Efficacy of Mobile Application-based Cognitive Behavioral Therapy for Insomnia: A Multi-center, Single-blinded Randomized Clinical Trial

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Table of Contents

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Abstract

Background: Cognitive behavioral therapy for insomnia (CBTi) is the first-line therapy for chronic insomnia. Mobile-application-based CBTi (MCBTi) can enhance the accessibility of CBTi treatment; however, few studies have evaluated the effectiveness of MCBTi using a multi-center, randomized controlled trial (RCT) design.

Objective: We aimed to assess the efficacy of Somzz, an MCBTi that provides real-time and tailored feedback to users, comparing with an active comparator application.

Methods: In our multi-center, single-blinded RCT study, a total of 98 participants were recruited from three sites and randomized into a Somzz group and a sleep hygiene education (SHE) group at a 1:1 ratio. The intervention included six sessions for 6 weeks, with follow-up visits over a 4-month period. Somzz provided CBTi treatment through audiovisual sleep education, guidance on relaxation therapy, and real-time customized feedback on participants' sleep behavior by analyzing the data entered into the app. The primary outcome was the Insomnia Severity Index (ISI), and secondary outcomes included sleep diary measures and mental health self-reports. We analyzed the outcomes based on the intention-to-treat principle.

Results: ISI scores for the Somzz group were significantly lower at post-intervention (8.30 vs. 12.9, $P < .001$) and at the 3-month follow-up visit (11.26 vs. 14.70, $P = .007$) compared to the SHE group. The Somzz group had maintained their treatment effect at post-intervention and follow-ups, with a moderate-to-large effect size (Cohen's d = ?0.68 to ?1.45). Furthermore, the Somzz group showed better outcomes in sleep efficiency ($P = .015$) and mental health, including depression ($P = .009$), anxiety ($P = .011$), and quality of life ($P = 0.008$) at post-intervention. Among those in the Somzz group, 42 (95.45%) participants finished the intervention. Our study had an attrition rate of 4.55% (2 of 44) post-intervention among the Somzz group.

Conclusions: Somzz outperformed SHE in improving insomnia, mental health, and quality of life. MCBTi can be a highly accessible, time-efficient, and effective treatment option for chronic insomnia, with high compliance. Clinical Trial: cris.nih.go.kr KCT0007292; https://cris.nih.go.kr/cris/search/detailSearch.do?seq=22214&search_page=L.

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Abstract

Background:

Cognitive behavioral therapy for insomnia (CBTi) is the first-line therapy for chronic insomnia. Mobile-application-based CBTi (MCBTi) can enhance the accessibility of CBTi treatment; however, few studies have evaluated the effectiveness of MCBTi using a multi-center, randomized controlled trial (RCT) design.

Objective:

We aimed to assess the efficacy of Somzz, an MCBTi that provides real-time and tailored feedback to users, through comparison with an active comparator application.

Methods:

In our multi-center, single-blinded RCT study, participants were recruited from three university hospitals and randomized into a Somzz group and a sleep hygiene education (SHE) group at a 1:1 ratio. The intervention included six sessions for 6 weeks, with follow-up visits over a 4-month period. The Somzz group received audiovisual sleep education, guidance on relaxation therapy, and real-time feedback on sleep behavior. The primary outcome was the Insomnia Severity Index (ISI), and secondary outcomes included sleep diary measures and mental health self-reports. We analyzed the outcomes based on the intention-to-treat principle.

Results:

A total of 98 participants were randomized into the Somzz (n = 49) and SHE (n = 49) groups. ISI scores for the Somzz group were significantly lower at post-intervention (9.0 vs. 12.8, t = 3.85, $F_{2, 95}$ = 22.76, η_p^2 = 0.13, P < .001) and at the 3-month follow-up visit (11.3 vs. 14.7, t = 2.61, $F_{2,68}$ = 5.85, η_p^2 = 0.03, P = .011) compared to the SHE group. The Somzz group had maintained their treatment effect at post-intervention and follow-ups, with a moderate-to-large effect size (Cohen's d = −0.62 to -1.35, all ps < 0.01). Furthermore, the Somzz group showed better sleep efficiency (t=-3.32, $F_{2,91}$=69.87, η_p^2 = 0.41, P = .001), wake after sleep onset (t=2.55, $F_{2,91}$=51.81, η_p^2 = 0.36, P = .013), and satisfaction (t=-2.05, $F_{2,91}$=26.63, η_p^2 = 0.20, P = .043) related to sleep, and mental health outcomes, including depression (t=2.11, $F_{2,94}$=29.64, η_p^2 = 0.21, P = .038) and quality of life (t=-3.13, $F_{2,94}$=54.20, η_p^2 = 0.33, P = .002), compared to the SHE group after the intervention. The attrition rate in the Somzz group was 12.2% (6 of 49 participants).

Conclusions:

Somzz outperformed SHE in improving insomnia, mental health, and quality of life. MCBTi can be a highly accessible, time-efficient, and effective treatment option for chronic insomnia, with high compliance.

Trial registration number: cris.nih.go.kr KCT0007292; https://cris.nih.go.kr/cris/search/detailSearch.do?seq=22214&search_page=L.

Keywords: digital therapeutics; mobile-application-based cognitive behavioral therapy for insomnia; cognitive behavioral therapy; insomnia; mental health.

Introduction

Insomnia is a highly prevalent (global prevalence of 2.3%–25.5%) sleep disorder that substantially impacts population health worldwide [1]. Individuals with insomnia often experience decreased quality of life [2] and have a higher risk for developing psychiatric illnesses [3], as well as medical conditions including cardiometabolic and neurocognitive disorders [4].

Although cognitive behavioral therapy for insomnia (CBTi) is the first-line treatment of insomnia [5-7], its accessibility is limited. These limitations arise due to the time-consuming nature of this treatment and the shortage of trained physicians worldwide [8-10]. Therefore, many individuals face difficulties in obtaining face-to-face CBTi treatment. However, considering the busy working hours coupled with the high penetration of smartphones in modern society, mobile-application-based digital CBTi (MCBTi) may offer easy accessibility to a larger population, with minimal space constraints. Digital CBTi is a type of digital therapeutics that uses qualified software programs to deliver evidence-based therapeutic interventions to patients [11], to prevent, manage, or treat medical conditions through effective therapeutic techniques.

Among the various methods of delivering digital CBTi, web-based CBTi, in which a real or virtual therapist provides feedback and supervision, is considered optimal for improving sleep efficiency, sleep onset latency (SOL), and wake after sleep onset (WASO) [12]. Although there have been numerous studies regarding the effectiveness of web-based CBTi [13], the efficacy of MCBTi for improving insomnia and mental health remains unknown [12]. Previous studies using MCBTi, among the various delivery methods of digital CBTi, randomized controlled trials (RCTs) were relatively scarce [14] and/or the control group did not use the same modality (e.g., non-application-using control, waitlist control) [15, 16]. One MCBTi study with an RCT design used the same modality control, as an active comparator application that provided feedback in

chatbot form [10]; the study participants had an Insomnia Severity Index (ISI) score of 15 or higher, indicating a moderate degree of insomnia. Another multi-center RCT study demonstrated the effectiveness of MCBTi [17], suggesting including mental health outcomes in the future studies.

Here, we considered a CBTi mobile application, Somzz, that can be applied to a wider range of insomniacs, ranging from those that experience mild insomnia (ISI score ≥ 8) to those with severe insomnia. With this application, CBTi treatment is provided through audiovisual sleep education, guidance on relaxation therapy, and real-time customized feedback on participants' sleep behavior by analyzing the data entered into the app. Cognitive therapy through a chatbot format is used to correct dysfunctional beliefs related to sleep. Additionally, because the effectiveness of sleep restriction has consistently been reported [18], daily "push-alarm" reminders were used to ensure adherence to the prescribed time in bed.

We aimed to compare the treatment effect of Somzz with an active comparator application providing sleep hygiene education (SHE). We hypothesized that participants using Somzz would demonstrate better outcomes in measures such as the ISI, Epworth Sleepiness Scale (ESS), and sleep diary measures (including sleep efficiency (SE), SOL, WASO, total sleep time (TST), refreshment after sleep, and sleep satisfaction). Additionally, we hypothesized that mental health-related issues, including depression, anxiety, and quality of life, would show greater improvement in the Somzz group.

Methods

Participants

This multi-center study recruited participants from Seoul National University Hospital, Korea University Hospital, and Samsung Medical Center through advertisements placed in the hospitals and local community (trial registration number: KCT0007292). Psychiatrists (H.-J L., S.J.K, and Y.J.L) used the International Classification of Sleep Disorders, Third Edition to confirm chronic insomnia diagnoses. The participants were recruited between January and May 2022.

Participants had to meet all of the following inclusion criteria: (1) age 19 years or older, (2) meeting the diagnostic criteria for chronic insomnia disorder according to the International Classification of Sleep Disorders, Third Edition (ICSD-3), (3) ISI score ≥ 8, (4) users of Android phones with OS version 7.0 or above, (5) voluntary decision to participate in the clinical trial and provide written consent on the informed consent form, and (6) willingness to

comply with the clinical trial protocol.

Participants were excluded from the study if any of the following exclusion criteria were met: (1) presence of sleep disorders other than chronic insomnia disorder (e.g., hypersomnia, narcolepsy, sleep-disordered breathing), (2) presence of serious medical illnesses, (3) underlying disorders that could be exacerbated by sleep restriction (e.g., bipolar disorder, psychosis), (4) severe depression defined by a Hamilton Depression Rating Scale score of 24 or higher, (5) presence of medications (e.g., chronic use of stimulant medication) or lifestyle factors that provoke insomnia (e.g., caffeine, alcohol, tobacco addiction), (6) individuals who have challenging schedules that make it difficult to receive sleep interventions (e.g., night shift workers, rotating shift workers), (7) presence of auditory or cognitive impairments that make it difficult to undergo treatment with the investigational medical device for the clinical trial, (8) individuals who have difficulty using universal devices such as smartphones, (9) individuals who have not completed electronic sleep diaries on at least seven occasions within 10 days from the first day of electronic sleep diary entry, (10) pregnant or lactating women, (11) individuals currently participating in another clinical trial or who had participated in another clinical trial within 90 days from the screening date, and (12) individuals, in the judgment of the investigator, deemed inappropriate for participation in the clinical trial due to the ethical or potential impact on the clinical trial results.

Individuals who met the study inclusion criteria were randomly assigned to either the Somzz or SHE group at a 1:1 ratio. In this single-blinded RCT, the participants were blinded to group allocation. Random allocation was performed using an interactive web response system and a predetermined randomization list. Stratified block randomization was implemented by statisticians using the SAS PROC PLAN procedure; the block size was predetermined for each clinical trial site. Stratification was conducted based on the recruiting institution. The block size and seed number used are selected randomly by the responsible statistician for randomization.

The intervention and control groups had the same visit schedule, and visits were supervised by clinicians or trained psychologists. Written consent was obtained prior to clinical assessments (e.g., vital signs, physical examination, assessment of combination therapy, completion of self-reported scales, System Usability Scale [SUS] assessment). However, all therapeutic interventions for insomnia were exclusively administered through the Somzz application. There were six visits in total; visit 1 involved screening for study eligibility, visit 2 (week 0) encompassed the collection of baseline demographic and Insomnia Severity Index (ISI) data, visits 4 (week 2) and 6 (post-treatment) involved assessment of treatment adherence and completion of sleep-related, mental health, and quality of life scales, and visits 3 (week 1) and 5 (week 4)—both telephone visits—consisted of ISI and Epworth Sleepiness Scale (ESS)

completion.

The study protocol was approved by the Institutional Review Board (IRB) for Human Subjects of Seoul National University Hospital (IRB No. 2109-145-1258). Detailed information about the study was provided to the participants, and written informed consent was obtained before enrollment.

Sample Size Calculation

Sample size was calculated on the basis of group differences and standard deviations reported in previous papers regarding digital CBTi (the FDA-approved "SHUT-I" program) [19, 20]. Assuming an intergroup difference of -4.6, a standard deviation of 6.2, a significance level of 5%, and a power of 90%, the sample size calculation yielded 39 participants per group. Assuming a dropout rate of 20%, we intended to recruit 49 participants per group—98 participants in total.

Intervention

Somzz is a mobile-application software medical device designed for the treatment of chronic insomnia. It implements the CBTi protocol, incorporating stimulus control, sleep restriction, SHE, and cognitive therapy, the first-line treatment of chronic insomnia. The application consists of six steps conveyed for six weeks: (1) general sleep education, (2) stimulus control and sleep restriction, (3) SHE, (4) relaxation techniques, (5) cognitive therapy, and (6) relapse prevention and termination (Table 1). The Somzz group participants were provided with real-time data-based customized feedback, daily assignments, behavioral interventions [e.g., recommendations for time in bed (TIB)], and push notification messages (e.g., when to write daily in the sleep diary, when to go to bed considering past TIB) during the six-week intervention. The intervention was conducted in a fully automated manner. The screenshots of the Somzz are presented in Figure 2.

Table 1. Contents of the Somzz sessions

Session	Contents	Additions
Session 1: Basic education	When a patient first signs up on the app, they undergo a sleep assessment to evaluate their basic information, the severity of insomnia symptoms, and the presence of comorbid conditions. Additionally, they receive basic education and set goals.	Homework
Session 2: Stimulus	Somzz provides education on stimulus control, behavioral interventions, and feedback. The goal is to use the bed or	Homework, Feedback,

	bedroom solely for sleeping purposes and to engage in sleep-disruptive activities outside the bedroom. This aims to regulate sleep by adjusting the sleep environment, bedtime, and bedroom conditions in relation to sleep. It is a behavior therapy technique that associates healthy habits conducive to falling asleep and modifying maladaptive conditioning related to sleep. Avoiding activities such as watching TV, work-related behaviors, and using the internet or mobile phones in bed is encouraged, and daily compliance is recorded and reviewed during CBTi sessions.	TIB recommendation
control & sleep restriction	Somzz also provides education on sleep restriction, behavioral interventions, and feedback. In other words, we assess the patient's sleep duration through a sleep diary to implement sleep restriction. Taking into account the patient's sleep efficiency, we determine the target sleep duration and wake-up time. We gradually adjust the total time in bed (TIB) by 15 min per week until reaching the target sleep efficiency of 85%.	
Session 3: Sleep hygiene education	Somzz provides education on sleep hygiene, behavioral interventions, and feedback. This involves examining factors that can impact sleep, such as excessive consumption of coffee or alcohol, and conducting education to establish healthy habits for sleep. Subsequently, we encourage daily recording of sleep habits and provide feedback on them.	Homework, Feedback, TIB recommendation
Session 4: Relaxation therapy	Somzz provides education on relaxation therapy, behavioral interventions, and feedback. This includes training in relaxation techniques such as diaphragmatic breathing and progressive muscle relaxation, providing a structured self-training schedule, and offering feedback on performance.	Homework, Feedback, TIB recommendation
Session 5: Cognitive	Somzz provides cognitive therapy counseling and feedback.	Homework,

therapy	This therapy aims to address and correct automatic thoughts related to insomnia that contribute to worsening sleep. It focuses on examining and correcting dysfunctional thoughts associated with excessive worry about insomnia, anxiety arising from perceived health and psychological effects of insomnia, and thoughts characterized by excessive preoccupation with sleep duration. The therapy also targets catastrophic thinking regarding the consequences of poor sleep and generalizations attributing discomforting symptoms solely to sleep-related causes.	Feedback, TIB recommendation
Session 6: Relapse prevention & termination	Somzz conducts a reassessment of symptoms prior to program termination and provides feedback on progress compared to the initial evaluation. We also provide feedback and perform a relapse prevention education session, followed by a final evaluation.	Homework, Feedback

Real-time TIB recommendations constitute a primary feature of Somzz. Based on each participant's sleep schedule, as recorded in their sleep diary, the app calculates their sleep efficiency and prompts them to adjust their TIB as necessary. If a participant stays in bed longer than the recommended time, real-time feedback is provided in the form of alarms. Additionally, as part of a daily "to-do" list, push notifications encourage participants to complete > 6,000 steps during the day and ensure sufficient exposure to sunlight. Somzz also incorporates a chatbot module, allowing users to change any dysfunctional beliefs related to insomnia by answering the chatbot therapist's questions. The same user interface was utilized for SHE, although the sleep diary module was only 6 weeks in duration, and no TIB recommendations were provided. These differences in features may have led to differences in long-term treatment outcomes between the Somzz and SHE groups, as revealed by the linear mixed model analysis of ISI scores, ESS scores, and SE.

The SHE group participants also installed the active comparator application on their phone that comprised SHE and a writing daily sleep diary. However, no push notification messages or TIB prescriptions were sent to the participants. Sleep education in both applications is provided through audiovisual materials (e.g., movie clips including narrations and texts).

Participants were followed for six weeks during the intervention, and those who consented to extended follow-ups were evaluated for an additional four months after the intervention (with four additional visits per month) to assess the maintenance of treatment effects.

Outcomes and Measures

The primary outcome was the comparison of total ISI score between the Somzz and SHE groups at each clinical and post-intervention follow-up visit [21]. Secondary outcomes included sleep diary and psychiatric measures. Sleep diary measures recorded by the Somzz application included SOL, SE, TST, number of awakenings during sleep (NWAK), WASO, refreshment after waking up (refreshment), and satisfaction with sleep (satisfaction). Psychiatric measures included daytime sleepiness, as indicated by the ESS [22]; dysfunctional beliefs, measured by the Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS) [23]; depressive symptom severity, measured by the Patient Health Questionnaire-9 (PHQ-9) [24]; anxiety symptom severity, measured by the Generalized Anxiety Disorder Assessment-7 (GAD-7) [25]; fatigue, measured by the Fatigue Severity Scale (FSS) [26]; and health-related quality of life, measured by the Short Form Health Survey-36 (SF-36) [27] and the five-level EuroQol (EQ-5D-5L) [28].

ISI and ESS scores were obtained at each visit, and sleep diary measures were evaluated daily. Other self-report scales, including psychiatric, fatigue, and quality-of-life measures, were completed at baseline, post-intervention, and during the 4-month follow-up period. We defined remission as an ISI score of < 8 after treatment; thus, a decrease in the ISI score of > 7 points from baseline was defined as a treatment response.

Statistical Analysis

Demographic data were compared between the Somzz and SHE groups, using a Student's *t*-test for continuous variables and a chi-square test for categorical variables. ISI scores, sleep diary, and psychiatric measures were compared between the two groups using an Analysis of Covariance adjusting for baseline severity and within groups using a paired *t*-test. Regarding the calculation of effect sizes in the paired t-test, s_p is the pooled s_d, n is the number of paired observations, X_i represents difference in each paired observations, $\acute{X}$ is the mean of these differences.

$$s_p = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \acute{X})^2}{n-1}}$$

Linear-mixed model analysis was conducted to examine the group–time interaction regarding

ISI and ESS scores and sleep diary measures. Factors associated with remission (ISI score < 8) and response (ISI score decrease from baseline > 7) were evaluated using binary logistic regression. The primary and secondary outcomes were analyzed using the intention-to-treat principle; the analysis included all participants randomly allocated to either the Somzz or SHE group. Additionally, the last observation carried forward method was used to handle missing data. All analyses were performed using R, version 4.2.0 (R Core Team, 2022). We used the R package lme4 (Bates et al., 2007) to fit the linear mixed model.

Results

A total of 98 participants were randomly assigned to the Somzz and SHE groups, with each group consisting of 49 individuals. Among these participants, five individuals from the Somzz group and four from the SHE withdrew their consent, and one participants in each group did not complete the study (Figure 1). The baseline demographic data are presented in Table 2. In total, 71 participants (34 of 49 in the Somzz group and 37 of 49 in the SHE group) consented to participate in the extended (4-month) follow-up study.

Table 2. Baseline demographic data for the Somzz and SHE groups

	Number (%) or mean (SD)	
	Somzz (n = 49)	**SHE (n = 49)**
Sex		
Male	20 (40.8%)	18 (36.7%)
Female	29 (59.2%)	31 (63.3%)
Age (years)	44.1 (13.1)	40.5 (12.8)
Insomnia duration		
3–6 months	2 (4.1%)	4 (8.2%)
6–12 months	4 (8.2%)	5 (10.2%)
1–3 years	17 (34.7%)	12 (24.5%)
3–5 years	7 (14.3%)	12 (24.5%)
5 years~	19 (38.8%)	16 (32.7%)
Occupation		
Full-time	13 (26.5%)	20 (40.8%)
Part-time	9 (18.4%)	8 (16.3%)
Retired	1 (2.0%)	2 (4.1%)
Student	4 (8.2%)	6 (12.2%)
Unemployed	14 (28.6%)	8 (16.3%)
Other	8 (16.3%)	5 (10.2%)
Current medical illness	17 (34.7%)	17 (34.7%)
Current use of hypnotics	9 (18.4%)	9 (18.4%)
Days of use/week	3.9 (2.5)	4.2 (2.6)
Caffeine		
Current user	35 (71.4%)	36 (73.5%)

Caffeine unit	1.7 (1.1)	1.5 (1.0)
Ex-user	2 (4.1%)	1 (2.0%)
Never	12 (24.5%)	12 (24.5%)
Smoking		
Current smoker	9 (18.4%)	4 (8.2%)
Smoking unit	4.8 (4.8)	3.5 (2.4)
Duration of use (years)	9.9 (10.0)	11.8 (7.7)
Ex-smoker	4 (8.2%)	8 (16.3%)
Never-smoker	36 (73.5%)	37 (75.5%)
Drinking		
Current drinker	26 (53.1%)	28 (57.1%)
Drinking unit	2.5 (3.0)	3.5 (4.5)
Duration of use (years)	19.8 (12.5)	14.9 (11.4)
Ex-drinker	1 (2.0%)	4 (8.2%)
Never-drinker	22 (44.9%)	17 (34.7%)
Psychiatric diagnosis	5(11.4%)	5 (11.4%)
Depressive disorder	4	4
Anxiety disorder	1	
Panic disorder	1	1
Bipolar II disorder	1	1
Alcohol use disorder	1	

Data are number (%) or mean (SD)
SD, standard deviation; SHE, sleep hygiene education.

Primary Outcomes

Comparison of the ISI scores between the Somzz and SHE groups showed that the scores of the Somzz group were lower post-intervention (9.0 vs. 12.8, t = 3.85, $F_{2,\ 95}$ = 22.76, η_p^2 = 0.13, P < .001), and at the 1-month follow-up (10.3 vs. 14.2, t = 3.24, $F_{2,\ 68}$ = 18.63, η_p^2 = 0.14, P = .002), 2-month follow-up (10.9 vs. 14.7, t = 2.51, $F_{2,68}$ = 10.94, η_p^2 = 0.09, P = .015), and 3-month follow-up (11.3 vs. 14.7, t = 2.61, $F_{2,68}$ = 5.85, η_p^2 = 0.03, P = .011) (Figure 3A). At the 4-month follow-up, no difference in ISI was found between the two groups (12.1 vs. 13.7, t = 0.95, $F_{2,68}$ = 6.19, η_p^2 = 0.07, P = .347). The linear mixed model analysis with a random slope revealed a significant group–time interaction effect in baseline to post-intervention (estimate = 0.76, t = 3.02, df = 96.00, marginal R^2 = 0.55, P = .003) and post-intervention to the 4-month follow-up (estimated = -0.72, t = −2.64, df = 70.25, marginal R^2 = 0.47, P = .010). However, when considering the baseline to 4-month follow-up period, the model was not significant (estimate = 0.32, t = 1.94, df = 79.61, marginal R^2 = 0.45, P = .056).

The Somzz group showed treatment effects on the ISI score from intervention week 2

(Cohen's d = -0.59, P = .018); the effect was sustained to the 4-month follow-up (Cohen's d = -0.62, P = .003) compared to the baseline ISI score (Figure 3B). The maximum treatment effect was shown at post-intervention (Cohen's d = −1.35, P < .001). The SHE also showed improvement at intervention week 2 (Cohen's d = -0.55, P = .004), week 4 (Cohen d = -0.71, P < .001), post-intervention (Cohen's d = -0.61, P = .002), and at the 4-month follow-up (Cohen's d = -0.35, P = .041) (Figure 3B).

Both Somzz and SHE groups showed improvements in ISI scores compared to baseline. In the Somzz group, the maximum improvement in ISI score was observed at post-intervention (Cohen's d = −1.35), and the intervention effect decreased gradually during the follow-up period (Figure 3B). The treatment effect was maintained at the 4-month follow-up in the Somzz group (Cohen's d = −0.62) (Figure 3B). However, there was no difference between the groups at that point (estimated = 1.16, t = 0.95, η_p^2 = 0.07, P = 0.347) (Figure 3A).

The number of individuals in remission at post-intervention was 22 (44.9%) in the Somzz group, while in the SHE, the corresponding number was 6 (12.2%) (risk ratio = 3.67; 95% CI: 1.32, 10.20, P = .013), and the risk difference was 0.33 (95% CI: 0.11-0.54, P = .002). Regarding the intervention response, there were 28 (57.1%) responders in the Somzz group and 11 (22.4%) responders in the SHE group (risk ratio = 2.55; 95% CI: 1.06, 6.12, P = 0.037), and the risk difference was 0.35 (95% CI: 0.10, 0.60, P = .006).

Sleep Diary Measures

The sleep diary measures were compared between the two groups with adjustment for baseline measures (Table 3). Significant group differences were observed in SE during treatment sessions 2–6 (Table 3, Figure 4). The Somzz group also had a shorter WASO, and higher satisfaction levels after sleep, compared to the SHE group after the intervention.

The linear mixed model analysis with a random slope revealed significant group–time interaction effects on SE in the treatment sessions (estimate =-1.00, t = −2.70, df =92.00, adjusted R^2 = 0.71, P =.008).

Table 3. Sleep diary outcomes compared between Somzz and SHE groups

	Somzz (n = 47)		SHE (n = 47)		ANCOVA Statistics
	Mean (SD)	*d*	Mean (SD)	*d*	
Nap (min)					
Baseline	23.7 (24.4)	N/A	22.5 (28.0)	N/A	
Session 2	22.2 (34.1)	-0.04	24.6 (33.2)	0.05	t=0.39, $F_{2,91}$=1.94, η_p^2 = 0.02, P = .697
Session 3	19.9 (26.5)	-0.16	26.5 (34.8)	0.09	t=1.13, $F_{2,91}$=3.86, η_p^2 = 0.03, P

					= .262
Session 4	20.7 (27.5)	-0.10	18.4 (22.7)	−0.12	t=-0.39, $F_{2,91}$=1.89, η_p^2 = 0.02, P = .697
Session 5	20.2 (29.1)	−0.12	11.4 (16.9)	−0.37*	t=-1.79, $F_{2,91}$=5.48, η_p^2 = 0.04, P = .076
Session 6	20.7 (27.7)	−0.10	17.5 (26.4)	−0.15	t=-0.52, $F_{2,91}$=3.62, η_p^2 = 0.04, P = .602
Total sleep time (min)					
Baseline	317.1 (74.5)	N/A	326.0 (100.3)	N/A	
Session 2	341.8 (94.2)	0.32	350.1 (117.5)	0.36	t=0.03, $F_{2,91}$=53.33, η_p^2 = 0.37, P = .974
Session 3	342.9 (95.3)	0.34	362.2 (106.3)	0.71	t=0.86, $F_{2,91}$=67.42, η_p^2 = 0.42, P = .394
Session 4	338.3 (86.7)	0.25	344.9 (99.4)	0.33	t=0.02, $F_{2,91}$=39.99, η_p^2 = 0.30, P = .987
Session 5	346.4 (82.6)	0.41	356.0 (98.7)	0.36	t=0.26, $F_{2,91}$=30.69, η_p^2 = 0.25, P = .796
Session 6	355.0 (86.3)	0.48*	347.1 (91.1)	0.33	t=-1.01, $F_{2,91}$=36.72, η_p^2 = 0.29, P = .315
Sleep efficiency (%)					
Baseline	65.7 (14.8)	N/A	64.9 (15.5)	N/A	
Session 2	74.5 (15.1)	0.82**	67.8 (16.9)	0.27	t=-2.87, $F_{2,91}$=71.04, η_p^2 = 0.42, P = .005
Session 3	75.2 (16.0)	0.80**	69.8 (15.8)	0.48	t=-2.19, $F_{2,91}$=60.55, η_p^2 = 0.39, P = .031
Session 4	76.4 (14.2)	0.91***	69.4 (16.8)	0.51	t=-3.08, $F_{2,91}$=71.92, η_p^2 = 0.42, P = .003
Session 5	76.6 (15.9)	1.06***	70.4 (16.2)	0.56	t=-2.76, $F_{2,91}$=82.57, η_p^2 = 0.46, P = .007
Session 6	78.3 (15.3)	1.16***	70.6 (16.7)	0.53	t=-3.32, $F_{2,91}$=69.87, η_p^2 = 0.41, P = .001
Sleep onset latency (min)					
Baseline	82.3 (62.0)	N/A	97.1 (78.1)	N/A	
Session 2	55.1 (43.4)	-0.57*	91.3 (72.2)	–0.11	t=3.14, $F_{2,91}$=55.60, η_p^2 = 0.34, P = .002
Session 3	52.5 (50.6)	-0.54*	86.9 (77.5)	−0.22	t=2.57, $F_{2,91}$=53.95, η_p^2 = 0.34, P = .012
Session 4	59.8 (78.2)	−0.44	88.1 (84.1)	−0.19	t=1.43, $F_{2,91}$=80.07, η_p^2 = 0.46, P = .156
Session 5	51.5 (76.9)	−0.57*	88.5 (86.5)	−0.17	t=2.17, $F_{2,91}$=71.29, η_p^2 = 0.42, P

Session 6	54.1 (78.0)	−0.62	80.3 (68.4)	−0.31	= .032 t=1.45, $F_{2,91}$=66.57, η_p^2 = 0.41, P = .150
Number of awakenings					
Baseline	1.5 (0.9)	N/A	1.8 (1.8)	N/A	
Session 2	1.5 (1.4)	-0.02	1.8 (2.8)	-0.002	t=-0.30, $F_{2,91}$=160.40, η_p^2 = 0.64, P = .764
Session 3	1.4 (1.1)	−0.14	1.7 (1.8)	−0.16	t=0.11, $F_{2,91}$=188.10, η_p^2 = 0.67, P = .912
Session 4	1.3 (1.2)	−0.30	1.6 (1.7)	−0.29	t=0.68, $F_{2,91}$=134.20, η_p^2 = 0.59, P = .496
Session 5	1.3 (1.1)	−0.28	1.6 (1.8)	−0.27	t=0.49, $F_{2,91}$=125.00, η_p^2 = 0.58, P = .625
Session 6	1.3 (1.1)	−0.30	1.6 (1.9)	−0.42	t=0.51, $F_{2,91}$=189.00, η_p^2 = 0.67, P = .612
Wake after sleep onset (min)					
Baseline	89.9 (70.1)	N/A	81.2 (49.0)	N/A	
Session 2	66.7 (64.8)	−0.41	75.0 (56.7)	−0.16	t=1.52, $F_{2,91}$=38.76, η_p^2 = 0.30, P = .132
Session 3	63.7 (64.4)	−0.45	70.3 (48.6)	−0.32	t=1.38, $F_{2,91}$=37.57, η_p^2 = 0.29, P = .172
Session 4	58.7 (56.1)	−0.55*	66.5 (47.2)	−0.44	t=1.59, $F_{2,91}$=37.18, η_p^2 = 0.29, P = .116
Session 5	62.1 (57.3)	−0.56*	63.6 (40.7)	−0.54	t=0.94, $F_{2,91}$=50.79, η_p^2 = 0.36, P = .349
Session 6	53.0 (52.4)	−0.79**	65.3 (41.1)	−0.44	t=2.55, $F_{2,91}$=51.81, η_p^2 = 0.36, P = .013
Refreshment after sleep					
Baseline	2.7 (0.5)	N/A	2.5 (0.6)	N/A	
Session 2	2.7 (0.6)	0.07	2.6 (0.7)	0.19	t=0.22, $F_{2,91}$=56.08, η_p^2 = 0.38, P = .825
Session 3	2.7 (0.6)	0.09	2.7 (0.7)	0.28	t=0.61, $F_{2,91}$=43.44, η_p^2 = 0.32, P = .544
Session 4	2.8 (0.5)	0.18	2.6 (0.6)	0.26	t=-0.10, $F_{2,91}$=52.83, η_p^2 = 0.36, P = .922
Session 5	2.8 (0.5)	0.38	2.7 (0.7)	0.26	t=-0.58, $F_{2,91}$=39.10, η_p^2 = 0.29, P = .562
Session 6	2.9 (0.5)	0.62*	2.7 (0.6)	0.27	t=-1.95, $F_{2,91}$=40.17, η_p^2 = 0.28, P = .054
Satisfaction after sleep					

Baseline	2.6 (0.5)	N/A	2.5 (0.6)	N/A	
Session 2	2.7 (0.6)	0.14	2.6 (0.7)	0.23	t=0.19, $F_{2,91}$=47.70, η_p^2 = 0.34, P = .848
Session 3	2.8 (0.6)	0.27	2.6 (0.6)	0.26	t=-0.36, $F_{2,91}$=38.00, η_p^2 = 0.29, P = .720
Session 4	2.8 (0.5)	0.35	2.6 (0.7)	0.26	t=-0.78, $F_{2,91}$=40.91 η_p^2 = 0.30, P = .437
Session 5	2.9 (0.6)	0.43*	2.7 (0.7)	0.36	t=-0.82, $F_{2,91}$=34.35, η_p^2 = 0.27, P = .416
Session 6	2.9 (0.6)	0.55**	2.7 (0.6)	0.26	t=-2.05, $F_{2,91}$=26.63, η_p^2 = 0.20, P = .043

*p < 0.05, **p < 0.01, ***p < 0.001.

Cohen's d represents the effect sizes of within-group comparisons (with baseline score as the reference) performed using paired t-tests.

t- and p-values are for group comparisons performed using ANCOVA.

SHE: sleep hygiene education.

Self-report Questionnaires

With adjustment for baseline severity, scores for self-report measures including the ESS, DBAS, PHQ, FSS, and SF-36 significantly differed between the Somzz and SHE groups after the intervention (Table 4). In particular, the differences in DBAS and FSS scores persisted at the 4-month follow-up (Table 4).

Table 4. Comparisons of self-report questionnaires between the Somzz and SHE groups

	Somzz (n = 49)		**SHE (n = 49)**		**ANCOVA Statistics**
	Mean (SD)	**d**	**Mean (SD)**	**d**	
ESS					
Baseline	6.7 (3.9)	N/A	6.4 (3.4)	N/A	
Post-intervention	4.3 (3.2)	-0.72**	6.6 (4.3)	0.01	t=3.82, $F_{2,94}$=32.38, η_p^2 = 0.22, P < .001
4-month follow-up	6.1 (3.7)	-0.51	5.8 (3.6)	−0.17	t=0.84, $F_{2,67}$=26.10, η_p^2 = 0.28, P = .406
DBAS					
Baseline	107.3 (21.2)	N/A	99.8 (25.8)	N/A	
Post-intervention	74.0 (33.7)	−1.01***	98.4 (20.3)	−0.10	t=5.32, $F_{2,94}$=21.55, η_p^2 = 0.10, P < .001
4-month follow-	80.2 (28.5)	−1.06***	94.9	−0.17	t=3.35, $F_{2,67}$=12.97, η_p^2 = 0.13, P

up			(22.8)		= .001
PHQ-9					
Baseline	9.4 (4.9)	N/A	10.4 (5.0)	N/A	
Post-intervention	6.6 (5.2)	−0.67**	8.7 (3.9)	−0.36	t=2.11, $F_{2,94}$=29.64, η_p^2 = 0.21, P = .038
4-month follow-up	6.8 (4.6)	−0.62*	8.6 (4.8)	−0.34	t=1.21, $F_{2,67}$=9.90, η_p^2 = 0.11, P = .233
GAD-7					
Baseline	6.6 (4.5)	N/A	7.6 (4.6)	N/A	
Post-intervention	4.9 (4.5)	−0.44	6.7 (3.7)	−0.27	t=1.69, $F_{2,94}$=35.36, η_p^2 = 0.25, P = .095
4-month follow-up	5.4 (4.6)	−0.28	6.3 (4.5)	−0.38	t=0.35, $F_{2,67}$=6.96, η_p^2 = 0.09, P = .730
FSS					
Baseline	39.8 (12.8)	N/A	44.8 (8.9)	N/A	
Post-intervention	33.6 (13.8)	−0.71*	44.5 (9.0)	-0.13	t=3.88, $F_{2,94}$=87.91, η_p^2 = 0.41, P < .001
4-month follow-up	34.5 (12.6)	−0.60	42.1(10.0)	−0.39	t=2.04, $F_{2,67}$=41.62, η_p^2 = 0.33, P = .046
SF-36					
Baseline	65.4 (16.9)	N/A	62.5 (15.2)	N/A	
Post-intervention	72.4 (16.8)	0.58*	63.5 (14.1)	0.08	t=-3.13, $F_{2,94}$=54.20, η_p^2 = 0.33, P = .002
4-month follow-up	68.9 (20.8)	0.21	66.0 (14.3)	0.19	t=-0.59, $F_{2,67}$=12.07, η_p^2 = 0.15, P =0.556
EQTOTAL					
Baseline	7.6 (2.0)	N/A	8.2 (2.0)	N/A	
Post-intervention	7.3 (2.3)	−0.19	7.8 (1.9)	−0.21	t=0.40, $F_{2,94}$=44.30, η_p^2 = 0.31, P = .688
4-month follow-up	7.2 (1.9)	-0.19	7.4 (2.6)	−0.22	t=0.02, $F_{2,67}$=4.75, η_p^2 = 0.06, P = .981

*P < 0.05, **P < 0.01, ***P < 0.001.

d: Cohen's d represents the effect sizes of within-group comparisons (with baseline score as the reference) performed using paired t-tests.

t- and p-values are for group comparisons performed using ANCOVA.

DBAS, Dysfunctional Beliefs and Attitudes About Sleep Scale; ESS, Epworth Sleepiness Scale; EQ-5D-5L, five-level EuroQol; FSS, Fatigue Severity Scale; GAD-7, Generalized Anxiety Disorder Assessment-7; PHQ, Patient Health Questionnaire-9; SF-36, Short Form Health Survey-36

Note: in the Somzz and SHE groups, 34 of 46 and 37 of 46 participants, respectively, consented to take part in the 4-month follow-up.

The linear mixed model analysis with a random slope revealed a significant group–time interaction effect on ESS from baseline to post-intervention (estimate: 0.59, t = 3.48, df =90.90, marginal R^2 = 0.51, P < .001), post-intervention to the four-month follow-up (estimate: -0.49, t = -2.58, df = 300.56, marginal R^2 = 0.43, P = 0.010), and baseline to the 4-month follow-up period (estimate: 0.28, t = 3.35, df = 79.11, marginal R^2 = 0.49, P = 0.001).

Concurrent Medications

Medications related to sleep were used by 9 participants in the Somzz group and 9 participants in the SHE group (X^2 = 0, P = 1.000). Specifically, mirtazapine was used by one participant in the Somzz group and none in the SHE group, and benzodiazepines were used by four participants in the Somzz group and seven participants in the SHE group. Z-drugs were used by five participants in each group. Antihistamines were used by one participant in the Somzz group and six participants in the SHE group.

Factors associated with remission and response in the Somzz group

Binary regression analysis of remission in the Somzz group revealed that higher DBAS and non-drinking were associated with non-remission (DBAS: estimate = 0.11, z = 2.05, P = .041; drink: estimate = 4.39, z = 2.25, P = .025). In addition, the binary regression model of responders indicated that a younger age (estimate = 0.28, z = 2.07, P = .039), absence of medical history (estimate = −8.01, z = −2.01, P = .045), and shorter TIB (estimate = 0.03, z = 2.11, P = .035) at baseline were significantly associated with the treatment response in the Somzz group.

Discussion

Principal Findings

In the current study, we found that the Somzz group showed significantly better improvements in ISI, ESS, SE, WASO, and satisfaction after sleep at post-intervention compared to the SHE group. The effect on ISI persisted at the four-month follow-up in the Somzz group. In addition, the Somzz group exhibited lower scores in ESS, DBAS, PHQ, FSS, and SF-36 at post-intervention than the SHE group. Among the various methods for delivering digital or internet-based CBTi, to our knowledge, this study is the first to investigate effect of mobile application-based

CBTi on sleep, as well as mental health, with a multi-center RCT design using active control. The Somzz group achieved a favorable follow-up rate of 12.2% suggesting that Somzz is an efficacious insomnia treatment with high sustainability of usage.

The Somzz group demonstrated a decrease in insomnia severity, as measured by the ISI, starting from the two week after intervention with gradual decrease until post-intervention visit. The treatment effect was sustained until the four-month follow-up, with a moderate to large effect size observed from the second week of intervention to the four-month follow-up, compared to the baseline ISI score. In the Somzz group, basic education was implemented in the first week, followed by stimulus control and sleep restriction in the second week. It appears that stimulus control and sleep restriction play more critical roles in improving insomnia with more decrease in ISI at the week 2. Furthermore, CBTi can initially reduce sleep time, resulting in a possible aggravation of insomnia symptoms, which improve with time [29]. The active comparator app of SHE, on the other hand, only includes SHE and a sleep diary module. The SHE group also presented with reduced insomnia severity compared to the baseline from intervention week 3 to post-intervention, with a smaller effect size compared to that of the Somzz group. The findings indicate that SHE has some effect, but not sufficient to invoke insomnia improvement [10, 30, 31], which can be reinforced by other components of CBTi as indicated by a larger effect size in the Somzz group. Moreover, the impact of SHE might have been influenced by the Hawthorne effect [32] and the natural progression of insomnia [33]. Furthermore, participants with mild insomnia (ISI score of 8 or higher and less than 15) may have partially benefited from SHE. The larger effect size of the ISI decrease observed in the Somzz group indicates a superior treatment effect on insomnia severity compared to the SHE group.

Group differences in ISI was noted post-intervention while no significant differences in ISI were observed between the Somzz and SHE groups at week 1, 2, and 4. Cognitive therapy, TIB restriction and relapse prevention were the components of the Somzz from week 4 to post-intervention. Assuming the "additive model" posited by a component network meta-analysis [18], where the combination therapy effect is viewed as a simple sum of effects without interaction, it is presumed that cognitive therapy and TIB restriction may be important factors in improving subjective sleep quality in this study, which aligns with the results of the meta-analysis. Given the limitations of cognitive therapy provided in MCBTi compared to face-to-face CBTi, it is believed that the significant effect may be due to the consistent TIB restriction over the six weeks in this study. Additionally, significant

differences in SE and SOL between the two groups were observed at session 2. This suggests that combination of TIB restriction and stimulus control may have significant effects on SE and SOL, which is also consistent results with the meta-analysis [18]. However, the conclusions should be interpreted meticulously due to the possible complex interactions among the components of CBTi. Further component network meta-analyses encompassing more MCBTi studies would be helpful for more accurate conclusions.

Although insomnia severity remained significantly reduced compared to baseline at the four-month follow-up, it showed an increasing trend after intervention in both the Somzz and SHE groups. Group differences in ISI scores were observed at post-intervention and at the one-, two-, and three-month follow-ups, but these differences disappeared at the four-month follow-up. The lack of difference between the two groups was also observed in an earlier study, in which group differences in ISI were observed at the three-month follow-up, but not at the six-month follow-up [10]. These results suggest that additional booster sessions around three months after intervention may be beneficial in sustaining the better treatment effect of MCBTi. However, the ISI score decrease was relatively maintained in the CBTi group in the previous study [10]. An internet-based CBTi program also showed sustained treatment effects on ISI, with a notable effect of continuously decreasing ISI scores observed at the one-year follow-up. [30]. That study did not include a relaxation session; instead, the focus was on other components of CBTi, such as sleep restriction, stimulus control, cognitive restructuring, and sleep hygiene in six sessions [30]. This suggests that these components, aside from relaxation therapy, play a critical role in maintaining long-term treatment effects. If we had added a session to reinforce the cognitive component [18], thus providing seven sessions similar to a previous study on CBTi [10], the effects of CBTi may have been better sustained. Additionally, our active comparator application also included SHE, providing the same content as Somzz. The education had some treatment effect on insomnia severity in the SHE group, which may have obscured the differences in ISI scores between the two groups at the four-month follow-up. In addition, the waxing/waning nature of insomnia disorder may have contributed to a slight insomnia improvement at the four-month follow-up in the SHE group.

Furthermore, the effectiveness of the Somzz application could have been confounded by the natural progression of insomnia and the Hawthorne effect. A population-based study reported cumulative remission rates for insomnia disorder among good sleepers of 13.4% after 1 month and 14.2% after 3 months [33], compared with our rate of 51.16% at 6 week post-intervention. However, because the group classification criteria differed between our study and the previous study,

the results should be compared with caution. Another study investigating the natural history of insomnia over 3 years reported that 74% and 46% of the participants had persistent insomnia for 1 and 3 years, respectively [34]. Although the follow-up period in our study was shorter, and considering that insomnia symptoms may wax and wane, it can be inferred that insomnia disorder is able to persist without treatment. Parallel RCTs including a third group with no intervention would be optimal for excluding any possible impact of the natural progression of insomnia or the Hawthorne effect on the outcomes of Somzz.

Our study found that the Somzz group had better outcomes in SE, WASO, and satisfaction related to sleep based on sleep diary measures compared to the SHE, which aligns with previous studies [10, 30]. Daytime sleepiness measured by ESS was also improved in the Somzz group, with a significant group difference compared to the SHE at post-intervention. The Somzz group also showed treatment effects on depression, and quality of life at post-intervention, again consistent with previous studies [35-37]. Although the scores of PHQ-9 and SF were lower than the baseline at the four-month follow-up, the scores showed a worsening trend in the Somzz group from post-intervention to the four-month follow-up. This trend may be correlated with increased insomnia severity after the intervention, and the correlation can be attributed to the well-established bi-directional interaction of insomnia with depression and quality of life [37]. Similar results were noted in a web-based CBTi study, which showed a treatment effect on depression, and suicidal ideation at week 6, but not at the six-month follow-up when measured by the Psychiatric Symptom Frequency scale [35].

Additionally, the Somzz group had significantly lower scores on the DBAS compared to the SHE group, and this improvement was maintained at the four-month follow-up. Moreover, higher DBAS scores at baseline were a significant predictor of non-remission. Dysfunctional beliefs about sleep are a crucial factor in perpetuating insomnia, as they can provoke a fear of losing control over sleep, worry about the negative consequences of insomnia, and feelings of hopelessness and anxiety [23]. This, in turn, could potentially prolong insomnia symptoms. The results suggest that targeting dysfunctional beliefs may be crucial in effectively treating insomnia with CBTi. Furthermore, a shorter total TIB at baseline was a significant predictor of remission, highlighting the importance of sleep restriction through TIB prescription as a crucial intervention for treating insomnia.

Our study had a drop-out attrition rate of 12.2% (6 of 49) post-intervention among randomized participants in the Somzz group. This shows relatively good compliance

compared to other delivery forms of digital CBTi, with an attrition rate of 21.6% ± 16.9% [13] and face-to-face CBTi with a drop-out rate of 14%–40% [38]. This suggests that the use of MCBTi has the potential to decrease the prevalence of insomnia through high compliance with treatment.

Limitations

There are several limitations to our study. First, we conducted follow-up for four months (18 weeks), which is a relatively short time to infer the long-term effects of Somzz. Second, the impact of Somzz might have been modulated by the Hawthorne effect or the natural progression of insomnia. However, we compared Somzz with SHE in an effort to minimize any influence of such effects. A parallel RCT including a third group with no intervention, and with a longer follow-up period and larger sample size, is needed to validate our results. Finally, we only used subjective measures of sleep in our study. However, subjective sleep measures including sleep diaries are known to be reliable and valid measures of sleep and correlate with objective measures of sleep [39].

Conclusions

Our study provides strong evidence that MCBTi can effectively treat insomnia by improving sleep-related variables, depression, and social functioning. MCBTi provides a highly accessible, time-efficient treatment option with high compliance that is suitable for industrious society.

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Conflicts of Interest

None declared.

Abbreviations

CBTi: cognitive behavioral therapy for insomnia
DBAS: Dysfunctional Beliefs and Attitudes About Sleep Scale
EQ-5D-5L: five-level EuroQol
FSS: Fatigue Severity Scale
GAD-7: Generalized Anxiety Disorder Assessment-7

ICSD-3: International Classification of Sleep Disorders, Third Edition
ISI: Insomnia Severity Index
MCBTi: mobile-application-based digital CBTi
NWAK: number of awakenings during sleep
PHQ-9: Patient Health Questionnaire-9
Refreshment: refreshment after waking up
RCT: randomized controlled trial
Satisfaction: satisfaction with sleep
SE: sleep efficiency
SF-36: Short Form Health Survey-36
SHE: sleep hygiene education
SOL: sleep onset latency
TIB: time in bed
TST: total sleep time
WASO: wake after sleep onset

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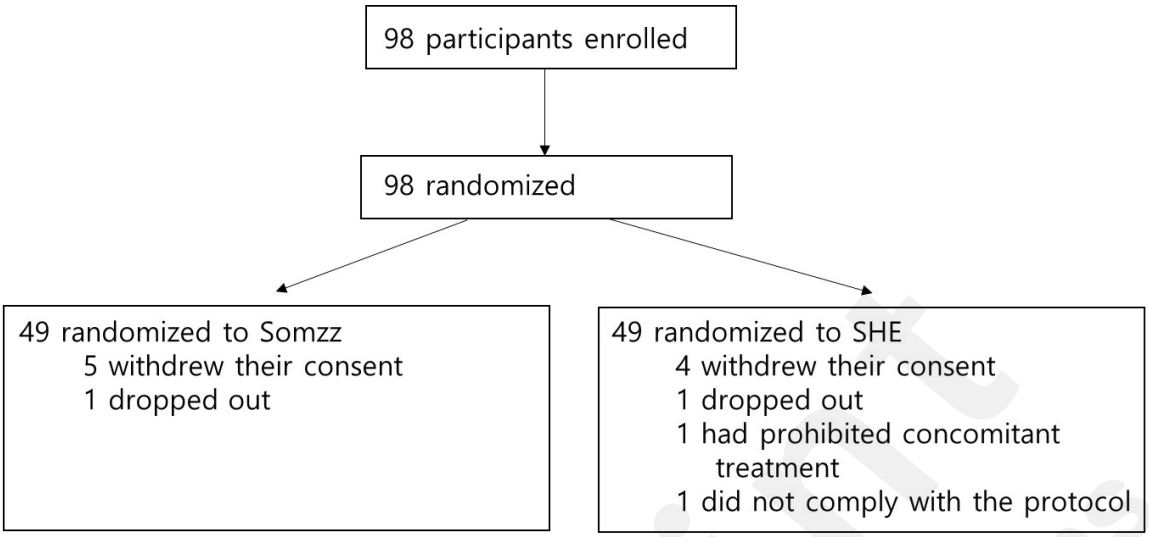


Figure 1. Flow chart of participant enrollment.

Figure 2. Example screenshots of the Somzz

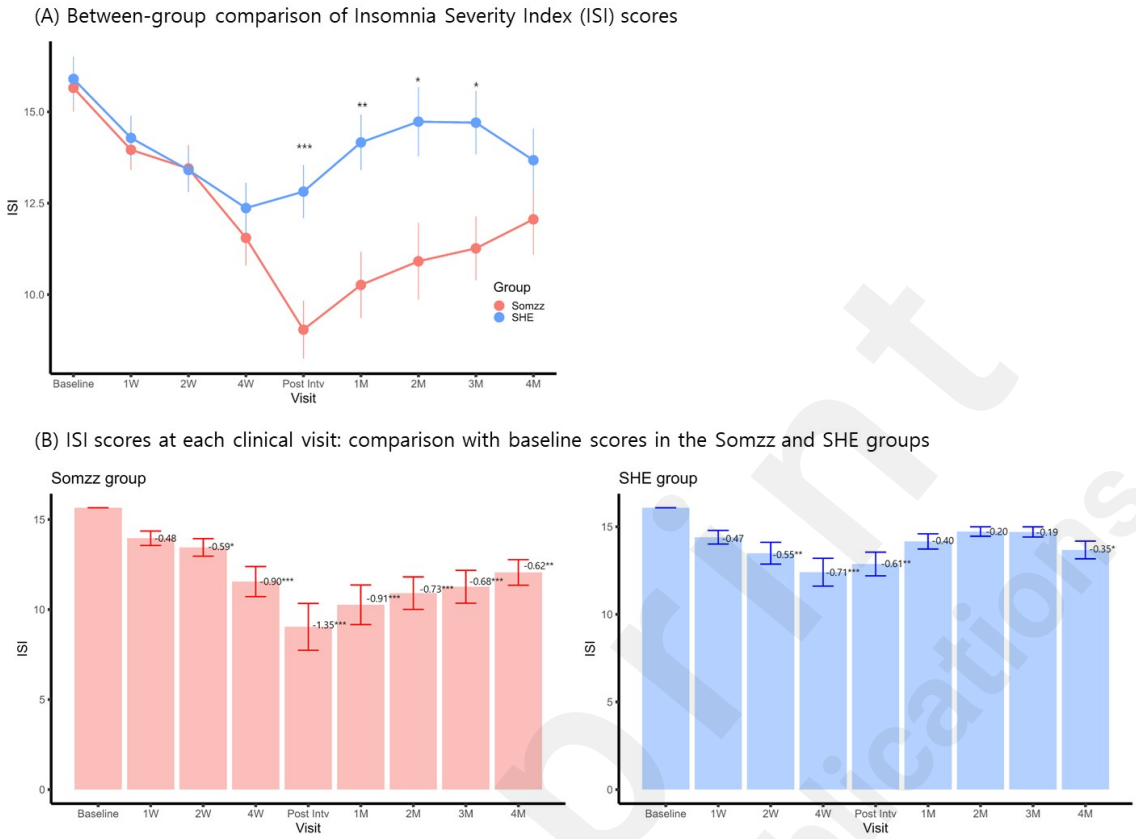


Figure 3. Insomnia Severity Index (ISI) scores at each timepoint.
(A) Between-group comparison of ISI scores at each timepoint (ANCOVA).
(B) Within-group analysis of ISI scores at each clinical visit compared with baseline scores (paired t-test). The numbers on bar graphs are Cohen's *d* values. Error bars are also presented. *p < 0.05, **p < 0.01, ***p < 0.001.
SHE, sleep hygiene education; W, weeks after baseline; Post intv, post-intervention (6–9 weeks after baseline), M, months post-intervention.
Note: in the Somzz and SHE groups, 34 and 37 participants, respectively, consented to take part in the 4-month follow-up.

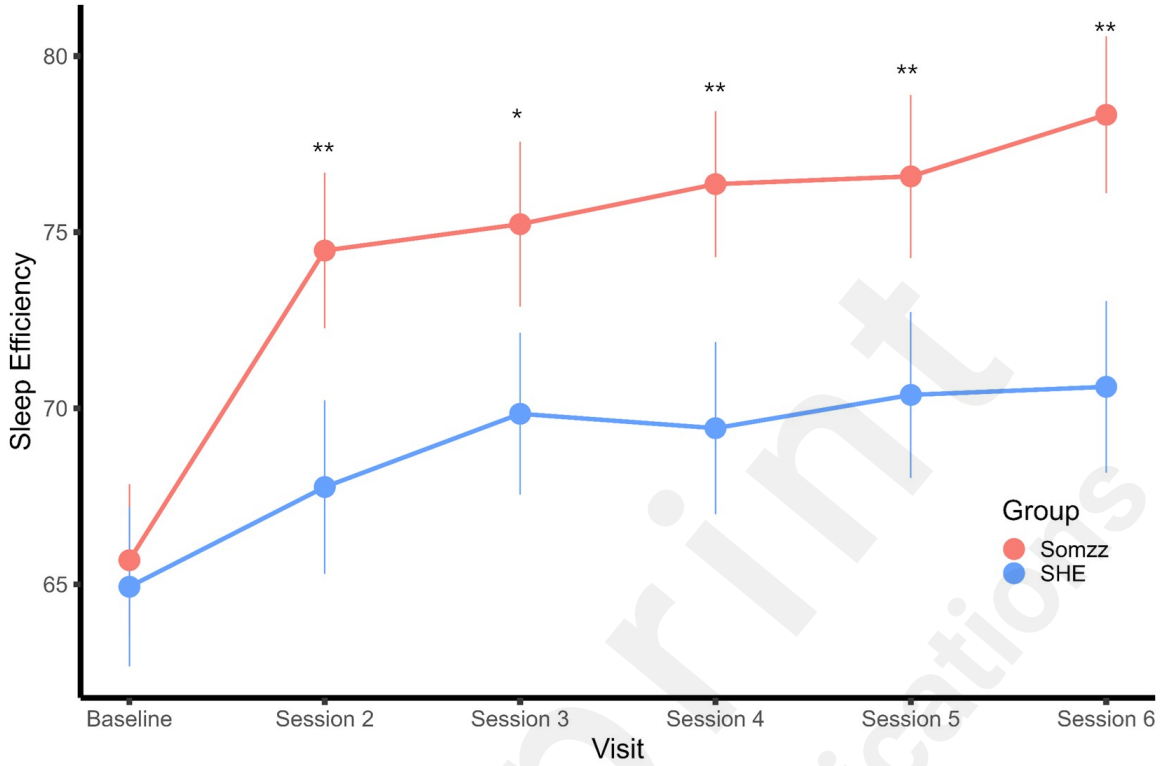
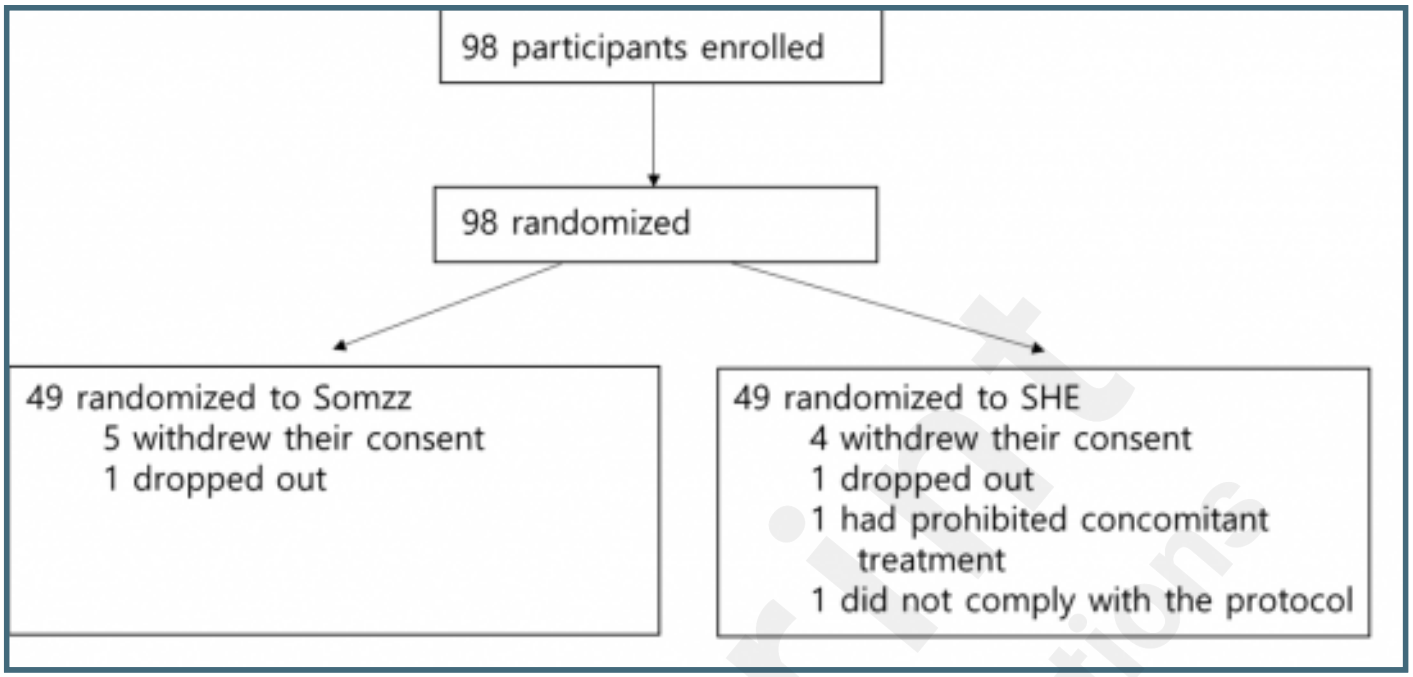


Figure 4. Comparison of sleep efficiency on sleep diary between the Somzz and SHE groups. Group comparison of ISI scores at each timepoint using ANCOVA adjusting for the baseline score.
*p < 0.05, **p < 0.01, ***p < 0.001.
SHE, sleep hygiene education.

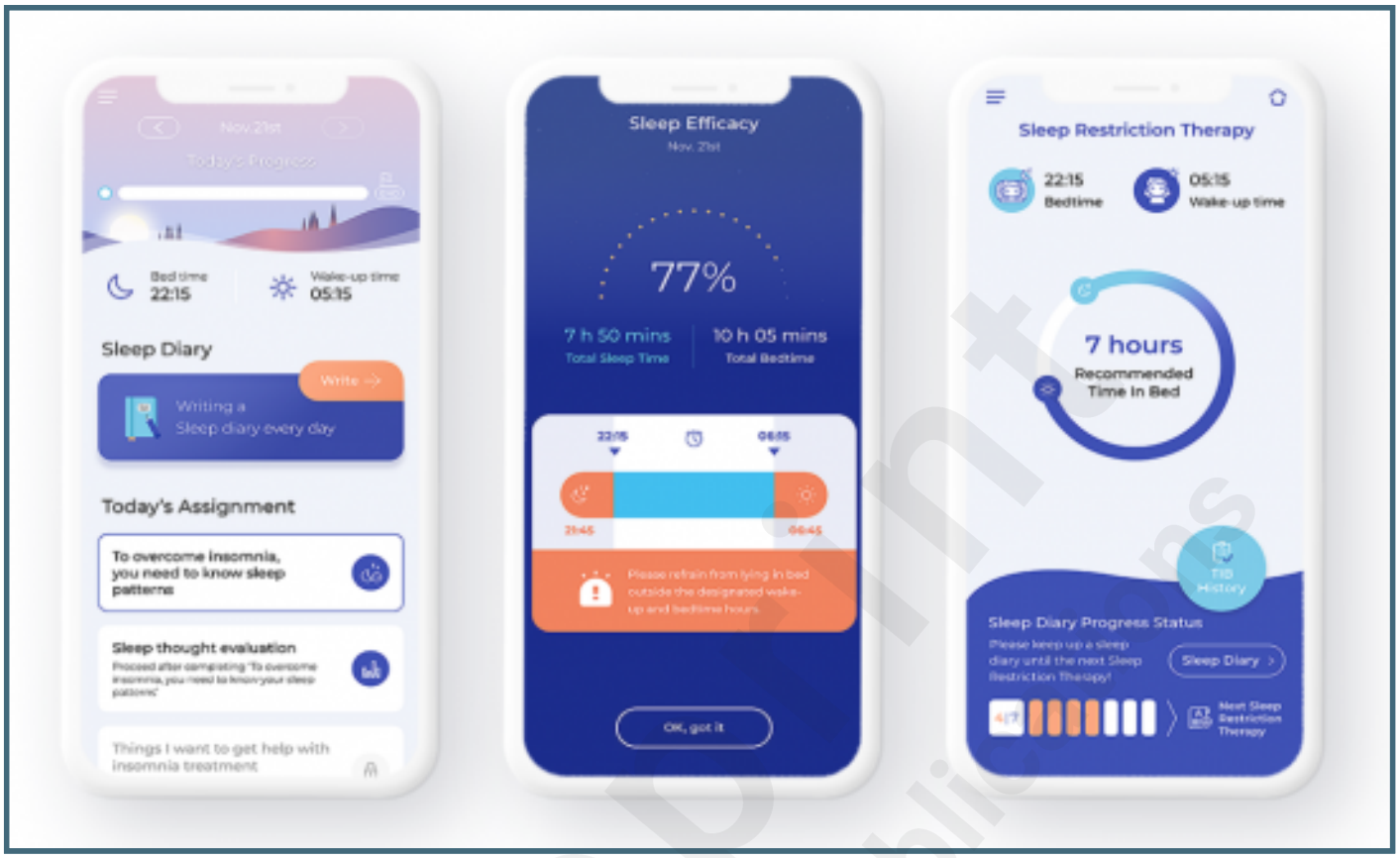
Supplementary Files

Figures

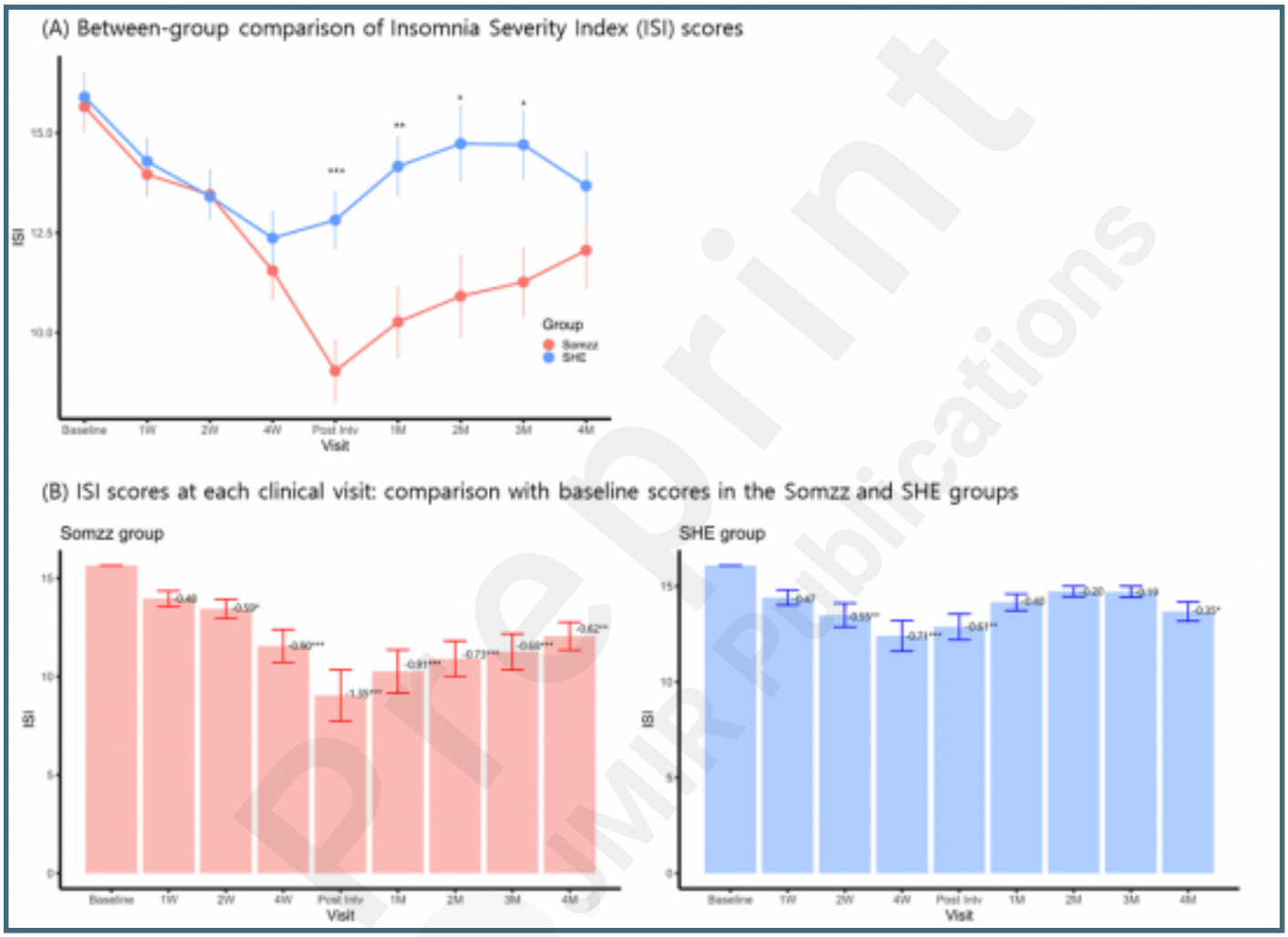
Flow chart of participant enrollment.



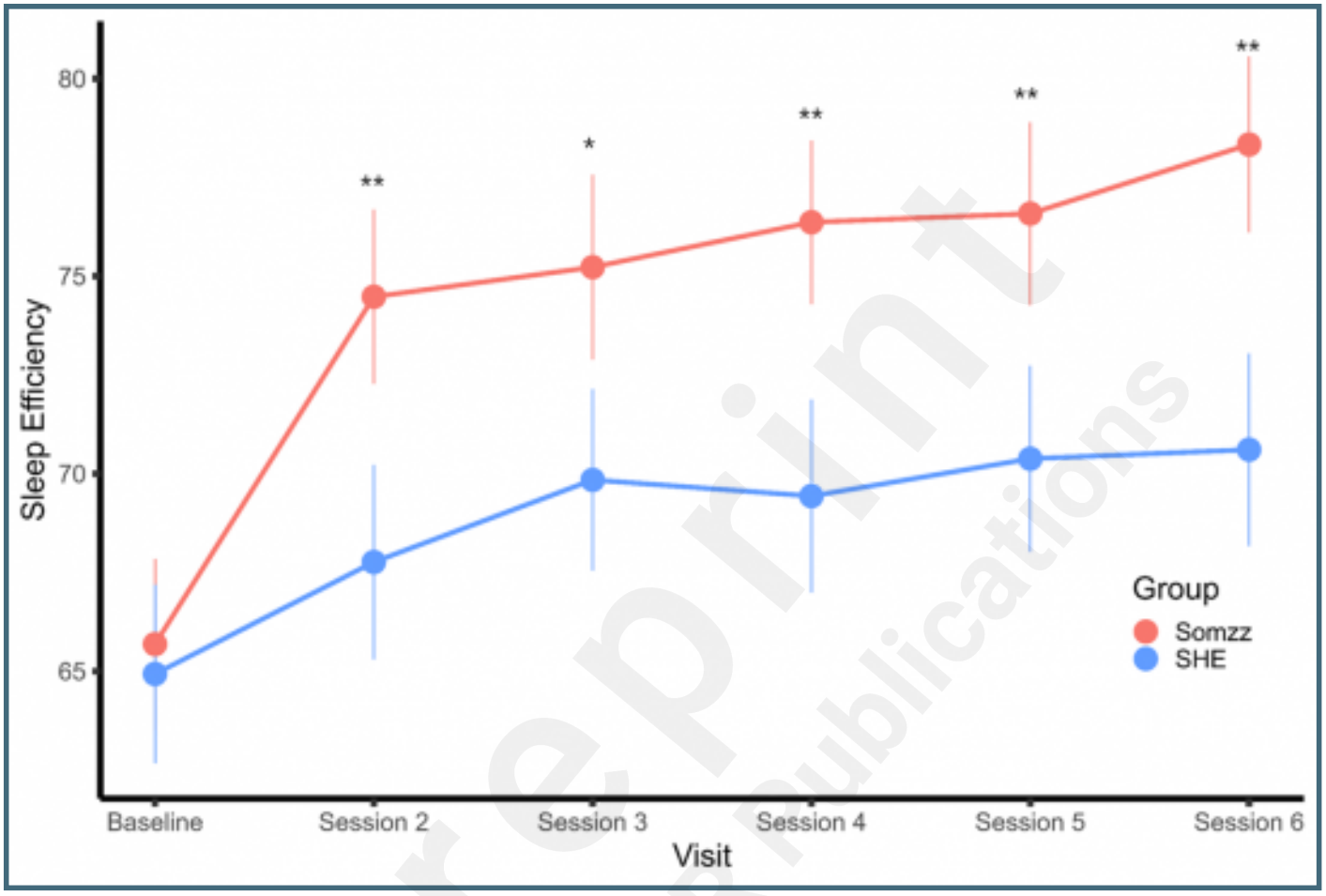
Example screenshots of the Somzz.



Insomnia Severity Index (ISI) scores at each timepoint. (A) Between-group comparison of ISI scores at each timepoint (ANCOVA). (B) Within-group analysis of ISI scores at each clinical visit compared with baseline scores (paired t-test). The numbers on bar graphs are Cohen's d values. Error bars are also presented. *p < 0.05, **p < 0.01, ***p < 0.001. SHE, sleep hygiene education; W, weeks after baseline; Post intv, post-intervention (6–9 weeks after baseline), M, months post-intervention. Note: in the Somzz and SHE groups, 34 and 37 participants, respectively, consented to take part in the 4-month follow-up.



Comparison of sleep efficiency on sleep diary between the Somzz and SHE groups. Group comparison of ISI scores at each timepoint using ANCOVA adjusting for the baseline score. *p < 0.05, **p < 0.01, ***p < 0.001. SHE, sleep hygiene education.



CONSORT (or other) checklists

This is the CONSORT checklist.
URL: http://asset.jmir.pub/assets/e928eeb08d29e4be6372e5c63447a1ed.pdf

TIDieR checklist.
URL: http://asset.jmir.pub/assets/ca4a4d10886c8965c9109e972dd5e3a3.pdf