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Protocol

Comparative effectiveness of Satipaṭṭhāna-based thought purification therapy, mindfulness-based cognitive therapy and treatment as usual in patients with depressive disorders: study protocol for a three-arm parallel-group superiority randomized controlled trial

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ABSTRACT

Background: Depression is a significant global public health challenge, and mindfulness-based cognitive therapy (MBCT) is an evidence-based secular intervention for depression; however, it incorporates partially Buddhist mindfulness practices. The Satipaṭṭhāna-based thought purification therapy (SB-TPT) is a structured, seven-week intervention that integrates systematic contemplation of the body, feelings, mind, and mental phenomena based on Theravāda Buddhist meditation teachings. This trial aims to assess the comparative effectiveness of SB-TPT, MBCT, and treatment-as-usual (TAU) in adults diagnosed with depressive disorders.
Methods: This study is a parallel-group, three-arm superiority randomized controlled trial. 92 adults aged 18-45 years, who have been diagnosed with depressive disorders (HAM-D-17 >8 and ≤24) according to ICD-10 and DSM-5-TR, will be recruited from a tertiary-care academic psychiatry centre in Varanasi, India. Participants will be randomized (1:1:1) to: SB-TPT plus TAU; MBCT plus TAU; and TAU alone. The primary outcome is change in clinician-rated depressive symptom severity measured by the HAM-D-17. Secondary outcomes include depressive symptoms (BDI-II), mindfulness (FFMQ-H), quality of life (WHOQOL-BREF), and rumination (RRQ). Assessments will be conducted at baseline, post-intervention, and at the 3-month follow-up. Data will be analyzed using repeated-measures analysis of variance and intention-to-treat principles.
Conclusions: This trial will provide the first randomized evaluation of a structured Satipaṭṭhāna-based intervention compared with MBCT and treatment as usual for depressive disorders. Findings may contribute to understanding the clinical effectiveness of traditionally grounded contemplative approaches within contemporary mental health settings.
Trial Registration: Clinical Trials Registry of India (https://ctri.nic.in): CTRI/2025/05/087988. 30 May 2025.

Keywords: Depressive disorders, MBCT, Mindfulness, Satipaṭṭhāna meditation

INTRODUCTION

Depressive disorders are common and disabling mental health conditions characterized by persistent low mood, anhedonia, fatigue, difficulty concentrating, changes in appetite or sleep, and feelings of worthlessness or guilt.[1] These symptoms impair emotional well-being, relationships, work performance, and overall quality of life, and increase the risks of suicide and cardiovascular mortality.[2-4] Globally, depression affects over 322 million people and is a leading cause of disability.[5] In India, about 5.1% of the population experiences common mental disorders, with an estimated 23 million individuals requiring care for depression.[6] More than 50% of patients with depressive disorder do not respond adequately to first-line antidepressant treatments, and recurrence

increases from 50% after one episode to 90% after three or more episodes.[7,8] Despite advances in treatment options, treatment resistance and relapse remain common in depressive disorders, emphasizing the importance of culturally appropriate, accessible, affordable, and sustainable psychotherapeutic strategies that can complement or enhance current treatments.[9,10]

Mindfulness-based cognitive therapy (MBCT) is an eight-week, manualized intervention that integrates mindfulness meditation with elements of cognitive-behavioural therapy to prevent relapse in recurrent major depression.[11] MBCT is recommended and effective for the acute treatment and relapse prevention of depression.[12] However, MBCT outcomes are heterogeneous, with its effectiveness being moderated by baseline symptom severity, cognitive reactivity, and treatment engagement. Practical barriers to participation and sustained home practice may limit benefits for some individuals, leading to residual symptoms or an increased risk of relapse.[13,14]

MBCT emphasizes decentering from maladaptive thought patterns by cultivating nonjudgmental present-moment awareness through practices such as the body scan, sitting and walking meditation, mindful movement, and informal awareness of daily activities.[11] Conceptually, MBCT is rooted in Buddhist meditation teachings and practices on mindfulness; however, MBCT adapts traditional Buddhist teaching and practices into a secular, clinical framework aligned with cognitive-behavioral theory.[15-17]

A recent theoretical study found that core MBCT exercises align with the four foundations of mindfulness (satipaṭṭhāna) described in the Satipaṭṭhāna Sutta, a foundational discourse in the Pāli Canon (Tipiṭaka), particularly contemplation of the body (kāyānupassanā), feelings (vedanānupassanā), and mind (cittānupassanā).[16] However, MBCT primarily focuses on cognitive decentering and present-moment awareness, partially addressing detailed contemplation of bodily and mental phenomena, and it does not explicitly cultivate insight into impermanence (anicca), suffering (dukkha), and non-self (anattā), which are key elements of traditional Buddhist mental developmental procedure.[16,17]

From a Buddhist perspective, mindfulness (sati) is traditionally developed through structured contemplative practices embedded in the Satipaṭṭhāna discourse that presents the four foundations of mindfulness as "the direct path for the purification of beings (sattānaṃ visuddhiyā), for the overcoming of sorrow and lamentation, for the cessation of pain and distress, for the attainment of the right path, and for the realization of Nibbāna".[18] These four foundations, contemplation of the body (kāyānupassanā), feelings (vedanānupassanā), mind (cittānupassanā), and mind-objects (dhammānupassanā), are operationalized through a comprehensive set of practices, including mindfulness of breathing (ānāpānasati), awareness of postures and daily activities (iriyāpatha and sampajañña), contemplation of body parts and elements (paṭikūlamanasikāra and dhātumanasikāra), charnel-ground contemplations, systematic observation of affective tones, and examination of mental states, hindrances, aggregates, and the four noble truths.[19] These practices aim to purify the mind of cognitive and emotional patterns, such as attachment, aversion, and ignorance, and to foster the development of insight (vipassanā) and wisdom (paññā) that lead to liberation from suffering (dukkha). They cultivate mindfulness (sati) and clear comprehension (sampajañña), enabling practitioners to perceive the true nature of phenomena. Furthermore, the current literature on Buddhist meditation in clinical psychology remains limited and fragmented. Most studies in clinical psychology have focused on standardized mindfulness-based interventions such as MBSR, MBCT, rather than on interventions fully rooted in the Satipaṭṭhāna framework or traditional Buddhist practices.[20]

To address these theoretical and cultural gaps, we developed Satipaṭṭhāna-based thought-purification therapy (SB-TPT), a seven-week structured intervention that systematically applies the four foundations of mindfulness to the identification, observation, and gradual "purification" of maladaptive thought patterns, emotional reactivity, and avoidance behaviors, with explicit emphasis on insight into impermanence and non-self, as articulated in the Satipaṭṭhāna Sutta.[19,21] Building on previous theoretical work on MBCT and Satipaṭṭhāna as well as analyses of Theravāda meditation practices in MBIs, SB-TPT seeks to offer a culturally grounded, theoretically coherent, and clinically applicable protocol aligned with South Asian contemplative traditions and contemporary psychotherapeutic principles.[22] A summary of the SB-TPT is included in Table 2.

Preliminary evidence supports the feasibility of such an approach. For instance, a recent case series found that a mindfulness program based on traditional Satipaṭṭhāna practice produced therapeutic effects comparable to those of standard secular mindfulness programs.[23] Moreover, meta-analytic research on global mental health shows that culturally adapted psychotherapies often yield greater symptom reduction than non-adapted interventions.[24] By explicitly situating mindfulness practice in its Indian/Buddhist context, SB-TPT is designed to enhance relevance and adherence. It remains neutral and clinical in its framing (no ritual or metaphysical claims), while preserving the structured logic of the four foundations. SB-TPT is a culturally grounded extension of mindfulness therapy, hypothesized to augment the effects of MBCT in this population.

The primary objective of this trial is to determine whether SB-TPT plus treatment-as-usual (TAU) will lead to greater reductions in clinician-rated depressive symptoms (HAM-D-17) than TAU alone. A secondary objective is to test the non-inferiority of SB-TPT compared with MBCT delivered under similar conditions. Additional secondary objectives include evaluating whether SB-TPT or MBCT participants show greater improvements in rumination,

self-compassion, mindfulness skills, and quality of life than TAU recipients. All outcomes will be assessed at baseline, post-intervention, and 3-month follow-up.

METHODS

Study design

This study will be a single-blind, three-arm RCT design. Participants diagnosed with depressive disorders as per ICD-10 or DSM-5-TR will be randomly allocated in a 1:1:1 ratio to one of the following conditions: SB-TPT plus treatment-as-usual (TAU), MBCT plus TAU, or TAU alone. Due to the nature of psychological interventions, blinding of participants and intervention therapists is not feasible. However, the outcome assessors responsible for the clinician-rated measure (HAM-D-17) will remain blinded to group allocation to minimize assessment bias. The schedule of enrollment, interventions, and assessments is presented in Table 1. The protocol has been developed in accordance with standard protocol items: recommendations for interventional trials (SPIRIT) guidelines.[25]

Setting

The present study is conducted at the Centre of Excellence for Mental Health, Department of Psychiatry, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi, India (trial period: June 2025 – December 2026). The center provides both outpatient and inpatient services and receives referrals from urban, semi-urban, and rural regions across Uttar Pradesh, Bihar Pradesh, Uttarakhand Pradesh, and Madhya Pradesh. It serves a socioeconomically and demographically diverse population with varied prior exposure to mental health services and varying levels of health literacy. The department manages approximately 850 outpatient consultations weekly, with approximately 4% presenting with depressive disorders, positioning the site as capable of recruiting the required sample over the planned enrollment period. The department has dedicated psychotherapy rooms, assessment facilities, and a multidisciplinary team that includes psychiatrists, clinical psychologists, and social workers. The infrastructure supports both clinical services and academic research, making it well-suited for the implementation of structured psychotherapeutic trials.

Participants will be recruited from the outpatient department, where each patient undergoes an initial comprehensive psychiatric evaluation by consultant psychiatrists. Following diagnosis and treatment planning by the psychiatrist, eligible patients are referred to clinical psychologists for further psychotherapeutic assessment and baseline outcome measurement. Standard clinical care typically includes pharmacotherapy, brief psychoeducation, psychotherapeutic consultations, and follow-up appointments, adjusted according to clinical needs.

Participants

Inclusion criteria

Participants will be adults aged 18–45 years who meet ICD-10 or DSM-5-TR diagnostic criteria for depressive disorders, specifically MDD (single or recurrent episode) or persistent depressive disorder. Only individuals with mild to moderate depressive severity (HAM-D ≥8 and ≤24) will be eligible. Eligible participants must be able to read and comprehend English and communicate in Hindi or English, have completed at least 10th grade education, provide written informed consent, and be deemed clinically suitable for outpatient psychotherapeutic intervention following psychiatric evaluation.

Exclusion criteria

Participants will be excluded if they have a current or past diagnosis of a comorbid psychiatric disorder other than depressive disorder, including bipolar disorder, psychotic spectrum disorders, or substance use disorder. Individuals assessed as being at high suicide risk, or those presenting with acute medical or neurological conditions that may be life-threatening or interfere with consistent participation in outpatient psychotherapy (e.g., pregnancy or early postpartum period, breastfeeding, severe medical instability, or significant physical or sensory impairment), will also be excluded.

Participants currently receiving concurrent structured psychotherapy or intensive psychiatric treatment for conditions other than depression will not be eligible. In addition, individuals with a history of formal, intensive mindfulness-based interventions (e.g., MBCT, MBSR, or residential meditation retreats) within the past three years will be excluded to minimize confounding effects of prior training.

Withdrawal criteria and discontinuation criteria

Participants may be discontinued from the assigned psychological intervention (SB-TPT or MBCT), however, they will be retained in the study for outcome assessments in accordance with the intention-to-treat principle if any of the following occur: attendance of fewer than 70% of scheduled sessions (i.e., <5 of 7 SB-TPT sessions or <6 of 8 MBCT sessions), with reasons for non-attendance documented; emergence of acute suicidal risk, defined as suicidal ideation with intent or a specific plan, or a suicide attempt, necessitating crisis evaluation and/or hospitalization; occurrence of serious adverse events, including onset of bipolar disorder, psychotic symptoms, or a substance-related crisis; or voluntary discontinuation of the intervention by the participant.

In such cases, TAU will continue in accordance with standard clinical practice, and participants will be encouraged to complete all scheduled outcome assessments unless they withdraw consent.

Table 1: Schedule of enrollment, interventions, and assessments.

Study phase	Trial period				
	Screening	Baseline	Intervention	Post-intervention	Follow-up
Time point	**-t1**	**T0**	**Weeks 1–8**	**T1 (week 8; post-intervention)**	**T2 (week 20; 3-month follow-up after T1)**
Enrollment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions					
SB-TPT (+ TAU)			X (7 weeks + consolidation week)		
MBCT (+ TAU)			X (8 weeks)		
TAU alone			X (8 weeks)		
Assessments					
Demographics	X				
Primary outcome					
HAM-D-17 (clinician)		X		X	X
Secondary outcomes					
BDI-II (self-report)		X		X	X
FFMQ-H (mindfulness)		X		X	X
WHOQOL-BREF		X		X	X
RRQ (rumination)		X		X	X
Safety/adverse events			X	X	X

SB-TPT includes 7 active sessions followed by a consolidation week prior to week 8 assessment

Table 2: Summary of Satipaṭṭhāna-based thought purification therapy (SB-TPT) sessions.

Week/ session	Session theme	Satipaṭṭhāna focus	Core practices/activities (examples)	Therapeutic focus
Week 1	Agitated mind	Kāyānupassanā (contemplation of the body)	Restless-mind exercise; bare-attention meditation; contemplative walking; loving-kindness meditation	Grounding attention; recognizing restless and ruminative mental states; developing foundational mindfulness skill on present-moment attention.
Week 2	Posture awareness	Kāyānupassanā (contemplation of the body)	Standing-posture relaxation; “silent breath” seated awareness; “sleep with mind” night-time practice; contemplative walking; loving-kindness meditation	Enhancing body and posture awareness; integrating posture–breath–mind connection; preparing for sustained home practice and improved sleep quality
Week 3	Thoughts awareness	Vedanānupassanā + Cittānupassanā (contemplation of feelings and mind)	Mindful feeling exploration; sensory awareness journey (SAJ); breath progression awareness (BPA); advanced contemplative walking; mindful daily-activity expansion	Differentiating feeling-tone from emotion; improving emotion identification; extending mindfulness into daily activities (sampajañña)
Week 4	Sensation awareness	Vedanānupassanā (contemplation of feelings)	Sensation awareness meditation; refined body scan; attachment versus non-attachment exercises; wholeness breath meditation; advanced body-parts (anatomical) awareness	Deepening awareness of pleasant, unpleasant, and neutral sensations; reducing experiential avoidance; increasing tolerance of internal experience

Continued.

Week/ session	Session theme	Satipaṭṭhāna focus	Core practices/activities (examples)	Therapeutic focus
Week 5	Insightful awareness	Cittānupassanā (contemplation of mind)	Insightful awareness meditation; total body awareness (sabba-kāya-paṭisaṃvedī); hindrance awareness; aggregate awareness	Observing and mapping mental states (e.g., craving, aversion, delusion, concentration); strengthening metacognition, insight, and cognitive flexibility
Week 6	Self-elevate meditation	Dhammānupassanā (mind-objects, realizations the nature)	Self-elevate (four noble truths) meditation (dukkha, samudaya, nirodha, magga); symphony of the Senses; daily sensory exploration; compassion meditation	Applying the four noble truths to depressive experience; cultivating meaning-making, hope, and agency in recovery
Week 7	Disengage from discontent/ emotional liberation	Dhammānupassanā (seven factors of enlightenment integrated with four noble truths)	Radiant mind: seven-factor meditation (mindfulness, investigation, effort, rapture, tranquility, concentration, equanimity); noble truths integration meditation; closing reflection and continuation planning	Integrating insight and regulatory skills; consolidating emotional regulation and equanimity; preparing for ongoing practice beyond the structured program
Week 8	Consolidation and integration	Integration of all four foundations	Guided review meditation; relapse-prevention reflection; practice planning; Q&A	Consolidation of learning; strengthening autonomous practice; preparation for follow-up

Ethical approval and consent procedure

This study was approved by the Institutional Ethics Committee (IEC), Institute of Medical Sciences, Banaras Hindu University, Varanasi, India, through a full review process held on 16 December 2024 (Ref: IMS/IEC/2024/7772). The study will be conducted in accordance with ethical principles outlined in the Declaration of Helsinki and the Indian Council of Medical Research (ICMR) guidelines. Participants will be recruited from outpatient services following the standard workflow: psychiatric evaluation, diagnosis, clinical stability, and study invitation. Decision-making capacity will be assessed before obtaining consent by a trained clinical psychologist or research assistant who is not involved in the participant's clinical decision-making. IEC-approved consent forms in English and Hindi will be provided both verbally and in writing. Participation is entirely voluntary, with the right to withdraw at any time without affecting clinical care. No financial incentives will be offered; participants will benefit from structured therapeutic interventions. All data will be de-identified, with personally identifiable information stored separately in password-protected files. Any important protocol modifications will be submitted for IEC approval prior to implementation and updated in the CTRI record; relevant study personnel (and participants, where applicable) will be informed.

Clinical trial registry and status

The trial has been registered with the Clinical Trials Registry of India (CTRI; www.ctri.nic.in) under registration number CTRI/2025/05/087988 (registered on 30 May 2025). Participant recruitment commenced in June 2025 and is ongoing at the time of manuscript submission. To date, 21 participants have been enrolled across the three study arms. The expected duration of the study is approximately 12–18 months (June 2025-December 2026), including participant recruitment (target n=72), intervention delivery, post-intervention assessments, and a planned 3-month follow-up evaluation.

Randomization and treatment allocation

Following the informed consent and completion of baseline assessments, participants will be randomly allocated in a 1:1:1 ratio to one of three study arms: SB-TPT plus TAU, MBCT plus TAU, or TAU alone. The randomization sequence was computer-generated in advance using Microsoft Excel (RAND function; Version 2025) by an independent statistician uninvolved in recruitment, intervention delivery, or outcome assessment. To ensure allocation concealment while accommodating sequential OPD recruitment, the sequence was printed on individual cards, folded, and sealed in sequentially numbered, opaque envelopes (SNOSE method) by an independent administrator. Eligible OPD patients are assigned sequentially by envelope number (e.g., patient #5 opens envelope #5 post-consent), maintaining blinding until allocation. Due to the nature of the psychological interventions, blinding of participants and interventionists is not feasible; However, outcome assessors responsible for clinician-rated HAM-D-17 assessments remained blinded to group allocation. At each assessment visit, assessors record whether they inadvertently learned the participant's allocation, providing an objective measure of blinding integrity.

Interventions

The Satipaṭṭhāna-based thoughts-purification therapy

SB-TPT is a seven-week, manualized mindfulness meditation-based intervention derived from the classical Satipaṭṭhāna Sutta of the Theravāda Buddhist canon. The program is grounded in systematic experiential training in the Four Foundations of Mindfulness, mindfulness of the body, feelings, mind, and mental objects, and incorporates structured psychoeducation and guided reflective practices aimed at identifying, observing, and purifying maladaptive thought patterns. Weekly sessions, each lasting approximately 2.5 hours, will be delivered individually and facilitated by a clinical psychologist trained in Buddhist contemplative frameworks and psychological therapy. Participants will also receive home practice assignments, including meditation exercises included in the SB-TPT manual. The current version of the SB-TPT manual has been publicly archived to facilitate transparency and replication.[26] The manual is available via the open science framework (OSF) repository.

Mindfulness-based cognitive therapy

Participants assigned to the MBCT group will receive the psychotherapeutic intervention according to the published MBCT protocol.[11] The intervention consists of 8 weekly sessions, each lasting approximately 2.5 hours, and 1 day of silent practice. The MBCT program includes both formal meditation practices, such as body scan, sitting meditation, walking meditation, and yoga, and informal practices that involve cultivating present-moment awareness during everyday activities. The intervention integrates mindfulness meditation practices with cognitive-behavioral therapeutic components, emphasizing awareness of automatic cognitive patterns, decentering from negative thoughts, and strategies for preventing depressive relapse.[27,28]

Treatment-as-usual control

All participants will receive standard psychiatric care at IMS-BHU Psychiatry, which includes pharmacotherapy as clinically indicated, brief psychoeducation, and routine outpatient follow-up. TAU excludes any structured or manualized psychotherapy. All TAU components, such as medications, visit frequency, and psychoeducation, will be documented individually to evaluate their effects as covariates. Psychotherapy will not be provided during the 8-week intervention phase of this clinical trial.

Outcome measures

Outcomes will be assessed at baseline (T0; week 0), post-intervention (T1: week 7 to 8), and 3-month follow-up from T1 (T2: week 12 to 13 from post-intervention) by blinded assessors, except for self-reported measures. The primary outcome is depressive symptom severity, measured using the 17-item Hamilton depression rating scale (HAM-D-17).[29] Analysis will focus on the time × group interaction using repeated-measures ANOVA from baseline to post-intervention. Blinded assessors will be trained to achieve inter-rater reliability $\kappa>0.80$, with 10% of assessments double-scored to ensure consistency in rating. Secondary outcome measures such as depressive symptoms, thought ruminations, quality of life, and mindfulness skills will include self-reported questionnaires/ inventories, such as Beck depression inventory-II (BDI-II), rumination-reflection questionnaire (RRQ), the WHOQOL-BREF (WHOQOL), and the five facet mindfulness questionnaire (FFMQ).[30-33] The FFMQ-H assesses attentional stability, the RRQ evaluates cognitive rumination, and the WHOQOL-BREF measures overall life satisfaction within a quality-of-life framework. All instruments have been validated in Indian populations and demonstrate satisfactory internal consistency and validity.[34,35]

Data and statistical analyses

Baseline comparability

In this study, one-way ANOVA will be used to compare baseline continuous variables (age, baseline HAM-D-17, BDI-II scores), while chi-square tests will be used for categorical variables (gender, education level, employment status).

Primary and secondary analyses

In the primary analysis, a repeated-measures ANOVA will test the time × group interaction for changes in HAM-D-17 scores from baseline (T0) to post-intervention (T1) across three groups, with multiple testing corrections at T2 (3-month follow-up). A two-sided $p<0.05$ will be considered statistically significant. The same conditions apply to secondary analyses. Corresponding 95% CIs will be calculated whenever possible.

In secondary analyses, continuous outcomes from baseline (T0) to post-intervention (T1: week 8) and to the 3-month follow-up (T2: week 20) will be analyzed using general linear mixed models. Main predictors of interest include time, treatment group, and their interaction, with age, gender, education level, and baseline scores entered as covariates and participant ID as a random effect.

Restricted maximum likelihood will be adopted in the mixed models. The above analyses will be repeated after supplementing T2 follow-up scores to assess treatment maintenance.

Intention-to-treat analysis and missing data handling

All analyses will be conducted according to the intention-to-treat (ITT) principle, including all randomized participants (n=72) in the groups to which they were initially assigned, regardless of intervention adherence or

completion. This approach minimizes attrition bias and maintains the integrity of randomization.

Missing data diagnostics will be performed using Little's MCAR test to assess the assumption of missing completely at random. If the data are not MCAR, we will examine the patterns of missing data to determine whether the missing at random (MAR) assumption is appropriate. Upon confirmation of the MAR assumption, multiple imputation using the multivariate imputation by chained equations (MICE) algorithm will be employed, creating 20 imputed datasets in accordance with best-practice recommendations.[36,37] Results will be pooled using Rubin's rules to generate combined parameter estimates and standard errors.[37] Sensitivity analyses testing missing-not-at-random (MNAR) assumptions will use "best-case" and "worst-case" imputation scenarios to assess the robustness of the findings.

Durability analysis

Beyond the primary and secondary analyses at post-intervention, the analyses will be repeated after supplementing 3-month follow-up scores to assess the sustainability and maintenance of treatment effects beyond the active intervention period. A repeated-measures ANOVA, extended from baseline through 3-month follow-up, will evaluate whether treatment-group differences persist and whether therapeutic gains are maintained, diminish, or continue to improve over time. Time-by-group interactions at the follow-up timepoint will indicate whether treatment groups show differential trajectories of symptom change or stability post-treatment, informing conclusions about the durability of intervention benefits.

Power and sample size

Sample size was calculated based on detecting a medium effect size (f=0.25) in repeated-measures ANOVA examining time × group interaction across three groups and three timepoints, using G*Power (version 3.1).[38] With 80% power and α=0.05, the minimum required sample size is n=66 (22 per group). This effect size aligns with meta-analytic findings on mindfulness interventions for depression and assumes a r=0.50 correlation across repeated measures.[39] Given an anticipated attrition rate of 10%, a total of 72 participants will be recruited (24 per group). This sample size provides sufficient statistical power (actual power=0.82) to detect clinically meaningful differences in depressive symptom severity (HAM-D-17) and secondary outcomes across the intervention and control groups over time. The target sample of 72 exceeds the minimum requirement and provides a buffer against attrition, ensuring the trial maintains adequate power for primary and secondary intention-to-treat (ITT) analyses. Post-hoc sensitivity analyses will explore power across effect sizes (f=0.20–0.40) and attrition rates (5–15%) to assess the robustness of the conclusions.

Data collection and management

Data will be collected at three assessment time points: baseline (prior to randomization), post-intervention (immediately after completion of the 7-week SB-TPT to 8-week MBCT program), and 3-month follow-up. Trained research assistants will be blinded to treatment allocation and will administer all standardized clinician-rated and self-report measures.

Participant responses will be recorded on standardized data entry forms and entered into preformatted Microsoft Excel (version 2025) spreadsheets. Each participant will be assigned a unique identification code. personally identifiable information (name, contact, hospital record number) stored separately in password-protected electronic files, accessible only to authorized personnel. Hard copies of assessment forms and consent documents will be securely stored in locked filing cabinets at the research site. Electronic data will be routinely backed up and stored in secure, encrypted digital formats, with access restricted to authorized personnel.

Data validation checks will be conducted regularly to ensure accuracy and completeness of all entries. Records will be retained for a minimum of 15 years in accordance with ethical standards and national regulations governing the management and confidentiality of human-subject research data. All data management procedures will adhere to guidelines established by the Institutional Ethics Committee (IEC) and comply with national and institutional regulations regarding human subject research, informed consent, and data confidentiality. Trial results will be reported in the Clinical Trials Registry of India (CTRI) and disseminated through publication in a peer-reviewed journal and presentation at scientific conferences. De-identified participant data (and the data dictionary) and statistical code will be made available after publication via an open repository (e.g., OSF) or on reasonable request, subject to IEC approval and a data-use agreement to protect confidentiality.

Trial oversight and monitoring

The trial will be supervised by the principal investigator and site investigators through routine internal checks of recruitment, informed consent, protocol compliance, and data quality. As this is a low-risk psychotherapy trial with a fixed sample size, an independent Data Monitoring Committee will not be established. Participant safety and protocol-related issues, including serious adverse events such as acute suicidality, will be documented and reported to the IEC in accordance with institutional requirements. No interim analyses are scheduled.

DISCUSSION

Mindfulness-based interventions such as MBCT have demonstrated efficacy in reducing depressive symptoms and preventing relapse.[40] However, a significant

proportion of patients continue to experience incomplete treatment response or experience relapses despite being treated with pharmacotherapy and/or third-generation psychotherapies, highlighting the need for additional scalable psychotherapeutic approaches. Therefore, this current trial is designed to evaluate the therapeutic effectiveness of SB-TPT in comparison with MBCT and TAU in managing depressive symptoms in patients with depressive disorders.

Secondary outcomes, such as mindfulness, rumination, self-compassion, and quality of life, will provide insight into clinically meaningful changes beyond symptom reduction and inform future investigations into underlying mechanisms.

Cultural acceptability, engagement, and sustainability are critical determinants of any intervention, as SB-TPT aligned with indigenous belief systems and traditional practices would foster greater engagement and long-term treatment adherence. The scriptural foundations of SB-TPT may enhance its acceptance in populations familiar with contemplative and meditative traditions, thereby strengthening its real-world effectiveness.

Moreover, structuring therapy sessions, documenting them, and open-archiving the SB-TPT protocol promote methodological transparency, reproducibility, and the broader dissemination of findings across clinical and research settings.

Nevertheless, the study will possess several methodological strengths, including an adequate sample, rigorous procedures, an active-comparator, blinded clinician-rated outcomes, and adherence to ITT analysis. Although the study will also have some limitations. For instance, participant recruitment will be restricted to a single site, which may limit the generalizability of the findings. Further, outcome assessors will remain blinded to group allocation, and participants and therapists cannot be blinded following randomization due to the nature of the psychological interventions.

CONCLUSION

This RCT will systematically evaluate the clinical effectiveness of SB-TPT in comparison with MBCT and TAU for depressive disorders. Structuring the session module of SB-TPT would have immense clinical and research utility. By employing a rigorous three-arm design and a framework, the findings are expected to clarify the relative benefits of SB-TPT on depressive symptoms and associated cognitive–affective processes, while also informing its feasibility for routine mental health service delivery. If SB-TPT demonstrates either superior or comparable efficacy, it may represent a scalable, cost-effective, and culturally adaptable strategy for broadening access to evidence-based psychological care for depression.

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