Trials

STUDY PROTOCOL

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Combining cognitive remediation and metacognitive therapy for improving cognitive functions and reducing symptoms severity of adult patients with obsessive–compulsive disorder in Tehran, Iran: study protocol for a randomized, controlled trial

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Abstract

Introduction Patients with obsessive–compulsive disorder (OCD) experience various cognitive impairments, yet typical treatments do not address these deficits. Goal management training (GMT) is a structured cognitive remediation therapy to enhance executive function. GMT serves as a metacognitive strategy training, improving cognitive control and mindfulness related to executive dysfunction. Given OCD patients' challenges with attention flexibility and control, the efficacy of GMT may be enhanced when combined with a preparatory intervention that builds foundational metacognitive knowledge. Metacognitive therapy (MCT), which targets maladaptive metacognitive beliefs linked to OCD symptoms, has been shown to enhance attentional flexibility and address cognitive deficits in these patients.

Method This paper describes the protocol for a randomized controlled trial with a superiority framework that investigates the effectiveness of cognitive rehabilitation as a novel approach combining GMT-derived protocol and MCT for treating OCD.

Thirty-six adult patients with a primary diagnosis of OCD will be randomly assigned to either an intervention group, an 8-week cognitive remediation group therapy, or an 8-week waitlist group. Participants will be recruited from Iran Psychiatry Hospital (a specialized psychiatric hospital) and the Brain and Cognition Clinic (an outpatient facility) in Tehran, Iran.

Key inclusion criteria include aged 18–65 years and diagnosis of OCD. Exclusion criteria include comorbid severe mood or psychotic disorders, active medical comorbidity, or history of traumatic brain injury. Recruitment will commence on May 15, 2025.

Participants will be randomly allocated in a 1:1 ratio to intervention or waitlist control. Randomization will not involve stratification variables. Researchers conducting assessments will be blinded to group allocation, therapists will be

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blinded to test results, data analysts will be independent of the intervention team, and participants will be instructed not to disclose group material to assessors. Clinical research assistants will recruit participants following diagnostic confirmation by psychiatrists.

The initial three of the eight sessions will focus on MCT, and the last five will focus on GMT. Each session will last 2 h.

Symptom severity of participants and multiple, separable cognitive aspects sensitive to OCD (attention and response inhibition, processing speed, planning, organization, problem-solving, verbal memory, and pre-morbid intellectual functioning) will be assessed at baseline, after treatment, and at a 3-month follow-up. The primary outcome will be changes in Yale-Brown Obsessive–Compulsive Scale (Y-BOCS; range 0–40, with higher scores indicating more severe symptoms) total, obsessive, and compulsive scores. Secondary outcomes will be performance scores on Conners' continuous performance task (CPT), Stroop Color and Word Test (SCWT), and Tower of London (TOL).

Conclusion We hypothesize that this novel cognitive rehabilitation approach can positively impact cognitive deficits and reduce the severity of symptoms in adult patients with OCD.

Trial registration The trial was registered at the Iranian Registry of Clinical Trials on 19/01/2025 (https://irct.behdasht.gov.ir/trial/81348 (IRCT IRCT20170123032145N8)).

Keywords Cognitive function, Obsessive–compulsive disorder, Metacognition, Cognitive remediation

Introduction

Obsessive–compulsive disorder (OCD) is a major psychiatric disorder that is characterized by repetitive and unwanted thoughts, impulses, or mental pictures that cause anxiety or distress in patients and can be accompanied by purposeful mental or motor acts to alleviate the distress [1]. OCD is generally a chronic and disabling disorder that affects different aspects of function, quality of life, and well-being [2–6]. This disorder affects 1–3% of the worldwide population [7, 8]. OCD has a significant negative impact on public health and causes severe economic and psychological burdens [9–12].

Patients with OCD have deficits in a wide variety of cognitive aspects [13–15]. Executive function, nonverbal and verbal memory, attention, and processing speed are impaired in individuals with OCD, with meta-analyses indicating small-to-moderate deficits (approximately $d \approx 0.30$–0.60) across executive function, memory, and processing speed [13, 14, 16–20]. These cognitive impairments have also been detected as endophenotypes of OCD [21–24] and are correlated with the insight of patients [25, 26] and the severity [27–30] of symptoms of this disorder. Some studies suggested the association between neuropsychological deficits and response to pharmacological or nonpharmacological treatment of individuals with OCD [31–33].

One of the most frequently proposed cognitive deficits in OCD patients is the impairment in the executive function of these individuals [16–18, 26, 31, 34]. Some studies argued that executive dysfunctions can be the central deficits affecting the abilities of patients with OCD [16]. It has been shown that executive dysfunctions are independent of comorbidities such as depression, conditions such as psychomotor slowness, and even symptom relief after treatment [17, 35, 36].

Executive functions consist of advanced cognitive skills that regulate goal-oriented actions, such as planning, monitoring, controlling impulses, task-switching, and maintaining sustained attention [37, 38]. These impairments considerably affect patients' abilities to acquire, preserve, and relearn the skills necessary to perform competently in everyday tasks and real-world functioning. Therefore, it logically supports the impact of cognitive impairments, executive dysfunction in particular, on real-life achievements, and the quality of life of OCD patients [39].

Currently, the first-line treatment for OCD includes selective serotonin reuptake inhibitors (SSRIs) and/or cognitive behavioral therapy (CBT) [40]. Even with receiving these regular and standard treatments, 40–60% of patients with OCD remain symptomatic and suffer a decline in their functioning and quality of life [41, 42]. Moreover, despite the importance of neurocognitive impairments in OCD patients, typical treatments do not target these deficits.

The current approach to addressing psychiatric disorders does not just involve managing symptoms; it also places a significant emphasis on functional capabilities [43]. Hence, there has been a noticeable increase in the popularity of therapeutic methods to enhance cognitive abilities over the past decades [44]. As a result, many cognitive-enhancing interventions have been designed to primarily focus on cognitive functions and then extend to reducing symptom severity and improving daily functioning [45].

Goal management training (GMT) is a short-term, group-based, structured cognitive remediation therapy focusing on executive function by teaching problem-solving and attention processing [46, 47]. The GMT program follows a structured format involving 20 h of weekly group meetings, including three key elements: therapist-led instruction, in-class activities, and group discussions [48]. The underlying theory of GMT suggests that the sustained attention system is responsible for keeping higher-order goals in mind while suppressing automatic processes. Executive deficits occur when this integrated system is disrupted, allowing automatic processes to precede higher-order goals. GMT teaches individuals how to interrupt automatic processing periodically, refocus on their main goal, break down the overall goal into smaller subgoals, and assess their performance. This is achieved through narrative, psychoeducation, and in-session and between-session exercises. GMT also integrates mindfulness meditation, which enhances training by bringing attention to the present moment and monitoring the connection between current circumstances and higher-order goals [47, 49]. Repeating directed and cognitively demanding tasks during the treatment causes permanent change through neuroplasticity [50].

GMT is among the earliest executive function interventions evaluated in randomized controlled trials [46]. It has emerged as a leading cognitive rehabilitation method for patients with executive deficits with various diagnoses [47]. GMT has been researched across multiple patient populations, including those with traumatic brain injury (TBI) [47, 51–53], schizophrenia [54–56], depression [57, 58], ADHD [59, 60], substance use disorder [50, 61, 62], multiple sclerosis (MS) [63], spina bifida [64], post-discharge intensive care unit [65], posttraumatic stress disorder (PTSD) [66, 67], and older adults [68–73]. Many of these studies have used a modified version of GMT or/and have used GMT in combination with other interventions such as mindfulness meditation [62], problem-solving therapy [74], psycho-education [54], emotional regulation [75], and errorless learning [51, 76]. A systematic review of the effectiveness of GMT in improving executive functions of the adult population with TBI has suggested that the combined models of GMT can be more effective as a stand-alone intervention [77].

To date, only one pilot study has focused on the efficacy of GMT in individuals with OCD [78]. In this study, 19 patients diagnosed with OCD were randomized to receive either 9 weeks of GMT or to complete the same amount of time on the waitlist. This study showed that the GMT group experienced significant improvement in problem-solving, attention, organization, impulsivity, and subjective cognition compared to the controls. Notwithstanding the benefits, based on the qualitative exit interview of this study, it was found that while the participants generally liked the program and experienced personal benefits, they thought it was too lengthy and felt that the content progressed slowly. This study suggested that a shorter format of GMT (half the length) is more suitable for the OCD population. This adaptability of GMT, which can be tailored to suit the needs of the OCD population better, should provide a foundation for an adapted cognitive remediation protocol. Moreover, regarding other diagnoses, studies showed that integrating other protocols into GMT improves executive function, reassuring the audience of its potential effectiveness [77].

GMT is metacognitive strategy training to enhance cognitive control and promote a mindful approach to executive dysfunction. Considering the problems of OCD patients in attention flexibility and control [79, 80], the efficacy of GMT may be optimized when combined with a preparatory intervention that establishes foundational metacognitive knowledge and attentional control. Metacognitive therapy (MCT) [81], which directly addresses maladaptive metacognitive beliefs and thought patterns underlying OCD symptoms, is one of the emerging treatments of OCD and has been shown to improve attentional flexibility and deficits [82, 83]. By focusing initially on MCT, patients develop awareness of the metacognitive processes that sustain OCD and gain insight into how their beliefs about thinking influence their behavior and emotional responses [82]. This initial focus on metacognitive knowledge and attentional skills creates a "prepared mind" for engaging in GMT's more structured, goal-oriented strategies, potentially enhancing patients' engagement with and adherence to GMT techniques [84]. Not only can this sequencing help to prepare patients with metacognitive knowledge and attentional skills before introducing goal-directed and practical training, but also, as MCT's design is based on the metacognitive model of OCD, it can address the limitation that GMT is not initially designed for OCD patients. By choosing this strategy, we can provide a change in all three levels of metacognitive knowledge, metacognitive experiences, and metacognitive strategies [85].

This paper describes the protocol for a randomized controlled trial that investigates the effectiveness of cognitive rehabilitation as a novel approach combining GMT-derived protocol and MCT for treating OCD. The objectives of this study are to determine whether this treatment has a positive effect on cognitive deficits and symptom severity of adult patients with OCD.

Methods and materials

Study design

The proposed study is a two-arm, parallel-group randomized controlled trial (RCT) with a 1:1 allocation ratio, designed within a superiority framework comparing a combination of GMT-derived protocol and MCT to a passive control intervention (wait-list), using a repeated-measures design in preintervention (T1), postintervention (T2), and 3-month follow-up (T3) time points.

This protocol is by the guidelines for Consolidated Standards of Reporting Trials guidelines (CONSORT) [86] and Good Clinical Practice (GCP) [87]. The study has been registered and received ethical approval from the Medical Ethical Committee of the Iran University of Medical Sciences (IUMS) (protocol number IR.IUMS.FMD.REC.1403.025). The trial was registered at the Iranian Registry of Clinical Trials on 19/01/2025 (https://irct.behdasht.gov.ir/trial/81348 (IRCT20170123032145N8)). Figure 1 illustrates the timeline for participants and interventions in this study.

Sample size

Using G-power 3.1.9.4 [88], with ANOVA-repeated measures, within-between interaction, an effect size of 0.25, type I error of 5%, power of 80%, two groups, and three numbers of measurements, we calculated a sample size of 28. Considering a dropout rate of 30%, the final number of 36 (18 in each group) will be considered for the sample size.

An effect size of 0.25 (medium) was selected based on previous cognitive remediation studies in psychiatric populations, including the only pilot trial of GMT in OCD [78], which reported moderate-to-large effects on cognition and symptom reduction. Translating this to the primary outcome (Y-BOCS), an effect size of 0.25 corresponds to an expected mean difference of approximately 4–5 points between intervention and control groups, which represents a clinically meaningful reduction in symptom severity.

Although the intervention is delivered in groups, the expected intraclass correlation coefficient (ICC) for psychological group interventions is typically small [89, 90]. Given our limited resources and sample size, we did not inflate the sample size for clustering. However, this potential design effect is acknowledged as a limitation.

Participants and randomization

Thirty-six adult patients (aged 18–65 years) with a primary diagnosis of OCD will be chosen from an outpatient sample of Iran Psychiatry Hospital and Brain and Cognition Clinic, Tehran, Iran (April 2025–March 2026). The diagnosis of OCD will be established by a psychiatrist based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR).

Participants will be recruited through clinician referrals, flyers, and posters displayed in outpatient clinics, and announcements in hospital waiting areas. If needed, recruitment will also be supported through the hospital's social media platforms to ensure that the target sample size is achieved.

Participants will be included if they (1) are between 18 and 65 years old; (2) exhibit clinically significant obsessive–compulsive symptoms, as indicated by a total score of 17 or more on the Yale-Brown Obsessive–Compulsive Scale (Y-BOCS); (3) have been on a stable dose of OCD medication for a minimum of 8 weeks before the study, if applicable; (4) have not undergone more than 8 CBT sessions for OCD in the last 6 months; (5) agreed to refrain from participation in any new treatment (including CBT, other kinds of psychotherapy, new medicine, or change in dosage of medicines) throughout the study; and (6) can provide written informed consent.

Patients will be excluded if they (1) concurrently meet DSM-5-TR criteria for a severe mood disorder, substance abuse/dependence (other than nicotine and caffeine), schizophrenia, or other psychotic disorders; (2) have a mental impairment or suspected organic pathology; (3) have active medical comorbidity that might require necessary intervention during the trial; (4) have a history of medical disorders known to significantly affect cognition (such as heart disease) in the past year; (5) have a history of traumatic brain injury, loss of consciousness, or concussion; and (6) receive treatments known to significantly affect cognition (such as anticholinergic agents or receiving electroconvulsive therapy within the past 6 months).

At the end of the clinical screening, research assistants will introduce potential participants to the study and provide detailed information about its design and procedures. Those interested will provide written informed consent. The participants will be informed that they can leave the trial at any time without affecting their usual treatment. No participant data or biological specimens are collected in our study.

Randomization will be performed using www.randomization.com, an online tool that allocates each participant to a treatment group using randomly permuted blocks. This generator also varies the block sizes (ranging from 1 to 4 per group) to make it unclear when a block is completed, making it impossible to predict the remaining treatment assignments [91].

As the intervention is psychotherapy, blinding of participants and therapists cannot be fully achieved. However, assessors and analysts will remain blinded. Other procedures to maximize the blinding will be as follows:

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT**	*-8 weeks*	0	*Week 0*	*Week 8*	*3 months*
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Cognitive rehabilitation			X		
Wait-list			X		
ASSESSMENTS:					
Psychiatry diagnosis	X	X			
Yale-Brown Obsessive Compulsive Scale (Y-BOCS)			X	X	X
Conners' Continuous Performance Task (CPT)			X	X	X
The Stroop Color and Word Test (SCWT)			X	X	X
The Tower of London (TOL)			X	X	X

Fig. 1 Participant timeline

(1) researchers who conduct baseline, after-study, and follow-up assessments will be blinded to treatment groups; (2) therapists who administer the interventions will be blinded to test performance and assessments; (3) technicians who perform data analysis will be separate researchers (from assessment researchers and therapists); and (4) participants will be instructed not to talk about course material with researchers evaluating them or with other possible participants outside of their group;

Measures and materials

Symptom measures

Yale-Brown Obsessive–Compulsive Scale The Y-BOCS is the gold standard rating scale for evaluating the intensity of both obsession and compulsion symptoms. The Y-BOCS consists of 10 Likert scale items rated 0–4 ranging from 0 (no symptoms) to 4 (severe symptoms), giving a total score range of 0–40, where 0–7 = subclinical, 8–15 = mild, 16–23 = moderate, 24–31 = severe, and 32–40 = extreme OCD symptoms. Research demonstrates that both the self-report and clinician interview versions of the Y-BOCS possess robust psychometric properties and effectively measure the impact of treatment. Additionally, it has been reported that both subscales (obsessions and compulsions) and the overall Y-BOCS score exhibit high internal consistency [92, 93].

Neurocognitive assessment

Multiple, separable cognitive aspects that are sensitive to OCD will be assessed: attention and response inhibition (by Conners' continuous performance task (CPT) [94]); processing speed (by The Stroop Color and Word Test [95]); planning, organization, and problem-solving (by The Tower of London [96]).

Conners' continuous performance task CPT is developed to evaluate attention-related issues across four domains (inattentiveness, impulsivity, sustained attention, and vigilance). Participants sit in front of a computer and respond when any letter except for "X" appears on the screen, referred to as the non-X paradigm. CPT displays 360-scored trial stimuli (i.e., individual letters) on the screen, with interstimulus intervals (ISI) of 1, 2, or 4 s between the presentation of letters. These 360 trials are organized into six blocks, each containing three sub-blocks with 20 trials. The ISI are counterbalanced throughout these blocks. Administering the Conners CPT 3 takes approximately 14 min [94].

The Stroop Color and Word Test [95] SCWT is a neuropsychological assessment tool widely used for research and clinical purposes. It evaluates the capacity to inhibit cognitive interference, which occurs when the processing of one aspect of a stimulus impacts the simultaneous processing of another characteristic of that same stimulus [97]. Participants are asked to read three distinct tables as quickly as they can. Two of these represent the "congruent condition." In the first table, individuals read color names displayed in black ink (W), and in the second table, participants identify various color patches (C). In contrast, in the third table, the color-word (CW) condition consists of color-words printed in mismatched color ink. Therefore, in this incongruent condition, participants must specify the ink color (less automatic activity) rather than reading the word (inhibiting the more automatic activity) [98]. Although the SCWT is predominantly used to assess the capacity to inhibit cognitive interference, some studies also indicate its use in evaluating other cognitive functions, including processing speed, attention, cognitive flexibility [99], and working memory [100].

The Tower of London [96] TOL evaluates multiple essential components of executive functions, including organization, problem-solving, and planning. Participants are required to transfer disks, which range in size from small to large, across three pegs to recreate a specified tower using the least number of moves possible. While assembling the target towers, participants must adhere to two rules: (a) move only a single disk at a time and (b) never place a larger disk on top of a smaller disk [101]. Studies have shown that better performance in TOL is associated with shorter movement execution and longer preplanning time [102].

Procedures

Participants will be randomly assigned to either (1) an intervention group, an 8-week structured group cognitive remediation program, or (2) a control group, an 8-week waitlist group. Evaluations will occur at baseline, after treatment, and at a 3-month follow-up.

Participants in both groups may continue stable pharmacological treatment throughout the study. Initiation of new psychotherapy for OCD or changes in psychiatric medication are prohibited during the trial period.

Participants may discontinue the intervention at their own request, in case of clinical deterioration judged by the study psychiatrist (e.g., significant worsening of OCD symptoms or emergence of suicidality), or due to repeated non-attendance at sessions. No modifications of the allocated intervention are planned, but participants who discontinue will be offered appropriate clinical referral and support.

Adherence to the intervention will be monitored by recording attendance at each session. To support adherence, participants will receive reminders via phone or text before each session, and missed sessions will be followed up with a reminder and encouragement to continue. For the waitlist control group, adherence will be monitored by confirming that participants do not initiate concurrent psychotherapy for OCD during the waiting period.

Intervention group

The treatments will be provided at the Brain and Cognition Clinic in Tehran as an 8-week group therapy. Each group will consist of nine participants. A consistent team of therapists, including a clinical psychologist and a psychiatry resident, will facilitate the groups. The therapists will receive training and participate in regular supervision sessions with the first author.

Before the group meetings start, all attendees will join an online message board (Telegram/WhatsApp channel). After each session, summary worksheets will be posted on this channel. Additionally, a daily reminder message will be sent through this channel to encourage the use of meeting strategies or to provide homework assignments. The resources required for completing homework will be shared on the channel following each session.

Metacognitive therapy The initial three of the eight sessions will focus on MCT. Each session will last 2 h and feature a short break.

Three key topics from the metacognitive protocol, tailored explicitly for OCD and not included in the GMT protocol, have been chosen. These topics include (1) education about symptoms, which is an essential part of the program; (2) metacognitive beliefs, which are integral to the metacognitive approach; and (3) attention training.

The structure and format of each session will be as follows: (1) homework review: at the beginning of each session (excluding the first), the homework assigned during the previous session will be discussed; (2) introduction of the session's content; (3) in-session exercises and activities; (4) explanation of the homework and distribution of the associated worksheet; (5) summary provided by one of the participants; (6) distribution of a brochure/handout followed by the conclusion of the session.

At this point in the study, the resources shared on the online message board (such as audio recordings, supplementary scenarios) will be more comprehensive, which will enhance these resources and address the limitations caused by the brevity and reduced number of sessions in this segment.

Each of the three MCT sessions is detailed further in Table 1.

Goal management training The last five of the eight sessions will focus on GMT. Each session will last 2 h and feature a short break.

All essential subjects of GMT are incorporated into this program. The total duration of the sessions has been reduced by eliminating certain portions that were repeated throughout the therapy, making it more concise.

The structure and format of each session will be as follows: (1) homework review: at the beginning of each session (excluding the first), the homework assigned during the previous session will be discussed; (2) introduction of the session's content; (3) in-session exercises and activities; (4) explanation of the homework and distribution of the associated worksheet; (5) summary provided by one of the participants; (6) distribution of a brochure/handout followed by the conclusion of the session.

The program also includes real-life examples provided by the group therapist and participants to demonstrate both failures and successes in achieving goals. Practical exercises during sessions simulate challenging real-life tasks for those with executive function deficits, such as planning and set-shifting activities.

Each of the five GMT sessions is detailed further in Table 2.

Control group

Participants assigned to this group will need to wait for 8 weeks without engaging in traditional CBT or any other form of psychotherapy for OCD. If they take medication, they must maintain a stable dosage throughout the study.

Table 1 Overview of metacognitive therapy sessions

MCT session	Description
Session one: learning more about OCD	• Group welcome, introduction, and overview of the course • Psychoeducation on the primary symptoms of OCD and its cycle • Insight into metacognitive beliefs related to OCD and their impact on symptoms
Session two: what are the key beliefs associated with OCD?	• Emphasizing the significance of metacognitive beliefs in OCD • Understanding that having intrusive thoughts is a common experience, while obsessive symptoms are extreme reactions • Recognizing and acknowledging their own metacognitive beliefs
Session three: attention training	• Learning the attention training technique and its application • Insight into how excessive focus on thoughts impacts OCD • Learning to shift attention in a more adaptable way • Discovering how to apply this method to obsessive–compulsive symptoms

Table 2 Overview of goal management training sessions

GMT session	Description
Session one: psychoeducation about executive functions	Psychoeducation and increasing awareness of executive function issues in daily life: • Understanding the concept of executive function • Recognizing common challenges associated with executive function deficits • Learning about the significance and relevance of enhancing executive functions and its impact on OCD Exploring the concepts of being present-minded versus absent-minded
Session two: returning to the present	Instructing on how to come back to the present moment and persist with goal-oriented actions: • Presenting the principles of mindfulness • Acquiring the skill to apply a specific mindfulness technique (e.g., body scan, raisin) • Identifying the autopilot state and employing mindfulness to disrupt it
Session three: autopilot	Recognizing when in autopilot mode and applying the STOP! Technique: • An overview of the STOP! technique • Integrating the STOP! technique with the beware method • Utilizing sorting cards • Practicing mindfulness through breathing exercises
Session four: pursuing goals	The skill to set and split goals: • Practicing visualization techniques to minimize slips by focusing on the target • Learning how to split complex goals • Explaining working memory using the "mental blackboard" analogy • Training on updating information in working memory and applying it to monitor goal progress • Review and rehearse skills
Session five: integration of skills	• Combining learned abilities • Merging mindfulness with the STOP! technique • Assessing the materials and abilities from both the metacognitive and GMT segments

Those on the waitlist will be informed that they will have the opportunity to participate in therapist-led group treatment (same program as the intervention group) at the conclusion of the study.

A waitlist control group was chosen for this trial in order to establish feasibility and obtain initial efficacy estimates of combining GMT and MCT before testing against an active comparator such as CBT. This design allows control for the passage of time and repeated assessments, while ensuring fairness to participants by offering them the intervention after the waiting period.

Data management and monitoring

Structured clinical interviews, standardized cognitive assessments, and self-report questionnaires will be used to collect data for this study. Trained research staff will run the evaluations and document responses on organized data collection sheets. Participants will complete self-report questionnaires on paper or digitally on a secure, encrypted online survey platform.

To ensure accuracy, all data will be entered into an electronic database twice by independent research assistants. Any inconsistencies will be resolved through verification by a senior researcher.

The research data in digital form will be stored on an institution-hosted server with password protection and encryption, with authorized personnel as the only allowed users. The research facility will maintain the security of paper-based documents by utilizing locked filing cabinets. Personal identification data, such as names and contact details from participants, will be separated from the research data through the use of unique participant codes, which serve to protect confidentiality. A secure cloud-based storage, together with offline encrypted hard drive backups, will contain regular data backups.

The datasets can be accessed by submitting a reasonable request to the corresponding author. The research team will decide on data sharing in accordance with ethical and legal obligations.

Raw data will be retained for the necessary duration in accordance with institutional and ethical guidelines. After this period, paper data will be shredded, and digital data will be permanently deleted.

No individual participant data will be made publicly available due to ethical and confidentiality restrictions. However, de-identified aggregated data and statistical code may be made available upon reasonable request to the corresponding author. In addition, the statistical analysis plan and analysis code may be available from the corresponding author upon reasonable request after completion of the trial.

The research operation center will be based at the Brain and Cognition Clinic in Tehran, Iran. The principal investigator (PI) will oversee all aspects of the study, including the management of all research staff at the center, such as clinical coordinators, research assistants, data managers, and statisticians. These team members will be

responsible for participant recruitment, data collection, monitoring, and analysis.

The current study will not utilize a formal data monitoring committee (DMC). Given that both cognitive remediation and metacognitive therapy interventions present minimal risk to participants, the study concludes that ongoing external data monitoring is unnecessary. Instead, the Trial Steering Committee (TSC) will oversee data by regularly reviewing participant progress, adherence to the study protocol, and any reported adverse events.

The Trial Steering Committee (TSC) will comprise an unbiased panel of experts. This will include a chairperson who will lead the meetings and ensure that the trial adheres to ethical and scientific guidelines. Additionally, the committee will feature an independent statistician, clinical experts knowledgeable in OCD treatment, cognitive remediation, and MCT, as well as an ethics representative.

The Trial Steering Committee (TSC) meets regularly to monitor the trial's progress and review safety reports. Its purpose is to guide any necessary adjustments to ensure the study remains ethical, practical, and scientifically robust. The TSC has the authority to recommend suspending the trial if serious safety risks arise or if compelling evidence of efficacy is presented.

The trial will undergo scheduled internal audits, as well as external audits, to verify the execution of research protocols and adherence to ethical standards in conjunction with regulatory requirements. Internal audits of the study design will be run by the research team approximately every 3 months to check data integrity, together with protocol procedure adherence and participant safety. External audits conducted by the Medical Ethical Committee of the Iran University of Medical Sciences (IUMS) will concentrate on proof of informed consent practice and data accuracy and overall trial management. The TSC will receive all critical audit outcomes, which will prompt additional examination by the TSC, along with suitable corrective procedures as necessary.

Patient or public involvement

Patients or members of the public were not involved in the design, conduct, reporting, or dissemination of this trial. Recruitment materials and treatment protocols were developed exclusively by the research team. However, future dissemination will include sharing the findings with participants upon request.

Statistical analysis

The full statistical analysis plan will be uploaded to an open-source repository (e.g., OSF) before data analysis commences. IBM SPSS Statistics version 25 or higher will be utilized for statistical analysis. Continuous variables will be reported as mean ± standard deviation (SD), while categorical variables will be represented as counts and percentages. Mean differences (MDs) between groups will be presented along with their 95% confidence intervals. Fisher's exact test or the chi-square (χ^2) test will be employed for comparisons among categorical variables. The independent samples *t*-test will be used to compare continuous variable values.

To assess changes in symptom severity and neurocognitive scores within and between groups over the 8-week study period and following 3 months of follow-up, a two-factor repeated-measures analysis of variance (ANOVA) will be performed, with estimates of partial-eta squared for effect size (interpreted conservatively as small = 0.01, medium = 0.09, and large = 0.25). When the sphericity of the data cannot be assumed using Mauchly's test, the Greenhouse–Geisser correction for degrees of freedom will be applied. A p-value of ≤ 0.05 will be considered statistically significant. Changes from baseline scores for the participants in each group will be analyzed using the paired samples *t*-test. Baseline demographic and clinical characteristics of participants will be summarized descriptively for each group without statistical significance testing.

Missing data will be addressed using multiple imputation under the assumption of missing at random. In addition, mixed-effects models, which are robust to missing data, will be applied for the primary analysis.

To account for potential clustering of outcomes within therapy groups, sensitivity analyses will be conducted using linear mixed-effects models with group as a random effect. This will allow us to assess whether clustering materially affects the results compared with the primary repeated-measures ANOVA approach.

All randomized participants will be included in the primary analyses according to the intention-to-treat principle, analyzed in the groups to which they were originally allocated, regardless of adherence to the intervention. Per-protocol analyses, including only participants who complete at least 75% of sessions, will be conducted as sensitivity analyses.

At the primary analysis level, the primary outcome (Y-BOCS scores) will be analyzed using repeated measures ANOVA and confirmed with linear mixed-effects models to account for potential clustering and missing data. Secondary cognitive outcomes (CPT, SCWT, TOL) will be analyzed using the same approach, and categorical secondary outcomes will be compared using chi-square tests where appropriate. All results will be presented with effect sizes and 95% confidence intervals.

This study does not include interim analyses, and the decision to proceed with the study will be based on final analyses.

Discussion

Present psychiatric disorder management includes the treatment of symptoms while simultaneously working to improve patient functionality. Public demand for therapeutic approaches focusing on cognitive ability enhancement has increased strongly in the past few decades. One such method is goal management training (GMT), which involves metacognitive strategy training designed to enhance cognitive control and promote a mindful approach to executive dysfunction. Metacognitive therapy (MCT), which explicitly targets maladaptive metacognitive beliefs and thought patterns associated with obsessive–compulsive disorder (OCD), is an emerging treatment option. By initially concentrating on developing metacognitive knowledge and attentional skills, we can help create a "prepared mind" that is better equipped to engage in GMT's more structured, goal-oriented strategies. This approach may improve patients' engagement with and adherence to GMT techniques while facilitating changes across three levels: metacognitive knowledge, metacognitive experiences, and metacognitive strategies. We hypothesize that this novel approach, cognitive rehabilitation combining GMT-derived interventions and MCT for OCD treatment, can positively impact cognitive deficits and reduce the severity of symptoms in adult patients with OCD. In this study, we present the rationale, design, and methodology for a randomized controlled trial (RCT) to assess the efficacy of cognitive rehabilitation (incorporating the combination of GMT-derived interventions and MCT) for individuals with OCD. This study has several strengths, including a standard sample size (rather than a pilot design), randomization, and blinding at every stage of the research, with long-term follow-up. However, there are also limitations. One key limitation is the use of a waitlist control group instead of an active treatment group. This choice can be improved once the treatment's efficacy is established compared to a passive control in this study. Nonetheless, using a passive control group in a first-of-its-kind study that relies on human resources and therapists can help ensure treatment integrity. Another limitation is that, although the intervention was delivered in groups, the sample size calculation did not adjust for clustering effects. The intraclass correlation coefficient (ICC) in psychological group interventions is typically small [89], but this design effect cannot be entirely excluded. Another limitation noted in similar studies is the high rate of participant dropouts during long-term follow-up. We aim to minimize this issue by keeping participants engaged on an online message board throughout the study.

Trial status

The recruitment process for participants in this protocol (version 1.0- 22nd April 2024) commenced on May 15, 2025, and is anticipated to span a duration of 8 weeks. Following the completion of recruitment, the interventions will begin.

All significant changes to the protocol will be promptly communicated to stakeholders. Any modifications require official documentation and must be evaluated and approved by the ethics committee before taking effect. The research team will then obtain updated protocol versions to implement the approved changes.

The research findings will be published in journals focusing on psychiatry, cognitive remediation, and obsessive–compulsive disorder (OCD). Additionally, they will be presented at both local and international conferences. Participants will receive a clear summary of the results; however, we will ensure confidentiality by omitting any identifiable information.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-09219-5.

Supplementary Material 1.

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Data availability
N/A.

Declarations

Ethics approval and consent to participate
The participants will provide written informed consent. The study has been registered and received ethical approval from the Medical Ethical Committee of the Iran University of Medical Sciences (IUMS) (protocol number IR.IUMS.FMD.REC.1403.025). The trial was registered at the Iranian Registry of Clinical Trials on 19/01/2025 (www.irct.ir; IRCT ID: IRCT IRCT20170123032145N8). This study will be conducted according to the declaration of Helsinki and subsequent revisions.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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