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Short-term improvement in insomnia symptoms predicts long-term improvements in sleep, pain, and fatigue in older adults with comorbid osteoarthritis and insomnia

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ABSTRACT

In a primary care population of 367 older adults (aged ⩾60 years) with osteoarthritis (OA) pain and insomnia, we examined the relationship between short-term improvement in sleep and long-term sleep, pain, and fatigue outcomes through secondary analyses of randomized controlled trial data. Study participants, regardless of experimental treatment received, were classified either as improvers (⩾30% baseline to 2-month reduction on the Insomnia Severity Index [ISI]) or as nonimprovers. After controlling for treatment arm and potential confounders, improvers showed significant, sustained improvements across 18 months compared with nonimprovers in pain severity ($P < 0.001$, adjusted mean difference = −0.51 [95% CI: −0.80, −0.21), arthritis symptoms ($P < 0.001$, 0.63 [0.26, 1.00]), and fear avoidance ($P = 0.009$, −2.27 [−3.95, −0.58]) but not in catastrophizing or depression. Improvers also showed significant, sustained improvements in ISI ($P < 0.001$, −3.03 [−3.74, −2.32]), Pittsburgh Sleep Quality Index Total ($P < 0.001$, −1.45 [−1.97, −0.93]) and general sleep quality ($P < 0.001$, −0.28 [−0.39, −0.16]) scores, Flinders Fatigue Scale ($P < 0.001$, −1.99 [−3.01, −0.98]), and Dysfunctional Beliefs About Sleep Scale ($P = 0.037$, −2.44 [−4.74, −0.15]), but no improvements on the Functional Outcomes of Sleep Questionnaire or the Epworth Sleepiness Scale. We conclude that short-term (2-month) improvements in sleep predicted long-term (9- and 18-month) improvements for multiple measures of sleep, chronic pain, and fatigue. These improvements were not attributable to nonspecific benefits for psychological well-being, such as reduced depression. These findings are consistent with benefits of improved sleep for chronic pain and fatigue among older persons with osteoarthritis pain and comorbid insomnia if robust improvements in sleep are achieved and sustained. Trial Registration: ClinicalTrials.gov Identifier: NCT01142349.

1. Introduction

A growing literature suggests that poor nighttime sleep is associated with reduced pain and increased next-day pain reports [15,19,34,36]. If so, improving sleep in pain populations might improve chronic pain outcomes [31]. Several trials evaluating cognitive behavioral therapy for insomnia (CBT-I) in pain populations have found improved sleep outcomes, but the benefits of CBT-I for pain outcomes have been inconsistent [6,10,18,39]. However, these studies had significant limitations, including small sample sizes, inadequate controls, recruitment of convenience samples, and short follow-ups, making it difficult to draw clear conclusions on the impact of improved sleep on pain.

Recently, we reported results from Lifestyles, a randomized controlled trial of CBT for pain and insomnia (CBT-PI) among older

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adults with comorbid osteoarthritis pain and insomnia [22,38]. The Lifestyles trial had notable strengths: a large, population-based sample (N = 367); broad eligibility criteria; primary care treatment delivery; high participant retention; and a highly credible, well-accepted attention control. Over a 9-month assessment period, combination CBT-PI was associated with more favorable outcomes for insomnia severity than either CBT for pain alone (CBT-P) or control [38]. However, at 18 months benefits were nonsignificant for all treatment arms [22]. Post hoc analyses of participants with greater baseline insomnia and pain severity showed significant reductions in pain for CBT-PI compared with CBT-P and moderate, albeit nonsignificant, treatment effects for insomnia severity and sleep efficiency in the CBT-PI group [22]. Further, although unadjusted effect sizes for sleep and pain were attenuated over time, they were greater at 18 months for both outcomes for CBT-PI compared with the other 2 treatment arms [22]. Thus Lifestyles trial results showed a pattern of treatment estimates consistent with the a priori hypothesis that improving sleep could improve pain.

The failure to find statistically significant and sustained improvements may have resulted from trial limitations [22,38] including: (1) many participants had relatively mild pain and insomnia at study entry, attributable to screening to baseline regression to the mean; and (2) greater than planned intraclass correlations of pain and sleep because of group-based interventions, which reduced the effective sample size of the trial [1,28]. Given these unanticipated limitations, it is possible that Lifestyles was unable to detect clinically meaningful benefits of CBT-PI for sleep and pain outcomes, particularly among patients with less severe insomnia at baseline. Fortunately, the Lifestyles trial provides an opportunity to assess the relationship of short-term sleep improvement, regardless of experimental treatment received in the trial, with long-term sleep, pain, and fatigue outcomes, by comparing persons from all treatment groups whose sleep improved in the short term with those whose sleep did not improve.

Here we report secondary analyses of Lifestyles data, testing the hypotheses that short-term (2-month) improvements in sleep predict long-term benefits in sleep, pain, and fatigue outcomes over 9–18 months.

2. Methods

The Lifestyles trial was a double-blind, cluster-randomized, controlled trial of a 6-week cognitive behavioral pain coping skills intervention (CBT-P), CBT-PI, and an education-only attention control, all delivered as group interventions to improve sleep and pain outcomes. The study was approved by Group Health, an integrated practice health care management organization in Western Washington State, and University of Washington institutional review boards. Study recruitment began January 2009 and the last 18-month assessment was made May 2012. Details describing Lifestyles' study design rationale, recruitment, screening, randomization procedures, and intervention protocols have been published elsewhere [23,42], as have the primary outcome results from initial (post-treatment and 9-month) and long-term (18-month) assessments [22,38].

2.1. Participants

Three hundred sixty-seven Western Washington members of Group Health, aged ⩾60 years, were enrolled in the Lifestyles trial (Fig. 1). When screened for trial eligibility, all participants had clinically significant pain and insomnia. Significant arthritis pain was defined by Grade II, III, or IV pain on the Graded Chronic Pain Scale [41]. Significant insomnia was defined by self-reported sleep difficulties (trouble falling asleep, difficulty staying asleep, waking up too early, or waking up unrefreshed) 3 or more nights per week during the past month with at least 1 daytime sleep-related problem, consistent with established research diagnostic criteria [8].

Exclusion criteria were initially determined through electronic health records and included a 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 [42]. Additional screening occurred during telephone contact by study staff; potentially eligible subjects with a score of ⩾7 on the Blessed Short Orientation Memory and Concentration Test or with a score >32 on the sleep apnea subscale of the Sleep Disorders Questionnaire were also excluded, as well as those who self-reported any of the following limitations or chronic conditions: unable to read a newspaper; difficulty hearing in a group situation; unable to walk across a room without help; and persons reporting the following chronic conditions: periodic leg movement disorder; rapid eye movement behavior disorder; sleep apnea; Parkinson's disease; rheumatoid arthritis [42].

2.2. Comparison groups

For the current analyses, the 367 Lifestyles participants, regardless of randomly assigned treatment arm, were defined either as improvers (⩾30% baseline to 2-month [post-treatment] reduction on the Insomnia Severity Index [ISI]) or as nonimprovers. We employed a ⩾30% reduction in the ISI to identify improvers based on a convention established for defining clinically significant improvement in pain severity [7], since a standard for identifying clinically significant improvement has not been defined for sleep outcomes.

2.3. Data collection

Baseline, 2-month (post-treatment), and 9- and 18-month follow-up assessments were each carried out at 2 visits to participants' homes 1 week apart. Actigraphy and sleep diary data were collected during the intervening week.

2.4. Measures

2.4.1. Pain outcomes

- *Pain severity:* Six Graded Chronic Pain Scale [41] items assessing arthritis pain intensity (average pain, worst pain, pain right now), and interference with usual work, recreational, social, and family activities (possible range 0–10; higher is worse).
- *Arthritis symptoms*: A 3-item arthritis symptom subscale from the Arthritis Impact Measurement Scales Version 2, Short Form, Revised [14,24,29], which queried 3 pain-related questions: How often did you have severe pain from your arthritis? How often did your morning stiffness last more than 1 hour from the time you woke up? How often did your pain make it difficult for you to sleep? (possible range 1–10, higher is better).
- *Catastrophizing*: The Pain Catastrophizing Scale [33] consists of 13 items describing different thoughts and feelings that individuals may experience when they are in pain (possible range 0–52, higher is worse).
- *Fear avoidance*: Participants completed a 10-item version of the Tampa Scale for Kinesiophobia [5,25,40]. This measures fear of movement, pain, and injury on a 4-point scale (possible range 17–68, higher is worse).

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