

Effects of ICT-based cognitive behavioral therapy using Smart Sleep for insomnia in older adults: Randomized controlled trial

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Effects of ICT-based cognitive behavioral therapy using Smart Sleep for insomnia in older adults: Randomized controlled trial

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Abstract

Background: Insomnia is a common sleep disorder, especially among the elderly, with a significant impact on the quality of life (QoL) and is associated with various comorbidities. Traditional pharmacotherapy for insomnia is often unsuitable for older adults because of potential drug interactions and side effects, making non-pharmacological interventions such as cognitive behavioral therapy for insomnia (CBT-I) more appropriate. However, delivering CBT-I in a traditional face-to-face setting poses challenges including accessibility and adherence, particularly for older adults.

Objective: This study aimed to evaluate the effectiveness of an information and communication technology (ICT)-based CBT-I program, "Smart Sleep," specifically designed to improve insomnia among community-dwelling elderly persons.

Methods: A randomized, single-blind controlled trial was conducted with 59 elderly participants from Incheon, South Korea. Participants were divided into an intervention group, which used the Smart Sleep mobile app, and a control group. The intervention group received 8 weeks of non-face-to-face CBT-I through the application, which included sleep diaries, relaxation exercises, and real-time consultations. Outcomes were measured at baseline, week 4, and week 8, with a focus on insomnia severity, sleep quality, sleep efficiency, dysfunctional beliefs about sleep, depression, and QoL.

Results: The intervention group showed significant improvements in insomnia severity, sleep quality, sleep efficiency, and dysfunctional beliefs about sleep compared with the control group. However, there was no significant difference in the QoL between the two groups ($F=0.998$, $p=.372$). Participation rates in the Smart Sleep program were high, with a 94% completion rate for sleep diary tasks and 100% participation in real-time consultations.

Conclusions: The ICT-based CBT-I program "Smart Sleep" effectively improved sleep-related outcomes among elderly participants, demonstrating the potential of non-face-to-face interventions in managing insomnia in this population. The program is user-friendly, and ICT-based coaching contributed to high engagement. To ensure broader access for the elderly, distribution through community welfare or public health centers is recommended. Clinical Trial: [cris.org KCT0007287](https://cris.org/KCT0007287)

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Original Manuscript

Original Paper

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Abstract

Background: Insomnia is a common sleep disorder, especially among the elderly, with a significant impact on the quality of life (QoL) and is associated with various comorbidities. Traditional pharmacotherapy for insomnia is often unsuitable for older adults because of potential drug interactions and side effects, making non-pharmacological interventions such as cognitive behavioral therapy for insomnia (CBT-I) more appropriate. However, delivering CBT-I in a traditional face-to-face setting poses challenges including accessibility and adherence, particularly for older adults.

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Conclusions: The ICT-based CBT-I program "Smart Sleep" effectively improved sleep-related outcomes among elderly participants, demonstrating the potential of non-face-to-face interventions in managing insomnia in this population. The program is user-friendly, and ICT-based coaching contributed to high engagement. To ensure broader access for the elderly, distribution through community welfare or public health centers is recommended.

Trial Registration: cris.org KCT0007287

Keywords: Insomnia; Cognitive Behavioral Therapy; Community Health Nursing; Mobile Applications; Information Communication Technology

Introduction

Insomnia, which refers to difficulty falling asleep and maintaining sleep [1], is a prevalent public health issue across a variety of age groups worldwide. This condition is often unrecognized or underreported and is considered a disease with significant economic costs [2]. The prevalence of insomnia increases significantly with age, with studies reporting a chronic insomnia prevalence of 20% to 40% among individuals aged 65 years and older [3]. Insomnia is associated with a high comorbidity with other physical and mental disorders, exhibiting a bidirectional relationship in which each can influence the other [4]. In particular, insomnia in the elderly can increase the risk of falls, as well as the onset and worsening of neuropsychiatric disorders, such as depression and dementia, and chronic diseases, such as cardiovascular disease, diabetes, and obesity, thereby reducing the overall quality of life (QoL) [5]. Considering these factors, insomnia in the elderly can ultimately have a negative impact on their overall health, necessitating appropriate treatment.

The most common treatments for insomnia include medications and cognitive behavioral therapy for insomnia (CBT-I) [6]. Pharmacological treatments are widely used for insomnia in clinical settings. However, pharmacotherapy may not be appropriate for elderly people or those with various comorbidities because of drug-drug interactions and side effects [7]. Researches have shown that long-term BZD use in older adults is associated with an increased risk of falls, hip fractures, and cognitive decline [8-10]. Considering that the elderly population may be more sensitive to drug side effects than other age groups, it is especially important to focus on non-pharmacological approaches to treating insomnia [11]. According to insomnia treatment guidelines, sleep medicine researchers strongly recommend nonpharmacological treatments, particularly CBT-I [12].

CBT-I aims to change dysfunctional thoughts, attitudes, and sleep-related habits. It consists of sleep restriction, stimulus control therapy, relaxation techniques, and sleep hygiene education [13]. Unlike drug therapy, in which patients passively follow a treatment regimen, CBT-I requires patients to actively recognize and assess their problems and engage in the process [14]. For effective treatment, it is essential that patients adhere to the treatment schedule and faithfully follow the recommended sleep-related measures. However, there are practical challenges in providing CBT-I to insomnia patients, such as participant adherence, costs, and time and space constraints [15].

For addressing these cost and accessibility issues, information and communication technologies (ICT) can be utilized to provide therapeutic tools such as CBT-I, enabling the delivery of these interventions in a non-face-to-face manner. By employing ICT, it is possible to overcome the limitations of time and space, making it easier for older adults, who may have difficulty visiting clinics multiple times, to receive treatment [15]. Additionally, ICT facilitates real-time monitoring and feedback to participants, which can help enhance patient engagement [16]. Previous studies have demonstrated the effectiveness of internet- or telephone-based CBT-Is in adults with insomnia [17-20]. However, to the best of our knowledge, few programs have specifically applied mobile app-based non-face-to-face CBT-I to improve insomnia among community-dwelling elderly people. Therefore, this study aimed to implement and evaluate the effectiveness of an ICT-based CBT-I program, "Smart Sleep" developed for elderly individuals with insomnia in the community.

Methods

Study Design and Setting

This randomized, single-blind, controlled study was conducted between May 2022 and October 2022 in Incheon Metropolitan City, Republic of Korea. This study was approved by the Gachon University Institutional Review Board (1044396-202203-HR-068-01) and registered at cris.org (KCT0007287). Approval from the institutional research ethics committee was obtained before the experiment began,

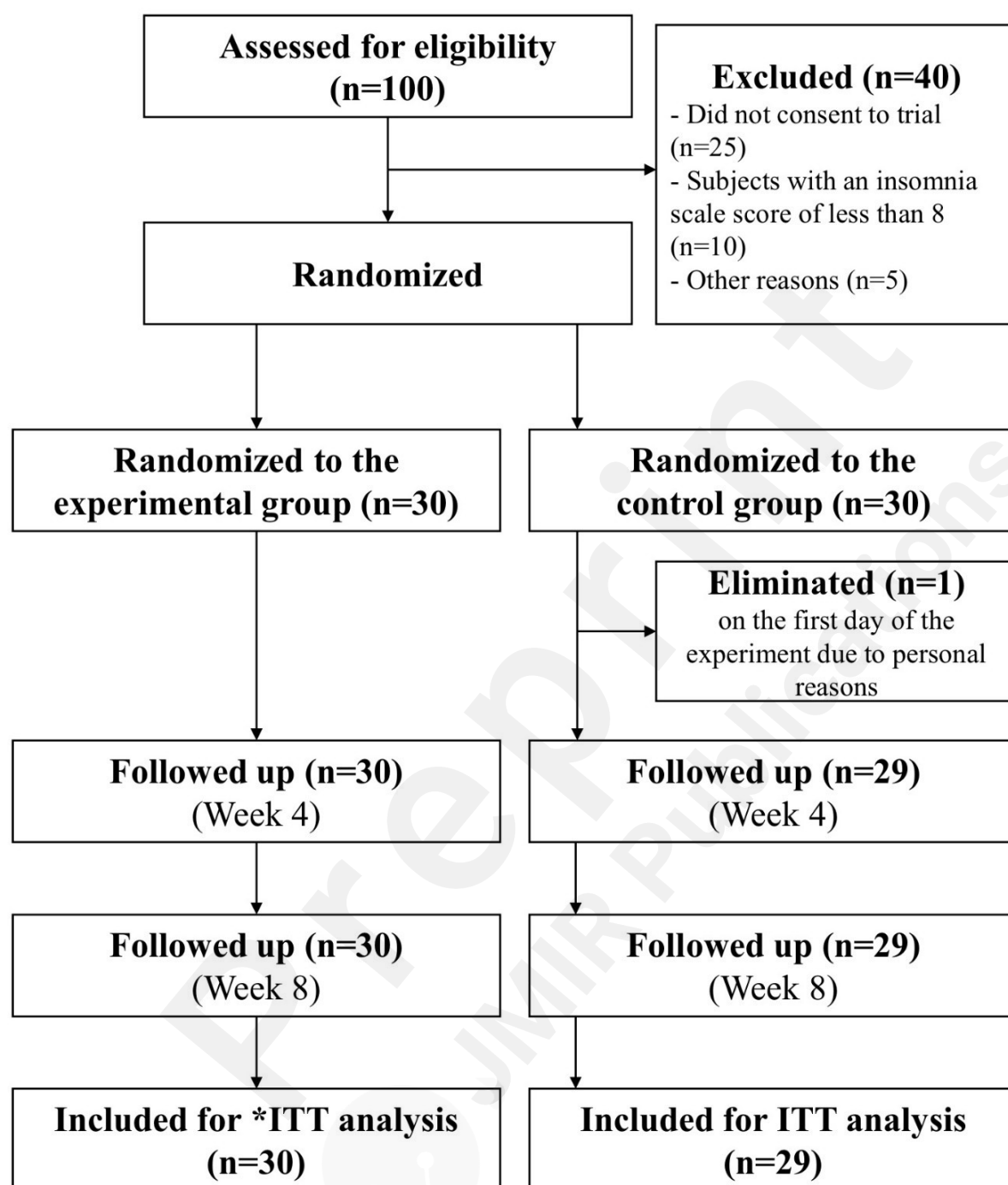
and the study was conducted in accordance with the principles set forth in the Declaration of Helsinki. Participants were briefed on the purpose of the study and the measures taken to protect their privacy before the study commenced. All participants provided written informed consent.

Participants

One hundred participants were enrolled in this study between May 2022 and July 2022. We included community-dwelling elderly people over 60 years of age living in Incheon City, and those scoring 8 or higher in the insomnia severity index (ISI) questionnaire [21] were selected as subjects. People with serious neuropsychiatric problems, hearing or seeing difficulties, or a history of alcohol or drug abuse were excluded from the selection criteria.

Of the 100 patients, 25 did not consent to participate in the study, 1 was excluded due to difficulty in walking, 10 were excluded due to a score of less than 8 on the insomnia scale, and 4 were excluded for personal reasons. Finally, 60 patients were included in the study. On the first day of the study, one participant in the control group was excluded for personal reasons and expressed refusal. Ultimately, the intervention was conducted on 30 participants in the experimental group and 29 participants in the control group (Figure 1).

G power 3.1.9.7 software (Helsinki Heine University, Dusseldorf, Germany) was used to determine the sample size. To calculate the sample size, alpha error probability and power were set to 0.05 and 0.95, respectively. Additionally, a medium effect size (0.25) was set based on Cohen's method 35. Therefore, a sample size of 44 was required. In total, 25% more participants were recruited to prepare for unexpected natural attrition.



*ITT(Intention to treat) : This refers to analysis based on the initial treatment group division, rather than dividing the patient group according to whether the patient actually received treatment.

Figure 1. Research flow chart

Randomization and Blinding

Simple randomization and hidden assignments were performed using a computer-generated randomization table before data collection. Participants were randomly classified into two groups: (a) intervention group and (b) control group. The order of the assignments was hidden from the

participants until the intervention was complete. To reduce bias, controls were also provided with tablets (Lenovo, 10.1, 1920×1200) and smart bands (Story4you, Korea) and were trained on how to use basic devices.

Intervention

The intervention provided CBT to elderly people with insomnia using a Smart Sleep application for 8 weeks. ICT-based applications have been developed through a systematic review and needs survey for preference analysis [22-23].

Preliminary training was conducted for 5 days before the intervention. All conditions were identical between the groups, except for the program, which ensured that the control group received the same conditions as the intervention group. This included training in tablet use, internet access, and provision of digital devices (tablets and smart bands) with limited content on today's to-do tasks to the control group. During the intervention, non-face-to-face services were used for the experimental group for 8 weeks to manage the participants. Questions and answers from users were answered, and participation was encouraged. The control group received usual care at a public health center. After all interventions and outcome measures were completed in the experimental group, the wait-listed participants in the control group received the intervention.

The main program content consisted of sleep information (sleep diary), relaxation training, sleep-related videos, exercise, and real-time consultation (Table 1). All contents were set and managed in the today's to-do list according to their frequency.

Sleep information was collected and an appropriate sleep plan was presented to each individual. Based on the sleep information collected through the sleep diary and sleep band, such as the time the participant went to bed, the time they actually fell asleep, the time they woke up in the morning, and the time they fully woke up, the sleep time appropriate for the participant was presented on the My Sleep Plan screen of sleep management. The participants completed a sleep diary every day for 8 weeks to obtain subjective sleep data. Sleep activity records were automatically uploaded and managed daily on the administrator's screen by having patients wear a sleep band.

Table 1. Contents of the CBT-I program "Smart sleep."

Contents of program	Program Frequency	Description
Sleep diary	Daily	Self-reporting information about last night sleep
Sleep band	Daily	Collecting sleep information wearing a sleep band
Survey	Once a week	Self-reporting the insomnia questionnaire using the ISI-K
Sleep management	Daily	Self-reporting the sleep habits questionnaire Based on sleep information by diary, band, and survey, providing recommendations on appropriate sleep duration for sleep restriction
Relaxation training video	Daily	Providing video for relaxation technique
Sleep helper	Daily	Equipped with sleep-aiding meditation, sleep music, and nature sounds
Sleep-related educational video	Daily	Providing video about correct information about sleep, proper sleep hygiene, and sleep stimulus control methods, etc
Exercise	Daily	Offering a real-time exercise program twice a week and fall prevention exercise video

Today's to-do list	Daily	Providing a pop-up notification to encourage walking 7,000 steps Sending push notification for incomplete tasks Applying goal achievement stamp for completed tasks
Real-time training and consulting	Once a week, with additional sessions upon request	Based on sleep information by diary, band, and survey, providing personalized sleep consultation and improving sleep-related cognition

The videos included relaxation training and educational videos. The participants were encouraged to watch relaxation and abdominal breathing training videos daily. In addition, in the sleep helpers category, meditation, sounds of nature, and sleeping music were included to help participants sleep with peace of mind. The educational videos included videos on sleep and insomnia, healthy sleeping habits, insomnia treatment, and relaxation training. By watching educational videos and providing accurate information about sleep through real-time education, sleep awareness was improved. For real-time exercise, participants were asked to engage twice a week in silver gymnastics and a walking program conducted at the public health center. In addition, one of the regular exercises was to walk more than 7,000 steps per day. The number of steps was measured using a sleep band and uploaded to the manager's program.

The researchers monitored participants' engagement and encourage active participation, with the program content provided exclusively to the intervention group. When today's to-do tasks were not implemented, the manager delivered a push notification to the target person so that they can perform today's to-do tasks. In addition, feedback was provided to participants at least once a week using video or phone calls connected to the mobile application. Live classes included consultations and training. Through real-time consultation and education, we communicated with researchers and developed knowledge about sleep to correct cognitive distortions. Additionally, pre-registered participants, along with their families and friends, were allowed video calls to provide emotional support.

Outcome Measures

All assessments were performed in the same week for both the intervention and control groups at baseline (week 0) and weeks 4 and week 8. We collected data through a self-administered survey conducted when the participants visited the public health center.

Insomnia Severity

The ISI, an insomnia severity scale, was adapted by Cho [24] from the tool developed by Bastein [21]. Higher scores indicate more severe insomnia.

Quality of Sleep

Sleep quality was measured using the Pittsburgh sleep quality index (PSQI) [25], a self-report measure of perception of habitual sleep translated by Sohn [26] into the Korean version (of the PSQI (PSQI-K)). The PSQI-K comprises 19 items. The total score ranges from a minimum of 0 to a maximum of 21, with higher scores indicating poorer sleep quality.

Sleep Efficiency

Sleep efficiency is calculated as a percentage by dividing the total sleep time by the total time spent in bed and is the most common indicator for objectively evaluating sleep quality. Total sleep time

was calculated as the total time spent in bed minus sleep latency and awakening time after sleep [27-28]. In our program, sleep efficiency was calculated based on sleep diaries.

Dysfunctional Beliefs and Attitudes about Sleep (DBAS)

DBAS is a self-report scale with a total of 16 questions developed to evaluate insomnia patients' incorrect beliefs and attitudes about sleep developed by Morin [29]. This study used the Korean version of the DBAS (K-DBAS-16), adapted and validated by Yoo [30]. The lower the score on the DBAS, the more positive results can be inferred from CBT-I.

Depression

The depression scale translated by Cho [31] was used, based on the geriatric depression scale (GDS) [32]. The total score is 15 points; the higher the score, the higher the level of depression.

QoL

Euro-quality of life-5 dimension (EQ-5D) is a tool developed by the EuroQol Group to measure health-related QoL and consists of five items: exercise ability, self-care, daily activities, pain/inconvenience, and anxiety/depression [33].

Statistical Analysis

The collected data were analyzed using SPSS WIN26.0. The general characteristics of participants were analyzed using the chi-square test and t-test. After testing the normality of each variable using the Shapiro–Wilk test, all indicators were normally distributed and were analyzed using an independent t-test to test the normality of each variable. The results of the application usability measurement conducted in the 8th week for the experimental group were analyzed using means and standard deviations. To analyze the mean differences between groups and over time, repeated measures ANOVA was conducted on sleep quality, depression, QoL, dysfunctional beliefs and attitudes toward sleep, insomnia, and sleep efficiency. A paired t-test was used to compare changes in sleep quality, depression, QoL, dysfunctional beliefs and attitudes toward sleep, insomnia scale, sleep efficiency, and baseline scores between the experimental and control groups over time. The significance level was set at $p < .05$.

Results

Participant Characteristics

One of the 60 participants was excluded from the trial for personal reasons after randomization on the first day of the experiment (one from the control group). A total of 59 participants (30 in the experimental group and 29 in the control group) completed the study. All baseline general characteristics were well-matched between the experimental and control groups (Table 2). The average age of the participants was 70.70 years ($SD=4.49$) in the experimental group and 70.27 years ($SD=4.97$) in the control group. The experimental and control groups included 6 men (20%) and 24 women (80%), and 6 men (20.6%) and 23 women (79.3%), respectively.

As a result of testing the homogeneity of the research variables before the experiment using a t-test, there was no significant difference between the experimental and control groups in terms of the main research variables (Table 2). For the insomnia scale, the scores were 14.47 ± 4.52 points in the experimental group and 17.28 ± 5.87 points in the control group. Sleep quality was rated at 11.73 ± 3.33 points in the experimental group and 10.24 ± 3.94 points in the control group. The recorded sleep efficiency was 61.25 ± 16.64 in the experimental group and 59.13 ± 9.88 in the control

group.

Table 2. Baseline characteristics of participants.

Parameter	Experimental group (n=30)	Control group (n=29)	P value
Age, Mean (SD)	70.70 (4.49)	70.27 (4.97)	.585
Sex, n (%)			
Men	6 (20)	6 (20.6)	.754
Women	24 (80)	23 (79.3)	
Education, n (%)			
uneducated	1 (3.3)	2 (6.9)	.285
Elementary school	8 (26.7)	9 (31)	
Middle school	10 (33.3)	6 (20.6)	
High school	8 (26.7)	9 (31)	
≥ College	3 (20)	2 (6.8)	
Living state, n (%)			
Alone	25 (83.3)	23 (79.3)	.436
With family	5 (16.6)	6 (20.6)	
No. of drugs, n (%)			
≤ 3	25 (83.3)	26 (89.6)	.448
≥ 4	5 (16.7)	5 (16.7)	
Smoking, n (%)			
Yes	2 (6.6)	2 (6.8)	.161
No	28 (93.3)	27 (93.1)	
Drinking, n (%)			
Yes	3 (10)	4 (13.7)	.739
No	27 (90)	25 (86.2)	
Use of sleeping pills, n (%)			
Yes	13 (43.3)	10 (34.4)	.230
No	17 (56.6)	19 (65.5)	
ISI-K, Mean (SD)	14.47 (4.52)	14.93 (6.09)	.510
Sleep efficiency, Mean (SD)	61.25 (16.64)	59.13 (18.75)	.557
PSQI-K, Mean (SD)	11.73 (3.33)	10.24 (3.94)	.915
K-DBAS-16, Mean (SD)	104.4 (32.55)	109.9 (35.45)	.648
SGDS-K, Mean (SD)	6.23 (3.99)	6.65 (4.58)	.270
EQ-5D, Mean (SD)	0.75 (0.16)	0.65 (0.22)	.908
ISI: insomnia severity scale, PSQI: Pittsburgh sleep quality index, DBAS-16: dysfunctional beliefs and attitudes about sleep, SGDS: short geriatric depression scale, EQ-5D: Euro-quality of life-5 dimension			

Comparison of the Effects Between the Intervention and Control Groups

Statistically significant differences were observed in the ISI-K, PSQI-K, sleep efficiency, K-DBAS-16, and SGDS-K scores ($p < .001$ for all), whereas the EQ-5D scores ($p = .372$) did not show statistical significance. The control group showed no significant changes in any of the indicators before or after the intervention (Table 3).

In the intervention group, the ISI-K scores showed a statistically significant reduction at weeks 4 (-6.76, 95% CI: -9.19 to -4.34) and 8 (-9.90, 95% CI: -12.24 to -7.55). Similarly, the PSQI-K scores demonstrated a notable decline at week 4 (-4.96, 95% CI: -6.54 to -3.39) and further at week 8 (-

6.83, 95% CI: -8.40 to -5.26) from the baseline. In terms of sleep efficiency, there was a significant increase at weeks 4 (16.91, 95% CI: 10.25 to 23.58) and 8 (23.32, 95% CI: 16.86 to 29.68). The K-DBAS-16 scores also showed a considerable drop, with week 4 recording a decrease of -51.0 (95% CI: -65.96 to -36.03) and week 8 showing a further reduction to -71.86 (95% CI: -86.18 to -57.55). Lastly, the SGDS-K scores were significantly lower by week 4 (-3.06, 95% CI: -4.97 to -1.15) and continued to decrease by week 8 (-3.96, 95% CI: -5.75 to -2.17) compared with the baseline. Although the EQ-5D scores tended to increase at week 8 (0.10, 95% CI 0.03 to 0.18) from the baseline, the difference between the two groups was not statistically significant. In the within-group comparison before and after the intervention, the experimental group showed a significant difference at 8 weeks ($p=.006$), whereas the control group did not ($p=.440$).

Data analysis revealed the following results regarding the interaction effects between time points and groups. Insomnia severity ($F=18.923$), sleep quality ($F=97.806$), sleep efficiency ($F=22.394$), DBAS ($F=77.233$), and depressive symptoms ($F=25.715$) showed statistically significant interactions between time points and groups ($p<.001$ for all). In contrast, QoL scores did not show a statistically significant interaction between time points and groups ($F=0.998$, $p=.372$). However, there were significant differences between the groups ($F=9.779$, $p=.003$) and across time points ($F=5.423$, $p=.006$).

Table 3. Comparison of the effects between the intervention and control groups.

	Mean±SD			Change from baseline, Mean (95% CI)		Time X Group interaction, P value
	Baseline	Week 4	Week 8	Week 4	Week 8	
ISI-K						<.001
Intervention	14.47 (4.52)	7.70 (4.85)	4.57 (4.55)	-6.76 ^a (-9.19, -4.96)	-9.90 ^a (-12.24, -7.55)	
Control	17.28 (5.87)	14.93 (6.09)	15.00 (6.38)	0.00 (-3.20, 3.20)	-2.27 (-5.50, 0.94)	
PSQI-K						<.001
Intervention	11.73 (3.33)	6.77 (2.74)	4.90 (2.72)	-4.96 ^a (-6.54, -3.39)	-6.83 ^a (-8.40, -5.26)	
Control	10.24 (3.94)	11.72 (3.98)	11.48 (4.02)	1.48 (-0.60, 3.56)	1.24 (-0.85, 3.33)	
Sleep efficiency						<.001
Intervention	61.25 (16.64)	78.16 (7.44)	84.57 (5.06)	16.91 ^a (14.13, 19.69)	23.32 ^a (21.43, 25.21)	
Control	59.13 (9.88)	59.0 (8.06)	58.04 (8.94)	-0.04 (-3.05, 2.97)	-1.09 (-4.43, 2.25)	
K-DBAS-16						<.001
Intervention	104.0 (32.56)	53.40 (54.85)	32.58 (21.78)	-51.0 ^a (-65.96, -36.03)	-71.86 ^a (-86.18, -57.55)	
Control	109.93 (35.45)	107.28 (30.43)	109.83 (28.5)	-2.65 (-20.03, 14.72)	-0.10 (-17.02, 16.81)	
SGDS-K						<.001
Intervention	6.23 (3.99)	3.17 (3.36)	2.27 (2.83)	-3.06 ^a (-4.97, -1.15)	3.96 ^a (-5.75, -2.17))	

Control	6.66 (4.59)	6.76 (4.37)	7.72 (4.68)	0.1 (-2.25, 2.46)	1.06 (-1.36, 3.50)	0.372
EQ-5D						
Intervention	0.75 (0.16)	0.80 (0.14)	0.85 (0.11)	0.05 (-0.02, 0.13)	0.1 (0.03, 0.18)	
Control	0.65 (0.22)	0.68 (0.21)	0.69 (0.2)	0.37 (-0.78, 0.15)	0.04 (-0.06, 0.15)	

ISI: insomnia severity scale, PSQI: Pittsburgh sleep quality index, DBAS-16: dysfunctional beliefs and attitudes about sleep, SGDS: short geriatric depression scale, EQ-5D: Euro-quality of life-5 dimension

^at-test for change from baseline between groups: $p < .05$

Participation Rate and Comparative Analysis based on the Smart Sleep Application Participation Rate in the Experimental Group

Participation rates in the Smart Sleep program were high, with a 94% completion rate for sleep diary tasks and 100% participation in real-time consultations.

Differences in outcome measures according to the participation rate in the Smart Sleep application program were investigated. In the experimental group, participants were divided into high- and low-participation groups based on a 70% total participation rate in the Smart Sleep program. Neither group followed a normal distribution; therefore, the Wilcoxon test was conducted. The results showed that changes in the ISI-K, PSQI-K, sleep efficiency, K-DBAS-16, and SGDS-K scores before and after the intervention were significant in the group with high participation rates. Participants with a participation rate of 70% or higher showed an improvement in their QoL, while the EQ-5D results did not significantly change in the group with lower participation rates after the intervention (Table 4).

Table 4. Subgroup analysis according to program participation in the intervention group.

Outcome measures	Group ^a	Baseline, Mean (SD)	Week 8, Mean (SD)	Comparison by time in group, z (p)
ISI-K				
	High (n=20)	14.2 (4.50)	4.25 (4.15)	-3.826 (<.001)
	Low(n=10)	15.00 (4.76)	5.20 (5.43)	-2.805 (.005)
Sleep efficiency				
	High	61.25 (18.33)	85.00 (4.54)	-3.824 (<.001)
	Low	60.90 (13.16)	83.90 (6.22)	-2.805 (.005)
PSQI-K				
	High	11.60 (3.66)	4.95 (2.62)	-3.931 (<.001)
	Low	12.00 (2.70)	4.80 (3.04)	-2.814 (.005)
K-DBAS-16				
	High	100.80 (32.99)	31.85 (24.19)	-3.920 (<.001)
	Low	111.60 (32.11)	33.90 (17.01)	-2.803 (.005)
SGDS-K				
	High	4.90 (3.38)	1.40 (1.84)	-3.768 (<.001)
	Low	8.90 (3.90)	4.20 (3.61)	-2.809 (.005)
EQ-5D				
	High	0.78 (0.14)	0.87 (0.12)	-2.741 (.003)
	Low	0.68 (0.19)	0.81 (0.07)	-1.886 (.059)

ISI: insomnia severity scale, PSQI: Pittsburgh sleep quality index, DBAS-16: dysfunctional beliefs and attitudes about sleep, SGDS: short geriatric depression scale, EQ-5D: Euro-quality of life-5 dimension

^aHigh and low groups are classified based on a participation rate of 70% in the intervention group

Discussion

Effects of ICT-based CBT-I on Insomnia

This study confirmed that a mobile app-based CBT-I program is highly effective in improving sleep in elderly people. Significant improvements were observed in sleep-related indicators, including insomnia severity, sleep efficiency, sleep quality, and DBAS, in the intervention group compared with the control group.

The significant improvement in the ISI scores was consistent with previous CBT-I studies on the elderly using a telephone- or internet-based program [17-18, 34]. However, to the best of our knowledge, only a few studies have examined CBT-I programs using ICTs (mobile or digital CBT-I) that are more advanced than web-based CBT-I in older adults. A case report of mobile application-assisted CBT-I for older adults in Taiwan reported that a 64-year-old woman successfully quit sleeping pills, and her sleep quality, evaluated using a Likert scale, improved after using a mobile app [34]. In addition, a pre-post comparison study using a mobile app in Korea found that changes in subjective sleep quality based on the PSQI after the intervention were significant [35]. Although this study was not an RCT, it demonstrated the possibility that a mobile phone-based self-help CBT-I app could be useful in improving sleep in older adults [35]. Other possible reasons why the treatment program used in this study might have been effective include various elements based on CBT-I, such as sleep diaries for sleep stimulus control and sleep hygiene improvement, non-face-to-face counseling, sleep management for sleep restriction, and exercise programs for relaxation training, which are expected to have contributed to the systematic improvement of participants' sleep patterns and perceptions about sleep.

In this study, sleep restriction was somewhat more flexible than in the general population, considering the characteristics of elderly users, which may have helped to keep participants more engaged. The use of a moderated sleep restriction approach specifically tailored for older adults led to improvements in sleep-related measures, even among the elderly people targeted in this study. Older adults may struggle with strict components of CBT-I, such as sleep restriction, due to the physical and cognitive demands of aging [36]. Considering the characteristics of the elderly with reduced adaptability to abrupt changes in sleep patterns [37], sleep restriction was not excessively enforced, but was gradually adjusted to improve sleep efficiency at an appropriate pace. While previous studies have set the sleep efficiency target for adults at 85% [38-39], we adjusted the target to 75% to account for the unique sleep characteristics of older individuals. In addition, by combining the subjective sleep diary, which participants filled out themselves, with objective sleep data collected from wearable devices, more appropriate sleep restrictions could be applied to each individual. Using a combination of subjective and objective sleep data may help correct sleep misperceptions in older adults, allowing for a more accurate sleep plan. Older adults tend to overestimate or underestimate their actual sleep duration, making it difficult to accurately assess sleep problems based solely on subjective data [40]. Therefore, this study supplemented subjective perceptions by rechecking objective data from a wearable device, leading to more accurate sleep prescriptions and effective outcomes for insomnia. Significant improvements were observed in the ISI scores and sleep efficiency among participants in our study, which is consistent with the findings of other studies conducted in adult populations [41-42].

Moreover, cognitive restructuring through cognitive therapy components, sleep stimulus control methods, and sleep hygiene in our treatment program may have led to improvements in the dysfunctional beliefs scored using the DBAS scale. A previous mobile CBT-I study did not show a significant improvement in the DBAS scores, possibly because of its sole focus on sleep restriction [41]. Dysfunctional beliefs about sleep and insomnia may be better addressed with a cognitive therapy component. This study used a multifaceted approach of various components of CBT-I, including a cognitive therapy component. In our study, sleep stimulus control was adjusted to suit the adaptability of the older adults. While recommendations for adults suggest leaving the bed after 15-20 min of being awake [39], we modified the protocol to allow up to 30 min before instructing the participants to leave the bed. This adjustment aimed to provide a more flexible approach that was better suited to the needs of elderly individuals, ensuring that they could adapt to changes more comfortably, while maintaining the principles of stimulus control therapy. Additionally, sleep hygiene practices, such as avoiding coffee and alcohol consumption and maintaining a quiet, dark environment, were recorded daily using a checklist. Non-face-to-face counseling was conducted to encourage older adults to continuously check and improve their sleep hygiene.

Moreover, this study suggests that despite being provided in a non-face-to-face manner, the program can successfully alter participants' perceptions of sleep. Although CBT-I is a highly effective treatment for insomnia, its limited availability and accessibility mean that only a small number of insomnia patients benefit from it [43]. Therefore, Smart Sleep using ICT may offer an opportunity to provide CBT-I to a larger number of insomnia patients, and it is thought that it can contribute to the improvement of insomnia.

Effects of ICT-based CBT-I on QoL

The results of this study showed that QoL improved in the intervention group before and after the intervention, whereas the control group did not show a statistically significant difference. However, when comparing the intervention and control groups, there was no significant difference in the improved QoL. The effect of CBT-I on QoL has shown varying results across studies, with some finding it effective and others not [22, 44]. QoL is a multidimensional concept comprising physical, mental, and economic factors. Since CBT-I mainly focuses on improving sleep quality, its impact on other aspects of QoL may be relatively small or indirect. Even if sleep quality improves, the overall effect on the QoL may be limited, if elements such as physical health or pain, as measured by the EQ-5D used in this study, do not improve. In particular, older adults have multiple medical and psychiatric comorbidities and environmental factors that are difficult to change; therefore, global QoL improvement from improving insomnia may be limited. Nevertheless, the significant effects observed before and after the intervention in the intervention group, unlike in the control group, suggest that ICT-based CBT-I has the potential to improve QoL. In our study, QoL also improved in the high adherence group ($\geq 70\%$ adherence), suggesting that improving adherence will lead to improved QoL. Future studies should consider how ICT-based CBT-I programs can improve other factors related to the QoL, such as emotional stability, stress management, and social interaction, in addition to sleep.

Boosting Engagement in Non-Face-to-Face CBT-I: Insights into Adherence

This study showed a dropout rate of 1.6%, which is lower than the 6 to 48% reported in other studies [45]. In addition, the sleep diary mission completion rate was 94%, and the real-time consulting participation rate was 100%, both of which were very high. Due to cognitive decline, older adults find it easier to record sleep patterns using simple, predefined options rather than writing complex responses [36]. Reflecting on this characteristic of the elderly, this study designed a sleep diary that proceeds automatically by presenting questions with a simple touch, allowing participants to complete the survey more easily. This could be a key factor in increasing adherence rates among

older adults. Although older adults may be slower to adapt to ICT, such as mobile applications, than younger generations, the design of mobile applications with high user-friendliness and appropriate feedback and support, such as telephone coaching, can lead to higher treatment retention rates and better treatment outcomes.

Increasing the participation rate in non-face-to-face interventions is a challenging task [46]. In this study, the analysis of the Smart Sleep application participation rate showed that the group with a high participation rate showed improvement in both the sleep scale and QoL, whereas the group with a low participation rate did not show a significant improvement in the QoL. Therefore, enhancing user involvement is crucial for the effective treatment of insomnia in non-face-to-face environments. This is consistent with an important element of CBT-I, which improves misconceptions about insomnia through the active participation of subjects. Additionally, strategies such as goal achievement stamps and incentives to encourage continuous participation are believed to enhance this effect. As this study was based on data limited to a specific population, further research is required on the relationship between program components, participation rates, and outcomes.

Limitations

This study was conducted in a specific group (i.e., community-dwelling elderly), and the sample size was small, which limited the generalizability of the results to all elderly people. Further studies should involve diverse regions and larger sample sizes to validate the effectiveness of the program. Second, insomnia is a chronic condition with a risk of recurrence, making continuous management and monitoring necessary, even after short-term treatment. While CBT-I was effective for insomnia in this study, symptoms may recur because of factors such as stress or life changes. Therefore, long-term follow-up is essential to assess the sustained effects of the intervention. Finally, the elderly might require more time to adapt to program usage than the younger age groups. In this study, an experiment was conducted while the researcher continued to educate participants on how to use the program. In the case of the elderly, programs that are easy to use, either by telephone coaching, as in this study, or by being very interactive, should be developed, and ongoing efforts should be made to improve and evaluate the usability of treatment programs.

Conclusions

The results of this study showed that Smart Sleep is an ICT-based CBT-I that can provide effective non-face-to-face treatment for older adults with insomnia. Individuals who participated in the Smart Sleep program were able to effectively improve their sleep and most related measures through various treatment contents such as sleep assessment, sleep diary and sleep monitoring via wearable devices, sleep restriction, stimulus control, cognitive therapy, sleep hygiene education, relaxation techniques, sleep knowledge education, exercise programs, and telephone coaching. The program is easy to use and has an intuitive menu structure, which makes it easy for the elderly to use, and the telephone coaching is thought to have contributed to the high usage rate. In the future, to effectively provide Smart Sleep to the elderly in the community, it is recommended to distribute it through community welfare or public health centers to improve the sleep health of many elderly people.

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Conflicts of Interest

None declared.

Abbreviations

ANOVA: analysis of variance
 CBT-I: cognitive behavioral therapy for insomnia
 DBAS: dysfunctional beliefs and attitudes about sleep
 EQ-5D: euro-quality of life-5 dimension
 GDS: geriatric depression scale
 ICT: information and communication technologies
 ISI: insomnia severity index
 PSQI: Pittsburgh sleep quality index
 QOL: quality of life
 SPSS: statistical package for the social sciences

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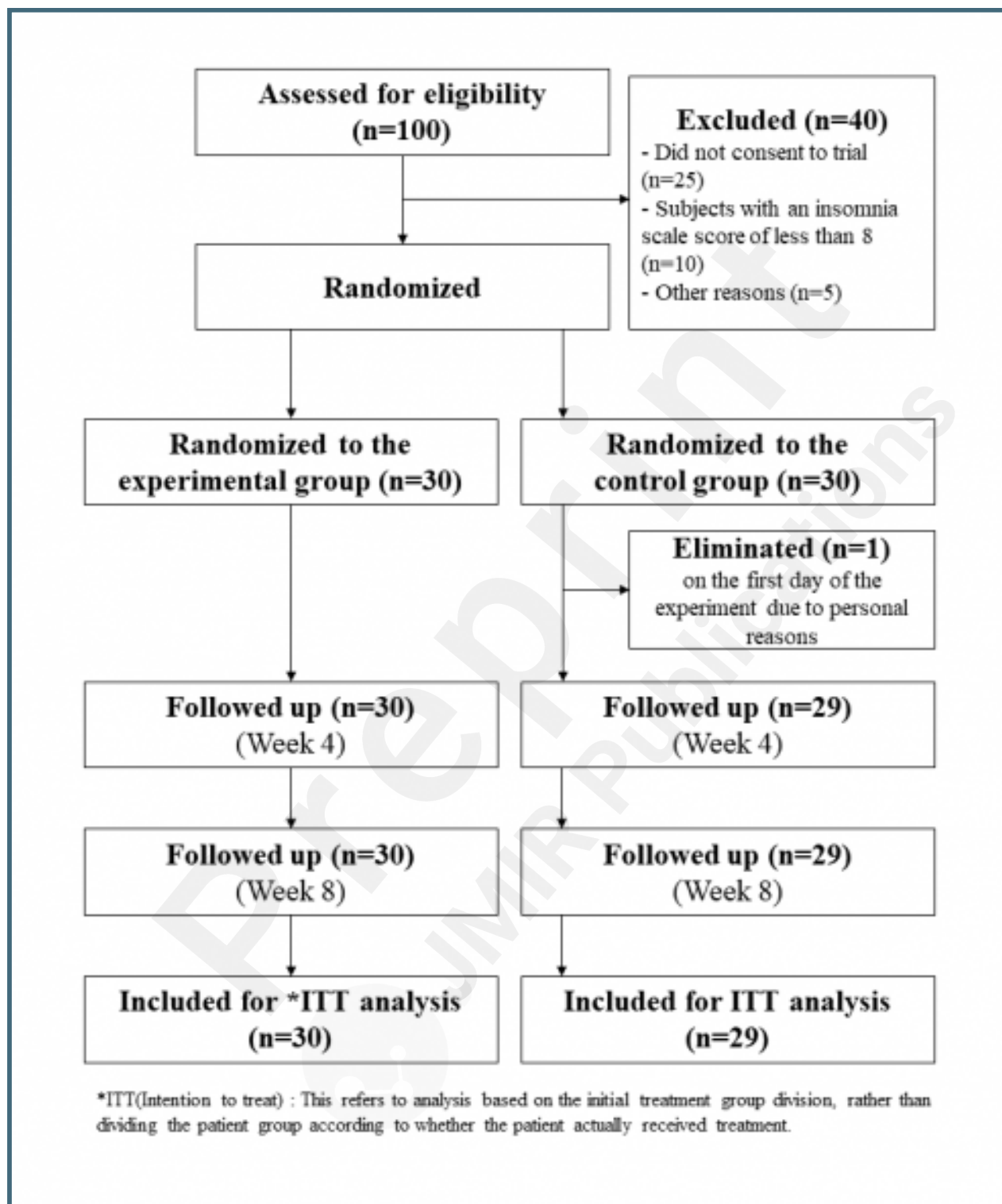
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Supplementary Files

Figures

Research flow chart.



CONSORT (or other) checklists

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