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Cognitive Behavioral Therapy for Insomnia in Older Veterans Using Nonclinician Sleep Coaches: Randomized Controlled Trial

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Abstract

OBJECTIVES—To test a new cognitive behavioral therapy for insomnia (CBT-I) program designed for use by nonclinicians.

DESIGN—Randomized controlled trial.

SETTING—Department of Veterans Affairs healthcare system.

PARTICIPANTS—Community-dwelling veterans aged 60 and older who met diagnostic criteria for insomnia of 3 months duration or longer (N = 159).

INTERVENTION—Nonclinician "sleep coaches" delivered a five-session manual-based CBT-I program including stimulus control, sleep restriction, sleep hygiene, and cognitive therapy (individually or in small groups), with weekly telephone behavioral sleep medicine supervision. Controls received five sessions of general sleep education.

MEASUREMENTS—Primary outcomes, including self-reported (7-day sleep diary) sleep onset latency (SOL-D), wake after sleep onset (WASO-D), total wake time (TWT-D), and sleep efficiency (SE-D); Pittsburgh Sleep Quality Index (PSQI); and objective sleep efficiency (7-day wrist actigraphy, SE-A) were measured at baseline, at the posttreatment assessment, and at 6- and 12-month follow-up. Additional measures included the Insomnia Severity Index (ISI), depressive symptoms (Patient Health Questionnaire-9 (PHQ-9)), and quality of life (Medical Outcomes Study 12-item Short-form Survey version 2 (SF-12v2)).

RESULTS—Intervention subjects had greater improvement than controls between the baseline and posttreatment assessments, the baseline and 6-month assessments, and the baseline and 12-month assessments in SOL-D (−23.4, −15.8, and −17.3 minutes, respectively), TWT-D (−68.4,

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−37.0, and −30.9 minutes, respectively), SE-D (10.5%, 6.7%, and 5.4%, respectively), PSQI (−3.4, −2.4, and −2.1 in total score, respectively), and ISI (−4.5, −3.9, and −2.8 in total score, respectively) (all $P < .05$). There were no significant differences in SE-A, PHQ-9, or SF-12v2.

CONCLUSION—Manual-based CBT-I delivered by nonclinician sleep coaches improves sleep in older adults with chronic insomnia.

Keywords

insomnia; sleep; cognitive behavioral therapy; aged; randomized controlled trial

Insomnia is the most common sleep problem in adults, with 30% to 50% reporting symptoms.[1] Insomnia is particularly problematic in older adults, in whom it is often chronic and comorbid with other health conditions. [2,3] Insomnia and sleep disturbance are associated with poor health,[4] including greater risk of depression,[5] falls,[6] stroke,[7] cognitive decline,[8] and impaired functional status.[9] Older adults are more likely than younger adults to take sedative–hypnotics,[10] despite evidence that these agents increase falls,[11,12] fractures,[13] healthcare costs,[12] and mortality.[14]

Behavioral sleep interventions, such as cognitive behavioral therapy for insomnia (CBT-I), are highly effective in treating chronic insomnia in older adults,[15,16] including individuals with selected comorbid medical and psychiatric conditions.[17] CBT-I typically combines stimulus control (associating the bed and bedroom with sleep), sleep restriction (increasing the homeostatic drive to sleep and reducing time in bed) and cognitive therapy (addressing maladaptive beliefs about sleep and reducing anxiety about sleep and the consequences of not sleeping).[15] Sleep hygiene (establishing behavioral routines to promote restorative sleep) and other components may be included. Improvements in sleep with CBT-I are equal or greater in magnitude and more durable than improvements seen with sedative–hypnotics.[18]

Treatment guidelines universally recommend behavioral therapies as first-line treatment for insomnia in older adults,[3,19] but these treatments have not been widely implemented. Many primary care providers do not use behavioral therapies because of time constraints, cost, and perceived difficulty motivating people to see a therapist.[20] Limited access to behavioral sleep medicine (BSM) specialists is also a hurdle to widespread implementation. Alternative approaches have been developed, such as brief treatment programs,[21] self-help manuals,[22] video educational programs,[23] and online approaches,[24] but uptake of these approaches in primary care has also been limited, particularly in older adults and those with comorbidities. A new, manual-based CBT-I program designed to be delivered by nonclinicians with BSM telephone supervision was developed and tested to address this. This model of CBT-I was tested in older veterans with chronic insomnia disorder based on established diagnostic criteria.[25] It was hypothesized that sleep outcomes would improve more at 6-month follow-up in the intervention group than in controls and that these improvements would be maintained for up to 12 months.

METHODS

Trial Design

This study was a randomized controlled trial comparing CBT-I provided by nonclinicians in a small-group or individual (one-on-one) format, with weekly telephone supervision by a BSM specialist, with a general sleep education control condition delivered in a group format by a similar nonclinician health educator. Recognizing that the intervention might be implemented in the future in group or individual settings, both formats were tested. Eligible subjects were community-dwelling veterans aged 60 and older with chronic (≥3 months' duration) insomnia disorder (based on International Classification of Sleep Disorders, Second Edition (ICSD-2) criteria).[25] Eligible subjects were randomized 1:1:1 to group CBT-I, individual CBT-I, or the control condition. Group and individual CBT-I were pooled to form the intervention group for analyses. Objective and subjective measures of sleep were collected at baseline, the posttreatment assessment, and 6- and 12-month follow-up. Subject recruitment and randomization ran from June 2010 to January 2012; follow-up testing ran from September 2010 to March 2013. The institutional review board of the Veterans Affairs (VA) Greater Los Angeles Healthcare System approved the study procedures, and written informed consent was obtained from all subjects (ClinicalTrials.gov Identifier: NCT00781963).

Subjects

The VA national data warehouse was used to identify veterans with at least one outpatient visit at one urban VA healthcare system in the prior 18 months and lived within 30 miles of the facility. A 25-item postal survey that operationalized ICSD-2 criteria for insomnia disorder was mailed. Surveys were mailed over a 20-month enrollment period. A second postal survey was mailed to nonresponders. Of 9,080 veterans mailed a survey, 4,717 (51.9%) returned a completed survey (mean respondent age 74.1, range 60–100, 98.2% male, 78.6% non-Hispanic white), 2,461 (52.2%) of whom provided responses that met ICSD-2 diagnostic criteria for insomnia disorder with symptoms present for 3 months or longer. Of these, 1,947 (79.1%) indicated on their returned survey that they were willing to have the research team contact them, and 1,663 of these were assessed for eligibility for the study in a screening telephone call (221 could not be reached, 33 responded after study enrollment had ended, and 30 refused).

The figure shows the Consolidated Standards of Reporting Trials[26] flow diagram of the 1,663 individuals assessed for eligibility using a multistep process over the telephone followed by in-person assessment. Subjects were excluded if their Mini-mental State Examination (MMSE)[27] score was less than 24, they reported a history of sleep apnea or in-home portable sleep monitoring (using WatchPAT 200, Itamar Medical, Ltd, Caesarea, Israel) performed during assessment estimated an apnea-hypopnea index (AHI) greater than 20 (because the intervention did not address sleep apnea), or they had a severe unstable medical disorder (e.g., <6-month life expectancy) or active severe mental disorder (e.g., current active substance abuse, psychiatric hospitalization within the past 90 days, documented bipolar disorder). Trained research staff at a VA healthcare system collected all data.

Randomization

Subjects meeting eligibility criteria were randomized (using random allocation concealment) to one of three treatment groups (1:1:1 allocation to group CBT-I, individual CBT-I, or control), so two-thirds of subjects were randomized to intervention and one-third to control. Before the study began, a statistician (MM) created a randomization sequence using Stata version 13.1 (Stata Corp., College Station, TX), stratified according to nighttime sleep efficiency (<80%, ≥80%) estimated from the wrist actigraph in the WatchPAT device. A separate senior research staff member (KR) not involved in subject enrollment, assessment, or intervention prepared the opaque sequentially numbered envelopes and implemented the random allocation sequence. Subjects and assessment research staff were blinded to group assignment.

Intervention and Control Conditions

The CBT-I intervention was structured and manual based, with hard-copy materials provided to subjects, and delivered individually or in small groups of three to five subjects. Content included training in aspects of stimulus control, sleep restriction, cognitive therapy, and sleep hygiene, as defined above. The intervention was provided in five 1-hour sessions over 6 weeks (with a brief telephone check-in during Week 5). Specific content included (Session 1) sleep restriction and stimulus control, (Session 2) sleep hygiene and adjustment of sleep restriction parameters, (Session 3) cognitive therapy and adjustment of sleep restriction parameters, (Session 4) review of prior material and adjustment of sleep restriction parameters, and (Session 5) relapse prevention.

One of three nonclinicians (sleep coaches) with a master's degree (public health, social work, or communication) delivered the intervention. Training of the sleep coaches included attendance at a 2-day educational workshop on CBT-I or completion of a six-session webinar published by the American Academy of Sleep Medicine.[28] A clinical sleep psychologist investigator (JM) provided additional training on the study intervention materials and observed each sleep coach provide the intervention in a small number of pilot subjects. During the intervention period, a psychologist with BSM expertise (LF or JM) supervised the sleep coach weekly in a telephone consultation (one telephone call lasting 60–90 minutes) to discuss all currently active intervention subjects, review subject progress, and help solve problems with adherence. Fidelity of the intervention was monitored during these telephone consultations, and session content checklists (that the sleep coach completed during each intervention session) were reviewed to verify that topics had been covered as outlined in the treatment manual. Subjects in the group and individual active intervention conditions received identical intervention materials.

The control condition was a structured, manual-based, general sleep education program delivered in group format at the same frequency and intervals as the intervention condition to account for social attention and to encourage subject retention. A separate master's-level nonclinician (with a master's degree in public health) without CBT-I training delivered the control condition.

Subject Characteristics

Information on descriptive characteristics (e.g., age, sex, race and ethnicity, educational level, marital status, employment status) was collected at baseline. Self-reported comorbidity was recorded as number of health conditions endorsed (from a list of 36 common medical and psychiatric disorders).[29] The seven-item pain intensity subscale of the Geriatric Pain Measure (GPM) was also administered. [30] All medication use (prescription and over the counter) was recorded for 1 week at each timepoint, and the total number of medications taken (excluding vitamins and other supplements) was calculated. Whether the subject took prescription medications commonly used for insomnia or other sedative medications, based on previously published definitions,[10] was also recorded. As mentioned above, research staff also administered the MMSE and WatchPAT was used to estimate AHI.

Outcome Measures

Research staff blinded to group assignment, study research questions, and content of the intervention and control conditions collected information on outcome measures at baseline, within 1 week posttreatment, and at 6- and 12-month follow-up (from the date of randomization).

Primary sleep outcomes were measured using a sleep diary, wrist actigraphy, and sleep questionnaire. Subjects completed a 7-day sleep diary including bedtime, nighttime awakenings, rise time, and other items. Primary sleep diary variables included sleep onset latency (SOL-D (amount of time it takes to fall asleep)), wake after sleep onset (WASO-D), total wake time (TWT-D), and sleep efficiency (SE-D, time asleep divided by time in bed). Wrist actigraphy (Actiwatch Spectrum, Respironics) was performed during the same week as the sleep diary to estimate nighttime sleep efficiency (SE-A).[31] The primary sleep questionnaire measure of subjective sleep quality was the Pittsburgh Sleep Quality Index (PSQI, total score 0–21; higher scores indicate worse sleep quality).[32] The Insomnia Severity Index (ISI, total score 0–28; higher scores indicate worse insomnia severity) was included as a secondary measure of insomnia symptoms.[33]

Additional measures included the Patient Health Questionnaire-9 (PHQ-9, a 9-item scale, total score 0–27; higher scores indicate more-severe depressive symptoms)[34] and the Medical Outcomes Study 12-item Short-Form Health Survey version 2 (SF-12v2)[35] Mental Component Summary (MCS) and Physical Component Summary (PCS) scales (total score 0–100; higher scores indicate better functioning).

At the end of treatment, intervention and control subjects rated the program they received on four credibility items (total score for each item 0–6, higher scores indicate greater credibility).[36] The items assessed how logical, successful, and acceptable they found the program and how confident they were that they would recommend the program to someone else.

Statistical Analysis

Baseline differences between the treatment and control groups were assessed using two-sample *t*-tests for continuous variables and chi-square tests for categorical variables.

The primary hypothesis was that sleep outcomes would show greater improvement from baseline to 6-month follow-up for the intervention group than for controls. The a priori primary sleep outcomes of interest were sleep diary SOL-D, WASO-D, and SE-D; SE-A; and PSQI total score. Secondary hypotheses were that sleep outcomes would show greater improvement in the intervention group than in controls from baseline to the posttreatment assessment and from baseline to the 12-month follow-up. The primary and secondary hypotheses were also assessed for the secondary outcomes (ISI, PHQ9, MCS, PCS) at these time points.

Mixed-effects models were used to test the hypotheses regarding difference in change in sleep outcomes between the intervention and control groups. When applied to repeated-measures designs, mixed-effects models accommodate incomplete data across time points (such as occurs with dropout or data missing at a particular time point) and can permit specification of a wide variety of residual covariance structures.[37] Each outcome was analyzed using a two by four factorial mixed-effects model with a fixed intercept in which treatment group was a two-level between-subjects factor (intervention vs control), and time was a four-level repeated-measures factor (baseline, posttreatment, 6 months, 12 months). For each outcome, the best-fitting (based on the Bayesian information criterion) residual covariance structure was specified (unstructured residual covariance matrix for SOL-D, WASO-D, TWT-D, SE-D; compound symmetry for SE-A, PSQI, ISI, PHQ9, MCS, PCS).

The primary hypotheses were tested using an interaction contrast that compared change in outcome from baseline to 6 months in the treatment group with change in the control group. The intervention effect was estimated as the change in the intervention group from baseline to 6 months minus the change in the control group from baseline to 6 months, and a 95% confidence interval for this effect was computed. The intervention effect was also estimated using a variation of Cohen's d formulated for a pretest-posttest-control (PPC) design that forms a standardized measure of the difference in the change (from baseline to follow-up) between the intervention group and the control group.[38] The secondary hypotheses were tested in a similar manner, but focusing on the change from baseline to posttreatment and from baseline to 12 months.

Sample size calculations performed before the start of the study established that a total sample size of 150 subjects (using $\alpha = 0.05$ and power = 80%) would be adequate to test for differences between groups (intervention vs control) in outcome variables. The study was not designed to compare individual with group CBT-I, and because there were not significant differences between individual and group CBT-I in primary outcomes, subjects who received individual and group CBT-I were pooled to form the intervention group.

All outcomes were assessed using intention-to-treat analyses. Systematic attrition was tested for using two-sample *t*-tests to compare the baseline characteristics for each outcome variable of those who did and did not have complete data at each follow-up time point. No such tests were significant ($P > .05$), indicating no evidence of systematic attrition.

Data preparation and data analyses were performed using Stata version 13.1. The linear mixed models were fit using the Stata mixed command. All significance tests were two-

tailed and tested using $\alpha = 0.05$. No adjustments were made for multiple tests, so the tests with regard to the secondary hypotheses and secondary outcomes should be considered exploratory.

RESULTS

Of 1,663 postal survey respondents screened for study eligibility over the telephone, 519 (31.9%) completed in-person eligibility screening, and 159 were randomized to intervention (n = 106; n = 52 group CBT-I, n = 54 individual CBT-I) or control (n = 53, Figure 1).

Table 1 provides information on baseline demographic characteristics, sleep measures, and other characteristics of randomized subjects. Subjects were predominantly non-Hispanic white men with a mean age of 72.2 (range 60–91) and reported an average of six comorbidities. More than 90% of subjects reported that their sleep problems had been present for longer than 12 months. There were no significant differences in these characteristics between the intervention and control groups at baseline.

Attendance and Attrition

Attendance at the five intervention or control sessions was 100% for individual CBT-I subjects, 85% for group CBT-I subjects, and 100% for control subjects. At the conclusion of treatment, the range of mean responses to the credibility items of intervention and control subjects was 4.6–5.8 (on a 6-point scale, with higher scores indicating better credibility). Control subjects reported lower program credibility than intervention subjects (all $P < .05$), although the largest difference in mean credibility between the intervention and control groups on an item was only 0.8. No harms or unintended effects were identified in either group.

Outcomes

Table 2 presents the mean values and 95% confidence intervals for sleep and other measures at each time point (baseline, posttreatment, 6- and 12-month follow-up) for the intervention and control groups. Table 3 presents the results of the repeated-measures analysis comparing change in sleep outcomes in the intervention and control groups from baseline to posttreatment, from baseline to 6 months, and from baseline to 12 months. For example, decrease in time to fall asleep from baseline to the posttreatment assessment was 23.4 minutes greater for the intervention than the control group (SOL-D, $P < .001$), decrease in time awake once they fell asleep was 17.7 minutes greater (WASO-D, $P = .01$), decrease in time awake throughout the night was 68.4 minutes greater (TWT-D, $P < .001$), and sleep efficiency improved 10.5% more (SE-D, $P < .001$). At 6 months (the primary outcome time point), the intervention group showed significantly greater improvements in SOL-D ($P = .02$), TWT-D ($P = .004$), and SE-D ($P = .005$) than controls but not in WASO-D ($P = .21$). At 12 months, treatment effects remained significant for SOL-D, TWT-D, and SE-D (all $P < .05$). The effect sizes for the significant treatment effects in sleep diary measures ranged from 0.34 to 0.76. In contrast, there was no significant treatment effect for SE-A at any time point.

Significant treatment effects were also observed for self-reported sleep quality. Intervention subjects had decreases (improvement) in PSQI total score from baseline that were 3.4 points

better than those of controls at the posttreatment assessment, 2.4 points better at 6 months, and 2.1 points better at 12 months (all $P < .05$). Effect sizes for improvement in PSQI ranged from 0.63 to 0.98. Although not a primary outcome measure, the ISI also showed significantly greater improvement from baseline in intervention subjects than controls at each follow-up time point, with effect sizes that ranged from 0.54 to 0.85.

There were no significant treatment effects for the mental and physical components of the SF-12 or for the PHQ-9 between baseline and any follow-up time point. In secondary analyses, there were no significant differences in treatment effect between subjects who did and did not receive medications commonly used for insomnia or other sedative medications. In the intervention group, there were also no significant differences between intervention subjects receiving individual and group CBT-I on any outcome at any time point (data not shown). In particular, there were no significant differences for the primary sleep outcomes between individual and group CBT-I in change from baseline to 6 months (all $P > .12$).

DISCUSSION

A manual-based behavioral insomnia treatment program delivered by nonclinician sleep coaches with weekly telephone supervision by a psychologist with expertise in BSM improved subjective sleep measures and self-reported sleep quality in older adults with chronic insomnia. Overall effectiveness of the intervention on sleep outcomes was similar to findings from reviews of insomnia treatment studies in older adults involving CBT-I or sedative–hypnotics, [16,39] and most improvements were maintained for 12 months.

This intervention provides a promising option for increasing access to behavioral treatment for insomnia in older adults, in keeping with treatment guidelines that recommend behavioral therapy for older adults.[3,19] Several approaches to provide behavioral treatment for insomnia have been developed, such as brief treatment programs with a sleep psychologist,[21] self-help manuals,[22] video educational programs,[23] and online approaches,[24] but use of these approaches in clinical settings has been limited, and many people do not receive behavioral treatment for their insomnia.

The intervention tested in this trial addresses several barriers to implementation of behavioral therapies for insomnia. First, use of a nonclinician, non-mental health provider to interact directly with individuals may increase access to treatment and address concerns of people who do not want to see a mental health specialist for treatment of their insomnia. Second, this program provides for supervision by BSM specialists (who are limited in number), which may increase treatment fidelity and effectiveness while efficiently using this scarce resource. Finally, the program offers in-person support from the sleep coach, which may be helpful for older adults with comorbidities.

There were also several strengths of the study design, particularly the randomized controlled methodology with long-term follow-up. It is likely that the clinical population–based screening with a postal survey provided a study sample that was more representative of the general clinical population than recruitment from sleep clinics or self-referral through advertisements. In addition, the high adherence to the intervention suggests good feasibility

of providing the intervention in clinical care. Finally, the active control condition delivered by an individual with a comparable education level using similarly formatted program materials provided a strong comparison group to address potential nonspecific placebo effects. The high adherence to control sessions and the high program credibility ratings of control subjects suggests they remained blinded to group assignment.

A potential limitation of the study was the predominantly male veteran population; findings may not be generalizable to older women and nonveterans. In addition, although home sleep apnea testing was used to exclude those with severe sleep-disordered breathing, polysomnography was not performed, and SE-A did not show a treatment effect. Nevertheless, diagnostic criteria for insomnia are based on self-report, and objective sleep measurement is not required unless another sleep disorder (e.g., sleep apnea) is suspected.[25,40] As such, subjective improvement in sleep is generally the critical measure of effectiveness in treatment of insomnia. There is often a mismatch between subjective and objective measures of sleep,[41,42] and prior studies of sedative–hypnotics[43] and CBT-I[44] have found greater subjective than objective improvements in sleep. As a final limitation, diagnostic criteria for insomnia in use at study commencement (ICSD-2)[25] were recently updated (ICSD-3).[39] In addition to other changes, ICSD-3 criteria require symptoms to occur at least three times per week, which was not a diagnostic criterion used to identify participants for the study.

In summary, a structured, manual-based CBT-I program delivered by nonclinician sleep coaches significantly improved subjective sleep measures and self-reported sleep quality in older adults with chronic insomnia, and these improvements in sleep were maintained for up to 12 months. This intervention provides a promising option for increasing access to CBT-I in older adults, including those with significant comorbidity, which is in keeping with treatment guidelines that recommend behavioral therapies as first-line management of insomnia in older adults.

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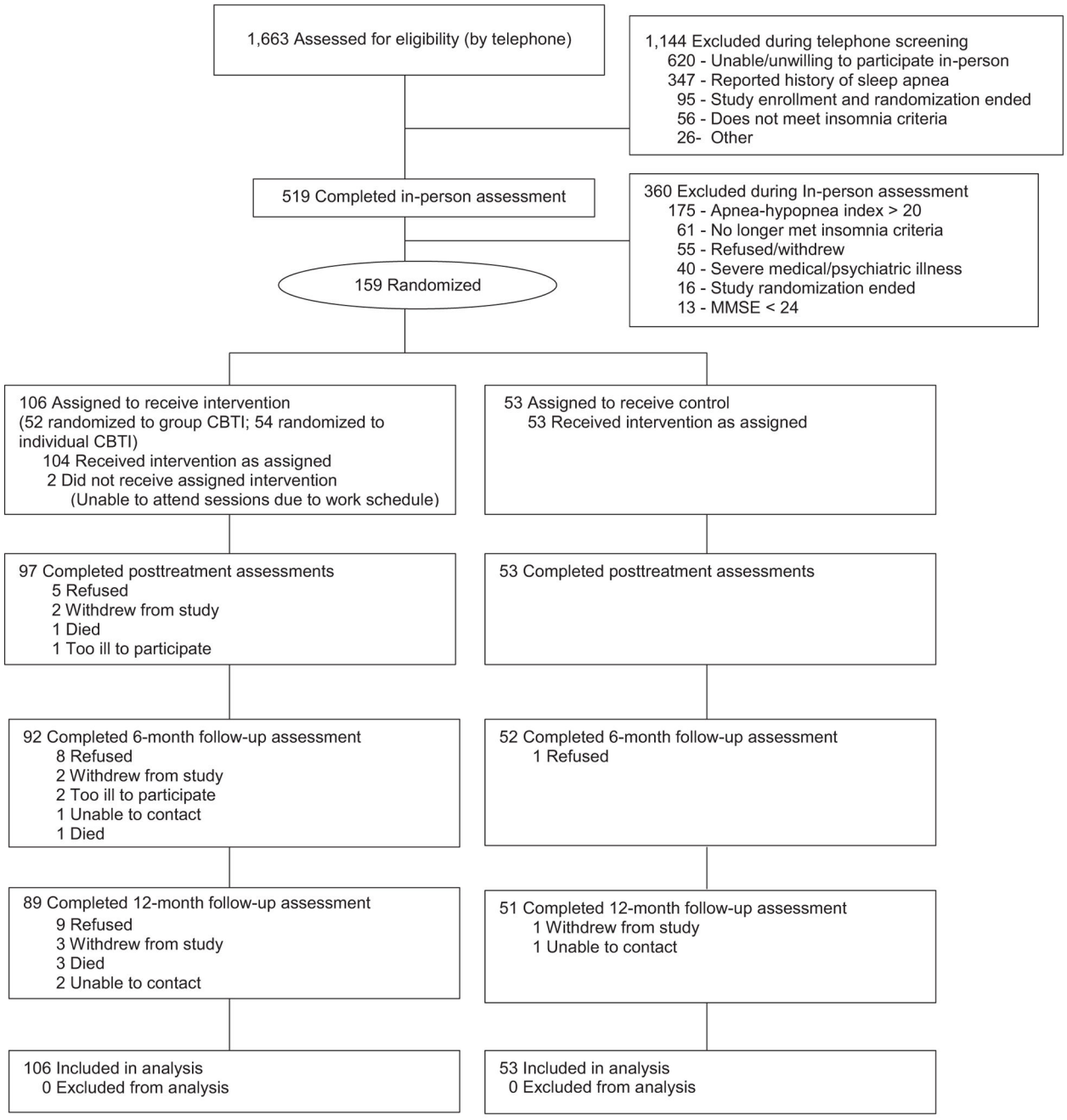

Figure 1.
Participant flow in the study.

Table 1

Baseline Demographic, Sleep, and Other Characteristics of Randomized Subjects

Variable	Overall, N = 159	Intervention, n = 106	Control, n = 53
Demographic			
Age, mean±SD	72.2 ± 7.7	72.1 ± 7.9	72.4 ± 7.3
Male, n (%)	154 (96.9)	102 (96.2)	52 (98.1)
Race and ethnicity, n (%)[a]			
Hispanic	10 (6.3)	7 (6.6)	3 (5.7)
Black	7 (4.4)	6 (5.7)	1 (1.9)
White	125 (78.6)	83 (78.3)	42 (79.2)
Other	12 (7.6)	7 (6.6)	5 (9.4)
No response	5 (3.1)	3 (2.8)	2 (3.8)
Education			
<High school	6 (3.8)	6 (5.7)	0 (0.0)
High school graduate	25 (15.7)	18 (17.0)	7 (13.2)
Some college	70 (44.0)	44 (41.5)	26 (49.1)
College graduate	30 (18.9)	18 (17.0)	12 (22.6)
Postbaccalaureate	28 (17.6)	20 (18.9)	8 (15.1)
Marital status			
Married	66 (41.5)	43 (40.6)	23 (43.4)
Living as married	11 (6.9)	8 (7.5)	3 (5.7)
Divorced, separated	48 (30.2)	34 (32.1)	14 (26.4)
Widowed	14 (8.8)	10 (9.4)	4 (7.5)
Single, never married	20 (12.6)	11 (10.4)	9 (17.0)
Employment			
Not working	121 (76.1)	81 (76.4)	40 (75.5)
Working part time	31 (19.5)	19 (17.9)	12 (22.6)
Working full time	7 (4.4)	6 (5.7)	1 (1.9)
Sleep measures			
From sleep diary, mean ± SD			
Sleep onset latency, minutes	41.4 ± 42.4	43.3 ± 47.9	37.5 ± 28.5
Wake after sleep onset, minutes	56.6 ± 49.0	55.8 ± 40.3	58.1 ± 63.3
Total wake time, minutes	143.2 ± 88.9	144.0 ± 89.5	141.6 ± 88.5
Sleep efficiency, %	72.3 ± 15.4	72.0 ± 14.8	72.8 ± 16.8
Sleep efficiency from actigraphy, %, mean±SD	83.4 ± 6.3	83.7 ± 6.1	82.8 ± 6.9
Pittsburgh Sleep Quality Index, total score, mean±SD	9.1 ± 3.4	9.4 ± 3.5	8.3 ± 3.2
Duration of sleep problems > 12 months, n (%)	144 (90.6)	96 (90.6)	48 (90.6)
Insomnia Severity Index, total score, mean±SD	11.1 ± 5.3	11.7 ± 5.3	10.1 ± 5.3
Apnea–hypopnea index, mean±SD	9.4 ± 5.3	9.9 ± 5.4	8.3 ± 5.1

Variable	Overall, N = 159	Intervention, n = 106	Control, n = 53
Other measures, mean±SD			
Comorbidity index[b]	6.6 ± 3.4	7.0 ± 3.5	6.0 ± 3.0
Geriatric Pain Measure 7-item pain intensity subscale	14.8 ± 11.5	15.0 ± 11.6	14.3 ± 11.3
Patient Health Questionnaire-9 score	4.8 ± 4.3	5.1 ± 4.3	4.4 ± 4.3
Medical Outcomes Study 12-item Short-form Survey v2			
Mental Component Summary	52.8 ± 9.5	52.9 ± 10.0	52.6 ± 8.3
Physical Component Summary	45.3 ± 10.7	44.2 ± 10.9	47.6 ± 10.3

SD = standard deviation.

[a]Participants were asked to select all that applied.

[b]Total number of self-reported health conditions endorsed.

Table 2

Sleep and Other Outcome Measures at Each Time Point According to Treatment Group (n = 106 Intervention, n = 53 Control)

	Mean (95% Confidence Interval)			
Outcome	**Baseline Assessment**	**Posttreatment Assessment**	**6-Month Assessment**	**12-Month Assessment**
According to sleep diary				
Sleep onset latency, minutes				
Intervention	43.3 (35.3–51.3)	18.7 (14.7–22.7)	21.3 (16.8–25.8)	24.0 (18.3–29.7)
Control	37.5 (26.2–48.9)	36.3 (31.0–41.7)	31.3 (25.4–37.2)	35.5 (28.2–42.9)
Wake after sleep onset, minutes				
Intervention	55.8 (46.5–65.1)	24.7 (19.1–30.3)	30.3 (22.9–37.7)	34.5 (27.7–41.2)
Control	58.1 (45.0–71.3)	44.7 (37.0–52.4)	42.8 (33.0–52.7)	38.9 (30.3–47.4)
Total wake time at night, minutes				
Intervention	144.0 (127.1–160.9)	59.1 (48.9–69.3)	73.4 (61.4–85.4)	85.9 (72.8–99.0)
Control	141.6 (117.7–165.5)	125.1 (111.2–138.9)	108.0 (91.8–124.1)	114.4 (97.3–131.5)
Sleep efficiency, %				
Intervention	72.0 (69.0–74.9)	85.9 (83.8–88.0)	84.8 (82.6–87.1)	82.5 (80.1–84.8)
Control	72.8 (68.7–76.9)	76.2 (73.4–79.1)	79.0 (76.0–82.0)	77.8 (74.7–80.9)
Sleep efficiency according to actigraphy, %				
Intervention	83.7 (82.4–85.1)	84.7 (83.4–86.1)	82.7 (81.3–84.1)	82.4 (81.0–83.8)
Control	82.8 (80.9–84.7)	82.5 (80.6–84.4)	83.1 (81.2–85.0)	82.6 (80.7–84.5)
Pittsburgh Sleep Quality Index, total score				
Intervention	9.4 (8.8–10.1)	5.5 (4.8–6.2)	6.0 (5.3–6.7)	6.5 (5.8–7.2)
Control	8.3 (7.3–9.2)	7.7 (6.7–8.6)	7.2 (6.2–8.2)	7.5 (6.5–8.5)
Insomnia Severity Index, total score				
Intervention	11.7 (10.7–12.7)	6.0 (5.0–7.0)	5.5 (4.4–6.5)	6.5 (5.4–7.5)
Control	10.1 (8.7–11.5)	8.9 (7.5–10.3)	7.8 (6.4–9.2)	7.7 (6.3–9.1)
Patient Health Questionnaire-9, total score				
Intervention	5.1 (4.3–5.8)	3.1 (2.3–3.9)	3.0 (2.2–3.8)	3.4 (2.6–4.2)
Control	4.4 (3.3–5.4)	2.9 (1.9–4.0)	3.3 (2.2–4.4)	2.6 (1.5–3.7)
Mental Outcomes Study 12-item Short-Form Study				
Mental Component Summary				
Intervention	52.9 (51.1–54.7)	52.6 (50.7–54.4)	53.3 (51.5–55.2)	52.5 (50.6–54.4)
Control	52.6 (50.0–55.1)	54.7 (52.2–57.3)	54.4 (51.8–56.9)	53.0 (50.4–55.6)
Physical Component Summary				
Intervention	44.2 (42.2–46.1)	45.9 (43.9–47.9)	44.8 (42.8–46.9)	43.7 (41.7–45.8)
Control	47.6 (44.8–50.4)	49.8 (47.0–52.6)	46.7 (43.9–49.5)	48.4 (45.5–51.2)

Table 3

Results of Repeated-Measures Analysis Comparing Difference in Change in Sleep Outcomes from Baseline to Each Follow-Up Time Point Between the Intervention (n = 106) and Control (n = 53) Groups

Outcome	Difference Between Groups in Change from Baseline (95% Confidence Interval)	*P*-Value	Effect Size
According to sleep diary			
Sleep onset latency, minutes			
Posttreatment assessment	−23.4 (−37.2 to −9.7)	<.001	−0.55
6 months	−15.8 (−28.7 to −3.0)	.02	−0.37
12 months	−17.3 (−30.2 to −4.4)	.009	−0.41
Wake after sleep onset, minutes			
Posttreatment assessment	−17.7 (−31.5 to −3.8)	.01	−0.36
6 months	−10.2 (−26.3–5.9)	.21	−0.21
12 months	−2.1 (−19.2–15.1)	.81	−0.04
Total wake time at night, minutes			
Posttreatment assessment	−68.4 (−96.4 to −40.4)	<.001	−0.76
6 months	−37.0 (−62.2 to −11.7)	.004	−0.41
12 months	−30.9 (−57.8 to −4.1)	.02	−0.34
Sleep efficiency, %			
Posttreatment assessment	10.5 (5.5–15.5)	<.001	0.68
6 months	6.7 (2.0–11.3)	.005	0.43
12 months	5.4 (0.5–10.4)	.03	0.35
Sleep efficiency according to actigraphy, %			
Posttreatment assessment	1.3 (−0.6–3.2)	.17	0.20
6 months	−1.4 (−3.3–0.5)	.15	−0.22
12 months	−1.1 (−3.0–0.9)	.27	−0.17
Pittsburgh Sleep Quality Index, total score			
Posttreatment assessment	−3.4 (−4.4 to −2.3)	<.001	−0.98
6 months	−2.4 (−3.5 to −1.3)	<.001	−0.69
12 months	−2.1 (−3.2 to −1.0)	<.001	−0.63
Insomnia Severity Index, total score, total score			
Posttreatment assessment	−4.5 (−6.2 to −2.8)	<.001	−0.85
6 months	−3.9 (−5.7 to −2.1)	<.001	−0.74
12 months	−2.8 (−4.6 to −1.1)	.002	−0.54