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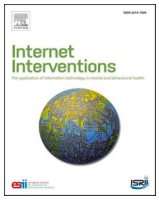

# Culturally adapted digital cognitive behavioral therapy for insomnia in South Korea – a double-blind randomized controlled trial☆

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ABSTRACT

Culturally adapted digital cognitive behavioral therapy for insomnia (dCBT-I) has the potential to enhance engagement and treatment outcomes, yet its efficacy compared to patient education (PE) remains understudied. This multicenter, double-blind, randomized controlled trial evaluated dCBT-I versus a PE application in individuals with chronic insomnia in South Korea. The primary outcome was Insomnia Severity Index (ISI) scores. Secondary and exploratory outcomes included sleep diary measures, self-reported scales assessing sleep quality, maladaptive sleep-related beliefs, daytime sleepiness, anxiety, and depressive symptoms. Of 52 participants (mean [SD] age, 38.6 [12.4] years; 64% female), 27 were randomized to digital cognitive behavioral therapy for insomnia (dCBT-I) and 25 to patient education (PE). Post-intervention data were available for 50 participants (dCBT-I: n = 25; PE: n = 25). Further exploratory 3-month follow-up data were available for 25 participants in the dCBT-I group. Both groups showed significant within-group improvements in ISI scores, with no significant between-group differences. The dCBT-I group demonstrated greater improvements in sleep quality (PSQI: Cohen d = 1.02, P = .012) and maladaptive sleep-related beliefs (DBAS-16: Cohen d = 1.24, P = .003). Sleep diary data indicated significant reductions in sleep onset latency (Cohen d = −0.15, P = .005) and increases in sleep efficiency (Cohen d = 0.16, P = .003) in the dCBT-I group. Adherence to dCBT-I was high (89% completed all modules), and satisfaction ratings were higher than in the PE group. While both interventions improved insomnia severity, dCBT-I provided additional benefits in sleep-related outcomes, supporting the feasibility and potential clinical utility of this culturally adapted intervention.
*Clinical Trial Registration:* https://clinicaltrials.gov/study/NCT05822999, ClinicalTrials.gov (NCT05822999).

## 1. Introduction

Chronic insomnia is a prevalent disorder characterized by persistent difficulties initiating or maintaining sleep, resulting in fatigue and impairment in daily functioning (American Psychiatric Association D and Association AP, 2013; World Health O, 1992). Epidemiologically, chronic insomnia affects approximately 10–15% of adults in industrialized countries (Ohayon and Reynolds III, 2009), with increasing rates in South Korea [hereafter referred to as Korea] reported at 14% in 2020 (Ahn et al., 2024). It is associated with various adverse health outcomes, including depression, anxiety, cognitive decline, hypertension, metabolic syndrome, and reduced quality of life (Léger et al., 2012; Zhang

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et al., 2021; Markwald et al., 2013; Malik et al., 2014; Breslau et al., 1996; Baglioni et al., 2011; Neckelmann et al., 2007; Mayer et al., 2011; Yaffe et al., 2014).

Cognitive behavioral therapy for insomnia (CBT-I) is recommended as the first-line treatment for adults of all ages by international guidelines (Riemann et al., 2023; Chung and Korean Neuropsychiatric Association, 2019; Qaseem et al., 2016). Typically delivered in individual or group settings, CBT-I incorporates psychoeducation, relaxation techniques, stimulus control, and sleep restriction alongside cognitive strategies to address nighttime rumination and challenge dysfunctional sleep beliefs (Krystal et al., 2019; Van Straten et al., 2018). Research has demonstrated the effectiveness of CBT-I in improving insomnia symptoms, sleep efficiency, and overall sleep quality across diverse populations (Koffel et al., 2015; Wu et al., 2015; Smith et al., 2002; Edinger et al., 2001). While pharmacological treatments may provide immediate symptom relief, CBT-I offers superior long-term benefits with minimal side effects (Smith et al., 2002; Backhaus et al., 2001). However, the widespread implementation of CBT-I faces numerous barriers (Moon et al., 2024), including a shortage of trained professionals, a lack of awareness among healthcare providers, and logistical challenges in accessing in-person therapy (Thomas et al., 2016; Rossman, 2019; Fields et al., 2013).

To address these challenges, digital CBT-I (dCBT-I) has emerged as a scalable and accessible alternative to traditional face-to-face interventions. dCBT-I retains the key components of CBT-I, such as sleep education and sleep hygiene, stimulus control to strengthen the bed–sleep association, sleep restriction to consolidate sleep and improve sleep efficiency, cognitive techniques to address maladaptive beliefs and pre-sleep rumination, and relaxation strategies to reduce physiological and cognitive arousal (Soh et al., 2020). These elements are typically delivered through digital platforms, including websites and mobile applications, which may incorporate interactive tools like sleep diaries, patient feedback, and educational resources (Zachariae et al., 2016; van der Zweerde et al., 2020). Studies have shown that dCBT-I effectively alleviates insomnia symptoms, enhances sleep efficiency, and improves daytime functioning with sustained benefits observed over the long term (Soh et al., 2020; Zachariae et al., 2016; Ebert et al., 2018; Espie et al., 2019; Lorenz et al., 2019; Luik et al., 2017). Evidence suggests that digital CBT-I produces meaningful improvements in insomnia symptoms, and in some trials and meta-analyses its effects on key sleep outcomes have been comparable to those of therapist-delivered, face-to-face CBT-I, although direct head-to-head comparisons in clinical samples have yielded mixed results (Carlbring et al., 2018; Kallestad et al., 2021; Luo et al., 2020). By leveraging mobile technology, dCBT-I has the potential to bridge the gap in treatment access and support the broader adoption of evidence-based insomnia care (Ebert et al., 2018; Luik et al., 2017).

However, the effectiveness and acceptability of CBT-I can be influenced by cultural factors, necessitating tailored adaptations to align with different populations' values, beliefs, and behavioral patterns (Benish et al., 2011; Smith et al., 2011). Cultural adaptation involves systematically modifying an evidence-based intervention to ensure its relevance to the target population by incorporating language, social norms, and contextual elements (Castro et al., 2010). Previous research has shown that culturally adapted psychotherapy is more effective than non-adapted interventions (Benish et al., 2011; Soto et al., 2018), with meta-analysis indicating that greater levels of adaptation are associated with improved treatment outcomes (Hall et al., 2016). Given the benefits of cultural adaptation in face-to-face CBT-I, similar approaches may be relevant for digital interventions. Digital platforms provide opportunities to incorporate culturally specific elements that could enhance engagement and treatment adherence. While some studies have shown promising results for culturally tailored digital interventions (Abi Ramia et al., 2018; Zhang et al., 2023; Lindegaard et al., 2021; Harper Shehadeh et al., 2016; Zhou et al., 2022), further research is needed to understand their impact across diverse populations and evaluate their implementation in clinical practice. More broadly, digital mental health interventions are increasingly being discussed within the wider development of technology-supported and, in some cases, AI-enabled psychotherapy. Recent literature highlights the potential of such approaches to improve personalization, engagement, and implementation while also emphasizing the importance of ethical governance and responsible integration in clinical care (Beg et al., 2025; Beg, 2025). In this context, cultural adaptation may represent one important strategy to improve the relevance and acceptability of digital interventions across diverse populations.

This study aimed to evaluate the efficacy of a culturally adapted dCBT-I intervention for individuals with chronic insomnia in Korea compared to a patient education (PE) application. The primary objective was to assess changes in insomnia severity, while secondary outcomes included sleep quality, maladaptive sleep-related beliefs, daytime sleepiness, anxiety, and depressive symptoms. Additionally, exploratory analyses examined changes in sleep parameters based on subjective sleep diaries. By examining these outcomes, this study sought to contribute to the growing body of evidence on the role of cultural adaptation in digital interventions and provide considerations for future implementation in clinical practice.

## 2. Methods

### 2.1. Study design

This study was a multicenter, two-arm, double-blind, parallel-group, randomized controlled trial (RCT) designed to evaluate the efficacy of dCBT-I compared to a patient education (PE) application providing sleep education and a sleep diary in patients with chronic insomnia. The trial was conducted between December 2021 and June 2022 at Yonsei Severance Hospital and Yongin Severance Hospital in Korea. Ethical approval was obtained from the Institutional Review Board (IRB) of Yonsei Severance Hospital (Approval No. 2021-2580-001) and Yongin Severance Hospital (Approval No. 2021-0328-002). The trial was conducted in compliance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment. Participation in the study was voluntary, and participants were informed of their right to withdraw from the study at any time without providing a reason.

### 2.2. Participants

Recruitment for the study was conducted through various channels, including clinic bulletin boards, clinic websites, printed flyers, and personal recommendations. Prospective participants were provided with detailed information about the study and invited to attend an in-person screening session. A board-certified psychiatrist (EL, KP) assessed their eligibility by reviewing their medical and medication history and conducting evaluations using the Mini-International Neuropsychiatric Interview (MINI) to screen for psychiatric comorbidities alongside a general health examination (Sheehan et al., 1998). Insomnia disorder was diagnosed according to DSM-5 criteria, defined as difficulty initiating sleep, difficulty maintaining sleep, or early-morning awakening occurring at least three nights per week for a minimum duration of three months, accompanied by clinically significant distress or impairment in daytime functioning, despite adequate opportunity for sleep (American Psychiatric Association D and Association AP, 2013). An ISI cutoff score of $\geq$8 was used to include individuals with at least subthreshold insomnia symptoms, consistent with established ISI severity classifications (Maurer et al., 2025). This threshold has been used in insomnia research and digital CBT-I trials to capture individuals with clinically relevant insomnia symptoms, including subthreshold cases that may benefit from early intervention (Kater et al., 2025). Detailed inclusion and exclusion criteria are provided in Table 1.

**Table 1**
Inclusion and exclusion criteria.

| | |
|---|---|
| Inclusion criteria | - Aged 19–65 years<br>- Fulfilled DSM-5 criteria for insomnia disorder<br>- Insomnia severity score (ISI) $\geq$ 8<br>- Proficient in Korean language<br>- Smartphone ownership and ability to use mobile apps<br>- Completed at least 4 entries in the 7-day baseline sleep diary<br>- Provided informed consent and understood study requirements |
| Exclusion criteria | - coexisting sleep disorder, including obstructive sleep apnea, parasomnia, or restless legs syndrome.<br>- psychiatric disorder such as schizophrenia spectrum disorder, bipolar disorder, or depressive disorder<br>- suicidality (Columbia-suicide severity rating scale score $\geq$ 4)<br>- history of harmful substance use or dependency, including alcohol and hypnotics.<br>- Recent (within 3 months) adjustments in the dose or regimen of medications impacting sleep, including hypnotics, sedatives, antidepressants, anxiolytics, anticonvulsants, or antipsychotics<br>- Current or recent psychotherapy (within the past 3 months)<br>- Pregnancy or plans for pregnancy during study period<br>- Shift work or safety risks due to sleep deprivation<br>- Had serious medical conditions, including active or progressive physical illnesses (e.g., congestive heart failure, chronic obstructive pulmonary disease, or acute pain), neurological conditions (e.g., stroke), neurodegenerative diseases (e.g., dementia, multiple sclerosis), or unstable health with a life expectancy of less than six months.<br>- Participation in another clinical trial within 4 weeks prior to screening |

### 2.3. Procedure

After providing written informed consent, participants attended a screening visit, during which a board-certified psychiatrist assessed eligibility and collected sociodemographic information. Participants completed self-reported baseline questionnaires and a seven-day paper-based sleep diary, which served as the baseline measure for sleep parameters. To ensure robust baseline data, participants were required to complete at least four entries in the seven-day sleep diary. Eligible participants were then randomly assigned in a 1:1 ratio to the dCBT-I or PE groups. Participants used either the dCBT-I or the PE app for six weeks. Telephone visits were conducted every two weeks during the app usage period to monitor adherence and document adverse events. After completing app use, participants attended an in-person post-intervention visit to evaluate safety and efficacy using the same validated questionnaires as at baseline. The dCBT-I group underwent an additional 3-month follow-up period to assess sustained effects. Post-intervention and follow-up assessments were conducted using the same self-report questionnaires administered at baseline, without additional therapeutic guidance. Throughout the study, participants were permitted to use stable doses of hypnotics, antidepressants, anxiolytics, anticonvulsants, sedatives, or antipsychotics.

### 2.4. Randomization and blinding

Participants were randomly assigned in a 1:1 ratio to either the dCBT-I group or the PE group using stratified block randomization. Stratification factors included the use of prescription-based sleep medications and study sites. A statistician not involved in the clinical trial independently performed the randomization using the PLAN procedure in SAS (version 9.4, SAS Institute, Cary, NC, USA).

Double blinding was maintained throughout the study period. Neither participants nor investigators were aware of group assignments. A 3-month follow-up period was conducted for the dCBT-I group only, during which blinding procedures were no longer necessary as no control group was involved.

### 2.5. Interventions

#### 2.5.1. Culturally adapted digital CBT-I

Participants used a culturally adapted mobile application to deliver dCBT-I through a fully automated, interactive, and tailored platform. Its development involved collaboration among a multidisciplinary team, including clinicians, software developers, product designers, and behavioral scientists, to ensure clinical validity and user accessibility. The intervention was adapted using the Ecological Validity Model (EVM) (Bernal et al., 1995), which outlines eight culturally sensitive dimensions -language, persons, metaphors, content, concepts, goals, methods, and context - ensuring the intervention aligns with the sociocultural characteristics of the target population.

The app featured a modular design incorporating educational content, self-monitoring tools, interactive exercises, goal-setting capabilities, and relaxation techniques. The CBT-I modules were presented sequentially. The program began with psychoeducation, providing knowledge about sleep and insomnia. Subsequent modules introduced stress models and relaxation techniques, bedtime restriction to improve sleep efficiency, and sleep hygiene education to encourage healthy sleep habits. Stimulus control strategies were included to address behaviors that associate the bedroom with wakefulness, while cognitive restructuring targeted unhelpful beliefs and attitudes about sleep. The program concluded with relapse prevention strategies aimed at supporting the sustained management of insomnia symptoms. The intervention consisted of eight sequential modules delivered over a six-week period. Modules were unlocked in a predefined order to support stepwise acquisition of CBT-I skills, with each module combining brief educational content, interactive exercises, and daily sleep diary completion. This structure was designed to balance treatment fidelity with the low-intensity, self-guided format typical of dCBT-I interventions. In addition, relaxation techniques, including mindfulness and progressive muscle relaxation, were available daily to encourage ongoing practice. Participants logged their sleep data in an integrated sleep diary. Based on these inputs, the app provided personalized recommendations for time in bed, supporting bedtime restriction practices.

Cultural adaptations were included to ensure the intervention's relevance to Korean participants by addressing linguistic, behavioral, and contextual modifications. The app content utilized Korean linguistic expressions, idiomatic phrases, and examples consistent with local cognitive patterns, lifestyles, and beliefs about sleep. The formal honorific language aligned with Korean cultural norms and created a sense of respect and engagement. A key feature of the app was the inclusion of a virtual guide, “SSAM,” modeled as a professional female doctor in a white coat. The term SSAM was derived from the Korean word for teacher, commonly used in Korea as a respectful way to address medical doctors. SSAM guided participants through the program, providing instructions, feedback, and encouragement. Participants were encouraged to access the app at their convenience, spending approximately 10 to 15 min interacting with the content daily and completing exercises (supplementary Fig. 1.). The adaptation focused on contextual and presentation-level modifications while preserving the core evidence-based components of CBT-I, including sleep restriction, stimulus control, and cognitive restructuring. Content development involved iterative review by clinicians with expertise in sleep medicine and psychiatry to ensure clinical appropriateness and cultural relevance prior to study implementation.

#### 2.5.2. Patient education with sleep diary

Participants in the PE group received a mobile intervention providing general sleep education and a daily sleep diary. The app included standardized, non-tailored information about insomnia, addressing its causes, epidemiology, symptoms, and effects. It also offered guidance on when to consult a physician and outlined basic strategies to improve sleep, such as lifestyle adjustments and environmental modifications (Chung and Korean Neuropsychiatric Association,

2019; Medicine AAoS, 2012). All content was presented in a simple, fixed format without interactive features. Upon their first login, participants were granted immediate access to the complete set of materials and could revisit the content as often as desired throughout the six-week intervention period. In addition to the educational content, the app included a sleep diary for daily monitoring, like the dCBT-I group. The application did not contain content specific to CBT.

### 2.6. Outcomes

The primary outcome was the change in insomnia severity, measured using the Insomnia Severity Index (ISI) (Cho et al., 2014; Bastien et al., 2001; Morin et al., 2011). The ISI is a widely used 7-item questionnaire that evaluates the severity of insomnia symptoms over the past two weeks, with items rated on a 5-point Likert scale from 0 (not at all) to 4 (extremely). Scores range from 0 to 28, with higher scores indicating greater insomnia severity.

Secondary outcomes included patient-reported measures of sleep-related thoughts, sleep quality, daytime functioning, psychological symptoms, and quality of life. Maladaptive sleep-related thoughts were assessed using the Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-16), a 16-item questionnaire rated on an 11-point Likert scale, with higher scores reflecting more unhelpful beliefs about sleep (Morin et al., 2007; Yu et al., 2009). Sleep quality was measured using the Pittsburgh Sleep Quality Index (PSQI) (Sohn et al., 2012; Buysse et al., 1989). This validated instrument assesses various aspects of sleep disturbances and overall sleep quality over the past month. A higher PSQI score indicates poorer sleep quality, with a cutoff score greater than 5 suggesting significant impairment. Daytime sleepiness was assessed using the Epworth Sleepiness Scale (ESS), which evaluates the likelihood of dozing off in 8 everyday situations (Johns, 1991; Cho et al., 2011). Each item is rated on a 4-point Likert scale from 0 (no chance of dozing) to 3 (high chance of dozing), resulting in a total score between 0 and 24. Higher scores indicate greater levels of perceived daytime sleepiness. Psychological symptoms were assessed using the Generalized Anxiety Disorder-7 (GAD-7) and the Patient Health Questionnaire-9 (PHQ-9). The GAD-7 is a 7-item scale for evaluating anxiety symptoms, with each item scored from 0 to 3 and a total score ranging from 0 to 21 (Spitzer et al., 2006; Lee et al., 2022). Higher scores reflect greater anxiety severity. Depression was assessed using the PHQ-9, a 9-item tool that measures depressive symptoms, with a total score range of 0 to 27, where higher scores indicate greater symptom severity (Martin et al., 2006; Park et al., 2010). Quality of life was evaluated using the EQ-VAS, a self-rated visual analog scale assessing overall health status, with scores ranging from 0 (worst imaginable health) to 100 (best imaginable health) (Herdman et al., 2011; Kim et al., 2016).

Exploratory outcomes included subjective sleep diary measures of sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), and sleep efficiency (SE, calculated as TST divided by time in bed and expressed as a percentage). These sleep diary measures were prespecified as exploratory outcomes because the study's sample size calculation was based on the ISI as the primary outcome, and the diary parameters were included to provide complementary information on behavioral sleep changes.

Treatment satisfaction was assessed using four questions: (1) willingness to recommend the program (0 = not at all, 10 = completely willing), (2) overall satisfaction with the program (1 = very dissatisfied, 5 = very satisfied), (3) perceived improvement in understanding insomnia and its treatment (1 = no improvement, 5 = significant improvement), and (4) perceived usefulness of the app in treating insomnia (1 = not useful at all, 5 = very useful). Adherence in the dCBT-I group was assessed post-intervention based on the lesson completion rate, defined as the proportion of participants who completed all assigned lessons within the six-week intervention period.

### 2.7. Statistical analysis

The sample size calculation was based on the ISI as the primary outcome measure, with participants allocated 1:1 between the dCBT-I and PE groups. The expected mean (SD) improvement in ISI scores after treatment was estimated to be 4.5 (4.05) for the dCBT-I group compared to the control group. Assuming a two-sided significance level ($\alpha$) of 0.05 and a statistical power ($1 - \beta$) of 90%, the required sample size was calculated to be 18 participants per group using PASS software version 11.0 (NCSS Statistical Software). To account for an anticipated dropout rate of 30% based on previous studies (Takano et al., 2025), the total required sample size was adjusted to approximately 52 participants, with 26 participants per group.

Descriptive statistics were used to summarize the baseline characteristics of participants. Continuous variables were reported as means and SD, while categorical variables were presented as frequencies and percentages. Between-group differences were tested using independent *t*-tests or Mann-Whitney *U* tests for non-normally distributed data, while categorical variables were analyzed using chi-square tests or Fisher's exact tests when expected frequencies were low.

Multilevel models with random intercepts were applied to assess changes in sleep measures (SE, WASO, SOL, TST) and self-reported outcomes (ISI, DBAS-16, PSQI, ESS, EQ-VAS, GAD-7, PHQ-9). The models included time, group, and their interaction as fixed effects, while random intercepts for participants accounted for within-subject correlations over repeated measures. Pairwise comparisons of estimated marginal means (EMMs) were conducted to assess within-group changes and adjusted using Bonferroni correction to control for multiple comparisons. Effect sizes for main and interaction effects were quantified using Cohen's d, calculated according to Feingold's recommendations (Feingold, 2013), with 95% confidence intervals provided. Statistical analyses were performed using R, version 4.4.1 (R Project for Statistical Computing), with a two-sided significance level of $P < .05$ considered statistically significant.

## 3. Results

### 3.1. Participant characteristics

A total of 64 participants were screened for eligibility, of whom 52 met the inclusion criteria and were randomized 1:1 to the dCBT-I group ($n = 27$) or the PE group ($n = 25$) (Fig. 1). Of these, 50 participants completed the post-intervention assessments (25 in each group), while 2 participants in the dCBT-I group could not be reached for the post-intervention visit. 25 participants in the dCBT-I group completed the 3-month follow-up assessment.

The mean (SD) age of participants was 37.56 (11.80) years in the dCBT-I group and 39.84 (13.15) years in the PE group. Most participants were female, comprising 55.56% of the dCBT-I group and 72.00% of the PE group. Baseline characteristics were comparable between the two groups, with no significant differences in sociodemographic or clinical variables, such as years of education, employment status, or living arrangements. Most participants had no prior treatment for insomnia, with one participant in the dCBT-I group reporting current use of hypnotics. Baseline ISI scores were comparable between groups (dCBT-I: 18.37 [4.53] vs PE: 17.64 [3.57]; $P = .520$). Most participants in both groups were in the moderate insomnia range (Table 2). The analyses below include all 52 randomized participants.

### 3.2. Primary outcome

The ISI demonstrated significant within-group improvements in the dCBT-I and PE groups (Fig. 2a, Table 3, Supplementary Table 1). The dCBT-I group showed a reduction from 18.37 (4.53) at baseline to 12.22 (5.19) at post-intervention ($P < .001$). In exploratory within-group follow-up analyses, ISI scores in the dCBT-I group were 10.84 (4.14)

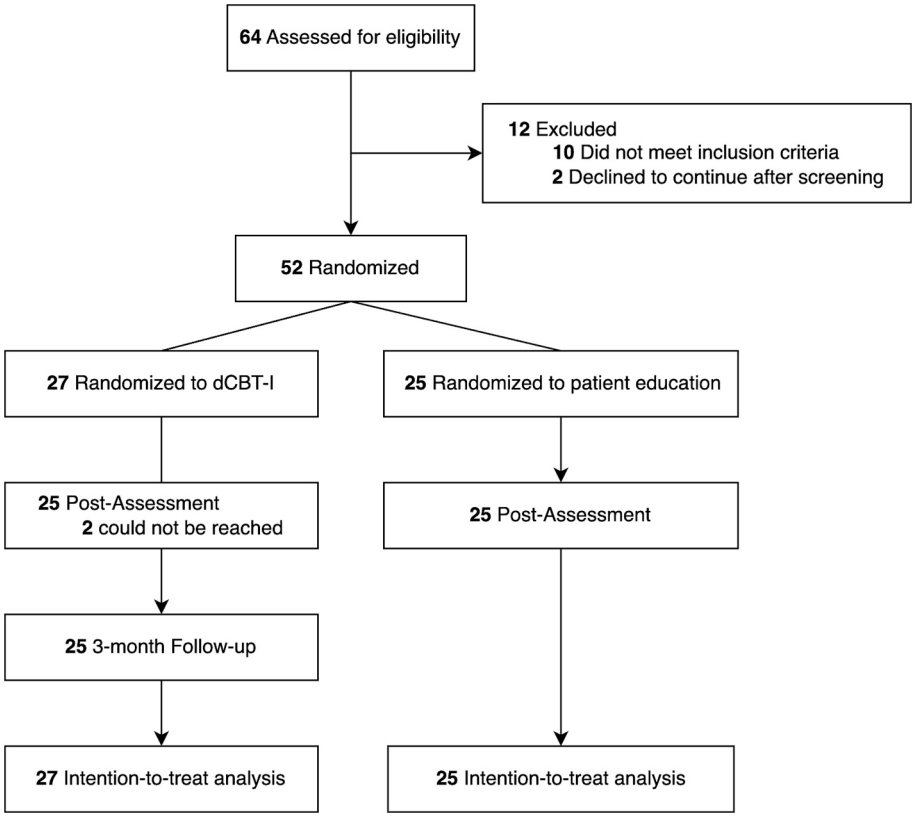


**Fig. 1.** CONSORT diagram of study enrollment flow.

at 3 months ($P < .001$). The PE group decreased from 17.64 (3.57) to 13.44 (4.81) at post-intervention ($P < .001$). However, the group × time interaction at post-intervention was not statistically significant ($P = .098$), indicating comparable improvements in insomnia severity between groups.

A sensitivity analysis restricted to participants with moderate or severe insomnia at baseline (ISI ≥ 15) yielded results consistent with the primary analysis. In the dCBT-I group, ISI scores decreased from 20.0 (3.67) at baseline to 13.4 (4.79) at post-intervention ($P < .001$). In the PE group, scores decreased from 18.9 (2.77) to 14.2 (4.81) ($P < .001$). The group × time interaction was not statistically significant ($P = .170$).

### 3.3. Secondary outcomes

Secondary outcomes included measures of sleep quality, maladaptive sleep-related beliefs, daytime sleepiness, anxiety, depression, and quality of life (Fig. 2b–g, Table 3, Supplementary Table 1). For the DBAS-16, scores in the dCBT-I group decreased from 6.69 (1.44) at baseline to 5.40 (1.87) post-intervention ($P < .001$). Exploratory follow-up analyses in the dCBT-I group indicated scores of 4.85 (2.04) at 3 months ($P < .001$). The interaction effect between time and group at post-intervention was significant ($P = .003$), indicating greater improvements in maladaptive beliefs about sleep in the dCBT-I group compared to the PE group (Cohen d = 1.24, 95% CI = 0.47 to 2.01). Similarly, for the PSQI, the dCBT-I group improved from 11.07 (3.10) at baseline to 8.59 (2.79) at post-intervention ($P < .001$). In exploratory follow-up analyses, PSQI scores in the dCBT-I group were 8.36 (2.58) at 3 months ($P < .001$). A significant interaction effect at post-intervention ($P = .012$) indicated greater improvements in sleep quality for the dCBT-I group compared to the PE group (Cohen d = 1.02, 95% CI = 0.25 to 1.79).

No significant interaction effects were observed for the ESS, PHQ-9, GAD-7, and EQ-VAS, indicating that changes over time were comparable between the dCBT-I and PE groups. However, significant within-group improvements were observed in the dCBT-I group for the PHQ-9 and GAD-7. The PHQ-9 scores in the dCBT-I group decreased from 8.56 (5.33) at baseline to 6.56 (4.79) at post-intervention ($P = .049$) and further to 5.64 (4.09) at follow-up ($P = .002$), reflecting reductions in depressive symptoms. Similarly, the GAD-7 scores in the dCBT-I group declined from 6.18 (5.29) at baseline to 5.85 (4.83) at post-intervention ($P = 1.000$) and were 4.64 (3.81) at follow-up ($P = .016$), indicating improvements in anxiety symptoms over time. No significant changes within the group were observed for the ESS and EQ-VAS in either group.

### 3.4. Exploratory outcomes

Exploratory analyses assessed sleep parameters derived from sleep diaries, including SE, WASO, SOL, and TST. Weekly means were calculated for each sleep measure across the six-week intervention period to evaluate trends over time (Fig. 3 and Supplementary Table 2).

In the dCBT-I group, SE significantly improved from 62.85% (16.42) at baseline to 73.78% (14.51) at week 6 ($P < .001$), whereas no significant changes were observed in the PE group ($P = .392$). A significant interaction effect ($P = .003$) indicated a greater increase in SE in the dCBT-I group compared to the PE group (estimate = 1.20, SE = 0.40). However, the effect size was small (Cohen's d = 0.16, 95% CI = 0.05 to 0.26).

For SOL, significant within-group improvements were observed in the dCBT-I group, with a decrease from 58.08 (42.41) minutes at baseline to 35.31 (29.02) minutes at week 6 ($P = .006$), while no significant within-group changes were observed in the PE group. The interaction effect ($P = .005$) indicated a greater reduction in SOL in the dCBT-I group compared to the PE group (estimate = −3.47, SE = 1.21), with a small effect size (Cohen's d = −0.15, 95% CI = −0.26 to −0.05).

For WASO and TST, no significant within-group changes were observed in either group, and the interaction effects were not

**Table 2**
Participant baseline characteristics.

| Characteristic | dCBT-I (n = 27) | PE (n = 25) | *P*-value[1] |
|---|---|---|---|
| Age, mean (SD), years | 37.56 (11.80) | 39.84 (13.15) | 0.533 (w) |
| Sex, n(%) | | | 0.219 (c) |
| Male | 12 (44.44) | 7 (28.00) | |
| Female | 15 (55.56) | 18 (72.00) | |
| Height, mean (SD), cm | 165.46 (9.68) | 165.16 (7.46) | 0.904 (t) |
| Weight, mean (SD), kg | 68.03 (21.55) | 67.32 (17.77) | 0.920 (w) |
| BMI, mean (SD), kg/m$^2$ | 24.42 (5.95) | 24.50 (5.20) | 0.956 (w) |
| Years of Education, mean (SD) | 14.89 (2.17) | 15.76 (1.85) | 0.135 (w) |
| Employment status, n(%) | | | 0.715 (c) |
| Employed | 16 (59.26) | 17 (68.00) | |
| Unemployed | 11 (40.74) | 8 (32.00) | |
| Marital status, n(%) | | | 0.131 (c) |
| Married | 9 (33.33) | 9 (36.00) | |
| Single | 14 (51.85) | 16 (64.00) | |
| Divorced, widowed | 4 (14.81) | 0 | |
| Living status, n(%) | | | 0.860 (c) |
| Living alone | 7 (25.93) | 8 (32.00) | |
| Living with others | 20 (74.07) | 17 (68.00) | |
| Smoking status, n(%) | | | 1.000 (f) |
| Never | 17 (62.96) | 16 (64.00) | |
| Former | 3 (11.11) | 3 (12.00) | |
| Current | 7 (25.93) | 6 (24.00) | |
| Alcohol consumption, n(%) | | | 0.403 (f) |
| Never | 6 (22.22) | 10 (40.00) | |
| Former | 4 (14.81) | 2 (8.00) | |
| Current | 17 (62.96) | 13 (52.00) | |
| Former treatment for insomnia, n (%) | | | 1.000 (f) |
| None | 26 (96.30) | 25 (100.00) | |
| Non-pharmacological treatment | 0 | 0 | |
| Pharmacological treatment | 1(3.70) | 0 | |
| Current Use of Hypnotics, n(%) | 1(3.70) | 0 | 1.000 (f) |
| Baseline clinical measures | | | |
| ISI | 18.37 (4.53) | 17.64 (3.57) | 0.520 (t) |
| Subthreshold insomnia, n (%)[2] | 6 (22.2) | 5(20) | |
| Moderate insomnia, n(%)[2] | 15 (55.6) | 17 (68) | |
| Severe insomnia, n(%)[2] | 6 (22.2) | 3 (12) | |
| DBAS16 | 6.69 (1.44) | 6.26 (1.39) | 0.270 (t) |
| PSQI | 11.07 (3.10) | 11.32 (2.32) | 0.746 (t) |
| ESS | 8.89 (4.90) | 10.84 (4.49) | 0.140 (t) |
| EQ-VAS | 65.07 (17.5) | 66.20 (15.1) | 0.941 (w) |
| GAD-7 | 6.18 (5.29) | 4.56 (3.76) | 0.328 (w) |
| PHQ-9 | 8.56 (5.33) | 8.08 (4.35) | 0.883 (w) |
| SE | 62.85 (16.42) | 57.53 (17.4) | 0.263 (t) |
| WASO | 30.11 (21.67) | 42.08 (37.23) | 0.369 (w) |
| SOL | 58.08 (42.41) | 66.63 (53.0) | 0.742 (w) |
| TST | 320.01 (104.2) | 277.52 (96.28) | 0.132 (t) |

Abbreviations: ISI = Insomnia Severity Index; DBAS-16 = Dysfunctional Beliefs and Attitudes About Sleep; PSQI = Pittsburgh Sleep Quality Index; ESS = Epworth Sleepiness Scale; EQ-VAS = EuroQol Visual Analogue Scale; GAD-7 = Generalized Anxiety Disorder-7; PHQ-9 = Patient Health Questionnaire-9; SE, sleep efficiency; WASO, wake after sleep onset; SOL, sleep onset latency; TST, total sleep time.

[1] *P*-values were calculated using independent samples *t*-tests (t), Mann-Whitney *U* tests (w) for non-normally distributed data, chi-square tests (c), or Fisher's exact tests (f), as appropriate.

[2] ISI severity categories were defined as subthreshold insomnia (ISI score 8-14), moderate clinical insomnia (ISI score 15-21), and severe clinical insomnia (ISI score 22-28).

statistically significant.

### 3.5. Other outcomes

Participants in the dCBT-I group reported significantly higher overall satisfaction with the program compared to the PE group (median [IQR]: 4 [3–5] vs. 3 [2–4], $P = .02$). Perceived improvement in understanding insomnia and its treatment was also greater in the dCBT-I group (4 [4–5]) than in the PE group (4 [3–4], $P = .01$). Additionally, participants in the dCBT-I group rated the app as more useful for managing insomnia (4 [3–4]) compared to the PE group (3 [2–4], $P = .007$). No significant difference was observed between the groups in willingness to recommend the program (dCBT-I: 7.63 [1.72] vs. PE: 6.92 [2.03], $P = .17$). Adherence to the dCBT-I intervention was high, with 24 out of 27 participants (88.89%) completing all assigned lessons during the intervention period, indicating strong engagement with the culturally adapted digital intervention. No adverse events were reported in either group throughout the study period.

## 4. Discussion

This randomized controlled trial assessed the efficacy of a culturally adapted dCBT-I intervention compared to a PE application among individuals with chronic insomnia in Korea. Both groups showed significant within-group improvements in insomnia severity, with no between-group differences, indicating comparable effects. The improvements observed in the PE group may reflect the provision of sleep education and the use of a daily sleep diary (Feingold, 2013; Chung et al., 2017), although nonspecific factors such as attention, expectancy, or general participation effects may also have contributed. Unlike previous studies that provided sleep education website content or used waitlist controls (Espie et al., 2019; Hagatun et al., 2019; Ritterband et al., 2009; Ritterband et al., 2017; Vedaa et al., 2020; Schuffelen et al., 2023), this study employed a double-blind design, ensuring comparable app-based interfaces and daily monitoring for both groups. These methodological features may have contributed to the observed improvements in the PE group. The absence of a significant between-group difference in the primary outcome should therefore be interpreted in light of the active comparator used in this study.

However, the dCBT-I group showed greater improvements in secondary outcomes, specifically in maladaptive sleep-related beliefs and sleep quality, with moderate to large effect sizes. These findings suggest that the structured, interactive nature of dCBT-I, which incorporates cognitive and behavioral components, offers benefits beyond sleep education. Nevertheless, these findings should be interpreted cautiously, given the modest sample size, the number of secondary outcomes examined, and the reliance on self-reported measures. Accordingly, the observed effect sizes should be considered preliminary rather than evidence of clinically meaningful differences. Rather, these findings may indicate relevant treatment-related changes in sleep-related cognitions and perceived sleep quality that warrant confirmation in further studies.

This pattern is consistent with prior research on culturally tailored dCBT-I, including a large randomized trial, which demonstrated that cultural adaptation primarily enhanced engagement and completion rather than producing markedly greater reductions in insomnia severity compared with a standard dCBT-I. Similar to those findings, the present results are compatible with the possibility that cultural adaptation may contribute to acceptability and engagement, with downstream benefits in sleep-related beliefs, sleep quality, and behavioral sleep parameters rather than insomnia severity alone (Zhou et al., 2022), although the present design does not allow its specific effect to be distinguished from the broader effects of CBT-I content and structure. Additionally, exploratory follow-up assessments conducted in the dCBT-I group indicated sustained improvements in insomnia symptoms over time and reductions in anxiety and depressive symptoms, consistent with previous studies (Ritterband et al., 2017; Alimoradi et al., 2022). However, as no follow-up data were collected in the PE group, direct comparisons could not be made, limiting the ability to determine whether these improvements were unique to the dCBT-I intervention. Future research should include long-term follow-up assessments in both groups to better understand the sustained effects of dCBT-I compared to sleep education.

Exploratory sleep diary analyses further revealed significant improvements in SE and SOL in the dCBT-I group, albeit with small effect sizes. In the context of CBT-I, improvements in sleep efficiency may

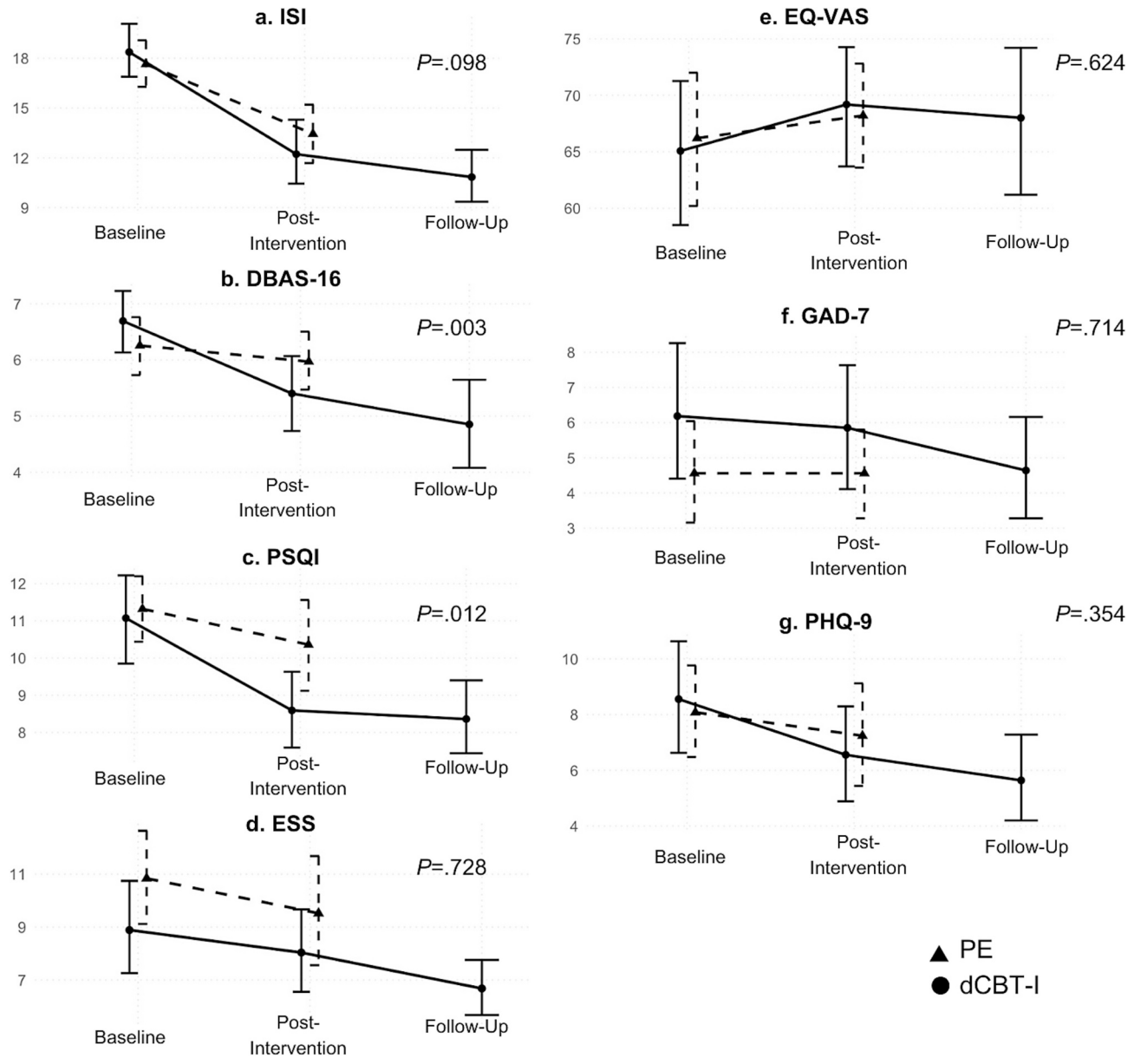


**Fig. 2.** Changes in primary and secondary outcomes

Mean values with 95% confidence intervals for primary and secondary outcomes at baseline and post-intervention for the digital cognitive behavioral therapy for insomnia (dCBT-I) and patient education (PE) groups, and at exploratory 3-month follow-up for the dCBT-I group only. ISI: Insomnia Severity Index; DBAS-16: Dysfunctional Beliefs and Attitudes about Sleep Scale; PSQI: Pittsburgh Sleep Quality Index; ESS: Epworth Sleepiness Scale; EQ-VAS: EuroQol Visual Analog Scale; GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9. *P*-values represent the interaction effect between groups at post-intervention.

partly reflect adherence to the prescribed sleep window, as sleep efficiency is calculated as the ratio of TST to time in bed. These findings align with previous research demonstrating the impact of CBT interventions on sleep parameters (Espie et al., 2019; Schuffelen et al., 2023). However, no significant changes were observed in other sleep measures, such as WASO and TST, which may suggest the need for more targeted strategies to address these aspects of sleep disturbance.

The high adherence rates and positive satisfaction ratings in the dCBT-I group support the feasibility and acceptability of the culturally adapted intervention. Participants in this group reported significantly greater satisfaction, improved understanding of insomnia and its treatment, and higher perceived usefulness of the app compared to the PE group. Differences in satisfaction, perceived usefulness, and adherence may reflect several factors, including the structured therapeutic format and content of CBT-I, as well as the culturally tailored design of the intervention (Armaou et al., 2020; Balci et al., 2022). More broadly, these findings align with emerging discussions in digital mental health research emphasizing that the successful implementation of digital and AI-supported psychotherapies depends not only on technological capabilities but also on user engagement, perceived relevance, and responsible integration into clinical care. Recent conceptual and qualitative work highlights the importance of usability, personalization, and ethical governance when developing technology-supported mental health interventions (Beg et al., 2025; Beg, 2025; Beg and Verma, 2025).

Despite these promising findings, several limitations should be acknowledged. The relatively small sample size may limit the generalizability of the results, warranting further research with larger samples. Additionally, the current study design did not directly compare culturally adapted and non-adapted versions of dCBT-I. Because the comparator consisted of a PE application rather than a non-adapted CBT-I

**Table 3**
Primary and key secondary outcomes at baseline and post-intervention.

| Outcome | Time | dCBT-I, mean (SD) | PE, mean (SD) | Estimate (SE)[1] | *P* value for interaction (group×time) |
|---|---|---|---|---|---|
| ISI | Baseline | 18.37 (4.53) | 17.64 (3.57) | 1.95 (1.16) | 0.098 |
| | Post-Intervention | 12.22 (5.19) | 13.44 (4.81) | | |
| PSQI | Baseline | 11.07 (3.10) | 11.32 (2.32) | 1.52 (0.58) | 0.012 |
| | Post-Intervention | 8.59 (2.79) | 10.36 (3.28) | | |
| DBAS-16 | Baseline | 6.69 (1.44) | 6.26 (1.39) | 1.01 (0.32) | 0.003 |
| | Post-Intervention | 5.40 (1.87) | 5.97 (1.38) | | |
| ESS | Baseline | 8.89 (4.90) | 10.84 (4.49) | −0.47 (1.34) | 0.728 |
| | Post-Intervention | 8.04 (4.07) | 9.52 (5.45) | | |
| PHQ-9 | Baseline | 8.56 (5.33) | 8.08 (4.35) | 1.16 (1.24) | 0.354 |
| | Post-Intervention | 6.56 (4.79) | 7.24 (5.04) | | |
| GAD-7 | Baseline | 6.18 (5.29) | 4.56 (3.76) | 0.33 (0.90) | 0.714 |
| | Post-Intervention | 5.85 (4.83) | 4.56 (3.42) | | |
| EQ-VAS | Baseline | 65.07 (17.49) | 66.20 (15.09) | −2.11 (4.28) | 0.624 |
| | Post-Intervention | 69.19 (14.46) | 68.20 (12.40) | | |

Abbreviations: ISI = Insomnia Severity Index; DBAS-16 = Dysfunctional Beliefs and Attitudes About Sleep; PSQI = Pittsburgh Sleep Quality Index; ESS = Epworth Sleepiness Scale; EQ-VAS = EuroQol Visual Analogue Scale; GAD-7 = Generalized Anxiety Disorder-7; PHQ-9 = Patient Health Questionnaire-9; PE = Patient Education; dCBT-I = Digital Cognitive Behavioral Therapy for Insomnia.

[1] Estimates represent the group × time interaction derived from the mixed-effects models.

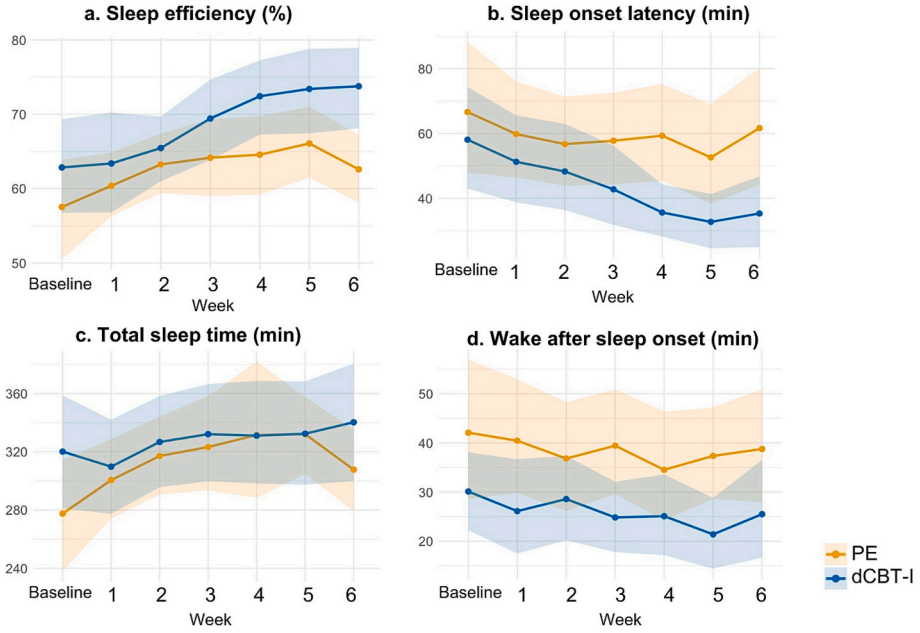


**Fig. 3.** Changes in sleep parameters over the intervention period
Mean weekly values with 95% confidence intervals for sleep efficiency (SE), sleep onset latency (SOL), total sleep time (TST), and wake after sleep onset (WASO) in the digital cognitive behavioral therapy for insomnia (dCBT-I) and patient education (PE) groups over the 6-week intervention period.

intervention, differences between groups may reflect the specific CBT-I components, the structured therapeutic format, or differences in treatment credibility and expectancy, rather than cultural adaptation alone (Harper Shehadeh et al., 2016; Fu et al., 2020; Spanhel et al., 2021). Future research should consider comparative designs to evaluate the added value of cultural tailoring. Although the study was designed to be double-blind, differences in interactivity, personalization, and CBT-specific components between the two applications may have allowed some participants to infer their group allocation during the intervention period. In addition, regular telephone contacts conducted to monitor adherence and adverse events may have increased participant engagement in both groups and could have functioned as an unintended co-intervention.

In addition, the study relied on self-reported sleep outcomes and sleep diaries and did not include objective measures such as actigraphy or polysomnography. Furthermore, while the follow-up assessments in the dCBT-I group indicated promising sustained effects, the absence of follow-up data in the PE group precludes direct comparisons. Accordingly, the 3-month follow-up was exploratory in nature and intended to examine the persistence of dCBT-I effects rather than to support between-group comparisons over time. Long-term follow-up studies, including both groups, are necessary to evaluate the durability of treatment effects and potential relapse prevention benefits of dCBT-I.

This study demonstrated that a culturally adapted dCBT-I intervention was associated with improvement in insomnia severity and related outcomes in individuals with chronic insomnia in Korea. While both dCBT-I and PE interventions led to significant symptom reductions, dCBT-I showed greater improvements in sleep-related beliefs and sleep quality, suggesting added benefits from structured, interactive CBT-I elements. High adherence and satisfaction rates further support the feasibility and acceptability of this culturally adapted intervention, although these findings cannot be attributed to cultural adaptation alone. The absence of long-term follow-up data in the PE group and the lack of a non-adapted dCBT-I comparator highlight the need for future

research to understand the impact of cultural adaptations and sustained treatment effects.

## Abbreviations

| | |
|---|---|
| CBT-I | Cognitive Behavioral Therapy for Insomnia |
| dCBT-I | Digital Cognitive Behavioral Therapy for Insomnia |
| PE | Patient Education |
| ISI | Insomnia Severity Index |
| PSQI | Pittsburgh Sleep Quality Index |
| DBAS-16 | Dysfunctional Beliefs and Attitudes about Sleep Scale |
| ESS | Epworth Sleepiness Scale |
| GAD-7 | Generalized Anxiety Disorder-7 |
| PHQ-9 | Patient Health Questionnaire-9 |
| EQ-VAS | EuroQol Visual Analog Scale |
| SOL | Sleep Onset Latency |
| WASO | Wake After Sleep Onset |
| TST | Total Sleep Time |
| SE | Sleep Efficiency |
| RCT | Randomized Controlled Trial |
| IRB | Institutional Review Board |

## CRediT authorship contribution statement

**Abdallah Kabbani:** Writing – original draft, Writing – review & editing. **Mona Passler:** Visualization, Writing – review & editing. **Kyungmee Park:** Investigation, Writing – review & editing. **Eun Lee:** Investigation, Writing – review & editing, Supervision. **Yujin Lee:** Methodology, Writing – review & editing, Funding acquisition. **Marc Jansen:** Writing – review & editing. **Daa Un Moon:** Conceptualization, Methodology, Formal analysis, Visualization, Writing – original draft, Writing – review & editing, Supervision.

## Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Yujin Lee reports financial support was provided by Korea Ministry of Health and Welfare. Yujin Lee reports a relationship with WELT Corp. Ltd. that includes: employment. Daa Un Moon was previously employed by WELT Corp. Ltd. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2026.100933.

## Data availability

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

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