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Mindfulness-based intervention for prodromal sleep disturbances in older adults: Design and methodology of a randomized controlled trial

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ABSTRACT

Sleep problems are prevalent among older adults, often persist untreated, and are predictive of health detriments. Given the limitations of conventional treatments, non-pharmacological treatments such as mindfulness-based interventions (MBIs) are gaining popularity for sleep ailments. However, nothing is yet known about the impact of MBIs on sleep in older adults with prodromal sleep disturbances. This article details the design and methodology of a 6-week parallel-group RCT calibrated to test the treatment effect of the Mindful Awareness Practices (MAPs) program versus sleep hygiene education for improving sleep quality, as the main outcome, in older adults with prodromal sleep disturbances. Older adults with current sleep disturbances will be recruited from the urban Los Angeles community. Participants will be randomized into two standardized treatment conditions, MAPs and sleep hygiene education. Each condition will consist of weekly 2-hour group-based classes over the course of the 6-week intervention. The primary objective of this study is to determine if mindfulness meditation practice as engaged through the MAPs program leads to improved sleep quality relative to sleep hygiene education in older adults with prodromal sleep disturbances.

Mindfulness meditation versus sleep hygiene education for sleep disturbances in older adults: Design and methodology of a randomized controlled trial.

Sleep problems are a significant health issue among older adults. Approximately 50% of older adults have difficulties initiating or maintaining sleep [1,2]. Sleep problems increase the risk for health ailments in older adults. Chronic inadequate sleep can adversely affect quality of life by impacting functional capabilities including memory, learning, and attention [1–3]. Sleep problems are also prospectively linked to significant psychological and physical morbidity [4]. Older adults who report sleep problems experience more symptoms of anxiety and depression than those who report no sleep problems [2,5]. Physical health consequences of sleep problems include increased risk for cardiovascular disease, respiratory disorders, and metabolic disorders [6–8]. In addition, sleep disturbances predict physical decline with age and are associated with increased risk for all-cause mortality [3]. The effects of inadequate sleep are cumulative [9], making those with sleep disturbances particularly vulnerable to compounding health problems. The burden of sleep problems on the older adult population represents a significant public health concern that requires low-cost and readily accessible treatment approaches that have the capacity to impart lasting effects.

Sleep problems are undertreated in older adults [10,11]. Moreover, among those who receive treatment, pharmacological therapies are often provided, even though sleep medications are associated with a host of adverse side effects and dependency syndrome [10,11]. As such, non-pharmacological interventions for sleep problems are gaining popularity.

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Moreover, treatments for insomnia symptoms such as Cognitive Behavioral Therapy for Insomnia (CBT-I) can be somewhat effective, yet they require a highly trained therapist, are not routinely implemented due to complexity issues, and are typically only delivered in a clinical setting [12]. These limiting factors indicate the need for approaches that can be more readily delivered in the community. Mindfulness-based interventions (MBIs) are particularly promising non-pharmacological treatments, and have gained substantial popularity in recent years for use with a variety of health-related issues, including sleep problems. MBIs train participants in the systematic and secular practice of continually attending to moment-by-moment experiences, thoughts, and emotions from an open, non-judgmental perspective [13,14].

The one review on MBIs and sleep to date indicates that mindfulness-based interventions (MBIs) can improve some sleep parameters in younger and mid-age adult samples, yet the data remained insufficient to draw concrete conclusions [15]. Many MBIs for sleep have been fraught with methodological limitations that limit interpretation of findings, such as underpowered sample sizes, lack of control conditions, sleep problems as a secondary outcome to a primary condition such as cancer and anxiety, and a generalizability restricted to clinical populations [16–19]. As such, a major gap remains in the research regarding the effect MBIs on sleep disturbances in older adults with prodromal sleep disturbances.

Sleep problems may also have adverse effects on inflammatory processes [20,21]. Evidence indicates that disturbances in sleep quality and quantity are associated with increases in peripheral markers of inflammation [9,21]. The impact of sleep problems on inflammation may have implications for health issues. Many of the inflammatory markers that can increase as a result of sleep problems have been linked to health problems such as cardiovascular disease [8,9]. As older adults are prone to both increased risk for diseases associated with inflammation and sleep disturbances, treatments that can beneficially impact inflammation as well as sleep parameters have potential to improve health outcomes in this population.

Initial evidence indicates that MBIs and movement forms of meditation such as Tai Chi can modulate inflammatory biomarkers. For example, findings from our RCT of a movement meditation Tai Chi versus stress and health education showed that meditation reduced levels of an upstream pro-inflammatory transcription marker (i.e. NF-κB) in older adults at immediate post-intervention [22]. While these findings indicate promising potential for meditation practices to reduce inflammatory response factors, more research is needed to specifically understand the impact of MBIs on biological markers of inflammation in older adults.

Understanding the impact of MBIs on sleep may elucidate a new non-pharmacological approach for the treatment of prodromal sleep disturbances in older adults in the community setting. This article describes the methodology and design of a randomized controlled trial that aims to test whether participation in a MBI results in improved sleep parameters and reduced pro-inflammatory transcription factor (i.e. NF-κB) compared to a sleep hygiene education (SHE) control condition in older adults with sleep problems. This research effort is novel as it compares two community-based treatment offerings, MBI vs SHE, in a randomized controlled trial. This study is also the first MBI trial to target sleep disturbances in a sample comprised solely of older adults.

1. Study objectives

The primary aim of this study is to determine if an ongoing curriculum-based MBI that is available to the general community, Mindful Awareness Practices (MAPs), leads to greater improvements in sleep quality, represented by reductions in global Pittsburgh Sleep Quality Index (PSQI) score, compared to SHE in older adults with sleep disturbances. We anticipate that SHE will improve sleep, but that MAPs will lead to greater improvements in PSQI scores. In order accomplish this aim, we will test the treatment effect of MAPs in comparison to SHE on PSQI scores. Secondary aims are to test if MAPs versus SHE leads to relative improvements in sleep-related daytime impairments (i.e., insomnia, fatigue, depressive, stress, and anxiety symptoms) as well as levels of Nuclear Factor (NF)-κB. NF-κB is a transcription factor that regulates genes responsible for the inflammatory response.

2. Study design

In older adults with sleep problems, this single-site, parallel-group randomized controlled trial with a pretest and immediate posttest design will test the relative effect of the MAPS to SHE program for improving sleep and secondary outcomes of daytime impairment. Participants will be randomized into one of two experimental conditions: (1) the MAPs course at the University of California, Los Angeles or (2) sleep hygiene education (SHE). Both study conditions will be comprised of a standardized 6-week group-based intervention administered at the UCLA Westwood Medical Campus. The UCLA Institutional Review Board has approved all study procedures. This trial will be registered at clinicaltrials.gov.

3. Participants

Participants will include older adult community volunteers between the ages of 55 and 90 (an average age of 65 is expected). Participants will be recruited over a six-month period through advertisement in the local newspaper and flyers posted at our university medical center and affiliated clinical institutes located in Los Angeles, CA. Trained data collectors will screen all interested participants via a 15-minute telephone interview to ascertain sleep problems and study eligibility. Participants will be compensated up to $50 in gift cards and will receive parking vouchers for each visit at the medical center. Eight visits will be requested, including 1 pretest assessment, 6 intervention sessions, and 1 post-test assessment.

4. Power analysis

A priori power analysis was conducted in Gpower, and is based on previous research showing that MBIs and psychoeducational interventions can have between-group medium-sized effects on self-reported sleep quality (e.g., PSQI) in adults with sleep problems [23]. Given 80% power, $p < .05$ (two-sided), 2 treatment groups with 2 assessment points, and a .60 test–retest r (PSQI) [24], the estimated final sample size

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