Critical Appraisal Form-Quantitative Study

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Study Level of Evidence, What Type of Study?

Level I: X RCT
Level II: ___Cohort trial ___Case-control trial ___Non-randomized control trial
Level III: ___Case-control ___no pre-post test
Level IV: ___Single case study ___Case series ___No comparison group
Level V: ___Descriptive study ___Narrative review ___Expert opinion

Purpose of Study: Is purpose clear? x yes ___no

Describe researchers question/purpose:
Whether mindfulness meditation, delivered using MSBR (which is a standard meditation program) or using MTBI (a custom meditation program with behavioral strategies for insomnia) would be superior to a self-monitoring control.

METHODS
Were there any biases or ethical concerns in the study design?
The authors said that "we cannot rule out investigator bias" within the discussion section of the study. There was a potential bias with the sample volunteering for study participation. The participants signed informed consent and the study was approved by the Rush University Medical Center Institutional Review Board.

POPULATION
Who was the sample, how many subjects?
- N= 54 Adults over the age of 21
- Recruited mainly through posted advertisements
- N= 16 Arm1 MBSR
- N= 18 Arm2 MBTI
- N= 16 Arm3 self-monitoring

Inclusion Criteria:
- Adults over the age of 21
- Insomnia disorder, defined as difficulty initiating or maintaining sleep that occurs despite opportunity to sleep
- Having at least one symptom of an associated daytime impairment
- Specification for frequency, chronicity, and symptom of heightened cognitive or somatic arousal

Exclusion Criteria:

- Uncontrolled medical condition that was suspected to interfere with sleep or that required immediate treatment outside the study
- Uncontrolled psychiatric condition requiring immediate treatment outside of the study
- Comorbid sleep disorders
- Use of hypnotics or sedating medication
- Inadequate proficiency in English

What was the Intervention? Frequency, Setting?

- **Arm1:** The Mindfulness-based Stress Reduction (MBSR) treatment consisted of 8-weekly 2.5-hour group meetings, with one 6-hour meditation retreat that took place between the fifth and seventh weeks.
- MBSR intervention included meditation practice (breathing meditation, body scan meditation, walking meditation), discussion about at-home meditation, and education about how to apply meditation in daily life.
- **Arm2:** The Mindfulness-based Therapy for Insomnia (MBTI) consisted of 8-weekly 2.5-hour group sessions.
- MBTI sessions included formal mindfulness meditations that included one quiet and one movement meditation, a period of discussion, and a focus on specific behavioral strategies for insomnia
- **Arm3:** Self-Monitoring group consisted of 8 weeks of self-monitoring and keeping sleep journals
- The setting of all groups was the Rush University Medical Center

Relevant outcomes to OT?	**How measured?**
1.)_Pre-sleep wakefulness	Pre-Sleep Arousal Scale (PSAS)
2.) Nighttime and daytime symptoms of insomnia	Insomnia Severity Index
3.) Patient-reported pre-sleep arousal	Sleep journals
4.) Total time awake	Total Wake Time (TWT)- sleep journal

Were the tests valid? Explain: The tests exhibited validity in that they tested what they said they would test and measured accordingly.

Were the tests reliable? Explain:
The PSAS and ISI are standardized assessments that have established reliability

RESULTS, CONCLUSIONS, CLINICAL IMPLICATIONS:

What were the findings? Was there:
Statistically significant change?

- Meditation groups had statistical significant change on ISI (p <0.0001) with decreased insomnia

- Meditation groups had statistical significant change on PSAS ($p < 0.002$), indicating decreased pre-sleep arousal
- The findings revealed evidence of treatment efficacy for meditation-based treatments to reduce patient-reported TWT in bed and sleep-related arousal.

Clinically significant change?
There were clinically significant improvements with amount of time sleeping and reduced psychophysiological arousal, a common waking correlate of chronic insomnia disorders. Participants who received either MBSR or MBTI reported a mean reduction in total wake time from baseline to post-treatment of 43.75 minutes. This is ¾ of an hour extra of sleep. This would have a major positive effect on a client who was having difficulties with their ADL Sleep.

What did the author conclude?: The author concluded that the study found that mindfulness meditation appears to be a viable treatment option for adults with chronic insomnia and could provide an alternative to traditional treatments for insomnia.

My Brief Summary:
What I see as study strengths: The study focused on alternative/holistic treatments that aid individuals who have insomnia instead of focusing on medication treatments. Also this study expanded upon a pilot study the researchers created to gather preliminary evidence for treatment efficacy in a randomized control trial.

What I see as limitations:
A limitation of the study was that it a small sample size that consisted mostly of Caucasian females. Also the participants were required to report elevated sleep-related arousal which is not commonly reported in studies on the efficacy of treatments for insomnia. Therefore the results cannot be generalized for all individuals who experience chronic insomnia. There was also a limited set of providers in this study which would have created investigator bias. Also, this study was not designed to detect treatment effects on objective measures of sleep. Lastly, blinding of the participants or the researches was not used which could have created bias.

How is the study's findings relevant to OT?
Both mindfulness-based stress reduction (MBSR) and mindfulness-based therapy for insomnia resulted in reduced total wake time for people with insomnia, however MBTI elicited a greater reduction in the severity of symptoms. As an OT working with a patients with chronic insomnia, it helps to know that mindfulness will help with symptoms, and mindfulness with a behavioral component works even better. In order to produce long term change in an individual with insomnia, MBTI should be utilized over MBSR. Sleep is an important daily occupation that is necessary for occupational performance, so we as OT's need to consider the type and amount of sleep our clients are getting.

How do I intend to use these results?
It is important to include mindfulness in practice because it causes a person to be aware of their behaviors and how it is affecting the body. Not only will I include mindfulness, but also how to incorporate mindfulness into changing behavior. The behavioral component is what will bring about change in patients and leave lasting results.