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A Randomized Controlled Trial of an Internet Intervention for Adults with Insomnia: Effects on Comorbid Psychological and Fatigue Symptoms

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Abstract

Objective—Insomnia is frequently comorbid with other medical and psychological disorders. This secondary data analysis investigated whether an Internet-delivered cognitive behavioral therapy for insomnia (CBT-I) intervention could also reduce comorbid psychological and fatigue symptoms.

Method—Data from a pilot randomized controlled trial (RCT) testing the efficacy of Internet-delivered CBT-I relative to a waitlist control was used to examine changes in symptoms of depression, anxiety, mental health quality of life (QOL), and fatigue.

Results—Group by time interactions from repeated measures analyses revealed significant post intervention improvements in Internet participants (n = 22) relative to control participants (n = 22) on all psychological symptoms, mental health QOL, and fatigue. A small post hoc subsample of Internet participants with mild or moderate depression also showed large effect size changes in these constructs (depression, anxiety, mental health QOL, and fatigue).

Conclusion—Internet-delivered CBT-I appears to not only improve sleep but also reduce comorbid psychological and fatigue symptoms.

Keywords

insomnia; eHealth; depression; anxiety; fatigue; Internet; online; CBT; CBT-I; cognitive behavioral therapy; web

Insomnia is a significant public health problem frequently accompanied by psychological symptoms. Epidemiologic studies indicate that 30% to 48% of the adult population report insomnia symptoms (Ohayon, 2002), with approximately 6%–10% meeting criteria for chronic insomnia (Ford & Kamerow, 1989; Mellinger, Balter, & Uhlenhuth, 1985; Ohayon,

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Subsequent to conducting this study, Drs. Ritterband, Thorndike, Gonder-Frederick, and Morin became equity owners in a company that now makes the Internet intervention commercially available. The company had no role in preparing this manuscript.

2002). The co-occurrence of insomnia and psychological disorders, such as depression and anxiety, has been well documented (Breslau, Roth, Rosenthal, &Andreski, 1996; Buysse et al., 2008; Chang, Ford, Mead, Cooper-Patrick, & Klag, 1997; Johnson, Roth, & Breslau, 2006; Manber & Chambers, 2009;Roberts&Duong, 2012;Roth, 2001; Sivertsen et al., 2012; Tsuno, Besset, &Ritchie, 2005). Adults with insomnia are roughly three times more likely to meet diagnostic criteria for another psychological disorder than adults without sleep problems (Ford & Kamerow, 1989). In fact, more than 25% of adults with insomnia also have a current diagnosis of a mental disorder, and another 25% report a psychiatric history (Ohayon & Roth, 2003).

Although insomnia was initially viewed as a symptom of psychological disorders, it has subsequently been acknowledged that insomnia frequently exists as a comorbid but distinct diagnostic entity (Perlis et al., 2006). In addition, insomnia may be an important predictor or independent risk factor for the development of concomitant mental disorders (Baglioni & Riemann, 2012; Breslau et al., 1996; Manber & Chambers, 2009; Perlis et al., 2006; Riemann, 2007; Taylor, Lichstein, Durrence, Reidel, & Bush, 2005). The complaint of insomnia may be serving as an early indication of a prodromal psychological disorder (Ford & Kamerow, 1989; Ford&Cooper-Patrick, 2001; Riemann, 2007).Related to depression, adults with a prior history of insomnia have been found to be almost four times as likely to develop depression (Breslau et al., 1996), and time sequence analyses show that the onset of insomnia precedes the onset of depression in the majority of cases (Ohayon, 2007; Roberts & Duong, 2012; Sivertsen et al., 2012).

The more recent emphasis on the independent importance of insomnia in psychological disorders has led to speculation that insomnia treatment may improve psychological outcomes for adults with certain mood disorders (Ford & Cooper-Patrick, 2001; Riemann, 2007). Researchers have found some evidence that insomnia treatment, either pharmacological or behavioral, can affect treatment course and outcome for nonsleep aspects of psychological disorders, even when those symptoms are not specifically targeted (Krystal, 2006a; Krystal, 2006b). Further, Manber and colleagues (2008) have found that augmenting an antidepressant medication with brief cognitive behavioral therapy for insomnia (CBT-I) is promising as an improved treatment approach for individuals with insomnia comorbid with major depression (Manber et al., 2008). Thus, insomnia treatment may provide an important approach for reducing concurrent psychological symptoms, and may even serve to prevent subsequent development of psychological problems in the future.

Treatment for Insomnia

Although there are effective pharmacological interventions for insomnia over the short-term, the long-term success rates for these medications have not been documented (National Institutes of Health, 2005); and for some patients, these medications are not well tolerated due to side effects (Buscemi et al., 2007). Pharmacotherapy use has also been decreasing despite increasing prevalence rates for sleep problems (Walsh & Schweitzer, 1999;Walsh, 2004). Fortunately, there are effective behavioral treatments for insomnia, with evidence indicating that 70%–80% of treated patients obtain benefit from CBT (Morin, Culbert, & Schwartz, 1994; Morin et al., 1999; Murtagh & Greenwood, 1995). CBT-I (Morin, 1993;

Morin & Espie, 2003) works by targeting the maladaptive behaviors and dysfunctional thoughts believed to perpetuate sleep problems, going beyond mere sleep hygiene interventions (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Morin et al., 1999; Morin et al., 2006; National Institutes of Health, 2005). More specifically, CBT-I encompasses five primary treatment components: sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention (Morin, 1993; Morin et al., 2006; Morin et al., 2006; Morin & Espie, 2003; Morin, 2006). Despite the strong efficacy supporting CBT-I, it is not widely available to patients due to a lack of trained clinicians, poor geographical distribution of knowledgeable professionals, and expense (Edinger & Means, 2005; Espie, 2009).

Internet Interventions

To increase access to care and expand the availability of specialized behavioral treatments, researchers have been developing online interventions for a range of behavioral and mental health problems (Andersson, Ljótsson, &Weise, 2011; Benight, Ruzek, &Waldrep, 2008; Bewick et al., 2008; Bock, Graham, Whiteley, & Stoddard, 2008; Davies, Spence, Vandelanotte, Caperchione, &Mummery, 2012; Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006; Kazdin & Blase, 2011; Kiluk et al., 2011; Marks, Cavanagh, & Gega, 2007; Murray, Burns, See, Lai, & Nazareth, 2005; Richards&Richardson, 2012; Ritterband et al., 2003; Saperstein, Atkinson,&Gold, 2007; Schubart, Stuckey, Ganeshamoorthy, & Sciamanna, 2011; Solomon, Wagner, & Goes, 2012; van den Berg, Schoones, & Vliet-Vlieland, 2007), including insomnia (Cheng & Dizon, 2012; Espie et al., 2012; Lancee, van den Bout, van Straten, & Spoormaker, 2012; Ritterband et al., 2009; Ritterband et al., 2011; Ström, Pettersson, & Andersson, 2004; Suzuki et al., 2008; Vincent & Lewycky, 2009). These online programs have developed amidst the backdrop of high Internet access rates (Horrigan, 2009) and evidence that users are already turning to the Internet for health information and treatment strategies (Fox, 2006). These Internet-delivered programs are typically behavioral interventions that are based on effective face-to-face treatments (Ritterband et al., 2003). They have been adapted for online delivery and operate by being self-guided or semi-self-guided; personalized to the user; interactive; tailored to provide follow-up and feedback; and enhanced by the capabilities of web-based technologies (e.g., graphics, animations, audio, video; Ritterband et al., 2003).

Sleep Healthy Using the Internet (SHUTi)

Our research group previously developed and tested an Internet intervention for insomnia: Sleep Healthy Using the Internet (SHUTi, www.shuti.org). SHUTi is based on the above-described research supporting the efficacy of face-to-face CBT-I and includes sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention. The intervention does not, however, specifically target comorbid psychological symptoms. Additional details are provided below in the Method section.

To briefly summarize the findings from the primary trial, SHUTi was found to be efficacious in improving sleep, including insomnia severity, wake after sleep onset (WASO), and sleep efficiency (SE; Ritterband et al., 2009). As stated in the primary

outcome paper, group (Internet and waitlist control group) × time (pre and post assessment) repeated measures analysis of variance were conducted to compare pre to post changes on the primary sleep outcomes, including insomnia severity and the diary-derived variables of WASO, sleep onset latency (SOL), and SE. 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 the Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001) scores from post- to 6-month follow-up. Intent-to-treat analyses showed that scores on the ISI significantly improved from 15.73 (95% confidence interval [CI], 14.07–17.39) to 6.59 (95% CI, 4.73–8.45) for the Internet group, but did not change for the control group, 16.27 (95% CI, 14.61–17.94) to 15.50 (95% CI, 13.64–17.36), $F (1, 42) = 29.64$, $p < .001$. The Internet group maintained their reductions in insomnia severity at 6-month follow-up. Internet participants also achieved significant decreases in WASO (55%; 95% CI, 34%–76%) and increases in SE (16%; 95% CI, 9%–22%) compared to the nonsignificant control group changes of WASO (8%; 95% CI, −17%−33%) and SE (3%; 95% CI, −4%–9%). There was no significant interaction for SOL; the Internet group decreased by 43% (95% CI, 13%–73%), while the control group decreased by 8% (95% CI, −19%–34%).

Research Questions: SHUTi and Improvement in Psychological Symptoms

Although sleep improvements using Internet interventions have begun to be documented in the literature (Cheng & Dizon, 2012; Espie et al., 2012; Lancee et al., 2012; Ritterband et al., 2009; Ritterband et al., 2011; Ström et al., 2004; Suzuki et al., 2008; Vincent & Lewycky, 2009), little is known about whether online programs designed to improve sleep can secondarily affect comorbid psychological symptoms. The present paper is a secondary data analysis evaluating the effect of an Internet intervention designed to treat insomnia on concurrent psychological symptoms in a sample of adults seeking treatment for insomnia. The main outcomes investigated in this secondary analysis are changes in measures of depression, anxiety, and mental health quality of life (QOL). Because other treatments, including self-help treatments for insomnia, have found improvements in depression and anxiety, even when these nonsleep outcomes were not specifically treated (Currie, Clark, Hodgins, & El-Guebaly, 2004; Mimeault & Morin, 1999), we predicted that adults randomly assigned to receive SHUTi would experience greater improvements in psychological symptoms compared to those in a waitlist control group. We also explored whether fatigue was reduced following use of the intervention. This exploratory investigation was of interest given limited evidence in the literature that improved sleep leads to reductions in fatigue among adults with insomnia (Morin et al., 2006).

Method

Participants

Methodological details describing the participants, procedure, and intervention have been reported elsewhere (Ritterband et al., 2009), but are summarized here. To meet eligibility criteria, adults between 18 and 65 years of age had to have insomnia as defined by the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition Text Revised (DSM-IV-TR) primary insomnia definition (American Psychiatric Association, 2000), report sleep complaints for at least 6 months (difficulty initiating sleep, 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 (e.g., fatigue, performance impairment), and have regular Internet access. These criteria were assessed during a baseline structured clinical interview. Although baseline sleep diaries (described in more detail below) were collected, these diaries were not individually reviewed to confirm eligibility.

Participants were excluded if they met criteria for other sleep disorders (e.g., restless legs syndrome, periodic limb movements, obstructive sleep apnea) or major medical disorders that could account for the sleep disruption (e.g., cancer). These disorders were determined during the structured clinical interview by probing about previous diagnoses, as well as specific symptoms (Morin, 1993; Morin & Espie, 2003).With respect to psychiatric disorders, participants were excluded if they were currently experiencing a major depressive episode or met criteria for recurrent major depression, bipolar I or bipolar II disorder (see below). Participants were also excluded for the following reasons: (a) current psychological treatment, (b) unstable medication regimens as determined by a change in either sleep or nonsleep medications within the past three months, (c) shift work interfering with the establishment of regular sleep patterns, and (d) pregnancy during study. Written, informed consent was obtained from all individuals who participated, and participants were compensated $100 for completion of both in-person assessments. This study was approved by the Internal Review Board at the University of Virginia Health System.

Design

This was a secondary data analysis from a 2 group (Internet vs. waitlist control) × 2 time (pre vs. post) randomized controlled trial (RCT) design to evaluate the efficacy of an Internet intervention for insomnia (SHUTi). This analysis investigated the effect of SHUTi on comorbid symptoms, including depression, anxiety, mental health QOL, and fatigue.

Procedure

Participants were interviewed in person to collect demographic data, obtain a sleep history, and assess for medical and other sleep disorders using elements of a structured insomnia interview (Morin, 1993). To determine psychiatric comorbidity, participants first completed the Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, & Williams, 1999) and investigators probed positive responses which could be indicative of a current major depressive episode (MDE), recurrent major depression (MDE > 2), or bipolar I or II disorder with the Structured clinical interview for the DSM-IV (SCID; First, Gibbon, Spitzer, & Williams, 1995). Individuals who met these classifications were excluded. Participants also completed self-report questionnaires to assess depression, anxiety, QOL, and fatigue. After the initial in-person assessment, participants were taught how to complete online sleep diaries and navigate the online program.

Relevant for the primary sleep outcomes for the RCT, participants completed 10 online sleep diary entries (Carney et al., 2012) within a 2-week period before the intervention period. Upon completion of the baseline sleep diaries, participants were randomly assigned to either the Internet (SHUTi) or the control (waitlist) group based on a preset computer-generated randomization schedule. Internet participants were then granted access to the

Internet-delivered CBT-I intervention for 9 weeks. After 9 weeks, all participants were prompted to complete another 10 online sleep diaries within a 2-week period, and complete a final in-person assessment. The in-person post assessment included all of the same self-report measures, except the PHQ which had been administered to help determine eligibility.

Internet Intervention

SHUTi is based on well-established face-to-face CBT-I (Morin, 1996; Morin, 1993) and comprises six intervention Cores. The Cores include the behavioral, educational, and cognitive techniques typically taught in CBT-I, and act as an online analog for the weekly sessions conducted in face-to-face CBT-I. Each Core follows a similar structure: (a) provision of Core objectives, (b) review of previously assigned homework, (c) introduction of new content, (d) assignment of exercises/tasks for the coming week, and (e) review of material learned in the Core. The intervention functions by assigning users a new Core one week after the user completes the previous Core, thereby allowing users to practice and integrate strategies before obtaining new information and recommendations. Each Core typically requires 45–60 minutes to complete but users are able to return to previously completed Cores and review materials at any time. Users are also prompted to enter daily online diaries. One of the distinguishing features of SHUTi is that algorithms have been integrated and are applied to inputted symptom information, such as sleep diaries, providing the user with automated, tailored recommendations. SHUTi operates without any clinical support or supervision. Participants are able to seek technical support as needed (e.g., if a password is forgotten), but no clinical direction is given. A more detailed description of SHUTi can be found in Thorndike et al. (2008).

Study Flow

The CONSORT diagram depicts the flow of participants throughout the study (Figure 1). A power analysis indicated that a minimum of 40 subjects (20 per condition) would be needed to detect a medium effect size (ES) of d = .5 for the primary insomnia outcomes, with power of 80%, p = .01, and 15% attrition. Thus, 45 adults with primary insomnia were recruited to participate in the pilot trial.

Measures

The Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996; Vanheule, Desmet, Groenvynck, Rosseel, & Fontaine, 2008) was administered to test the effect of SHUTi on comorbid depressive symptoms. The BDI-II is a 21-item scale designed to assess current depressive symptoms over the preceding 2 weeks. Confirmatory analyses of the BDI-II suggest that it is internally reliable (alpha = .92; Beck et al., 1996), has good construct validity (Beck et al., 1996), and comprises two underlying factors assessing cognitive and somatic-affective symptoms of depression (Beck et al., 1996). Although other factor models of the BDI-II have been proposed and evaluated, Vanheule and colleagues concluded that the two-factor model Beck formulated for their clinical sample was best suited for the assessment of depression dimensions (Vanheule et al., 2008). Therefore, we elected to use the two- factor (cognitive and somatic-affective) model when evaluating scores on the BDI-II in this study.

The State-Trait Personality Inventory (STPI-Trait only; Spielberger, 1995) was also administered to test whether comorbid psychological traits change following intervention use. The STPI comprises four 10-item scales designed to measure dispositional anxiety, depression, anger, and curiosity in adults. Cronbach's alphas range from .82 to .85, suggesting good levels of internal consistency, and test-retest reliabilities are also satisfactory, with coefficients ranging from .60 to .80 (Ritterband&Spielberger, 1996; Spielberger, 1995).For purposes of the current investigation, the dispositional anxiety and depression scale scores are reported.

The SF-12 (Ware, Kosinski, & Keller, 1994) was administered to test the effect of SHUTi on overall QOL, including mental health QOL. This brief version of the Medical Outcomes Study 36-Item Short-Form Health Survey (Ware, Snow, Kosinsi, & Gandek, 1993; Ware, Kosinski, & Keller, 1994) is an extensively used measure of functioning, health status, and well-being to quantify QOL in the general population and various medical patients. This 12-item scale has been found to be a reliable and valid patient-based assessment of physical and mental health (Ware et al., 1996). For current purposes, only the mental health component is reported.

The Multidimensional Fatigue Symptom Inventory-Short Form (MFSI-SF; Stein, Jacobsen, Blanchard, & Thors, 2004) was administered to test whether levels of fatigue change following intervention use. This 30-item scale is designed to assess different types of fatigue over the last 7 days. Studies document internal consistency (subscale alphas ranged between 0.87 and 0.96) and adequate concurrent validity (moderate to high correlations with other relevant instruments of fatigue; Stein et al., 2004).

Data Analysis

Descriptive statistics were computed and groups were compared on baseline characteristics and baseline outcome measures using *t* tests and chi-square tests as appropriate. To evaluate efficacy, 2 (group) × 2 (time) repeated measures analysis of variance (RM ANOVAs) were conducted to compare pre to post changes across groups. The model included the baseline outcome score as a covariate if groups differed significantly on that measure at baseline. Follow-up paired *t* tests by group were conducted on significant interaction results. Analyses included an intent-to-treat approach using last observation carried forward (LOCF) for the one case who did not provide data at post.

The Benjamini and Hochberg method (Benjamini & Hochberg, 1995), involving an incremental application of the Bonferroni correction for multiple testing, was used for testing the four main outcome variables in this secondary data analysis (BDI-II, STPI-Depression, STPI-Anxiety, mental health QOL). As the remaining analyses are exploratory, no correction for multiple testing was applied. The alpha criterion level for significance was $p \leq .05$ for calculating the correction for multiple testing as well as for uncorrected exploratory analyses.

Effect sizes were computed by group as mean pre-post differences and standardized using the full sample standard deviations of pretreatment scores. Effect sizes were corrected for small sample size following Hedges and Olkin's (1985) recommendations. If a covariate

was included in the model as indicated above, then estimated marginal means were used in the computation of ES.

Although participants with a current major depressive disorder were excluded, participants still reported a range of concurrent depressive and anxious symptoms. For exploratory purposes, a subgroup with more depressive symptoms (high BDI-II Internet subgroup $n = 5$; high BDI-II control subgroup $n = 4$) was identified post hoc by selecting those participants with a score of 14 or higher on the BDI-II (i.e., “mild” or “moderate” depression; Beck et al., 1996). Exploratory post hoc descriptive statistics and ESs were examined with this subgroup. The one higher BDI-II subgroup participant with missing post data was not included.

All analyses were conducted using IBM SPSS Statistics 20.

Data Preparation

All variables were examined for accuracy of data entry, missing values, and fit with the assumption of normality. In one case where our tests revealed the pre-post difference to be slightly to moderately skewed (MFSI total score), we used a square root transformation and performed the analysis on the new, normally distributed variable. Results were very similar to the results with the nontransformed variable. The nontransformed variable is thus presented throughout the paper for simplicity.

Results

Demographic Variables

Demographic, baseline sleep, and baseline computer use variables are presented in Table 1. Participants were mostly female (77%), Caucasian (93%), approximately 45 years old (M_{age} = 44.86 years, SD = 11.03 years), and highly educated (44% had a BA/BS, 47% had a graduate degree). On average, the 44 participants reported a history of sleep difficulties of more than 10 years (M = 127.09 months, SD = 106.73 months) and disruptive sleep more than 5 nights per week in the past month (M = 5.52 nights, SD = 1.44). Overall, 77% of the participants indicated that they were “very comfortable” or “expert” at using the Internet. All participants reported that they checked their email and used the Internet at least once each week, 91% stated that they checked email at least daily, and 86% stated that they used the Internet at least daily. Baseline descriptive statistics for the high BDI-II subgroup were similar to the baseline statistics for the whole sample. Among this more symptomatic group, the average BDI-II score was 18, ranging from 14 to 26. This score reflects a moderate level of depressive symptoms (Beck et al., 1996; Steer, Brown, Beck, & Sanderson, 2001).

Baseline comparisons did not reveal significant differences between groups on demographic variables, computer use, and sleep variables (Table 1). However, there were two trends, indicating that the Internet group had a higher proportion of participants who use the Internet daily (95.5% vs. 77% for the control group), and that the control group participants had more nights of sleep difficulties (5.91 nights/week compared to 5.14 for the Internet group).

Preintervention Symptom Scores

Independent-samples *t* tests were conducted to compare the main outcome scores for the Internet and control group at baseline. The means by group for these scores are displayed in Table 2. There were no significant differences between groups on the BDI-II Total, $t(42) = 1.37$, $p = .178$, or the BDI-II Somatic-Affective subscale, $t(42) = .67$, $p = .51$; however, there was a significant difference on the BDI-II Cognitive subscale, $t(34) = 2.42$, $p = .02$, with the Internet participants reporting a higher score. There were no significant group differences on the STPI-Depression scale, $t(42) = 1.00$, $p = .32$, the STPI-Anxiety scale, $t(42) = 1.70$, $p = .10$, the SF-12 Mental Health scale, $t(41) = -1.51$, $p = .14$, or the MFSI Total score, $t(42) = 1.00$, $p = .33$.

Psychological Outcomes

BDI-II—The group (Internet vs. control) × time (pre vs. post) interaction effect for the BDI-II Total Score was significant, $F(1, 42) = 5.00$, $p = .03$ (corrected alpha: $p \leq .05$). Follow-up paired *t* tests indicated significant improvement from pre to post assessment in the Internet group, $t(21) = 2.75$, $p = .01$, and insignificant change in the control group, $t(21) = .12$, $p = .91$. For the Cognitive subscale of the BDI-II, the group × time interaction (with baseline scores as covariate) was not significant, $F(1, 41)=0.98$, $p = .33$.Atrendwas found on the Somatic/Affective subscale interaction, $F(1, 42) = 3.88$, $p = .06$. For the Internet group, the ESs for pre to post changes in the BDI-II Total Depression score and Somatic/Affective subscale score were large, while the Cognitive subscale score ES was small: $d = .72$, $d = .69$, $d = .34$, respectively. For the control group, the ESs indicated little improvement: BDI-II Total Depression score: $d = .02$; Cognitive subscale score: $d = .05$; Somatic-affective subscale score: $d = .11$. See Table 2 for a listing of group × time interaction statistics; pre and post means and SDs; and pre to post ESs.

Results for the BDI-II were also computed without the sleep item to examine the extent to which the sleep item might be influencing the results, and thus confounding improvements in sleep with improvements in depression. This procedure was similar to that followed by others who simultaneously investigated sleep and depression (Franzen, Buysse, Rabinovitz, Pollock, & Lotrich, 2010; Quesnel, Savard, Simard, Ivers, & Morin, 2003). Without the sleep item, results were similar and slightly stronger: the BDI-II Total Score was significant, $F(1, 42) = 6.44$, $p = .02$, and the BDI-II Somatic-Affective subscale was significant, $F(1, 42) = 5.91$, $p = .02$.

STPI-Trait—On the STPI-Trait Depression scale, the group × time interaction was significant, $F(1, 42) = 10.63$, $p = .002$ (corrected alpha: $p \leq .013$). Follow-up paired *t* tests indicated a significant improvement from pre to post assessment in the Internet group, $t(21) = 3.14$, $p = .01$, and insignificant change in the control group, $t(21) = -1.38$, $p = .18$. On the Anxiety scale of the STPI-Trait, the group×time interaction was also significant, $F(1, 42) = 8.28$, $p = .006$ (corrected alpha: $p \leq .025$). Follow-up paired *t* tests indicated a significant improvement from pre to post assessment in the Internet group, $t(21) = 3.31$, $p \leq .01$, and insignificant change in the control group, $t(21) = -1.01$, $p = .33$. The ESs were medium for the Internet group, STPI-Depression $d = .55$ and STPI-Anxiety $d = .57$. For the control

group, ESs were in the opposite direction, indicating worsening of symptoms, STPI Depression d=−.22, and STPI Anxiety d = −.21.

SF-12 QOL—On the Mental Health component of the SF-12, the group×time interaction was significant, $F(1, 41) = 5.18$, $p = .028$ (corrected alpha: $p \leq .038$). Follow-up paired t tests indicated a significant improvement from pre to post assessment in the Internet group, $t(21) = -2.60$, $p = .02$, and insignificant change in the control group, $t(20) = 0.23$, $p = .77$. The ES for the Internet group was large ($d = .80$), and the ES for the control group indicated a slight worsening of symptoms ($d = -.11$).

Psychological Outcomes for BDI-II Subgroup

Depression, anxiety, and mental health QOL measures were also examined post hoc among a BDI-II subgroup of nine mildly or moderately depressed individuals. All post hoc descriptive statistics for this subgroup are shown in Table 3.

BDI-II—Among the BDI-II subgroup with mild to moderate symptoms, descriptive statistics indicate improvement in the Internet group. For BDI-II Total score, the ES for the BDI-II Internet subgroup was large, $d = 3.40$; and the ES for the BDI-II control subgroup was medium, $d = .53$. The ES for the BDI-II Internet group for the Cognitive subscale ($d = 2.00$) and the Somatic subscale ($d = 2.48$) were also large, while the corresponding ESs for the BDI-II control subgroup were in the same direction but smaller in magnitude, Cognitive subscale: $d = .09$; Somatic subscale: $d = .54$.

STPI-Trait—On the STPI-Trait Depression scale, ESs similarly indicate a large decrease in depression from pre to post assessment in the BDI-II Internet subgroup ($d = 1.62$), and no change in the BDI-II control subgroup ($d = .00$). On the Anxiety scale of the STPI, the BDI-II Internet subgroup showed large improvements in anxiety ($d = 1.24$), while the ES for the BDI-II control subgroup was in the opposite direction ($d = -.25$).

SF-12 QOL—On the SF-12 QOL Mental Health subscale, the ES for the BDI-II Internet subgroup was large ($d = 2.07$), and the ES for the BDI-II control subgroup was in the opposite direction ($d = -.12$).

Exploratory Outcome: Fatigue

Fatigue in the full sample—On the Multidimensional Fatigue Symptom Inventory-Short Form Total Fatigue score, there was a significant group × time interaction, $F(1, 42) = 9.89$, $p < .01$. The Internet group improved from a baseline mean (SD) of 19.46 (17.65) to a post mean of 3.82 (13.90), while the control group increased in fatigue from a baseline mean (SD) of 14.73 (13.87) to a post mean of 16.18 (16.16). Follow-up paired t tests indicated a significant improvement from pre to post assessment in the Internet group, $t(21) = 3.30$, $p \leq .01$, and insignificant change in the control group, $t(21) = -0.55$, $p = .59$. The ES for the Internet group was large, $d = .97$, while the ES for the control group was in the opposite direction, $d = -.09$.

Fatigue in the BDI-II subgroup—Among the BDI-II subgroup with mild to moderate depressive symptoms, the BDI-II Internet subgroup improved from a baseline mean (*SD*) of 45.50 (15.28) to a post mean of 3.60 (20.02) on the MFSI-SF Total Fatigue Score, with a corresponding ES of $d = 2.16$. The BDI-II control subgroup remained at approximately the same level of fatigue, with a baseline mean (*SD*) of 29.25 (16.98) and a post mean of 28.50 (9.95), and a corresponding ES of $d = .04$.

Discussion

Results from this secondary data analysis indicate that adults treated for primary insomnia with an interactive and tailored Internet-delivered CBT-I intervention (SHUTi) experience reductions in psychological symptoms as well, even when these symptoms are not specifically targeted in the intervention. In comparison to adults who did not receive the Internet-delivered intervention for insomnia, SHUTi participants reported greater improvements in depression, anxiety, and mental health QOL. In order to explore the efficacy of SHUTi among the more symptomatic participants (relatively higher BDI-II scores), post hoc ESs were calculated among a small group of participants who scored higher in the depression range. Effect sizes of this post hoc subgroup of SHUTi participants with mild or moderate depressive symptoms were, in all cases, large, suggesting that the more symptomatic participants were also able to experience improvements in depression, anxiety, and mental health QOL following use of the intervention.

To place these findings in context of the existing Internet intervention literature for insomnia, these secondary analyses were compared to the mood specific findings reported in a recent meta-analysis on computerized/Internet interventions for insomnia (Cheng & Dizon, 2012). Of the six published papers on computerized/Internet interventions for insomnia in the meta-analysis, one is based on the same study as the current secondary analysis and one is a separate evaluation of SHUTi among cancer survivors with insomnia (Ritterband et al., 2011). In the SHUTi cancer survivor trial, ESs for depression and anxiety on the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) were medium to large (HADS-depression: $d = .63$; HADS-anxiety: $d = .70$), which are similar in magnitude to the ESs reported in the current investigation. Of the four other Internet intervention studies for insomnia reported in the meta-analysis, three did not investigate changes in mood variables (e.g., depression, anxiety; Riley, Mihm, Behar, & Morin, 2010; Ström et al., 2004; Vincent & Lewycky, 2009), and one did not find significant or notable pre to post changes in mood following use of the Internet intervention (Suzuki et al., 2008). However, in the case of the intervention that found no mood improvements, the program was a 2-week abbreviated CBT-I intervention (Suzuki et al., 2008). Perhaps including more CBT elements and/or providing the intervention over a longer period of time is necessary to achieve additional benefits in mood. Future investigation is needed to help clarify whether online insomnia interventions reliably result in secondary improvements in mood and, if so, which conditions or components are responsible for this improvement.

Interestingly, the large ESs found for the reduction of depression and anxiety in the present analysis are similar in magnitude to (or larger than) the ESs found in many Internet interventions specifically targeting depression and anxiety (Spek et al., 2007).More

specifically, a meta-analysis of CBT delivered Internet interventions for depression and anxiety found an overall small ES in reducing depression symptoms (d = .27), and an overall large ES in reducing anxiety symptoms (d = .96; Spek et al., 2007). Caution in comparing the ESs, however, should be taken as the interventions in the meta-analysis above were specifically targeting adults with clinical levels of depression, whereas participants in the current study were experiencing relatively mild levels of symptoms. Furthermore, each of these interventions is different with respect to sophistication of the technology, amount (if any) of tailoring, level of interactivity, and other program features that can strongly affect both adherence and outcomes in these programs.

On a related note, it would also be interesting to evaluate whether interventions targeting depression or anxiety also note comorbid improvements in sleep. It is strongly recommended that research investigations in both domains (mood and insomnia) secondarily measure and report the other domain. In the literature, one online intervention for depression reports adding a module about sleep to improve QOL (Andersson et al., 2005); however, including measurement and analysis of both domains in these online interventions will allow the field to better understand the effect of treatment on the bi-directional relationship of sleep and mood.

If providing an online CBT-I intervention for patients with both insomnia and a comorbid psychological condition can yield improvements in sleep, as well as improvements in mood, this suggests that patients can initiate treatment for insomnia, even in the presence of psychological symptoms of depression or anxiety. That is, patients may not have to wait to seek help for insomnia until their psychological distress is fully resolved. This is of importance given that some clinicians believe patients with insomnia and comorbid psychological symptoms cannot benefit from insomnia treatment until the psychological issue is resolved, particularly if that intervention is conducted online. Although these preliminary findings suggest that this may not be the case for patients with mild levels of symptoms, the issue needs to be more fully investigated with more symptomatic patients.

SHUTi participants also showed significant reductions in fatigue. This is of importance given an American Academy of Sleep Medicine review that indicated a lack of clear evidence that behavioral treatments result in reductions in fatigue (Morin et al., 1999). Analyses of the post hoc subgroup of participants with mild or moderate depression revealed a large ES reduction in fatigue among the subgroup with mild or moderate depressive symptoms, again suggesting that the more distressed participants may still be able to benefit from the program with respect to fatigue. One plausible explanation for the large ES is that the baseline fatigue in these more symptomatic participants reflected fatigue due to both depression and insomnia symptoms. Then, because both types of symptoms improved, there was ample room for fatigue to improve as well.

These fatigue findings were also compared to those reported in the meta-analysis on computerized/Internet interventions for insomnia (Cheng & Dizon, 2012). Of the five trials (not including the one on which this secondary analysis is based), three did not investigate fatigue, but two also found that participants using an insomnia Internet intervention experienced significant reductions in fatigue (Ritterband et al., 2011; Vincent & Lewycky,

2009). The pre to post fatigue ES for the cancer survivors using SHUTi was large (d = .80), a finding comparable to what was observed in the current analysis with adults with primary insomnia.

In sum, this secondary analysis responds to the call for increased investigation of mood and psychological symptoms within insomnia treatment research. It adds evidence in favor of the hypothesis that insomnia treatment can improve psychological outcomes (Ford & Cooper-Patrick, 2001; Krystal, 2006a; Krystal, 2006b;Riemann, 2007), at least among those with mild to moderate symptoms, and extends the call for examining mood variables in insomnia treatment to the field of Internet-delivered interventions for insomnia as well. Further, given evidence that insomnia often precedes the onset of depression (Ohayon, 2007), effective insomnia interventions may also have potential as a preventative approach for addressing psychological disorders. Given that Internet interventions improve treatment access for patients, Internet interventions may allow researchers to more readily evaluate and follow the large number of participants needed to conduct these large-scale prevention trials.

Limitations

Although the study results are encouraging, there are important limitations. First, the study comprised people with primary insomnia and excluded participants with comorbid mood disorders, including major depression and bipolar disorder. Therefore, it is possible that adults with more significant depressive or other psychological symptoms would respond differently to the online intervention. Our post hoc examination of the ESs for the mildly to moderately depressed subgroup do not suggest this pattern, but the SHUTi subgroup with higher BDI-II scores was small, identified post hoc, and not representative of the most depressed individuals, preventing further conclusions from being drawn. In addition, there were noteworthy differences at baseline between groups within this subsample, so that regression to the mean could have made improvements appear overly strong.

As mentioned in the primary outcome paper from which this analysis is based, other limitations include the relatively small and homogenous sample (primarily Caucasian and well educated). Although these demographics are similar to those in many samples of treatment seeking adults with insomnia, it remains unclear whether findings will generalize to a more diverse sample. Further limitations include use of a waitlist control rather than a placebo control group and use of self-reported measures for the secondary variables (e.g., depression, anxiety) rather than a clinician-administered interview at both assessment points. Last, additional follow-up assessments of the secondary variables beyond posttreatment were not conducted.

Future directions

In line with recent theoretical papers stressing the importance of testing the efficacy of cognitive-behavioral treatment for insomnia comorbid with psychiatric disorders (Smith, Huang, & Manber, 2005), this study further encourages such research. In particular, these findings build rationale for evaluating the efficacy of Internet-delivered interventions for patients with insomnia comorbid with psychological disorders, including depression and anxiety, and highlights the importance of measuring other comorbid symptoms (e.g.,

fatigue). Evaluating Internet interventions with more heterogeneous populations and utilizing less stringent eligibility criteria can allow for greater generalization of findings. Determining for whom and through which mechanism these Internet interventions work is an essential step in moving forward the eHealth field generally, and the field of Internet-delivered interventions for insomnia specifically. Last, it is important to conduct longer term follow-up with participants who use these online insomnia programs to determine not only if gains are maintained but also if Internet interventions for insomnia can serve as a prevention tool for people at risk of developing depression.

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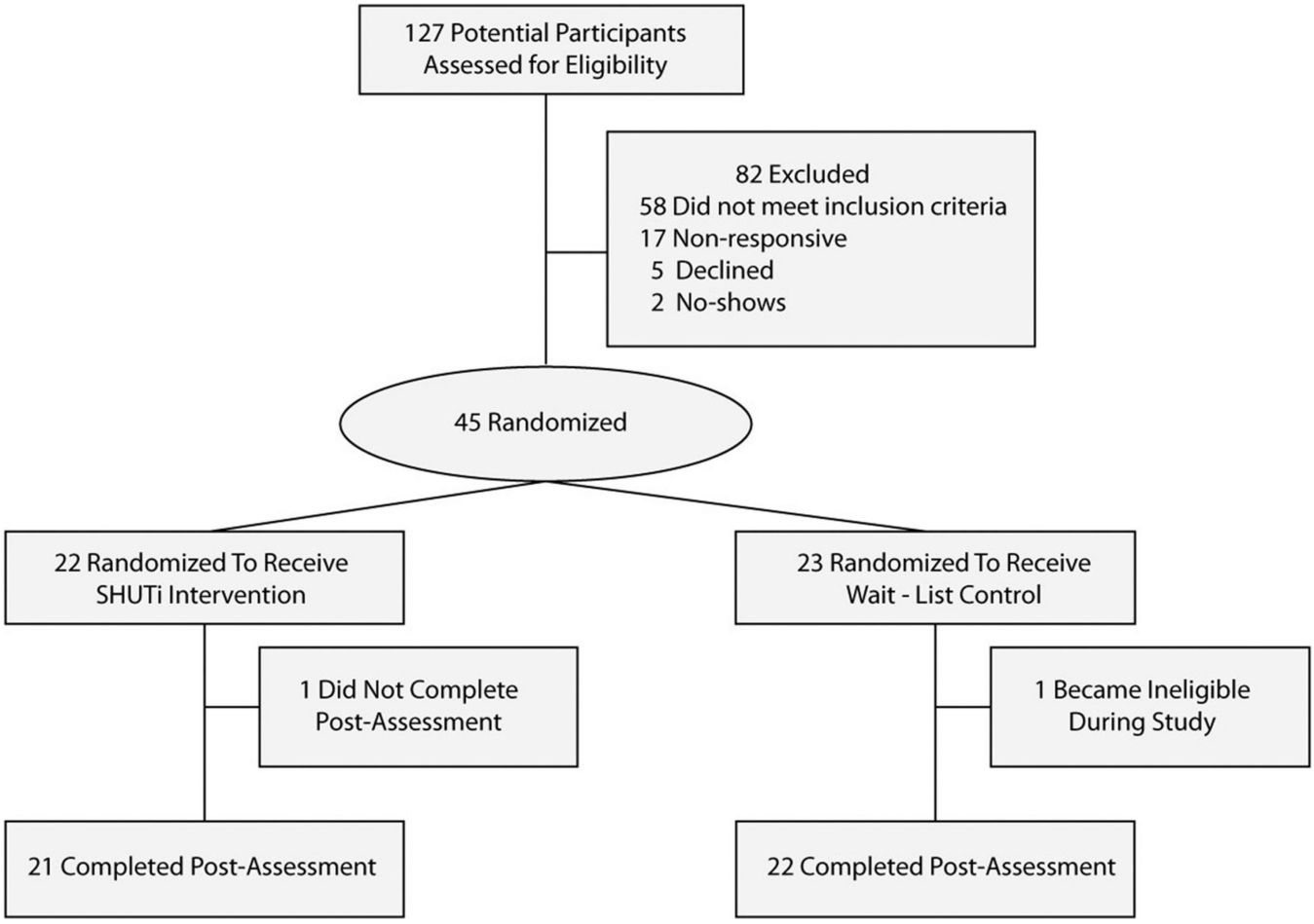

Figure 1.
Study enrollment flow.

Table 1

Baseline Characteristics of Participants Compared by Treatment Group

	Mean (*SD*) or frequency (%)			
	Internet (*n* = 22)	**Control (*n* = 22)**	**Total (*n* = 44)**	***p***
Age	44.68 (10.61)	45.05 (11.67)	44.86 (11.03)	.91
Gender				
Women	18 (82%)	16 (73%)	34 (77%)	.47
Men	4 (18%)	6 (27%)	10 (23%)	
Race				
White	21 (95.5%)	20 (91%)	41 (93%)	.55
Other	1 (4.5%)	2 (9%)	3 (7%)	
Education[a]				
High school	3 (14%)	1 (5%)	4 (9%)	.44
BA/BS	8 (36%)	11 (52%)	19 (44%)	
Graduate degree	11 (50%)	9 (43%)	20 (47%)	
Computer use				
Check e-mail daily	20 (91%)	20 (91%)	40 (91%)	1.00
Use Internet daily	21 (95.5%)	17 (77%)	38 (86%)	.08
Very comfortable w/Internet	18 (82%)	16 (73%)	34 (77%)	.47
Sleep				
Months of sleep difficulties	121.73 (99.12)	132.45 (115.94)	127.09 (106.73)	.74
Sleep difficulties, nights/week	5.14 (1.54)	5.91 (1.24)	5.52 (1.44)	.07

Note. *p* values are based on *t*-test for continuous variables or on Pearson's χ^2 tests for dichotomous variables. SD = standard deviation.

[a]Control group *n* = 21.

Table 2

Pre-Post Comparison of Internet and Control Groups on Psychological Symptoms

	Internet (*n* = 22)			Control (*n* = 22)				
Measure	**Pre (*SD*)**	**Post (*SD*)**	***d***	**Pre (*SD*)**	**Post (*SD*)**	***d***	***F***	***p***
BDI-II								
Total	9.73 (7.57)	4.91 (6.00)	.72	7.05 (5.21)	6.91 (5.89)	.02	5.00	.03*
Cognitive[a]	2.91 (2.83)	1.55 (2.13)	.34	1.23 (1.63)	1.64 (2.68)	.05	0.98	.33
Somatic	6.82 (5.61)	3.36 (4.35)	.69	5.82 (4.22)	5.27 (4.10)	.11	3.88	.06
STPI-Trait								
Depression	18.62 (4.27)	16.23 (5.34)	.55	17.32 (4.31)	18.27 (4.05)	−.22	10.63	< .01*
Anxiety	19.77 (4.32)	17.32 (3.70)	.57	17.64 (4.01)	18.55 (4.71)	−.21	8.28	< .01*
SF-12 QOL[b] Mental Health	42.34 (9.11)	49.16 (8.15)	.80	46.15 (7.31)	45.61 (9.39)	−.11	5.18	.03*

Note. SD = standard deviation; BDI = Beck Depression Inventory; STPI = State Trait Personality Inventory; SF-12 QOL = SF-12 Quality of Life. *F* = test statistic from repeated measures ANOVA/ANCOVA; *d* = effect size, which was corrected for small sample size.

[a]Baseline scores were included in the analysis to control for baseline group differences. *d* was computed using estimated marginal means.

[b]For the SF-12 measure, one Control participant had missing data (Control *n* = 21).

*Alpha displays significance according to the corrected criterion alpha for that variable. Corrected criterion alphas are: BDI-II Total, *p* = .050; STPI-Depression, *p* = .013; STPI-Anxiety, *p* = .025; SF-12 QOL, Mental Health, *p* = .038.

Table 3

Exploratory Pre-Post Comparison of Internet and Control Groups on Psychological Symptoms for Participants in Higher BDI Subgroup

	Internet subgroup (n = 5)			Control subgroup (n = 4)		
Measure	**Pre (*SD*)**	**Post (*SD*)**	***d***	**Pre (*SD*)**	**Post (*SD*)**	***d***
BDI-II						
Total	20.20 (4.32)	4.20 (6.10)	3.40	15.25 (1.89)	12.75 (4.19)	.53
Cognitive	6.60 (1.67)	1.00 (1.22)	2.00	3.50 (2.38)	3.25 (3.59)	.09
Somatic	13.60 (4.83)	3.20 (4.97)	2.48	11.75 (1.89)	9.50 (2.52)	.54
STPI-Trait						
Depression	20.20 (2.59)	14.40 (1.82)	1.62	20.00 (4.24)	20.00 (4.55)	.00
Anxiety	23.60 (3.36)	17.40 (3.65)	1.24	19.50 (5.07)	20.75 (4.43)	−.25
SF-12 QOL Mental Health	34.40 (11.99)	56.85 (1.55)	2.07	41.08 (4.87)	39.80 (12.30)	−.12

Note. Data comes from a subsample of participants who scored ≥ 14 on the BDI-II Total. SD = standard deviation; BDI = Beck Depression Inventory; STPI = State Trait Personality Inventory; SF-12 QOL = SF-12 Quality of Life, Mental Health Subscale. *d* = effect size, which was corrected for small sample size.