

BMJ Open Mindfulness-based and acceptance-based programmes in the treatment of obsessive-compulsive disorder: a study protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Cognitive-behavioural therapy (CBT) with exposure and response prevention is the recommended standard for the treatment of obsessive-compulsive disorder (OCD). However, a high proportion of patients refuse this treatment, do not respond or relapse shortly after treatment. Growing evidence suggests that mindfulness-based and acceptance-based programmes (MABPs) are an effective option for the treatment of OCD. This systematic review and meta-analysis will examine the effectiveness of MABPs in treating OCD. We also aimed to explore potential moderators of the programmes' effectiveness.

Methods and analysis We will systematically search MEDLINE, Embase, PsycINFO, PSYINDEX, Web of Science, CINAHL and Cochrane Register of Controlled Trials (no language restrictions) for studies that evaluate the effect of MABPs on patients with OCD. We will conduct backward and forward citation searches of included studies and relevant reviews and contact corresponding authors. The primary outcome will be pre-post intervention change in symptom severity. A secondary outcome will be change in depressive symptoms. Two reviewers will independently screen the records, extract the data and rate the methodological quality of the studies. We will include both controlled and uncontrolled trials. Randomised controlled trials will be meta-analysed, separately assessing between-group effects. A second meta-analysis will assess the within-group effect of all eligible studies. We will explore moderators and sources of heterogeneity such as the specific programme, study design, changes in depressive symptoms, hours of guided treatment, control condition and prior therapy (eg, CBT) using metaregression and subgroup analyses. We will perform sensitivity analyses using follow-up data. A narrative synthesis will also be pursued. We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence.

Ethics and dissemination Ethical approval is not required. Results will be published in peer-reviewed journals and presented at international conferences.

Strengths and limitations of this study

- We conduct the first systematic review and meta-analysis on the effectiveness of mindfulness-based and acceptance-based programmes (MABPs) in the treatment of obsessive-compulsive disorder.
- We separately provide effect estimates for different MABPs, namely, mindfulness-based cognitive therapy and acceptance and commitment therapy.
- We explore potential moderators of the effect and sources of between-study heterogeneity using pre-specified subgroup analyses and meta-regressions.
- Insufficient data might prevent the analysis of potential moderators such as comorbid depressive symptoms.
- We will use the Grading of Recommendations Assessment, Development and Evaluation system to assess the quality of the evidence.

INTRODUCTION

Rationale

Obsessive-compulsive disorder (OCD) is a mental disorder characterised by persistent and intrusive thoughts, urges or images (obsessions) along with repetitive behaviour or mental acts (compulsions; eg, washing, checking and counting).¹ OCD has a lifetime prevalence of approximately 2%.² It is one of the most debilitating mental health conditions, which is difficult and cost-intensive to treat,^{1 3-5} with onset typically occurring in teenage years.^{2 6} OCD usually takes a chronic course in the absence of adequate treatment.⁷ Furthermore, OCD is associated with substantially impaired occupational and social functioning,¹ resulting in a significantly reduced quality of life.⁵ Accordingly, between a third and half of all patients with OCD meet the criteria for a comorbid depression at the time of diagnosis.²

Cognitive-behavioural therapy (CBT) with exposure and response prevention (ERP) has sound evidence for the successful treatment of OCD⁸ and is recommended as the standard treatment. Large effect sizes of approximately Hedge's $g=1.3$ have repeatedly been reported in comparison to control conditions.⁸ However, approximately 15% of patients refuse standard treatment; 15%–25% drop out from the according protocol^{8,9}; up to 30% fail to respond with clinically significant reductions in symptom severity¹⁰; and 20% relapse shortly after treatment.¹¹ This may be due to the inherently fear-provoking and aversive nature of the intervention. ERP is based on the assumption that repeated exposure to the feared stimuli in different contexts is necessary to initiate habituation and inhibitory learning.^{1,12} However, repeated exposure is particularly challenging for patients with OCD as, by definition, they engage in catastrophising interpretations of their intrusive thoughts. Patients with OCD often experience strong fusion between thoughts and actions, making it challenging not to engage in compulsive behaviour.¹³ Willingness to experience unpleasant thoughts, emotions and bodily sensations in an open, accepting and non-judgemental way appears to be a predictor of successful ERP.¹⁴ Therefore, techniques that promote tolerance towards unpleasant thoughts and emotions may address the limitations of classical treatment. Particularly promising approaches for the reduction of symptom severity in OCD are mindfulness-based and acceptance-based programmes (MABPs) such as mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), dialectical-behavioural therapy (DBT) and acceptance and commitment therapy (ACT).^{15–17} MABPs aim to promote the observation of thoughts, emotions and bodily sensations in a non-reactive, open and non-judgemental way.^{17,18} The beneficial effects of MABPs have repeatedly been shown in both clinical and healthy samples.^{18–24}

For the people with OCD, practising mindfulness and cultivating an accepting attitude may foster non-judgemental awareness of obsessive thoughts.^{15,25} This, in turn, may prevent automated thought suppression or neutralisation and promote habituation.²⁶ After prolonged engagement in mindfulness and acceptance practices, patients with OCD may increasingly experience their obsessive thoughts as transient mental events that are distinct from facts.^{27,28} Consequently, mindfulness and acceptance may reduce the perceived importance of intrusive thoughts, and thereby reduce anxiety and the urge for compulsive behaviour.^{15,27} Accordingly, correlative findings suggest that adults with OCD seeking treatment report lower trait mindfulness compared with non-clinical controls.²⁹ Higher self-reported mindfulness is associated with lower symptom severity and higher distress tolerance in patients suffering from OCD.³⁰ Acceptance of present-moment experience is associated with increased willingness to experience intrusive thoughts.³¹ The ability to non-judgementally accept thoughts and emotions predicts the reduction of OCD symptom

severity after CBT.³² Thus, mindfulness and acceptance might be considered as a prerequisite and as an amplifier of ERP and inhibitory learning.¹⁴ However, a causal effect of increased mindfulness and acceptance on the reduction of OCD symptoms can only be shown in studies that aim to manipulate mindfulness and acceptance.

In recent years, a growing number of RCTs^{33–40} and non-randomised trials (NRTs)^{16,25,41–45} on the effectiveness of MABPs for patients diagnosed with OCD have been published. Further RCTs are also expected to be available soon.⁴⁶ Previous reviews hint at the usefulness of MABPs for people with OCD.^{15,16,47,48} However, a systematic review of all available evidence including a meta-analysis on the effectiveness of MABPs in the treatment of OCD is still lacking.

Objectives

In the planned systematic review and meta-analysis, we aim to examine the effectiveness of MABPs for the treatment of OCD. We will explore moderators of the effect and sources of between-study heterogeneity, such as the specific programme, study design, changes in depressive symptoms, hours of guided treatment and prior therapy (eg, CBT). We aim to provide healthcare policy makers, practitioners and researchers with a comprehensive overview of the current body of knowledge in a growing field of intervention research.

METHODS

This protocol follows the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.⁴⁹ We will prepare our systematic review and meta-analysis in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.⁵⁰ We have prospectively registered this systematic review and meta-analysis at the International Prospective Register of Systematic Reviews platform (registration number: CRD42020197308). We will closely follow the rigorous methodology established by the authors of a previous review.^{51,52}

Eligibility criteria

Population

We aimed to examine the effectiveness of MABPs for the treatment of OCD. Eligible study populations include patients who were validly diagnosed with OCD based on *Diagnostic and Statistical Manual of Mental Disorders*-based or *International Classification of Diseases*-based criteria through a validated diagnostic interview or validated self-report (eg, Yale-Brown Obsessive Compulsive Scale (Y-BOCS)). We will exclude trials with non-clinical samples, trials with undiagnosed patients, and trials with mixed samples with different diagnoses or with clinical and non-clinical participants if they cannot be differentiated. Inclusion and exclusion criteria are listed in [table 1](#).

Interventions

Mindfulness can be described as moment-to-moment awareness, cultivated by paying attention to the present

Table 1 Inclusion and exclusion criteria

Criterion	Inclusion	Exclusion
Population	Patients diagnosed with OCD	Non-clinical samples, undiagnosed patients, mixed samples
Intervention	Programmes explicitly based on mindfulness and/or acceptance	Programmes without explicit focus on mindfulness and/or acceptance
Comparator	Randomised controlled trials and non-randomised trials, including non-controlled before–after studies	Case–control studies, single case studies, systematic reviews, meta-analyses, clinical case studies, qualitative studies
Outcome	OCD symptoms measured with validated self-reports and/or clinician rated quantitative measures, pre and post intervention	Self-report questionnaires without validation
Language	All languages	None
Publication date	All dates	None

OCD, obsessive–compulsive disorder.

moment in a non-reactive and non-judgemental way.⁵³ Acceptance can be characterised as the willingness to experience unwanted or unpleasant thoughts or emotions without attempting to avoid, escape, change or terminate them.²⁸ Mindfulness and acceptance are closely related concepts¹⁷ that are often taught jointly in MABPs. Although these programmes are rooted in different traditions, they follow a coherent conceptual foundation¹⁷ and are often jointly investigated in systematic reviews and meta-analyses.^{18–23 54} As we seek to provide a summary of the effectiveness of MABPs in their practical application, we must not neglect the extensive use of various forms of MABPs beyond established programmes based on manuals such as MBSR, MBCT, DBT and ACT. Therefore, we include all eligible references that evaluate manualised MABPs for patients with OCD but also include references that explicitly state that their programme is based on mindfulness and/or acceptance. However, we will exclude interventions that do not explicitly state that they are based on mindfulness or acceptance and those that are only informed by mindfulness or acceptance.

Study design and comparators

We will include RCTs as well as NRTs including non-controlled before–after studies. We will perform a separate meta-analysis on RCTs using between-group data. In the RCTs, all types of randomly assigned control conditions will be accepted. While RCTs allow the most accurate effect estimate,⁵⁵ the exclusion of NRTs may lead to neglecting evidence,⁵⁶ whereas inclusion may enable us to identify moderators within a broader database. We want to provide healthcare policy makers, practitioners and researchers with a comprehensive quantitative and qualitative overview of the current knowledge. To this end, all available evidence will be considered. A second meta-analysis will summarise pre-post intervention data of all eligible studies, including RCTs and NRTs. We will aggregate RCTs according to the control condition used, if at least two studies have chosen the same control condition.

ERP is the standard treatment for OCD. Therefore, studies with ERP as the control condition will be aggregated separately to estimate the potential increment of MABPs and MABPs in combination with ERP over ERP alone.

Outcome measures

The primary outcome will be changes in OCD symptom severity from preintervention to postintervention, assessed using validated measures. We will also examine whether changes are maintained when taking follow-up data. The Y-BOCS is considered the gold standard for the measurement of OCD symptom severity.⁵⁷ For studies applying Y-BOCS, we will extract the overall score. In addition, we will assess changes in depressive symptoms as a secondary outcome, as one-third to one-half of all patients with OCD meet the criteria for a comorbid depression at the time of diagnosis.² Comorbid depression is also associated with elevated levels of suicidality,⁴ mediates treatment success⁵⁸ and predicts completion of the treatment.⁵⁹

Search strategy

Studies indexed in MEDLINE, Embase, PsycINFO, PSYINDEX, Web of Science, CINAHL or Cochrane Register of Controlled Trials (CENTRAL) will be screened, without restrictions for language or publication date.^{51 52} We will translate articles in foreign languages with the help of neural machine translation. Search terms are related to (1) mindfulness and acceptance, (2) programmes/interventions and (3) OCD, using subject headings (including MeSH terms) and text words. Searches in MEDLINE, PsycINFO, PSYINDEX, Web of Science, CINAHL and CENTRAL are specified in the online supplemental material. We will perform also backward and forward citation searches of all included studies and relevant reviews.^{16 47 48} To find studies in the grey literature, we will contact the authors of included studies or relevant conference abstracts of unpublished

studies identified through the database, backward or forward searches.

Study selection

We will use Rayyan⁶⁰ to screen the studies and Zotero⁶¹ to manage the studies. Two reviewers (JJB and JCF) will independently screen titles and abstracts of all articles identified in the bibliographical databases. We will obtain the full text if at least one reviewer judges an article to meet the inclusion criteria. Independent full-text screening by the two reviewers will follow. Discrepancies will be resolved through discussion and consensus. If discrepancies cannot be resolved, a third reviewer (SS) will be consulted. We will calculate Cohen's kappa to determine the agreement between reviewers.⁶² A PRISMA flowchart will illustrate the study selection process.⁵⁰

Data extraction

Two reviewers (JJB and JCF) will independently extract the information from eligible studies using a standardised Excel 2010 extraction sheet. The extraction sheet will be pilot tested and modified if necessary. We will extract information on (1) the study: authors, publication date, country, experimental design and type of control (eg, waitlist, psychoeducation); (2) the population: sample size (treatment/control), dropout rate, mean age, sex ratios, mean duration of illness and prior therapy (eg, CBT); (3) the intervention: duration of an average single session, number of sessions, implemented programme (MBCT, ACT, etc), use of measurement tools for intervention integrity including adherence to the protocol (eg, Mindfulness-Based Interventions–Teaching Assessment Criteria⁶³), treatment standardisation (yes/no), group setting (yes/no), group size and use of measurement tools to assess the clinical and programme experience of the therapist; and (4) the outcomes: means and SD for OCD symptom severity and depressive symptoms for all conditions and measurement points (pre, post and follow-ups). Extracted data will be entered into the statistical software R. We will contact the authors of studies that provide insufficient data.

Risk of bias and quality assessment in individual studies

Two reviewers (JJB and JCF) will independently assess the studies' risk of bias. Discrepancies will be resolved through discussion and consensus. Remaining discrepancies will be discussed and resolved with a third reviewer (SS). For RCTs, we will use the revised Cochrane risk of bias tool for randomised trials (ROB V.2.0).⁶⁴ ROB V.2.0 is a domain-based evaluation considering (1) bias arising from the randomisation process, (2) deviations from intended interventions, (3) missing outcome data, (4) measurement of the outcome and (5) selection of the reported result. Based on the single ratings of domains as 'low risk of bias', 'some concerns' or 'high risk of bias', a corresponding overall rating will be derived. For NRTs, we will use the Effective Public Health Practice Project Quality Assessment tool for quantitative studies (EPHPP).⁶⁵ EPHPP rates the study

quality in eight domains: (1) selection bias, (2) study design, (3) confounders, (4) blinding, (5) data collection methods, (6) withdrawals and dropouts, (7) intervention integrity and (8) quantitative analyses of single studies. Based on the single ratings of domains as 'strong', 'moderate' or 'weak', a corresponding overall rating will be derived. Cohen's kappa will be calculated to determine inter-rater reliability.⁶²

Risk of bias across studies

We will compute Egger's regression test⁶⁶ and Rosenthal's fail-safe N.⁶⁷ In addition, we will visually inspect funnel plots to assess potential publication bias. We will address selective publication and reporting through the retrieval of study registrations and study protocols. To assess the overall quality of the evidence, we will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Dimensions of the GRADE rating are (1) risk of bias, (2) inconsistency of results, (3) indirectness of evidence, (4) imprecision of effect size and (5) publication bias.⁶⁸ Two reviewers (JJB and JCF) will rank the overall quality of evidence into 'high', 'moderate', 'low' or 'very low', reflecting the degree of confidence in the aggregated effect estimate. We will use the GRADE ratings to assess the overall strength of evidence.

Data synthesis

We will analyse identified studies using the intention-to-treat principle.⁵⁵ We will calculate standardised mean differences as effect size in individual studies, using the baseline value and the first assessment following the intervention. To this end, we will compute Hedges' *g*, its 95% CI and associated *p* values. Studies will be weighted using the inverse-variance method. In addition, for those studies assessing OCD symptom severity with Y-BOCS, we will calculate a weighted mean difference. We will carry out two separate meta-analyses: the first meta-analysis will summarise the between-group data of RCTs. The second meta-analysis will summarise the within-group pre-post intervention data of all eligible studies. We will use a random effects model to undertake meta-analytic pooling and produce forest plots for between-group and pre-effect–posteffect sizes. We will assess heterogeneity of included studies by providing *I*² statistics.⁶⁹ In accordance with the Cochrane and GRADE handbooks, *I*² values will be interpreted as unimportant (*P*<40%), moderate (30%–60%), substantial (50%–90%) or considerable heterogeneity (>75%).⁵⁵ To explore the sources of between-study heterogeneity and potential moderators of effects, we prespecify subgroup analyses on the influence of the specific programme, the study design and prior therapy (eg, CBT). Furthermore, we will aggregate RCTs according to the control condition used, if at least two studies have chosen the same control condition. For example, we will perform a subgroup analysis to compare MABPs with MABPs combined with ERP and with ERP alone. Furthermore, we prespecify that if we find at least two studies based on mindfulness or acceptance but added to existing protocols (eg, CBT), we perform a subgroup

analysis to compare their effect to those that involve only mindfulness or acceptance. We prespecify metaregressions to determine the influence of the hours of guided treatment and changes in depressive symptoms. Furthermore, we will conduct sensitivity analyses to examine whether results are maintained when taking follow-up instead of postintervention data. Finally, we will conduct a comprehensive narrative synthesis of the study characteristics. The qualitative synthesis is of special relevance if the heterogeneity of the included studies is considerably large. In accordance with the GRADE approach, we will provide a ‘summary of findings’ table.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

ETHICS AND DISSEMINATION

Ethical approval is not required. Results will be published in peer-reviewed journals and presented at international conferences.

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