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Impact of Adherence to Digital Cognitive Behavioral Therapy for Insomnia Effectiveness

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Purpose: Although digital cognitive behavioral therapy for insomnia (dCBT-I) offers a promising solution to the accessibility limitations of traditional face-to-face CBT-I, few studies have examined dCBT-I against a sham app and adherence issues remain. This study assessed the efficacy of dCBT-I compared with a sham app and investigated whether adherence predicts sleep outcomes.

Materials and Methods: In this combined analysis of two multicenter, double-blind, sham-controlled randomized controlled trials, 120 patients with insomnia were randomized to use the dCBT-I app (n=60) or a sham app (n=60). The primary outcome was the change in sleep efficiency (SE) from baseline after the 6-week intervention. The relationship between adherence to sleep restriction therapy (SRT) and sleep outcomes post-intervention was assessed.

Results: After adjusting for age, sex, sleep medication use, and baseline levels of each outcome variable, the dCBT-I group demonstrated better treatment outcomes than the sham app group, with significant improvements of 7.69% in SE [95% confidence interval (CI), 3.09% to 12.30%; p=0.001], -16.77 minutes in sleep onset latency (95% CI, -31.48 to -2.06 minutes; p=0.026), and -0.97 in dysfunctional beliefs about sleep (95% CI, -1.46 to -0.48; p<0.001) from baseline. Poorer adherence to SRT was associated with reduced SE (p=0.006) and increased nighttime wakefulness (p=0.002) after controlling for age, sex, years of education, and the baseline value of each outcome variable.

Conclusion: This combined analysis demonstrates the efficacy of dCBT-I in improving sleep outcomes compared with a sham app and highlights the role of adherence to SRT in enhancing treatment efficacy. The two studies were registered with ClinicalTrials.gov (NCT05822999, NCT05809544).

Key Words: Adherence, cognitive behavioral therapy, insomnia, digital therapeutics

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INTRODUCTION

Cognitive behavioral therapy for insomnia (CBT-I) is recommended as a primary intervention for insomnia in most treatment guidelines.[1,2] However, due to the limited accessibility of CBT-I and the shortage of trained CBT-I therapists, prescribing sedatives often takes precedence over CBT-I.[3] Patients' challenges in accessing guideline-recommended therapy have prompted the development of digital CBT-I (dCBT-I), which seems to be a promising solution for promoting widespread dissemination. Previous randomized controlled trials (RCTs) have demonstrated that dCBT-I is as effective as face-to-face

CBT-I in improving sleep-related symptoms among insomnia patients.[3-5] A recent cohort study also showed dCBT-I to be more effective than pharmacological therapy, offering long-term benefits for insomnia.[6]

Although many studies have demonstrated the efficacy of dCBT-I, research comparing dCBT-I with a sham intervention or examining the relationship between dCBT-I adherence and treatment outcomes remains limited. Establishing well-defined control groups, including sham controls, is crucial for adequately evaluating the effect of dCBT-I; merely demonstrating the benefits of dCBT-I compared with no-treatment or wait-list controls is insufficient for establishing a causal link with the active component of the intervention, as the study participants' use of the application affects their expectations, motivation, and engagement.[7] In a recent systematic review, only five of 43 sham-controlled trials of digital therapeutics focused on insomnia patients, indicating a lack of sufficient sham-controlled studies of dCBT-I.[7]

Given that therapist involvement is minimal or absent in dCBT-I and that the average adherence for technology-mediated, non-face-to-face insomnia treatment is approximately 50%,[8] adherence to dCBT-I needs our attention. Research on the relationship between adherence to CBT-I and treatment outcomes has also increased in recent decades, and one study demonstrated that even slight improvements in CBT-I adherence can lead to better treatment outcomes.[9] However, there is considerable heterogeneity in how both global adherence and adherence to individual CBT-I components are measured.[10] Sleep restriction therapy (SRT) and stimulus control therapy are considered key components of CBT-I[11] and have been the first and second most frequently assessed individual CBT-I components, respectively.[10,12] Since patients undergoing SRT and stimulus control are instructed to reduce their time spent in bed (TIB) as part of the treatment protocol to enhance homeostatic sleep pressure and improve sleep efficiency (SE),[13] these two behavioral therapies can impose a substantial burden on insomnia patients, raising the likelihood of adverse effects that hinder adherence. Although adherence is a key predictor of treatment outcomes in the context of digital therapeutics research,[8] the importance of assessing adherence to behavioral therapies remains undervalued. Moreover, studies evaluating adherence to dCBT-I are scarce, and those that have been conducted predominantly focused on online module completion.[10]

In this study, we aimed to 1) examine the effects of dCBT-I on self-reported insomnia symptoms, sleep diary measures, dysfunctional beliefs and attitudes about sleep, and depression and anxiety symptoms compared with a sham app and 2) investigate whether adherence predicts treatment outcomes. Given that sleep restriction and stimulus control are more effective than other CBT-I components,[14] and that among behavioral therapies, SRT allows for the assessment of adherence, we hypothesized that adherence to SRT would be better reflected by SE rather than subjective sleep quality. Therefore, SE was chosen as the primary outcome.

MATERIALS AND METHODS

Study design

In these two multicenter, double-blind, sham-controlled RCTs, we evaluated the efficacy and safety of a 6-week smartphone-based CBT-I program compared with a sham app as a control. The first clinical trial was conducted as a traditional RCT, whereas the second clinical trial took the form of a decentralized clinical trial (DCT). DCTs present a potential advantage over traditional RCTs by reducing or eliminating scheduled clinic visits, thereby alleviating geographical limitations.[15] As the two clinical trials had similar protocol designs except for DCT, we combined individual patient data from both studies. The Institutional Review Board (IRB) required an on-site visit for the written informed consent process instead of allowing an e-consent procedure due to concerns related to patient identification. Participants were enrolled via advertisements on websites and outpatient sleep clinic recruitment at Severance Hospital and Yongin Severance Hospital. The two studies were approved by the IRB at Severance Hospital of the Yonsei University Health System, Seoul, Korea (1-2021-0069, 9-2021-0146, 1-2022-0054). All participants provided written informed consent.

Participants

We recruited individuals who were aged 19 years or older but younger than 65 years, owned a smartphone, and were able to independently install and use the Android or iOS smartphone application, which was developed by WELT Corp. At the initial screening visit, the study personnel obtained informed consent from the participants after providing them with information about the study and collecting demographic information.

Individuals were eligible to participate if they 1) had been diagnosed with insomnia disorder based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria and 2) scored 8 or higher on the Insomnia Severity Index (ISI). The inclusion criteria were identical for both trials, except that the second trial additionally required an SE of less than 80%. Participants were excluded if they 1) had been diagnosed with sleep disorders other than insomnia, such as sleep-related breathing disorder, parasomnia, restless legs syndrome, narcolepsy, or circadian rhythm disorder, 2) were currently undergoing non-pharmacological treatment for insomnia (e.g., CBT-I, light therapy, sleep-related traditional medicine treatment), 3) had active and progressive physical conditions (e.g., congestive heart failure, chronic obstructive pulmonary disease, acute pain), neurological disorders (e.g., cerebrovascular diseases), neurodegenerative diseases (e.g., dementia, multiple sclerosis), unstable medical conditions, or a life expectancy of less than 6 months, 4) had received continuous counselling therapy, such as CBT, motivational enhancement therapy, psychother-

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apy, or psychoanalysis, within the previous 3 months, 5) had been diagnosed with major psychiatric disorders based on the Mini International Neuropsychiatric Interview,[16] 6) were at risk of suicide (i.e., had a Columbia-Suicide Severity Rating Scale score of 4 or higher) or had attempted suicide within the previous 2 weeks, 7) underwent adjustments in the dosing or schedule of their sleep medications, antidepressants, anxiolytics, anticonvulsants, sedatives, antipsychotics, or prescribed PRN sleep medications within the previous 3 months, 8) were suspected of dependence on sedatives based on investigator judgment, 9) had a history of alcohol or other substance abuse, 10) were at risk of occupational accidents due to sleep deprivation, 11) engaged in shift work, 12) were pregnant or planning a pregnancy during the clinical trial period, 13) were deemed by the investigator to have difficulties understanding or communicating about the clinical trial, or 14) had participated in another clinical trial within the 4 weeks before screening. The exclusion criteria were identical in both trials, except that the second trial additionally excluded individuals who faced difficulties conducting virtual procedures.

Intervention

dCBT-I was delivered to the intervention group for 6 weeks using the smartphone-based app "WELT-I." The program content of WELT-I was based on face-to-face CBT-I programs being implemented at Severance Hospital[17] and included six sessions of a multicomponent intervention, including sleep hygiene education, stimulus control, sleep restriction, cognitive restructuring, and relaxation therapy. Participants recorded daily sleep diary entries in the app and underwent SRT based on their sleep diary data from the previous week. The sleep window was titrated weekly considering each participant's SE. The recommended time in bed (rTIB) was reduced by 15 minutes when the average SE over the previous 5 days was lower than 80%, increased by 15 minutes when SE was greater than 90%, and maintained when SE was 80%–90%. The value of rTIB was set to a minimum of 300 minutes and a maximum of 720 minutes. Lessons in the app were unlocked one by one once a week based on the number of sleep diary entries and dates. The sham app was designed to mirror WELT-I's installation, login, user engagement, and content delivery processes while maintaining double-blind protocols. The sham app provided sleep hygiene education that covered the effects of sleep-disruptive substances, such as caffeine, nicotine, and alcohol; guidance on establishing a conducive sleeping environment; and recommendations for sleep-supporting foods. Whereas the sleep lessons in WELT-I were sequentially unlocked, those in the sham app were available all at once.

Study procedures

The eligible participants were sequentially assigned a randomization number and allocated to either the intervention or control group in a 1:1 ratio via an interactive web response system (IWRS) based on the pre-generated randomization sequence at the baseline visit. To minimize allocation bias, allocation was conducted using the stratified block randomization method with two stratification factors: "study site" and "administration of sleep medication" at baseline. The participants and investigators were blinded to the group assignments. The unblinded statistician generated the randomization sequence using Python (version 3.0 or higher) with the Numpy module (version 1.20.0 or higher). To reduce predictability, a combination of block sizes (e.g., 4 and 2) was employed. To ensure allocation concealment, only the IWRS developer had access to the randomization list, while investigators and participants remained unaware of the randomization details until the unblinding procedure following database lock. The unblinded research nurses were assigned to facilitate app installation and record adverse events, but were not involved in data analysis or outcome assessments. Participants were identified solely by their randomization numbers throughout the clinical trial, and randomization details were concealed until the unblinding procedure was complete. Each participant received an individual access code to download and log in to the trial app (WELT-I or the sham app, based on the allocation results) on their smartphone.

In the classical trial, participants underwent a total of three in-person visits: screening, baseline, and termination visits. In the 1st, 3rd, 5th, and 7th weeks after the initiation of app usage, participants were encouraged to complete sleep diary entries through phone calls. In the DCT, which did not include an initial screening visit, participants underwent remote assessments and were encouraged to complete sleep diary entries via phone calls in the 1st week (baseline), 3rd week, and 6th week following the initiation of app usage. In the classical trial, both the WELT-I and sham app groups were instructed to complete daily sleep diary entries from 1 week before starting the app to 1 week after the end of its use. In the DCT, the WELT-I group was asked to maintain a daily sleep diary from the initiation to the end of app usage, whereas the sham app group was only instructed to use their sleep diary during the first and final weeks of app usage.

The use of sleep medication was assessed at baseline and the 6-week follow-up. Participants were coded as "yes" if they reported current use of at least one of the following sleep medications: zolpidem IR, zolpidem CR, eszopiclone, zaleplon, triazolam, doxepin, trazodone, or melatonin prolonged release. Otherwise, they were coded as "no."

Outcome measures

The primary outcome of this combined analysis was the change in SE post intervention. The secondary outcomes were the changes in other sleep parameters, including sleep onset latency (SOL), wake after sleep onset (WASO), total sleep time (TST), number of awakenings during sleep (NA), sleep quality (SQ), and ISI scores. SE was calculated by dividing TST by TIB and multiplying the result by 100. TST was defined as the actual time spent sleeping (in minutes) while in bed. SOL was as-

sessed as the time taken to fall asleep (in minutes) after going to bed, and WASO was assessed as the amount of time (in minutes) spent awake from the initial onset of sleep until the final awakening before getting out of bed. SQ was evaluated using a single-item questionnaire rated on a 5-point scale, with higher scores indicating better sleep quality. The ISI is a retrospective self-report questionnaire that assesses the perceived severity of insomnia symptoms[15,18]; its summed scores range from 0 to 28, with higher scores indicating a higher severity of insomnia symptoms.

We also evaluated psychological outcomes, including depression, anxiety, and sleep-related attitudes and beliefs. Depression was evaluated using the 9-item Patient Health Questionnaire (PHQ-9),[19,20] the total scores of which range from 0 to 27, with higher scores indicating more severe depressive symptoms. Anxiety symptom severity was assessed using the 7-item Generalized Anxiety Disorder assessment (GAD-7) [21,22]; its scores range from 0 to 21, with higher scores indicating higher anxiety symptom severity. Dysfunctional beliefs and attitudes about sleep were assessed with the 16-item Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS-16).[23,24] The mean scores of these items range from 1 to 10, with higher scores indicating a greater level of endorsement of dysfunctional beliefs about sleep.

Statistical analysis

In both trials, the sample size was calculated using PASS 2020,[25] with an alpha of 0.05 and power of 1-beta=0.9, to detect an effect size of 1.13 based on the results of Ritterband, et al.[26] Considering an expected attrition rate of 30%, the initial recruitment target was set to 26 participants per group for each trial. There were no significant differences in demographic or clinical characteristics between the two studies (Supplementary Table 1, only online), which confirmed the suitability of data pooling. All outcomes from the WELT-I and sham app groups from both studies were combined into one dataset. Analyses of the primary and secondary outcomes were based on the full analysis dataset, which included participants who used the app at least once after randomization and had analyzable primary sleep diary variables after the baseline assessment. The full analysis dataset was analyzed using the intention-to-treat principle. Q–Q plots and the Shapiro–Wilk test were used to assess normality. The continuous variables of the two groups were compared using independent t-tests for normally distributed variables or the Mann–Whitney U test for non-normally distributed variables. The chi-square test or Fisher's exact test was used to compare categorical variables from the two groups. Within-group changes were evaluated using paired t-tests. To assess between-group differences in sleep diary measures and post-intervention ISI, PHQ-9, GAD-7, and DBAS-16 scores, an analysis of covariance (ANCOVA) was conducted, controlling for age, sex, baseline use of sleep medication, and the baseline value of each outcome variable. For all effects from the ANCOVA, we calculated the effect size using partial eta squared (η_p^2), with values of 0.01, 0.06, and 0.14 indicating small, medium, and large effect sizes, respectively.[27] To assess the relationship between adherence to SRT and sleep outcomes post-intervention, we conducted a multivariable linear regression analysis, adjusting for covariates such as age, sex, level of edu-

Table 1. Baseline Characteristics of Participants

Variables	WELT-I app (n=55)	Sham app (n=51)	*p*
Age (yr)	35 (19–63)	36 (19–64)	0.850
Sex			0.880
Male	18 (32.7)	16 (31.4)	
Female	37 (67.3)	35 (68.6)	
Education			0.650
High school	13 (23.6)	9 (25.5)	
University degree	34 (61.8)	32 (62.7)	
Postgraduate degree	8 (14.5)	10 (19.6)	
Employment status			0.750
Employed	34 (61.8)	30 (58.8)	
Unemployed	21 (38.2)	21 (41.2)	
Smoking status			0.360
Never	41 (74.5)	33 (64.7)	
Previous	4 (7.3)	8 (15.7)	
Current	10 (18.2)	10 (19.6)	
Alcohol intake			0.830
Never	19 (34.5)	19 (37.3)	
Previous	4 (7.3)	5 (9.8)	
Current	32 (58.2)	27 (52.9)	
Marital status			0.080
Married	24 (43.6)	21 (41.2)	
Single	26 (47.3)	30 (58.8)	
Divorced	5 (9.1)	0 (0.0)	
Sleep medication			0.710
Taking	3 (5.5)	2 (3.9)	
Not taking	52 (94.5)	49 (96.1)	
Sleep diary			
SE (%)	63.46±14.92	59.63±11.74	0.147
WASO (min)	21.43 (0.00–141.43)	33.14 (3.57–165.57)	0.053
SOL (min)	49.71 (9.29–196.00)	50.00 (12.14–274.29)	0.400
TST (min)	318.64±85.63	297.32±63.40	0.151
SQ, total score	2.42±0.48	2.56±0.50	0.149
NA	1.29 (0.00–5.57)	1.43 (0.29–3.57)	0.285
ISI, total score	16 (8–26)	16 (10–26)	0.957
PHQ-9, total score	8 (1–23)	7 (2–19)	0.261
GAD-7, total score	4 (0–21)	4 (0–19)	0.163
DBAS-16, total score	6.70±1.29	6.49±1.29	0.403

DBAS-16, 16-item Dysfunctional Beliefs and Attitudes about Sleep scale; GAD-7, 7-item Generalized Anxiety Disorder assessment; ISI, Insomnia Severity Index; NA, number of awakenings during sleep; PHQ-9, 9-item Patient Health Questionnaire; SE, sleep efficiency; SOL, sleep onset latency; SQ, sleep quality; TST, total sleep time; WASO, wake after sleep onset.
Data are presented as median (interquartile range), mean±standard deviation, or n (%).

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cation, and the baseline value of each outcome variable. The significance threshold was 0.05 for all analyses, and all analyses were performed using IBM SPSS Statistics software version 26.0 and R version 4.3.1.

Adherence

To evaluate adherence to SRT in the WELT-I group, the time deviation of TIB was calculated as the mean of all differences between rTIB and actual TIB (aTIB) based on sleep diary data: $\Sigma_{i=1}^{n}(rTIB_i - aTIB_i)$, where n is the number of days in which rTIB was generated. A greater difference between rTIB and aTIB indicates poorer adherence to SRT. We also calculated the proportion of participants in the WELT-I group who completed all lessons after the 6-week intervention.

RESULTS

Participants

A total of 153 potential individuals were screened in both trials, 120 of whom were randomized to use either WELT-I or the sham app. Of the randomized participants, 116 received the allocated intervention, 103 (88.8%) of whom completed the 6-week intervention. Following the intention-to-treat principle, 106 individuals were included in the full analysis dataset after excluding cases with uncertain reliability of the assessments and sleep diaries or insufficient sleep diary entries.

At baseline, there were no significant differences in any demographic or clinical characteristics or sleep and cognitive-emotional symptoms between the WELT-I and sham app groups (Table 1). Fig. 1 presents the CONSORT flowchart, which illustrates the participant flow from both trials. Flow charts for the first and second clinical trials can be found in Supplementary Figs. 1 and 2 (only online), respectively.

Intervention effects on sleep and cognitive-emotional symptoms

The WELT-I group demonstrated significant improvements in all sleep outcomes including SE, dysfunctional beliefs, and depressive symptoms post intervention. In the sham app group, significant improvements were observed post intervention compared with baseline, excluding SOL, WASO, and anxiety symptoms. Detailed comparisons are provided in Supplementary Table 2 (only online).

After controlling for age, sex, baseline use of sleep medication, and baseline levels of each outcome variable, the significant differences in mean change between the two groups were 7.69% [95% confidence interval (CI), 3.09% to 12.30%; p=0.001] for SE, -16.77 minutes (95% CI, -31.48 to -2.06 minutes; p=0.026) for SOL, and -0.97 (95% CI, -1.46 to -0.48; p<0.001) for DBAS-16, supporting the superiority of WELT-I compared with the sham app. WASO also showed a trend toward statistical significance, with a difference in mean change of -9.82 minutes (95% CI, -20.05 to 0.40 minutes; p=0.060). The effect size was medium for SE (η_p^2=0.099), small for SOL (η_p^2=0.049), and large for DBAS-16 (η_p^2=0.135). Details on the between-group differences are provided in Table 2.

Adverse events

Adverse events were reported by 13 of the 55 participants in the WELT-I group and 13 of the 51 participants in the sham app group. There was no significant difference in the occurrence

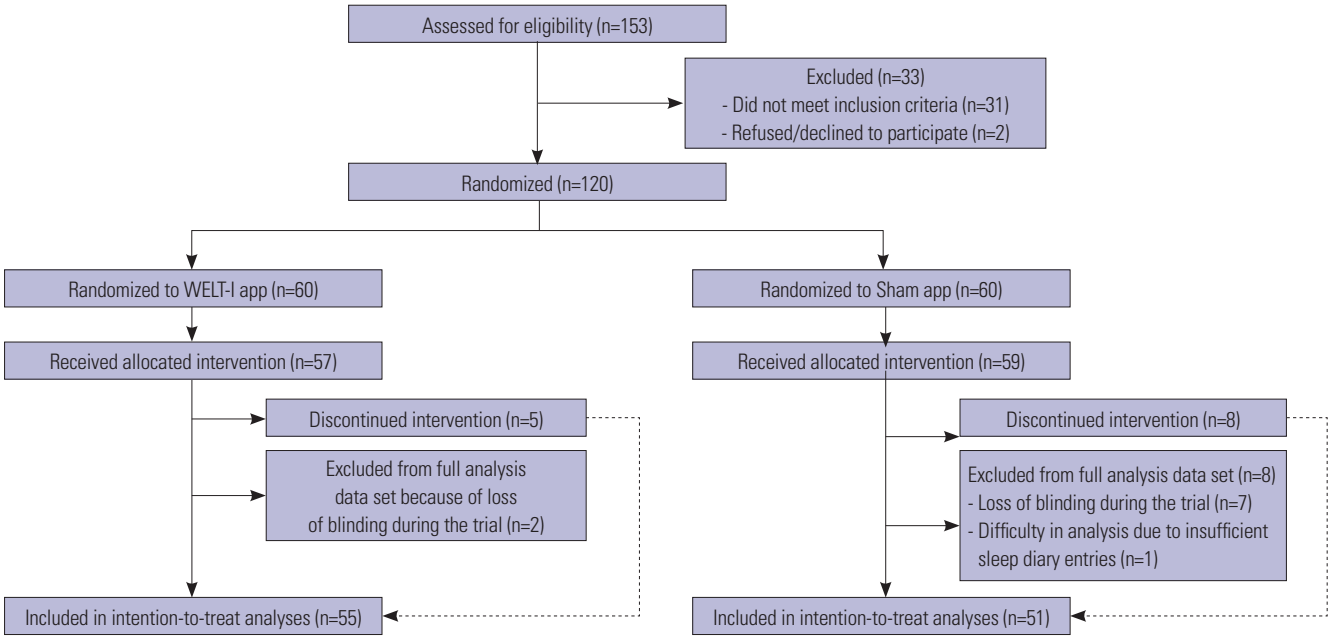

Fig. 1. Participant enrollment flowchart.

Table 2. Treatment Effects of the WELT-I and Sham App

Variable	Adjusted mean difference	95% CI	Effect of group		Effect size (partial η^2)
			F	*p*	
SE	7.69	3.09 to 12.30	10.996	0.001	0.099
ISI	-1.49	-3.17 to 0.19	3.105	0.081	0.030
SOL	-16.77	-31.48 to –2.06	5.114	0.026	0.049
WASO	-9.82	-20.05 to 0.40	3.631	0.060	0.035
TST	7.76	-20.05 to 35.58	0.307	0.581	0.003
SQ	0.11	-0.08 to 0.29	1.280	0.261	0.013
NA	-0.06	-0.38 to 0.26	0.147	0.702	0.001
DBAS-16	-0.97	-1.46 to -0.48	15.566	<0.001	0.135
PHQ-9	-1.36	-2.93 to 0.21	2.969	0.088	0.029
GAD-7	-0.37	-1.70 to 0.97	0.296	0.588	0.003

CI, confidence interval; DBAS-16, 16-item Dysfunctional Beliefs and Attitudes about Sleep scale; GAD-7, 7-item Generalized Anxiety Disorder assessment; ISI, Insomnia Severity Index; NA, number of awakenings during sleep; PHQ-9, 9-item Patient Health Questionnaire; SE, sleep efficiency; SOL, sleep onset latency; SQ, sleep quality; TST, total sleep time; WASO, wake after sleep onset.

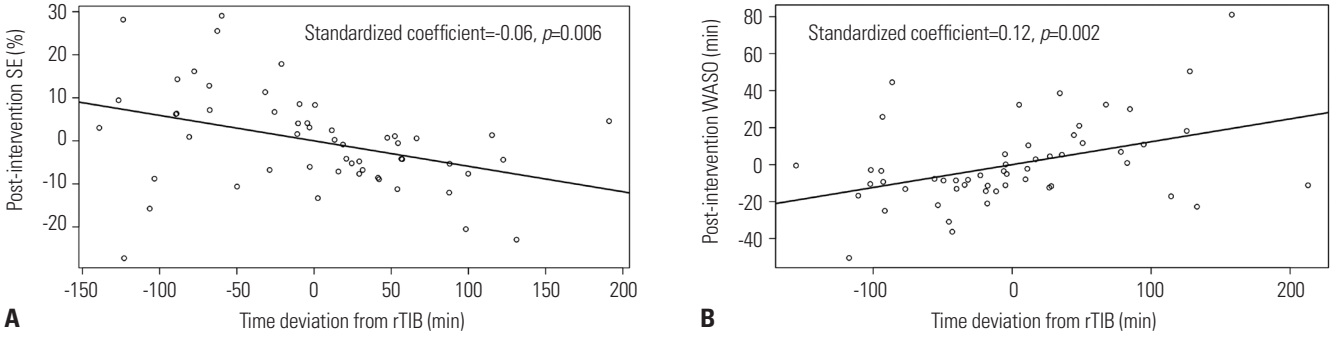

Fig. 2. The association between adherence and post-intervention (A) SE and (B) WASO in a multivariable linear regression model after controlling for age, sex, years of education, and baseline values of SE and WASO, respectively. Greater deviations from rTIB indicate lower adherence. rTIB, recommended time in bed; SE, sleep efficiency; WASO, wake after sleep onset.

of adverse events between the two groups, nor were there any significant adverse events or cases of study discontinuation due to adverse events. The most common adverse event during the trial was COVID-19 infection (11 of 26).

Relationship between adherence and post-intervention sleep outcomes

The time deviation from rTIB, indicative of adherence to SRT, showed significant relationships with post-intervention sleep outcomes. Specifically, an increased time deviation from rTIB was related to lower SE (R^2=0.47, β=-0.06, t=-2.86, *p*=0.006) and longer WASO (R^2=0.43, β=0.12, t=3.21, *p*=0.002) after controlling for age, sex, years of education, and the baseline value of each outcome variable (Fig. 2). No significant associations were observed between adherence to SRT and the remaining outcome variables. Among the 55 WELT-I participants, 47 (85.5%) completed every lesson.

DISCUSSION

In this combined analysis of two randomized, double-blind, sham-controlled clinical trials, we assessed the efficacy of WELT-I. Compared to the sham app, WELT-I showed robust efficacy in improving SE, the primary outcome of this study, as well as SOL and dysfunctional beliefs about sleep. The between-group effect size was medium for SE, small for SOL, and large for dysfunctional beliefs in favor of WELT-I, all of which are comparable to the effect sizes observed in previous meta-analyses.[28,29] Our findings also showed that poorer adherence to a recommended bedtime schedule was associated with poorer sleep outcomes, specifically lower SE and longer WASO.

The significant improvements in SE, SOL, and dysfunctional beliefs about sleep during the WELT-I intervention are consistent with the results of recent meta-analyses.[29-31] The trend-level decrease in WASO (*p*=0.060) following the WELT-I intervention corroborates that CBT-I's mechanism of action involves increasing sleep continuity and facilitating cognitive restructuring.[32] These results also provide additional evidence of the efficacy of dCBT-I in improving sleep-related outcomes.[29,33] In contrast to the results of other studies, we did not find significant between-group differences in ISI scores from baseline to post intervention. Unlike previous studies using wait-list controls, treatment as usual, or sleep hygiene education with a dif-

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ferent interface from the dCBT-I intervention, our study employed a sham app control group that received sleep hygiene information, potentially contributing to these non-significant results. Although there is no universal definition for a digital sham, it can be described as a comparator that mimics a digital therapeutic in design, components, and treatment duration while removing or reducing the intensity of the digital therapeutic's active principle or component.[7] These characteristics enable double-blinding and may reduce the risk of false-positive outcomes when evaluating the effect of the digital therapeutic. Considering the absence of a consensual definition for digital shams[7] and the dearth of studies using sham app controls in dCBT-I interventions,[34,35] validation of the digital sham will be necessary in future research with larger sample sizes.

Although dCBT-I studies often use the number of completed online modules as a measure of global adherence,[10] it is worth noting that online module completion does not necessarily indicate adherence to behavioral recommendations, such as SRT or stimulus control. Considering the meta-analysis finding that the sleep restriction and stimulus control components of CBT-I are more effective than sleep hygiene or relaxation therapy,[14] and given its ease of measurement with sleep diaries, we chose deviation from rTIB as an indicator of adherence to dCBT-I. Previous studies of face-to-face CBT-I have used various proxies to measure adherence to SRT, including deviation from rTIB, the percentage of patients who adhere to their prescribed TIB/rise time/bedtime within specific periods (1, 15, 30, or 60 minutes), and the percentage of days in which patients adhere to their prescribed TIB/rise time/bedtime within specific periods (1, 15, 30, or 60 minutes).[13] We deemed deviation from rTIB to be a useful measure in this study (as well as in face-to-face CBT-I studies) as there is currently insufficient empirical evidence to establish a meaningful specific time period cutoff. Moreover, using time deviations from specific time cutoffs to measure adherence may categorize patients who fall asleep later than the recommended bedtime as non-adherent to SRT. For instance, when SRT is combined with stimulus control, going to bed later than the prescribed bedtime may align with the principles of stimulus control, which suggest that patients only go to bed when they feel sleepy. The observed association between better adherence to rTIB and improved sleep continuity following the dCBT-I intervention in our study underscores the role of sleep restriction and stimulus control as integral elements of CBT-I. The TIB restriction reduces wakefulness in bed, promoting a consistent pairing of bed with sleepiness, if well adhered to, thereby counterconditioning against the typical wake–bed association presumed in insomnia.[36] A consistent bedtime schedule enhances regulatory sleep control by the internal circadian pacemaker and normalized exposure to external zeitgebers, such as light and meal times.[36] This interaction between the circadian pacemaker and homeostatic sleep pressure, which enables one to keep a regular bedtime schedule, could promote predictability in sleep and stabilize the circadian sleep-wake cycle.[37-39]

The current study has several limitations. First, the study sample predominantly consisted of women and individuals with few psychiatric and physical comorbidities, which limits our ability to generalize the results to the general population. The reproducibility and validity of the results should be verified through a future study with a larger sample size in a real-world setting. Second, the present study assessed only post-intervention outcomes and did not evaluate long-term results; thus, it is unclear whether sustained benefits might have been observed over an extended period. Third, only self-reported data were used in this study. Though all variables in this study were derived from standardized questionnaires and psychological distress outcomes are intrinsically subjective, future studies would benefit from incorporating objective measures, perhaps through the use of actigraphy or wearable devices, to evaluate the effects of dCBT-I. Fourth, we operationalized adherence to dCBT-I exclusively in terms of adherence to SRT. As such, our analyses do not encompass adherence to all components of dCBT-I, nor do they include other adherence-related factors, such as time spent using the app. Lastly, due to the low proportion (4.7%) of participants using sleep medication in this study, we were unable to identify changes in medication use following the dCBT-I intervention. Given the existing evidence demonstrating the effectiveness of combining CBT-I with pharmacotherapy as well as the risk of dependency and side effects of sleep medication,[40,41] further investigation into the role of dCBT-I in tapering or maintaining the lowest effective dose of medication in a large-scale real-world setting is warranted. Despite these limitations, our findings contribute additional scientific evidence that dCBT-I can significantly enhance sleep outcomes compared to a sham app. Furthermore, our results demonstrate that adherence to SRT can predict treatment efficacy.

In summary, the present combined analysis demonstrates not only the efficacy of dCBT-I in addressing insomnia symptoms and dysfunctional beliefs about sleep compared with sham controls but also that adherence to SRT is associated with enhanced dCBT-I outcomes. Future studies with a validated digital sham intervention are necessary and should explore the impact of adherence on treatment outcomes and examine predictors of adherence using larger sample sizes in real-world settings.

DATA AVAILABILITY

The data used in this study are available from the corresponding authors upon reasonable request.

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AUTHOR CONTRIBUTIONS

Conceptualization: all authors. Data curation: Suonaa Lee, Eun Chae Choi, and Do Hyun Lee. Formal analysis: Suonaa Lee and Do Hyun Lee. Funding acquisition: Eun Lee and Yujin Lee. Investigation: Suonaa Lee, Kyung Mee Park, Do Hyun Lee, and Eun Chae Choi. Methodology: all authors. Project administration: Eun Lee and Yujin Lee. Resources: Eun Lee and Yujin Lee. Software: Eun Lee and Yujin Lee. Supervision: Eun Lee. Validation: Suonaa Lee. Visualization: Suonaa Lee. Writing—original draft: Suonaa Lee. Writing—review & editing: Suonaa Lee, Yujin Lee, and Eun Lee. Approval of final manuscript: all authors.

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