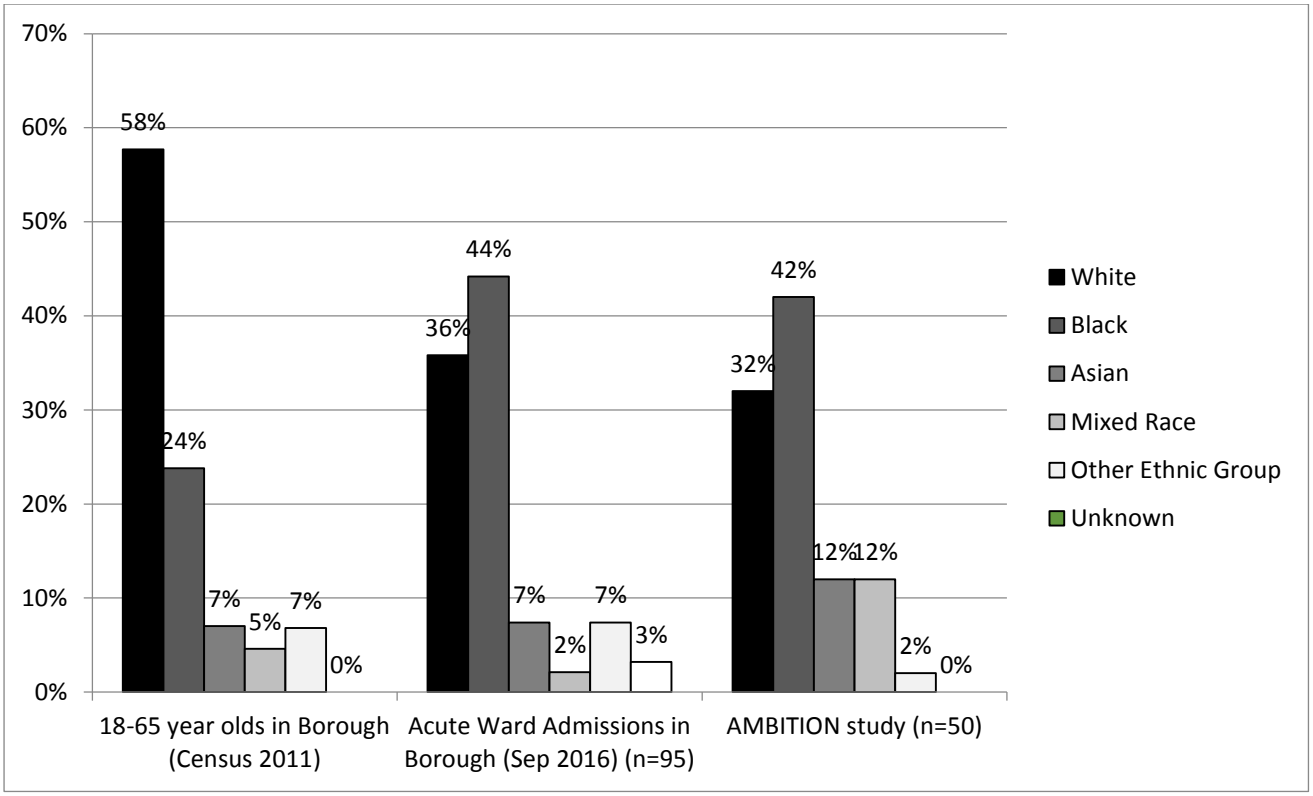


Figure 10 Ethnicity data for local London borough

Table 13 also shows data indicating the social and occupational functioning of the participant group. In general, there was a range of people's overall level of functioning. Some participants were functioning very well prior to their crisis, for example, working or studying full-time. However, the majority of participants were either unemployed, or were unable to work due to their mental health difficulties and were in receipt of disability benefits. Most participants were not in a relationship, but some were single parents with dependent children. Approximately half of all participants lived alone.

Table 14 Clinical Characteristics of Participants at Baseline

	SAT (N=24)	MBCI (N=26)	ALL PARTICIPANTS (N=50)
CLINICAL CHARACTERISTICS			
Diagnosis			
- F20-29 (Schizophrenia-spectrum)	17 (71%)	20 (77%)	37 (74%)
- F30-39 (Mood disorder)	7 (29%)	6 (23%)	13 (26%)
Psychotic symptoms (self-report)			
- Delusions only	12 (50%)	14 (54%)	26 (52%)
- Voices only	1 (4%)	0 (0%)	1 (2%)
- Delusions + voices	11 (46%)	12 (46%)	23 (46%)
Legal status on admission			
- Informal	6 (25%)	8 (31%)	14 (28%)
- MHA Sec 2	13 (54%)	14 (54%)	27 (54%)
- MHA Sec 3	5 (21%)	3 (11%)	8 (16%)
- MHA Sec 37	0 (0%)	1 (4%)	1 (2%)
Open to CMHT on admission			
- Yes	12 (50%)	10 (38%)	22 (44%)
- No	12 (50%)	16 (62%)	28 (56%)
Psychiatric medication on admission			
- Prescribed at least one medication	20 (83%)	19 (73%)	39 (78%)
- Prescribed anti-psychotic	18 (75%)	18 (69%)	36 (72%)
- Prescribed an anti-depressant	3 (13%)	4 (15%)	7 (27%)
- Prescribed a mood-stabilizer	5 (21%)	1 (4%)	6 (12%)

Years known to services			
- <1 year	5 (21%)	4 (15%)	9 (18%)
- 1-5 years	4 (17%)	6 (23%)	10 (20%)
- 6-10 years	6 (25%)	8 (31%)	14 (28%)
- 11-15 years	2 (8%)	2 (8%)	4 (8%)
- >15 years	7 (29%)	6 (23%)	13 (26%)
Previous admissions			
- Yes	14 (58%) (mean = 5.64, range 1-14)	21 (81%) (mean= 4.00, range 1-10)	35 (70%) (mean = 4.66, range 1-14)
- No	10 (42%)	5 (19%)	15 (30%)
Admission in previous 12 months			
- Yes	7 (29%)	8 (31%)	15 (30%)
- No	17 (71%)	18 (69%)	35 (70%)
Reported suicidal thoughts/acts on admission			
- Yes	6 (25%)	3 (12%)	9 (18%)
- No	18 (75%)	23 (88%)	41 (82%)
Psychological therapy in past 5 years			
- None	11 (46%)	12 (46%)	23 (46%)
- Offered	3 (12%)	4 (15%)	7 (14%)
- Received	10 (42%)	10 (39%)	20 (40%)

The majority of participants had schizophrenia-spectrum diagnoses (F20-29). The participants with F30-39 diagnoses had either a bipolar affective disorder diagnosis, or a depressive disorder diagnosis with psychotic symptoms. As part of the eligibility assessment for the trial, people had to self-report at least one positive psychotic symptom. All but one participant reported delusions, half of whom additionally reported hearing voices. Only one participant reporting voices only with no delusions. The most common delusion type was persecutory (61%), followed by grandiose beliefs (22%).

In terms of understanding triggers for admission for this group, risk of harm to self was not a major feature, as fewer than 20% of people in the sample reported suicidal thoughts when assessed in the admission clerking interview with the ward doctor. The majority of participants were admitted under a section of the mental health act, indicating that most people either did not agree with the need for inpatient care, or lacked capacity to make their own treatment decisions. People's routes into hospital were often complex, including multiple assessments and involvement from different teams including community mental health teams (CMHTs), home treatment teams, A&E and the police. Most participants were already known to mental health services, with 78% on psychiatric medication prior to admission, although only 44% were open to their community mental health team (secondary services). This may reflect service changes over recent years, with open-ended periods of care with CMHTs being phased out even for those service users with longer-term histories of mental health difficulties. Most participants had a history of previous hospital admissions, with approximately a third having had an admission within the 12 months prior to the current admission. There was also a subset of participants who were less well-known to services, and were on their 1st or 2nd admission, and so met criteria for psychosis early interventions services on discharge (which now has no age restrictions within local services). Since this was a group of people who agreed to have a talking therapy, rates of previous therapy were quite high, with 40% having documented evidence of previous psychological therapies in the past 5 years, most of which was individual CBT. However, the majority of participants had not had any therapy in the past 5 years (although some had been previously offered it). This indicated that people were interested in taking up the offer of a talking therapy during an acute admission even if they had previously declined therapy in the community, or indeed had never been offered any.

6.6 Description of treatment

Treatment variables are shown in Table 15. Therapy credibility, assessed just after randomisation, was high in both treatment conditions, with participants rating the therapy on average between 7 and 8 on a scale of 0-10, where 10 is extremely helpful. Therapy credibility did not differ significantly between treatment condition ($t(48) = -0.09$, $p=0.93$). Consent to audio-taping was high, with almost three-quarters of participants consenting to the recording of at least 1 session. Written consent to audio-tape was given at the beginning of the study along with general consent, but verbal consent was also sought at the beginning of each therapy session. Participants were informed they could change their mind at any time, or ask for the recorder to be turned off at any point in a session, in order to try and promote a sense of control over the process. Participants were also offered a copy of the therapy recordings, but take-up of this offer was low (less than 10%).

The average number of sessions people attended was 3 (range 1-5), and this was comparable between treatment conditions. A record was also kept of appointments offered but not attended. The overall 'Did Not Attend' rate was low (less than 1 scheduled session per participant). Whilst 100% of participants attended at least 1 session, the proportion decreased with each subsequent therapy session. Approximately half of all participants attended at least 3 sessions, and a quarter of participants attended the maximum of 5 sessions. The main determinant of number of sessions was the length of admission, with some participants having admissions of less than a week, with others running into several months. In order to account for varying and unpredictable lengths of admission, the trial protocol designated a maximum 'therapy envelope' of 35 days (i.e. maximum of 5 sessions, spaced at maximum of weekly intervals). As can be seen in Table 15, this was successfully achieved, with the maximum therapy envelope being 28 days. Most admissions were residents in the local borough, however due to bed shortages, sometimes people living in neighbouring boroughs were also admitted. If people were admitted 'out of borough' they were sometimes transferred to their resident borough hospital part-way through their admission. People were also sometimes transferred to a specialist early intervention ward at another hospital site. Internal transfers between wards in the same hospital sometimes also occurred due to bed shortages or other clinical reasons. In line with the trial protocol, participants continued to be offered therapy sessions if they were transferred to a different ward within the same trust

(including to different hospital sites). Overall, 6 participants (3 in each arm) were transferred to another hospital site after enrolment in the trial, and all continued with their treatment sessions, so this did not lead to any drop-out during the treatment phase. Therapy had to be suspended for one participant who became disinhibited towards the therapist, but who was then discharged the next day, before safety for any further sessions could be assessed.

The maximum length of a therapy session was 60 minutes, but the length of session was adaptable to meet the needs of participants. The average length of session 1 was 42 minutes in the SAT group, and 45 minutes in the MBCI condition. The average length of each session did not differ much over the course of subsequent session in the SAT group. However, in the MBCI group, the average length of session decreased by a few minutes with each subsequent session, with the average length of session 5 being 28 minutes. There were occasionally reasons why sessions had to be ended early. This was usually due to participants being called out of therapy sessions to attend other clinical meetings (such as ward round), or to see other visitors. The maximum frequency of therapy sessions was daily, and the minimum frequency was weekly. Occasionally there was a gap of longer than 7 days between sessions, which arose from participants missing sessions which were offered, which was sometimes due to them being transferred to other wards. However, the most common interval between sessions was 1-3 days.

For the purposes of the trial, therapy was provided in addition to treatment as usual (TAU), and this could include any of the standard range of interventions available on an acute ward. This included additional group or individual therapy, including the continuation of therapy that had been started in the community prior to admission. In reality, TAU mainly consisted of medication (98% of participants were prescribed at least one medication), and rates of other psychological interventions were low. It is important to note that for the duration of the recruitment period for the study (15 months), there was no regular ward psychologist assigned to any of the wards where recruitment took place. There was one Band 7 Clinical Psychology post based at the hospital site, which covered all 4 wards plus a psychiatric intensive care unit (PICU), however the post-holder was on long-term sick-leave. There was occasional cover from a Consultant Psychologist, but as the post covered an additional 3 hospital sites in addition to the recruitment site, input was very limited and was usually in response to direct referrals from ward teams, which were made infrequently. Psychological

therapy groups (as opposed to general activity/occupational therapy groups) were not widely available. The Consultant Psychiatrist on Ward A ran a weekly psychodynamic therapy group with the ward manager, but a record of group attendance was not routinely made in patient's notes, so it was difficult to record reliably which participants from Ward A attended this group. A trainee clinical psychologist occasionally ran groups with the Consultant Psychologist, but this was only for limited periods over the recruitment period. As can be seen in Table 15, only 6/50 participants (12%) attended therapy groups during their admission.

Finally, participants were asked to rate their satisfaction with therapy at the end of the trial (6-month follow-up). Satisfaction was very high in both groups (10 being completely satisfied). The average satisfaction rating was very slightly higher in the MBCI group compared to the SAT group (9.11 vs. 8.27) but this difference was not statistically significant ($t(39) = -1.68$, $p = 0.10$).

Table 15 Treatment Details

	SAT (N=24)	MBCI (N=26)	ALL PARTICIPANTS (N=50)
Therapy credibility • Mean (SD) • Range 0=Not helpful at all 10=Extremely helpful	 7.71 (2.79) 1-10	 7.77 (2.08) 3-10	 7.74 (2.42) 1-10
Agreed to audio-taping at least one session - Yes - No	 18 (75%) 6 (25%)	 18 (69%) 8 (31%)	 36 (72%) 14 (28%)
Number of therapy sessions **Attended** - Mean (SD) - Range **Offered** - Mean (SD) - Range **Did not attend** - Mean (SD) - Range	 3.04 (1.49) 1-5 3.96 (1.60) 1-8 0.92 (1.02) 0-4	 2.81 (1.47) 1-5 3.69 (1.78) 1-8 0.88 (0.95) 0-3	 2.92 (1.47) 1-5 3.82 (1.7) 1-8 0.90 (0.97) 0-4
Number of participants attending each session number - Session 1 - Session 2 - Session 3 - Session 4 - Session 5	 24 (100%) 20 (83%) 14 (58%) 8 (33%) 7 (29%)	 26 (100%) 20 (77%) 13 (50%) 9 (35%) 5 (19%)	 50 (100%) 40 (80%) 27 (54%) 17 (34%) 12 (24%)

Duration of therapy sessions (minutes)			
Session 1			
- Mean (SD)	42 (10)	45 (9)	44 (9)
- Range	21-55	20-60	20-60
Session 2			
- Mean (SD)	41 (12)	39 (13)	40 (13)
- Range	7-57	5-57	5-57
Session 3			
- Mean (SD)	43 (9)	40 (12)	42 (11)
- Range	24-59	15-57	15-59
Session 4			
- Mean (SD)	42 (14)	34 (6)	38 (11)
- Range	15-59	26-45	15-59
Session 5			
- Mean (SD)	42 (12)	28 (6)	36 (12)
- Range	21-58	19-33	19-58
Average gap between therapy sessions			
Sessions 1-2			
- 1-3 days	10	13	23
- 4-7 days	8	7	15
- 8-14 days	0	0	0
- >14 days	2	0	2
Sessions 2-3			
- 1-3 days	11	6	17
- 4-7 days	3	4	7
- 8-14 days	0	3	3
- >14 days	0	0	0
Sessions 3-4			
- 1-3 days	5	6	11
- 4-7 days	3	2	5
- 8-14 days	0	1	1
- >14 days	0	0	0
Sessions 4-5			
- 1-3 days	5	2	7
- 4-7 days	1	3	4
- 8-14 days	0	0	0

- >14 days	1	0	1
Therapy Envelope Number of days between 1st and last therapy sessions - Mean (SD) - Range	 8 (7) 0-28	 7 (7) 0-23	 7 (7) 0-28
Description of Treatment as Usual (TAU) during admission - Prescribed at least one medication - Prescribed anti-psychotic - Prescribed an anti-depressant - Prescribed a mood-stabilizer - Attended therapy group on ward - Attended 1:1 psychology session (in addition to trial therapy)	 23 (96%) 21 (88%) 5 (21%) 4 (17%) 2 (8%) 0 (0%)	 26 (100%) 25 (96%) 5 (19%) 1 (4%) 4 (15%) 0 (0%)	 49 (98%) 46 (92%) 10 (20%) 5 (10%) 6 (12%) 0 (0%)
Duration of inpatient admission (days) - Mean (SD) - Range - Admission ≤30 days - Admission >30 days	 32 (23) 9-93 17 (71%) 7 (29%)	 31 (20) 4-97[13] 15 (60%) 10 (40%)	 31 (21) 4-97 32 (65%) 17 (35%)

[13] One participant in the MBCI arm had an admission of 160 days, and so was excluded from descriptive statistics for this variable on the basis it was a clear outlier (more than 60 days longer than next longest admission)

Satisfaction with therapy at 6-month follow-up - Mean (SD) - Range 0=Not satisfied at all 10=Completely satisfied	 8.27 (1.91) 2-10	 9.11 (1.1) 7-10	 8.66 (1.62) 2-10

6.7 Treatment Fidelity & Adherence

A sample of tapes was checked for fidelity and adherence by an independent rater. The rater was blind to treatment condition, and was not otherwise involved in the trial. They were a senior Clinical Psychologist, with many years' experience of training and assessing competencies in CBT for psychosis. One-hundred and eight recorded sessions were available (52 MBCI; 56 SAT). Twenty sessions were randomly selected (10 from each condition), representing 16 different participants (some sessions were from the same participant, but no more than 2 per participant). Sessions from 1-5 were all represented at least once in the random sample, ensuring that fidelity was assessed from later as well as earlier sessions. As outlined in Chapter 4, there were 4 sub-scales to the adherence and competency scale. Scale A was on non-specific therapy factors, which should have been present in both treatment conditions (agenda, feedback, understanding, interpersonal effectiveness, collaboration & homework). These factors were rated as 'present' in all sessions. Scale B was on MBCI-specific components (formulation, mindfulness skills & values). These components were rated as present in all of the MBCI sessions rated, and absent in all the SAT sessions rated. The converse was true for Scale C, which was on SAT-specific components (activities & response to distress). Scale D was on components from CBT for psychosis that would be proscribed in both treatment conditions (Columbo style, evidence for beliefs, verbal challenge, validity testing, schemas). These factors were rated as 'absent' in all sessions. For all therapy components which were rated as 'present', the minimum competency rating was always at least 3 ('satisfactory'). All 20 sessions were correctly identified as coming from either a SAT or MBCI session. In summary, fidelity to treatment model was 100% across all sessions rated, and competency was at least satisfactory for all therapy components that were present within a session.

6.8 Adverse Events

Three participants experienced adverse events over the course of the trial (2 SAT; 1 MBCI). One participant was assaulted by another patient during their admission, but did not require medical treatment. One participant presented to A&E on 2 occasions in the follow-up period, reporting having taken a paracetamol overdose in response to social stressors. They were admitted to a general medical ward overnight for observation on both occasions but did not require further treatment. The third participant fractured their shoulder falling down stairs, which required a brief hospital admission stay for treatment. This occurred in the follow-up period. A month later the same participant took a medication overdose in response to distress associated with persecutory beliefs, and was admitted to a general hospital for observation before being medically cleared and transferred to a psychiatric ward. These adverse events were all reported to the chair of the Trial Steering Committee who was in agreement that they were highly unlikely to be related to trial participation.

6.9 Qualitative Outcomes

As outlined in Chapter 4 (section 4.8.2), all trial participants were invited to complete a feedback questionnaire with PJ at the end of the trial, at 6-month follow-up. The questionnaire asked about their experience of taking part in the study, and their experiences of the therapy they received (see Trial Master File, 10.15 for topic guide). Forty participants (80%) completed feedback questionnaires. Additionally, participants were asked about their willingness to complete an additional feedback interview, on the same topics, conducted by a service user researcher. Five participants (10%; three SAT, two MBCI) went on to complete an interview with a service user researcher, which was audio-recorded and transcribed verbatim for analysis. Staff from the in-patient units where patients were recruited were also invited to give feedback on the trial via an individual interview with two assistant psychologists who had not otherwise been involved in the trial (see Trial Master File, 10.16 for topic guide). A total of eight staff interviews were conducted, including staff from all four wards from which trial participants were recruited (three ward managers, two staff nurses and three consultant psychiatrists). Staff interviews were also audio-recorded and transcribed verbatim for analysis. A full qualitative analysis of participant and staff experience of the trial is outside the intended scope of this thesis, and so is not reported. In summary, participants reported finding the opportunity to have a talking therapy during their

admission helpful in terms of helping them to understand themselves better, the opportunity for self-reflection and expression of feelings within a safe therapeutic relationship. Several participants also mentioned that boredom, or monotony of routine on the ward, was a motivation for them being interested in taking part in the study in the first place, and that this also provided an impetus to attend sessions regularly once they started therapy. Staff talked about valuing talking therapies as an 'adjunct' to standard care on the ward (i.e. medication and nursing care). Nurses also acknowledged that the business of their roles on the wards often limited the time they had to talk to patients, so a therapist offering extra 1:1 time was seen as very valuable, and something that could take the pressure off the nursing team for short periods during a shift.

6.10 Summary of key feasibility outcomes

8) Number of eligible participants identified over study period

   65 (22% of patients identified as initially eligible on admission (n=302), and 37% of people then assessed further for eligibility, n=175).

9) Total numbers recruited into trial and recruitment rate (benchmark of 80% of target)

   50 (83%)

10) Proportion of participants who dropped out during the intervention stage

    No participants stated they did not wish to continue with any further sessions offered during their admission. Therapy was suspended for one participant who became disinhibited towards the therapist during a session (and who then was discharged before safety could be assessed for future sessions).

11) Range and average number of sessions completed (including number of sessions attended as a proportion of those offered)

Range 1-5 sessions, mean number of sessions completed= 3.04 in SAT group, and 2.81 MBCI group. Total number of sessions attended/offered= 146/191 (76%).

12) Reasons for participants dropping out during the intervention stage

No drop-out during intervention stage.

13) Number lost to follow-up and reasons (benchmark of less than 20% to be set in line with previous studies)

At 6-month trial end-point: - 1 (2%) participant lost to follow-up for service use outcomes (readmission), 7 (14%) participants lost to follow-up for clinical measure outcomes (self-report questionnaires). Reasons for loss to follow-up: - not able to contact (n=2), DNA follow-up appointment (n=3), moved abroad (n=1), in prison (n=1).

14) Any unexpected adverse effects of participating in the trial

Three participants experienced adverse events, none of which was considered likely to be related to their participation in the trial.

Chapter 7: Results: Pilot Outcome Measures

7.1 Overview

This chapter reports the results on the pilot outcome measures for the trial. Results are firstly reported for service use outcomes, collected from clinical notes (see Table 16), and secondly for clinical measures (self-report questionnaires; Table 18). The overall re-admission rate at 6-month follow-up was 22% (11/49), and there was little difference between groups with 6 (24%) readmissions in the MBCI group vs. 5 (21%) in the SAT group. Relapse rate was calculated based on clinical note review and was defined as documented evidence of exacerbation in psychotic symptoms and associated change in clinical management, with or without admission. There was also little difference between groups on relapse rates – 6 (25%) in MBCI and 7 (29%) in SAT. Only 2 people (both in the SAT group) experienced a stand-alone episode of care with the home treatment team in the follow-up period (i.e. one that did not overlap with an inpatient admission). Time to first re-admission was slightly shorter in the MBCI group (mean of 80 days compared to 101 in the SAT group), and total number of occupied bed days was slightly lower (45 vs. 51 in the SAT group). However, 95% confidence intervals were large for both these variables, and overlapped between groups. Just over a third of participants were discharged under the care of an early intervention service (18/48) and almost all participants were still under the care of secondary mental health services at 6-month follow-up (46/48). A third of participants had at least one session of Cognitive Behavioural Therapy or Family intervention during the 6-month follow-up period. The number of people who had psychological therapy post-discharge was slightly higher in the MBCI group compared to the SAT group (10 (42%) vs. 6 (25%)).

On the clinical measures, in general symptom scores followed a pattern of improvement from baseline to post-therapy, but with little or no evidence of additional gains over the 6-month follow-up period after discharge. However, the recovery and mindfulness measures showed no change over time in either group. After adjusting for baseline score, there was little difference in mean scores at 6-month follow-up between groups on any measures, except for some of the voices measures, which indicated higher ratings of voice frequency in the MBCI group.

7.2 Service use outcomes

Service Use Outcomes are shown in Table 16.

Table 16 Results - Service Use Outcomes

	Up to F2 (0-6mths)	
Outcome	**MBCI (N=25[14])**	**SAT (N=24)**
8) Re-hospitalisation (≥1 OBD[15])		
- Yes	6 (24%)	5 (21%)
- No	19 (76%)	19 (79%)
9) Time to first re-admission (days)		
- Mean (SD)	80 (29)	101 (56)
- Range	41-122	58-176
- 95% CI	49-111	32-171
10) Total number of OBDs		
- Mean (SD)	45 (38)	51 (44)
- Range	2-83	4-117
- 95% CI	4-85	0-105
11) Episodes of care with crisis/home treatment team (HTT)[16]		
- Yes	0 (0%)	2 (8%)
- No	25 (100%)	22 (92%)

[14] Re-admission data not available for 1 participant (moved abroad)
[15] OBD=occupied bed day
[16] Stand-alone episodes of care only (i.e. not overlapping with inpatient admissions)

	MBCI (N=24)[17]	SAT (N=24)
12) No. of contacts with CMHT[18] - Mean (SD) - Range - 95% CI	 14 (7) 0-32 10-17	 13 (7) 3-34 10-16
13) Reference to therapy goal, which was shared with team - Yes - No	 21(88%) 3 (12%)	
14) Relapse Exacerbation in psychotic symptoms + change in clinical management - Yes - No	 6 (25%) 18 (75%)	 7 (29%) 17 (71%)

[17] Notes not available for 2 participants (1 moved abroad/1 in prison)
[18] CMHT=community mental health team; no. of contacts excluding therapy appointments

Additional outcomes not pre-specified in trial protocol: -		
15) Received therapy in community		
No therapy	14 (58%)	18 (75%)
Any therapy	10 (42%)	6 (25%)
CBT only	6 (25%)	4 (17%)
Family Intervention only	3 (13%)	2 (8%)
CBT + Family Intervention	1 (4%)	0 (0%)
16) Open to EIS[19] service on discharge		
- Yes	10 (42%)	8 (33%)
- No	14 (58%)	16 (67%)
17) Still open to CMHT at F2		
- Yes	23 (96%)	23 (96%)
- No	1 (4%)	1 (4%)

7.2.1 Readmission rates

The number of people who had at least one hospital re-admission at 6-month follow-up was very similar between groups (odds ratio=1.20, 95% CI: 0.312-4.61). Six people (24%) in the MBCI group, and 5 people (21%) in the SAT group were re-admitted to hospital in the 6 months following discharge. There was little difference in the average total number of OBDs between groups (MBCI – 45; SAT - 51). Episodes of care with home treatment teams (HTTs) were relatively rare as stand-alone episodes of care (i.e. not overlapping with an inpatient admission). Only 2 participants in the trial had HTT involvement, but did not require inpatient admission (both in the SAT group). Relapse rates were also similar between the 2 groups (odds ratio=0.81, 95% CI: 0.26-2.90). Six people (25%) in the MBCI group and 7 (29%) people in the SAT group met criteria for relapse, as assessed through clinical note review. Relapse was defined as an exacerbation in psychotic symptoms followed by a documented change in clinical management, as outlined in Chapter 4. In most cases there

[19] EIS=Early Intervention Service

was no difference between readmission/relapse ratings, as most relapses of psychotic symptoms resulted in an inpatient admission. There were a few exceptions to this. One participant in the MBCI group experienced 2 very short re-admissions during the follow-up period of only 1 bed day each. This was under a CTO (community treatment order) recall so that depot medication could be administered, although the participant was not experiencing any relapse in symptoms. Another participant in the MBCI group was judged to be relapsing in the community, and so a recommendation was made for a voluntary admission. However, there was a delay as no psychiatric bed could be found. After a few days, the person's mental state stabilised and they were not re-admitted to hospital in the end. In the SAT group, 7 people met criteria for relapse, whereas only 5 people were re-admitted to hospital (the additional 2 people being those who had stand-alone episodes of care with the HTT). These data are summarised in Figure 11, which also shows the breakdown in numbers between the F1 and F2 period (0-3 months, and 3-6 months), as well as the overall follow-up period (0-6 months).

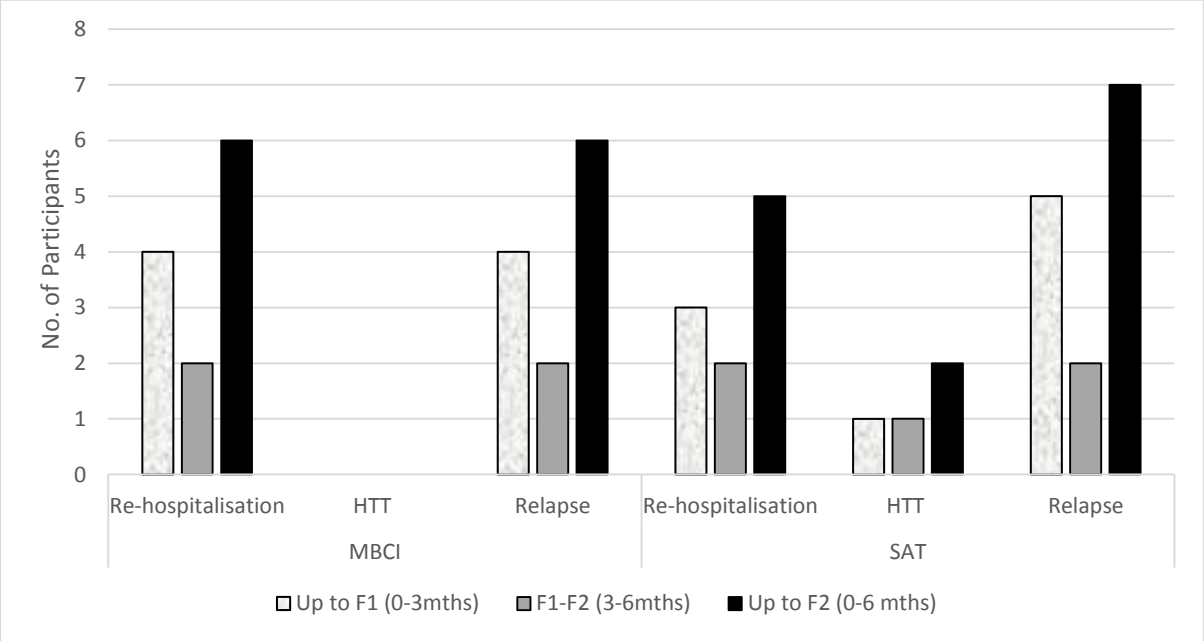


Figure 11 Re-hospitalisation, HTT and relapse data by group

As described in the analysis plan in chapter 5, the 6-month follow-up period was calculated from discharge date, rather than randomisation date, to account for varying lengths of admission. As a secondary analysis, readmission rates at 6-month follow-up were re-calculated using randomisation date as the anchor, rather than discharge date. This resulted in 5 readmissions in the MBCI group (20%) and 3 readmissions in the SAT group (12%). The slightly higher number in the MBCI group reflects the fact that time to readmission was somewhat shorter in the MBCI group (mean average 80 days) compared to the SAT group (mean average 101 days).

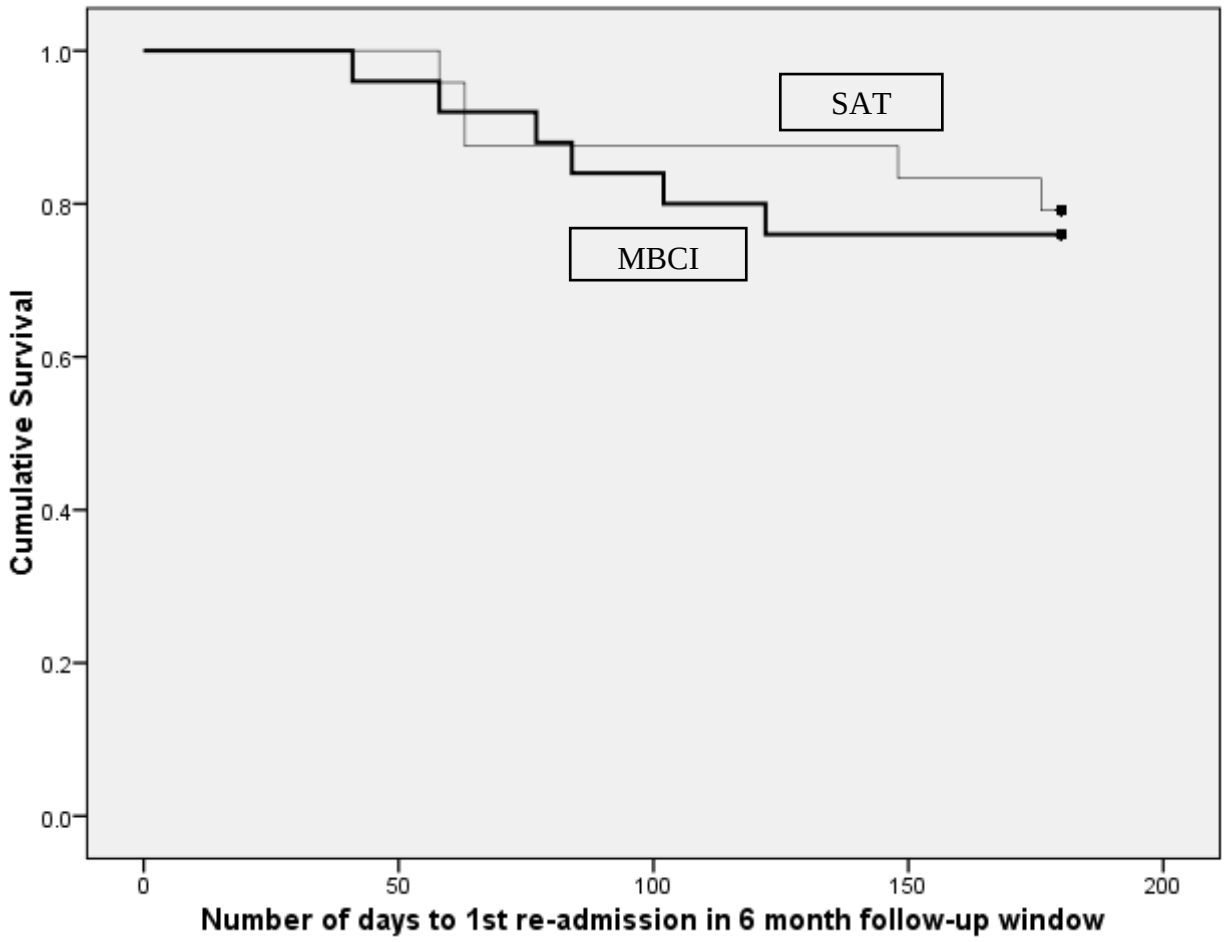


Figure 12 Survival curve of re-admission to hospital: Kaplan-Meier Plot

Time to re-admission is shown in Figure 12 as a Kaplan-Meier plot. This shows that the survival curve is similar for both groups. The re-admissions in the MBCI group occur slightly earlier than in the SAT group (between 41 and 122 days post-discharge for MBCI

compared to between 58 and 176 days post-discharge for SAT). However, due to small numbers this may not be a reliable finding and should be interpreted with caution. The results of a Log Rank test confirmed that there was no statistically significant difference between the survival curves for the 2 groups (χ^2 (1, N=49) =0.09, p=0.76).

It is of interest to characterise the clinical and demographic profiles of the 11 people who were re-admitted in the 6-month follow-up period, across both groups. Nine of them lived alone (81%), compared to 48% in the overall sample. Six out of the 11 (55%) had housing problems identified on admission (i.e. homelessness, rent arrears), compared to 39% in the overall sample. Almost all of them (10/11 – 91%) had a history of previous inpatient admissions at baseline, compared to 70% in the overall sample. Only 2 out of the 11 were open to Early Intervention services on discharge (18%), compared to 30% in the general sample. Overall, this picture points to a group of people experiencing a more adverse social environment, with more chronic difficulties including a history of previous hospital admissions.

7.2.2 Risk factors for time to readmission

As a secondary analysis, Cox regression was used to explore possible factors associated with time to re-admission during the 6-month follow-up period. In model 1, therapy group (MBCI vs. SAT) was entered as a co-variate on its own. This analysis confirmed that therapy group did not significantly predict time to readmission in the 6 months post-discharge (hazard ratio=0.83, 95% CI 0.25-2.73, p=0.761). In model 2, three clinically relevant (binary) variables were entered as co-variates. From the baseline data, 1) any previous admission, and 2) any admission in the previous 12 months, were both entered on the basis that people with previous admissions might be at higher risk for quicker re-admission. The third variable was discharge to an early intervention service, on the basis that people might receive a better standard of psychosocial care from such teams compared to standard community health teams. In fact, the results of the Cox regression indicated that none of these 3 variables was a significant predictor of time to re-admission (Table 17).

Table 17 Cox Regression Model: Clinical variables

	Hazard Ratio (95% CI)	**P value**
Any previous admissions[20] (yes/no)	0.41 (0.04-3.81)	0.433
Admission in previous 12 months[20] (yes/no)	0.41 (0.12-1.48)	0.174
Discharged to Early Intervention Service	2.31 (0.48-11.1)	0.297

7.2.3 Contact with services post-discharge

Additional data were collected on participants' contact with mental health services in the 6 months post-discharge. This helps to contextualise the re-admission/relapse data (Table 16). All participants (100%) were discharged to a CMHT immediately upon discharge. Only 44% of participants were open to a CMHT on admission, so this constituted a new referral, or a re-referral, for just over half the participants. Approximately a third of participants were discharged to an early intervention service (EIS) (18/48). The overall number of CMHT contacts in the 6 months post-discharge did not differ between EIS and non-EIS participants (mean average of 13.7 vs 13.8 respectively). For the MBCI group, where a goal from therapy was shared with their care team on discharge, there was some reference to the goal in the notes for most people (21/24). However, it is important to note that this included any reference to the goal in general, rather than being a measure of whether the goal was achieved or not. The vast majority of participants were still under the care of a CMHT at 6-month follow-up (46/48). Two participants (1 in each group) were discharged back to the care of their GP by mutual consent with their CMHT as they did not feel they needed continuing care from secondary services.

[20] Not counting the admission in which they took part in the trial

Approximately a third of participants had psychological therapy (either CBT or FI) in the 6 months after discharge. Participants in the MBCI group were twice as likely to have therapy as those in the SAT group (odds ratio=2.14, 95% CI: 0.63-7.33). However, the odds ratio 95% confidence interval is large and includes 1, indicating that this may not be a reliable finding. Those in EIS services were 3 times more likely to receive a psychological therapy in the 6 months post-discharge, compared to those not in EIS services (odds ratio=3.29, 95% CI: 0.94-11.5). However, as the 95% confidence interval includes 1, this may also not be a reliable finding.

7.3 Clinical measures outcomes

7.3.1 Descriptive Statistics

This section reports the data from the clinical outcome measures (self-report questionnaires). As the proportion of missing data was less than 20% at all time points, there was no attempt to account for missing data using imputation methods. Furthermore, everyone in the trial received at least one therapy session (minimum therapy dose), therefore treatment compliance could not have been a predictor of drop-out/missing data. In line with the statistical analyses plan, all analyses were conducted on an intention-to-treat (ITT) basis, analysing participants as randomised, regardless of actual treatment received. However, for this trial, intention-to-treat and per protocol methods of analysis were in fact equivalent, as all participants received the minimum therapy dose. Where individual items were missing in a scale, pro-rating was successfully applied in every case as no more than 20% of items were missing. The number of participants with pro-rated data was low (N=3), and in all cases related to a maximum of 1 questionnaire measure per assessment point.

In line with the analysis plan, descriptive statistics were first calculated based on unadjusted means, before adjusting for baseline score. Unadjusted means are shown in Table 18, by assessment point and treatment group (MBCI vs. SAT). Data are presented separately for beliefs (delusions) and voices for the self-rating psychotic symptom scales. Participants reported delusions more commonly than voices, so the sample size is larger for the delusions ratings.

Table 18 Questionnaire measures (unadjusted means)

	T1 (Baseline)		**T2 (End of therapy)**		**F1 (3-month follow-up)**		**F2 (6-month follow-up)**	
	MBCI N=26	**SAT** N=23	**MBCI** N=23	**SAT** N=23	**MBCI** N=20	**SAT** N=20	**MBCI** N=21	**SAT** N=19
Self-rating of psychotic symptoms (Beliefs)								
Frequency (1-7)								
Mean S.D (95% CI)	5.58 1.65 (4.91-6.24)	5.65 1.34 (5.07-6.23)	3.17 2.15 (2.25-4.1)	3.61 2.08 (2.71-4.51)	3.25 2.33 (2.16-4.34)	3.00 2.36 (1.89-4.11)	2.57 1.89 (1.71-3.43)	2.63 2.03 (1.65-3.61)
Distress (0-10)								
Mean S.D (95% CI)	6.69 3.42 (5.31-8.07)	7.70 3.42 (6.22-9.17)	2.83 2.82 (1.61-4.05)	5.26 3.40 (3.79-6.73)	3.70 3.94 (1.86-5.54)	2.90 3.43 (1.29-4.51)	2.24 3.21 (0.78-3.70)	2.16 2.97 (0.73-3.59)
Believability (0-10)								
Mean S.D (95% CI)	8.15 3.08 (6.91-9.40)	7.48 3.38 (6.02-8.94)	4.70 3.61 (3.13-6.26)	6.00 3.45 (4.51-7.49)	3.95 4.12 (2.02-5.88)	3.90 4.41 (1.84-5.96)	4.38 4.41 (2.37-6.39)	3.74 4.01 (1.80-5.67)

	T1		T2		F1		F2	
	MBCI N=12	**SAT** N=12	**MBCI** N=11	**SAT** N=12	**MBCI** N=9	**SAT** N=11	**MBCI** N=9	**SAT** N=10
Self-rating of psychotic symptoms (Voices)								
Frequency (1-7)								
Mean S.D (95% CI)	5.08 1.62 (4.06-6.11)	5.58 1.5 (4.63-6.54)	4.09 2.07 (2.70-5.48)	3.42 2.11 (2.08-4.76)	3.00 2.18 (1.32-4.68)	2.73 2.15 (1.28-4.17)	4.22 2.33 (2.43-6.02)	2.30 1.95 (0.91-3.69)
Distress (0-10)								
Mean S.D (95% CI)	6.50 3.03 (4.57-8.43)	8.42 2.50 (6.83-10.01)	3.27 3.10 (1.19-5.36)	3.75 3.82 (1.32-6.18)	2.22 3.15 (0.00[21]-4.65)	1.18 2.44 (0.00-2.82)	3.00 4.03 (0.00-6.10)	1.80 2.62 (0.00-3.67)
Believability (0-10)								
Mean S.D (95% CI)	6.83 3.24 (4.77-8.89)	6.17 3.22 (4.12-8.21)	4.00 3.58 (1.6-6.40)	5.17 4.26 (2.46-7.87)	3.11 3.98 (0.05-6.17)	2.45 3.75 (0.00-4.97)	4.78 4.60 (1.24-8.32)	2.90 4.01 (0.03-5.77)
HPSVQ (0-36) (Hamilton Program for Schizophrenia Voices Questionnaire)								
Mean S.D (95% CI)	20.67 8.49	25.5 4.78	16.45 8.10	13.00 10.87	9.44 8.99	8.55 9.13	13.63[22] 10.66	5.70 7.60

[21] Lower Bound Confidence Interval truncated to 0 where calculated value is negative to indicate floor effect

[22] N=8 in MBCI group for HPSVQ as 1 participant failed to complete all measures in the F2 assessment

	(15.27-25.06)	(22.46-28.54)	(11.01-21.90)	(6.09-19.91)	(2.54-16.4)	(2.41-14.7)	(4.71-22.5)	(0.26-11.14)
	T1		**T2**		**F1**		**F2**	
	MBCI N=24	**SAT** N=26	**MBCI** N=23	**SAT** N=24	**MBCI** N=20	**SAT** N=21	**MBCI** N=20[23]	**SAT** N=20
Mood (DASS-21; Depression, anxiety & stress) **Depression (0-42)**								
Mean S.D (95% CI)	15.77 12.44 (10.75-20.79)	20.75 14.62 (14.58-26.92)	9.04 10.48 (4.51-13.57)	15.42 12.28 (10.23-20.60)	13.7 10.53 (8.77-18.63)	11.81 12.18 (6.27-17.35)	12.60 11.86 (7.05-18.15)	13.80 12.66 (7.87-19.73)
Anxiety (0-42)								
Mean S.D (95% CI)	15.85 13.25 (10.49-21.20)	19.75 11.67 (14.82-24.68)	10.00 8.66 (6.26-13.74)	15.17 12.17 (10.03-20.31)	8.5 8.15 (4.68-12.32)	9.52 10.52 (4.73-14.31)	7.70 10.61 (2.74-12.66)	10.40 10.21 (5.62-15.18)
Stress (0-42)								
Mean S.D (95% CI)	19.31 11.76 (14.56-24.06)	25.58 11.57 (20.7-30.47)	15.04 9.36 (11.00-19.09)	17.58 10.23 (13.26-21.90)	13.50 11.20 (8.26-18.74)	9.62 11.57 (4.35-14.89)	11.40 11.75 (5.90-16.90)	12.40 9.37 (8.01-16.79)

[23] 1 MBCI participant failed to complete all questionnaire measures in the F2 assessment

	T1		T2		F1		F2	
	MBCI N=24	**SAT** N=26	**MBCI** N=23	**SAT** N=24	**MBCI** N=20	**SAT** N=21	**MBCI** N=20	**SAT** N=20
Recovery (0-88) (QPR; Questionnaire about the Process of Recovery) Mean S.D (95% CI)	 65.31 13.25 (69.96-70.66)	 60.58 18.75 (52.67-68.5)	 67.09 13.94 (61.06-73.11)	 61.00 13.20 (55.42-66.58)	 63.40 15.04 (56.36-70.44)	 63.52 15.26 (56.58-70.47)	 62.20 20.45 (53.49-68.51)	 61.00 16.06 (53.49-68.51)
	MBCI N=24	**SAT** N=26	**MBCI** N=23	**SAT** N=23	**MBCI** N=20	**SAT** N=21	**MBCI** N=20	**SAT** N=19[24]
Mindfulness (0-96) (SMQ; Southampton Mindfulness Questionnaire) Mean S.D (95% CI)	 56.27 14.96 (50.23-62.31)	 47.25 14.67 (41.05-53.45)	 58.13 12.28 (52.82-63.44)	 53.26 14.08 (47.17-59.35)	 57.50 11.88 (51.94-63.06)	 57.57 16.52 (50.05-65.09)	 55.00 11.81 (49.47-60.53)	 57.05 12.84 (50.86-63.24)

Data for each questionnaire measure are presented in graphical form in Figure 13 to Figure 18 in the following section.

[24] 1 participant in the SAT group did not complete the SMQ at F2

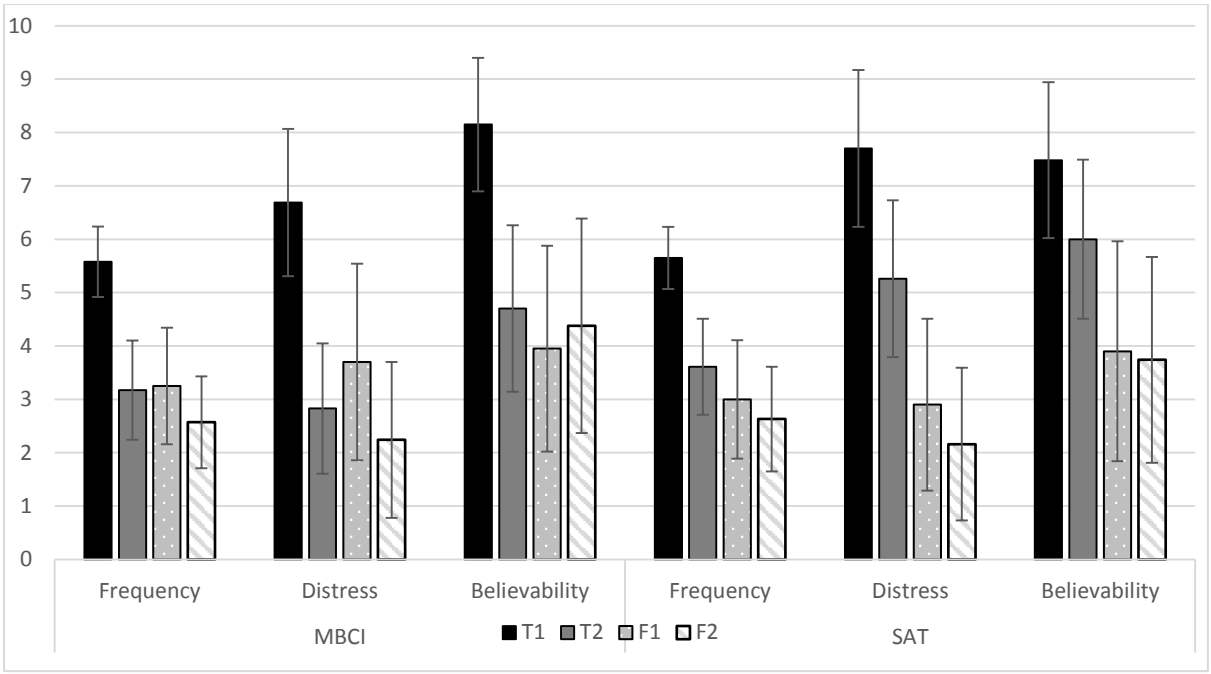


Figure 13 Psychotic Symptoms (Beliefs); error bars 95% CI

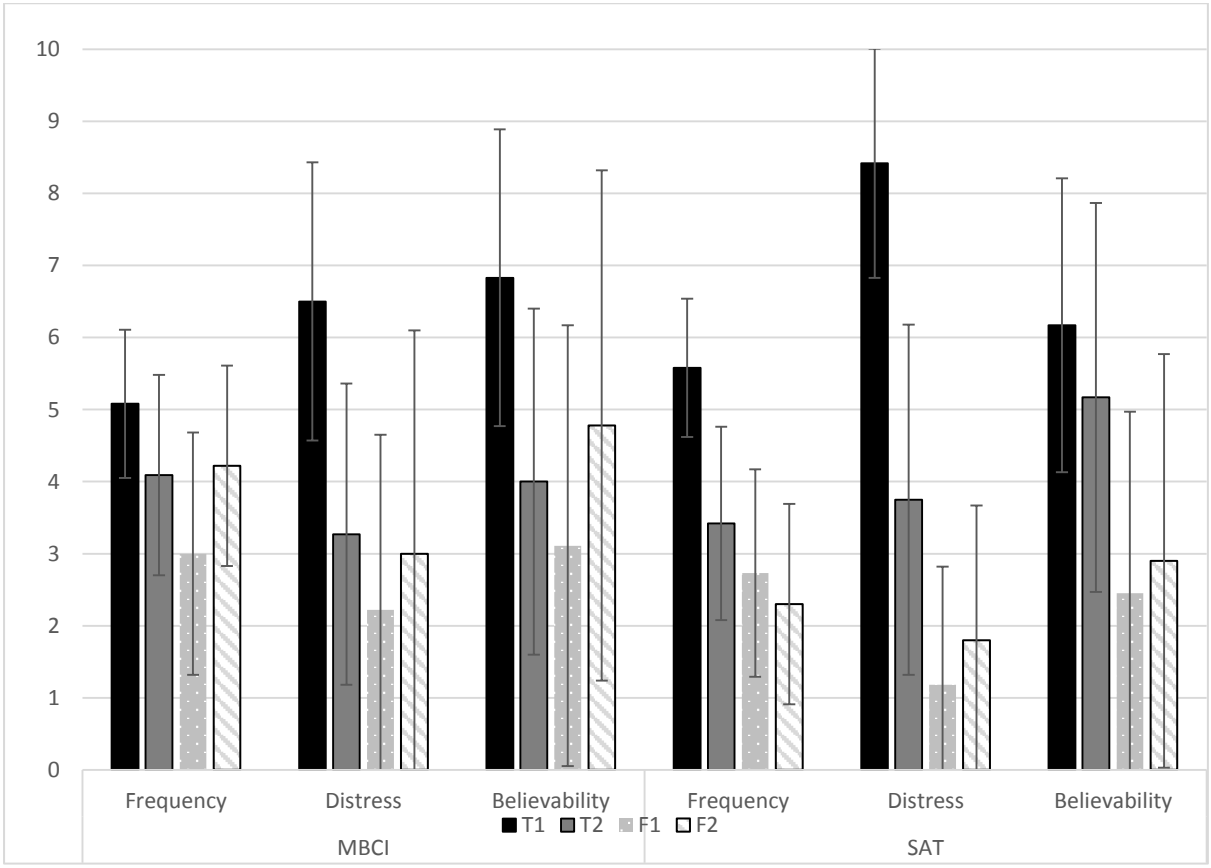


Figure 14 Psychotic Symptoms (Voices); error bars 95% CI

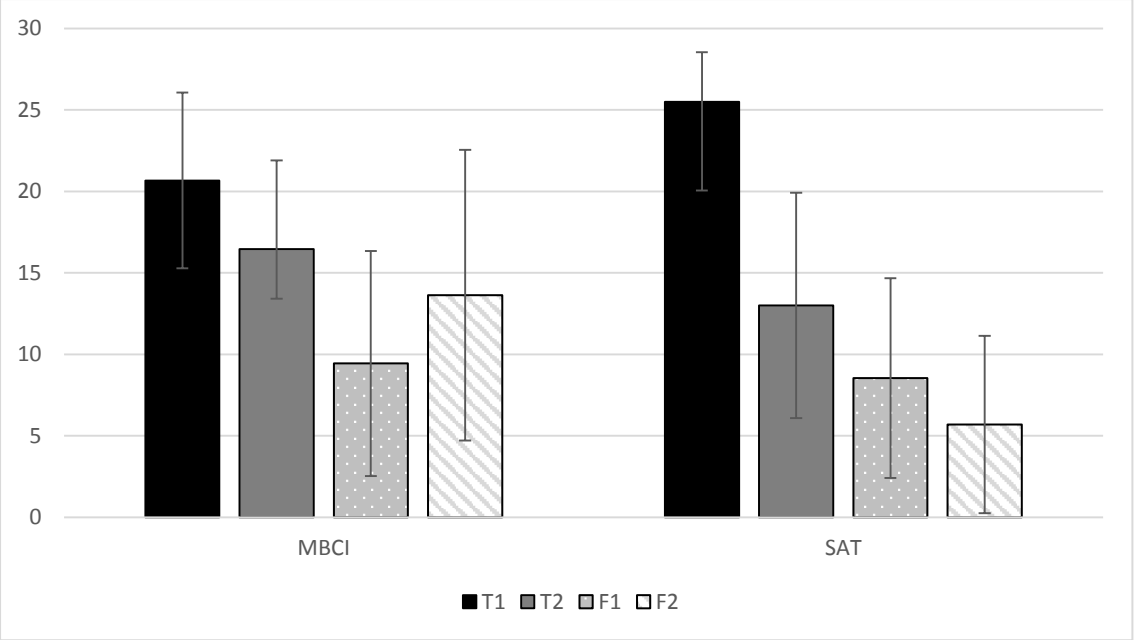


Figure 15 Hamilton Voices Questionnaire; error bars 95% CI

As shown in Figure 13, ratings of frequency, distress and believability for delusions all reduced from baseline (T1) to end of therapy (T2) which would be as expected as the crisis resolves and the person's mental state improves over the course of their admission. In the MBCI group, the 95% error bars are non-overlapping from T1 to T2 for frequency, distress and believability, whereas this is only the case for frequency within the SAT group. Within both groups, the 95% error bars all overlap for time-points T2-F2, indicating that there may not be any reliable difference in scores between these time-points. This pattern of results is mirrored in the data for voices (Figure 14), however as data are available for a smaller number of participants, the 95% error bars have larger margins, and so the data are harder to interpret. Small numbers also limit interpretation of the HPSVQ scale (Hamilton Program for Schizophrenia Voices Questionnaire). In general, scores reduce over time from T1 to F1, before levelling off between F1 and F2 (Figure 15). In the MBCI group, the 95% error bars overlap across all 4 time points. However, in the SAT group, the 95% error bars are non-overlapping between T1 and T2. In general, the psychotic symptom data are consistent with a pattern of recovery and improvement over the course of the inpatient admission (T1-T2), but there is not much evidence of additional gains over the follow-up period 6 months post-discharge.

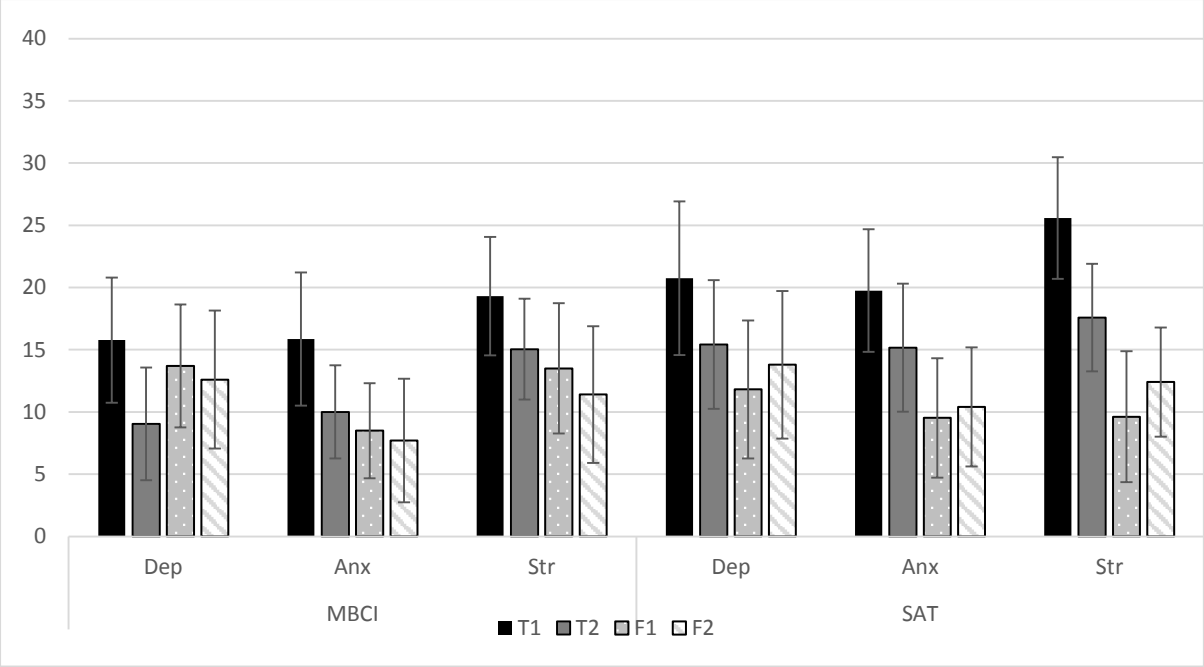


Figure 16 Mood (DASS21); error bars 95% CI

For the mood data (depression, anxiety and stress), the general pattern of improvement from T1-T2 was also seen, with a flattening-off effect between T2 and F2 (Figure 16). For the MBCI group, 95% error bars were over-lapping between all time points across depression, anxiety and stress. However, in the SAT group the 95% error bars were non-overlapping between T1 (baseline) and F1/F2 (follow-up), for anxiety and stress, although not for depression. For both groups, average depression scores were in the moderate range (14-20) at Tl (baseline) and in the mild range (10-13) at F2 (6-month follow-up). Average anxiety scores were in the severe range (15-19) at T1 for both groups, and this dropped to the normal range (0-7) at F2 in the MBCI group and the moderate range (10-14) for the SAT group. Average stress scores were in the moderate range (19-25) at T1, and dropped to the normal range (0-14) at F2 in both groups.

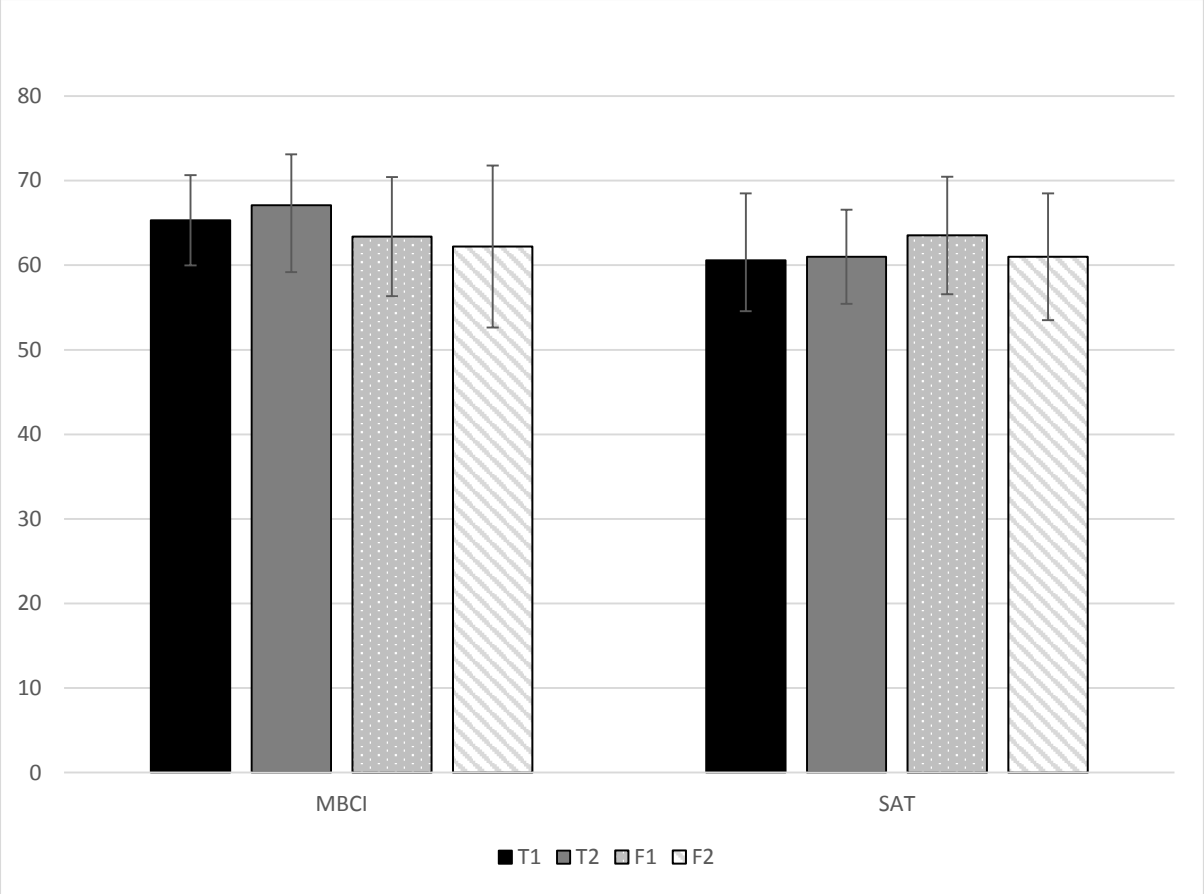


Figure 17 Recovery (QPR); error bars 95% CI

Interestingly, there was no evidence of any change over time in people's self-rated recovery (Figure 17). Error bars are overlapping within and between both groups over each time point from T1-F2. There are no formal categories of scores for the QPR. However, the authors of the scale quote a mean average score of 50.13 (standard deviation 11.56, range 15-75) in a sample of 335 people with experience of psychosis (Law *et al.*, 2014). In this study, the T1 score (baseline) was higher than 50 for both the MBCI and SAT group (65 & 60 respectively), with higher scores indicating better subjective recovery. Mean scores in both groups were above 60 at all 4 assessment points.

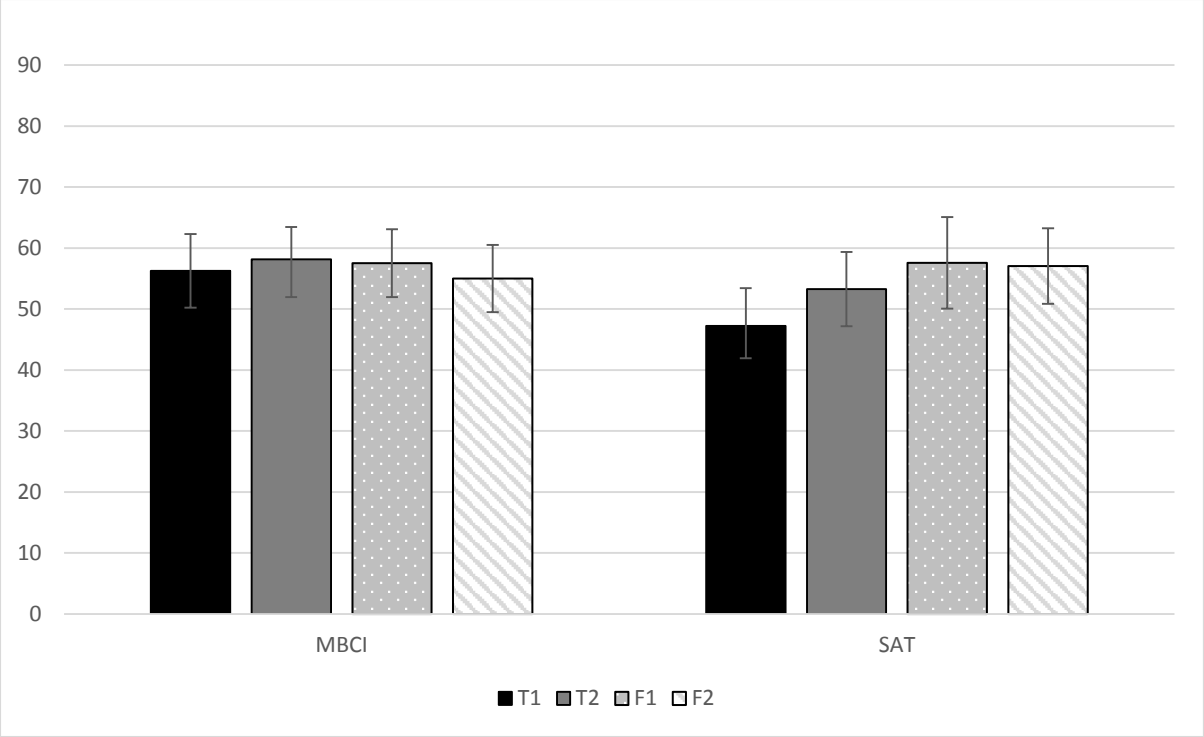


Figure 18 Mindfulness (SMQ); error bars 95% CI

A similar pattern is seen for the Mindfulness scores, with little change in either group across all time points (Figure 18). Error bars are overlapping within and between both groups over each time point from T1-F2. Previous studies have reported scores on the SMQ in clinical psychosis samples of mean=37 (N=122, Chadwick *et al.* (2008)) and mean=47 (N=83; Peters *et al.* (2016)). Participants in both MBCI and SAT groups scored above this (indicating greater mindfulness of thoughts or images). In the MBCI group, the mean score was 56 at T1 (baseline), and 55 at F2 (6-month follow-up). In the SAT group, the mean score was 47 at T1, and 57 at F2.

7.3.2 Adjusting for baseline score

In line with the statistical analysis plan, a secondary analysis on the clinical measures was calculated using the general linear model, co-varying for baseline score and treatment condition. The dependent variable in each case was score at F2 (6 month-follow-up), with 2 independent variables: treatment condition (MBCI vs. SAT) as a fixed factor and score at T1 (baseline score) as a co-variate. Co-efficient estimates (B) of the differences in means between treatment condition at F2, with 95% confidence intervals, are reported in Table 19.

Table 19 Coefficient estimates (B) of difference in group means at 6-month follow-up

	MBCI[25] (N=21) **SAT (N=19)**
Self-rating of psychotic symptoms (Beliefs) **Frequency** **Coefficient estimate (B)** **(95 % CI)** **Distress** **Coefficient estimate (B)** **(95 % CI)** **Believability** Coefficient estimate (B) (95 % CI)	 -0.02 -1.18 to 1.15 -0.46 -2.27 to 1.34 -0.38 -2.69 to 1.93
	MBCI (N=9) **SAT (N=10)**
Self-rating of psychotic symptoms (Voices) **Frequency** **Coefficient estimate (B)** **(95 % CI)**	 -2.612 -4.76 to -0.48

[25] Reference category for comparison in group means is MBCI (i.e. positive values favour MBCI)

Distress **Coefficient estimate (B)** **(95 % CI)** **Believability** **Coefficient estimate (B)** **(95 % CI)** **HPSVQ** **(Hamilton Program for Schizophrenia Voices Questionnaire)** **Coefficient estimate (B)** **(95 % CI)**	 -2.00 -5.39 to 1.38 -2.33 -5.46 to 0.81 -11.85 -20.82 to -2.89
	MBCI (N=20) **SAT (N=20)**
Mood (DASS-21; Depression, anxiety & stress) **Depression** **Coefficient estimate (B)** **(95 % CI)** **Anxiety** **Coefficient estimate (B)** **(95 % CI)** **Stress** **Coefficient estimate (B)** **(95 % CI)**	 1.27 -6.73 to 9.27 2.23 -4.17 to 8.63 0.71 -6.39 to 7.81

	MBCI (N=20) **SAT (N=20)**
Recovery (QPR; Questionnaire about the Process of Recovery) Coefficient estimate (B) (95 % CI)	 1.06 -10.56 to 12.69
	MBCI (N=20) **SAT (N=19)**
Mindfulness **(0-96)** **(SMQ; Southampton Mindfulness Questionnaire)** **Coefficient estimate (B)** **(95 % CI)**	 3.92 -4.57 to 12.42

As can be seen in Table 19, there are only small differences in mean scores between the MBCI and SAT groups at 6 month-follow-up, after controlling for baseline score. The confidence intervals cross 0 for most measures indicating no significant difference between groups. The only exception to this is for some of the voice measures (self-rated frequency of voices and HPSVQ score). As the sample size is smaller for the voice measures, since only about half of participants reported hearing voices at baseline, these results should be interpreted with caution, but may indicate that the MBCI group in fact reported more frequent voices at 6-month follow-up compared to the SAT group. However, it is important to note that in the MBCI group, voice frequency and HPSVQ scores were still lower at 6-month follow-up than at baseline and discharge.

7.4 Summary of key findings on the pilot outcome measures

- The total re-admission rate at 6-month follow-up was 22%, and the number of re-admissions in each group was similar (6 in the MBCI group and 5 in the SAT group).
- The relapse rate (6 in the MBCI group and 7 in the SAT group) was similar to the re-admission rate, indicating a documented relapse in psychotic symptoms without a subsequent inpatient admission was relatively rare.
- A third of participants had psychological therapy in the 6 months following discharge, and the rates were slightly higher in the MBCI group compared to the SAT group (10 vs. 6 people).
- Symptom measures showed an improvement in scores from baseline to post-therapy, but little evidence of additional gains over the 6-month follow-up period.
- After adjusting for baseline score, there was little difference in mean scores at 6-month follow-up between groups on any measures, except for higher ratings of voice frequency in the MBCI group.
- Neither group showed increased recovery or mindfulness scores over the course of the study.

Chapter 8: Discussion

8.1 Overview

This chapter first re-caps the aims and objectives of the study, before summarising the main findings, relating to both feasibility and pilot outcome measures. Strengths and limitations of the study are considered, relating to the design of the study, and the generalisability of the findings. The results of this study are then discussed in relation to previous inpatient studies, including both UK and US trials. Finally, the implications for planning of future trials to further evaluate MBCI are discussed, as well as implications for inpatient and crisis research in general.

8.2 Evidence before this study – Systematic Review Findings

There is an established evidence base for psychological therapies for psychosis, including CBT for psychosis and Family Intervention. However, current guidelines are based mainly on studies conducted in community, not inpatient settings. Therapies are often adapted for delivery within inpatient settings from standard protocols, or are based on untested novel protocols. The evidence base for the added value of psychological therapies for psychosis on acute psychiatric wards is unclear. A systematic scoping review of psychological therapies for psychosis on acute psychiatric wards was therefore conducted (Chapter 2). It was found that many different types of therapies have been evaluated with varying study quality. There were significant sources of heterogeneity in the existing literature, including the types of outcome assessments used. Only a minority of studies specifically focused on evaluating impact on readmission/relapse. Promising pilot trials from the US on the use of brief inpatient therapies to reduce short-term readmission rates had not yet been replicated in UK NHS settings.

8.3 Aims and objectives of study

The amBITION study was a feasibility randomised controlled trial (RCT) of a manualised brief talking therapy on acute inpatient wards (Mindfulness-Based Crisis Intervention; MBCI). Inpatients were eligible for the study if they reported at least one positive psychotic symptom, and were willing and able to engage in a talking therapy. In addition to treatment as usual (TAU), participants were randomly allocated to receive either MBCI or a control intervention (Social Activity Therapy; SAT) which was based on doing activities on the ward with the therapist. Participants received between 1 and 5 sessions of therapy during their inpatient admission. The primary objective of this study was to find out whether it was possible to carry out this kind of trial successfully within UK NHS inpatient settings and whether patients found it an acceptable intervention (i.e. high satisfaction ratings and low drop-out during therapy). The secondary objective was to collect pilot data on clinical outcomes, including hospital readmission and symptom measures. Participants were followed up 3 and 6 months after discharge.

8.4 Summary of findings

8.4.1 Feasibility outcomes

Fifty participants were randomised into the trial over a 15-month recruitment period (83% of pre-set target). There was no pre-set recruitment window, however recruitment rate was mainly limited by resource issues (i.e. PJ as the single trial therapist with no additional staff to carry out the research assessments). All participants received at least one therapy session, and no-one dropped out during the intervention stage. The average number of sessions completed was 3 in both arms of the trial. At 6-month trial end-point, only one participant was completely lost to follow-up as they moved abroad immediately upon discharge. Data on hospital re-admission was available for the remaining 49 participants (98% follow-up). Follow-up rate for clinical outcomes (self-report questionnaires) was 86%, which exceeded the 80% benchmark set in the trial protocol. Three participants experienced adverse events, none of which were judged to be related to their participation in the trial. Satisfaction with therapy was high in both the MBCI and SAT groups. Forty participants (80%) completed feedback questionnaires at the end of the study, and five participants (10%; three SAT, two MBCI) went on to complete an interview with a service user researcher. Eight members of staff (three ward managers, two staff nurses and three consultant psychiatrists) completed feedback interviews with two independent assistant psychologists. Qualitative feedback highlighted reasons for people wanting to take part in the study, what they found helpful about an inpatient talking therapy, and what staff thought was helpful about talking therapies being offered on wards.

8.4.2 Pilot outcome measures

The overall re-admission rate at 6-month follow-up was 22% (11/49), and there was little difference between groups (6 readmissions in the MBCI group (24%) vs. 5 (21%) in the SAT group). Readmission rate based on psychiatric admission alone (for any reason), was similar to relapse rate based on clinical note review. Just over a third of participants were discharged under the care of an early intervention service (18/48) and almost all participants were still under the care of secondary mental health services at 6-month follow-up (46/48). A third of participants had at least one session of Cognitive Behavioural Therapy or Family intervention

during the 6-month follow-up period. The number of people who had psychological therapy post-discharge was slightly higher in the MBCI group compared to the SAT group (10 vs. 6). On the clinical measures, in general symptom scores followed a pattern of improvement from baseline to post-therapy, but with little evidence of additional gains over the 6-month follow-up period after discharge. After adjusting for baseline score, there was little difference in mean scores at 6-month follow-up between groups on any measures, except for some of the voices measures, which favoured SAT. Measures of recovery and mindfulness showed no change for either group over the course of the study.

8.5 Comparison to previous studies

8.5.1 Feasibility outcomes

The current findings confirm the results of previous studies that it is possible to recruit and retain people in therapy trials within inpatient settings. A direct comparison between this study and the US pilot trials of brief therapies (Bach and Hayes, 2002, Gaudiano and Herbert, 2006) on key feasibility outcomes is limited by the information available in the previous trial reports. The current trial identified 65 eligible participants from 590 consecutive acute admissions (of whom 302 met initial eligibility criteria). Bach and Hayes randomised 80 participants, and reported that 1 in 5 people approached agreed to participate (suggesting that 400 people in total were approached). However, it is not clear to what degree patients were pre-screened for eligibility, for example by consultation with the team or clinical note review. The Gaudiano study reports that 40 people were recruited from a total of 60 people who were assessed for eligibility, suggesting in contrast a high level of pre-screening (as 67% of people approached agreed to take part, compared to 20% in the Bach study). Treatment drop-out was low in the Gaudiano study, with 1 drop-out in each treatment arm. Treatment drop-out is not reported in the Bach study, and the absence of a CONSORT diagram also limits understanding of drop-out in the follow-up stage. The average (3) and range (1-5) of therapy sessions completed in this study matches exactly the results of the Gaudiano study. Comparable data on average number of sessions, and proportion of people completing all 4 offered sessions, are not reported in the Bach study. However, overall the findings of the current study that the treatment is highly acceptable to inpatients in terms of low drop-out rates during therapy, is consistent with these previous findings. This contrasts with findings

from some of the previous UK inpatient studies offering longer courses of treatment. For example, in the North Wales trial (Startup *et al.*, 2004), 45% of people discontinued treatment prematurely when up to 25 sessions were offered (with a minimum of 12 planned sessions).

Retention in this trial was slightly higher than in previous studies. At 6-month trial end-point, 1 (2%) participant was lost to follow-up for the main service use outcome (readmission), and 7 (14%) participants were lost to follow-up for clinical outcomes (questionnaire measures). In the Bach study, the loss to follow-up at the 4-month trial end-point was 12.5% for the primary outcome (readmission); this was mainly due to people moving out of the area. This might suggest a more mobile population in the area where the study was conducted (Reno, in the US state of Nevada). Questionnaire measures were also completed with participants at the 4-month follow-up, but it is unclear how many people completed these measures, and whether this number was lower than for the number of people for whom readmission data were available. In the Gaudiano study, loss to follow-up was only 5% for readmission data at 4-month follow-up. Questionnaire measures were not taken at follow-up, only at baseline and immediately post-treatment.

8.5.2 Pilot outcome measures

This study found no difference between readmission rates at 6-month follow-up, which is in direct contrast to the findings of the previous US pilot trials. Bach and Hayes report that 20% of the participants in the treatment arm were re-admitted to hospital at 4-month follow-up, compared to 40% in the control arm. Gaudiano and Herbert report similar re-admission rates (28% in the treatment group vs. 45% in the control). The most obvious difference between the current trial, and the US trials, is that the US baseline re-admission rate seems to be much higher. This is likely to be linked to shorter admissions in the US, and differences in community care, as the health-care system is funded differently than in the UK. Length of stay is not reported in the Bach study; however, it is reported that the 4 therapy sessions took place at 2-3 day intervals, suggesting a therapy envelope of around 2 weeks. Average length of stay in the Gaudiano study was 10 days, which was considerably shorter than in the current trial (31 days). It is possible that this kind of brief intervention has a demonstrable effect on readmission rates only in a care context in which admissions are short, therapy sessions are therefore closer together, and the baseline readmission rate is high. Another factor to

consider is that both the US studies used TAU (or a slightly 'enhanced' TAU in the Gaudiano study) as the control condition, which was a less robust control for non-specific therapy factors than the social activity therapy (SAT) used in this trial. It is possible MBCI would have shown a reduced re-admission rate compared to a TAU comparator, but no advantage over an 'active' therapy control condition. Future studies could test this by adding a TAU arm to the design (as in the SOCRATES study, which had 3 treatment arms, including CBT, supportive counselling and TAU). The only subsequent trial which attempted to directly replicate the Bach/Gaudiano trials was done by Tyrberg *et al.* (2016) in Sweden. This was a small study however, with only 22 participants (12 in the ACT condition and 10 in TAU). One person was re-admitted in the ACT group at 4-month follow-up, and four in the TAU group. Although the proportion re-admitted was much lower in the ACT condition compared to the TAU condition (9% vs. 40%), the 95 % confidence intervals were very wide for the odds ratio given the small sample size, and the results were not statistically significant. The average length of admission in the Swedish study was reported to be approximately three weeks.

Direct comparison of re-admission rates with the UK inpatient studies discussed in Chapter 1 is not possible. This is because they all used much longer courses of therapy than 5 sessions, and report re-admission to hospital over longer time periods than 6 months. In the SOCRATES trial, they report readmission rates of 33% in the CBTp group and 36% in the TAU group at 18-month follow-up (Tarrier *et al.*, 2004). The North Wales trial reported readmission rates of 61% in the CBTp and 70% in the TAU group at 2-year follow-up (Startup *et al.*, 2005). The higher rates in the latter study are partly due to the longer follow-up period, but are also likely attributable to a difference in clinical sample (early intervention in the SOCRATES trial vs. a more mixed, chronic group in the North Wales study). Drury and colleagues report 5-year readmission data for their trial, but do not give numbers for the proportion of people in each group experiencing at least one re-admission (the average number of admissions was just over 1 per participant; Drury *et al.* (2000)).

The findings on the clinical outcome measures will be briefly considered here. There was a general trend for improvement in symptom scores over time (psychotic symptoms and mood), which would be an expected consequence of admission. Most of the improvement appeared to happen between baseline (T1) and end of therapy/discharge (T2) with a general

flattening out in scores over the 6-month follow-up period. There was little indication of a significant difference between the MBCI and SAT groups on any symptom measures, although formal significance testing was not applied due to the trial not being powered for efficacy. After adjusting for baseline score, the only measures on which the 95% confidence interval of the parameter estimate did not include 0 at 6-month follow-up, was for frequency ratings of voices, and total Hamilton Questionnaire score (HPSVQ), both favouring SAT. This finding is difficult to interpret, however, due to small numbers (N=9 in the MBCI group, N=10 in SAT group), and even in the MBCI group, scores at 6 months were below those for baseline and discharge. However, it is interesting to note that Bach and colleagues also report that more people in the Acceptance and Commitment Therapy (ACT) group reported symptoms (both voices and delusions) at 4-month follow-up compared to the TAU group (55% vs. 16% for voices specifically). Given that fewer people in the ACT group were re-admitted to hospital, despite reporting more symptoms, they interpreted the findings as indicating that frequency might in fact be an indirect measure of acceptance. They suggest:- "*If participants were more accepting of symptoms that occurred, they presumably would be more likely to acknowledge than deny them*" (p. 1133, Bach and Hayes (2002)). However, distinguishing between true improvement/deterioration in symptoms, and confounding shifts in willingness to report symptoms, remains a challenge.

Finally, neither the recovery measure (QPR) nor the mindfulness measure (SMQ) distinguished between groups, and neither group showed any change over time on these measures. The QPR has not been widely used in previous clinical trials, so prior evidence on its sensitivity to change over time is limited. However, it was used as a secondary measure in the ADAPT trial of acceptance and commitment therapy for post-psychosis depression (Gumley *et al.*, 2017). The authors similarly report that they found it did not discriminate between groups at follow-up, although they do not give the actual scores, precluding direct comparison between studies. One interpretation of the findings of the current study is that much of the recovery had already taken place by the time the person was enrolled into the trial. All participants had been in hospital for at least 3 days by the time they completed the baseline measures, and 80% of participants had been in hospital for at least a week by baseline. They were no longer at the peak of their crisis, and were receiving care in hospital, which they may have perceived as helpful to their recovery (even for people under section), and therefore they scored quite highly on the measure. Finally, participants also scored quite

highly on the SMQ (higher than previous clinical groups as outlined in Chapter 7). It is difficult to know how best to interpret this finding. It could simply be measurement error due to small sample size. As above, it could be that recovery and perhaps decentring from distressing experiences was underway by the time baseline data were taken. It could also reflect a response to demand characteristics in a therapy trial context, rather than a cross-sectional study as in previous studies (Chadwick *et al.*, 2008, Peters *et al.*, 2016). It is also important to note that on average participants received only 15 minutes of mindfulness practice during their admission (5 mins per session, with an average of 3 sessions per participant), and therefore it would not be expected that much change would be shown on mindfulness. Furthermore, participants were not given any audio files of guided practises or other resources to support home practice, so a group difference 6 months post-discharge is not to be expected.

8.6 Strengths and limitations

In order to better inform the interpretation of the findings of the study, the main strengths and limitations will be considered in this section.

The question this trial was designed to answer related primarily to feasibility; can this trial be done in a UK NHS setting? The answer, based on good recruitment and retention within the trial, is clearly yes. However, generalisation to the wider NHS acute services is unknown. This trial was completed successfully using a single trial therapist, who did not conduct the therapy as part of routine practice, but rather whose time was funded to provide 'extra' therapy sessions as part of the research study. Whether the trial could be done using ward psychologists to provide all the therapy sessions within routine practice is not yet known. Likewise, all participants were recruited from a single site, at a teaching hospital with close research links to its partner university, which provided a favourable research environment for the trial. Whether the trial could be done at a different hospital, with a different clinical and research environment, is not known. The impact of the intervention on short-term outcomes after discharge is also likely to be highly sensitive to the care context. For example, the baseline rate of re-admissions within 6 months post-discharge may vary across geographical location, due to factors such as varying bed numbers and differing availability of follow-up care in the local area. One example of this is the varying access to talking therapies in the

community post-discharge across different parts of the country. The overall rate of therapy in the 6 months post-discharge for this trial (18/48; 33%) is consistent with the general rate in the London NHS trust in which the trial was conducted (Colling *et al.*, 2017). However, rates of NICE-recommended psychological therapy for psychosis varies widely across the country. For example, Haddock and colleagues report only a 5% rate for service user receipt of such therapies in the North-West of England (Haddock *et al.*, 2014). The impact on re-admission rates found at any one site may not therefore be readily generalisable to other sites. It should also be noted that relapse was defined for the purposes of the trial as a documented exacerbation in psychotic symptoms, followed by a change in clinical management. Using this definition therefore means that relapse is partly defined by the response of clinical services, i.e. the system around the service user, rather than purely the individual's experience and self-reported difficulties. The impact of the intervention on short-term relapse will also therefore be highly sensitive to the care context, and the system as a whole, rather than being solely mediated through changes in the individual's well-being.

Again, a common criticism of clinical trials is that over-restrictive eligibility criteria leads to unrepresentative patient samples, limiting the generalisability of such trials to routine clinical practice. This is particularly relevant to trials within challenging clinical settings such as psychiatric wards. People requiring inpatient care often have complex and chronic difficulties, in the context of highly adverse social environments. The eligibility criteria for this trial were therefore designed to be as broad and inclusive as possible. For example, there were no exclusions made for people who were homeless, or in temporary housing, even though these people are more challenging to follow-up and may be more likely to drop-out of the study. In fact, 14 participants (28%) were identified as having housing issues at baseline (including homelessness, rent arrears, threat of eviction etc.), indicating that this is a commonly occurring social difficulty for people on admission. Likewise, there was no exclusion for co-morbid substance use, which is also a common characteristic of this clinical group. However, detailed information on substance use was not assessed at baseline, nor were participants asked about problems during the follow-up period, so the impact of substance use on outcomes cannot be determined from the data collected for this trial.

All consecutive admissions were screened for eligibility, and data were collected on the reasons for not participating in the trial (including distinguishing between people who did not

meet eligibility criteria, and people who met criteria but did not take part for other reasons). These rich and detailed data are very helpful for assessing feasibility. They give a baseline rate for how many admissions in general fit the eligibility criteria, which is important for assessing whether the intervention is addressing a common, or rare, clinical presentation. In fact, almost 50% of all acute admission screened met the initial eligibility criteria. Just under 20% of eligible patients ended up taking part in the study, which again gives a helpful estimate of how many people would have to be screened overall to achieve a certain sample size in a later efficacy trial.

As is usual with psychological therapy trials, participants were not blind to condition, in that they were told whether they had been randomly assigned to either therapy 1 (SAT) or therapy 2 (MBCI). A brief explanation of what each therapy involved was given within the study information sheet, and was repeated immediately after randomisation. The two therapy conditions were labelled neutrally (therapy 1 vs. therapy 2) on both patient and staff information sheets, in an attempt to engender clinical equipoise (a belief that there is not one better intervention between those on offer in the trial). This seems to have been successful as the treatment credibility scores were high in both conditions, and did not differ significantly between those in the MBCI group and those in the SAT group.

Ward staff were blinded to treatment condition as they were not explicitly told whether participants had been randomised to MBCI or SAT. Standard templates were used for all therapy notes and letters, which were added to electronic patient notes, and shared with staff. These standard templates did not contain any information about the content of the sessions, which might have accidentally unblinded staff to treatment condition. However, participants were not explicitly forbidden to share with staff what they were doing in the therapy sessions. This was with the aim of assessing whether participant disclosure was a significant threat to unblinding staff. Based on feedback interviews with ward staff (nurses and psychiatrists), it appears that participant disclosure was not a significant threat to blinding, as most staff reported that they had no discussions about the content of any of the sessions with participants. Furthermore, although all staff interviewed said they understood it was a randomised trial with an active control arm, they displayed little interest in which treatment arm participants were in, suggesting they perhaps did not think one was probably superior to the other. However, this was not systematically tested, for example by asking ward staff to

make a guess as to which treatment arm each participant had been in. Staff were also not asked to make therapy credibility ratings in the same way as participants were, so it is possible that they may not have regarded the 2 therapies as equally helpful in the same way as participants.

There was also no attempt to measure or control for 'contamination' between therapy arms (in which trial participants receive aspects of the intervention to which they were not randomised, through contact with participants in the other treatment arm). It is challenging to define and detect contamination in therapy trials. For example, if two participants in separate therapy arms just talk about their respective therapies, does this constitute contamination, or does it require active sharing of therapy resources such as handouts or skills learned within therapy? If so, how common is it that participants share therapy resources with one another in this way, and how can it best be quantified? These remain unanswered questions. One solution to avoid therapy contamination is to use a cluster randomised design, in which participants in different treatment conditions do not come into contact with each other because they are on different wards, or at different sites. However, randomising by ward or hospital site raises additional methodological challenges, such as accounting for systematic differences between clusters (i.e. different levels of TAU between different sites).

As the trial therapist, PJ was of course not blind to therapy condition, and she also conducted all the research assessments, from baseline to 6-month follow-up. Although all the questionnaire measures used were self-report, there was still potential risk of bias from PJ's involvement in the follow-up measures due to a conflict between the role of therapist and researcher. For example, participants might have responded to demand characteristics and under-reported symptoms due to an implicit expectation that they would have benefitted from the therapy. The main service use data (readmission and relapse rates) were however rated by an independent clinician who was blind to treatment condition (and who was otherwise not involved in the study).

8.7 Implications for planning of subsequent trials

Progression to a further trial is warranted given feasibility was clearly demonstrated according to all pre-set benchmarks. In order to address some of the limitations of the trial as discussed

above, it would be helpful to design the next trial to address some of the key issues, before progression to a full efficacy trial would be warranted. The appropriate next step would be to move from single-site to multi-site, and also from a single trial therapist, to delivery by ward psychologists in routine practice with independent assessors.

Looking ahead to a future efficacy trial - what should the primary outcome be? Selection of an appropriate outcome measure, which genuinely reflects real-world concerns of service users and clinicians, is probably one of the most important decisions in trial design (Heneghan *et al.*, 2017). Reducing short-term readmission rates is certainly of concern to the NHS given the economic cost of frequency hospital admission. However, perhaps we need to understand more about the personal, social and occupational costs of hospital readmissions from a service user perspective. Therefore, further work to understand the impact of short-term re-admission to hospital would be valuable, including ascertaining an appropriate trial end point. For example, is 6 months an appropriate trial end point, or should the follow-up period be shorter or longer? Even the definition of 'relapse' is contentious. This trial found very little difference between readmission rate, and relapse rate from clinical note review. This might reflect the fact that most people who require a change in clinical management arising from an exacerbation in psychotic symptoms tend to go on to require hospital admission. Only two participants in the trial had an episode of care with the home treatment team (HTT), and avoided subsequent hospital admission. However, differences between readmission and relapse rate is also likely to be context-sensitive (for example, it might depend on how over-burdened HTTs are or how severe bed shortages are locally).

8.8 General directions for future research

This is an exciting time for inpatient research in psychosis, with several pilot trials currently testing brief interventions within this setting. For example, Lisa Wood and colleagues adapted a CBT intervention for internalised stigma into a brief intervention and successfully piloted it with acute inpatients with psychosis (Wood, 2017). Daniel Freeman and colleagues have highlighted the importance of sleep disruption in psychosis (Waite *et al.*, 2016), and have recently completed a pilot trial of a brief CBT for sleep intervention for people with psychosis during an inpatient admission (Sheaves *et al.*, 2017). These innovations in the field lead to the possibility that in the future, when someone is admitted to hospital during a mental

health crisis, there could be a menu of choices available to them of brief, evidence-based interventions. Brevity of admission, or concerns that 'now is not the right time', should no longer be used as an excuse for withholding talking therapies in inpatient setting. There is clear emerging evidence that brief inpatient interventions are feasible, safe and acceptable to both service users and ward staff. However, much more work is needed to further evaluate such interventions in larger, robustly designed and adequately powered trials. Looking to the future, the challenge of how to measure and quantify the benefit of inpatient therapies looms large on the horizon. A shift away from symptom measures, to a greater focus on functional outcomes guided by service user priority, may be a productive direction. The use of questionnaires as process measures (e.g. psychological flexibility) will continue to play an important role in evaluating whether hypothesised mechanisms change as predicted over the course of treatment. This will help us to understand the active ingredients of any intervention, which is essential for refinement and improvement of interventions over time.

8.9 The Final Word

Although analysis of the qualitative data gathered as part of the trial is not reported within this thesis, it feels appropriate to give the final word back to the trial participants. An admission to hospital can be one of the worst experiences someone ever goes through, and the fact that so many people were willing to take part in this research to improve services for the future is truly humbling. The following quote from one of the participants who was in the MBCI group encapsulates some of the wisdom many participants expressed about what they learnt from their experience of engaging with therapy at such a difficult time.

"We actually, erm, recomposing yourself and… erm, how can I say it, recomposing yourself and just taking the moment out from that environment to… you know what I mean, to just be at peace with yourself. Yeah, and just staying sort of focused even though there's noise all around. There's always going to be noise and stuff…in life, you know what I mean?"

Chapter 9: References

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Chapter 10: Selected documents from Trial Master File

10.1 Trial Master File Index

1. **Protocol**

    1.1 Current protocol

2. **Ethics Committee**

    2.1 NRES application
    2.2 Letter of favourable opinion
    2.3 Annual progress reports with cover letters
    2.4 Notice to REC of trial completion

3. **R&D**

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    3.2 R&D approval
    3.3 R&D Notification of trial completion
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    4.2 Funding approval
    4.3 Research budget
    4.4 KCL clinical trials insurance

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6. Study Related Documents

6.1 Sample CRF
6.2 Therapy manual & materials
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8. Participant logs & ID key

8.1 ID key

8.2 Participant enrolment, withdrawal and completion log

9. Monitoring and adverse event reporting

9.1 Adverse events

10. Trial management and statistics

10.1 Randomisation documents

10.2 Service user advisory group minutes

10.3 Trial steering committee minutes

10.4 Statistical Analysis Plan

10.5 Data Management Plan

11. Publications & study report

10.2 Letter of favourable opinion from ethics committee

London - Camberwell St Giles Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone:
01173421330 29 September 2015

Dr Pamela Jacobsen
NIHR Clinical Doctoral Research Fellow
King's College London
Department of Psychology (PO 78)
Institute of Psychiatry, Psychology & Neuroscience
De Crespigny Park
London
SE5 8AF

Dear Dr Jacobsen

Study title:	**MINDFULNESS-BASED CRISIS INTERVENTIONS (MBCI) FOR PSYCHOSIS WITHIN ACUTE INPATIENT PSYCHIATRIC SETTINGS; A FEASIBILITY RANDOMISED CONTROLLED TRIAL**
REC reference:	**15/LO/1338**
Protocol number:	**N/A**
IRAS project ID:	**177667**

Thank you for your letter of 14 September 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 01 September 2015

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [Participant information sheet v.1.8_14.09.15]	1.8	14 September 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]		30 June 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [KCL insurance policy]		
GP/consultant information sheets or letters [Letter to GP/community care team]	1	30 June 2015
Interview schedules or topic guides for participants [Patient feedback topic guide]	1.4	07 July 2015
Interview schedules or topic guides for participants [Staff feedback topic guide]	1.4	07 July 2015
IRAS Checklist XML [Checklist_21072015]		21 July 2015
Letter from funder [NIHR funding letter]		16 September 2014
Letter from statistician [Letter from statistician]		16 July 2015
Non-validated questionnaire [Therapy Credibility]	1	16 July 2015
Non-validated questionnaire [Self-rating of psychotic symptoms - voices]	1	16 July 2015
Non-validated questionnaire [Self-rating of psychotic symptoms - Beliefs]	1	16 July 2015
Non-validated questionnaire [Stress bubbles]	1	16 July 2015
Other [CV 2nd supervisor]		16 July 2015
Other [Assessment plan]	1	14 July 2015
Participant consent form [Patient consent form]	1.4	25 June 2015
Participant consent form [Patient consent form - Audio-taping feedback interview]	1	22 June 2015
Participant consent form [Staff consent form_feedback interview]	1	04 June 2015
Participant information sheet (PIS) [Brief participant leaflet]	1.4	25 June 2015
Participant information sheet (PIS) [Brief clinician leaflet]	1.3	25 June 2015
Participant information sheet (PIS) [Staff information sheet for trial feedback]	1.3	16 July 2015
Participant information sheet (PIS) [Participant information sheet v.1.8_14.09.15]	1.8	14 September 2015
REC Application Form [REC_Form_16072015]		16 July 2015
Research protocol or project proposal [Trial protocol]	1.7	14 July 2015

15/LO/1338	Please quote this number on all correspondence	
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		16 July 2015
Summary CV for supervisor (student research) [CV 1st supervisor]		16 July 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Plan]	1	16 July 2015
Validated questionnaire [DASS-21]		
Validated questionnaire [HPSVQ]		
Validated questionnaire [SMQ]		
Validated questionnaire [QPR]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

Yours sincerely

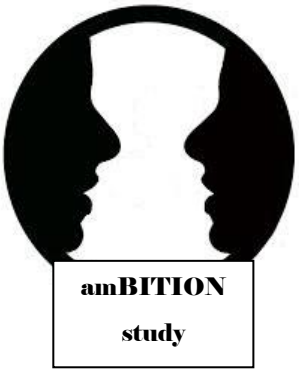
Aliki Sifostratoudaki REC Assistant

E-mail: nrescommittee.london-camberwellstgiles@nhs.net

Copy to: Mr Keith Brennan, King's College London
Ms Jennifer Liebscher, South London and Maudsley NHS Foundation Trust

10.3 Sample Case Report Form (CRF)

KING'S College LONDON



CASE REPORT FORM

MINDFULNESS-BASED CRISIS INTERVENTIONS (MBCI) FOR PSYCHOSIS WITHIN ACUTE INPATIENT PSYCHIATRIC SETTINGS; A FEASIBILITY RANDOMISED CONTROLLED TRIAL

BrIef Talking therapIes ON wards (amBITION study)

ISRCTN37625384

Participant ID: ☐☐☐

Hospital Site: ☐☐☐☐☐☐☐☐☐

Ward: ☐☐☐☐☐☐☐☐☐☐☐☐

INSTRUCTIONS FOR COMPLETION

Complete all sections. Do not leave any boxes blank. Write NK for "not known" where applicable.

Write legibly, in black ink, and in block capitals.

Do not write outside of the designated boxes. Write **BRIEF** comments within free space boxes where provided.

Completely fill in each box using leading '0' if needed.

Use DDMMYY for all date formats

Ensure that the participant ID is completed in the header on each page.

If a mistake is made, never obliterate or over-write an entry. Corrections will be made as follows:

- Cross out the incorrect entry with a single line so that the incorrect entry should still be readable. Never use correction fluid.
- Enter the correct data.
- Initial and date the correction

CRFs will be kept in a secure location during the course of the trial. Once the trial has closed the CRFs will then be archived with all other essential documentation.

Section 1: SCREENING	INITIAL ELIGIBILITY SCREEN

Identified by clinical team as i) experiencing distressing psychotic symptoms AND Iii)F20-39 diagnosis	YES ☐ NO ☐
Trial therapist has capacity for new participant	YES ☐ NO ☐
Primary/allocated nurse gives permission for researcher to approach	YES ☐ NO ☐ If no, specify reason below: ☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐
Participant given brief information leaflet	YES ☐ NO ☐ Date given: ☐☐☐☐☐☐ (DDMMYY)
Participant gives consent for researcher to access clinical notes for further eligibility screen	YES ☐ NO ☐ Date given: ☐☐☐☐☐☐ (DDMMYY)

DEMOGRAPHICS	
DATE OF BIRTH (DDMMYY)	☐☐☐☐☐☐
ETHNICITY CODE LABEL	☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐
SEX	MALE ☐ FEMALE ☐
DIAGNOSIS ICD-10 CODE	☐☐☐☐☐☐

Section 1: SCREENING	INCLUSION/EXCLUSION CRITERIA

The following criteria MUST be answered YES for participants to be included in the trial		YES	NO
1.	Aged 18 or above	☐	☐
2.	Current psychiatric inpatient on a working-age adult ward	☐	☐
3.	Diagnosis of schizophrenia-spectrum disorder or psychotic symptoms in the context of an affective disorder (ICD-10 codes F20-39)	☐	☐
4.	Reports at least one current distressing positive psychotic symptom	☐	☐
5.	Able to give informed consent to participate in trial, as assessed by consultant psychiatrist/responsible clinician	☐	☐
6.	Willing and able to engage in psychological therapy	☐	☐
If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.			

The following criteria MUST be answered NO for participants to be included in the trial		YES	NO
7.	Diagnosis of learning disability, or major cognitive impairment arising from underlying medical condition	☐	☐
8.	Unable to engage in a talking therapy in English, or to complete simple written questionnaires in English	☐	☐
9.	Primary diagnosis of substance misuse	☐	☐
10.	Does not report any current distressing psychotic symptoms	☐	☐
11.	Lacks capacity to consent to participation in research trial	☐	☐
12.	Unable to take part in individual therapy due to risk of aggression/violence	☐	☐
13.	Mental state precludes possibilty of engaging in a talking therapy, e.g. significant thought disorder	☐	☐
If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.			

Section 1: SCREENING	PARTICIPANT ELIGIBILITY REVIEW

Is the participant eligible to take part in the trial? Investigator's Signature:_____ Investigator's Name:_____ Date: ☐☐☐☐☐☐ (DDMMYY)	**YES** ☐ **NO** ☐

Section 1: SCREENING	INFORMED CONSENT AND RANDOMISATION

Participant given information sheet	YES ☐ NO ☐ Date given: ☐☐☐☐☐☐ (DDMMYY)
Participant agreed to participate	YES ☐ NO ☐ If no, give reason: Not interested ☐ Not feeling well enough ☐ Not wanting talking therapy ☐ Not agreeing to randomisation ☐ Other:_____
Participant gave written informed consent	YES ☐ NO ☐ Date: ☐☐☐☐☐☐ (DDMMYY)
Patient was randomised	YES ☐ Date: ☐☐☐☐☐☐ (DDMMYY) NO ☐ If no, give reason: Discharged ☐ Lost capacity ☐ Changed mind ☐ Transferred out of SLaM ☐ Other:_____
Patient randomised to condition **Therapy credibility score** (0-10) ☐	Therapy 1 ☐ Therapy 2 ☐

Section 2: BASELINE DATA	DEMOGRAPHIC DATA

1. Relationship status ☐Not currently in a relationship ☐In a relationship, but not living with partner ☐In a relationship and living with partner	4. Highest level of education ☐No formal qualifications ☐GCSE (or equivalent) ☐A-Levels (or equivalent) ☐Graduate ☐Post-graduate ☐Other (specify)_____
2a. Where they live ☐Supported accommodation ☐Temporary accommodation ☐Rented (council) ☐Rented (private) ☐Own property ☐In family home 2b. Live alone? ☐Yes ☐No (tick all that apply) Partner/spouse ☐ Parents ☐ Children under 18 ☐ Children over 18 ☐ Siblings ☐ Other family ☐ Friend ☐ Flatmates ☐ Other:_____	5. Employment status (tick all that apply) ☐Working part-time ☐Working full-time ☐Studying ☐Volunteering ☐Retired ☐Looking after family ☐Unemployed ☐Claiming DLA/ESA
3. Housing problems identified on admission? ☐No ☐Yes (tick all that apply) Homeless ☐ Unsuitable accommodation ☐ Rent/mortgage arrears ☐ Threat of eviction ☐ Other:_____	6a. Migrated to the UK? ☐Yes ☐No 6b. Asylum-seeker/refugee status? ☐Yes ☐No 6c. English as first language? ☐Yes ☐No

Section 2: BASELINE DATA	CLINICAL DATA
1. Psychiatric Diagnoses (list ICD-10 code) ☐☐☐☐☐☐ ☐☐☐☐☐☐ ☐☐☐☐☐☐ ☐☐☐☐☐☐	5a. Open to CMHT on admission? ☐Yes ☐No 5b. On Care Programme Approach (CPA)? ☐Yes ☐No
2a. Date of admission ☐☐☐☐☐☐ (DDMMYY) 2b. Legal status on admission ☐Informal ☐MHA (section_____) 2c. Date of discharge ☐☐☐☐☐☐ (DDMMYY)	5c. If open to CMHT, date and nature of last contact: ☐☐☐☐☐☐ (DDMMYY) ☐In person ☐Phone ☐Letter
3. Previous admissions? ☐No ☐Yes (if yes, specify no.)_____ (no. in past 12 months)_____	6. Psychological therapy in past 5 years ☐None ☐Offered (type)_____ ☐Received (type)_____
4a. Date first presented to services ☐☐☐☐☐☐ (DDMMYY) 4b. Date first presented to SLaM ☐☐☐☐☐☐ (DDMMYY)	7a.Suicidality in lead-up to crisis? ☐Yes ☐No 7b. Suicide attempts in past 12 mths? ☐Yes ☐No

SECTION 3: OUTCOMES	CHECKLIST FOR COMPLETION

T1: BASELINE	T2: POST-THERAPY	F1: 3 MONTH FOLLOW-UP	F2: 6 MONTH FOLLOW-UP
☐☐☐☐☐☐ Date (DDMMYY)	☐☐☐☐☐☐ Date (DDMMYY)	☐☐☐☐☐☐ Date (DDMMYY)	☐☐☐☐☐☐ Date (DDMMYY)
Self-report measures completed: **PSRS -V** Y ☐ N ☐ **PSRS-B** Y ☐ N ☐ **HPSVQ** Y ☐ N ☐ **DASS-21** Y ☐ N ☐ **SMQ** Y ☐ N ☐ **QPR** Y ☐ N ☐	Self-report measures completed: **PSRS -V** Y ☐ N ☐ **PSRS-B** Y ☐ N ☐ **HPSVQ** Y ☐ N ☐ **DASS-21** Y ☐ N ☐ **SMQ** Y ☐ N ☐ **QPR** Y ☐ N ☐	Self-report measures completed: **PSRS -V** Y ☐ N ☐ **PSRS-B** Y ☐ N ☐ **HPSVQ** Y ☐ N ☐ **DASS-21** Y ☐ N ☐ **SMQ** Y ☐ N ☐ **QPR** Y ☐ N ☐	Self-report measures completed: **PSRS -V** Y ☐ N ☐ **PSRS-B** Y ☐ N ☐ **HPSVQ** Y ☐ N ☐ **DASS-21** Y ☐ N ☐ **SMQ** Y ☐ N ☐ **QPR** Y ☐ N ☐
Medication log completed: Y ☐ N ☐ Adverse events log completed: Y ☐ N ☐	Medication log completed: Y ☐ N ☐ Adverse events log completed: Y ☐ N ☐	Medication log completed: Y ☐ N ☐ Adverse events log completed: Y ☐ N ☐	Medication log completed: Y ☐ N ☐ Adverse events log completed: Y ☐ N ☐
	TAU in addition to trial:- Attended therapy groups ☐ 1:1 therapy input ☐	Service use data completed: Y ☐ N ☐	Service use data completed: Y ☐ N ☐

SECTION 3: OUTCOMES	SELF-REPORT MEASURES

	PSRS-V	PSRS-B	HPSVQ (0-36)	DASS-21	SMQ (0-96)	QPR (0-88)
T1: BASELINE	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	☐☐	Dep (0-42) ☐ Anx (0-42) ☐ Str (0-42) ☐	☐☐	☐☐
T2: POST-THERAPY	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	☐☐	Dep (0-42) ☐ Anx (0-42) ☐ Str (0-42) ☐	☐☐	☐☐
F1: 3 MONTH FOLLOW-UP	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	☐☐	Dep (0-42) ☐ Anx (0-42) ☐ Str (0-42) ☐	☐☐	☐☐
F2: 6 MONTH FOLLOW-UP	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	Frequency (1-7) ☐ Distress (0-10) ☐ Believability (0-10) ☐	☐☐	Dep (0-42) ☐ Anx (0-42) ☐ Str (0-42) ☐	☐☐	☐☐

SECTION 4: THERAPY LOG

Session No.	Date scheduled (DD/MM/YY)	Attended?	Audio-recorded?	Session duration (mins)	Breaks	Session ended early (EE) OR interrupted (I)?	Risk issues?
☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No
☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No
☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No

☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No
☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No
☐	☐☐☐☐☐☐	☐**Yes** ☐**No** (if no, give reason) ☐Therapist cancelled ☐Pt declined ☐Pt asleep ☐Pt in other meeting ☐Pt not on ward	☐**Yes** ☐**No** (if no, give reason) ☐Pt declined ☐Recorder not available ☐Equipment failure	☐☐ Adequate engagement? ☐Yes ☐No	No. of breaks ☐ Duration (total in mins) ☐☐	☐Yes – EE ☐Yes - I (specify who by) ☐No	☐Yes (if so, specify) ☐No

SECTION 5: WITHIN-SESSION MEASURES – STRESS BUBBLES

	STRESS (1-6)		INTERFERENCE (1-6)		HOPEFULNESS (1-6)	
Session No.	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
1	☐	☐	☐	☐	☐	☐
2	☐	☐	☐	☐	☐	☐
3	☐	☐	☐	☐	☐	☐
4	☐	☐	☐	☐	☐	☐
5	☐	☐	☐	☐	☐	☐

SECTION 6: SERVICE USE DATA AT FOLLOW-UP

	Re-admission?	Days to 1st re-admission	Number of re-admissions	Total no. OBDs	Episodes with HTT	Relapse	No. of contacts with CMHT	Reference to therapy goal in notes?
F1: 3 MONTH FOLLOW-UP	☐YES ☐NO	☐☐	☐☐	☐☐☐	☐YES ☐NO If yes, no. of episodes: ☐	☐Type 1 (true relapse) ☐Type 2 (exacerbation) ☐Non-relapse ☐Unable to rate	In person ☐ Phone ☐ Letter ☐	☐YES ☐NO
F2: 6 MONTH FOLLOW-UP	☐YES ☐NO	☐☐	☐☐	☐☐☐	☐YES ☐NO If yes, no. of episodes: ☐	☐Type 1 (true relapse) ☐Type 2 (exacerbation) ☐Non-relapse ☐Unable to rate	In person ☐ Phone ☐ Letter ☐	☐YES ☐NO

SECTION 7: PSYCHIATRIC MEDICATION LOG			T1: BASELINE			
No.	**Medication name (specify generic or brand)**	**Dose (specify units)**	**Route**	**Frequency Record if PRN (specify units)**	**Compliance – self-report**	**Compliance – collateral source (specify:)**
1.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
2.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
3.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
4.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial

SECTION 7: PSYCHIATRIC MEDICATION LOG	T2: END OF THERAPY

No.	Medication name (specify generic or brand)	Dose (specify units)	Route	Frequency Record if PRN (specify units)	Compliance – self-report	Compliance – collateral source (specify:)
1.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
2.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
3.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
4.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial

SECTION 7: PSYCHIATRIC MEDICATION LOG	F1: 3 MONTH FOLLOW-UP

No.	Medication name (specify generic or brand)	Dose (specify units)	Route	Frequency Record if PRN (specify units)	Compliance – self-report	Compliance – collateral source (specify:)
1.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
2.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
3.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
4.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial

SECTION 7: PSYCHIATRIC MEDICATION LOG	F2: 6 MONTH FOLLOW-UP

No.	Medication name (specify generic or brand)	Dose (specify units)	Route	Frequency Record if PRN (specify units)	Compliance – self-report	Compliance – collateral source (specify:)
1.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
2.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
3.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial
4.					☐ Yes ☐ No ☐ Partial	☐ Yes ☐ No ☐ Partial

SECTION 8: ADVERSE EVENTS LOG: DEFINITIONS

Related to Study?

1 (Highly Likely) – temporal relationship is reasonable and there is no other cause to explain event

2 (Likely) - temporal association is reasonable and event is more likely to be due to study intervention than other cause

3 (Unlikely) - temporal relationship unlikely or event likely to be better explained by another cause

4 (Highly Unlikely) - temporal relationship not reasonable or event explained in isolation by another cause

Classification

Serious:
Class A: Incidents that result in death (they include, but are not limited to, homicide, suicide, death by accidental causes, sudden/unexpected death)
Class B: Incidents which acutely jeopardise the health or psychological well-being of the individual, resulting in injury requiring immediate hospital admission and/or permanent disability.
Class C: Incident which acutely jeopardise the health or psychological well-being of the individual, resulting in injury requiring medical attention and/or, for staff, more than 3 days sick leave.
Non-Serious
Class D: These are incidents which result in minor injury, and, for staff, requiring less than 3 days sick leave.
Class E: Incidents, which result in no injury.

SECTION 8: ADVERSE EVENTS LOG

Has the participant experienced any adverse events for the duration of the trial?

NO ☐ **YES** ☐ (If yes, complete log below)

No.	Description of event	Start Date (DD/MM/YY)	End Date (DD/MM/YY)	Related to study?	Classification	If applicable: Date reported (DD/MM/YY)
1.		☐☐☐☐☐☐	☐☐☐☐☐☐	☐1(Highly Likely) ☐2 (Likely) ☐3 (Unlikely) ☐4 (Highly unlikely)	☐A ☐B ☐C ☐D ☐E	☐☐☐☐☐☐
2.		☐☐☐☐☐☐	☐☐☐☐☐☐	☐1(Highly Likely) ☐2 (Likely) ☐3 (Unlikely) ☐4 (Highly unlikely)	☐A ☐B ☐C ☐D ☐E	☐☐☐☐☐☐
3.		☐☐☐☐☐☐	☐☐☐☐☐☐	☐1(Highly Likely) ☐2 (Likely) ☐3 (Unlikely) ☐4 (Highly unlikely)	☐A ☐B ☐C ☐D ☐E	☐☐☐☐☐☐
4.		☐☐☐☐☐☐	☐☐☐☐☐☐	☐1(Highly Likely) ☐2 (Likely) ☐3 (Unlikely) ☐4 (Highly unlikely)	☐A ☐B ☐C ☐D ☐E	☐☐☐☐☐☐

SECTION 9: TRIAL COMPLETION

Did participant complete the trial?	☐ **YES**, please provide date of last visit:- ☐☐☐☐☐☐ (DDMMYY) ☐ **NO**, please provide date of withdrawal and give reason below:- ☐☐☐☐☐☐ (DDMMYY)

Early withdrawal – please tick the most appropriate reason for participant not completing the trial:-

☐ Adverse events related, specify AE: _____

☐ Participant's decision, specify: _____

☐ Investigator's decision, specify: _____

☐ Sponsor's decision, specify: _____

☐ Lost to follow-up, specify reason if known: _____

☐ Other, specify: _____

SECTION 10: PRINCIPAL INVESTIGATOR SIGN-OFF

Principal Investigator's Signature Statement:	
I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by myself or by a person under my supervision who has signed the Delegation and Signature Log.	
Principal Investigator's Signature: _____ Principal Investigator's Name: _____	Date of Signature: ☐☐☐☐☐☐ (DDMMYY)
ONCE SIGNED, NO FURTHER CHANGES CAN BE MADE TO THIS CRF WITHOUT A SIGNED DATA QUERY FORM	

10.4 Therapy Manual (MBCI)

MINDFULNESS-BASED CRISIS INTERVENTIONS (MBCI) FOR PSYCHOSIS WITHIN ACUTE INPATIENT PSYCHIATRIC SETTINGS; A FEASIBILITY RANDOMISED CONTROLLED TRIAL

Mindfulness-Based Crisis Interventions (MBCI)

Therapy Manual

1. INTRODUCTION/ENGAGEMENT

1.1 Therapist role and introductions

First session and re-cap at subsequent sessions: -

Hello, my name is [give first name and last name] and I'm a [give professional background]. I'll be your therapist for these sessions. My role is to work together with you to offer some help at this difficult time.

First session and re-cap at subsequent sessions:-

At the beginning of each session we'll decide together how we want to use the time we have. At the end of the session we'll also discuss together something you might want to practice, or a small goal you want to achieve, before the next session. We'll check in with how this "homework" went at the beginning of the next session.

1.3 Frequency/duration of sessions

First session and re-cap at subsequent sessions: -

We have up to an hour to meet today. You can take a break, or stop early anytime you need. This is your [insert session number] session. We can have anywhere from 1- 5 sessions together while you are an inpatient here on the ward, and the sessions will stop whenever you get discharged. We can decide together when and how often you would like to have your therapy sessions.

1.4 Confidentiality

First session and re-cap at subsequent sessions: -

I'd also just like to explain how confidentiality works for the purposes of these sessions. I will let your care team both here on the ward and in the community know that you are attending sessions, but I won't share any details about the content of what we discuss. However, with your agreement, I would like to be able to share any goals we have come up with together with your community team so that they can help support you in working towards those goals. If you tell me anything that makes me concerned for your safety, or for the safety of others I will have to share that straight away with your care team. If you are unhappy with anything on the ward relating to your care in general, I am happy to help you discuss that with your primary/allocated nurse if you would like but I'm afraid I won't be able to address any of those problems myself.

1.5 Consent for taping

First session (and re-check at subsequent sessions):-

Before we start I'd like to ask whether you would be happy for me to record these sessions using this digital voice recorder. One reason is that it would help you and me to remember what we talked about in the sessions, because it's easy to forget things when there is a lot to think about and a lot going on at the moment. Another reason is that it can be helpful for my supervisor to be able to listen to the tape to check that I am doing things properly. All the recordings will be stored securely and anonymously and will be destroyed after the study has been written up, unless you give consent for them to be kept for educational/training purposes. If you like, you can have a copy of the recording of each session to listen to between the sessions and keep for the future. You can also ask me to turn the recorder off at any time. How does that sound to you? Do you have any more questions about recording the sessions?

2. SESSION PLAN

Each session should follow a set format as below:-

2.1 Brief mindfulness practice
2.2 Check-in with how the client has been since the last session
2.3 Set agenda collaboratively with client
2.4 Review homework
2.5 Discuss agreed topic(s)
2.6 Set homework/practice activities collaboratively (client and therapist take written note)
2.7 Therapist to ask for client feedback on session, including any concerns or confusion that may have arisen
2.8 Set the time and date of the next session (recorded on appointment card for client)
Reminder of what happens next in case of unexpected discharge before next meeting

3. SESSION CONTENT

3.1 Adaptations to working in acute settings

MBCI is delivered between 1 and 5 sessions, of up to an hour in duration. Sessions may be scheduled daily as a maximum frequency, and weekly as a minimum frequency. Each session is designed to be "stand-alone" and contains the key components of the intervention. The therapist should therefore approach each session as if it were the only session. However, for clients who do take part in more than 1 session, any given session can of course refer back to previous sessions, with the aim of building and expanding on ideas and skills that have already been discussed, modelled and practised. All sessions take place on the ward.
There are 3 key components which each session should include, in the suggested order within each session:-

i. **Developing mindfulness skills (guided practice)**
ii. **Making sense of crisis using mindfulness model**
iii. **Identifying values and committed action**

The therapist should aim to begin each session with a brief guided mindfulness practice. For the 1st session, this can be simply introduced as a way to "arrive" in the present moment of starting the session. Formulation of the crisis using the mindfulness model is likely to take up more of session 1 than in later sessions. Given the time constraints of the setting, this may require more of a psycho-educational than a fully socratic approach as might be more appropriate in longer-term therapy.

3.2 MBCI Key components

3.2.1 Developing mindfulness skills

The therapist should aim to introduce the concept of mindfulness in an accessible and understandable way.

Have you heard of mindfulness before? Is this something you have tried out for yourself before?

Mindfulness means being aware of our experience in the current moment, whatever that might be, without needing to fix or change things. For example, you might just notice

The therapist should explain why it's important to practice mindfulness skills.

Mindfulness is a skill that takes time to learn. It's a bit like learning to ride a bike, it's something you have to try out for yourself, you can't just read about it in a book! It also takes time to learn and you get most out of it if you practice regularly. In these sessions, I'd like to try out some simple mindfulness practices with you, which you can also practice by yourself between sessions and after the therapy has finished.

The therapist should lead a guided mindfulness meditation in line with mindfulness for psychosis guidelines (e.g. brief practices, with frequent grounding and use of everyday, concrete language). See section 4 – THERAPY RESOURCES for examples of different mindfulness meditations which can be used flexibly, to best meet the individual's needs.

I'm curious to know what you noticed during that practice. Remember we're just practicing being with our experience in the moment, just as it is, whatever that might be.

Key insights might include noticing the mind's tendency to wander away from the present moment, what the mind habitually wanders away to, noticing how thoughts/voices/bodily sensations come and go over time, and noticing habitual reactions such as trying to push away unwanted experiences.

That's really interesting how you were able to notice sensations in the soles of your feet, and how these were changing from moment to moment. It's also great that you were able to be aware that your mind often wandered away from the sensations in the soles of your feet. It sounds like your mind got quite busy with voices at a certain point, but you were then gently able to direct your awareness to come back to sensations in the soles of the feet at other times.

It is very common for people to confuse being mindful with being relaxed, emptying the mind or having a focusing attention like a laser. If this comes up the therapist can gently remind the client that this isn't the intention behind mindful meditation, whilst also acknowledging how helpful it is to notice such judgements or expectations coming up in the mind.

Isn't it interesting when we practice mindfulness how our minds often get caught up in expectations of how we think things should be, or judgements of how well we're doing? When we practice mindfulness, we can thank our minds for these expectations and judgements, without needing to buy into them. Mindfulness isn't about emptying the mind, getting relaxed or stopping the mind from wandering. It's just about noticing, with kindness and curiosity, what's in our experience in the present moment.

3.2.2 Making sense of crisis using mindfulness model

The therapist should aim to develop a collaborative understanding with the client of what has brought them into crisis on this occasion, focussing on how the person usually tries to cope with difficult thoughts, feelings and experiences and how well these strategies are working for the person. The crisis formulation template (therapy resource 4.1) should be completed together with the client if possible. The starting point for the formulation is always with the identifying and naming of the overwhelming emotions at the heart of the crisis.

> *We're going to start by naming some of those really difficult emotions that were around for you, and putting them in the centre here in the jagged hole. This sharp, spiky shape represents how painful these emotions can be to be in contact with.*

Recent stressors to the crisis should then be identified such as social (e.g. housing, finances) and personal problems (e.g. relationships). More distal factors which the client identifies as vulnerability factors may be appropriately named and validated, without being discussed in detail (e.g. childhood abuse).

> *What has been going on for you recently? Has anything in particular been upsetting you or worrying you lately?*

This then leads on to a discussion of how the client was trying to deal with these difficult thoughts, emotions and psychotic symptoms. Given time constraints, therapists will share a formulation and example strategies (e.g. Chadwick, 2006), asking the client to connect with and provide examples of his or her own habitual reactions. In line with the formulation, the therapist should pay particular attention to attempts to either block out, suppress or otherwise escape from unwanted internal experiences, or reactions that mean getting caught up in struggling with internal experiences (rumination, fighting). Mindfulness is located as a middle way between these two reactive styles.

It sounds like things have been really difficult for you, and you've been trying to cope with things as best you can. It also sounds like some of the things you did to try and cope (e.g. drinking alcohol to block out voices) sometimes helped at the time, but other times the voices just got louder or they came back to bother you later on. This is typical of what happens to a lot of people who are trying to cope with difficult experiences. It sounds very frustrating and I'd like to work together with you to help find other ways of relating to your experiences, which might work out better for you. Mindfulness is one approach we'll be exploring together in these sessions. It's kind of like a middle way between these 2 extremes – not running away from experiences, but not getting caught up in fighting against them either.

Finally, the therapist should also help the client to identify their existing strengths and adaptive coping skills (e.g. seeking support from friends) which can be built on, and these should be noted on the formulation.

What other things do you try and do to help you cope? Do you do other things which you feel work better for you? What would you say are your personal strengths? What about someone who knew you well as a person – what would they say?

3.2.3 Identifying values and committed action

The therapist should work with the client to identify their values (e.g. family, work, health, society), and discuss specific behavioural goals consistent with these values.

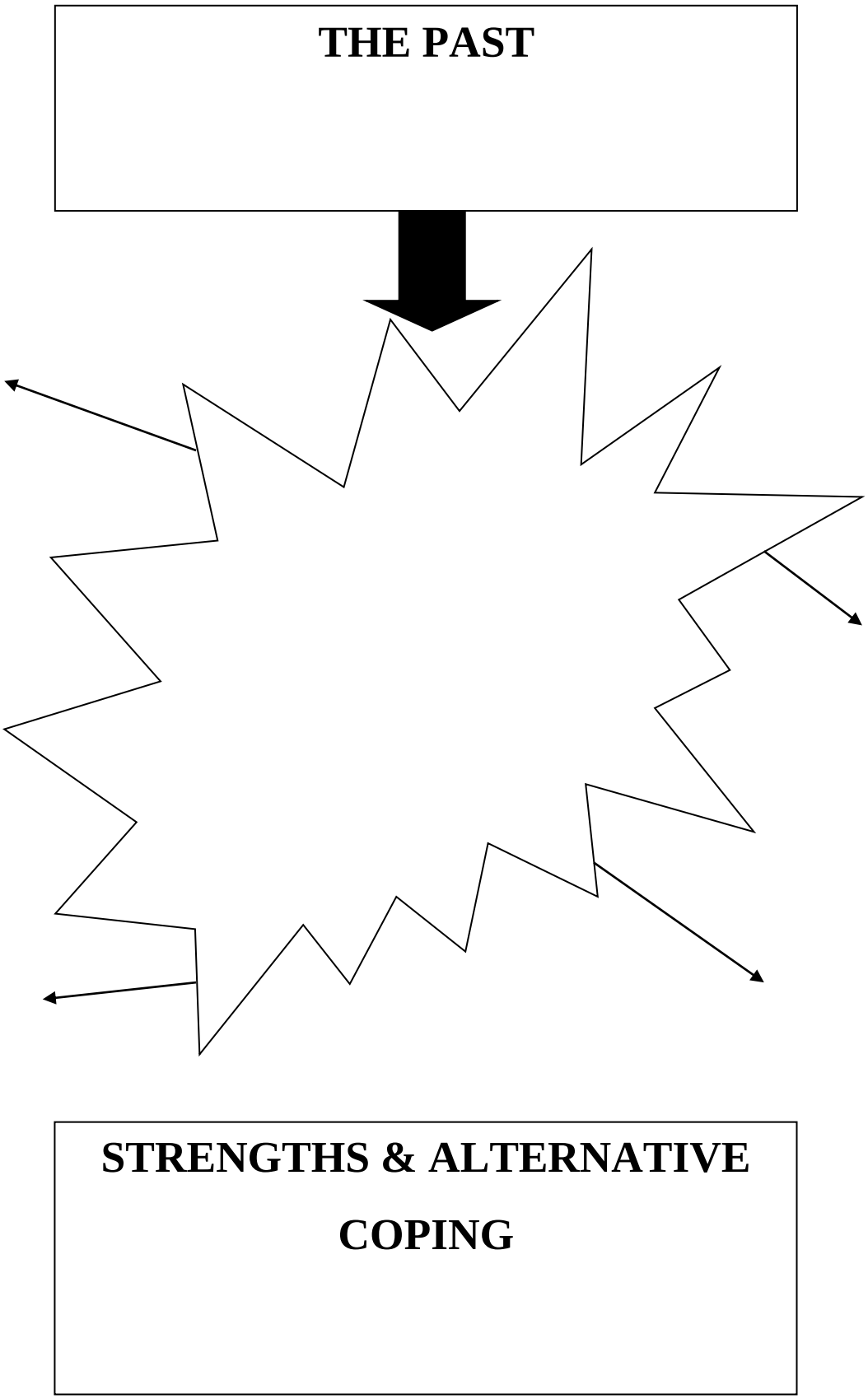
I'd be interested in knowing more about your values. By this I mean, the things that really mean something to you deep down. The things that you would like your life to stand for. This is about the values you have freely chosen, rather than what other people have told you about what you should want in life.

The valued living questionnaire (resource 4.5) can be used to help the client to identify their values. The therapist should then discuss with client the difference between values and goals, using a metaphor to illustrate (section 4.6).

Values are like the direction you are heading in, and goals are like the destinations you reach along the way. I'd like to start thinking with you about setting some goals which are consistent with your values. What sort of things would you be doing, how would you be spending your time, if you weren't struggling with (e.g. voices, worries, anxiety)?

Clients should be encouraged to set a small, achievable goal for homework at the end of each session which can be reviewed at the beginning of next session (and recorded using record form 4.7). In preparation for discharge, longer-term goals can also be identified (e.g. starting a college course) and should be shared with the client's community care team at the end of therapy, with their permission. This can then act as a bridge to carrying on committed action post-discharge and helping the person to build up a valued life in the community.

4 THERAPY RESOURCES – Index


THE PAST
STRENGTHS & ALTERNATIVE COPING

Step 1: Name the horrible feelings

- Stick to emotion words (e.g. angry, sad, scared)
- OK to be flexible and use people's own words
- Validate!! Don't get drawn into fixing/challenging….
- Empathise and normalise
- Be patient and gently persevere – both therapist and client can be guilty of wanting to avoid talking about emotions

Step 2: The past

- Identify triggering factors to horrible feelings
- Start with most recent factors e.g. relationship problems, financial worries
- If appropriate, can also name more distant factors
- Can name and acknowledge past trauma without needing to go into detail

Step 3: Identify maintaining factors

- What are the behaviours that have brought someone into hospital?
- How is the person trying to cope?
- Remember people do things for understandable reasons
- Validate not judge

Step 4: Identify strengths and alternative coping strategies

- Identify strengths – personal qualities, values, resilience in the face of adversity, what is important to the person?
- Alternative coping – let the person tell you!!
- Social support, maintaining well-being, religious/spiritual practices, coping strategies (existing or need to be developed)

10.5 Therapy Manual (SAT)

MINDFULNESS-BASED CRISIS INTERVENTIONS (MBCI) FOR PSYCHOSIS WITHIN ACUTE INPATIENT PSYCHIATRIC SETTINGS; A FEASIBILITY RANDOMISED CONTROLLED TRIAL

Social Activity Therapy (SAT)[26]

Therapy Manual

[26] Based on protocol developed by Haddock et al (2009) for the PICASSO project

4. INTRODUCTION/ENGAGEMENT

4.1 Therapist role and introductions

First session and re-cap at subsequent sessions: -

Hello, my name is [give first name and last name] and I'm a [give professional background]. I'll be your therapist for these sessions. My role is to work together with you to offer some help at this difficult time.

First session and re-cap at subsequent sessions: -

At the beginning of each session we'll decide together how we want to use the time we have. At the end of the session we'll also discuss together something you might want to practice, or a small goal you want to achieve, before the next session. We'll check in with how this "homework" went at the beginning of the next session.

4.3 Frequency/duration of sessions

First session and re-cap at subsequent sessions: -

We have up to an hour to meet today. You can take a break, or stop early anytime you need. This is your [insert session number] session. We can have anywhere from 1- 5 sessions together while you are an inpatient here on the ward, and the sessions will stop whenever you get discharged. We can decide together when and how often you would like to have your therapy sessions.

4.4 Confidentiality

First session and re-cap at subsequent sessions: -

I'd also just like to explain how confidentiality works for the purposes of these sessions. I will let your care team both here on the ward and in the community know that you are attending sessions, but I won't share any details about the content of what we discuss. However, with your agreement, I would like to be able to share any goals we have come up with together with your community team so that they can help support you in working towards those goals. If you tell me anything that makes me concerned for your safety, or for the safety of others I will have to share that straight away with your care team. If you are unhappy with anything on the ward relating to your care in general, I am happy to help you discuss that with your primary/allocated nurse if you would like but I'm afraid I won't be able to address any of those problems myself.

4.5 Consent for taping

First session (and re-check at subsequent sessions): -

Before we start I'd like to ask whether you would be happy for me to record these sessions using this digital voice recorder. One reason is that it would help you and me to remember what we talked about in the sessions, because it's easy to forget things when there is a lot to think about and a lot going on at the moment. Another reason is that it can be helpful for my supervisor to be able to listen to the tape to check that I am doing things properly. All the recordings will be stored securely and anonymously and will be destroyed after the study has been written up, unless you give consent for them to be kept for educational/training purposes. If you like, you can have a copy of the recording of each session to listen to between the sessions and keep for the future. You can also ask me to turn the recorder off at any time. How does that sound to you? Do you have any more questions about recording the sessions?

5. SESSION PLAN

Each session should follow a set format as below:-

5.1 Check-in with how the client has been since the last session
5.2 Set agenda collaboratively with client
5.3 Review homework
5.4 Discuss agreed topic(s)
5.5 Set homework/practice activities collaboratively (client and therapist take written note)
5.6 Therapist to ask for client feedback on session, including any concerns or confusion that may have arisen
5.7 Set the time and date of the next session (recorded on appointment card for client)
Reminder of what happens next in case of unexpected discharge before next meeting

6. SESSION CONTENT

SAT is delivered between 1 and 5 sessions, of up to an hour in duration. Sessions may be scheduled daily as a maximum frequency, and weekly as a minimum frequency. Each session is designed to be "stand-alone" and contains the key components of the intervention. The therapist should therefore approach each session as if it were the only session. However, for clients who do take part in more than 1 session, any given session can of course refer back to previous sessions, building on activities and interests that have already been identified. The purpose of SAT is to collaboratively work with the client to identify activities they enjoy and which they can engage in during sessions, and, between sessions as they wish. The aim is to provide a supportive environment with a therapist using non-specific aspects of therapy (e.g. agenda setting, collaboration, feedback, empathy). All sessions take place on the ward.

Key aspects include:

- Review and discussion around activities which the client currently engages in (using interest/activity checklist if helpful)
- Discussion of activities which the client has enjoyed previously
- Discussion of any activities which the client would like to engage with during the therapy sessions e.g. playing games, puzzles, arts & crafts, reading magazines etc. (subject to risk management issues)
- Collaborative setting of homework to carry out enjoyable and achievable activities between sessions (using homework/apt card to record the agreed activity). Only a small and realistic goal should be set as homework e.g. read for 20 mins after dinner.

The therapist should aim to be supportive, collaborative and empathic at all times and to adhere in general to all non-specific therapy factors in cognitive-behavioural therapy (CBT), as defined by the Cognitive Therapy Scale for Psychosis (CTS-PSY; Haddock et al, 2001). However, the therapist should not employ any therapy techniques specific to any model of therapy, including CBT for psychosis or mindfulness-based therapies. The therapist should aim to keep the sessions activity focussed. If the client raises any emotional difficulties during the sessions, or becomes distressed, the therapist should aim to validate and contain the client's distress rather than offer advice or counselling. The therapist can sign-post to other sources of support, including staff on the ward and the client's community care team if required.

7. THERAPY RESOURCES – Index

- Interest/activity checklist
- Homework/apt card

10.6 Fidelity and Adherence Scale

Brlef Talking theraples ON wards (amBITION study)

MBCI = Mindfulness Based Crisis Interventions/SAT = Social Activity Therapy

Therapist: _____

Client ID number: _____

Session Number: _____

Rater: _____

Date of Rating: _____

(After rating completed) Which therapy do you think is being delivered? MBCI ☐ SAT ☐

INSTRUCTIONS

The scale consists of 4 sub-scales, as follows:-

A: Non-specific Cognitive Therapy Scale (essential to MBCI & SAT) - pgs. 2-3

B: MBCI-specific Therapy Scale (unique to MBCI) - pg.4

C: SAT-specific Therapy Scale (unique to SAT) - pg.4

D: CBT for psychosis Therapy Scale (proscribed for both MBCI & SAT) - pg.5

Within each sub-scale each key component is rated on **Adherence** (A) and **Competence** (C).

Adherence: For each key component, assess whether this was demonstrated by the therapist during the session. Where relevant, examples of relevant behaviours are listed below each component. Focus on what the therapist attempted to do, whether or not those attempts were successful or not. If the component is present, score the item as '1' (present). Any components which are not demonstrated should be scored as '0 (absent)'. Enter either '0' or '1' in the adherence column for each key component.

0= Absent 1= Present

Competence: For each component which has been identified as present (i.e. scored 1 in the adherence column), rate how well the therapist carried out the particular component. Use the following scale to rate each component and enter that number in the competence column. The competence column should be left blank for any components which were not demonstrated (i.e. which are rated absent under the adherence column).

Always consider the whole session when rating each item.

Rating scale for assessing competence

0	1	2	3	4	5	6
Poor	Barely Adequate	Mediocre	Satisfactory	Good	Very Good	Excellent

A: Non-specific Cognitive Therapy Scale[27]

Adherence	Competence	Key components
		1) Agenda **Did the therapist set an agenda?** Examples of relevant therapist behaviours include:-
		- The therapist noted client's current emotional status regarding agenda setting
		- Therapist and patient established agenda for session
		- Priorities for agenda items were established
		- Agenda was appropriate for time allotment (neither too ambitious nor too limited)
		- The agenda that provided an opportunity for the client to discuss salient events or problems occurring during the time since the last session
		- The agenda was adhered to during the session where appropriate
		2) Feedback **Did the therapist ask for and respond to feedback?** Examples of relevant therapist behaviours include:-
		- Therapist asked for feedback regarding previous session
		- Therapist asked for feedback and reactions to present session
		- Therapist asked client specifically for any negative reactions to therapist, content, problem formulation, etc.
		- Therapist attempted to respond to client's feedback
		- Therapist checked that the client clearly understood the therapist's role and/or the purpose and limitations of sessions
		- Therapist checked that s/he had fully understood the client's perspective by summarising and asking client to fine-tune as appropriate
		3) Understanding **Did the therapist express warmth, respect and empathy for the client?** Examples of relevant therapist behaviours include:-
		- Therapist conveys understanding by rephrasing or summarising what the client had said
		- Therapist shows sensitivity e.g. by reflecting back feelings as well as ideas
		- Therapist's tone of voice was empathic
		- Therapist acknowledged client's viewpoint as valid and important
		- Therapist did not negate client's point of view
		- Where differences occurred, they were acknowledge and respected

[27] Taken from Cognitive Therapy Scale for Psychosis (CTS-PSY); Haddock et al, 2001

Adherence	Competence	Key Components
		4) <u>Interpersonal Effectiveness</u> **Did the therapist communicate effectively during the session?** Examples of relevant therapist behaviours include:-
		- Therapist seemed open rather than defensive, shown by not holding back impressions or information, nor evading client's questions
		- Content of what therapist said communicated warmth, concern and caring rather than cold indifference
		- The therapist did not criticise, disapprove or ridicule the client's behaviour or point of view
		- The therapist responded to, or displayed, humour when appropriate
		- Therapist made clear statements without frequent hesitations or rephrasing
		- Therapist was in control of the session, s/he was able to shift appropriately between listening and leading
		5) <u>Collaboration</u> **Did the therapist collaborate effectively with the client?** Examples of relevant therapist behaviours include:-
		- Therapist asked client for suggestions on how to proceed and offered choices when feasible
		- Therapist ensured that client's suggestions and choice were acknowledged
		- Therapist explained rationale for intervention(s)
		- Flow of verbal interchange was smooth with a balance of listening and talking
		- Therapist worked with client even when using a primarily educative role
		- Discussion was pitched at a level and in a language that was understandable by the client
		6) <u>Homework</u> **Did the therapist set and review homework?** Examples of relevant therapist behaviours include:-
		- Therapist explicitly reviewed previous week's homework
		- Therapist summarised conclusions derived, or progress made, from previous homework
		- Appropriate homework was assigned
		- Therapist explained rationale for homework assignment
		- Homework was specific and details were clearly explained
		- Therapist asked patient if s/he anticipated problems in carrying out the homework

B: MBCI-specific Therapy Scale

Adherence	Competence	Key components
		1) Making sense of crisis using mindfulness model[28] **Did the therapist work together with the client to build up a shared understanding of what has brought them into crisis, including identifying habitual responses to internal experiences, and formulating this within the mindfulness model?**
		2) Developing mindfulness skills[29] **Did the therapist lead a brief mindfulness practice in line with mindfulness for psychosis guidelines?**
		3) Identifying values and committed action[30] **Did the therapist help the client to identify (and distinguish between) values and goals, and to identify achievable short terms goals in line with their values?**

C: SAT-specific Therapy Scale[31]

Adherence	Competence	Key components
		1) Within-session activities **Did the therapist discuss with the client which activities they would like to engage with during the session, and carry these out?**
		2) Response to emotional distress **Did the therapist respond to any distress expressed by the client ONLY by validation and containment?**

[28] Adapted from Durrant, Clarke, Tolland, & Wilson (2007)
[29] Following Chadwick (2006)
[30] Hayes, Strosahl & Wilson (2011)
[31] Taken from Haddock et al (2009) – PICASSO project

D: CBT for psychosis Therapy Scale[32]

Adherence	Competence	Key components
		1) Columbo style **Did the therapist help the client to explain their reasons for holding a belief by apologizing for being confused but then carefully questioning to gain the details?**
		2) Evidence for delusional beliefs **Did the therapist assess the evidence that the client uses to support his/her delusional beliefs?**
		3) Verbal challenge of delusions **Did the therapist challenge the client's beliefs through discussion?**
		4) Validity Testing **Did the therapist encourage the client to 1) engage in specific behaviours for the purpose of testing the validity of their beliefs, OR 2) make explicit predictions about external events so that the outcomes of those events could serve as tests of those predictions OR 3) review the outcome of previous validity tests?**
		5) Schemas **Did the therapist assess and formulate underlying schemas and dysfunctional assumptions OR intervene on the basis of previous assessment of such schemas?**

[32] Taken from Rollinson et al. (2008)- Revised Cognitive Therapy for Psychosis Adherence Scale (R-CTPAS)

10.7 Self-rating of psychotic symptoms (beliefs)

Rating scale – Beliefs V.1 16.07.15

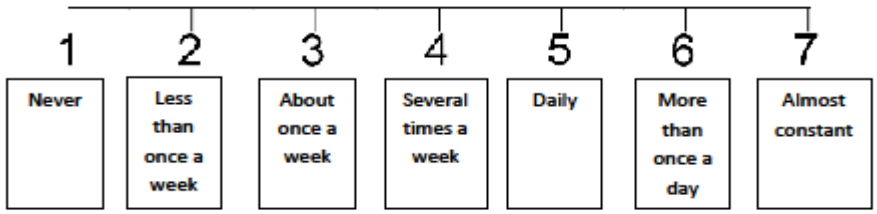
Write down the belief you are rating in your own words:

---

1) Frequency

On average, how often have you thought about this belief in the past week?

Please circle a number.

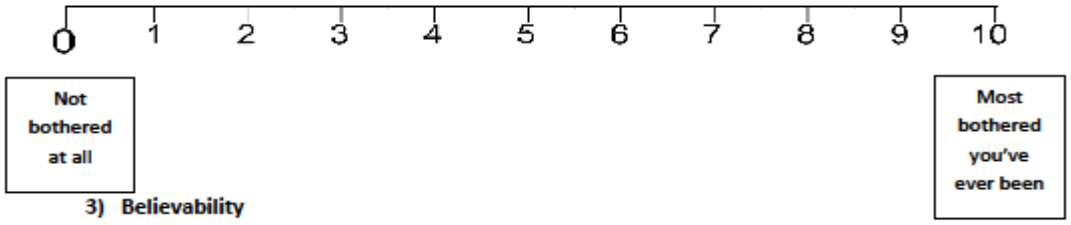


2) Distress

On a scale from 0 to 10, how bothered are you when you think about this belief?

Please circle a number.

(0 means not bothered at all and 10 means the most bothered you've ever been)

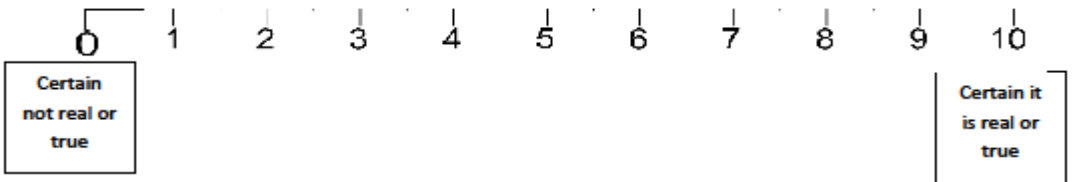


3) Believability

On a scale from 0 to 10, when you think about this belief, how much do you believe that it is real, or true?

Please circle a number.

(0 means that you are certain it is not real or true, and 10 means you are absolutely certain that it is real or true?)



Participant ID: Date: Assessment point:

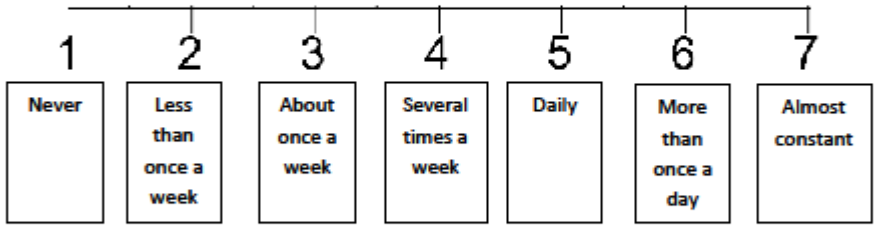
10.8 Self-rating of psychotic symptoms (voices)

Rating scale – Voices V.1 16.07.15

1) Frequency

On average, how often have you heard voices in the past week?

Please circle a number.

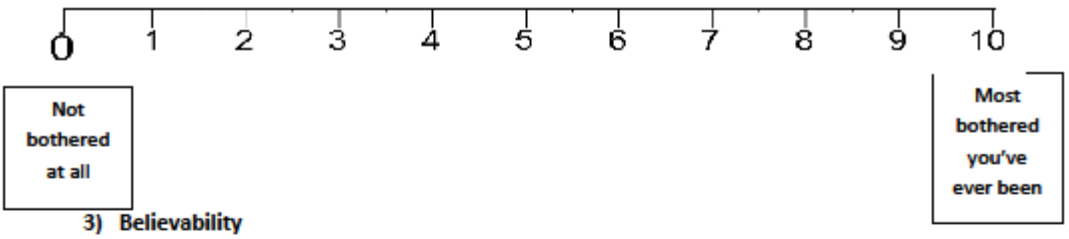


2) Distress

On a scale from 0 to 10, how bothered are you when you hear the voices?

Please circle a number.

(0 means not bothered at all and 10 means the most bothered you've ever been)

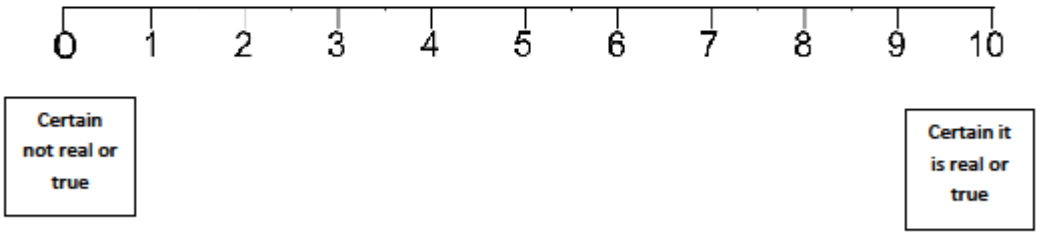


3) Believability

On a scale from 0 to 10, how much do you believe that when you hear voices that they are real, or true?

Please circle a number.

(0 means that you are certain it is not real or true, and 10 means you are absolutely certain that it is real or true?)



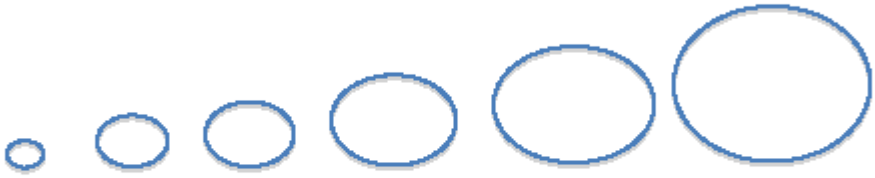
Participant ID: Date: Assessment point:

10.9 Stress Bubbles

Stress bubbles V.1 16.07.15

Mark the bubble that fits the best.

1. How stressed do you feel right now?

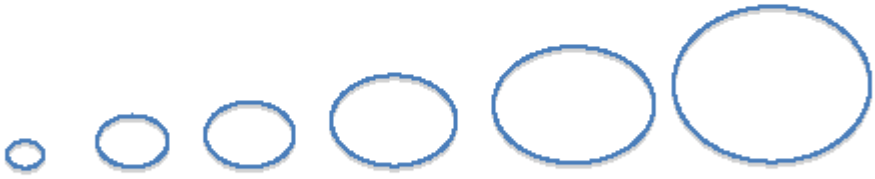


No stress Very stressed

2. How interfering are your thoughts/images/voices right now?

Not at all Extremely

3. How positive are you feeling about the future?



Not at all Extremely

Participant ID:___ Session ___ Pre ☐ Post ☐

10.10 Therapy Credibility

How helpful does therapy sound **V.1** **16.07.15**

If therapy 1:

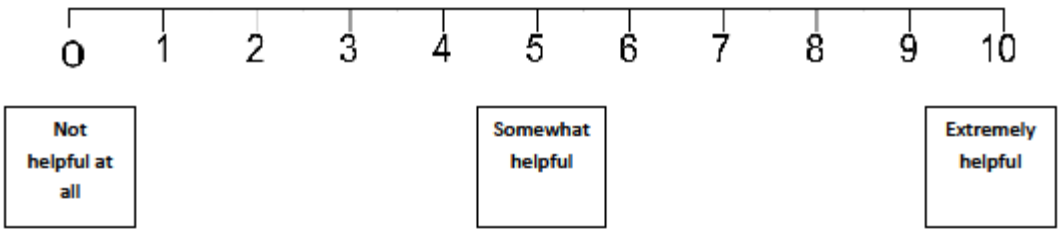
You have been randomly allocated to receive therapy 1. You will have between 1 and 5 sessions while you are an inpatient here on the ward. This will involve identifying and carrying out some simple activities you enjoy together with your therapist on the ward. We know people sometimes find this helpful.

OR

If therapy 2:

You have been randomly allocated to receive therapy 2. You will have between 1 and 5 sessions while you are an inpatient here on the ward. This will involve developing a shared understanding of your recent difficulties, and helping you develop some alternative ways of coping. We know people sometimes find this helpful.

1) **On a scale of 0-10, how helpful do you think this therapy sounds?**



Participant ID: **Date:** **Assessment point:**

10.11 Hamilton Program for Schizophrenia Voices Questionnaire (HSPVQ)

HSPVQ

Please circle the **ONE** box that best describes your experience of voices **DURING THE PAST WEEK**, including today.

1. How ***frequently*** did you hear a voice or voices?

No voices	Less than once a day	Once or twice a day	Several times a day	All of the time/Constantly

2. How ***bad*** are the things the voices say to you?

No voices saying bad things	Not that bad	Fairly bad	Very bad	Horrible

3. How ***loud*** are the voices?

Voices not present	Very quiet (like whispering)	Average (same as my own voice)	Fairly loud	Very loud (yelling or shouting)

4. How ***long*** do the voices usually last?

Voices not present	A few seconds to 1 minute	A few minutes	More than 10 minutes but less than an hour	Longer than 1 hour/they just seem to persist

5. How much do the voices ***interfere*** with your daily activities?

No interference	A little bit	Moderately	Quite a bit	Extremely interfering

6. How ***distressing*** are the voices that you hear?

No voices are distressing me	A little bit	Moderately	Quite a bit	Extremely distressing

7. How ***bad*** (worthless/useless) do the voices make you ***feel about yourself?***

No voices make me feel bad	A little bit	Fairly bad	Very bad	Extremely bad (as bad as I can feel)

8. How ***clearly*** do you hear the voices?

Voices not present	Very mumbled	Fairly mumbled	Fairly clear	Very clear voices

9. How often do you **DO** what the voices say?

No voices telling me what to do	Rarely	Sometimes	Often	Always

Participant ID: Date: Assessment point:

10.12 Depression, anxiety and stress scales (DASS-21)

DASS21

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Participant ID: Date: Assessment point:

10.13 Questionnaire about the Process of Recovery (QPR)

The Process of Recovery Questionnaire (QPR)

We developed this questionnaire in order to understand more about the process of recovery; what's helpful and what's not so helpful. Everyone is different and there will be differences for everyone. The items on this questionnaire were developed through a process of interviewing service users about their recovery journeys. We hope that by filing in this questionnaire you will help us find out information that is important to you and your own recovery. Not all factors will be important to you, since everyone is different. This questionnaire is not intended to be used to impose anything against your wishes.

If you would like to fill in the questionnaire, please take a moment to consider and sum up how things stand for you at the present time, in particular over the last 7 days, with regards to your mental health and recovery. Please respond to the following statements by putting a tick in the box which best describes your experience.

		Disagree strongly	Disagree	Neither agree nor disagree	Agree	Agree Strongly
1.	I feel better about myself					
2.	I feel able to take chances in life					
3.	I am able to develop positive relationships with other people					
4.	I feel part of society rather than isolated					
5.	I am able to assert myself					
6.	I feel that my life has a purpose					
7.	My experiences have changed me for the better					
8.	I have been able to come to terms with things that have happened to me in the past and move on with my life					
9.	I am basically strongly motivated to get better					
10.	I can recognise the positive things I have done					
11.	I am able to understand myself better					
12.	I can take charge of my life					
13.	I am able to access independent support					
14.	I can weigh up the pros and cons of psychiatric treatment					
15.	I feel my experiences have made me more sensitive towards others					
16.	Meeting people who have had similar experiences makes me feel better					
17.	My recovery has helped challenge other peoples views about getting better					
18.	I am able to make sense of my distressing experiences					
19.	I can actively engage with life					
20.	I realise that the views of some mental health professionals is not the only way of looking at things					
21.	I can take control of aspects of my life					
22.	I can find the time to do the things I enjoy					

Participant ID: Date: Assessment point:

10.14 Southampton Mindfulness Questionnaire; SMQ

SMQ

Usually, when I have distressing thoughts or images

	Agree Totally	Agree Strongly	Agree Slightly	Unsure	Disagree Slightly	Disagree Strongly	Disagree Totally
1. I am able just to notice them without reacting							
2. They take over my mind for quite a while afterwards							
3. I judge the thought/image as good or bad							
4. I feel calm soon after							
5. I am able to accept the experience							
6. I get angry that this happens to me							
7. I notice how brief thoughts and images really are							
8. I judge myself as good or bad, depending what the thought/image is about							
9. I 'step back' & am aware of the thought or image without getting taken over by it							
10. I just notice them and let them go							
11. I accept myself the same whatever the thought/image is about							
12. In my mind I try and push them away							
13. I keep thinking about the thought or image after it's gone							
14. I find it so unpleasant I have to distract myself & not notice them							
15. I try just to experience the thoughts or images without judging them							
16. I lose myself in the thought/images							

Participant ID: Date: Assessment point:

10.15 Participant Feedback Topic Guide

(Suggestions in italics can be used as prompts in interviews/focus groups)

Taking part in the study

1) At the time, did you feel that you were given enough information about the study?
   (e.g. too much, too little, use of jargon)
2) Was there anything in particular that almost put you off taking part?
   (e.g. *concerns about taking part in research, unsure about therapy)*
3) Was there anything in particular that made you keen to take part?
   (e.g. *boredom on ward, wanting someone to talk to)*
4) Did you understand why you were randomly allocated to either therapy 1 or 2 (rather than being able to choose yourself?)
   (e.g. concerns about randomisation, was the process explained well)
5) What did you think of the questionnaires you were asked to fill out?
   (e.g. too few, too many, did they seem relevant?)

Experiences of therapy

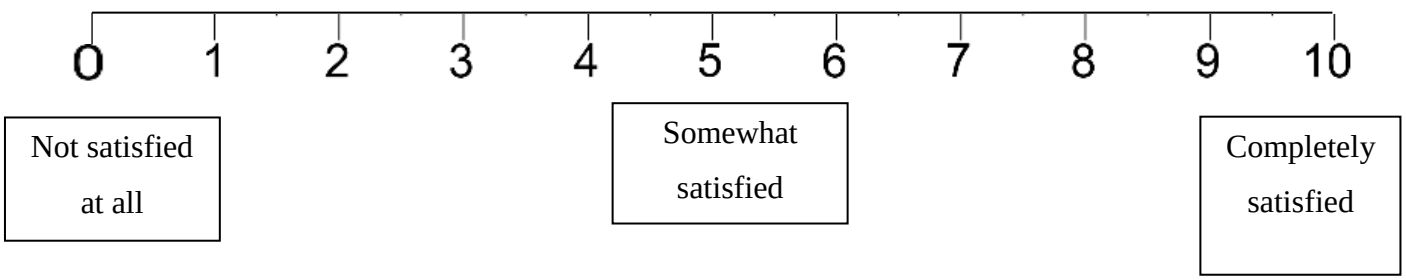
6) How did you find having therapy sessions within the ward environment?
   (e.g. problems with noise, lack of privacy?)
7) What did you think about the timing and frequency of therapy sessions?
   (*e.g. convenience, sessions too often/not often enough)*
8) What did you think about the number of sessions you were offered?
   (e.g. too many/few, about right?)
9) Have you ever been offered any therapy like this before, either in hospital or in the community?
   (e.g. was offer taken up, how did this compare with previous experiences?)
10) a. What was the most helpful thing about the therapy?
   (e.g. understanding experience, chance to talk, coping skills, sharing goal with team)
   b. What was the least helpful thing about the therapy?
   (e.g. difficult to concentrate, too much to take in at that time)
11) Have you done any mindfulness practice, or attended a mindfulness group in the past 6 months? If so, where did you do this?

Overall Satisfaction

On scale of 0 to 10, how satisfied were you with the therapy overall?

Please circle a number.

(0 means not satisfied at all, and 10 means completely satisfied).



10.16 Staff Feedback Topic Guide

(Suggestions in italics can be used as prompts in interviews/focus groups)

Views on the study

1) Was the information you were provided about the study easy to understand?
   (e.g. too much, too little, use of jargon)
2) Was there anything that made you reluctant to allow patients to take part in the study?
   (e.g. *concerns about research procedures, unsure whether therapy would help)*
3) Was there anything that made you keen for patients to take part in the study?
   (e.g. *promoting research on ward, potential benefits of therapy)*
4) Did you understand why patients were randomly allocated to either therapy 1 or 2 (rather than being able to choose themselves?)
   (e.g. concerns about randomisation, was the process explained well)
5) a. Could you guess which therapy was the control condition?
   b. Could you guess (or did patients tell you) which therapy condition they had been randomised to?
6) What outcome measures did you think the study should be focussing on?
   (e.g. symptom measures, functioning, well-being, recovery)

Views on therapy

11) What did you think about the therapy sessions taking place within the ward environment?
    (e.g. problems with room space, lack of privacy?)
12) What did you think about the timing and frequency of therapy sessions that were offered?
    (*e.g. sessions too often/not often enough)*
13) What did you think about the number of sessions that were offered?
    (e.g. too many/few, about right?)
14) What therapy are patients normally offered on your ward?
    (e.g. who offers this, is it normally taken up by patients?)
15) a. Did patients tell you anything that was helpful about the therapy?
    (e.g. understanding their experiences, chance to talk, coping skills)
    b. Did patients tell you anything that was unhelpful about the therapy?
    (e.g. difficult to concentrate, too much to take in at that time)

10.17 Patient Information Sheet

Participant Information Sheet

BrIef Talking therapIes ON wards (amBITION study)

You are being invited to take part in a research study. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read this information sheet carefully and decide if you would like to take part or not.

What is the study about?

We know that people having distressing experiences sometimes come into hospital in crisis. The aim of this study is to develop brief talking therapies which might be helpful for people when they are in hospital. Everyone in the study will be offered one of two possible talking therapies, allocated at random. This will either involve doing activities on the ward, or talking about how you are coping with things.

Why have I been asked to take part in this study?

You have been invited to take part because the Consultant Psychiatrist in charge of your care on the ward has identified you are experiencing some distress and might be willing to try out a talking therapy.

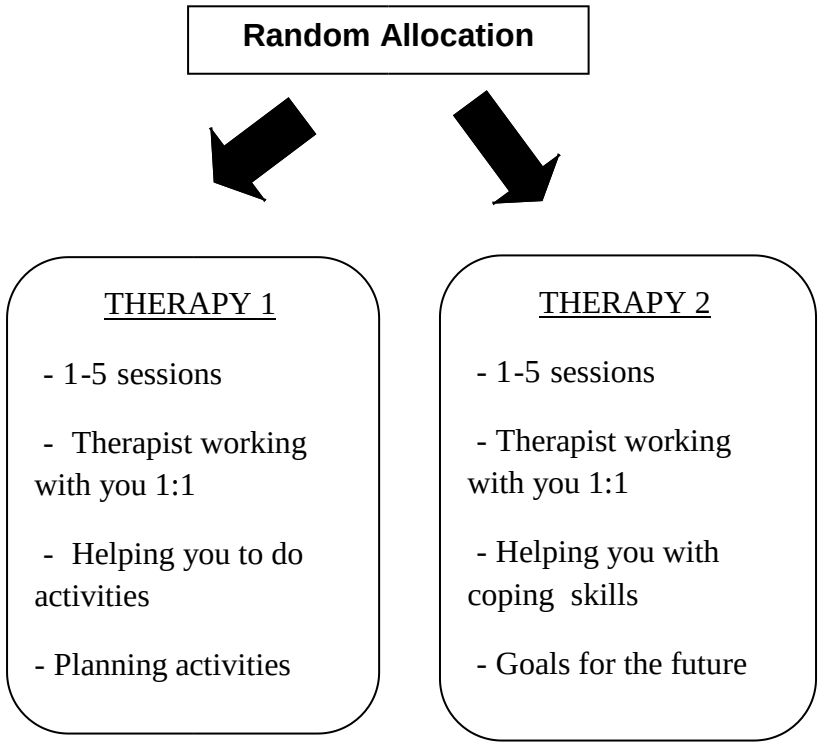
Do I have to take part?

No. Participation is entirely voluntary, which means it is up to you whether you want to take part. If you do decide to take part, but later change your mind, you are free to withdraw at

any time without giving a reason. If you decide not to take part in the study, or later withdraw from the study, this will not in any way affect the normal care you receive.

What will happen to me if I take part?

- If you decide to take part, you will be asked to sign a consent form (you will be given a copy to keep along with this information sheet).
- You will complete a brief research assessment, completing questionnaires about your current difficulties and your general well-being. This should take no longer than 20 minutes.
- You will then be randomly allocated to one of the two therapies and be given your first appointment for therapy. This will be done by computer. Random allocation means by chance, a bit like flipping a coin. This is to make sure the study is a fair test .



- You will be asked your permission for the therapy sessions to be audio-taped. You can ask for a copy of the recordings. You can still take part in the study even if you do not agree for the sessions to be recorded.

- After you have finished the therapy sessions the researchers will ask you to complete the same questionnaires as before you started therapy. We will then contact you again at 3 and 6 months from when you leave hospital to ask you to complete the questionnaires again. We will also be interested in your views about taking part in the study and how you found the therapies. We will ask you if you would be willing to take part in a feedback interview, or a focus group, but you do not have to if you do not want to.

- Some of the information we would like to collect about your contact with services in the Trust before and after therapy will be recorded in your clinical notes. We will ask your permission to gather this information from your notes, even if you decide to withdraw early from the study, and do not want to be contacted further by the researchers.

- Throughout your involvement in the study all other care / treatments will remain the same unless changed by your care team.

Will I be compensated for my time?

You will be compensated £10 for your time to complete each research assessment. If you choose to take part in a feedback interview or focus group, you will be reimbursed £20 to cover your time and travel expenses.

What are the possible disadvantages and risks of taking part?

The main disadvantage is that the talking therapies may not be helpful. Talking therapies can sometimes involve talking about feelings, thoughts or experiences which may be upsetting at times. This is a completely normal part of therapy and the therapist is very experienced in keeping this to a level you can manage. It is always possible to stop a therapy session or indeed to stop therapy altogether. For the research assessments, there are no right or wrong answers and you do not have to answer any questions you do not want to. You are free to ask the interviewer to move on to another subject or to stop the session altogether if you find any of the questions upsetting.

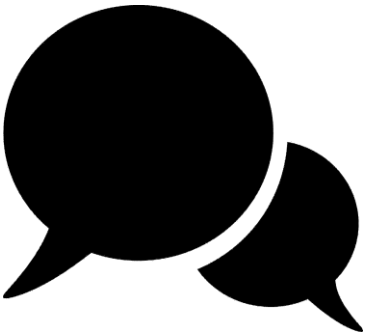
What are the possible advantages or benefits of taking part?

Both therapies are likely to have some benefit. However, this will vary from person to person. The information we collect during the study will help us to decide on whether brief talking therapies will be helpful for people on wards in the future.

Will my responses be confidential?

Yes. All data collected will be kept confidential, and identified only by an anonymous identification code that will not personally identify you. No names will be used when the results of the study are published or talked about so your identity will never be revealed in any reports based on this study. Some quotes may be used from feedback interviews or focus groups to illustrate themes in the research report, but these will all be anonymised and not used in a way that could personally identify you.

The researchers will let your care team on the ward and in the community (including your GP) know that you are attending therapy sessions as part of the study, and a brief entry will be made in your clinical notes after each session. This will not include any details about the content of what is discussed in the sessions.



If you tell the therapist something that makes them concerned for your safety, or the safety of others they will have to share this information with your care team on the ward and other professionals involved in your care as appropriate.

What will happen to the results of the research study?

The research should be completed by the end of 2017 and the results of the study will be published in an academic journal. You are welcome to have a copy of the results of the study once it is completed, if you wish.

Who is organising and funding the research?

This research is being funded by the National Institute for Health Research (NIHR). King's College London is the lead sponsor of the research. South London and Maudsley NHS Foundation Trust (SLaM) is the co-sponsor for the research.

Who has reviewed the study?

This research was reviewed and funded by the NIHR. People with experience of using local mental health services have provided advice on study procedures and documents so that the study will be carried out in the best possible way. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion (approved) by the London-Camberwell St Giles Research Ethics Committee on 29th Sep, 2015.

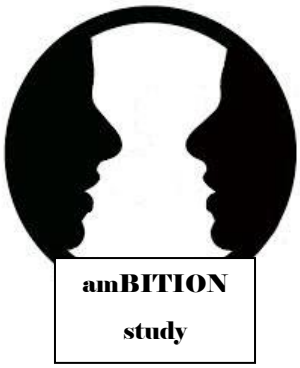
What should I do if I have questions or concerns about the research?

If you have any concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (Dr. Pamela Jacobsen, Chief Investigator, 07541 736129). If you would rather speak to someone else then you can contact the project supervisors Professor Paul Chadwick or Dr. Emmanuelle Peters at King's College London on 020 7848 0033. If you wish to complain formally, you can do this through the NHS Complaints Procedure. You can call the Patient Advice and Liaison Service (PALS) freephone on 0800 731 2864 for information on how to do this.

10.18 Patient Consent Form

KING'S College LONDON

South London and Maudsley NHS
NHS Foundation Trust



Consent Form – Part 1

Brlef Talking therapIes ON wards (amBITION study)

Consent for initial screening:
Do you consent to your electronic/written records being screened to ensure you are eligible to take part in the study? (witness should sign for verbal consent) ☐
Signature (participant/witness):- **Signature (researcher):-**
Date:- **Date:-**

1. I confirm that I have read the information sheet dated ..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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 the researchers will access relevant sections of my electronic records to record my contact with services for follow-up data after I leave hospital. I understand that if I withdraw early from the study I will not be contacted further by the researchers but this follow-up data will still be collected from my records. ☐

4. I understand that the key members of my care team will be told that I am taking part in this study (this will include, if relevant, my community consultant, care co-ordinator, GP and any therapists working with me). ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

KING'S College LONDON

Consent Form – Part 2

Brief Talking therapIes ON wards (amBITION study)

Additional consent for audio-taping of therapy sessions:

1. I agree to audio-taping of my therapy sessions for use by my therapist and their clinical supervisor to ensure a high quality of therapy. I understand that all recordings will be stored securely and identified only by anonymous identification code. I understand I can request a copy of the recordings to keep. ☐

2. I agree to audio recordings to be used for purposes of checking how well the therapy was delivered at the end of study. ☐

Signature (participant):-
Date:-

Signature (researcher):-
Date:-

10.19 Trial Steering Committee Meeting Minutes

Trial Steering Committee (TSC) Meeting 28/04/16 – Minutes

1. Welcome, introductions and apologies

Attended: Katherine Berry (Independent Chair)
Pamela Jacobsen (Chief Investigator)
Paul Chadwick (PhD Supervisor)
(Service User Advisory Group representative)

Apologies: Emmanuelle Peters (PhD Supervisor)
Emily Robinson (Trial Statistician)

2. Review Trial Report

PJ gave a summary of the trial protocol and the intervention. KB asked about the qualitative component of the study. PJ clarified this was to get participants and staff views on the trial procedures and intervention. The plan is to invite participants to give feedback via an individual interview or small focus group, led by a member of the Service User Advisory Group. KB suggested thinking about whether we have enough resources to interview everyone, and being realistic about the amount of qualitative data we could reasonably analyse. We could instead aim to interview a small number of people (e.g. 10%, N=6) but in more depth.

PJ summarised recruitment so far. Recruitment started at the Maudsley Hospital on 1 of the male wards in November 2015 (AL3), and recruitment was extended to 1 of the female wards (AL2) at the end of February 2016. Recruitment has been 2-3 participants a month so far. In order to achieve a rate of 5-6 participants a month, another male ward will be added in May (ES2) and PJ will have some extra help with recruitment from the local Clinical Research Network (CRN) who have just assigned 2 clinical studies officers (CSOs) to the study. CSOs can check patient's notes for eligibility and also do the initial approach to patients on wards to see if they are interested in participating.

Retention within the trial is good so far. All participants have received at least 1 session of therapy (which is defined as the minimum 'dose'), and no-one has been lost to follow-up. Data completeness is also high, with 100% of participants having complete baseline assessments, and 92% having complete post-therapy measures. The first wave of 3 month follow-ups have just begun. PC queried how we define "lost to follow-up" and PJ suggested this should be based on whether data on the primary outcome is available (re-admission to hospital) rather than completion of questionnaire measures, as these are secondary outcomes. Service-data will available for all participants from their SLaM electronic records, however we might not know about admissions to other trusts if someone has moved away or spent time out of the area during the follow-up period. PJ will therefore record admissions to SLaM inpatient wards, and also any collateral information on admissions elsewhere for participants who move out of area. It is possible that this information may not be available for participants who move away and cannot be contacted further.

PJ reported that 1 participant had been withdrawn from the trial due to risk to therapist (but is still open to follow-up). This led on to a discussion on how we define 'discontinued intervention', given that participants have varying number of sessions anyway depending on the length of admission. PJ suggested this should be defined on whether more sessions could have been offered had the participant not been withdrawn.

There have 2 adverse events (1 in each arm), neither of which was considered to be related to participation in the trial.

3. Any other business

No other business to discuss

4. Date and time of next meeting

We agreed it would be helpful to meet again in about 6 months' time, towards the end of the recruitment window. PJ will send round some suggested dates in November via a doodle poll. PJ will also send round a recruitment update in the interim period, in 3 months' time.

Trial Steering Committee (TSC) Meeting 13/03/17 – Minutes

1. Welcome, introductions and apologies

Attended: Katherine Berry (Independent Chair – via skype)
Pamela Jacobsen (Chief Investigator)
Paul Chadwick (PhD Supervisor)
Emmanuelle Peters (PhD Supervisor)
Emily Robinson (Trial Statistician)
(Service User Advisory Group representative)

2. Review Trial Report

PJ gave a summary of the trial report. Recruitment has now finished (N=50). Everyone in the trial received at least 1 session of therapy (defined as the minimum dose). The strategy of randomising at the beginning of session 1 was therefore a very successful way of eliminating any drop-out between randomisation and the start of therapy. Follow-ups will continue over the next 6 months until August 2017. Retention in the trial remains good. Follow-up rates are over 95% for the primary outcome (readmission rate) and over 85% for the secondary outcomes (self-report clinical measures). The trial will be written up according to the new CONSORT extension guidelines for pilot and feasibility trials. There was a suggestion to separate out those assessed further for eligibility from those not assessed further for eligibility on the CONSORT diagram to improve clarity. The ward teams and consultants are currently being asked to give some qualitative feedback on the trial, via individual interviews and focus groups. These will be conducted by assistant psychologists who work in the trust, but who were not directly involved in the trial. Garry and Christine have conducted service-user led feedback interviews with 4 trial participants so far, and the plan is to conduct between 4-6 more over the next few months.

3. **Any other business**

KB suggested thinking about sources for funding for a subsequent trial to build on this work. This could include a HTA programme grant from the NIHR or a post-doctoral fellowship award for PJ.

4. **Date and time of next meeting**

The suggested date of the next meeting will be Oct 2017. All follow-ups will have been completed by this time, and the main feasibility outcome data will be available for review. PJ will send out some dates via an online poll closer to the time.

Trial Steering Committee (TSC) Meeting 02/11/17 – Minutes

1. **Welcome, introductions and apologies**

Attended: Katherine Berry (Independent Chair)
Pamela Jacobsen (Chief Investigator)
Paul Chadwick (PhD Supervisor)
Emily Robinson (Trial Statistician)
(Service User Advisory Group representative)
(Service User Advisory Group representative)
Nancy Carney-Holland (Psychology BSc student)
Apologies: Emmanuelle Peters (PhD Supervisor)

2. **Review Trial Report**

PJ gave a summary of the trial report, highlighting that most of the data is the same as presented in the last meeting. However, we now have final figures on retention in the trial, as all follow-ups have been completed. Retention in the trial is very good, and exceeds the pre-set benchmark of no more than 20% loss to follow-up at trial end-point of 6 months post-discharge. The follow-up rate was 98% for service use data (from clinical notes) and 86% for self-report questionnaire measures. KB asked about any factors we felt were important in being able to achieve good retention in the trial. PJ commented that she felt flexibility and persistence were important in following people up, as sometimes people would be difficult to contact, or might miss appointments. However, in general people were very committed to the trial, and were sometimes willing to meet with her for the follow-up, even if they were not engaging with their community team in general. This is also seemed to reflect the fact that people valued the therapy they received as part of the trial, regardless of which arm of the trial they were in.

3. **Trial close-up and dissemination plans**

PJ and CA presented their draft of the feedback summary for participants. A parallel version can be written to feedback to ward staff. PC suggested reminding people about confidentiality and anonymity. ER also suggested some re-wording to make clear that the

main trial paper would be open access, and therefore accessible online to everyone, not just health professionals.

We briefly discussed the publication plan for the trial. PJ suggested two separate papers, a main report focussing only on the feasibility outcomes, and then a secondary paper reporting on the clinical outcomes. PJ will apply for HRA approval to collect service use data (from clinical notes only) for a further 6 months, so we have data on readmissions/relapse for up to 12 months post-discharge. The final 12-month follow-up window would be in Feb 2018.

We also talked about ideas for broader dissemination. GE suggested it might be possible to go to community meetings on the acute wards, where they have slots for external speakers, and which are attended by staff and patients. We agreed it might be a good idea to contact local mental health charities such as Rethink and Mind, and see whether they might be interested in including the study in their newsletters or online. We should also consider a press release when the trial paper is published, given the novelty of the study, and the potential impact on improving inpatient care for the future.

4. Any other business

As the trial is completed, this was the final TSC. PJ thanked all members of the committee for all their hard work and input over the course of the trial. PJ particularly thanked KB for giving her time and expertise as Chair of the TSC, and to GE and CA who have been with the project throughout the whole three years, and also conducted some of the follow-up interviews with participants.

10.20 Data Management Plan

DMP title

Project Name Mindfulness-Based Crisis Interventions (MBCI) for psychosis within acute inpatient psychiatric settings; A feasibility randomised controlled trial

Project Identifier ISRCTN: 376253384

Grant Title DRF-2014-07-003

Principal Investigator / Researcher Pamela Jacobsen

Description Feasibility randomised controlled trial of a brief mindfulness-based talking therapy for psychiatric inpatients with psychosis. The primary aim is to assess whether the trial is feasible in terms of recruitment and retention in the trial, and whether patients and staff find it an acceptable intervention. The secondary aim is to collect data on pilot outcome measures, including re-admission rates at 6-month follow-up and clinical outcome measures.

Institution King's College London

Data Collection

What data will you create or collect? (Data type, volume, methods of data capture)

The majority of the data generated by this trial will be quantitative. This will include both continuous (e.g. questionnaire scores) and categorical data (demographic characteristics). The primary data for each trial participant will be recorded on individual Case Report Forms (CRFs), which range from 500-800kb in file size (in word document format). There will be a maximum of 60 trial participants, hence a maximum of 60 CRFs will be generated. There will also be some qualitative data generated, both in the form of written feedback questionnaires and audio-taped individual interviews with trial participants and ward staff.

What formats will you use to create or collect your data?

Participant Case Report Forms (CRFs) will be saved in Microsoft Word format, but these can easily be converted into other formats such as PDF if required. Screening logs will be saved in Microsoft Excel format. The main trial database will be saved using IBM SPSS (version 24). Audio recordings, of therapy sessions and feedback interviews, will be saved in mp3 format, but can also be converted into other formats as required.

Data Documentation and Metadata

What documentation and metadata will accompany the data?

As is good practice with clinical trials, a Trial Master File (TMF) will be compiled, which will be fully indexed and organised according to a standard format. The essential documents that make up the file will be kept in a secure but accessible manner. The TMF will be kept up-to-date, to help with efficient trial management, and to comply with any required audits or investigations of how the trial was conducted.

As a general principle for good file management, file names will be generated in a standard format, and organised into clearly labelled folders, to ensure consistency between files and to make it easy to find and understand key files. For example, the digital copies of the CRFs will be labelled using a standard format so that the participant ID number is clearly identifiable, and appears at the beginning of each file name. Likewise, weekly screening logs will be labelled by ward name and date, and organised in folders according to ward, then month, to make files easy to navigate and identify.

Ethical & Legal Compliance

How will you obtain consent for data preservation and sharing?

All trial participants give written informed consent to take part in the study. The participant information sheet and consent form were submitted for review as part of the NHS ethics application, and were approved by the London-Camberwell St Giles Research Ethics Committee (REC Number: 15/LO/1338). Trial participants have the option to give additional consent to have their therapy sessions audio-taped for the purposes of checking treatment fidelity, on the basis that the recordings are stored securely and identified only by anonymous identification code. Participants and staff who take part in audio-taped feedback interviews give informed consent on the same basis, and additionally give consent for anonymous verbatim quotes to be used in research reports, which are not personally identifiable.

How will you protect the identity of participants if required?

All participant data is anonymised, and identified only by a participant identifiation number. There is an ID key, which is a password-protected excel document, which links participant names to their study indentification number. This is the only document which contains any personally identifiable information.

Data Storage and Security

How will the data be stored and backed up during the research?

All electronic data are saved on the secure networked server at King's College London (KCL) using the personal file store of the Chief Investigator. KCL file servers are managed by IT and provide regular backups. In addition to the on-site and off-site back-ups provided by KCL IT, the Chief Investigator will back up all the study files using OneDrive for Business (remote cloud storage) on a weekly basis.

How will you manage data containing confidential or sensitive information?

The storage of data containing sensitive or confidential information will be kept to a minimum. The only file for the whole trial which contains personally identifiable information (the ID key which links names to participant identification numbers) is password-protected and stored on the secure KCL network drive. Audio-recordings of therapy sessions and feedback interviews will be downloaded from the digital recorder as soon as possible (preferably within 24 hours) and saved as digital files with anonymous identification codes. Audio-recordings will be deleted from the digital recorder as soon as they have been downloaded. The paper files for each participant which contain paper copies of questionannires and therapy session records are

identified only by anonymous identification code and will be stored securely in a locked filing cabinet in a locked office. They will not be taken out of the office or stored elsewhere until they are archived at the end of the trial.

Data Archiving and Preservation

What is the long-term preservation plan for the dataset?

Once the project has ended, data that supports published research and/or has long term value will be deposited with the King's RDM System to ensure long term preservation and accessibility. King's is committed to preserving research data for a minimum of 10 years since last use of the data.

Data Sharing

How will you share your data?

When the dataset is ready to be shared it will be made publicly available via the King's RDM System. Where there are no restrictions on data sharing, datasets deposited with King's will be issued with a DOI. A metadata record for the dataset will also be published in the university's data catalogue to further increase discoverability and impact.

When will you share the data?

The funder of this trial, NIHR, does not specify when and for how long data should be archived. A summary of anonymised data could be made available to share after the publication of the main trial paper, after further consultation with NIHR.

Will there be any restrictions on sharing the data?

The data will be shared in line with policy of the funder, the NIHR. No sensitive or personally identifiable data would be shared in any case. NIHR guidelines do stipulate that "Data generated through participation of patients and the public should be put to maximum use by the research community and, whenever possible, translated to deliver patient benefit."

Responsibilities and Resources

What resources will be required to preserve and share your data?

There are no additional costs or resources anticipated in implementing this data management plan, above those already stipulated in the trial protocol and research budget.

Who will be responsible for making sure that this plan is followed?

The Chief investigator will be responsible for making sure the data management plan is followed.

Appendix 1: Data Extraction Template (incorporating MMAT)

Form version/date	Version 2/03.01.17
Review Title	Psychological therapies for psychosis within acute psychiatric inpatient settings; A systematic review of current evidence
PROSPERO ID	CRD42015025623
Name of review author completing this form	
Date form completed	
Reference of record being reviewed	
Notes (Unpublished – for own use)	*E.g. References to be followed up, source of information (especially if multiple reports of same trial, or unpublished data/personal communication included).*
METHODS	
Aim of intervention	*(as stated in the trial report/s. What was the problem that this intervention was designed to address?)*
Aim of study	*(as stated in the trial report/s. What was the trial designed to assess?)*
Study design	*(Case study/case series/observational study/uncontrolled trial/RCT etc.)*
Methods of recruitment of participants	*(how were potential participants approached and invited to participate?)*
Inclusion/exclusion criteria for participation in study	
Informed consent obtained?	*(Yes / No / Unclear)*
Ethical approval?	*(Yes / No / Unclear)*
Funding	*(including source, amount, if stated)*
Statistical methods and their appropriateness	*(if relevant - just brief overview required)*
RCTs ONLY: Power calculation?	*(Yes / No / Unclear)*
CLINICAL SETTING	
How ward is described	*e.g. acute, triage*
Characteristics of wards	*e.g. gender mix, no. of beds*
Country	

PARTICIPANTS	
Clinical details (e.g. diagnosis, no. of admissions)	
Number participated:	*Total and number in each group if applicable*
RCTs ONLY: appropriate CONSORT diagram included?	*Yes (state if significant elements missing)/No*
Age: range, mean (standard deviation)	
Gender	
Ethnicity	
Other health problem/s (if relevant)	
Stage of problem/illness (if relevant)	
Treatment received/receiving	*Description of TAU if relevant*
Other social/demographic details (e.g. literacy or reading level)	
INTERVENTIONS	
Details of intervention	*Brief description of therapy as described in paper. (Capture this information for each arm of the study, eg. Intervention A, Intervention B…)*
CBT or non-CBT based?	*State if unclear or therapy model not described*
Sub-type of therapy (if relevant)	*e.g. ACT, compassion-focused*
Mode of delivery	*e.g. individual, group, family*
Details of control/usual or routine care	
Delivery of intervention	*(eg. stages, timing, frequency, duration) (for each intervention included in the study, e.g. Intervention A; Intervention B…)*
Details of providers	*(Who delivers the intervention? Number of providers; training of providers in delivery of intervention; specify profession and role).*
Intervention quality (if relevant):	*(record any information on the quality of the intervention - assessed by study authors, others, or*

	by you - such as the evidence base of the intervention, or the quality of staff training for intervention delivery)
Fidelity/integrity	*(Was the intervention delivered as intended? Record any assessment of this*).
Did therapy continue post-discharge?	
Adaptations to standard protocols/procedures	
OUTCOMES	
Principal and secondary outcome measures	*As stated in paper - note if not explicitly stated or unclear*
Questionnaires/ assessment tools used	*(give reference for standard measures or state if unvalidated or new measure)*
Methods of assessing outcome measures	*(eg. Phone survey, questionnaire, physical measurements (for each outcome))*
Methods of follow-up for non-respondents	
Timing of outcome assessment	*(including frequency, length of follow up (for each outcome))*
Data for meta-analysis could be extracted from paper for primary outcome measure (Dichotomous or Continuous?)?	*Yes/No/Partial (state what missing if relevant)*
Any mention of Adverse events?	*Yes/No e.g. whether formally monitored or not, mention of incidents which would be considered an adverse event (whether or not explicitly labelled as such)*
Details of any Adverse events?	*(eg. Complaints, levels of dissatisfaction, adverse incidents, side effects)*

QUALITY ASSESSMENT (MMAT, 2011)					
Types of mixed methods study components or primary studies	**Methodological quality criteria (see tutorial for definitions and examples)**	**Responses**			
		Yes	**No**	**Can't tell**	**Comments**
Screening questions (for all types)	Are there clear qualitative and quantitative research questions (or objectives), or a clear mixed methods question (or objective)?				
	Do the collected data address the research question (objective)? E.g. consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components)				
	Further appraisal may not be feasible or appropriate when the answer is 'no' or 'can't tell' to one or both of the screening questions				

Types of mixed methods study components or primary studies	Methodological quality criteria (see tutorial for definitions and examples)	Responses			
		Yes	No	Can't tell	Comments
1. Qualitative	1.1 Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?				
	1.2 Is the process for analyzing qualitative data relevant to address the research question (objective)?				
	1.3 Is appropriate consideration given to how findings relate to the context, e.g. the setting in which the data were collected?				
	1.4 Is appropriate consideration given to how findings relate to researchers' influence e.g. through their interactions with participants?				
2. Quantitative randomized controlled (trials)	2.1 Is there a clear description of the randomization (or an appropriate sequence generation?)				
	2.2 Is there a clear description of the allocation concealment (or blinding when applicable?)				
	2.3 Are there complete outcome data (80% or above?)				
	2.4 Is there low withdrawal/drop-out (below 20%)?				

Types of mixed methods study components or primary studies	Methodological quality criteria (see tutorial for definitions and examples)	Responses			
		Yes	No	Can't tell	Comments
3. Quantitative non-randomised	3.1 Are participants recruited in a way that minimizes selection bias?				
	3.2 Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?				
	3.3 In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls) are the participants comparable, or do researchers take into account (control for) the difference between these groups?				
	3.4 Are there complete outcome data (80% or above), and when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up?)				

Types of mixed methods study components or primary studies	Methodological quality criteria (see tutorial for definitions and examples)	Responses			
		Yes	No	Can't tell	Comments
4. Quantitative descriptive	4.1 Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?				
	4.2 Is the sample representative of the population understudy?				
	4.3 Are measurements appropriate (clear origin, or validity known, or standard instrument?)				
	4.4 Is there an acceptable response rate (60% or above?)				
5. Mixed Methods *Criteria for the qualitative component (1.1. to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4, or 4.1 to 4.4) must also be applied*	5.1 Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective?)				
	5.2 Is the integration of qualitative and quantitative data (or results) relevant to address the research question (objective?)				
	5.3 Is appropriate consideration given to the limitations associated with this integration e.g. the divergence of qualitative and quantitative data (or results) in a triangulation design?				

Appendix 2: Paper Publication of Trial Protocol in *Pilot and Feasibility Trials*

Jacobsen *et al. Pilot and Feasibility Studies* (2016) 2:43
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Pilot and Feasibility Studies

STUDY PROTOCOL Open Access

Mindfulness-Based Crisis Interventions for patients with psychotic symptoms on acute psychiatric wards (amBITION study): protocol for a feasibility randomised controlled trial

Pamela Jacobsen[1*], Emmanuelle Peters[1,2] and Paul Chadwick[1]

Abstract

Background: Inpatient psychiatric care is a scarce and expensive resource in the National Health Service (NHS), with chronic bed shortages being partly driven by high re-admission rates. People often need to go to a hospital when they have a mental health crisis due to overwhelming distressing psychotic symptoms, such as hearing voices (hallucinations) or experiencing unusual beliefs (delusions). Brief talking therapies may be helpful for people during an acute inpatient admission as an adjunct to medication in reducing re-admission rates, and despite promising findings from trials in the USA, there have not yet been any clinical trials on this kind of intervention within NHS settings.

Methods/design: The amBITION study is a feasibility randomised controlled trial (RCT) of a manualised brief talking therapy (Mindfulness-Based Crisis Intervention (MBCI)). Inpatients on acute psychiatric wards are eligible for the study if they report at least one positive psychotic symptom and are willing and able to engage in a talking therapy. In addition to treatment as usual (TAU), participants will be randomly allocated to receive either MBCI or a control intervention (social activity therapy (SAT)) which will be based on doing activities on the ward with the therapist. The primary objective of the study is to find out whether it is possible to carry out this kind of trial successfully within UK inpatient settings and to find out whether patients and staff find it an acceptable intervention. The secondary objective is to collect pilot data on primary and secondary outcome measures, including re-admission rates at 6-month follow-up. This will provide information on the appropriateness of re-admission as the primary outcome measure for future efficacy trials, as well as data on the acceptability and utility of the clinical self-report measures.

Discussion: The results of the feasibility trial will indicate whether a subsequent efficacy pilot trial is warranted and, if so, will provide vital information for the planning of such a trial (e.g. pilot data on expected effect sizes). If future research finds that MBCI is an effective and safe intervention, then patients will benefit from access to better treatment within inpatient care which would reduce re-admission rates. This trial therefore addresses an area of urgent concern for service users, clinicians and the wider NHS.

Trial registration: Current controlled trials ISRCTN37625384

Keywords: Randomised controlled trial, Crisis intervention, Inpatients, Psychosis, Psychological therapy, Mindfulness

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Background

People often need to go to a hospital when they have a mental health crisis due to overwhelming distressing psychotic symptoms, such as hearing voices (hallucinations) or experiencing unusual beliefs (delusions). However, inpatient care is the most costly, and over-subscribed, form of care provided by NHS mental health trusts. Mental health trusts across the United Kingdom (UK) can neither afford, nor physically accommodate, all the patients requiring admissions [1]. Reducing admission rates is therefore an area of urgent priority given on-going bed closures, with a recent study reporting a 62 % reduction in psychiatric beds nationwide from 1988 to 2008 [2]. Psychological interventions are well-established in their efficacy for reducing psychotic symptoms that have not responded adequately to pharmacological intervention [3]. However, most therapy trials in the UK have been conducted in outpatient settings, with therapy lasting approximately 6 months [4]. There is a dearth of robust evidence for the feasibility and efficacy of brief psychological interventions exclusively within acute inpatient settings. This could be due to unfounded assumptions that inpatients are always too unwell to make use of therapy or that therapy always has to be lengthy to be of any benefit. However, this may represent a missed opportunity to engage patients in psychological therapies at a critical point in the care pathway, using crisis-focused interventions. When people are admitted to a hospital at times of crisis, this can be an ideal time to offer psychological interventions as problematic thoughts, feelings and behaviours are readily accessible and the inpatient setting provides wider support. Two research studies conducted in the USA have investigated brief psychological interventions for inpatients with psychotic symptoms [5, 6]. Participants received between one and five individual sessions of an acceptance-based therapy known as acceptance and commitment therapy (ACT). Brief crisis-focused interventions target risk of future relapse and re-admission by seeking to help a person understand how their existing coping strategies have brought them into crisis and to develop skills in alternative coping strategies. ACT interventions aim to increase what is termed *psychological flexibility*, defined as "the ability to contact the present moment more fully and without needless defence" [7]. Patients' existing coping strategies are often lacking in psychological flexibility, relying instead heavily on experiential avoidance (i.e. attempts to avoid unwanted thoughts, feelings or sensations) [8]. For example, a study of 50 patients experiencing voices in the context of a psychotic illness found that being less accepting towards internal experiences was positively associated with behavioural attempts to resist voices [9]. For example, people may cope with unpleasant auditory hallucinations by drinking alcohol or using illicit drugs in an attempt to block them out. Someone experiencing persecutory delusions may choose to avoid the anxiety they feel when they go out in public by isolating themselves at home. These behaviours not only stop the person from being able to function normally in their everyday life but also increase the risk of serious self-neglect and re-admission. ACT therefore aims to help people to accept symptoms, rather than trying to avoid or eliminate them, and to defuse or step back from them, while promoting behaviours which are consistent with the person's underlying values and goals in life [7]. This acceptance-based approach is also consistent with Chadwick's model of mindfulness for psychosis, in which people are taught skills in relating mindfully to psychotic symptoms, as an alternative to either experiential avoidance or simply getting lost in struggle and rumination [10].

The two USA studies found that the intervention was successful in reducing re-admission rates at 4-month follow-up. Bach and Hayes reported that the re-hospitalisation rate of the ACT group was half that of the treatment as usual (TAU) group (20 vs. 40 % respectively), a statistically significant difference. Gaudiano and Herbert (2006) reported the same trend (28 % ACT vs. 45 % TAU respectively), but these results did not reach statistical significance. It is not yet known whether such brief crisis-focused interventions would translate effectively to NHS inpatient care in the UK. As brief crisis-focused psychological interventions have not been subject to controlled trials in the UK, this study will be a feasibility trial providing valuable data to inform possible later efficacy pilot trials (BrIef Talking therapIes ON wards (amBITION) study). A brief, manualised therapy (Mindfulness-Based Crisis Intervention (MBCI)) will be compared with an active control condition (social activity therapy (SAT)) to help account for non-specific elements of therapy, such as having individual attention from an empathic therapist.

The primary objective of the study is to find out whether it is possible to carry out this kind of trial successfully within inpatient settings and to find out whether patients and staff find it an acceptable intervention. The secondary objective is to collect pilot data on primary and secondary outcome measures.

Methods/design

Study design and timeline

This study is a single-centre, parallel-groups, feasibility randomised controlled trial. Trial procedures and the assessment schedule are shown in the study plan (Fig. 1). In brief, service use data (re-hospitalisation rate, use of crisis team, relapse rate) will be collected using case note review at 3- and 6-month follow-up. Self-report clinical measures will be taken at baseline, post-therapy and at 3-month (mid-point) and 6-month follow-up after discharge (end-point). The 3-month mid-point follow-up

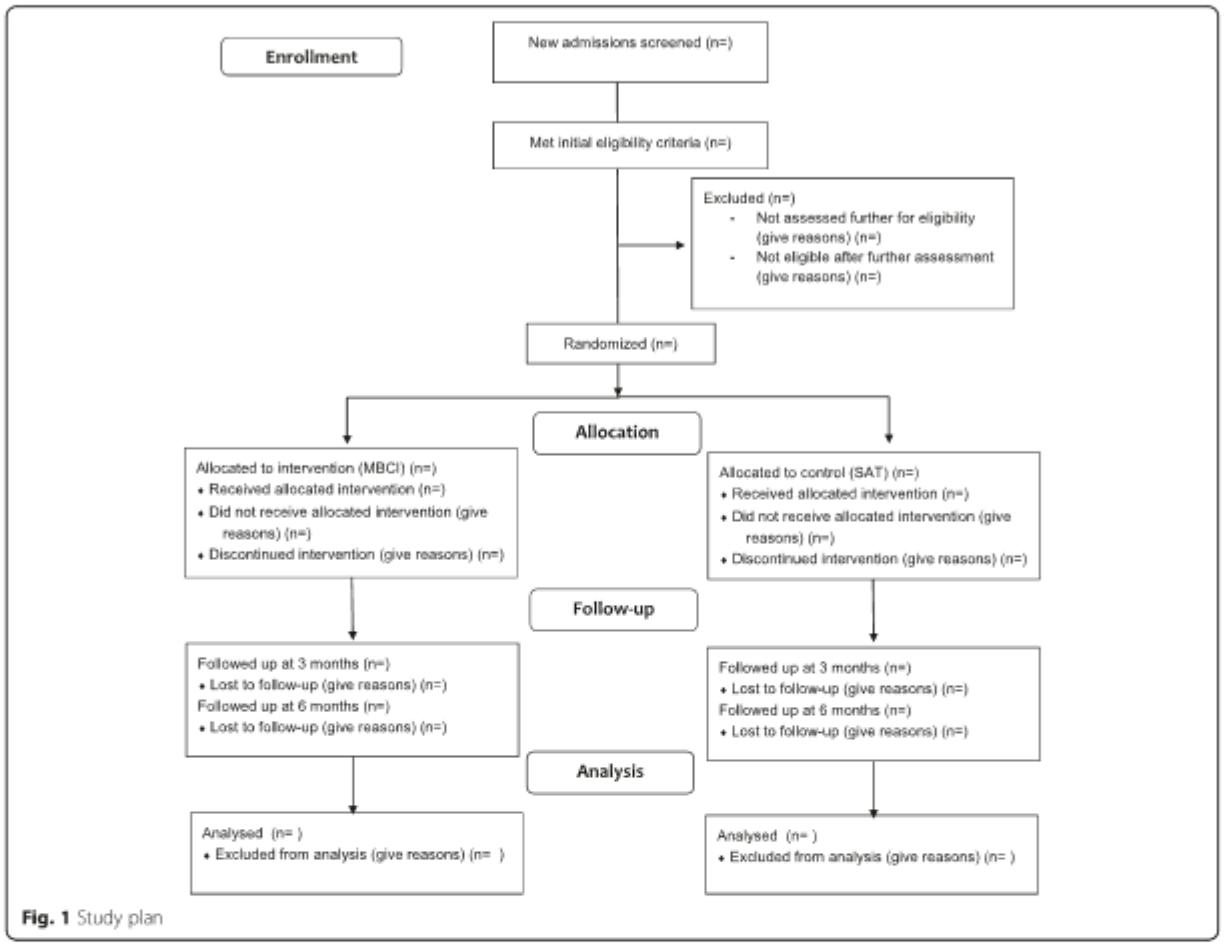

Fig. 1 Study plan

was included in order to minimise missing data arising from loss to follow-up and to provide more detailed information on symptom change in the short-term after discharge. The service use data will provide information on the appropriateness and sufficiency of re-admission as the primary outcome measure for future efficacy trials or whether an additional primary outcome would be indicated (e.g. relapse rate from case note review). The trial will also provide important data on the acceptability and utility of the self-report clinical measures, for example, whether participants are willing and able to complete the measures and whether they show sensitivity to change over time.

Study population

Inclusion criteria

i) Aged 18 or above
ii) Current psychiatric inpatient on a working-age adult ward
iii) Diagnosis of schizophrenia-spectrum disorder or psychotic symptoms in the context of an affective disorder (ICD-10 codes F20-39; [11])
iv) Reports at least one current positive psychotic symptom (scores >1 on frequency on self-report symptom scale)
v) Able to give informed consent to participate in trial, as assessed by consultant psychiatrist/responsible clinician
vi) Willing and able to engage in psychological therapy

Exclusion criteria

i) Established diagnosis of learning disability or major cognitive impairment arising from any underlying medical condition (e.g. head injury, neurological disorder) resulting in significant functional impairment
ii) Unable to engage in a talking therapy in English or to complete simple written questionnaires in English
iii) Primary diagnosis of substance misuse
iv) Lacks capacity to consent to participation in research trial
v) Unable to take part in individual therapy due to risk of aggression/violence

vi) Mental state precludes possibility of engaging in a talking therapy, e.g. significant thought disorder

Recruitment, randomisation and blinding

Patients will be recruited from acute inpatient psychiatric wards from a large mental health trust in South London, serving a local population of 1.1 million people, with approximately 6000 acute inpatient admissions a year. Potentially eligible patients will be identified by their inpatient care team and will be approached to take part by the researcher with permission of their inpatient Consultant Psychiatrist and primary nurse. Patients may take part in the trial if they are admitted under a section of the Mental Health Act (MHA) so long as they are deemed to have retained capacity to consent to participation in research. Further eligibility screening by reference to electronic clinical notes will be conducted with written consent from patients who have been approached and are potentially interested in participating. Patients will be given a copy of the brief patient leaflet at this point to introduce them to the main aims of the study. Once the researcher has confirmed the patient's eligibility, she will approach the patient again to give them a copy of the full patient information sheet and to talk it over with them and explain the study further. Patients will be given sufficient time (at least until the next day) to read over the information, think it over, ask questions and to discuss their participation with anyone they may wish to (e.g. primary nurse, family member). After giving informed consent, eligible participants will first complete baseline measures and then be randomised using a computerised service at the Kings Clinical Trials Unit (KCTU). Due to the nature of the intervention, blinding of participants and therapist is not possible. The participant's inpatient and community care team will however be blinded to treatment allocation, as far as possible. Conservative measures will be used such as not referring to any content of the therapy sessions in clinical notes and conducting all therapy sessions in a private room on the ward. The two therapies will be referred to by neutral labels in all participant and staff literature (therapy 1 vs. therapy 2) in order to promote equal treatment credibility between the conditions. Block randomisation will be used, with randomly varying block sizes to ensure allocation concealment. As this is a feasibility trial, the primary outcomes relate to feasibility data rather than clinical outcomes. PJ will be primarily responsible for gathering all trial data and will not be blinded to treatment condition, but some follow-up data may also be collected wherever possible by appropriately trained staff independent of the clinical team (e.g. research nurse, postgraduate students). The study will be conducted in line with Good Clinical Practice (GCP) guidelines for clinical trials [12]. The data management plan includes standard procedures such as the use of anonymous identification codes.

Sample size

A power calculation to determine a sample size is not appropriate for a feasibility trial, as the purpose of the trial is not to establish efficacy. However, the data from this trial could be used to inform a sample size calculation for a later efficacy pilot trial. The target recruitment for this feasibility trial will be $N = 60$ (30 in each arm).This was determined with reference to existing studies in the field and is consistent with good practice recommendations for feasibility/pilot studies [13, 14].

Description of therapies

Therapy sessions in both conditions will be delivered on an individual basis in a private room on an inpatient ward. The trial therapist in both conditions will be PJ, who is a Clinical Psychologist registered with the UK Health and Care Professions Council (HCPC) and has expertise in cognitive behavioural therapy for psychosis (CBTp) and mindfulness interventions as well as experience of working in acute settings. Although not matched on a case by case basis, therapy sessions in both conditions will range from one to five sessions, depending on length of admission, with the frequency of sessions adjusted as needed between a minimum of weekly and maximum of daily. All sessions will follow a stand-alone, self-contained format in order to accommodate unpredictable lengths of stay and unexpected discharges. Participants in the trial will continue to receive treatment as usual (TAU) both during their inpatient admission and post-discharge. In practice, this may include medication, attendance at activity and/or therapy groups, individual therapy sessions and family therapy sessions.

Mindfulness-Based Crisis Interventions (MBCI)—experimental intervention

MBCI was developed in line with the model of mindfulness for psychosis proposed by Chadwick [10]. People who experience positive psychotic symptoms (e.g. voices, paranoid thoughts) often respond by trying to avoid experiences (experiential avoidance) or at the other end of the spectrum, by getting lost in engaging with them (rumination, confrontation). Mindfulness offers an alternative way of responding, with acceptance and non-judgemental awareness in each moment, allowing psychotic symptoms to move in and out of awareness without the person getting caught up in struggling against them. The treatment protocol for the current trial was adapted for use within an acute crisis setting, partly based on PJ's clinical experience of working within inpatient settings and in consultation with ACT experts in the USA, including the lead author of one of the key inpatient trials [6].

There are three key components to be included in each session:

i. Developing mindfulness skills (guided practice)
ii. Making sense of crisis using mindfulness model
iii. Identifying values and setting goals

A typical session will start with a 5-min mindfulness practice, including frequent guidance that includes reference to psychotic experience and uses everyday, concrete language. The therapist will then move on to developing a collaborative understanding with the participant of what has brought them to a hospital on this occasion, focussing on how they usually try to cope with difficult voices, thoughts, feelings and experiences and how well these strategies are working for them. Given the time constraints, therapists will share a formulation and example strategies (following Chadwick [10]), asking the participant to connect with and provide examples of his or her own habitual reactions. In line with the formulation, the therapist will highlight the participant's attempts to either block out, suppress or otherwise escape from unwanted internal experiences or reactions that mean getting caught up in struggling with internal experiences (rumination, fighting). Mindfulness is located as a middle way between these two reactive styles. Finally, the therapist will work with the participant to identify their values (e.g. family, work, health, society) and discuss specific behavioural goals consistent with these values. Participants are then helped to set a small, achievable goal for homework at the end of each session which can be reviewed at the beginning of next session, where possible. In preparation for discharge, longer-term goals can also be identified (e.g. starting a college course) and will be shared with the community care team at the end of therapy, to act as a bridge to carrying on the recovery process in the community.

Social activity therapy (SAT)—control intervention

This control condition is taken from the PICASSO trial of CBTp for people with psychosis and a history of violence and was conducted partly on inpatient wards [15]. SAT involves collaboratively working with the participant to identify activities they enjoy and which they can engage in during sessions and between sessions as they wish (e.g. board games, puzzles). The aim is to provide a supportive environment with a therapist using non-specific aspects of therapy (e.g. agenda setting, collaboration, feedback, empathy). The therapist aims to keep the sessions activity focussed and to be supportive, collaborative and empathic without employing any therapy techniques specific to any model of therapy, including CBTp or mindfulness-based therapies.

Treatment fidelity

The trial therapist will receive regular supervision from an independent clinical supervisor with expertise in acute care and mindfulness-based approaches. Therapy sessions will be audio-taped with participant consent (the proportion of participants who consent to audio-recording will also be recorded and reported as part of the trial outcomes). A sample of therapy sessions will be assessed by a blinded and independent rater for therapy fidelity. An adherence and competency scale for the trial has been developed for this purpose, based on existing scales from other therapy trials [15–17] and relevant theoretical papers and therapy manuals [7, 10, 18].

Outcome measures

Primary objective—feasibility/acceptability data

1) Number of eligible participants identified over study period
2) Total numbers recruited into trial and recruitment rate (benchmark of 80 % of target)
3) Proportion of participants who drop out during the intervention stage
4) Range and average number of sessions completed (including number of sessions attended as a proportion of those offered)
5) Reasons for participants dropping out during the intervention stage
6) Number lost to follow-up and reasons (benchmark of less than 20 % to be set in line with previous studies)
7) Any unexpected adverse effects of participating in the trial

Qualitative data on acceptability

1) Participant feedback on trial procedures, randomisation and credibility of two therapies
2) Staff feedback on trial procedures, recruitment strategies and blinding procedures

At the end of the study, participants will be asked if they are willing to give feedback on trial procedures and therapy by way of a follow-up interview or focus group. Participation will be optional. The feedback interviews/focus groups will be conducted by an appropriately trained service user researcher. Staff from the inpatient units where patients were recruited will also be invited to give feedback on the trial via interview or focus group and will be asked to give informed written consent. Interviews and focus groups will be audio-recorded, with written consent from all participants. Qualitative data will be analysed using thematic analysis [19], which is a commonly used approach within applied health research.

The data will be initially coded line-by-line to identify emergent themes, which will then be grouped together into larger themes and sub-themes. The data will be coded by at least two people, in order to allow some degree of inter-rater reliability.

Secondary objective—pilot data

Pilot outcome measures (service use and clinical measures) will be collected, as detailed in Table 1. A cost-effectiveness analysis of the intervention is outside the scope of this feasibility study; however, the service-use data collected would be relevant to the future assessment of economic costs. This is in addition to data on therapy costs which will be collected, such as the average number of sessions received per participant.

Description of clinical measures

1) Therapy credibility
   Immediately after randomisation, participants will be read a brief description of the therapy they have been assigned to. They will then be asked to rate on a scale from 0 (not helpful at all) to 10 (extremely helpful) how helpful they think this therapy sounds.
2) Stress bubbles
   The use of within-session measures can be helpful in measuring change in brief interventions, by capturing small shifts in key processes that may occur over the course of a therapy session. Stress bubbles are a form of visual analogue scale, with six bubbles gradually increasing in size from "not at all" (1) to "extremely" (6). Respondents rate three items

Table 1 Summary of outcome measures

Pilot data—inpatient/crisis service use

Outcome	Method	Time period
Primary outcome:		
1) Re-hospitalisation (≥1 OBD)	Clinical notes	Discharge—3- and 6-month follow-up
Secondary outcomes:		
2) Time to re-admission (days)	Clinical notes	Discharge—3- and 6-month follow-up
3) Total number of OBDs	Clinical notes	Discharge—3- and 6-month follow-up
4) Episodes of care with crisis/home treatment team	Clinical notes	Discharge—3- and 6-month follow-up
5) Contact with CMHT (number of meetings/contact with CMHT including care co-ordinator)	Clinical notes	Discharge—3- and 6-month follow-up
6) Reference to therapy goal which was shared with team	Clinical notes	Discharge—3- and 6-month follow-up
7) Relapse rate	Clinical notes	Discharge—3- and 6-month follow-up

Pilot data—clinical measures

Construct assessed	Questionnaire	Method	Time points
Credibility of therapy	1) Therapy credibility	Self-report	Baseline only (immediately post-randomisation)
In the moment rating of stress and interference from symptoms and hope for the future	2) Stress bubbles	Self-report	At the beginning and end of every therapy session
Frequency, distress and believability of most distressing symptom	3) Self-ratings of psychotic symptoms (based on Bach and Hayes, 2002; Gaudiano and Herbert, 2006)	Self-report	Baseline, end of therapy, 3-month mid-point and 6-month follow-up
Mood—depression, anxiety and stress	4) DASS-21 (Depression, Anxiety and Stress Scale; Lovibond and Lovibond, 1995)	Self-report	Baseline, end of therapy, 3-month mid-point and 6-month follow-up
Self-defined recovery	5) QPR (Questionnaire about the Process of Recovery; Neil et al 2009)	Self-report	Baseline, end of therapy, 3-month mid-point and 6-month follow-up
Voices (incl. frequency, distress, interference and compliance)	6) HPSVQ (Hamilton Program for Schizophrenia Voices Questionnaire; Van Lieshout and Goldberg, 2007)	Self-report	Baseline, end of therapy, 3-month mid-point and 6-month follow-up
Mindfulness	7) SMQ (Southampton Mindfulness Questionnaire; Chadwick et al, 2008)	Self-report	Baseline, end of therapy, 3-month mid-point and 6-month follow-up

OBD occupied bed day, *CMHT* community mental health team

(stress, interference from symptoms and hope for the future) at the beginning and end of every session. These unpublished scales have been successfully used in a previous study of mindfulness interventions for psychosis [20].

3) Self-ratings of psychotic symptoms
This is a self-report scale which asks respondents to rate their psychotic symptoms (voices and/or distressing beliefs) on a scale of 1–7 (frequency) and 0–10 (distress and believability). These scales were used in the ACT inpatient trials [5, 6] and were found to be easy for participants to complete and showed sensitivity to change over time.
4) Depression, Anxiety and Stress Scales (DASS-21) [21]
The DASS-21 is a short-form version of the original 42-item DASS comprising seven items on each of the three sub-scales for depression, anxiety and stress. It is a self-report scale with respondents scoring each item on a four-point scale from 0 (never) to 3 (almost always). The DASS-21 has been well-validated in both clinical [22] and non-clinical samples [23]. The DASS-21 is particularly suitable for this study, being relatively quick and easy to complete, and has been shown to have good internal consistency and convergent validity in an acute psychiatric population [24] and is suitable for use with people experiencing psychotic symptoms [25].
5) Questionnaire about the Process of Recovery (QPR) [26]
The QPR is a 22-item self-report measure based on service user accounts of the process of recovery from psychosis. It has two sub-scales assessing both intrapersonal and interpersonal processes in recovery. Each item is rated on a five-point scale from 0 (disagree strongly) to 4 (agree strongly). Neil et al. [26] report that the scale has good internal consistency, construct validity and reliability.
6) Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) [27]
The HPSVQ is a 13-item self-report measure in which respondent rate the first nine items on a five-point Likert scale from zero (lowest severity) to four (highest severity). The total score of these nine items is intended to indicate the severity of auditory verbal hallucinations and includes items on frequency, distress and interference with daily activities. There are an additional four qualitative items, not included for the purposes of this study. Kim et al. [28] reported high test-retest reliability and good convergent validity with established clinician-rated scales (PSYRATS-AH [29]; PANSS [30]) when used in a clinical sample of people with a diagnosis of schizophrenia.
7) Southampton Mindfulness Questionnaire (SMQ) [31]
The SMQ is a 16-item self-report measure designed to assess mindfulness of difficult thoughts and images. Each item is scored on a seven-point scale ranging from 0 (totally agree) to 6 (disagree totally). The SMQ has been validated in a clinical sample of people experiencing distressing psychotic symptoms. Chadwick et al. [31] report that the SMQ has good internal reliability and shows convergent reliability with other established mindfulness scales (e.g. MAAS; [32]).

Service user involvement

Service user involvement has been the key to the development of the trial protocol through consultation with local groups. Service users who have been consulted have supported the aims of the trial enthusiastically because they report feeling the provision of talking therapies on inpatient units is a very neglected and under-researched part of mental health care. A Service User Advisory Group (SUAG) has also been convened for the purposes of providing further consultation over the course of the study. Members of the SUAG will provide input to the Trial Steering Committee (TSC), in addition to taking the lead on carrying out feedback interviews and running focus groups with participants after the trial has ended.

Analysis plan

Descriptive statistics will be reported for the key outcomes on the feasibility data (including mean averages, standard deviations and ranges where appropriate). Flow through the trial will also be presented in a standard CONSORT diagram, showing number approached to participate, number randomised, drop-outs before the end of treatment and numbers retained in the trial at 3- and 6-month follow-up. Pilot data on the primary outcome of re-hospitalisation at 6-month follow-up will be analysed using survival analysis. The proportion n (%) of patients readmitted at 3 and 6 months will be reported, with the difference in time to re-admission between intervention and control groups being formally compared using Kaplan-Meier/Log rank survival analysis. Odds ratios with 95 % confidence intervals will be calculated and used to provide an indicator of measurement precision. This will help provide information on the appropriateness of re-admission as the primary outcome measure for future trials. In order to provide data for future sample size calculations, pilot data on clinical measures will be analysed using the general linear model, co-varying for baseline score and treatment condition. All analyses will be done on an intention-to-treat principle, in consultation with the KCTU. As this is a feasibility study, it is not powered to detect treatment efficacy and accordingly all hypothesis testing should be treated as preliminary and interpreted with caution.

Discussion

This protocol describes the first RCT of a brief talking therapy for psychosis (MBCI) designed specifically for delivery in acute inpatient settings in the UK. It builds on encouraging pilot trials from the USA which indicate that brief ACT interventions during inpatient admissions may help people to stay out of hospital for longer after discharge [5, 6]. Service users consistently report they do not have good enough access to talking therapies during inpatient admissions, although this is something they rate as a high priority [33, 34]. This research proposal therefore addresses an area of urgent concern for service users, as well an area of clinical and economic concern for the NHS, given the high cost of inpatient care. The so-called bed crisis in UK psychiatric acute care has been well-publicised recently and unfortunately shows no signs of abating. This crisis has led the Royal College of Psychiatrists to establish an independent Commission to review the provision of acute inpatient psychiatric care for adults in the UK, in response to widespread concern about whether there are sufficient beds available [35]. Providing high-quality care during an inpatient admission may help to reduce the demand for inpatient beds by reducing re-admissions rates. As well as the economic costs of "failed" discharges leading to rapid re-admission, there is of course a great personal and social cost to such failures in mental health care. Service users often report a psychiatric admission as a highly distressing, disruptive and stigmatising experience and one to be avoided at all cost [36].

Conclusion

In summary, the results of this feasibility trial will indicate whether a subsequent efficacy pilot RCT is warranted and, if so, will provide vital information for the planning of such a trial. If future research finds that MBCI is an effective and safe intervention, then patients will benefit from access to better treatment within inpatient care which could help them stay out of hospital for longer after discharge. This would also help NHS mental health trusts to deliver more cost-effective inpatient care as savings would be made over the longer-term due to reduced service use by patients.

Trial status

In preparation.

Abbreviations

ACT, acceptance and commitment therapy; CBTp, cognitive behavioural therapy for psychosis; CMHT, community mental health team; DASS-21, Depression, Anxiety and Stress Scales-21; HCPC, Health and Care Professions Council; HPSVQ, Hamilton Program for Schizophrenia Voices Questionnaire; ICD-10, International Statistical Classification of Diseases and Related Health Problems, tenth edition; KCTU, King's Clinical Trials Unit; MBCI, Mindfulness-Based Crisis Interventions; MHA, Mental Health Act; NHS, National Health Service; PANSS, Positive and Negative Syndrome Scale; PSYRATS-AH, Psychotic Symptom Rating Scales—Auditory Hallucinations; RCPsych, Royal College of Psychiatrists; RCT, randomised controlled trial; REC, Research Ethics Committee; SAT, social activity therapy; SMQ, Southampton Mindfulness Questionnaire; SUAG, Service User Advisory Group; TAU, treatment as usual; TSC, Trial Steering Committee; UK, United Kingdom; QPR, Questionnaire about the Process of Recovery

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Authors' contributions

All authors participated in the design of the trial. PJ wrote the manuscript, and all authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Ethical approval for the study was given by the London-Camberwell St Giles Research Ethics Committee (REC reference number: 15/LO/1338). This ethics committee is part of the UK Health Departments' Research Ethics Service. This service functions to protect the rights, safety, dignity and well-being of research participants whilst facilitating and promoting ethical research of potential benefit to participants, science and society.

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