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Efficacy of Distress Tolerance Techniques of Dialectical Behavior Therapy in Persons with Obsessive-Compulsive Disorder: a study protocol for a randomized controlled trial

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Abstract

Background

Obsessive-compulsive disorder (OCD) is a chronic and debilitating mental health condition that significantly impairs the quality of life. Although cognitive-behavioral therapy (CBT), particularly exposure and response prevention (ERP), is considered the gold standard, many patients remain symptomatic or find these approaches challenging due to emotional and cognitive barriers. Distress Tolerance Techniques (DTT), a component of Dialectical Behavior Therapy (DBT), have demonstrated efficacy in various conditions, including substance dependence, binge eating, and depression, by managing negative emotional states and enhancing coping mechanisms beyond their original focus on borderline personality disorder. However, the application of DTT in the treatment of patients with OCD has not been extensively explored. This study aims to evaluate the efficacy of DTT in reducing OCD severity and improving psychological outcomes.

Methods

This prospective, single-center, open-label randomized controlled trial will recruit 60 adults (18–40 years) diagnosed with OCD (ICD-10 criteria, Y-BOCS score ≥ 16) from the Department of Psychiatry, All India Institute of Medical Sciences, Bhopal. Participants will be randomized 1:1 using a random number table to either the intervention or active control group. Participants in the intervention group will engage in a 12-week structured DTT program specifically tailored for Obsessive-Compulsive Disorder (OCD), whereas those in the active control group will undergo standard treatment of exposure and response prevention (ERP).The primary outcome will be OCD severity, measured using the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS). Secondary outcomes included distress tolerance (measured using the Distress Tolerance Scale), depressive symptoms (measured using the Beck Depression Inventory), coping strategies (measured using the Dialectical Behavior Therapy-Ways of Coping Checklist), mindfulness (measured using the Kentucky Inventory of Mindfulness Skills), and acceptance (measured using the Acceptance and Action Questionnaire-II). Outcomes for the treatment groups will be evaluated before randomization (baseline, T1) and 12 weeks (end of treatment, T2). The protocol was approved by the Institute Ethical Committee (approval number) and was performed in strict adherence to the Declaration of Helsinki formulated by the World Medical Association.

Discussion

This trial will explore the efficacy of Distress Tolerance Techniques in patients with OCD. This study will provide evidence for a therapeutic approach that addresses the limitations of traditional CBT and improves outcomes for patients with OCD.

Trial Registration:

Central Trial Register of India, CTRI/2024/09/073672, registered on 21 December 2024

Background

Obsessive-compulsive disorder (OCD) is a chronic and severely impairing mental health condition characterized by the presence of obsessions—recurrent, intrusive, and unwanted thoughts, images, or urges—and compulsions, which are repetitive behaviors or mental acts performed to alleviate the distress caused by obsessions[1]. Although these compulsions may offer temporary relief, they often perpetuate a cycle of distress and functional impairment, contributing to a significant psychosocial burden [2]. The global prevalence of OCD among adults ranges from 0.7–3% [3], while estimates in pediatric populations range from 0.25–0.30% [4]. India has a prevalence that was reported to be more than the global range (3.3%), with an additional 8.5% meeting the criteria for subthreshold OCD [5]. The burden of OCD extends beyond clinical symptoms to encompass both direct and indirect costs [6, 7]. Direct costs include healthcare utilization, medications, and psychiatric care, whereas indirect costs involve reduced productivity, work absenteeism, and diminished educational and occupational attainment [8]. Economic analyses have estimated the annual cost of OCD to range from approximately $6.6 billion [9] to $8.4 billion [10], with an average annual cost of approximately $9,300 per affected individual, underscoring the substantial public health and economic implications of the disorder [9].

A wide array of psychological and pharmacological interventions is available for treating obsessive-compulsive disorder (OCD). Among these, cognitive-behavioral therapy (CBT)—particularly its exposure and response prevention (ERP) component—has emerged as the most empirically supported first-line treatment [11–13]. ERP systematically exposes individuals to anxiety-inducing stimuli while simultaneously preventing both overt and covert compulsive rituals. This approach reduces distress by promoting habituation and cognitive restructuring through experiential learning [14]. In contrast, cognitive therapy (CT), although comparatively less frequently studied and less robustly established in the empirical literature, has demonstrated efficacy in targeting core cognitive distortions. CT primarily focuses on modifying maladaptive appraisals and dysfunctional beliefs associated with intrusive thoughts, with the goal of reducing both obsessions and compulsions [15–18]. Notably, studies examining the combined use of ERP and CT have

consistently shown superior outcomes compared to either ERP or CT alone, suggesting that the integration of these approaches may yield additive benefits and enhance treatment efficacy across symptom dimensions [19].

Pharmacological treatment, especially with selective serotonin reuptake inhibitors (SSRIs), is also widely employed, either as monotherapy or in combination with CBT, depending on the symptom severity and functional impairment [20]. According to the National Institute for Health and Care Excellence (NICE, 2005), treatment recommendations for OCD vary in intensity based on the severity of symptoms [21]. For adults with mild functional impairment, low-intensity psychological interventions, such as brief individual CBT (including ERP) or group therapy, are recommended. For those with moderate impairment, more intensive CBT or SSRIs are advised, whereas individuals with severe OCD should receive a combination of intensive CBT and pharmacotherapy [21, 22].

Despite the availability of evidence-based interventions for obsessive-compulsive disorder (OCD), a substantial proportion of individuals continue to experience suboptimal outcomes due to various factors. Up to 50% of patients fail to achieve clinically meaningful improvement with exposure and response prevention (ERP) alone [23], and dropout rates remain high because of the distressing nature of exposure-based exercises [24]. Moreover, even among those who complete treatment, residual symptoms frequently persist, indicating the need for further exploration of factors influencing therapy outcomes [25].

Pharmacological interventions, particularly selective serotonin reuptake inhibitors (SSRIs), are also a cornerstone of OCD management. These agents have been shown to improve symptom severity and enhance the overall quality of life [19, 20]. However, SSRIs are not without limitations; therapeutic response typically requires a latency period of at least 8 weeks, and treatment is often accompanied by dose-dependent adverse effects, such as gastrointestinal disturbances and sexual dysfunction [28]. High relapse rates following discontinuation further complicate long-term management, often necessitating prolonged pharmacological therapy [26, 27]. For patients with treatment-resistant OCD, clinical guidelines recommend switching to another SSRI or clomipramine or augmenting the existing treatment with atypical antipsychotics [29]. Evidence also supports the combined use of SSRIs with CBT or ERP, which tends to yield superior outcomes compared to pharmacotherapy alone [21, 29].

Importantly, the National Institute for Health and Care Excellence (NICE) guidelines caution against the routine use of antidepressants, such as tricyclics (excluding clomipramine), serotonin-norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs), and antipsychotic monotherapy in OCD, due to insufficient efficacy and safety data [21]. These limitations highlight the ongoing need for adjunctive or novel interventions that more effectively target transdiagnostic processes, such as emotional

dysregulation and distress intolerance, which may underlie poor response to conventional treatments and contribute to chronicity.

Moreover, many treatment protocols, including ERP, do not explicitly address transdiagnostic mechanisms, such as emotional dysregulation and distress intolerance, which may play a pivotal role in maintaining symptoms and contributing to treatment resistance or partial response [30]. Emerging research suggests that enhancements in distress tolerance and emotion regulation are significantly associated with reductions in OCD symptomatology [31], as well as in other psychiatric conditions, including borderline personality disorder, generalized anxiety disorder, and substance use disorders [32]. These findings underscore the potential value of integrating emotion-focused strategies into standard OCD interventions to improve treatment response and long-term outcomes.

Distress tolerance (DT), the perceived or actual capacity to withstand aversive emotional states, is a key transdiagnostic factor implicated in a range of psychiatric disorders, including obsessive-compulsive and related disorders (OCRDs) [33]. Within a cognitive-behavioral framework, DT influences how individuals anticipate, experience and respond to distressing stimuli. Specifically, it shapes predictions about the severity of emotional discomfort, modulates the actual experience of distress, and informs coping strategies in the face of aversive internal conditions. DT is considered a relatively stable, trait-like construct that varies both within and across individuals with OCRDs, and its relevance to OCD is increasingly recognized [34–36]. A growing body of research highlights a robust inverse relationship between DT and obsessive-compulsive symptomatology, with a lower DT associated with greater symptom severity [37]. Poor DT has also been linked to heightened anxiety sensitivity and intolerance of uncertainty—factors that are transdiagnostically relevant across disorders such as generalized anxiety disorder, social anxiety disorder, and OCD [37]. In the context of OCD, individuals with reduced DT are more likely to engage in maladaptive neutralization strategies in response to intrusive thoughts and experience elevated anxiety during post-neutralization periods [38]. These findings suggest that DT is a critical mechanism underlying the development and maintenance of obsessions. Consequently, interventions that directly enhance DT may hold particular promise for reducing obsessive symptoms and improving overall treatment outcomes [38, 39].

Research evidence suggests that improvements in DT may serve as a central mechanism through which ERP-based treatments achieve symptom reduction in individuals with OCD. [40]. ERP facilitates therapeutic change not by merely focusing on habituation to anxiety-inducing stimuli but by enhancing individuals' capacity to endure aversive emotional experiences without resorting to compulsive behaviors [40, 41]. By mediating the relationship between exposure and clinical improvement, DT emerges as a promising transdiagnostic target for optimizing ERP outcomes in Obsessive-Compulsive Disorder

(OCD). Despite well-established theoretical models and emerging empirical evidence linking DT to OCD, clinical studies directly evaluating DT-focused interventions are limited. Although several psychotherapeutic approaches implicitly address DT as part of broader emotional regulation strategies, few interventions have explicitly targeted DT in the OCD population [17].

Dialectical Behavior Therapy (DBT) is a structured, evidence-based psychotherapy that comprises modules on mindfulness, distress tolerance, emotion regulation, interpersonal effectiveness, and acceptance. Initially developed by Linehan (1993) for individuals with borderline personality disorder (BPD) and chronic suicidality [42], DBT has since been demonstrated to be effective across a range of psychiatric conditions, including eating disorders, substance use disorders, and mood disorders [43–47].

Despite DBT's growing application of DBT across a range of psychiatric conditions, its specific utility in the treatment of obsessive-compulsive disorder (OCD) remains markedly underexplored [48]. The current clinical landscape necessitates integrated, multidimensional approaches that align with the World Health Organization's broader perspective on mental health, which emphasizes not only symptom reduction but also personal growth, emotional resilience, and adaptive functioning. In this context, third-wave psychotherapies, particularly DBT and its DT module, offer promising avenues for extending OCD treatment beyond the conventional cognitive-behavioral therapy (CBT) paradigm [38, 39].

Although the role of DT in anxiety-spectrum disorders has received growing attention[49], there remains a significant lack of empirical research exploring its specific effects within OCD populations.. Existing literature suggests that DT is intricately linked to the severity and persistence of obsessive-compulsive symptoms, indicating its relevance as a potential transdiagnostic mechanism [38, 39, 48]. Despite its potential, DBT research is still in its nascent stages, with a paucity of systematic research on its change mechanisms or effectiveness in addressing OCD. This research gap is particularly concerning given the considerable treatment challenges and scarcity of specialized psychotherapeutic resources available to diverse populations across India.

This study aimed to address this critical gap by systematically evaluating the efficacy of distress tolerance techniques derived from DBT in adults diagnosed with OCD. By targeting DT as a modifiable mechanism, this study aims to promote not only symptomatic relief but also enhanced emotional regulation and long-term psychological well-being. Accordingly, the current randomized controlled trial will investigate the impact of DBT-based DT interventions in a clinical sample of Indian adults with OCD, offering important implications for developing culturally responsive, mechanism-driven treatment models.

Design and methods

Design

We will conduct a randomized controlled trial (RCT) with a pre-test–post-test design and follow-up assessments at three months (12 weeks) post intervention. Patients will be recruited from consecutive referrals to the outpatient psychiatric department of the All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, an institute of national importance located in central India. Following eligibility screening and informed consent, participants will be randomly allocated into two parallel groups: (1) Exposure and Response Prevention (ERP) and (2) Distress Tolerance (DT) skills training. The number of excluded patients and refusals and their reasons will be noted accordingly. Blinded outcome assessors, who are trained in clinical research and include professionals such as psychiatrists and clinical psychologists, will conduct both self-report measures and semi-structured clinical interviews at baseline (pre-treatment) and immediately following the final treatment session (post-treatment, which serves as the primary endpoint) of the 12-week therapy program (fig. 1). In the case of dropouts, measurements and interviews are also administered directly after treatment ends whenever feasible.

The study was approved by the Institutional Ethics Committee of the All India Institute of Medical Sciences, Bhopal (protocol: ihecsr/aiimsbpl/aug/27) and registered with the Clinical Trials Registry of India (CTRI/2024/09/073672). Data will be anonymized and securely stored in accordance with data protection regulations. This study will adhere to the CONSORT and SPIRIT guidelines for clinical trial design and reporting. Fig. 2 presents a flowchart detailing the progression of the study from patient enrolment to data analysis and reporting. This study adhered to the SPIRIT guidelines [50]. The SPIRIT diagram is shown in Fig. 3. The SPIRIT checklist is available in the Additional File 1.

Sample size

No studies are available that directly compare ERP with distress tolerance techniques. We designed our study with sufficient statistical power to detect a large between-group effect size (Cohen’s f = 0.50), which is considered both statistically robust and clinically meaningful in psychotherapeutic research. A larger effect size was deemed unlikely because of the well-established efficacy of ERP alone in reducing OCD symptoms, whereas detecting smaller effects might provide limited practical guidance for treatment recommendations.

We conducted an a priori power analysis using G*Power version 3.1 for repeated-measures ANOVA with between-group factors. The analysis included two treatment groups (ERP and Distress tolerance techniques), two assessment points (pre-treatment and post-treatment), and assumed a correlation of 0.50 among repeated measures. To detect a large effect size

(f = 0.50) at an alpha significance level of α = 0.05 and a power level of 0.99 (99%), the required total sample size was 58 participants, equating to 29 participants per treatment group. To allow for equal allocation and a small buffer for attrition, we will recruit 60 participants (30 per group). This slightly increased the achieved power above 0.99 without altering the other parameters.

Although multiple outcome analyses increase the risk of Type I error, reducing statistical power increases the risk of Type II error, which could obscure real treatment effects. Given that Y-BOCS scores are the primary outcome, significance will be tested at α = 0.05. For secondary outcomes (e.g., distress tolerance, anxiety, depression, emotion regulation, and quality of life), a Bonferroni correction will be applied to control for multiple comparisons, resulting in an adjusted significance threshold of α = 0.01 (0.05/5 = 0.01). This sample size is consistent with previous randomized trials of ERP in OCD populations [51, 52] and is expected to yield sufficient power to detect clinically meaningful improvements in both symptom severity and emotion regulation outcomes.

Participant enrolment and randomization

A total of 60 adult patients (aged 18–40 years) with a primary diagnosis of obsessive-compulsive disorder (OCD) will be recruited from consecutive referrals to outpatient psychiatry and the inpatient department of psychiatry, All India Institute of Medical Sciences, Bhopal, India. Diagnosis will be established according to the ICD-10 criteria (World Health Organization, 1992) for OCD, including F42.0 (predominantly obsession), F42.1 (predominantly compulsion), and F42.2 (mixed type). Eligible participants must have OCD symptoms lasting more than six months, a Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score of 16 or higher, and adequate comprehension of Hindi or English language. Individuals will be excluded if they have a history of organic illness, epilepsy, neurological deficits, intellectual disability, psychotic disorders, severe depression, or active suicidal ideation. Additionally, those who have received psychological treatment for OCD in the past six months or have any prior history of psychiatric medication use will be excluded. After a thorough clinical screening and informed consent process, eligible participants will be randomly assigned in a 1:1 ratio to one of two treatment conditions: (1) exposure and response prevention (ERP) alone or (2) ERP augmented with distress tolerance (DT) skills derived from Dialectical Behavior Therapy (DBT). Randomization will be conducted using a randomization table to ensure balanced allocation over time and prevent predictability in allocation (Fig. 2). The randomization sequence will be generated by an independent statistician, and group assignment will be implemented by a research assistant who is not involved in the treatment delivery or assessment. To control for therapist effects, all therapists will be trained in both therapies; however, each arm will be delivered by a different therapist within a cohort. Specifically, one therapist will provide the experimental intervention (distress tolerance), while another therapist—who has no

contact with the experimental participants—will deliver standard ERP to the control group. Therapists will work in separate, non-overlapping treatment blocks to avoid contamination. To minimize attrition, participants will receive reminder calls/texts and be offered flexible scheduling for sessions and assessments. Participants who discontinue or deviate from the protocol will still be contacted for post-test assessments so that the available outcome data can be included in longitudinal/intention-to-treat analyses.

Outcome Measures

All outcome assessments will be conducted in either Hindi or English, based on the participant's language preference, and administered in person across all time points, including follow-up assessments. Diagnostic confirmation, clinician-rated evaluations, and self-report measures will be administered in person by trained clinicians.

Primary Outcome

The primary outcome of interest for this DT superiority trial is the severity of obsessive-compulsive symptoms post-treatment, assessed using the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) [53]. The Y-BOCS is a widely recognized clinician-administered semi-structured interview and is considered the gold standard for assessing OCD symptom severity. It comprises 10 items—five assessing obsessions and five assessing compulsions—each rated on a 5-point scale from 0–4, yielding a total score ranging from 0–40. The scale has demonstrated strong psychometric properties, including good internal consistency for both the obsession and compulsion subscales and the total score. It is also highly sensitive to treatment-related changes, making it an appropriate measure for evaluating therapeutic outcomes in patients with OCD [54, 55].

Secondary outcomes

Secondary outcomes include validated self-report questionnaires to assess comorbid affective symptoms and emotional functioning. The Beck Depression Inventory-II (BDI-II) [56] will be used to evaluate the presence and severity of depressive symptoms. This widely used 21-item scale assesses the cognitive, behavioral, and somatic components of depression, with items scored on a 1–4 Likert scale. It has demonstrated high internal consistency ($\alpha = .93$) and acceptable validity in both international and Indian clinical population.

The Distress Tolerance Scale (DTS) [57] will serve as another secondary outcome measure. This 15-item self-report instrument assesses individuals' perceived capacity to tolerate emotional distress. It evaluates four domains: emotional regulation, absorption by distress, acceptability of distress, and perceived ability to withstand distress. The DTS has

shown excellent internal consistency (α = .92) and good test–retest reliability and is sensitive to changes over time in clinical samples.

Process measures

Three self-report measures will be used to assess the hypothesized process variables associated with treatment mechanisms in both arms of the study. The Acceptance and Action Questionnaire-II (AAQ-II [58]) is a 7-item scale that assesses experiential avoidance and psychological flexibility. Higher scores reflect greater avoidance and immobility, whereas lower scores reflect increased acceptance and action. The AAQ-II has shown adequate internal consistency (α = .74–.81) and test–retest reliability (.67–.77).

The Kentucky Inventory of Mindfulness Skills (KIMS [59]) is a 39-item instrument that measures mindfulness across four domains: Observing, Describing, Acting with Awareness, and Accepting without judgment. Each item is rated on a 5-point Likert scale, and the scale has demonstrated high internal consistency (α = .87–.91) and good construct validity.

Finally, the Dialectical Behavior Therapy–Ways of Coping Checklist (DBT-WCCL [60]) assesses the frequency of DBT skill use in response to stressful situations. The 59-item checklist includes both adaptive (skillful) and maladaptive (unskillful) coping strategies. Items were rated on a 0–4 Likert scale. The scale has excellent internal consistency (α = .92–.96) and acceptable test–retest reliability.

These process measures will help evaluate changes in mindfulness, experiential avoidance, and coping strategies, which are hypothesized to mediate treatment outcomes, particularly in the ERP arm of this trial.

Interventions

The interventions will be delivered in an outpatient clinical setting where Exposure and Response Prevention (ERP) is routinely provided as standard care for OCD. In this randomized controlled trial, participants will be assigned to either ERP or DBT-based Distress Tolerance techniques. Both interventions will consist of 12 weekly individual sessions lasting approximately 45–60 min. A minimum of eight completed sessions will be required for participants to be considered treatment completers in the statistical analysis. The therapies will be delivered by trained clinical psychologists with experience in ERP and DBT training. Those providing the DT intervention will also receive additional training in DBT-based techniques. To ensure treatment fidelity, all therapists will receive monthly supervision, and a random selection of sessions will be reviewed using standardized adherence checklists.

The ERP protocol used in this study was based on the inhibitory learning model of extinction, which posits that fear associations are not erased but rather inhibited by the formation of new, non-threatening associations [61]. ERP treatment is divided into three main phases. In the first phase, patients will be introduced to the behavioral model of OCD, and a detailed anxiety hierarchy was developed. In the second phase, both in-session and homework-based exposure exercises, either imaginal or in vivo, are conducted, beginning with moderately distressing situations and progressing to more anxiety-provoking stimuli. Compulsion prevention is conducted simultaneously, with patients actively supported in resisting compulsive behaviors. In the final phase, a collaborative relapse prevention plan is formulated, outlining individualized strategies to sustain therapeutic progress and cope with future triggers of anxiety. The emphasis throughout ERP is on expectancy violation and variability across exposure tasks to optimize inhibitory learning and reduce the risk of relapse [23, 40, 61].

In the DT condition, a structured DBT-based Distress Tolerance module derived from Marsha Linehan’s model [42, 45]. This module will be implemented over the same 12-week period and is divided into five phases. These five phases, summarized in Table 1 [42], include establishing rapport and understanding the patient's symptom history. The first phase lays the foundation for collaborative treatment planning and readiness to acquire new coping skills. The second phase comprises five sessions and introduces crisis survival strategies designed to help patients endure distress without resorting to compulsions. Key techniques in this phase include the ACCEPTS strategy (Activities, Contributing, Comparisons, Emotions, Pushing away, Thoughts, and Sensations) to provide distraction from distressing emotional stimuli, self-soothing exercises using the five senses to promote calmness, and the IMPROVE technique (Imagery, Meaning, Prayer, Relaxation, One thing in the moment, Vacation, Encouragement) to introduce positive emotional experiences [42]. Additionally, pros and cons analyses are used to help patients make more adaptive decisions when facing overwhelming emotions or urges.

Table 1 Overview of the Four-Phase Distress Tolerance (DT) Module Based on Dialectical Behavior Therapy (DBT)

Phase	Session (Week)	Module / Techniques	Procedures
I. (Engagement & Orientation)	1	Rapport formation; Case history; Psychoeducation (OCD, ERP, Distress-Tolerance framework)	• Guided clinical interview and symptom mapping • Explain OCD model, ERP rationale, and why DT skills are added • Introduce self-monitoring (obsessions, compulsions, distress ratings)
	2	Treatment contracting; Psychoeducation continuation; Monitoring tools	• Review psychoeducation with visuals/handouts • Finalize treatment contract and session structure • Train on SUDS, urge logs, and daily monitoring diaries
II. (Distress Tolerance – Crisis Survival)	3	“ACCEPTS” Distraction skills (Activities, Contributing, Comparisons, Emotions, Pushing away, Thoughts, Sensations)	• Teach each ACCEPTS component with personalized examples • Behavioral rehearsal of at least two chosen strategies • Create a crisis card listing patient-selected distraction options
	4	Self-soothing via five senses	• Sensory kit creation (e.g., scent, texture, music) • Guided practice of soothing exercises in session • Identify triggers where self-soothing will be deployed first
	5	“IMPROVE the moment” (Imagery, Meaning, Prayer/Values, Relaxation, One-thing in the moment, Vacation, Encouragement)	• Guided imagery of safe/secure place vs. distress cue • Meaning and values clarification exercise • Brief relaxation training; mindful single-task focus drill
	6	Pros & Cons analysis; Urge surfing	• Role-play “pause–weigh–act” sequence for common urges • Fill out written Pros & Cons for a live/imagined

			urge • Introduce urge surfing metaphor and short practice
	7	Individualized crisis plan; Chain analysis of a recent episode	• Functional chain analysis: trigger → thoughts → feelings → behavior → consequences • Map which DT skills fit each link in the chain • Develop laminated coping cards / phone notes
III. (Mindfulness Training)	8	Breath-focused mindfulness; 3-minute breathing space	• Guided breath observation and body scan • Practice the “STOP” or “3-minute breathing space” exercise • Debrief experiences, normalize wandering mind
	9	Mindful awareness of routine activities (informal practice)	• Plan and rehearse mindful eating/walking/cleaning in session • Use “noting” technique for thoughts/urges during tasks • Set frequency/duration targets for home practice
IV. (Acceptance Skills)	10	Radical acceptance; Myths about acceptance	• Discuss difference between acceptance and passivity • Reattribution exercise: compare outcomes of accepting vs. rejecting a distressing event (Pros & Cons) • Guided practice of saying “yes” to the present moment
	11	Willingness vs. Willfulness; Adaptive (benign) denial; Metaphors	• Metaphor work (e.g., “You can’t stop the ball by refusing to see it”) • Rewrite willful statements into willing ones • Identify “unwanted” thoughts/behaviors and reframe via adaptive denial

V. (Consolidation & Termination)	12	Review & relapse-prevention plan; Termination	• Review homework logs and skill use across phases • Create personalized relapse-prevention/action plan • Post-treatment assessment and scheduling of booster/follow-up

Note: This table is adapted from the *DBT Skills Training Manual* by Marsha Linehan (2015), reflecting the structure and sequencing of the Distress Tolerance module [42].

The third and fourth phases of DT training focus on integrating mindfulness and acceptance-based skills across two sessions each. Patients are taught to engage with the present moment through awareness of their breath and everyday activities, helping to reduce automatic behavioral responses driven by ruminative thoughts. The fourth phase emphasizes the development of a non-judgemental stance through techniques such as radical acceptance, adaptive denial, and the replacement of willfulness with willingness, allowing patients to tolerate emotional distress rather than attempting to suppress or avoid it. The final phase consists of a single session dedicated to reviewing the skills learned, consolidating gains, and collaboratively creating a future-oriented plan to manage distress. The session also serves as a termination point, summarizing the therapy course and preparing the patient for sustained independent use of skills[44–46].

The DT aims to improve emotional regulation, enhance adherence to exposure exercises, and reduce dropout rates by equipping individuals with practical tools for tolerating distressing affective states. A detailed overview of the treatment is presented in Table 1. Full intervention manuals are available upon request from the corresponding author of this study.

Statistical Analysis

All data will be analyzed using IBM SPSS Statistics for Windows, Version 25. Given the anticipated dropout and the uneven intervals between assessment points, linear mixed-effects models (LMMs) will be employed, as they are well-suited for repeated-measures designs by accounting for intra-individual dependency and effectively handling missing data [62]. If missing data are determined to be Missing at Random (MAR), the corresponding covariates will be included in the analysis to adjust for potential bias. Conversely, if Missing Not At Random (MNAR) patterns emerge, pattern mixture models will be utilized. Baseline scores for repeated measures will be used as covariates in mixed models. Baseline demographic and clinical characteristics will be summarized using descriptive statistics to assess group comparability and potential imbalances in the

groups. Model diagnostics involve examining the residual plots for homoscedasticity and normality. If these assumptions are violated, nonparametric bootstrapping using R statistical software [63] will enhance the robustness of the statistical inference.

The LLM fixed effects will include time, treatment condition (ERP vs. DT), and their interaction. Variables associated with missing data will be included as additional fixed effects, when appropriate. The Benjamini–Hochberg procedure [64] will correct for multiple testing and control the false discovery rate, with a two-tailed significance threshold set at $p < 0.05$ for all interaction effects. A first-order autoregressive structure (AR(1)) will be used to model correlations among repeated measures. Treatment × time interactions will be explored through pairwise comparisons of estimated marginal means (EMMs) at each time point using the Least Significant Difference (LSD) method. We anticipate statistically significant interaction effects reflecting differential trajectories of symptom change, particularly a more pronounced symptom decline in the DT group than in the ERP group.

Cohen's *f* effect sizes will be computed from the LLM to quantify the magnitude of treatment effects and facilitate interpretation within the ANOVA framework. Cohen's f provides a standardized measure of variance explained by the interaction and main effects in the mixed-effects model, aligning with our repeated-measures analytical approach. Specifically, the primary treatment × time interaction will be assessed in terms of Cohen's f, with effect sizes interpreted based on the standard benchmarks (small = 0.10, medium = 0.25, large = 0.40). We anticipate medium to large Cohen's f effect sizes for the treatment × time interaction, consistent with the clinically meaningful differences. Effect sizes will be calculated and reported for both the intent-to-treat (ITT) and completer samples.

The primary analyses will adhere to the ITT principle, including all randomized participants with at least one post-baseline measurement. Secondary per-protocol analyses will focus only on participants who completed a minimum of eight sessions without medication changes during the treatment. The clinical significance will be evaluated using reliable change indices, and dropout rates will be descriptively examined to provide insights into adherence and acceptability.

Endpoints

The clinical significance of the treatment outcomes will be evaluated according to the criteria proposed by Jacobson and Truax [65]. Participants will be classified as recovered if they (a) score within the non-clinical range on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS), defined as a post-treatment score ≤ 14, and (b) demonstrate statistically reliable improvement on the Y-BOCS, operationalized as a reliable change index (RCI) of ≥ 10 [65]. Participants meeting only one of these two criteria will be classified as improved

but not recovered. A more stringent category of asymptomatic will be used to identify participants who achieve a post-treatment Y-BOCS score of ≤ 7—indicating near-complete absence of OCD symptoms—and also meet the reliable change index. In addition, diagnosis-free status, defined as the absence of an OCD diagnosis at post-treatment based on clinical assessment, will be used as an additional indicator of clinically significant change.

Discussion

DT strategies, as conceptualized in DBT, represent a promising alternative to the current gold standard treatment (ERP) for OCD. Unlike ERP, which focuses on confronting and reducing compulsive behaviors and avoidance, DT targets the underlying metacognitive and emotional regulation deficits that may perpetuate OCD symptoms [47]. According to Linehan's biosocial theory of emotional dysregulation, individuals with heightened emotional vulnerability and inadequate emotion regulation strategies often engage in maladaptive behaviors to alleviate distress [42, 44, 66]. In the context of OCD, compulsive rituals can be viewed as maladaptive attempts to reduce emotional discomfort associated with intrusive thoughts and obsessive fears. [48]. Therefore, incorporating DT techniques into traditional Exposure and Response Prevention (ERP) may enhance an individual's ability to tolerate the emotional discomfort evoked by exposure tasks, thereby reducing reliance on compulsions as a coping mechanism [66].

Our central hypothesis is that DT strategies may lead to greater improvements in OCD symptoms than ERP. Since there is a wide variation in symptom presentation across OCD subtypes, but relatively stable beliefs about the meaning of intrusions and rituals, DT-enhanced ERP could provide a more flexible and universally applicable intervention framework. Furthermore, DT techniques—such as mindfulness, radical acceptance, and distress survival strategies—may be perceived as less burdensome by patients, potentially increasing adherence, particularly for those who find traditional ERP overwhelming owing to the intensity of exposure tasks.

While ERP remains the gold standard for treating OCD, emerging theoretical models suggest that integrating emotion regulation strategies may further enhance its efficacy. Distress intolerance has been identified as a core transdiagnostic factor contributing to compulsive behavior; however, no previous studies have directly tested the DT techniques derived from DBT in individuals with OCD. Although prior research has explored the effects of combining ERP with Cognitive Therapy (CT) [67–70] or Metacognitive Therapy (MCT)[51, 71–73], the effect of DT techniques in patients with OCD remains unexamined. Therefore, this study presents the rationale and design of the first randomized controlled trial (RCT) to evaluate the efficacy of ERP versus DT. By targeting emotional dysregulation

and maladaptive coping in the context of OCD, this trial aims to fill a critical gap in the treatment literature on OCD.

This study has several methodological strengths. First, participants will be randomized into two active treatment conditions, facilitating direct and robust comparisons of intervention efficacy. Second, separate therapists will deliver each treatment condition exclusively, eliminating potential therapist cross-contamination and significantly enhancing treatment fidelity. Finally, this study will include a clinically representative sample of individuals diagnosed with OCD, enhancing ecological validity and generalizability.

This study has some limitations that need to be acknowledged. Conducting protocolized interventions in community outpatient settings may pose challenges in terms of consistency and fidelity. To mitigate this, therapists receive specialized training, and active cases are regularly reviewed during consultation meetings. Additionally, treatment integrity was systematically monitored using adherence checklists and supervision sessions. Despite these limitations, this study provides valuable insights into whether the addition of DT techniques enhances the effectiveness of ERP in treating OCD. Positive findings could support the integration of emotional regulation strategies into standard ERP protocols and inform future clinical guidelines for OCD treatment.

Trial Status

This study was approved by the Institutional Human Ethics Committee of the All India Institute of Medical Sciences, Bhopal (IHEC/AIIMSBPL/AUG/27) on August 12, 2024. Participant recruitment will begin in January 2025. To date, 20 participants have been enrolled and randomized. Recruitment is ongoing and is expected to be completed by December 2025.

Abbreviations

AAQ-II: Acceptance and Action Questionnaire-II; AR(1): First-order autoregressive; BDI: Beck Depression Inventory; CBT: Cognitive Behavioral Therapy; CT: Cognitive Therapy; DBT: Dialectical Behavior Therapy; DBT-WCCL: Dialectical Behavior Therapy–Ways of Coping Checklist; DSM: Diagnostic and Statistical Manual of Mental Disorders; DT: Distress Tolerance; DTS: Distress Tolerance Scale; ERP: Exposure and Response Prevention; ES: Effect Size; ICD-10: International Classification of Diseases, 10th Revision; ITT: Intention-to-treat; KIMS: Kentucky Inventory of Mindfulness Skills; LMM: Linear Mixed-effects Model; MAR: Missing at Random; MNAR: Missing Not at Random; OCD: Obsessive-Compulsive Disorder; RCT: Randomized Controlled Trial; SD: Standard Deviation; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials;

SPSS: Statistical Package for the Social Sciences; SSRI: Selective Serotonin Reuptake Inhibitor; Y-BOCS: Yale-Brown Obsessive-Compulsive Scale.

Declarations

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Availability of Data and Materials

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Authors' Contributions

MK,VS, RK, ARR, contributed substantially to the conception and design of the study. MK is the lead investigator responsible for data acquisition. VS, RK, ARR is supervising the trial and contributed significantly to the power analysis. MK,VS, AKS, SK, and K, drafting the analysis and interpretation sections. , MK,VS, RK AKS, SK, K, VKS and RC made major contributions to manuscript writing. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work regarding accuracy and integrity.

Ethics Approval and Consent to Participate

The study has received ethical approval from the Institutional Human Ethics Committee at All India Institute of Medical Sciences, Bhopal (IHEC/AIIMSBPL/AUG/27).

Consent for Publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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Figures

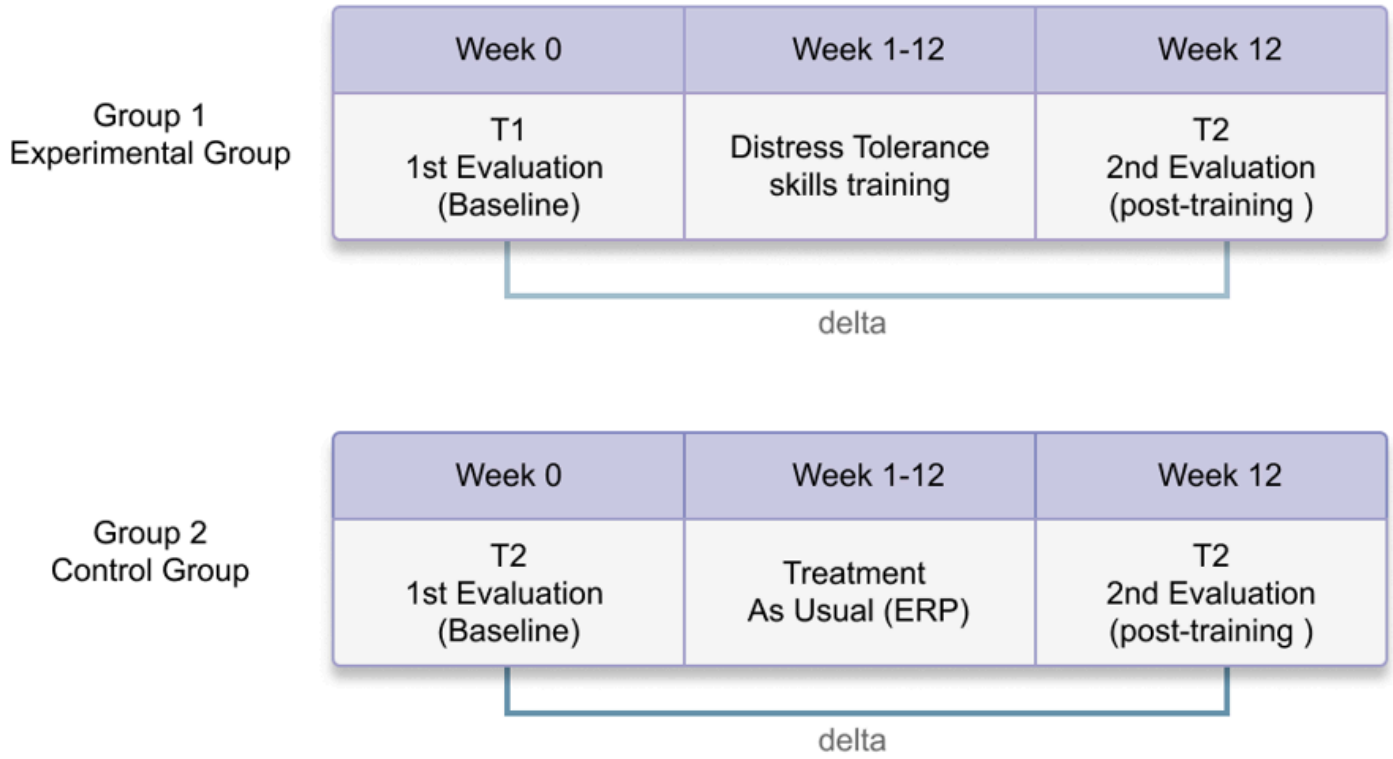


Figure 1

Study Design Timeline for the Experimental and Control Groups.

Note: ERP = Exposure and response prevention

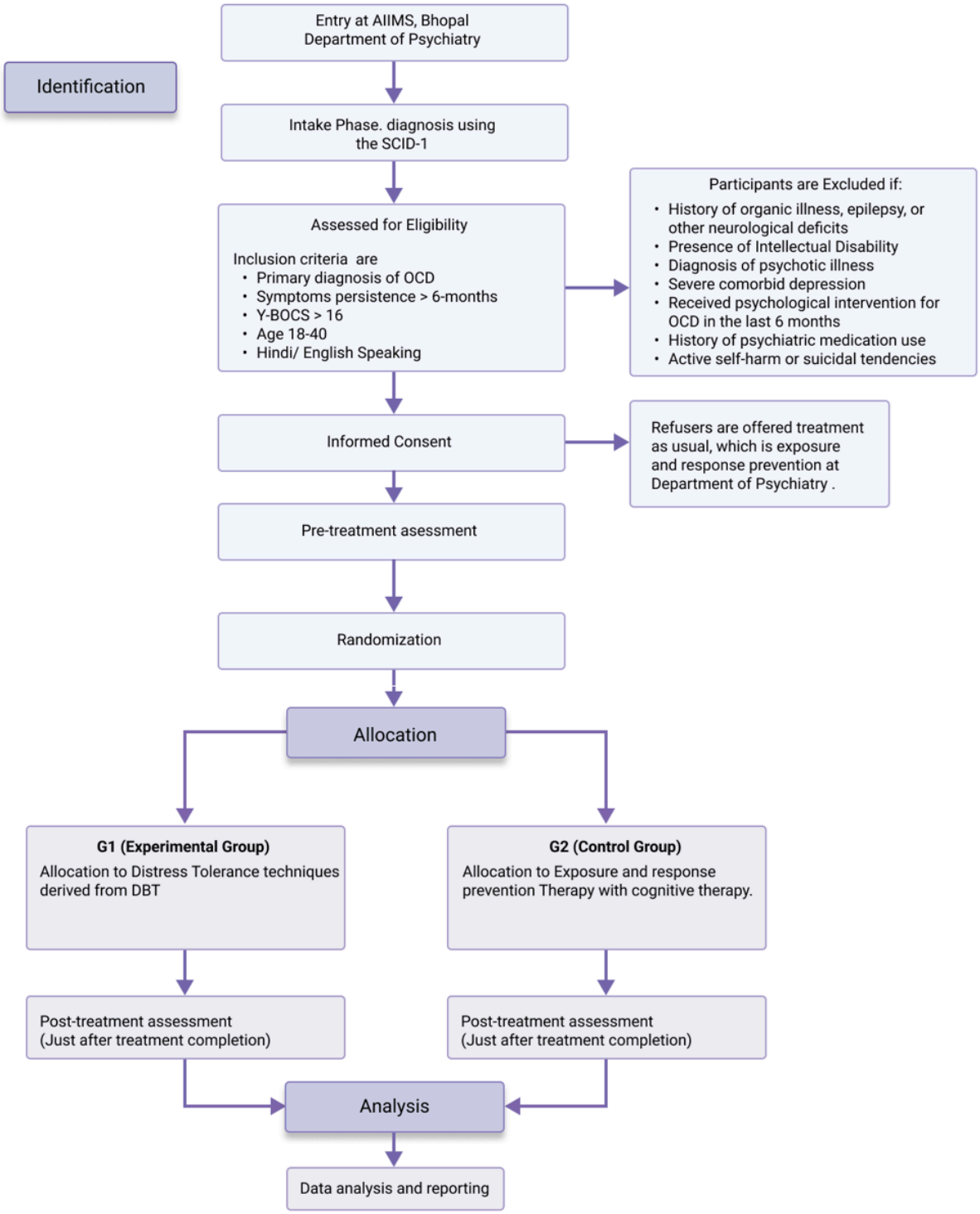


Figure 2

Flowchart of the study

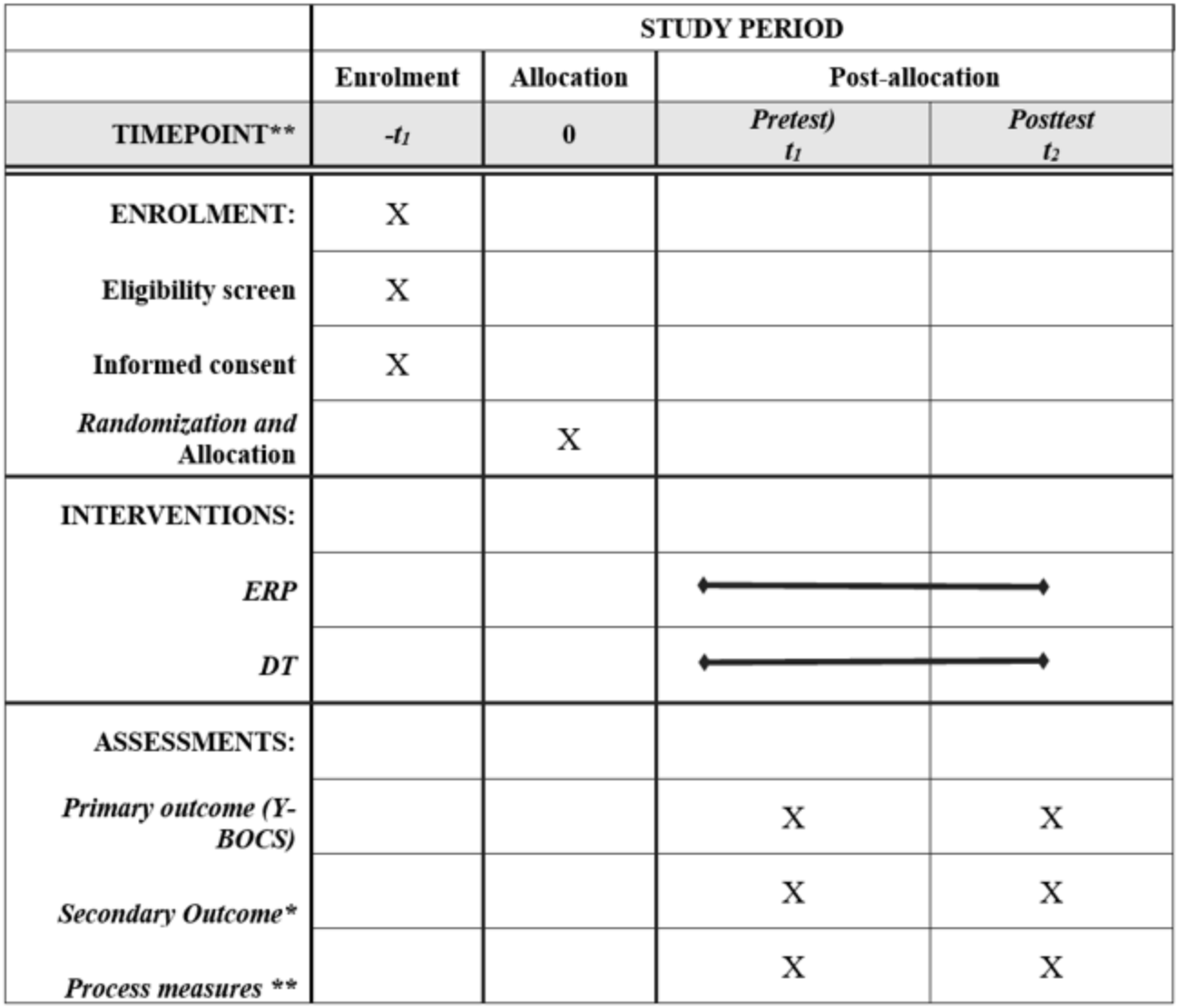


Figure 3

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). Diagram of enrolment, interventions, and assessments over time. ERP: Exposure and Response Prevention; DT: Distress Tolerance; Y-BOCS: Yale-Brown Obsessive Compulsive Scale. *Secondary outcomes: Beck Depression Inventory (BDI) and Distress Tolerance Scale (DTS). **Process measures: Dialectical Behavior Therapy – Ways of Coping Checklist (DBT-WCCL); Acceptance and Action Questionnaire-II (AAQ-II); Kentucky Inventory of Mindfulness Skills (KIMS).

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