Efficacy of an Internet-Based Behavioral Intervention for Adults With Insomnia

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Context: Insomnia is a major health problem with significant psychological, health, and economic consequences. However, availability of one of the most effective insomnia treatments, cognitive behavioral therapy, is significantly limited. The Internet may be a key conduit for delivering this intervention.

Objective: To evaluate the efficacy of a structured behavioral Internet intervention for adults with insomnia.

Design, Setting, and Participants: Forty-five adults were randomly assigned to an Internet intervention (n=22) or wait-list control group (n=23). Forty-four eligible participants (mean [SD] age, 44.86 [11.03] years; 34 women) who had a history of sleep difficulties longer than 10 years on average (mean [SD], 10.59 [8.89] years) were included in the analyses.

Intervention: The Internet intervention is based on well-established face-to-face cognitive behavioral therapy incorporating the primary components of sleep restriction, stimulus control, sleep hygiene, cognitive restructuring, and relapse prevention.

Main Outcome Measures: The Insomnia Severity Index and daily sleep diary data were used to determine changes in insomnia severity and the main sleep variables, including wake after sleep onset and sleep efficiency.

Results: Intention-to-treat analyses showed that scores on the Insomnia Severity Index significantly improved from 15.73 (95% confidence interval [CI], 14.07 to 17.39) to 6.59 (95% CI, 4.73 to 8.45) for the Internet group but did not change for the control group (16.27 [95% CI, 14.61 to 17.94] to 15.50 [95% CI, 13.64 to 17.36]) (F1,42=29.64; P<.001). The Internet group maintained their gains at the 6-month follow-up. Internet participants also achieved significant decreases in wake after sleep onset (55% [95% CI, 34% to 76%]) and increases in sleep efficiency (16% [95% CI, 9% to 22%]) compared with the nonsignificant control group changes of wake after sleep onset (8% [95% CI, −17% to 33%]) and sleep efficiency (3%; 95% CI, −4% to 9%).

Conclusions: Participants who received the Internet intervention for insomnia significantly improved their sleep, whereas the control group did not have a significant change. The Internet appears to have considerable potential in delivering a structured behavioral program for insomnia.

Trial Registration: clinicaltrials.gov Identifier: NCT00328250

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Beyond the termination of active treatment,10 in addition, individuals receiving CBT rate this intervention as more effective and acceptable than medication.10,17

Unfortunately, availability of CBT is severely limited for many reasons, including lack of trained clinicians, poor geographical distribution of knowledgeable professionals, expense, and inaccessibility to treatment and clinicians.18 One way to overcome these barriers is to use the Internet to deliver treatment, potentially making this highly effective intervention more widely available to an underserved patient population. The Internet has already become a critical source of health care and medical information.19,20 Although the vast majority of health Web sites provide static information,19,21 there is a growing research literature on the development and evaluation of Internet interventions.22-25 These online programs are typically behaviorally based interventions that have been operationalized and transformed for delivery via the Internet. They are usually highly structured; self-guided or semi–self-guided; based on effective face-to-face treatment; personalized to the user; interactive; enhanced by graphics, animations, audio, and possibly video; and tailored to provide follow-up and feedback.24

This study investigates the feasibility and efficacy of using the Internet to deliver a fully automated CBT intervention for adults with primary insomnia. This Internet program, SHUTi (Sleep Healthy Using the Internet, http://www.shuti.net), incorporates the primary treatment components of CBT for insomnia, including sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention. We hypothesized that adults randomly assigned to receive SHUTi would experience significant reductions in the overall severity of insomnia as well as show greater improvements compared with those in a wait-list control group in wake after sleep onset (WASO) and sleep-onset latency (SOL). We also expected Internet participants to show significant improvements in sleep efficiency, total sleep time, number of nighttime awakenings, and self-ratings of sleep restoration and restfulness on awakening.

METHODS

PARTICIPANTS

Participants were recruited through newspaper advertisements, online postings, radio broadcasts, public service announcements, flyers, and physician referrals in the central Virginia area (Figure 1). To participate in the study, adults aged between 18 and 65 years had to meet DSM-IV-TR26 criteria for primary insomnia, report sleep difficulties for at least 6 months (difficulty initiating sleep, difficulty maintaining sleep, and/or early morning awakenings), endorse sleep difficulties 3 or more nights per week, report significant daytime impairments due to their sleep disturbance (eg, fatigue, performance impairment), and have regular Internet access. Participants were taught how to complete sleep diaries and navigate the online program. To protect confidentiality, participants were assigned unique user names and passwords for purposes of log-in.

Participants were randomly assigned to either the experimental (Internet) or control condition following preassessment based on a preset computer-generated randomization schedule established by the study project coordinators (F.P.T. and D.K.S.). At baseline, participants completed 10 sleep diary entries within a 2-week period before being notified of their group assignment by e-mail. Automated reminders to complete diary entries were sent daily via e-mail. Internet participants were then granted access to the intervention for 9 weeks. After the 9-week intervention period, all participants completed an additional 10 days of online sleep diaries within a 2-week period and then returned to the research center to complete a second in-person assessment. Internet participants were contacted at a 6-month follow-up and asked to complete a brief online questionnaire that included the Insomnia Severity Index (ISI).11,27 Control participants were given access to SHUTi following postassessment, but no follow-up data were collected.

Figure 1. Study enrollment flow.

the internal review board at the University of Virginia Health System. Written informed consent was obtained from all individuals who participated. Participants were compensated $100 for completion of both in-person assessments.

STUDY PROCEDURES

Interested individuals were screened sequentially through an online interest form, a 15-minute telephone screen, and an in-person semistructured interview. Participants also completed questionnaires to further assess sleep behaviors and psychological functioning. After initial assessment, participants were taught how to complete sleep diaries and navigate the online program. To protect confidentiality, participants were assigned unique user names and passwords for purposes of log-in.

Participants were randomly assigned to either the experimental (Internet) or control condition following preassessment based on a preset computer-generated randomization schedule established by the study project coordinators (F.P.T. and D.K.S.). At baseline, participants completed 10 sleep diary entries within a 2-week period before being notified of their group assignment by e-mail. Automated reminders to complete diary entries were sent daily via e-mail. Internet participants were then granted access to the intervention for 9 weeks. After the 9-week intervention period, all participants completed an additional 10 days of online sleep diaries within a 2-week period and then returned to the research center to complete a second in-person assessment. Internet participants were contacted at a 6-month follow-up and asked to complete a brief online questionnaire that included the Insomnia Severity Index (ISI).11,27 Control participants were given access to SHUTi following postassessment, but no follow-up data were collected.
PROCEDURES FOR THE INTERNET INTERVENTION FOR INSOMNIA

The SHUTi program is based on well-established face-to-face CBT for insomnia.\textsuperscript{11,28} It can be conceptualized as 6 cores that include behavioral, educational, and cognitive techniques. These cores make up the treatment content of SHUTi. The first core, overview, introduces the intervention and provides a rationale for treatment. There are 2 behavioral cores that incorporate sleep restriction\textsuperscript{29} and stimulus control,\textsuperscript{30,31} providing a set of rules to follow to regulate the sleep-wake schedule and strengthen the association between the bed or bedroom, bedtime, and sleep. Stimulus control procedures involve going to bed only when sleepy, getting out of bed when unable to sleep and returning to bed only when sleep is imminent, curtailting sleep-incompatible activities in the bedroom (eg, reading, problem solving, watching television), avoiding daytime napping, and arising at the same hour every day. Sleep restriction involves limiting the amount of time spent in bed (sleep window) to the actual amount of sleep to strengthen the homeostatic sleep drive and increase sleep efficiency. The educational core (also called sleep hygiene) focuses on general education about sleep and improving sleep hygiene practices (eg, increasing exercise and avoiding nicotine, caffeine, and alcohol before bedtime). The cognitive core (also called cognitive restructuring) attempts to address and change the unhelpful beliefs (eg, the absolute necessity for 8 hours of sleep) and thoughts (eg, worry about the consequences of insomnia) about sleep and insomnia that may exacerbate sleep difficulties. Finally, the last core, consolidation or relapse prevention, integrates the behavioral, educational, and cognitive elements, promotes adherence, generalizes the information, helps identify risk situations, and incorporates strategies to reduce relapse. The structured nature of insomnia treatment makes it an ideal intervention to be adapted as a Web program and delivered via the Internet.

At the beginning of each new core, participants completed the ISI online and received new recommendations for sleep restriction treatment based on the participant’s previous week of sleep diaries. These individually tailored recommendations were computed automatically using algorithms developed for the Internet intervention. On subsequent visits to the Web site during the 7 days before beginning new treatment cores, participants were encouraged to complete their daily online sleep diary and review relevant information from completed treatment cores. Participants were unable to move forward to the next core until the prescribed time had elapsed. If participants completed fewer than 5 diaries in a given week, they could move forward to the next core but were not given new recommendations for sleep restriction.

The highly interactive intervention presents information through the use of text, graphics, and animations. It also uses vignettes, quizzes, and brief games as a way of delivering pertinent information. Automated e-mails are sent when it is time to complete a new treatment core. Midweek reminders to enter sleep diaries, implement learned strategies, and begin the new core in 4 days are also sent. Other automated e-mails include disuse reminders and relapse prevention prompts.

**DEPENDENT MEASURES**

**Interviews**

At preassessment and postassessment, participants were asked a series of descriptive and demographic questions as well as for their retrospective accounts of their sleep history and sleep impairment. The in-person interview was based on a clinical interview\textsuperscript{32} designed to obtain a sleep history and to assess for psychiatric and medical comorbidity, including other sleep disorders. The Primary Care Evaluation of Mental Disorders\textsuperscript{32} was also administered to further screen for comorbid psychiatric disorders.

**Sleep Diary**

Participants completed online sleep diaries\textsuperscript{33} every day during the preassessment and postassessment periods (10 diaries within a 2-week period were required to move forward in the study). Internet participants were also encouraged to complete sleep diaries each day while using the Internet intervention. The diary consisted of 10 standard questions, including the following: time to fall asleep; number and length of any awakenings at night; time of awakening and arising from bed in the morning; length of any naps; subjective sense of how refreshed they felt on awakening as well as how sound they slept during the night; and amount of medication and alcohol used as a sleep aid. Data suggest that tracking sleep parameters through these diaries can provide a more comprehensive understanding of sleep problems than can typically be achieved using polysomnography administered over 1 or 2 nights.\textsuperscript{33}

**Insomnia Severity Index**

The 7-item ISI\textsuperscript{11,27} provides a quantitative index of overall sleep impairment. Participants rate the severity of problems with sleep onset, sleep maintenance, and early morning awakening; interference with daytime functioning; how noticeable the impairment is to others; distress or concern caused by the sleep problem; and satisfaction with the current sleep pattern on a 5-point Likert scale. Scores range from 0 to 28, with higher scores indicating more severe insomnia. The ISI has been shown to be a valid and reliable measure that is sensitive to changes in treatment studies.\textsuperscript{27} It was administered at preassessment and postassessment for all participants as well as at the 6-month follow-up and before each of the program cores for participants who received SHUTi.

**STATISTICAL ANALYSIS**

Descriptive statistics including age, sex, marital status, education, comfort with the Internet, history of sleep difficulties, and nights per week experiencing sleep difficulties were computed. One-way analyses of variance were used to compare the groups on the continuous variables (eg, age, education), and \(\chi^2\) tests were used with the categorical variables (eg, sex, race) at baseline. Because the main sleep outcome variables met parametric assumptions, 2 (Internet and control group) \times 2 (preassessment and postassessment) repeated-measures analyses of variance were conducted to compare changes across assessments. Paired-sample \(t\) tests were used to examine time effects within each condition if the overall interaction effect was significant as well as to examine the changes in ISI scores from postassessment to the 6-month follow-up. An intention-to-treat analysis was conducted to analyze the ISI data using the last observation carried forward method. Completer analyses were used for the sleep diary data as all participants provided preassessment and postassessment diary data. Sample size calculations were based on previous CBT self-help for insomnia trial data\textsuperscript{34} reporting effect size differences between the intervention and wait-list control conditions on preassessment to postassessment changes on key sleep variables, including the ISI score (\(d=1.26\)), WASO (\(d=0.74\)), SOL (\(d=0.26\)), and sleep efficiency (\(d=0.68\)). Therefore, expecting differences at posttreatment between a self-help Internet intervention for insomnia and a wait-list control group using a medium effect size of 0.5 with power of 80%, \(P = .01\), and 15% attrition, a minimum

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 Forty-five participants were enrolled from February 15, 2007, to June 18, 2008, with 22 participants randomly assigned to receive immediate Internet (SHUTi) treatment and 23 serving as wait-list control participants. Attrition was 4% (2 of 45 participants) from preassessment to postassessment, with 1 participant (Internet condition) completing the first behavior core stressing sleep restriction (effect size=0.26) and the final core stressing relapse prevention (effect size=0.26). This indicates that the largest changes in scores occurred after completing the first behavior core stressing sleep restriction and stimulus control (effect size=0.32) and the final core stressing relapse prevention (effect size=0.26). No significant differences were found between the Internet and control groups in terms of severity between the 2 groups: Internet and control group mean ISI scores, 15.73 (95% confidence interval [CI], 14.07-17.39) and 16.27 (95% CI, 14.61-17.94), respectively. However, the mean ISI scores at postassessment were 6.59 (95% CI, 4.73-8.45) for the Internet group and 15.50 (95% CI, 13.64-17.36) for the control group. The Internet group also maintained these gains at 6 months (mean ISI score, 7.32 [95% CI, 5.05-9.59]), with no significant increase in ISI scores from postassessment to the 6-month follow-up (Figure 2).

Changes in ISI scores indicate not only statistically significant improvements after using SHUTi but also clinically significant improvements. At baseline, no participant in either group fell in the category of no clinically significant insomnia as defined by an ISI score lower than 8.37 However, after SHUTi, 16 of the 22 Internet participants (73%) were in remission and in this category at postassessment, whereas no control participant met this criterion ($\chi^2=25.14; P<.001$). At the 6-month follow-up, 11 of the 18 Internet participants (61%) were still in remission, notably a significant change from postassessment.

Internet participants also completed the ISI before each treatment core, with 20 of the 22 participants (91%) completing the ISI at all 7 times. Review of the insomnia severity ratings throughout the Internet intervention indicates that the largest changes in scores occurred after completing the first behavior core stressing sleep restriction and stimulus control (effect size=0.32) and the final core stressing relapse prevention (effect size=0.26).

**RESULTS**

To evaluate changes in insomnia severity, participants completed the ISI at preassessment and postassessment. The Internet group also completed the ISI at the 6-month follow-up. There was a significant group x time interaction effect showing a marked improvement from preassessment to postassessment in the Internet group and little change in the control group ($F_{1,42}=29.64; P<.001$). At preassessment, there were no differences in insomnia severity between the 2 groups: Internet and control group mean ISI scores, 15.73 (95% confidence interval [CI], 14.07-17.39) and 16.27 (95% CI, 14.61-17.94), respectively. However, the mean ISI scores at postassessment were 6.59 (95% CI, 4.73-8.45) for the Internet group and 15.50 (95% CI, 13.64-17.36) for the control group. The Internet group also maintained these gains at 6 months (mean ISI score, 7.32 [95% CI, 5.05-9.59]), with no significant increase in ISI scores from postassessment to the 6-month follow-up (Figure 2).

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SLEEP VARIABLES

Repeated-measures analysis of variance examining the preassessment and postassessment diary data (Table 2) showed a significant time × group interaction effect for WASO (P = .002), with the Internet group experiencing a 55% decrease (95% CI, 34% to 76%; P ≤ .001) and the control group having a decrease in WASO of only 8% (95% CI, −17% to 33%; P = .31). There was no significant interaction for SOL even though the Internet group had a decrease of 43% (95% CI, 13% to 73%), while the control group had a decrease of 8% (95% CI, −19% to 34%).

There was also a significant time × group interaction for sleep efficiency (P = .006), with a 16% (95% CI, 9% to 22%) increase for the Internet group (P ≤ .001) and a 3% (95% CI, −4% to 9%) increase for the control group (P = .14). There was a significant time × group interaction for number of nighttime awakenings (P = .01), with nighttime awakenings decreasing by 36% (95% CI, 16% to 56%; P = .005) for the Internet group and increasing by 1% (95% CI, −21% to 19%; P = .91) for the control group. There was a trend toward a significant time × group interaction for total sleep time (P = .09), and there was no significant time × group interaction for time in bed (P = .92). Participants were also asked to rate in the sleep diaries how restored they felt each morning and how restless or sound their sleep was each night. There were trends toward significant time × group interactions for feeling restored (P = .02) and soundness of sleep (P = .09).

Although medication titration was not specifically addressed in the intervention, exploratory analyses were conducted to examine changes in prescription medication use. At baseline, 15 of the 44 participants (6 Internet and 9 control) reported taking prescription medication for sleep (including benzodiazepine receptor agonists or sedating antidepressants), with no significant differences between groups. At postassessment, 4 Internet and 10 control participants reported taking these sleep medications (χ² = 3.77; P = .05). No changes in medication use were noted between postassessment and the 6-month follow-up for the Internet participants.

This study demonstrates that using the Internet to deliver an interactive and tailored behavioral intervention for adults with insomnia can significantly decrease insomnia severity and contribute to overall sleep improvements. These results suggest that an Internet-based CBT program for insomnia may be an effective first step in providing care to adults with insomnia. Overall, severity of insomnia as measured by the ISI significantly decreased for those who received the Internet intervention. While participants on average initially fell in the moderate severity range for insomnia, those who received SHUTi no longer met criteria for clinically significant insomnia at postassessment and 6-month follow-up. Based on sleep diary data, significant improvements were found for WASO, sleep efficiency, and number of nighttime awakenings for those who received the online program.

These findings contribute to the relatively small but growing Internet intervention literature. To our knowledge, only 1 other published trial has examined the use of the Internet in treating insomnia; the trial used a program created and tested by researchers in Sweden. However, that study found significant sleep improvements in both the treatment and control groups and had more substantial attrition than our study, making the findings difficult to interpret. It also used human support (therapists responding via e-mail) to promote adherence and monitor assignments, reducing the ability to widely disseminate that intervention without a significant increase in cost.

The improvements in sleep after using SHUTi are very similar to those from other insomnia treatment outcome trials. In fact, the percentage of change in sleep efficiency (16%) was almost identical to that found in other CBT self-help bibliotherapy (16%), group (15%), telephone (21%), face-to-face (17%), and pharmacotherapy (13%) studies. The results of this study are also consistent with the conclusions from a 2006 systematic and seminal review of the effectiveness of psychological and behavioral treatment of insomnia. It is important to highlight that the treatment effect sizes found using this Internet intervention, which was delivered with no human support and at a relatively low cost, are comparable to those found in face-to-face studies.

Although these findings are promising, they should be considered in light of several methodological limitations. First, the sample used in this study was small, relatively homogeneous, well educated, and restricted to individuals with primary insomnia and no comorbidities. Future studies should enroll larger and more heterogeneous samples to improve the generalizability of the findings. For example, it will be important to assess whether similar sleep improvements are found in patients with insomnia comorbid with medical or psychiatric problems. Second, this study had remarkably low attrition (4% at postassessment), a rate...
much lower than the average attrition found in other Internet interventions (21%), which is likely owing to the seemingly motivated, self-selected sample in our study. The level of motivation exhibited by this sample, reflected in their willingness to complete sleep diaries and the intervention cores, may not be representative of the larger population of individuals with insomnia. Third, the findings presented here are based on self-report measures. Although sleep diaries represent a core assessment component in insomnia research, polysomnography would be needed to confirm objective changes in sleep. Fourth, participants were not blinded to their group assignment. Following completion of the initial diaries, participants knew whether they were receiving SHUTi or were in the wait-list control group, resulting in the potential for some bias in self-report measures. Finally, this study used a wait-list control group, which does not control for all nonspecific effects such as participant expectation. Future studies should include placebo control groups who are provided with some type of intervention (such as patient education Web sites).

In summary, these findings provide support for using the Internet as an efficacious method for delivering CBT for insomnia. An Internet intervention has the potential of meeting the large unmet treatment need of the population with insomnia by providing effective treatment through the Web. Although an Internet intervention may not be the treatment of choice for all patients, it may be a significant first step in a stepped care model of treatment. Treating as many patients as possible with the least intensive treatment necessary to reach clinically significant outcomes allows more intensive resources (eg, face-to-face CBT) to be allocated to those who require additional care. Although some patients may prefer face-to-face care, others may prefer treatment delivered via the Internet. An effective and inexpensive Internet intervention would expand treatment options for large numbers of adults with insomnia, especially those whose geographical location prohibits access to relevant care, and could be a substantive first-line treatment choice.

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Role of the Sponsors: The National Institutes of Health reviewed the design of the study and annual progress reports but did not participate in conducting the study; in the collection, management, analysis, or interpretation of the data; or in the preparation, review, or approval of the manuscript.

Previous Presentations: This paper was presented in part at the Third Meeting of the International Society for Research on Internet Interventions; October 11, 2007; Charlottesville, Virginia; at the 22nd Annual Meeting of the Associated Professional Sleep Societies; June 11, 2008; Baltimore, Maryland; at the 19th Congress of the European Sleep Research Society; September 12, 2008; Glasgow, Scotland; and at the 42nd Annual Convention of the Association for Behavioral and Cognitive Therapies; November 14, 2008; Orlando, Florida.

Additional Contributions: Jonathan Cole Sletten, BA, and Dominion Digital provided expertise in developing the SHUTi program, William Pascarella, BS, provided technical support, Holly Lord, PhD, provided statistical support, Michelle Hilgert, MED, provided design expertise, and Kaveh Ardalan, BS, helped in examining the medication use data. Compensation or course credit was provided to these individuals in association with their work.

REFERENCES


LETTER TO THE EDITOR
Matters Arising

A reader questioned a discrepancy between the financial interests disclosed in an article that I published in 20061 and my recent Archives article2 in which I revealed no financial interests. In the prior article, I disclosed grant support from Janssen for a clinical trial of risperidol in autism completed in 2003, some academic lectures sponsored by AstraZeneca, and a consultation with Shire Pharmaceuticals, all in 2004. I did not disclose these financial interests in the Archives article because they were not relevant to the subject of the article. The article reported on the longitudinal course of preschool depression and made no recommendations about treatment. Furthermore, my program of research has not supported the use of antidepressants in preschool depression and none of these pharmaceutical companies market antidepressant drugs. However, as some feel that any financial relationships with a pharmaceutical company imply a potential conflict of interest, I wish to bring these past financial relationships to the attention of the readers.

[Editor’s Note: The policy of the Archives is that “authors... provide detailed information about all relevant financial interests and relationships or financial conflicts within the past 5 years.” Our Instructions to Authors provide this illustration: “For example, authors of a manuscript about depression should report all financial relationships they have with all manufacturers of products used in the management of depression, not only those relationships with companies whose specific products are mentioned in the manuscript. If authors are uncertain about what constitutes a relevant financial interest or relationship, they should contact the editorial office.”]

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Error in Results. In the Original Article titled “Efficacy of an Internet-Based Behavioral Intervention for Adults With Insomnia” by Ritterband et al, published in the July 2009 issue of the Archives (2009;66[7]:692-698), 2 minor computation errors occurred in the secondary variables time in bed and sleep efficiency. These computation corrections do not substantively change any of the results and do not alter any conclusions reached about the impact of the Internet intervention on sleep. The findings should have been reported as follows. There was no significant time × group interaction for time in bed (F1,42 = 0.88, P = .35), with a mean (SD) of 482.45 (56.15) minutes at preassessment and 468.48 (66.53) minutes at postassessment for those receiving SHUTi and 487.09 (46.93) minutes at preassessment and 493.57 (46.72) minutes at postassessment for those in the wait-list control group. There was a significant time × group interaction for sleep efficiency (F1,42 = 10.40, P = .002), with those receiving SHUTi experiencing a significant improvement (P = .001) from a mean (SD) of 72.3% (16.1%) at preassessment to 86.4% (5.3%) at postassessment and those in the wait-list control group experiencing a nonsignificant change (P = .16) from 74.7% (8.7%) at preassessment to 76.8% (7.6%) at postassessment.