
Design: Randomized clinical trial

Population/sample size/setting:
- 60 patients (27 men, 33 women, mean age 45) treated for insomnia secondary to chronic pain in a rehabilitation facility in Ottawa
- Eligibility criteria were nonmalignant pain of musculoskeletal origin, age under 60, reported sleep difficulties, and willingness to undergo random assignment to one of the experimental conditions
- Exclusion criteria were major medical or psychiatric comorbidities (e.g., major depression) and fibromyalgia
- Diagnoses of insomnia were made by doctoral students in clinical psychology using interviews based on DSM-IV and on a structured interview for sleep disorders from the DSM-III-R; eligibility required meeting DSM-IV criteria for insomnia secondary to a general medical condition of chronic pain

Main outcome measures:
- After baseline assessment, patients were randomized to either cognitive-behavioral therapy (CBT, n=32) or to a waiting list control (WLC, n=30)
- CBT was provided in the form of seven weekly 2-hour group sessions (5 to 7 participants); sessions included basic education about sleep, and emphasized sleep restriction and stimulus control as the basic interventions, with relaxation training provided as an additional skill
- CBT sessions were conducted by doctoral candidates in psychology, with supervision weekly (by unspecified supervisors)
- WLC group kept a sleep diary for the same 7 weeks that the CBT group had its therapy; each participant was contacted by phone weekly for 10 minutes to encourage adherence with diary completion
- Primary outcome measures were based on the sleep diaries and were related to different dimensions of sleep, mainly total sleep time, time in bed, sleep onset latency, number of awakenings, wake time after sleep onset, and sleep efficiency (sleep time/time in bed)
- Actigraph units were worn on the nondominant wrist to monitor movements during the night for 2 consecutive nights; these were compared at the end of the 7 week treatment program and again at a 3 month follow-up assessment
- The Pittsburgh Sleep Quality Index (PSQI) was used as a global measure of sleep quality; this is a 19 item questionnaire asking about the participant’s sleep quality for the past month; scores of 6 or higher are indicative of poor sleep quality
- Pain severity was assessed with the Multidimensional Pain Inventory Pain Severity scale (MPI-PS), which scores three items on a 7 point scale: present pain level, average pain severity over the past week, and extent of suffering because of pain
Medication Quantification Scale (MQS) is calculated by taking a consensus-based detriment weight for a given pharmacologic class and multiplying it by a score for dosage; MQS was measured to determine if use of prescription medication had been affected by the study interventions.

Sleep diary records showed that CBT group was superior to WLC group in post-treatment sleep onset latency, sleep efficiency, wake after sleep onset, and PSQI; these advantages were observed again at the 3 month follow-up.

The groups did not differ significantly in total sleep time, pain severity, or MQS.

Nocturnal motor activity changed among CBT participants between baseline and post-treatment, but did not change in the WLC group.

Authors’ conclusions:
- CBT can relieve insomnia secondary to chronic pain
- Even though complete remission of insomnia was not attained by most patients in the CBT group, it was possible to reduce the severity of insomnia with nonpharmacological interventions
- The critical components of the treatment package were not determined; the relative contribution of group factors (peer support, etc.) and informational factors could not be distinguished; it is possible that some patients could benefit from a self-administered course of insomnia therapy and not require a group intervention
- Future attention needs to be directed toward other measures of improved function, such as daytime functioning and quality of life

Comments:
- Although numerous primary and secondary outcomes were tested, statistical significance testing was done using a conservative correction for multiple comparisons, and the group differences which were reported are probably robust
- Randomization and allocation concealment appear adequate; the fact the allocation was done after completion of the baseline assessment can be taken as satisfying its concealment; selection bias is unlikely
- Blinding could not be done, and there is some risk of bias from this source
- As the authors concede, daytime functioning was not measured, and this is not necessarily determined by the sleep measures which were used in the study
- The doctoral candidates who conducted the CBT sessions were supervised, but the qualifications of the supervisors were not specified; it is not clear what level of training is required to administer group CBT for insomnia
- The version of the MQS which was used for medication use was the one published in 1992; this was revised in 1998 (and further updated in 2003) and the revision should have been available for the 2000 study

Assessment: adequate for evidence that CBT can reduce the severity of insomnia in chronic pain patients.