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# Cognitive-Behavioral Treatment for Comorbid Insomnia and Osteoarthritis Pain in Primary Care: The Lifestyles Randomized Controlled Trial

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## Abstract

**OBJECTIVES—**To assess whether older persons with osteoarthritis (OA) pain and insomnia receiving cognitive–behavioral therapy for pain and insomnia (CBT-PI), a cognitive–behavioral pain coping skills intervention (CBT-P), and an education-only control (EOC) differed in sleep and pain outcomes.

**DESIGN—**Double-blind, cluster-randomized controlled trial with 9-month follow-up.

**SETTING—**Group Health and University of Washington, 2009 to 2011.

**PARTICIPANTS—**Three hundred sixty-seven older adults with OA pain and insomnia.

**INTERVENTIONS—**Six weekly group sessions of CBT-PI, CBT-P, or EOC delivered in participants' primary care clinics.

**MEASUREMENTS—**Primary outcomes were insomnia severity and pain severity. Secondary outcomes were actigraphically measured sleep efficiency and arthritis symptoms.

**RESULTS—**CBT-PI reduced insomnia severity (score range 0–28) more than EOC (adjusted mean difference = −1.89, 95% confidence interval = −2.83 to −0.96; $P < .001$) and CBT-P (adjusted mean difference = −2.03, 95% CI = −3.01 to −1.04; $P < .001$) and improved sleep



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**Author Contributions**: Vitiello, McCurry, Von Korff, and Shortreed had full and independent access to all of study data and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Vitiello, McCurry, Von Korff, Balderson, Keefe, Rybarczyk. Acquisition of data: Vitiello, McCurry, Von Korff, Baker. Analysis and interpretation of data: Vitiello, McCurry, Von Korff, Shortreed. Drafting of the manuscript: Vitiello, McCurry, Von Korff, Shortreed, Balderson, Baker, Keefe, Rybarczyk. Statistical analysis: Shortreed. Obtained funding: Vitiello, McCurry, Von Korff. Study supervision: Vitiello, McCurry, Von Korff, Balderson.

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efficiency (score range 0–100) more than EOC (adjusted mean difference = 2.64, 95% CI = 0.44–4.84; $P$ = .02). CBT-P did not improve insomnia severity more than EOC, but improved sleep efficiency (adjusted mean difference = 2.91, 95% CI = 0.85–4.97; $P$ = .006). Pain severity and arthritis symptoms did not differ between the three arms. A planned analysis in participants with severe baseline pain revealed similar results.

**CONCLUSION—**Over 9 months, CBT of insomnia was effective for older adults with OA pain and insomnia. The addition of CBT for insomnia to CBT for pain alone improved outcomes. J Am Geriatr Soc 2013.

### Keywords

aging; cognitive–behavioral therapy; insomnia; osteoarthritis; pain

More than half of all older adults have osteoarthritis (OA), and at least half of those report significant sleep disturbance.[1–3] Insomnia and pain adversely affect physical function, mood, and cognition and increase healthcare use and costs.[4–9] Recent research suggests that chronic pain may initiate, maintain, and exacerbate sleep disturbance, and disturbed sleep may maintain and exacerbate chronic pain.[10–13] Because sleep disturbance and pain are common in OA, with significant adverse effects, there is a compelling rationale for their integrated management,[14] particularly because pharmacological approaches to chronic pain management have significant limitations,[15] but the efficacy of behavioral pain management in individuals with OA patients is modest, with a recent meta-analysis reporting an effect size of only 0.18.[16] In contrast, the efficacy of behavioral interventions for sleep disturbance in older adults has been well demonstrated.[17,18] Effectively treating sleep disturbance in OA may thus enhance analgesic benefits of treatment of chronic pain,[19–22] but there has been limited controlled research testing this proposition.

Several small trials have evaluated cognitive-behavioral therapy for insomnia (CBT-I) in diverse pain populations.[19–22] Although insomnia typically improved, benefits for chronic pain were variable. These studies afforded only limited evaluation of cognitive–behavioral interventions for insomnia in pain conditions, and none involved pain-directed treatment beyond usual clinical care, failing to address the question of whether adding an insomnia treatment to pain therapy improves insomnia and pain outcomes.

The trial reported here was designed to address two questions: Will an integrated group-format cognitive– behavioral intervention for chronic pain and insomnia and a group cognitive–behavioral pain coping skills intervention differ in efficacy for sleep and pain outcomes from a group education–only control intervention? Will an integrated group behavioral intervention for chronic pain and insomnia differ in efficacy for sleep and pain from a group cognitive–behavioral pain coping skills intervention?

## METHODS

### Overview

The Lifestyles Trial was a double-blind, controlled, cluster-randomized trial of a 6-week group intervention of cognitive-behavioral therapy for pain and insomnia (CBT-PI), a cognitive-behavioral pain coping skills intervention (CBT-P), and an education-only control (EOC). Full details of the Lifestyles Study protocol have been published.[23] No CBT-I–only treatment arm was included in the study protocol because the efficacy of this intervention for insomnia has been well demonstrated.[17,18] This article reports the results of postintervention and 9-month assessments of the primary and secondary sleep and pain outcomes. Intervention group leaders were blinded to the control intention of the EOC

condition. Assessors were blinded to which of the intervention arms participants were assigned. Participants were blinded to which of the three study arms contained active treatments and were not informed of the content of alternative interventions. Participants were instructed not to discuss their treatment with assessors, and assessors stopped discussion of the intervention if the topic arose during assessments. The study was approved by the Group Health and University of Washington institutional review boards.

## Setting and Participants

Participants were paid volunteers. Members of Group Health, an integrated health maintenance organization in western Washington state, aged 60 and older who had received health care for OA at Group Health in the prior 3 years were screened for chronic pain and insomnia severity in a mailed survey (N = 3,321).

Persons with clinically significant pain and insomnia were eligible for enrollment. Significant arthritis pain was defined as Grade II, III, or IV pain on the Graded Chronic Pain Scale.[24] Significant insomnia was defined as meeting research diagnostic criteria for insomnia based on self-reported sleep difficulties (trouble falling asleep, difficulty staying asleep, waking up too early, or waking up unre-freshed), 3 or more nights per week during the past month with at least one daytime sleep-related problem.[25]

Exclusion criteria were determined through electronic health records and included diagnosis of rheumatoid arthritis, obstructive sleep apnea, periodic leg movement disorder, restless leg syndrome, sleep-wake cycle disturbance, rapid eye movement behavior disorder, dementia or receiving cholinesterase inhibitors, Parkinson's disease, cancer in the past year, receiving chemotherapy or radiation therapy in the past year, and inpatient treatment for congestive heart failure within the prior 6 months.[23]

At the time of telephone contact by study staff, potentially eligible subjects who were assessed to be cognitively impaired or likely to have sleep apnea were also excluded. At that telephone call, those who self-reported any of the following limitations or chronic conditions were also excluded: unable to read a newspaper, difficulty hearing in a group situation, unable to walk across a room without help, periodic leg movement disorder, rapid eye movement behavior disorder, sleep apnea, Parkinson's disease, and rheumatoid arthritis.

Of 3,321 individuals surveyed, 1,210 reported significant arthritis pain and insomnia; 998 of these agreed to medical record review and study contact, and 367 of those eligible and willing attended the first intervention session of the trial and were enrolled in the trial (Figure 1). Lifestyles enrollment details and predictors of participation have been published.[26]

## Randomization and Interventions

Eligible participants were assigned to CBT-PI, CBT-P, or EOC through a clustered randomization procedure. Clusters were participant groups who received one of three interventions in class format. Using a computer algorithm, the project programmer randomly assigned sets of nine groups to the three experimental conditions in one block of three groups and one block of six groups to balance assignments across the six participating primary care clinics. In the third set, 11 groups were randomly allocated (3 to CBT-PI, 3 to CBT-P, and 5 to EOC) to equalize accrual across experimental conditions due to chance fluctuations in group size. To achieve sample size goals, one group beyond the 38 initially planned was formed. This group was assigned to CBT-PI, the condition with the smallest cumulative sample size across the first 38 groups. Participants were enrolled in classes based on their preferred start date, without knowledge of the intervention assignment of their

selected session. Group sizes ranged from five to 12 individuals, with an average of 9.4 individuals per group.

Interventions were delivered in a classroom setting at participants' Group Health primary care clinics. Each class consisted of six weekly 90-minute sessions. CBT-P involved pain education, physical activation, goal setting, relaxation, activity pacing, guided imagery, and cognitive restructuring. CBT-PI added standard components of CBT for insomnia (sleep hygiene education, stimulus control, sleep restriction, and daily sleep monitoring) to the CBT-P intervention. The EOC intervention, designed as an attention control, contained educational content related to pain and sleep management, but classes were facilitated in a nondirective, self-help format that included no homework assignments, no guided practice or instruction in CBT principles, and no daily behavioral self-monitoring. A pair of mental health professionals (Master's-level family counselor and PhD psychologist) experienced in working with older adults co-led classes. Ninety-three percent of study participants attended at least four of six sessions (94.3% for EOC, 91.8% for CBT-P, and 93.4% for CBT-PI).

## Outcomes Assessment

Baseline, posttreatment, and 9-month assessments were each performed at two visits to participants' homes 1 week apart. This facilitated collection of actigraphy and diary data for the intervening week. At the end of the first intervention session and at the postintervention assessment, participants were asked to complete surveys evaluating the suitability, acceptability, and efficacy of the intervention.

## Measures

### Primary Outcomes

**Insomnia Severity:** Score on the Insomnia Severity Index (ISI[27]), a 7-item questionnaire assessing global insomnia severity. Items are rated on a 5-point scale, with total scores ranging from 0 to 28, with 28 indicating severe insomnia.

**Pain Severity:** Six graded Chronic Pain Scale[24] items assessing arthritis pain intensity (average pain, worst pain, pain right now), and interference with usual, work, recreational, social, and family activities. Items are rated from 0 to 10, with 10 representing worst pain or interference.

Clinically significant improvement was defined as a reduction of 30% or more from baseline.[28]

### Secondary Outcomes

**Sleep Efficiency:** Average time asleep as a percentage of daily time in bed, measured using wrist actigraphy (Actiwatch-2, Respironics, Inc., Bend, OR) for 1 week at each assessment. Bed and rising times were derived from a daily sleep log that participants kept.

**Arthritis Symptoms:** A three-item arthritis symptom subscale from the Arthritis Impact Measurement Scales Version 2, Short Form, Revised.[29–31] Scores range from 0 to 10, with 10 indicating high function and little pain.

## Covariates

**Depression—**The Geriatric Depression Scale,[32] a 30-item questionnaire assessing depressive symptoms in older persons.

**Mental Status—**The Modified Mini-Mental State Examination (3MS[33]), a 100-point cognitive screen based on an expanded version of Folstein's Mini-Mental State Examination.

**Analgesic or Hypnotic Use—**Subject self-report of current medication use to relieve pain or improve sleep.

## Statistical Analysis

Analysis of variance (ANOVA) and chi-square tests were used to compare baseline participant characteristics of the intervention arms (Table 1). ANOVA was used to compare training ratings of the three arms. Baseline information was collected on 365 persons; two individuals were excluded from all analyses because of missing baseline data. Follow-up data were collected on 354 participants (96%) at postintervention and 341 (93%) at 9-month assessments. Missing information varied according to treatment group, so sensitivity analyses using baseline value carried forward were conducted.

A modified intention-to-treat[34,35] analysis including all individuals who attended the first group session regardless of the number of sessions they completed over the 6-week intervention was used. For each outcome, the null hypotheses of no difference between the three intervention arms at a significance level of .05 was initially tested. For all outcomes for which this omnibus test was rejected, results of all three post hoc pair-wise tests and corresponding confidence intervals (CIs) are reported.

Intervention effects for primary and secondary outcomes were estimated from a repeated-measures linear regression using postintervention and 9-month follow-up data. Intervention effects for clinically significant reduction were estimated using repeated-measures logistic regression. Regression models were estimated using generalized estimating equations using an independence working correlation matrix.[36] The omnibus hypothesis of no difference between the three intervention arms was tested using the modified Wald test,[37,38] estimating the covariance matrix using the sandwich estimator to account for any within-group correlation and within-person correlation over time. A small-sample adjustment[39] was employed because standard error estimates using the sandwich estimator with fewer than 40 groups are biased downward.[40,41]

Linear regression models were adjusted for baseline values of the relevant outcome, age, depression, 3MS score, analgesic use, hypnotic use, an indicator of whether the outcome was measured at 9 months, and the clinic at which the intervention was delivered. Sensitivity analyses including an interaction between treatment and month of observation were performed. Sensitivity analyses excluding participants in the class assigned to CBT-PI without randomization were performed.[23] Unadjusted effect sizes and appropriate 95% CIs were calculated accounting for correlation between participants in the same class.[42] Intraclass correlations (ICCs) calculated using postintervention assessment data are reported.[42] Baseline and analysis of session surveys were performed in SAS 9.2 (SAS Institute, Inc, Cary, NC); all other analyses were performed using Stata 11.1 (Stata Corp., College Station, TX).

Power for primary and secondary outcomes analyses was calculated assuming an ICC of 0.022, estimated from pain severity data from a prior group intervention trial. Because comparable data for other outcomes were unavailable, an equal ICC (0.022) was assumed. Assuming 122 individuals in each treatment arm, an ICC of 0.022, within-person correlation of 0.5 for the two follow-up visits, and a 90% retention rate at each assessment, the effective sample size was 127 in each treatment arm.[34,43] In the conservative case that an intervention effect is observed in only one of the two arms, the Wald test is equivalent to a two-sample

test comparing means. Detectable effect sizes were based on a two-sample z-test comparing means with 80% power and a two-sided test with a significance level of .05. The estimated detectable standardized effect size for Lifestyles was approximately 0.35, ignoring any gains in efficiency realized through adjustment for baseline scores.

## RESULTS

The Lifestyles Study included 367 participants (mean age 73.1; 78.5% female) assigned to three experimental arms (Figure 1).[23] Treatment arms did not differ significantly according to age, sex, ethnicity, education, or primary or secondary outcome measures at baseline (Table 1). Differences between treatment groups were observed in the proportion of participants using analgesics and hypnotics; for this reason, these covariates were adjusted for in all regression models. Nine-month retention rates were 89% for CBT-PI, 92% for CPT-P, and 98%, for EOC. The unadjusted ICCs of primary and secondary outcomes were 0.11 for insomnia severity, 0.10 for pain severity, 0.12 for sleep efficiency, and 0.09 for arthritis symptoms. The observed ICCs were considerably larger than those used to power the trial.

Average ratings of perceived suitability, acceptability, effectiveness, and trainer quality for all intervention arms at the end of the first class were high (means ranging from 5.1 to 6.1 on a 7-point scale), with CBT-P generally receiving the highest ratings. Average ratings of perceived suitability, acceptability, effectiveness, and trainer quality for all intervention arms at the posttreatment assessment continued to be high (means ranging from 4.1 to 6.0), with CBT-PI tending to have the highest ratings. Mean postintervention participant-perceived improvement in sleep and pain differed significantly between arms (EOC = 1.9 ± 0.9, CBT-P = 2.4 ± 1.0, CBT-PI = 2.8 ± 1.1, $P < .001$, on a 5 point scale), with the CBT-PI arm rated highest.

Raw means for the primary and secondary outcomes at baseline, postintervention, and 9 months for the three intervention arms are presented in Figure 2. Unadjusted baseline, adjusted postintervention and 9-month means, adjusted mean 9-month change from baseline, and treatment effect estimates are presented in Table 2. Insomnia severity decreased for all participants. Pain severity decreased slightly for all participants. Sleep efficiency increased for CBT-P and CBT-PI participants and decreased for EOC participants. All participants had higher arthritis symptom scores, indicating higher function and less pain than at baseline.

The modified Wald test to evaluate the hypothesis of no difference between the three intervention arms was rejected at the .05 level for insomnia severity and sleep efficiency but not for pain severity or arthritis symptoms (Table 2). CBT-PI participants had significantly greater improvements in insomnia severity than those in EOC and CBT-P. Adjusted treatment effect estimates were −1.89 (95% CI = −2.83 to −0.96; $P < .001$) and −2.03 (95% CI = −3.01 to −1.04; $P < .001$), respectively. The estimated treatment effect for insomnia severity comparing CBT-P with EOC was 0.13 (95% CI = −0.89–1.16; P = .80). The estimated treatment effect for pain severity was 0.082 (95% CI = −0.21–0.38) comparing CBT-P with EOC and −0.095 (95% CI = −0.37–0.18) comparing CBT-PI with EOC.

CBT-PI and CBT-P were associated with significantly greater sleep efficiency than EOC. The estimated treatment effect for sleep efficiency was 2.91 (95% CI = 0.85–4.97; P = .006) comparing CBT-P with EOC and 2.64 (95% CI = 0.44–4.84; P = .02) comparing CBT-PI with EOC. Sleep efficiency was similar between CBT-PI and CBT-P participants. The treatment effect estimate for arthritis symptoms was −0.06 (95% CI = −0.39–0.28) comparing CBT-PI with EOC and 0.20 (95% CI = −0.26–0.66) comparing CBT-PI with EOC.

Study results were robust to sensitivity analyses for missing data and removing the nonrandomized group, indicating little bias resulting from a complete case analysis or including the nonrandomized treatment group in the primary analysis.

A planned subgroup analysis was performed on participants with baseline pain severity scores of at least 5.0. Somewhat stronger treatment effect sizes were observed for all but the arthritis symptoms scale in this analysis. Conclusions about statistical significance of treatment effects based on P-values remained the same in this subgroup analysis.

Table 3 summarizes the analysis results of clinically significant (30%) change from baseline for the primary outcomes: insomnia severity and pain severity.[25] These results are similar to the main analyses. The odds of having a clinically significant reduction in ISI was 2.72 (95% CI = 1.59–4.64) times as great in the CBT-PI arm as in the CBT-P and 2.20 (95% CI = 1.25–3.90) times as great as in the EOC arm. There was no statistically significant difference between any of the arms for a clinically significant reduction in pain severity. The same general pattern was observed in the severe baseline pain subgroup.

## DISCUSSION

Adding an insomnia treatment to behavioral pain therapy improved outcomes. CBT-PI was associated with more-favorable outcomes for self-reported insomnia severity over a 9-month assessment period than EOC and CBT-P. CBT-PI and CBT-P resulted in better sleep efficiency than EOC, although this improvement was based on a decline in sleep efficiency in the EOC arm. In the planned subgroup analysis of subjects with more-severe OA pain at baseline, a similar pattern comparing intervention groups was observed. These findings support previous smaller trials with less-rigorous control groups that have reported that CBT-I yields improved sleep outcomes in individuals with chronic pain.[19–22] Although improved sleep was not associated with significantly improved pain, the unadjusted effect size for improved pain in the CBT-PI group with severe pain was similar to previously reported results for CBT-I in individuals with OA.[22]

Contrary to some previous studies,[16] CBT-P alone did not improve pain outcomes, despite a validated CBT-P protocol,[23] positive participant expectations for all three treatment groups after the initial intervention class meeting and at the end of the intervention, and excellent intervention attendence.[23] Possible explanations for this include the inclusion of a highly credible control arm that controlled for potential nonspecific effects of a group behavioral intervention and screening-to-baseline regression to the mean of pain outcomes, such that pain severity was less at baseline assessment than at screening.[23] Prior studies have found CBT-P to be most effective for individuals with risk factors for pain-related functional disability (e.g., more-severe pain), but pain outcomes were no different in the subgroup analyses for persons with more-severe pain.[44] CBT-P resulted in greater sleep efficiency than EOC. Possible explanations may be that CBT-P included treatment components that might influence insomnia, including behavioral activation (more daytime activity) and relaxation training (less arousal).

This study had notable strengths, including a large population-based sample with frequent and multiple comorbidities in addition to insomnia and OA (Table 1), primary care clinic–based treatment delivery, low study attrition, ongoing monitoring of treatment fidelity,[23] and a highly credible attention control condition that was well received by study participants. The EOC arm, which controlled for information and nonspecific effects of group participation, was an important feature of the Lifestyles Study design.[23] It differed from many prior evaluations of CBT for insomnia or pain, which have often used wait-list, usual-care, or written-information control conditions. The EOC equalized attention and contact

time; was credible to participants, as measured according to high participation rates and self-report; and blinded participants to whether they received an active or control intervention, providing a rigorous test of whether the specific active interventions in the CBT-PI and CBT-P arms were efficacious.

Another important design feature and strength of the study was the use of a population-based screening within Group Health primary care clinics. This screening meant that persons with a broader spectrum of insomnia and pain severity and the comorbid illnesses common in older adults were enrolled in the Lifestyles Study than is typical in trials that recruit participants from specialty referral centers. This makes the results more generalizable to representative populations of people with OA seen in community practice, but it also resulted in people with less-severe OA pain being enrolled. Although results were obtained from a single health maintenance organization in western Washington state, potentially limiting generalizability, numerous behavioral interventions developed and evaluated in the Group Health population have been widely disseminated to diverse populations with comparable effectiveness (e.g.,[45–47]).

Some study limitations should be noted. It is conceivable that dividing focus between insomnia treatment and pain treatment in the CBT-PI intervention may have diluted the insomnia treatment efficacy of that integrated intervention arm. Lifestyles was designed as a population-based trial with broad entry criteria to treat OA-related insomnia and pain complaints in a primary care population and was designed to examine efficacy and effectiveness, rather than recruiting only the individuals with severe physiological insomnia typically treated in smaller efficacy-focused trials. Furthermore, exclusionary screening was done primarily through patient records and not according to clinical interview, such that it is possible that additional comorbidities in addition to those noted in Table 1 may have been present in the study sample. The composition of the study sample could well have diluted treatment efficacy. Regression to the mean by measures of pain between screening and study entry and much higher than anticipated ICCs may each have limited the ability to detect treatment-related changes in pain. Additionally, because *P*-values were not adjusted for multiple comparisons, the results of secondary outcomes and the subgroup analysis should be interpreted cautiously because of the potential for type 1 error.

These observations have potential implications for targeting interventions in primary care settings that deserve attention in future research. Future population-based trials might consider screening at two points in time to eliminate persons whose pain or insomnia spontaneously improves and similarly might consider the effect of high ICCs when conducting group interventions.

Adding an insomnia-specific therapy to a behavioral pain therapy improves outcomes. CBT-PI is effective in improving self-report and objective sleep quality in persons with OA over 9 months, even persons with significant comorbid pain.

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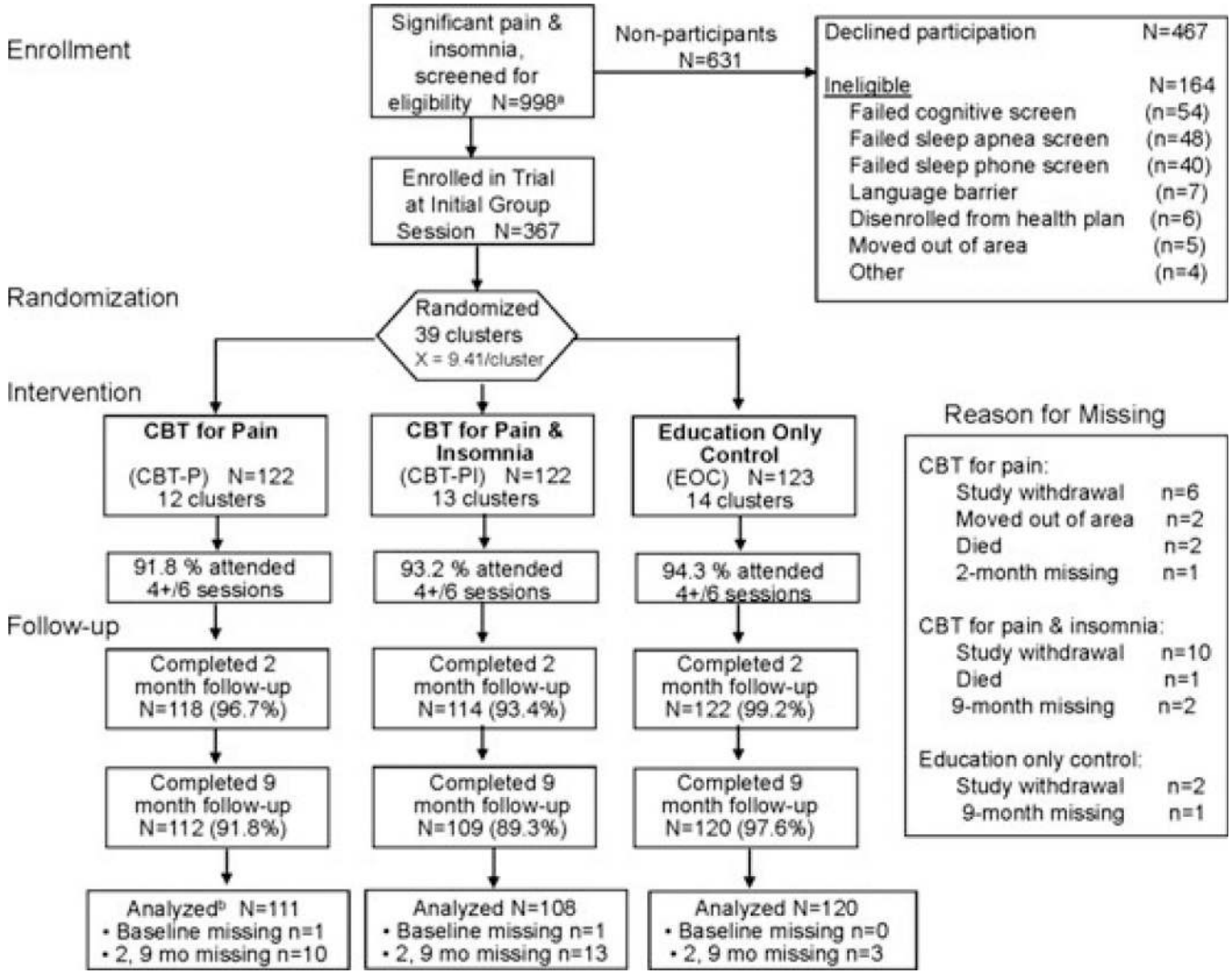


**Figure 1.**

CONSORT flow diagram for enrollment of potentially eligible participants. Eligible individuals were identified by screening survey of persons with osteoarthritis visits (N = 3,321); 1,210 respondents (36%) reported clinically significant arthritis pain and insomnia, and 998 of 1,210 persons initially eligible (82.5%) agreed to medical record review and contact by the study. “Baseline missing” is the number of individuals excluded because of missing baseline information; “2, 9 mo missing” is the number excluded because they were missing 2- and 9-month follow-up information. CBT-P = cognitive–behavioral therapy for pain; CBT-PI = cognitive–behavioral therapy for pain and insomnia; EOC = education-only control.

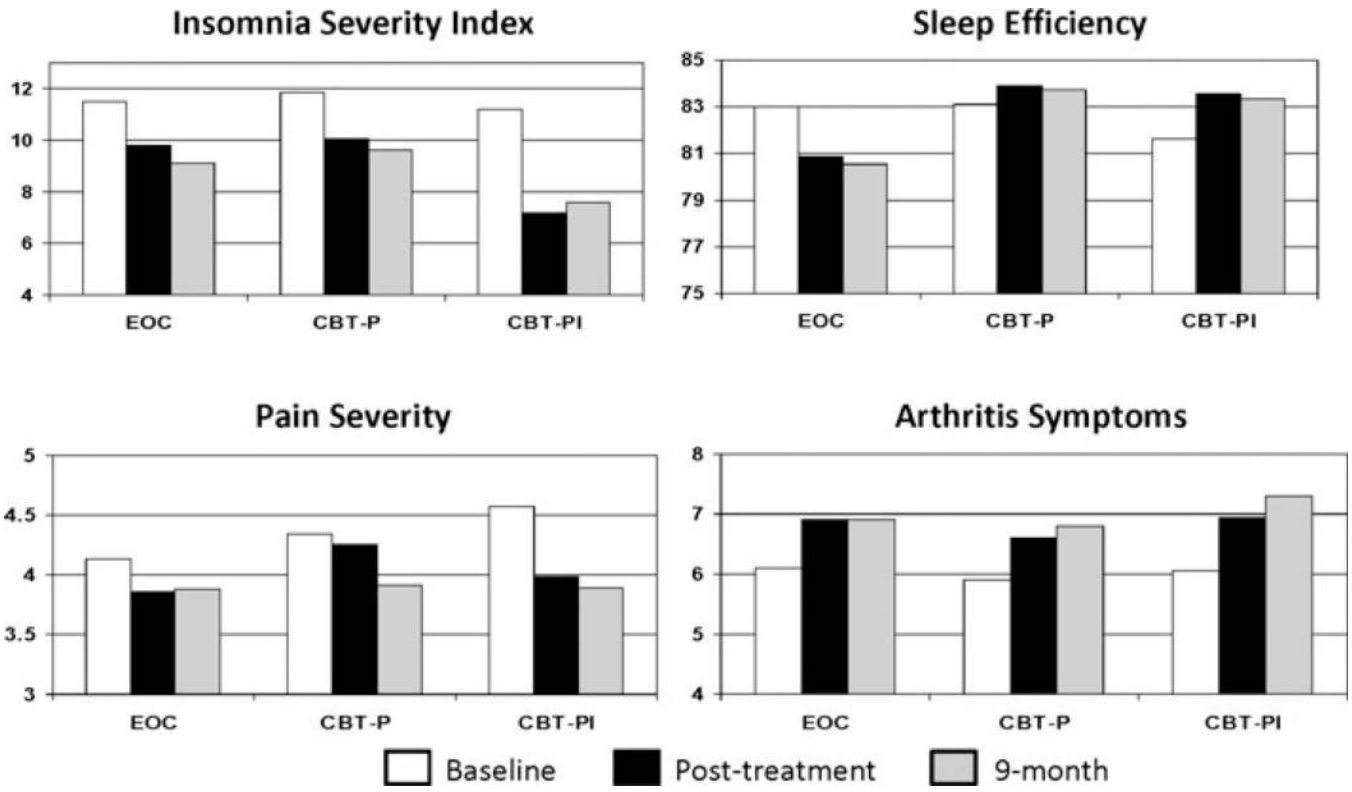


**Figure 2.**

Mean primary and secondary sleep and pain outcome scores at baseline, posttreatment, and 9-month assessments for the education-only control (EOC), cognitive–behavioral therapy for pain (CBT-P), and cognitive–behavioral therapy for pain and insomnia (CBT-PI) groups. Lower scores indicate improvement on Insomnia Severity Index and pain severity; higher scores indicated improvement on sleep efficiency and arthritis symptoms.

## Table 1

Baseline Values of Demographic, Health, Sleep, and Pain Measures for the Education-Only Control (EOC), Cognitive-Behavioral Therapy for Pain (CBT-P) and Cognitive-Behavioral Therapy for Pain and Insomnia (CBT-PI) Groups

| Measure | EOC, n = 123 | CBT-P, n = 122 | CBT-PI, n = 122 | P-Value[a] |
|---|---|---|---|---|
| Age, mean ± SD | 73.1 ± 8.0 | 73.0 ± 8.4 | 73.2 ± 8.1 | .97 |
| Female, % | 75.6 | 80.3 | 79.5 | .63 |
| Retired, % | 78.2 | 73.6 | 83.6 | .16 |
| Caucasian, % | 90.2 | 91.7 | 91.8 | .89 |
| Some college, % | 87.8 | 86.9 | 84.4 | .73 |
| Modified Mini-Mental State Examination score (range 0–100) | | | | |
| Mean ± SD | 93.1 ± 5.3 | 94.0 ± 4.8 | 93.3 ± 4.4 | .37 |
| < 90, % | 15.5 | 17.2 | 18.0 | .86 |
| Geriatric Depression Scale score (range 0–30) | | | | |
| Mean ± SD | 7.0 ± 5.6 | 6.6 ± 4.5 | 6.5 ± 5.1 | .64 |
| >14, % | 17.1 | 9.1 | 9.8 | .11 |
| Chronic illness, % | 49.6 | 49.2 | 59.8 | .17 |
| Medications, % | | | | |
| Antidepressants | 17.1 | 23.8 | 26.5 | .19 |
| Antipsychotics | 0 | 0.8 | 0.8 | .60 |
| Anxiolytics | 8.1 | 9.0 | 12.4 | .50 |
| Hypnotics | 10.6 | 20.5 | 22.3 | .04 |
| Analgesics | 92.7 | 94.3 | 84.3 | .02 |
| Insomnia Severity Index (range 0–28) | | | | |
| Mean ± SD | 11.5 ± 5.1 | 11.8 ± 4.7 | 11.2 ± 5.2 | .60 |
| >15, % | 24.4 | 26.2 | 28.7 | .75 |
| Sleep efficiency, mean ± SD (range 0–100)[b] | 83.0 ± 8.9 | 83.1 ± 8.7 | 81.6 ± 9.1 | .37 |
| Total sleep time, mean ± SD[b] | 413.8 ± 66.6 | 430.2 ± 63.9 | 417.7 ± 73.6 | .16 |
| Total wake time, mean ± SD[b] | 85.3 ± 46.4 | 89.1 ± 47.9 | 93.9 ± 48.4 | .39 |
| Pain severity (range 0–10) | | | | |
| Mean ± SD | 4.1 ± 1.5 | 4.3 ± 1.6 | 4.6 ± 1.5 | .09 |
| >5, % | 33.3 | 35.3 | 42.6 | .28 |
| Arthritis symptoms, mean ± SD (range 0–10) | 6.1 ± 2.2 | 5.9 ± 2.3 | 6.1 ± 2.1 | .75 |
| Average pain, mean ± SD (range 0–10) | 4.7 ± 1.6 | 4.8 ± 1.6 | 4.9 ± 1.4 | .57 |
| Pain disability, mean ± SD (range 0–100) | 34.6 ± 23.2 | 36.0 ± 22.5 | 38.6 ± 22.2 | .38 |

SD = standard deviation.

[a] P-values are for chi-square tests for dichotomous variables and analyses of variance for continuous variables.

[b] Actigraphically derived.

**Table 2**

Modified Intention-to-Treat Analysis for Primary and Secondary Sleep and Pain Outcomes for the Entire Sample and for the Subgroup Analysis of Participants with Severe Pain at Baseline

| | Baseline | | Postintervention | | 9-Month Follow-Up | | A Baseline to 9 Months[3] | Treatment Effect[3] | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Measure | N | Mean (95% CI) | N | Adjusted Mean (95% CI)[b] | N | Adjusted Mean (95% CI)[b] | Adjusted Mean A (95% CI)[b] | Estimate (95% CI)[b] | Omnibus P-Value[c] | Pair-Wise P-Value[d] | Unadjusted Effect Size |
| Entire sample | | | | | | | | | | | |
| Insomnia severity | | | | | | | | | | | |
| EOC | 123 | 11.51 (10.61–12.42) | 122 | 10.39 (9.36–11.42) | 120 | 10.18 (8.96–11.40) | −1.35 (−2.57 to −0.13) | N/A | <.001 | N/A | |
| CBT-P vs EOC | 122 | 11.85 (11.01–12.69) | 117 | 10.53 (8.69–12.36) | 111 | 10.31 (8.33–12.29) | −1.21 (−3.19–0.76) | 0.13 (−0.89–1.16) | | .80 | 0.08 (−0.11–0.26) |
| CBT-PI vs EOC | 122 | 11.20 (10.28–12.13) | 113 | 8.50 (6.77–10.22) | 108 | 8.28 (6.43–10.13) | −3.24 (−5.09 to −1.39) | −1.89 (−2.83 to −0.96) | | <.001 | −0.40 (−0.59 to −0.21) |
| CBT-PI vs CBT-P | | | | | | | | −2.03 (−3.01 to −1.04) | | <.001 | −0.48 (−0.67 to −0.29) |
| Pain severity | | | | | | | | | | | |
| EOC | 123 | 4.13 (3.86–4.41) | 122 | 4.08 (3.68–4.48) | 120 | 3.96 (3.45–4.48) | −0.38 (−0.90–0.13) | N/A | **.54** | **N/A** | |
| CBT-P vs EOC | 122 | 4.34 (4.06–4.62) | 117 | 4.16 (3.64–4.69) | 111 | 4.04 (3.44–4.65) | −0.30 (−0.91–0.30) | 0.082 (−0.21–0.38) | | **N/A** | 0.13 (−0.05–0.32) |
| CBT-PI vs EOC | 122 | 4.57 (4.30–4.84) | 113 | 3.99 (3.45–4.52) | 108 | 3.87 (3.26–4.48) | −0.48 (v1.09–0.13) | −0.095 (−0.37–0.18) | | **N/A** | 0.04 (−0.15–0.23) |
| Sleep efficiency[e] | | | | | | | | | | | |
| EOC | 118 | 83.01 (81.40–84.63) | 115 | 81.02 (79.11–82.93) | 107 | 80.85 (78.70–83.00) | −1.74 (−3.88–0.41) | N/A | .006 | **N/A** | |
| CBT-P vs EOC | 114 | 83.09 (81.49–84.70) | 101 | 83.93 (80.85–87.00) | 93 | 83.76 (80.61–86.91) | 1.17 (−1.98–4.33) | 2.91 (0.85–4.97) | | .006 | 0.35 (0.15–0.54) |
| CBT-PI vs EOC | 112 | 81.62 (79.93–83.32) | 96 | 83.66 (80.05–87.28) | 94 | 83.49 (79.74–87.25) | 0.91 (−2.85–4.66) | 2.64 (0.44–4.84) | | **.02** | 0.31 (0.11–0.51) |
| CBT-PI vs CBT-P | | | | | | | | −0.26 (−2.82–2.29) | | **.84** | −0.04 (−0.25–0.16) |
| AIMS symptom subscale | | | | | | | | | | | |
| EOC | 123 | 6.10 (5.71–6.50) | 122 | 6.70 (6.32–7.07) | 120 | 6.86 (6.41–7.31) | 0.84 (0.38–1.29) | N/A | .53 | **N/A** | |

| | Baseline | | Postintervention | | 9-Month Follow-Up | | A Baseline to 9 Months[3] | Treatment Effect[3] | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Measure | N | Mean (95% CI) | N | Adjusted Mean (95% CI)[b] | N | Adjusted Mean (95% CI)[b] | Adjusted Mean A (95% CI)[b] | Estimate (95% CI)[b] | Omnibus P-Value[c] | Pair-Wise P-Value[d] | Unadjusted Effect Size |
| CBT-P vs EOC | 122 | 5.90 (5.49–6.31) | 117 | 6.64 (6.02–7.26) | 111 | 6.80 (6.12–7.48) | 0.78 (0.10–1.46) | −0.06 (−0.39–0.28) | | **N/A** | −0.10 (−0.28–0.08) |
| CBT-PI vs EOC | 121 | 6.06 (5.68–6.44) | 112 | 6.90 (6.17–7.64) | 107 | 7.06 (6.32–7.81) | 1.04 (0.29–1.79) | 0.20 (−0.26–0.66) | | **N/A** | 0.10 (−0.09–0.29) |
| Participants with severe pain at baseline | | | | | | | | | | | |
| Insomnia severity | | | | | | | | | | | |
| EOC | 41 | 13.51 (11.94–15.08) | 41 | 12.25 (10.05–14.46) | 40 | 12.14 (9.65–14.63) | −0.79 (−3.28–1.70) | N/A | **.01** | **N/A** | |
| CBT-P vs EOC | 43 | 12.67 (11.11–14.24) | 42 | 11.96 (8.12–15.80) | 41 | 11.84 (7.81–15.88) | −1.08 (−5.12–2.95) | −0.29 (−2.36–1.77) | | **.78** | −0.17 (−0.45–0.11) |
| CBT-PI vs EOC | 52 | 12.67 (11.25–14.09) | 48 | 9.55 (5.41–13.68) | 44 | 9.43 (5.18–13.68) | −3.50 (−7.75–0.75) | −2.71 (−4.91 to −0.51) | | .02 | −0.49 (−0.74 to −0.24) |
| CBT-PI vs CBT-P | | | | | | | | −2.42 (−4.15–0.68) | | .006 | −0.32 (−0.59 to −0.06) |
| Pain severity | | | | | | | | | | | |
| EOC | 41 | 5.89 (5.67–6.12) | 41 | 5.42 (4.69–6.16) | 40 | 5.29 (4.38–6.20) | −0.69 (−1.60–0.22) | N/A | .27 | N/A | |
| CBT-P vs EOC | 43 | 6.07 (5.78–6.36) | 42 | 5.26 (4.15–6.37) | 41 | 5.13 (3.96–6.30) | −0.85 (−2.02–0.32) | −0.16 (−0.68–0.37) | | N/A | 0.03 (−0.26–0.33) |
| CBT-PI vs EOC | 52 | 5.98 (5.77–6.19) | 48 | 4.98 (3.83–6.12) | 44 | 4.84 (3.64–6.04) | −1.14 (−2.34 to −0.06) | −0.44 (−1.00–0.11) | | N/A | −0.18 (−0.46–0.09) |
| Sleep efficiency[e] | | | | | | | | | | | |
| EOC | 41 | 81.24 (78.34–84.14) | 41 | 79.26 (75.86–82.66) | 36 | 78.88 (75.44–82.32) | −1.83 (−5.27–1.61) | N/A | .004 | N/A | |
| CBT-P vs EOC | 40 | 79.92 (76.19–83.65) | 32 | 84.70 (79.76–89.64) | 32 | 84.32 (79.75–88.90) | 3.62 (−0.96–8.19) | 5.45 (1.56–9.33) | | .006 | 0.50 (0.20–0.80) |
| CBT-PI vs EOC | 46 | 80.91 (78.36–83.46) | 40 | 82.94 (77.22–88.66) | 36 | 82.56 (76.43–88.70) | 1.86 (−4.28–7.99) | 3.69 (0.72–6.66) | | .01 | 0.44 (0.19–0.69) |
| CBT-PI vs CBT-P | | | | | | | | −1.76 (−6.10–2.58) | | .43 | −0.09 (−0.37–0.19) |
| AIMS symptom subscale | | | | | | | | | | | |
| EOC | 41 | 4.88 (4.26–5.49) | 41 | 5.60 (4.75–6.44) | 40 | 5.87 (4.89–6.86) | 1.01 (0.02–2.00) | N/A | .79 | N/A | |

| Measure | Baseline N | Baseline Mean (95% CI) | Postintervention N | Postintervention Adjusted Mean (95% CI)[b] | 9-Month Follow-Up N | 9-Month Follow-Up Adjusted Mean (95% CI)[b] | A Baseline to 9 Months[3] Adjusted Mean A (95% CI)[b] | Treatment Effect[3] Estimate (95% CI)[b] | Omnibus P-Value[c] | Pair-Wise P-Value[d] | Unadjusted Effect Size |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CBT-P vs EOC | 43 | 4.67 (3.95–5.39) | 42 | 5.64 (4.32–6.97) | 41 | 5.92 (4.52–7.32) | 1.06 (−0.34–2.45) | 0.05 (−0.60–0.69) | | N/A | −0.07 (−0.36–0.22) |
| CBT-PI vs EOC | 52 | 5.02 (4.45–5.58) | 48 | 5.87 (4.35–7.40) | 44 | 6.15 (4.55–7.75) | 1.29 (−0.31–2.88) | 0.28 (−0.55–1.10) | | N/A | 0.06 (−0.21–0.32) |

CI = confidence interval; N/A = not applicable; AIMS = Arthritis Impact Measurement Scale.

[a] Decrease indicates improvement for insomnia severity and pain severity; increase indicates improvement for sleep efficiency and arthritis symptoms.

[b] Means and treatment effect estimates adjusted for baseline values of relevant outcome, age, depression, modified Mini-Mental State Examination score, analgesic use, hypnotic use, an indicator of whether the outcome was measured at 9 months, and the clinic at which the intervention was delivered.

[c] P-value for omnibus Wald test employing both posttreatment visits (postintervention and 9 months) controlled for baseline values, depression, cognitive status, opioid and hypnotic medication use, and clinic.

[d] Pair-wise P-values for cognitive–behavioral therapy for pain (CBT-P) minus education-only control (EOC), cognitive–behavioral therapy for pain and insomnia (CBT-PI) minus EOC, and CBT-PI minus CBT-P. P-values correspond to a two-sided test of the null hypothesis that the difference between the two means is 0.

[e] Sample size differs for sleep efficiency analysis because some actigraphic data were lost because of recording failure; this equipment failure was completely at random. Participants were required to have a minimum of 3 nights of actigraphy data to be included in the analysis (range 3–7 days, mean 6.88 at baseline, 6.83 at posttreatment, and 6.89 days at 9-month assessments).

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**Table 3**

Modified Intention-to-Treat Analysis for Clinical Significance of Primary Outcomes for the Entire Sample and for the Subgroup Analysis of Participants with Severe Pain at Baseline

| | Postintervention | | 9-Month Follow-Up | | Treatment Effect | | |
|---|---|---|---|---|---|---|---|
| Measure | N | With 30% Reduction, n (%) | N | With 30% Reduction, n (%) | OR (95% Confidence Interval)[c] | Omnibus P-Value[a] | Pair-Wise P-Value[b] |
| Entire sample | | | | | | | |
| Insomnia severity | | | | | | | |
| EOC | 122 | 36 (29.5) | 120 | 49 (40.8) | N/A | <.001 | N/A |
| CBT-P vs EOC | 117 | 33 (28.0) | 111 | 40 (35.7) | 0.81 (0.48–1.36) | | .43 |
| CBT-PI vs EOC | 113 | 62 (52.4) | 108 | 55 (50.5) | 2.20 (1.25–3.90) | | .007 |
| CBT-PI vs CBT-P | | | | | 2.72 (1.59–4.64) | | <.001 |
| Pain severity | | | | | | | |
| EOC | 122 | 21 (17.2) | 120 | 29 (24.2) | N/A | .77 | N/A |
| CBT-P vs EOC | 117 | 20 (17.0) | 111 | 23 (20.5) | 0.79 (0.39–1.60) | | N/A |
| CBT-PI vs EOC | 113 | 23 (20.2) | 108 | 30 (27.5) | 0.96 (0.55–1.68) | | N/A |
| Participants with severe pain at baseline | | | | | | | |
| Insomnia severity | | | | | | | |
| EOC | 41 | 13 (31.7) | 40 | 16 (40.0) | N/A | .04 | N/A |
| CBT-P vs EOC | 42 | 13 (30.2) | 41 | 15 (35.7) | 0.75 (0.27–2.07) | | .58 |
| CBT-PI vs EOC | 48 | 25 (52.1) | 44 | 23 (52.3) | 2.41 (0.93–6.21) | | .07 |
| CBT-PI vs CBT-P | | | | | 3.21 (1.22–8.43) | | .02 |
| Pain severity | | | | | | | |
| EOC | 41 | 10 (24.4) | 40 | 10 (25.0) | N/A | .79 | N/A |
| CBT-P vs EOC | 42 | 9 (20.9) | 41 | 12 (28.6) | 1.18 (0.49–2.85) | | N/A |
| CBT-PI vs EOC | 48 | 11 (22.9) | 44 | 14 (31.8) | 1.36 (0.57–3.24) | | N/A |

N/A = not applicable.

[a] *P*-value for omnibus Wald test employing both posttreatment visits (postintervention and 9-months) controlled for baseline values, depression, cognitive status, opioid and hypnotic medication use, and clinic.

[b] Pair-wise *P*-values for cognitive–behavioral therapy for pain (CBT-P) minus education-only control (EOC), cognitive–behavioral therapy for pain and insomnia (CBT-PI) minus EOC, and CBT-PI minus CBT-P. *P*-values correspond to a two-sided test of the null hypothesis that the difference between the two means is 0.

[c]Odds ratio (OR) estimates from repeated-measures logistic regression adjusted for baseline values of relevant outcome, age, depression, modified Mini-Mental State Examination score, analgesic use, hypnotic use, an indicator of whether the outcome was measured at 9 months, and the clinic at which the intervention was delivered.