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Reducing Distress and Supporting Positive Mental Health with Mindfulness

Section A: Mindfulness-based interventions for adults experiencing Borderline Personality Disorder: A systematic review and meta-analysis

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Section B: Living Well with Mindfulness (LiveMind): A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

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Summary of the Major Research Project

Section A describes a systematic review and meta-analysis of the literature around mindfulness-based interventions (MBIs) and brief exposures of mindfulness for individuals with a diagnosis of Borderline Personality Disorder (BPD). Eligible studies are critically evaluated and synthesised with reference to existing models of BPD development and maintenance (Selby, Fehling, Panza, & Kranzler, 2016), and transdiagnostic processes underlying the effectiveness of mindfulness (Roemer & Orsillo, 2002). Questions relating to efficacy, effectiveness, and acceptability are explored.

Section B describes a randomised controlled trial and qualitative observational study exploring the feasibility of a novel four-session transdiagnostic MBI developed for secondary care mental health service-users; Living Well With Mindfulness (LiveMind). Questions concerning rates of recruitment, retention, acceptability, and preliminary effectiveness are reported.

Section C contains additional information and appendices

Contents

SECTION A: LITERATURE REVIEW PAPER

What effects do mindfulness-based interventions have for adults with a diagnosis of Borderline Personality Disorder: A systematic review and meta-analysis?

Word Count: 7581

Abstract

Secondary Care NHS services brief Mindfulness-Based Interventions (MBIs) are increasingly offered. However, little is known about their effectiveness in this context. This study explores the effects of MBIs for adults with a commonly encountered secondary care presentation: Borderline Personality Disorder (BPD). Six electronic databases were systematically searched with keywords, and 15 reports of 11 studies were selected for inclusion. Eligibility criteria stipulated that studies were investigating either MBIs (n=8), or brief manipulations of mindfulness (n=3), and had recruited adults with a confirmed diagnosis of BPD. A meta-analysis of four studies revealed a statistically significant, medium sized effect of MBIs on BPD symptom severity. This was significantly larger than the effect of the leading intervention for BPD: Dialectical Behaviour Therapy. Empirical evidence also indicated that MBIs led to positive outcomes on a range of mood variables and impulsivity for adults with BPD. Several candidates for mediators were explored and preliminary evidence suggested that higher levels of MBI input may be linked with better outcomes. Limitations include small sample sizes, high drop-out, and a wide range of outcome measures across studies. Service providers and clinicians should focus on promoting engagement to MBIs, and further research should investigate the acceptability of MBIs for this population in a naturalistic setting (i.e. everyday clinical practice).

Keywords: borderline personality disorder, mindfulness, positive mental health

Introduction

Borderline Personality Disorder (BPD) is characterised by a pervasive pattern of instability in affect regulation, impulse control, self-image and interpersonal relationships (American Psychiatric Association [APA], 2001; 2013). The prevalence of BPD in the general population is estimated to be around 0.7% (Coid, Yang, & Tyrer, 2006), and the rate of diagnosis is higher for women than for men (APA, 2013). Between 90-97% of people with BPD have a comorbid condition (Pfohl et al. 1986). Common comorbidities include depression, anxiety, bipolar disorder (the symptoms of which are often confused with BPD) eating disorders, alcohol or drug misuse, and post-traumatic stress disorder (National Institute for Clinical and Health Excellence [NICE], 2009).

Clinical signs of BPD include marked functional impairment (Skodol, et al., 2005), emotion dysregulation, repeated self-injury, impulsive aggression, and chronic suicidal tendencies (Lieb, Zanarini, Schmahl, Linehan, & Bohus, 2004). Compared to other personality disorders, anxiety disorders, and mood disorders, BPD is diagnosed increasingly in mental health settings (Beckwith, Moran, & Reilly, 2014). Having a diagnosis of BPD is correlated with markedly high levels of service utilisation (Ansell, Sanislow, McGlashan, & Grilo, 2007; Bender, et al., 2001). BPD is also often considered to be unresponsive to treatment or therapy (National Institute for Mental Health in England, 2003), suggesting that more empirical evidence is needed to inform clinical decision-making around how to best support this population.

Evidence-base for BPD interventions

Guidelines for the treatment and management of BPD recommend psychotherapy accompanied by symptom-targeted pharmacotherapy (NICE, 2015). The psychotherapy approach or model is not specified by the guidelines unless

reducing self-harm is a priority, in which case Dialectical Behaviour Therapy (DBT; Linehan, 1993a) is the leading treatment (NICE, 2015). In all other cases, the guidelines recommend that psychotherapy is provided within a coherent theoretical framework and a structured programme of other inputs, with access to support between sessions (NICE, 2015). The first version of this guideline appraised the evidence base as "relatively poor" (NICE, 2009). Surveillance reviews of the evidence in relation to this guideline have reported uncertainty over drug treatment, the cost effectiveness of psychological interventions, and screening for BPD based on systematic review evidence published up to October 2014 (NICE, 2015). However, no changes have been made to the guidelines since they were first published.

Meta-analytic evidence published after October 2014 suggests that interventions delivered via group-based sessions lead to significant reductions in depression and self-harm, and improved social functioning, while interventions offering individual sessions do not (Omar, Tejerina-Arreal, & Crawford, 2014). Group-based therapies for BPD are used extensively in healthcare settings (Lorentzen & Ruud, 2013), and may present an economically favourable alternative to individual therapies. A systematic review investigating the evidence of effectiveness for group therapies for BPD suggested that they offer a promising platform on which interpersonal difficulties can be normalised and addressed (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014). The meta-analysis in this study, of RCT evidence revealed a medium to large effect on measures of BPD symptom severity for Schema Focused Therapy (SFT; Young, Klosko, & Weishaar, 2003) and Emotion Regulation Group Training (ERGT; Gratz & Gunderson, 2006), and a small to medium effect for Mentalization-Based Treatment (MBT; Bateman & Fonagy, 2004).

In addition, meta-analyses for Systems Training for Emotional Predictability and Problem Solving for Borderline Personality Disorder (STEPPS; Bartels & Crotty, 1992) and DBT studies revealed large confidence intervals around the pooled effect estimates, and these included one indicating a degree of imprecision and no reliable evidence of a difference in BPD symptom severity between these interventions and their control conditions (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014). The guideline recommending DBT for BPD is based on evidence that this approach is effective in reducing self-harm in women (NICE, 2015). However, the longer term social and vocational outcomes following DBT are moderate at best (McMain, Guimond, Cardish, Streiner, & Links, 2012).

Given the length of the DBT intervention (i.e. 12 months; Linehan 1993a), and the high rate of drop out (i.e. 43% more likely than a control, with the true population effect between 66% less likely and 315% more likely; Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014), services appear to be continuing to expend substantial resources with the possibility of little apparent benefit (Palmer, 2002). Outcome data for brief interventions is limited (McMain, Guimond, Barnhart, Habinski, & Streiner, 2016), and their role in the treatment of BPD is unclear (Omar, Tejerina-Arreal, & Crawford, 2014). In the absence of reliable evidence informing practice, therapeutic optimism diminishes (King, 2014). Therefore there is a need for further research examining the impact of innovative and acceptable interventions.

Mindfulness-Based Interventions

Mindfulness-based interventions (MBIs) appear to meet NICE recommendations for BPD psychotherapies (NICE, 2015) in that they are frequently offered as an adjunct to other therapeutic inputs (e.g. Lee, et al., 2007) and are informed by a coherent theoretical framework that draws on contemplative traditions,

science, medicine, psychology and education (Crane, et al., 2016). Mindfulness is a state of consciousness characterised by the self-regulation of attention towards current experiences coupled with an acceptance of these experiences (Bishop, et al., 2004). Individuals are encouraged, during an MBI, to develop a new relationship with their experiences through mindfulness meditation practices that offer an opportunity to experiment with present-moment focus, decentering and an approach orientation (Crane, et al., 2016).

It has been suggested that the encouragement within mindfulness practices to approach, rather than avoid, moment-to-moment internal and external experiences can enable a disengagement from maladaptive patterns of intrusive negative thinking (Roemer & Orsillo, 2002). Increased mindfulness capacity has also been linked with reduced impulsive behaviour (Zylowska, et al., 2008), emotional reactivity (Feliu-Soler, et al., 2014), and enhanced executive attention in situations requiring emotional self-regulation (Fernandez-Duque, Baird, & Posner, 2000). Mindfulness is implicated in the development and maintenance of BPD (Selby, Fehling, Panza, & Kranzler, 2016), indicating that MBIs may have the potential to alleviate some of the problems experienced by individuals with BPD.

Clinical opinion suggests that treatment of BPD can be beneficial by alleviating co-morbid conditions (NICE, 2009), and MBIs have a strong evidence-base for reducing vulnerability to stress and emotional distress (Kabat-Zinn, 1982; Grossman, Niemann, Schmidt, & Walach, 2004), as well as the recurrence of depression (Teasdale, et al., 2000; Ma & Teasdale, 2004; Kuyken, et al., 2008). MBIs may also address drop-out, a key limitation of existing interventions, by fostering engagement-promoting qualities such as compassion, wisdom, joy, and equanimity (Brown, Ryan, & Creswell, 2007; Crane, et al., 2016).

Mindfulness meditation practice has been incorporated into DBT, and this aspect of the intervention is reportedly one of the most practiced of all the skills taught (Lindenboim, Comtois, & Linehan, 2007) suggesting that mindfulness may be acceptable to a BPD population. However, the unique contribution of mindfulness to DBT remains unclear (Sng & Janca, 2016; Chafos & Economou, 2014). Given the pervasiveness and chronicity of BPD, and encouraging evidence linking mindfulness deficits to some of the difficulties experienced by this population, it is unsurprising that this area has become the focus of intensifying study. Two reviews have investigated MBIs for BPD and both concluded that further research was needed to draw firm conclusions due to the paucity of studies, small sample sizes with underpowered statistical analyses, unclear eligibility criteria around BPD diagnoses, and few outcomes in common across studies (Sng & Janca, 2016; Chafos & Economou, 2014). Several RCTs of MBIs for BPD have been published since the date of the most recent review's literature search, and outcomes relating to BPD symptom severity from MBIs have not previously been subjected to meta-analytic aggregation, indicating that an updated review is timely.

Aims of this review

In sum, although a very popular treatment, it remains unclear whether MBIs are effective for reducing BPD symptom severity. Therefore, the primary goal of the present review was to explore the efficacy of MBIs for decreasing BPD symptom severity in a BPD population. This review also sought to compare the effect of MBIs on BPD symptom severity with the effects of existing psychotherapeutic interventions with a group component on BPD symptom severity. Additional aims were to investigate the effect of MBIs on various indices of mood and attention, assess the acceptability of MBIs, and explore whether participants who received

greater mindfulness input tended to report greater clinical change compared to participants who received less mindfulness input. Finally, a goal of this review was to explore what experimental studies can tell us about the immediate effects of a brief manipulation of mindfulness for adults with a diagnosis of BPD.

Method

A systematic search and review (Grant & Booth, 2009) was used to locate the best evidence available in this field. Meta-analysis (Grant & Booth, 2009) was considered appropriate for the primary question of this review as individual studies were small, lacking power to detect an effect. Meta-analysis increased the power of the test, improved precision, and settled controversies in the literature by formally assessing the degree of conflict between studies. Meta-analysis was deemed inappropriate for secondary research questions and a narrative approach (Grant & Booth, 2009) to synthesizing research evidence was used.

Eligibility criteria

Studies were selected if: (1) primary research was presented in English, (2) the intervention used mindfulness meditation practice as the core element; including it in all therapy sessions and recommending between session practice, (3) at least 80% of the studies' sample, or a specified sub-sample, met criteria for BPD according to the DMS-5 (APA, 2013), or equivalently Emotionally Unstable Personality Disorder (EUPD) according to ICD-10 (WHO, 2008), and (4) outcome measures were related to one of the questions posed by this review. Quantitative studies were included in the meta-analysis if they provided sufficient independent data on a measure of BPD symptom severity to perform effect size analyses (i.e. means and

standard deviations, *t* or *F* values, change scores, frequencies, or probability levels). Where insufficient data was reported, corresponding authors were contacted.

Studies were excluded if recruitment was based on the general concept of borderline personality organisation (i.e. individuals with a diagnosis of BPD, a suspected diagnosis of BPD, or BPD traits) as too broad a diagnostic concept may have obscured important distinctions within treatment implications (Holzman & Perry , 2016). Studies were also excluded if the MBI was delivered alongside either DBT or Acceptance and Commitment Therapy (Hayes, Strosahl, & Wilson, 1999), as the presence of multiple components in these lengthy intervention programmes (i.e. individual therapy, mindfulness-based group skills training, telephone coaching, and a therapist consultation team), make them less comparable with other MBIs. Dismantling studies of DBT were included where the above inclusion criteria were met.

As the number of studies that met these inclusion criteria was felt to be somewhat limited (n=8), laboratory-based studies that had examined, experimentally, the effects of a brief manipulation of mindfulness on emotional and behavioural processes indicative of psychological health for adults with BPD or EUPD were also included.

Search strategy

Six electronic databases (Psycharticles, Psychinfo, Medline, Web of science, the Cochrane library, and Prospero) were searched from inception to June 30, 2016 using keywords: *borderline personality disorder, or emotionally unstable personality disorder, or complex trauma, or emotional intensity disorder AND mindfulness.* For details of the contents of each database, see Appendix A. Google Scholar was used to

identify additional articles that had cited an included study and reference lists from included reports and previous reviews were systematically searched by hand.

Electronic search results were collated using *RefWorks,* and duplicates were cautiously removed before title screening. Any obviously irrelevant records were marked for exclusion and abstracts of the remaining records were examined. In cases where it was unclear whether eligibility criteria had been met, full text articles were retrieved so that additional details could be checked. Multiple reports of the same study were identified and marked to avoid double counting of data (Tramer, Reynolds, Moore, & McQuay, 1997).

Data collection process

Study data were extracted from each report twice to minimise the likelihood of human error, and entered into a spreadsheet where it was cleaned (i.e. checked for anomalies and implausible data). Information was extracted based on the characteristics of the study (i.e. publication year, authors, design, randomization, binding, therapist qualifications, and time to follow-up) and the standard PICO information (see table 1).

Where no total scaled score was available for a measure of BPD symptom severity, and a choice of subscales was needed for inclusion in the meta-analysis, priority was given to subscales measuring distress as this seemed most clinically relevant. Where intent-to-treat (ITT) and per protocol (PP) analyses were reported, the ITT data were extracted, providing a more conservative estimate of treatment effects.

Assessment of study quality

Methodological quality was assessed using a quality scale that had been used in a systematic review of mindfulness-based stress reduction for healthy individuals

(Khoury, Sharma, Rush, & Fournier, 2015). This scale consisted of ten items (Table 2), and the scoring system gave each study with a summary score out of 10. Study quality was assessed by the author and an independent researcher. Percentage agreement between the two researchers (97%) indicated good inter-rater reliability and any disagreement was settled through a discussion.

Study element	Information extracted
Participants	Sample size, gender, age, diagnosis, and rate of attrition
Interventions	Name, number and duration of sessions, rate of drop-out
Control conditions	Type (i.e. active or passive), number and duration of sessions if active
Outcomes	Pre- and post- intervention means and standard deviations, plus for measures of BPD symptom severity; *t* or *F* values, change scores, frequencies, or probability levels

Table 1. Information extracted from eligible studies

Analysis

The characteristics of included studies and their samples, interventions and outcome measures were outlined with descriptive statistics. The effect of MBIs, compared to a control, on BPD symptom severity was assessed using meta-analysis. Given the clinical, methodological and statistical heterogeneity across studies, a random-effects model of meta-analysis was chosen (Glass, 1976; Nikolakopoulou, Mavridis, & Salanti, 2014). Revman (2014) was used to conduct the meta-analysis using post-intervention means, their standard deviations, and sample size for each group. The size of the effect (Hedge's g and its 95% confidence interval) was interpreted according to Cohen's (1988) rule of small (0.2), medium (0.5), and large (0.8), and a forest plot was created to illustrate the findings. Effect sizes were

compared with the findings from a previous review (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014) to assess efficacy of MBIs relative to the evidence-based psychotherapies for BPD with a group component reported (e.g. DBT, MBT, SFT, ERGT, and STEPPS). A narrative approach was used to synthesise data relating to the impact of MBIs on BPD symptom severity in uncontrolled studies, measures of mood and impulsivity, rates of drop-out, and proposed mechanisms of the effect of MBIs.

	Quality criteria
1	Did the study draw comparisons with a control group?
2	Did the control group take part in a comparable treatment?
3	Did the study adhere to an established treatment protocol?
4	Did the study administer measures at follow up?
5	Did the study use validated outcome measures?
6	Were the therapists clinically trained (i.e. clinical psychologists, trainees in clinical psychology, or social workers)?
7	Were the therapists trained in mindfulness (i.e. formal training in validated protocols, or mindfulness meditation training/ experience)?
	Additional criteria for controlled studies only:
8	Was the study described as randomized?
9	Did participants in both groups spend an equal amount of time in treatment?
10	Were the experimenters blinded to condition (mindfulness or control) and/or were participants blinded to the study hypotheses?

Table 2. Quality rating scale

Results

Of the 1,221 records identified as potentially relevant by the electronic databases searched, 15 papers, covering 11 separate studies met eligibility criteria and were included in the review (Figure 1). For the final stage of full-text screening see Appendix B. Seventy-three percent of these studies (n=8) had not been included in a previous systematic review of treatments for BPD (e.g. Sng & Janca, 2016; Chafos & Economou, 2014), supporting the case for this review being needed.

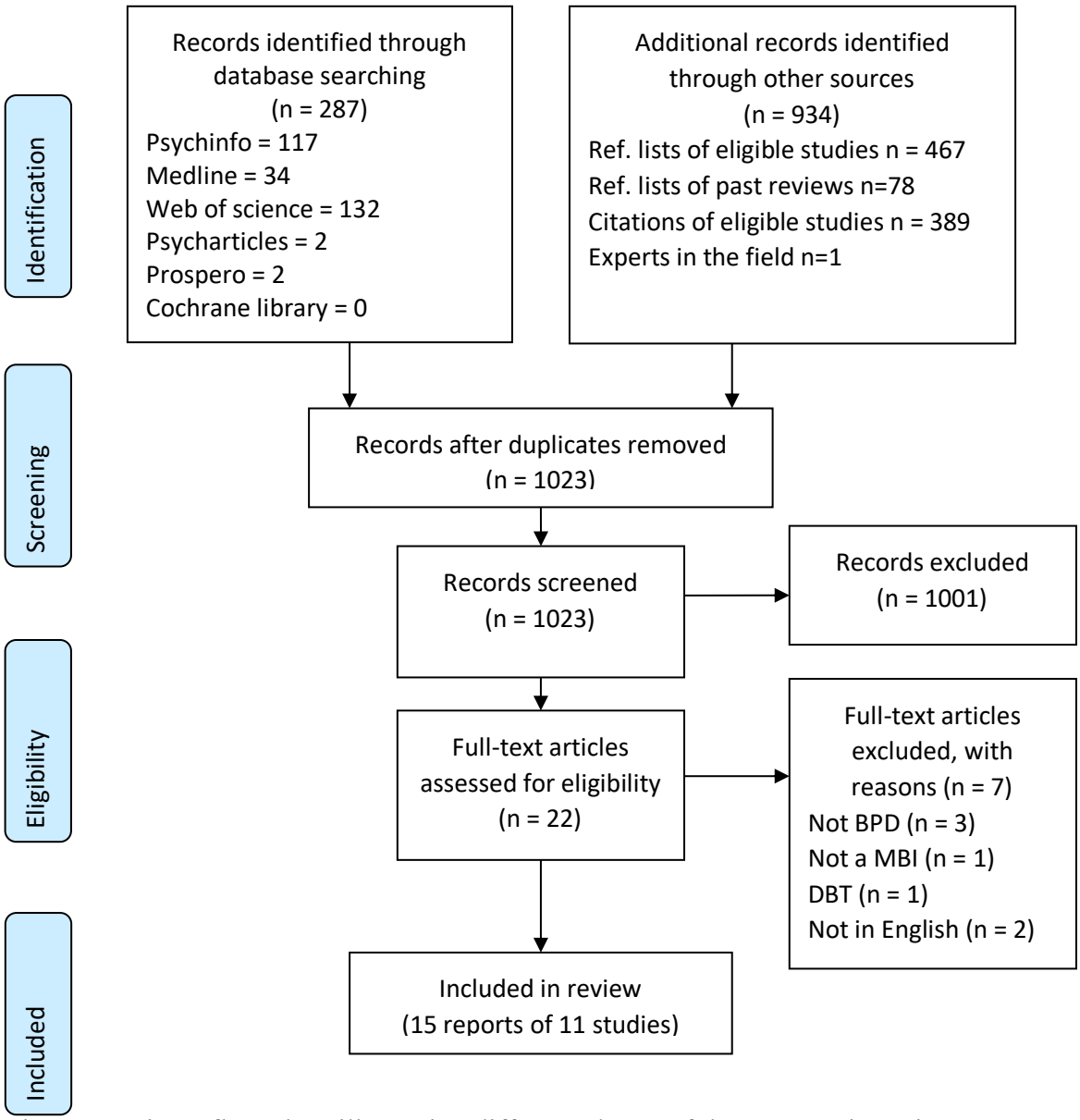

Figure 1. Prisma flow chart illustrating different phases of the systematic review

Characteristics of studies

Key characteristics of included studies are displayed in Table 3. The review found four naturalistic RCTs (Soler, et al., 2009; Elices, et al., 2016; Feliu-soler, et al., 2016; Kramer, et al., 2016), two non-randomised controlled trials (Soler, et al., 2012; Feliu-Soler, et al., 2014), and two uncontrolled pre-post studies (Federici, 2008; Sachse, Keville, & Feigenbaum, 2011). Studies with these designs have the potential to clarify directional links between MBIs and a range of measures of psychological wellbeing. The review also found one independent-groups experimental RCT (Sauer & Baer, 2012), and two multi-methods quasi-experimental studies (Kuo, Fitzpatrick, Metcalfe, & McMain, 2016; Scherpiet, et al., 2015). Studies with these laboratory-based designs have the potential to isolate, experimentally, the immediate effects of a brief exposure to mindfulness on various indices of emotional and behavioural functioning. Relative quality ratings are considered in detail as each research questions is addressed. See Appendix C for a graphic presentation of quality appraisal scores.

Five studies were linked by common authors and conducted at the same university hospital in Spain (Feliu-soler, et al., 2016; Feliu-Soler, et al., 2014; Elices, et al., 2016; Soler, et al., 2009; Soler, et al., 2012). Two studies were conducted in Canada (Federici, 2008; Kuo, Fitzpatrick, Metcalfe, & McMain, 2016), one was conducted in Switzerland (Scherpiet, et al., 2015), and the remaining three studies were conducted in Europe (Kramer, et al., 2016; Sachse, Keville, & Feigenbaum, 2011), or America (Sauer & Baer, 2012).

Study	Total sample size	Mindfulness intervention (n)	Control (n)	BPD symptom severity measure(s)	Other outcome measures relevant to this review	Quality rating
Elices et al. (2016)	64	Mindfulness training based on DBTm (32)	Active (interpersonal effectiveness skills training; 32)	BSL23	Mindfulness (FFMQ)	8
Federici (2008)	33	Mindfulness training based on DBTst (33)	None	BEST	Mindfulness (KIMS), depression (BDI-II), anxiety (BAI), and anger (STAXI)	3
Feliu-Soler et al. (2014)	35	Mindfulness training based on DBTm (18)	Inactive (treatment as usual; 17)	BSL23 (ITT & PP)	Decentering (EQ), and depression (HRSD-17)	5
Feliu-Soler et al. (2016)	32	Mindfulness continuation training (16)	active (loving kindness/ compassion meditation; 16)	BSL23 (ITT & PP)	Mindfulness (PHLMS)	7
Kramer et al. (2016)	41	Mindfulness training based on DBTst (21)	Inactive (treatment as usual; 20)	OQ-45	None	7
Kuo et al. (2016)	55	Momentary mindful awareness	Active (distraction), and inactive (react as normal)	None	Physiological signs of emotional functioning (heart rate, electrodermal activity, and respiratory sinus arrhythmia)	3
Sachse et al. (2011)	30	Mindfulness training based on MBCT (22)	None	None	Mindfulness (FFMQ), depression (BDI-II), and anxiety (STAI)	3

Sauer & Baer (2012)	40	Momentary mindful self-focus (20)	Active (ruminative self-focus; 20)	None	Anger (PANAS-X), distress tolerance (PASAT-C)	1
Scherpiet et al. (2015)	38	Momentary mindful self-reflection	Active (cognitive self-reflection), and inactive (neutral)	None	Brain activation patterns (fMRI), mindfulness (FMI, MAAS)	1
Soler et al. (2009)	59	Mindfulness training based on DBTst (29)	Active (standard group therapy; 30)	CGI-BPD	Depression (HRSD-17), anxiety (HRSA), and anger	8
Soler at al. (2012)	59	Mindfulness training based on DBTm (40)	Inactive (treatment as usual; 19)	None	Mindfulness (FFMQ), decentering (EQ), depression (HRSD-17), and anxiety (POMS)	6

Notes. Follow-up data were available for Federici (2009) only. BSL-23 = Borderline Symptom List, FFMQ = Five Facet Mindfulness Questionnaire, EQ = Experiences Questionnaire, BPRS = Brief Psychiatric Rating Scale, HRSD-17 = Hamilton Rating Scale-Depression, PHLMS = Philadelphia Mindfulness Scale, OQ-45 = Outcome Questionnaire, CHI-BPD = Clinical Global Impression-Borderline Personality Disorder, HRSA = Hamilton Rating Scale-Anxiety, BEST = Borderline Evaluation of Severity over Time, BAI = Beck Anxiety Inventory, BDI-II = Beck Depression Inventory, KIMS = Kentucky Inventory of Mindfulness Skills, STAI = State-Trait Anxiety Inventory, STAXI = State-Trait Anger Expression Inventory, PANAS-X = Positive and Negative Affect Schedule, PASAT-C = Paced Auditory Serial Addition Test, fMRI = functional Magnetic Resonance Imaging, FMI = Freiburg Mindfulness Inventory, MAAS = Mindful Attention and Awareness Scale.

Table 3. Key Characteristics of studies included in the review

Characteristics of samples

Sample sizes ranged from 30 to 64. Given the links found between authors and study sites, scrutiny of the independence of samples seemed important. Comparison of key characteristics and recruitment methods indicated that ten of the eleven samples were independent. However, Feliu-soler, et al., (2016) recruited a subset (i.e. those who completed the intervention) of the sample from their earlier study (2014). To avoid double counting of individuals, the following sample characteristics do not include the Feliu-soler et al. (2016) sample (n=32). Within randomized studies, no statistically significant differences were reported between groups for any participant characteristics, indicating that randomization had been successful in creating two comparable groups. Eligibility criteria across studies were similar, supporting the comparisons of findings. Diagnoses of BPD were made using validated assessment tools (i.e. SCID-II, DIB-r etc.), and the representativeness of samples to the BPD population in clinical settings was also fairly good in terms of multiple co-morbid mental health problems. However, the ratio of women to men in the studies included (9:1) was somewhat higher than estimates from the general population (4:1; Oldham, 2004). In addition, studies typically excluded individuals who were assessed as being at increased risk of self-harm, which may have lowered the average severity of risk.

Characteristics of Interventions

All therapeutic interventions used mindfulness as the core component of treatment; mindfulness exercises were practiced in every session and regular mindfulness practice at home was encouraged. Interventions were based on components of DBT (Linehan, 1993a; 1993b), or were adapted from MBCT (Teasdale, Segal, Williams, Ridgeway, Soulsby, & Lau, 2000). One study delivered a novel intervention (Feliu-soler et al., 2016). Therapy sessions varied in duration and

adaptations that were made to the original therapy protocol, making it more suitable for adults with a diagnosis of BPD (Table 4).

Study	Therapy protocol	Duration	Adaptations
Elices et al. (2016)	DBTm	25 hrs (10 X 150 mins)	Longer duration (no module repetition), briefer meditation practices, inclusion of acceptance skills taken from the distress tolerance module
Federici (2008)	DBTst	40 hrs (20 x 120 mins)	Shortened duration (no module repetition) Inclusion of pre-treatment orientation session. Inclusion of an additional module on dialectics
Feliu-Soler et al. (2014)	DBTm	20 hrs (10 x 120 mins)	Longer duration (10 versus 4), inclusion of acceptance skills taken from the distress tolerance module
Feliu-Soler et al. (2016)	Novel intervention	6 hrs (3 x 120 mins)	n/a
Kramer et al. (2016)	DBTst	30 hrs (20 X 90 mins)	Shortened duration (no module repetition)
Sachse et al. (2011)	MBCT	20 hrs (8 x 150 mins)	Longer duration (20 versus 8), longer sessions (180 minutes versus 120 minutes), a narrower range of mindfulness exercises (no silence or bells exercises), and extended psycho-education (covering anxiety and general distress as well as depression)
Soler et al. (2009)	DBTst	26 hrs (13 x 120 mins)	Shortened duration (no module repetition), inclusion of printout of reinforcement exercises
Soler at al. (2012)	DBTm	16 hrs (8 x 120 mins)	Briefer meditation practices with self-determined length and instructions to continue for at least one more minute after deciding to finish early

Table 4 Intervention duration and adaptations from original therapy protocols

Experimental mindfulness induction exercises were all momentary (i.e. 1,000 to 2,000 milliseconds), and consisted of mindful awareness or self-reflection prompted by verbal or on-screen instructions. Findings in relation to each of the research questions will now be considered in turn.

What evidence is there for the efficacy of MBIs for adults with a diagnosis of BPD?

BPD symptom severity. Four RCTs examined the efficacy of an MBI on BPD symptom severity relative to interpersonal effectiveness skills training (Elices, et al., 2016), standard group therapy (Soler, et al., 2009) or treatment as usual controls (Feliu-Soler, et al., 2014; Kramer, et al., 2016). A random effects meta-analysis on the between group, post-intervention effect sizes across all four RCTs revealed a medium sized pooled effect estimate (g = -0.77, 95% CI -1.14 to -0.41), with significantly lower symptoms for MBI than control participants. Only three of these studies found significant positive intervention effects based on an alpha level of .05 (Elices, et al., 2016; Feliu-soler, et al., 2014; Kramer, et al., 2016). Figure 2 shows a forest plot of the respective four effect sizes. Across study heterogeneity in effect sizes was low (Tau^2 =0.05 with I^2 = 35%, χ^2 = 4.50, p = 0.20), suggesting that it was appropriate to pool these studies. Figure 3 shows a funnel plot of the four effect sizes and asymmetry can be seen; studies with small sample sizes and small or negative effect sizes are lacking. However, this is a small number of studies for a meta-analysis and so it is likely that publication bias would be difficult to spot.

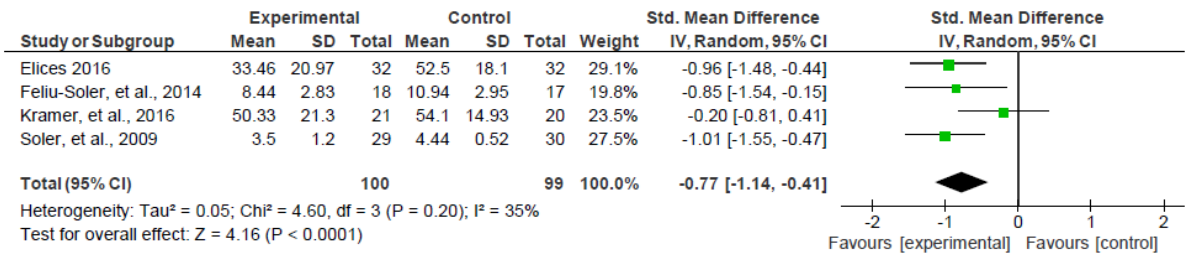

Figure 2. Forest plot of symptom severity effect estimates

This meta-analysis provides some evidence that, on average, MBIs are more effective than either a passive or an active control condition at reducing the severity of BPD symptoms. The studies included in this analysis were given good quality ratings (mean = 7), largely due to their robust RCT design allowing for the examination of the MBI relative to a control condition. However, one study reported a trend towards a significant difference (p= 0.06) in the number of Axis I co-morbid disorders between groups (Kramer, et al., 2016), where participants in the control group had a higher number than the intervention group. This was not controlled for in the analysis on the basis that the number of central BPD symptoms and number of axis II co-morbid diagnoses were comparable between groups. In addition, the control group did not experience the same number of contact hours with professionals. Therefore, the changes observed may have been related to this, rather than to the content of the mindfulness-based intervention.

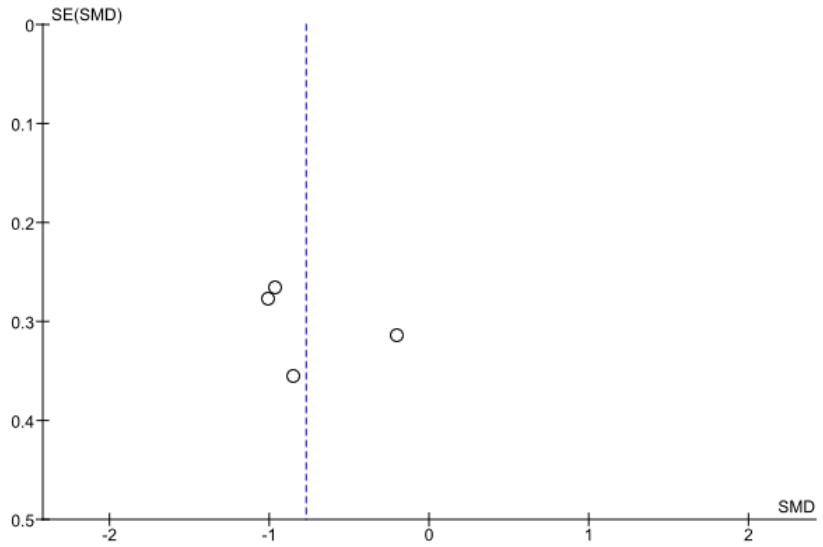

Figure 3. Funnel plot of effect sizes included in the meta-analysis

By using an active control group, two of the RCTs in this meta-analysis increase the likelihood that specific therapeutic factors (i.e. mindfulness techniques and practices) led to the effect, as non-specific therapeutic factors (i.e. therapeutic alliance and therapist competence) were controlled for. Only one of these studies presented follow-up data (Kramer, et al., 2016) which indicated that the observed effects did not last for three months. However, we cannot be sure about the longevity of this intervention given the paucity of follow-up data from RCTs. Conclusions are also limited by small samples across the four RCTs (total n = 186), and so the findings should be generalized with caution.

Another RCT examined the efficacy of a brief continuation of a MBI relative to an alternative treatment at reducing BPD symptom severity (Feliu-Soler, et al., 2016). Data from this study was not aggregated in the above meta-analysis as participants were recruited from the completer subgroup of an earlier study that was included (Feliu-Soler, et al., 2014), and so the data did not meet the meta-analytic assumption of independence. No effect of MBI was found on a measure of BPD symptom severity and pre-post differences in BPD symptom severity were non-significant for participants allocated to the MBI group. However, pre-post differences were significant for the alternative treatment of loving kindness and compassion meditation, indicating that the non-significant result was unlikely to have been the result of a floor effect following the effectiveness of the first MBI participants completed. The MBI was used as a control condition in this study, and as participants were not blinded to the study hypotheses, we cannot rule out the possibility that results were affected by experimenter bias. Another potential mediator may be increases in compassion.

Further evidence from an uncontrolled study supports the meta-analysis findings by indicating that an MBI was linked to a significant reduction in BPD symptom severity (Federici, 2008). Follow-up data was collected in this study, and indicates that the gains were maintained at three months post-treatment. However, data were not available to calculate the correlation between pre- and post- means. Therefore, an effect-size calculation for comparison with the above meta-analysis, correcting for dependence among the means, was not possible. Also, given the within-subjects study design (i.e. absence of a control group) in this study, we can't be certain that these changes wouldn't have occurred without the intervention.

Taking into account the limitations described above, empirical evidence from studies investigating the effectiveness of MBIs for adults with a diagnosis of BPD indicates MBIs have the potential to be more effective at reducing BPD symptom severity when compared to either an active control condition or a passive control condition, although further research is needed including definitive trials with a placebo control condition to control for non-specific effects. However, empirical evidence from a study investigating an alternative therapy with an MBI as a control condition found no significant pre-post differences for the MBI group. Only two studies explored the longevity of the effects, and their findings were contradictory, suggesting again that further research is needed.

Comparison with existing psychotherapeutic interventions. The pooled effect estimate from the meta-analysis described above was compared with three other pooled effect estimates from meta-analyses exploring the effect of interventions with a group component on measures of BPD symptom severity (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014). As this comparison data comes from unpublished work, caution should be taken in interpreting the findings as the study

has not been subject to peer review. Table five shows these effect estimates together with their 95% confidence intervals. The findings suggest that a MBI may have a larger effect than two of the leading treatments for this population; DBT and MBT. In addition, the confidence interval around the pooled effect estimate for DBT doesn't appear to overlap with the confidence interval around the pooled effect estimate for MBIs. This suggests that there is a significant difference between these two treatments, with MBIs leading to a significantly greater reduction in BPD symptom severity.

The sample used in the DBT meta-analyses (n=378) is larger than the sample in the MBI meta-analysis (n=199), indicating that the DBT pooled effect estimate is more likely to represent the real population effect. However, as DBT is the frontline treatment for individuals with high levels of suicidality, these studies may have recruited samples with more severe difficulties. Another explanation for the difference could be that the DBT studies were better controlled and of higher quality, as higher quality studies sometimes show smaller effects. An RCT that directly compares the effects of these two interventions on BPD symptom severity is needed to address this question. Nevertheless, the favorable comparison with DBT suggests, at least, that MBIs have promise that is worthy of further examination. Overlapping confidence intervals around the pooled effect estimate for MBIs, MBT, and ERGT indicates that there may be no difference between the effectiveness of these psychotherapeutic interventions on measures of BPD symptom severity, or the difference may be so small as to be inconsequential.

Intervention approach (number of RCTs included in the meta-analysis)	Total sample size	Pooled effect estimate (Hedge's g)	95% confidence interval
Mindfulness-based Interventions (n=4; full meta-analysis described in detail above)	199	-0.77	-1.14 to -0.41
Dialectical Behavior Therapy (n=5)[a]	378	-0.16	-0.36 to 0.05
Mentalisation-based Treatment (n=3)[a]	233	-0.33	-0.60 to -0.07
Emotion Regulation Group Training (n=2)[a]	83	-1.19	-1.66 to -0.72

[a] Data draw from unpublished MSc dissertation (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014). This study has not been published in a peer-reviewed journal and findings should therefore be treated with some caution.

Table 5. Pooled effect estimates of psychotherapeutic interventions with a group component on BPD symptom severity, and their 95% confidence intervals.

Depression. All three controlled studies that measured the impact of a MBI on depression found a significant effect of group, indicating that the MBI led to a greater reduction in depression scores relative to standard group therapy (Soler, et al., 2009), or treament as usual (Feliu-Soler, et al., 2014; Soler, et al., 2012). The pre-post difference in depression scores for the control group in one of these studies was non-significant (Soler, et al., 2009) which may have inflated the significance of the group effect. Nevertheless, this evidence suggests that the established effect of MBIs on depression holds true for adults with a diagnosis of BPD. This finding is supported by evidence of a link between a significant decrease in depression scores and completing a MBI in two uncontrolled studies (Federici, 2008; Sachse, Keville, & Feigenbaum, 2011).

Anxiety, dissociation, emptiness and affect instability. No significant effects of an MBI on anxiety were found (Sachse, Keville, & Feigenbaum, 2011; Soler, et al., 2009; Soler, et al., 2012). However, treatment completers who reported

significantly improved mindfulness capacity also reported a significant reduction in physical dissociation experiences (Sachse, Keville, & Feigenbaum, 2011). In addition, the MBI was found to be superior to standard group therapy on measures of emptiness and affect instability, with the MBI leading to significantly greater reductions in these negative mood states (Soler, et al., 2009).

Irritability and anger. A significant effect was also found in an RCT where the impact of a MBI on irritability was measured, indicating a greater reduction of irritability following the MBI relative to standard group therapy (Soler, et al., 2009). In an uncontrolled study, the difference between pre- and post- intervention scores on a measure of anger was non-significant (Federici, 2008). However, as the sample size in this study was small, it is possible that the effect of MBIs on anger was missed due to a type II error. To further investigate this effect, anger was measured before and after an experimental procedure designed to elevate angry feelings and then facilitate a period of self-focus that was either ruminative or mindful in nature (Sauer & Baer, 2012). Findings from this study indicated that the positive effect of mindful self-focus on anger ratings following the anger induction was significantly greater than the positive effect of ruminative self-focus. This supports the idea that rumination may underpin psychological difficulties and mindfulness may be a potentially therapeutic strategy. In a second part of the study, participants were then asked to complete a frustrating computer task, and those who had been allocated to the mindful self-focus group demonstrated an increased willingness to tolerate the distress associated with this task compared to the rumination group. The increased control over independent variables in experimental studies such as this one enables stronger conclusions about causal effects to be drawn. However, as the number of studies (n=3) and their sample sizes are both small, we need to exercise caution about the extent to which we can be

confident that MBIs have a positive impact on irritability and anger for this population and further research, including definitive randomised controlled trials with placebo control groups are now needed.

General distress. In a RCT where coping style was measured, significant post-intervention increases were observed in relatedness coping where stressors were appraised as a challenge, and decreases in autonomy coping where stressors were appraised as a threat (Kramer, et al., 2016). Further analysis of this data revealed that these changes predicted the changes in general distress and borderline symptomatology.

Attentional control, mindful awareness and meta-cognitive awareness. Participants who completed a MBI demonstrated significantly enhanced attentional control (STROOP test), indicating a correlation between these variables (Sachse, Keville, & Feigenbaum, 2011). This provides tentative support for an attentional model of the effects of mindfulness in BPD. Evidence of a significant positive effect of MBI on inattention variables (Soler, et al., 2012) provides further support for this model and the theory that attentional mechanisms may underpin core mindfulness skills. A correlation was also found between MBIs and increases in mindful awareness (Sachse, Keville, & Feigenbaum, 2011; Federici, 2008), that was supported by evidence from a RCT suggesting a causal link between MBIs and increases in mindful awareness (Elices, et al., 2016). However, without a mediation analysis, we cannot be sure that these results did not occur by chance.

Another potential mediator is meta-cognitive awareness (i.e. the ability to decenter from thoughts or feelings and view them as passing events rather than identifying with them or believing that they accurately represent reality). RCT

evidence (Feliu-Soler, et al., 2014) suggests that participants in the MBI group had significantly improved in their ability to decenter over time, and although the group effect was just shy of statistical significance (p=0.06), it is possible that this trend is highlighting a mediator. Decentering was also measured in a larger RCT and a regression analysis indicated that changes in decentering capacity explained 27% of BPD symptom severity change (Elices, et al., 2016). These findings are promising as they indicate the potential for a mediator in this population which could support the targeting of MBIs.

In summary, the evidence suggests that MBIs may have a positive effect on mood and attention, as measured by a range of indices. The evidence of a positive effect of an MBI is strongest for depression outcomes where a consensus was found between robust RCT and experimental study findings. This is interesting as arguably the effects of MBIs on mood problems are particularly strong in the wider clinical literature (Hoffman, Sawyer, Witt & Oh, 2010). No negative changes on any mood measures were found following an MBI indicating that even where mindfulness is not associated with a significant improvement in a mood state, nor is it associated with a worsening of symptoms.

What evidence of MBI acceptability is there for adults with a diagnosis of BPD?

Rates of dropout from a MBI were only reported across 50% of the intervention studies included in this review. In one study, a series of plots illustrating post-intervention outcomes for the MBI group contained data points for only 11 out of the 18 participants, although no data relating to treatment dropout was reported (Feliu-Soler, et al., 2014). This lack of reporting around rates of dropout from the intervention raises questions about treatment acceptability. From the data available,

rates of dropout from MBI studies in this review (15-24%) were broadly comparable with studies of other interventions with a group component for adults with BPD (e.g. Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, unpublished data). Comparison of the dropout across different treatment conditions in the studies included in this review revealed no significant differences between a MBI and an interpersonal effectiveness skills training group (Elices, et al., 2016). However, a significant difference was found in dropout from a MBI relative to standard group therapy (Soler, et al., 2009), with less dropout in the MBI condition. This evidence suggests that MBIs may be more acceptable to adults with a diagnosis of BPD. However, as participants often receive more support to engage with an intervention in a clinical study than they would in routine clinical practice, more research is needed to explore acceptability in a naturalistic setting. For example, interviews with participants after they have had an opportunity to complete a MBI as part of a research trial alongside naturalistic studies exploring dropout rates from MBIs in everyday clinical practice could broaden our understanding of group MBI acceptability, including understanding potential barriers to engagement.

What evidence is there for a dosage effect of MBIs?

If there was a dosage effect of MBIs, participants who received greater mindfulness input would be more likely to report greater clinical change compared to participants who received less mindfulness input. Evidence of a dosage effect was examined in four of the studies included in this review. Firstly, the MBCTa intervention had a greater effect for those who attended more sessions according to measures of mindfulness, somatoform dissociation, state anxiety, and experiential avoidance (Sachse, Keville, & Feigenbaum, 2011). Secondly, more significant improvements were detected when data from the DBTst completer sample only were

analysed (Federici, 2008). Thirdly, an average of participants' maximal minutes of daily formal practice was significantly related with affective symptoms whereby more minutes of mindfulness practice was linked with fewer depression symptoms (Soler et al., 2012). However, this correlation did not hold true for attention measures. Lastly, strong correlations were found between mean duration of daily mindful practice and self-reported emotional response to the emotion induction procedure whereby more practice was significantly related to less emotion activation, and more emotion dominance, but not to emotion valance. (Feliu-soler et al., 2014).

This evidence provides tentative support for a dosage effect of MBIs on measures of mindfulness and some affective symptoms but not on measures of attention. Due to the correlational nature of these analyses, our ability to draw causal conclusions from the findings is limited as variables may improve as a consequence of a reduction in BPD symptomology or improvements in mood rather than being a cause of this.

What can experimental research tell us about the efficacy of mindfulness for individuals with a diagnosis of BPD?

One quasi-experimental study used functional Magnetic Resonance Imaging (fMRI) to compare the brain activation patterns of BPD participants with non-BPD participants during periods of brief mindful introspection, cognitive self-reflection, and a neutral condition (Scherpiet, et al., 2015). The results indicated that mindful self-focused attention was effective at regulating amygdala activity, a part of the brain linked with emotion regulation, across both groups. This suggests that mindfulness has a similarly positive effect at a neurobiological level, irrespective of clinical diagnosis. The experimental study design enabled close control of variables increasing our ability to draw causal conclusions. However, as the sample was small

and included female only participants, the results may not generalise to the general population.

A second quasi-experimental study also investigated emotional regulation abilities in a BPD group, relative to a non-BPD group (Kuo, Fitzpatrick, Metcalfe, & McMain, 2016). Participants underwent a baseline assessment of self-report and physiological measures of emotional functioning (i.e. heart rate, sweating and breathing), and were then presented with a series of neutral and BPD-relevant negative images. Participants were instructed to react as they usually would to the image, or to use a specific strategy of either mindfulness or distraction to help them feel less negative. Comparison of the groups at baseline indicated a significant difference where participants with a diagnosis of BPD had, on average, an elevated heart rate indicating heightened emotional intensity and vulnerability. Nevertheless, despite this increased heart rate, the mindfulness findings indicated that both groups demonstrated an ability to implement mindful awareness and distraction effectively, leading to a slowing of their heart rate when images changed from neutral to emotion-laden. As participants across the BPD group had a high number of co-morbid mental health problems, it is possible that baseline differences may have been indicative of heightened emotional intensity linked to transdiagnostic psychopathology, rather than BPD specifically, and the study was limited by having a small sample size. However, the results still support the idea that individuals with BPD may have a similar experience to individuals without this diagnosis in terms of their orienting response to unpleasant or threatening stimuli whereby heightened sensory input is facilitated through cardiac deceleration.

Discussion

Summary of results

This study represents the largest review of MBIs for adults with a diagnosis of BPD to date. The primary aim was to explore the efficacy of MBIs for decreasing BPD symptom severity in a BPD population. Findings from four robust RCT's were pooled and the results provide some evidence that, on average, MBIs are more effective than either a passive or an active control condition at reducing the severity of BPD symptoms. This was supported by findings from two further studies that could not be included in the meta-analysis. Compared to a meta-analysis of DBT studies, the pooled effect estimate for studies of MBI in relation to measures of BPD symptom severity was significantly larger. Further studies offering a direct comparison are needed to draw firm conclusions.

A clear convergence of findings was found across experimental and intervention studies with regards to the positive effects of mindfulness on various indices of mood and attention. Three potential mediators of the effects of a MBI for adults with a diagnosis of BPD are proposed: attentional control, mindful awareness and meta-cognitive awareness (i.e. decentering). No studies reported iatrogenic effects. However, sample sizes were small across all studies and very few studies repeated their measures at follow-up, leading to questions about the longevity of the positive effects of MBIs. In addition, the rate of drop-out from a MBI was high, raising questions about the acceptability of this treatment approach. Tentative support for a dosage effect was found whereby more practice of mindfulness exercises appears to be correlated with more significant effects on measures of affect but not for measures of attention.

Comparison with the wider literature

Comparison of these results with previous reviews (e.g. Sng & Janca, 2016; Chafos & Economou, 2014) indicates that sixty-seven percent (n=8) of the studies had not been included in a previous systematic review, indicating that this review is timely and warranted. The positive effects of mindfulness on measures of psychological wellbeing reported for other clinical populations (Khoury, Sharma, Rush, & Fournier, 2015) appear to hold true for a BPD population. Compared to other intervention trials for adults with a diagnosis of BPD (Droscher, Startup, Petfield, Horsman, & Cartwright-Hatton, 2014), MBI trials compares favourably, with what appears to be a significantly larger effect of MBIs compared to DBT. Given that DBT contains a mindfulness component, this suggests that the unique contribution of mindfulness to DBT may be key in reducing BPD symptom severity.

The favourable comparison of MBIs with existing treatment suggests that MBIs may provide a promising alternative or adjunct to existing treatments for this population. In addition, the preliminary evidence from this review that mindful awareness and meta-cognitive awareness have a mediating effect on MBI's for adults with a diagnosis of BPD provides support for the theory that low mindfulness and rumination are implicated in the development and maintenance of BPD (Selby, Fehling, Panza, & Kranzler, 2016). These mediating variables are also implicated in the development and maintenance of a range of other mental health problems, and emerging literature on transdiagnostic approaches to supporting people with co-morbid complex and enduring mental health problems, by targeting underlying mechanisms, appears promising (Sauer-Zavala, Bentley, Wilner, & Barlow, 2015).

High treatment drop-out is common across interventions for adults with a diagnosis of BPD (Holzman & Perry, 2016; Droscher, Startup, Petfield, Horsman, &

Cartwright-Hatton, 2014). However, mindfulness skills are reportedly the most practiced out of all skills taught through the four DBT skills training modules, indicating that this acceptance-based approach may be more acceptable than other approaches. Rates of drop-out from the studies included in this review are high, suggesting that further research is needed to explore the acceptability of this approach.

It has been suggested that too broad a diagnostic concept may have obscured important distinctions within treatment implications (Holzman & Perry , 2016). In addition, the BPD population appear to have a high number of co-morbid mental health conditions, indicating that a transdiagnostic approach to treatment may be more appropriate. Given the prevalence of BPD in secondary care services, and the level of distress experienced by this population, the maintenance of effects is a key issue regardless of whether MBIs are offered to a BPD-specific population or to transdiagnostic groups. Previous reviews of this evidence-base highlighted that further research is needed to explore the effectiveness of brief interventions (Sng & Janca, 2016).

Implications for research and practice

As MBI's have shown promise in the treatment of adults with a diagnosis of BPD, further studies exploring the efficacy of this approach are needed. The suggestion that some of the mediators underpinning the effectiveness of this intervention may be implicated in a range of other mental health problems, together with the observation that many adults with BPD experience multiple co-morbid mental health conditions, indicates that a transdiagnostic approach may be particularly helpful for this population.

In addition, a direct comparison of MBI's with existing interventions is warranted, to draw firm conclusions around relative efficacy. Future research investigating mechanisms underlying BPD, and the psychological processes mediating the effectiveness of MBIs, is needed so that mindfulness practices can be targeted to better suit the needs of this population in clinical practice. A clinical implication of the preliminary evidence that a dosage effect exists for MBI's for this population, together with the observation that rates of drop out are high, is the need for engagement-promoting strategies to be employed at an early stage and groundwork to be laid preparing individuals for this intervention approach. It also seems pertinent to explore whether individuals with a diagnosis find this treatment approach acceptable, and if not, whether anything could be done to make mindfulness more acceptable given the potential benefits of practicing.

Strengths and limitations of the findings

Much of the strength of these findings is based on the robust and systematic search methods, specific eligibility criteria, and inclusion of meta-analysis which has never been conducted before on this literature. The random-effects model of meta-analysis used, offers advantages over a fixed effects model in terms of generalising the results back to the clinical setting. The review benefits from the consideration of the effectiveness of MBIs on broader characteristics such as mood and attention, and the exploration of mechanisms by which MBIs may be effective for adults with a diagnosis of BPD. Alternative scales designed to assess the methodological quality of trials were considered, such as the Jadad scale (Clark, 1999) and the Delphi list (Verhagen et al., 1998). However, these scales are very general, whereas the scale chosen for use in this review included items specifically related to the quality of MBI trials. For example: "Were the therapists mindfulness trained". In addition, it is

possible for researchers to design an RCT of a psychological therapy that scores 5/5 on the Jadad scale. However, if the intervention was not delivered properly in that RCT, the results would be meaningless. While it is arguable that the increased focus on intervention quality (i.e. therapist training and experience) made the scale more relevant to naturalistic intervention trials compared to experimental trials, it was nonetheless considered to be more suitable than alternatives. In particular, scales and lists such as Delphi and Jadad are better suited to medication trials where the assumption generally holds true that when someone is prescribed 10mg of a medication that is exactly what they receive. The same is not true for psychological therapies, hence a more nuanced approach to assessing quality is required.

Limitations of the findings are based on the paucity of studies and the inclusion of a higher number of women compared to men in study samples than is found in the general population of adults with a diagnosis of BPD. Caution should therefore be taken when generalizing the results of this review to men. In addition, the generalisability of the findings in relation to ethnicity is uncertain given the ethnicity of participants in many samples was not reported. Finally, given that DBT is recommended as the frontline treatment where reducing self-harm is a priority, DBT studies may have inadvertently recruited a higher proportion of individuals with chronic suicidality making their findings less comparable to other interventions.

Conclusion

It is important that individuals with a diagnosis of BPD are provided with effective psychotherapeutic interventions to reduce the experience of distress linked with this diagnosis, and to support psychological wellbeing. The current review supports the use of MBIs with adults who have a diagnosis of BPD. Further research

is required to better understand the underlying mechanisms that mediate the effectiveness of this approach as well as considering how best to increase levels of engagement to MBIs for either a targeted sample of adults with a diagnosis of BPD in a naturalistic setting (i.e. everyday clinical practice), or as part of a transdiagnostic group intervention.

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SECTION B: EMPIRICAL RESEARCH STUDY

Living Well Through Mindfulness (LiveMind): A Feasibility Randomised Controlled Trial of a Brief Mindfulness-Based Intervention in a Mental Health Secondary Care setting

Word Count: 7927

For submission to *Mindfulness (see Appendix V for authors guidelines)*

Abstract

New and better interventions for mental health and stigma are needed. Progress in mindfulness-based interventions (MBIs) and research for adults with severe and enduring mental health problems has been gradual, held back in part by a belief that mindfulness may be harmful for this client group. Brief MBIs have shown promise in the treatment of two commonly presenting problems in secondary care services, psychosis and borderline personality disorder, and emerging evidence suggests that this approach is both safe and therapeutic. The effectiveness of a transdiagnostic brief MBI in mental health secondary care services is relatively unexplored. Feasibility studies play an important role in the evaluation of complex interventions such as a brief MBI. A randomized controlled feasibility study was conducted to explore rates of recruitment and retention, acceptability and preliminary effectiveness. The findings indicated recruitment methods were feasible (n=26 in three months). Dropout was no higher than comparative trials, although problems were identified in the rate of measure completion. The study protocol could be improved by including additional strategies to increase the rate of outcome measure completion. A content analysis of semi-structured interviews (n=15) suggested that most participants found the intervention helpful, albeit challenging at times. Four overarching themes emerged: perceived effects on wellbeing, change processes, internal factors, and practicalities. Improvement was found on self-report measures of mindfulness, self-compassion, anxiety, and depression across both arms of the trial. These results indicate that a transdiagnostic brief MBI delivered in a mental health secondary care setting may have benefits, warranting further testing in a definitive trial.

Key words: mindfulness-based intervention; mental health; secondary care

Introduction

The impact of a having a severe and enduring mental health problem on life expectancy is generally higher than smoking, diabetes and obesity (Chang, et al., 2011; NHS England, 2014; 2016). Furthermore, the link between mental health problems and early mortality may be worsening over time (Hoang, Stewart, & Goldacre, 2011). However, public attitudes towards mental health are improving (NHS England, 2014; 2016a; 2016b), and the development and implementation of new and better interventions for mental health and stigma are among the top priorities for mental health research worldwide (Wykes et al., 2015).

In recent years, attention has turned towards transdiagnostic interventions (e.g. Newby, McKinnon, Kuyken, Gilbody, Dalgleish, 2015). This approach does not rely on diagnosis, which can be inaccurate or unreliable both in research (Davis, Sudlow, & Hotopf, 2016; Roth & Fonagy, 2013; Olatunji, Cisler, & Tolin, 2010) and clinical practice (Swets, 1988; Frances, 2013; Terrace, 2003). Instead, transdiagnostic interventions focus on psychological processes that may underpin a range of mental health problems. Examples include rumination and worry (McEvoy, Watson, Watkins, & Nathan, 2013), emotional avoidance (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996), cognitive biases (Harvey, Watkins, Mansell, & Shafran, 2004), anticipation, and the intolerance of uncertainty (Grupe & Nitschke, 2013).

The most widely evaluated transdiagnostic psychological interventions are cognitive-behavioural therapy and mindfulness-based treatments (Newby, McKinnon, Kuyken, Gilbody, Dalgleish, 2015). Mindfulness describes a state of consciousness characterised by the self-regulation of attention towards current experiences coupled with acceptance of these experiences (Bishop, et al., 2004). Cognitive theory suggests

that encouragement within mindfulness practices to approach, rather than avoid, moment-to-moment internal and external experiences can enable a disengagement from maladaptive patterns of intrusive negative thinking (Roemer & Orsillo, 2002). Correlations have been observed between mindfulness, rumination and experiential avoidance whereby more mindfulness practice is related to less rumination and experiential avoidance (Baer, 2007). In addition, mindfulness training has been linked to increases in quantity and quality (i.e. less biased, inflexible, and reactive) of self-focused attention (Ingram, 1990). However, much of this research is based on experienced meditators and further research is needed to clarify whether the effects of mindfulness interventions are related to these transdiagnostic processes.

Mindfulness meditation practices have been incorporated into a range of interventions such as Dialectical Behaviour Therapy (DBT; Linehan, 1993a) and Mindfulness-Based Cognitive Therapy (Teasdale et al., 2000). Evidence is consistent with the theory that learning mindfulness through mindfulness-based interventions (MBIs) can be of therapeutic benefit for individuals experiencing some mental health problems (Grossman, Niemann, Schmidt, & Walach, 2004; Keng, Smoski, & Robins, 2011; Hofmann, Sawyer, Witt, & Oh, 2010). MBCT was recommended in 2002, and retained in 2009, as a key priority for implementation in the UK health service for individuals who have experienced three or more episodes of depression and are currently in remission (NICE, 2009). However, MBCT requires a substantial commitment to attend the therapy group over an eight-week period, and practice mindfulness meditation for forty minutes a day, six days a week. Offering MBCT also involves a commitment from the NHS to train teachers to deliver these interventions, to provide room space, and sufficient time for therapists to deliver this eight-week therapy (Crank & Kuyken, 2012).

Research has cautioned that observing constantly changing external and internal stimuli as they arise through lengthy mindfulness practices can heighten distress for people who are currently distressed (e.g. Finucane & Mercer, 2006). Studies have typically recruited from primary care settings, so the potential benefits of this intervention in secondary care are not well understood (e.g. Kuyken et al, 2016; Strauss et al, 2014). Evidence suggests that some benefit may be gained with briefer and less intense forms of MBIs (Chadwick, Taylor, & Abba, 2005; Davies, 2013; Droscher, 2017; Hale, Strauss, & Taylor, 2013). Brief MBIs may be particularly helpful when MBCT may not be suitable (e.g. because of increased distress).

In addition to the clinical rationale there is also a drive to widen the availability of MBIs from both clinicians (Shonin, Van Gordon & Griffiths, 2013) and service users (Kingston, Dooley, Bates, Lawlor & Malone, 2007). A novel four-session group MBI designed to be suitable transdiagnostically was developed recently through a process of formal consultation with clinicians working in secondary care mental health settings. An empirical study of this intervention's effectiveness is timely. As this intervention was not routinely being offered in services, this empirical study best fits under the heading of research as opposed to service evaluation.

Group psychotherapies are considered to be complex interventions because they have several interacting components (Campbell et al., 2000). A phased approach to the evaluation of complex interventions has been recommended because they can be more difficult to develop, identify, document, and reproduce (Campbell et al., 2000, Craig, et al., 2008). Five phases have been proposed (see Figure 1).

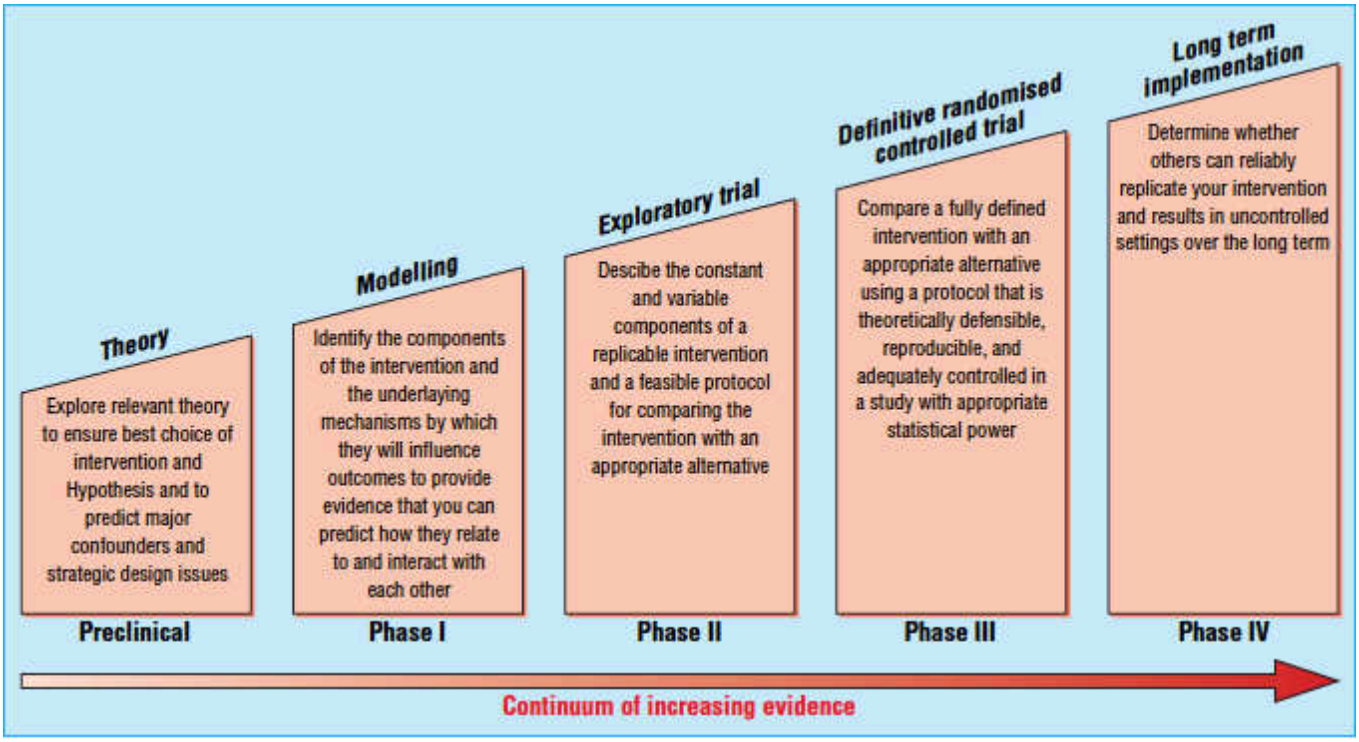

Figure 1. Phases of developing randomized controlled trials of complex interventions (Campbell et al., 2000).

Given that the theoretical and modeling work has already been undertaken in relation to the novel four-session MBI presented here, an exploratory or phase II trial is warranted. Feasibility in this context refers to issues of implementation success such as levels of access (i.e. recruitment), engagement (i.e. retention) and treatment acceptability (Campbell et al., 2000, Craig, et al., 2008; Bowen et al., 2009). In addition, it has been suggested that the potential impact of the intervention should be measured in a phase II trial to support sample size calculations for a definitive trial (Thabane, 2010). This study aims to explore these issues through the research questions outlined below:

Recruitment

1. Is it possible to recruit to a brief MBI study in a mental health secondary care service? A recruitment target of more than 24 participants within six months was set.

Retention

2. Are secondary-care services-users willing to be randomly allocated to a wait-list control group, as demonstrated by dropout?
3. Are participants willing to complete a battery of outcome measures? A target was set with at least 70% of participants completing all measures.
4. Are participants willing to engage with a MBI in the context of a research study? A retention target was set of at least 70% of participants attending two or more intervention sessions (50% of sessions) and engaging with at least four mindfulness practices at home during the study.

Acceptability

5. Do participants find the intervention acceptable, as indicated by responses to a post-intervention questionnaire?
6. What are the subjective experiences of participants taking part in the intervention, as measured by responses to a post-intervention interview?

Preliminary efficacy

7. What preliminary evidence of effectiveness is there for a brief MBI in a mental health secondary care setting, as measured by the effect size on measures of mindfulness, compassion, wellbeing, anxiety, and depression?

Methods

It should be noted that the current study was not the study that was originally proposed. The sequence of events is outlined in Appendix D. In brief, the original research proposal (Appendices E) was to investigate an 8-session MBI for adults experiencing borderline personality disorder. This proposal was taken through the full approvals process (Appendices F to K), and stopped after encountering recruitment difficulties. Subsequently, a second proposal to use archival data from a study called LiveMind was submitted to the course team (Appendix L). This was approved on the basis that a number of research competencies had already been demonstrated (Appendix M).

Design

The LiveMind study had a randomized controlled trial (RCT) design with a wait-list control. It was advertised for six months and recruitment ran in two phases with an aim of 12 participants per phase (allowing for a minimum group size of six). Given that the study was aiming to test feasibility issues, power calculations were not conducted to determine sample size. Guidelines for pilot RCT sample sizes were considered (e.g. Julious, 2005) and a conservative assumption was made that 50% of the sample would agree to take part in the interview stage. Based on this, it was decided that 12 participants per study arm would allow sufficient feedback on the therapy and the research protocol (Graneheim & Lundman, 2004).

In the first phase, 14 participants consented to take part, completed baseline measures and were randomly allocated by independent researcher to a LiveMind intervention group, or a wait-list control group. An online random number generator was used to allocate participants at a 1:1 ratio. This process was repeated in the

subsequent second phase in which 12 participants consented, completed baseline measures and were randomised in the same manner. Across both recruitment waves, the baseline assessment point was named Time 0 (henceforth referred to as T0). The intervention arm began their LiveMind group within six weeks of this point.

All participants completed measures again after the intervention arm had completed LiveMind. This time point was named Time 1 (henceforth referred to as T1). Wait-list participants were then offered an opportunity to receive the LiveMind intervention, and completed measures for a third time afterwards. This was called Time 2 (henceforth referred to as T2). All participants were invited to take part in a semi-structured interview after completing their LiveMind group (i.e. at T1 for the LiveMind arm, and at T2 for the wait-list arm).

Ethical and governance approvals

Prior to my involvement in the LiveMind trial, it had already received National Research Ethics Service (NRES) approval (Appendix O) and NHS research and development approval. Measures were in place to manage risks, distress, and burden on participants, and to ensure all trial data remained anonymous. For example, appropriately trained clinical psychologists facilitated the intervention, and study data was made anonymous using unique participant ID codes. The LiveMind trial had also been registered with the National Institute for Health Research's clinical research portfolio and had been assigned an international standard randomised controlled trial Number (16944868).

Participants

Eligibility was determined according to specific inclusion and exclusion criteria (Table 1).

Inclusion criterion:	
1	Currently accessing a secondary care mental health service in Sussex Partnership NHS Foundation Trust
Exclusion criteria:	
1	Are not willing and able to work safely in a therapy group
2	Experience problematic substance abuse that may adversely influence the therapy group
4	Have experienced a recent (i.e. within the past month) serious life event/crisis, or suicidal ideation with intent to commit suicide, which would make an MBI inappropriate at this time
5	Have taken part, are taking part, or planning to take part in another clinical MBI (in a research or a service context), or are taking part in research investigating new medicinal products

Table 1 Eligibility criteria

Participants were nineteen women, six men, and one gender questioning individual, aged between 22 and 78 years old. Results of a t-test and Fisher's exact test revealed no significant between-group differences on any reported variables (Table 2). Frequencies of diagnoses far exceeded the number of participants in each group, suggesting that participants were experiencing multiple co-morbid mental health problems (Table 3). This diagnostic profile confirms that participants were representative of a secondary care mental health service population (i.e. would be unlikely to be referred to a primary care mental health services such as the Increasing Access to Psychological Therapies program; Clark, 2011). The two-tailed probability of obtaining this distribution of each diagnosis between groups was calculated using Fisher's exact test using a significance level of 0.05. The results revealed no significant differences in diagnosis between groups. Together, these tests suggest that randomisation was successful in creating two similar groups.

Variable	LiveMind (n=13)	Control (n=13)	Difference
Age, mean (+/- SD)	44.69 (11.29)	41.33 (16.42)	t(23)=0.60, *p*=0.55
Education, n (%)			
Left school at or before 16	6 (46%)	4 (31%)	
Completed/completing college/university course	7 (54%)	9 (69%)	*p* =0.69
English as a first language, n (%)	12 (92%)	12 (92%)	
Gender identity, n (%)			
Female	9 (69%)	10 (77%)	
Male	4* (23%)	3 (23%)	*p* =1.00
Medication, n (%)			
Taking psychiatric medications	12 (92%)	10 (77%)	
Not taking psychiatric medications	1 (8%)	3 (23%)	*p* =0.59
Prior experience of psychological therapy	11 (85%)	11 (85%)	
Employment, n (%)			
Employed	3 (23%)	6 (46%)	
Not currently working	8 (62%)	6 (46%)	*p* =0.40
Marital status, n (%)			
Single/ divorced/ separated/ widowed	10 (77%)	8 (62%)	
In a long-term relationship/ married/ civil partnership	3 (23%)	5 (31%)	*p* =0.67

Notes. The gender-questioning participant was added to the male count to assess the significance of the largest possible difference between groups.

Table 2 Participant characteristics across groups.

Variable	LiveMind (n=13)	Control (n=13)	Difference
MINI Axis-I diagnoses, n (%)			
Anxiety	7 (54%)	9 (69%)	P=0.69
Depression	8 (62%)	6 (46%)	P=0.70
Mania	1 (8%)	5 (38%)	P=0.16
Psychosis	9 (69%)	8 (62%)	P=1.00
Alcohol/drug	1 (8%)	6 (46%)	P=0.07
Eating disorder	1 (8%)	1 (8%)	P=1.00
Carenotes current diagnoses, n (%)			
Psychosis spectrum	3 (23%)	3 (23%)	P=1.00
Bipolar disorder	2 (15%)	6 (46%)	P=0.20
EUPD/BPD	0 (0%)	2 (15%)	P=0.48
Recurrent depression	2 (15%)	2 (15%)	P=1.00
Other	3 (23%)	0 (0%)	P=0.22
Unknown	3 (23%)	0 (0%)	P=0.22

Notes. MINI = the Mini-International Neuropsychiatric Interview

Table 3 Frequencies of mental health diagnoses

Measures

Research activity log. An entry was made in the log for every participant who gave his or her consent to take part in the study. The log recorded each participant's name, unique participant number, contact details, date of recruitment to the study, attendance at LiveMind intervention sessions, and completion of outcome measures.

Baseline measures. The following measures were administered at T0 to assess rates of recruitment, eligibility, and sample characteristics (see Appendix P for full versions).

The Mini-International Neuropsychiatric Interview (MINI). The MINI; Lecrubier, et al., 1997). The MINI is a diagnostic interview exploring 17 Axis-1 mental health problems as

described by the Diagnostic and Statistical Manual (DSM-5; APA, 2013). The MINI has been used widely in mental health research, and shows good psychometric properties (Sheehan, et al., 1997).

Questions About You (QAY). The QAY was developed for this study and, as is usual for questions eliciting demographic information, had not undergone psychometric evaluation. It contains 21 items exploring participant demographics (10 items), and experiences of past mental health and psychological interventions (10 items).

In addition, the electronic record system, CareNotes, was screened to gather data relating to each participant's primary diagnosis.

Preliminary efficacy measures. The following measures were administered at T0 and T1 for all participants, and at T2 for participants in the wait-list arm, to explore preliminary efficacy. For full versions, see appendix P.

Five Factor Mindfulness Questionnaire Short Form (FFMQ-SF). The FFMQ-SF (Bohlmeijer, ten Klooster, & Fledd, 2011) comprises 24 Likert questions covering five facets/subscales; observing, describing, acting with awareness, non-judging of inner experiences, and non-reactivity. The observing facet has eight items and a maximum score of 40 points. An example item is: "includes noticing or attending to internal and external experiences, such as sensations, cognitions, emotions, sights, sounds, and smells" (Baer et al, 2008, p.330). The describing facet has four questions and a maximum score of 20 points. An example item is: "refers to labelling internal experiences with words" (Baer et al, 2008, p.330). The acting with awareness facet has five items and a maximum score of 25 points. An example item is: "includes attending to one's activities of the moment and can be contrasted with behaving mechanically while attention is focused elsewhere (often called automatic pilot)" (Baer et al, 2008, p.330). The non-judging of inner experience has five items and a

maximum score of 25 points. An example item is: "refers to taking a non-evaluative stance toward thoughts and feelings" (Baer et al, 2008, p.330). Finally, the non-reactivity to inner experience also has five items and a maximum score of 25 points. An example item is: "the tendency to allow thoughts and feelings to come and go, without getting caught up in or carried away by them" (Baer et al, 2008, p.330). All facets scores, except observing, can be added to find a total FFMQ-SF score from 0-155. Higher scores represent higher levels of mindfulness. The FFMQ-SF preserves the good content validity and psychometric properties of the original 39-item scale (Bohlmeijer, ten Klooster, & Fledd, 2011).

Self-compassion Scale Short Form (SCS-SF). The SCS-SF (Raes, Pommier, Neff, & Van Gucht, 2011) is a reliable and valid 12-item Likert-style measure of self-compassion. Respondents indicate how often experiences occur (e.g. “when something upsets me I try to keep my emotions in balance”). The SCS–SF has demonstrated adequate internal consistency (Cronbach's alpha ≥ 0.86 in all samples) and has a strong correlation with the original scale (r ≥ 0.97 all samples) (Raes, Pommier, Neff, & Van Gucht, 2011).

The Short Warwick-Edinburgh Mental Well-being Scale (SWEMEBS). The SWEMEBS (Stewart-Brown, et al., 2009) comprises seven Likert-style items measuring mental wellbeing (e.g. “I’ve been able to make up my own mind about things” or “I’ve been dealing with problems well”). The scale is correlated with the original 14-item scale (r = 0.95), which has good internal consistency (Cronbach's alpha = 0.89 in a student sample, and 0.91 in a population sample), and high test-retest reliability at one week (r = 0.83) (Stewart-Brown, Tennant, Tennant, Platt, Parkinson, & Weich, 2009).

*Generalised Anxiety Disorder Questionnaire (GAD-7). T*he GAD-7 (Spitzer, Kroenke, & Williams, 2006) contains seven Likert-style items exploring generalised anxiety disorder symptoms (DSM-5; APA, 2013) over the past two weeks. Example items are

"trouble relaxing", and "feeling nervous, anxious, or on edge". The GAD-7 is psychometrically valid (Spitzer, Kroenke, & Williams, 2006).

Patient Health Questionnaire (PHQ-9). The PHQ-9 (Spitzer, Kroenke, & Williams, 1999) consists of nine Likert-style items exploring the severity for depressive symptoms (DSM-5; APA, 2013), during the previous two weeks. Example items are "feeling down, depressed or hopeless" and "feeling tired or having little energy". The PHQ-9 is also a psychometrically validated tool (Spitzer, Kroenke, & Williams, 1999).

Acceptability measures. The following measures were administered at T1 for the LiveMind arm, and at T2 for the wait-list arm to explore acceptability. For full versions, see Appendix P.

The QAY-post intervention (QAY-post). The QAY-post included some items that were from the QAY administered at T0, plus eight new items designed to explore the participant's experiences of the intervention (i.e. likelihood of recommending the intervention to friends and family if they needed treatment). This questionnaire comprised open-ended questions, questions with yes/no or multiple choice answers, and Likert-style questions. It was developed for this study and has not undergone psychometric evaluation.

The Change Interview. The Change Interview (Elliott, Slatick, & Urman, 2001) is a qualitative interview protocol designed to explore three change process issues (e.g. Greenberg, 1986): pre-post changes, helpful factors, and hindering factors (Elliott & James, 1989). It asks respondents to describe any changes they experienced over the course of therapy, their attributions for these changes, and helpful aspects of their therapy. Information on negative aspects of therapy and medications is also collected.

Intervention development and overview

Prior to this feasibility study, the LiveMind protocol was developed through a rigorous consultation process with experienced MBCT teachers. LiveMind was conducted over four ninety-minute sessions, with up to ten participants per group. Two facilitators led each session, at least one of whom was an experienced mindfulness teacher meeting the UK Good Practice Guidelines (Mindfulness Teachers UK, 2015). As well as the topics discussed below, facilitators also incorporated psycho-education around each session theme. See Appendix N for the full study protocol.

Session 1 – being in the present moment

- Introduction to the group
- Establish ground rules
- Complete two formal mindfulness practices (mindful walking practice, and mindfulness of the breath) for no longer than 10 minutes each.
- Reflection on these practices
- Participants invited to complete home tasks

Session 2 – letting go of judging

- Recap of the ground rules
- Complete two further concrete mindfulness practices
- Inquiry on these practices
- Reflect on home tasks and discussion of further home tasks

Session 3 – turning towards the difficult

- Complete two mindfulness practices, this time very gently inviting participants to bring in a difficult experience, if this feels appropriate
- Inquiry
- Reflect on home tasks and discussion of further home tasks

Session 4 – making choices and taking mindfulness forward

- Complete two mindfulness practices
- Inquiry
- Discuss taking mindfulness forward
- Goodbyes

Procedure

The study was advertised to secondary care mental health assessment and treatment service-users through posters and flyers in the service waiting rooms, and an information sheet passed on by clinicians in the team. A mail-out was also sent to the research network; a database developed and maintained by the NHS trusts' research and development team of service-users who are willing to be contacted regarding the possibility of participating in research trials.

Service users who expressed an interest in participating were invited to meet a research assistant at a convenient time and place. At this meeting the participant information sheet was reviewed and the service user was encouraged to ask questions about the study. If appropriate, it was explained that an interview would take place after the consent form had been signed to determine if the service user met the study criteria.

The MINI was administered and those service-users who met current criteria for an axis 1 disorder were then asked to complete baseline measures (T0). It was explained in a sensitive way to service users who did not have a current axis 1 disorder, as determined by the MINI, that it would not be appropriate for them to participate in this study. It was made clear to participants who were eligible that they were free to end their participation at any point, without giving a reason and without affecting the care they would receive afterwards. Participant travel expenses were reimbursed for this meeting.

Once a minimum of 12 (maximum of 20) people had been recruited, this wave of participants was randomised to LiveMind or a wait-list. The study recruited across two waves. Participants in the LiveMind arm were given financial support to attend sessions where needed. The LiveMind facilitator noted attendance at each session. Participants in the wait-list group continued to receive treatment as usual from their care team. After the intervention arm completed their LiveMind group, participants from both arms of the study met with a research assistant to complete measures (T1). Participants in the LiveMind arm had acceptability measures included in their T1 measure pack. Wait-list participants were then offered LiveMind. After their final session they met with a research assistant once more to complete measures (T2). Acceptability measures were included in their T2 measure pack.

Interviews were conducted by a team of clinical research coordinators (CRC's) made up of mental health nurses and psychology graduates, who were familiar with the LiveMind intervention manual and resources. CRC's had developed a relationship with participants by assisting with travel arrangements throughout the study. An interview schedule was used to increase the consistency of data collection and CRCs were transparent about both confidentiality and their independent position in relation to clinical teams, to foster trust. The interviewers collected data by making handwritten notes during interviews. Responses were checked with the participant where necessary to increase the accuracy and credibility of the data (Graneheim & Lundman, 2004). Each interview lasted approximately 30 minutes.

Original verbatim interview notes, anonymised with a unique participant ID code, were made available in the NHS building where they were being securely stored. Permission was granted by the NHS information governance team for notes to be electronically scanned and taken off-site for transcription. PDF files were saved securely on an encrypted memory stick and these electronic copies were used to transcribe the data into Microsoft Word. Due to the small population of texts available, sampling was deemed inappropriate. Therefore, the

entire sample of interviews was analyzed. Participants who had not engaged with the intervention (i.e. attended fewer than two sessions and did fewer than four practices at home over the course of the study) were not excluded from qualitative analysis as the subjective experience of not attending, and the reasons for this, were considered relevant to the research question.

Data analysis

Quantitative data analysis. Recruitment and retention rates, user satisfaction data and outcomes data were analysed descriptively. Participant flow through the study was reported in detail in line with CONSORT guidance (Moher, Schulz, Altman, & Lepage, 2001). Between-group differences on demographic and baseline characteristics were analysed to assess whether randomisation was successful in creating two similar groups. The software program SPSS (version 24) was used to conduct t-tests (IBM Corp, 2016) for continuous variables (e.g. age) and Chi-squared tests (Campbell, 2007) for categorical variables (e.g. gender, or presence of a specific diagnosis). See Appendix S for SPSS syntax.

The study was not designed to be powered to reduce the chances of Type II errors to an acceptable level; therefore significance testing was deemed inappropriate. The t-distribution was used to calculate the 95% confidence intervals for T0 and T1 means. Due to the small sample size, comparison of completers and non-completers was also deemed inappropriate. Post-intervention between-group effect sizes and their 95% confidence intervals were calculated using Cohen's d (Cohen, 1992) to support sample size calculations for a larger trial, and to provide an initial estimate of the effect of the intervention, relative to control, on measures of mindfulness, compassion, wellbeing, anxiety, and depression.

Qualitative data analysis. Responses to the change interview were analyzed using content analysis (Hseih & Shannon, 2005; Krippendorff, 2004; Taylor-Powell & Renner,

2003). Content analysis is an empirically grounded method for seeking valid knowledge characterized by being exploratory in process and predictive or inferential in intent (Krippendorff, 2004). Content analysis was originally used in the analysis of text but has been applied to transcriptions of verbal reports and interviews to understand human behaviour in various contexts (Waltz, Strickland & Lenz, 1991). This method was chosen because the research was motivated by an epistemic question about previously inaccessible phenomena (i.e. what are the subjective experiences of participants after taking part in LiveMind?).This method is aligned with previous studies of similar research questions (e.g. Finucane & Mercer, 2006; Hertenstein, et al., 2012). Expressions of attitude and evaluations were the focus of this analysis, and a one-to-one correlation between textual units and the phenomena articulated in them was assumed (Krippendorff, 2004).

Transcripts were read and re-read, and mutually exclusive recording units (i.e. a sentence or paragraph) were identified and described using a code (i.e. labelled by a term that seemed close to the passage itself) using comment bubbles. To avoid the risk of losing meaning of the text during the condensation and abstraction process, the unit of analysis for this study was the complete thought (Graneheim & Lundman, 2004). This ranged from one word to several sentences. Patterns between transcripts were identified and discussed regularly with research supervisors (Appendix Z). The analysis also focused on the relative importance of each category. Checks were made that no relevant data had been inadvertently or systematically excluded, or irrelevant data included (Graneheim & Lundman, 2004). One transcript was recoded by an independent rater, and percentage agreement was calculated to provide an indication of inter-rater reliability. Any disagreements about the way the data had been labelled and sorted in the coding frame were discussed (Woods & Catanzaro, 1988). Tabulations were used to summarize the absolute and relative frequencies of each category (Krippendorff, 2004).

Roles and responsibilities

Three researchers from two local universities took the LiveMind study through the ethical approvals process and provided research and clinical supervision to everyone else involved. This included a team of clinical studies coordinators (CSCs) and research assistants from the host NHS Trust's research and development team who were responsible for coordinating recruitment, administering measures and logging recruitment and retention data. A group of clinical psychologists from the host NHS Trust's mental health secondary care assessment and treatment service delivered the LiveMind intervention and kept attendance records. Finally, my role in relation to the LiveMind study was to enter, tidy and screen the data already collected, to review medical records to extract further data, to transcribe interviews, to refine plans for quantitative analysis, to develop research questions and devise an analytic plan for qualitative data, to conduct analyses and interpret findings, to prepare a short report for dissemination of the findings to participants (Appendix T), to refine plans for wider dissemination of the findings (Appendix U), and to contribute preparing this manuscript for submission to the journal Mindfulness (Appendix V).

Results

Recruitment

The first research question outlined the recruitment target for this trial, which was set at recruiting at least 24 participants within six months. Recruitment records confirmed that referrals (n=39) from care coordinators were received over a period of three months. Two thirds of the individuals (n=26) referred into the study consented to take part and were assessed at baseline (Table 4), suggesting that recruitment into an RCT of a transdiagnostic brief MBI is feasible in an NHS mental health secondary care setting.

Research stage		*N*	Proportion (95% CI*)
1	Numbers referred into the study	39	
2	Of #1, numbers consented and assessed at T0	26	67% (50.98 to 79.37)
3	Of #2, number randomised	26	67% (50.98 to 79.37)
4	Of #3, number completing assessment at T0 and T1	18	69% (50.01 to 83.50)
5	Of those randomised to the intervention arm, number attending at least 2 sessions and doing at least four practices at home	9	69% (42.37 to 87.32)
6	Of those allocated to the wait-list control group, number attending at least 2 sessions and doing at least four practices at home	6	46% (23.20 to 70.85)

Table 4 Descriptive statistics illustrating rates of recruitment and retention

Retention

Retention to the study and the intervention were assessed across three research questions. Each of these is described in turn. Retention through the process of randomly allocating participants to a wait-list control arm was assessed by observing the rate of drop-out at the point that group allocation was revealed. Recruitment records revealed that no participants dropped out of the study after finding out which group they had been allocated to (Table 4), suggesting that randomisation of secondary care mental health service-users to a wait-list control group is feasible.

A target for outcome measure completion was set at 70% of participants completing measures at T0 and T1. Recruitment records indicated that this target was missed by a small margin (i.e. 18 out of 26, 69% of participants, completed measures at T0 and T1). This suggests that outcome measure completion was not entirely feasible as this rate of response in a full RCT would signify a large quantity of missing data. The 95% confidence interval of this proportion, including a continuity correction, is 48% to 85%, indicating that the target of

70% is within the estimated range of plausible values for outcome measure completion that could be obtained in a subsequent RCT. However, this confidence interval also includes values lower than the target. This finding suggests that the study protocol could be improved by including additional strategies to improve the rate of outcome measure completion.

A target for engagement with the intervention was set for at least 70% of participants attending two or more intervention sessions, and engaging with at least four mindfulness practices at home during the study. Attendance records revealed that the number of participants allocated to the intervention group who attended at least two therapy sessions and engaged with at least four mindfulness practices at home fell just short of the target (i.e. nine out of the thirteen participants, 69%, CI 23-71). See Figure 2 for further details of the flow of participants through the study.

The four participants who did not successfully complete the intervention varied in their level of engagement. One participant attended one session only and three participants did not attend any sessions. Further exploration of attendance data revealed that there was a trend for participants who began the intervention within a month of being recruited to engage more than participants who were asked to wait for two or more months before beginning the intervention. However, this may have been down to chance fluctuation.

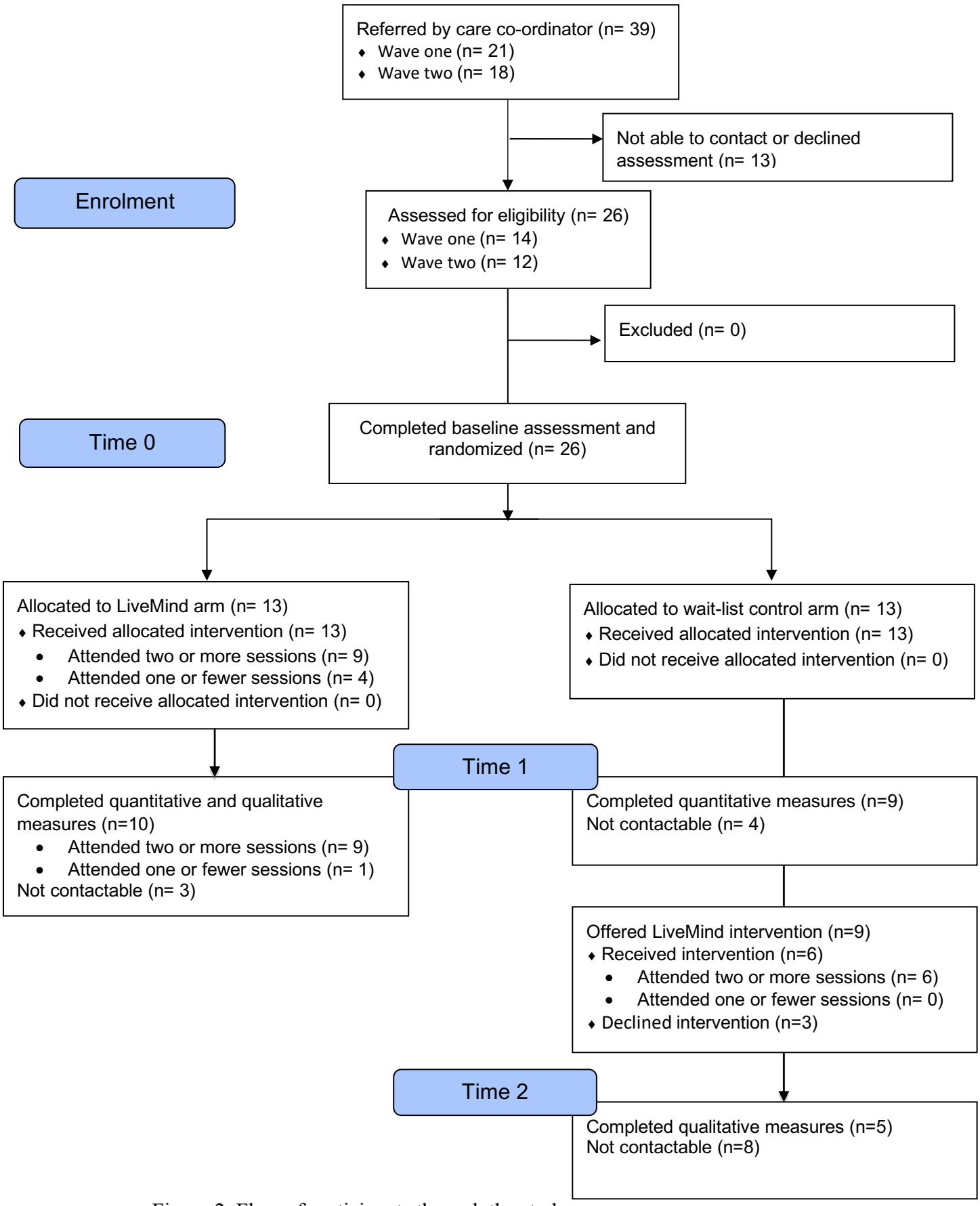

Figure 2. Flow of participants through the study

Acceptability

Intervention acceptability was assessed quantitatively and qualitatively using two measures, the QAY-post and the change interview. Ten participants allocated to the intervention arm of the study and five participants allocated to the wait-list control arm of the study agreed to complete these measures. Given that all 15 respondents had experienced the LiveMind intervention, data were combined across groups. Attendance was good across the combined group of respondents, with 14/15 (93%) present at two or more intervention sessions.

Responses to items on the QAY-post indicated that most of these participants (87%) intended to keep practicing mindfulness after the study, and nearly three-quarters (73%) were quite or very likely to recommend the intervention to family or friends. Over half of these participants (60%) thought the intervention had helped their wellbeing either ‘quite a lot’ or ‘very much’. The remaining participants (40%) were ‘not sure’ whether the intervention had helped their wellbeing.

Aspects of the intervention that were perceived as being positive or helpful and aspects that were perceived as being negative or unhelpful were described by participants during the change interview. Categories and themes that emerged are described below, illustrated by the words the participants used to communicate their experiences. The categories and themes that emerged from the data were not mutually exclusive and it was a common occurrence that several were described simultaneously. A high-percentage of agreement (92%) was found when one transcript was re-coded by an independent rater, indicating good inter-rater reliability of the coding frame.

Although helpful and unhelpful aspects of the intervention were both sometimes expressed within one category, each participant communicated what appeared to be a predominant feeling of one or the other. Four categories emerged from the data; perceived effects on wellbeing, change processes, internal experience, and practicalities (Table 5).

In relation to the perceived effects of the LiveMind intervention on wellbeing, all respondents (n=15) reported that the overall effect had been positive. For example, one participant said: *"[I'm] emotionally stronger. I recognize that I can deal with life challenges much easier. I often reflect from doing the course how out of control I was and now how I'm able to change that from negatives to positives. I feel more in control. It's almost like I've learnt a new form of management which includes kindness to myself, loving myself."* Alongside talking about the positive effects on wellbeing, most participants (n=9) also reported that there had been some challenging experiences. These included fatigue, and the foregrounding of difficulties. One participant said: *"I'm more active. I feel more tired. I'm sleeping better through the night though",* and another said: *"Having to look at yourself and past experiences, being aware that you're going to have to suffer with mental health".*

A range of change processes were identified by participants. Some participants (n=4) identified only positive change processes, while the majority (n=8) identified a mixture of positive and challenging processes that had contributed to a positive overall impression. One participant commented only on negative change processes. The experience of receiving support from others was described only in positive terms. One participant said: *"I spoke to mum about the course and she said it sounded interesting so that was encouraging".* In contrast, the experience of cultivating mindfulness was described in mixed terms. For example, one participant said: *"The draining and nourishing exercises were good and made you think how you approached things and made me think about nourishing activities I used to do but got out of the habit",* while another said: *"In the course, walking around in circles, I*

had to sit down but I found this very rewarding. I still made movements with my legs…

initially I thought it wasn't helpful, but then realized it was."

Categories	Subcategories (proportion of participants)
Perceived effects on wellbeing	Positive overall impression:
	Feeling more at ease (10/15; more relaxed, more in control)
	Feeling generally better (7/15; more optimistic about the future, happier)
	More active (5/15; getting things done, decisive, trying new things)
	Improved sleep (2/15)
	Challenging experiences, but positive overall impression:
	More tired (1/15)
	Fore grounded difficulties (8/15; difficult memories, difficult feelings)
Change processes	Positive overall impression:
	Support from others (4/15; family, therapist, friends)
	Challenging but positive overall impression:
	Cultivating mindfulness (8/15; mindful movement, practicing regularly)
	Group process (5/15; increase in support, dominant characters)
	Overall negative:
	Getting started (1/15)
Internal experience	Positive overall impression:
	Being receptive to mindfulness (11/15; motivated, willing to try)
	Inner strength (7/15; survival instinct, confidence)
	Challenging but positive overall impression:
	Motivation to change (4/15; being ready, confidence in ability to change)
	Mood (7/15; expectations of self, fears, intensity, negative focus)
	Cognitions (6/15; difficult thoughts, critical thinking)
Practicalities	Challenging but positive overall impression:
	Delivery (7/15; increase preparedness, noisy venue, good facilitation, breaks needed, NHS venue, timing)
	Duration (5/15; too short)
	Overall negative:
	Group size (3/15; too small)
	Access (7/15; sitting in one position, mindful movement, CD only)

Table 5. Categories and subcategories that emerged from qualitative data

The process of being in a group was also described in mixed terms. For example, one participant said: *"*[The course*] was very well done, we were given a chance to explain how we felt after each exercise – [I] found this very useful*", while another said: *"One old man tried to dominate the group straight from the start and tried to make the focus on him. I reiterated the ground rules to him to try and avoid it happening again, but ended up tuning him out".* The participant who only described negative change processes appeared to be an exception.

Several phenomena emerged as perceived influences on the internal experience of taking part in the study. An equal number of participants described only positive internal factors as only positive change processes (n=4), although these were not the same individuals. The remainder of participants (n=9) described a mixture of positive and challenging internal factors. Most participants described the positive internal experience of being receptive to mindfulness. For example, one participant said: "*I went in to it open minded. I didn't expect it to be magical… although it can be quite magical! [I'm] feeling optimistic about continuing to practice*", while another said: *"You need to be in the course and you need to focus on it, which I did".* Over half of the participants talked about connecting with their inner strength. One participant said: *"I'm determined. I'm not going to let it beat me. I may not win the battle today, but I'll win the war eventually",* while another said: *"It's given me a stronger, more relaxed mind, able to hold back and think things through".*

Inner aspects were mostly described as challenging at the time, but not sufficiently challenging to view the course as unhelpful overall. Participants described challenges around their motivation to change, mood and cognitions. For example, one participant said: "[I was] *wanting the course to help, wanting to see a change, I think in the past I've attended things because I've been told to. This was different. The motivation came from me. I'm ready for a*

change… I was apprehensive before starting as on a previous course of mindfulness, I had to pull out early owing to a family bereavement and was concerned that this may trigger those feelings again but it didn't."

Practicalities were described more often in negative terms, with three participants describing only negative experiences of the practicalities of taking part, and all remaining participants (n=12) describing a mixed picture with some challenges and some positive experiences. Subcategories for those who found the practical elements challenging but had a good overall experience appeared related to delivery and duration. One participant said: *"[I needed more] awareness. It requires so much patience to be part of the group. People need to realize that things get easier after the first week and emphasis needs to be placed on this. Whole set up of the group/ research was very good. Booklet and CD were very good and helped learning away from the course. I really appreciate the whole set up, it was good. So empowering"*. A third of the participants said that they wanted the course to be longer. For example one participant said: *"I wanted the course to last longer and for more people to join the course... open up the course to more people, advertise widely, drop-in centers, libraries etc."*

Negative aspects of the practicalities associated with the experience included the group being too small. For example, one participant said: *"The small group was good, but then if 1 or 2 couldn't make it then the group would be too small. So maybe a slightly bigger group, but not more than 8 or 10… it could get overwhelming"*. Other participants described difficulties accessing the exercises due to physical problems or not having electronic access to the audio tracks. One participant said: *"Doing the mindfulness practice at home was harder than in class. Sitting in the same position for long periods. I found several distractions at home. An app on my phone would have been better"*. Another participant said: *"I don't have a mobile CD player, so can't listen to the CD when I want to practice outside. CD*

should be on YouTube then I can access it on my smart phone. There are other exercises on YouTube, but none are relevant to the course material".

Potential for impact

A total of eighteen participants completed measures at both T0 and T1. Nine of these had been allocated to the LiveMind arm and nine had been allocated to the wait-list arm. A comparison of clinical and demographic variables between study completers and study dropouts revealed some differences between these two groups (Table 6). Study completers (i.e. participants completing measures at T0 and T1) appeared to be, on average, an older and more homogenous group in terms of age than study dropouts (i.e. participants not completing measures at T0 and T1). The magnitude of this effect was approaching medium in size (d =0.48) but was non-significant (t (23) = -1.08, p =.29). However, given the non-significant difference and wide confidence interval around the effect size, caution should be taken when interpreting this finding. The difference between study completers and study dropouts on the baseline measures of depression, anxiety, compassion, wellbeing, and mindfulness were small and non-significant. This suggests that baseline differences in mental health, self-compassion or mindfulness may not have contributed to dropping out of the study, although this would need to be explored again in a definitive trial, because the lack of significance might be due to lack of statistical power. Comparison of study completers and study dropouts across a range of categorical variables at baseline (T0) revealed a number of differences between these two groups.

The odds of leaving school before the age of 16 were 33% higher for study dropouts than for study completers, with a 95% confidence interval of 0.05% to 221%. The odds of being employed were 22% higher for study dropouts compared to study completers, with a confidence interval of 0.07% to 216%. Both of these confidence intervals were entirely above zero, indicating statistically significant findings. However, there may be Type 1 errors due to

multiple comparisons given the number of variables examined. Finally, the odds of being in a long-term relationship, marriage, or civil partnership were 39% higher for study completers compared to study dropouts. As none of the participants who dropped out of the study were in a relationship, the true population effect for this variable was not calculable.

Continuous variables	Study completers n=18 Mean (SD)	Study dropouts n=8 Mean (SD)	Mean difference (Std. Error Difference)	Cohen's *d* (95% CI)
Age	45.12 (12.01)[a]	38.75 (17.07)	-6.37 (5.89)	0.48 (-5.06 to 12.31)
Depression (PHQ-9 at T0)	12.28 (8.31)	13.88 (8.13)	1.60 (3.51)	-0.20 (-4.04 to 5.43)
Anxiety (GAD at T0)	8.44 (6.98)	10.75 (6.73)	2.31 (2.94)	-0.35 (-3.57 to 4.32)
Compassion (SCS at T0)	28.17 (8.82)	32.00 (13.47)	3.83 (4.42)	-0.38 (-4.46 to 8.95)
Wellbeing (Warwick at T0)	20.00 (7.63)	20.25 (3.99)	0.25 (2.29)	-0.04 (-3.56 to 2.73)
Mindfulness (FFMQ at T0)	55.17 (12.99)	53.50 (11.70)	-1.67 (5.15)	0.14 (-5.86 to 8.25)
Categorical variables (T0)	**Study completers n=18 n (%)**	**Study dropouts n=8 n (%)**	**Difference in proportions**	**Odds ratio (95% CI)**
Left school at or before the age of 16	3 (16.7%)	3 (37.5%)	20.8%	0.33 (0.05 to 2.21)
English as a first language	16 (88.9%)	8 (100%)	11.1%	0 (not calculable)
Female	13 (72.2%)	6 (75%)	2.8%	0.87 (0.13 to 5.82)
Had tried mindfulness meditation before	12 (66.7%)	5 (62.5%)	4.2%	1.2 (0.21 to 6.80)
Employed	5 (27.8%)	4 (50%)	22.2%	0.38 (0.07 to 2.16)
In a long-term relationship/ married/ civil partnership	7 (38.9%)	0 (0%)	38.9%	0 (not calculable)

Notes. [a] One study completer did not disclose their age, therefore n=17 for this analysis

Table 6. Comparison of study completers and study dropouts on a range of demographic and clinical variables

Pre-post changes on all measures from the completer sample (i.e. participants with full T0 and T1 datasets) were analyzed in more detail. However, given some of the differences between study completers and study dropouts and the small sample size, these findings should be interpreted with caution. Across measures of mindfulness, self-compassion, and wellbeing an increased score from T0 to T1 indicates improvement. Comparison of T0 to T1 scores revealed either equal or higher T1 scores for both groups on all three measures (Table 7). This suggests a trend towards increased wellbeing, mindfulness, and self-compassion for all participants in the trial. However, the main analysis of interest is the controlled between-group comparison. Intervention participants showed greater T0-T1 improvement in mindfulness than wait-list participants, with between-group differences on FFMQ subscales being in the medium range. Intervention participants also showed greater T0-T1 improvement in self-compassion than wait-list participants, with between-group differences on the SCS being in the large range. Whilst encouraging, this study wasn't powered to find significant effects, and the 95% confidence intervals for all effect sizes crossed zero meaning that it remains plausible that there is no difference between the two arms.

For measures of depression and anxiety a decreased score indicates an improvement. Comparison of T0 to T1 scores revealed a difference between groups on these measures. For the intervention group, lower T1 scores on both measures were found, indicating trends towards clinical improvement in depressive symptoms and towards worsening in anxiety symptoms for controls (Table 7). Again, the main analysis of interest is the controlled between-group comparison. Intervention participants showed greater T0-T1 improvement in depression and anxiety than wait-list participants, with between-group differences in T0-T1 changes on the PHQ-9 and GAD-7 being in the medium range. Again, while this finding is encouraging, this study wasn't powered to find significant effects, and the 95% confidence

intervals for all effect sizes crossed zero meaning that it remains plausible that there is no difference between the two arms.

To explore the magnitude of change, effect sizes were calculated using the within group paired difference means, standard deviations, and sample sizes. Based on benchmarks suggested by Cohen (1988), the results indicated a small effect of intervention over control on measures of mindfulness (d =-0.31) and wellbeing (d =0.17). The effect of intervention over control for measures of depression (d =0.46), and anxiety (d =0.49) were approaching a medium size, and a large effect of intervention over control on a measure of compassion (-1.05). However, large confidence intervals around all of these effects sizes suggest that the findings should be interpreted with caution. For further details see Appendix Q for SPSS syntax and Appendix S for testing output.

	T0 Mean (SD)		T1 Mean (SD)		Within-group change (i.e. T1-T0) Mean (SD)		Between-group differences in T0-T1 change scores. Mean (SD)	Between-group differences in T0-T1 change score effect sizes. Cohen's *d* (95% CI)
	LiveMind (n=9)	Waitlist (n=9)	LiveMind (n=9)	Waitlist (n=9)	LiveMind	Waitlist		
FFMQ total	57.67 (10.27)	52.67 (15.45)	64.22 (12.69)	56.55 (9.40)	-6.56 (7.60)	-3.89 (10.34)	5.22 (8.91)	-0.31 (-5.28 to 6.44)
Non-react	9.44 (3.13)	9.44 (3.47)	14.11 (4.62)	12.22 (3.03)	-4.67 (2.65)	-2.78 (4.02)	3.72 (3.44)	-0.59 (-2.32 to 2.04)
Observe	12.44 (4.22)	11.33 (2.55)	13.67 (4.82)	11.11 (2.67)	-1.22 (2.22)	0.22 (2.91)	0.50 (2.62)	-0.59 (-2.04 to 1.31)
Act-aware	17.11 (4.28)	13.33 (4.36)	18.78 (3.31)	13.44 (1.81)	-1.67 (3.04)	-0.11 (4.76)	0.89 (3.95)	-0.41 (-2.40 to 2.70)
Describe	15.11 (3.79)	15.78 (5.24)	16.78 (4.47)	16.11 (4.76)	-1.67 (2.35)	-0.33 (2.35)	1.00 (2.38)	-0.60 (-2.14 to 0.93)
Non-judge	16.00 (4.06)	14.11 (5.04)	14.56 (5.08)	14.78 (5.38)	1.44 (4.10)	-0.67 (3.57)	-0.39 (3.88)	-0.58 (-2.10 to 2.91)
SCS	27.00 (8.41)	29.33 (9.57)	36.56 (13.43)	32.56 (11.08)	-9.56 (7.92)	-3.22 (4.47)	6.39 (7.04)	-1.05 (-6.22 to 1.87)
Warwick	20.33 (7.62)	19.67 (8.09)	20.33 (8.85)	20.89 (3.79)	0.00 (9.49)	-1.22 (4.99)	0.61 (7.38)	0.17 (-6.03 to 3.43)
GAD-7[a]	8.33 (6.89)	8.56 (7.49)	7.00 (6.76)	8.67 (4.77)	1.33 (1.22)	-0.11 (4.20)	-0.61 (3.09)	0.49 (-0.30 to 3.24)
PHQ-9[a]	12.56 (6.93)	12.00 (9.92)	9.89 (8.12)	11.00 (6.73)	2.67 (3.67)	1.00 (4.09)	-1.83 (3.87)	0.46 (-1.94 to 3.13)

Notes. [a] Lower scores indicate fewer or less intense symptoms. On all other scales the reverse is true (i.e. higher scores indicate fewer or less intense symptoms)

Table 7. Descriptive statistics for study completers only (i.e. participants who completed measures at both T0 and T1.

Discussion

This feasibility study aimed to explore rates of recruitment and retention acceptability, and preliminary efficacy of a brief MBI in a secondary care mental health setting (LiveMind). Seven research questions were examined. The first question concerned the feasibility of the study protocol in terms of recruitment. The methods were found to be both feasible and effective. However, as the original research study used the same recruitment methods, and recruitment was found to be unfeasible, there may have been other factors impacting on the rate of recruitment, such as transdiagnostic approach, or the availability of alternative routinely offered clinical interventions. Further research is needed to explore this in more detail. The remaining six research questions were explored using archival data from the LiveMind trial.

The next three research questions concerned the feasibility of the study protocol in terms of retention. Firstly, at the point of randomisation it was found that participants did not drop out after being allocated to the wait-list condition. This suggests that a RCT design is feasible. Secondly, rates of outcome measure completion were lower than the target set, suggesting that the study protocol could be improved with additional engagement strategies (Brueton, et al., 2011). Examples include reimbursing participant travel costs and using email, text, or post to contact participants in addition to phone calls. In addition, a trend was found for participants engaging more if they began the LiveMind intervention within a month of being recruited. The implications of this for a definitive trial are that an active control arm may improve engagement. Thirdly, attendance to sessions and between session practices were lower than the target set, suggesting that there may have been barriers to engagement. While the findings were not far below the thresholds set for outcome measure completion or engagement with the intervention,

further research exploring barriers to engagement could be conducted to further refine the study protocol prior to a definitive trial.

The fifth and sixth research questions concerned acceptability. It was found that participants spoke about the intervention and study protocol in positive terms and reported that they were likely to recommend the intervention to friends and family. Furthermore, none of the respondents perceived that the intervention had a negative effect on their wellbeing. Categories that emerged from the qualitative data were perceived effects on wellbeing, change processes, internal factors, and practicalities. Within each of the four categories, participants described having had more positive or helpful experiences, or challenging experiences that led to a positive overall impression, than negative or unhelpful experiences. In relation to change processes, participants demonstrated considerable insight into their experience that being receptive to mindfulness and the intervention made them more able to make use of the meditation practices. This finding is consistent with an established theory of readiness to change (Prochaska & DiClemente, 1986), suggesting that the results presented here are in line with change literature. In relation to practicalities, a subcategory highlighted the perception that LiveMind materials could be improved by being accessible online. This finding is in line with evidence suggesting that the most effective form of MBI delivery is online (Newby, McKinnon, Kuyken, Gilbody, Dalgleish, 2015). In practice, the question of how individuals intend to access resources could be usefully added to pre-intervention discussions with individuals interested in attended a MBI.

The last research question concerned preliminary efficacy. As the analysis explored the completer sample only, study completers and dropouts were compared first on a range of demographic and clinical variables. It was found that some differences existed between these groups that support hypotheses around barriers to engagement. For example, participants who

dropped out were more likely to be employed and less likely to have a long-term partner. Employment may have served as a barrier to attending a fixed time group intervention for practical reasons, and having a long-term partner may have provided support and encouragement to engage with the LiveMind sessions and meditation practices.

For the key comparison of interest in relation to preliminary efficacy (i.e. the between-group differences in T0-T1 change scores), a trend towards improvement was found on measures of mindfulness, self-compassion, wellbeing, anxiety, and depression. The largest effect was found on a measure of self-compassion. This is consistent with preliminary theoretical (Gu, Strauss, Bond & Cavanagh, 2015) and empirical (Kuyken et al., 2010) work that suggests improvements in compassion can be a mediator of the beneficial effects of MBIs on mental health.

Strengths and limitations of the findings

A strength of this feasibility study is that the research questions and mixed-methods design were aligned with guidelines for the evaluation of a complex intervention (Craig, et al., 2008). The inclusion of qualitative data enabled a rich exploration of the participant perspective, generating useful and meaningful information for refining a definitive trial protocol. The credibility of the qualitative findings was increased by including the experiences of participants allocated to the wait-list arm, in accordance with best practice (Patton, 1987; Adler & Adler, 1988). However, there was no random sampling of the qualitative data. Therefore, sampling biases inherent in the interviews (i.e. there being relatively few study dropouts) may have impacted the findings.

Additional study limitations include not being powered to address efficacy questions, not including any measure of adherence to the LiveMind protocol, and not rendering participants

blind to their group allocation. The sample size could be considered on the small side. However, it is not unusual to run feasibility studies with this number of participants (Lancaster, Dodd, & Williamson, 2004; Julious, 2005). Furthermore, no data relating to the ethnicity of participants was collected. See Appendix W for a broader consideration of study limitations.

Conclusion

A range of methods were used to analyse archival data from the LiveMind trial. It was found that recruitment methods were feasible, but the protocol would benefit from being refined to improve retention. Evidence from a qualitative analysis suggested that the LiveMind intervention was acceptable, and evidence from a quantitative analysis suggested that the LiveMind intervention has the potential to be effective. Combined, these results indicate that a definitive LiveMind trial is warranted.

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SECTION C: APPENDIX OF SUPPORTING MATERIAL

Materials related to section A

Appendix A: Contents of each electronic database searched

Database	Contents
Medline	over 16 million journal articles from the 1950s onwards, including 5,200 journals in 37 languages
Psycharticles	more than 181,200 full text articles from 1894 onwards, including 102 psychology specific journals
Psychinfo	more than 3.6 million records from 1597 onwards, including nearly 2,500 psychologically relevant journals from more than 50 countries
Web of Science	Citations from 6,000 major scientific, technical and medical journals as well as published literature from conferences, symposia, seminars, colloquia workshops and conventions
the Cochrane library	over 5,000 systematic reviews and over 650,000 other data records, covering clinical trials, methods, technology and economic evaluations
Prospero	international records of all prospectively registered systematic reviews in health and social care, welfare, public health, education, crime, justice, and international development, where there is a health-related outcome

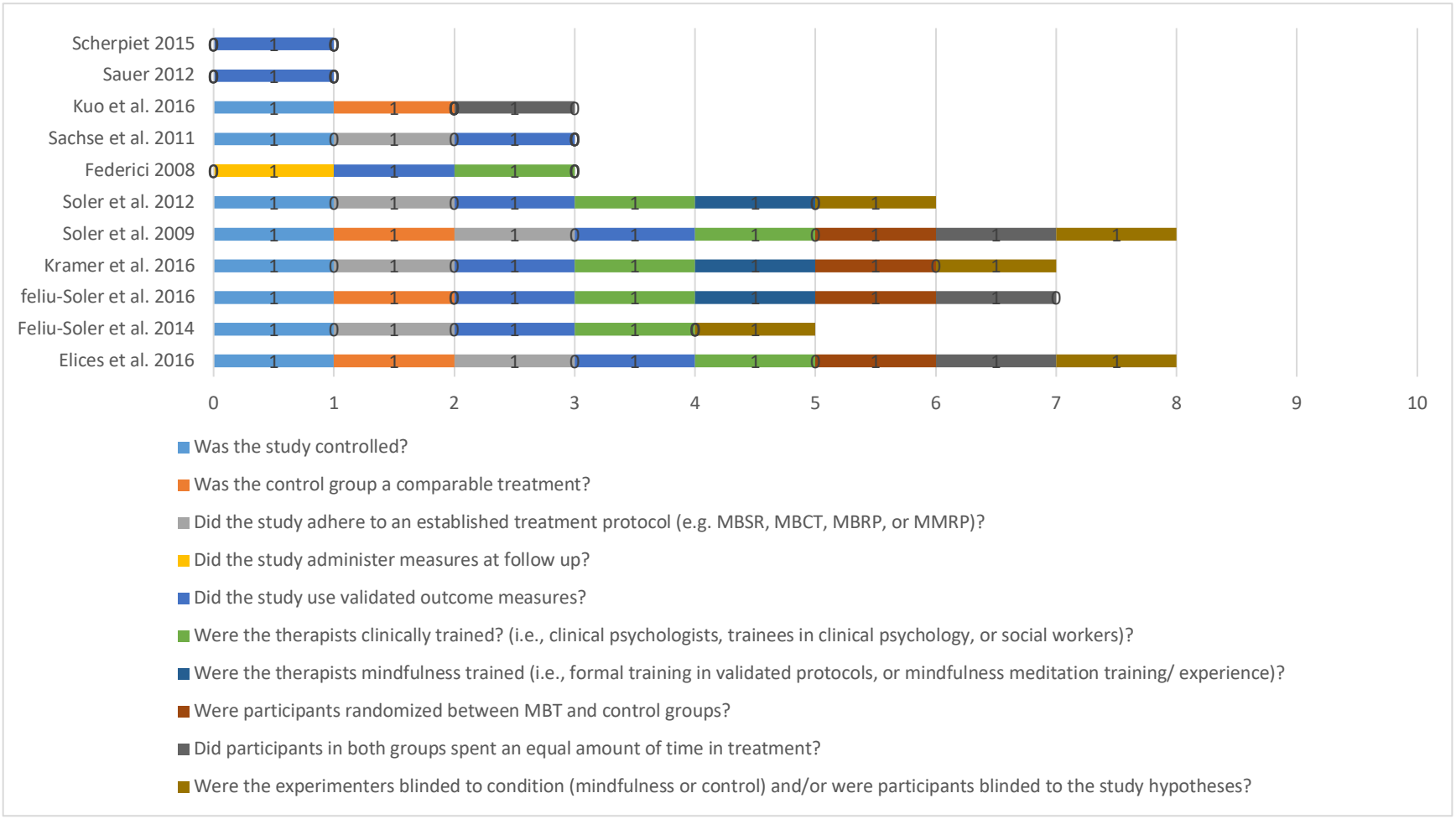
Appendix B: Full-text article screening records

	Citation	Included? (reasons for exclusion)
1	Dixon-Gordon, K. L., Chapman, A. L., & Turner, B. J. (2015). A preliminary pilot study comparing dialectical behaviour therapy emotion regulation skills with interpersonal effectiveness skills and a control group treatment. *Journal of Experimental Psychopathology, 6*(4), 369-388. doi:10.5127/jep.041714	No (full DBT intervention delivered, therefore cannot isolate impact of MBI)
2	Elices, M., Pascual, J. C., Portella, M. J., FeliuSoler, A., MartinBlanco, A., Carmona, C., & Soler, J. (Jun 2016). Impact of mindfulness training on borderline personality disorder: A randomized trial. *Mindfulness, 7*(3), 584-595.	Yes *same sample as Soler (2016)
3	Farinacci, C., Eisen, L., & Johnson, A. (2005). The effectiveness of mindfulness training for borderline personality disorder. *Australian Journal of Psychology, 57*, 203-204.	No (full text not available, therefore cannot extract data)
4	Federici, A. (2010). Effectiveness of a dialectical behaviour therapy skills group for the treatment of suicidal/self-injurious behaviour and eating disorder symptoms in patients with borderline personality disorder. *Dissertation Abstracts International: Section B: The Sciences and Engineering, 70*(9-B), 5817.	Yes
5	FeliuSoler, A., Pascual, J. C., Borras, X., Portella, M. J., MartinBlanco, A., Armario, A., Soler, J. (Jul-Aug 2014). Effects of dialectical behaviour therapy-mindfulness training on emotional reactivity in borderline personality disorder: Preliminary results. *Clinical Psychology & Psychotherapy, 21*(4), 363-370.	Yes *same sample as Feliu-Soler et al., (2016)
6	FeliuSoler, A., Pascual, J. C., Elices, M., MartinBlanco, A., Carmona, C., Cebolla, A., Soler, J. (2016). Fostering self-compassion and loving-kindness in patients with borderline personality disorder: A randomized pilot study. *Clinical Psychology & Psychotherapy,*	Yes *same sample as Feliu-Soler et al., (2014)
7	Fitzpatrick, S., & Kuo, J. R. (2016). The impact of stimulus arousal level on emotion regulation effectiveness in borderline personality disorder. *Psychiatry Research, 241*, 242-8. doi:10.1016/j.psychres.2016.05.004	Yes *same sample as Kuo et al., (2016)
8	Huss, D. B., & Baer, R. A. (Feb 2007). Acceptance and change: The integration of mindfulness-based cognitive therapy into ongoing dialectical behaviour therapy in a case of borderline personality disorder with depression. *Clinical Case Studies, 6*(1), 17-33.	No (MBCT delivered alongside full DBT intervention, therefore cannot isolate impact of MBI)

9	Kramer, U., (2016). The Role of Coping Change in Borderline Personality Disorder: A Process-Outcome Analysis on Dialectical-Behaviour Skills Training. *Clinical Psychology & Psychotherapy.* doi:10.1002/cpp.2017	Yes *same sample as Kramer et al., (2016)
10	Kramer, U., Pascual-Leone, A., Berthoud, L., de Roten, Y., Marquet, P., Kolly, S., Page, D. (2016). Assertive anger mediates effects of dialectical behaviour-informed skills training for borderline personality disorder: A randomized controlled trial. *Clinical Psychology & Psychotherapy, 23*(3), 189-202. doi:10.1002/cpp.1956	Yes *same sample as Kramer (2016)
11	Kuo, J. R., Fitzpatrick, S., Metcalfe, R. K., & McMain, S. (2016). A multi-method laboratory investigation of emotional reactivity and emotion regulation abilities in borderline personality disorder. *Journal of Behaviour Therapy and Experimental Psychiatry, 50*, 52-60. doi:10.1016/j.jbtep.2015.05.002	Yes *same sample as Fitzpatrick & Kuo (2016)
12	Magyari, T. (2015). Chapter: Teaching mindfulness-based stress reduction and mindfulness to women with complex trauma. 140-156.	No (no clear diagnosis of BPD, therefore cannot compare results with other studies)
13	Sachse, S., Keville, S., & Feigenbaum, J. (2011). A feasibility study of mindfulness-based cognitive therapy for individuals with borderline personality disorder. *Psychology & Psychotherapy: Theory, Research & Practice, 84*(2), 184-200.	Yes
14	Sauer, S. E., & Baer, R. A. (2012). Ruminative and mindful self-focused attention in borderline personality disorder. *Personality Disorders-Theory Research and Treatment, 3*(4), 433-441. doi:10.1037/a0025465	Yes *same sample as Sauer (2014)
15	Sauer, S. E. (2014). The effect of mindfulness and rumination on tolerance of anger in individuals with borderline personality disorder. *Dissertation Abstracts International: Section B: The Sciences and Engineering, 75(6-B* (E), Sefe.	Yes *same sample as Sauer & Baer (2014)
16	Scherpiet, S., Herwig, U., Opialla, S., Scheerer, H., Habermeyer, V., Jancke, L., & Bruhl, A. B. (Sep 2015). Reduced neural differentiation between self-referential cognitive and emotional processes in women with borderline personality disorder. *Psychiatry Research: Neuroimaging, 233*(3), 314-323.	Yes
17	Shaw Welch, S., Rizvi, S., & Dimidjian, S. (2006). Chapter: Mindfulness in dialectical behaviour therapy (DBT) for borderline personality disorder. 117-139.	No (no empirical study data reported)
18	Soler, J., Elices, M., Pascual, J. C., Martin-Blanco, A., Feliu-Soler, A., Carmona, C., & Portella, M. J. (2016). Effects	Yes

	of mindfulness training on different components of impulsivity in borderline personality disorder: Results from a pilot randomized study. *Borderline Personality Disorder and Emotion Dysregulation, 3*, 1-1. doi:10.1186/s40479-015-0035-8	
19	Soler, J., Valdeperez, A., Feliu-Soler, A., Pascual, J. C., Portella, M. J., Martin-Blanco, A., Perez, V. (2012). Effects of the dialectical behavioural therapy-mindfulness module on attention in patients with borderline personality disorder. *Behaviour Research and Therapy, 50*(2), 150-157. doi:10.1016/j.brat.2011.12.002	Yes
20	Soler, J., Elices, M., Pascual, J. C., Martin-Blanco, A., Feliu-Soler, A., Carmona, C., & Portella, M. J. (2016). Effects of mindfulness training on different components of impulsivity in borderline personality disorder: results from a pilot randomized study. *Borderline Personality Disorder and Emotion Dysregulation, 3*(1), 1-10.	Yes *same sample as Elices (2016)
21	Williams, J. M. G., & Swales, M. (Oct-Dec 2004). The use of mindfulness-based approaches for suicidal patients. *Archives of Suicide Research, 8*(4), 315-329.	No (no clear diagnosis of BPD therefore cannot compare results with other studies)
22	Veerkamp, M., Gotink, R. & Schoorl, M. (2016) Mindfulness based emotion regulation training. *Tijdschr Psychotherapy*, 42(19), doi: 10.1007/s12485-015-0109-5	No (full text not available in English therefore cannot screen)

Appendix C: Graphic presentation of quality appraisal scores



Materials related to Section B

Appendix D: Sequence of events

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Appendix E: My original research proposal

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Appendix F: Outcome evaluation by the course team for my original research proposal

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Appendix G: The second version of my original research proposal, following the outcome evaluation by the course team

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Appendix H: My fully worked up research protocol, based on my original research proposal, and developed according to my local trust's R&D practice

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Appendix I: Approval from the course team for extra funds for my original proposal

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Appendix J: REC provisional approval for my original research proposal

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Appendix K: HRA approval for my original research proposal

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Appendix L: My revised research proposal

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Appendix M: Outcome evaluation by the course team for my revised research proposal

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Appendix N: LiveMind course protocol

LiveMind

Living Well Through Mindfulness

Course Protocol

Version 2.1 (April 2016)

This four session mindfulness-based intervention has been developed specifically for people who may find a standard eight week course (MBCT or MBSR) too challenging because of current mental health difficulties. It may also be helpful for people who are unsure or ambivalent about committing to an eight week course.

This course was developed in consultation with MBCT teachers working in mental health services and we are very grateful to the teachers who gave their time and thought to helping develop this protocol. The course is strongly influenced by the MBCT course protocol (Segal et al, 2002) and we acknowledge and thank the authors for providing inspiration for the LiveMind protocol. We are also very grateful to Lizzie Clark who did a tremendous amount of work in organising the consultation and in helping to develop this protocol.

There is no orientation session for LiveMind. Our consultation suggested that this could make the course seem too long and might detract from our intention of offering a brief introductory MBI. Instead there is an information sheet for participants, given prior to the course starting, and a course workbook for participants to support their learning.

Finally, it is important to say that this protocol has not been widely implemented or evaluated. This means that we do not know if people will find it beneficial or helpful. We therefore do not recommend its use outside of a research context which will help us to learn about its potential effectiveness.

* Please note that transcripts of mindfulness practices and audio recordings are available to support this protocol.

Session 1: Being in the Present Moment

Session objectives

The aim of the first session is to provide an introduction to mindfulness and to overview the format of the course. In this session we discuss how many of us live our lives on 'auto-pilot' and how being in a 'doing mode' may not always be beneficial. Participants will begin to practice and discuss how we can shift from the doing mode by paying attention mindfully to everyday experiences (such as the breath) and how we can use the breath to return to the here and now. The session will end with an invitation for participants to practice mindfulness at home the next session.

10 mins Introductions. Facilitators introduce themselves and participants introduce each other in pairs/three just saying name and how travelled today and then to the group (maybe introducing their partner to the group)

10 mins Facilitator explains the purpose of the group, group structure (number of sessions, length of sessions etc.) including attitudinal foundations of mindfulness

15 mins Group develop shared group rules together to support the group to feel a safe and comfortable place to be, inviting group members to suggest rules and write these up on flip chart and to have up in each session. Ensure this list includes:

- Confidentiality (and what this means – i.e. OK to share your experiences of the group with others but not other people's experiences)
- Respecting other people (ok to have different opinions, giving people time to talk, no obligation to contribute)
- Time keeping (try and be on time if possible but come if you are going to be late, that's fine, if you are going to be late or miss a session please let facilitator know (give contact details)
- Commitment (no obligation to keep coming but let us know if you can't come, inviting daily mindfulness practice 10 mins a daily as best you can, but do what feels manageable)

10 mins Mindful walking practice* (or inviting people to sit and raise legs up and down as an alternative)

10 mins Inquiry about walking practice – what was noticed during the practice, weaving in learning about mindfulness (esp. especially in relation to session theme - being in the present moment, automatic-pilot etc.)

10 mins Mindfulness of the breath practice* (focusing on contact with the chair, or feet on the floor as an alternative if the breath is particularly challenging)

15 mins Inquiry about mindfulness of breath practice, weaving in learning about mindfulness (esp. in relation to session theme - being in the present moment, automatic-pilot etc.)

10 mins Home tasks – explaining why we have home tasks. Hand out Session 1 summary and CDs with practices (and/or give participants opportunity to download as MP3 files to their

phones), invite to listen to the mindfulness of body and breath practice (10 mins) every day and to bring mindfulness to an everyday activity

Session 2: Noticing Judging and letting it be

Session objectives

In this session group members will recap briefly on how they found the first session and will then begin to reflect upon how we can relate differently to our experiences. Through starting to notice judgements we all experience, the group will begin to discuss that thoughts may not necessarily be true (i.e. thoughts are not facts). Through inquiry the group can begin to notice that we can be aware of judgements and other difficult thoughts without getting lost in them. Bringing in self-compassion gently and carefully as this can result in deepening of self-judgements. As a first step with being more self-compassionate we focus on noticing judgements (especially about the self) and allowing these to pass.

10 mins	Welcome and revisit group rules
10 mins	Mindfulness of walking practice* (noticing preferences, what we like and don't like)
15 mins	Inquiry about walking practice (weaving in learning – e.g. noticing how easily judgements come in about not doing the practice properly)
15 mins	Reflecting on home practice, what was noticed, helpful, challenging, looking at building in daily practice, challenges (discussing in pairs then as whole group)
15 mins	Mindfulness of sounds and thoughts practice* (noticing preferences, what we like and don't like, urges)
15 mins	Inquiry about practice (weaving in learning – e.g. noticing how easily judgements come in about thoughts, noticing 'thoughts are not facts')
5 mins	Home tasks – read Session 2 summary and listen to mindfulness of body and breath practice daily if possible (10 mins) and bringing in mindfulness to an everyday activity

Session 3: Mindfulness in Daily Life

Session objectives

In the penultimate week, the group will think more about bringing mindfulness to our daily lives, noticing nourishing and draining activities in our lives and using mindfulness as a way of making more conscious choices about how we spend our time.

5 mins	Welcome and revisit group rules
15 mins	Mindfulness of body and breath practice*, noticing anything in experience right now that we might wish to be different, noticing choices we have available and being mindful when making and following choices
15 mins	Inquiry about in-session practice and home practice (weaving in learning around making choices)
10 mins	Walking practice*
10 mins	Inquiry about walking practice (weaving in learning in relation to mindfulness of choices)
25 mins	Nourishing/draining activities (in pairs then as a group noticing nourishing/draining activities from the past week and considering nourishing activities for the following week and writing these down)
5 mins	3-minute breathing space* (emphasising this can be helpful during the day at times of difficulty and how this can help us to choose how best to respond)
5 mins	Home tasks – read Session 3 summary and listen to mindfulness of body and breath practice daily if possible (10 mins), keeping a nourishing/draining activities daily diary, bringing mindfulness to an everyday activity and to walking in daily life and bringing in the breathing space when this seems helpful.

Session 4: Taking Mindfulness Forward

Session objectives

In the final session we will reflect more on intentional skilful action – we can respond more promptly and effectively to signs of diminishing mood by learning about our own patterns of mind and body. We will review the planned nourishing activities from the previous week and will contemplate further on how we can make mindful decisions and choices in our lives, and seeing this as a way of being kind to ourselves. We will also discuss how we might want to take mindfulness forward in our lives. This will include making intentions (where appropriate) about mindfulness practice and potentially about deepening of mindfulness practice.

5 mins	Welcome and revisit group rules
10 mins	Walking practice* (depending on space available), inviting mindfulness of choices
10 mins	Inquiry about practice (weaving in learning about mindful choosing)
20 mins	Reviewing nourishing and draining activities diary from previous week, paying equal attention to nourishing activities and planning nourishing activities for the following week and weeks
15 mins	Sharing experiences of the LiveMind course (in pairs) – what has changed for me personally? what do I want to remember? what do I want to keep doing?
15 mins	Sharing experiences of the LiveMind course as a whole group, including facilitators. Perhaps sharing a memento of the group.
5 mins	3-min breathing space*
10 mins	Where next? Taking mindfulness practice forwards, keeping up with practice (formal informal) and further courses
5 mins	Goodbyes and keeping up the good work

Appendix O: LiveMind study protocol and recruitment materials

A Feasibility Randomised Controlled Trial of a Brief Mindfulness-Based Intervention in a Mental Health Secondary Care Setting

STUDY PROTOCOL

Chief Investigator: Dr Clara Strauss a, b

Co-Investigator: Dr. Kate Cavanagh [a]

Study Sponsor: Sussex Partnership NHS Foundation Trust

[a] *University of Sussex*

[b] *Sussex Partnership NHS Foundation Trust*

Contents

1. Study Summary

There is a proliferation of research investigating the effectiveness of mindfulness-based interventions for mental health difficulties. Learning mindfulness is thought to be of therapeutic benefit (Keng, Smoski, & Robins, 2011) and, as a consequence, has been incorporated into a number of mindfulness-based interventions (MBIs) for a wide range of mental health difficulties (Fuchs, Lee, Roemer & Orsillo, 2013).

However, traditional mindfulness-based therapies require a large commitment from participants (in terms of group attendance and practice) and from the National Health Service to be able to offer mindfulness-based interventions to those who may find this intervention useful (Crank & Kuyken, 2012; Langdon, Jones, Hutton & Holtum, 2011). As mindfulness can have beneficial effects of mental health when offered in a brief, or self-help format (Thompson et al., 2010; Walker, 2010; Meyers, 2009), it seems pertinent to investigate the feasibility of offering low-intensity mindfulness interventions. Consequently, our research team has developed a brief mindfulness-based intervention, which can be delivered in a secondary care mental health setting, which will provide participants with a taster of some basic mindfulness skills.

We propose to conduct a randomised controlled trial to investigate the feasibility of this brief mindfulness intervention. Twenty-four to forty service users from secondary care services in Sussex Partnership Trust will be recruited. We will examine a number of feasibility issues:

a) Are there service users eligible for this intervention in Sussex Partnership Trust?

b) Is it possible to recruit service users to a brief mindfulness-based intervention?

c) Is randomisation to the intervention arm and the control arm feasible?

d) Rates of retention of service users to a brief MBI.

e) Rates of completion of the questionnaires.

f) Are the measures suitable?

In addition, we plan to conduct a qualitative interview with participants after they have completed the therapy. In this interview we will ask for participants views on the intervention and the study. We will use

this information to further guide any changes that may be required to the therapy protocol and to the design of the study.

2. Introduction

There is a proliferation of research investigating the effectiveness of mindfulness-based interventions for mental health difficulties. Mindfulness is state of consciousness characterised by the self-regulation of attention towards current experiences coupled with acceptance of these experiences (Bishop et al., 2004). Learning mindfulness is thought to be of therapeutic benefit (Keng, Smoski, & Robins, 2011) and, as a consequence, mindfulness training has been incorporated into a number of mindfulness-based interventions (MBIs). The evidence for effectiveness for MBIs is strongest for the use of mindfulness-based cognitive therapy (MBCT) in preventing depressive relapse for individuals who have experienced three or more previous episodes of depression (Teasdale et al., 2000; Ma & Teasdale, 2004; Kuyken et al., 2008). Recent meta-analytic work suggests that mindfulness approaches may also be beneficial for individuals currently experiencing a depressive episode (Clark, Cavanagh & Strauss, in preparation). However, the evidence for the effectiveness of MBIs in mental health settings beyond depression is limited. Indeed, people experiencing more severe mental health difficulties such as psychosis are typically excluded from MBCT groups.

In the UK National Health Service (NHS) individuals who experience severe and enduring mental health conditions (e.g. longstanding psychosis, personality disorders or treatment-resistant depression/anxiety disorders) are seen by secondary care mental health teams. The predominant evidence-based mindfulness-based intervention for mental health difficulties, MBCT, was not designed for people currently experiencing symptoms of a mental health difficulty (Segal, Williams & Teasdale, 2002) . Indeed caution is advised given the lengthy mindfulness practices and that MBIs can heighten distress for people who are currently distressed (e.g. Finucane & Mercer, 2006). For this reason, an MBI based on briefer mindfulness practices and shorter session duration, may be of benefit to this group of people. To our knowledge however, this has not been systematically evaluated.

In addition to the clinical rationale for a brief mindfulness-based intervention, there may also be a secondary rationale to test the effectiveness of a brief MBI. There is currently a push to widen the availability of MBIs from both clinicians (Shonin, Van Gordon & Griffiths, 2013) and service users

(Kingston, Dooley, Bates, Lawlor & Malone, 2007). However, levels of demand for psychological therapies are out stripping demand (Mind, 2013). When traditional models of psychological therapy cannot meet current demand, alternative forms of delivery such as brief therapies, or self-help can provide useful alternatives (Power & Gilbody, 2005). If a brief mindfulness-based intervention in a secondary care service is effective, this could increase the accessibility of this therapy for service users in comparison to a longer-duration therapy. Encouraging evidence suggests mindfulness-based interventions can be beneficial when delivered in a self-help or brief format in student samples (Cavanagh et al., (2013), as well as individuals experiencing symptoms of depression (Thompson et al., 2010; Walker, 2010).

As a consequence of the clinical and service-level need for a brief mindfulness-based intervention, our research team, through a formal consultation with clinicians in Sussex Partnership NHS Trust, have developed a brief, four-session MBI for delivery in a secondary care mental health setting, developed to be suitable transdiagnostically. We propose to test the feasibility of this brief MBI by conducting a feasibility randomised controlled trial in which we will recruit twenty-four to forty service users from secondary care services in Sussex Partnership NHS Foundation Trust. Feasibility studies are recommended before conducting large-scale study of a new intervention in order to try and identify and amend issues such as acceptability, recruitment and retention, that can raise problems in the large-scale study. This means that the purpose of feasibility research is not to test the effectiveness of the intervention (Medical Research Council, 2008, National Institute of Health Research, 2014). Instead, this feasibility work will enable the research team to determine if the study and the intervention are feasible. We will be able to, based on the results from the present study to adapt the therapy and the study protocol if necessary.

We will examine a number of feasibility issues in this study:

a) Are there secondary care service users eligible for the brief intervention in secondary care mental health services?

b) Is it possible to recruit service users to a brief mindfulness-based intervention?

c) Rates of retention of service users to a brief MBI.

d) Rates of completion of the assessment questionnaires.

e) Are the measures suitable?

f) Are participants willing to be randomised to a treatment and wait-list arm?

In addition we will conduct preliminary analysis on the data to estimate the effect size of the intervention relative to the wait-list control group.

In line with good practice for feasibility studies, further to the quantitative work, we plan to conduct a qualitative interview (Elliot et al's 2001 change interview) with participants after they have completed the brief mindfulness intervention. In this interview we will ask for participants' views on the intervention and the study. We will use this information to guide any changes that may be required to the MBI protocol and to the design of the study.

3. Proposed Methodology

3.1 Study Design

The quantitative study will utilise a randomised controlled trial study design (Barker, Pistrang & Elliot, 2002) with a waiting-list control arm. Once the post group assessment has been completed (time 2 in the diagram below), the waiting-list arm will then be offered the brief mindfulness intervention, meaning the study will then have an observational design.

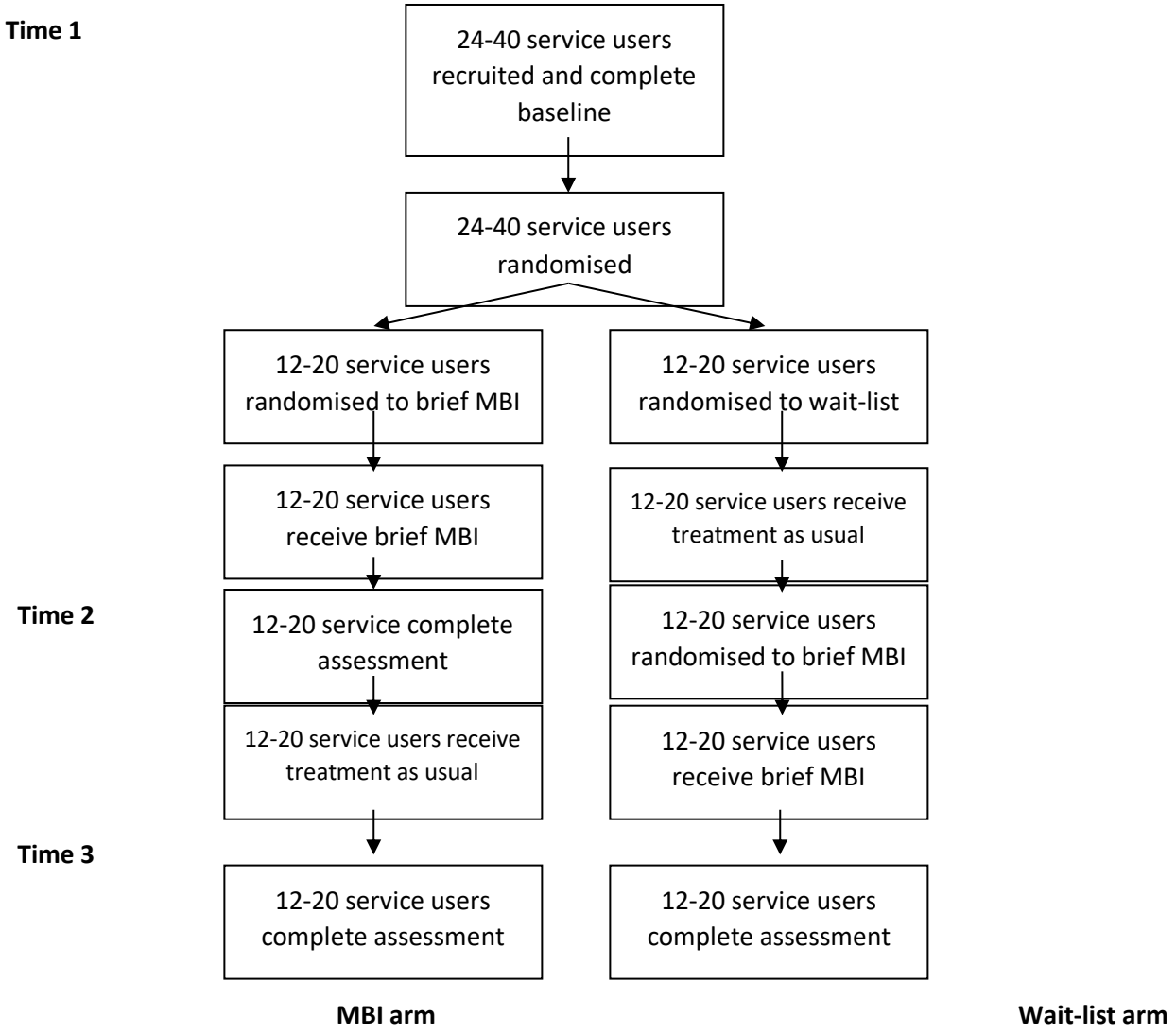

Figure 1. Anticipated flow of participants through study

A trial with 24-40 participants will allow us to run four therapy groups and, conservatively assuming 50% of participants take part in the interview stage, will allow sufficient feedback on the therapy and the research protocol. Sample sizes for randomised feasibility trials can vary greatly, but a sample size of approximately forty participants has been used when testing the feasibility of other psychological interventions (e.g. Kazak et al., 2005; Scott et al., 2001).

3.2 Participants

Twenty-four to forty participants will be recruited from secondary care mental health services in Sussex Partnership NHS Foundation Trust. Service users will either be referred into the study by care team staff from Sussex Partnership, or will be identified as suitable for the study via Sussex Partnership's Research Network. More information on the recruitment strategy is provided in section 3.5 of the protocol.

As this research is a feasibility study, power calculations have not been used to determine sample size. This is because the aim of this study surrounds pragmatic issues (such as recruitment and retention etc.), as opposed to estimating the effect size for the intervention. This means that the purpose of feasibility research is not to test the effectiveness of the intervention (Medical Research Council, 2008, National Institute of Health Research, 2014), therefore power calculations are not required.

Potential participants must meet the following inclusion criteria:

- Currently accessing a secondary care mental health service in Sussex Partnership NHS Foundation Trust
- Have an assigned lead practitioner/care co-ordinator
- Have a current risk assessment
- Meet criteria for a current axis 1 disorder as assessed by the Mini International Neuropsychiatric Interview

Potential participants will be excluded if:

- Are not willing and able to work safely in a therapy group
- Experience problematic substance abuse that may adversely influence the therapy group
- There is a risk of current or recent (past month) active suicidal attempt or intent
- Have experienced a recent (past month) serious life event/crisis, which would make an MBI inappropriate at this time.
- At the point of consent, a service user will be excluded from the study if they are, or have plans to take part in another form of psychological therapy (in a research or a service context), or are taking part in research investigating new medicinal products.

3.3 Measures and Assessment Process

All questionnaire assessments and interviews will be conducted by a research assistant. All of the questionnaires (items 2-6 below) will be completed at time point 1, 2 and 3. The mini-international neuropsychiatric interview (item 1 in the list) will only be completed at time point 1. The data collected from this interview will be used to assess eligibility for the study and will also be used by the research team to describe the sample in terms of diagnosis. Finally Elliot's change interview (item 7), which participants who consent to take part in, will only be completed once the therapy is over (i.e. at time 2 for participants in the MBI arm and at time 3 for participants in the waiting-list arm.

All of the questionnaire measures numbered 2-6 have been validated in psychological research. The MINI interview has also undergone rigorous research and is deemed psychometrically sound. We have adapted the interview schedule from Elliot's (2001) change interview to make the questions more relevant to the aims of our study. We are using the same adaptations to the interview as other studies that have taken place in Sussex Partnership Trust

The collection of data at assessment sessions will follow a strict protocol and include the following psychometrically robust measures:

1. *Mini-International Neuropsychiatric Interview (MINI, Sheehan et al., 1998).* The MINI is a short structured diagnostic interview and was designed to meet the need for a short, but accurate psychiatric interview using DSM-IV or ICD10 criteria. The interview has been used widely in psychological and psychiatric research and shows good psychometric properties.

2. *Five Factor Mindfulness Questionnaire Short Form (FFMQ-SF, Bohlmeijer, ten Klooster, Fledderus, Veehof & Baer, 2011).* The short form of the FFMQ provides a reliable and valid instrument (24 items) to measure the five factors of mindfulness, without the time burden of the longer version of the questionnaire. Participants use a 5 point Likert scale ranging from *never or very rarely true – very often or always true* to indicate responses to items such as *"I make judgements about whether my thoughts are good or bad"* and *"I tell myself I shouldn't be thinking the way I'm thinking"*.

3. *Self-compassion Scale Short Form (SCS-SF, Raes, Pommier, Neff & Van Gucht, 2011).* The short form of the self-compassion scale has near perfect correlations with the long scale when examining total scores. The short-form shows good psychometric properties on the total scores (but less reliable subscale scores). The questionnaire incorporates 12 items, using a 5 point scale of almost never – almost always including items such as *"I try to see my failings as part of the human conditions"* and *"when something upsets me I try to keep my emotions in balance"*.

4. *The Short Warwick-Edinburugh Mental Well-being Scale (SWEMEBS, Stewart-Brown et al., 2009).* The SWEMEBS is a 7 item measure of mental well-being (focusing primarily on psychological and eudemonic well-being and few covering hedonic well-being or affect). Participants are asked, on a 5 point Likert scale ranging from *none of the time* – all *of the time* to answer questions such as *"I've been able to make up my own mind about things"* and *"I've been dealing with problems well"*. The SWEMEBS has been found to satisfy the strict unidimensionality of the Rasch model and be largely free of bias.

5. *Generalised Anxiety Disorder Questionnaire (GAD-7; Spitzer et al., 2006).* The GAD-7 is an easy to use self-administered patient questionnaire that is a psychometrically validated screening tool and severity measure for generalised anxiety disorder. The scale uses a 4 point Likert scale ranging from *not at all – nearly every day*, with items asking respondants to reflect on how often they have experienced symptoms of generalised anxiety such *"feeling afraid as if something awful might happen"* or *"feeling nervous, anxious, or on edge"*.

6. *Patient Health Questionnaire (PHQ-9; Kroenke; Spitzer & Williams, 2001).* The PHQ-9 is a psychometrically validated 9 item questionnaire which scores the nine DSM-IV criteria as 0 – not there at all – 3 nearly every day. Items include *"feeling down, depressed or hopeless"* and *"feeling tired or having little energy"*.

7. *Elliot's (2001) Change Interview.* The Change Interview is a semi-structured questionnaire designed to ask participants their experiences of a psychological intervention. Specifically it asks about changes that have occurred in the person's life since starting the intervention and what they attribute these changes to. Changes can be attributed to the intervention or to other factors. Finally, participants are asked to comment on the aspects of the intervention that helped change to occur and those aspects that might have hindered change from occurring.

In addition to these interviews and measures, participants will complete a series of short demographic questions and questions about their mental health at time 1, along with a couple of questions about their experience of mindfulness and meditation practices. At times 2 and 3 a series of short questions will be asked to participants in both arms of the study about their practice of mindfulness and their intentions to practice mindfulness. Questions about participants experience of therapy and their medication will be repeated at times 2 and 3.

3.4 Therapy Protocol

The protocol for this therapy was developed through a rigorous consultation process with experienced MBCT teachers and secondary care clinicians. Therapy will be conducted over 4 one and a half hour sessions, with up to ten people in a group. The mindfulness groups will be facilitated by two facilitators, at least one of whom is an experienced mindfulness facilitator. As well as the topics discussed below facilitators will also incorporate psychoeducation around the session themes.

Session 1 – being in the present moment

- Introduction to the group
- Establish ground rules
- Complete two concrete mindfulness practice (such as mindful walking practice, or mindfulness of the breath)
- Reflection on these practices
- Participants invited to complete home tasks

Session 2 – letting go of judging

- Recap of the ground rules
- Complete two further concrete mindfulness practices
- Inquiry on these practices
- Reflect on home tasks and discussion of further home tasks

Sessions 3 – turning towards the difficult

- Complete two mindfulness practices, this time very gently inviting participants to bring in a difficult experience, if this feels appropriate
- Inquiry

- Discussion of home tasks

Sessions 4 – making choices and taking mindfulness forward

- Complete two mindfulness practices
- Inquiry
- Discuss taking mindfulness forward
- Goodbyes

3.5 Procedure

Participation within the study will involve the following stages:

1) Recruitment will take place using three strategies:

    a. Initially Research Assistants and Clinical Research Coordinators (CRCs) will attend team meetings in secondary care mental health services to discuss the study. Team members will be asked to identify service users who meet the study inclusion/exclusion criteria and refer service users into the study. Before referring service users into the study, secondary care clinicians will ask service users if they are happy for the research team to possess the contact information that is listed on the referral form (i.e. contact details etc.). If service users provide verbal agreement, the clinician will then pass the referral form with this personal information on to the research team.

    b. The Sussex Partnership Trust Research Network will also be screened by CSOs in the Research and Development department of Sussex Partnership Trust. The Research Network is a database of service users and staff from Sussex Partnership Trust who have consented to be contacted about research studies they may be eligible to take part in and also have provided consent for their notes to be screened to check their eligibility for research studies. Clinical studies officers will then use the electronic care plan approach (eCPA) to determine if the service user has a lead practitioner or care co-ordinator. eCPA is the electronic system where clinical notes are reported. Specifically, notes are held surrounding assessments, plans and reviews of individual's mental health care needs. If the

service user does have a lead practitioner/ care co-ordinator and appears to meet the study inclusion/exclusion criteria the CSO will send the service users information about the study.

c. Posters and leaflets proving information about the study will be made available to service users. These posters and leaflets will be available in waiting areas in the recruiting mental health team bases in order to inform service users about the study. The posters and leaflet provide brief information about the study and direct service users to the lead Clinical Research Coordinator (CRC) for the study in the R&D department where they can find out more about the study. If the service user has a lead practitioner/care co-ordinator and appears to meet the study inclusion/exclusion criteria the CRC will send the service user information about the study.

2) Service users who express an interest in participation will be invited to meet with a study research assistant at a time and place that is convenient. At this meeting the participant information sheet will be reviewed and the service user will be encouraged to ask questions about the study. If appropriate, the consent form will then be completed. It will be made to clear to participants both through the participant sheet, and in the meeting with the research assistant, that signing the consent form for the study does not mean service users are eligible for the study. It will be explained that an interview that will take place after the consent form has been signed will determine if the service user meets the study criteria.

3) The MINI will then be conducted. If participants meet current criteria for an axis 1 disorder the questionnaire measures will then be completed. If the service user does not have a current axis 1 disorder as determined by the MINI it will be explained to them in a sensitive way that they are not appropriate for the current research

4) In the assessment meeting it will be made clear to all service users that they are free to end their participation within the study at any point, without giving a reason and without affecting the care they receive. Participant travel expenses will be reimbursed for this meeting.

5) Once 12-20 people have been recruited participants will be randomised to either the brief MBI group, or to the waiting-list arm.

6) Participants in the brief MBI group will be offered the intervention, whilst participants in the waiting-list group will continue the treatment they would receive as normal from their care team.

7) All participants will complete the questionnaire measures with a study research assistant at time point 2.

8) Participants in the waiting-list arm will then be offered the brief MBI.

9) All participants will complete the questionnaire measures for the final time.

10) Participants will also be asked if they would like to take part in Elliot's (2001) change interview about their experience taking part in the brief mindfulness intervention and also their experience of being part of the study. The interview will be offered to participants once they have completed the brief intervention (i.e. at time point 2 for the brief MBI arm and at time point 3 for the waiting-list arm).

3.6 Planned Data Analysis

The primary aim of the quantitative study is to assess the feasibility of running a larger randomised control trial. Feasibility will be assessed by examining the following questions:

a) Are there service users eligible for this intervention in Sussex Partnership Trust? We will deem the study feasible if there are a minimum of 12 service users eligible for the study in each of the two sites in Sussex Partnership Trust.

b) Is it possible to recruit service users to a brief mindfulness-based intervention? Recruitment will be deemed feasible if we can recruit at least 12 service users in each of the sites across a six month period. As we will be using a couple of recruitment strategies we will also examine which strategy is most effective.

c) Do services users complete a brief mindfulness intervention? Sufficient completion of the intervention is defined as attending at least 50% of the therapy sessions and engaging with at least four practices/ exercises during the intervention.

d) Do participants complete questionnaire mesures? A completion rate of 70% will deem the study feasible.

e) Are the measures suitable? The suitability of the measures will be determined from the qualitative information provided in the interview.

f) Are participants willing to be randomised to a treatment and wait-list arms? If a large percentage of individuals (i.e. 30%) are not willing to take part in the study because of randomisation, randomisation will not be deemed feasible.

The data from the client change interview schedule will be transcribed and analysed using thematic analysis (see Boyatzis, 1998; Braun & Clarke, 2006). Thematic analysis was chosen because it was seen as a suitable method of disseminating what was said in the interviews, identifying patterns and offering some interpretation of the data. A data-driven approach (Braun & Clarke, 2006) was adopted for interpretation of the data as this was an exploratory study that did not intend to fit with any specific theories but instead aimed to explore the participants experience as presented.

3.8 Ethical considerations

All ethical guidelines outlined by the British Psychological Society (2010), such as allowing participants the right to withdraw from research, debriefing etc. will be adhered to.

Health care

Based on a pragmatic RCT design the study does not require any restriction to standard, clinical care, whether this is medication or delivery of NICE-recommended psychological therapy. At no stage will anyone involved in the study request or encourage any professional to make restrictions to clinical care from either brief MBI or waiting-list participants. As such, for participants they will receive the therapy in addition to their usual clinical care.

Managing Distress

Each group will be facilitated by two individuals. At least one of the facilitators in each therapy group will be an experienced mindfulness therapist in the local NHS mental trust and will have delivered 8-week mindfulness interventions before. Mindfulness therapy does not typically generate high levels of distress (Goyal et al., 2014). The likelihood of distress occurring will be further minimized by:

- Employing at least one trained and experienced facilitator per group.
- All facilitators receiving regular supervision.

It is possible a participant could become distressed during data collection. The Chief Investigator has experience in conducting research with individual experience severe and enduring mental health problems

and feels they could handle such a situation should it arise. If a participant were to become upset a number of routes would be taken to try and safely contain this distress:

- Participants would be offered a break from the data collection
- The Chief Investigator would talk through coping strategies they could use to ease their distress
- The Chief Investigator would ensure that the participant had contact details for their care team and mental health charities, such as the Samaritans
- The Chief Investigator would inform participants that the Chief Investigator would inform their care team of their distress in order for this to be further followed up by a qualified clinician, should they feel this is necessary.
- Participants would be told they can make a further appointment to complete the data collection if it this is preferable. Alternatively it would be reiterated that participants could drop-out of the research if it is too distressing.

Managing Risk

All of the individuals that will participate within the study will be in receipt of ongoing clinical care from Sussex Partnership NHS Trust. Should an individual present with any difficulties of clinical significance during any stage of the research, the research team member will pass concerns on to their care coordinator or lead practitioner, after discussing their concerns with the service user in the first instance where at all possible. If a participant discloses information that leads the study team member to believe she or he might harm themselves or others, the therapist or Chief Investigator will be obliged to pass on this information following Sussex Partnership Trust protocol. The limits of confidentiality in this respect will be made explicit. These guidelines will apply to individuals who consent to and complete therapy, individuals who consent to and subsequently withdraw from the process and individuals who do not give consent (and consequently do not participate). The participant will be free to withhold information or withdraw from the study at any time without giving reason.

Consent Process

The research assistant will be responsible for obtaining informed consent from participants. The student has an undergraduate and post-graduate psychology degree, experience of working with adults with

longstanding mental health problems and clinically-relevant research experience. The student has received training from in obtaining informed consent from Dr. Mark Hayward (Director of Research, Sussex Partnership NHS Foundation Trust) and has completed Good Clinical Practice Training. In addition the student will be supervised in obtaining consent and in other aspects of their role by their supervisors (Dr. Clara Strauss and Dr. Kate Cavanagh), both of whom are clinical psychologists with experience of conducting NHS are research.

Lone working

When the Chief Investigator meets with service users when both discussing the study, and collecting data for the study, service users will be provided with the option to meet the researcher at either a Sussex Partnership Trust building, or at the service users homes. When meetings take place at both of the locations, Sussex Partnership Trust and the University of Sussex Lone Working Policy will be followed to ensure the researchers safety. This policy includes adhering to the following regulations.

- Contacting a member of the service users care team to ensure that the service user can be met by an individual working alone. If lone working is not advised another member of Trust staff will be present during meetings.
- The researcher positioning themselves next to the nearest exit during meetings.
- The researcher carrying a charged mobile phone which will be available to use, if needed.

All appointments will take place during working hours (i.e. Monday-Friday 9-5). When visiting a participants home, the Chief Investigator will check in and check out of the interview via their mobile phone, with a member of the supervisory team. Details of the locations of home visits will be made available to members of the supervisory team also. If the Chief Investigator does not call in, and the supervisors cannot make contact with the Chief Investigator, the supervisor will raise the necessary alerts, following Sussex Partnership Trust policy

4. Publication and Dissemination Strategy

The feasibility and both the quantitative and qualitative outcomes of the study will be written-up for submission to a peer reviewed journal.

Papers for presentation will be targeted at the annual meetings and conferences of the British Psychological Society's Division of Clinical Psychology, the British Association of Cognitive and Behavioural Psychotherapists and the Sussex Mindfulness Centre.

Findings will be disseminated to study participants and service user groups. A summary of findings will be written up for participants and service users and findings will be presented at service user workshops and conferences.

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Living Well Through Mindfulness: A Four Session Mindfulness Course

A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

Information Leaflet

What is mindfulness?

Mindfulness is a way of paying attention to, and seeing clearly whatever is happening in our everyday lives. By being mindful we can observe the thoughts and feelings we are experiencing and learn to be kinder to ourselves. This means that we can learn to let thoughts and feelings pass – we treat them like clouds in the sky and let them float by. Mindfulness can allow us to notice difficult thoughts and feelings without getting caught up with them.

What is the LiveMind research study?

We are running research study of a four session mindfulness course for people receiving care in the Brighton and Hove Assessment and Treatment Service of Group Treatment Service. Our course is an introduction to mindfulness and we will practice mindfulness together and begin to think about how we could start applying mindfulness to our daily lives.

How do I find out more?

If you would like to find out more about the study please contact [name] by phone on [phone number] or [phone number] or by email at [email address]

LiveMind Sussex Partnership NHS
NHS Foundation Trust

Living Well Through Mindfulness: A Four Session Mindfulness Course

A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

Mindfulness is a way of paying attention to, and seeing clearly whatever is happening in our everyday lives. By being mindful we can observe the thoughts and feelings we are experiencing and learn to be kinder to ourselves.

LiveMind is a research study of a four session mindfulness course for people receiving care in the Brighton and Hove Assessment and Treatment Service of Group Treatment Service.

If you would like to find out more please contact [name] by phone on [phone number] or [phone number] or by email at [email address]

A feasibility RCT of a brief mindfulness therapy in secondary care

Information Poster 22.03.16 Version 1

REC Reference Number: 14/LO/1964

A Feasibility Randomised Controlled Trial of a Brief Mindfulness-Based Intervention in a Mental Health Secondary Care Setting

We require the following form to be completed for referral into the study. Please note, further screening by the research team will take place after referral, therefore referral into the study does not guarantee participation. Only return this sheet to the research team once the service user has provided verbal consent for the research team to contact them about the research.

Service user name: _____ DOB: _____

Address: _____

Telephone number: _____

eCPA number: _____

Care team & contact number: _____

Lead practitioner/ care co-ordinator: _____

Please can all referrers complete the following questions referring to the service user named above. It is important these boxes are completed accurately, so as to ensure the participant meets the eligibility criteria for this study.

The aforementioned service user is currently accessing a secondary care service in Sussex Partnership Trust	YES	NO
The aforementioned service user has an assigned lead practitioner/care coordinator	YES	NO
The aforementioned service user has a current risk assessment	YES	NO
The aforementioned service user is willing and able to work safely in a therapy group	YES	NO
The aforementioned service user experiences problematic substance abuse that may adversely influence a therapy group	YES	NO
There is a risk of current or recent (i.e. in the past month) active suicidal attempt or intent for the aforementioned service user	YES	NO
The aforementioned service user has experienced a recent (i.e. in the past month) serious life event/crisis which would make a mindfulness intervention inappropriate at this time	YES	NO

Please note, all clinicians referring service users into the study are required to inform the research team if, at any point during the study, the answers provided to the questions above change for the aforementioned service user

Referrer's name _____ Referrer's signature _____

Referrer's role within the team _____ Date _____

E-mail to be sent to lead practitioners/ care co-coordinators regarding the study

Dear X,

As you may know a service user (eCPA number: XXX), who is under your care, has shown an interest in taking part in the study titled “A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting”.

This email is to let you know that the service user met with me and consented to take part in the study *and was eligible to take part* / *however was not eligible to take part* [the research assistant will delete as appropriate].

[If eligible to take part the following sentence will be included]

Participants will soon be randomised to receive the brief mindfulness intervention imminently, or in a couple of months’ time.

If you would like any more information about the study, or the therapy please feel free to get in touch with me on email, or on [phone number here].

Thank you for your support of the study.

Best wishes,

[name]

Participant information leaflet

A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

Before you decide whether to take part in any research study it is important to understand why the research is being done and what it will involve. Please take time to read the following information about this study carefully, and discuss it with friends, relatives or a member of your care team if you wish. If you have any questions please feel free to contact the study research assistant, [name], or the project leader, [name] can be contacted on [phone number]

Please note, unfortunately you will not be able to take part in this study if you are currently:

- taking part in any research study involving a psychological therapy
- taking part in any research involving medication or medical interventions
- are currently receiving, or plan to receive a psychological therapy in the next few months

Thank you for reading on.

What is the purpose of the study?

Over the last fifteen years many research studies have looked at the benefits of mindfulness-based interventions on people's physical and emotional health. These mindfulness-based interventions have typically involved a long course or therapy, which requires a large commitment from participants. Within Sussex Partnership Trust we have developed a brief mindfulness-based intervention that will be delivered in a group format. We plan to carry out a study to explore whether it is possible to research this new mindfulness group. Specifically, we will be addressing the question *'is it feasible to study a brief mindfulness-based intervention in secondary care?'*

Why have I been asked?

Individuals who are in contact with Sussex Partnership are being asked to participate. Specifically, we are looking for people who access secondary care services within the Trust. Your care team within Sussex Partnership Trust have suggested that you may wish to take part. We are hoping to recruit a total of 40 individuals.

Do I have to take part?

It is entirely your decision whether or not to take part. If you decide to participate you will be able to discuss the study with the researcher before signing the consent form. Even then you may change your mind and withdraw at any time, without giving a reason. Accepting or declining to be

in this study will not in any way affect the standard of health care you receive. You will be given a copy of the signed consent form to keep along with this information sheet.

What will happen if I decide to participate?

Firstly you will speak with the researcher over the phone, who will speak to you about the study and what taking part will involve. If you are interested in taking part, you can then meet with a researcher ask any questions you may have, and, if you are happy to, consent to take part in the project. Once people have consented to take part in the study, you will complete an interview with the researcher to establish if you are eligible for the study. This means that not everyone who wants to take part in this research may be eligible to. If you are not eligible this means you are not currently suitable for the study at this time and will not be able to take part in this piece of research. We estimate this meeting with take approximately 60 minutes.

If the interview results indicate you are eligible to take part in this study, the researcher will then ask you to complete a questionnaire about you, which will ask you about your age, gender, occupation and your history using mental health services. We will then complete some questionnaires asking about your emotional well-being. Specifically there will be five tick-box questionnaires that will ask you about:

1. How mindful you are in everyday life
2. Your self-compassion
3. Your recent experiences of depression
4. Your recent experiences of anxiety
5. Your quality of life

This visit will take approximately 40-50 minutes and can take place at your home or at a Sussex Partnership Trust building.

After this interview half of the people who take part in the study will be picked at random to be offered a place on the brief mindfulness course straight away. This course will be offered over a four week period.

Once the brief mindfulness course has finished all people taking part in the project will be asked if they would meet with [name here], the research assistant, and will complete the aforementioned questionnaires for a second time.

The group of people who did not get offered the mindfulness course initially will then be offered a place on the course. Once this course has completed, the research assistant, [name here], will meet with all participants for a final time and complete the questionnaires.

When you have completed the brief mindfulness course we will ask you if you would like to take part in an interview with another research assistant. You will be asked a series of questions about your experiences of taking part in the brief mindfulness intervention, and also about your experiences of taking part in the research study. This interview will be recorded on an audio device. This visit will take approximately 30 minutes and can take place at your home or at a Sussex Partnership Trust building.

In short, all participants will meet with a research assistant at four-five time points over approximately a four month period to complete a series of questionnaires. At one of these time points you will also be asked if you would be willing to be interviewed about your experience of the brief mindfulness intervention, and about your experience in taking part in the study. By taking part in the study, all participants will be offered the chance to attend a brief mindfulness group – some will be offered the group approximately six weeks earlier than others.

What will happen in the group?

If you take part in the study you will receive in the post some detailed information about the mindfulness group. The group will run over a total of four weeks. In the group participants will be invited to try mindfulness and will have the opportunity to discuss their experiences with experienced mindfulness teachers. All activities and discussions in the group are optional.

Between the group sessions there will be mindfulness practices and activities the mindfulness teacher will invite you to do – again, these practices are all optional.

What are the possible disadvantages and risks of taking part?

The risks of taking part are very small. Previous studies using mindfulness-based interventions indicate that mindfulness does not have negative side effects. However, we are testing a new type of mindfulness therapy that has not been used before, so we cannot be sure how people will find the group. However, the group will be led by experienced mindfulness teachers and the research team have previous experience in researching new mindfulness interventions. If you do experience persisting problems you can contact your care team, the study team, phone the Samaritans (08457 909090 – 24 hours) or phone Sussex Mental Healthline (0300 5000101 – 5pm-9am Mon to Fri, all day weekends and bank holidays).

Will there be possible benefits of taking part in this study?

This study is being conducted to help us decide if this mindfulness-based intervention is appropriate to research and so it is difficult to predict how or whether the group will help you. However, by taking part in the research you will have the opportunity to shape future research that may go on within Sussex Partnership Trust.

Will I get paid for taking part?

You will not receive any payment for taking part in the study. However if you incur any reasonable financial costs, for example by travelling to meet the research team, or to attend the mindfulness group, we will be able to reimburse you for your expense. However, you will have to have some proof of your expense. If you would like to claim back any expenses during the course of the study please talk to [name here], the research assistant about this first.

Will my taking part be kept confidential?

Your care team will be made aware that you are taking part in this research project. We will keep all information we collect from you during the course of the research strictly confidential to the study team. Any information about you will have your name and address removed so that you cannot be recognised from it and it will be stored in locked cupboards and password controlled computers, to which access will be confined to the research team. However, if we have any concern about your safety, or the safety of somebody else we are under legal obligation to pass this on to the relevant authority.

When taking part in the study, the research team would like to have access to your relevant medical records. However, your records would only be accessed for the purposes of the study. This would include the research team checking what medication you are taking, finding out about whether you have accessed psychological therapies, and determining any diagnosis you may have received.

What happens when the study is finished?

When the researchers have finished analysing the results of the study, they will send you a summary of the findings. They will also write articles about the study for psychology journals. Nothing in these pieces will allow someone to identify you as having taken part.

What if something goes wrong?

If you wish to make a complaint please contact [name] on [phone number] or [email address], or the Patient Advice & Liaision Service (PALS) on 01323 446042 (East Sussex), 01903 843185 (West Sussex), 01273 716588 (Brighton & Hove) or PALS@sussexpartnership.nhs.uk

In the unlikely event that you become ill or injured as a result of taking part in this study you will be covered by insurance held by Sussex Partnership NHS Foundation Trust.

Who has reviewed this study?

A NHS Research Ethics Committee have reviewed this study. This study has been reviewed and received favourable opinion by the South East-Coast Surrey Research Ethics Committee.

Who is organising and funding this study?

The study is being organised and part funded by Sussex Partnership NHS Foundation Trust and The University of Sussex. The Economic and Social Research Council (ESRC) have also provided funding for this study.

Where can I find out more?

If you would like any more information then please feel free to contact the study research assistant, [name] on [phone number] or [email address] the project leader, Dr. [name] can be contacted on [phone number] or [email address]

Thank you for your interest in this study.

Participant Identification Number:

CONSENT FORM

Title of Project: A feasibility randomised controlled trial of a brief mindfulness-based intervention in a mental health secondary care setting

Name of Researcher leading the study: [name]

Please initial box

1 I confirm that I have read and understand the Participant Information Sheet dated 23.09.15 (version 3) for the above study and have had the opportunity to ask questions. ☐

2 I understand that my participation is voluntary and that I am free to withhold personal information or to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐

3 I understand that if I choose to withdraw that any information I have already provided will be kept by the research team. ☐

4 I give permission for my care team to be informed of my participation in this study. ☐

5 I give permission for the research team to access my relevant medical records where it is relevant for the purposes of the study. ☐

6 I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my relevant records. ☐

7 I understand that in the event that I disclose information which may indicate new risk to myself or others, the researcher will be obliged to follow Trust risk procedures that may require release of my personal data. ☐

8 I give permission to be audio-recorded for the sole purposes of the study. ☐

9 I agree to take part in the above study

Name of participant	Date	Signature
Researcher	Date	Signature

Please tick this box if you would like to receive a copy of findings from the study ☐

If you would like a copy of findings please indicate if you would like these by post ☐ or by email ☐

A feasibility RCT of a brief mindfulness therapy in secondary care

Consent Form 23.09.15 Version 3
REC Reference Number: 14/LO/1964

Appendix O: LiveMind REC approval

This has been removed from the electronic copy

Appendix P: LiveMind outcome measures

M.I.N.I.

MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW

English Version 5.0.0

DSM-IV

USA: D. Sheehan, J. Janavs, R. Baker, K. Harnett-Sheehan, E. Knapp, M. Sheehan
University of South Florida - Tampa

FRANCE: Y. Lecrubier, E. Weiller, T. Hergueta, P. Amorim, L. I. Bonora, J. P. Lépine
Hôpital de la Salpétrière - Paris

DISCLAIMER

Our aim is to assist in the assessment and tracking of patients with greater efficiency and accuracy. Before action is taken on any data collected and processed by this program, it should be reviewed and interpreted by a licensed clinician.

This program is not designed or intended to be used in the place of a full medical and psychiatric evaluation by a qualified licensed physician – psychiatrist. It is intended only as a tool to facilitate accurate data collection and processing of symptoms elicited by trained personnel.

M.I.N.I. 5.0.0 (July 1, 2006)

Patient Name:		*Patient Number:*	
Date of Birth:		*Time Interview Began:*	
Interviewer's Name:		*Time Interview Ended:*	
Date of Interview:		*Total Time:*	

	MODULES	TIME FRAME	MEETS CRITERIA	DSM-IV	ICD-10	
A	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)	☐	296.20-296.26 Single	F32.x	☐
		Recurrent	☐	296.30-296.36 Recurrent	F33.x	☐
	MDE WITH MELANCHOLIC FEATURES	Current (2 weeks)	☐	296.20-296.26 Single	F32.x	☐
	Optional			296.30-296.36 Recurrent	F33.x	☐
B	DYSTHYMIA	Current (Past 2 years)	☐	300.4	F34.1	☐
C	SUICIDALITY	Current (Past Month)	☐			☐
		Risk: ☐ Low ☐ Medium ☐ High				
D	MANIC EPISODE	Current	☐	296.00-296.06	F30.x-F31.9	☐
		Past	☐			
	HYPOMANIC EPISODE	Current	☐	296.00-296.89	F31.0-F31.9/F34.0	☐
		Past	☐			
E	PANIC DISORDER	Current (Past Month)	☐	300.01/300.21	F40.01-F41.0	☐
		Lifetime	☐			
F	AGORAPHOBIA	Current	☐	300.22	F40.00	☐
G	SOCIAL PHOBIA (Social Anxiety Disorder)	Current (Past Month)	☐	300.23	F40.1	☐
H	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)	☐	300.3	F42.8	☐
I	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)	☐	309.81	F43.1	☐
J	ALCOHOL DEPENDENCE	Past 12 Months	☐	303.9	F10.2x	☐
	ALCOHOL ABUSE	Past 12 Months	☐	305.00	F10.1	☐
K	SUBSTANCE DEPENDENCE (Non-alcohol)	Past 12 Months	☐	304.00-.90/305.20-.90	F11.1-F19.1	☐
	SUBSTANCE ABUSE (Non-alcohol)	Past 12 Months	☐	304.00-.90/305.20-.90	F11.1-F19.1	☐
L	PSYCHOTIC DISORDERS	Lifetime	☐	295.10-295.90/297.1/	F20.xx-F29	☐
		Current	☐	297.3/298.8/298.9/ 295.40/295.70		
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime	☐	296.24/296.34/296.44	F32.3/F33.3/ F31.2/F31.5	☐
		Current	☐	296.24/296.34/296.44	F30.2/F31.2/F31.5 F31.64/F31.74/F39	☐
M	ANOREXIA NERVOSA	Current (Past 3 Months)	☐	307.1	F50.0	☐
N	BULIMIA NERVOSA	Current (Past 3 Months)	☐	307.51	F50.2	☐
	ANOREXIA NERVOSA, BINGE/PURGING TYPE	Current	☐	307.1	F50.0	☐

O	GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)	☐	300.02	F41.1	☐
P	ANTISOCIAL PERSONALITY DISORDER Optional	Lifetime	☐	301.7	F60.2	☐

Which problem troubles you the most? Indicate your response by checking the appropriate check box(es).

GENERAL INSTRUCTIONS

The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization for lay interviewers for ICD-10). The results of these studies show that the M.I.N.I. has acceptably high validation and reliability scores, but can be administered in a much shorter period of time (mean 18.7 ± 11.6 minutes, median 15 minutes) than the above referenced instruments. It can be used by clinicians, after a brief training session. Lay interviewers require more extensive training.

INTERVIEW:

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

GENERAL FORMAT:

The M.I.N.I. is divided into **modules** identified by letters, each corresponding to a diagnostic category.
•At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.
•At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

CONVENTIONS:

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « **bold** » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them (➡) indicate that one of the criteria necessary for the diagnosis(es) is not met. In this case, the interviewer should go to the end of the module, circle « **NO** » in all the diagnostic boxes and move to the next module.

When terms are separated by a *slash* (/) the interviewer should read only those symptoms known to be present in the patient (for example, question H6).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

RATING INSTRUCTIONS:

All questions must be rated. The rating is done at the right of each question by circling either Yes or No. Clinical judgment by the rater should be used in coding the responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.

The clinician should be sure that each dimension of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives).
Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. Plus has questions that investigate these issues.

For any questions, suggestions, need for a training session, or information about updates of the M.I.N.I., please contact :

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A MAJOR DEPRESSIVE EPISODE

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

A1	Have you been consistently depressed or down, most of the day, nearly every day, for the past two weeks?	NO	YES
A2	In the past two weeks, have you been much less interested in most things or much less able to enjoy the things you used to enjoy most of the time?	NO	YES
	IS A1 OR A2 CODED YES?	➡ NO	YES

A3 Over the past two weeks, when you felt depressed or uninterested:

a	Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by ±5% of body weight or ±8 lbs. or ±3.5 kgs., for a 160 lb./70 kg. person in a month)? IF YES TO EITHER, CODE YES.	NO	YES *
b	Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES
c	Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day?	NO	YES *
d	Did you feel tired or without energy almost every day?	NO	YES
e	Did you feel worthless or guilty almost every day?	NO	YES
f	Did you have difficulty concentrating or making decisions almost every day?	NO	YES
g	Did you repeatedly consider hurting yourself, feel suicidal, or wish that you were dead?	NO	YES

ARE 5 OR MORE ANSWERS (A1-A3) CODED YES?

NO **YES ***

MAJOR DEPRESSIVE EPISODE, CURRENT

IF PATIENT HAS CURRENT MAJOR DEPRESSIVE EPISODE CONTINUE TO A4, OTHERWISE MOVE TO MODULE B:

A4 a	During your lifetime, did you have other episodes of two weeks or more when you felt depressed or uninterested in most things, and had most of the problems we just talked about?	➡ NO	YES
b	In between 2 episodes of depression, did you ever have an interval of at least 2 months, without any depression and any loss of interest?		

NO **YES**

MAJOR DEPRESSIVE EPISODE, RECURRENT

* If patient has Major Depressive Episode, Current, use this information in coding the corresponding questions on page 5 (A6d, A6e).

MAJOR DEPRESSIVE EPISODE WITH MELANCHOLIC FEATURES (optional)

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

IF THE PATIENT CODES POSITIVE FOR A CURRENT MAJOR DEPRESSIVE EPISODE (A3 = YES), EXPLORE THE FOLLOWING:

A5	a	During the most severe period of the current depressive episode, did you lose almost completely your ability to enjoy nearly everything?	NO	YES
	b	During the most severe period of the current depressive episode, did you lose your ability to respond to things that previously gave you pleasure, or cheered you up? IF NO: When something good happens does it fail to make you feel better, even temporarily?	NO	YES
		IS EITHER **A5a** OR **A5b** CODED YES?	➡ NO	YES
A6		**Over the past two week period, when you felt depressed and uninterested:**		
	a	Did you feel depressed in a way that is different from the kind of feeling you experience when someone close to you dies?	NO	YES
	b	Did you feel regularly worse in the morning, almost every day?	NO	YES
	c	Did you wake up at least 2 hours before the usual time of awakening and have difficulty getting back to sleep, almost every day?	NO	YES
	d	IS **A3c** CODED YES (PSYCHOMOTOR RETARDATION OR AGITATION)?	NO	YES
	e	IS **A3a** CODED YES FOR ANOREXIA OR WEIGHT LOSS?	NO	YES
	f	Did you feel excessive guilt or guilt out of proportion to the reality of the situation?	NO	YES

ARE 3 OR MORE **A6** ANSWERS CODED YES?

NO YES

Major Depressive Episode with Melancholic Features: Current

B. DYSTHYMIA

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

IF PATIENT'S SYMPTOMS CURRENTLY MEET CRITERIA FOR MAJOR DEPRESSIVE EPISODE, DO NOT EXPLORE THIS MODULE.

B1	Have you felt sad, low or depressed most of the time for the last two years?	➡ NO	YES
B2	Was this period interrupted by your feeling OK for two months or more?	NO	➡ YES
B3	**During this period of feeling depressed most of the time:**		
a	Did your appetite change significantly?	NO	YES
b	Did you have trouble sleeping or sleep excessively?	NO	YES
c	Did you feel tired or without energy?	NO	YES
d	Did you lose your self-confidence?	NO	YES
e	Did you have trouble concentrating or making decisions?	NO	YES
f	Did you feel hopeless?	NO	YES
	ARE 2 OR MORE B3 ANSWERS CODED YES?	➡ NO	YES
B4	Did the symptoms of depression cause you significant distress or impair your ability to function at work, socially, or in some other important way?		

NO **YES**

DYSTHYMIA
CURRENT

C. SUICIDALITY

In the past month did you:

				Points
C1	Suffer any accident? IF NO TO C1, SKIP TO C2; IF YES, ASK C1a:	NO	YES	0
C1a	Plan or intend to hurt yourself in that accident either passively or actively? IF NO TO C1a, SKIP TO C2: IF YES, ASK C1b:	NO	YES	0
C1b	Did you intend to die as a result of this accident?	NO	YES	0
C2	Think that you would be better off dead or wish you were dead?	NO	YES	1
C3	Want to harm yourself or to hurt or to injure yourself?	NO	YES	2
C4	Think about suicide?	NO	YES	6

IF YES, ASK ABOUT THE INTENSITY AND FREQUENCY OF THE SUICIDAL IDEATION:

Frequency		Intensity	
Occasionally	☐	Mild	☐
Often	☐	Moderate	☐
Very often	☐	Severe	☐

→ Can you control these impulses and state that you will not act on them while in this program?
Only score 8 points if response is NO.

	NO	YES	8
C5 Have a suicide plan?	NO	YES	8
C6 Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die?	NO	YES	9
C7 Deliberately injure yourself without intending to kill yourself?	NO	YES	4
C8 Attempt suicide?	NO	YES	10

Hoped to be rescued / survive ☐
Expected / intended to die ☐

In your lifetime:

C9 Did you ever make a suicide attempt?	NO	YES	4

IS AT LEAST 1 OF THE ABOVE (EXCEPT C1) CODED YES?

NO **YES**

IF YES, ADD THE TOTAL NUMBER OF POINTS FOR THE ANSWERS (C1-C9) CHECKED "YES" AND SPECIFY THE LEVEL OF SUICIDE RISK AS INDICATED IN THE DIAGNOSTIC BOX:

MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURRENT AND NEAR FUTURE SUICIDE RISK IN THE SPACE BELOW:

SUICIDE RISK CURRENT

1-8 points	Low	☐
9-16 points	Moderate	☐
≥ 17 points	High	☐

D. (HYPO) MANIC EPISODE

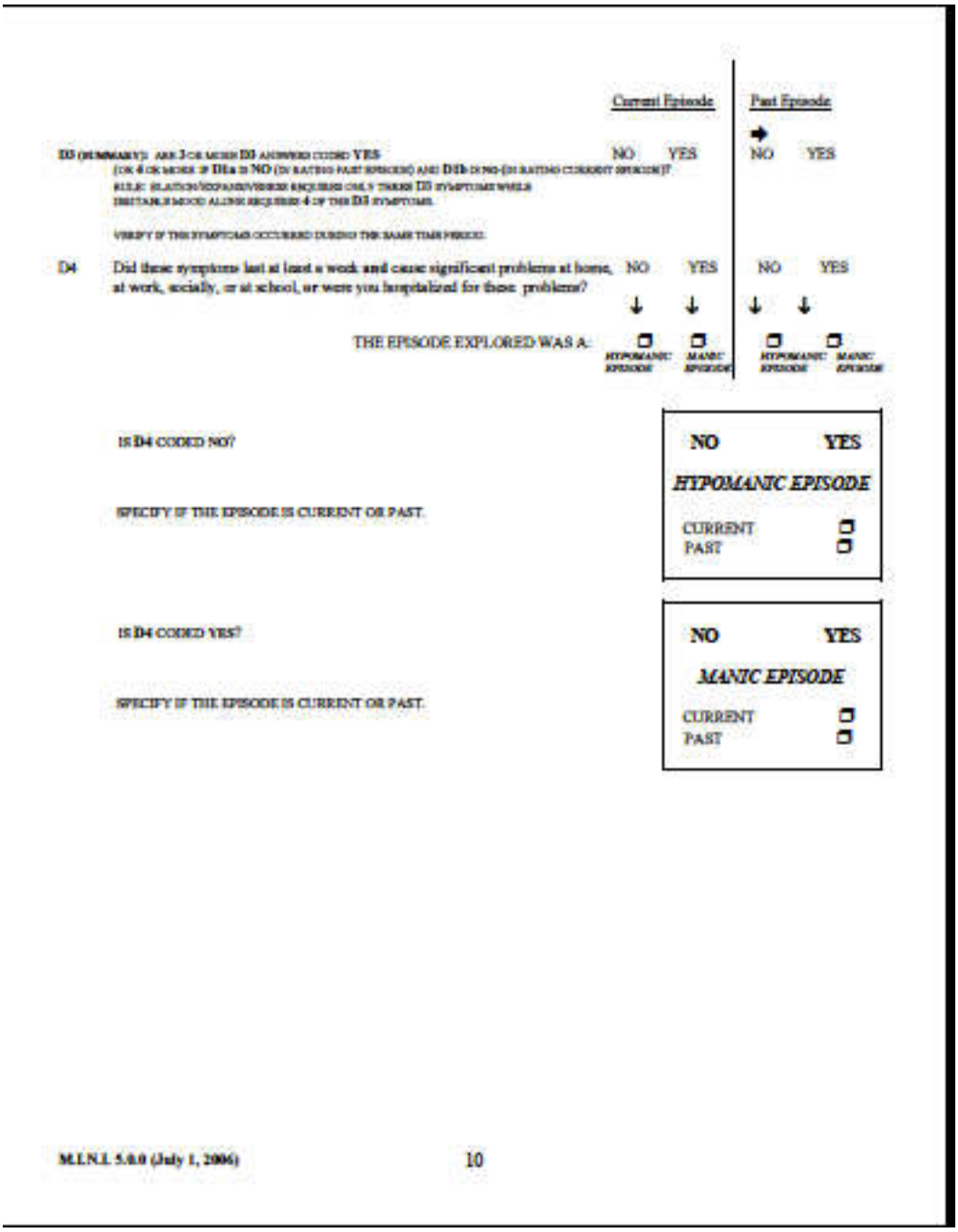
(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

D1	a	Have you ever had a period of time when you were feeling 'up' or 'high' or 'hyper' or so full of energy or full of yourself that you got into trouble, or that other people thought you were not your usual self? (Do not consider times when you were intoxicated on drugs or alcohol.) IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT YOU MEAN BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS: By 'up' or 'high' or 'hyper' I mean: having elated mood; increased energy; needing less sleep; having rapid thoughts; being full of ideas; having an increase in productivity, motivation, creativity, or impulsive behavior. IF NO, CODE NO TO **D1b**: IF YES ASK:	NO	YES
	b	Are you currently feeling 'up' or 'high' or 'hyper' or full of energy?	NO	YES
D2	a	Have you ever been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified? IF NO, CODE NO TO **D2b**: IF YES ASK:	NO	YES
	b	Are you currently feeling persistently irritable?	NO	YES
		IS D1a OR D2a CODED YES?	NO ➡	YES

D3 IF **D1b** OR **D2b** = YES: EXPLORE THE CURRENT AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE
IF **D1b** AND **D2b** = NO: EXPLORE ONLY THE MOST SYMPTOMATIC PAST EPISODE

During the times when you felt high, full of energy, or irritable did you:

		Current Episode		Past Episode	
a	Feel that you could do things others couldn't do, or that you were an especially important person? IF YES, ASK FOR EXAMPLES. THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL STATE. ☐ No ☐ Yes	NO	YES	NO	YES
b	Need less sleep (for example, feel rested after only a few hours sleep)?	NO	YES	NO	YES
c	Talk too much without stopping, or so fast that people had difficulty understanding?	NO	YES	NO	YES
d	Have racing thoughts?	NO	YES	NO	YES
e	Become easily distracted so that any little interruption could distract you?	NO	YES	NO	YES
f	Become so active or physically restless that others were worried about you?	NO	YES	NO	YES
g	Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)?	NO	YES	NO	YES



		Current Episode		Past Episode	
				→	
D3 (SUMMARY): ARE 3 OR MORE D3 ANSWERS CODED YES (OR 4 OR MORE IF D1a IS NO (IN RATING PAST EPISODE) AND D1b IS NO (IN RATING CURRENT EPISODE))? IN I.E. RELATION/ROOMMATE/FRIENDSHIP REQUIRES ONLY THREE D3 SYMPTOMS WHILE IRRITABLE MOOD ALONE REQUIRES 4 OF THE D3 SYMPTOMS. VERIFY IF THE SYMPTOMS OCCURRED DURING THE SAME TIME PERIOD.		NO	YES	NO	YES
D4	Did these symptoms last at least a week and cause significant problems at home, at work, socially, or at school, or were you hospitalized for these problems?	NO	YES	NO	YES
		↓	↓	↓	↓
	THE EPISODE EXPLORED WAS A:	☐ HYPOMANIC EPISODE	☐ MANIC EPISODE	☐ HYPOMANIC EPISODE	☐ MANIC EPISODE

IS D4 CODED NO?	NO	YES
	HYPOMANIC EPISODE	
SPECIFY IF THE EPISODE IS CURRENT OR PAST.	CURRENT	☐
	PAST	☐

IS D4 CODED YES?	NO	YES
	MANIC EPISODE	
SPECIFY IF THE EPISODE IS CURRENT OR PAST.	CURRENT	☐
	PAST	☐

E. PANIC DISORDER

(➡ MEANS : CIRCLE NO IN E5, E6 AND E7 AND SKIP TO F1)

E1	a	Have you, on more than one occasion, had spells or attacks when you suddenly felt anxious, frightened, uncomfortable or uneasy, even in situations where most people would not feel that way?	NO	YES
	b	Did the spells surge to a peak within 10 minutes of starting?	NO	YES
E2		At any time in the past, did any of those spells or attacks come on unexpectedly or occur in an unpredictable or unprovoked manner?	NO	YES
E3		Have you ever had one such attack followed by a month or more of persistent concern about having another attack, or worries about the consequences of the attack or did you make a significant change in your behavior because of the attacks (e.g., shopping only with a companion, not wanting to leave your house, visiting the emergency room repeatedly, or seeing your doctor more frequently because of the symptoms)?	NO	YES
E4		**During the worst spell that you can remember:**		
	a	Did you have skipping, racing or pounding of your heart?	NO	YES
	b	Did you have sweating or clammy hands?	NO	YES
	c	Were you trembling or shaking?	NO	YES
	d	Did you have shortness of breath or difficulty breathing?	NO	YES
	e	Did you have a choking sensation or a lump in your throat?	NO	YES
	f	Did you have chest pain, pressure or discomfort?	NO	YES
	g	Did you have nausea, stomach problems or sudden diarrhea?	NO	YES
	h	Did you feel dizzy, unsteady, lightheaded or faint?	NO	YES
	i	Did things around you feel strange, unreal, detached or unfamiliar, or did you feel outside of or detached from part or all of your body?	NO	YES
	j	Did you fear that you were losing control or going crazy?	NO	YES
	k	Did you fear that you were dying?	NO	YES
	l	Did you have tingling or numbness in parts of your body?	NO	YES
	m	Did you have hot flashes or chills?	NO	YES
E5		ARE BOTH E3, AND 4 OR MORE E4 ANSWERS, CODED YES?	NO	YES
		IF YES TO E5, SKIP TO E7.		
E6		IF E5 = NO, ARE ANY E4 ANSWERS CODED YES?	NO	YES
		THEN SKIP TO F1.		
E7		In the past month, did you have such attacks repeatedly (2 or more) followed by persistent concern about having another attack?	NO	YES

F. AGORAPHOBIA

F1	Do you feel anxious or uneasy in places or situations where you might have a panic attack or the panic-like symptoms we just spoke about, or where help might not be available or escape might be difficult: like being in a crowd, standing in a line (queue), when you are alone away from home or alone at home, or when crossing a bridge, traveling in a bus, train or car?	NO YES

IF F1 = NO, CIRCLE NO IN F2

F2	Do you fear these situations so much that you avoid them, or suffer through them, or need a companion to face them?	NO YES AGORAPHOBIA CURRENT

IS F2 (CURRENT AGORAPHOBIA) CODED NO

and

IS E7 (CURRENT PANIC DISORDER) CODED YES?

NO YES

PANIC DISORDER without Agoraphobia CURRENT

IS F2 (CURRENT AGORAPHOBIA) CODED YES

and

IS E7 (CURRENT PANIC DISORDER) CODED YES?

NO YES

PANIC DISORDER with Agoraphobia CURRENT

IS F2 (CURRENT AGORAPHOBIA) CODED YES

and

IS E5 (PANIC DISORDER LIFETIME) CODED NO?

NO YES

AGORAPHOBIA, CURRENT without history of Panic Disorder

G. SOCIAL PHOBIA (Social Anxiety Disorder)

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

G1	In the past month, were you fearful or embarrassed being watched, being the focus of attention, or fearful of being humiliated? This includes things like speaking in public, eating in public or with others, writing while someone watches, or being in social situations.	➡ NO	YES
G2	Is this social fear excessive or unreasonable?	➡ NO	YES
G3	Do you fear these social situations so much that you avoid them or suffer through them?	➡ NO	YES
G4	Do these social fears disrupt your normal work or social functioning or cause you significant distress?		

SUBTYPES

Do you fear and avoid 4 or more social situations?

IF YES Generalized social phobia (social anxiety disorder)

IF NO Non-generalized social phobia (social anxiety disorder)

NOTE TO INTERVIEWER: PLEASE ASSESS WHETHER THE SUBJECT'S FEARS ARE RESTRICTED TO NON-GENERALIZED ("ONLY 1 OR SEVERAL") SOCIAL SITUATIONS OR EXTEND TO GENERALIZED ("MOST") SOCIAL SITUATIONS. "MOST" SOCIAL SITUATIONS IS USUALLY OPERATIONALIZED TO MEAN 4 OR MORE SOCIAL SITUATIONS, ALTHOUGH THE DSM-IV DOES NOT EXPLICITLY STATE THIS.

EXAMPLES OF SUCH SOCIAL SITUATIONS TYPICALLY INCLUDE INITIATING OR MAINTAINING A CONVERSATION, PARTICIPATING IN SMALL GROUPS, DATING, SPEAKING TO AUTHORITY FIGURES, ATTENDING PARTIES, PUBLIC SPEAKING, EATING IN FRONT OF OTHERS, URINATING IN A PUBLIC WASHROOM, ETC.

NO	YES

SOCIAL PHOBIA
(Social Anxiety Disorder)
CURRENT

GENERALIZED ☐

NON-GENERALIZED ☐

H. OBSESSIVE-COMPULSIVE DISORDER

(➔ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

H1	In the past month, have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? (For example, the idea that you were dirty, contaminated or had germs, or fear of contaminating others, or fear of harming someone even though you didn't want to, or fearing you would act on some impulse, or fear or superstitions that you would be responsible for things going wrong, or obsessions with sexual thoughts, images or impulses, or hoarding, collecting, or religious obsessions.) (DO NOT INCLUDE SIMPLY EXCESSIVE WORRIES ABOUT REAL LIFE PROBLEMS. DO NOT INCLUDE OBSESSIONS DIRECTLY RELATED TO EATING DISORDERS, SEXUAL DEVIATIONS, PATHOLOGICAL GAMBLING, OR ALCOHOL OR DRUG ABUSE BECAUSE THE PATIENT MAY DERIVE PLEASURE FROM THE ACTIVITY AND MAY WANT TO RESIST IT ONLY BECAUSE OF ITS NEGATIVE CONSEQUENCES.)	NO YES ↓ SKIP TO H4
H2	Did they keep coming back into your mind even when you tried to ignore or get rid of them?	NO YES ↓ SKIP TO H4
H3	Do you think that these obsessions are the product of your own mind and that they are not imposed from the outside?	NO YES checkbox
H4	In the past month, did you do something repeatedly without being able to resist doing it, like washing or cleaning excessively, counting or checking things over and over, or repeating, collecting, arranging things, or other superstitious rituals?	NO YES compulsions
	IS H3 OR H4 CODED YES?	➔ NO YES
H5	Did you recognize that either these obsessive thoughts or these compulsive behaviors were excessive or unreasonable?	➔ NO YES
H6	Did these obsessive thoughts and/or compulsive behaviors significantly interfere with your normal routine, your work or school, your usual social activities, or relationships, or did they take more than one hour a day?	NO YES *O.C.D. CURRENT*

I. POSTTRAUMATIC STRESS DISORDER (optional)

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

I1	Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury to you or someone else? EXAMPLES OF TRAUMATIC EVENTS INCLUDE: SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, SUDDEN DEATH OF SOMEONE CLOSE TO YOU, WAR, OR NATURAL DISASTER.	➡ NO	YES
I2	Did you respond with intense fear, helplessness or horror?	➡ NO	YES
I3	During the past month, have you re-experienced the event in a distressing way (such as, dreams, intense recollections, flashbacks or physical reactions)?	➡ NO	YES
I4	**In the past month:**		
a	Have you avoided thinking about or talking about the event ?	NO	YES
b	Have you avoided activities, places or people that remind you of the event?	NO	YES
c	Have you had trouble recalling some important part of what happened?	NO	YES
d	Have you become much less interested in hobbies or social activities?	NO	YES
e	Have you felt detached or estranged from others?	NO	YES
f	Have you noticed that your feelings are numbed?	NO	YES
g	Have you felt that your life will be shortened or that you will die sooner than other people?	NO	YES
	ARE 3 OR MORE I4 ANSWERS CODED YES?	➡ NO	YES
I5	**In the past month:**		
a	Have you had difficulty sleeping?	NO	YES
b	Were you especially irritable or did you have outbursts of anger?	NO	YES
c	Have you had difficulty concentrating?	NO	YES
d	Were you nervous or constantly on your guard?	NO	YES
e	Were you easily startled?	NO	YES
	ARE 2 OR MORE I5 ANSWERS CODED YES?	➡ NO	YES

I6	During the past month, have these problems significantly interfered with your work or social activities, or caused significant distress?

NO	YES
POSTTRAUMATIC STRESS DISORDER CURRENT	

J. ALCOHOL ABUSE AND DEPENDENCE

(➔ MEANS: GO TO DIAGNOSTIC BOXES, CIRCLE NO IN BOTH AND MOVE TO THE NEXT MODULE)

		➔ NO	YES
J1	**In the past 12 months**, have you had 5 or more alcoholic drinks within a 5 hour period on 5 or more occasions?		
J2	**In the past 12 months:**		
a	Did you need to drink more in order to get the same effect that you got when you first started drinking?	NO	YES
b	When you cut down on drinking did your hands shake, did you sweat or feel agitated? Did you drink to avoid these symptoms or to avoid being hungover, for example, "the shakes", sweating or agitation? (IF YES TO BOTHER, CIRCLE YES)	NO	YES
c	During the times when you drank alcohol, did you end up drinking more than you planned when you started?	NO	YES
d	Have you tried to reduce or stop drinking alcohol but failed?	NO	YES
e	On the days that you drank, did you spend substantial time in obtaining alcohol, drinking, or in recovering from the effects of alcohol?	NO	YES
f	Did you spend less time working, enjoying hobbies, or being with others because of your drinking?	NO	YES
g	Have you continued to drink even though you knew that the drinking caused you health or mental problems?	NO	YES

ARE 3 OR MORE J2 ANSWERS CODED YES?

NO **YES***

* IF YES, SKIP J3 QUESTIONS, CIRCLE N/A IN THE ABUSE BOX AND MOVE TO THE NEXT DISORDER. DEPENDENCE PREEMPTS ABUSE.

ALCOHOL DEPENDENCE
CURRENT

J3	**In the past 12 months:**		
a	Have you been intoxicated, high, or hungover more than once when you had other responsibilities at school, at work, or at home? Did this cause any problems? (CIRCLE YES ONLY IF THIS CAUSED PROBLEMS.)	NO	YES
b	Were you intoxicated more than once in any situation where you were physically at risk, for example, driving a car, riding a motorbike, using machinery, boating, etc.?	NO	YES
c	Did you have legal problems more than once because of your drinking, for example, an arrest or disorderly conduct?	NO	YES
d	Did you continue to drink even though your drinking caused problems with your family or other people?	NO	YES

ARE 1 OR MORE J3 ANSWERS CODED YES?

NO **N/A** **YES**

ALCOHOL ABUSE
CURRENT

K. NON-ALCOHOL PSYCHOACTIVE SUBSTANCE USE DISORDERS

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

Now I am going to show you / read to you a list of street drugs or medicines.

			➡ NO	YES
K1	a	**In the past 12 months**, did you take any of these drugs more than once, to get high, to feel better, or to change your mood?		

CIRCLE EACH DRUG TAKEN:

Stimulants: amphetamines, "speed", crystal meth, "crank", "rush", Dexedrine, Ritalin, diet pills.

Cocaine: snorting, IV, freebase, crack, "speedball".

Narcotics: heroin, morphine, Dilaudid, opium, Demerol, methadone, codeine, Percocet, Darvon, OxyContin.

Hallucinogens: LSD ("acid"), mescaline, peyote, PCP ("angel dust", "peace pill"), psilocybin, STP, "mushrooms", "ecstasy", MDA, MDMA, or ketamine ("special K").

Inhalants: "glue", ethyl chloride, "rush", nitrous oxide ("laughing gas"), amyl or butyl nitrate ("poppers").

Marijuana: hashish ("hash"), THC, "pot", "grass", "weed", "reefer".

Tranquilizers: Quaalude, Seconal ("reds"), Valium, Xanax, Librium, Ativan, Dalmane, Halcion, barbiturates, Miltown, GHB, Rooffinol, "Roofies".

Miscellaneous: steroids, nonprescription sleep or diet pills. Any others?

SPECIFY MOST USED DRUG(S): _____

CHECK ONE BOX

ONLY ONE DRUG / DRUG CLASS HAS BEEN USED ☐

ONLY THE MOST USED DRUG CLASS IS INVESTIGATED ☐

EACH DRUG CLASS USED IS EXAMINED SEPARATELY (PHOTOCOPY K2 AND K3 AS NEEDED) ☐

b SPECIFY WHICH DRUG/DRUG CLASS WILL BE EXPLORED IN THE INTERVIEW BELOW IF THERE IS CONCURRENT OR SEQUENTIAL POLYSUBSTANCE USE: _____

			NO	YES
K2		**Considering your use of (NAME THE DRUG / DRUG CLASS SELECTED), in the past 12 months:**		
	a	Have you found that you needed to use more (NAME OF DRUG / DRUG CLASS SELECTED) to get the same effect that you did when you first started taking it?	NO	YES
	b	When you reduced or stopped using (NAME OF DRUG / DRUG CLASS SELECTED), did you have withdrawal symptoms (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feeling agitated, anxious, irritable, or depressed)? Did you use any drug(s) to keep yourself from getting sick (withdrawal symptoms) or so that you would feel better?	NO	YES
		IF YES TO EITHER, CODE YES.		
	c	Have you often found that when you used (NAME OF DRUG / DRUG CLASS SELECTED), you ended up taking more than you thought you would?	NO	YES
	d	Have you tried to reduce or stop taking (NAME OF DRUG / DRUG CLASS SELECTED) but failed?	NO	YES
	e	On the days that you used (NAME OF DRUG / DRUG CLASS SELECTED), did you spend substantial time (>2 HOURS), obtaining, using or in recovering from the drug, or thinking about the drug?	NO	YES

f Did you spend less time working, enjoying hobbies, or being with family or friends because of your drug use? NO YES

g Have you continued to use (NAME OF DRUG / DRUG CLASS SELECTED), even though it caused you health or mental problems? NO YES

ARE 3 OR MORE K2 ANSWERS CODED YES?

SPECIFY DRUG(S): _____

NO **YES ***

SUBSTANCE DEPENDENCE
CURRENT

* IF YES, SKIP K3 QUESTIONS, CIRCLE N/A IN THE ABUSE BOX FOR THIS SUBSTANCE AND MOVE TO THE NEXT DISORDER. DEPENDENCE PREEMPTS ABUSE.

Considering your use of (NAME THE DRUG CLASS SELECTED), in the past 12 months:

K3 a Have you been intoxicated, high, or hungover from (NAME OF DRUG / DRUG CLASS SELECTED) more than once, when you had other responsibilities at school, at work, or at home? Did this cause any problem? NO YES

(CODE YES ONLY IF THIS CAUSED PROBLEMS.)

b Have you been high or intoxicated from (NAME OF DRUG / DRUG CLASS SELECTED) more than once in any situation where you were physically at risk (for example, driving a car, riding a motorbike, using machinery, boating, etc.)? NO YES

c Did you have legal problems more than once because of your drug use, for example, an arrest or disorderly conduct? NO YES

d Did you continue to use (NAME OF DRUG / DRUG CLASS SELECTED), even though it caused problems with your family or other people? NO YES

ARE 1 OR MORE K3 ANSWERS CODED YES?

SPECIFY DRUG(S): _____

NO **N/A** **YES**

SUBSTANCE ABUSE
CURRENT

L. PSYCHOTIC DISORDERS AND MOOD DISORDER WITH PSYCHOTIC FEATURES

ASK FOR AN EXAMPLE OF EACH QUESTION ANSWERED POSITIVELY. CODE YES ONLY IF THE EXAMPLES CLEARLY SHOW A DISTORTION OF THOUGHT OR OF PERCEPTION OR IF THEY ARE NOT CULTURALLY APPROPRIATE. BEFORE CODING, INVESTIGATE WHETHER DELUSIONS QUALIFY AS "BIZARRE".

DELUSIONS ARE "BIZARRE" IF: CLEARLY IMPLAUSIBLE, ABSURD, NOT UNDERSTANDABLE, AND CANNOT DERIVE FROM ORDINARY LIFE EXPERIENCE.

HALLUCINATIONS ARE SCORED "BIZARRE" IF: A VOICE COMMENTS ON THE PERSON'S THOUGHTS OR BEHAVIOR, OR WHEN TWO OR MORE VOICES ARE CONVERSING WITH EACH OTHER.

		Now I am going to ask you about unusual experiences that some people have.			BIZARRE
L1	a	Have you ever believed that people were spying on you, or that someone was plotting against you, or trying to hurt you? NOTE: ASK FOR EXAMPLES TO RULE OUT ACTUAL STALKING.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →L6
L2	a	Have you ever believed that someone was reading your mind or could hear your thoughts, or that you could actually read someone's mind or hear what another person was thinking?	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →L6
L3	a	Have you ever believed that someone or some force outside of yourself put thoughts in your mind that were not your own, or made you act in a way that was not your usual self? Have you ever felt that you were possessed? CLINICIAN: ASK FOR EXAMPLES AND DESCRIBE ANY THAT ARE NOT PSYCHOTIC.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →L6
L4	a	Have you ever believed that you were being sent special messages through the TV, radio, or newspaper, or that a person you did not personally know was particularly interested in you?	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do you currently believe these things?	NO	YES	YES →L6
L5	a	Have your relatives or friends ever considered any of your beliefs strange or unusual? INTERVIEWER: ASK FOR EXAMPLES. ONLY CODE YES IF THE EXAMPLES ARE CLEARLY DELUSIONAL. IDEAS NOT EXPLORED IN QUESTIONS L1 TO L4, FOR EXAMPLE, SOMATIC OR RELIGIOUS DELUSIONS OR DELUSIONS OF GRANDEUR, JEALOUSY, GUILT, RUIN OR PERSECUTION, ETC.	NO	YES	YES
	b	**IF YES OR YES BIZARRE:** do they currently consider your beliefs strange?	NO	YES	YES
L6	a	Have you ever heard things other people couldn't hear, such as voices? HALLUCINATIONS ARE SCORED "BIZARRE" ONLY IF PATIENT ANSWERS YES TO THE FOLLOWING:	NO	YES	
		IF YES: Did you hear a voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO		YES
	b	**IF YES OR YES BIZARRE TO L6a:** have you heard these things in the past month? HALLUCINATIONS ARE SCORED "BIZARRE" ONLY IF PATIENT ANSWERS YES TO THE FOLLOWING: Did you hear a voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO	YES	YES →L8a

L7 a Have you ever had visions when you were awake or have you ever seen things other people couldn't see? NO YES

CLINICIAN: CHECK TO SEE IF THERE ARE CULTURALLY INAPPROPRIATE.

b IF YES: have you seen these things in the past month? NO YES

CLINICIAN'S JUDGMENT

L8 b IS THE PATIENT CURRENTLY EXHIBITING INCOHERENCE, DISORGANIZED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS? NO YES

L9 b IS THE PATIENT CURRENTLY EXHIBITING DISORGANIZED OR CATATONIC BEHAVIOR? NO YES

L10 b ARE NEGATIVE SYMPTOMS OF SCHIZOPHRENIA, E.G. SIGNIFICANT AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION), PROMINENT DURING THE INTERVIEW? NO YES

L11 a ARE 1 OR MORE « a » QUESTIONS FROM L1a TO L7a CODED YES OR YES BIZARRE AND IS EITHER:

MAJOR DEPRESSIVE EPISODE, (CURRENT OR RECURRENT)
OR
MANIC OR HYPOMANIC EPISODE, (CURRENT OR PAST) CODED YES? NO → L12 YES

IF NO TO L11 a, CIRCLE NO IN BOTH 'MOOD DISORDER WITH PSYCHOTIC FEATURES' DIAGNOSTIC BOXES AND MOVE TO L13.

b You told me earlier that you had period(s) when you felt (depressed/high/persistently irritable).

Were the beliefs and experiences you just described (SYMPTOMS CODED YES FROM L1a TO L7a) restricted exclusively to times when you were feeling depressed/high/irritable?

IF THE PATIENT EVER HAD A PERIOD OF AT LEAST 2 WEEKS OF HAVING THESE BELIEFS OR EXPERIENCES (PSYCHOTIC SYMPTOMS) WHEN THEY WERE NOT DEPRESSED/HIGH/IRRITABLE, CODE NO TO THIS DISORDER.

IF THE ANSWER IS NO TO THIS DISORDER, ALSO CIRCLE NO TO L12 AND MOVE TO L13

NO	YES
MOOD DISORDER WITH PSYCHOTIC FEATURES	
LIFETIME	

L12 a ARE 1 OR MORE « b » QUESTIONS FROM L1b TO L7b CODED YES OR YES BIZARRE AND IS EITHER:

MAJOR DEPRESSIVE EPISODE, (CURRENT)
OR
MANIC OR HYPOMANIC EPISODE, (CURRENT) CODED YES?

IF THE ANSWER IS YES TO THIS DISORDER (LIFETIME OR CURRENT), CIRCLE NO TO L13 AND L14 AND MOVE TO THE NEXT MODULE.

NO	YES
MOOD DISORDER WITH PSYCHOTIC FEATURES	
CURRENT	

L13 ARE 1 OR MORE « b » QUESTIONS FROM L1b TO L6b, CODED YES BIZARRE?

OR

ARE 2 OR MORE « b » QUESTIONS FROM L1b TO L10b, CODED YES (RATHER THAN YES BIZARRE)?

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1 MONTH PERIOD?

NO YES

PSYCHOTIC DISORDER
CURRENT

L14 IS L13 CODED YES

OR

ARE 1 OR MORE « a » QUESTIONS FROM L1a TO L6a, CODED YES BIZARRE?

OR

ARE 2 OR MORE « a » QUESTIONS FROM L1a TO L3a, CODED YES (RATHER THAN YES BIZARRE)

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1 MONTH PERIOD?

NO YES

PSYCHOTIC DISORDER
LIFETIME

M. ANOREXIA NERVOSA

(➡ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

M1	a	How tall are you?	❑ft ❑❑in. ❑❑❑cm.
	b	What was your lowest weight in the past 3 months?	❑❑❑lbs. ❑❑❑kgs.
	c	IS PATIENT'S WEIGHT EQUAL TO OR BELOW THE THRESHOLD CORRESPONDING TO HIS / HER HEIGHT? (SEE TABLE BELOW)	➡ NO YES

In the past 3 months:

M2		In spite of this low weight, have you tried not to gain weight?	➡ NO YES
M3		Have you intensely feared gaining weight or becoming fat, even though you were underweight?	➡ NO YES
M4	a	Have you considered yourself too big / fat or that part of your body was too big / fat?	NO YES
	b	Has your body weight or shape greatly influenced how you felt about yourself?	NO YES
	c	Have you thought that your current low body weight was normal or excessive?	NO YES
M5		ARE 1 OR MORE ITEMS FROM M4 CODED YES?	➡ NO YES
M6		FOR WOMEN ONLY: During the last 3 months, did you miss all your menstrual periods when they were expected to occur (when you were not pregnant)?	➡ NO YES

FOR WOMEN: ARE M5 AND M6 CODED YES?

FOR MEN: IS M5 CODED YES?

NO	YES
ANOREXIA NERVOSA CURRENT	

HEIGHT / WEIGHT TABLE CORRESPONDING TO A BMI THRESHOLD OF 17.5 KG/M²

Height/Weight														
ft/in	4'9	4'10	4'11	5'0	5'1	5'2	5'3	5'4	5'5	5'6	5'7	5'8	5'9	5'10
lbs.	81	84	87	89	92	96	99	102	105	108	112	115	118	122
cm	145	147	150	152	155	158	160	163	165	168	170	173	175	178
kgs	37	38	39	41	42	43	45	46	48	49	51	52	54	55

Height/Weight					
ft/in	5'11	6'0	6'1	6'2	6'3
lbs.	125	129	132	136	140
cm	180	183	185	188	191
kgs	57	59	60	62	64

The weight thresholds above are calculated using a body mass index (BMI) equal to or below 17.5 kg/m² for the patient's height. This is the threshold guideline below which a person is deemed underweight by the DSM-IV and the ICD-10 Diagnostic Criteria for Research for Anorexia Nervosa.

N. BULIMIA NERVOSA

(➡ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

N1	In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period?	➡ NO YES
N2	In the last 3 months, did you have eating binges as often as twice a week?	➡ NO YES
N3	During these binges, did you feel that your eating was out of control?	➡ NO YES
N4	Did you do anything to compensate for, or to prevent a weight gain from these binges, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications?	➡ NO YES
N5	Does your body weight or shape greatly influence how you feel about yourself?	➡ NO YES
N6	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO YES ↓ Skip to N8
N7	Do these binges occur only when you are under (____lbs./kgs.)? INTERVIEWER: WRITE IN THE ABOVE PARENTHESES THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.	NO YES
N8	IS N5 CODED YES AND IS EITHER N6 OR N7 CODED NO?	**NO YES** ***BULIMIA NERVOSA*** **CURRENT**
	IS N7 CODED YES?	**NO YES** ***ANOREXIA NERVOSA*** *Binge Eating/Purging Type* **CURRENT**

O. GENERALIZED ANXIETY DISORDER

(➔ MEANS : GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

O1	a	Have you worried excessively or been anxious about several things over the past 6 months?	➔ NO	YES
	b	Are these worries present most days?	➔ NO	YES
		IS THE PATIENT'S ANXIETY RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT?	NO	➔ YES
O2		Do you find it difficult to control the worries or do they interfere with your ability to focus on what you are doing?	➔ NO	YES
O3		FOR THE FOLLOWING, CODE NO IF THE SYMPTOMS ARE CONFINED TO FEATURES OF ANY DISORDER EXPLORED PRIOR TO THIS POINT.		
		When you were anxious over the past 6 months, did you, most of the time:		
	a	Feel restless, keyed up or on edge?	NO	YES
	b	Feel tense?	NO	YES
	c	Feel tired, weak or exhausted easily?	NO	YES
	d	Have difficulty concentrating or find your mind going blank?	NO	YES
	e	Feel irritable?	NO	YES
	f	Have difficulty sleeping (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES

ARE 3 OR MORE O3 ANSWERS CODED YES?

NO **YES**

GENERALIZED ANXIETY DISORDER
CURRENT

P. ANTISOCIAL PERSONALITY DISORDER (optional)

(➡ MEANS : GO TO THE DIAGNOSTIC BOX AND CIRCLE NO.)

P1	**Before you were 15 years old, did you:**		
a	repeatedly skip school or run away from home overnight?	NO	YES
b	repeatedly lie, cheat, "con" others, or steal?	NO	YES
c	start fights or bully, threaten, or intimidate others?	NO	YES
d	deliberately destroy things or start fires?	NO	YES
e	deliberately hurt animals or people?	NO	YES
f	force someone to have sex with you?	NO	YES
		➡	
	ARE 2 OR MORE P1 ANSWERS CODED YES?	NO	YES
	DO NOT CODE YES TO THE BEHAVIORS BELOW IF THEY ARE EXCLUSIVELY POLITICALLY OR RELIGIOUSLY MOTIVATED.		
P2	**Since you were 15 years old, have you:**		
a	repeatedly behaved in a way that others would consider irresponsible, like failing to pay for things you owed, deliberately being impulsive or deliberately not working to support yourself?	NO	YES
b	done things that are illegal even if you didn't get caught (for example, destroying property, shoplifting, stealing, selling drugs, or committing a felony)?	NO	YES
c	been in physical fights repeatedly (including physical fights with your spouse or children)?	NO	YES
d	often lied or "conned" other people to get money or pleasure, or lied just for fun?	NO	YES
e	exposed others to danger without caring?	NO	YES
f	felt no guilt after hurting, mistreating, lying to, or stealing from others, or after damaging property?	NO	YES
	ARE 3 OR MORE P2 QUESTIONS CODED YES?	NO	YES

NO	YES
	ANTISOCIAL PERSONALITY DISORDER **LIFETIME**

THIS CONCLUDES THE INTERVIEW

REFERENCES

Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Janavs J, Weiller E, Bonora LI, Keskiner A, Schinka J, Knapp E, Sheehan MF, Dunbar GC. Reliability and Validity of the MINI International Neuropsychiatric Interview (M.I.N.I.): According to the SCID-P. European Psychiatry. 1997; 12:232-241.

Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Sheehan K, Janavs J, Dunbar G. The MINI International Neuropsychiatric Interview (M.I.N.I.) A Short Diagnostic Structured Interview: Reliability and Validity According to the CIDI. European Psychiatry. 1997; 12: 224-231.

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Translations	M.I.N.I. 4.4 or earlier versions	M.I.N.I. 4.6/5.0, M.I.N.I. Plus 4.6/5.0 and M.I.N.I. Screen 5.0:
Afrikaans	R. Emsley	W. Maartens
Arabic		O. Osman, E. Al-Radi
Bengali		H. Banerjee, A. Banerjee
Braille (English)		
Brazilian Portuguese	P. Amorim	P. Amorim
Bulgarian	L.G.. Hranov	
Chinese		L. Carroll, Y-J. Lee, Y-S. Chen, C-C. Chen, C-Y. Liu, C-K. Wu, H-S. Tang, K-D. Juang, Yan-Ping Zheng.
Czech		P. Zvolsky
Danish	P. Bech	P. Bech, T. Schiltz
Dutch/Flemish	E. Criez, K. Shrauwen, T. Overbeek, K. Demyttenaere	I. Van Vliet, H. Leroy, H. van Megen
English	D. Sheehan, J. Janavs, R. Baker, K. Harnett-Sheehan, E. Knapp, M. Sheehan	D. Sheehan, R. Baker, J. Janavs, K. Harnett-Sheehan, M. Sheehan
Estonian		J. Shlik, A. Aluoja, E. Khil
Farsi/Persian		K. Khooshabi, A. Zomorodi
Finnish	M. Heikkinen, M. Lijestrőm, O. Tuominen	M. Heikkinen, M. Lijestrőm, O. Tuominen
French	Y. Lecrubier, E. Weiller, I. Bonora, P. Amorim, J.P. Lepine	Y. Lecrubier, E. Weiller, P. Amorim, T. Hergueta
German	I. v. Denffer, M. Ackenhill, R. Dietz-Bauer	G. Stotz, R. Dietz-Bauer, M. Ackenhail
Greek	S. Bentila	T. Calligas, S. Bentila
Gujarati		M. Patel, B. Patel, Organon
Hebrew	J. Zohar, Y. Sasson	R. Barda, I. Lavirason, A. Aviv
Hindi		C. Mittal, K. Batra, S. Gambhir, Organon
Hungarian	I. Bitter, J. Balazs	I. Bitter, J. Balazs
Icelandic		J.G. Stefansson
Italian	I. Bonora, L. Conti, M. Piccinelli, M. Tansella, G. Cassano, Y. Lecrubier, P. Donda, E. Weiller	L. Conti, A. Rossi, P. Donda
Japanese		T. Otsubo, H. Watanabe, H. Miyaoka, K. Kamijima, J.Shinoda, K.Tanaka, Y. Okajima
Kannada		Organon
Korean		K.S. Oh and Korean Academy of Anxiety Disorders
Latvian	V. Janavs, J. Janavs, I. Nagobads	V. Janavs, J. Janavs
Lithuanian		A. Bacevicius
Malayalam		Organon
Marathi		Organon
Norwegian	O. Pedersen, S. Blomhoff	K.A. Leiknes , U. Malt, E. Malt, S. Lagerløv
Polish	M. Masiak, E. Jasiak	M. Masiak, E. Jasiak
Portuguese	P. Amorim	P. Amorim, T. Guimarães
Punjabi		A. Gahunia, S. Gambhir
Romanian		O. Dripa
Russian		A. Byvsttnsky, E. Sultova, M. Byvstnsky, L. Shunyak, M. Klimenka.
Serbian	I. Timotijevic	I. Timotijevic
Setswana		K. Kefilognotswe
Slovenian		M. Kocmur, M. Kocmur
Spanish	L. Fernando, J. Bobes-Garcia, J. Gilbert-Rahola, Y. Lecrubier	L. Fernando, L. Franco-Alfonso, M. Soto, J. Bobes-Garcia, O. Soto, L. Franco, G. Heinze, C. Santana, R. Hidalgo
Swedish	M. Waern, S. Arolarsch, M. Humble	C. Allgulander, H. Agran M. Waern, A. Brinne, M. Humble.
Tamil		Organon
Telugu		Organon

Thai		P. Kittiratanapaiboon, S. Mahatnirunkul, P. Uthaveesi, P. Silpakit, M. Khamwongpin, S. Srikiaad.
Turkish	T. Örnek, A. Keskiner, I. Vahip	T. Örnek, A. Keskiner, A.Ergüler
Urdu		S. Gambhir

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A FEASIBILITY RANDOMISED CONTROLLED TRIAL OF A BRIEF MINDFULNESS-BASED INTERVENTION IN A MENTAL HEALTH SECONDARY CARE SETTING

QUESTIONNAIRE PACK

TIME 1 QUESTIONNAIRE

Participant ID code: ……..

Date: ……/……/…….

A pilot RCT of a brief mindfulness therapy in secondary care
Questionnaire pack time 2 10.10.14 Version 1
REC Reference Number: 14/LO/1964

Participant ID: ……

QUESTIONS ABOUT YOU

1) What is your age?

……

2) What gender are you?

Yes ☐

No ☐

Other ☐

If other, please describe here:

……

3) What is your marital status?

Married/ in a civil partnership ☐

Single ☐

In a long term relationship ☐

Widowed ☐

Divorced/ separated ☐

Other ☐

If other, please describe here:

……

4) What is your country of birth?

……

5) What is your first language?

……

6) Please tick the box that best describes your ethnic group.

White (British)	☐	White (other)	☐
Asian/ Asian British	☐	Black/ African/ Carribean/ Black British	☐
Chinese/ Chinese British	☐	Mixed ethnicity	☐
Other	☐	I would rather not disclose	☐

If other, please describe here:

……

7) Please indicate which of the following best describes when you left education.

Left school before 16 ☐

Left school at 16 ☐

Left school at 17/18 ☐

Completed/ completing College course ☐

Completed/ completing University course ☐

8) Please provide details of the highest level of educational qualification you have

……

9) Do you currently work? (n.b. this includes paid, or voluntary work)

Yes ☐

No ☐

10) If you answered *yes* to question nine, which of the options below best summarises your work

Employed full-time (paid)	☐	Employed part-time (paid)	☐
Employed full-time (voluntary)	☐	Employed part-time (voluntary)	☐
Unemployed (on benefits)	☐	Unemployed (not on benefits)	☐
Student	☐	Retired	☐
Self-employed	☐	Home-maker	☐
Other	☐		

If you ticked **other**, please provide details:

……

11) If you answered yes to question nine, what is your job title (or job role)?

……

……

12) Are you aware of having ever received a mental health diagnosis/ diagnoses? If yes, please give details.

……

……

13) If applicable, when did you receive this diagnosis/ diagnoses?

……

……

14) Are you currently taking any medication for any mental health diagnosis?

Yes ☐

No ☐

15) If you answered *yes* to question 10, what medication (and in what doses) are you taking?

……

……

……

……

……

Nb. If you are not sure of your medication, are you happy for the research team to contact your care team to find out?

Yes ☐

No ☐

16) In the past have you received any psychological therapy?

Yes ☐

No ☐

17) If you answered *yes* to question 15, please can you provide some details on the psychological therapy (i.e. what type of therapy did you receive, when did you receive it, how long did you have the therapy, who delivered the therapy).

……

……

……

……

……

Nb. If you are not sure of your experience of therapy, are you happy for the research team to contact your care team to find out?

Yes ☐

No ☐

18) Do you have any previous experience of mindfulness meditation?

I have no previous experience ☐

I have tried mindfulness meditation once before ☐

I have tried mindfulness meditation several times before ☐

I have participated in a mindfulness meditation course before ☐

I am currently participating in a mindfulness meditation course ☐

I practice mindfulness meditation regularly ☐

19) If you have tried mindfulness meditation before, please could you provide some details of your experience of mindfulness.

……

……

……

……

20) Do you have any experience of any other forms of meditation?

I have no previous experience ☐

I have tried another form of meditation once before ☐

I have tried another form of meditation several times before ☐

I have participated in a course of another form of meditation ☐

I am currently participating in a course of another form of meditation ☐

I practice another form of meditation regularly ☐

21) If you have tried another form of meditation before, please could you provide some details of your experience of meditation.

……

……

……

……

Participant ID: ……

Five Facet Mindfulness Questionnaire (FFMQ): Short form

Below is a collection of statements about your everyday experience. Please indicate, by circling the number in the box to the right of each statement, how frequently or infrequently you have had each experience in the last two weeks. Please answer according to what really reflects your experience rather than what you think your experience should be.

	Never or very rarely true	Not often true	Sometimes true, sometimes not true	Often true	Very often or always true
1. I'm good at finding the words to describe my feelings	1	2	3	4	5
2. I can easily put my beliefs, opinions, and expectations into words	1	2	3	4	5
3. I watch my feelings without getting carried away by them	1	2	3	4	5
4. I tell myself that I shouldn't be feeling the way I'm feeling	1	2	3	4	5
5. it's hard for me to find the words to describe what I'm thinking	1	2	3	4	5
6. I pay attention to physical experiences, such as the wind in my hair or sun on my face	1	2	3	4	5
7. I make judgments about whether my thoughts are good or bad.	1	2	3	4	5
8. I find it difficult to stay focused on what's happening in the present moment	1	2	3	4	5
9. when I have distressing thoughts or images, I don't let myself be carried away by them	1	2	3	4	5
10. generally, I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing	1	2	3	4	5

11. when I feel something in my body, it's hard for me to find the right words to describe it	1	2	3	4	5
	Never or very rarely true	**Not often true**	**Sometimes true, sometimes not true**	**Often true**	**Very often or always true**
12. it seems I am "running on automatic" without much awareness of what I'm doing	1	2	3	4	5
13. when I have distressing thoughts or images, I feel calm soon after	1	2	3	4	5
14. I tell myself I shouldn't be thinking the way I'm thinking	1	2	3	4	5
15. I notice the smells and aromas of things	1	2	3	4	5
16. even when I'm feeling terribly upset, I can find a way to put it into words	1	2	3	4	5
17. I rush through activities without being really attentive to them	1	2	3	4	5
18. usually when I have distressing thoughts or images I can just notice them without reacting	1	2	3	4	5
19. I think some of my emotions are bad or inappropriate and I shouldn't feel them	1	2	3	4	5
20. I notice visual elements in art or nature, such as colours, shapes, textures, or patterns of light and shadow	1	2	3	4	5
21. when I have distressing thoughts or images, I just notice them and let them go	1	2	3	4	5
22. I do jobs or tasks automatically without being aware of what I'm doing	1	2	3	4	5
23. I find myself doing things without paying attention	1	2	3	4	5
24. I disapprove of myself when I have illogical ideas	1	2	3	4	5

Participant ID: ……

Self-Compassion Scale (SCS): Short Form

How I typically act towards myself in difficult times …

Please read each statement carefully before answering; using the scale given below indicate, to the right of each item, how often you behave in the stated manner:

		almost never				almost always
1	when I fail at something important to me I become consumed by feelings of inadequacy	1	2	3	4	5
2	I try to be understanding and patient towards those aspects of my personality I don't like	1	2	3	4	5
3	when something painful happens I try to take a balanced view of the situation	1	2	3	4	5
4	when I'm feeling down, I tend to feel like most other people are probably happier than I am	1	2	3	4	5
5	I try to see my failings as part of the human condition	1	2	3	4	5
6	when I'm going through a very hard time, I give myself the caring and tenderness I need	1	2	3	4	5
7	when something upsets me I try to keep my emotions in balance	1	2	3	4	5
8	when I fail at something that's important to me, I tend to feel alone in my failure	1	2	3	4	5
9	when I'm feeling down I tend to obsess and fixate on everything that's wrong	1	2	3	4	5
10	when I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people	1	2	3	4	5
11	I'm disapproving and judgmental about my own flaws and inadequacies	1	2	3	4	5
12	I'm intolerant and impatient towards those aspects of my personality I don't like	1	2	3	4	5

Participant ID: ……

The Short Warwick Edinburgh Mental Well-Being Scale

Below are some statements about feelings and thoughts.

Please circle the number in the box that best describes your experience of each over the last 2 weeks.

	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future	1	2	3	4	5
2. I've been feeling useful	1	2	3	4	5
3. I've been feeling relaxed	1	2	3	4	5
4. I've been dealing with problems well	1	2	3	4	5
5. I've been thinking clearly	1	2	3	4	5
6. I've been feeling close to other people	1	2	3	4	5
7. I've been able to make up my own mind about things	1	2	3	4	5

Participant ID: ……

GAD-7

Over the last 2 weeks how often have you been bothered by the following problems? Please circle the number in the box to the right.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Total = ……

Spitzer et al (2006)

Participant ID: ……

PHQ-9

Over the last 2 weeks how often have you been bothered by any of the following problems? Please circle the number in the box to the right.

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

QUESTIONS ABOUT YOU

(Post-Intervention)

22) Have you received a mental health diagnosis/ diagnoses since your previous assessment for this research study?

Yes ☐

No ☐

23) If you answered yes, please could you specify the diagnosis/ diagnoses?

……

……

……

24) Since the last meeting for this research project, has your medication changed?

Yes ☐

No ☐

25) If you answered *yes* to question 10, what medication (and in what doses) and you taking?

……
……
……
……
……
……
……
……
……

Nb. if you are not sure of your medication, are you happy for the research team to contact your care team to find out?

Yes ☐

No ☐

26) Have you received any other psychological therapy (other than the therapy you may have received as part of this research study) since your initial assessment for this research study?

Yes ☐

No ☐

27) If you answered *yes* to question five, please can you provide some details on the psychological therapy (i.e. what type of therapy are you receive, how long have you been receiving the therapy, who delivers the therapy).

……
……
……

……
……
……
……
……
……

Nb. if you are not sure of your experience of therapy, are you happy for the research team to contact your care team to find out?

Yes ☐

No ☐

28) What is your experience of mindfulness meditation since we last completed a questionnaire?

I have not practiced mindfulness ☐

I have tried mindfulness meditation once ☐

I have tried mindfulness meditation several times ☐

I have participated in a mindfulness meditation course ☐

I am currently participating in a mindfulness meditation ☐

I have practiced mindfulness meditation regularly ☐

29) If you answered have practiced mindfulness, please could you provide some details of your experience of mindfulness.

……
……
……
……
……
……

30) What is your experience of any other form of meditation since we last completed a questionnaire?

I have no previous experience ☐

I have tried another form of meditation once ☐

I have tried another form of meditation several times ☐

I have participated in a course of another form of meditation ☐

I am currently participating in a course of another form of meditation ☐

I practice another form of meditation regularly ☐

31) If you have practiced meditation please could you provide some details of your experience of meditation.

……
……
……
……
……
……

Nb. for researcher

This participant was assigned to:

Brief mindfulness arm ☐

Waiting list arm ☐

QUESTIONS TO BE COMPLETED BY PEOPLE WHO WERE RANDOMISED TO THE BRIEF MINDFULNESS INTERVENTION ARM

1) **On average, how regularly did you practice formal mindfulness meditation (i.e. using a CD from the group) whilst you were attending the four week mindfulness group?**

I practiced everyday ☐

I practiced 5-6 times a week ☐

I practiced 3-4 times a week ☐

I practiced 2-3 times a week ☐

I practiced once a week ☐

I did not practice at all ☐

I can't remember ☐

2) **On average, how regularly did you practice informal mindfulness meditation (i.e. applying mindfulness to a daily experience like**

walking, or breathing or brushing your teeth) whilst you were attending the four week mindfulness group?

I practiced everyday ☐

I practiced 5-6 times a week ☐

I practiced 3-4 times a week ☐

I practiced 2-3 times a week ☐

I practiced once a week ☐

I did not practice at all ☐

I can't remember ☐

3) **During the four week mindfulness course, on how many occasions per week (on average) did you bring the ideas or principles from the course to experiences in your everyday life?**

.....

4) **Did you use any other mindfulness materials, or practices that were not included during the four week mindfulness course? (Nb. these could include mindfulness practices online, or books etc.)**

Yes ☐

No ☐

5) **If you answered yes to question 14, please provide details of these materials and how often you used them.**

……
……
……
……
……

6) **Do you intend to keep practicing mindfulness now the group is over?**

Yes ☐

No ☐

7) **Do you plan to keep practicing formal mindfulness mediation (i.e. using a CD from the group) now the group is over?**

I plan to practice every day ☐

☐

I plan to practice 5-6 times a week

I plan to practice 3-4 times a week ☐

I plan to practice 2-3 times a week ☐

I plan to practice once a week ☐

I'm not sure if I plan to practice ☐

I don't plan to practice at all ☐

8) Do you plan to keep practicing informal mindfulness meditation (i.e. applying mindfulness to a daily experience like walking, or breathing or brushing your teeth), now the group is over?

I plan to practice every day ☐

I plan to practice 5-6 times a week ☐

I plan to practice 3-4 times a week ☐

I plan to practice 2-3 times a week ☐

I plan to practice once a week ☐

I'm not sure if I plan to practice ☐

I don't plan to practice at all ☐

9) Do you plan to use, or search for any other mindfulness materials, practices, or groups now the four week course is over? (Nb. These could include mindfulness practices online, or books etc.)

Yes ☐

No ☐

10) If you answered yes to question 19, please provide details of these materials.

……
……
……
……
……

11) How much do you really feel this intervention has helped your well-being? Please answer on a score of 1-5 where 1 = not at all and 5 = very much.

Not at all		I'm not sure		Very much
1	2	3	4	5

12) How likely are you to recommend this mindfulness course to friends and family if they needed treatment?

Not at all		I'm not sure		Very much
1	2	3	4	5

Change Interview for LightMind

(Adapted from Elliott, 2006)

Interview Strategy: This interview works best as a relatively unstructured empathic exploration of the client's experience of the mindfulness course. Think of yourself as primarily trying to help the client tell you the story of his or her the mindfulness course so far. It is best if you adopt an attitude of curiosity about the topics raised in the interview, using the suggested open-ended questions plus empathic understanding responses to help the client elaborate on his/her experiences. Thus, for each question, start out in a relatively unstructured manner and only impose structure as needed. For each question, a number of alternative wordings have been suggested, but keep in mind that these may not be needed.

- Ask client to provide as many details as possible
- Use the "anything else" probe (e.g., "Are there any other changes that you have noticed?"): inquire in a non-demanding way until the client runs out of things to say

Introduction given to clients: After the mindfulness course, clients are asked to come in for an hour-long semi-structured interview. The major topics of this interview are any changes you have noticed since the mindfulness course began, what you believe may have brought about these changes, and helpful and unhelpful aspects of the mindfulness course. The main purpose of this interview is to allow you to tell us about the mindfulness course and the research in your own words. This information will help us to understand better how the mindfulness course works; it will also help us to improve the mindfulness course. This interview is audio-recorded for later transcription. Please provide as much detail as possible.

Interview Schedule:

1. ***Changes***: [about 10 min]
1a. What changes, if any, have you noticed in yourself since the mindfulness course started? *(Interviewer: Reflect back change to client and write down brief versions of the changes for later. If it is helpful, you can use some of these follow-up questions: For example, Are you doing, feeling, or thinking differently from the way you did before? What specific ideas, if any, have you gotten from the mindfulness course so far, including ideas about yourself or other people? Have any changes been brought to your attention by other people?)*

1b. Has anything changed for the worse for you since the mindfulness course started?

i. ……

ii. ……

iii. ……

iv. ……

v. ……

1c. Is there anything that you wanted to change that hasn't since the mindfulness course started?

i. ……

ii. ……

iii. ……

iv. ……

v. ……

2. ***Change Ratings***: [about 10 min] (Go through each change and rate it on the following three scales:)
2a. For each change, please rate how much you expected it vs. were surprised by it? (Use this rating scale:)

(1) Very much expected it
(2) Somewhat expected it
(3) Neither expected nor surprised by the change
(4) Somewhat surprised by it
(5) Very much surprised by it

2b. For each change, please rate how likely you think it would have been if you hadn't done the mindfulness course? (Use this rating scale:)

(1) Very unlikely without the mindfulness course (clearly would not have happened)
(2) Somewhat unlikely without the mindfulness course (probably would not have happened)
(3) Neither likely nor unlikely (no way of telling)
(4) Somewhat likely without the mindfulness course (probably would have happened)
(5) Very likely without the mindfulness course (clearly would have happened anyway)

2c. How important or significant to you personally do you consider this change to be? (Use this rating scale:)

(1) Not at all important
(2) Slightly important
(3) Moderately important
(4) Very important
(5) Extremely important

	Expected it? (1-5)	Likely? (1-5)	Importance? (1-5)
Change 1:			
Change 2:			
Change 3:			
Change 4:			
Change 5:			

3. ***Attributions***: [about 5 min] In general, what do you think has caused the various changes you

described? In other words, what do you think might have brought them about? (Including things both outside of the mindfulness course and in the mindfulness course)

……

……

……

……

4. ***Helpful Aspects***: [about 10 min] Can you sum up what has been helpful about the mindfulness course so far? Please give examples. (For example, general aspects, specific events)

……

……

……

……

5. ***Resources***: [about 5 min]
5a. What personal strengths do you think have helped you make use of the mindfulness course to deal with your problems? (what you're good at, personal qualities)

……

……

……

……

5b. What things in your current life situation have helped you make use of the mindfulness course to deal with your problems? (family, job, relationships, living arrangements)

……

……

……

……

6. ***Problematic Aspects***: [about 5 min]
6a. What kinds of things about the mindfulness course have been hindering, unhelpful, negative or disappointing for you? (For example, general aspects. specific events)

……

……

……

……

6b. Were there things in the mindfulness course which were difficult or painful but still OK or perhaps helpful? What were they?

……

……

……

……

6c. Has anything been missing from your treatment? (What would make/have made the mindfulness course more effective or helpful?)

……

……

……

……

7. ***Limitations***: [about 5 min]
7a. What personal limitations do you think have made it harder for you to use the mindfulness course to deal with your problems? (things about you as a person)

……

……

……

……

7b. What things in your life situation have made it harder for you to use the mindfulness course to deal with your problems? (family, job, relationships, living arrangements)

……

……

……

……

8. ***Suggestions***. [about 5 min] Do you have any suggestions for us, regarding the research or the mindfulness course? Do you have anything else that you want to tell me?

……

……

……

……

Rating Scales:

1	2	3	4	5
Very much expected the change to happen	Somewhat expected the change to happen	Neither expected the change to happen nor was surprised by it	Somewhat surprised by the change	Very much surprised by the change

1	2	3	4	5
Very unlikely without the mindfulness course (clearly would not have happened)	Somewhat unlikely without the mindfulness course (probably would not have happened)	Neither likely nor unlikely (no way of telling)	Somewhat likely without the mindfulness course (probably would have happened)	Very likely without the mindfulness course (clearly would have happened anyway)

1	2	3	4	5
Not at all important	Slightly important	Moderately important	Very important	Extremely important

Appendix Q: SPSS syntax for analysis

```
DATASET ACTIVATE DataSet1.

RECODE T1.SCS.item1 T1.SCS.item4 T1.SCS.item8 T1.SCS.item9 T1.SCS.item11
T1.SCS.item12 T2.SCS.item1 T2.SCS.item4 T2.SCS.item8 T2.SCS.item9 T2.SCS.item11
T2.SCS.item12 (1=5) (2=4) (3=3) (4=2) (5=1) INTO T1.SCS.item1r T1.SCS.item4r
T1.SCS.item8r T1.SCS.item9r T1.SCS.item11r T1.SCS.item12r T2.SCS.item1r T2.SCS.item4r
T2.SCS.item8r T2.SCS.item9r T2.SCS.item11r T2.SCS.item12r.

COMPUTE T1.SCStotalscore=T1.SCS.item1r + T1.SCS.item4r + T1.SCS.item8r +
T1.SCS.item9r + T1.SCS.item11r + T1.SCS.item12r + T1.SCS.item2 + T1.SCS.item3 +
T1.SCS.item5 + T1.SCS.item6 + T1.SCS.item7 + T1.SCS.item10.

COMPUTE T2.SCStotalscore=T2.SCS.item1r + T2.SCS.item4r + T2.SCS.item8r +
T2.SCS.item9r + T2.SCS.item11r + T2.SCS.item12r + T2.SCS.item2 + T2.SCS.item3 +
T2.SCS.item5 + T2.SCS.item6 + T2.SCS.item7 + T2.SCS.item10.

RECODE T1.FFMQ.item4 T1.FFMQ.item5 T1.FFMQ.item7 T1.FFMQ.item8 T1.FFMQ.item11
T1.FFMQ.item12 T1.FFMQ.item14 T1.FFMQ.item17 T1.FFMQ.item19 T1.FFMQ.item22
T1.FFMQ.item23 T1.FFMQ.item24 T2.FFMQ.item4 T2.FFMQ.item5 T2.FFMQ.item7
T2.FFMQ.item8 T2.FFMQ.item11 T2.FFMQ.item12 T2.FFMQ.item14 T2.FFMQ.item17
T2.FFMQ.item19 T2.FFMQ.item22 T2.FFMQ.item23 T2.FFMQ.item24 (1=5) (2=4) (3=3) (4=2)
(5=1) INTO T1.FFMQ.item4r T1.FFMQ.item5r T1.FFMQ.item7r T1.FFMQ.item8r
T1.FFMQ.item11r T1.FFMQ.item12r T1.FFMQ.item14r T1.FFMQ.item17r T1.FFMQ.item19r
T1.FFMQ.item22r T1.FFMQ.item23r T1.FFMQ.item24r T2.FFMQ.item4r T2.FFMQ.item5r
T2.FFMQ.item7r T2.FFMQ.item8r T2.FFMQ.item11r T2.FFMQ.item12r T2.FFMQ.item14r
T2.FFMQ.item17r T2.FFMQ.item19r T2.FFMQ.item22r T2.FFMQ.item23r T2.FFMQ.item24r.

COMPUTE T1.FFMQ.nonreact=T1.FFMQ.item3 + T1.FFMQ.item9 + T1.FFMQ.item13 +
T1.FFMQ.item21.

COMPUTE T1.FFMQ.observe=T1.FFMQ.item6 + T1.FFMQ.item10 + T1.FFMQ.item15 +
T1.FFMQ.item20.

COMPUTE T1.FFMQ.actaware=T1.FFMQ.item8r + T1.FFMQ.item12r + T1.FFMQ.item17r +
T1.FFMQ.item22r + T1.FFMQ.item23r.

COMPUTE T1.FFMQ.describe=T1.FFMQ.item1 + T1.FFMQ.item2 + T1.FFMQ.item5r +
T1.FFMQ.item11r + T1.FFMQ.item16.

COMPUTE T1.FFMQ.nonjudge=T1.FFMQ.item4r + T1.FFMQ.item7r + T1.FFMQ.item14r +
T1.FFMQ.item19r + T1.FFMQ.item24r.

COMPUTE T2.FFMQ.nonreact=T2.FFMQ.item3 + T2.FFMQ.item9 + T2.FFMQ.item13 +
T2.FFMQ.item18 + T2.FFMQ.item21.

COMPUTE T2.FFMQ.observe=T2.FFMQ.item6 + T2.FFMQ.item10 + T2.FFMQ.item15 +
T2.FFMQ.item20 .
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COMPUTE T2.FFMQ.actaware=T2.FFMQ.item8r + T2.FFMQ.item12r + T2.FFMQ.item17r +
T2.FFMQ.item22r + T2.FFMQ.item23r.

COMPUTE T2.FFMQ.describe=T2.FFMQ.item1 + T2.FFMQ.item2 + T2.FFMQ.item5r +
T2.FFMQ.item11r + T2.FFMQ.item16.

COMPUTE T1.FFMQ.total=T1.FFMQ.nonreact + T1.FFMQ.actaware + T1.FFMQ.describe +
T1.FFMQ.nonjudge.

COMPUTE T2.FFMQ.total=T2.FFMQ.nonreact + T2.FFMQ.actaware + T2.FFMQ.describe +
T2.FFMQ.nonjudge.

COMPUTE T2.FFMQ.nonjudge=T2.FFMQ.item4r + T2.FFMQ.item7r + T2.FFMQ.item14r +
T2.FFMQ.item19r + T2.FFMQ.item24r.

COMPUTE T1.PHQtotalscore=T1.PHQ.item1 + T1.PHQ.item2 + T1.PHQ.item3 +
T1.PHQ.item4 + T1.PHQ.item5 + T1.PHQ.item6 + T1.PHQ.item7 + T1.PHQ.item8 +
T1.PHQ.item9.

COMPUTE T2.PHQtotalscore=T2.PHQ.item1 + T2.PHQ.item2 + T2.PHQ.item3 +
T2.PHQ.item4 + T2.PHQ.item5 + T2.PHQ.item6 + T2.PHQ.item7 + T2.PHQ.item8 +
T2.PHQ.item9.

COMPUTE T1.GADtotalscore=T1.GAD.item1 + T1.GAD.item2 + T1.GAD.item3 +
T1.GAD.item4 + T1.GAD.item5 + T1.GAD.item6 + T1.GAD.item7.

COMPUTE T2.GADtotalscore=T2.GAD.item1 + T2.GAD.item2 + T2.GAD.item3 +
T2.GAD.item4 + T2.GAD.item5 + T2.GAD.item6 + T2.GAD.item7.

COMPUTE T1.Warwicktotalscore=T1.Warwick.item1 + T1.Warwick.item2 + T1.Warwick.item3 +
T1.Warwick.item4 + T1.Warwick.item5 + T1.Warwick.item6 + T1.Warwick.item7.

COMPUTE T2.Warwicktotalscore=T2.Warwick.item1 + T2.Warwick.item2 + T2.Warwick.item3 +
T2.Warwick.item4 + T2.Warwick.item5 + T2.Warwick.item6 + T2.Warwick.item7.

COMPUTE Diff.FFMQ.nonreact=T2.FFMQ.nonreact - T1.FFMQ.nonreact.

COMPUTE Diff.FFMQ.observe=T2.FFMQ.observe - T1.FFMQ.observe.

COMPUTE Diff.FFMQ.actaware=T2.FFMQ.actaware - T1.FFMQ.actaware.

COMPUTE Diff.FFMQ.describe=T2.FFMQ.describe - T1.FFMQ.describe.

COMPUTE Diff.FFMQ.nonjudge=T2.FFMQ.nonjudge - T1.FFMQ.nonjudge.

COMPUTE Diff.FFMQ.total=T2.FFMQ.total - T1.FFMQ.total.

COMPUTE Diff.SCS=T2.SCStotalscore - T1.SCStotalscore.

COMPUTE Diff.Warwick=T2.Warwicktotalscore - T1.Warwicktotalscore.

COMPUTE Diff.GAD=T2.GADtotalscore - T1.GADtotalscore.

COMPUTE Diff.PHQ=T2.PHQtotalscore - T1.PHQtotalscore.

EXECUTE.
```

```
EXAMINE VARIABLES=Diff.FFMQ.nonreact BY T2.QAY.item10.Nb
/PLOT NONE
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
EXECUTE.
FREQUENCIES VARIABLES=Diff.FFMQ.nonreact Diff.FFMQ.observe Diff.FFMQ.actaware
Diff.FFMQ.describe Diff.FFMQ.nonjudge Diff.FFMQ.total Diff.SCS Diff.Warwick Diff.GAD
Diff.PHQ
  /STATISTICS=RANGE MINIMUM MAXIMUM STDDEV MEAN MEDIAN
  /FORMAT=LIMIT(50)
  /ORDER=ANALYSIS.
T-TEST GROUPS=T2.QAY.item10.Nb (0,1) /VARIABLES=Age.
EXECUTE.
```

Appendix R: qualitative theme development

Codes relating to effects on wellbeing

BR17	BR26	CA02	CA14	CH06	CO09	DE10	FA13	FO08	HA12	HU07	KN20	LA05	RE19	SM01
More relaxed	Comforted	Working with a more informal way of doing things	More active	Emotionally stronger	(Not long enough for significant change)	Deciding on actions more	More present-moment awareness	Fore-grounded mindfulness	More tolerant	More cognitive space	More present moment awareness	Relating differently to negative events	Noticing more	More confident
More in control	More hopeful	Noticing feelings more	More tired	Dealing with life challenges more easily	Relaxing and resting more	Noticing sensory experiences more	More aware of need for nourishment	Improved sleep	More relaxed	More self-compassion	More detached from others	Improved mood	More self-aware	More prepared
More tolerant of others	Calmer	Noticing cognitions more	Sleeping better	More in control	More present moment awareness	More present moment awareness	More guilt for not already knowing about nourishing self	More cognitively able	Improved wellbeing	More self-aware	Not able to establish a meditation routine	More likely to pause to think	Behaviour al activation	
More annoyed	More detached	Concerned around likelihood of triggering difficult feelings	Happier	More able to change negatives to positives	No changes for the worse	Nothing has changed for the worse	More present moment awareness needed	Not motivated enough	More self-aware	Trying new things		More measured		
Less pins and needles feeling	Noticing thoughts more		Calmer	Kindness and love as a new form of management	No change in optimism for the future	Not enough theory		Not confident enough with managing difficult thoughts and feelings	Better interperson al relations	More present-moment awareness		More anxious		
More frustrated	More able to get on and get everything done		More satisfied/ things falling into place	Nothing has changed for the worse, only improvement s		First two sessions less relevant				More memory problems		Increased awareness		
Would like to be calmer	More relaxed		Thinking differently	There's nothing left that I still want to change						Not enough stamina				
Would like to be less judgmental			No change in focus on pain							Mood change with meditation still takes an hour				

Effects on wellbeing														
BR17	BR26	CA02	CA14	CH06	CO09	DE10	FA13	FO08	HA12	HU07	KN20	LA05	RE19	SM01
More relaxed	Comforted	Working with a more informal way of doing things	More active	Emotionally stronger	Relaxing and resting more	Deciding on actions more	More present-moment awareness	Fore-grounded mindfulness	More tolerant	More cognitive space	More present moment awareness	Relating differently to negative events	Noticing more	More confident
More in control	More hopeful	Noticing feelings more	More tired	Dealing with life challenges more easily	More present moment awareness	Noticing sensory experiences more	More aware of need for nourishment	Improved sleep	More relaxed	More self-compassion	More detached from others	Improved mood	More self-aware	More prepared
More tolerant of others	Calmer	Noticing cognitions more	Sleeping better	More in control		More present moment awareness	More guilt for not already knowing about nourishing self	More cognitively able	Improved wellbeing	More self-aware	Not able to establish a meditation routine	More likely to pause to think	More active	
More annoyed	More detached	Concerned around likelihood of triggering difficult feelings	Happier	More able to change negatives to positives		Not enough theory	Would like more present moment awareness	Not motivated enough	More self-aware	Trying new things		More measured		
Less pins and needles feeling	Noticing thoughts more		Calmer	Kindness and love as a new form of management				Not confident enough with managing difficult thoughts and feelings	Better relationships	More present-moment awareness		More anxious		
More frustrated	More able to get on and get everything done		More satisfied							More memory problems		Increased awareness		
Would like to be calmer	More relaxed		Things falling into place							Not enough stamina				
Would like to be less judgmental			Thinking differently											

Coding frame

Categories	Subcategories (concepts)	Concepts
Effects on wellbeing	Positive overall impression:	
	Feeling more at ease	more relaxed, more in control
	Feeling generally better	more optimistic about the future, happier
	More active	getting things done, decisive, trying new things
	Improved sleep	sleeping for longer or more soundly
	Challenging experiences, but positive overall impression:	
	More tired	feeling of fatigue
	Fore grounded difficulties	difficult memories, difficult feelings
Change processes	Positive overall impression:	
	Support from others	family, therapist, friends
	Challenging but positive overall impression:	
	Cultivating mindfulness	mindful movement, practicing regularly
	Group process	increase in support, dominant characters
	Overall negative:	
	Getting started	beginning a mindfulness practice
Internal experience	Positive overall impression:	
	Being receptive to mindfulness	motivated, willing to try
	Inner strength	survival instinct, confidence
	Challenging but positive overall impression:	
	Motivation to change	a positive intention, readiness
	Mood	being ready, confidence in ability to change
	Cognitions	expectations of self, fears, intensity, negative focus
		difficult thoughts, critical thinking

Practicalities	Challenging but positive overall impression:	
	Delivery	increase preparedness, noisy venue, good facilitation, breaks needed, NHS venue, timing
	Duration	too short
	Overall negative:	
	Group size	group felt too small
	Access	sitting in one position, mindful movement, CD only

Abridged research diary

This has been removed from the electronic copy

Sections of coded transcripts

This has been removed from the electronic copy

Appendix S: SPSS output

Explore

Nb. for researcher. This participant was assigned to:

Case Processing Summary

	Nb. for researcher. This participant was assigned to:	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
Diff.FFMQ.nonreact	brief mindfulness arm	9	100.0%	0	0.0%	9	100.0%
	waiting list arm	9	100.0%	0	0.0%	9	100.0%

Descriptives

	Nb. for researcher. This participant was assigned to:			Statistic	Std. Error
Diff.FFMQ.nonreact	brief mindfulness arm	Mean		4.6667	.88192
		95% Confidence Interval for Mean	Lower Bound	2.6330	
			Upper Bound	6.7004	
		5% Trimmed Mean		4.5741	
		Median		4.0000	
		Variance		7.000	

		Std. Deviation	2.64575	
		Minimum	1.00	
		Maximum	10.00	
		Range	9.00	
		Interquartile Range	3.00	
		Skewness	.827	.717
		Kurtosis	1.281	1.400
	waiting list arm	Mean	2.7778	1.34141
		95% Confidence Interval for Mean — Lower Bound	-.3155	
		95% Confidence Interval for Mean — Upper Bound	5.8711	
		5% Trimmed Mean	3.0309	
		Median	3.0000	
		Variance	16.194	
		Std. Deviation	4.02423	
		Minimum	-6.00	
		Maximum	7.00	
		Range	13.00	

	Interquartile Range	5.00	
	Skewness	-1.345	.717
	Kurtosis	2.123	1.400

Frequencies

Statistics

		Diff.FFMQ.nonreact	Diff.FFMQ.observe	Diff.FFMQ.actaware	Diff.FFMQ.describe	Diff.FFMQ.nonjudge	Diff.FFMQ.total	Diff.SCS	Diff.Warwick	Diff.GAD	Diff.PHQ
N	Valid	18	18	18	18	18	18	18	18	18	18
	Missing	8	8	8	8	8	8	8	8	8	8
Mean		3.7222	.5000	.8889	1.0000	-.3889	5.2222	6.3889	.6111	-.6111	-1.8333
Median		4.0000	.0000	.0000	1.0000	-.5000	5.5000	5.5000	2.0000	-.5000	-3.0000
Std. Deviation		3.44376	2.61781	3.95398	2.37635	3.88267	8.90839	7.03887	7.38153	3.08962	3.86918
Range		16.00	11.00	18.00	8.00	13.00	30.00	21.00	33.00	14.00	15.00
Minimum		-6.00	-6.00	-10.00	-3.00	-7.00	-12.00	-2.00	-24.00	-7.00	-9.00
Maximum		10.00	5.00	8.00	5.00	6.00	18.00	19.00	9.00	7.00	6.00

Frequency Tables

Diff.FFMQ.nonreact

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-6.00	1	3.8	5.6	5.6
	.00	1	3.8	5.6	11.1
	1.00	1	3.8	5.6	16.7
	2.00	3	11.5	16.7	33.3
	3.00	1	3.8	5.6	38.9
	4.00	3	11.5	16.7	55.6
	5.00	3	11.5	16.7	72.2
	6.00	2	7.7	11.1	83.3
	7.00	2	7.7	11.1	94.4
	10.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.FFMQ.observe

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-6.00	1	3.8	5.6	5.6
	-3.00	1	3.8	5.6	11.1
	-1.00	3	11.5	16.7	27.8
	.00	5	19.2	27.8	55.6
	1.00	3	11.5	16.7	72.2

	2.00	1	3.8	5.6	77.8
	3.00	1	3.8	5.6	83.3
	4.00	2	7.7	11.1	94.4
	5.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.FFMQ.actaware

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-10.00	1	3.8	5.6	5.6
	-3.00	1	3.8	5.6	11.1
	-2.00	1	3.8	5.6	16.7
	-1.00	1	3.8	5.6	22.2
	.00	6	23.1	33.3	55.6
	2.00	3	11.5	16.7	72.2
	3.00	2	7.7	11.1	83.3
	6.00	2	7.7	11.1	94.4
	8.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		

Total		26	100.0		

Diff.FFMQ.nonjudge

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-7.00	1	3.8	5.6	5.6
	-5.00	2	7.7	11.1	16.7
	-4.00	2	7.7	11.1	27.8
	-3.00	1	3.8	5.6	33.3
	-2.00	1	3.8	5.6	38.9
	-1.00	2	7.7	11.1	50.0
	.00	2	7.7	11.1	61.1
	1.00	2	7.7	11.1	72.2
	3.00	1	3.8	5.6	77.8
	4.00	1	3.8	5.6	83.3
	5.00	2	7.7	11.1	94.4
	6.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.FFMQ.total

	Frequency	Percent	Valid Percent	Cumulative Percent

Valid	-12.00	1	3.8	5.6	5.6
	-7.00	1	3.8	5.6	11.1
	-6.00	1	3.8	5.6	16.7
	-3.00	1	3.8	5.6	22.2
	-2.00	1	3.8	5.6	27.8
	1.00	1	3.8	5.6	33.3
	2.00	1	3.8	5.6	38.9
	4.00	1	3.8	5.6	44.4
	5.00	1	3.8	5.6	50.0
	6.00	1	3.8	5.6	55.6
	7.00	1	3.8	5.6	61.1
	9.00	1	3.8	5.6	66.7
	12.00	1	3.8	5.6	72.2
	13.00	2	7.7	11.1	83.3
	16.00	1	3.8	5.6	88.9
	18.00	2	7.7	11.1	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.SCS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-2.00	1	3.8	5.6	5.6
	-1.00	2	7.7	11.1	16.7
	.00	2	7.7	11.1	27.8
	1.00	2	7.7	11.1	38.9
	3.00	1	3.8	5.6	44.4
	5.00	1	3.8	5.6	50.0
	6.00	2	7.7	11.1	61.1
	8.00	1	3.8	5.6	66.7
	9.00	1	3.8	5.6	72.2
	11.00	1	3.8	5.6	77.8
	16.00	2	7.7	11.1	88.9
	18.00	1	3.8	5.6	94.4
	19.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.Warwick

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-24.00	1	3.8	5.6	5.6
	-5.00	2	7.7	11.1	16.7
	-2.00	2	7.7	11.1	27.8
	-1.00	1	3.8	5.6	33.3
	.00	1	3.8	5.6	38.9
	1.00	1	3.8	5.6	44.4
	2.00	2	7.7	11.1	55.6
	3.00	1	3.8	5.6	61.1
	4.00	2	7.7	11.1	72.2
	5.00	2	7.7	11.1	83.3
	6.00	1	3.8	5.6	88.9
	9.00	2	7.7	11.1	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.GAD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-7.00	1	3.8	5.6	5.6
	-5.00	1	3.8	5.6	11.1
	-3.00	2	7.7	11.1	22.2

	-2.00	2	7.7	11.1	33.3
	-1.00	3	11.5	16.7	50.0
	.00	5	19.2	27.8	77.8
	2.00	2	7.7	11.1	88.9
	3.00	1	3.8	5.6	94.4
	7.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		
Total		26	100.0		

Diff.PHQ

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	-9.00	1	3.8	5.6	5.6
	-7.00	1	3.8	5.6	11.1
	-5.00	1	3.8	5.6	16.7
	-4.00	3	11.5	16.7	33.3
	-3.00	4	15.4	22.2	55.6
	-2.00	2	7.7	11.1	66.7
	-1.00	1	3.8	5.6	72.2
	2.00	1	3.8	5.6	77.8
	3.00	3	11.5	16.7	94.4
	6.00	1	3.8	5.6	100.0
	Total	18	69.2	100.0	
Missing	System	8	30.8		

Total	26	100.0		

T-Test

Group Statistics

	Nb. for researcher. This participant was assigned to:	N	Mean	Std. Deviation	Std. Error Mean
Age listed in first data collection booklet	brief mindfulness arm	9	48.7778	10.18305	3.39435
	waiting list arm	8	41.0000	13.21255	4.67134

Independent Samples Test

			Levene's Test for Equality of Variances		t-test for Equality of Means						
			F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
										Lower	Upper
Age listed in first data collection booklet	Equal variances assumed	.440	.517	1.369	15	.191	7.77778	5.68269	-4.33460	19.89015	
	Equal variances not assumed			1.347	13.138	.201	7.77778	5.77434	-4.68358	20.23913	

Appendix T: Draft end of study letter for participants

Hello,

Thank you for taking part in our study and for attending the mindfulness group.

We ran the research project alongside the group to help us understand if it was possible to run a mindfulness group in a secondary care mental health service. We were also interested to find out whether this particular group was useful for people experiencing mental health problems.

The study has finished now, and here is a short summary of the findings:

- 26 people took part in the study, and 69% of them finished the group.

The questionnaires and interviews showed that after the group:

- People had gained new knowledge about mindfulness
- People were feeling more compassionate, less worried, and less depressed
- Most people found the group positive and helpful and were intending to continue practicing mindfulness. However, the questionnaires did not show any changes in how people were feeling day to day or stress
- People suggested some changes to the group, but overall they enjoyed working with other service-users and facilitators.

Thank you again for taking the time to participate in the study, if you would like more information about the findings please let a member of the ATS team know and I will send a longer report.

Best wishes,

Appendix U: Planned dissemination strategy

Academic papers:

- How do mindfulness-based interventions affect adults experiencing Borderline Personality Disorder: A systematic review and meta-analysis

To be prepared for submission to Clinical Psychology Review

- Living Mindfully (LiveMind): A Feasibility Randomised Controlled Trial of a Brief Mindfulness-Based Intervention in a Mental Health Secondary Care Setting

To be prepared for submission to Mindfulness, guidelines for authors attached

Feedback with research team:

- Feedback results at steering group meeting May 2017

Feedback to relevant stakeholders:

- Project report for participants
- Feedback to clinicians working within the ATS services in Brighton and Hove at team meeting May 2017
- Feedback to NHS ethics panel May 2017

Appendix V: Author guidelines for Mindfulness

Springer

Psychology - Cognitive Psychology | Mindfulness - incl. option to publish open access

Cognitive PsychologyHome > Psychology > Cognitive Psychology

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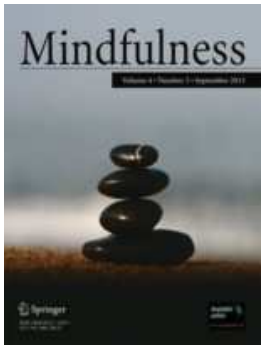

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Title Page

The title page should include:

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- A concise and informative title
- The affiliation(s) and address(es) of the author(s)
- The e-mail address, and telephone number(s) of the corresponding author
- If available, the 16-digit ORCID of the author(s)

Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

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Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
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- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

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LaTeX macro package (zip, 182 kB)

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Please use no more than three levels of displayed headings.

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Abbreviations should be defined at first mention and used consistently thereafter.

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Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data).

Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

TERMINOLOGY

• Please always use internationally accepted signs and symbols for units (SI units).

SCIENTIFIC STYLE

Generic names of drugs and pesticides are preferred; if trade names are used, the generic name should be given at first mention.

Please use the standard mathematical notation for formulae, symbols etc.:

Italic for single letters that denote mathematical constants, variables, and unknown quantities

Roman/upright for numerals, operators, and punctuation, and commonly defined functions or abbreviations, e.g., cos, det, e or exp, lim, log, max, min, sin, tan, d (for derivative)

Bold for vectors, tensors, and matrices.

REFERENCES

Citation

Cite references in the text by name and year in parentheses. Some examples:

Negotiation research spans many disciplines (Thompson 1990).

This result was later contradicted by Becker and Seligman (1996).

This effect has been widely studied (Abbott 1991; Barakat et al. 1995; Kelso and Smith 1998; Medvec et al. 1999).

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

Reference list entries should be alphabetized by the last names of the first author of each work.

- Journal article

  Harris, M., Karper, E., Stacks, G., Hoffman, D., DeNiro, R., Cruz, P., et al. (2001).

  Writing labs and the Hollywood connection. Journal of Film Writing, 44(3), 213–245.

- Article by DOI

Slifka, M. K., & Whitton, J. L. (2000) Clinical implications of dysregulated cytokine production. Journal of Molecular Medicine, doi:10.1007/s001090000086

- Book

Calfee, R. C., & Valencia, R. R. (1991). APA guide to preparing manuscripts for journal publication. Washington, DC: American Psychological Association.

- Book chapter

O'Neil, J. M., & Egan, J. (1992). Men's and women's gender role journeys: Metaphor for healing, transition, and transformation. In B. R. Wainrib (Ed.), Gender issues across the life cycle (pp. 107–123). New York: Springer.

- Online document

Abou-Allaban, Y., Dell, M. L., Greenberg, W., Lomax, J., Peteet, J., Torres, M., & Cowell, V. (2006). Religious/spiritual commitments and psychiatric practice.

Resource document. American Psychiatric Association. http://www.psych.org/edu/other_res/lib_archives/archives/200604.pdf. Accessed 25 June 2007.

Journal names and book titles should be italicized.

For authors using EndNote, Springer provides an output style that supports the formatting of intext citations and reference list.

EndNote style (zip, 3 kB)

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"The average article length is approximately 30 manuscript pages. For manuscripts exceeding the standard 30 pages, authors should contact the Editor in Chief, Nirbhay N. Singh directly at nirbsingh52@aol.com."

TABLES

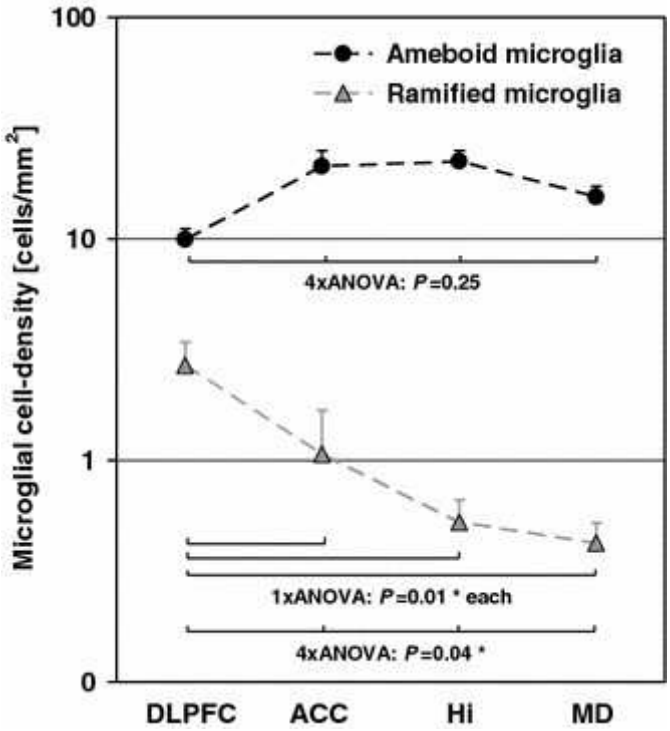
- All tables are to be numbered using Arabic numerals.
- Tables should always be cited in text in consecutive numerical order.
- For each table, please supply a table caption (title) explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.
- Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

ARTWORK AND ILLUSTRATIONS GUIDELINES

Electronic Figure Submission

- Supply all figures electronically.
- Indicate what graphics program was used to create the artwork.
- For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.
- Vector graphics containing fonts must have the fonts embedded in the files.
- Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



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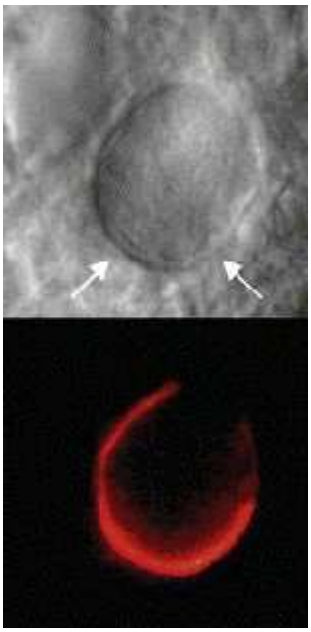
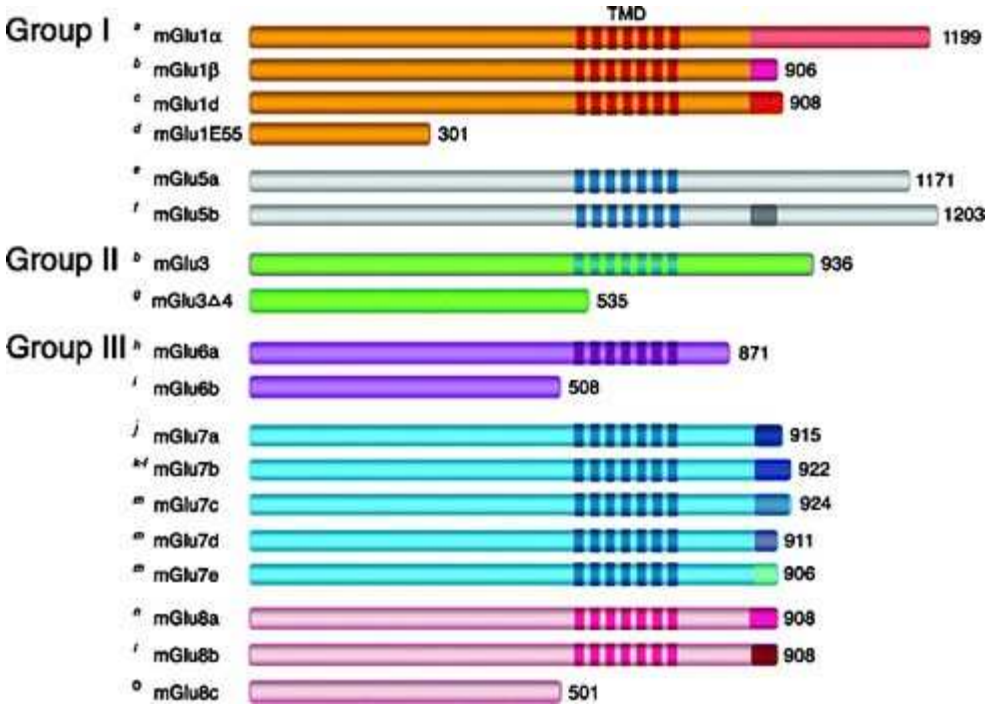


Combination Art



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Appendix W: Critical appraisal

This appendix offers a critical evaluation of the feasibility studies reported in Section B. A number of methodological issues will be considered, including an examination of risk management strategies, dropout significance, different ways of measuring feasibility, and the wider context as to the relevance of engagement in offering a Brief Mindfulness Intervention. Reflections on the research skills and abilities developed by the principal researcher will be explored throughout and then the reporting responsibilities associated with running a study linked to the NIHR portfolio, and how this MRP is independent of these, will be presented.

Risk management strategies

Within my original research protocol I identified a number of risks and developed procedures to manage them, taking into consideration both the likelihood of harm occurring and the degree of harm that could result. A research ethics committee and a trust research and development team approved my research proposal, and this gave me confidence that my risk management strategies were appropriate. Out of all of the risks I considered, the possibility that my research study could generate distress was foremost in my mind. I considered the chance that after undergoing my screening assessment, service users could find out that they either do or do not have a diagnosis of BPD when they previously thought the opposite was the case. Furthermore, I considered that completing my outcome measures could bring service users closer to their lived experience of adversity. My strategies for mitigating these risks included excluding service-users based on vulnerability, ensuring that all of the individuals participating were in receipt of ongoing clinical care from the mental health trust we were recruiting through, providing clear information in

the participant information sheet about the study procedure, reminding participants before, during, and after the screening assessment that they could decline to answer questions and were free to withdraw from the study at any time without giving reason and without any negative effects on future treatment they may receive from the NHS. I also planned to avoid back-to-back sessions and to conduct all assessment sessions in NHS buildings and in normal working hours giving me time to provide any support needed. I developed a letter for participants to be given following the screening assessment to reinforce the assessment outcome, next steps, and further sources of support. I proposed that two appropriately qualified and experienced professionals (i.e. clinical psychologists with experience of facilitating a mindfulness group) would facilitate the mindfulness groups. Therefore, distress during sessions could be actively managed and an opportunity to discuss individual concerns after sessions could also be provided if required.

Two potential participants had registered an interest in the study when it was stopped. I used some of the wording from my 'not eligible' letter in my email informing these two individuals about the study stopping and there were no adverse events or near misses reported. I would therefore consider using similar strategies again in the future. When I received the LiveMind study protocol, I noticed that the procedures for managing the likelihood of generating distress were very similar. Four extra points were included in the LiveMind protocol that I had not explicitly written down when I was developing my original research proposal. These were 1) offering participants a break from assessments or an opportunity to reschedule if needed, 2) passing on concerns to the service users' care coordinator or lead practitioner after discussing their concerns with the service user in the first instance where at all possible, 3) making the limits of confidentiality in this respect explicit, and 4) ensuring that all facilitators receive regular supervision. On reflection, although these were not detailed in my original research protocol, I think that I would have naturally put these

additional strategies into place the occasion arose as they very much mirrored the approach I take to risk management on placement. I remember discussing the point about supervision in a research planning meeting and coming to the conclusion that my supervisors, who had agreed to facilitate the intervention, would meet together to make arrangements for this. However, it was not documented and I can understand the importance of making these points explicit, particularly in the protocol for a larger trial. There were no untoward events or near misses for the LiveMind study indicating that these strategies were successful. Although, there is the outside chance that the lack of issues came about as a result of chance. Nonetheless, excluding individuals at high risk was likely to have increased this chance, and employing strategies to manage those at risk but nevertheless included in the intervention additionally was likely to have increased this chance. With the benefit of hindsight, one thing that was missing from both protocols was the fine details around the procedure for following up on participants who had were uncontactable. In the LiveMind study, this information was passed on to the health care team so that they could check how the individual was doing and reassess risk. In future, I would include this detailed process to avoid the risk that each team (research and clinical) thinks the other team is in contact with a vulnerable individual, when perhaps neither is.

Significance of drop out

In my original research proposal, I planned for the study to be introduced to potential participants by someone they were familiar with (i.e. during routine appointments with the assessment and treatment service). This decision was informed by advice I received from the service-user advisory group ResearchNet. Members of this group shared their experiences of using mental health services and being approached by strangers in the waiting area in relation to clinical research studies. There was a sense that it can be a stressful experience waiting for a clinical

appointment, and while for some having a distraction with recruitment questions could be a positive thing, the majority felt that it would not be helpful. In addition, the group felt that uptake to the study is likely to be higher if someone with more responsibility over their care introduced the study. There was something around knowing that their lead clinician was in support of this extra activity. I shared my experiences with the group of being on the other side of this interaction, as a research assistant, recruiting service-users from the waiting room of a mental health service. We talked about what might improve the experience of hearing about research and the most popular idea was to go through someone with whom the potential participant had already developed a relationship. Based on advice from my research supervisors, I also planned for the study to be advertised directly to participants using a poster in the assessment and treatment service waiting room, and through a mail-out to the research network. The aim of this was to increase the reach of the recruitment campaign in an unobtrusive way. I addition, based on experiences gained from recruiting to previous trials, it felt important to avoid placing too much extra demands on the assessment and treatment service staff.

To support assessment and treatment service staff to fully understand the study, I planned to hand out written information about the study (i.e. the participant information sheet), and to make myself available to answer questions during staff meetings. I was in email contact with the team leader prior to introducing the study to the team and was advised to present the study at a business meeting in order to reach the most clinicians in one go. I introduced the study to the team in August, which was several months later than originally planned. With the benefit of hindsight, it might have been better to delay the beginning of this recruitment drive for one more month because many clinicians were on annual leave. In addition, there were other psychotherapeutic interventions being advertised at the same time. One of the study exclusion criteria was that participants had no plans to engage in any other

interventions during the study period. Therefore, the availability of alternative interventions reduced the number of eligible service-users.

All of the recruitment materials developed for the original research proposal invited potential participants to contact me via telephone or email to express their interest in taking part. No one had made contact at the point the study was withdrawn and this evidence supported my decision to halt the study. However, as mentioned above in the risk management strategies section, two potential participants made contact after the study had been halted. Both of these individuals had heard about the study from the waiting room posters, and I learnt through this that poster recruitment has the potential to be a very helpful adjunct, with little extra cost, to other methods of recruitment.

My analysis of the research activity in LiveMind indicated that engagement with the study and the intervention fell a little short of the targets set. The same recruitment methods had been used, with posters and referrals from an assessment and treatment service. Although a team of research assistants and clinical research coordinators had recruited to the study rather than just one researcher in isolation. There was no data gathered about the way in which participants had heard about the study. This meant that I was unable to compare the relative success of different recruitment methods. In a future feasibility trial, this might be useful information to gather because it could inform the design of the recruitment methods in a full-scale trial leading to more efficient methods. Additional strategies included in both study protocols to foster engagement included scheduling meetings with participants at a time and place that was convenient, and encouraging participants to ask questions if they had any queries at any stage of the study. Despite this effort to engage participants, the log had details of participants who had dropped out. It struck me, when I was reading this, that several participants were assumed to have dropped out after several attempts to contact them had failed. Therefore, these individuals had

not been offered the opportunity to take part in the change interview. Only one participant who had dropped out of the intervention engaged with the qualitative interview. It is therefore possible that some of the more robust barriers to taking part were not captured by the study. If I were conducting this research again, I would perhaps add in an extra procedure after dropout from the intervention to distinguish between this and dropout from the study. In addition, based on the need for further engagement strategies, I would consider adding more regular phone calls between the research team and participants in a future trial. I also think that reimbursing travel expenses incurred by research activities (i.e. travelling to meet a researcher to complete measures) is important and has the potential to increase engagement in research.

Different ways of measuring feasibility

Both of the feasibility studies described in section B of this thesis addressed the issues of recruitment, retention, acceptability, and preliminary efficacy in relation to a brief mindfulness intervention. This fits with the MRC guidelines for the development and evaluation of complex interventions (reference). There are, however, a number of other ways of measuring feasibility in clinical psychology (reference). For example, the acceptability of the intervention to providers, the consistency with which the intervention is delivered, and costs to patients, carers, and society. (research other models of feasibility in clinical psychology to expand this section slightly). Cost has particular relevance in the current economic climate, as socio-economic forces continue to impinge on service delivery. A limitation of the reported study is that it did not investigate any of these issues. The MRC guidelines state that a series of feasibility studies may be required to progressively refine the design of a study investigating a complex intervention. Therefore, a pilot study may be warranted to address uncertainties identified by this feasibility study and any

outstanding feasibility issues. Alternatively, a full-scale trial could helpfully address some of these issues by including additional outcome measures (i.e. addressing cost-effectiveness by including economic outcomes).

The wider context as to the relevance of engagement in offering a Brief Mindfulness Intervention

The research I have conducted over the course of this doctoral training has taught me that there is a place for brief mindfulness interventions in secondary care mental health services. Evidence suggests that adherence to interventions and care outcomes improve when individuals are more involved in informed shared decision making (Towle & Godolphin, 1999). Therefore, at the very least, a brief mindfulness intervention that is delivered in a group format, is acceptable, and does not cause any harm, can provide an opportunity for experiencing a psychotherapeutic intervention in a safe way. This can subsequently place individuals in a better position to provide more fully informed consent for future group psychotherapeutic interventions.

A question remains around the impact of offering a brief mindfulness intervention to transdiagnostic groups in contrast to narrower populations of individuals with very similar difficulties. I learnt from the recruitment difficulties I encountered while delivering my original research proposal, that one of the dominant opinions in the setting I was conducting my research in was that the benefits of diagnostic labels are extremely limited. Teaching throughout my clinical training has introduced me to the idea that the clinical utility of mental health diagnoses has shifted over time. Evidenced in particular by the fierce debate that arose around the time of the publication of DSM-5. While presented my original study to the assessment and treatment service, I heard the term ‘emotionally unstable personality

disorder' and it's abbreviation 'EUPD' used. This refers to an ICD-10 diagnosis that is considered to be broadly equivalent to BPD. However, the way in which the term was used by the team was starkly different to the way I heard the term BPD being used in that it sounded less pejorative. My impression was that the transdiagnostic approach to the brief mindfulness intervention that was being investigated through the LiveMind study was more acceptable to the team. Therefore a level of engagement was generated that may have spread out from clinicians to service-users through the language used when referring to the study. With the benefit of hindsight, if I were conducted the research again, I would consider seeking guidance on the accessibility and acceptability of study materials from clinicians as well as a service-user advisory group, particularly for research in which recruitment is partially reliant on clinician referrals.

Reporting responsibilities

The empirical study presented in section B of this MRP is independent from the reporting responsibilities to the NIHR portfolio, as the findings were used as an archival dataset. The research activity coordinator was responsible for uploading the number of consented participants to the portfolio on a monthly basis. My roles and responsibilities in relation to the empirical study were entry, tidying and screening of data, reviewing electronic records to extract additional demographic data, transcribing interviews, refining plans for quantitative analysis, developing research questions and devising an analytic plan for qualitative data, conducting analyses and interpreting findings. The Salomons course team approved this approach on the basis that I had already developed the competencies of devising a proposal and taking it all the way through the regulatory process. Although my first study fell through, it was nonetheless a good learning experience as it allowed me to choose measures, write an ethics form, and start the process in relation to recruitment. On a

personal level I also learnt to recognize my limits in relation to prior research knowledge and experience, and I learnt how to go about asking for additional help and support. One area I feel I would like more experience of in the future is the specifics around data collection, as that is the bit I feel I missed. However, as the course guidelines state that MRP's don't have to do demonstrate every research method, and some use archival data, I feel satisfied that the research I conducted meets the marking criteria as outlined in the course handbook.

References

Towle, A., & Godolphin, W. (1999). Framework for teaching and learning informed shared decision making. BMJ : British Medical Journal, 319(7212), 766–771.