Enhancing CBT for chronic insomnia: An RCT of additive components of Mindfulness or Cognitive Therapy.

Short title: Enhancing CBT for insomnia

Mei Yin Wong[1], Melissa J Ree[2] , and Christopher Lee [1]

[1]School of Psychology and Exercise Sciences

Murdoch University, Perth, Western Australia

[2]The Marian Centre

Wembley, Western Australia

Address for correspondence:

Dr Christopher Lee

School of Psychology

Murdoch University

South St

Murdoch WA

Australia 6150

Phone number: 61-421131042 Fax number: 61-893606878

Email address: chris.lee@murdoch.edu.au

Abstract

Although Cognitive Behavioral Therapy for insomnia (CBT-I) has resulted in significant reductions in symptoms, most patients are not classified as good sleepers after treatment. The present study investigated whether additional sessions of Cognitive Therapy (CT) or Mindfulness Based Therapy (MBT) could enhance CBT in 64 participants with primary insomnia. All participants were given 4 sessions of standard CBT as previous research had identified this number of sessions as an optimal balance between therapist guidance and patient independence (Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007). Participants were then allocated to further active treatment (4 sessions of CT or MBT) or a no further treatment control. The additional treatments resulted in significant improvements beyond CBT on self-report and objective measures of sleep and were well tolerated as evidenced by no drop outs from either treatment. The effect sizes for each of these additional treatments were large and clinically significant. For example the mean scores on the primary outcome measure, the Insomnia Severity Index, were 5.74 for CT and 6.69 for MBT. These scores are within the good-sleeper range. Treatment effects were maintained at follow-up. There were no significant differences between CT and MBT on any outcome measure. These results provide encouraging data on how to enhance CBT for treatment of insomnia.

Key practitioner messages

- CBT treatments for insomnia can be enhanced using recent developments in cognitive therapy.
- CBT treatments for insomnia can be enhanced using mindfulness based treatments.
- Both cognitive therapy and mindfulness produce additional clinically significant change.

Insomnia is a highly prevalent condition with a high disease burden (Mai & Buysse, 2008). Research has suggested that insomnia may increase the risk of health problems, mood disorder, accidents, and poorer quality of life (Roth, 2007). Given this high disease burden and insomnia prevalence rates as high as 10% (e.g., Ohayon, & Reynolds, 2009), investigations to improve the effectiveness of treatment is an important priority.

Cognitive Behavior Therapy for insomnia has demonstrated efficacy and has been recommended as the first line of treatment for chronic insomnia (e.g., Buysee, 2013; Stepanski, 2005). Many studies demonstrate that CBT interventions bring about significant improvements in sleep (e.g., Harvey et al., 2014; Lynch, Courtney, Jarvis, DeBellis, & Morin, 2007), quality of life, and daytime depressive mood (Okajima, Komada & Inoue, 2011).

Despite strong evidence for the efficacy and effectiveness of CBT for improving insomnia, it may benefit from future refinement. Morin and Benca (2012) reported that 70-80% of patients with insomnia benefitted from CBT but only approximately 40% achieved clinical remission. Harvey and Tang (2003) also highlighted that effect sizes for CBT for insomnia are lower than that observed for CBT for a range of other psychological disorders including panic disorder (Clark et al., 1999) and depression (Dobson, 1989).

The present study aims to investigate whether the effects of CBT for insomnia could be enhanced by adding other emerging, evidence-based treatment components. Findings from two fields of clinical psychology, namely Cognitive Therapy (CT) and Mindfulness Based Therapy (MBT), may have the potential to offer improved treatment outcomes for insomnia.

In contrast to CBT treatment programs, where cognitive processes often are only a small part of treatment focus, CT for Insomnia assumes that insomnia is maintained by a number of cognitive processes that operate at night as well as during the day (Harvey,

2002). Like CBT, CT addresses the role of unhelpful thoughts and worry, but it also suggests that other cognitive processes perpetuate insomnia, namely: (i) selective attention and monitoring of sleep related threat, (ii) misperception of sleep and daytime deficits, (iii) dysfunctional thoughts or beliefs, and (iv) counter-productive safety behaviors. The cognitive processes mutually influence each other, thus creating a vicious cycle that maintains insomnia.

With respect to selective attention and monitoring, people with insomnia have been found to focus their attention on monitoring sleep-related threats more than good sleepers (e.g., bodily sensations indicating arousal at night or signs of fatigue during the day). This selective attention and monitoring has been shown to increase worry, sleep onset latency, and self -reported sleepiness (Semler & Harvey, 2007).

The second additional maintaining factor in the Cognitive Model of Insomnia is safety behaviors. A safety Behavior is an overt or covert behavior adopted to avoid feared outcomes. Examples of night-time safety behaviors include spending excessive amount of time in bed (leading to sleep fragmentation), or drinking alcohol (that may promote short-term sleep but is likely to result in poorer quality of sleep). Examples of daytime safety behaviors include cancelling appointments after a night of insomnia, napping, and excessive caffeine use. Ree and Harvey (2004) found a relationship between safety behaviors and insomnia finding that patients with insomnia, relative to good sleepers, used more sleep-related safety behaviors (as assessed by the Sleep Related Behaviors Questionnaire, SRBQ).

The third cognitive process suggested to perpetuate insomnia is misperception of sleep and daytime deficit. It is common for people with insomnia to overestimate how long it takes them to fall asleep and underestimate how long they sleep in total, relative to normal sleepers (Perlis, Smith, Andrews, Orff, & Giles, 2001). They are also more likely to perceive greater daytime deficits following a night of poor sleep (Semler & Harvey, 2006).

The fourth and final cognitive factor in Harvey's Cognitive Model is unhelpful beliefs about sleep (see also Morin, 1993; Morin et al., 2002). Examples of unhelpful beliefs include 'I must get eight hours of sleep most nights', 'If I need to go to the bathroom, my night's sleep is wrecked', 'I am worried that insomnia is causing serious physical health consequences'. In a sample of over 1800 participants, Carney et al. (2010) found that participants seeking treatment for insomnia had higher levels of unhelpful sleep-related beliefs than did normal sleepers. Further evidence that supports the significant role of unhelpful beliefs about sleep in insomnia are reported in studies that show that better treatment outcomes are associated with reductions in unhelpful beliefs (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Morin et al., 2002).

In addition to the experimental evidence to support the role of each of the factors in the Cognitive Model of insomnia, the efficacy of CT as a stand-alone treatment has been examined in two direct treatment evaluations. Firstly, an open trial that evaluated the contribution of CT to sleep improvement found that CT for insomnia was acceptable to patients, improved sleep (Cohen's d effect size of 5 on the primary outcome measure), and improved daytime tiredness (Harvey, Sharpley, Ree, Stinson, & Clark, 2007). Secondly, a randomized controlled trial comparing CT, CBT, and Behavior Therapy also supported that CT was effective (Harvery et al., 2014).

The other potentially promising treatment for insomnia is Mindfulness-Based Therapy (MBT). Mindfulness is the skill of bringing non-judgmental awareness to what is happening in the present moment to the exclusion of thoughts about the past or the future. Mindfulness approaches are meditation based and have been used in the treatment of a wide range of psychological and physical health diagnoses, including, more recently, difficulties with sleep. When learning Mindfulness skills, patients learn to notice negative thoughts, and

redirect attention to other aspects of the present moment, such as their breath, their body, or environmental sounds. Patients learn to stay in touch with the present moment, reducing rumination about the past, or worry about the future.

In Baer's (2003) review of 22 studies that used MBT, support was found for the efficacy of mindfulness for anxiety, depression, binge eating, chronic pain, fibromyalgia, psoriasis, stress related to cancer, and medical and psychological functioning among non-clinical populations. With respect to the emerging support for Mindfulness based therapies use in the treatment of insomnia, Ong, Shapiro and Manber (2008) suggest that mindfulness could be relevant for sleep improvement by reducing cognitive and somatic arousal, as well as decentering from worrisome and intrusive thoughts (Winbush, Gross & Kreitzer, 2007). Furthermore, mindfulness could potentially contribute to sleep improvement as it aims to assist individuals in increasing acceptance of their current sleep state, and highlights the notion that sleep cannot be forced (Ong et al., 2008; Manber, Hydes & Kuo, 2004).

The combination of mindfulness meditation with CBT has been found to lead to symptom reduction in an uncontrolled study of 30 insomnia sufferers (Ong et al., 2008). However, since the Ong et al study was uncontrolled, it is possible that the symptom improvement could have been due to the CBT alone. Similarly in another uncontrolled study MBT on its own was found to lead to promising symptom reduction in 14 participants, including those with comorbid sleep disorders (e.g., sleep apnea, restless legs syndrome) following 8-2 hour sessions (Heidenreich, Tuin, Pflug, Michal & Michalak, 2006). In a systematic review by Winbush, Gross & Kreitzer (2007) on the effects of MBT on sleep disturbance, it was reported that increased practice of mindfulness techniques was associated with sleep improvement and a decrease in sleep interfering cognitive processes (e.g., worry). A recent controlled study of mindfulness meditation for insomnia also found

encouraging results at post treatment and 6 month follow-up (Ong, Manber, Segal, Xia, Shapiro, & Wyatt, 2014).

In summary, a wealth of evidence from controlled studies exists to suggest that CBT is effective in treating chronic insomnia. There is, however, a sizeable proportion of patients who do not respond optimally. There exists evidence that mindfulness based interventions and cognitive therapy interventions for insomnia are effective but there is no controlled evidence to suggest whether they offer additional benefit over and above the gold standard treatment, CBT-I. Specifically, the present study investigated whether four sessions of CT or Mindfulness enhanced the effects of a standard, four session CBT package in the treatment of chronic insomnia. Significant reductions in insomnia severity after CBT were hypothesized, and that an additional 4 sessions of components of CT or Mindfulness, would contribute to further significant reductions in insomnia severity. This study also aimed to investigate whether the key processes thought to underlie CT and Mindfulness were affected by treatment and the degree to which these processes were involved in any improvement.

Method

Study Design

This study employed a randomized mixed group design. After an initial wait list period of 4 weeks (to assess for changes relating to the passage of time), participants were individually administered 4 sessions of CBT for insomnia. They were then randomly allocated (computer generated random numbers) to immediate or delayed conditions (see Figure 1). This was to allow determination of whether the second treatment improved outcomes beyond the passage of time alone. Participants were also randomly allocated to one of two treatments following CBT; 4 sessions comprising of components of CT for Insomnia (Harvey, 2002; 2005; Harvey et al., 2007) or 4 sessions comprising components of MBT (Segal et al., 2002).

Participants

The sample was recruited from general practitioners, psychologists, local pharmacies and advertisements in the local press. Potential participants contacted the researcher to express interest to participate, and underwent telephone screening. See Figure 1 for details regarding participant attrition.

Insert Figure 1 here

Selection Criteria

The inclusion criteria were: (i) 18 – 65 years of age; (ii) complaint of difficulty initiating or maintaining sleep for at least six months; (iii) mean sleep onset latency or minutes awake after sleep for longer than 30 minutes for at least three nights per week (Lichstein, Durrence, Taylor, Bush, & Riedel, 2003) as assessed by one week sleep diary; (iv) interference in daytime functioning; (v) total sleep time on sleep diary under 6.5 hours for more than 3 nights out of every 7; (vi) taking no medication to assist sleep or be taking a stable dose of medication (stable for 1 month).

Individuals were excluded if (i) they presented clear evidence of other sleep disorders (sleep apnea, periodic leg movements during sleep, nightmare disorder, narcolepsy, parasomnia) based on a sleep history assessment interview protocol (Morin & Espie, 2003) and interview guide for assessment of insomnia (Isler, Peterson & Isler, 2005); (ii) they were receiving treatment of insomnia from another mental health professional; (iii) they presented with sleep disturbances due to a medical / physical condition as assessed by clinical interview; (iv) they had sleep disturbances due to the physiological effect of a substance; (v) the insomnia was assessed as purely secondary to another psychological disorder.

Outcome Measures

(1) Primary Outcome Measure: Insomnia Severity

(a) *Insomnia Severity Index* (ISI; Bastien, Vallieres, & Morin, 2001)**.** The ISI is a 5-item scale that assesses severity of both nighttime and daytime symptoms of insomnia over the period of the past week. The ISI has adequate internal consistency (Cronbach alpha=0.74 to 0.78) with evidence supporting concurrent, predictive and content validity (Bastien et al., 2001). The total score of the ISI was used to indicate overall severity of insomnia, higher scores indicate greater severity.

Secondary Outcome Measures: Sleep quality, Sleep log, Actigraphy and Mood Symptoms

(a) *Pittsburgh Sleep Quality Index* (PSQI; Buysse, Reynolds, Monk, Berman & Kupfer, 1989). The PSQI assesses Subjective Sleep Quality, Sleep Latency, Sleep Duration, Habitual Sleep Efficiency, Sleep Disturbances, Use of Sleep Medications, and Daytime Dysfunction. The PSQI contains 19 items that sum to yield a global score. Higher scores indicate greater severity. Its internal consistency (Cronbach alpha =0.83) and test-retest reliability (r=0.85) are acceptable (Buysse et al., 1989; Carpenter & Andrykowski, 1998).

(b) *Sleep Log.* Participants recorded daily lights-out time, waking and rising times, estimates of sleep onset latency, number of nocturnal awakenings and wake time after sleep onset for each night of sleep. The sleep log included items recordings of alcohol, caffeine, and sleeping tablet consumption as well ratings of sleep quality (1=very poor, 10=excellent) and daytime tiredness (0=not at all tired, 10=extremely tired).

(c) Actigraphy. Actigraphy provides the means to objectively detect and quantify human movement, via a wristwatch-like device. An algorithm infers states of

wake or sleep from the specific pattern of movement (Smith & Wegner, 2003). Actigraphy in the present study served to augment the self-report data presented in sleep logs recorded by the participants.

(d) Depression, Anxiety and Stress Scale (DASS; Lovibond & Lovibond, 1995). The 21-item self-report DASS was used to screen for the presence of clinically significant symptoms of anxiety and depression. The DASS has demonstrated good convergent validity with other scales designed to discriminate between depression and anxiety (Lovibond & Lovibond, 1995). The internal consistency of the DASS-21 is as follows: Depression (range=0.91 to 0.97); Anxiety (range=0.81 to 0.92); and Stress (range=0.88 to 0.95) (Lovibond & Lovibond, 1995).

Procedure

Pretreatment Assessment

After completion of a phone screen, eligible participants attended a face-to-face clinical interview. The face-to-face clinical interview included questions adapted from the Sleep History Assessment (Morin & Espie, 2003) and an interview guide for assessment of insomnia (Ong et al., 2008). Eligible participants were then asked to complete pencil and paper pre-treatment questionnaires described above. They then kept a sleep diary for one week, and simultaneously collected one week of wrist Actigraphy data. After completion of the pre-intervention measures, participants waited four weeks without treatment. Participants were then invited to complete the outcome measures described above before commencing CBT treatment.

Therapist

The first author, a Registered Psychologist, delivered all interventions to the participants. Regular clinical supervision by independent experts, both clinical psychologists, was received in CBT, CT and Mindfulness. The researcher had specific training in CBT, CT, and MBT.

Cognitive Behavior Therapy

All participants received four 1-hour intervention sessions following a standard CBT for primary insomnia protocol (Edinger & Carney, 2008). This included sleep and insomnia education, steps for sleep restriction therapy, and sleep hygiene interventions. Cognitive strategies included a constructive worry worksheet and a cognitive restructuring worksheet. Although CBT has been given in dosages ranging from 1 to 8 treatment sessions, the 4-session model has been found to provide an optimal balance between therapist guidance and patient independence (Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007).

Participants were then randomly assigned to a four-week wait or immediate treatment. They were then assigned to CT or MBT.

Cognitive Therapy

Half of the remaining 57 patients were randomly selected to receive four 1-hour CT sessions that included components of CT (Harvey, 2005; Harvey et al., 2007). Individual 'vicious cycles' of insomnia, based on the cognitive model, were then derived to assist each participant in conceptualizing how cognitive maintaining factors feed into each other (Harvey, 2006). Tailored behavioral experiments (Ree & Harvey, 2004) were developed to assist in reversing these factors:

(i) misperception of sleep and daytime tiredness, (ii) worry, (iii) selective attention and monitoring, (iv) safety behaviors and (v) unhelpful beliefs about the sleep.

Mindfulness Based Therapy

Half of the remaining 57 patients were randomly selected to receive four 1-hour MBT sessions. These sessions focused on Mindfulness skills and Cognitive Therapy elements were not included. Session content was derived heavily from Segal et al. (2002). In session meditations were included at each session and participants were encouraged to listen to Mindfulness Meditation CDs 6 days out of 7 (including Body Scan meditation and Sitting meditation). Participants were advised to practice prior going into bed, after they awoke in the morning (out of the bed) and / or any other times during the day. Additionally, participants were assigned informal mindfulness tasks each week (e.g., mindful eating and any other activity whereby attention is focused on one activity over a period of time).

The 3-Minute Breathing Space was also introduced for bringing formal meditation practice into daily life. Participants were encouraged to carry out the practice of 3-Minute Breathing Space three times daily at set times and also at any other times when they felt stressed. Barriers and benefits of practice were discussed at each session. Discussion also focused on the identification of specific warning signals of insomnia and drawing up an action plan with strategies.

Results

Sample Characteristics

Of 64 adults eligible to participate in the study, 40 were females (62.5%) and 24 were males (37.5%). Ages ranged from 21 to 66 years. The mean age (SD) was 49.46 (12.48). At the beginning of the study, participants reported sleeping just over 5 hours and physiological recordings suggested 5.75 hours (see Table 1). Participants also reported being awake for over an hour when in bed before they first fell asleep (mean= 69.14 mins, SD=49.99) although the mean was less severe on physiological recordings (mean= 27.54,

SD=14.74). Prior to intervention , sleep efficiency was very poor . The mean score for self-report data was 58.93 (12.25) percent and for actigraphy 71.52 (7.68) percent. Mean scores on the DASS were 9.20 (8.83) for Depression, 5.78 (6.13) for Anxiety, and 14.50 (9.42) for Stress. Initial scores on the ISI and PSQI suggested participants were in the clinical range for insomnia (see Table 1).

Insert Table 1 here

Effects of CBT

Preliminary assumption testing was conducted prior to all analyses carried out in this and subsequent subsections, to check for normality, linearity, outliers, homogeneity of variance matrix and multicollinearity. No violations were noted in any of the ANOVAs or MANOVAs. To determine whether participants would show significant reductions in insomnia severity after treatment of CBT an ANOVA was computed for data collected at baseline, pre CBT treatment, and post CBT. MANOVAs were computed for some secondary measures such as the subscales of the DASS and the two measures of sleep time (Actigraphy and sleep logs).

The following results are an intent- to- treat analysis and include the data of the 7 non-completers who dropped out during CBT. Missing post-treatment data was replaced with pretreatment scores. Nevertheless using this conservative approach, all pre- to post treatment changes were significant.

Effect of CBT on ISI and PSQI

A one way repeated measures Analysis of Variance (MANOVA) with time as a repeated measure was computed. The means and standard deviations for all outcome measures are presented in Table 1. Univariate analyses showed that both the primary ISI

scores ($F (2, 126) = 107.09$, $p < .001$, $\eta^2 = .63$) and the secondary PSQI scores ($F (2, 126) = 79.89$, $p < .001$, $\eta^2 = .56$) were significantly different over Time.

Within-subject contrasts comparing baseline and pre CBT showed no changes on either the ISI ($F (1, 63) = .54$, $p = .47$) or PQSI ($F (1, 63) = 2.79$, $p = .09$). Whereas there were significant differences in both the ISI ($F (1, 63) = 164.04.$, $p < .001$, $\eta^2 = .72$) and PSQI ($F (1, 63) = 134.53$, $p < .001$, $\eta^2 = .68$) between start of CBT and post CBT.

Effects of CBT on Actigraphy and Sleep Log Results

We calculated one way repeated measure Multivariate Analysis of Variance (MANOVA) with (Time: e.g., baseline vs post treatment) x (Sleep Parameters: SE vs TST vs SOL vs AWAK vs WASO) separately for Actigraphy Data and sleep log data. Whenever there was a significant main or interaction effect this was followed up with separate univariate analysis for each sleep parameter. In all cases there were no differences between these parameters in terms of finding significance or not. Therefore to simplify the results only total sleep time univariate analysis with associated means and standard deviations were reported. MANOVAS and other sleep parameter means are available on request.

The TST pretreatment mean for Actigraphy was 345.88 (34.00) and post treatment this improved to 446.71(64.03). Similarly TST pretreatment mean for Sleep Log Data was 308.56(38.69) post treatment this improved to 387.89(48.73). These improvements were significant for both the Actigraphy ($F(1,63) = 174.58$, $p < .001$, $\eta^2 = .74$) and the Sleep log data ($F(1,63) = 181.80$, $p < .001$, $\eta^2 = .74$).

Effects of CBT on DASS scores

Overall, CBT had a significant impact on the reduction of DASS means for depression, anxiety and stress. A one way repeated measures Multivariate Analysis of

Variance (MANOVA) with (Time: baseline vs pretreatment vs post treatment) x (DASS components: Depression vs Anxiety vs Stress) was computed. Time was the repeated measure and DASS components were the dependent variables. There was a significant effect of Time for the outcome measures, Wilks' Lambda =.57, ($F (6, 58) = 7.18$, $p < .001$, multivariate $\eta^2 = .43$). Within-subject contrasts comparing baseline and pre CBT showed no changes on either for DASS depression ($F (1, 63) = .58$, $p = .45$) or DASS anxiety ($F (1, 63) = .01$, $p = .91$) but a small reduction in DASS stress ($F (1, 63) = 8.87$, $p < .01$, $\eta^2 = .11$). Whereas there were significant differences significant reductions in means at post CBT for DASS depression ($F (1, 63) = 7.21$, $p < .001$, $\eta^2 = .10$), anxiety ($F (1, 63) = 13.34$, $p < .001$, $\eta^2 = .18$) and stress ($F (1, 63) = 30.99$, $p < .001$, $\eta^2 = .33$).

Demographics and Clinical Characteristics of Participants in Treatment (MBT and CT) at Pretreatment

Fifty seven participants remained in the study after CBT and were administered either MBT or CT. Both treatments had mainly female participants (MBT :65.6%, CT:61.3%).

The mean (SD) age of participants in the MBT and CT treatment conditions were 49.96 (12.6) years and 48.97(13.4) years, respectively. There was no significant difference in age for participants in the MBT and CT conditions ($t = -.287$, $p = .775$).

Comparison of CT, MBT, and waitlist

Table 1 presents the means and standard deviations of ISI, PSQI, and TST (both as assessed by Actigraphy and sleep log data) for the waitlist period and pre, post and follow-up for CT and MBT. In order to assess for differences between CT and MBT at pretreatment, independent-samples t-tests were conducted for each of the primary sleep

outcome measures. No significant differences were found in pretreatment scores between MBT and CT after correcting for the number of comparisons.

The hypothesis that insomnia severity would reduce further following four sessions of CT or MBT compared to no treatment was tested with an ANOVA. For the primary outcome measure the ISI, the changes that occurred during treatment were significantly greater than that during the waitlist period ($F (1, 55) = 7.27$, $p < .01$, $\eta^2 = .12$). This was also true for the PSQI ($F (1, 55) = 21.54$, $p < .001$, $\eta^2 = .28$). There were no significant differences between post treatment and follow-up.

Table 1 also details the mean and standard deviations for the TST at pretreatment post treatment and follow-up. There was improvement over time and the differences were significant for both the Actigraphy ($F (1, 55) = 23.19$, $p < .001$, $\eta^2 = .29$) and sleep log data. ($F (1, 55) = 85.81$, $p < .001$, $\eta^2 = .61$).

Differential Effects of MBT versus CT

A 3 (Time: pretreatment vs post treatment vs follow-up) x 2 (Intervention: MBT vs CT) repeated measures MANOVA was computed to compare scores on the ISI and the PSQI. A significant effect for time Wilks' Lambda = .33, ($F (4, 52) = 26.22$, $p < .001$, $\eta^2 = .67$) was found, but not for Intervention Wilks Lambda = .96, ($F (2, 54) = 1.14$, $p = .33$, $\eta^2 = .04$). The Time x Intervention (MBT vs. CT) interaction was also not significant Wilks' Lambda = .92, ($F (4, 52) = 1.08$, $p = .38$, $\eta^2 = .08$).

Similarly a 3 x 2 MANOVA for TST was calculated for Actigraphy and Sleep Log Data separately. A significant effect for time was found in both Actigraphy, Wilks' Lambda = .76, ($F (2, 54) = 8.61$, $p < .001$, $\eta^2 = .24$) and Sleep Log Data, Wilks' Lambda = .25, ($F (2, 54) = 83.35$, $p < .001$, $\eta^2 = .76$). The crucial Time x Intervention (MBT vs. CT)

interaction was also not significant for either Actigraphy (F (2, 52) = 1.79, p = .18, η^2 = .06) or Sleep Log Data (2, 52) = .76, p = .47, η^2 = .03).

Discussion

The standard, 4-session CBT package given to participants in this study resulted in significant reductions in measures of insomnia severity, improvements in sleep efficiency, and total sleep time. The changes during CBT were also significantly greater than those that occurred during the waitlist period. In comparison to previous studies of CBT, the current study often obtained larger effect sizes than reported in a recent meta-analysis (Okajima et al., 2011). The large effect size achieved in the present study for the ISI (1.98) was larger than for the Insomnia Index (0.94) employed in the Okajima study (a composite measure that contained the ISI items). This may be due to the items in addition to the ISI that were included in the Okajima insomnia composite measure. It is also possible that the outcomes in the current study were due to a random effect in a small sample.

Despite the large pre-post CBT effect size, but in line with previous studies, the findings were mixed as to whether CBT in this study achieved clinically significant change. For example the 42% reduction in ISI suggests that insomnia severity moved from a moderate to sub-threshold level. The 39% reduction in PSQI after CBT resulted in a PSQI global score of (7.72) which is indicative still of significant sleep disturbance (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006). These findings underscore the importance of working to develop more effective methods for treating insomnia.

Significant reductions in insomnia severity (over and above no treatment) were found after further treatment with either CT or MBT. Significant reductions were also found for the Actigraphy measures and sleep log outcomes. Both CT and MBT resulted in

significant improvements in total sleep time, WASO, and sleep efficiency. The overall effect size for eight sessions of treatment (CBT plus CT or MBT) on the ISI was 3.08 for CBT plus cognitive therapy and 3.12 for mindfulness based cognitive therapy and CBT. On the PSQI this was 2.41 for CT plus CBT and 1.69 for MBT plus CBT. These effects were maintained at follow-up and are larger than those reported in a previous meta-analysis for standard CBT (0.93) for a similar number of sessions (Okajima et al., 2011). The current results are consistent with the notion that switching from a predominantly behavioral therapeutic modality after 4 sessions to a more cognitively-oriented treatment may offer additional benefit over and above additional 'traditional' CBT sessions that tend to have a greater behavioral focus. This result is in line with Harvey et al. (2014) who found that 8 sessions of CBT which emphasized both behavioral and cognitive therapy elements was more effective than 8 sessions of either behavioral or cognitive therapy alone.

In terms of clinical significance, the ISI means achieved after CT (5.74) and MBT (6.69) suggested that on average, participants had moved into the good sleeper range. The improvements as a result of MBT and CT over and above CBT were not just on self-report measures but also on Actigraphy data.

There are several study limitations to note, the first is that no formal fidelity treatment checks were carried out. However, video and auditory recordings were reviewed during regular supervision of the therapist delivering the sessions by relevant experts in each approach. The design could have been improved by comparing MBT and CT to four additional sessions of CBT in addition to the waitlist period. The design of the study could also be improved by the post-treatment measures being collected by someone independent to the delivery of the treatment. However, the fact an objective measure of sleep showed the same response pattern to the self-report measures supports that this was not a major flaw.

With respect to the use of actigraphy and not polysomnography (PSG), although PSG is the gold standard for objectively assessing sleep on a given night, it is not generally viewed as an adequate assessment of insomnia (e.g., Edinger, Ulmer & Means, 2013). This is due both to the impracticality of conducting PSG over multiple nights which is necessary to assess insomnia (1-2 weeks is often recommended as the time-frame required to assess insomnia) and that PSG, due to its invasiveness, can alter (for better or worse) how an individual sleeps on the assessment night (Edinger et al. 2013). Indeed, a recent study suggested that the use of PSG-based selection criteria in insomnia research may exclude many who meet current diagnostic criteria for an insomnia disorder (Edinger et al. 2013).The lack of laboratory diagnostic tests such as PSG was, however, a limitation in the current study in that it meant we did not have access to objective information to diagnose conditions such as obstructive sleep apnea (OSA). We did, however, screen for OSA in the clinical interview.

In conclusion, the current findings build on past research that suggest four sessions of CBT can be beneficial for sleep improvement though not enough to move participants, on average, into the good sleeper range. The addition of CT or MBT to four sessions of CBT for insomnia appears to significantly enhance treatment outcomes, and suggests that switching treatment modality during treatment may be beneficial. In light of pressure to develop brief and cost-effective treatments, it would be useful for future research to investigate whether this may be particularly the case for those participants who did not attain an optimal outcome following a standard dose of CBT.

References

Ancoli-Israel, S., Cole, R., Alessi, C., Chambers, M., Moorcroft, W., & Pollak, C. P. (2003). The role of actigraphy in the study of sleep and circadian rhythms. *Sleep, 26*(3), 342-392.

Baer, R.A. (2003). Mindfulness training as a clinical intervention: A conceptual and empirical review. *Clinical Psychology: Science and Practice*, 10, 125-143. doi: 10.1093/clipsy.bpg015

Baer, R.A., Smith, G.T., & Allen, K.B. (2004). Assessment of mindfulness by self-report: The Kentucky inventory of mindfulness skills. *Assessment*, 11, 191-206. doi: 10.1177/1073191104268029

Baer, R.A., Smith, G.T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment*, 13(1), 27-45. doi: 10.1177/1073191105283504

Barrett, B., Byng, R., Evans, A., Mullan, E. & Teasdale, J.D. (2008). Mindfulness-based cognitive therapy to prevent relapse in recurrent depression. *Journal of Consulting and Clinical Psychology,* 76 (6), 966-978. doi: 10.1037/a0013786

Bastien, C., Vallieres, A., & Morin, C.M. (2001). Validation of the insomnia severity index as a clinical outcome measure for insomnia research. *Sleep Medicine,* 2, 297-307. doi: 10.1016/S1389-9457(00)00065-4

Buchheld, N., Grossman, P., & Walach, H. (2001). Measuring mindfulness in insight meditation (Vipassana) and meditation-based psychotherapy: The development of the Freiburg Mindfulness Inventory (FMI). *Journal for Meditation and Meditation Research, 1(1),* 11-34

Buysse, D. J. (2013). Insomnia. *Journal of the American Medical Association*, *309*(7), 706–716. doi:10.1001/jama.2013.193

Buysse, D.J., Reynolds, C.F., Monk, T.H., Berman, S.R., & Kupfer, D.J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research*, 28, 193-213. doi: 10.1016/0165-1781(89)90047-4

Buysse, D.J., & Reynolds, C.F. (2000). Pharmacological treatment. In K.L. Lichstein, & C.M. Morin (Eds.), *Treatment of late-life insomnia (pp.231-267).* Thousand Oaks, CA: Sage.

Buysse, D.J., Ancoli-Israel, S., Edinger, J.D., Lichstein, K.L., & Morin, C.M.(2006). Recommendations for a standard research assessment of insomnia. *Sleep*, 29(9), 1155-1173.

Carney, C.E., Edinger, J.D., Morin, C.M., Manber, R., Rybarczyk, B., Stepanski, E.J., Wright, H., & Lack L. (2010). Examining maladaptive beliefs about sleep across insomnia patient groups. *Journal of Psychosomatic Research*, 68(1), 57-65. doi: 10.1016/j.jpsychores.2009.08.007

Carpenter, J.S. & Andrykowski, M.A. (1998). Psychometric evaluation of the Pittsburgh Sleep Quality Index. *Journal of Psychosomatic Research.* 45(1), 5-13. doi: 10.1016/S0022-3999(97)00298-5

Chadwick,P., Hember, M., Mead, S., Lilley, B.,& Dagnan, D. (2005). Responding mindfully to unpleasant thoughts and images: Reliability and validity of the Mindfulness Questionnaire. Unpublished manuscript.

Clark, D.M., Salkovskis, P.M., Hackmann, A, Wells, A., Ludgate, J., & Gelder, M. (1999) Brief cognitive therapy for panic disorder: a randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 67, 583-589. doi: 10.1037/0022-006X.67.4.583

Dobson, K.S. (1989). A meta-analysis of the efficacy of cognitive therapy for depression. *Journal of Consulting and Clinical Psychology*, 57, 3, 414-419. doi: 10.1037/0022-006X.57.3.414

Edinger, J.D, & Carney, C.E. (2008). Overcoming insomnia: A cognitive-behavioral therapy approach workbook. New York ,NY: Oxford University Press.

Edinger, J.D., & Sampson, W.S. (2003). A primary care "friendly" cognitive behavioral insomnia therapy. *Sleep*, 26 (2), 177- 182.

Edinger, J.D., Ulmer, C.S., & Means, M.K. (2013).. Sensitivity and specificity of polysomnographic criteria for defining insomnia. *Journal of Clinical Sleep Medicine*, 9 (5), 481-491. doi: 10.5664/jcsm.2672

Edinger, J.D., Wohlgemuth, W.K., Radtke, R.A., Coffman, C.J., & Carney, C.E. (2007). Dose-response effects of cognitive-behavioral insomnia therapy: a randomized clinical trial. *Sleep*, 30 (2): 203-212

Harvey, A.G. (2002). A cognitive model of insomnia. *Behavior Research and Therapy*, 40 (8), 869-894. doi: 10.1016/S0005-7967(01)00061-4

Harvey, A.G. (2005). A cognitive theory of and therapy for chronic insomnia. *Journal of Cognitive Psychotherapy*, 19 (1), 41-59. doi: 10.1891/jcop.19.1.41.66332

Harvey, A.G., Sharpley, A.L., Ree, M.J., Stinson, K. & Clark, D.M. (2007). An open trial of cognitive therapy for chronic insomnia. *Behavior Research and Therapy*, 45 (10), 2491-2501. doi: 10.1016/j.brat.2007.04.007

Harvey, A.G., & Tang, N, K, Y. (2003). Cognitive behavior therapy for primary insomnia: can we rest yet? *Sleep medicine reviews*, 7 (3), 237-262. doi: 10.1053/smrv.2002.0266

Harvey, A,G.,˙ Bélanger, L., Talbot, L., Eidelman, P., Beaulieu-Bonneau, S., Fortier-Brochu, É., Ivers, H., Lamy, M˙, Hein, K., Soehner, A.M˙, Mérette, C¨ Morin, C.M. (2014). Comparative efficacy of behavior therapy, cognitive therapy, and cognitive behavior therapy for chronic insomnia: a randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 82 (4), 670-83. doi: 10.1037/a0036606

Heidenreich, T., Tuin, I., Pflug, B., Michal, M. & Michalak, J. (2006). Mindfulness-based cognitive therapy for persistent insomnia: A pilot study. *Psychotherapy and Psychosomatics*, 75 (3), 188-189. doi: 10.1159/000091778

Isler, W.C.III., Peterson, A.L. & Isler, D.E. (2005). Behavioral treatment of insomnia in primary care settings. In L.C. James & R.A. Rolen (Eds.), *The primary care consultant: The next frontier for psychologists in hospitals and clinics* (pp.121-151). Washington, DC: American Psychological Association. doi: 10.1037/10962-007

Kim, B., Kim, M.Y., & Kim, M.J. (2008). Use of mindfulness-based cognitive therapy for treating insomnia in patients with anxiety disorders: A pilot study. *Journal of Nervous and Mental Disease*, 196 (6), 501-503. doi: 10.1097/NMD.0b013e31817762ac

Lichstein, K.L., Durrence, H.H., Taylor, D.J., Bush, A.J. & Riedel, B.W. (2003). Quantitative criteria for insomnia. *Behavior Research and Therapy*, 41 (4), 427-445. doi: 10.1016/S0005-7967(02)00023-2

Lovibond, P.F. & Lovibond, S.H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behavior Research and Therapy, 33*, 335-343. doi: 10.1016/0005-7967(94)00075-U

Lynch, A.M., Jarvis, C.I., DeBellis, R.J., & Morin, A.K. (2007). State of the art reviews: Nonpharmacologic approaches for the treatment of insomnia. *American Journal of Lifestyle Medicine, 1 (4),* 274-282. doi: 10.1177/1559827607301397

Mai, E., & Buysse, D. J. (2008). Insomnia: Prevalence, Impact, Pathogenesis, Differential Diagnosis, and Evaluation. *Sleep Medicine Clinics*, *3*(2), 167–174. doi:10.1016/j.jsmc.2008.02.001

Manber, R., Hydes, N., & Kuo, T. (2004). What aspects of cognitive-behavioral therapy for insomnia do patients find helpful? *Sleep. 27:*A282.

Morin, C.M. (1993) *Insomnia: Psychological Assessment and Management.* Guilford Press, 1993.

Morin, C. M., & Benca, R. (2012). Chronic insomnia. *The Lancet, 379*(9821), 1129-1141. doi: 10.1016/S0140- 6736(11)60750-2

Morin, C.M., Blais, F.C. & Savard, J. (2002). Are changes in beliefs and attitudes about sleep related to sleep improvements in the treatment of insomnia? *Behavior research and therapy*, 40 (7) 741 – 752. doi: 10.1016/S0005-7967(01)00055-9

Morin, C.M. & Espie, C.A. (2003). Insomnia: A clinical guide to assessment and treatment. New York, NY: Kluwer Academic/Plenum Publishers.

Nolen-Hoeksema, S. (1991). "Responses to depression and their effects on the duration of depressive episodes". *Journal of Abnormal Psychology , 100 (4):* 569–582.

Ong, J.C., Manber, R., Segal, Z., Xia, Y., Shapiro, S., and Wyatt, J.K. (2014). A randomized controlled trial of mindfulness meditation for chronic insomnia. *Sleep, 37*(9):1553-63. doi: 10.5665/sleep.4010

Ohayon, M. M., & Reynolds, C. F. (2009). Epidemiological and clinical relevance of insomnia diagnosis algorithms according to the DSM–IV and the International Classification of Sleep Disorders (ICSD). *Sleep Medicine,* 10, 952-960. doi: 10.1016/j.sleep.2009.07.008

Okajima, I., Komada, Y., & Inoue, Y. (2011). A meta- analysis on the treatment effectiveness of cognitive behavioral therapy for primary insomnia. *Sleep and Biological Rhythms,* 9 (1), 24–34. doi: 10.1111/j.1479-8425.2010.00481.x

Ong, J.C., Shapiro, S.L. & Manber, R. (2008). Combining mindfulness meditation with cognitive-behavior therapy for insomnia: A treatment-development study. *Behavior Therapy,* 39 (2), 171-182. doi: 10.1016/j.beth.2007.07.002

Ong, J.C., Shapiro, S.L. & Manber, R. (2009). Mindfulness meditation and CBT for Insomnia: A naturalistic 12-month follow-up. *Explore,* 5 (1), 30-36. doi: 10.1016/j.explore.2008.10.004

Ong, J.C., & Sholtes, D. (2010). A mindfulness-based approach to the treatment of insomnia. *Journal of Clinical Psychology*, 66 (11), 1175–1184. doi: 10.1002/jclp.20736.

Perlis, M. L., Smith, M. T., Orff, H. J., Andrews, P. J., & Giles, D. E. (2001). The mesograde amnesia of sleep may be attenuated in subjects with primary insomnia. *Physiology & Behavior, 74*(1-2), 71-76. doi: 10.1016/0272-7358(88)90050-5

Ree, M.J. & Harvey, A.G. (2004), Behavioral experiments in chronic insomnia. In J .Bennett-Levy, G. Butler, M. Fennell, A. Hackmann, M. Mueller, & D. Westbrook (Eds.), *Oxford Guide to Behavioral Experiments in Cognitive Therapy* (pp.287-308). Oxford, UK: Oxford University Press.

Roth, T. (2007) Insomnia: Definition, Prevalence, Etiology, and Consequences. *Journal of Clinical Sleep Medicine,* 15 (3), 125-128

Schwartz, D. R., & Carney, C. E. (2012). Mediators of cognitive-behavioral therapy for insomnia: A review of randomized controlled trials and secondary analysis studies. *Clinical Psychology Review, 32*(7), 664-675. doi: 10.1016/j.cpr.2012.06.006

Segal, Z.V., Williams, J.M.G. & Teasdale, J.D. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. New York, NY: Guilford Press.

Semler, C.N., & Harvey, A.G. (2004). Monitoring for sleep-related threat: A pilot study of the sleep associated monitoring index (SAMI). *Psychosomatic Medicine,* 66 (2), 242-250. doi: 10.1054/p0066884

Semler, C.N. & Harvey, A.G. (2006). Daytime functioning in primary insomnia: Does attentional focus contribute to real or perceived impairment? *Behavioral Sleep Medicine* 4 (2), 85-103. doi: 10.1207/s15402010bsm0402_2

Semler, C.N. & Harvey, A.G. (2007). An experimental investigation of daytime monitoring for sleep-related threat in primary insomnia. *Cognition & Emotion*, 21 (1), 146-161. doi: 10.1080/02699930600639462

Stepanski, E.J. (2005). Hypnotics should not be considered for the initial treatment of chronic insomnia. *Journal of Clinical Sleep Medicine*, 1 (2), 125-128. doi: 10.1012/50011-3988(01)00546-6

Teasdale, J.D., Segal, Z.V., Williams, J.M.G., Ridgeway, V., Soulsby, J., & Lau, M. (2000). Prevention of relapse/recurrence in major depression by mindfulness-based cognitive therapy. *Journal of Consulting and Clinical Psychology*, 68 (4), 615-623. doi: 10.1037/0022-006X.68.4.615

Westbrook (Eds.), *Oxford Guide to Behavioral Experiments in Cognitive Therapy* (pp.287-308). Oxford, UK: Oxford University Press.

Winbush, N.Y., Gross, C.R., & Kreitzer, M.J. (2007). The effects of mindfulness-based stress reduction on sleep disturbance: A systematic review. *Explore*, 3, 585-591. doi:10.1016/j.explore.2007.08.003

Winbush, N.Y., Gross, C.R., & Kreitzer, M.J. (2007). The effects of mindfulness-based stress reduction on sleep disturbance: A systematic review. *Explore*, 3, 585-591. doi:10.1016/j.explore.2007.08.003