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SCIENTIFIC INVESTIGATIONS

Improving Daytime Functioning, Work Performance, and Quality of Life in Postmenopausal Women With Insomnia: Comparing Cognitive Behavioral Therapy for Insomnia, Sleep Restriction Therapy, and Sleep Hygiene Education

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Study Objectives: Insomnia is a chief complaint among postmenopausal women, and insomnia impairs daytime functioning and reduces quality of life. Recent evidence supports the efficacy of cognitive behavioral therapy for insomnia (CBTI) for menopausal insomnia, but it remains unclear whether treating insomnia improves daytime function in this population. This study evaluated whether CBTI improves daytime fatigue, energy, self-reported sleepiness, work productivity, and quality of life in postmenopausal women with insomnia, and whether sleep restriction therapy (SRT)—a single component of CBTI—is equally efficacious.

Methods: Single-site, randomized control trial. One hundred fifty postmenopausal women (56.44 ± 5.64 years) with perimenopausal or postmenopausal onset or exacerbation of chronic insomnia were randomized to 3 treatment conditions: sleep hygiene education control (SHE), SRT, and CBTI. Blinded assessments were performed at pretreatment, posttreatment, and 6-month follow-up.

Results: CBTI and SRT produced moderate-to-large improvements in fatigue, energy, sleepiness, and work function at posttreatment and 6 months later. The CBTI group reported better quality of life as indicated by substantial improvements in emotional wellbeing and resiliency to physical and emotional problems, whereas the SRT and SHE groups only showed improvements in resiliency to physical problems. Pain complaints decreased as sleep improved but were not associated with specific treatment conditions. Similarly, insomnia remitters reported fewer daytime and nighttime hot flashes, although reductions were not associated with any specific treatment.

Conclusions: CBTI and SRT are efficacious options for postmenopausal women with chronic insomnia. Both interventions improve daytime function, quality of life, and work performance, although CBTI produces superior results including the added benefit of improved emotional health.

Clinical Trial Registration: Registry: ClinicalTrials.gov; Title: Behavioral Treatment of Menopausal Insomnia; Sleep and Daytime Outcomes; Identifier: NCT01933295; URL: https://clinicaltrials.gov/ct2/show/record/NCT01933295

Keywords: fatigue, hot flashes, menopause, quality of life, sleep, sleepiness, work impairment

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Insomnia is common among women during and after menopause transition. Recent evidence shows cognitive-behavioral therapy for insomnia (CBTI) and sleep restriction therapy (SRT) to improve sleep for women with menopausal insomnia. However, insomnia is a 24-hour disorder characterized by difficulty sleeping at night and impaired function and quality of life during the day.

Study Impact: Impaired daytime function is a primary motivator for insomnia treatment-seeking, yet it remains unclear whether CBTI or SRT improve insomnia-related daytime impairment and poor quality of life in postmenopausal patients. In this trial, we showed that CBTI and SRT improve daytime fatigue and energy, quality of life, and work performance relative to sleep hygiene control. Importantly, CBTI produced even larger treatment effects than SRT in addition to improving emotional health.

INTRODUCTION

For many women, the menopause transition brings about distressing hot flashes, decreased quality of life, increased fatigue, and impaired work performance.[1–5] Insomnia is also one of the most common complaints in the menopause transition and afterward.[6–9] Indeed, nearly half of postmenopausal women (43% to 48%) report trouble sleeping,[6] and insomnia has been linked to the very same daytime impairments associated with the menopause transition.[10–13] Thus, not only is menopause transition a window of vulnerability for hot flashes, decreased quality of life, persistent fatigue, and impaired work productivity, but women with menopausal insomnia are likely at even greater risk for daytime impairment and poor quality of life owing to the added burden of poor sleep. It is therefore imperative to identify safe and efficacious treatments for

menopausal insomnia that also alleviate daytime impairment and poor quality of life that are typically associated with both insomnia and difficult menopause transition.

Menopause itself—via hormonal changes and related symptoms—disrupts sleep and increases risk for insomnia disorder.[7,14] Recent evidence from randomized control trials (RCTs)—including the MSFlash trials and our own—show that nonpharmacological insomnia treatments substantially reduce insomnia symptoms in perimenopausal and postmenopausal women.[15,16] Specifically, cognitive behavioral therapy for insomnia (CBTI) and sleep restriction therapy (SRT; a brief nonpharmacological insomnia treatment composed of a single component of CBTI) delivered via face-to-face[16] or telemedicine[15] produce much larger reductions in menopause-related nocturnal insomnia symptoms than sleep hygiene education, hormone replacement therapy, antidepressant medication, yoga, and exercise.[15–17] These data support CBTI and SRT as efficacious treatments to improve nighttime symptoms associated with menopausal insomnia.

Yet, insomnia is a 24-hour disorder marked by difficulty sleeping at night, significant functional impairment during the day, and reduced overall quality of life. Indeed, untreated insomnia is associated with a wide range of daytime impairments and areas of poor life quality, including worse overall health, high fatigue, poor work performance and attendance, and—unique to midlife women—increased hot flashes.[10,12,13,18–22] As perimenopausal and postmenopausal women struggle with many of these same impairments,[1,3,4] women with menopausal insomnia likely suffer severely impaired daytime function and poor quality of life. Importantly, individuals struggling with insomnia typically seek treatment only when daytime functioning becomes impaired due to their sleep problems.[23] Although hypnotics and sedatives have traditionally been used to treat insomnia, these medications can actually impair daytime function[24] and are thus not recommended for use by midlife women during or after menopause.[25] Identifying efficacious nonpharmacological interventions for menopause-related insomnia to improve daily functioning and quality of life is crucial, and CBTI has been identified as a promising intervention to improve nocturnal and daytime symptoms of menopausal insomnia.[25]

The primary goal of this RCT was to compare CBTI, SRT, and sleep hygiene education (SHE) minimal intervention control for the treatment of menopause-related sleep and daytime impairment outcomes. The nocturnal insomnia findings of this RCT have been reported previously (outcomes were self-reported global insomnia severity, total sleep time, sleep quality, sleep latency, nighttime awakenings, wake after sleep onset, and sleep efficiency).[16] The previous report showed that CBTI and SRT produce large reductions in insomnia symptoms, whereas SHE was not supported as a viable treatment for menopausal insomnia. Further, CBTI outperformed SRT in regard to sleep maintenance and produced higher rates of remission. However, we had not yet explored whether these nocturnal improvements translated to increases in daytime function. The present study sought to determine whether CBTI and SRT improve daytime function, work performance, and quality of life as compared to SHE control for postmenopausal women with chronic insomnia. We hypothesized that patients receiving CBTI or SRT would report improvements in all outcomes as compared to patients receiving SHE upon completing treatment and then again 6 months later. In addition, we anticipated that the additional components of CBTI (ie, cognitive therapy, progressive muscle relaxation, stimulus control, and sleep hygiene) would have substantial incremental value to treatment and produce larger and more durable effects than SRT in regard to improving daytime functioning and quality of life.

METHODS

Participants and Procedure

This study was conducted in a six-hospital health system in Metro Detroit. All study procedures were approved by the institutional review board. Women were recruited from primary care and a sleep clinic, the community via newspaper advertisements, and from a database of prior sleep center studies. To be eligible, women must have been postmenopausal (12 consecutive months without menses), reported average wake after sleep onset (wakefulness in the middle of the night after falling asleep) of an hour or more on ≥ 3 nights per week, and met criteria for chronic DSM-5[26] insomnia disorder that onset or worsened during the perimenopausal or postmenopausal period per clinical interview with a registered nurse with specialty training in behavioral sleep medicine. In addition, objective sleep disturbance had to be evident per mean wake after sleep onset of 45 minutes or more on two overnight polysomnography (PSG) studies (adaptation night + baseline night, neither of which could have wake after sleep onset < 30 minutes). Exclusionary criteria also included prior or current DSM-5 major depression per diagnostic interview, sleep-wake disorders other than insomnia (examined on PSG adaptation night [obstructive sleep apnea defined as apnea-hypopnea index ≥ 15 events/h, periodic limb movements defined as arousal frequency ≥ 15] and per patient report), and medications influencing sleep (prescription and non-prescription sleep aids, herbal supplements, and any antidepressants taken at night), although women receiving hormone therapy were permitted to participate.

Refer to **Figure 1** flow chart of study enrollment and participation. A total of 317 postmenopausal women were screened for eligibility. Of these individuals, 107 women were ineligible and another 56 declined to participate or had scheduling conflicts. Reasons for ineligibility included subclinical insomnia, insomnia unrelated to menopause, comorbid sleep apnea, comorbid restless legs syndrome, low wake after sleep onset on PSG, comorbid bipolar disorder, and prior exposure to CBTI treatment. Thus, 154 postmenopausal women were randomized to 1 of 3 treatment conditions: SHE treatment as usual (n = 50), (2) SRT (n = 52), and CBTI (n = 52). Two participants in both the SRT and CBTI conditions were disqualified during treatment for changes in medication or new onset comorbid sleep disorder. This resulted in 50 participants completing treatment in each of the 3 conditions. While double-blind could not be achieved given the nature of the behavioral interventions, participants

were not informed which treatments were considered control versus active or of the specific hypotheses. Assessments of sleep, depression, daytime function, and quality of life were collected prior to treatment, at posttreatment (within 2 weeks of completing treatment), and 6 months after treatment completion. Of the 150 who completed treatment, 126 women provided 6-month follow-up data (**Figure 1**).

Cognitive Behavioral Therapy for Insomnia

Women randomized to CBTI completed 6 face-to-face sleep therapy sessions with a registered nurse who specializes in behavioral sleep medicine. CBTI is a structured, multi-modal treatment that targets sleep-disruptive behaviors and beliefs (Perlis et al[27]). Data from clinical trials consistently show that CBTI is as efficacious as pharmacological treatment in the short-term, but produces superior treatment response in the long-term.[28,29] CBTI patients received 6 weekly sessions that covered behavioral (sleep restriction and stimulus control) and cognitive (eg, cognitive restructuring) components, as well as relaxation strategies (eg, progressive muscle relaxation and autogenic training) and sleep hygiene education. Fidelity monitoring for the nurse therapist included weekly supervision meetings with one of two licensed PhD clinical psychologists, both of whom are certified in behavioral sleep medicine. Supervision meetings included discussions of cases, problem-solving, and listening to and providing feedback based on recorded therapy session.

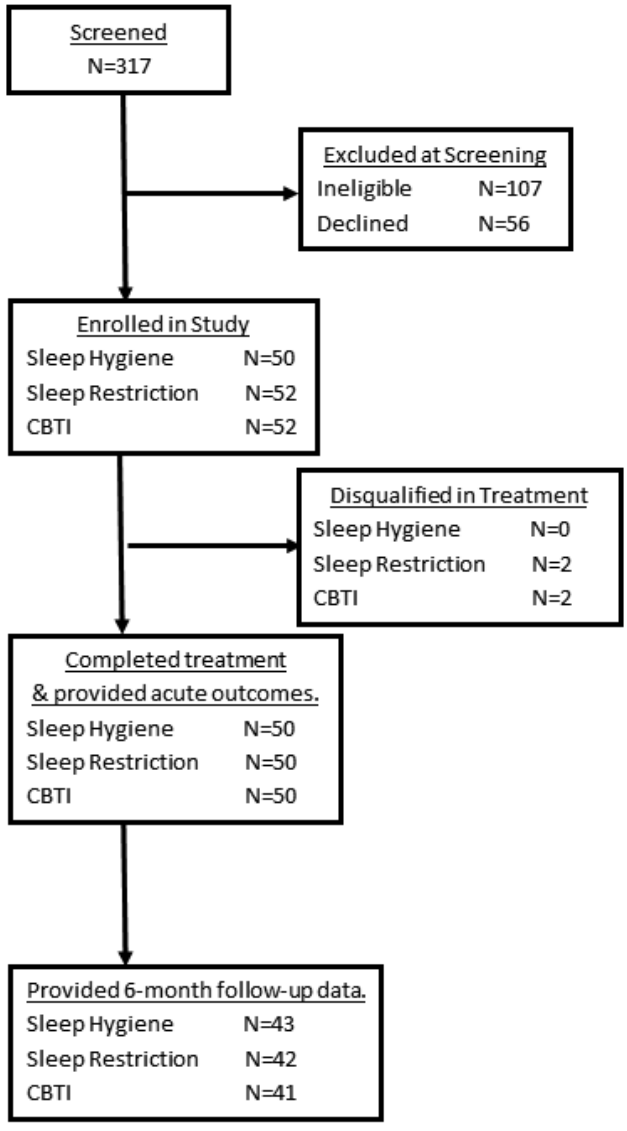
Sleep Restriction Therapy

SRT is an effective standalone behavioral treatment for insomnia.[30] Although SRT actually predates CBTI, SRT is now commonly packaged as part of CBTI and is typically considered one of the main active ingredients of CBTI. As CBTI consists of SRT plus multiple other components, SRT is the briefer of the two interventions. Here, SRT was delivered as a 2-week intervention. Specifically, the initial face-to-face session consisted of reviewing patient sleep history, education and rationale for sleep restriction practices, and behavioral homework. Then four follow-up sessions (three phone contacts, each 3–4 days apart, followed by a second face-to-face session) were delivered across the following 2 weeks and were used to titrate sleep schedules based on sleep diary data. Fidelity monitoring for the SRT condition was the same as described in the CBTI section above.

Sleep Hygiene Education

SHE was the minimal intervention control condition. Women randomized to the online SHE condition received 6 weekly emails including general, non-personalized information on the following topics: the basics of endogenous sleep regulation; the impact of sleep on health problems such as obesity, diabetes, and hypertension; the effects of stimulants and other sleep-disruptive substances; the relationship between sleep, diet, and exercise; and tips on creating a sleep-conducive bedroom environment. Sleep hygiene is neither the primary cause nor a sufficient therapeutic target in insomnia disorder and therefore served as an ideal minimal intervention control condition and real-world comparator.[31]

Figure 1—Flow chart of study enrollment, participation, and analysis inclusion.



CBTI = cognitive behavioral therapy for insomnia.

Measures

Daytime fatigue was measured using the Fatigue Severity Scale (FSS).[32] Scores range from 9 to 63, with higher scores indicating greater fatigue, and scores above 36 indicate severe fatigue. Sleepiness was measured using two surveys: (1) the Epworth Sleepiness Scale (ESS),[33] an 8-item questionnaire of daytime sleep propensity with scores ranging from 0 to 24 and higher scores indicating greater likelihood of falling asleep during the day. ESS scores above 10 indicate excessive daytime sleepiness. (2) Patients completed electronically-delivered sleep diaries at pretreatment, posttreatment, and 6-month follow-up. These diaries were based on the consensus sleep diaries[34] but were modified to also measure patient sleepiness over the past 24 hours on a 0 "none" to 10 "highest" scale. Scores in this study represent the daily mean for sleepiness ratings for each assessment period. Work function/

impairment was measured using the Work Productivity and Activity Impairment (WPAI)[35] questionnaire, which we modified to be specific to work issues associated with menopausal insomnia. WPAI outcomes are expressed as impairment percentages across four domains, with higher numbers indicating greater impairment and less productivity: (1) percentage of work time missed due to insomnia, (2) percentage of work time impaired due to insomnia, (3) percentage of activity impairment due to insomnia, and (4) percentage of overall work impairment due to insomnia. Quality of life was measured using the 36-item Medical Outcomes Study Short Form Health Survey (SF-36),[36] which measures eight quality of life domains: general health; energy; physical functioning; role limitations due to physical functioning; emotional wellbeing; role limitations due to emotional problems; social functioning; and pain. Domain scores range from 0 to 100 with higher scores indicating better quality of life. Daytime and nighttime hot flashes were reported on sleep diaries and are represented in this study by daily means. Lastly, insomnia symptoms were assessed using the Insomnia Severity Index (ISI) with scores ≥ 15 indicating clinically significant insomnia symptoms, and ISI scores ≤ 7 after treatment indicate remission.[37] All measures were single entries at pretreatment, posttreatment, and 6-month follow-up, except sleep diary-based ratings of sleepiness and hot flashes. Sleep diary data are presented as mean values across 14 days of data entries at each assessment period.

Analysis Plan

Analyses were conducted using SPSS version 25. Overall demographics and pretreatment characteristics were first presented and compared across the 3 treatment conditions using one-way analysis of variance (ANOVA) to identify group differences before treatment. To test treatment effects, we first ran 3 × 2 repeated measures ANOVAs to examine treatment × time interactions for changes in daytime function and quality of life from pretreatment to immediate posttreatment. After testing for treatment × time interaction effects, paired samples *t* tests were conducted within each condition to test for potential simple effects; significant results were then followed-up with Cohen *d* estimation of effect size specifically designed for paired samples *t* tests, which accounts for the correlation between the pretreatment and posttreatment values.[38] In addition, cross-sectional one-way ANOVAs with Bonferroni *post hoc* comparisons were used to compare mean levels for each treatment outcome to determine differences in symptom levels across groups. These analyses were then repeated for 6-month follow-up data. After evaluating specific treatment effects, we then ran exploratory bivariate correlations between changes in insomnia symptoms (pretreatment to posttreatment, and then pretreatment to 6-month follow-up) and changes in each of our primary outcome variables. These results showed whether changes in daytime function and quality of life were associated with improvements in insomnia symptoms, irrespective of treatment condition. Lastly, we compared daytime function and quality of life between remitters and non-remitters at posttreatment and 6-month follow-up.

RESULTS

Pretreatment Sample Characteristics

Refer to **Table 1** for full sample characteristics. Our sample comprised non-Hispanic white (52.0%) and non-Hispanic black women (39.3%). Prior to treatment, mean ISI scores were in the clinical range (ISI: 15.17 ± 3.98). Mean FSS scores were 32.52 ± 11.47 with 40.0% of the sample having severe fatigue. Participants reported moderate levels of daytime energy on the SF-36 (52.65 ± 19.44) and diary-based sleepiness (5.00 ± 1.67). And 16.0% of the sample endorsed clinically relevant daytime sleepiness on the ESS. Although absenteeism was low, work impairment and activity impairment affected approximately one-third of the sample (**Table 2**). Groups did not differ significantly on demographics or pretreatment levels of study outcomes.

Treatment Effects on Fatigue, Energy, and Sleepiness

We first evaluated changes in FSS scores; see **Table 2** for full results. A 3 × 2 repeated measures ANOVA testing changes in FSS scores from pretreatment to posttreatment showed a significant treatment × time interaction ($P = .04$). Follow-up paired samples *t* tests revealed moderate decreases in FSS scores in the SRT group ($d = .44$) and the CBTI group ($d = .43$), but no change in the SHE group ($P = .84$). We then ran a repeated measures ANOVA evaluating changes in fatigue scores from pretreatment to 6-month follow-up. A significant treatment × time interaction was again observed ($P < .01$), and the SRT group showed a moderate decrease in fatigue ($d = .48$), whereas the CBTI group showed a large decrease in fatigue ($d = .81$). Notably, the SHE group did not report changes in FSS scores ($P = .50$). The CBTI group reported lower FSS scores 6 months after completing treatment than the SHE group, whereas neither group differed from SRT.

We then evaluated changes in energy ratings on the SF-36 energy scale; see **Table 2** for full results. A 3 × 2 repeated measures ANOVA testing changes in SF-36 energy scores from pretreatment to posttreatment showed a significant treatment × time interaction ($P < .01$). Patients in the CBTI and SRT groups reported more energy after treatment than the SHE group. Follow-up paired samples *t* tests revealed moderate increases in energy in the SRT group ($d = .61$) and the CBTI group ($d = .56$), but no change in the SHE group ($P = .70$). We then ran a repeated measures ANOVA evaluating changes in energy scores from pretreatment to 6-month follow-up. A significant treatment × time interaction was observed ($P < .01$), and the CBTI and SRT groups continued to report more energy 6 months after treatment than the SHE group. The SRT group reported a medium-large increase in energy ($d = .71$), whereas the CBTI group reported a large increase in energy ($d = .90$). No changes were reported by patients receiving SHE ($P = .21$).

We next evaluated treatment effects on both daytime sleep propensity (ie, ESS scores) and sleepiness severity (ie, daily diary ratings); see **Table 2** for full results. A repeated measures ANOVA revealed a near-significant treatment × time interaction ($P = .05$) such that the CBTI group reported modest decreases in ESS scores ($d = .31$). At 6-month follow-up, this

Table 1—Sample characteristics prior to treatment.

	All Participants (n = 150)	SHE (n = 50)	SRT (n = 50)	CBTI (n = 50)	
Age	56.44 ± 5.64	57.24 ± 5.55	56.76 ± .5.39	55.32 ± 5.90	$F_{2,147}$ = 1.58, P = .21
Race, n (%)					
White	78 (52.0)	26 (52.0)	28 (56.0)	24 (48.0)	
Black	59 (39.3)	20 (40.0)	17 (34.0)	22 (44.0)	
Hispanic or Latin	1 (0.7)	–	1 (2.0)	–	
Multiracial	1 (0.7)	–	1 (2.0)	–	
Other	2 (1.3)	1 (2.0)	–	1 (2.0)	
Did not answer	9 (6.0)	3 (6.0)	3 (6.0)	3 (6.0)	
Hormone replacement therapy	4 (2.7)	3 (6.0)	1 (2.0)	0 (0.0)	
Medical or surgical menopause	35 (23.3)	9 (18.0)	12 (24.0)	14 (28.0)	
Years since last menstruation	7.12 ± 7.04	7.33 ± 7.79	6.93 ± 6.79	7.09 ± 6.65	$F_{2,147}$ = 0.04, P = .96
Pretreatment					
FSS fatigue severity	32.52 ± 11.47	32.50 ± 11.68	33.28 ± 11.99	31.78 ± 10.89	$F_{2,147}$ = 0.21, P = .81
SF-36 energy/fatigue	52.65 ± 19.44	52.70 ± 19.51	52.76 ± 21.02	52.50 ± 18.11	$F_{2,146}$ = 0.00, P > .99
ESS daytime sleepiness	7.34 ± 3.61	7.34 ± 3.21	7.08 ± 4.25	7.60 ± 3.35	$F_{2,147}$ = 0.26, P = .77
Diary-based daytime sleepiness	5.00 ± 1.67	5.01 ± 1.65	4.87 ± 1.70	5.13 ± 1.68	$F_{2,147}$ = 0.30, P = .74
Working	n = 107	n = 36	n = 32	n = 39	
WPAI % missed work	1.38 ± 3.95	1.34 ± 3.61	0.46 ± 1.31	2.16 ± 5.38	$F_{2,147}$ = 1.66, P = .20
WPAI % impaired at work	29.62 ± 27.18	28.06 ± 27.03	27.74 ± 24.59	32.56 ± 29.62	$F_{2,147}$ = 0.36, P = .70
WPAI % activity impairment	38.19 ± 26.08	38.61 ± 24.75	39.33 ± 25.86	36.92 ± 28.02	$F_{2,147}$ = 0.08, P = .93
WPAI % total work impairment	30.38 ± 27.38	29.00 ± 27.04	28.06 ± 24.63	33.50 ± 30.05	$F_{2,147}$ = 0.41, P = .67
SF-36 general health	73.49 ± 16.02	72.70 ± 17.44	74.59 ± 16.48	73.20 ± 14.24	$F_{2,146}$ = 0.18, P = .83
SF-36 physical function	87.99 ± 14.26	84.40 ± 18.42	89.80 ± 10.56	89.80 ± 12.08	$F_{2,146}$ = 2.43, P = .09
SF-36 role limitations, physical	70.64 ± 34.60	64.00 ± 34.32	73.47 ± 36.59	74.50 ± 32.53	$F_{2,146}$ = 1.40, P = .25
SF-36 emotional wellbeing	76.27 ± 15.36	75.20 ± 15.03	76.65 ± 16.96	76.96 ± 14.24	$F_{2,146}$ = 0.19, P = .83
SF-36 role limitations, emotional	76.06 ± 34.46	72.67 ± 36.07	87.07 ± 25.29*	68.67 ± 38.34†	$F_{2,146}$ = 4.06, P = .02
SF-36 social functioning	81.63 ± 20.83	79.00 ± 22.22	83.16 ± 22.03	82.75 ± 18.19	$F_{2,146}$ = 0.60, P = .55
SF-36 pain	73.99 ± 22.63	73.55 ± 25.83	71.07 ± 22.21	77.30 ± 19.41	$F_{2,146}$ = 0.95, P = .39
Hot flashes, daytime	2.07 ± 1.63	2.36 ± 1.80	1.89 ± 1.64	1.97 ± 1.42	$F_{2,147}$ = 1.19, P = .31
Hot flashes, nighttime	1.68 ± 1.23	1.69 ± 1.26	1.62 ± 1.16	1.72 ± 1.29	$F_{2,147}$ = 0.09, P = .91

F statistics represent one-way analysis of variances comparing scores across groups. *Significantly different from CBTI. †Significantly different from SRT. CBTI = cognitive behavioral therapy for insomnia, ESS = Epworth Sleepiness Scale, FSS = Fatigue Severity Scale, SF-36 = 36-item Medical Outcomes Study Short Form Health Survey, SHE = sleep hygiene education, SRT = sleep restriction therapy, WPAI = Work Productivity and Activity Impairment.

interaction was nonsignificant (P = .18) but the CBTI group continued to report modest improvements in sleep propensity from pretreatment levels (d = .35). Regarding diary-based sleepiness, both the SRT (d = .44) and CBTI (d = .41) groups reported moderate decreases in sleepiness severity from baseline, although a treatment × time interaction was not significant (P = .32). But 6 months after treatment, the treatment × time interaction was significant (P < .01) and both the SRT (d = .78) and CBTI (d = .88) groups reported large decreases in sleepiness as compared to pretreatment levels. Importantly, both the SRT and CBTI groups reported less sleepiness than the SHE group, who reported no immediate or long-term changes.

Treatment Effects on Work Performance

Full results for treatment effects on work performance are reported in **Table 2**. No changes or group differences in absenteeism were observed. When using repeated measures ANOVAs to test treatment effects on percentage of work time impaired by insomnia, treatment × time interactions were observed at both posttreatment (P < .01) and 6-month follow-up (P = .02). At posttreatment, reductions in work time impairment were moderate in the SRT (d = .50) and CBTI (d = .56) groups, whereas the SHE group did not change from pretreatment. The CBTI group reported less work time impairment than the SHE group, although neither group differed from the SRT group. Six months after treatment, the SRT group reported a large decrease in work time impairment (d = .84) and the CBTI group reported a medium-large decrease (d = .70). Similar patterns were observed for activity impairment and overall total work impairment such that the SRT and CBTI groups reported improvements from pretreatment levels of activity impairment and total work impairment immediately after completing treatment and 6 months later, but the SHE group showed no changes in work activity and productivity.

Table 2—Comparing CBTI versus SRT versus SHE on daytime fatigue, energy, sleepiness, and workplace performance.

	Posttreatment	Δ Pretreatment to Posttreatment	6-Month Follow-Up	Δ Pretreatment to 6-Month Follow-Up
FSS Fatigue Severity	$F_{2,147}$ = 1.63, P = .20	$F_{2,147}$ = 3.24, P = .04	$F_{2,128}$ = 4.67, P = .01	$F_{2,128}$ = 5.53, P < .01
SHE	32.32 ± 11.95	t_{49} = −0.20, P = .84	32.31 ± 10.95 [c]	t_{44} = −0.69, P = .50
SRT	29.90 ± 12.08	t_{49} = −3.14, P < .01, d = .44	28.49 ± 10.74	t_{42} = −3.13, P < .01, d = .48
CBTI	28.20 ± 10.32	t_{49} = −3.01, P < .01, d = .43	25.35 ± 10.41 [a]	t_{42} = −5.35, P < .001, d = .81
SF-36 Energy	$F_{2,146}$ = 4.38, P = .01	$F_{2,145}$ = 7.55, P < .01	$F_{2,147}$ = 7.04, P < .01	$F_{2,126}$ = 6.11, P < .01
SHE	52.10 ± 19.77 [b,c]	t_{49} = −0.39, P = .70	54.55 ± 19.10 [b,c]	t_{43} = 1.27, P = .21
SRT	61.33 ± 17.76 [a]	t_{47} = 4.12, P < .001, d = .61	65.70 ± 17.48 [a]	t_{41} = 4.57, P < .001, d = .71
CBTI	61.90 ± 18.07 [a]	t_{49} = 3.96, P < .001, d = .56	67.79 ± 16.49 [a]	t_{42} = 5.92, P < .001, d = .90
ESS Daytime Sleepiness	$F_{2,147}$ = 1.61, P = .20	$F_{2,147}$ = 3.05, P = .05	$F_{2,128}$ = 0.09, P = .91	$F_{2,128}$ = 1.73, P = .18
SHE	7.72 ± 3.33	t_{49} = 1.24, P = .22	7.00 ± 3.51	t_{44} = 0.18, P = .86
SRT	6.72 ± 3.45	t_{49} = −0.90, P = .37	6.77 ± 3.31	t_{42} = −1.24, P = .22
CBTI	6.64 ± 3.27	t_{49} = −2.20, P = .03, d = .31	6.70 ± 3.71	t_{42} = −2.28, P = .03, d = .35
Diary-Based Sleepiness	$F_{2,146}$ = 1.14, P = .32	$F_{2,146}$ = 1.16, P = .32	$F_{2,141}$ = 6.70, P < .01	$F_{2,141}$ = 7.22, P < .01
SHE	4.72 ± 2.06	t_{49} = −1.09, P = .28	4.73 ± 1.97 [b,c]	t_{46} = −1.54, P = .13
SRT	4.09 ± 2.07	t_{49} = −3.08, P < .01, d = .44	3.47 ± 2.04 [a]	t_{48} = −5.40, P < .001, d = .78
CBTI	4.36 ± 2.16	t_{48} = −2.86, P < .01, d = .41	3.43 ± 1.90 [a]	t_{47} = −6.10, P < .001, d = .88
WPAI % Missed Work	$F_{2,108}$ = 0.50, P = .61	$F_{2,102}$ = 0.13, P = .88	$F_{2,91}$ = 0.32, P = .73	$F_{2,88}$ = 0.28, P = .76
SHE	0.94 ± 4.22	t_{35} = −0.38, P = .71	1.43 ± 3.73	t_{30} = 1.59, P = .12
SRT	0.64 ± 2.61	t_{31} = 0.48, P = .64	0.92 ± 3.86	t_{26} = 0.56, P = .58
CBTI	2.74 ± 16.02	t_{36} = 0.33, P = .74	2.18 ± 9.40	t_{32} = −0.22, P = .83
WPAI % Impaired at Work	$F_{2,108}$ = 3.80, P = .02	$F_{2,101}$ = 5.11, P < .01	$F_{2,91}$ = 2.79, P = .07	$F_{2,87}$ = 4.24, P = .02
SHE	30.79 ± 26.75 [c]	t_{35} = 0.81, P = .42	25.16 ± 27.79	t_{30} = −1.10, P = .28
SRT	18.53 ± 19.56	t_{30} = −2.69, P = .01, d = .50	12.67 ± 15.74	t_{25} = −3.92, P < .01, d = .84
CBTI	17.44 ± 21.24 [a]	t_{36} = −3.27, P < .01, d = .56	13.03 ± 25.55	t_{32} = −4.01, P < .001, d = .70
WPAI % Activity Impairment	$F_{2,108}$ = 2.84, P = .06	$F_{2,100}$ = 2.74, P = .07	$F_{2,91}$ = 3.47, P = .04	$F_{2,86}$ = 1.59, P = .21
SHE	33.42 ± 29.25	t_{35} = −1.22, P = .23	33.23 ± 26.25	t_{30} = −1.56, P = .13
SRT	22.65 ± 22.47	t_{29} = −3.50, P < .01, d = .64	18.67 ± 23.60	t_{24} = −4.60, P < .001, d = .92
CBTI	20.51 ± 23.39	t_{36} = −3.77, P < .01, d = .63	17.58 ± 28.40	t_{32} = −2.97, P < .01, d = .87
WPAI % Total Work Impairment	$F_{2,108}$ = 2.95, P = .06	$F_{2,101}$ = 3.37, P = .04	$F_{2,91}$ = 2.47, P = .09	$F_{2,87}$ = 4.34, P = .02
SHE	31.34 ± 27.00	t_{35} = 0.76, P = .45	25.85 ± 28.38	t_{30} = −1.05, P = .30
SRT	19.05 ± 19.57	t_{30} = −2.79, P < .01, d = .52	13.56 ± 15.61	t_{25} = −3.45, P < .01, d = .73
CBTI	20.09 ± 24.93	t_{36} = −2.20, P = .03, d = .36	14.17 ± 27.21	t_{32} = −4.03, P < .001, d = .70

F statistics in the posttreatment and 6-month follow-up columns represent one-way analysis of variances comparing scores across groups. Superscript letters indicate: a = significantly different from SHE, b = significantly different from SRT, c = significantly different from CBTI. *F* statistics in the Δ pretreatment to posttreatment and Δ pretreatment to 6-month follow-up columns represent treatment × time interactions in a 3 × 2 repeated measures one-way analysis of variance. *t* statistics represent results from paired samples *t* tests. CBTI = cognitive behavioral therapy for insomnia, ESS = Epworth Sleepiness Scale, FSS = Fatigue Severity Scale, SF-36 = 36-item Medical Outcomes Study Short Form Health Survey, SHE = sleep hygiene education, SRT = sleep restriction therapy, WPAI = Work Productivity and Activity Impairment.

Treatment Effects on Quality of Life and Hot Flashes

See **Table 3** for full results for treatment effects on quality of life as measured by the SF-36. Treatment effects were not observed for reports of general health, physical functioning, or pain. However, at posttreatment, the SRT group reported small improvements in resiliency to physical problems, and they were less restricted by physical problems than the SHE group. At 6-month follow-up, all 3 treatment groups reported fewer role limitations due to physical problems, with the SRT (d = .52) and CBTI (d = .48) groups showing moderate improvements, and the SHE group reporting small improvement (d = .33). Notably, the CBTI group reported more resilience to physical problems at the 6-month follow-up than the SHE group, although neither group differed from the SRT group.

The CBTI group reported the only improvement in SF-36 emotional wellbeing and resilience to role limitations related to emotional problems; see **Table 3**. At posttreatment, the CBTI group reported moderate improvement in emotional wellbeing (d = .42) and continued to report improved emotional wellbeing 6 months later (d = .38). At the 6-month follow-up, the CBTI group reported better emotional wellbeing than the SHE group, although neither group differed from the SRT group. No treatment effects were observed for SF-36 role limitations due to emotional problems until the CBTI group reported 6 months after treatment that their resilience to emotional problems was moderately improved (d = .53). The SHE group reported a small improvement in social functioning upon completing treatment (d = .33), but this effect was no longer observed 6 months later (P = .08).

Daytime hot flashes reduced acutely only in the SRT group (d = .46), but by 6-month follow-up, all three groups reported moderate reductions in daily hot flashes (**Table 3**). Nighttime hot flashes reduced in all three groups upon completing treatment and remained lower that pretreatment levels at 6-month follow-up (**Table 3**).

Table 3—Comparing CBTI versus SRT versus SHE on quality of life and hot flashes.

	Posttreatment	Δ Pretreatment to Posttreatment	6-Month Follow-Up	Δ Pretreatment to 6-Month Follow-Up
SF-36 General Health	$F_{2,147} = 0.39$, $P = .68$	$F_{2,146} = 0.45$, $P = .64$	$F_{2,127} = 2.57$, $P = .08$	$F_{2,126} = 1.14$, $P = .32$
SHE	75.40 ± 16.03	$t_{49} = 1.72$, $P = .09$	73.07 ± 17.06	$t_{43} = -0.05$, $P = .96$
SRT	76.50 ± 16.88	$t_{48} = 1.09$, $P = .28$	79.88 ± 13.21	$t_{41} = 1.93$, $P = .06$
CBTI	73.70 ± 14.91	$t_{49} = 0.28$, $P = .78$	73.37 ± 16.79	$t_{42} = -0.06$, $P = .96$
SF-36 Physical Functioning	$F_{2,147} = 1.41$, $P = .25$	$F_{2,146} = 1.94$, $P = .15$	$F_{2,127} = 2.70$, $P = .07$	$F_{2,126} = 1.66$, $P = .19$
SHE	85.70 ± 18.87	$t_{49} = 0.87$, $P = .39$	83.98 ± 21.20	$t_{43} = -0.63$, $P = .53$
SRT	87.10 ± 17.35	$t_{48} = -1.25$, $P = .22$	89.19 ± 15.31	$t_{41} = -0.68$, $P = .50$
CBTI	91.10 ± 13.37	$t_{49} = 1.11$, $P = .28$	92.21 ± 12.31	$t_{42} = 1.78$, $P = .08$
SF-36 Role Limitations, Physical	$F_{2,146} = 4.66$, $P = .01$	$F_{2,145} = 0.91$, $P = .40$	$F_{2,127} = 4.06$, $P = .02$	$F_{2,126} = 0.22$, $P = .81$
SHE	67.00 ± 35.87 [b]	$t_{49} = 0.65$, $P = .52$	73.86 ± 33.22 [c]	$t_{43} = 2.20$, $P = .03$, $d = .33$
SRT	86.73 ± 28.46 [a]	$t_{47} = 2.35$, $P = .02$, $d = .35$	87.79 ± 27.48	$t_{41} = 3.19$, $P < .01$, $d = .52$
CBTI	79.00 ± 32.48	$t_{49} = 0.85$, $P = .40$	89.53 ± 22.65 [a]	$t_{42} = 3.07$, $P < .01$, $d = .48$
SF-36 Emotional Wellbeing	$F_{2,146} = 1.13$, $P = .33$	$F_{2,145} = 0.95$, $P = .39$	$F_{2,127} = 3.98$, $P = .02$	$F_{2,126} = 1.98$, $P = .14$
SHE	76.80 ± 16.80	$t_{49} = 1.02$, $P = .31$	73.18 ± 14.83 [c]	$t_{43} = -0.51$, $P = .62$
SRT	79.92 ± 16.16	$t_{47} = 1.42$, $P = .16$	79.72 ± 15.72	$t_{41} = 1.01$, $P = .32$
CBTI	81.36 ± 13.29	$t_{49} = 2.98$, $P < .01$	81.67 ± 13.56 [a]	$t_{42} = 2.47$, $P = .02$
SF-36 Role Limitations, Emotional	$F_{2,146} = 2.03$, $P = .14$	$F_{2,145} = 0.70$, $P = .50$	$F_{2,127} = 0.87$, $P = .42$	$F_{2,126} = 6.27$, $P < .01$
SHE	78.67 ± 32.13	$t_{49} = 1.42$, $P = .16$	78.03 ± 32.90	$t_{43} = 0.73$, $P = .47$
SRT	88.44 ± 28.51	$t_{47} = -0.14$, $P = .89$	82.17 ± 29.41	$t_{41} = 1.17$, $P = .25$
CBTI	76.00 ± 35.66	$t_{49} = 1.23$, $P = .23$	86.82 ± 30.98	$t_{42} = 2.25$, $P = .03$
SF-36 Social Functioning	$F_{2,146} = 0.71$, $P = .49$	$F_{2,145} = 0.46$, $P = .63$	$F_{2,127} = 0.84$, $P = .44$	$F_{2,126} = 0.22$, $P = .80$
SHE	85.25 ± 20.62	$t_{49} = 2.52$, $P = .02$, $d = .36$	84.09 ± 21.46	$t_{43} = 1.79$, $P = .08$
SRT	89.54 ± 17.37	$t_{47} = 1.91$, $P = .06$	87.21 ± 19.95	$t_{41} = 1.16$, $P = .25$
CBTI	85.50 ± 21.78	$t_{49} = 0.98$, $P = .33$	89.53 ± 17.45	$t_{42} = 1.69$, $P = .10$
SF-36 Pain	$F_{2,146} = 1.32$, $P = .27$	$F_{2,145} = 1.30$, $P = .28$	$F_{2,127} = 2.20$, $P = .12$	$F_{2,126} = 1.81$, $P = .17$
SHE	69.70 ± 25.52	$t_{49} = 1.46$, $P = .15$	68.35 ± 27.20	$t_{43} = 1.62$, $P = .11$
SRT	72.70 ± 21.96	$t_{47} = 0.54$, $P = .59$	74.65 ± 19.36	$t_{41} = 0.66$, $P = .51$
CBTI	77.05 ± 20.31	$t_{49} = -0.13$, $P = .90$	78.37 ± 20.17	$t_{42} = 0.51$, $P = .61$
Hot Flashes, Daytime	$F_{2,145} = 2.18$, $P = .12$	$F_{2,145} = 0.65$, $P = .53$	$F_{2,139} = 1.13$, $P = .33$	$F_{2,139} = 1.47$, $P = .23$
SHE	2.21 ± 1.79	$t_{49} = -1.15$, $P = .26$	1.67 ± 1.65	$t_{46} = -5.01$, $P < .001$, $d = .74$
SRT	1.50 ± 1.60	$t_{48} = -3.17$, $P < .01$, $d = .46$	1.27 ± 1.17	$t_{47} = -3.68$, $P < .01$, $d = .56$
CBTI	1.80 ± 1.71	$t_{48} = -1.34$, $P = .19$	1.63 ± 1.44	$t_{46} = -3.16$, $P < .01$, $d = .47$
Hot Flashes, Nighttime	$F_{1,145} = 0.50$, $P = .61$	$F_{2,145} = 0.71$, $P = .49$	$F_{2,140} = 1.07$, $P = .35$	$F_{2,140} = 0.43$, $P = .65$
SHE	1.48 ± 1.34	$t_{49} = -2.11$, $P = .04$, $d = .31$	1.31 ± 1.18	$t_{46} = -4.33$, $P < .001$, $d = .67$
SRT	1.23 ± 1.13	$t_{48} = -4.45$, $P < .001$, $d = .65$	1.04 ± 0.95	$t_{47} = -5.18$, $P < .001$, $d = .76$
CBTI	1.40 ± 1.24	$t_{48} = -3.18$, $P < .01$, $d = .47$	1.33 ± 1.11	$t_{47} = -3.96$, $P < .001$, $d = .67$

F statistics in the posttreatment and 6-month follow-up columns represent one-way analysis of variances comparing scores across groups. Superscript letters indicate: a = significantly different from SHE, b = significantly different from SRT, c = significantly different from CBTI. *F* statistics in the Δ pretreatment to posttreatment and Δ pretreatment to 6-month follow-up columns represent treatment × time interactions in a 3 × 2 repeated measures one-way analysis of variance. *t* statistics represent results from paired samples *t* tests. CBTI = cognitive behavioral therapy for insomnia, SF-36 = 36-item Medical Outcomes Study Short Form Health Survey, SHE = sleep hygiene education, SRT = sleep restriction therapy.

Improved Sleep Is Linked to Improvements in Daytime Function and Quality of Life

Finally, we explored associations between reductions in insomnia symptoms (ie, change scores for ISI; see Drake et al for full insomnia outcomes for this trial[16]) and changes in our primary outcomes; see **Table 4** for full results. Decreases in insomnia symptoms were strongly correlated with improvements in both fatigue (posttreatment $r = .32$, 6-month: $r = .40$) and energy (posttreatment $r = -.32$, 6-month $r = -.38$). Indeed, insomnia remitters (ISI ≤ 7) reported substantially lower levels of fatigue than non-remitters (ISI > 7) at posttreatment ($d = .71$) and 6-month follow-up ($d = .90$), see **Table 5**. Along these lines, insomnia remitters reported more energy compared to non-remitters at both posttreatment ($d = .82$) and 6-month follow-up ($d = .89$), see **Table 5**.

Reductions in daytime sleep propensity (ESS scores) were associated with reduced insomnia symptoms upon completing treatment ($r = .33$), and decreases in diary-based sleepiness were associated with insomnia improvements at 6-month follow-up ($r = .23$; **Table 4**). Even so, ESS scores did not differ between remitters and non-remitters at any point after treatment (**Table 5**). However, diary-based sleepiness ratings were lower among remitters at both posttreatment ($d = .59$) and 6-month follow-up ($d = .84$; **Table 5**).

Patients who remitted from insomnia reported better work function than non-remitters across all domains of work activity and productivity, except for absenteeism (**Table 5**), and improvements in work function were related to improvements in insomnia (**Table 4**). Regarding quality of life measures, decreases in insomnia were only directly related

Table 4—Correlations between changes in insomnia symptoms and changes in daytime function.

	Δ ISI	
	Pretreatment to Posttreatment	Pretreatment to Follow-Up
Δ FSS fatigue severity	.32**	.40**
Δ SF-36 energy	−.32**	−.38**
Δ ESS daytime sleepiness	.33**	.11
Δ Diary-based sleepiness	.11	.23**
Δ WPAI % missed work	−.05	.211*
Δ WPAI % impaired at work	.24*	.11
Δ WPAI % activity impairment	.38**	.20
Δ WPAI % total work impairment	.34**	.40**
Δ SF-36 general health	−.14	−.15
Δ SF-36 physical functioning	.03	−.05
Δ SF-36 role limitations, physical	−.23**	−.30**
Δ SF-36 emotional wellbeing	−.11	−.17
Δ SF-36 role limitations, emotional	−.05	−.13
Δ SF-36 social functioning	−.20*	−.14
Δ SF-36 pain	−.24*	−.20*
Δ Hot flashes, daytime	.15	−.05
Δ Hot flashes, nighttime	.15	.09

*P < .05. **P < .01. ***P < .001. ESS = Epworth Sleepiness Scale, FSS = Fatigue Severity Scale, ISI = Insomnia Severity Index, SF-36 = 36-item Medical Outcomes Study Short Form Health Survey, WPAI = Work Productivity and Activity Impairment. All correlations represent associations between changes in ISI and a primary outcome variable.

to improved resilience to physical problems, social functioning, and pain (**Table 4**). However, those who remitted from insomnia reported better general health, physical function, resilience to physical problems, emotional wellbeing, resilience to emotional problems, and social functioning, and less pain than patients who did not remit; this pattern was observed at both posttreatment and 6-month follow-up (**Table 5**).

DISCUSSION

In a sample of 150 postmenopausal women with chronic insomnia, we evaluated the efficacy of CBTI and SRT in comparison to sleep hygiene education to improve daytime function, work performance, and quality of life. Both CBTI and SRT outperformed SHE treatment as usual and resulted in improvements in fatigue, energy, and sleepiness. Patients receiving CBTI or SRT also reported less impairment at work after treatment compared to patients receiving SHE. Treatment effects on quality of life were mixed. The most robust findings showed that both CBTI and SRT improved patients' resilience to physical problems, and that only CBTI improved patients' emotional wellbeing and resilience to emotional problems. Six months after completing treatment, patients whose insomnia remitted reported fewer hot flashes during the day and night, but these effects did not appear to be specific to any treatment modality. Overall, evidence indicated that nonpharmacological insomnia interventions improve daytime function, work performance, and some aspects of life quality in women with menopause-related chronic insomnia.

Alleviating Insomnia Improves Daytime Function

Sleep disorders such as insomnia typically invoke mentation of nocturnal symptomatology, but the truth is that insomnia is a 24-hour disorder with sleep disturbance at night and marked functional impairment during the day. Indeed, individuals struggling with insomnia typically seek treatment only when daytime functioning becomes impaired due to their sleep problems.[23] Although fatigue and low energy are common motivators for treatment-seeking behavior among those with insomnia,[23] behavioral therapy for insomnia and CBTI have produced somewhat mixed results for fatigue outcomes.[20] In the present study, reductions in fatigue and increases in energy were the largest and most robust treatment effects for patients receiving active treatment, but particularly for those undergoing CBTI. Importantly, improvements in fatigue and energy were directly linked to treatment-related alleviations of insomnia symptoms, and patients whose insomnia did not remit continued to endorse high levels of fatigue and low levels of energy after treatment.

Daytime sleepiness, unlike fatigue, is not a cardinal feature of daytime impairment associated with insomnia. Nevertheless, some patients with insomnia—particularly among older populations—endorse elevated sleepiness associated with insomnia (daytime sleepiness was endorsed by only 16.0% of our patients per the ESS). In support of prior trials showing improvement in daytime sleepiness,[39] we found modest support for CBTI and SRT treatment effects on daytime sleepiness as compared to SHE, with CBTI producing greater improvement than SRT overall. Reductions in sleepiness were correlated with treatment-related improvements in insomnia symptoms. Insomnia remitters reported less sleepiness than

Table 5—Comparing daytime function, work performance, and quality of life between insomnia patients who remit versus non-remitters.

	Posttreatment			6-Month Follow-Up		
	Remitters (n = 48)	Non-Remitters (n = 102)		Remitters (n = 57)	Non-Remitters (n = 69)	
FSS fatigue severity	24.85 ± 11.18	32.63 ± 10.87	$t_{148} = 4.05^{***}$ $d = .71$	23.79 ± 8.27	32.65 ± 11.36	$t_{124} = 4.91^{***}$ $d = .90$
SF-36 energy	68.13 ± 16.65	53.81 ± 18.33	$t_{147} = -4.58^{***}$ $d = .82$	71.05 ± 14.69	55.88 ± 19.24	$t_{123} = -4.88^{***}$ $d = .89$
ESS daytime sleepiness	6.27 ± 2.06	6.27 ± 3.18	$t_{148} = 1.90$ $P = .06$	6.68 ± 3.52	6.93 ± 3.38	$t_{124} = .39$ $P = .69$
Diary-based sleepiness	3.58 ± 1.95	4.77 ± 2.06	$t_{147} = 3.36^{**}$ $d = .59$	4.42 ± 1.88	6.68 ± 3.52	$t_{123} = 3.84^{***}$ $d = .84$
WPAI % missed work	2.94 ± 17.15	0.83 ± 3.49	$t_{109} = -1.04$ $P = .30$	0.45 ± 3.02	2.63 ± 8.33	$t_{89} = 1.64$ $P = .11$
WPAI % impaired at work	8.53 ± 13.06	28.44 ± 24.45	$t_{109} = 4.47^{***}$ $d = 1.06$	11.14 ± 21.91	21.49 ± 24.76	$t_{89} = 2.11^{*}$ $d = .44$
WPAI % activity impairment	10.88 ± 17.64	32.08 ± 26.12	$t_{109} = 4.31^{***}$ $d = .97$	13.18 ± 21.11	32.13 ± 29.04	$t_{89} = 3.54^{**}$ $d = .76$
WPAI % total work impairment	11.47 ± 20.32	28.99 ± 24.55	$t_{109} = 3.64^{***}$ $d = .78$	11.59 ± 21.88	22.88 ± 26.11	$t_{89} = 2.23^{*}$ $d = .47$
SF-36 general health	79.69 ± 16.19	73.08 ± 15.38	$t_{148} = -2.41^{*}$ $d = .42$	80.53 ± 16.22	71.69 ± 15.10	$t_{123} = -3.15^{**}$ $d = .56$
SF-36 physical functioning	93.02 ± 9.38	85.59 ± 18.83	$t_{148} = -2.59^{*}$ $d = .53$	94.56 ± 7.69	83.46 ± 20.99	$t_{123} = -3.79^{***}$ $d = .77$
SF-36 role limitations, physical	89.06 ± 24.14	72.03 ± 35.58	$t_{147} = -3.00^{**}$ $d = .57$	94.30 ± 13.38	73.53 ± 35.06	$t_{123} = -4.22^{***}$ $d = .86$
SF-36 emotional wellbeing	84.42 ± 12.84	76.95 ± 16.12	$t_{147} = -2.81^{*}$ $d = .52$	83.37 ± 12.53	74.00 ± 15.46	$t_{123} = -3.67^{***}$ $d = .67$
SF-36 role limitations, emotional	88.89 ± 26.93	77.23 ± 34.30	$t_{147} = -2.07^{*}$ $d = .38$	92.40 ± 17.84	74.02 ± 36.35	$t_{123} = -3.48^{**}$ $d = .68$
SF-36 social functioning	92.97 ± 15.23	83.79 ± 21.33	$t_{147} = -2.67^{*}$ $d = .50$	93.20 ± 14.19	81.62 ± 21.65	$t_{123} = -3.46^{**}$ $d = .65$
SF-36 pain	79.53 ± 20.13	70.12 ± 23.39	$t_{147} = -2.40^{*}$ $d = .43$	79.82 ± 19.90	68.60 ± 24.48	$t_{123} = -2.78^{**}$ $d = .51$
Hot flashes, daytime	1.57 ± 1.62	1.97 ± 1.75	$t_{146} = 1.31$ $P = .19$	1.18 ± 1.18	1.72 ± 1.56	$t_{122} = 2.13^{*}$ $d = .39$
Hot flashes, nighttime	1.15 ± 1.15	1.48 ± 1.27	$t_{146} = 1.51$ $P = .13$	0.95 ± 0.88	1.36 ± 1.16	$t_{122} = 2.15^{*}$ $d = .40$

* $P < .05$. ** $P < .01$. *** $P < .001$. Insomnia severity index score of 7 or below after treatment indicates remission. At posttreatment, the number of remitters in each condition was: SHE (n = 2), SRT (n = 19), and CBTI (n = 27). At 6-month follow-up, the number of remitters in each condition was: SHE (n = 6), SRT (n = 24), and CBTI (n = 29). CBTI = cognitive behavioral therapy for insomnia, ESS = Epworth Sleepiness Scale, FSS = Fatigue Severity Scale, SF-36 = 36-item Medical Outcomes Study Short Form Health Survey, SHE = sleep hygiene education, SRT = sleep restriction therapy, WPAI = Work Productivity and Activity Impairment.

non-remitters after treatment, but they did not differ on functional sleep propensity. As daytime sleepiness is not a primary complaint among most insomniacs, improved daytime sleepiness is clearly unnecessary for disorder remission. Even so, CBTI improves this daytime impairment in the subpopulation of insomniacs that present with this problem. Also important to emphasize here is that we found no indication that CBTI or SRT increases daytime sleepiness, and are thus likely safe treatment options for postmenopausal women with insomnia.

Struggling with insomnia tends to diminish work productivity and increase work absenteeism,[10,12] thus we examined whether insomnia treatment would improve work performance. Consistent with having more energy and less fatigue during the day, work productivity and activity were improved in patients who received CBTI and SRT. Indeed, we observed mostly moderate-to-large reductions in time spent impaired at work, activity impairment, and total work impairment in the CBTI and SRT groups upon completing treatment and 6 months later. The SHE group reported no changes in work performance. Importantly, improvements in work performance were directly linked to treatment-related improvements in insomnia symptoms, and remitters reported overall superior work performance to non-remitters. The only measured domain of work performance unaffected by treatment and changes in sleep was absenteeism. It is worth highlighting, however, that absenteeism rates were low in this sample

before treatment (1.38% ± 3.95% of work time missed), thus it is unclear whether improving insomnia does not reduce absenteeism (as suggested by our inferential statistics) or if pretreatment levels of absenteeism in our sample were too low to improve upon significantly.

Alleviating Insomnia Improves Quality of Life

Untreated individuals with insomnia have poor quality of life.[10,11,40] Unsurprisingly, postmenopausal women who remitted from chronic insomnia in our trial (ISI ≤ 7 after treatment) reported better general health, physical functioning, resilience to physical problems, emotional wellbeing, resilience to emotional problems, and social functioning, and less pain than those whose insomnia did not remit. Despite these widespread life quality differences between remitters and non-remitters, specific treatment effects were more circumscribed.

CBTI produced durable improvements in emotional wellbeing, and resilience to physical and emotional problems. SRT also improved resilience to physical problems immediately and long-term. Notably, increased resilience to physical problems was directly related to improved sleep, whereas improvements in emotional wellbeing and resilience to emotional problems were not directly related to alleviation of insomnia symptoms. These findings suggest that components of CBTI—perhaps not directly sleep-targeting, per se—directly target emotional health to improve wellbeing and resilience.

Hot flashes are the most common complaint related to menopause,[41] and nighttime hot flashes disrupt sleep and contribute to menopausal insomnia.[13] Thus, we posited that cognitive and behavioral strategies to combat insomnia would also reduce the perception of hot flashes at night, particularly during the sleep period. We reasoned that postmenopausal women who sleep through hot flashes will report fewer nighttime hot flashes; ie, they still experience the same frequency of hot flashes during the sleep period, but do not awaken when they occur and thus perceive fewer hot flashes. Data from the present study, however, did not support our hypothesis. Participants in all three treatment conditions reported fewer hot flashes during the day and night after treatment, which is supported by insomnia remitters reporting fewer hot flashes than non-remitters. However, reductions in insomnia symptoms were not directly associated with changes in hot flashes after treatment. Thus, mechanisms driving reductions in both daytime and nighttime hot flashes after long-term insomnia remission are unclear. Future studies need to test whether these results replicate and, if so, identify factors that mediate insomnia remission and decreased hot flashes.

Importantly, these null treatment effects for hot flashes are consistent with results from the MSFlash Trial showing that telephone-based CBTI does not reduce hot flashes.[15] Even so, the MSFlash trial showed that CBTI reduces hot flash interference, which is an important benefit of CBTI for quality of life for women with menopausal insomnia. Unfortunately, the present trial did not assess hot flash interference, thus we could not test for replication.

Limitations and Future Directions

The present study should be interpreted in light of certain limitations. Our primary limitation concerns a lack of follow-up assessments beyond 6 months after treatment. Longer-term prospective data would improve our understanding of the durability of these effects in postmenopausal women. A recent study suggests that durability of CBTI is maintained 10 years after treatment for sleep outcomes,[42] although comparatively less is known about longer-term durability for daytime functioning and quality of life. Another limitation centers on treatment delivery differing across the three conditions. CBTI was entirely face-to-face, whereas SRT was a mix of face-to-face and telemedicine, and SHE was entirely online. Some research shows differential rates of treatment engagement, adherence, and preference across modalities.[43–45] Thus, we cannot rule out any effects of treatment modality on our study results. Even so, it is worth noting that even when attendance and adherence differ between modalities for patients receiving CBTI, overall clinical outcomes remain similar.[43] Regarding generalizability, our sample was recruited from the Metro Detroit area and certain racial and ethnic groups were either underrepresented or completely unrepresented, such as individuals identifying as Hispanic, Asian, or Middle Eastern, which may limit generalizability.

CONCLUSIONS

Women with menopausal insomnia report less fatigue and sleepiness, more energy, greater resilience to physical problems, and better work productivity and activity after receiving CBTI or SRT. Although both CBTI and SRT produced improvements in these areas, CBTI appeared to be the superior treatment due to larger improvements in fatigue, energy, and daytime sleep propensity. Moreover, only CBTI improved emotional wellbeing and resilience to emotional problems, which is a critical advantage of this treatment option given the elevated levels of emotional distress reported by patients with insomnia.[46–50] Importantly, postmenopausal women who remitted from insomnia also reported better general health and social functioning, less pain, and fewer hot flashes during the day and night. Although these health benefits were not directly related to any specific treatment modality, they further highlight the importance of resolving chronic insomnia in postmenopausal women to improve quality of life.

ABBREVIATIONS

ANOVA, analysis of variance
CBTI, cognitive behavioral therapy for insomnia
DSM, Diagnostic and Statistical Manual of Mental Disorders
ESS, Epworth Sleepiness Scale
FSS, Fatigue Severity Scale
ISI, Insomnia Severity Index
MsFLASH, Menopause Strategies: Finding Lasting Answers for Symptoms and Health
PSG, polysomnography
SF-36, 36-item Medical Outcomes Study Short Form Health Survey
SHE, sleep hygiene education

SRT, sleep restriction therapy
WPAI, Work Productivity and Activity Impairment

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