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Mindfulness-based exposure and response prevention for obsessive compulsive disorder: Findings from a pilot randomised controlled trial

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ABSTRACT

Background: Only about half of people with obsessive compulsive disorder (OCD) show clinically significant improvement following the recommended therapy, exposure and response prevention (ERP), partly due to poor therapy acceptability. A mindfulness-based approach to ERP (MB-ERP) has the potential to improve acceptability and outcomes.

Methods: This was an internal pilot randomised controlled trial (RCT) of group MB-ERP compared to group ERP. 37 participants meeting DSM-IV OCD criteria were randomly allocated to MB-ERP or ERP.

Results: Both groups improved in OCD symptom severity. However, MB-ERP did not lead to clinically important improvements in OCD symptom severity at post-intervention compared to ERP – the minimum clinically important difference was not contained in the 95% confidence intervals. There were negligible between-group differences in engagement and MB-ERP did not appear to have broader benefits compared to ERP on depression, wellbeing or OCD-related beliefs. Conversely, MB-ERP led to medium/medium-large improvements in mindfulness compared to ERP.

Conclusions: MB-ERP is unlikely to lead to clinically meaningful improvements in OCD symptom severity compared to ERP alone. We underline the importance of adhering to treatment guidelines recommending ERP for OCD. Insufficient attention may have been given to mindfulness practice/discussion in MB-ERP and further research is recommended to explore this possibility.

1. Introduction

Obsessive compulsive disorder (OCD) is characterised by persistent intrusive thoughts that cause significant anxiety and repetitive behaviours aimed at neutralising anxiety or preventing a dreaded event (American Psychiatric Association, 2013). OCD has a lifetime prevalence of 0.7–2.5 percent (Crino, Slade, & Andrews, 2005) and is associated with poor quality of life (Macy et al., 2013).

Practice guidelines recommend exposure and response prevention (ERP), delivered with or without cognitive therapy, as the psychological therapy for OCD (American Psychiatric Association, 2007; National Institute of Health and Care Excellence [NICE], 2005). Whilst ERP is effective for OCD, around 50% of people do not recover after therapy (Öst, Havnen, Hansen, & Kvale, 2015).

Exposure-based therapies are theorised to work through habituation to the obsession (Ponniah, Magiati, & Hollon, 2013) and/or through inhibitory learning, i.e. strengthening competing non-fear memories about the feared object/event (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014). Frequent, repeated exposure tasks are required for both these processes to occur, with inhibitory learning theory emphasising the context-specific nature of new learning (Craske et al., 2014). Recovery is therefore unlikely in the absence of frequent, repeated ERP tasks performed in various contexts. By definition ERP is anxiety-provoking and yet, people with OCD can be particularly intolerant of anxiety (Cougle, Timpano, Fitch, & Hawkins, 2011; Olatunji, Deacon, & Abramowitz, 2009). It has been suggested that poor engagement with ERP might explain disappointing recovery rates. Indeed, a naturalistic study found that 25% of adults with OCD refused CBT despite professional recommendation (Mancebo, Eisen, Sibrava, Dyck, & Rasmussen, 2011) whilst Öst et al., Öst et al. (2015) reported a 19.1% dropout rate for ERP. Even when people complete a course of ERP, task engagement may be insufficient to achieve recovery. For example, Simpson et al.

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(2011) found that adherence to between-session ERP tasks significantly predicted treatment outcome and that adherence had to be high (75–90% of all ERP task assignments) to achieve a clinically significant change in OCD symptoms.

Enhancing the acceptability of ERP might increase engagement and thereby improve outcomes. Mindfulness can be defined as "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994) (p. 4). It can be cultivated through mindfulness practice to increase non-judgemental awareness and skills in responding to thoughts and feelings (Bishop, 2004). Mindfulness-based interventions (MBIs) have demonstrated positive outcomes for clinical populations with a broad range of mental health difficulties (Khoury et al., 2013; Kuyken et al., 2016; Strauss, Cavanagh, Oliver, & Pettman, 2014). Preliminary evidence suggests that MBIs could also benefit OCD (Hale, Strauss, & Taylor, 2013; Key, Rowa, Bieling, McCabe, & Pawluk, 2017). Metacognitive Therapy is an approach with some theoretical and therapeutic similarities to MBIs (Wells, 1997). In the treatment of OCD, metacognitive beliefs about intrusive thoughts are identified and reappraised and what is termed 'detached mindfulness' exercises are practiced. This involves noticing intrusive thoughts and allowing them to naturally pass without engaging with them. Preliminary research on Metacognitive Therapy for OCD suggests it can lead to clinically important changes in symptom severity (Fisher & Wells, 2008). Whilst MBIs and related approaches has potential in the treatment of OCD there is a risk that the benefits of ERP are lost in these novel approaches. Given the strength of evidence for ERP (Öst et al., 2015), we suggest combining an MBI with ERP has the greatest potential to provide benefit.

The present study proposes that a mindfulness-based approach to ERP (MB-ERP) could enhance engagement in ERP and improve outcomes for three reasons. First, through mindfulness practice and discussion, MBIs invite and support people to allow thoughts into awareness with acceptance, and without judging or attempting to suppress them (Segal, Williams, & Teasdale, 2013). Whilst traditional ERP involves exposure to intrusive thoughts as a core part of the therapy, strategies to facilitate exposure to intrusive thoughts are not well established and may in part explain poor rates of ERP task engagement. We suggest that guided mindfulness practice could enable people to fully exposure to intrusive thoughts. In-the-moment verbal guidance is given during mindfulness practice in session and between-session mindfulness practice is supported through the use of audio recordings. The verbal guidance encourages noticing and sitting with difficult thoughts as they arise with curiosity and acceptance. Therefore MB-ERP could enable people to expose to and accept intrusive thoughts and to remain engaged in ERP tasks despite such thoughts. Second, people with OCD have a heightened intolerance of anxiety (Cougle et al., 2011). This is particularly problematic for ERP which by definition is an anxiety-provoking intervention. Whilst traditional ERP encourages people to stay with feelings of anxiety during tasks as a core part of the intervention, strategies that enable people to do this are not well understood and may well explain poor rates of engagement with ERP tasks. We suggest that a mindfulness-based approach could provide a means to cultivate the ability to sit with high levels of anxious arousal. Guided mindfulness practice invites people to carefully observe and accept unpleasant physical sensations of anxiety with a sense of kindness and curiosity, and in-the-moment verbal guidance may be particularly important when cultivating this ability in the face of present-moment anxiety (Segal et al., 2013). Therefore, MB-ERP could provide a means through which people are better able to attend to and accept these sensations during ERP tasks and nevertheless, sustain task engagement. Third, MBIs encourage people to be aware of behavioural choices available in response to an event, rather than reacting automatically (Segal et al., 2013).Guidance offered during mindfulness practice draws attention to in-the-moment behavioural choices that may otherwise go unnoticed. We suggest that this may help to cultivate the ability to notice and choose how best to respond to compulsive urges rather than reacting to them automatically. MB-ERP could therefore help people to consciously choose to resist urges to engage in compulsions during ERP tasks.

In line with MRC guidance in the UK on the sequential phases of development of RCTs for complex interventions (Medical Research Council, 1998) and from the National Institute for Health Research in the UK (National Institute for Health Research, 2017), this study was an internal pilot RCT conducted in anticipation of a definitive trial that examines whether group MB-ERP is more effective at reducing OCD symptom severity and better at enhancing therapy engagement than standard group ERP for people with OCD. An internal pilot RCT is a smaller version of a fully powered definitive trial that is run prior to the definitive trial to check trial procedures are running smoothly and to estimate the sample size required for the definitive trial, and indeed to determine if a definitive trial is warranted (National Institute for Health Research, 2017). The primary aim of this internal pilot study was to estimate the size and direction of the potential treatment effect, and the corresponding 95% confidence interval, by comparing MB-ERP groups to standard ERP groups on the primary outcome measures of OCD symptom severity and therapy engagement. Measures of other outcome (depression and wellbeing) and process (mindfulness and obsessive-compulsive beliefs) were included.

A definitive trial of the same study design was planned if the direction of potential treatment effect was in favour of MB-ERP over ERP. Hypotheses for the definitive trial would be that MB-ERP in comparison to ERP would lead to greater improvements in OCD symptom severity at post-intervention (primary hypothesis), and that this would be mediated by greater engagement with ERP tasks. Greater improvements in depression symptom severity and wellbeing (secondary hypotheses) and greater improvements in mindfulness and obsessive-compulsive beliefs (process hypotheses) for MB-ERP in comparison to ERP would also be hypothesised.

2. Material method

2.1. Design and sample size

This is an internal pilot for a pragmatic single centre, assessor-blind, superiority RCT, with two parallel-groups and 1:1 allocation to either MB-ERP or ERP alone. The trial was registered prior to recruitment commencing (ISRCTN52684820. Registered on 30 January 2014) and the therapy protocol was published prior to recruitment ending ([author names removed to preserve anonymity]). This study received ethical approval through the South East Coast (Surrey) arm of the National Research Ethics System in the UK (reference: 13/LO/1768). Recruitment occurred between March 2014 and January 2015.

2.2. Participants

Inclusion criteria were that participants: (1) met DSM-IV (American Psychiatric Association, 2013) diagnostic criteria for OCD based on the Mini International Neuropsychiatric Interview [MINI 6.0.0] (Sheehan et al., 2010); (2) were stable on psychiatric medication for at least 3 months prior to consent; (3) had no plans for changing psychiatric medication during the study; (4) had not received psychological therapy in the past three months and had no plans for commencing therapy during the study; and (5) were 18 years or older. It should be noted that the DSM-IV version of the MINI (6.0.0) was used as the DSM-5 version (MINI 7.0.0) was not available at the time of recruitment.

People were excluded if they had an identified organic cause for their OCD symptoms, a diagnosed learning disability, or met DSM-IV diagnostic criteria for a psychotic disorder, post-traumatic stress disorder (PTSD), anorexia nervosa, alcohol abuse or substance abuse based on MINI 6.0.0 interview (Sheehan et al., 2010). Psychosis, anorexia and PTSD were exclusion criteria because of concerns that mindfulness practice can heighten distress or exacerbate symptoms in the face of

psychotic experiences, bodily sensations and cognitions associated with anorexia and in the face of intrusive traumatic memories. Research exploring the safety of MBIs in these populations is limited and as such they were added as exclusion criteria. People with hoarding-only compulsions were excluded as this is no longer considered a subtype of OCD (American Psychiatric Association, 2013).

2.3. Procedure

Recruitment occurred in two sites within an NHS Mental Health Trust in the South of the England. The research assistant completed baseline assessments within four weeks of the therapy groups starting. Following the baseline assessment, participants were randomly allocated to an MB-ERP or an ERP group. Measures were taken at baseline (Time 1), post-therapy (Time 2) and at 6-months post-therapy (Time 3).

2.4. Interventions

Further details of the intervention protocols are in the published protocol ([author names removed to preserve anonymity]). To minimise therapist effects all therapy sessions (MB-ERP and ERP) were facilitated by the same two clinical psychologists, one of whom was an accredited Cognitive Behavioural Therapy (CBT) therapist and accredited MBCT teacher. Supervision was provided for both group facilitators by an expert in ERP. Mindfulness supervision was provided by an accredited MBCT supervisor

2.4.1. ERP groups

The ERP group consisted of 10 two-hour sessions based on treatment recommendations derived from inhibitory learning theory (Abramowitz & Arch, 2014; Arch & Abramowitz, 2015). Session 1 introduced the rationale for ERP. Sessions 2–9 involved participants designing in-vivo and between-session ERP tasks. Participants were strongly encouraged to engage in their planned ERP tasks at least daily between group sessions and to use their ERP daily diaries to monitor engagement with tasks. Participants were also encouraged to conduct unplanned ERP tasks in daily life when facing obsessional cues. Session 10 focused on consolidating learning. If a participant missed a session they were contacted by phone by one of the group facilitators immediately after the session to explore reasons for missing the session and to identify and plan daily ERP tasks.

2.4.2. MB-ERP groups

The MB-ERP group consisted of 10 two-hour sessions. Session 1 introduced the rationale for ERP alongside the rationale for including mindfulness. Sessions 2–9 each began with a 10-min guided mindfulness practice: mindfulness of the breath and body (session 1); mindfulness of the breath, body, sounds and (intrusive) thoughts (sessions 2–3); mindfulness of (intrusive) thoughts (session 4–5); and mindfulness of body, (intrusive) thoughts, urges and action (sessions 6–10). Verbal guidance for the mindfulness practice was developed particularly for this study by an expert in MBIs and OCD, focusing on the three mechanisms outlined earlier: (1) mindfulness of intrusive thoughts, (2) mindfulness of body sensations of anxiety, and (3) mindfulness of compulsive urges. The guidance differed to that found in MBCT and other related approaches. The verbal guidance explicitly invited people to notice intrusive thoughts, bodily sensations associated with intrusive thoughts/anxiety and compulsive urges and to bring a sense of acceptance to these experiences. Mindfulness practices were followed by a 20-min Socratic inquiry. A three-minute mindfulness breathing space practice (Segal, Williams, & Teasdale, 2002) was also introduced from session 6 onwards. The final 90 min of MB-ERP session followed the same ERP protocol outlined above. During ERP tasks, participants were encouraged to bring mindfulness to the tasks. Session 10 focused on consolidating learning from the therapy. If a participant missed a session they were contacted by phone by one of the group facilitators immediately after the session to explore reasons for missing the session, to identify and plan daily ERP tasks and to support continued home mindfulness practice.

2.5. Outcome measures

2.5.1. Therapy fidelity

Therapy sessions were audio recorded and three randomly selected sessions from each group in each site were rated for fidelity to the relevant protocol (MB-ERP or ERP) by an OCD expert. Each element of the therapy protocol was scored on a 0–2 scale (0 = element not present; 1 = element partially present; 2 = element fully present) and total percentage fidelity calculated.

2.5.2. Diagnostic status

The Mini International Neuropsychiatric Interview (MINI version 6.0.0) (Sheehan et al., 2010). DSM-IV OCD diagnosis was established at all time points using the OCD section of the MINI 6.0.0. At baseline, in order to determine possible reasons for exclusion, the MINI 6.0.0 was also administered for psychotic disorder, post-traumatic stress disorder, anorexia nervosa, alcohol abuse or substance abuse.

2.5.3. Primary outcome measures

Yale-Brown Obsessive Compulsive Scale – Second Edition (YBOCS-II) (Goodman, Rasmussen, Price, & Storch, 2006). The YBOCS-II is a measure of OCD symptom severity and has excellent indices of reliability and validity (Storch et al., 2010). The overall score for YBOCS-II varies between 0 and 50 with ten items, each rated on a 0–5 scale, with higher scores indicating greater OCD symptom severity. A minimum clinically important difference (MCID) of 5 would represent an average difference of 0.5 per item. This was determined through consultation with the Lived Experience Advisory Panel (LEAP) for the study who provided consultation during the development and implementation of the trial. The LEAP suggested that an average improvement of half a point per item on the YBOCS-II would constitute a meaningful level of improvement.

ERP engagement. Engagement was measured as: (1) the number of therapy sessions attended (0–10), and (2) the number of ERP tasks performed between sessions. Participants were given daily diaries to record ERP home tasks.

2.5.4. Secondary outcome measures

Short Warwick-Edinburgh Mental Well-Being Scale (Stewart-Brown et al., 2009). This is a 7-item measure of well-being with items rated on a 5-point scale (items rated 1–5). A higher score indicates greater wellbeing. Stewart-Brown et al. (2011) reported strong internal consistency, test re-test reliability, and concurrent validity and found that the measure is sensitive to change in mental health populations.

Beck Depression Inventory – second edition (BDI-II) (Beck, Steer, & Brown, 1996). The BDI-II is a 21-item measure of depressive symptom severity with items rated on a 4-point (0–3) scale. Higher scores indicate greater depressive symptom severity. It has excellent internal consistency and test re-test reliability ($\alpha > 0.9$ for both). Concurrent validity with the Hamilton Psychiatric Rating Scale for Depression-Revised is good ($r = 0.71$).

Five-Facet Mindfulness Questionnaire – Short Form (FFMQ-SF) (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006; Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer, 2011). The FFMQ-SF is a 24-item self-report scale assessing five mindfulness factors: observing, describing, acting with awareness, non-judgement and non-reacting. Items are rated on a 5-point (1–5) scale and higher subscale/scale totals indicate greater levels of mindfulness. The short form has adequate indices of reliability ($\alpha > .73$ for each subscale) and validity (Bohlmeijer et al., 2011).

Obsessional Beliefs Questionnaire – Revised (OBQ-44) (Obsessive Compulsive Cognitions Working Group, 2005). The OBQ-44 is a 44-item self-report measure of OCD-related cognitions with items rated on

a 7-point (1–7 scale). Higher scores indicate greater endorsement of problematic OCD-related cognitions. The instrument has three subscales: (1) Responsibility/Threat Estimation, (2) Perfectionism/Certainty, and (3) Importance/Control of thoughts. The scales have excellent internal consistency ($\alpha > .89$ for each subscale), and the total score on the OBQ-44 distinguishes between people diagnosed with OCD and non-OCD anxious controls (OCCWG, 2005).

2.5.5. Attrition

Attrition was defined as the number of participants dropping out of the study for each study arm and at each time point.

2.6. Stop/go criteria

In order to proceed to a definitive trial, the between-group post-intervention difference on the YBOCS-II would need to be greater than 0 in favour of MB-ERP and the 95% CI for this effect would need to include the minimum clinically important difference (MCID) of 5 points.

2.7. Sample size

The sample size for this study was based on the recommended minimum of 12 completer participants per arm for a pilot RCT (Julious, 2005). We aimed to recruit approximately 20 people per arm to conservatively allow for up to 40% attrition.

2.8. Randomisation and blinding

To conceal allocation from the research team, an online randomisation system was set up by the independent Clinical Trials Unit (CTU) using 1:1 allocation to either an ERP group or a MB-ERP group using blocks of size two. The CTU were blind to participant details. A research assistant enrolled participants and assigned them to interventions through the CTU online system. The first and second set of groups took place in the two sites seven months apart. Post-therapy and six-month follow-up assessments were completed by a research assistant blind to treatment allocation. Breaches to research assistant blinding were addressed by recruiting another blinded research assistant to conduct the assessment. All participants were blind to study hypotheses.

2.9. Data & safety monitoring

During the study three Trial Steering Committee meetings were held to discuss the study's progress and report any adverse events. Data quality assurance was overseen by the trial statistician who co-ordinated a data checking process where 16% of the study data was re-entered by a research assistant external to the study and then checked for inconsistencies.

2.10. Data analysis

In line with the advice and guidance in the literature for evaluating pilot RCTs we did not carry out any hypothesis tests because the study was not intended or powered to detect statistically significant effects (Leon, Davis, & Kraemer, 2011). In pilot trials the guidance is only to report descriptive statistics (Lee, Whitehead, Jacques, & Julious, 2014). We report descriptive statistics for all participant characteristics and clinical outcomes in the form of counts, proportions, means, standard deviations and ranges as appropriate. Analysis was carried out on an intention-to-treat principle so all participant data was analysed according to their randomisation allocation. We were also interested in estimating treatment effects to look for an indication of potential superiority of the MB-ERP over ERP treatment on the primary outcome. Treatment effects were calculated at both post-therapy and the six-month follow-up time points separately using Linear Regression with the clinical measure as the outcome. Treatment group (ERP or MB-ERP) was entered into the regression as a factor and baseline clinical measures were entered as covariates. Corresponding 95% confidence intervals were calculated for all treatment effects. As the analysis was exploratory, no corrections were made for missing data in the analysis. Cohen's d was calculated from the unstandardized estimate of the between group difference divided by the pooled baseline standard deviation.

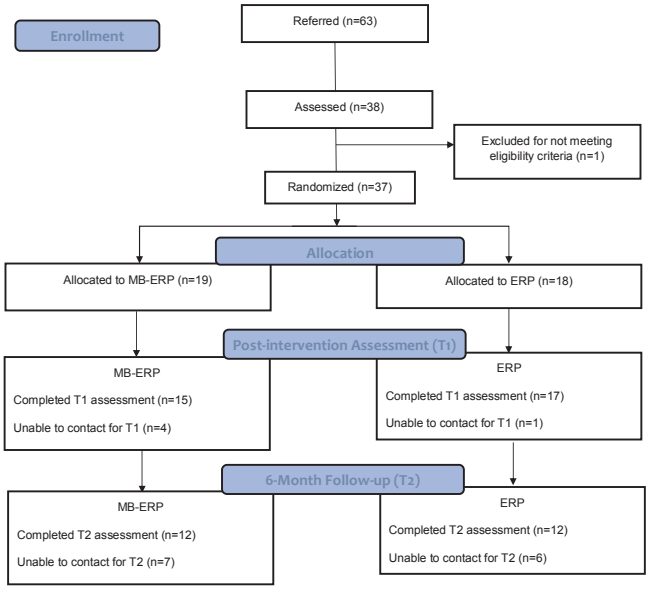

Fig. 1. CONSORT Diagram showing participant flow through the study.

3. Results

3.1. Participant and study characteristics

The consort diagram (Fig. 1) shows the trial profile. In total, 37 participants were randomised to an MB-ERP (n = 19) or ERP (n = 18) group. One person was screened out due to meeting exclusion criteria. Participant characteristics are shown in Table 1. All baseline participant characteristics were similar between groups.

Study retention was good at post-therapy: 86% of participants were followed up post-therapy and drop-outs totalled 1 (5.6%) participant in the ERP group and 4 (21%) in the MB-ERP group. The 6-months follow-up rate of 65% was below target; 6 (33%) participants dropped out from the ERP group and 7 (37%) from MB-ERP.

Data completeness for participants retained in the study was 97% at post-therapy and 87% at follow-up. The lower level of data completeness at follow-up was due to 3 (13%) participants providing incomplete scores on parts of the OBQ. On the primary outcome, data was only missing due to non-collection for 1 (4%) participant at follow-up.

Homework data collection was poor with 72% and 55% of weekly ERP homework diaries missing in the ERP and MB-ERP groups, respectively. In addition, 63% of the mindfulness diaries were missing in the MB-ERP group.

3.2. Main outcomes

3.2.1. OCD symptom severity

Table 2 shows the distribution of clinical outcomes by study arm by time point. At baseline, the distribution of YBOCS-II was similar in the two study arms with a mean of 29.1 (SD 6; range 19–40) in the MB-ERP group and 29.8 (SD 7.6; range 13–46) in the ERP group. Any between-group differences for all clinical outcomes were negligible at baseline.

The post-therapy distributions of the YBOCS-II indicated mean pre-

Table 1
Descriptive summary of participant characteristics.

	MB-ERP N = 19		ERP N = 18	
Gender				
Female	15	79%	9	50%
Male	4	21%	9	50%
Age median years (range)	33	(21–49)	27	(18–51)
Ethnicity				
White British	18	95%	18	100%
Black & Minority Ethnic	1	5%	0	0%
Site				
Site 1	10	53%	9	50%
Site 2	9	47%	9	50%
Employment Status				
Employed	12	63%	10	56%
Unemployed	4	21%	6	33%
Other	3	16%	2	11%
Education Level				
Left school before 16	4	21%	0	0%
Left school at 16	5	26%	3	17%
Left school at 17/18	1	5%	0	0%
Completing/completed College	4	21%	6	33%
Completing/completed University	5	26%	9	50%
Marriage Status				
single	12	63%	11	61%
married/civil partnership	4	21%	3	17%
cohabiting	3	16%	3	17%
separated/divorced	0	0%	1	6%

Values are numbers (percentages) unless otherwise indicated.

post therapy change in both study arms of 6.1 points in the MB-ERP arm and 9.1 points in ERP which increased from pre-therapy to six-month follow-up:10.8 points in the MB-ERP arm and 11.3 points in the ERP arm.

Table 3 shows estimated effect sizes for each clinical outcome by time point. At post-intervention, the between-group difference was 2.4 YBOCS-II points (95% CI −3.8 to 8.6) with a corresponding Cohen's *d* of 0.36 (95% CI −0.37,1.08) in favour of ERP. At 6-months follow-up the between-group difference was 0.3 YBOCS-II points in favour of MB-ERP (95% CI −11.4 to 10.8), Cohen's $d = -0.04$ (95% CI −0.9,0.8), suggesting negligible between-group differences. The 95% confidence interval at post-intervention excludes the minimum clinically importance difference (MCID) of a five point between-group difference on the YBOCS-II.

3.2.2. Engagement

A mean of 6.5 sessions (SD 3.4; range 0–10) out of 10 were attended with little difference between the two groups: MB-ERP had a mean session attendance of 6.6 (SD 3.4; range 1–10) and ERP had 6.4 (SD 3.4; range 0–10). The average number of ERP tasks per week was 20 in the ERP group and 16 in the MB-ERP group. On average five formal mindfulness practices were reported each week by participants in the MB-ERP arm.

3.2.3. Therapy fidelity

Therapist fidelity to the ERP and MB-ERP protocols were high at 90% and 93% respectively.

3.2.4. Secondary outcomes

Following treatment, participants in the MB-ERP condition showed greater levels of mindfulness on all subscales of the FFMQ compared to ERP. Between-group differences on FFMQ total was 6.0 points at post-intervention (95% CI −1.4,13.4), a medium effect (Cohen's $d = 0.53$) and 7.9 points at 6-months follow-up (95% CI −1.6, 17.4), a large effect (Cohen's $d = 0.70$). As shown in Table 3, summary estimates of the other secondary outcomes of wellbeing (SWEMWS) depression (BDI-II) and OCD-related beliefs (OBQ-44) showed negligible, small or medium between-group effect sizes that were mostly but not all in favour of the

Table 2
Descriptive statistics of clinical outcomes by study arm and time point.

		Study Arm			
	Measure	MB-ERP		ERP	
		N	Mean (SD)	N	Mean (SD)
Baseline	YBOCS II	19	29.11 (6.02)	18	29.83 (7.59)
T1		15	22.93 (8.15)	17	21.12 (9.78)
T2		11	17.27 (13.57)	12	18.17 (11.82)
Baseline	SWEMWBS	19	17.84 (3.98)	18	18.89 (4.70)
T1		15	19.33 (5.42)	17	20.29 (4.24)
T2		11	22.00 (5.81)	12	21.50 (5.37)
Baseline	BDI-II	19	25.68 (10.04)	18	25.39 (14.46)
T1		15	22.40 (14.81)	17	16.82 (12.26)
T2		12	17.08 (12.56)	11	17.18 (14.70)
FFMQ-SF					
Baseline	TOTAL	19	63.05 (9.97)	18	63.1 (12.77)
T1		15	74.73 (10.55)	17	69.82 (12.87)
T2		11	79.00 (11.61)	12	72.75 (15.90)
Baseline	Observing	19	12.47 (3.04)	18	11.39 (4.33)
T1		15	13.07 (3.24)	17	10.59 (4.98)
T2		12	14.00 (3.16)	12	12.67 (4.92)
Baseline	Describing	19	15.21 (3.36)	18	14.83 (4.45)
T1		15	16.20 (3.41)	17	16.18 (4.32)
T2		12	17.00 (2.63)	12	17.17 (4.76)
Baseline	Acting with Awareness	19	12.74 (4.29)	18	14.44 (4.55)
T1		15	15.33 (3.90)	17	15.94 (4.66)
T2		12	15.92 (3.68)	12	15.75 (5.10)
Baseline	Non-judging	19	11.00 (2.49)	18	12.67 (3.43)
T1		15	15.53 (3.74)	17	14.29 (3.95)
T2		11	15.64 (5.03)	12	13.92 (4.62)
Baseline	Non-reacting	19	11.63 (2.45)	18	10.28 (3.23)
T1		15	14.60 (4.12)	17	12.82 (3.56)
T2		12	15.67 (4.60)	12	13.25 (4.41)
OBQ-44					
Baseline	Total	19	201.58 (35.35)	18	201.39 (48.85)
T1		14	174.39 (53.01)	16	157.16 (48.18)
T2		9	166.44 (59.25)	12	159.83 (38.97)
Baseline	Responsibility/Threat estimation	19	78.32 (21.20)	18	77.94 (19.39)
T1		15	68.43 (23.50)	16	63.75 (21.21)
T2		10	66.90 (24.94)	12	63.25 (23.35)
Baseline	Perfectionism/Certainty	19	82.63 (16.16)	18	72.78 (25.08)
T1		15	72.93 (21.01)	16	55.03 (23.85)
T2		11	69.36 (22.73)	12	62.17 (20.67)
Baseline	Importance/Control of thoughts	19	40.63 (13.36)	18	50.67 (16.13)
T1		15	36.20 (16.41)	16	38.38 (14.52)

(*continued on next page*)

Table 2 (*continued*)

Measure	Study Arm			
	MB-ERP		ERP	
	N	Mean (SD)	N	Mean (SD)
T2	12	38.50 (22.81)	12	34.42 (12.66)

Note: Exposure Response Prevention (ERP), Mindfulness Based −Exposure Response Prevention MB-ERP; Yale-Brown Obsessive Compulsive Scale Second Edition (YBOCS II), Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB), Five Facets of Mindfulness Questionnaire − short form (FFMQ-SF), Beck Depression Inventory − second edition (BDI-II), Obsessional Beliefs Questionnaire − 44 item version (OBQ-44); Standard Deviation (SD); Post therapy (T1), 6 months follow-up (T2).

ERP group compared to MB-ERP.

3.2.5. Adverse events and serious adverse events

No adverse events were reported.

4. Discussion

This was an internal pilot RCT of MB-ERP compared to standard ERP groups not intended and underpowered to detect statistically significant effects. However, the 95% confidence intervals for between-group difference in improvements in OCD symptom severity at post-intervention did not include the minimum clinically important difference (MCID) on OCD symptom severity. This means that a definitive trial of the same design would be very unlikely to find that MB-ERP leads to clinically important improvements in OCD symptom severity in comparison to ERP alone. In addition, there were negligible between-group differences on measures of therapy engagement (session attendance and homework task completion).

The study also failed to support the suggestion that the MB-ERP protocol has potential to lead to greater improvements in OCD-related beliefs, depression or wellbeing than ERP alone either at post-therapy or at six-months follow-up. Although the study was underpowered to detect statistically significant differences, it is notable that almost all post-intervention and follow-up scores on the measures of depression, wellbeing and OCD-related beliefs were numerically in favour of ERP in comparison to MB-ERP. Given that the strongest evidence for MBIs in the context of mental health is in the treatment of depression (Kuyken et al., 2016; Strauss et al., 2014) this may seem somewhat surprising. However, MBIs may not be more effective in the treatment of depression when compared to alternative psychological interventions with equivalent therapist contact time (Farb et al., 2018) and therefore the findings in the current study are perhaps not so surprising. However, there was evidence that MB-ERP has the potential to improve mindfulness in comparison to ERP as between-group differences were in favour in MB-ERP at both post-therapy and follow-up, with medium to large effect sizes.

4.1. Findings in context

This study was based on the theoretical reasons proposed for why cultivating mindfulness might benefit outcomes for ERP for OCD (Strauss, Luke, Hayward, & Jones, 2015). First, MB-ERP with its teacher-led experiential mindfulness practice was expected to enable

Table 3
Unstandardised and standardised between-group effect sizes at post treatment and at follow-up.

		Unstandardised effects				Standardised between-group effects	
Clinical Measure	Time point	Effect size	95% CI for effect size	Standard Error	p-value	Cohen's d[a]	95% CI for Cohen's d
YBOCS-II	T1	2.40	(−3.77,8.57)	3.02	0.43	0.36	(−0.37,1.08)
	T2	−0.29	(−11.39,10.82)	5.32	0.96	−0.04	(−0.90,0.81)
SWEMWS	T1	−0.39	(−3.19,2.41)	1.37	0.78	−0.09	(−0.81,0.63)
	T2	1.22	(−2.28,4.72)	1.68	0.48	0.28	(−0.58,1.14)
BDI-II	T1	4.74	(−2.36,11.83)	3.47	0.18	0.39	(−0.34,1.11)
	T2	0.80	(−7.56,9.16)	4.01	0.84	0.07	(−0.79,0.92)
FFMQ-SF							
TOTAL	T1	5.99	(−1.6,17.44)	3.61	0.11	0.53	(−0.20,1.26)
	T2	7.92	(−1.6,17.4)	4.56	0.10	0.70	(−0.18,1.59)
Observing	T1	1.65	(−0.32,3.61)	0.96	0.10	0.44	(−0.28,1.17)
	T2	1.16	(−1.87,4.2)	1.46	0.43	0.31	(−0.53,1.16)
Describing	T1	0.37	(−1.99,2.72)	1.15	0.75	0.09	(−0.62,0.81)
	T2	0.83	(−1.39,3.05)	1.07	0.45	0.21	(−0.63,1.05)
Acting with Awareness	T1	0.55	(−1.91,3.02)	1.21	0.65	0.12	(−0.59,0.84)
	T2	1.26	(−1.48,3.99)	1.31	0.35	0.28	(−0.56,1.12)
Non-Judging	T1	1.91	(−0.99,4.81)	1.42	0.19	0.62	(−0.11,1.36)
	T2	2.32	(−1.95,6.59)	2.05	0.27	0.76	(−0.13,1.64)
Non-reacting	T1	1.14	(−1.64,3.92)	1.36	0.41	0.39	(−0.33,1.12)
	T2	1.58	(−1.68,4.85)	1.57	0.321	0.55	(−0.31,1.40)
OBQ-44							
Total	T1	11.53	(−23.22,46.28)	16.94	0.501	0.28	(−0.47,1.02)
	T2	6.96	(−34.46,48.38)	19.72	0.73	0.17	(−0.74,1.07)
Responsibility/Threat Estimation	T1	0.83	(−13.77,15.44)	7.13	0.91	0.04	(−0.69,0.77)
	T2	−3.05	(−22.37,16.27)	9.23	0.75	−0.15	(−1.03,0.73)
Perfectionism/Certainty	T1	9.09	(−4.61,22.78)	6.69	0.19	0.43	(−0.31,1.16)
	T2	2.46	(−13.16,18.08)	7.49	0.75	0.12	(−0.74,0.97)
Importance/Control of thoughts	T1	1.87	(−9.16,12.9)	5.39	0.73	0.12	(−0.61,0.85)
	T2	8.86	(−7.12,24.84)	7.68	0.26	0.57	(−0.28,1.43)

Note: Yale-Brown Obsessive Compulsive Scale Second Edition (YBOCS-II), Short Warwick-Edinburgh Mental Well-being Scale (SWEMWB), Beck Depression Inventory – second edition (BDI-II), Five Facets of Mindfulness Questionnaire – short form (FFMQ-SF), Obsessional Beliefs Questionnaire – 44 item version (OBQ-44); Standard Deviation (SD); Post therapy (T1), 6 months follow-up (T2); Confidence interval (CI)

[a] In interpreting the direction of effects, a negative Cohen's d would show that outcomes numerically favour MB-ERP in comparison to ERP for the following measures: Y-BOCS-II, BDI-II and OBQ-44. A positive Cohen's d would show that outcomes numerically favour MB-ERP in comparison to ERP for SWEMWS and FFMQ-SF scores.

people to accept intrusive thoughts elicited during ERP tasks and to remain engaged with the task. Second, it was expected, that teacher-guided mindfulness practice would enable people to fully attend to and accept physical sensations of anxiety that occur during ERP and, therefore, to remain fully engaged with the tasks. Third, because mindfulness practice places emphasis on bringing awareness to behavioural choices, MB-ERP was expected to enable people to recognise urges to engage in compulsive behaviours and choose to resist them. Findings from this study do not support these suggestions.

It could be argued that insufficient opportunity for participants to cultivate mindfulness in the MB-ERP groups, may explain the lack of apparent effects on OCD symptom severity. Indeed, time devoted to mindfulness practice and discussion in each session was considerably less than in MBCT. Only 30 min were devoted to mindfulness practice and discussion in each MB-ERP session (five h in total). This is far less than in MBCT, where the majority of 16–20 therapy hours is spent practicing mindfulness and discussing learning from mindfulness practice (Segal et al., 2013). In addition, mindfulness practices in MB-ERP were shorter (15 min maximum) than in MBCT (30 min maximum). Therefore, there was perhaps simply insufficient attention given to cultivating mindfulness in the current study.

Whilst these caveats are important to note, the between-group improvements in mindfulness for MB-ERP compared to ERP are of interest. Despite a reduced focus and time spent on mindfulness practice and discussion compared to MBCT, between-group differences in improvements in mindfulness were in the medium range at post-therapy ($d = 0.53$) and large range at six-months follow-up ($d = 0.70$). These between-group effect sizes on self-reported mindfulness compare favourably with a *meta*-analysis of RCTs of MBIs that reported a medium between-group effect on mindfulness (Hedges $g = 0.47$) (Visted, Vøllestad, Nielsen, & Nielsen, 2015) and with findings that MBIs with brief mindfulness practices can be of clinical benefit (Strauss, Luke, Hayward, & Jones, 2015). This suggests, (with the caveat that this is a pilot trial) that MB-ERP compared to ERP has the potential to improve mindfulness whilst not improving OCD symptom severity or mechanisms of OCD-related beliefs. This challenges the theoretical notion that improving mindfulness should improve OCD symptoms by enabling non-judgemental acceptance of intrusive thoughts, non-judgemental acceptance of bodily sensations of anxiety and greater choice in responding to compulsive urges (Strauss, Luke, et al., 2015).

On average, participants attended 6.5 of the ten group sessions, with little difference in this rate between treatment arms. In order to maximise engagement with each intervention, and in line with the treatment protocols, if a participant missed a session they were contacted by phone by one of the group facilitators immediately after the session to explore reasons for missing the session and to identify and plan daily ERP tasks. In the MB-ERP arm this also included an exploration of experiences of home mindfulness practice and an encouragement to continue with mindfulness practice at home. In future studies further efforts to improve session attendance should be included such as holding groups in venues that minimise the need for participant travel.

4.2. Strengths and limitations

Strengths of this study include its design. Randomisation was conducted independently and post-therapy assessments were conducted blind to allocation. Moreover, and unusually for a study of psychological therapy, participants were blind to study hypotheses, thus reducing a common potential source of bias. The trial protocol ensures transparency in publication.

Limitations of this study also pertain to its design. This is a pilot study, underpowered to detect statistically significant effects and liable to biases inherent in small sample sized studies. Despite this, it is possible to draw conclusions about the primary hypotheses as the 95% confidence intervals for the between-group effect on OCD symptom severity at post-intervention did not include the MCID. This means, that a definitive trial would be highly unlikely to find that MB-ERP is more effective than ERP at improving OCD symptom severity. The design however does mean that we need to be cautious in over-interpreting findings on other outcomes where confidence intervals are wide and cross zero. Another limitation is that no formal measure of intervention acceptability was included. Whist rates of intervention engagement were similar between the two treatment arms, which could be taken as a proxy indicator of intervention acceptability, future research should include a formal measure. A further limitation was that participants in the ERP arm of the study received more therapist-assistant ERP time than MB-ERP participants as a proportion of each MB-ERP session was devoted to mindfulness practice and inquiry. Whilst the addition of mindfulness practice and inquiry was explicitly to improve engagement with ERP, the reduced time spent on ERP tasks may have contributed to the findings. Finally, study retention at follow-up was 65%, lower than expected. It is possible that this has led to a biased account of effects at follow-up if retained participants were those who had better outcomes. Future studies should include methods for improving study retention including maintaining contact with participants during the follow-up period, paying participants for their time to complete assessments and having the option to complete assessments online and so avoid the need for participants to travel.

4.3. Clinical implications

In the context of a proliferation in interest in mindfulness, evidence from our study suggests that adding mindfulness to ERP (at least in the way it was done in this study) may not improve symptom severity compared to ERP alone. Findings suggest that whilst MBIs may have much to offer people experiencing a range of mental health difficulties, we should not abandon well-established, well-evidenced interventions. In short, we recommend that current guidelines for OCD are followed; that people with OCD are given access to ERP with or without cognitive therapy (American Psychiatric Association, 2007; National Institute of Health and Care Excellence [NICE], 2005). This is not to rule out the possibility that MB-ERP may have benefits over ERP for sub-groups of people with OCD and future qualitative and quantitative research could explore this given the theoretical rationale for adding a mindfulness-based approach to ERP.

4.4. Implications

It would be premature to abandon research exploring the potential of learning mindfulness for people experiencing OCD based on the findings of this pilot trial for a number of reasons. As noted above, the amount of time devoted to mindfulness practice and discussion was much reduced compared to well-established interventions such as MBCT. Although the point estimate on between-group differences in mindfulness suggested that MB-ERP can lead to improvements in mindfulness relative to ERP, the 95% confidence interval for this effect crossed zero meaning that this point estimate must be treated cautiously. Future research should examine the effects of cultivating mindfulness for OCD using a more intensive approach, perhaps based on the well-established MBCT protocol, but adapting this for OCD. In addition, whilst speculative, it may be the case that ERP and MB-ERP are effective for different groups of people with OCD. Whilst the current study does not allow an exploration of participant moderators of outcome, qualitative research of MB-ERP may help to elucidate if this intervention has greater potential for subgroups of people with OCD in comparison to ERP. Finally, therapy format (group versus individual) may have a bearing on effectiveness. Whilst group ERP is recommended for OCD (National Institute of Health and Care Excellence [NICE], 2005), an individual approach has potential advantages in terms of more closely tailoring the treatment plan to the participant, more closely monitoring participant progress and facilitating disclosure of shame-related OCD thoughts and beliefs. Future research could explore

the potential of MB-ERP delivered in individual format where such factors could be attended to.

4.5. Conclusions

Although underpowered to draw definitive conclusions, findings from this pilot RCT suggest that adding a brief mindfulness-based intervention to ERP may not lead to clinically meaningful improvements in OCD symptom severity outcomes compared to ERP alone. Furthermore, findings suggest that improvements in mindfulness may not translate into improvements in OCD symptom severity. Clinical implications are to underline the importance of adhering to current treatment guidelines and to continue to offer ERP to people with OCD. Further research is now needed to investigate if a greater focus on cultivating mindfulness and decoupling learning mindfulness from an explicit focus ERP has potential, in addition to exploring participant-level moderators of therapy outcome (i.e. that different approaches may lead to better outcomes for different people). It is important not to abandon work in this area based on findings from the current pilot study, particularly given the sound theoretical reasons why cultivating mindfulness might have much to offer people struggling with OCD.

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Data statement

Due to ethical concerns, supporting data cannot be made openly available. Further information about the data and conditions for access are available by contacting the corresponding author.

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