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SCIENTIFIC INVESTIGATIONS

Effects of a Brief Behavioral Treatment for Late-Life Insomnia: Preliminary Findings

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Study Objectives: Insomnia is a chronic and prevalent sleep disorder in adults older than 65 years. Hypnotics raise safety concerns in this group, and standard behavioral treatments are time consuming. This preliminary report addresses the effects of a brief behavioral treatment for insomnia in older adults who present with the typical psychiatric and medical comorbidities of aging.

Methods: Thirty-five older adults (10 men, 25 women, mean age = 70.2 ± 6.4 years old) were randomly assigned to a brief behavioral treatment for insomnia (BBTI; n = 17) or to an information-only control (IC; n = 18) condition. All subjects completed clinician-administered and self-report measures of sleep quality, as well as a sleep diary, at baseline. Interventions were delivered in a single individual session with a booster session administered 2 weeks later. Postintervention assessments were completed after 4 weeks.

Results: Significant improvements in self-report and sleep diary measures and mild-to-moderate improvement in anxiety and depression were observed after treatment in participants randomly assigned to BBTI, as compared with participants randomly assigned to IC. At post-treatment assessment, 12 BBTI participants (71%) and 7 IC participants (39%) met criteria for response. Nine BBTI participants (53%) met criteria for remission, whereas, in the IC group, 3 participants (17%) met the criteria.

Conclusion: BBTI was associated with significant improvements in sleep measures and in daytime symptoms of anxiety and depression. BBTI appears to be a promising intervention for older adults with insomnia.

Keywords: Insomnia, aging, sleep, stimulus control, sleep restriction

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Insomnia is a prevalent disorder among older adults and a frequent complaint encountered in primary care clinics.[1-3] Because more than 75% of patients with insomnia receive treatment in primary care settings,[4] finding effective interventions for this population that could be delivered in primary care settings is an important goal for aging and mental health services research.

Although hypnotics can be efficacious for the short-term treatment of insomnia, their use raises safety concerns regarding side effects, including cognitive impairment and risks of injuries in older adults.[6,7] Behavioral interventions for insomnia may offer safer alternatives for older adults. Meta-analyses support the efficacy of stimulus control[5] and sleep restriction[6] for the behavioral treatment of insomnia[7,8] in both younger and older adults,[9,10] whereas sleep hygiene has shown little efficacy when used alone.

Typically, behavioral insomnia treatments are delivered by highly trained clinicians in individual or group sessions over a 6- to 8-week period. These resources may not be readily available or practical in usual care settings. Recent studies have focused on briefer interventions[11,12] and interventions that can be delivered by primary care nurses.[13] We present a study that is a preliminary report of findings from an ongoing study of a brief behavioral treatment of insomnia (BBTI) in older adults with the typical psychiatric and medical comorbidities associated with aging.

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METHODS

Participants

Participants were recruited from primary care clinics and the general public via media advertisements. Data collected from participants enrolled between May 2004 and July 2005 are included in the present report. Written informed consent was obtained from all participants. Eligible participants were older than 60 years and met Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition diagnostic criteria for primary insomnia but without the medical or psychiatric exclusion criteria. Participants with stable medical or psychiatric conditions were allowed to participate. The Charlson Comorbidity Index was used to screen for medical conditions,[14,15] and the PRIME-MD Patient Health Questionnaire was used to screen for mood, anxiety, and substance use disorders.[16] Sleep disorders were assessed using a structured interview developed locally.

Disclosure Statement

This was not an industry supported study. Dr. Buysse is a consultant for Actelion, Cephalon, Eli Lilly, GlaxoSmithKline, Merck, Neurocrine, Neurogen, Pfizer, Respironics, Sanofi-Aventis, Servier, Sepracor, and Takeda. Dr. Reynolds has received research support from GlaxoSmithKline, Pfizer, Forest, BMS, and Lilly. Drs. Germain, Moul, Franzen, Miewald, and Monk have indicated no financial conflicts of interest.

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Individuals using prescribed or over-the-counter hypnotics were included if they reported insomnia and agreed to continue to use the sleep aids. Individuals with unstable or untreated psychiatric, medical, or sleep disorders were excluded. This was determined based on the review of clinical data obtained during the face-to-face visit, in which clinician-administered assessments, self-report measures, and the review of medical charts were gathered from each participant. This review was conducted during weekly consensus meetings. Nine participants who were found to require prompt attention for the presence of new or worsening mood (n = 5) or anxiety disorders (n = 4) were excluded. One participant was excluded during the screening procedures for substance abuse disorder, and another was excluded due to worsening of a neurodegenerative disease. Participants who endorsed symptoms of restless legs syndrome, periodic leg movement disorder, or delayed sleep phase syndrome on most nights associated with difficulty falling or staying asleep were excluded at the clinical interview (n = 5) and referred to their primary care physicians with specific recommendations for further evaluation. Participants who endorsed symptoms consistent with sleep apnea (e.g., snoring, recalled or witnessed apneas, subjective reports of excessive daytime sleepiness) were referred to their primary care doctors for further evaluation (n = 7). For some individuals who reported symptoms consistent with sleep apnea, screening sleep studies were conducted; 3 participants were excluded due to significant sleep apnea (AHI > 20) and referred to their primary care physicians. None of the participants included in the present study had a diagnosis of obstructive sleep apnea.

MEASURES

Sleep measures included the Pittsburgh Sleep Quality Index (PSQI)[17] and the Pittsburgh Sleep Diary.[18] The PSQI is a 19-item self-report questionnaire that assesses 7 clinically relevant components of sleep quality (subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction) in the preceding month. Each component is rated on a 0- to 3-point scale referring to the composite score derived from the frequencies of each disturbance, in which 0 is equal to not in the past month and 3 is equal to 3 or more times a week, with a global score range from 0 to 21. The global PSQI score is then the sum of these 7 component scores. A cut-off score of 5 has been shown to discriminate between good and bad sleepers.[17] The PSQI has good internal consistency (Cronbach $\alpha = .83$) and test-retest reliability ($r = .85$). The Pittsburgh Sleep Diary is a diary of sleep-wake behavior that comprises wake time and bedtime portions. The wake time portion is completed upon awakening in the morning and asks questions regarding the times at which the participant went to bed and attempted to fall asleep; the number, cause, and duration of nocturnal awakenings; the final time out of bed; and the total estimated time spent asleep while in bed. The bedtime portion of the diary is completed right before bedtime and asks questions about the preceding day, including the times of meals, naps, and exercise sessions; the consumption of caffeine, alcohol, and tobacco; and the use and doses of medications (prescribed and over-the-counter). Sleep diary measures of interest included sleep latency, total sleep time, wake time after sleep onset (WASO), and sleep efficiency. Sleep efficiency was calculated as the percentage of time spent asleep divided by the total time spent in bed. Depression and anxiety were assessed by the Hamilton Rating Scale for Depression[19] and the Hamilton Rating Scale for Anxiety.[20] An independent assessor who completed these latter clinician-administered scales remained blind to participants' assignments. Participants were also instructed not to discuss the intervention they received with the assessor.

Treatments

Seventeen participants (12 women; age mean ± SD 70.9 ± 5.3 years) were randomly assigned to receive BBTI, and 18 (13 women; age 69.6 ± 7.3 years) were randomly assigned to receive an information-only control (IC) condition. The computer-generated blocked randomization scheme was stratified by sex and by age (< 74 years old, > 74 years old), and the randomization sequence was concealed until interventions were assigned.

BBTI participants received a single, 45-minute intervention session conducted by a masters-level adult psychiatric and primary care nurse practitioner who had been trained to deliver the BBTI intervention. This session included education about mechanisms that regulate sleep, factors that influence sleep, and behaviors that promote or interfere with sleep quality. Participants received a workbook containing educational material and treatment instructions. Based on information derived from baseline assessment of sleep diary measures, simple tailored instructions based on stimulus control and sleep restriction were provided to each participant. Specifically, 4 instructions, tailored for each BBTI participant, included: (1) reduce time spent in bed to closely match your number of hours of sleep; (2) get up at the same time every day of the week; (3) do not go to bed unless you are sleepy; and (4) don't stay in bed unless you are asleep. For safety reasons, the minimum time allowed in bed each night was 6 hours. Activities to be performed during the day and night while awake were also discussed. Participants were instructed to follow these instructions for the following 4 weeks. Two weeks later, BBTI participants returned for a 30-minute booster session. This second session aimed at reviewing educational material, assessing treatment adherence, and modifying recommended sleep schedules if necessary. Specific recommendations to increase time spent in bed included: (1) increase time in bed by 15 minutes if the sleep latency is less than 30 minutes and WASO is less than 30 minutes each night; (2) maintain the new time in bed for 1 week; and (3) increase the time in bed by 15 minutes if the sleep latency and WASO remain less than 30 minutes, and decrease time in bed by 15 minutes if the sleep latency and WASO are longer than 30 minutes.

The IC condition was intended to emulate the type of behavioral instructions most primary care patients might receive. Participants assigned to IC received 3 brochures published by the American Academy of Sleep Medicine on insomnia, sleep and aging, and sleep hygiene. The nurse practioner also led this session. The subjects were instructed to read and review the brochures over the following weeks. Two weeks later, they received a follow-up telephone call from the nurse practioner to answer questions that may have arisen. Posttreatment assessments were completed 4 weeks after the first visit. After the randomly assigned intervention, IC participants were then offered BBTI. None of these subjects are included in the current report.

Treatment response was defined as a reduction of 3 points or more[21] on the PSQI or an increase in sleep efficiency of at least

10%, based on sleep diary measures. Remission was defined as meeting response criteria and having a PSQI score of 5 or less after treatment or sleep efficiency greater than 85% after treatment. The latter remission criteria reflect clinical thresholds for identifying good sleepers.[17,22]

Statistics

Independent t-tests were computed to assess group differences on baseline measures and on pretreatment to posttreatment score changes on sleep and clinical measures. The magnitude of pretreatment to posttreatment changes was also assessed using Cohen d effect-size coefficients.[23]

Specifically, Cohen's d effect sizes were computed by using the mean change scores for each treatment group. Because of the paired design, conservative effect sizes estimates were computed using original standard deviations.[24] Small, medium, and large effect sizes are indicated by d values of .20, .50, and .80, respectively.

RESULTS

Thirty-five participants (25 women; age 70.2 ± 6.4 years) were randomly assigned to the 2 interventions. Mean insomnia duration was 18.0 years (SD = 18.5 years; range = 1.3 to 57.7 years). All but 2 participants were Caucasian. No participant was withdrawn or withdrew after randomization.

Eleven participants were recruited from primary care clinics (6 randomly assigned to BBTI, 5 to IC), and 24 (11 in BBTI, 13 in IC) were recruited via advertisements and referrals. The treatment groups did not differ at baseline on sleep and clinical measures (all p values > .1). Six BBTI participants and 8 IC participants were currently using hypnotics. The mean number of current comorbid medical conditions (mean ± SD = 5.2 ± 1.7 in BBTI and 6.1 ± 3.0 in IC) did not differ between the 2 groups (p > .1). The most common medical conditions were arthritis and joint diseases (n= 12 in BTTI; n = 14 in IC), irregular heart rate (n= 3 in BBTI, n = 10 in IC), and high blood pressure (n= 8 in BBTI, n = 9 in IC), bladder problems (n= 8 in BBTI, n = 7 in IC), cancer (n = 7 in both groups), and other health problems (n = 10 in BBTI, n = 9 in IC). Overall, most participants endorsed subthreshold psychiatric symptoms on the PHQ. Ten BBTI participants and eight IC participants endorsed mild depressive symptoms (PHQ scores = 5 to 9). Two IC participants endorsed moderate depressive symptoms (PHQ scores = 9 and 10). The most common psychiatric condition was generalized anxiety (n = 8 in BBTI, n = 9 in IC). No participant met criteria for panic disorder. One BBTI participant and two IC participants endorsed symptoms consistent with generalized anxiety disorder on the PHQ.

No adverse events were reported in either treatment group. Pretreatment to posttreatment differences for sleep diary, PSQI, and clinical ratings were significantly greater in the BBTI group, compared with the IC group (Table 1). Twelve of the 17 BBTI participants (71%) met criteria for response, and 9 (53%) also met criteria for remission after treatment. Seven of the 18 participants assigned to the IC condition (39%) met criteria for response, and 3 (17%) met criteria for remission.

DISCUSSION

These preliminary findings suggest that a brief behavioral intervention can reduce insomnia in older adults presenting with the typical comorbidities of aging. The BBTI group showed large improvements in overall sleep quality, sleep latency, WASO, and sleep efficiency, as well as marked reductions in depression and small changes in anxiety, whereas the IC group did not. Total sleep time was not significantly increased after treatment in the BBTI group and likely reflects a direct consequence of acute, mild sleep restriction and stimulus control as part of the BBTI condition. Of note, previous meta-analyses have generally reported small effect sizes and high variability for the effects of behavioral interventions on total sleep time in older adults.[10] In a study of the effectiveness of a 6-session cognitive-behavioral treatment of chronic insomnia in primary care patients, Espie and colleagues[13] observed minimal improvements in total sleep time after treatment and a mean increase of 34 minutes at a 1-year follow-up assessment. An assessment of the durability of the observed therapeutic gains associated with BBTI is currently under way and will clarify whether total sleep time increases at follow-up assessments. All other sleep measures indicated an overall clinically significant improvement in sleep consolidation

Table 1—Sleep and Clinical Scores Before and After Intervention in the 2 Study Groups

Measures	BBTI (n = 17)				Information Control (n = 18)				Score Differences Between Groups	
	Before		After		Before		After			
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Student t test	Cohen d
PSQI	10.59	2.67	6.65	3.41	9.94	3.76	10.0	2.70	-4.06‡	1.37
Sleep Diary										
SL, min	38.32	30.80	16.80	10.03	29.67	19.83	26.85	22.02	-2.13*	.80
TST, min	340.52	72.15	333.04	64.21	387.08	74.75	393.05	72.72	-1.79†	-.63
WASO, min	61.21	42.66	27.72	29.22	47.91	27.44	35.55	28.59	-2.28*	.67
SE, %	76.96	12.34	86.82	10.46	83.10	6.79	86.41	7.17	1.84†	.64
Depression[a]	4.94	2.86	2.64	2.17	6.53	3.69	7.47	5.19	-2.11*	.67
Anxiety[a]	3.24	1.39	2.57	1.91	3.83	2.31	4.47	4.03	-0.95	.34

BBTI refers to brief behavioral treatment of insomnia; PSQI, Pittsburgh Sleep Quality Index; SL, sleep latency; TST, total sleep time; WASO, wake after sleep onset; SE, sleep efficiency.
*p < .05
†.05 < p < .10
‡p < .01
[a]Mean scores reflect total scale score minus sleep-item scores.

after treatment in the BBTI group, reflected in improved sleep quality.

The magnitude of effect sizes observed for BBTI on other sleep variables (quality, sleep latency, WASO, sleep efficiency) is comparable with those reported for standard longer behavioral and cognitive-behavioral interventions for insomnia.[7-9,10] Specifically, large effect sizes ($d \geq 1.00$) for sleep quality and moderate to large effect sizes for sleep latency (range: 0.52 - 1.00) and WASO (range: 0.64 to 1.03) have been reported for behavioral treatments of insomnia in both young and older adults. Effect size estimates for sleep efficiency are lower in older adults (0.38), compared with younger ones.[10]

These preliminary findings are consistent with previous studies that have shown that brief behavioral insomnia interventions can be efficacious[13] and remain efficacious in older adults who present with the typical psychiatric and medical comorbidities associated with aging. The response rate observed in the present study (71% for BBTI) is slightly higher than the response rate reported by Edinger and colleagues (38% to 60%) 3 months after a 2-session intervention that combined sleep education, sleep restriction, and stimulus control.[11] However, the use of different measures to assess treatment response (sleep efficiency and PSQI scores in the present study vs sleep latency and WASO in Edinger et al) may explain this difference. Remission rates based on achieving normal scores on self-report questionnaires in the study by Edinger et al and the present one are nevertheless similar: 56% at the 3-month follow-up and 53% after treatment, respectively.

This preliminary report has some limitations. Given the relatively small sample size, it is not possible to further investigate the possible role of concurrent use of hypnotics or other medications known to affect sleep (e.g., antidepressants, β-adrenergic receptor-blocking agents) on the effects of BBTI, nor is it possible to investigate these medications as possible moderators of treatment response and remission. Similarly, the number of psychiatric and medical comorbidities may also influence treatment outcomes. Future analyses in a larger sample will be needed to assess the possible effects of these factors on BBTI outcomes. Nevertheless, the present preliminary findings are encouraging and suggest that BBTI may be amenable to use in primary care settings.

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