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Effect of a Web-Based Cognitive Behavior Therapy for Insomnia Intervention With 1-Year Follow-up
A Randomized Clinical Trial

Lee M. Ritterband, PhD; Frances P. Thorndike, PhD; Karen S. Ingersoll, PhD; Holly R. Lord, PhD; Linda Gonder-Frederick, PhD; Christina Frederick, BS; Mark S. Quigg, MD, MSc; Wendy F. Cohn, PhD; Charles M. Morin, PhD

IMPORTANCE Although cognitive behavior therapy for insomnia (CBT-I) has been established as the first-line recommendation for the millions of adults with chronic insomnia, there is a paucity of trained clinicians to deliver this much needed treatment. Internet-delivered CBT-I has shown promise as a method to overcome this obstacle; however, the long-term effectiveness has not been proven in a representative sample with chronic insomnia.

OBJECTIVE To evaluate a web-based, automated CBT-I intervention to improve insomnia in the short term (9 weeks) and long term (1 year).

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial comparing the internet CBT-I with internet patient education at baseline, 9 weeks, 6 months, and 1 year. Altogether, 303 adults with chronic insomnia self-referred to participate, of whom 151 (49.8%) reported at least 1 medical or psychiatric comorbidity.

INTERVENTIONS The internet CBT-I (Sleep Healthy Using the Internet [SHUTi]) was a 6-week fully automated, interactive, and tailored web-based program that incorporated the primary tenets of face-to-face CBT-I. The online patient education program provided nontailored and fixed online information about insomnia.

MAIN OUTCOMES AND MEASURES The primary sleep outcomes were self-reported online ratings of insomnia severity (Insomnia Severity Index) and online sleep diary–derived values for sleep-onset latency and wake after sleep onset, collected prospectively for 10 days at each assessment period. The secondary sleep outcomes included sleep efficiency, number of awakenings, sleep quality, and total sleep time.

RESULTS Among 303 participants, the mean (SD) age was 43.28 (11.59) years, and 71.9% (218 of 303) were female. Of these, 151 were randomized to the SHUTi group and 152 to the online patient education group. Results of the 3 primary sleep outcomes showed that the overall group × time interaction was significant for all variables, favoring the SHUTi group (Insomnia Severity Index [$F_{3,1063}$ = 20.65, P < .001], sleep-onset latency [$F_{3,1042}$ = 6.01, P < .001], and wake after sleep onset [$F_{3,1042}$ = 12.68, P < .001]). Within-group effect sizes demonstrated improvements from baseline to postassessment for the SHUTi participants (range, Cohen d = 0.79 [95% CI, 0.55-1.04] to d = 1.90 [95% CI, 1.62-2.18]). Treatment effects were maintained at the 1-year follow-up (SHUTi Insomnia Severity Index d = 2.32 [95% CI, 2.01-2.63], sleep-onset latency d = 1.41 [95% CI, 1.15-1.68], and wake after sleep onset d = 0.95 [95% CI, 0.70-1.21]), with 56.6% (69 of 122) achieving remission status and 69.7% (85 of 122) deemed treatment responders at 1 year based on Insomnia Severity Index data. All secondary sleep outcomes, except total sleep time, also showed significant overall group × time interactions, favoring the SHUTi group.

CONCLUSIONS AND RELEVANCE Given its efficacy and availability, internet-delivered CBT-I may have a key role in the dissemination of effective behavioral treatments for insomnia.

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Supplemental content

Author Affiliations: Center for Behavioral Health & Technology, Department of Psychiatry and Neurobehavioral Sciences, University of Virginia School of Medicine, Charlottesville (Ritterband, Thorndike, Ingersoll, Lord, Gonder-Frederick, Frederick); The F.E. Dreifuss Comprehensive Epilepsy Program, Department of Neurology, University of Virginia School of Medicine, Charlottesville (Quigg); Department of Public Health Sciences, University of Virginia School of Medicine, Charlottesville (Cohn); Department of Psychology, Université Laval, Laval, Quebec, Canada (Morin).

Corresponding Author: Lee M. Ritterband, PhD, Department of Psychiatry and Neurobehavioral Sciences, Center for Behavioral Health & Technology, University of Virginia School of Medicine, PO Box 801075, Charlottesville, VA 22908 (leer@virginia.edu).

Insomnia is a significant public health problem with substantial medical, psychiatric, and financial ramifications. Simply defined, insomnia is difficulty falling asleep or maintaining sleep, and it is one of the most common health concerns today.[1] Approximately 35% to 50% of the general adult population experience insomnia symptoms,[2] with 12% to 20% meeting criteria for insomnia as a disorder.[3,4] Insomnia is highly comorbid with medical[5] and psychiatric[6] disorders. The combined direct and indirect costs associated with insomnia exceed $100 billion in the United States alone.[7] Given the high prevalence and detrimental effect of insomnia, finding effective, accessible, and affordable treatment is critical.

Cognitive behavior therapy (CBT) and pharmacotherapy are the only 2 treatments with sufficient empirical support to be recommended for treating chronic insomnia (>1 month).[8,9] While medication use is readily accessible and effective in the short term, CBT for insomnia (CBT-I) has longer-lasting benefits, with fewer adverse effects.[10] It is now recommended as a first-line treatment.[1,9] Most important, CBT-I addresses the problematic thoughts and behaviors believed to have developed in response to acute insomnia or a short-term sleep problem (days or weeks).

Although there is strong empirical support for CBT-I, the lack of trained clinicians and expense, while cost-effective,[11] limits access. To overcome these barriers, innovative methods of delivering CBT-I have been developed, and initial evidence supports their feasibility and efficacy.[12] To date, internet-based trials with published outcomes have been small, homogeneous, and limited in their generalizability and have excluded individuals with insomnia co-occurring with medical and psychiatric disorders.[13]

The present study was designed to address several limitations that exist within the internet-delivered CBT-I literature.[12] This large-scale randomized clinical trial tested the long-term effect of a fully automated internet CBT-I intervention in a heterogeneous sample representing geographic, psychiatric, and medical diversity. In contrast to those with access to an insomnia education website, the internet CBT-I participants were hypothesized to show greater improvements in the primary sleep outcomes of Insomnia Severity Index (ISI), sleep-onset latency (SOL), and wake after sleep onset (WASO). It was also hypothesized that the internet CBT-I participants would demonstrate greater improvements in the secondary sleep outcomes, including sleep efficiency, number of awakenings, sleep quality, and total sleep time. Intervention use and clinical significance are also described.

Key Points

Question What is the efficacy of a fully automated internet-delivered cognitive behavior therapy for insomnia intervention compared with an insomnia patient education website with respect to the primary sleep outcomes of Insomnia Severity Index, sleep onset latency, and wake after sleep onset in a heterogeneous sample?

Findings In this randomized clinical trial of 303 adults with chronic insomnia, those who received the internet cognitive behavior therapy for insomnia intervention (Sleep Healthy Using the Internet [SHUTi]) had significantly improved sleep compared with those who received access to the patient education website, with 56.6% achieving insomnia remission status and 69.7% deemed treatment responders at 1 year.

Meaning Achieving improved sleep outcomes using an internet intervention without human support that are similar in magnitude to those reported in trials with face-to-face cognitive behavior therapy for insomnia has important implications for public health.

Methods

Design

This single-blind (participant) randomized clinical trial included 303 adults aged 21 to 65 years with chronic insomnia. Outcome data were collected online in this 2-group (internet-delivered CBT-I vs online patient education [PE]) trial at 4 assessment points, including baseline, 9 weeks, 6 months, and 1 year. All participants gave informed consent by providing a digital signature to the online form after discussion with study staff (including one of us, C.F.) by telephone. The study design and protocol (Supplement 1) were approved by the Institutional Review Board for Health Sciences Research at the University of Virginia, Charlottesville.

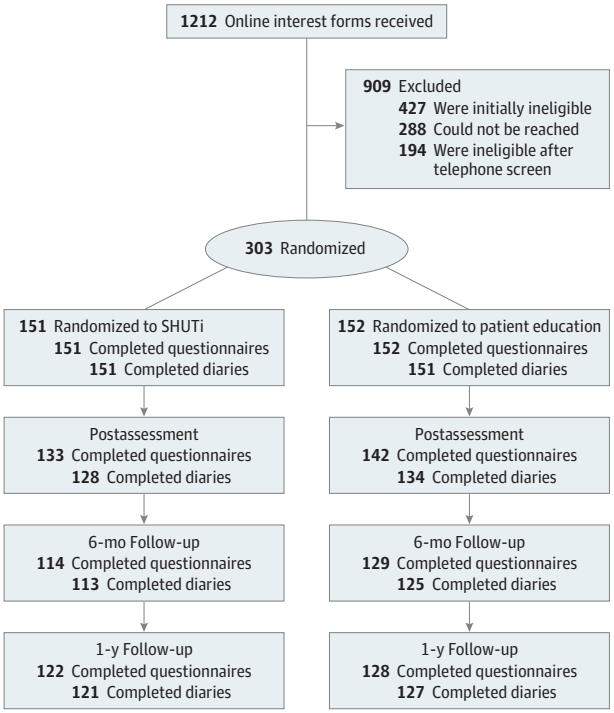
Participants

Adults with regular internet access were eligible to participate if they met the following criteria: (1) they required more than 30 minutes to fall asleep at the beginning of the night (sleep-onset insomnia) or more than 30 minutes of time awake after initially falling asleep (sleep maintenance insomnia) for at least 3 nights per week for at least 6 months, (2) their total sleep time averaged 6.5 hours or less, and (3) they manifested sleep disturbances (or associated daytime symptoms) causing significant distress or impairment in social, occupational, or other areas of functioning. Exclusion criteria included the following: (1) the presence of another untreated sleep disorder, (2) an irregular schedule that would prevent adoption of intervention strategies (ie, work schedule resulting in usual bedtime earlier than 8 PM or later than 2 AM or arising time earlier than 4 AM or later than 10 AM), (3) pregnancy, (4) current or past behavioral treatment for insomnia, and (5) initiation of any psychological treatment within the previous 3 months. Comorbid psychiatric disorders were included unless the individual met criteria for any of the following: moderate to high current risk of suicide, severe major depression, bipolar disorder, or alcohol or drug abuse within the past year. Comorbid medical conditions were included unless they were deemed active, unstable, and degenerative (eg, congestive heart failure or multiple sclerosis) in a manner that could worsen the insomnia. Participants could be taking medications, including sleep medications, if the medication regimen had not been changed in the previous 3 months.

Outcome Measures

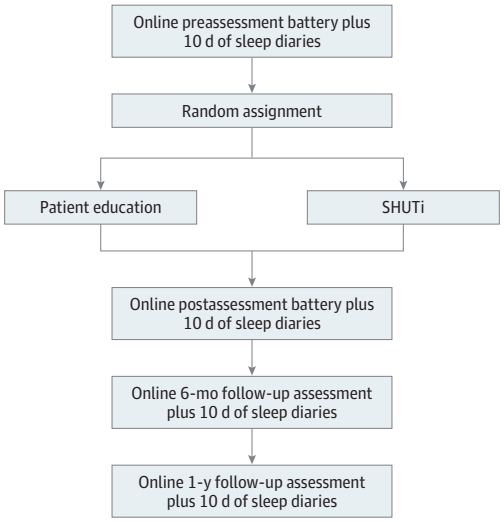
Measures used in this study included the ISI,[14] a 7-item global index of self-reported insomnia symptom severity that has been shown to be valid, reliable, and sensitive to changes in insomnia treatment[14,15] and validated for online use.[16] Daily

Figure 1. CONSORT Diagram of Study Enrollment Flow



CONSORT indicates Consolidated Standards of Reporting Trials; SHUTi, Sleep Healthy Using the Internet.

Figure 2. Study Procedure



SHUTi indicates Sleep Healthy Using the Internet.

sleep diaries[17] based on consensus sleep diary questions[17] were collected online prospectively during a 2-week period at each of the 4 assessment periods. A semistructured clinical telephone interview was conducted to obtain a detailed sleep and health history, screen for other sleep disorders, and assess for psychiatric comorbidity using the Mini-International Neuropsychiatric Interview[18] and included components of the Diagnostic Interview for Insomnia.[19] Finally, intervention use and adherence were measured using login frequency, diary count, and number of cores completed. More details are available in the eAppendix in Supplement 2.

Interventions

Internet CBT-I (Sleep Healthy Using the Internet)

Sleep Healthy Using the Internet (SHUTi) is a fully automated, interactive, and tailored web-based program that incorporates the primary tenets of face-to-face CBT-I, including sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention.[20-22] Other content areas that are occasionally included in CBT-I, such as relaxation and medication titration, were not included (details are available in the eAppendix in Supplement 2).

Online PE

The online PE program provided nontailored and fixed material about insomnia symptoms and the effect, prevalence, and causes of insomnia. It also discussed when to see a physician and basic lifestyle, environmental, and behavioral strategies to improve sleep (details are available in the eAppendix in Supplement 2).

Procedure

Participants were recruited online (**Figure 1** and **Figure 2**). Those enrolled completed a baseline assessment that included questionnaires and 10 days of sleep diaries. They then received access to their assigned web program for 9 weeks, followed by postassessment data collection after the intervention period and again at 6 months and 1 year that included questionnaires and sleep diaries. Participants received online gift certificates for completing the postassessment and 6-month follow-up ($50 each) and the 1-year follow-up ($100).

Statistical Analysis

Sample size was calculated based on an effect size between groups of Cohen d = 0.20 on each of the 3 primary sleep outcomes (ISI, SOL, and WASO) and an anticipated 35.0% attrition rate across the 1-year study. Powering the study at 80% to detect pre-post differences between groups with α = .05 (using G*Power 3 software[23]), a sample size of 300 individuals was planned to achieve 220 participants after expected attrition.

Differences by treatment group in baseline characteristics, rates of postassessment and follow-up nonadherence, and posttreatment ISI response and remittance were analyzed with t tests for continuous variables, Wilcoxon rank sum tests for skewed continuous variables, and χ^2 tests for categorical variables. Statistical significance was set at α = .05. Sleep-onset latency, WASO, and number of awakenings were skewed and were therefore log-transformed before analysis. The diaries of participants were averaged at each time point to create summary scores for the diary variables. The primary and secondary sleep outcomes, missing data, and sleep medication use were modeled with multilevel mixed-effects regression (linear or logistic as appropriate) using a software program (Stata, version 14; StataCorp LP). For all outcomes, group × time interactions were examined, accounting for

Table 1. Baseline Characteristics

Characteristic	Patient Education (n = 152)	SHUTi (n = 151)	Total (N = 303)	Test Statistic	*P* Value[a]
Age, mean (SD), y[b]	42.81 (11.86)	43.75 (11.34)	43.28 (11.59)	$t = 0.70$	.49
Female, No. (%)	115 (75.7)	103 (68.2)	218 (71.9)	$x^2 = 2.08$	.15
Race, No. (%)					
White	126 (82.9)	128 (84.8)	254 (83.8)	$x^2 = 1.02$	.80
Black	12 (7.9)	9 (6.0)	21 (6.9)		
Asian	5 (3.3)	7 (4.6)	12 (4.0)		
Other	9 (5.9)	7 (4.6)	16 (5.3)		
Hispanic, No. (%)	12 (7.9)	12 (7.9)	24 (7.9)	$x^2<0.01$	.99
College degree or higher, No. (%)	119 (78.3)	116 (76.8)	235 (77.6)	$x^2 = 0.09$	.76
Employed full-time, No. (%)	90 (59.2)	85 (56.3)	175 (57.8)	$x^2 = 0.27$	.61
Married or living with partner, No. (%)	94 (61.8)	87 (57.6)	181 (59.7)	$x^2 = 0.56$	.45
Years of sleep problems, median (IQR)	7 (4-10)	10 (5-15)	9 (5-15)	$z = 2.73$	.006
Nights per week of sleep difficulties, median (IQR)	6 (5-7)	6 (5-7)	6 (5-7)	$z = 1.57$	.12
Check email daily, No. (%)	147 (96.7)	145 (96.0)	292 (96.4)	$x^2 = 0.10$	.75
Use internet daily, No. (%)	148 (97.4)	149 (98.7)	297 (98.0)	$x^2 = 0.67$	.41
Very comfortable with internet, No. (%)	133 (87.5)	135 (89.4)	268 (88.4)	$x^2 = 0.27$	.60

Abbreviations: IQR, interquartile range; SHUTi, Sleep Healthy Using the Internet.

[a] Significance test results are from *t* tests for normally distributed continuous variables (*t* statistic), Pearson χ^2 tests for categorical variables (x^2 statistic), or Wilcoxon rank sum tests for skewed continuous variables (*z* statistic).

[b] In the patient education group, 4 participants did not provide their age, so the total for age is 299.

baseline group differences. Group × time × comorbidity interactions were also examined. Time was treated as a categorical variable to model its nonlinear effects, and an unstructured covariance matrix was assumed. Random effects were modeled for time. Within-group effect sizes were computed as the modeled mean difference between baseline and each postassessment divided by the full sample baseline SD. To compare postassessment ISIs by completers and noncompleters, analysis of covariance was conducted with core completion as predictor and baseline ISI as covariate. An intent-to-treat approach included all participants in the mixed model. The Consolidated Standards of Reporting Trials diagram (Figure 1) shows details of assessment completion rates. Group type was not significantly associated with attrition from preassessment to postassessment or overall.

Results

Between October 19, 2011, and July 2, 2013, a total of 1212 individuals submitted online forms that indicated interest in participating in this trial. Of them, 303 were enrolled, living in 41 different states in the United States and the District of Columbia, and were instructed to complete the online baseline assessment that included questionnaires and prospective sleep diaries. After baseline data collection, 151 were randomized to receive SHUTi, and 152 were randomized to receive access to online PE.

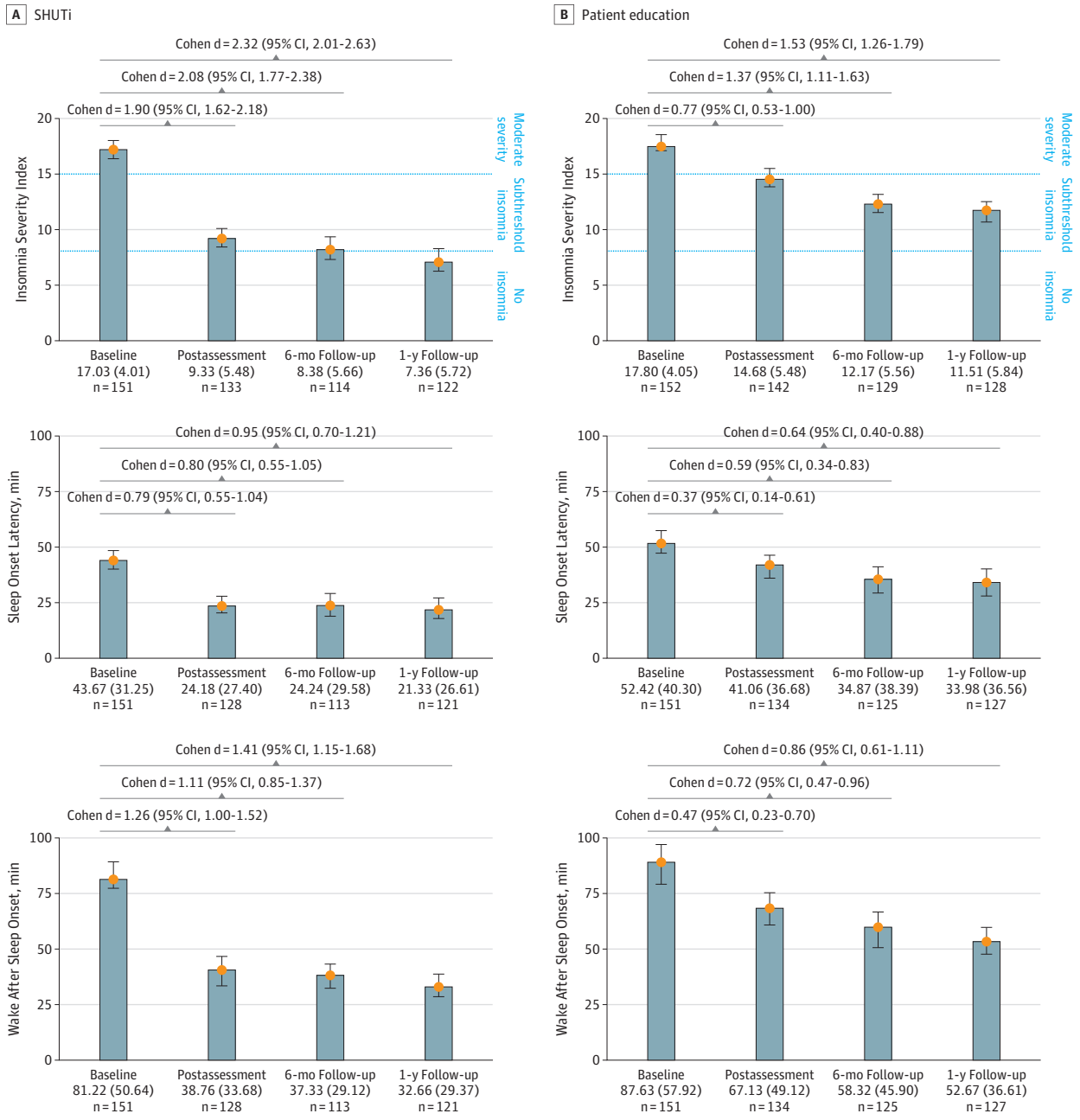
Table 1 lists baseline characteristics by group. The groups differed on 1 baseline characteristic, with the SHUTi group reporting more years of sleep problems than the PE group. Across both groups, participants were mostly female (71.9% [218 of 303]), of white race and non-Hispanic ethnicity (83.8% [254 of 303]), and well educated (77.6% [235 of 303] with at least a college degree). Participants also reported experiencing chronic insomnia, with a median of 9 years of sleep difficulties occurring most nights of the week (median, 6 nights per week). In addition, 29.0% (88 of 303) of participants had a medical comorbidity, 30.7% (93 of 303) had a psychiatric comorbidity, and 49.8% (151 of 303) had a medical or psychiatric comorbidity or both.

During baseline diary collection, of 151 participants, 51.0% (n = 77) of the SHUTi group and 45.7% (n = 69) of the PE group reported taking a sleep aid (prescription or nonprescription) at least 1 night during the baseline period. Among those who reported using a sleep aid, an average of 56% of baseline nights were classified as medicated nights. Numbers of participants reporting at least 1 medicated night decreased during the postassessment, 6-month follow-up, and 1-year follow-up periods, with values of 38.3% (49 of 128), 37.2% (42 of 113) and 33.1% (40 of 121) for the SHUTi group and 42.5% (57 of 134), 34.4% (43 of 125), and 33.9% (43 of 127) for the PE group, respectively. A logistic mixed-model analysis examining sleep medication use over time by group shows that, while the groups did not differ over time ($\chi^2 = 3.00$, $P = .39$), there was an effect for time ($\chi^2 = 18.32$, $P < .001$), indicating that both groups reduced sleep aid use over time. Participants also reported a high rate of comfort in using the internet, and most indicated that they check email and use the internet daily.

Primary Sleep Outcomes

Results of the 3 primary sleep outcomes are shown in **Figure 3**. The overall group × time interactions were significant for the ISI ($F_{3,1063} = 20.65$, $P < .001$), SOL ($F_{3,1042} = 6.01$, $P < .001$), and WASO ($F_{3,1042} = 12.68$, $P < .001$). Within-group time effects, from baseline to postassessment, were large for the SHUTi group (range, 0.79-1.90) and small to large for the PE group (range, 0.37-0.77). At the 1-year follow-up, the SHUTi group experienced significant improvements from baseline on the ISI (Cohen $d = 2.32$; 95% CI, 2.01-2.63), SOL (Cohen $d = 0.95$; 95% CI, 0.70-1.21), and WASO (Cohen $d = 1.41$; 95% CI, 1.15-1.68). The PE group also experienced improvements (although

Figure 3. Insomnia Severity Index, Sleep Onset Latency, and Wake After Sleep Onset at Baseline, Postassessment, 6-Month Follow-up, and 1-Year Follow-up



Wake after sleep onset includes early morning awakening. There was a significant overall group × time interaction effect for the Insomnia Severity Index, sleep-onset latency, and wake after sleep onset. Raw means (SDs) and total participants are shown beneath each bar, within-group effects for each time point from baseline to each postassessment and follow-up are shown in the top bars, and error bars show 95% CIs. Cohen *d* values are calculated using the model mean difference divided by the whole-sample preassessment SD. SHUTi indicates Sleep Healthy Using the Internet.

smaller than those of the SHUTi group) on the ISI (Cohen *d* = 1.53; 95% CI, 1.26-1.79), SOL (Cohen *d* = 0.64; 95% CI, 0.40-0.88), and WASO (Cohen *d* = 0.86; 95% CI, 0.61-1.11). These findings are similar to those reported in studies of face-to-face CBT-I.[24]

An evaluation of clinical significance also demonstrated the superiority of SHUTi, with 52.6% (70 of 133) of the SHUTi group deemed treatment responders (defined by a reduction of >7 points on the ISI[15]) from baseline to postassessment compared with only 16.9% (24 of 142) of the PE group. At the 6-month follow-up, 59.7% (68 of 114) of the SHUTi group and 35.7% (46 of 129) of the PE group were considered responders, while 69.7% (85 of 122) of the SHUTi group and 43.0% (55 of 128) of the PE group were deemed responders at the 1-year

Table 2. Secondary Sleep Outcomes[a]

Sleep Variable	Patient Education			SHUTi			F Value	P Value
	No.	Mean (SD)	Cohen *d* (95% CI)	No.	Internet CBT-I, Mean (SD)	Cohen *d* (95% CI)		
Sleep Efficiency								
Baseline	151	70.47 (14.22)	NA	151	73.24 (12.56)	NA	$F_{3,1042}$ = 8.39	<.001
Postassessment	134	77.17 (14.49)	0.49 (0.25-0.72)	128	85.59 (11.01)	0.92 (0.67-1.16)		
6-mo Follow-up	125	80.06 (14.64)	0.69 (0.45-0.94)	113	86.30 (10.48)	0.92 (0.67-1.18)		
1-y Follow-up	127	81.79 (11.96)	0.84 (0.59-1.08)	121	87.81 (10.73)	1.04 (0.79-1.30)		
No. of Awakenings								
Baseline	151	1.98 (1.27)	NA	151	1.87 (1.19)	NA	$F_{3,1042}$ = 3.41	.02
Postassessment	134	1.66 (1.13)	0.34 (0.10-0.57)	128	1.31 (1.29)	0.65 (0.41-0.90)		
6-mo Follow-up	125	1.65 (1.18)	0.41 (0.17-0.64)	113	1.32 (1.30)	0.58 (0.33-0.82)		
1-y Follow-up	127	1.54 (1.18)	0.55 (0.31-0.79)	121	1.22 (1.32)	0.71 (0.47-0.96)		
Sleep Quality								
Baseline	151	2.75 (0.58)	NA	151	2.85 (0.52)	NA	$F_{3,1042}$ = 2.93	.03
Postassessment	134	3.03 (0.69)	0.53 (0.29-0.77)	128	3.33 (0.65)	0.87 (0.63-1.12)		
6-mo Follow-up	125	3.13 (0.70)	0.70 (0.46-0.94)	113	3.38 (0.67)	0.95 (0.69-1.20)		
1-y Follow-up	127	3.24 (0.70)	0.88 (0.63-1.13)	121	3.54 (0.61)	1.23 (0.96-1.49)		
Total Sleep Time								
Baseline	151	5.59 (1.32)	NA	151	5.77 (1.24)	NA	$F_{3,1042}$ = 0.40	.76
Postassessment	134	6.13 (1.36)	0.42 (0.18-0.65)	128	6.26 (1.22)	0.38 (0.14-0.61)		
6-mo Follow-up	125	6.41 (1.36)	0.62 (0.38-0.87)	113	6.46 (1.14)	0.52 (0.27-0.77)		
1-y Follow-up	127	6.53 (1.22)	0.72 (0.48-0.96)	121	6.60 (1.10)	0.62 (0.37-0.86)		

Abbreviations: NA, not applicable; SHUTi, Sleep Healthy Using the Internet.

[a] Raw means (SDs) are presented. *F* values are from the overall contrast for group × time (2 × 4) interaction. Cohen *d* values are within-group time effects for baseline to each postassessment using the model mean difference divided by the whole-sample preassessment SD.

follow-up. A similar pattern was observed using criteria of insomnia remittance (<8 on the ISI[15]): 40.6% (54 of 133) (baseline to postassessment), 49.1% (56 of 114) (baseline to 6-month follow-up), and 56.6% (69 of 122) (baseline to 1-year follow-up) of the SHUTi group were deemed insomnia remitters compared with 11.3% (16 of 142) (baseline to postassessment), 24.0% (31 of 129) (baseline to 6-month follow-up), and 27.3% (35 of 128) (baseline to 1-year follow-up) of the PE group.

Primary Sleep Outcomes by Comorbidity

Additional mixed-model interactions were used to examine whether the presence of a comorbid condition influenced the treatment effect on the primary sleep outcomes. The 3 comorbidity groupings were categorized as (1) the presence or absence of medical comorbidity, (2) the presence or absence of psychiatric comorbidity, and (3) the presence or absence of any comorbidity. In all cases, those with a comorbidity did not show significantly different changes over time by group in sleep outcomes than those without a comorbidity.

Secondary Sleep Outcomes

Significant group × time interaction effects were found on the secondary sleep outcomes of sleep efficiency ($F_{3,1042}$ = 8.39, P < .001), number of awakenings ($F_{3,1042}$ = 3.41, P = .02), and sleep quality ($F_{3,1042}$ = 2.93, P = .03) but not total sleep time ($F_{3,1042}$ = 0.40, P = .76). Effect sizes showed patterns similar to those of the primary sleep outcomes (**Table 2**). Specifically, the SHUTi group experienced larger effects from baseline to the postassessment, 6-month follow-up, and 1-year follow-up compared with the PE group for all secondary sleep variables except total sleep time, for which effects increased similarly in both groups.

Use and Adherence

The SHUTi group logged in between 0 and 142 times during the 9-week intervention period, with a median login count of 25. The SHUTi group submitted a median of 44 sleep diaries during this same intervention period, ranging from 0 to 70. A total of 60.3% (91 of 151) of the SHUTi group completed all 6 cores of the program. In contrast, 3.3% (5 of 151) of the SHUTi group did not complete any of the cores, 3.3% (5 of 151) completed only the tutorial core explaining how the program works, 5.3% (8 of 151) completed through the first core, 11.3% (17 of 151) completed through the second core, 9.3% (14 of 151) completed through the third core, 0.7% (1 of 151) completed through the fourth core, and 6.6% (10 of 151) completed through the fifth core.

For those in the SHUTi group who completed all 6 cores, the estimated marginal mean (EMM) (SD) ISI at postassessment was 7.99 (0.47) compared with 12.24 (0.69) (P < .001 for group difference) for those who completed less than 6 cores. However, during the 1-year follow-up period, the difference in EMM (SD) ISIs for those who completed all 6 cores and those who did not diminished. At the 6-month follow-up and 1-year follow-up, those who completed all 6 cores had EMM (SD) ISIs of 7.90 (0.53) and 6.91 (0.57), respectively, while those who did not complete all 6 cores had EMM (SD) ISIs of 9.98 (0.97) and 8.56 (0.93), respectively.

Discussion

This randomized clinical trial is the first to evaluate the long-term efficacy of a fully automated internet-delivered CBT-I intervention to improve sleep in a heterogeneous sample of adults with chronic insomnia. The SHUTi group experienced significant improvements in ISI, SOL, and WASO—the 3 primary sleep outcomes. With all participants averaging in the moderate severity insomnia range of 15 to 21 on the ISI at baseline, those in the SHUTi group had a mean ISI of less than 8 (denoting no insomnia) at the 1-year follow-up, whereas the PE group was in the subthreshold insomnia range of 8 to 14.

The study design was of particular importance in evaluating the efficacy of online CBT-I. The PE condition formed an active control, offering high-quality information similar to that found in a PE booklet or in patient-oriented online materials, and some improvements were expected. The finding of greater improvement in all measures among the SHUTi groups demonstrates the value of the metered, interactive, and tailored format analogous to what typically occurs in face-to-face CBT-I.

Previous studies have documented the efficacy of online CBT-I to improve insomnia, but these early investigations used small samples, homogeneous populations, and limited comparison conditions and relied on costly human support to guide users through the program or failed to include long-term follow-up.[12] The present study addresses these issues and demonstrates that positive outcomes can be achieved and maintained when using a robust internet intervention for insomnia in a general population of adults with insomnia.

Participants in this trial represented a symptomatic group with a long history of insomnia. Consistent with previous trials of SHUTi[25,26] but in contrast to the general internet intervention literature,[27] dropout attrition (participants not completing follow-up measures) was low, with 9.2% (28 of 303) lost at the postassessment and 17.5% (53 of 303) lost at the 1-year follow-up. Nonuse attrition (participants who do not complete all cores of the intervention) was low at 39.7% (60 of 151). This finding is notable given that no clinical support was provided as part of the intervention. Although there is limited research examining why completion rates differ across programs, many researchers speculate that increased interactivity and tailoring may foster engagement and ultimately program adherence.[13,28]

Limitations

Although this study addresses many shortcomings of previous internet-delivered CBT-I studies, our findings must still be considered in light of several limitations. The sample is primarily of white race and non-Hispanic ethnicity, well educated, and comfortable using the internet. With that said, this sample is more heterogeneous than other internet-delivered CBT-I studies because it included a national (US) sample of participants in which 16.2% (49 of 303) were of nonwhite race; 7.9% (24 of 303) were of Hispanic ethnicity, and 49.8% (151 of 303) had a comorbid condition. However, the full range of medical and psychiatric conditions that co-occur with insomnia is not represented in this study. Another limitation is that the SHUTi group had sleep difficulties for a significantly longer time (10 years) compared with the PE group (7 years). That said, this difference would likely result in more conservative findings if it had any effect on outcomes. In addition, minimal masking occurred because savvy participants could deduce the web program to which they were randomized based on their online experience. Finally, no objective measure of sleep was used; however, while some researchers may question the validity of self-reported sleep data, daily sleep diaries are used in more than 90% of treatment studies of insomnia,[29] and tracking sleep variables during multiple weeks provides a more comprehensive understanding of sleep problems than polysomnography, which is usually only administered for 1 to 3 nights.[29] Sleep diaries are reliable and valid measures of sleep and correlate strongly with findings using other objective measures of sleep, such as polysomnography,[30-34] actigraphy,[35-39] and spousal reports.[33,39]

Conclusions

Internet-delivered CBT-I provides a less expensive, scalable treatment option that could reach previously unimaginable numbers of people. Future studies are necessary to determine who may be best served by this type of intervention and how the next steps of dissemination should occur. Ensuring that these interventions work with different patient populations, whether tailored or not for those groups, should also be examined. In addition, exploring the use of these interventions with lower educated, less technologically experienced, and older populations will be critical to broad dissemination efforts.

This study provides compelling evidence that the self-guided, web-based CBT-I intervention SHUTi can effectively treat insomnia. It extends findings that internet-delivered CBT-I can meaningfully improve insomnia symptoms and sleep variables, including when insomnia is comorbid with other conditions.

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Study concept and design: Ritterband, Thorndike, Ingersoll, Gonder-Frederick, Quigg, Cohn, Morin.
Acquisition, analysis, or interpretation of data: Ritterband, Thorndike, Ingersoll, Lord, Gonder-Frederick, Frederick, Quigg, Cohn.
Drafting of the manuscript: Ritterband, Thorndike, Ingersoll, Lord, Frederick.
Critical revision of the manuscript for important intellectual content: Ritterband, Thorndike, Ingersoll, Lord, Gonder-Frederick, Quigg, Cohn, Morin.
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Study supervision: Ritterband, Thorndike, Ingersoll, Gonder-Frederick, Quigg, Morin.

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