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Comparative Effectiveness of CBT Interventions for Co-Morbid Chronic Pain & Insomnia: A Pilot Study

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Abstract

Introduction—Chronic pain is difficult to treat and often precedes or exacerbates sleep disturbances such as insomnia. Insomnia, in turn, can amplify the pain experience. Both conditions are associated with inflammatory processes, which may be involved in the bidirectional relationship between pain and sleep. Cognitive behavioral therapy (CBT) for pain and CBT for insomnia are evidence based interventions for, respectively, chronic pain and insomnia. The study objectives were to determine the feasibility of combining CBT for pain and for insomnia and to assess the effects of the combined intervention and the stand alone interventions on pain, sleep, and mood outcomes compared to a control condition.

Methods—Twenty-one adults with co-occurring chronic pain and chronic insomnia were randomized to either CBT for pain, CBT for insomnia, combined CBT for pain and insomnia, or a wait-list control condition.

Results—The combined CBT intervention was feasible to deliver and produced significant improvements in sleep, disability from pain, depression and fatigue compared to the control condition. Overall, the combined intervention appeared to have a strong advantage over CBT for pain on most outcomes, modest advantage over both CBT for insomnia in reducing insomnia severity in chronic pain patients.

Discussion—CBT for pain and CBT for insomnia may be combined with good results for patients with co-occurring chronic pain and insomnia.

Keywords

Cognitive-behavioral therapy; Sleep; Insomnia; Pain; Chronic pain; Comparative effectiveness

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Chronic pain and chronic insomnia are each independently linked to disability (Katz, 2002; Kupperman, Lubeck, & Mazonson, 1995), medical morbidity (Suka, Yoshida, & Sugimori, 2003; Mander, Colecchia, Spiegel, & Van Cauter, 2001; Ryden, Knutson, Mander, & Van Cauter, 2002), psychiatric morbidity (Ford & Kamerow, 1989; Wilson, Mikail, D'Eon, & Minns, 2001) and decrements in quality of life (Skevington, Carse, & Williams, 2001; Smith, Carmody, & Smith, 2000; Zammit, Weiner, Damato, Sillup, & McMillan, 1999). The co-occurrence of pain and sleep problems is quite pronounced; 50–70% of chronic pain patients complain of significant sleep disturbance (Smith, Perlis, Smith, Giles, & Carmody, 2000; Allen, Renner, DeVellis, Helmick, & Jordan, 2008; Becker et al., 1997; Menefee et al., 1998; Morin, Gibson, & Wade, 1998) and consider it a major quality of life issue (Casarett, Karlawish, Sankar, Hirschmann, & Asch, 2001; Menefee et al., 2000). Both experimental and clinical data suggest that sleep and pain have a complex, bi-directional relationship wherein pain contributes to disrupted sleep, and sleep disturbance enhances pain perception (Chiu et al., 2005; Lautenbacher, Kundermann, & Krieg, 2006; Moldofsky, 2001; Smith & Haythornthwaite, 2004; Drewes, 1999; Turk & Cohen, 2009). As several of these authors posit, a vicious cycle can ensue whereby poor sleep lowers pain thresholds, which in turn contributes to hyperalgesia, which in turn increases the incidence and/or severity of insomnia.

These complexities create barriers for effective chronic pain management. Indeed, systemic reviews of chronic pain management strategies suggest that despite efficacy, the effect sizes for cognitive-behavioral therapy for pain (CBT-P) (Eccleston, Williams, & Morley, 2009), non-steroidal anti-inflammatory drugs (Roclofs & Deyo, 2008) and long term opiate use (Noble et al., 2010) are small, and that even the small-moderate effects of opioids are outweighed by increased risks of adverse events (Nuesch, Rutjes, Husni, Welch, & Juni, 2009).

Conversely, CBT for insomnia (CBT-I) is associated with large effects on sleep disturbance in the context of chronic pain, although pain itself is only minimally improved (Currie, Wilson, Pontefract, & deLaplante, 2000; Rybarczyk et al., 2005; Edinger, Wohlgemuth, Krystal, & Rice, 2005; Jungquist et al., 2010; Vitiello, Rybarczyk, von Korff, & Stepanski, 2009). Vitiello and colleagues (2009) have provided a conceptual model of how CBT-I might break the vicious pain-sleep cycle. CBT-I is a multi-component behavioral therapy that is usually comprised of two core behavioral treatments (sleep restriction and stimulus control) along with sleep education, sleep hygiene instructions, sleep specific cognitive therapy, and relaxation training. Sleep restriction therapy requires patients to limit the amount of time they spend in bed to an amount equal to their average total sleep time for a period of time (typically one week). When sleep proves to be efficient, total sleep time is incrementally increased on a week-to-week basis. Stimulus control therapy includes rationale and instructions to 1) restrict the behaviors that occur in the bedroom to sleep and sex, 2) limit the amount of time patients spend awake in bed or the bedroom, and 3) promote counter conditioning by insuring that the bed and bedroom environment are tightly coupled with sleepiness and sleep. It remains to be shown whether combining CBT approaches for pain and for sleep may produce greater improvements in pain and sleep outcomes compared to either approach in isolation.

The current pilot study was undertaken to: 1) establish the feasibility of delivering a form of CBT that combined standard CBT approaches for pain and for insomnia into one intervention and 2) test the efficacy of the combined intervention and singular CBT interventions for insomnia and for pain on pain, sleep, and mood outcomes. It was hypothesized that each study intervention would be associated with significant improvements on their target symptoms compared to a waitlist control condition with the most robust findings produced by the combined intervention.

METHOD

Study Sample

This randomized, open-label, parallel-arm, pilot study was conducted with institutional review board approval at the University of Rochester Medical Center. Men and women aged 35–75 experiencing chronic pain and insomnia were recruited from the community through newspaper advertisements and from local pain clinics via recruitment flyers. A total of 28 individuals were enrolled following a written informed consent process prior to participation. Following informed consent, participants completed an intake interview and baseline measures; had a physical examination with electrocardiogram, clinical chemistries and toxicology screens; completed daily pain-sleep diaries for two weeks; and then underwent a standard overnight polysomnography screen. Seven subjects were excluded prior to randomization (4 due to sleep apnea upon polysomnography screening, 1 did not meet pain severity criteria, and 2 subsequently declined to participate). Twenty-one subjects (14 women/7 men; 1 black/20 white/0 Hispanic; mean age = 50.7 ± 8.3) were randomized and received an intervention or were wait-listed after meeting the inclusion/exclusion criteria: chronic (≥ 6 months) non-malignant pain originating in the spine, shoulders, hips or limbs unrelated to autoimmune disease or fibromyalgia; insomnia defined as ≥ 30 minutes sleep latency and/or minutes awake after sleep onset for > 3 days/wk for ≥ 6 months) reported to originate after, and/or aggravated by the pain condition; preferred sleep phase between 10 pm and 8 am; apnea-hypopnea index < 10 ; no evidence of other intrinsic sleep disorders; stable pain treatment with no prior experience with CBT for pain; no current insomnia treatment; and otherwise medically and psychiatrically stable.

Outcome Measures

Primary outcomes measures included the 7-item Insomnia Severity Index (Bastien, Vallieres, & Morin, 2001; Morin, 1993); the 3-item pain severity scale of the Multidimensional Pain Inventory (Turk & Rudy, 1988); and the Center for Epidemiologic Studies Depression Scale-revised (Eaton, Smith, Ybarra, Muntaner, & Tien, 2004). Secondary outcomes included the Epworth Sleepiness Scale (Chervin, Aldrich, Pickett, & Guilleminault, 1997); one week mean values of daily sleep diary variables including total wake time (TWT), total sleep time (TST), and percent sleep efficiency (SE), the latter defined as the ratio of TST to total time in bed; the Pain Disability Index (Tait, Chibnall, & Krause, 1990); and the Multidimensional Fatigue Inventory (Smets, Garssen, Bonke, & De Haes, 1995).

Procedures

Following polysomnography, eligible subjects were randomized using a computer generated stratified, block randomization scheme in blocks of 2 (except for the final block which contained only 1 subject) to: (i) one of four study arms: wait-list control (WL; $n = 4$); CBT-P ($n = 5$); CBT-I (6); or the combined intervention (CBT-I/P; $n = 6$) and (ii) one of two therapists.

Each intervention consisted of a structured, 10-session protocol delivered in weekly individual sessions by one of two experienced CBT psychologists familiar with both CBT-I and CBT-P, who each provided approximately half of the interventions in each condition. CBT-P included pain psychophysiology education, relaxation training, pacing, pain-specific cognitive therapy, activity planning, problem-solving, communication skills, flare-up planning and relapse prevention. CBT-I included sleep education, sleep restriction therapy, stimulus control therapy, sleep hygiene, sleep-specific cognitive therapy, relaxation training, and relapse prevention. CBT-I/P included all components of the respective therapies. All sessions were videotaped and subsequently rated using a treatment fidelity instrument

created internally for this study. All participants (including those in WL condition) completed daily sleep diaries throughout the intervention period and completed the self-report outcome measures and had blood drawn following the 10-week intervention period. Study instruments were administered by research assistants blinded to condition.

Statistical Analysis

Since all 21 subjects randomized completed the study there were no missing data at the macro level. Self-report data were checked for completeness at each assessment so that any missing items were completed or corrected by participants at that time.

As the study involved a longitudinal design, the generalized estimating equations (GEE) was utilized to provide statistical inference. The GEE approach is widely used due to its less stringent distributional assumptions and robustness properties, yielding valid inference regardless of the data distribution (Kowalski & Tu, 2008). Thus, GEE provides more robust inference than the other popular generalized linear mixed-effects model, as the latter imposes analytic distributions that are often at odds with the distributions of data observed in some sleep instruments. As there was no missing data in the variables analyzed, the missing data issue does not arise.

To test for time by intervention effects, each treatment condition (CBT-P, CBT-I, and CBT-I/P) was compared to the WL control condition on each outcome variable. Scores across the two time points (pre- and post-treatment) were assessed using GEE in regression analyses with exchangeable or other working correlations as appropriate to address the correlated responses in the data. All analyses controlled for age and baseline depression (from the CES-D-R), which were treated as continuous covariates. The results were reported as mean $\pm$ SE; p-values (two-sided) are presented, but alpha values for statistical significance were corrected for multiple comparisons using the false discovery rate (Benjamini & Hochberg, 1995). All analyses were performed using SAS 9.3 version (SAS Institute, Inc., Cary, NC).

In addition, within-group effect sizes were calculated for each intervention and between-group effects calculated comparing each CBT intervention to the control condition. Given the small sample sizes, treatment effects are presented as Hedge's *g* (Hedges, 1981), which is a more conservative approach than Cohen's *d* (Cohen, 1988).

RESULTS

Compared to the WL control condition, the CBT-P intervention was not associated with any significant improvements, although the largest effects on pain outcomes were observed in this condition (see Table 1). In contrast, compared to the WL condition, both the CBT-I and the CBT-I/P interventions were associated with significant improvements in primary outcomes of insomnia severity and depression severity. After adjusting for multiple comparisons no secondary outcomes met significance tests in between-group comparisons. All intervention groups experienced some within-group improvements in pain disability (effect sizes ranging from 0.49 to 1.21), though these were not significant when compared to WL. The effect sizes listed in Table 1 provide one way to gauge the comparative effectiveness of the interventions.

DISCUSSION

Among patients with co-morbid pain and insomnia, CBT interventions explicitly addressing insomnia were superior to CBT-P alone in affecting sleep, depression and fatigue. Although the combined intervention was feasible to deliver, it was not associated with greater improvements in pain as assessed by the MPI or the PDI. The latter finding is not altogether

surprising given that effect sizes for even pain-specific CBT treatments tend to be small (Eccleston et al., 2009). Nonetheless, given that the combined intervention had the greatest observed effect on insomnia severity and that the CBT-P intervention had a larger effect on pain outcomes than CBT-I, we would expect the combined intervention to have the largest effects on pain outcomes. Even if a ceiling effect exists with respect to pain outcomes, we might still expect the combined intervention approximate the CBT-P effects on pain. One speculation with respect to this somewhat disparate finding is that individuals in the conditions that included CBT-I may have engaged in more physical activity as their sleep improved, which led to pain flare-ups. Participants provided some anecdotal reports to their therapists consistent with this view, although this was not measured. We noted similar observations in a previous study of CBT-I in chronic pain patients, which also reported limited improvements in pain outcomes (Jungquist et al., 2010). While this explanation has some face validity for individuals in the CBT-I only condition, this is not as convincing an argument for individuals in the combined condition, since part of the CBT-P intervention includes training in pacing activities to avoid pain flare-ups. Of course, this discussion is based upon a comparison of effect sizes; pain outcomes did not differ statistically between the active intervention conditions.

The foremost limitation of this pilot study is its small sample size, particularly for a four-arm design. In addition, the wait-list control condition does not control for non-specific factors of therapy. Accordingly, a cautious approach to the interpretation of the findings is warranted.

Importantly, CBT interventions targeting sleep were associated with the largest improvements in sleep, depression and fatigue. The combined intervention did not clearly outperform stand alone CBT-I or CBT-P on all measures. It was feasible, however, to combine CBT-I and CBT-P in one intervention. As a consideration for future work in this area, both participants and therapists noted that the 10-session format could have been reduced without affecting the ability to engage all the intervention components. Given the large effects on sleep and mood afforded by CBT-I, the findings do suggest that CBT-I is a potent intervention for insomnia in the context of chronic pain. Whether it would be most beneficial for such patients to receive CBT-I in a combined approach as we tested here, or in a sequential approach before or after a pain-specific intervention, remains to be established.

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Highlights

- An intervention combining two evidence-based interventions, cognitive behavioral therapy (CBT) for pain and for insomnia, was feasible to deliver in a 10-session individual format to individuals with co-occurring chronic pain and insomnia.
- The combined CBT intervention produced significant improvements in sleep, disability from pain, depression and fatigue compared to the control condition.
- The combined intervention appeared to be superior to CBT for pain and to CBT for insomnia with respect to sleep outcomes, but inferior to CBT for pain on pain outcomes.

Table 1

Treatment Outcomes Comparing CBT Interventions to Wait-List Control

TnQTable2TWT	Control	73.6 (17.1)	66.5 (18.0)		0.20	
	CBT-P	98.6 (18.8)	64.2 (23.0)	2.23	0.135	0.73 0.05
	CBT-I	147.9 (27.4)	33.4 (8.6)	5.24	0.022	2.30 1.20
	CBT-I/P	82.2 (11.3)	31.5 (5.5)	4.62	0.032	2.33 1.43
TST	Control	340.8 (46.2)	378.8 (28.0)			0.50
	CBT-P	361.4 (18.4)	378.2 (18.3)	0.81	0.369	0.41 0.01
	CBT-I	323.9 (32.3)	375.0 (17.7)	0.53	0.467	0.80 0.08
	CBT-I/P	377.0 (34.4)	425.9 (36.6)	0.05	0.820	0.56 0.60
SE (%)	Control	79.0 (7.9)	84.5 (4.4)			0.43
	CBT-P	77.6 (4.4)	84.5 (4.5)	0.07	0.787	0.83 0.01
	CBT-I	69.8 (7.1)	91.5 (1.9)	4.14	0.042	1.21 1.07
	CBT-I/P	78.3 (3.3)	91.7 (0.8)	1.53	0.216	0.49 1.28
ESS	Control	10.0 (2.6)	10.0 (3.6)			0.00
	CBT-P	8.2 (2.1)	6.4 (1.6)	0.37	0.541	0.43 0.64
	CBT-I	12.9 (2.7)	6.1 (2.4)	3.49	0.062	1.08 0.78
	CBT-I/P	10.5 (1.4)	6.2 (0.5)	3.00	0.083	1.68 1.09
PDI	Control	23.5 (4.9)	18.3 (6.8)			0.44
	CBT-P	25.9 (5.2)	11.1 (4.4)	0.62	0.432	1.21 0.53
	CBT-I	23.8 (4.6)	15.0 (4.9)	0.06	0.805	0.83 0.27
	CBT-I/P	20.0 (5.0)	14.1 (4.5)	0.02	0.882	0.49 0.33
MFI	Control	50.0 (2.6)	54.5 (3.7)			-0.67
	CBT-P	54.4 (3.8)	56.8 (7.8)	0.16	0.685	-0.17 0.16
	CBT-I	56.7 (2.5)	42.5 (7.5)	3.53	0.060	1.04 0.79
	CBT-I/P	54.4 (4.4)	46.1 (5.1)	2.80	0.094	0.71 0.77

^a Results are from generalized estimating equations with all degrees of freedom=1 and all controlling for age and baseline depression as continuous covariates.

^b Effect sizes from Hedge's *g*.

^c Bolded values indicate unadjusted significant group by time difference at *p* < .05, but only those values with an asterisk (*) remain significant after adjustment for multiple comparisons.

Abbreviations: CESD-R = Center for Epidemiologic Studies Depression Scale-revised; ESS = Epworth Sleepiness Scale; ISI = Insomnia Severity Index; MFI=Multidimensional Fatigue Inventory; MPI = Multidimensional Pain Inventory - Pain Severity Scale; PDI = Pain Disability Index; SL = Sleep latency; SE = Sleep Efficiency; TST = Total Sleep Time; WASO = Wake After Sleep Onset