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Development and feasibility of a novel online individual Mindfulness-integrated Trial-Based Cognitive Therapy (M-TBCT) intervention: a phase 1 single-arm pilot and feasibility study in judiciary workers

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Additional Declarations: Competing interest reported. One of the authors (I.R.O.) is the developer of Trial-Based Cognitive Therapy (TBCT), and another author (M.D.) is the developer of the Mindfulness-Based Health Promotion (MBHP) protocol, which informs the mindfulness strategies used in M-TBCT. This structural conflict of interest may have influenced decisions regarding intervention design, outcome

selection, and interpretation of findings, and should be considered when evaluating the conclusions reported here. The remaining authors declare no competing interests.

Abstract

Background: Work-related mental health problems are highly prevalent, yet scalable and context-sensitive integrative interventions remain underexplored in high-demand occupational settings. Objective: To examine the feasibility and acceptability of a novel online individual mindfulness-integrated Trial-Based Cognitive Therapy (M-TBCT) intervention in a real-world occupational context, describe its development, and, as an exploratory secondary aim, examine preliminary signals of change in psychological outcomes. This study was not designed to evaluate efficacy. Methods: This Phase 1 mixed-methods pilot study was conducted with judges and court employees from a Brazilian regional labor court. Participants were screened with the Self-Report Questionnaire (SRQ-20), and 30 eligible participants were offered an eight-session weekly online intervention. The intervention integrated mindfulness and self-compassion practices derived from the Mindfulness-Based Health Promotion (MBHP) protocol with Trial-Based Cognitive Therapy (TBCT). Feasibility was assessed through recruitment, retention, and attendance; acceptability was assessed through satisfaction ratings and qualitative feedback. Pre- and post-intervention outcomes included well-being (WHO-5), depressive symptoms (PHQ-9), anxiety symptoms (GAD-7), and self-care agency (ASAS-R). Results: Recruitment reached 100.0% of the target sample, and retention was 96.7%. Acceptability was high (M = 4.71, SD = 0.45; α = .95), with qualitative reports indicating perceived gains in self-awareness, emotional balance, tranquility, and assertiveness. Among participants with complete pre–post data (n = 28), changes coinciding with the intervention period were observed in well-being (MD = 19.00, 95% CI [12.24, 25.76]; d = 1.09), self-care agency (MD = 8.57, 95% CI [4.84, 12.30]; d = 0.89), anxiety (MD = −5.60, 95% CI [−7.91, −3.29]; d = 0.94), and depressive symptoms (MD = −3.22, 95% CI [−5.72, −0.72]; d = 0.50). These changes cannot be causally attributed to the intervention in the absence of a control group. Depressive symptom changes were more modest compared to other outcomes (d = 0.50), and the proportion of participants above the PHQ-9 clinical cutoff did not change appreciably between pre- and post-intervention. This suggests that clinical improvement in depression was less consistent across participants. Conclusions: This pilot study supports the feasibility and acceptability of M-TBCT and provides preliminary signals that justify progression to a controlled trial. Rather than providing evidence of efficacy, these findings support the implementation viability and conceptual plausibility of M-TBCT, thereby justifying progression to adequately powered randomized trials.

Key message

• What uncertainties existed regarding feasibility? It was unknown whether M-TBCT — a novel integrative intervention combining Mindfulness-Based Health Promotion (MBHP) with Trial-Based Cognitive Therapy (TBCT) delivered online in an individual format — could be feasibly implemented and acceptably received in a high-demand occupational setting such as the Brazilian judiciary.

• What are the key feasibility findings? Recruitment reached 100.0% of the target sample (n = 30), exceeding the pre-specified 70% threshold. Retention was 96.7%, exceeding the 80% threshold. Mean session attendance was 7.4 of 8 sessions. Acceptability was high (M = 4.71/5; SD = 0.45; α = .95),

corroborated by qualitative reports of perceived gains in self-awareness, emotional balance, tranquility, and assertiveness. No adverse events occurred.

• What are the implications for the design of the future definitive study? The strong feasibility and acceptability profile supports progression to a Phase 2 randomized controlled trial (ReBEC: RBR-6jsp9fs), currently underway, which incorporates a control group, a larger sample (n = 90), independent treatment fidelity monitoring through video recording of a random subset of sessions, and a 6-month follow-up assessment.

INTRODUCTION

Work-related mental health conditions remain among the leading contributors to absenteeism, presenteeism, and prolonged work disability. Contemporary evidence indicates that adverse psychosocial working conditions—including high demands, low control, effort–reward imbalance, insecurity, low support, and recurrent experiences of unfairness or devaluation—are robustly associated with common mental health problems such as anxiety and depression [1, 2, 3]. In response, the World Health Organization (WHO) and the International Labour Organization (ILO) have advocated for integrated workplace mental health strategies combining organizational risk reduction with individual-level prevention and support [4, 5].

Systematic reviews suggest that workplace-facilitated psychological interventions can improve emotional symptoms, stress, burnout, and selected work-related outcomes, although effects are often small to moderate and highly dependent on implementation quality, intervention fit, and comparator type [6, 7, 8]. This pattern has increased interest in brief, scalable, context-sensitive interventions that can be delivered in demanding occupational settings while remaining acceptable to workers and feasible for services.

Mindfulness-Based Interventions

Mindfulness-based interventions are one prominent candidate. Across randomized trials and meta-analytic syntheses, mindfulness-based programs have shown beneficial effects on distress, anxiety, depression, and well-being, with particularly relevant evidence emerging for workplace settings [9, 10, 11, 12]. Mechanism-focused work suggests that decentering, acceptance, self-compassion, and emotion regulation are plausible transdiagnostic pathways through which these practices may operate [13, 14]. Within this tradition, Mindfulness-Based Cognitive Therapy [15, 16] has demonstrated the feasibility of integrating mindfulness with cognitive strategies, showing that present-moment awareness and decentering can reduce the reactivation of depressogenic thinking patterns.

Similarly, Acceptance and Commitment Therapy [17, 18] has emphasized that experiential avoidance is a transdiagnostic process that can be addressed through acceptance-based and values-oriented strategies. Compassion-focused therapies [13, 14] have further shown how self-compassion can

counteract self-critical processing. These integrative precedents are relevant context for the present work.

Cognitive-Behavioral Therapies and Trial-Based Cognitive Therapy

Cognitive-behavioral therapies remain among the most empirically supported psychological approaches for emotional disorders. Recent meta-analyses indicate that CBT is effective across a broad range of adult mental disorders, and transdiagnostic cognitive-behavioral approaches appear especially relevant in settings where mixed anxiety–depression profiles are common [19, 20, 21, 22]. Mechanism-oriented syntheses further suggest that cognitive flexibility, reappraisal, and reductions in maladaptive automatic responding remain central pathways of change [22].

Within this tradition, Trial-Based Cognitive Therapy (TBCT) was developed to target dysfunctional core beliefs through a structured experiential format that uses a courtroom metaphor to help patients examine evidence for and against their beliefs [23, 24]. Initial evidence from [25] showed that trial-based procedures could improve quality of life and social anxiety-related outcomes. Subsequently, TBCT has been investigated in social anxiety with depressive comorbidity [26], obsessive-compulsive disorder [27], and other presentations.

The meta-analysis by [28] concluded that TBCT showed efficacy comparable to first-line psychotherapies for depressive and anxious symptoms. This line of work suggests that trial-based procedures may be transportable across diagnostic categories while retaining a shared focus on rigid interpretive styles and dysfunctional core beliefs—two constructs that are related but operate at different levels, the former reflecting processing inflexibility and the latter reflecting specific belief content that maintains distress.

Rationale for Integration and Differentiation from Existing Approaches

The integration of mindfulness-based practices with trial-based cognitive work is theoretically plausible. Several specific hypotheses motivate this combination. First, mindfulness may reduce defensive reactivity and create conditions of greater psychological openness that facilitate the cognitive restructuring work central to TBCT (consistent with Segal et al.'s [15] model of decentered awareness as a precondition for cognitive change). Second, TBCT's structured, experiential format may address engagement challenges sometimes observed in pure mindfulness programs by providing concrete, session-by-session tools for working with specific beliefs and interpersonal difficulties. Third, self-compassion practices may counteract the self-critical patterns that often maintain core beliefs (consistent with Gilbert's [29] model), while TBCT's trial-based procedures offer a structured method for testing and revising those beliefs. Together, these components are designed to target multiple, mutually reinforcing processes—attentional regulation, decentering, self-compassion, belief identification, and cognitive restructuring—in a coherent package. Thus, M-TBCT may be understood as a process-based integrative intervention targeting both attentional-experiential and cognitive-evaluative systems.

M-TBCT is distinct from existing integrative approaches in several respects. Unlike MBCT, which integrates mindfulness primarily with relapse-prevention strategies for depression, M-TBCT combines mindfulness with TBCT's experiential trial-based procedures that systematically target core beliefs across presentations. Unlike ACT, which emphasizes psychological flexibility through acceptance and values clarification, M-TBCT includes structured cognitive conceptualization at multiple levels and explicit belief restructuring through the trial metaphor. Unlike CFT, which centers on compassion as the primary change mechanism, M-TBCT incorporates compassion as one element within a broader integration of mindfulness, cognitive restructuring, and interpersonal skill-building. These distinctions are intended as complementary contributions to the growing family of integrative approaches, not as claims of superiority.

The Judiciary as a Context for Implementation

The judiciary is a context characterized by sustained cognitive load, time pressure, and emotionally demanding interpersonal work. Research with judges, court employees, and legal professionals has highlighted associations between occupational strain and outcomes such as common mental disorders, compassion fatigue, and vicarious trauma [30, 31, 32]. In Brazil, labor courts also operate under substantial institutional pressure, combining procedural deadlines, responsibility for decisions with marked human consequences, and hybrid forms of work that can blur boundaries between professional and personal time.

Implementation-Science Framing

From an implementation-science perspective, early-stage studies of complex psychological interventions should first clarify whether the intervention can be delivered as intended, whether it is acceptable to recipients, and whether it shows preliminary signals that justify larger controlled trials [33]. This distinction is particularly important in small uncontrolled pilot studies, which are not designed to evaluate efficacy [34] conceptualized acceptability as a multidimensional construct involving affective attitude, burden, coherence, perceived effectiveness, opportunity costs, ethicality, and self-efficacy. Feasibility indicators such as recruitment, retention, and attendance provide concrete information about whether an intervention has enough implementation traction to progress to controlled testing.

Accordingly, the present study was designed to make three contributions. First and foremost, it examines M-TBCT's feasibility and acceptability in a real-world pilot implementation with judiciary workers. Second, it describes the development and structure of M-TBCT. Third, as an exploratory, secondary aim not intended to support efficacy claims, it examines preliminary signals of change in psychological well-being, anxiety, depressive symptoms, and self-care agency. Consistent with the CONSORT extension for pilot and feasibility trials [33], the study was not designed or powered to evaluate efficacy. Accordingly, this study addresses three questions: (1) Is M-TBCT feasible in a judiciary context? (2) Is it acceptable to participants? and (3) as an exploratory question, are there descriptive signals of change in psychological outcomes that justify progression to a controlled trial?

METHODS

This Phase 1 mixed-methods pilot study followed the CONSORT extension for pilot and feasibility trials [33] and the TREND guidelines for transparent reporting of evaluations with nonrandomized designs. A CONSORT-style participant flow diagram is presented in Fig. 1. The overall study design, including Phases 1 and 2, has been previously described in the published protocol by [35].

Ethics Approval

The study was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and subsequent amendments. Ethical approval was granted by the Research Ethics Committee (Institutional Review Board) of the Federal University of São Paulo (UNIFESP), (CAAE 73817423.3.0000.5505), and all participants provided informed consent before participation. This study was registered with the Brazilian Clinical Trials Registry (ReBEC), registration number RBR-6jsp9fs.

Participants

Thirty judiciary employees and judges from the Regional Labor Court of the 5th Region (TRT5) who met the eligibility criteria were enrolled. Eligibility criteria were age 18 years or older, internet access, and a score of at least 7 on the Self-Report Questionnaire (SRQ-20). This cutoff has demonstrated adequate sensitivity and specificity for detecting common mental disorders in Brazilian occupational samples [36, 37], though it captures a heterogeneous range from mild to moderate distress.

Exclusion criteria were self-reported severe mental disorder or ongoing severe organic illness (e.g., personality disorder, schizophrenia, psychotic disorder), suicidal ideation, or substance use likely to impair attention and concentration; being in the initial phase of, or undergoing adjustments to, pharmacological and/or psychotherapeutic treatment; and regular practice of mindfulness, meditation, or related contemplative practices. We acknowledge that reliance on self-report for excluding severe mental disorders is a limitation; future studies should include brief structured screening instruments (e.g., MINI International Neuropsychiatric Interview) for more robust diagnostic exclusion. Informed consent to participate was obtained from all individual participants included in the study.

Sample Size

Sample size was informed by recommendations for Phase 1 feasibility studies. Following the parameters adopted by [38] for pilot studies of mindfulness-based interventions—who recommended samples of 20–40 participants for initial feasibility testing where the primary aim is to estimate feasibility parameters rather than to detect statistically significant treatment effects—a target of 30 participants was set. This target was set near the lower-to-middle end of the recommended range, balancing adequate feasibility estimation against the logistic constraints of delivering eight individual weekly sessions through a single facilitator. This target was achieved. Given the Phase 1 scope, the study was not powered for formal hypothesis testing of clinical outcomes.

Participant Characteristics

Of the 30 enrolled participants, 29 completed acceptability assessments and 28 provided complete pre–post outcome data. The mean age was 47 years (*SD* = 8.17), and 75.9% were women. Most participants were married or in a stable relationship (48.3%), had children (79.3%), and held postgraduate degrees at the specialization level (58.6%; referred to in Brazil as *lato sensu*, equivalent to a post-baccalaureate specialization certificate) and/or master's or doctoral level (10.3%; referred to as *stricto sensu*).

Regarding work characteristics, 55.2% reported a weekly workload of more than 35 and up to 45 hours, and 65.5% reported a hybrid work arrangement combining in-person and remote activities. It should be noted that the sample was predominantly female and highly educated; the extent to which this demographic profile reflects the broader Brazilian judiciary requires further investigation.

Procedure

Participants were recruited between January and February 2023 through an invitation disseminated via the institutional intranet. This self-selection recruitment strategy may have attracted participants already motivated for psychological intervention, which should be considered when interpreting acceptability and outcome results. Assessments were conducted immediately before (T1) and after (T2) the intervention. All online self-report questionnaires included an introductory page with information about the study, confirmation of anonymity, and assurance of voluntary participation.

Participants were explicitly informed that this was a pilot study testing a new intervention, that their responses would be anonymized, and that participation was entirely voluntary with no institutional consequences for non-participation or withdrawal. Participants provided informed consent before completing the questionnaires. The study was approved by the Ethics Committee of the Federal University of São Paulo and was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and its subsequent amendments.

Description of the Mindfulness-Integrated Trial-Based Cognitive Therapy Protocol (M-TBCT)

Participants individually received M-TBCT, delivered online over eight weeks in weekly 60-minute sessions. The intervention was designed to support participants in learning and practicing evidence-based skills to enhance psychological well-being. Mindfulness and self-compassion strategies were drawn from the Mindfulness-Based Health Promotion (MBHP) protocol [39]; trial-based cognitive strategies were drawn from Trial-Based Cognitive Therapy (TBCT; [24]).

The TBCT-specific procedures used within M-TBCT include three progressive levels of cognitive conceptualization. Level I involves identifying automatic thoughts, emotions, and behaviors in specific situations, using the Cognitive Distortions Questionnaire (CD-Quest; [24])—a 15-item self-report measure (9-item short form used here; referred to as CD-Quest-9) that helps participants identify cognitive distortions in their thinking patterns [40]. Level II involves identifying intermediate beliefs (conditional assumptions) and their relationship to core beliefs.

“Consensual role-play” refers to a structured TBCT technique in which the therapist and participant collaboratively enact a feared interpersonal situation to develop and practice alternative responses derived from cognitive restructuring. “Trial I” and “Trial II” refer to structured techniques within the trial procedures: Trial I involves the initial examination and cross-examination of evidence (analogous to prosecution and defense), followed by synthesis and verdict, in which the participant formulates a functional positive core belief. In Trial II, the newly formulated positive core belief is consolidated through a metacognitive process in which the Prosecutor—previously experienced as an internal critical voice—is put on trial by the patient, who assumes the role of plaintiff. This process aims to transform the internal critic into a more adaptive and balanced internal voice, thereby enhancing its credibility and functional role.

After each session, participants received by email the materials covered in that session and were encouraged to practice the techniques at home. The psychologist responsible for delivering M-TBCT created an individual Google Meet link for each participant, which was used across all sessions. The session structure is presented in Table 1.

Table 1
Session structure of M-TBCT

Session	Core intervention content	Home practice
1. Moving out of automatic pilot	Level I TBCT conceptualization diagram; CD-Quest-9; raisin exercise	CD-Quest-9; text on mindfulness; informal mindfulness during part of a meal
2. Mindfulness and cognitive distortions	Body scan; full intrapersonal thought record (with or without action plan)	Action plan if built in session; text on mindfulness practice; formal body scan
3. Body, thoughts, emotions, and behavior	Interpersonal thought record (with action plan) or participation grid (for guilt/shame); mindful breathing	Action plan; text on working with the body; formal breathing practice
4. Facing fears	Three-step breathing space; Level II TBCT conceptualization diagram; color-coded symptom hierarchy and action plan	Hierarchy and action plan; informal three-step practice
5.Expanding mindfulness	Basic sounds-and-thoughts practice; consensual role-play for a feared situation and action plan	Action plan; formal sounds-and-thoughts practice
6. Modifying core beliefs	Advanced sounds-and-thoughts practice with labeling and metaphors; Level III TBCT conceptualization diagram; Trial I (begin)	Positive-belief diary; formal advanced sounds-and-thoughts; informal mindful walking or another physical activity
7.Developing positive beliefs	Trial I (complete); compassion practice for self and other	Preparation for “the appeal”; text on mindfulness and compassion; formal compassion practice
8. Being one’s own therapist	Trial II; assertive letter to the prosecutor; self-compassion practice; final feedback	Text on acceptance of reality; personal curriculum based on tools learned

M-TBCT Facilitator and Supervision

M-TBCT was delivered by a judicial analyst/psychologist from TRT5 who was also a researcher involved in this study. At the time the study was conducted, she was the only professional within the institution with concurrent formal training both as a mindfulness instructor through the MBHP protocol at UNIFESP and in TBCT under the supervision of TBCT's developer.

The facilitator received ongoing clinical supervision from senior members of the research team throughout the intervention period. We acknowledge that the facilitator's simultaneous roles as institutional employee, researcher, and therapist represent an important limitation (discussed further below), and that this single-therapist delivery model limits the ability to separate therapist effects from intervention effects.

Treatment Fidelity

No formal, independent treatment fidelity assessment was conducted for this Phase 1 study. Sessions were not audio- or video-recorded, and no independent adherence ratings were obtained. The facilitator used a session-by-session checklist to ensure that all planned components were delivered and received ongoing supervision from senior investigators. In addition, the qualitative analyses in Phase 1 were conducted by two researchers (SB and VS), one of whom is a senior qualitative researcher (VS).

Although this analytic procedure contributed to the rigor of interpretation of participants' reports, it does not replace formal fidelity monitoring of intervention delivery. We therefore recognize the absence of formal fidelity assessment as a significant limitation. The Phase 2 trial, which is currently underway, includes video recording of a random subset of sessions and intensive supervision by the developers of the approaches underlying the M-TBCT protocol. A 6-month follow-up assessment has also been incorporated.

Safety Monitoring

Given that M-TBCT involves exploration of cognitive distortions, safety-seeking behaviors, core beliefs, and interpersonal difficulties - all of which can elicit emotional distress - safety procedures were in place. The facilitator assessed participant well-being at the beginning of each session and monitored for signs of acute distress throughout. If a participant exhibited psychological suffering indicating the need for specialized care, the facilitator - who is a licensed psychologist employed by the institution - could offer additional care outside the intervention protocol through the institution's Psychology Service or refer the participant to external mental health care, according to participant preference. No adverse events or clinical deteriorations requiring such intervention or referral occurred during the study period.

Measures

Screening Measure

Mental health screening was conducted using the Self-Report Questionnaire (SRQ-20), developed by the World Health Organization and validated for use in Brazil by Mari and Williams (1986). The instrument consists of 20 dichotomous ("yes"/"no") items assessing symptoms of common mental disorders, with a cutoff score of 7 indicating suspected cases. It has been widely used in occupational samples [37].

Outcome Measures

Well-being was assessed using the World Health Organization-Five Well-Being Index (WHO-5), a widely used outcome measure in clinical trials [41]. The instrument includes five items rated on a 5-point Likert scale ranging from 5 (*all the time*) to 0 (*at no time*). Raw scores are multiplied by 4, resulting in a scale from 0 (absence of well-being) to 100 (maximum well-being). Scores ≤ 50 indicate screening for clinical depression.

Depressive symptoms were measured using the Patient Health Questionnaire-9 (PHQ-9), which consists of nine items rated on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*nearly every day*), with a

cutoff score of 10 indicating major depressive symptoms [42]. The Brazilian validated version was used [43].

Anxiety symptoms were measured using the Generalized Anxiety Disorder-7 (GAD-7), which consists of seven items rated on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*nearly every day*), with a cutoff score of 10 indicating generalized anxiety symptoms [44]. Validity evidence for use in Brazil has been documented by the Mapi Research Institute [45].

Self-care agency was assessed using the Appraisal of Self-Care Agency Scale-Revised (ASAS-R), which evaluates health-promoting behaviors. It consists of 15 items rated from 1 (*strongly disagree*) to 5 (*strongly agree*). The scale was validated for use in Brazil by Damásio and Koller [46]. While the ASAS-R was not designed to capture mindfulness or cognitive restructuring specifically, self-care agency was included as an outcome because the capacity for deliberate health-promoting behavior is conceptually consistent with the self-regulatory gains targeted by both mindfulness (increased awareness and intentional responding) and TBCT (reduced automatic maladaptive patterns).

The CD-Quest-9 (Cognitive Distortions Questionnaire, 9-item; [24]); short version described in Morrison et al. [40] was used within sessions as a therapeutic tool to help participants identify cognitive distortions (Table 1, Session 1). It was administered as part of the clinical procedure rather than as an outcome measure per se and was therefore not included in the pre-post analyses.

Acceptability Measures

Acceptability was examined based on self-reported satisfaction and qualitative findings obtained through a post-intervention questionnaire. Session attendance was tracked as a feasibility indicator (see below) rather than as an acceptability criterion per se, following the conceptual distinction between these constructs outlined by [34]. The acceptability instrument is exploratory and not formally psychometrically validated.

The quantitative section consisted of 12 items rated on a Likert scale from 1 (*completely dissatisfied*) to 5 (*completely satisfied*), adapted from [47] and [38], covering motivation, therapist competence, format adequacy, session duration and frequency, quality of materials, perceived usefulness, expectation fulfillment, willingness to recommend, and overall satisfaction. The qualitative section consisted of nine open-ended questions adapted from [38] capturing perceptions of well-being and self-care, practices perceived as most relevant, challenges in participation, and strategies considered most accessible.

Feasibility Measures

Feasibility was evaluated based on predefined criteria adapted from Gould et al. [47]: recruitment of at least 80% of the target sample and retention of at least 60% at the final follow-up assessment. Session attendance was also monitored, with a descriptive threshold of more than 60% of sessions attended.

Statistical Analysis

Quantitative analyses were conducted using R version 4.3.2 and qualitative analyses were performed using Release One/NVivo 13. Analyses prioritized point estimates, 95% confidence intervals, and effect sizes. Two-tailed significance tests (α = .05) were computed only to inform the choice between paired t-tests and Wilcoxon signed-rank tests (see below) and are not reported as evidence of significance in the main text, consistent with the exploratory, non-confirmatory aim of this Phase 1 study. Effect sizes (Cohen's *d*) were interpreted as small (0.2), moderate (0.5), and large (≥ 0.8) according to Cohen [48]. Consistent with the CONSORT extension for pilot trials [33], inferential tests are presented as descriptive summaries of the data pattern rather than as evidence of efficacy.

For clinical outcomes (WHO-5, PHQ-9, GAD-7, and ASAS-R), pre–post changes were examined using mean differences, effect sizes, and repeated-measures tests. Data distribution was assessed using histograms and the Shapiro–Wilk test. Given the observed violations of normality for post-intervention PHQ-9 and GAD-7 scores, Wilcoxon signed-rank tests were used as the primary analyses for these outcomes, with paired t-tests reported as sensitivity analyses for comparability.

Associations between outcomes were examined using Spearman correlations, with 95% CIs approximated using Fisher's *r*-to-*z* transformation. Changes in risk classification were evaluated using McNemar's test, with exact binomial tests for discordant pairs. Given the Phase 1 nature of the study and the sample size (n = 28), no regression or moderation analyses are presented in this manuscript.

This decision was made because such models would be highly unstable and prone to overinterpretation in a pilot sample of this size. All data were processed and analyzed in anonymized form. As outlined in the study protocol, these findings may inform the design of Phase 2, corresponding to a randomized controlled trial.

Qualitative Analysis

Qualitative data from the open-ended questions were analyzed using thematic content analysis following [49], including pre-analysis, coding, data treatment, inference, and interpretation. Coding and analysis were conducted by two researchers from the study team (SB and VS), one of whom is a senior researcher with expertise in qualitative research (VS). The primary researcher first read all responses to develop familiarity with the data and then identified recurrent themes across responses. A second researcher subsequently reviewed the coding and thematic organization in order to supervise, refine, and validate the analytic interpretation until consensus was reached. Coding was initially conducted independently and required approximately 15 hours of analysis.

Although formal inter-coder reliability indices and member checking were not performed, the use of two analysts was intended to strengthen interpretive rigor and reduce individual bias. Reflexivity remains relevant because one of the analysts (SB) was also the intervention facilitator. Thematic categories were not mutually exclusive; participants could contribute to more than one category.

RESULTS

Participant Flow

Of the 30 enrolled participants, 29 completed the post-intervention acceptability questionnaire and qualitative assessment. One participant was lost to follow-up before the acceptability assessment. Of the 30 enrolled, 28 provided complete pre–post outcome data at both time points and constituted the analytic sample for clinical outcomes. Two participants were excluded from clinical outcome analyses due to missing data at one assessment point. Given the low proportion of missing data (6.7%), a complete-case analysis was adopted without imputation. A CONSORT-style flow diagram is presented in Fig. 1.

Acceptability of M-TBCT

Findings indicate that M-TBCT was acceptable. Self-reported satisfaction demonstrated high internal consistency and elevated mean scores (α = .95; *M* = 4.71; *SD* = 0.45; *n* = 29). Item 1.2, “Therapist competence,” was excluded from internal consistency analyses because it received the maximum score from all participants (*SD* = 0). This ceiling effect—all 29 respondents rated therapist competence at 5.00/5.00—is consistent with high perceived quality but may also reflect social desirability, given that the facilitator was a colleague within the same institution (discussed further in Limitations).

Descriptive results by item are presented in Table 2. The very high alpha coefficient (.95) for the remaining 11 items may also indicate item redundancy, suggesting that the scale functions largely as a global satisfaction rating rather than discriminating among distinct acceptability facets.

Table 2
Acceptability questionnaire item scores (*n* = 29)

Item	Description	M (SD)
1.1	Motivation to participate	4.68 (0.55)
1.2	Therapist competence	5.00 (0.00)
1.3	Online intervention format	4.61 (0.69)
1.4	Session duration	4.68 (0.67)
1.5	Weekly interval between sessions	4.75 (0.52)
1.6	Quantity and quality of intervention/materials	4.79 (0.57)
1.7	Usefulness of the program to cope with problems	4.61 (0.74)
1.8	Program met expectations	4.64 (0.68)
1.9	Would recommend the intervention	4.79 (0.42)
1.10	Would use the program again if needed	4.75 (0.52)
1.11	Program supported adherence to what was learned	4.57 (0.74)
1.12	Overall satisfaction with the program	4.68 (0.61)

Note. Items were answered on a 1–5 Likert scale. The therapist competence item showed zero variance and was excluded from Cronbach's alpha estimation. Overall acceptability: α = .95, *M* = 4.71, *SD* = 0.45.

Qualitative analysis complemented these findings. Participants' reports suggest that engagement in self-care is often constrained by workplace demands and personal responsibilities, particularly regarding time management. Nevertheless, M-TBCT was described as useful and relevant, as it expanded participants' coping repertoires and facilitated the integration of practices into everyday routines.

The main thematic categories that emerged regarding perceived contributions of M-TBCT to well-being and self-care were self-awareness, well-being and tranquility, physical/cognitive/emotional balance, and assertiveness (Table 3). Categories were not mutually exclusive; participants could be coded in more than one category. Quotes were selected to represent the range of demographic profiles in the sample.

Participants contributed to an average of 1.52 categories (range: 1–3).

Table 3
Perceptions of the contributions of M-TBCT to well-being and self-care (*n* = 29)

Thematic category	**Participants (*n* = 29)**
Self-awareness	17 (58.6%)
Well-being and tranquility	16 (55.2%)
Physical, cognitive, and emotional balance	7 (24.1%)
Assertiveness	4 (13.8%)

Note. Categories are not mutually exclusive. Percentages represent the proportion of participants with available qualitative responses who mentioned each theme.

The most frequent category was self-awareness (58.6%), indicating that many participants perceived M-TBCT as promoting greater emotional awareness, identification of cognitive distortions, pausing before automatic responses, and enhanced self-control. This was followed by well-being and tranquility (55.2%), which included reports of reduced anxiety, greater emotional stability, and a subjective sense of slowing down.

The category physical, cognitive, and emotional balance (24.1%) suggested a more integrated understanding of health beyond a purely symptom-based perspective. Finally, assertiveness (13.8%) reflected the perceived development of skills related to interpersonal positioning and clearer communication, particularly in the workplace. Illustrative excerpts:

I noticed that I became calmer when dealing with work demands and also with personal situations in daily life (female, married, 60–69 years, with children).

I feel that I was able to find a better balance between professional demands and my mental health (male, married, 40–49 years, with children).

I started to position myself more clearly at work, without avoiding difficult conversations as I used to (female, single, 30–39 years, without children).

I began to handle difficult situations at work better, managing to express myself more clearly and calmly (male, single, 30–39 years, without children).

These qualitative findings suggest that participants perceived M-TBCT as providing both subjective and practical resources for coping with institutional pressures and interpersonal demands. However, these reports should be interpreted in the context of potential social desirability effects, given the facilitator's institutional role.

Feasibility of M-TBCT

Based on the predefined criteria, M-TBCT was considered feasible: recruitment reached 100.0% (30/30), retention at the final assessment was 96.7% (29/30), and both indicators exceeded the pre-specified thresholds (80% and 60%, respectively). Regarding session attendance, 19 participants (63.3%) attended more than 60% of sessions, whereas 11 (36.7%) remained below this threshold. We note that for an 8-session individual intervention, a 60% threshold (approximately 5 sessions) may be considered lenient, and the fact that over one-third of participants fell below this level warrants attention in future refinements. The barriers reported qualitatively (see below) offer context for this attendance pattern.

Qualitative analysis identified practices perceived as most accessible for daily integration (Table 4). Breathing-based techniques were most frequently reported (*n* = 10; 34.5%), followed by mindfulness meditations supported by audio recordings (*n* = 7; 24.1%). Illustrative excerpts:

I started using breathing techniques when I notice I am becoming tense at work, which helps me regain focus (male, divorced, 50–59 years, with children).

Audio-guided meditations help me reorganize myself during the workday without having to stop everything (male, single, 30–39 years, without children).

Table 4
Practices perceived as most accessible for daily incorporation (*n* = 29)

Practice	**Participants**
Mindful breathing	10 (34.5%)
Mindfulness meditations (including audio-guided)	7 (24.1%)
Self-compassion meditation	3 (10.3%)
Body scan	2 (6.9%)
Sounds-and-thoughts practices	2 (6.9%)
Consensual role-play	1 (3.4%)

Practices such as self-compassion meditation, body scan, and sounds-and-thoughts practices were mentioned less frequently and were associated with situations requiring greater time availability or privacy. The majority of participants (*n* = 17; 58.6%) reported difficulties incorporating practices into their daily routines. Barriers related to workplace demands were most frequent (task overload, high-demand organizational culture), followed by difficulties prioritizing self-care and time management (*n* = 7; 24.1%), and barriers associated with physical or mental health conditions (*n* = 4; 13.8%).

These barriers provide context for the session attendance data: the 36.7% of participants who attended fewer than 60% of sessions likely faced the same workplace constraints that were reported as barriers to daily practice, suggesting that future implementations might benefit from more flexible scheduling or briefer session formats.

Exploratory Outcome Signals

Pre–post intervention descriptive statistics, effect sizes, and paired tests for the main outcomes are presented in Table 5. Figure 2 subsequently provides a graphical summary of the pre–post mean differences with their respective 95% confidence intervals. These are presented as descriptive summaries of the data pattern; in the absence of a control group, the observed changes cannot be causally attributed to M-TBCT. Alternative explanations—including regression to the mean, natural symptom fluctuation, non-specific therapeutic contact, expectancy effects, and demand characteristics—cannot be ruled out.

The issue of regression to the mean deserves particular attention. Participants were screened at elevated symptom levels (SRQ-20 ≥ 7), meaning that baseline scores were, by design, above the population average. In such selected samples, subsequent scores will tend to regress toward the population mean regardless of any intervention effect. Given measurement error in the screening and outcome instruments, a portion of the observed pre–post change is expected from regression to the mean alone.

Table 5
Pre–post changes in principal outcomes (*n* = 28)

Outcome	**Pre, *M* (*SD*)**	**Post, *M* (*SD*)**	**MD (95% CI)**	***d***
WHO-5 well-being	40.43 (15.86)	59.43 (14.10)	19.00 [12.24, 25.76]	1.09
PHQ-9 depression	11.29 (4.50)	8.07 (5.39)	−3.22 [− 5.72, − 0.72]	0.50
GAD-7 anxiety	10.89 (5.38)	5.29 (3.79)	−5.60 [− 7.91, − 3.29]	0.94
ASAS-R self-care	45.93 (9.10)	54.50 (8.50)	8.57 [4.84, 12.30]	0.89

Note. MD = post − pre. For PHQ-9 and GAD-7, post-intervention distributions deviated from normality; therefore, Wilcoxon signed-rank tests were treated as the primary analyses for these outcomes, and paired t-tests are reported as sensitivity analyses.

Changes coinciding with the intervention period were observed across all outcomes. Well-being increased by 19.00 points on the WHO-5 (*d* = 1.09), anxiety decreased by 5.60 points on the GAD-7 (*d* = 0.94), self-care increased by 8.57 points on the ASAS-R (*d* = 0.89), and depressive symptoms decreased by 3.22 points on the PHQ-9 (*d* = 0.50). The larger magnitudes of change were observed for well-being, anxiety, and self-care; the change in depressive symptoms was moderate. For PHQ-9 and GAD-7, primary Wilcoxon analyses and sensitivity paired t-tests yielded convergent results.

Regarding clinical significance, the PHQ-9 change of 3.22 points is clinically modest: the proportion of participants meeting the PHQ-9 ≥ 10 threshold was similar before and after the intervention, indicating that many participants who began above the clinical cutoff remained above it. In contrast, a difference was observed for the WHO-5: the proportion of participants scoring below 50 (the screening threshold for depression) was lower after the intervention than before, with 12 of 13 discordant pairs moving in the

direction of improvement. This PHQ-9 change (3.22 points) is also below the minimal detectable change with 95% confidence (MDC95) recently estimated for the PHQ-9 in a large individual participant data meta-analysis (5.72 points, 95% CI 5.54 to 5.90) [54], indicating that it cannot be distinguished with confidence from measurement error.

Associations Between Outcomes

Spearman correlations between outcomes at pre- and post-intervention are presented in Table 6 and Fig. 3. The correlations followed the expected pattern: higher well-being was associated with lower depression and anxiety and with higher self-care at both time points. These associations support the convergent validity of the measures but do not inform causal pathways.

Table 6
Spearman correlations among study outcomes

Pair	Pre-intervention ρ (95% CI)	Post-intervention ρ (95% CI)
WHO-5 – PHQ-9	−0.59 [− 0.79, − 0.28]	−0.72 [− 0.86, − 0.49]
WHO-5 – GAD-7	−0.70 [− 0.85, − 0.45]	−0.60 [− 0.79, − 0.30]
WHO-5 – ASAS-R	0.43 [0.07, 0.69]	0.57 [0.26, 0.77]
PHQ-9 – GAD-7	0.70 [0.45, 0.85]	0.65 [0.38, 0.82]
PHQ-9 – ASAS-R	−0.37 [− 0.65, − 0.00]	−0.38 [− 0.66, − 0.02]
GAD-7 – ASAS-R	−0.56 [− 0.77, − 0.24]	−0.56 [− 0.77, − 0.24]

DISCUSSION

This Phase 1 pilot study examined the feasibility and acceptability of M-TBCT, a novel online individual intervention integrating mindfulness-based practices with Trial-Based Cognitive Therapy strategies in a demanding occupational setting. Its principal contribution is not to establish efficacy - which this design cannot support - but to show that this integrative protocol could be implemented, delivered, and meaningfully received in a real-world context characterized by high cognitive load and institutional pressure [30, 31, 32].

Feasibility and Accessibility

The feasibility and acceptability profile was strong. Recruitment and retention exceeded pre-specified thresholds, and satisfaction scores were high. These indicators are encouraging because early-stage interventions often fail not because the conceptual model is weak, but because the intervention is too burdensome, poorly aligned with the context, or insufficiently coherent for participants. The online individual format, together with the brief structure and portability of several practices, may have contributed to contextual fit, which is consistent with the broader literature on digitally delivered and workplace-adapted mindfulness-based interventions [10, 50, 51].

However, the ceiling effect observed in satisfaction ratings - particularly the uniformly maximum rating for therapist competence - warrants cautious interpretation. Because the facilitator was a colleague embedded in the same institutional context and was also offering psychological care to that institutional community, participants may have felt especially reluctant to provide critical feedback about both the program and the facilitator. This possibility represents an additional source of social desirability bias [34].

Although the qualitative data provide richer texture and suggest genuine perceived benefit, this limitation also applies to those data. Qualitative responses were analyzed by two researchers (SB and VS), which strengthens interpretive rigor, but one of them was also the facilitator, so the possibility of allegiance effects cannot be fully excluded.

Preliminary Outcome Signals

The pre-post changes observed during the intervention period showed larger magnitudes for well-being, anxiety, and self-care (d = 0.89–1.09), and a moderate magnitude for depressive symptoms (d = 0.50). These signals are consistent with potential benefit but must be interpreted with substantial caution. Without a control group, regression to the mean is a particularly important alternative explanation. Participants were screened at elevated symptom levels (SRQ-20 > = 7), meaning that baseline scores were, by selection, above the population average. In such samples, a portion of the observed improvement is expected from regression to the mean alone, even in the absence of an effective intervention. Natural symptom fluctuation over eight weeks, non-specific effects of regular therapeutic contact, expectancy effects, and demand characteristics associated with the institutional context are also plausible explanations.

The PHQ-9 findings deserve particular consideration. Although the reduction in depressive symptoms (d = 0.50) was clinically modest, the proportion of participants meeting the PHQ-9 > = 10 threshold was similar before and after the intervention. Notably, the observed change (3.22 points) falls below the pooled minimal detectable change with 95% confidence (MDC95) recently estimated for the PHQ-9 (5.72 points, 95% CI 5.54 to 5.90) in a large individual participant data meta-analysis [54], further supporting a cautious interpretation of this signal. This pattern is coherent with the broader literature showing that depressive symptoms are often slower to remit and may require more sustained, structured, and longitudinal intervention than gains in anxiety regulation, subjective well-being, or self-care [20, 21].

One plausible hypothesis is that improvements in well-being, anxiety, and self-care represent earlier or more proximal changes that may subsequently contribute - indirectly or over a longer time frame - to reductions in depressive symptoms. This possibility should be examined in adequately powered trials with follow-up assessments.

Theoretical Considerations

Because mechanisms of change were not directly assessed in this study, the interpretations offered below are speculative and intended only to generate hypotheses for future mechanistic research, not to explain the observed signals. Mechanistically, the observed pattern is compatible with a model in which mindfulness-related processes - such as decentering, acceptance, self-compassion, and emotion regulation - operate alongside structured cognitive work on dysfunctional beliefs and interpersonal patterns [15, 16, 17, 18, 29, 52]. A particularly salient qualitative finding was the centrality of self-awareness as a perceived benefit. This is theoretically consistent with mindfulness-based approaches, which cultivate non-reactive awareness of internal experience, and also with TBCT procedures, which explicitly promote the identification and modification of maladaptive beliefs and cognitive distortions.

Although participants did not consistently identify TBCT-specific strategies as the easiest tools to apply in daily life, the cognitive-behavioral work embedded in TBCT may nevertheless have contributed to broader gains, although this cannot be confirmed with the present design, in self-understanding, emotional regulation, and assertiveness [23, 24].

This pattern suggests that, in integrative protocols such as M-TBCT, different components may operate at distinct levels. Some are more experientially salient and immediately portable to daily life, such as brief mindfulness practices, whereas others may contribute more implicitly to cognitive and emotional reorganization, such as structured work on negative core beliefs. In this sense, one hypothesis worth testing in adequately designed future research is whether gains observed in integrative protocols such as M-TBCT depend, at least in part, on delivery by a psychologist with specific training; the present study cannot address this question.

Because mechanisms of change were not directly assessed, however, these interpretations remain theoretically grounded rather than empirically demonstrated. Recent scoping work on target mechanisms in mindfulness-based programs reinforces the importance of directly measuring such processes in future trials [13].

Qualitative Implementation Insights

The qualitative findings added implementation depth that numerical indicators alone could not provide. Breathing practices and audio-guided meditations were perceived as most accessible because they could be implemented in brief windows amid demanding schedules. By contrast, practices requiring more privacy, time, or emotional readiness - such as self-compassion meditation, body scan practices, sounds-and-thoughts exercises, consensual role-play, and other TBCT-based strategies involving deeper cognitive engagement - were less easily routinized. This distinction is meaningful for protocol refinement because it indicates where M-TBCT may already be well adapted to occupational life and where additional scaffolding may be needed.

The barriers reported—primarily workplace overload, time constraints, and difficulty prioritizing self-care—provide context for the session attendance data, where 36.7% of participants attended fewer than 60% of sessions. For a brief 8-session individual intervention, this attendance pattern warrants attention in

future implementations, potentially through more flexible scheduling, briefer session formats, or additional engagement support.

Broader Context

The results are aligned with international recommendations for workplace mental health emphasizing comprehensive approaches that combine organizational action with individual support [3, 4, 53]. M-TBCT was not an organizational-level intervention and should not be interpreted as a substitute for systemic prevention. Rather, it offers one possible individual-level component within a broader response.

Plans for Phase 2

The present findings inform the design of the Phase 2 trial, which is currently underway. This next phase addresses several limitations identified here through the inclusion of a control group, a more robust sample (n = 90), video recording of a random subset of sessions for supervision by the developers of the approaches underlying the protocol, and a 6-month follow-up assessment. At the same time, transparency is important: other limitations will need to be addressed by future studies, particularly the direct identification of mechanisms of change and more systematic strategies for monitoring engagement with home practices.

LIMITATIONS

This study has several limitations that should be considered when interpreting the findings. First, as a Phase 1 study, the single-arm design without a control group prevents causal inference. Regression to the mean, natural symptom fluctuation, non-specific therapeutic contact, expectancy effects, and demand characteristics are all plausible alternative explanations for the observed changes.

Second, the facilitator served simultaneously as a psychologist embedded in the same institution, a member of the research team, and the sole intervention therapist. This triple role creates substantial potential for social desirability bias, therapist allegiance effects, and demand characteristics. Participants - colleagues within the same court system - may have felt implicit pressure to report positive outcomes. The ceiling effect on therapist competence ratings (5.00/5.00 for all respondents) is consistent with this concern. Qualitative responses were analyzed by two researchers rather than one, which strengthens the analysis, but one of those researchers was also the facilitator, so interpretive bias cannot be fully ruled out.

Third, no formal, independent treatment fidelity assessment was conducted. Without session recordings or independent adherence ratings, it is impossible to verify that the intervention was delivered exactly as intended or to separate therapist effects from intervention effects. Fourth, the qualitative analysis was conducted by two researchers, including one senior qualitative researcher (VS), but formal inter-coder reliability indices and member checking were not performed. The thematic categories should therefore be understood as analytically developed interpretations rather than independently validated findings.

Fifth, mechanisms of change were not directly assessed, limiting the ability to test whether the hypothesized synergistic processes were actually engaged. Sixth, the absence of follow-up data precludes conclusions regarding the sustainability of observed changes. Seventh, the specific occupational context and the self-selected, predominantly female, highly educated sample may limit generalizability. Eighth, the CD-Quest-9 was used as a clinical tool within sessions rather than as an outcome measure; its exclusion from pre–post analyses is a methodological choice that should be revisited in future studies where it could serve as a process measure. Ninth, the four principal outcomes (WHO-5, PHQ-9, GAD-7, and ASAS-R) were tested without correction for multiple comparisons; although this is consistent with the descriptive, non-confirmatory aim of a Phase 1 pilot study, it should be considered when interpreting the precision of the reported effects. Finally, the small sample size (n = 28) limits statistical power and increases the risk of unstable estimates.

CONCLUSIONS

This Phase 1 study supports the feasibility and acceptability of M-TBCT, a novel mindfulness-integrated Trial-Based Cognitive Therapy intervention delivered in an individual online format to judiciary workers. As an exploratory, secondary finding, the study also provides preliminary signals of change consistent with potential benefit; these signals are not evidence of efficacy and cannot be attributed to the intervention in the absence of controlled comparison. The strong feasibility indicators justify progression to the ongoing Phase 2 randomized controlled trial, which includes a control group and a 6-month follow-up assessment. Additional future studies will still be needed to clarify mechanisms of change and other aspects not yet fully addressed.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the ethical standards of the 1964 Declaration of Helsinki and subsequent amendments. Ethical approval was granted by the Research Ethics Committee (Institutional Review Board) of the Federal University of São Paulo — UNIFESP (CAAE 73817423.3.0000.5505). Informed consent to participate was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing Interests

One of the authors (I.R.O.) is the developer of Trial-Based Cognitive Therapy (TBCT), and another author (M.D.) is the developer of the Mindfulness-Based Health Promotion (MBHP) protocol, which informs the mindfulness strategies used in M-TBCT. This structural conflict of interest may have influenced decisions regarding intervention design, outcome selection, and interpretation of findings, and should be considered when evaluating the conclusions reported here. The remaining authors declare no competing interests.

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Author Contribution

S.B. contributed to study conception and design, data collection, data analysis, and drafting of the manuscript. J.R.F. contributed to data analysis and critically reviewed the manuscript for important intellectual content. V.S.J. conducted the qualitative analysis and critically reviewed the manuscript. I.R.O. and M.D. contributed to study conception, design, and supervision, and critically reviewed and revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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Data Availability

All trial data and informed consent forms are available from the corresponding author upon reasonable request.

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Figures

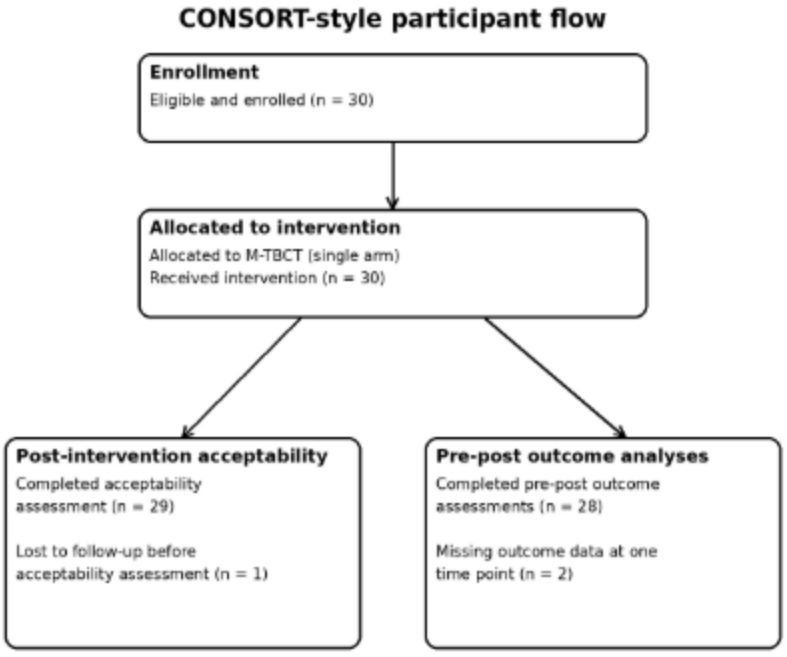


Figure 1

CONSORT-style participant flow diagram.

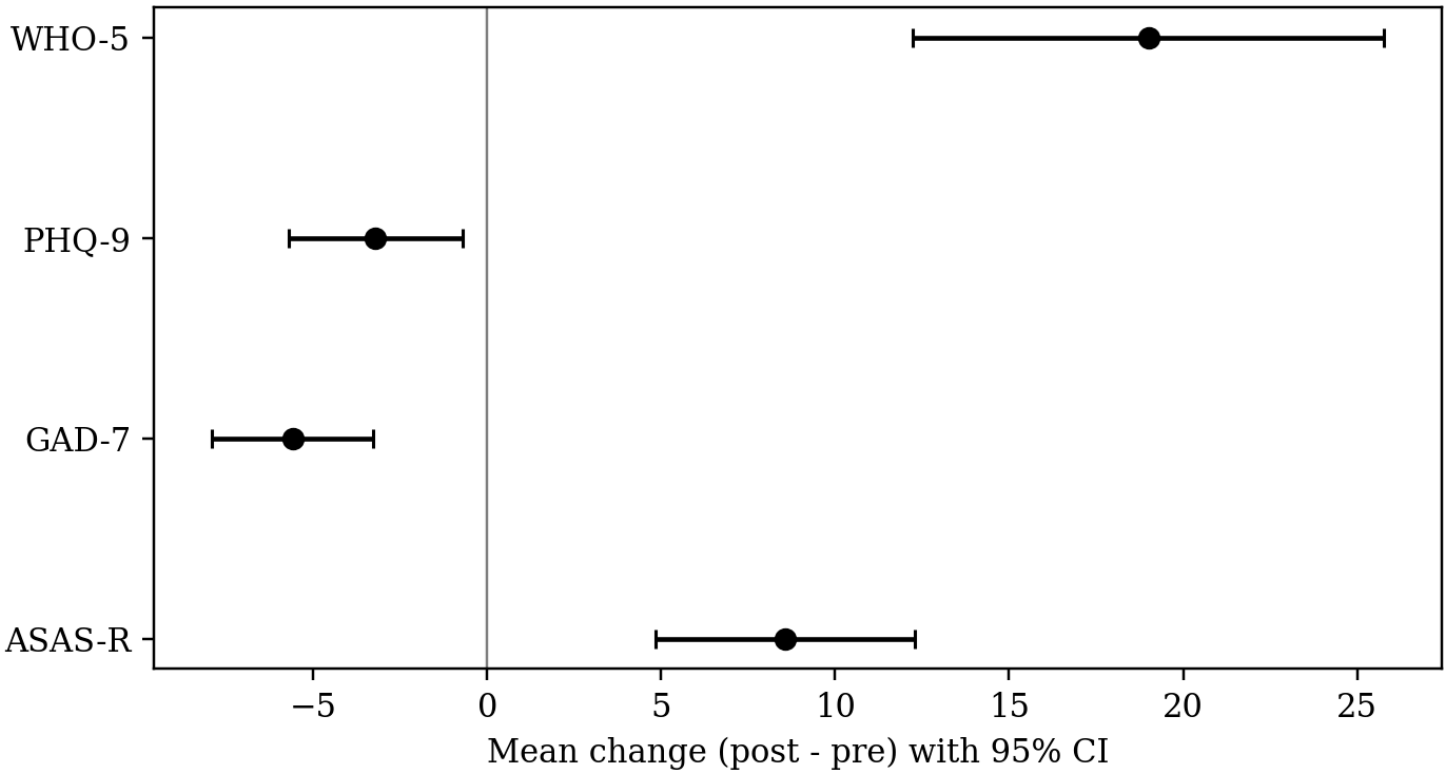


Figure 2

Pre-post mean changes across principal outcomes

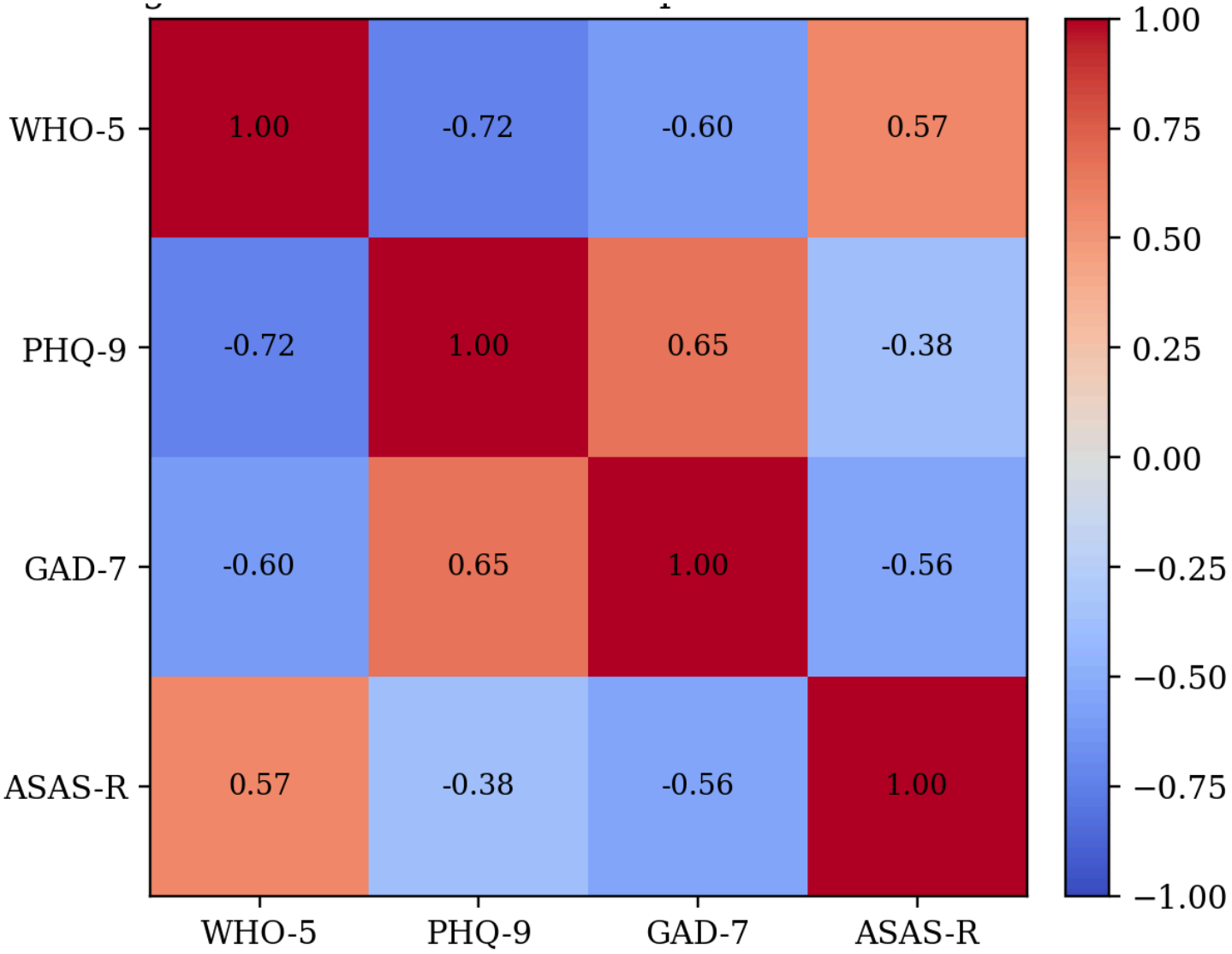


Figure 3

Post-intervention Spearman correlations