There is moderate evidence to support CBT and combined therapy for improving sleep efficiency in favor of pharmacotherapy. Neither CBT, combined therapy, or pharmacotherapy were found to be superior at increasing total sleep time for adults with insomnia.

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CLINICAL SCENARIO:

Client Population: Adults who have been diagnosed with primary or comorbid insomnia based upon the DSM-IV-TR.

Treatment context: In these studies, CBT was administered at two hospitals (Jacobs, Edward, Pace-Schott, Stickgold, and Otto, 2004; Morin, Vallieres, Guay, Ivers, Savard, Merette, Bastien, & Ballargeon, 2009) and one outpatient clinic (Sivertsen, Omvik, Pallesen, Bjorvatn, Havik, Kvale, Nielsen, & Nordhus, 2006).

Problem/Condition: Insomnia is a sleep-related condition that affects a person's daytime performance (Rosekind & Gregory, 2010). To be diagnosed clinically, an individual must have impaired daytime functioning and spend over 30 minutes falling asleep for three days a week or have difficulty maintaining sleep for over a month. There are various types of insomnia such as primary insomnia (e.g. problems sleeping without any other diagnosis) or comorbid insomnia (e.g. difficulties sleeping secondary to an illness) (American Psychological Association, 2000). Insomnia is a common diagnosis for individuals older than 55 years of age (Avidan, 2003). Insomnia causes fatigue, poor memory and concentration, reduced satisfaction with interpersonal relationships, and decreased quality of life (Mitchell, Gehrman, Perlis, and Umscheld, 2012). Poor sleep quality has also been linked with the development of mental illness, such as depression (Brown & Stoeffel, 2011), and may increase a person's risk of developing a disease or illness, such as diabetes (Knutson, Rydan, Mander, & Van Cauter, 2006) or heart disease (Ayas, White, Manson, Stampfer, Speizer, Malhotra, & Hu, 2003). Further, insomnia has been found to have a significant financial impact on the health care system (Mitchell et al., 2012).

Incidence/Prevalence: It is estimated that 6% of the population in the United States are diagnosed with primary insomnia, while 30% of Americans report having at least one symptom of insomnia (Roth, 2007).

Impact of this problem/condition on occupational performance: Insomnia is a disorder that is defined by a poor ability to engage in the activity of sleep, which according to the International Classification of Functioning, is a body function (World Health Organization, 2002). Individuals with insomnia experience symptoms, such as fatigue and poor memory, that lead to problems participating in occupations of work, home management, child care, and others (Roth, 2007). Individuals with insomnia also report decreased satisfaction with their quality of life; this is thought to be the result of the psychological, physical, and social problems caused by the illness (Ishak, Bagot, Thomas, Magakian, Bedwani, Larson, Brownstein, & Zaky, 2012).

Intervention: Cognitive behavior therapy for insomnia (CBT) is a non-pharmacological, multicomponent method that works to change an individual's faulty habits, beliefs, and anxiety

regarding sleep. This treatment consists of four parts: sleep restriction, stimulus control, cognitive therapy, and sleep hygiene. Sleep restriction consists of following a strict sleep schedule set by the physician and limits daytime napping. Stimulus control is a component that helps the individual reassociate their bed with sleep by following rules, such as getting out of bed after 15 minutes of being awake and not doing homework/watching television in bed. Cognitive therapy provides tools for individuals to challenge maladaptive, anxiety-producing beliefs about sleep. Sleep hygiene educates the individual about environmental factors that may lead to poor sleep, such as consuming caffeine in the evening or uncomfortable bedroom temperature. Some CBT programs include relaxation training, however, this is not part of the typical protocol. Based on the research studies in this appraisal, the treatment typically occurs over a series of weeks with weekly meetings and is administered individually, in a group, or via the internet/telephone. An important component in the implementation of this treatment is the use of a sleep diary, which is completed daily and allows the individual and health professional to track progress (Rybarczyk, Lund, Garroway, & Mack, 2013).

The comparison interventions for this CAT were medication and combined treatment. The pharmacological intervention included zopiclone (Sivertsen et al., 2006; Morin et al., 2009) and zolpidem (Jacobs, et al., 2004). Both of these medications are non-benzodiazepines (Wagner & Wagner, 2000). These medications were prescribed by the physician to be taken 30 minutes before bedtime (Sivertsen et al., 2006; Morin et al., 2009; Jacobs et al., 2004). The combined treatment groups received CBT and pharmacological intervention.

Science behind Intervention: Individuals with insomnia have been found to experience hyper-arousal and anxiety regarding sleep. The components of CBT for insomnia are designed to lessen sleep-related hyper arousal by using several approaches to challenge an individual's perceptions and change behaviors in order to increase self-efficacy. Sleep restriction is designed to create a state of sleep deprivation that overcomes the sleep-related arousal. This results in the person sleeping through the night, thus improving self-efficacy. Individuals with insomnia have become conditioned to be alert when in the bedroom. Therefore, CBT uses stimulus control to re-establish the individual's association with their bed through behavioral modification, such as only using the bed for sleep. Individuals with insomnia also experience irrational fears about their sleep patterns, which results in hyper-arousal. Cognitive therapy challenges the individual's maladaptive beliefs and replaces them with adaptive beliefs, thus reducing their anxiety about sleep. The sleep hygiene component is included because if environmental factors are not addressed, all other parts of the protocol are less effective (Rybarczyk et al., 2013).

Theoretical Basis of Cognitive Behavioral Therapy for Insomnia: The cognitive-behavioral frame of reference best supports the theory behind CBT for insomnia. The main concept of this frame of reference is that thoughts and perceptions influence a person's behavior and emotions. Therefore, the goal of the cognitive behavioral frame of reference is to address the person's maladaptive thoughts in order to change behavior, which will result in improved functioning (Bruce & Borg, 2002). This directly reflects the premise behind the cognitive therapy portion of CBT for insomnia, which is designed to change an individual's maladaptive thoughts about sleep to reduce the client's arousal and to improve the behavior of sleep (Rybarczyk et al., 2013). Further, the main outcomes of the cognitive-behavioral frame of reference are increased self-knowledge and self-efficacy (Bruce & Borg, 2002). CBT for insomnia addresses self-knowledge by providing an individual an education about sleep and promotes an increased awareness of their own sleep habits. Further, it leads to increased self-efficacy by providing an individual the tools and positive experiences that allow the participant to achieve a desired amount of rest (Rybarczyk et al., 2013).

Why this intervention is appropriate for occupational therapy: CBT for insomnia is an appropriate intervention for occupational therapy because its components fit directly within the scope of the Occupational Therapy Practice Framework. CBT is an intervention designed to directly improve an

individual's occupation of rest and sleep and indirectly improves a person's daytime performance of occupations and participation in valued roles by lessening fatigue. This intervention targets the individual's sleep-related habits and routines by using preparatory methods to facilitate a change in the client factors of global mental functions, in particular, the physiological process of sleep and arousal. CBT also acknowledges a person's cognitive performance skills. Some cognitive skills addressed in this intervention include judging and identifying maladaptive thoughts. An individual's physical and temporal contexts are also key components in this intervention (AOTA, 2013).

FOCUSED CLINICAL QUESTION:
- <u>Patient/Client Group:</u> Adults with insomnia
- <u>Intervention:</u> Cognitive Behavioral Therapy for insomnia
- <u>Comparison Interventions:</u> Pharmacological intervention or combined therapy consisting of CBT and medication
- <u>Outcomes:</u> Sleep efficiency and total sleep time

SUMMARY:
- The clinical question addressed whether cognitive behavioral therapy was more effective than pharmacotherapy or combined therapy at improving sleep efficiency and total sleep time for adults with insomnia
- Six databases were searched and six relevant articles were found. Of these articles, three randomized control trials were selected based on rigor of the study, population of the participants, primary diagnosis, interventions that were compared, and the dependent variables measured. The chosen studies had Pedro scores of 4/8 (Morin et al., 2009), 4/8 (Jacobs et al., 2004), and 6/8 (Sivertsen et al., 2006).
- The three articles reviewed provided moderate evidence to support the use of CBT and combined treatment at improving sleep efficiency in comparison to pharmacotherapy, suggesting that CBT is more effective than medication alone. There is inconclusive evidence to support the effectiveness of using CBT alone, CBT in combination with pharmacotherapy, or pharmacotherapy alone at improving total sleep time.

CLINICAL BOTTOM LINE: There is moderate evidence to support CBT and combined therapy for improving sleep efficiency in favor of pharmacotherapy. Neither CBT, combined therapy, or pharmacotherapy were found to be superior at increasing total sleep time for adults with insomnia.

Limitation of this CAT: This critically appraised topic has been reviewed by occupational therapy graduate students and the course instructor.

SEARCH STRATEGY:

Table 1: Search Strategy

Databases Searched	Search Terms	Limits used	Inclusion and Exclusion Criteria
Cochrane Central Register of Controlled Trials MEDLINE with Full Text (EBSCOhost) CINAHL Plus w/full text Google Scholar Alt HealthWatch	Cognitive Behavioral Therapy for Insomnia Cognitive Behavioral Therapy Insomnia, Medication Cognitive Behavior Therapy and Pharmacotherapy for Insomnia Cognitive-behavioral therapy of insomnia: A clinical case series study of patients with co-morbid disorders and using hypnotic medications An open trial of cognitive therapy for chronic insomnia Pharmacotherapy and CBT for Insomnia	Cognitive Behavioral Therapy and Pharmocotherapy	Inclusion: -English -RCT Exclusion: -Articles prior to 2003 -Pediatric Population

RESULTS OF SEARCH:

Table 2: Summary of Study Designs of Articles Retrieved

Level	Study Design/ Methodology of Articles Retrieved	Total Number Located	Data Base Source	Citation (Name, Year)
Level 1a	Systematic Reviews or Metanalysis of Randomized Control Trials	1	Google Scholar	Smith, 2002
Level 1b	Individualized Randomized Control Trials	1	Cochrane Central Register of Controlled Trials	Siversten, 2006
Level 2a	Systematic reviews of cohort studies			
Level 2b	Individualized cohort studies and low quality RCT's (PEDro < 6)	3	Google Scholar Google Scholar CINAHL Plus w/ full text	Dolan, 2009 Jacobs, 2004 Morin, 2009
Level 3a	Systematic review of case-control studies			

Level 3b	Case-control studies and non-randomized controlled trials	1	Google Scholar	Harvey, 2007
Level 4	Case-series and poor quality cohort and case-control studies			
Level 5	Expert Opinion			

STUDIES INCLUDED:

Table 3: Summary of Included Studies

	Study 1	Study 2	Study 3
Design	RCT	RCT	RCT
Level of Evidence	1b	1b	1b
PEDro score (only for RCT)	4	4	6
Population	-160 participants -Age Mean (SD): 50.3 (10.1) years -Gender: 97 Females, 63 Males -Education Mean (SD): 14.7 (3.5) years -Insomnia Duration Mean (SD): 16.4 (13.6) years -Ethnicity: 100% Caucasian	-63 participants -Age Mean (SD): 47.05 (9.275) years -Gender: 44 Females, 19 Males -Education Mean (SD): 16.225 (3.05) years -Insomnia Duration Mean (SD): 9.625 (8.575) years -Ethnicity: 83% Caucasian, 2% African American, 3% Hispanic, 11% Pacific Islander	-46 participants of Norwegian nationality -Age Mean (SD): 60.8 (5.4) years -Gender: 22 Females, 24 Males -Education mean (SD): 14.1 (5.4) years -Insomnia Duration: 14.1 years (1.43) years -Ethnicity: Information not provided
Intervention Investigated	*Initial Treatment:* 6 weekly, 90 minute group CBT sessions that addressed sleep restriction, stimulus control, cognitive therapy, and sleep hygiene education *Extended Treatment:* 6 months of individualized CBT or no CBT. Relaxation, worry management, and problem solving	4 individual, 30 minute sessions and 1 telephone treatment session over a period of 6 weeks. Sessions addressed sleep restriction, stimulus control, sleep hygiene, relaxation techniques, and cognitive therapy. Post-treatment outcome measures were conducted at 8 weeks.	6 individual, 50 minute treatment sessions that addressed sleep hygiene education, sleep restriction, stimulus control, cognitive therapy, and progressive relaxation techniques

	were addressed in the extended treatment based on individual's needs.		
Comparison Intervention	*-Initial Treatment:* CBT with same protocol mentioned above in initial treatment section, combined with 10 mg/d of zolpidem taken 30 minutes before bedtime. *-Extended Treatment:* 6 months of CBT with no medication or CBT plus 10 mg of zolpidem as needed. Extended Treatment CBT followed same protocol as mentioned above in extended treatment section.	*-Pharmacotherapy:* 10 mg of zolpidem for 28 days, 5 mg per night for 7 days, 5 mg per night every other day. All doses were taken 30 minutes before bedtime. Participants attended initial 30 minute meeting to discuss medication management and then 2 phone calls with physician over period of 6 weeks. In weeks 7 and 8, participants met 3 times and had 1 phone call with therapist to receive sleep education information. *-Combined CBT:* Combination of pharmacotherapy and CBT groups' protocol *-Placebo:* Same protocol as pharmacotherapy with inactive pill.	*-Pharmacotherapy:* 7.5 mg of Zopiclone that was taken 30 minutes before bedtime and met weekly with the physician. *-Placebo medication:* Same protocol as pharmacotherapy with inactive pill.
Dependent Variables	Sleep onset latency, time awake after sleep, total sleep time, sleep efficiency, and treatment response and remission rates.	Sleep onset latency, sleep efficiency, total sleep time, and mood-related daytime functioning.	Total wake time (summation of sleep-onset latency, wake time after sleep onset, and early morning awakening), total sleep time, sleep efficiency and slow wave sleep.
Outcome Measures	Sleep Diary, Polysomnography at clinic, and Insomnia Severity Index	Sleep Diary, Night Cap Sleep Monitor Recordings, Profile of Moods State Scale, and Beck Depression Inventory	Sleep Diary and Polysomnography in the home
Results	*Post-treatment* -Clinically important changes in CBT group at 6 weeks in sleep onset latency (d= -.83), wake time after sleep (d= -1.56), sleep efficiency (d=1.22). -Combined treatment had two clinically important changes in time awake after	*Mid-treatment* -Combined treatment showed greater reductions in sleep-onset latency at mid-treatment (P=.05). -CBT was found to significantly improve sleep efficiency at mid-treatment compared to placebo (P=.03). *Post-treatment* -Combined treatment and CBT group showed greater reductions	*Post-treatment* -After six weeks, total wake time for CBT group improved significantly more than placebo and zopiclone groups (P<.001). -No significant changes for total sleep time among groups after six weeks.

	sleep onset latency (d= -1.88) and sleep efficiency (d=1.34).

6-month follow up
-No clinically important changes found in 6 month treatment for four treatment groups in sleep onset latency, wake time, sleep efficiency, and total sleep time.
-Combined treatment produced higher remission rates compared with CBT alone during 6 month extended phase (P=.05)
-At 6 month follow-up, higher remission rates were found for patients being treated with combined treatment first, followed by CBT alone compared to patients who continued to take medication in the extended phase (P=.04). | on sleep onset latency compared to pharmacotherapy (P=.02 for combination, P=.03 for CBT) and placebo (P=.001 for combined treatment, P=.03 for CBT).
-After treatment, CBT group had greater increases in sleep efficiency compared to pharmacotherapy group (P=.007). CBT and combined treatment participants had significant increases in sleep efficiency in comparison to placebo (P=.02 for CBT, P=.01 for combined treatment).
-No significant differences found among groups in total wake time and daytime mood from pre-to post-treatment. | -The CBT group showed significantly greater sleep efficiency at 6 weeks compared to placebo (P=.004). No significant difference between CBT and zopiclone groups. The amount of slow-wave sleep significantly improved in CBT compared to placebo (P=.03) and zopiclone groups (P=.002).

6-month follow up
-At 6 month follow up, total sleep time improved significantly in CBT group compared to 6 weeks (P=.05). Zopiclone had no significant changes at six month follow-up.
-CBT had significant improvements compared to zopiclone in total wake time (P=.001), sleep efficiency (P=.008), and slow-wave sleep (P=.001). No significant changes in total sleep time. |
| **Effect Size** | -CBT compared to combined treatment had strong effect sizes for sleep onset latency (Sleep Diary d =2.94, polysomnography d=3.21) and total sleep time (Sleep diary d=2.24, polysomnography d=1.525). | -CBT compared to Zolpidem had medium effect size for sleep-onset latency (d=.54) and large effect size for sleep efficiency (d=-1.22) after completion of treatment.
-CBT compared to placebo had large effect size for sleep onset latency (d=.966), medium to large effect size for sleep efficiency (d=-.66 for sleep diary at mid-treatment, d=1.25 for night cap | -CBT compared zopiclone had strong effect size for total wake time (d=.952) and at 6 month follow-up (d=.92).
-For sleep efficiency, CBT compared to zopiclone had weak effect size post treatment (d=-.1) and strong effect size at |

	-For sleep efficiency, CBT compared to combined treatment had strong effect size for sleep diary (d=1.098) and medium effect size for polysomnography (d=-.546). -For time awake after sleep onset, CBT compared to combined treatment had strong effect size for sleep diary (d=-2.88) and weak effect size for polysomnography (d=.03). -Insomnia Severity Index had strong effect size (d=-1).	recording at post-treatment). -Combined treatment compared to placebo had large effect size for sleep onset latency (d=.97) and sleep efficiency (d=-1.26) at post-treatment. -Combined treatment compared to pharmacotherapy had medium effect size for sleep onset latency (d=.55) at post treatment. -CBT compared to combined treatment had minimal effect size for sleep onset latency (d=.002) and sleep efficiency (d=.01) at post-treatment.	follow up (d=-1.1). -CBT compared to zopiclone had strong effect size for slow wave sleep at post treatment (d=-.87) and at follow up (d= -1.05) -When comparing CBT to placebo, there was a small effect size for total wake time (d=-.224), medium effect size for sleep efficiency (d=-.626), and strong effect size for slow wave sleep (d=-1.326) at post treatment.
Conclusion	-CBT and combined treatment both had clinically important results in sleep onset latency and sleep efficiency at the end of 6 week treatment. In addition, CBT had a clinically meaningful change in wake time after sleep. -Long term results were most effective after initial six weeks of combined treatment followed by 6 months of CBT without medication -Between-groups comparison information was not provided, therefore, one cannot conclude whether the treatment groups were significantly different in sleep efficiency, sleep onset latency,	-CBT alone or combined treatment were more effective at increasing sleep efficiency and sleep onset latency than medication. There was no difference between groups for total sleep time. -Combined treatment provided no added advantage when compared to CBT alone. -No treatment group was found to be more effective at improving daytime mood.	-CBT was more effective post-treatment and in the long-term for most variables (except total sleep time) when compared to zopiclone and placebo. -CBT groups had lasting improvements in total wake time, sleep efficiency, and slow-wave sleep. No lasting treatment effects were found for pharmacotherapy group at post-treatment and 6 month follow-up.

	total wake time, and total sleep time.		

IMPLICATIONS FOR PRACTICE, EDUCATION and FUTURE RESEARCH:

Overall Conclusions

The studies reviewed in this CAT were fair (Morin et al., 2009; Jacobs et al., 2004) to moderate (Sivertsen et al, 2006) quality randomized control trials that studied various treatment for adults with insomnia. These articles compared the effectiveness of CBT intervention to medication or combined treatment at improving total sleep time and sleep efficiency. Among the studies, total sleep time was defined as the actual amount of time one spends asleep, while sleep efficiency was the ratio of total sleep time compared to total wake time during a sleep period.

There were no statistically significant differences found in total sleep time between treatment groups (Jacobs et al., 2004; Sivertsen et al., 2006). Morin et al., (2009) did not complete a between-groups comparison. After further analysis, it was found that there was a clinically meaningful difference between CBT and combined treatment. The statistical significance of this finding is not known and no claim can be made regarding the effectiveness of CBT in comparison to others at improving total sleep time (Morin et al., 2009). All CBT and combination groups had clinically meaningful changes in sleep efficiency, but no significant differences and small treatment effects were found between CBT and combination treatment. Thus, CBT was not found to be more effective than combination treatment or vice versa. CBT was more effective after 8 weeks of treatment (Jacobs et al., 2004) and 6 months after the conclusion of the treatment (Sivertsen et al., 2006).

All studies utilized CBT and combined therapy, which consisted of six weeks of active participation in individualized or group format treatment that was administered in an outpatient hospital or clinic. Morin et al., (2009) used a group format, which consisted of 6, 90 minute weekly sessions, with a follow-up six month extended individualized CBT. The other studies had individualized treatment sessions (Jacobs et al., 2004; Sivertsen et al., 2006). Jacobs et al. (2004) had 4, 30 minute treatment sessions with one telephone session, while Sivertsen et al. (2006) had 6, 50 minute treatment sessions. The four main components of CBT were included in all studies; however, the degree to which the CBT concepts were applied during treatment sessions was not clearly defined. Two studies also included relaxation techniques during the first six weeks of treatment (Jacobs et al., 2004; Sivertsen et al., 2006).

The effects of CBT were shown across all three studies that took place in different environments (clinic and home), utilized different outcome measures (polysomnography and night cap recordings), compared to different medications (Zolpidem and Zopiclone), and between countries (Norway and United States of America).

There is moderate evidence to support CBT for insomnia in favor of pharmacotherapy at improving sleep efficiency. CBT and combination treatment both had clinically meaningful changes, however, neither treatment was found to be more effective than the other at improving sleep efficiency. No treatment group was found to be more successful at increasing total sleep time. This CAT provides moderate evidence because the three randomized controlled trials reviewed included one high quality study with a PEDro level of 6 (Sivertsen et al., 2006).

Boundaries:

The studies reviewed in this CAT included a total of 269 participants, with at least 46 participants per study. All participants had a diagnosis of primary or comorbid insomnia, reported difficulty initiating sleep for at least thirty minutes three times per week for three months, and complained of impaired daytime functioning. All studies excluded individuals who performed shift work, had a sleep-altering medical condition or medication, such as a current diagnosis of depression, sleep apnea, or restless leg syndrome. Participants in this CAT were at least 25 years of age and the mean age was 52.7 years old. There were 163 females and 106 males included in this CAT with an average

of 14.1-16.2 years of education and insomnia duration of 13.38 years. Based on these boundaries, the results cannot be applied to individuals who have a diagnosis that was excluded or individuals under the age of 25.

Implications for Practice:

This CAT found that CBT and combined (CBT + medication) treatment had an advantage over pharmacotherapy at improving sleep. The lack of notable difference between the effectiveness of interventions, in particular CBT and combined treatment, suggests that one intervention is not superior. The effectiveness of CBT alone or in combination with medication provides another intervention tool for insomnia. Occupational therapy is a profession that has a role to play in the non-pharmacological treatment of sleep. Although CBT is a treatment commonly utilized by other professions, the concepts of CBT fall within the domain of occupational therapy practice. Based on the evidence reviewed, occupational therapists who work with populations at risk for sleep problems, such as mental health or geriatrics, should consider receiving further training in CBT treatment for insomnia.

Future research needs to be conducted to find the most effective treatment dosage of CBT for insomnia to allow for the most efficient treatment. Further, the studies reviewed excluded participants who had conditions that affect sleep quality. Therefore, research needs to be done to determine if the principles of CBT are effective for those individuals. Finally, research should focus on whether CBT and other sleep-related interventions are effective at improving an individual's daytime functioning and quality of life.

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