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Digital Emotion-Memory Training for Preventing Insomnia among Adults with Subclinical Insomnia: Protocol for a Community-Based Randomized Controlled Trial

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Study protocol

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Abstract

Background

Insomnia disorder is a prevalent, chronic, and recurrent sleep disorder associated with substantial mental, physical, and socioeconomic burden. Individuals with subthreshold insomnia are at increased risk of progression to insomnia disorder, yet scalable preventive interventions for this high-risk population remain limited. This multicenter randomized controlled trial (RCT) is designed to evaluate whether a smartphone-delivered emotional memory control intervention based on the Think/No-Think paradigm can reduce insomnia severity and prevent incident insomnia disorder in adults with subthreshold insomnia.

Methods

This community-based, three-arm, parallel RCT will recruit 750 adults aged 18–65 years with subthreshold insomnia, defined as insomnia symptoms below the diagnostic threshold for insomnia disorder and an Insomnia Severity Index score of 8–14. Participants will be randomly assigned in a 1:1:1 ratio to a suppress-negative group, a suppress-neutral group, or a waitlist control group. The intervention will be delivered through a smartphone mini-program over 2 weeks and will consist of two consecutive 6-day training phases based on the autobiographical Think/No-Think paradigm. The waitlist control group will receive no active training during Weeks 1–2 and will be offered the intervention after the 6-month follow-up. Primary outcomes are the change of insomnia severity and incidence of insomnia disorder assessed by clinical interview based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria. Assessments will be conducted at baseline, immediately and 1 month after intervention, and at 3, 6, 12, and 24 months after intervention. Outcomes will be analyzed on an intention-to-treat basis using mixed-effects models for repeated measures and survival models.

Discussion

This trial will evaluate whether a digital emotional memory control intervention can reduce insomnia symptoms and prevent progression to insomnia disorder. If effective, it may provide a scalable, low-cost, and mechanism-informed strategy for community-level insomnia prevention.

Trial registration:

Chinese Clinical Trial Registry, ChiCTR2600116389. Registered on January 9, 2026.

BACKGROUND

Insomnia disorder is characterized by persistent difficulties in sleep initiation, sleep maintenance, and/or early-morning awakening accompanied by daytime impairment[1]. Epidemiological studies indicate that approximately 10–15% of adults meet diagnostic criteria for insomnia disorder, and its prevalence has increased substantially over recent decades[2, 3]. Beyond sleep-related complaints, insomnia is associated with increased risk of occupational and traffic accidents, and elevated incidence of psychiatric and other medical disorders, including depression, anxiety, posttraumatic stress disorder, cardiovascular disorders, chronic pain, and gastrointestinal problems[4–8] resulting in a considerable public health and global socioeconomic burden[9–13].

Importantly, insomnia often follows a chronic and recurrent course[14]. Even with first-line treatment such as cognitive behavioral therapy for insomnia (CBT-I), many patients experience persistent symptoms or relapse, underscoring the limited reversibility once the disorder is established[15, 16]. This highlights the importance of early intervention and prevention in the initial stages of the insomnia trajectory[17]. However, no standardized or guideline-endorsed strategy specifically targets insomnia prevention. Current approaches are largely adapted from treatment models, including early CBT-I for individuals with subthreshold insomnia or other high-risk populations[18–21], as well as lifestyle- and behavior-based strategies such as physical activity, mindfulness-based intervention, and sleep hygiene[22–24]. Pharmacological approaches are not recommended for preventive use and are generally limited to short-term symptomatic management[2, 25]. When applied preventively, these approaches are constrained by accessibility, cost, adherence, and scalability, underscoring the need for effective, low-cost, and scalable non-pharmacological interventions for insomnia prevention.

Recent advances in sleep research have expanded the conceptualization of insomnia beyond a disorder of sleep–wake regulation to include prominent contributions from cognitive and affective processes related to hyperarousal[26, 27]. Within this framework, impaired regulation of emotionally salient thoughts and memories during wakefulness, particularly persistent negative memory representations, has been implicated in the development and maintenance of insomnia[26, 28–31]. Neurocognitive studies further suggest that reduced prefrontal inhibitory control and increased limbic responsivity contribute to a persistent state of hyperarousal that predisposes individuals to sleep disturbance[32, 33]. Converging findings from experimental and animal studies support a contributory role of emotion-related memory control deficits in insomnia, independent of direct sleep manipulation [17, 31, 34–39]. However, despite this mechanistic rationale, no emotional memory control–based intervention has yet been systematically developed or tested in randomized controlled trials for insomnia prevention.

To address these gaps, we developed a personalized digital emotional memory control training delivered via a smartphone-based mini-program. The intervention is based on the autobiographical Think/No-Think paradigm, a well-established task for studying the voluntary control of memory retrieval[36, 40–42]. In this paradigm, individuals are trained to suppress the retrieval of unwanted memories when confronted with reminder cues[43]. Notably, mounting evidence demonstrates that individuals diagnosed with psychiatric disorders, including post-traumatic stress disorder, depression, anxiety, and insomnia, showed deficits in controlling unwanted memories in the TNT[44–47]. Beyond this correlational

evidence, recent research has also shown that training thought control abilities using the TNT can causally improve mental health-related outcomes[37, 48].

Based on these work, the present multicenter randomized controlled trial aims to evaluate the efficacy and safety of this personalized digital memory control intervention in preventing insomnia and reducing insomnia severity among adults with subclinical insomnia. By translating insights from cognitive neuroscience into a practical digital format, this study seeks to establish an accessible, low-cost, and non-pharmacological preventive approach for insomnia and its associated mental health outcomes.

METHODS

This protocol has been developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines and the Consolidated Standards of Reporting Trials (CONSORT) statement for randomized trials of non-pharmacological interventions[49, 50]. The study also complies with the relevant national ethical guidelines for medical research involving human participants. To enhance sample representativeness and the generalizability of the findings across geographic, ethnic, and sociodemographic contexts, this multicenter trial will recruit participants from more than 10 provinces nationwide in China, with each participating center required to obtain independent ethical approval prior to enrollment. This report is based on protocol version 3.0, which has been approved by the Ethics Committee of Guangdong Provincial People's Hospital (trial sponsor, approval number: KY2025-035-05) and the Ethics Committee of the Affiliated Brain Hospital of Guangzhou Medical University (approval number:2025 – 251). The trial has been registered in the Chinese Clinical Trial Registry (registration number: ChiCTR2600116389), where the name and contact information of the trial sponsor are publicly available.

Overall design

This study is a prospective, community-based randomized controlled trial. The primary objective is to evaluate the efficacy of an emotional memory control intervention in reducing insomnia severity and preventing incident insomnia disorder among adults with subclinical insomnia. Secondary objectives are to examine the effects of the intervention on sleep quality and objective sleep–wake patterns, daytime sleepiness, mood symptoms (depressive and anxiety symptoms), circadian preference and rest–activity rhythms, psychosomatic symptoms and mental well-being, as well as thought control ability and physical activity, with changes assessed from baseline across all follow-up time points. The trial includes three prespecified analytical phases. We will assess the short-term effect at post-intervention and 1-month follow-up, the medium-term effects at 3- and 6-month follow-ups, and the long-term effects at 12- and 24-month follow-ups.

Participant recruitment commenced on January 10, 2026, and is expected to be completed by July 31, 2027. The 24-month follow-up assessment is scheduled to be completed by July 31, 2029.

Participants

Study settings

This is a multicenter randomized controlled trial coordinated by The Affiliated Brian Hospital of Guangzhou Medical University and Guangdong Provincial People's Hospital. Participants will be recruited from community settings and will complete screening, assessments, and interventions through a combination of online platforms.

Eligibility criteria

Inclusion criteria

Participants must meet **all** of the following criteria:

1. Adults aged 18–65 years at the time of providing informed consent, of any sex.
2. Chinese individuals who have resided in China long-term.
3. Presence of subthreshold insomnia symptoms, with an Insomnia Severity Index (ISI) score between 8 and 14[18, 51–53].
4. Agreeing to provide emotionally salient personal events that occurred within the past three years[37].
5. Ability to read and understand Mandarin Chinese and to operate electronic devices required for the digital intervention.
6. Provide written informed consent.

Exclusion criteria

Participants will be excluded if they meet **any** of the following conditions:

1. Diagnosis of insomnia disorder will be made according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), based on persistent difficulties in sleep initiation and/or maintenance occurring at least three nights per week for more than three months and accompanied by daytime impairment.
2. Current diagnosis of psychiatric disorders known to substantially affect sleep, such as anxiety disorders, depressive disorders, bipolar disorder, schizophrenia, or post-traumatic stress disorder.
3. Current diagnosis of other sleep disorders, such as restless legs syndrome or sleep apnea.
4. Current diagnosis of neurological disorders (e.g., epilepsy, stroke, Alzheimer's disease, Parkinson's disease) or a history of significant brain injury.
5. Current diagnosis of severe intellectual disability or severe physical illness.

6. Engagement in night shift work, rotating shift work, or employment involving frequent time zone changes.
7. Pregnancy or breastfeeding.

Interventions and controls

This digital intervention will be delivered via a WeChat-based mini-program through smartphones (Fig. 1). It was developed by our research team (Key Laboratory of Sleep and Biological Rhythms of Guangdong Province, Center for Sleep and Circadian Medicine, The Affiliated Brain Hospital, Guangzhou Medical University, Guangzhou, Guangdong, China; Department of Psychology, The University of Hong Kong, Hong Kong, China). Following eligibility screening and completion of baseline assessments, participants will be randomly assigned to one of three groups: suppress-negative group, suppress-neutral group, and waitlist control group. The intervention protocol will be identical across intervention arms, with the emotional valence of the suppressed memories differing between groups. Follow-up schedules will be identical across all groups.

Intervention procedures

Autobiographical memory generation and materials preparation

Autobiographical memories will be used as training materials. Three days prior to the start of training, participants will be assigned to intervention groups and will be asked to generate 42 autobiographical memories with distinct emotional valences: 14 negative, 14 positive, and 14 neutral events. Two autobiographical memories from each valence will be used for practice, while the remaining 12 autobiographical memories from each valence will be assigned to the formal training.

Each event will be required to meet the following requirements. First, each event has to include a two-character cue word and a brief event description. Second, cue words have to be derived from the corresponding event description and have to be unique across events to avoid confusion during training. Third, the cue word has to be sufficiently specific to evoke the targeted autobiographical event and could take the form of a noun or a brief action-related expression, provides that it uniquely corresponds to that event. Fourth, the event description has to be limited to 15 Chinese characters.

The content of each event will be required to meet six predefined criteria. First, positive events have to evoke pleasant or satisfying emotions, such as success in a romantic relationship or job promotion; neutral events have to be emotionally non-salient both at the time of occurrence and at recall, such as washing dishes after a meal; and negative events have to evoke distress, sadness, worry, or other negative emotions at recall, such as a traffic accident or the death of a relative or friend. Second, each event has to be a self-relevant personal experience centered on the participant, rather than a general

fact, an event experienced only by others, or something merely observed without direct personal involvement. Third, the event must have occurred within the past 3 years to ensure sufficient vividness and accessibility. Fourth, the event has to refer to a specific episode with a clear temporal and spatial context. Fifth, the duration of the event has to range from a few seconds to 1 day, rather than reflecting a prolonged state, repeated habit, or extended life period. Sixth, positive and negative events must have been voluntarily recalled at least once during the past year, whereas neutral events should be familiar and concrete daily-life episodes without strong emotional salience.

For each event, participants will be asked to provide a cue word and event description, which will be reviewed by trained experimenters according to the predefined criteria above. Events or cue words that do not meet these requirements will be revised or replaced before formal training.

Training structure

The emotion memory suppression training will last for two weeks and consist of two consecutive 6-day training phases. Participants will complete TNT-based training every day during each 6-day phase. Before the training begins, the 14 positive events and the 14 negative or neutral events will be divided equally between the two training weeks. Thus, each training week will include 14 autobiographical events in total. In the suppress-negative group, these 14 events will consist of 7 positive events and 7 negative events. In the suppress-neutral group, these 14 events will consist of 7 positive events and 7 neutral events. Within each training week, the 7 positive events will always be assigned to the Think condition. Participants will be instructed to recall the corresponding positive event when the cue word is presented. In the suppress-negative group, the 7 negative events will always be assigned to the No-Think condition. In the suppress-neutral group, the 7 neutral events will always be assigned to the No-Think condition. Participants will be instructed to prevent the corresponding negative or neutral event from entering awareness when the cue word is presented.

The cue-event pairing learning phase

On the first day of each week, participants will complete a learning task to establish cue word–event associations (Fig. 2**A**). The learning task will last approximately 5–10 minutes and will include both recognition and recall components. Each trial will begin with a fixation cross, followed by Question 1 (Q1), which asks whether the participant remembers the personal experience associated with a cue word (e.g., bike) provided. If the participant responds “Yes,” Question 2 (Q2) will present three candidate experiences, from which the participant will select the correct one. No matter which answer they choose, the correct one will be displayed as feedback. Participants will subsequently answer Question 3 (Q3), indicating whether the memory they initially recalled in Q1 was the correct one. Each trial will end with a 1-second inter-trial interval before the next fixation screen appears. A cue–event pairing will be considered successfully learned only if all three questions are answered correctly within the same trial, with up to four learning rounds permitted. Only participants achieving an accuracy rate of at least 90% will proceed to formal training.

Think/No-Think phase

Formal memory control intervention will be based on the Think/No-Think paradigm. Cue words associated with positive events (displayed in green) will be used in “Think” trials, whereas cue words associated with negative or neutral events (displayed in red) will be used in “No-Think” trials (Fig. 2**B**). The cue color remained constant across training.

During “Think” trials, participants will be instructed to retrieve the corresponding autobiographical memory as vividly and completely as possible. During “No-Think” trials, participants will first identify the associated memory and then actively suppress retrieval, maintaining a blank mental state while avoiding alternative thoughts.

Each daily session will include a brief practice phase followed by a formal training phase. In the practice phase, participant will complete the Think and No-Think trials twice. In the formal training phase, we will repeat 12 events (i.e., 6 Think and 6 No-Think) six times in a randomized order per day, with no more than two consecutive trials from the same condition. Each trial will consist of a 0.5-second fixation, a 4-second cue presentation, and a 0.6-second inter-trial interval. The formal training phase consisted of two blocks, each comprising 36 trials, for a total of 72 trials, with a total duration of approximately 10 minutes.

At the end of each training session, participants will complete self-report questionnaires adapted from previous TNT studies[43] to verify task compliance and strategy utilization. Standardized text-based strategy feedback will be automatically provided by the mini-program based on participants’ responses. These data will be used to monitor fidelity to the TNT procedure, while adherence was monitored automatically by the digital platform based on daily session completion.

Control condition

Participants assigned to the waitlist control group will complete the same autobiographical memory generation procedure at baseline. However, they will not receive the Think/No-Think training intervention during the two-week intervention period and will only complete outcome assessments at each scheduled time point. After completion of the 6-month follow-up assessment, participants in the waitlist group will be offered the opportunity to voluntarily receive the same training intervention as that provided to the intervention groups.

Concomitant interventions

Participants are allowed to continue stable usual care that does not involve structured cognitive or behavioral interventions targeting sleep or emotional regulation, provided such treatments were initiated at least four weeks prior to enrollment. Any concomitant treatments will be recorded throughout the study.

New interventions

Initiation of any new structured psychological interventions targeting sleep or emotional regulation, including CBT-I, will not be permitted during the intervention period unless clinically required. Initiation of

sleep-related pharmacological treatments will also be considered protocol deviations unless clinically required. All deviations will be documented and considered in sensitivity analyses.

Discontinuation of intervention

The allocated intervention may be discontinued if any of the following occurs: substantial worsening of insomnia, anxiety, or depressive symptoms requiring more active clinical management; severe distress during or after training; a serious adverse event judged by the investigator to make continued participation inappropriate; emergence of clinically significant suicidal ideation according to the predefined safety monitoring procedure; repeated non-adherence that prevents meaningful completion of the intervention; voluntary withdrawal by the participant; or any other condition in which the investigator judges that continued participation may pose a potential risk to the participant.

Adherence monitoring

Adherence to the intervention will be monitored automatically through the smartphone mini-program, including login records, training dates and times, completion of learning and training sessions, task accuracy during the learning phase, number of completed trials, and responses to post-session strategy-use and compliance questions. Participants will receive standardized reminders by research staff when scheduled sessions are missed.

To promote adherence, the intervention is designed as brief daily sessions lasting approximately 10 minutes and delivered remotely through a smartphone mini-program. Participants will receive clear instructions before training, practice trials before formal training, and technical support when needed. Training completion and adherence data will be reviewed regularly by the research team. Participants with poor adherence may be contacted to clarify barriers and encourage continued participation, without revealing group allocation to blinded outcome assessors.

Measures

The schedule of measures and test contents is summarized in **Table 1**.

Primary outcome

The primary outcomes are (1) the incidence of insomnia disorder assessed from the 3-month follow-up onwards, ascertained by clinical interview based on DSM-5 criteria, and (2) the change in insomnia symptom severity, as measured by the ISI at baseline, post-intervention, and at 1-, 3-, 6-, 12-, and 24-month follow-ups.

Secondary outcomes

Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI), sleep diaries, and actigraphy-derived parameters, including sleep duration, sleep latency, sleep efficiency, wake after sleep onset (WASO), total sleep time (TST), and bedtime and wake time, as well as rest–activity rhythm metrics such as L5 (least active 5-hour period), M10 (most active 10-hour period), relative amplitude

(RA), interdaily stability (IS), intradaily variability (IV), acrophase, and MESOR (midline estimating statistic of rhythm). Changes from baseline to each follow-up time point will be analyzed for all measures. A reduction of ≥ 3 points in the total PSQI score will be defined as an improvement in sleep quality.

Daytime sleepiness will be assessed using the Epworth Sleepiness Scale (ESS), with changes from baseline evaluated at all follow-up time points.

Mood symptoms will be assessed using the Beck Depression Inventory–II (BDI-II) and the Beck Anxiety Inventory (BAI). A total score ≥ 14 on the BDI-II will indicate the presence of depressive symptoms, and a total score ≥ 16 on the BAI will indicate the presence of anxiety symptoms[54–56].

Circadian preference and psychosomatic symptoms will be assessed using the Morningness–Eveningness Questionnaire (MEQ), Munich Chronotype Questionnaire (MCTQ), Patient Health Questionnaire-15 (PHQ-15), and the Warwick–Edinburgh Mental Well-being Scale (WEMWBS).

Cognitive control and physical activity will be assessed using the Thought Control Ability Questionnaire (TCAQ) and the short-form International Physical Activity Questionnaire (IPAQ Short Form).

Instruments

Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)

Clinical evaluation of insomnia disorders and related psychiatric symptoms will be conducted according to the diagnostic criteria outlined in the DSM-5[1].

Diagnostic Interview for Sleep Patterns and Disorders (DISP)

Sleep–wake patterns and potential sleep disorders were assessed using the DISP[57]. The DISP provided standardized, interviewer-based information to support the identification and characterization of sleep disturbances in the study population.

Personal Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a validated instrument comprising nine items corresponding to the diagnostic criteria for major depressive episodes[58]. Total scores range from 0 to 27, with higher scores indicating greater depressive symptom severity. Both the original and Chinese versions[59] have demonstrated satisfactory reliability and validity and have been widely used as standardized measures of depressive symptoms.

Generalized Anxiety Disorder-7 (GAD-7)

The GAD-7 is a seven-item instrument developed to assess generalized anxiety symptoms[60]. Scores range from 0 to 21, with higher scores indicating greater anxiety severity. The scale has been widely used

in clinical and community research, and the reliability and validity of the Chinese version[61] have been confirmed.

Big Five Inventory-2 (BFI-2)

The BFI-2 is a 60-item self-report personality questionnaire that assesses the Big Five domains—Extraversion, Agreeableness, Conscientiousness, Negative Emotionality (Neuroticism), and Open-Mindedness (Openness)—with three facet scales per domain (15 facets in total)[62]. Items are rated on a 5-point Likert scale from “strongly disagree” to “strongly agree,” and domain scores provide a broad description of stable personality traits relevant to emotional functioning, interpersonal behavior, and health outcomes. Soto and John demonstrated that the BFI-2 offers improved bandwidth and fidelity over the original BFI, with good internal consistency, test–retest reliability, and hierarchical structure in English-speaking samples[62]. A Chinese version of the BFI-2 was developed and comprehensively evaluated across four diverse Chinese samples, showing good structural equivalence to the original instrument, high internal consistency and test–retest reliability, and satisfactory convergent and discriminant validity, indicating that the Chinese BFI-2 is a robust tool for assessing Big Five personality traits in Chinese-speaking populations[63].

Insomnia Severity Index (ISI)

The ISI is a 7-item self-report scale that assesses the nature, severity, and impact of insomnia symptoms during the past 2 weeks, including difficulties with sleep onset, sleep maintenance, early-morning awakening, dissatisfaction with sleep, interference with daytime functioning, noticeability of impairment, and concern about sleep problems. Each item is scored from 0 to 4, yielding a total score of 0–28, with higher scores indicating more severe insomnia and commonly used cut-offs distinguishing absence, subthreshold, moderate, and severe clinical insomnia[64]. The ISI has demonstrated good internal consistency, construct validity, and sensitivity to treatment-related change in both clinical and community samples. A validated Chinese version of the ISI shows satisfactory psychometric properties in Chinese populations and will be used in the present study[65].

Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. The measure consists of 19 items generating seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of scores for these seven components yields one global score ranging from 0 to 21, with higher scores indicating poorer sleep quality. The PSQI has demonstrated good reliability and validity in distinguishing between good and poor sleepers in various patient populations and healthy individuals[66]. The validity and reliability of the Chinese version have been confirmed[67].

Epworth Sleepiness Scale (ESS)

The ESS is an 8-item self-report questionnaire measuring the propensity to doze in common daytime situations (e.g., sitting and reading, watching TV). Respondents rate their likelihood of dozing on a 0–3 scale, producing a total score between 0 and 24, with higher scores indicating greater daytime sleepiness. Johns showed that ESS scores distinguish patients with sleep disorders from healthy controls and correlate with objective sleepiness measures, establishing its clinical utility[68]. A Mandarin Chinese version of the ESS (CESS), translated and validated in patients with sleep-disordered breathing, demonstrated high internal consistency, strong correlation with the original English version, and good discriminative validity, and has since been widely used in Chinese sleep clinics[69].

Munich Chronotype Questionnaire (MCTQ)

The MCTQ is a self-administered questionnaire designed to assess individual chronotype by systematically capturing bedtimes, rise times, sleep latency, and sleep duration on both workdays and free days. Chronotype will be assessed using the Munich Chronotype Questionnaire and quantified as the midpoint of sleep on free days corrected for sleep debt accumulated on workdays (MSFsc), with later MSFsc values indicating a later chronotype. Roenneberg and colleagues showed that the MCTQ is sensitive to inter-individual differences in sleep–wake timing across the lifespan and correlates well with objective circadian markers, making it a widely used tool in chronobiology and epidemiological research[70]. The Chinese version was culturally adapted and validated in Chinese adolescents and adults, demonstrating high test–retest reliability and good convergence with established morningness–eveningness measures[71]. It is appropriate for assessing circadian preference in Chinese populations[71].

Morningness–Eveningness Questionnaire (MEQ)

The MEQ is a 19-item self-report instrument that assesses individual preference for activity and alertness in the morning versus evening. Items address preferred sleep–wake schedules, peak alertness times, and difficulty getting up in the morning; the total score classifies individuals into definite morning, intermediate, or definite evening types. Horne and Östberg originally validated the MEQ by relating scores to circadian variation in oral temperature and sleep–wake timing[72]. A Chinese version of the MEQ, developed and validated in Chinese clinical and community samples, has shown good internal consistency and criterion validity, with empirically derived cut-offs that effectively distinguish morningness and eveningness in Chinese populations[73].

Patient Health Questionnaire-15 (PHQ-15)

The PHQ-15 is a 15-item self-report measure derived from the full PHQ that assesses the severity of 15 common somatic symptoms over the past four weeks, each rated on a 0–2 scale (“not bothered at all” to “bothered a lot”), with total scores ranging from 0 to 30. Kroenke et al. demonstrated that the PHQ-15 has good internal consistency and convergent validity with functional impairment and health care utilization, and is useful for screening somatic symptom burden and somatoform disorders in primary care[74]. A Chinese version of the PHQ-15, validated in patients attending a tertiary hospital in China,

showed good reliability, unidimensional structure, and adequate discriminative validity for identifying individuals with high somatic symptom severity[75]

Warwick–Edinburgh Mental Well-being Scale (WEMWBS)

The WEMWBS is a 14-item self-report instrument to capture positive aspects of mental health, including optimism, feeling useful, relaxed, and close to others. Items are rated on a 5-point Likert scale from “none of the time” to “all of the time”. Total scores are summed and range from 14 to 70. Higher scores are associated with higher levels of mental wellbeing. WEMWBS demonstrates strong internal consistency, unidimensional structure, and good construct validity in general population samples[76]. Chinese version of WEMWBS has undergone rigorous linguistic and cultural validation in Hong Kong and mainland samples, yielding good internal consistency, test–retest reliability, and expected correlations with mental health indicators[77].

Beck Depression Inventory-II (BDI-II)

The BDI-II is a widely used 21-item self-report measure designed to assess the severity of depressive symptoms in adolescents and adults. Respondents rate each item on a 4-point scale (0 to 3) based on their experience over the preceding two weeks, with total scores ranging from 0 to 63. Higher scores indicate greater depressive severity, with established cut-off scores facilitating the interpretation of symptom levels as minimal, mild, moderate, or severe[78]. The BDI-II has demonstrated excellent psychometric properties in diverse populations, including high internal consistency, good test-retest reliability, and strong convergent validity with other depression measures and clinical diagnoses[78, 79]. A Chinese version of the BDI-II, translated and validated among Chinese middle-school teachers and other samples, has demonstrated good factor structure, internal consistency, and criterion validity[80].

Beck Anxiety Inventory (BAI)

The BAI is a 21-item self-report scale that measures the severity of anxiety symptoms experienced over the past week, focusing on somatic and cognitive manifestations such as nervousness, dizziness, and fear of losing control. Each item is rated from 0 (“not at all”) to 3 (“severely”), with total scores reflecting minimal to severe anxiety. The BAI demonstrates high internal consistency, good test–retest reliability, and strong convergent and discriminant validity, particularly in differentiating anxiety from depression across clinical and non-clinical samples[55]. The Chinese BAI has been validated in healthcare and general populations, showing good internal consistency and expected associations with anxiety-related constructs[81].

Thought Control Ability Questionnaire (TCAQ)

The TCAQ is a self-report instrument designed to measure an individual's perceived ability to control unwanted and intrusive thoughts[82]. The scale comprises 25 items. Respondents rate their agreement on a 4-point Likert scale ranging from 1 (definitely false) to 4 (definitely true). A total score is calculated by summing all items, with higher scores indicating a greater perceived ability to control unwanted thoughts. The Chinese version of the TCAQ has shown good internal consistency in Chinese samples and expected associations with rumination, neuroticism and depressive symptoms[83].

International Physical Activity Questionnaire – Short Form (IPAQ Short Form)

The IPAQ Short Form is an internationally standardized measure designed to assess physical activity levels in adults[84]. Its reliability and validity have been demonstrated across multiple populations, including Chinese samples[85], and it is commonly used in epidemiological and behavioral research.

Participant timeline

Figure3 shows the participant timeline.

Sample size

The sample size for this multicenter randomized controlled trial is determined using G*Power version 3.1 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany), based on two primary outcomes: short-term change in ISI score and medium- to long-term incidence of insomnia disorder.

For the short-term analysis, sample size estimation is based on a repeated-measures ANOVA framework for the group × time interaction effect in ISI scores, with three parallel arms and three assessment time points. Assuming a small-to-moderate interaction effect size (f = 0.15), a two-sided α of 0.05, and 90% power, 67 participants per arm are required, corresponding to a total sample size of 201. After allowing for an estimated dropout rate of 10% at the short-term endpoint, the adjusted recruitment target is 223 participants.

For the medium- and long-term analyses of ISI change, a more conservative group × time interaction effect size (f = 0.10) is applied under the same three-arm, three-time-point repeated-measures framework. This yields 148 participants per arm, corresponding to a total sample size of 444. After allowing for estimated dropout rates of 15% and 20%, the adjusted recruitment targets are 522 participants for the medium-term endpoint and 555 participants for the long-term endpoint, respectively.

For the medium- and long-term analyses of insomnia disorder incidence, sample size estimation is based on the expected transition from subthreshold insomnia to insomnia disorder. Previous longitudinal studies have reported an annual transition rate of approximately 13.8% among individuals with subsyndromal insomnia, with higher recurrence rates observed among individuals with a prior history of insomnia syndrome[86]. For the incidence-based sample size estimation, the control-group incidence of insomnia disorder is set at 20%, and a 50% relative reduction is considered clinically

meaningful, corresponding to an expected incidence of 10% in the intervention groups. With 80% power and a 95% confidence level, 199 participants per arm are required. Given the three-arm parallel design, the unadjusted total sample size is 597 participants. After allowing for an estimated dropout rate of 15% at the medium-term endpoint, the adjusted recruitment target is 702 participants. For the long-term endpoint, assuming a dropout rate of 20%, the adjusted recruitment target is 750 participants.

The final planned sample size is 750 participants, with approximately 250 participants per arm. This sample size accommodates expected attrition across follow-up and satisfies the most conservative requirement derived from the long-term incidence analysis.

Allocation and blinding

Randomization will be conducted through a centralized, computer-generated stratified block randomization system embedded in the study mini-program. The random allocation sequence will be generated by an independent statistician who is not involved in recruitment, intervention delivery, outcome assessment, or data analysis. Stratification factors will include sex, baseline ISI severity, and study center. Participants will be assigned in a 1:1:1 ratio to the suppress-negative group, suppress-neutral group, or waitlist control group. Block sizes will be prespecified and concealed from investigators, and allocation will be concealed through automated assignment until the intervention is assigned.

Due to the nature of the waitlist control condition, participants cannot be fully blinded to whether they receive immediate digital training or waitlist control. However, participants in the two intervention groups will be blinded to the specific emotional valence condition. The suppress-negative and suppress-neutral groups will use the same mini-program, training schedule, cue format, Think/No-Think task structure, and instructions, differing only in the emotional valence of No-Think events.

Outcome assessors and statisticians will remain blinded to group allocation until database lock. Unblinding will be permitted only when knowledge of allocation is necessary for participant safety, such as serious adverse events, marked symptom worsening, or suicidal ideation requiring clinical management. Any unblinding will be approved and documented by the principal investigator or an authorized senior investigator.

Data collection and management

Data will be collected through the digital mini-program and electronic case report forms (eCRFs). All data will be stored on encrypted servers with tiered access permissions. Automated range checks, logic checks, and audit logs will ensure data integrity. Data management will comply with Good Clinical Practice (GCP) and institutional data security policies. Only de-identified datasets will be used for analysis. Identifiable information will be stored separately.

Date monitoring

An independent Data Monitoring Committee (DMC) will oversee: trial conduct, participant safety, protocol adherence, and review of interim analyses. The DMC will meet at predefined intervals and will have the authority to recommend continuation, modification, or termination of the trial.

Trail monitoring

Trial conduct will be monitored regularly by the coordinating center. Monitoring procedures will include review of recruitment progress, informed consent records, eligibility confirmation, intervention adherence, follow-up completion, adverse event reporting, protocol deviations, and data completeness. The coordinating center will communicate with participating centers on a regular basis, provide staff training and retraining when needed, and conduct data quality checks through the study database and mini-program records. Any major protocol deviations or safety concerns will be reported to the principal investigators, DMC, and ethics committees as appropriate.

Harms

Although the intervention is considered low risk because it is a brief, non-invasive, smartphone-delivered behavioral training without pharmacological or physical manipulation, it involves the processing and suppression of emotionally salient autobiographical memories and may therefore cause transient psychological discomfort in some participants. Potential risks include temporary distress, frustration, or increased emotional arousal during memory generation or training, which could negatively affect short-term well-being in vulnerable individuals. To monitor these risks, psychological well-being will be assessed at each follow-up, and all adverse events (AEs) and serious adverse events (SAEs) will be recorded throughout the study.

Patient and public involvement

Patients and the public were not involved in the design, conduct, or reporting of this study.

Statistical Methods

Statistical analyses

All analyses will follow the intention-to-treat (ITT) principle, including all randomized participants regardless of adherence. The cumulative incidence of insomnia disorder will be estimated using Kaplan–Meier curves and compared between groups using log-rank tests. Participants who develop insomnia disorder during follow-up will be treated as incident cases, and the event time will be defined as the first scheduled assessment at which DSM-5 criteria for insomnia disorder are met. Participants who do not develop insomnia disorder by the 6-month follow-up will be censored at their last completed assessment. Cox proportional hazards models will be used to estimate hazard ratios and 95% confidence intervals for between-group differences. As a sensitivity analysis, discrete-time survival models will be used to account for the interval-based assessment schedule. For insomnia symptom severity, the analysis will examine between-group differences in change from baseline in ISI scores

across all follow-up time points. Mixed-effects models for repeated measures (MMRM) will be used, with fixed effects for group, time, and group × time interaction, and a random intercept for each participant. An unstructured covariance matrix will be used unless a more parsimonious structure provides a better fit. Least-square mean differences and 95% confidence intervals will be reported. Effect sizes will be calculated using standardized mean differences. All tests will be two-sided with $\alpha = 0.05$. Multiplicity will be addressed by controlling the false discovery rate in secondary analyses. Secondary outcomes (PSQI, ESS, PHQ-9, GAD-7, BDI-II, MEQ, MCTQ, PHQ-15, WEMWBS, IPAQ, TCAQ) will be analyzed using the same MMRM framework. Prespecified covariates include baseline ISI, age, sex, and study center.

Short-term effect analysis

Short-term effects will be evaluated at baseline (week 0), immediately post-intervention (week 3), and 1 month post-intervention (week 7) initiation. MMRM will be used to estimate early between-group divergence in ISI trajectories and secondary outcomes.

Medium- and long-term effect analyses

Medium-term analyses will be performed at baseline (week 0) and at 3 and 6 months post-intervention (weeks 15 and 27), and long-term analyses at baseline and at 12 and 24 months post-intervention (weeks 51 and 99). Longitudinal patterns across the entire 24-month period will be evaluated using MMRM and supplemented with generalized estimating equations for robustness.

Handling of missing data

Missing data will be addressed under the assumption of missing at random (MAR). MMRM inherently accommodates MAR, and results will be supplemented by multiple imputation (MI) for sensitivity testing and complete-case analysis as secondary evidence. Patterns of missingness will be examined visually and statistically.

Sensitivity analyses

Sensitivity analyses will include: per-protocol analysis (participants completing ≥ 70% of training sessions), complete-case analysis, model robustness checks using alternative covariance structures, and exclusion of participants receiving external psychological treatment during follow-up.

Subgroup analyses

Exploratory subgroup analyses will be conducted for the following domains: (1) demographic factors, including sex (male vs female) and age group (18–45 vs 46–65); (2) clinical characteristics, including baseline insomnia severity (ISI 8–10 vs 11–12 vs 13–14), study center, and personality traits assessed by the Big Five Inventory; (3) circadian and behavioral patterns, including chronotype (MEQ/MCTQ-based categories) and physical activity level (IPAQ); and (4) environmental and lifestyle factors, including

environmental light exposure, sleep–wake habits, and other baseline lifestyle characteristics. Group × subgroup interaction terms will be tested using mixed-effects models for repeated measures (MMRM).

Interim analyses

Two interim analyses are planned. The first interim analysis will be conducted after completion of the short-term follow-up assessment at week 7, corresponding to one month after intervention completion, for 223 participants. This analysis will focus on feasibility, adherence, recruitment progress, data completeness, and safety. The second interim analysis will be conducted when medium-term follow-up data at week 27, corresponding to six months after intervention completion, are available for 702 participants. This analysis will include a non-binding early efficacy evaluation, in addition to safety and feasibility monitoring. To preserve the overall type I error rate, O'Brien–Fleming α-spending boundaries will be applied to the interim efficacy analysis and the final primary efficacy analysis. Both interim analyses will be performed by an independent statistician, and results will be reviewed by the independent DMC, which may recommend continuation, modification, or early termination of the trial.

DISCUSSION

This protocol describes a multicenter randomized controlled trial designed to assess the preventive effectiveness of a digital emotion-memory–based intervention for adults with subthreshold insomnia symptoms. By embedding a validated autobiographical memory suppression paradigm into a smartphone mini-program, the study tests a mechanism-informed approach to insomnia prevention within a format that is easily scalable for population-level use. With a planned sample size of 750 community participants, the trial is adequately powered to detect clinically meaningful preventive effects and represents one of the few studies to examine insomnia prevention using a mechanistic digital intervention.

This study has several methodological strengths. First, the large sample size and multicenter community-based recruitment enhance the representativeness and generalizability of the findings across diverse populations. Second, the intervention is delivered via a fully digital preventive application informed by a neuroscience-based cognitive mechanism, enabling standardized implementation, individual-level tailoring, and scalability with relatively low personnel and cost requirements. Third, the inclusion of both neutral and negative emotional training conditions allows examination of mechanistic specificity. Fourth, outcomes are assessed at both short-term and long-term follow-up time points, extending up to 24 months, permitting evaluation of the durability of preventive effects. Finally, centralized digital data capture, rigorous randomization and blinding procedures, and the use of validated psychological and behavioral measures support internal validity and feasibility across study sites. Several challenges are anticipated, including maintaining participant engagement over extended follow-up and potential differential attrition. In addition, although TNT-based retrieval suppression has received supporting experimental evidence, its long-term durability, possible rebound effects, and broader psychological consequences have not been fully established, particularly in the context of

insomnia prevention. Some outcome may also rely on self-report, although the combination of repeated assessments and objective actigraphy-based sleep monitoring in a subsample is expected to improve the robustness of outcome evaluation.

In conclusion, this large-scale trial is expected to generate valuable evidence on whether targeted emotional-memory processing can lower the risk of insomnia onset. If effective, the intervention may provide a low-cost, scalable, and accessible strategy for community-level prevention of insomnia disorder and broader mental health promotion.

National collaboration

This study is an active national collaborative project involving ten medical centers across China that specialize in the management of sleep-related problems. The participating centers are distributed across eastern, western, southern, northern, and central regions of China. The collaborating institutions include Guangdong Provincial People's Hospital, the Affiliated Brain Hospital of Guangzhou Medical University, the First Affiliated Hospital of Jinan University, the University of Hong Kong, Shantou People's Hospital, the Second Affiliated Hospital of Harbin Medical University, Hangzhou Seventh People's Hospital, the Second Hospital of Shanxi Medical University, Linyi People's Hospital, the First People's Hospital of Kashi Prefecture, and Zhongnan Hospital of Wuhan University.

The Affiliated Brain Hospital of Guangzhou Medical University will serve as the coordinating center and will be responsible for overall trial coordination, staff training, site communication, data management supervision, and quality control across participating centers. A trial steering committee, consisting of the principal investigators and key investigators from participating centers, will oversee trial implementation, protocol adherence, recruitment progress, and major operational decisions. The data management team will be responsible for database design, data entry procedures, data quality checks, data security, and preparation of datasets for analysis. An independent Data Monitoring Committee will review recruitment progress, adherence, safety data, and interim analysis results, and may recommend continuation, modification, or early termination of the trial. Because the primary clinical endpoint of insomnia disorder will be assessed using predefined diagnostic criteria through structured clinical interviews, endpoint assessment will be conducted by trained assessors blinded to group allocation. If endpoint adjudication is required, uncertain cases will be reviewed by investigators who are independent of intervention delivery.

Declarations

Ethics approval and consent to participate

The study protocol (version 3.0) has undergone review by the Ethics Committee of Guangdong Provincial People's Hospital (approval number: KY2025-035-05), the Ethics Committee of the Affiliated Brain Hospital of Guangzhou Medical University (approval number: 2025-251), the Ethics Committee of Shantou People's Hospital (approval number: EC20251013(8)-P1), the Ethics Committee of the Second

Hospital of Shanxi Medical University (approval number: 2026006), the Ethics Committee of Linyi People's Hospital (approval number: 202602-H-019). Any amendment to the protocol will be reviewed by the Ethics Committees.

Ancillary and post-trial care

Any compensation for trial-related harm will be managed according to the policies of the participating institutions and the requirements of the relevant ethics committees.

Consent for publication

Electronic informed consent will be obtained through the mini-program prior to participation. Participants may withdraw at any time without consequence.

Confidentiality and access to data

All data will be de-identified, stored securely, and accessible only to authorized personnel. No identifiable information will appear in publications.

Data availability

Data sharing is not applicable to this study protocol, as no datasets were generated or analyzed during the current study. After completion of the trial, de-identified data may be made available from the corresponding author upon reasonable request and subject to ethical approval and applicable data protection regulations.

Competing interests

The authors declare that they have no competing interests.

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The sponsor institution provides administrative oversight but has no role in the independent statistical analysis, interpretation of results, manuscript preparation, or decision to publish beyond the responsibilities of the investigator team. The funders have no role in the trial design, conduct, data collection, data management, analysis, interpretation, or reporting.

Authors' contributions

WW, **HLF** and **XBZ** is responsible for contributing to initial project proposal. **WW**, **HLF** and **YY** is responsible for drafting the final protocol for publication. At each participating center, the local principal investigator is responsible for site-specific participant recruitment, data collection, and adherence to the study protocol. Specifically, **HLF** and **JHZ** (with support from **JY**, **YYZ**, **SMS** and **SYL**) are responsible for the Affiliated Brain Hospital of Guangzhou Medical University; **HLF** and **SBW** (with support from **SMS** and **SYL**) are responsible for the Guangdong Provincial People's Hospital; **YY** (with support from **YYH, SL**, **CL** and **QCR**) for the First Affiliated Hospital of Jinan University; **XQH** (with support from **XBZ**) for the University of Hong Kong; **SCL** for Shantou People's Hospital; **YC** for the Second Affiliated Hospital of Harbin Medical University; **LSR** for Hangzhou Seventh People's Hospital; **XLG** (with support from **MZM** and **LZ**) for the Second Hospital of Shanxi Medical University; **QXF** for Linyi People's Hospital; **NA** for the First People's Hospital of Kashi Prefecture; and **YML** (with support from **QC**) for Zhongnan Hospital of Wuhan University. **YML**, **DY**, **NYC**, **YYL**, **SZA**, **YPL** and **YKW** contributed to the study design and revised the research protocol. **HLF**, **XQH** and **JHZ** are the chief investigators of the project and contributing to all subsequent revisions of the protocol. All authors read and approved the final manuscript.

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Figures

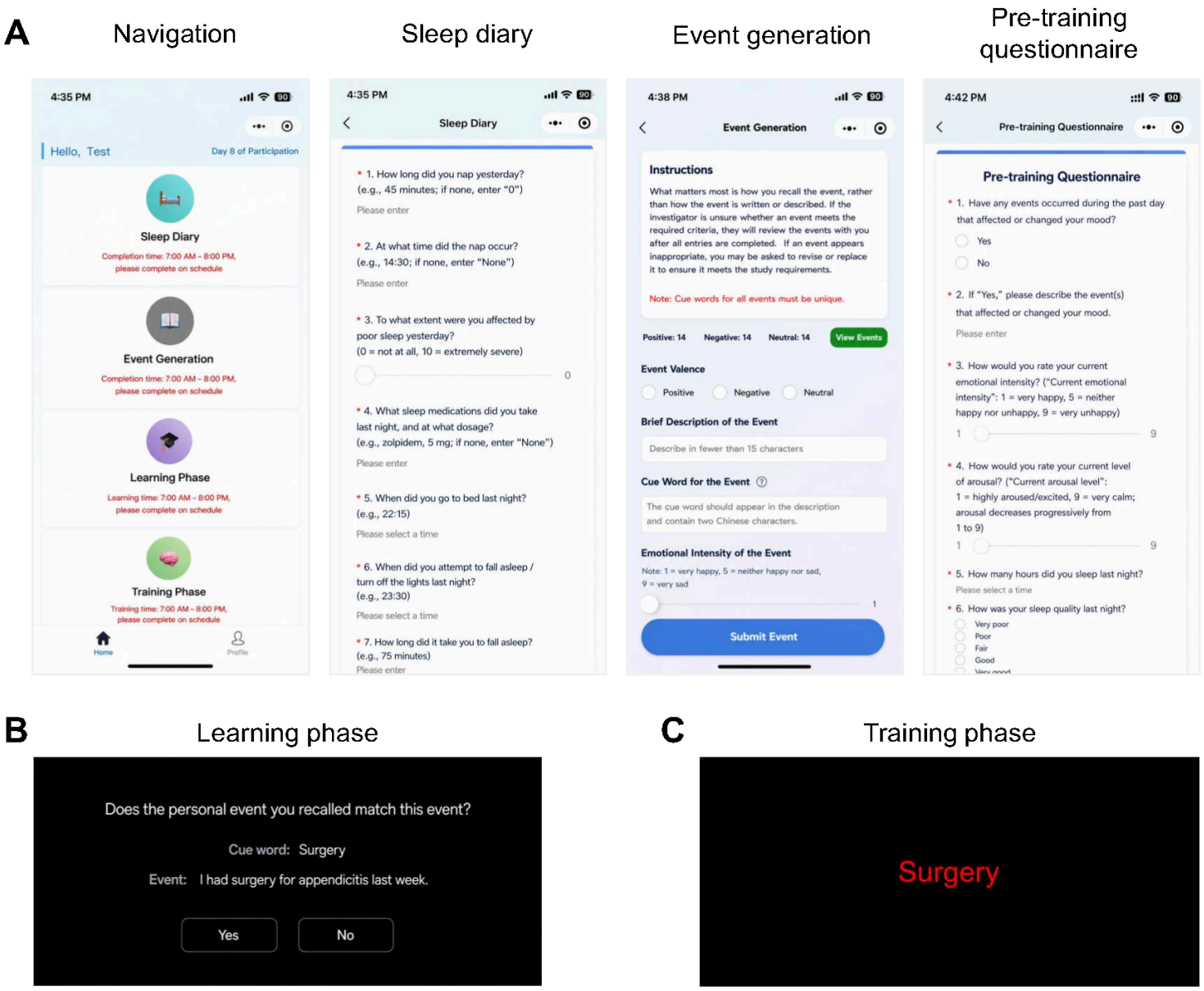

Figure 1

Screenshot examples of the emotional memory training Mini-Program. A, *Navigation* provides access to all training components. *Sleep diary* allows participants to record daily sleep patterns and related symptoms. *Event generation*allows users to enter emotionally valenced personal events (positive, negative, or neutral) for subsequent cue–event pairing training. The *pre-training questionnaire* assesses

participants' baseline emotional experiences and sleep status before initiating the training phase. **B**, Screenshot of the learning phase. **C**, Screenshot of the training phase. The original Mini-Program interface is in Chinese; the screenshots shown here have been translated into English to facilitate readability.

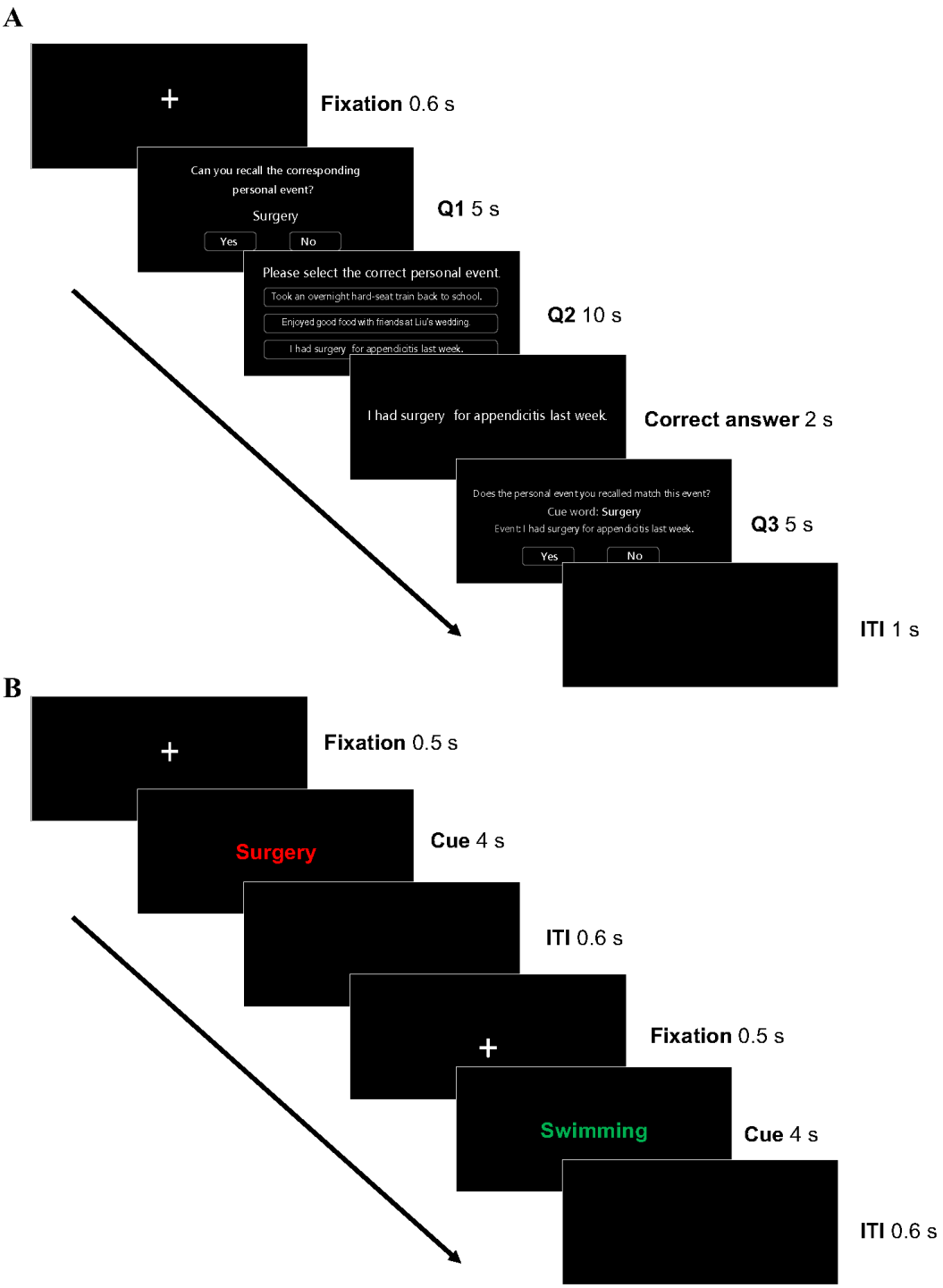

Figure 2

The diagram of Think/No-think tasks. A, Flowchart for the cue-event pairing learning phase. Each trial begins with a fixation cross, followed by Question 1 (Q1) asking participants whether they remember the personal experience associated with a cue word. If the participant responds “Yes,” Question 2 (Q2) presents three candidate experiences, and the participant selects the one that matches the cued memory. The correct personal experience is then displayed as feedback, regardless of whether the participant’s response is correct or incorrect. Participants subsequently answer Question 3 (Q3), indicating whether the memory they initially recalled in Q1 was the correct one. Each trial ends with an inter-trial interval (ITI) before the next fixation screen appears. A cue–event pairing is considered successfully learned when all three questions are answered correctly within a trial, and participants must achieve ≥90% accuracy across 14 pairings, with up to four learning rounds permitted. **B**, the flowchart for the training phase. Each trial begins with a fixation cross, followed by a cue word presented with a color-coded task condition: red for “No-Think” and green for “Think”. All task instructions and stimulus materials were presented in Chinese in the actual intervention. All task instructions and stimulus materials were presented in Chinese in the actual intervention; the diagram shown here has been translated into English to facilitate readability.

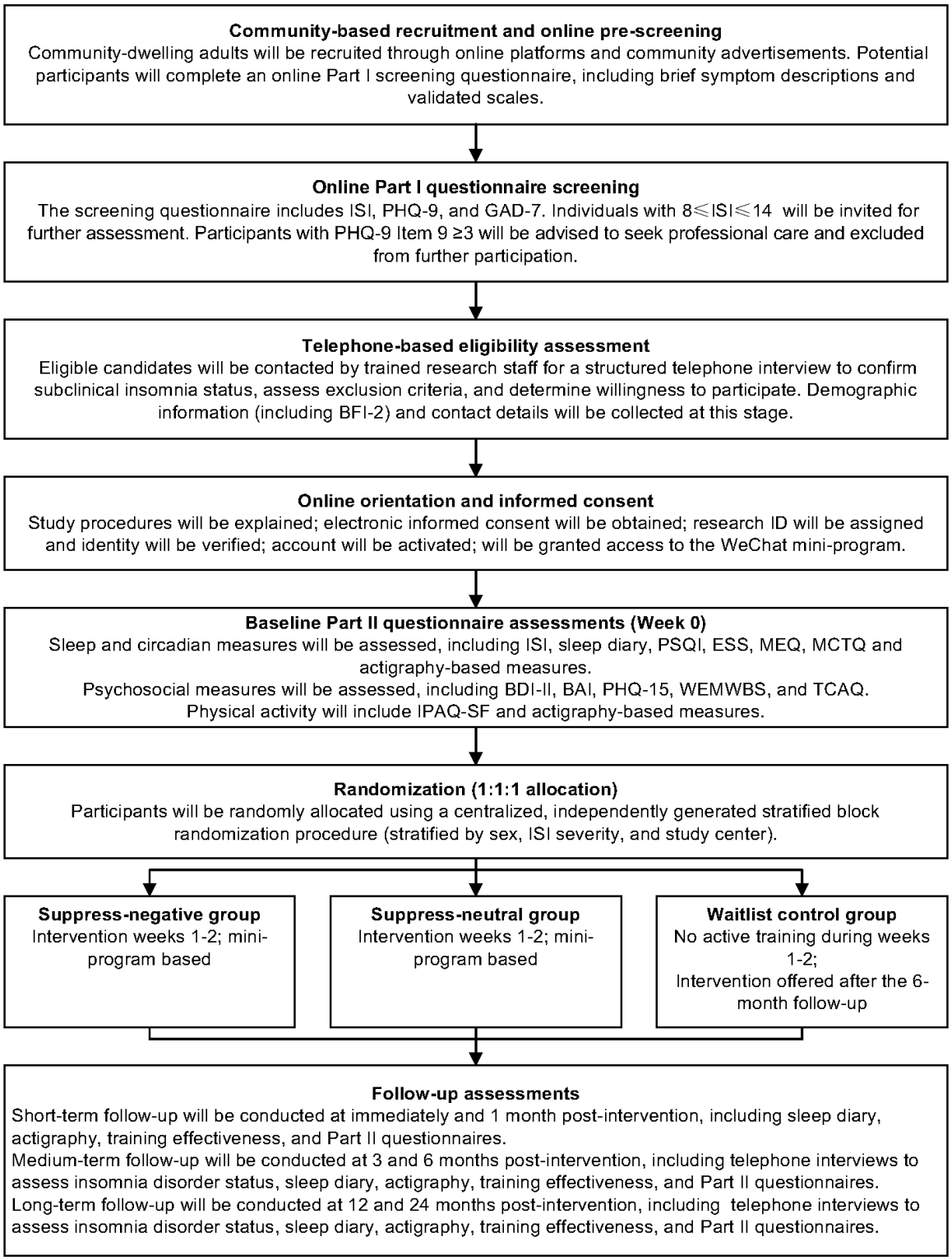

Figure 3

The participant timeline. ISI, Insomnia Severity Index; PHQ-9, Patient Health Questionnaire - 9; GAD-7, Generalized Anxiety Disorder-7; BFI-2, The Big Five Inventory-2; PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale; MEQ, Morningness-Eveningness Questionnaire; MCTQ (Munich Chronotype Questionnaire); BDI-II, Beck Depression Inventory-II; BAI, Beck Anxiety Inventory; PHQ-15, Patient Health

Questionnaire-15; WEMWB, Warwick Edinburgh Mental Well Being Scale; TCAQ, Thought Control Ability Questionnaire; IPAQ-SF, International Physical Activity Questionnaire-Short Form.