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Testing an app-based intervention to improve insomnia in patients with epilepsy: A randomized controlled trial☆

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ABSTRACT

Purpose: Insomnia has adverse effects on people with epilepsy. We aimed to test a novel cognitive behavioral therapy for insomnia (CBT-I) app-based intervention on insomnia symptoms and social psychological factors in people with epilepsy and to examine the possible mechanisms among the factors.
Methods: Participants were recruited from neurology clinics in Iran and comprised individuals diagnosed with epilepsy and having moderate to severe insomnia. A two-arm randomized controlled trial design was used, consisting of a treatment group (CBT-I; n = 160) and control group (patient education; n = 160). Primary outcomes were self-reported sleep quality, insomnia severity, and sleep hygiene behavior and objective sleep characteristics measured by actigraphy. Secondary outcomes were attitude, perceived behavioral control, intention, action planning, coping planning, behavioral automaticity, self-monitoring, anxiety, depression, and quality of life (QoL). All outcomes were measured at baseline, and at one, three, and six months postintervention, except objective sleep, which was assessed at baseline, and one and six months postintervention. Data were analyzed using linear mixed models.
Results: Current findings showed that sleep quality, insomnia severity, sleep hygiene behavior, and sleep onset latency were significantly improved in the CBT-I group compared with the patient education group at all measurement points. Also, the CBT-I group had significantly improved anxiety, depression, and QoL compared with the patient education group. Mediation analyses showed that attitude, intention, coping planning, self-monitoring, and behavioral automaticity significantly mediated the effect of the intervention on sleep outcomes.
Conclusion: Results support the use of the CBT-I app to improve sleep outcomes among people with epilepsy.

1. Introduction

Epilepsy is one of the most common neurological diseases globally, affecting around 50 million people worldwide [1]. Individuals with epilepsy often have other physical and mental health conditions [2]. For example, higher incidences of anxiety, depression, and sleep–wake disorders are commonly observed in people with epilepsy [2], all of which have been shown to be associated with insomnia [2].

Insomnia is characterized by difficulty initiating or maintaining sleep or early-morning awakening with an inability to return to sleep despite good opportunities for sleep [3]. Insomnia can have significant negative consequences on a person including disruptions to psychosocial functioning (e.g., depression, daytime dysfunction, reduced quality of life (QoL)) and occupational functioning (e.g., job absence, reduced ability to do tasks, lowered job satisfaction, poor decision-making), as well as an increased burden on society (e.g., increased health costs, reduced job productivity) [2–4]. Several treatment options have been used to manage insomnia in people with epilepsy; however, treatments are often dependent on the seizure type, the person's age, preexisting medical conditions, and potential side-effect profile [5]. Moreover, in Iran, the usual practice for improving sleep hygiene for those who have sleep difficulties is providing education through the provision of

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information sheets [4]. This practice is similar to those used in more developed countries, such as the US [6]. Given well-documented evidence that information provision alone is not sufficient to change behavior, and the wide-spread use and popularity of smartphones, disseminating sleep information alongside behavioral change techniques (BCTs) using app-based methods, may be a useful way forward to improve the sleep of people with epilepsy.

Indeed, the cognitive behavioral therapy for insomnia (CBT-I) app-based intervention (for details see Linardon et al. [7]) has shown to be effective in improving insomnia symptoms and that may overcome many of the challenges of treatment options for those with epilepsy. The CBT-I is a versatile program in that it can be held in individual or group sessions and either face-to-face or online (app-based), based on the therapist's priority, patient's progress, or both [8]. Currently, however, there is a lack of evidence for the efficacy of the smartphone-delivered CBT-I among people with epilepsy [9], although studies have demonstrated promising results among individuals with mental illnesses [7,10].

Building on previous research using CBT-I [11], the aim of this study was to test the novel CBT-I app-based intervention on insomnia symptoms and social psychological factors in people with epilepsy and to examine the possible mechanisms among the factors. It was expected that individuals randomized to the CBT-I group would exhibit greater improvements in insomnia, sleep, and social psychological outcomes at the follow-up assessment points compared with participants in the control (patient education) group. It was expected that the social psychological factors would be higher at follow-up assessment points in the CBT-I group compared with the control group, and that relevant beliefs about sleep hygiene behaviors as specified by theory would serve as mediators between intervention conditions and sleep behavior at follow-ups.

2. Material and methods

This double-blinded, randomized controlled trial was conducted on people diagnosed with epilepsy who have moderate to severe insomnia from August 2018 to October 2019. All procedures were carried out in compliance with the Helsinki Declaration. The study was approved by the Regional Science Ethical Committee (Registration No. IR.QUMS.REC.1397.129) and preregistered at ClinicalTrials.gov (NCT03683381).

2.1. Design and study population

This study used a two-armed randomized controlled trial design with four measurement points to evaluate the effectiveness of a CBT-I app-based intervention against a patient education only group on insomnia, sleep, and social psychological outcomes in people with epilepsy. Participants were recruited from four neurology clinics in

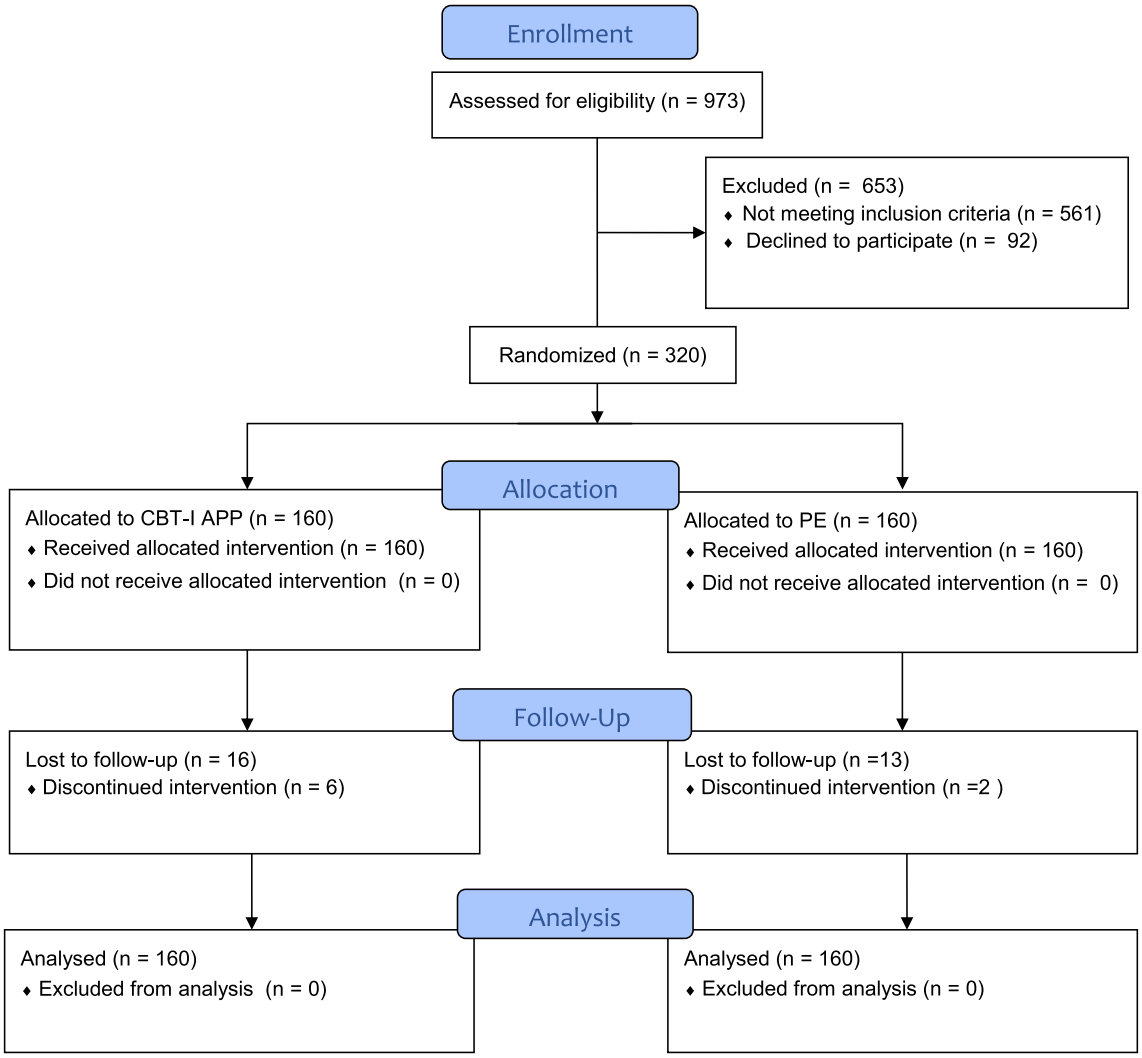

Fig. 1. Flow of participants through the study.

Tehran and Qazvin, Iran. A list of all people with epilepsy was obtained from the clinics. Potential participants were approached by a trained research assistant (nurse) using short message service (SMS) text and fully informed of the purpose of the research. Interested participants were then assessed for eligibility for inclusion in the study. Participants were eligible to enter the study if they met the following criteria: (1) a diagnosis of epilepsy according to the International League Against Epilepsy criteria; (2) aged 18 years or older; (3) moderate or severe insomnia as indicated by a score of 15 or higher on the Insomnia Severity Index (ISI); (4) speak, understand, and write in Persian; (5) no surgery planned in the next 6 months; (6) access to an Android smartphone or a desktop computer with Internet access; and (7) absence of major cognitive impairment assessed using the Telephone version of the Mini-Mental State Examination. Participants were excluded if they (1) were diagnosed with a rapidly progressing neurological or medical disorder, (2) had an intellectual disability, (3) reported drug or alcohol misuse, (4) had untreated sleep apnea identified by an overnight (manually scored) polysomnography, or (5) were pregnant.

The participants were first screened through an online interest form followed by a 20-minute telephone screening and an in-person semistructured interview. Through the interview, the inclusion and exclusion criteria were checked. Eligible participants then received information about the purpose of the study and were invited to participate. Participants who returned their signed informed consent form were asked to complete online baseline assessments as well as wearing an actigraphy watch for a week. All selected participants received a unique login username and password to access the CBT-I App. A total of 973 potential participants were contacted and screened and 512 (52.6%) participants qualified for this study. The flow of participants in the study is shown in Fig. 1.

2.2. Sample size

The sample size was calculated based on the effect size of previous online interventional studies on insomnia and specifically ISI [12,13]. Hence, using a two-tailed test with a small-to-medium effect size (Cohen d = 0.40), with 85% power, at $\alpha = 0.05$ and 25% dropout rate (taken into consideration, at least, 1-month follow-up), a total of 320 participants were recruited.

2.3. Randomization and blinding

Participants were randomly assigned to the CBT-I or patient education group using 1:1 allocation ratio. The randomization was stratified based on the clinics to avoid potential contamination. Randomization was performed by masked biostatistician using SAS 9.2 software. The participants, outcome assessors, and statisticians were blinded to group assignments.

2.3.1. Intervention

The intervention used the CBT-I mobile app [11], which was based on principles of prominent psychological theory [14] and self-help concepts [15]. Specific BCTs that mapped on to constructs underpinned in the theory were integrated into the mobile app, such as information about social and environmental consequences, advantages and disadvantages of performing sleep hygiene behaviors, habit formation, habit reversal, reconstructing the physical environment, reconstructing the social environment, action planning, problem-solving, and self-monitoring of behavior. The intervention content was designed to be delivered over six weeks with exercises provided each week on the mobile app. All engagement was online, including any correspondence between participant and support assistant (e.g., help needed to address challenges in accessing the program on the mobile phone) (see Majd et al. [11] for full details). Participants were instructed to engage in the content of the mobile app as it was released weekly to help treat their insomnia (see Tables 1 and 2 for BCTs and CBT-I content, respectively).

2.3.2. Patient education

The patient education group received standard information on insomnia symptoms every week. This included information on physiological controls of sleep, sleep hygiene practices, healthy sleep behaviors,

Table 1
Behavior change techniques (BCTs) included in the CBT-I mobile app and their targeted outcomes.

Behavior change technique (BCT)[a]	Examples of where BCTs are used in the CBT-I App	Targeted outcomes
BCT 5.3: Information about social and environmental consequences	Week 1: Providing evidenced-based information on sleep: Adults need more than 7–8 h of sleep per night to let the brain obtain full rest. Over one-third of adults have severe daytime sleepiness that interferes with work, driving, and social functioning.	Attitude and intentions to perform sleep hygiene behaviors
BCT 9.2: Advantages and disadvantages	Week 1: Getting participants to think of and weigh-up the advantages of having sufficient sleep and the disadvantages of insufficient sleep. For example, sample sentences such as 'If I sleep enough, I will have high performance' and 'If I sleep little, I will have health risk, such as high blood pressure' are presented.	Attitude and intentions to perform sleep hygiene behaviors
BCT 8.3: Habit formation	Week 2: Getting participants to build sleep patterns. For example, participants are encouraged to go to bed and wake up at the same time each day, including weekdays and weekend days. Participants are also encouraged to make a comfortable bedroom for sleeping through listening to their bodies, eating healthy foods, drinking safely, and doing relaxation exercises before sleep. Participants are further requested to actively perform at least one of these sleep hygiene behaviors and to write down the behavior that they will adopt for the week.	Behavioral automaticity
BCT 8.4: Habit reversal	Week 3: Having participants imagine a comfortable place each night before bedtime.	Behavioral automaticity
BCT 12.1: Reconstructing the physical environment	Week 2: Getting participants to actively make their bedrooms comfortable for sleeping, including appropriate lightening (e.g., dimmed light), temperature (e.g., 24 to 26 °C), and bed texture.	Perceived behavioral control
BCT 12.3: Reconstructing the social environment	Week 2: Advising participants to minimize their time usage on social media, and decrease their interactions with friends who have heavy drinking or smoking habits.	Perceived behavioral control
BCT 1.4: Action planning	Week 5: Getting participants to make two detailed plans regarding sleep hygiene behaviors. For example, specifying what the sleep hygiene behavior is, when (day) they will perform it, and where (place) they will perform it.	Action planning
BCT 1.2: Problem-solving	Week 5: Getting participants to identify potential barriers regrading when they try to sleep. Participants then are required to generate strategies to overcome the barriers. For example, 'If there is an important meeting the next day that disrupts my sleep, I will take a warm bath before I go to sleep'.	Coping planning
BCT 2.3: Self-monitoring of behavior	Week 4: Having participants monitor their sleep efficiency using a sleep chart.	Self-monitoring

[a] The BCTs are sourced from Michie et al.'s [40] taxonomy.

Table 2
CBT-I[a] content across the six weeks.

Week	Content
1	Week 1 focused on providing information. The importance of sleep, the amount of sleep needed, the main causes of insomnia, complications and outcomes of insufficient sleep (including short- and long-term), insomnia treatments (e.g., CBT-I), and the prevalence of insomnia in Iran were given. Additionally, participants were asked to list the potential costs of poor sleep and the potential benefits of good sleep. At the end of the first week, participants were encouraged to use a notebook that incorporated in the app's front page to record their sleeping information, including sleep time, wake-up time, and time spent being in bed.
2	Week 2 focused on developing good habits for healthy sleep. Participants were taught to identify negative habits which can disrupt sleep, such as smoking, caffeine intake close to bed, excessive worrying, and uncomfortable bedroom environment (e.g., a dark, calm, and cool bedroom). Participants were then encouraged to think up positive sleep habits to replace these negative sleep habits by reading a list of tips; for example, listening to their bodies, eating healthy foods, drinking safely, and engaging in relaxation exercises before sleep. Participants were requested to write down their new habits which they can use for practice in Week 2. Participants were also requested to list the habits that interrupt their sleep. At the end of this week, relaxation and meditation exercise techniques were provided in text and audio forms with music tracks for the participants to practice. Participants were requested to perform these exercises every night before going to bed in comfortable places (for example, in bed) without disturbance (e.g., setting their smartphones to silent mode).
3	Week 3 continued relaxation practices. Participants were asked to try and imagine a place where they feel comfortable (e.g., a pleasant place) before bedtime each night. In addition, participants were taught how to link the bedroom only with sleep; that is, limiting the amount of time that they spend in bed. Thus, participants were taught how to generate a 'sleep efficiency chart' and use this chart to calculate the amount of time that they are awake at night. Participants were also asked to use this chart together with their sleep notes to monitor their sleep performance. At the end of each week (after Week 3), they were able to visualize their sleeping efficiency.
4	At the beginning of Week 4, participants were asked to monitor their sleep efficiency, as was taught in Week 3. The aim of Week 4 was to change misconceptions on sleep. A list of common misconceptions with correct information about sleep was provided to participants. Participants were challenged for their misconceptions and reviewed the differences between their thoughts and feelings. In addition, participants were encouraged to identify their unhelpful thoughts by writing down the information regarding their last time efforts for sleeping in a table, including the situation, thoughts, feelings, and behaviors.
5	At the beginning of Week 5, participants were asked to review their sleep chart and check their sleep efficiency. In addition, participants were requested to write down two situations in which they had good or bad sleep in the past week. Moreover, their thoughts, feelings, and behaviors that accompanied the situations were requested to be written down as well. Participants were then asked to think up plans specifying what (sleep hygiene behaviors), when (day), and where (place) they would sleep. They were asked to use a tabular form in the app to write down this information. The app also reminded participants regarding their plans in their recorded sleeping information (sleep time, wake up time, and time spent being in the bed) during past night. In addition, participants were encouraged to identify potential barriers that might jeopardize their sleep, as well as strategies to overcome the barriers.
6	Week 6 focused on relating bed to sleep. Participants learned how to relate bed with sleep. All of the techniques learned in Weeks 1 to 5 (e.g., relaxation, sleep education, cognitive restructuring, action planning, and coping planning) were summarized for the participants in the app. During Week 6, paradoxical intention was used: participants were asked to sleep for fewer hours than normal sleep for one night to understand that sleep deprivation does not necessarily affect daily functioning. At the end of Week 6, participants were asked to keep a sleep diary.

[a] CBT-I = cognitive-behavioral therapy for insomnia.

and changing lifestyle to promote healthy sleeping behaviors. This information was presented as separate content from the CBT-I on the mobile app. Educational information was unlocked on a weekly basis for the participants to use and, as such, participants were asked to strictly follow the content of the mobile app as it was released weekly to help treat their insomnia. After the intervention, participants in control group were informed that they could access the CBT-I content of the app.

2.4. Outcomes

Primary outcomes were self-reported sleep quality (this scale, Pittsburgh Sleep Quality Index (PSQI), was included after preregistering in the ClinicalTrials.gov to further enrich our data and to conform with the Iranian neurology clinic protocols), insomnia severity, and sleep hygiene behavior and objective sleep characteristics measured by actigraphy. Secondary outcomes were attitude, perceived behavioral control, intention, action planning, coping planning, behavioral automaticity, self-monitoring, anxiety, depression, and QoL. All outcomes were measured at baseline, and at one month, three months, and six months postintervention, except objective sleep, which was assessed at baseline, and one month and six months postintervention. These timeframes were chosen to assess the short-, medium-, and long-term effects of CBT-I on participant's outcomes, despite the program itself lasting only 6 weeks—based on previous protocols (see Majd et al. [11]). All self-reported measures used in this study have been previously validated in Persian [11,16–23]. Detailed information on each of the measures is described below. Apart from the outcome measures described below, detailed information on participants' demographic characteristic and especially detailed information on their epileptic conditions such as type of seizure, age at onset, interventional types, type of antiepileptic drugs (mono/polytherapy), seizure frequency (30-day evaluation on both loss of awareness and aura in both partial and generalized seizures), seizure severity (using Liverpool Seizure Severity Scale), health literacy (using eHealth Literacy Scale), and comorbid conditions (using Charlson Comorbidity Index).

2.4.1. Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a 19-item self-rating questionnaire that can be completed within 5 to 10 min. It has seven component scores, which are made up of sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each of these component scores is weighted equally from 0 to 3 (0, not in the past month; 1, less than once per week; 2, once or twice per week; and 3, three or more times per week). A global PSQI score is gotten from the sum of all the seven components yielding a score from 0 to 21, with higher scores indicating poorer sleep quality [16,24].

2.4.2. Insomnia Severity Index (ISI)

The ISI is a seven-item self-report scale that assesses participants' level of insomnia over the past two weeks. All items are rated on a five-point Likert-type scale ranging from 0 (*no problem*) to 4 (*very severe problem*). A total score is generated by summing up all seven items ranging from 0 to 28 with five subscores: 0–7 (absence of insomnia), 8–14 (subthreshold insomnia), 15–21 (moderate insomnia), and 22–28 (severe insomnia) [17]. The internal consistency of the ISI in this present study was acceptable ($\alpha = 0.83$).

2.4.3. Sleep hygiene behavior

Sleep hygiene behavior was assessed using a three-item scale developed by Todd and Mullan [25]. The participants were asked to report how many days they had good sleep hygiene behavior over the past week ('How many days did you make your bedroom restful over the past week?') and then whether they avoided going to bed feeling hungry or thirsty, and avoided anxiety and stress-provoking activity before bed. Participants were asked to respond on an 8-point scale ranging from 0 to 7 [18]. The internal consistency of the sleep hygiene behavior scale in this present study was acceptable ($\alpha = 0.81$).

2.4.4. Objective sleep characteristics

Objective sleep characteristics were measured using a wrist actigraphy (Ambulatory Monitoring, Inc. USA). Actigraphy is a small and portable device that records information on movement in 1-minute epochs over extended periods of time. Sleep characteristics such as total sleep time and sleep efficiency were extracted from the wrist actigraphy using the Sadeh algorithm. Patients were asked to wear the Actigraph on their nondominant wrist for seven consecutive nights in three assessment periods (i.e., baseline, one month, and six months after baseline). A daily sleep diary was also completed assist in interpreting the wrist actigraph data.

2.4.5. Behavioral intention

Behavioral intention was assessed using a six-item scale (e.g., 'Over the next week, I intend to make my bedroom restful'), adapted from Kor and Mullan [26] and previous studies [4,18]. All items were scored on a five-point Likert scale, ranging from 1 (*totally disagree*) to 5 (*totally agree*).

2.4.6. Self-report Behavioral Automaticity Index (SRBAI)

The extent to which the sleep hygiene behaviors are habitual for an individual was assessed using the Self-report Behavioral Automaticity Index (SRBAI) [19,27]. The SRBAI for the current study contained four items that started with the stem "Sleep hygiene behaviour is something…" followed by "I do automatically', 'I do without having to consciously remember', 'I do without thinking', and 'I start doing before I realize I'm doing it' as used in previous study.

2.4.7. Action planning

Action planning was assessed using four items adapted from previous studies [4,18,20]. Participants were asked to indicate if they had made a detailed plan regarding (i) when, (ii) where, (iii) how, and (iv) how often they will perform sleep hygiene behaviors over the next six months. All items were scored on a five-point Likert scale, ranging from 1 (*totally disagree*) to 5 (*totally agree*).

2.4.8. Coping planning

Coping planning was assessed using five items (e.g., 'I have made a detailed plan regarding what to do if something interferes with my plans') adapted from previous studies [4,18,20]. All items were scored on a five-point Likert scale, ranging from 1 (*totally disagree*) to 5 (*totally agree*).

2.4.9. Perceived behavioral control

Perceived behavioral control was assessed using three items (e.g., 'I am confident that every day I can prevent anxiety-provoking activity before bedtime') adapted from previous studies [4,18]. All items were scored on a five-point Likert scale, ranging from 1 (*totally disagree*) to 5 (*totally agree*).

2.4.10. Self-monitoring of behavior

Self-monitoring of behavior was assessed using three items (i.e., "I keep track of how much time I spend sleeping", "I pay attention to how tired or rested I feel each day", and "I take care to note the time that I go to bed and wake each day) adapted from a previous study [11]. All items were scored on a five-point Likert scale, ranging from 1 (*never*) to 5 (*always*).

2.4.11. Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (HADS) is a 14-item scale that assesses anxiety (seven items) and depression (seven items) in patients with both somatic and mental problems. All items were scored on a 0–3 response scale with higher score representing higher levels of anxiety and depression [21,22].

2.4.12. Quality of Life in Epilepsy-31 Inventory (QOLIE-31)

The Quality of Life in Epilepsy-31 Inventory (QOLIE-31) is a 31-item questionnaire clustered in seven multiitem scales being (a) overall QoL, (b) emotional well-being, (c) energy/fatigue, (d) cognitive functioning, (e) medication effects, (f) seizure worry, and (g) social functioning and one single item on overall health [23,28]. The QOLIE-31 overall score was obtained using a weighted average of the multiitem scale scores. The scale scores and overall score values range from 0 to 100, where higher values reflect more favorable states [23,28].

2.5. Statistical analysis

The study conformed to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Intention-to-treat (ITT) analyses were carried out to handle attrition. Descriptive statistics were used to summarize participant characteristics. To evaluate the magnitude of changes in primary and secondary outcomes over time across the two groups, linear mixed models (PROCMIXED) were performed. Moreover, the linear mixed models controlled for baseline variables and covariates (age, gender, education, and severity of seizure) that related to the outcome(s). Given the robust estimation (through full information maximum likelihood estimation) that handles missing values common in repeated measured outcomes (e.g., loss-to-follow in posttreatment), the mixed modeling approach is a powerful statistical tool to evaluate group differences over time [29]. The analysis incorporated two between-participant effects (between groups and between participants within groups) and three within-participant effects (between times, group by time interactions, and random variation). All *p*-values were two-sided and evaluated as statistically significant at the 0.05 level. All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA).

3. Results

Table 3 shows that the demographic characteristics of both CBT-I and patient education groups were similar. Specifically, the mean age of the patients with insomnia in the CBT-I group was 38.37 ± 13.45 years and the mean age of those in the patient education group was 37.99 ± 9.88 years. Slightly less than half of the participants were

Table 3
Demographic and clinical characteristics of the participants in different groups.

	Group	
	PE ($n = 160$)	CBT-I ($n = 160$)
Age (year); $M \pm SD$	37.99 ± 9.88	38.37 ± 13.45
Years of education; $M \pm SD$	8.31 ± 4.51	8.75 ± 5.06
Duration of illness (year); $M \pm SD$	17.30 ± 4.29	17.78 ± 5.01
Gender; *n* (%)		
Female	90 (56.2%)	97 (60.6%)
Marital status; *n* (%)		
Single	30 (19.0%)	26 (16.3%)
Separated/divorced/widowed	4 (2.55%)	2 (1.3%)
Married/cohabiting	124 (78.5%)	132 (82.5%)
Employment status; *n* (%)		
Unemployed/retired	105 (65.6%)	109 (68.1%)
Type of epilepsy; *n* (%)		
Generalized	49 (30.6%)	47 (29.4%)
Focal	111 (69.4%)	113 (70.6%)
Age at the seizure onset; $M \pm SD$	20.38 ± 7.93	20.61 ± 6.31
Surgical intervention (yes); *n* (%)	19 (11.9%)	25 (15.6%)
Type of antiepileptic drug		
Polytherapy	83 (51.9%)	86 (53.8%)
Number of prescribed AEDs; $M \pm SD$	1.64 ± 0.73	1.71 ± 0.88
30-Day seizure frequency; $M \pm SD$	3.07 ± 6.68	3.13 ± 7.16
Liverpool Seizure Severity Scale; $M \pm SD$	52.34 ± 25.67	50.86 ± 23.70
The eHealth Literacy Scale; $M \pm SD$	20.82 ± 3.72	19.61 ± 4.96
Charlson Comorbidity Index; $M \pm SD$	2.31 ± 2.03	2.28 ± 2.30

Note. $M \pm SD$ = mean ± standard deviation; PE = patient education; CBT-I = cognitive behavioral therapy for insomnia.

Table 4
Descriptive statistics for all outcome measures by condition and time.

Outcome	Mean (SD)							
	PE				CBT-I			
	Baseline	Month 1	Month 3	Month 6	Baseline	Month 1	Month 3	Month 6
PSQI	14.24 (3.28)	13.18 (3.06)	13.13 (3.66)	13.10 (3.71)	14.33 (3.76)	10.04 (5.29)	9.96 (4.43)	9.93 (4.92)
ISI	20.08 (2.69)	17.29 (4.46)	16.77 (4.27)	17.32 (4.78)	20.29 (4.56)	13.00 (3.44)	12.74 (3.10)	12.81 (3.35)
Sleep hygiene behavior	8.51 (3.03)	12.01 (6.33)	11.99 (5.71)	12.04 (3.76)	8.44 (3.98)	14.94 (6.78)	15.17 (5.70)	15.24 (5.58)
Attitude	2.58 (0.92)	3.21 (1.05)	3.15 (1.22)	3.18 (1.10)	2.56 (0.72)	3.74 (0.83)	3.73 (0.67)	3.70 (0.61)
PBC	2.68 (1.00)	2.73 (0.53)	2.70 (1.08)	2.76 (0.84)	2.64 (0.92)	3.98 (0.92)	4.08 (0.72)	4.12 (0.81)
Intention	2.61 (1.18)	2.97 (1.21)	2.93 (1.22)	2.88 (1.01)	2.66 (1.08)	4.12 (0.98)	4.29 (1.20)	4.24 (1.28)
Action planning	1.96 (0.58)	2.22 (1.29)	2.26 (1.40)	2.29 (1.14)	1.97 (0.82)	3.66 (1.17)	3.60 (0.98)	3.67 (0.92)
Coping planning	2.30 (0.68)	2.53 (1.24)	2.49 (1.03)	2.51 (1.13)	2.28 (0.93)	3.69 (0.90)	3.81 (0.84)	3.83 (0.90)
Self-monitoring	2.35 (0.90)	2.36 (0.98)	2.44 (1.02)	2.39 (1.08)	2.41 (0.88)	3.29 (1.06)	3.37 (1.05)	3.39 (1.09)
SRBAI	3.10 (1.31)	3.15 (1.60)	3.17 (1.22)	3.14 (1.11)	3.01 (1.22)	4.40 (1.01)	4.38 (0.93)	4.43 (0.97)
Anxiety[a]	9.14 (3.76)	8.36 (5.07)	8.18 (4.98)	8.31 (4.39)	9.25 (4.02)	6.11 (3.58)	5.50 (2.81)	5.25 (2.62)
Depression[a]	6.24 (3.34)	6.11 (4.36)	6.03 (4.11)	6.10 (3.59)	6.26 (3.19)	3.85 (0.87)	3.21 (0.59)	3.04 (1.15)
QOLIE-31	56.44 (24.67)	60.23 (22.79)	60.90 (23.39)	58.67 (21.84)	57.27 (23.24)	66.41 (17.05)	67.18 (22.65)	65.99 (20.63)
SoL, min	28.32 (14.80)	28.05 (16.47)	NA	28.18 (15.02)	28.69 (13.86)	24.22 (19.81)	NA	24.06 (19.15)
WASO, min	42.73 (22.23)	40.71 (22.95)	NA	40.49 (23.21)	42.64 (27.84)	38.07 (26.89)	NA	37.49 (26.75)
TST, min	389.54 (91.13)	392.63 (93.73)	NA	391.16 (95.22)	386.23 (77.77)	398.70 (97.73)	NA	396.02 (99.52)
SE, %	71.40 (22.07)	72.45 (22.18)	NA	72.11 (30.50)	73.05 (18.61)	76.22 (23.12)	NA	76.31 (24.23)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; PSQI = Pittsburgh Sleep Quality Index; ISI = Insomnia Severity Index; PBC = perceived behavioral control; SRBAI = Self-Report Behavioral Automaticity Index; SOL = sleep onset latency; TST = total sleep time; WASO = Wake After Sleep; SE = sleep efficiency.
[a] Anxiety and depression were measured using Hospital Anxiety and Depression Scale.

male in each group (39.4% in the CBT-I group and 43.8% in the patient education group). The time used by all participants on the mobile app was 280 ± 127.16 min, with participants in the CBT-I group evidencing significantly longer duration of app use (mean 311 ± 154.39 min) compared with the patient education group (mean 250 ± 111.63 min; $p = 0.004$). Thirty-five (21.88%) and 32 (20%) patients in CBT-I and patient education group, respectively were found to be seizure-free over a 30-day baseline period.

The CBT-I group showed rapid improvement in all sleep outcomes over time. Further, there were improved health outcomes over time for the CBT-I group. The patient education group also showed gradual improvement in sleep outcomes over time. Further, there were slight differences in health outcomes over time for the patient education group (see Table 4).

There were significant intervention effects on the three primary outcomes: sleep quality (PSQI), severity of insomnia (ISI), and sleep hygiene behaviors. Specifically, sleep quality was improved in the CBT-I group compared with those in the patient education group at all follow-up time points ($ps < 0.001$ for 1, 3, and 6 months). Similar improvements were observed in severity of insomnia (i.e., a significant decrease in the severity of insomnia among the CBT-I group compared with those in the patient education group at 1, 3, and 6 months following the intervention, $ps < 0.001$). Again, for sleep hygiene behaviors, the CBT-I group significantly engaged in more sleep hygiene behaviors compared with those in the patient education group at 1 month ($p = 0.002$), 3 months ($p = 0.001$), and 6 months ($p = 0.001$) following the intervention. Table 5 shows the findings of the linear mixed models predicting primary outcomes between two groups, controlling for age, gender, education, and severity of seizure.

The results on objective measures of sleep revealed that the CBT-I group had better sleep onset latency ($ps < 0.001$ for 1 month and 6 months), wake after sleep onset ($p < 0.05$ for 6 months), and sleep efficiency ($p < 0.01$ for 6 months) compared with the patient education group. Table 6 shows the findings of the linear mixed models predicting the outcomes between two groups, controlling for age, gender, education, and severity of seizure.

Regarding the secondary outcomes, analyses indicated that the CBT-I group had better outcomes than did the patient education group(for detailed information see Appendix Tables 1–5). Mediation analyses further showed that the effects of the CBT-I on the primary outcome of sleep hygiene behaviors were mediated by changes in relevant social psychological factors toward sleep hygiene behaviors as specified by theory (for detailed information see Appendix Table 6).

4. Discussion

The present study aimed to test a novel CBT-I app-based intervention on insomnia symptoms and social psychological factors in people with epilepsy and to examine the possible mechanisms among the factors. Results demonstrated support for the CBT-I

Table 5
Linear mixed model results for self-reported sleep measures (primary outcomes).

	PSQI		ISI		Sleep hygiene behaviors	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	−0.08 (0.45)	0.86 (−0.96, 0.80)	−0.23 (0.43)	0.59 (−1.07, 0.61)	0.33 (0.58)	0.57 (−0.81, 1.47)
Month 1 (vs. baseline)	−1.05 (0.42)	0.01 (−1.87, −0.23)	−2.79 (0.34)	<0.001 (−3.46, −2.12)	3.51 (0.58)	<0.001 (2.37, 4.65)
Month 3 (vs. baseline)	−1.10 (0.41)	0.01 (−1.90, −0.30)	−3.31 (0.34)	<0.001 (−3.98, −2.64)	3.48 (0.54)	<0.001 (2.42, 4.54)
Month 6 (vs. baseline)	−1.14 (0.42)	0.01 (−1.96, −0.32)	−2.76 (0.35)	<0.001 (−3.45, −2.07)	3.52 (0.57)	<0.001 (2.40, 4.64)
CBT-I (vs. PE at 1 month)	−3.24 (0.59)	<0.001 (−4.40, −2.08)	−4.49 (0.49)	<0.001 (−5.45, −3.53)	2.59 (0.81)	0.002 (1.00, 4.18)
CBT-I (vs. PE at 3 months)	−3.27 (0.60)	<0.001 (−4.45, −2.09)	−4.24 (0.50)	<0.001 (−5.22, −3.26)	2.85 (0.83)	0.001 (1.22, 4.48)
CBT-I (vs. PE at 6 months)	−3.27(0.52)	<0.001 (−4.29, −2.25)	−4.72 (0.48)	<0.001 (−5.66, −3.78)	2.87 (0.80)	<0.001 (1.30, 4.44)
Age	0.02 (0.04)	0.62 (−0.06, 0.10)	0.01 (0.01)	0.32 (−0.01, 0.03)	−0.03 (0.02)	0.14 (−0.07, 0.01)
Female (vs. male)	−0.11 (0.28)	0.70 (−0.66, 0.44)	0.07 (0.32)	0.83 (−0.56, 0.70)	−0.31 (0.32)	0.33 (−0.94, 0.32)
Education	0.02 (0.03)	0.51 (−0.04, 0.08)	−0.02 (0.03)	0.51 (−0.08, 0.04)	−0.02 (0.03)	0.51 (−0.08, 0.04)
LSSS	0.01 (0.01)	0.32 (−0.01, 0.03)	0.01 (0.02)	0.62 (−0.03, 0.05)	0.01 (0.06)	0.87 (−0.11, 0.13)
Intercept	14.95 (0.65)	< 0.001 (13.68, 16.22)	19.44 (0.72)	<0.001 (18.03, 20.85)	9.65 (0.75)	<0.001 (8.18, 11.12)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; PSQI = Pittsburgh Sleep Quality Index; ISI = Insomnia Severity Index; LSSS = Liverpool Seizure Severity Scale.

Table 6
Linear mixed model results for objective measures of sleep.

	SOL		WASO		TST		SE	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	−0.39 (0.77)	0.61 (−1,90, 1.12)	−0.78 (2.72)	0.77 (−6.11, 4.55)	2.82 (3.34)	0.40 (−3.73, 9.37)	−1.67 (2.64)	0.53 (−6.84, 3.50)
Month 1 (vs. baseline)	−0.26 (0.70)	0.71 (−1.63, 1.11)	−2.01 (1.03)	0.052 (−4.03, 0.01)	3.08 (3.90)	0.43 (−4.56, 10.72)	1.05 (2.49)	0.67 (−3.83, 5.93)
Month 6 (vs. baseline)	−0.14 (0.54)	0.80 (−1.20, 0.92)	−2.24 (1.11)	0.04 (−4.42, −0.06)	1.62 (3.74)	0.67 (−5.71, 8.95)	0.71 (2.13)	0.74 (−3.46, 4.88)
CBT-I (vs. PE at 1 month)	−4.21 (0.75)	<0.001 (−5.68, −2.74)	−2.56 (1.45)	0.08 (−5.40, 0.28)	9.38 (5.49)	0.09 (−1.38, 20.14)	2.12 (1.29)	0.10 (−0.41, 4.65)
CBT-I (vs. PE at 6 months)	−4.94 (0.86)	<0.001 (−6.63, −3.25)	−2.90 (1.40)	0.04 (−5.64, −0.16)	8.17 (5.11)	0.11 (−1.85, 18.19)	2.55 (0.94)	0.01 (0.71, 4.39)
Age	−0.01 (0.03)	0.74 (−0.07, 0.05)	0.24 (0.13)	0.07 (−0.01, 0.49)	0.38 (0.42)	0.37 (−0.44, 1.20)	0.02 (0.01)	0.046 (0.0004, 0.04)
Female (vs. Male)	0.12 (0.65)	0.85 (−1.15, 1.39)	10.83 (4.67)	0.02 (1.68, 19.98)	0.38 (0.21)	0.07 (−0.03, 0.79)	−0.04 (0.07)	0.57 (−0.18, 0.10)
Education	0.03 (0.07)	0.67 (−0.11, 0.17)	0.53 (0.29)	0.07 (−0.04, 1.10)	0.34 (1.06)	0.75 (−1.74, 2.42)	0.05 (0.18)	0.78 (−0.30, 0.40)
LSSS	0.01 (0.02)	0.62 (−0.03, 0.05)	0.05 (0.05)	0.32 (−0.05, 0.15)	−0.19 (0.21)	0.37 (−0.60, 0.22)	−0.03 (0.04)	0.45 (−0.11, 0.05)
Intercept	28.65 (0.65)	<0.001 (27.38, 29.92)	43.44 (5.94)	<0.001 (31.80, 55.08)	372.96 (22.60)	<0.001 (328.66, 417.26)	73.50 (4.12)	<0.001 (65.42, 81.58)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; SOL = Sleep Onset Latency; TST = Total Sleep Time; WASO = Wake After Sleep; SE = Sleep Efficiency.

intervention in improving sleep outcomes as well as improved social cognitions and mental health outcomes. These findings are consistent with results of previous studies, which reported that mobile apps or internet-delivered CBT-I (or therapy) can be an effective method in treating insomnia [7,10,13]. Specifically, there were moderate-to-large effect sizes for the self-reported sleep outcomes but small effects for the objective actigraphy outcomes. The aforementioned findings indicate that the mobile app CBT-I improves sleep problems for people with epilepsy. Moreover, the improvements seem to be larger than prior studies using traditional CBT-I to treat insomnia for general populations or people with epilepsy [30]. A possible reason is that the mobile app CBT-I is more feasible than traditional CBT-I as a mobile app was not limited by time or space. Therefore, the participants in the present study might gain larger benefits of the CBT-I than those using a traditional CBT-I. The findings are important given previous research has demonstrated that insomnia impairs the psychosocial and occupational functioning of people with epilepsy [2–4]. Thus, it can be concluded that the mobile app CBT-I is an effective way to treat insomnia in people with epilepsy taking into consideration the effect of epilepsy severity, age at onset, and antiseizure medication on sleep. Also, current findings suggest effects last in the long-term (i.e., 6 months postintervention), an important contribution to the extant literature in this context as long-term effects of interventions are often not tested. Moreover, this study provided novel understandings of the key determinants in this context. In particular, attitudes, perceived behavioral control, action planning, coping planning, self-monitoring, and behavioral automaticity were found to be significant mediators of the intervention effect on sleep hygiene.

This study has important implications for people with epilepsy who have insomnia and highlights that an app-based CBT-I intervention may be superior to providing information alone. Empirical evidence has shown that knowledge provision alone often does not always translate into behavior change and that interventions based on theory may be more effective than interventions that are atheoretical [31]. Also, online interventions are flexible and cost-effective to deliver wide-ranging health programs [7,13,32], and demonstrate comparable efficacy to nononline interventions [33]. The findings from the current research support that an online, theory-based intervention is a promising approach to improving sleep and health outcomes of people with epilepsy; especially, those who can be trained to follow therapeutic instructions online or on the phone. In addition, this is the first study that examined the possible mechanisms involved in treating insomnia/sleep problems among people with epilepsy [11]. Thus, in as much as the health or psychological state is important, clinicians may also look at their attitude, intention, coping planning, self-monitoring, and behavioral automaticity as they do mediate the effect of the intervention on sleep outcomes. These findings, adding to existing predictive factors of insomnia [34–36], would help clinicians such as epileptologists to appreciate the need for a holistic view during assessment and treatment. It is also worth mentioning that the participants (Iranians) are more collectivistic-centered and are, therefore, more willing to follow instructions from authority figures than individuals from individualistic-centered society [37–39]. Thus, present findings may not translate to individuals from Western, individualistic cultures.

Key strengths of the current study include the use of a rigorous randomized controlled trial design and the recruitment of a clinical sample who have moderate to severe insomnia. While the outcomes are an extensive range of behavioral and psychological variables established to predict sleep outcomes, participants were not representative of the population of Iranian people with epilepsy. For example, participants in the present study needed to use the app to receive the intervention. Therefore, people with epilepsy who have little literacy in using smartphone or desktop computer or have challenges adhering to treatment protocols may not benefit from this mobile app CBT-I intervention. However, the online platform was useful in that it enabled monitoring of participant progress electronically and, thus, may have contributed to maintaining participant engagement throughout the program. Further, the mean age of participants was around 38 years; thus, findings may not generalize to younger or older samples. In addition, although the participants were blinded to group assignment, they could not be blinded to the intervention. Therefore, placebo effects on results cannot be excluded. However, given the sustained effects across the six-month follow-up, it is reasonable to conclude that the CBT-I is an effective program to treat insomnia among people with epilepsy. Future studies would, therefore, benefit from examining intervention effects among younger and older people with epilepsy. Furthermore, we did not assess change in antiepileptic drugs use across the intervention, which may provide informative knowledge to clinicians about the relationship between the intervention and antiepileptic drugs use, an area for future research to explore.

5. Conclusion

The results of the present study demonstrated that CBT-I has promising effects in treating sleep problems for people with epilepsy. The intervention proved successful in improving sleep quality, insomnia severity, sleep hygiene behavior, and sleep onset latency in those that received the CBT-I compared with those that only received patient education, and across all measurement points. Also, the CBT-I group had significantly improved anxiety, depression, and QoL compared with the patient education group. Further, mediation analyses showed attitude, intention, coping planning, self-monitoring, and behavioral automaticity significantly mediated the effect of the intervention on sleep outcomes. Healthcare

professional can, therefore, apply the CBT-I in their treatment programs with people with epilepsy that have insomnia.

Declaration of competing interest

The author has no conflict of interest.

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Appendix A

Appendix Table 1
Linear mixed model results for measures on Theory of Planned Behavior.

	Attitude		PBC		Intention	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	0.03 (0.10)	0.76 (−0.17, 0.23)	0.03 (0.11)	0.79 (−0.19, 0.25)	0.06 (0.14)	0.67 (−0.21, 0.33)
Month 1 (vs. baseline)	0.62 (0.09)	<0.001 (0.44, 0.80)	0.05 (0.10)	0.62 (−0.15, 0.25)	0.36 (0.12)	0.003 (0.12, 0.60)
Month 3 (vs. baseline)	0.56 (0.10)	<0.001 (0.36, 0.76)	0.06 (0.10)	0.55 (−0.14, 0.26)	0.31 (0.13)	0.02 (0.06, 0.56)
Month 6 (vs. baseline)	0.59 (0.11)	<0.001 (0.37, 0.81)	0.08 (0.09)	0.38 (−0.10, 0.26)	0.27 (0.11)	0.02 (0.05, 0.49)
CBT-I (vs. PE at 1 month)	0.56 (0.14)	<0.001 (0.29, 0.83)	1.30 (0.14)	<0.001 (1.03, 1.57)	1.10 (0.17)	<0.001 (0.77, 1.43)
CBT-I (vs. PE at 3 months)	0.61 (0.14)	<0.001 (0.34, 0.88)	1.38 (0.12)	<0.001 (1.14, 1.62)	1.32 (0.16)	<0.001 (1.01, 1.63)
CBT-I (vs. PE at 6 months)	0.57 (0.13)	<0.001 (0.32, 0.82)	1.37 (0.13)	<0.001 (1.12, 1.62)	1.30 (0.14)	<0.001 (1.03, 1.57)
Age	0.01 (0.03)	0.74 (−0.05, 0.07)	0.02 (0.04)	0.62 (−0.06, 0.10)	−0.07 (0.04)	0.08 (−0.15, 0.01)
Female (vs. male)	−0.03 (0.06)	0.62 (−0.15, 0.09)	0.14 (0.08)	0.08 (−0.02, 0.30)	0.06 (0.08)	0.45 (−0.10, 0.22)
Education	0.01 (0.06)	0.87 (−0.11, 0.13)	0.03 (0.07)	0.67 (−0.11, 0.17)	0.04 (0.09)	0.66 (−0.14, 0.22)
LSSS	−0.03 (0.05)	0.55 (−0.13, 0.07)	0.01 (0.02)	0.62 (−0.03, 0.05)	−0.02 (0.03)	0.51 (−0.08, 0.04)
Intercept	2.19 (0.13)	<0.001 (1.94, 2.44)	2.46 (0.17)	<0.001 (2.13, 2.79)	3.68 (0.20)	<0.001 (3.29, 4.07)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; PBC = perceived behavioral control; LSSS = Liverpool Seizure Severity Scale.

Appendix Table 2
Linear mixed model results for measures on Health Action Process Approach concepts.

	Action planning		Coping planning	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	0.01 (0.12)	0.93 (−0.23, 0.25)	0.03 (0.15)	0.84 (−0.26, 0.32)
Month 1 (vs. baseline)	0.26 (0.10)	0.01 (0.06, 0.46)	0.23 (0.10)	0.02 (0.03, 0.43)
Month 3 (vs. baseline)	0.31 (0.09)	0.001 (0.13, 0.49)	0.20 (0.10)	0.046 (0.004, 0.40)
Month 6 (vs. baseline)	0.34 (0.10)	0.001 (0.14, 0.54)	0.21 (0.11)	0.06 (−0.01, 0.43)
CBT-I (vs. PE at 1 month)	1.43 (0.13)	<0.001 (1.18, 1.68)	1.18 (0.15)	<0.001 (0.89, 1.47)
CBT-I (vs. PE at 3 months)	1.33 (0.15)	<0.001 (1.04, 1.62)	1.33 (0.15)	<0.001 (1.04, 1.62)
CBT-I (vs. PE at 6 months)	1.35 (0.12)	<0.001 (1.11, 1.59)	1.34 (0.14)	<0.001 (1.07, 1.61)
Age	−0.04 (0.06)	0.51 (−0.16, 0.08)	0.05 (0.03)	0.10 (−0.01, 0.11)
Female (vs. male)	0.11 (0.12)	0.36 (−0.13, 0.35)	−0.15 (0.09)	0.10 (−0.33, 0.03)
Education	0.09 (0.11)	0.41 (−0.13, 0.31)	0.01 (0.01)	0.32 (−0.01, 0.03)
LSSS	−0.04 (0.10)	0.69 (−0.24, 0.16)	−0.02 (0.03)	0.51 (−0.08, 0.04)
Intercept	1.68 (0.21)	<0.001 (1.27, 2.09)	2.34 (0.18)	<0.001 (1.99, 2.69)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; LSSS = Liverpool Seizure Severity Scale.

Appendix Table 3
Linear mixed model results for measures on Control Theory concept.

	SRBAI		Self-monitoring	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	0.08 (0.15)	0.59 (−0.21, 0.37)	0.05 (0.11)	0.65 (−0.17, 0.27)
Month 1 (vs. baseline)	0.05 (0.13)	0.70 (−0.20, 0.30)	0.08 (0.09)	0.38 (−0.10, 0.26)
Month 3 (vs. baseline)	0.07 (0.14)	0.62 (−0.20, 0.34)	0.09 (0.08)	0.26 (−0.07, 0.25)
Month 6 (vs. baseline)	0.05 (0.11)	0.65 (−0.17, 0.27)	0.04 (0.09)	0.66 (−0.14, 0.22)
CBT-I (vs. PE at 1 month)	1.34 (0.18)	<0.001 (0.99, 1.69)	0.87 (0.12)	<0.001 (0.63, 1.11)
CBT-I (vs. PE at 3 months)	1.31 (0.19)	<0.001 (0.94, 1.68)	0.83 (0.11)	<0.001 (0.61, 1.05)
CBT-I (vs. PE at 6 months)	1.30 (0.16)	<0.001 (0.99, 1.61)	0.94 (0.12)	<0.001 (0.70, 1.18)
Age	0.04 (0.04)	0.32 (−0.04, 0.12)	0.01 (0.04)	0.80 (−0.07, 0.09)
Female (vs. male)	0.17 (0.14)	0.23 (−0.10, 0.44)	0.03 (0.06)	0.62 (−0.09, 0.15)
Education	0.02 (0.05)	0.69 (−0.08, 0.12)	0.02 (0.09)	0.82 (−0.16, 0.20)
LSSS	−0.05 (0.08)	0.53 (−0.21, 0.11)	0.01 (0.02)	0.62 (−0.03, 0.05)
Intercept	3.09 (0.23)	<0.001 (2.64, 3.54)	1.73 (0.19)	<0.001 (1.36, 2.10)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; SRBAI = Self-Report Behavioral Automaticity Index; LSSS = Liverpool Seizure Severity Scale.

Appendix Table 4
Linear mixed model results for measures on psychological distress (anxiety and depression).

	Anxiety		Depression	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	−0.14 (0.45)	0.76 (−1.02, 0.74)	−0.02 (0.39)	0.96 (−0.78, 0.74)

Appendix Table 4 (*continued*)

	Anxiety		Depression	
	B (*SE*)	*p* (95%CI)	*B* (*SE*)	*p* (95%CI)
Month 1 (vs. baseline)	−0.78 (0.41)	0.06 (−1.58, 0.02)	−0.13 (0.37)	0.73 (−0.86, 0.60)
Month 3 (vs. baseline)	−0.96 (0.40)	0.02 (−1.74, −0.18)	−0.21 (0.35)	0.55 (−0.90, 0.48)
Month 6 (vs. baseline)	−0.83 (0.42)	0.049 (−1.65, −0.01)	−0.14 (0.39)	0.72 (−0.90, 0.62)
CBT-I (vs. PE at 1 month)	−2.37 (0.58)	<0.001 (−3.51, −1.23)	−2.28 (0.51)	<0.001 (−3.28, −1.28)
CBT-I (vs. PE at 3 months)	−2.80 (0.55)	<0.001 (−3.88, −1.72)	−2.83 (0.49)	<0.001 (−3.79, −1.87)
CBT-I (vs. PE at 6 months)	−3.18 (0.59)	<0.001 (−4.34, −2.02)	−3.18 (0.44)	<0.001 (−4.04, −2.32)
Age	0.01 (0.02)	0.62 (−0.03, 0.05)	0.02 (0.01)	0.046 (0.0004, 0.04)
Female (vs. male)	0.44 (0.29)	0.13 (−0.13, 1.01)	0.21 (0.23)	0.36 (−0.24, 0.66)
Education	−0.05 (0.03)	0.10 (−0.11, 0.01)	0.04 (0.03)	0.18 (−0.02, 0.10)
LSSS	0.04 (0.06)	0.51 (−0.08, 0.16)	0.02 (0.03)	0.51 (−0.04, 0.08)
Intercept	10.03 (0.65)	<0.001 (8.76, 11.30)	7.22 (0.54)	<0.001 (6.16, 8.28)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; LSSS = Liverpool Seizure Severity Scale.

Appendix Table 5
Linear mixed model results for measures on quality of life.

	QOLIE-31 (overall score)	
	B (*SE*)	*p* (95%CI)
CBT-I (vs. PE)	0.57 (2.47)	0.82 (−4.27, 5.41)
Month 1 (vs. baseline)	3.78 (1.23)	0.002 (1.37, 6.19)
Month 3 (vs. baseline)	4.46 (1.22)	<0.001 (2.07, 6.85)
Month 6 (vs. baseline)	2.22 (1.17)	0.06 (−0.07, 4.51)
CBT-I (vs. PE at 1 month)	5.35 (1.74)	0.002 (1.94, 8.76)
CBT-I (vs. PE at 3 months)	4.36 (1.70)	0.01 (1.03, 7.69)
CBT-I (vs. PE at 6 months)	6.50 (1.37)	<0.001 (3.81, 9.19)
Age	−0.10 (0.09)	0.27 (−0.28, 0.08)
Female (vs. male)	−1.96 (2.30)	0.40 (−6.47, 2.55)
Education	0.17 (0.24)	0.48 (−0.30, 0.64)
LSSS	−0.09 (0.07)	0.20 (−0.23, 0.05)
Intercept	64.62 (4.93)	<0.001 (54.96, 74.28)

PE = patient education; CBT-I = cognitive-behavioral therapy for insomnia; LSSS = Liverpool Seizure Severity Scale.

Appendix Table 6
Mediated effects of variables in theory of planned behavior (TPB), health action process approach (HAPA), and control theory (CT) in the impacts of the CBT-I APP intervention on self-reported sleep hygiene behaviors at three- and six-months' postintervention.

Outcome	Mediator	Intervention effect on outcome (C)	Intervention effect on mediator (A)	Mediator effect on outcome (B)	Mediated effect (A * B)
		SE/95% CI	SE/95% CI	SE/95% CI	SE/95% CI
Self-reported sleep hygiene behaviors at 3 months		2.85 (0.83/1.22, 4.48)			
	Attitude		0.56 (0.14/0.29, 0.83)	1.00 (0.33/0.35, 1.65)	0.56 (0.23/0.11, 1.01)
	PBC		1.30 (0.14/1.03, 1.57)	0.03 (0.30/−0.56, 0.62)	0.04 (0.39/−0.72, 0.80)
	Intention		1.10 (0.17/0.77, 1.43)	0.65 (0.28/0.10, 1.20)	0.72 (0.33/0.07, 1.37)
	Action planning		1.43 (0.13/1.18, 1.68)	0.14 (0.25/−0.25, 0.63)	0.20 (0.36/−0.51, 0.91)
	Coping planning		1.18 (0.15/0.89, 1.47)	0.17 (0.23/−0.28, 0.62)	0.20 (0.27/−0.33, 0.73)
	Self-monitoring		0.87 (0.12/0.63, 1.11)	0.74 (0.26/0.23, 1.25)	0.64 (0.24/0.17, 1.11)
	SRBIA		1.34 (0.18/0.99, 1.69)	0.81 (0.20/0.42, 1.20)	1.08 (0.31/0.47, 1.69)
Self-reported sleep hygiene behaviors at 6 months		2.87 (0.80/1.30, 4.44)			
	Attitude		0.56 (0.14/0.29, 0.83)	0.66 (0.28/0.11, 1.21)	0.37 (0.18/0.02, 0.72)
	PBC		1.30 (0.14/1.03, 1.57)	0.31 (0.21/−0.10, 0.72)	0.40 (0.28/−0.15, 0.95)
	Intention		1.10 (0.17/0.77, 1.43)	0.41 (0.24/−0.06, 0.88)	0.45 (0.27/−0.08, 0.98)
	Action planning		1.43 (0.13/1.18, 1.68)	0.14 (0.23/−0.31, 0.59)	0.20 (0.33/−0.45, 0.85)
	Coping planning		1.18 (0.15/0.89, 1.47)	0.51 (0.21/0.10, 0.92)	0.60 (0.26/0.09, 1.11)
	Self-monitoring		0.87 (0.12/0.63, 1.11)	0.72 (0.26/0.21, 1.23)	0.63 (0.24/0.16, 1.10)
	SRBAI		1.34 (0.18/0.99, 1.69)	0.42 (0.20/0.03, 0.81)	0.56 (0.28/0.01, 1.11)

PBC = Perceived behavioral control; SRBAI = Self-Report Behavioral Automaticity Index.
Note: the indirect effects were computed using a 95% bias-corrected bootstrap confidence interval based on 10,000 bootstrap samples.

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