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EMERGING TECHNOLOGIES

Cognitive Behavioral Therapy Using a Mobile Application Synchronizable With Wearable Devices for Insomnia Treatment: A Pilot Study

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Study Objectives: The use of telemedicine with a mobile application (MA) and a wearable device (WD) for the management of sleep disorders has recently received considerable attention. We designed an MA synchronizable with a WD for insomnia treatment. Our pilot study determined the efficacy of simplified group cognitive behavioral therapy for insomnia (CBT-I) delivered using our MA and assessed participant adherence to and satisfaction with the device.

Methods: The efficacy of the CBT-I using MA (CBT-I-MA) was assessed by comparing sleep variables (sleep efficiency [SE], Insomnia Severity Index [ISI], and Pittsburgh Sleep Quality Inventory [PSQI] scores) before and after a 4-week treatment protocol in 19 patients with insomnia disorder patients. SE was assessed using a sleep diary, actigraphy, and the PSQI.

Results: The intervention significantly improved all three measures of SE ($P < .05$), and the response rate to treatment was high (94.7%). Total ISI and PSQI scores and sleep latency, as measured by the sleep diary, improved significantly. Participants showed relatively good adherence to our MA, and sleep diary entries were made on 24.3 ± 3.8 of 28 days. Moreover, 94.7% of the participants reported that our MA was effective for treating insomnia.

Conclusions: Our pilot study suggested the clinical usefulness of a CBT-I-MA. We expect that our findings will lead to further development and replication studies of CBT-I-MA.

Keywords: cognitive behavioral therapy, insomnia, mobile application, telemedicine, wearable device

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INTRODUCTION

Cognitive behavioral therapy for insomnia (CBT-I) is the first-line treatment for chronic insomnia; however, the intervention requires an experienced therapist and is time consuming and expensive. For these reasons, self-help interventions have been widely investigated, and a recent meta-analysis found that therapist-guided online CBT-I was as effective as face-to-face treatment.[1] Although Internet-based self-help CBT-I is more convenient than personal visits, patients tend to experience decreased motivation to participate, attrition, and poor adherence under less interaction or communication with therapists.[1,2]

The increased use of mobile devices (eg, a smartphone or wearable device [WD]) that monitor activity and sleep, such as Fitbit trackers, is expected to expand the clinical applications of telemedicine for sleep disorders.[3] The combined use of a WD with a mobile application (MA) for CBT-I could facilitate objective sleep tracking and maintenance of a subjective sleep diary; it may thereby improve the accuracy and convenience of monitoring sleep quality. Furthermore, the highly portable nature of smartphones may increase adherence to CBT-I and resolve shortcomings of the Internet-based self-help CBT-I.[4] Thus, we developed an MA synchronizable with a WD for the treatment of insomnia.

The area of mobile health (mHealth) utilizing a MA has been studied extensively, particularly in the field of non-sleep medical diseases such as pulmonary disease and cardiac disease.[5,6] Although a number of such studies made successful cases, the area of sleep medicine has not been sufficiently studied so far. Several MAs have been developed to monitor sleep. For example, the CBT-I Coach,[4] Sleepio,[7] Win-Win aSleep,[8] and SleepRate[9] applications were developed to track sleep or facilitate CBT-I. Previous pilot studies found that CBT-I Coach improved sleep in 4 patients with cannabis-use disorder[10]; when used as an adjunct to CBT-I, the MA improved adherence and sleep outcomes.[11] However, to our knowledge, no previous study has investigated the efficacy of CBT-I using MA (CBT-I-MA) for the treatment of chronic insomnia.

Our pilot study aimed to (1) evaluate the efficacy of the simplified group CBT-I-MA in patients with insomnia disorder and (2) determine participant adherence to and satisfaction with our MA. As a subanalysis, we compared the efficacy and adherence/satisfaction between the group using a WD and the group not using a WD.

Table 1—Major components and contents of our mobile application synchronizable with wearable devices for insomnia treatment.

Component	Contents	Purpose, Effect, and Features
Sleep diary	• Daily mobile sleep diary o TTB, TOB, sleep latency, duration of being out of bed, TST, number of awakenings, wake time after sleep onset, time of final waking, napping o Use of hypnotic medications and caffeine	• Daily sleep diary is uploaded to the therapists' web server • Therapists can check sleep data and provide advice without requiring a face-to-face visit • Compute and display the average sleep diary data for the previous 7 days
Sleep and activity data from the wearable device	• Objective sleep and activity data of the Fitbit tracker is synchronized into the Fitbit app and our MA	• Compute and display the average sleep data for the previous 7 days in our MA
Sleep prescription	• Prescription of the TIB (sleep window)	• Facilitate the calculation and prescription of the TIB o Range of the sleep window set by therapist, and the SE simulated based on the current TST o TTB (or TOB) is automatically calculated upon entering the SE goal and TOB (or TTB)
Educational video clips	• About sleep and insomnia, sleep hygiene, and treatment of insomnia	• Education from experienced and specialized doctors
Sleep questionnaire self-evaluation	• Insomnia Severity Index • Epworth Sleepiness Scale	• Helps users and therapists to easily evaluate and see progress regarding insomnia and sleepiness
Instructions and list of suggestions for good sleep	• Suggested to-do list when sleepy before the prescribed TTB • Suggested to-do list in case of insomnia during TIB • Suggested to-do list when it is difficult to get up at the prescribed TOB • Caffeine use and reduction thereof • Checking the sleep environment	• Improve the sleep hygiene • Technical and practical tips for SRT and SCT
Ease your mind and body	• Respiration exercise • Muscle relaxation • Strategic worrying	• Reduce arousal and muscle tension • Reduce worry while in bed

MA = mobile application, SCT = stimulus control therapy, SE = sleep efficiency, SRT = sleep restriction therapy, TIB = time in bed, TOB = time out of bed, TST = total sleep time, TTB = time to bed.

METHODS

Development of the MA

Our MA was developed by board-certified psychiatrists specializing in sleep medicine in collaboration with an information technology company (EIP, Incheon, Republic of Korea). Because more than 90% of Korean smartphone users used the Android operating system in 2013, which is when we designed our MA, we developed only an Android version. The device was developed for research purposes and has not been released to the public. Our MA was made for an adjunct to face-to-face CBT-I; however, after acquiring a basic understanding of CBT-I and the MA, it can be used as a self-help tool with occasional therapist checkups. Moreover, the MA can be used with or without a WD depending on the user's preference.

The characteristics of our MA are shown in **Table 1**. The core treatments were sleep restriction therapy (SRT) and stimulus control therapy (SCT).[12,13] Our MA used a consensus sleep diary.[14] When the sleep diary was completed for the previous night, the total sleep time (TST) and sleep efficiency (SE) were automatically calculated. The sleep prescription menu calculated and displayed the mean sleep values (ie, average TST and SE) of the subjective sleep diary for the previous 7 days and facilitated the calculation of the recommended time in bed (TIB) for SRT. The recommended TIB was calculated according to the mean TST and SE of the previous week and the target SE for SRT. The WD used was the Fitbit Charge HR (Fitbit, San Francisco, California, United States), and the users were able to synchronize their sleep records with the Fitbit MA using Bluetooth connectivity. The sleep records were downloaded from the Fitbit web server and synchronized with our MA. The information from our MA was uploaded to the therapists' web server that was created for this research project.

Participants

The inclusion and exclusion criteria of the research participants are shown in **Table 2**. All participants met the diagnostic criteria of insomnia disorder based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5).[15] Board-certified psychiatrists specializing in sleep medicine evaluated the eligibility of participants using a semistructured interview based on the Structured Clinical Interview for DSM-5.[15,16] We obtained written informed consent from all participants, and the study was approved by the Gil Medical Center Institutional Review Board.

For the subanalysis, the participants were randomized into two groups (WD users [n = 10] and WD nonusers [n = 9]) to compare the treatment efficacy between two groups. The unblinded simple randomization[17] was performed using a Microsoft Excel

Table 2—Inclusion and exclusion criteria of this study.

Inclusion Criteria	• Aged 18–65 y • A history of illness lasting at least 3 mo • Meeting the diagnostic criteria of insomnia disorder in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders o Predominant complaint of dissatisfaction with sleep quantity or quality, associated with one (or more) of the following symptoms ▪ Difficulty initiating sleep ▪ Difficulty maintaining sleep ▪ Early-morning awakening with inability to return to sleep o Sleep disturbance causes clinically significant distress or impairment in functioning o Sleep difficulty occurs at least 3 nights/wk o Sleep difficulty occurs despite adequate opportunity for sleep o Insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder o Insomnia is not attributable to the physiological effects of a substance o Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia • Not receiving cognitive behavioral therapy for insomnia during the previous month • Having a smartphone running the Android operating system and being familiar with the use of an mobile application
Exclusion Criteria	• Diagnosis of psychiatric disorders such as schizophrenia spectrum disorders, bipolar disorders, alcohol or substance-use disorders, personality disorders, intellectual disability, or major neurocognitive disorders in a clinical interview • Serious medical, neurological, or psychiatric illness that may affect participation in this research • Inability to wear a wearable device and an actigraph on the wrist due to physical handicap or other reasons • Changing the psychotropic medication (antidepressant or benzodiazepine) or its dosage during the previous 2 mo

Table 3—Summary of the protocol of simplified group cognitive behavioral therapy for insomnia using our mobile application.

Week	Session Duration	Main Topics	Detailed Contents	Scales and Assigned Homework
Baseline (visit)	2 h	Concept of insomnia, and CBT-I-MA and our MA	• Introduction from the treatment team members and treatment outline • Education and watching a video about sleep, insomnia, and CBT-I-MA • Usage and setup instructions for the MA and WD	• Scale assessments (baseline) o ISI, PSQI, DBAS, ESS, BDI, and BAI • Instruction for the first week o Keep the usual sleep/wake schedule • Homework assignment o Sleep diary on MA (whole duration) o Wearing an actigraph (for first week) o Wearing a WD (only in the WD group, for the entire study)
Week 1 (telephone)	10 min	TIB prescription	• Review device usage and sleep diary § • Evaluate the average SE, TST, and TIB § • TIB prescription §	• Homework o Adhere to TIB § o Do not nap
Week 2 (visit)	1.5 h	SRT and SCT	• Review the sleep hygiene • Education about the SRT and SCT • Video watching and education about the respiration exercise and muscle relaxation	• Scale assessment o PSQI • Homework o Never go to bed during a non-TIB period o Get out of bed if not falling asleep
Week 3 (telephone)	10 min	TIB prescription	• Check compliance with SRT and SCT instructions	• Homework o Actigraphy (for fourth week)
Week 4 (visit)	1 h	Relapse prevention	• Review the treatment course and the improvement • How to prevent insomnia using our MA	• Scale assessments o ISI, PSQI, DBAS, ESS, BDI, BAI o Satisfaction with our MA

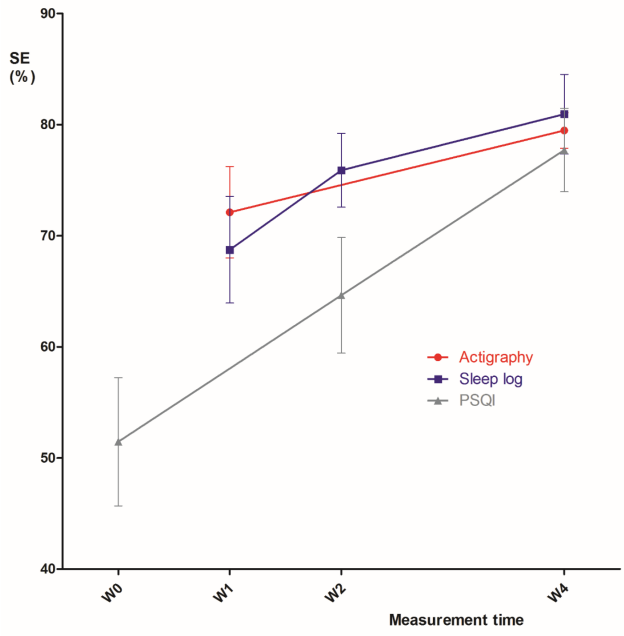
§ = every session from now on. BAI = Beck Anxiety Inventory, BDI = Beck Depression Inventory, CBT-I-MA = cognitive behavior therapy for insomnia using our mobile application, DBAS = Dysfunctional Beliefs and Attitudes about Sleep, ESS = Epworth Sleepiness Scale, ISI = Insomnia Severity Index, MA = mobile application, PSQI = Pittsburgh Sleep Quality Index, SCT = stimulus control therapy, SE = sleep efficiency, SRT = sleep restriction therapy, TIB = time in bed, TST = total sleep time, WD = wearable device.

spreadsheet (Microsoft Corporation, Redmond, Washington, United States).

Procedures

The CBT-I team consisted of a primary therapist, assistant therapist, and a research coordinator. The treatment protocol consisted of simplified group CBT-I using our MA, 3 face-to-face visits (baseline [W0], week 2 [W2], and week 4 [W4]), and 2 telephone sessions (week 1 [W1] and week 3 [W3]; **Table 3**). The core interventions were SRT and SCT.[12,13] SRT limits the TIB (sleep window) to the TST to increase the homeostatic sleep drive and SE.[13] The TIB settings and adjustments were based on those of previous studies.[13] SCT involves going to bed only when sleepy and getting out of bed when unable to sleep.[12]

Figure 1—Improvement in sleep efficiency after cognitive behavioral therapy for insomnia using a mobile application.



Data are mean and standard error of the mean. The SE when using the sleep logs and actigraphy is the average values during the first, second, and fourth weeks. PSQI = Pittsburgh Sleep Quality Index, SE = sleep efficiency, W0 = baseline, W1 = week 1, W2 = week 2; W4 = week 4.

Participants were required to keep a daily sleep diary in our MA. To compare average SE during the first and fourth weeks, participants were required to continue with their usual sleep cycle during the first week (days 0–6). On W1, W2, and W3, therapists recommended the TIB based on the sleep prescription menu of our MA. However, the sleep window and the TIB were adjusted over at least 4 hours and were slightly compromised according to the physical condition, emotional distress, and working schedule of each patient in certain instances. Participants were required to maintain their current dose of psychotropic medications and frequency of "as needed" hypnotic drugs; however, they were permitted to decrease the dose and frequency of hypnotic drugs upon request.

Measures

Participants were asked to complete the Korean version of Insomnia Severity Index (ISI)[18] and Pittsburgh Sleep Quality Inventory (PSQI)[19] based their symptoms during the previous week. The Korean version of the Dysfunctional Beliefs and Attitudes about Sleep,[20] Beck Depression Inventory,[21] and Beck Anxiety Inventory[22] were also administered.

All participants were required to wear an Actiwatch 2 monitor (Philips Respironics, Murrysville, Pennsylvania, United States) on their nondominant wrist during the first and fourth week of treatment. There were missing actigraphy data for 1 patient at W1 and in 7 patients at W4 due to device malfunction or charging failures. All actigraphy data in this analysis covered the entire TIB reported by participants. Those in the WD user group were required to wear the Fitbit Charge HR on their nondominant wrist throughout the experimental period to monitor sleep duration, number of awakenings, and SE using a triaxial accelerometer.

The WD user and WD nonuser groups were subjected to the same treatment, with the exception that, at W0, the WD user group received instructions for installing the Fitbit application, using the Fitbit tracker, and checking sleep measurements in our MA.

Outcome Measures

The primary outcome variable was postintervention change in SE as measured by sleep diary, actigraphy, and PSQI data from all participants (ie, WD users and WD nonusers). The secondary outcome variables were total ISI and PSQI scores and the sleep latency (SL) and TST data from the sleep diary. The average sleep values, including SE, as measured by the sleep diary and actigraphy, were compared for each week (ie, W1, days 0–6 versus W4, days 21–27). A treatment response was defined as a change in the PSQI score of ≥ 3 points or a $\geq 10\%$ increase in SE, as measured by the sleep diary.[23]

Next, we determined participant adherence to and satisfaction with our MA and as a subanalysis, we compared treatment efficacy in the WD user and WD nonuser groups.

Statistical Analysis

The Statistical Package for the Social Sciences version 23.0 (SPSS Inc., Chicago, Illinois, United States) and SAS 9.2 (SAS Institute, Cary, North Carolina, United States) were used to perform the statistical tests. The statistical tests used are shown in each table. Values of $P < .05$ (two-tailed) were deemed to indicate statistical significance. A *post hoc* power analysis was conducted with G*Power software (Universität Kiel, Germany) to determine the retrospective power of the key finding of this study.[24]

RESULTS

Demographic and Clinical Characteristics at Baseline

In total, 19 participants completed the study. The mean age was 45.1 years, and the average duration of insomnia disorder was 60.4 months (**Table 4**).

Treatment Outcomes

All measures of SE showed significant improvement ($P < .05$): SE improved from 68.7% at W1 to 80.9% at W4, as measured by the sleep diary and a *post hoc* power analysis indicated the power of 0.777; actigraphy showed an increase from 72.1% at W1 to 79.5% at W4; and the SE of PSQI increased from 51.5% at W0 to 77.7% at W4 (**Figure 1**, **Table 5**).

The total ISI and PSQI scores improved significantly between W0 and W4 (**Figure 2**, **Table 5**), and SL improved significantly, from 54.3 minutes at W1 to 32.9 minutes at W4. In total, 18 (94.7%) participants showed a treatment response at W4.

No participants increased the dose or frequency of their hypnotic drugs; however, 2 discontinued hypnotic medication during the study, and 1 participant arbitrarily stopped taking an antidepressant in response to improved sleep.

Table 4—Demographic and clinical characteristics of the participants at baseline.

Variable	All (n = 19)	CBT-I-MA with WD (n = 10)	CBT-I-MA without WD (n = 9)	Statistics
Age, y	45.1 ± 9.8	40.9 ± 9.7	49.8 ± 8.0	$t = -2.17$, $P = .045$
Sex, female	12 (63.2%)	6 (60.0%)	6 (66.7%)	$\chi^2 = 0.09$, $P = 1.000$*
Education, y	13.9 ± 2.1	14.0 ± 2.1	13.8 ± 2.1	$t = 0.23$, $P = .821$
Occupation				$\chi^2 = 4.34$, $P = .070$*
Employed	9 (47.4%)	7 (70%)	2 (22.2%)	
Not currently employed	10 (52.6%)	3 (30%)	7 (77.8%)	
Duration of insomnia disorder, mo	60.4 ± 50.6	68.7 ± 62.4	51.2 ± 34.5	$t = 0.77$, $P = .457$
ISI score	20.4 ± 4.9	17.5 ± 4.8	23.6 ± 2.6	$t = -3.28$, $P = .006$
PSQI score	15.6 ± 3.3	13.7 ± 3.2	17.7 ± 1.7	$t = -3.38$, $P = .004$
DBAS score	101.9 ± 27.5	93.4 ± 30.6	111.3 ± 21.3	$t = -1.49$, $P = .155$
ESS score	5.3 ± 4.2	4.9 ± 3.0	5.7 ± 5.4	$t = -0.39$, $P = .703$
BDI score	15.9 ± 11.3	11.7 ± 8.6	20.7 ± 12.6	$t = -1.83$, $P = .085$
BAI score	14.5 ± 11.7	11.7 ± 9.5	17.7 ± 13.6	$t = -1.19$, $P = .279$
Sedative-hypnotics use	11 (57.9%)	5 (50%)	6 (66.7%)	$\chi^2 = 0.54$, $P = .650$*
Psychiatric comorbidity				
Depressive disorders	4 (21.1%)	3 (30%)	1 (11.1%)	$\chi^2 = 1.02$, $P = .582$*
Anxiety disorders	2 (10.5%)	1 (10%)	1 (11.1%)	$\chi^2 = 0.01$, $P = 1.000$*

Data presented as mean ± standard deviation or n (%). * = Fisher exact test. BAI = Beck Anxiety Inventory, BDI = Beck Depression Inventory, CBT-I-MA = cognitive behavioral therapy for insomnia using our mobile application, DBAS = Dysfunctional Beliefs and Attitudes about Sleep, ESS = Epworth Sleepiness Scale, ISI = Insomnia Severity Index, PSQI = Pittsburgh Sleep Quality Index, WD = wearable device.

Table 5—Treatment outcome of cognitive behavioral therapy for insomnia using our mobile application (comparison between pretreatment and posttreatment).

Variable	Baseline	Week 1	Week 2	Week 4	Effect Size [a]	Statistics
Responder			15 (78.9%)	18 (94.7%)		
Diary SE, % [b]		68.7 ± 20.9	75.9 ± 14.4*	80.9 ± 15.6*	0.66 (0.33 to 0.99)	$F = 11.76$, $P < .001$
Actigraphy SE, % [c]		72.1 ± 14.3		79.5 ± 5.5*	0.40 (−0.03 to 0.82)	$t = 2.39$, $P = .036$
PSQI SE, % [b]	51.5 ± 25.2		64.6 ± 22.6*	77.7 ± 16.4*	1.24 (0.67 to 1.80)	$F = 16.42$, $P < .001$
PSQI total score [b]	15.6 ± 3.3		12.7 ± 3.9*	10.2 ± 3.7*	−1.56 (−2.20 to −0.92)	$F = 38.12$, $P < .001$
ISI score [c]	20.4 ± 4.9			11.7 ± 5.5*	−1.66 (−2.42 to −0.90)	$t = 6.11$, $P < .001$
Diary TIB, min [b]		480.4 ± 79.3	474.2 ± 81.6	452.8 ± 51.5	−0.40 (−0.73 to −0.06)	$F = 2.20$, $P = .125$
Diary TST, min [b]		336.4 ± 121.7	358.4 ± 89.1	366.6 ± 85.1	0.29 (0.03 to 0.54)	$F = 1.74$, $P = .190$
Diary SL, min [b,d]		54.3 ± 51.2	51.7 ± 50.4	32.9 ± 46.0*	−0.44 (−0.74 to −0.14)	$F = 9.46$, $P = .006$
DBAS score [c]	101.9 ± 27.5			83.8 ± 23.9*	−0.70 (−1.08 to −0.32)	$t = 4.50$, $P < .001$
BDI score [c,e]	15.9 ± 11.3			10.1 ± 9.5*	−0.56 (−0.95 to −0.17)	$Z = -3.32$, $P = .001$
BAI score [c,e]	14.5 ± 11.7			10.3 ± 8.2*	−0.42 (−0.78 to −0.06)	$Z = -2.38$, $P = .017$
Hypnotics use [f]	11 (57.9%)			9 (47.4%)		$P = .5$

Data presented as mean ± standard deviation or n (%). * = significant versus initial measurement. [a] = Cohen *d* (95% confidence interval), calculated as the mean difference between the posttreatment and pretreatment scores divided by the standard deviation of the score. [b] = repeated-measures one-way analysis of variance (ANOVA). [c] = paired *t* test. [d] = with Greenhouse and Geisser correction. [e] = Wilcoxon signed-rank test. [f] = McNemar exact test. BAI = Beck Anxiety Inventory, BDI = Beck Depression Inventory, DBAS = Dysfunctional Beliefs and Attitudes about Sleep, ISI = Insomnia Severity Index, PSQI = Pittsburgh Sleep Quality Index, SE = sleep efficiency, SL = sleep latency, TIB = time in bed, TST = total sleep time.

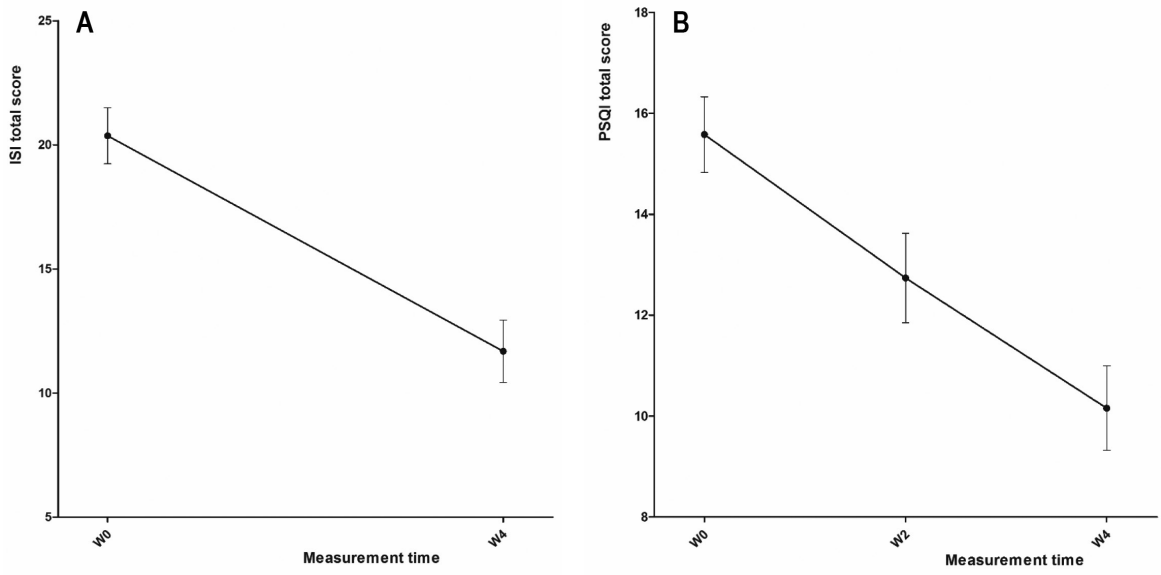
Adherence and Satisfaction to our MA

The study participants showed relatively good adherence to our MA (**Table 6**). They made entries in their sleep diary on 24.3 ± 3.8 days each month (28 days). Seventeen participants (89.5%) answered that our MA was convenient to use, 18 (94.7%) answered that they used our MA frequently, 18 (94.7%) answered that our MA was effective for coping with insomnia, and 19 (100%) answered that they would use it again in the future. No meaningful difference was found in the responses between the WD user and WD nonuser groups (**Table S1**, supplemental material).

Comparison of WD Users and Nonusers

The average SE recorded in the sleep diary had changed significantly more at W2 relative to W1 in the WD user group than in the WD nonuser group; however, no difference was

Figure 2—Improvement in Insomnia Severity Index and Pittsburgh Sleep Quality Index total score after the intervention.



Data are mean and standard error of the mean. **(A)** Improvement in ISI total score after the intervention. **(B)** Improvement in PSQI total score after the intervention. ISI = Insomnia Severity Index, PSQI = Pittsburgh Sleep Quality Index, W0 = baseline, W2 = week 2, W4 = week 4.

Table 6—Adherence to and satisfaction with the mobile app among all of the participants and in the WD user and WD nonuser groups.

Checklist for the Evaluation of the MA	All	WD User	WD Nonuser	Statistics
Sleep diary entries, days of 28 days [a]	24.3 ± 3.8	25.0 ± 4.6	23.6 ± 2.7	$t = -0.83$, $P = .420$
Convenient to use [b]	17 (89.5%)	10 (100%)	7 (77.8%)	$\chi^2 = 2.48$, $P = .115$
Used frequently [b]	18 (94.7%)	10 (100%)	8 (88.9%)	$\chi^2 = 1.17$, $P = .279$
Useful for overcoming insomnia [b]	18 (94.7%)	10 (100%)	8 (88.9%)	$\chi^2 = 1.17$, $P = .279$
Want to use it again in the future [b]	19 (100%)	10 (100%)	9 (100%)	

Data presented as mean ± standard deviation or n (%). [a] = independent *t* test, [b] = chi-square test. MA = mobile application, WD = wearable device.

found between the two groups at W4 (**Table S1**, supplemental material). No other change of the sleep measurements differed significantly between groups.

DISCUSSION

Our pilot study investigated the efficacy of CBT-I using an MA synchronizable with a WD. The main finding of this study was that CBT-I-MA administered through our MA induced significant improvements, with an intermediate effect size for the sleep diary SE and with a large effect size for the SE from PSQI. The SE from actigraphy also improved significantly, although the effect size was small. In addition to these findings, the response rate of the intervention was good, although the number of participants was small. We believe that these results suggest the clinical usefulness of a simplified and short-term CBT-I-MA, and that it has introduced a new treatment model.

Participants showed relatively good adherence to and overall satisfaction with our MA. Patients can use and enter data in their diary anywhere and more easily than an Internet-based sleep diaries, because no wired Internet connection is required. The alarm option of the MA could increase patients' completion rate of the sleep diary entry and adherence to the MA. Using an MA to keep sleep diaries could reduce the possibility of losing the sleep diary, unlike when using a pen/pencil-and-paper method. Using an MA also could make it easy for therapists and patients to review the diaries and calculate the average TST and SE for the most recent 1-week period. Because our MA enables therapists to review a sleep diary by transferring it via an Internet web server, therapists can understand the sleep condition of patients and provide necessary advice without any face-to-face visit.

There was no significant difference in the treatment efficacy, adherence, and satisfaction with the MA between WD user and WD nonuser groups. This study has several limitations in interpreting this finding: (1) such comparison was not the primary purpose of this study but was made as subanalysis, (2) the sample size was quite small and its randomization was not blinded, (3) two groups received the same treatment, except for the initial education session on how to use Fitbit, (4) certain confounding factors such as difference in age, employment status, and insomnia severity in ISI and PSQI scores

at baseline make it even harder to properly interpret the comparison results. In addition, the study design of categorizing patients into two groups for the subanalysis might have produced potential flaws in the study design for the primary research aim, although the two groups received almost the same treatment.

Other major limitations of this pilot study for the primary research aim are the small sample size for determining the efficacy of the CBT-I-MA and the lack of a wait list control group; therefore, we cannot exclude the possibility of type I error. In order to better appreciate the efficacy of a MA or CBT-I-MA, subsequent research needs to occur with a larger sample size and with a wait list control group. For better comparison of groups using a WD and not using a WD, an advanced study design will be also necessary, which satisfies the larger sample size, balanced matched control group for the demographic and clinical characteristics, and a blinded group randomization.

Another consideration necessary here is that, for the reason that this study intended to see the therapeutic effect of simplified group CBT-I-MA, the efficacy of the result here might have been affected by some other elements including, but not limited to, the competence of the therapists, the relatively frequent visits in this CBT-I protocol and the therapist/patient relationship.

In summary, our findings suggest that our CBT-I-MA can be clinically useful for the treatment of insomnia. Patients can use the MA anywhere, and it is more accessible than an Internet-based tool. Furthermore, our MA simplified the review of the sleep diary measurements and the calculations of average TST and SE for the previous week. Using the MA and the WD at the same time, although no meaningful result gained in this study, provides an objective measurement of sleep variables and might help in correcting the underestimation of TST and SE of patients with paradoxical insomnia. We anticipate that our findings will stimulate the further development and replication studies of an MA synchronizable with a WD for the treatment of sleep disorders.

ABBREVIATIONS

ANOVA, analysis of variance
BAI, Beck Anxiety Inventory
BDI, Beck Depression Inventory
CBT-I, cognitive behavior therapy for insomnia
CBT-I-MA, CBT-I using a mobile application
DBAS, Dysfunctional Beliefs and Attitudes about Sleep
DSM, Diagnostic and Statistical Manual of Mental Disorders
ESS, Epworth Sleepiness Scale
ISI, Insomnia Severity Index
MA, mobile application
PSQI, Pittsburgh Sleep Quality Index
SCT, stimulus control therapy
SE, sleep efficiency
SL, sleep latency
SRT, sleep restriction therapy
TIB, time in bed
TOB, time out of bed
TST, total sleep time
TTB, time to bed
W0, week 0 (baseline)
W1, week 1
W2, week 2
W3, week 3
W4, week 4
WD, wearable device

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EDITOR'S NOTE

The Emerging Technologies section focuses on new tools and techniques of potential utility in the diagnosis and management of any and all sleep disorders. The technologies may not yet be marketed, and indeed may only exist in prototype form. Some preliminary evidence of efficacy must be available, which can consist of small pilot studies or even data from animal studies, but definitive evidence of efficacy will not be required, and the submissions will be reviewed according to this standard. The intent is to alert readers of *Journal of Clinical Sleep Medicine* of promising technology that is in early stages of development. With this information, the reader may wish to (1) contact the author(s) in order to offer assistance in more definitive studies of the technology; (2) use the ideas underlying the technology to develop novel approaches of their own (with due respect for any patent issues); and (3) focus on subsequent publications involving the technology in order to determine when and if it is suitable for application to their own clinical practice. The *Journal of Clinical Sleep Medicine* and the American Academy of Sleep Medicine expressly do not endorse or represent that any of the technology described in the Emerging Technologies section has proven efficacy or effectiveness in the treatment of human disease, nor that any required regulatory approval has been obtained.