Effects of Sleep Hygiene Education on Sleep Health in Community-Dwelling Older Adults

NCT NUMBER: 05483920

01/01/2023

Study Protocol and Statistical Analysis Plan

We propose investigation into the efficacy of sleep hygiene interventions on Americans ages 50-80. This will be done by examining the effectiveness of two separate interventions on improving sleep hygiene habits and physiological markers of sleep provided by wearable technology on sleep efficiency, time in bed, time actually sleeping, and time spent at each stage of sleep. The proposed research project will evaluate the efficacy of sleep hygiene education on CDOA and assess the ability of daily automated text messaging in CDOA to serve as an effective augmentation for sleep hygiene education This research topic corresponds to the South Dakota Biomedical Research Infrastructure Network (BRIN) area of focus: "Physiological (including cellular) and developmental responses to stimuli." Physiological markers of sleep provided by wearable technology on sleep efficiency, time in bed, time actually sleeping, and time spent at each stage of sleep.

Research Plan

Specific Aim 1: Evaluate the efficacy and feasibility of sleep hygiene education on CDOA.

Rationale: Our first aim is to determine if sleep hygiene education can be beneficial in improving sleep health in the CDOA population. Sleep hygiene education has been shown to be effective in university students, high school students, athletes, and working adults, but up until very recently has yet to be shown in CDOA. Recently, Tucker et al. published a pilot study looking at virtual sleep health education in older adults and found significant changes in sleep quality, maladaptive sleep health behaviors, and daytime sleepiness compared to controls. In this six-week study, six 30-minute videos were used to educate participants on sleep health.[23] A variety of other sleep hygiene education tools have been used to assist in improving sleep health in younger populations, but a one-time educational video was chosen for this project as this was the most popular intervention in previous studies and because we wanted to explore if a one-time educational video would show similar findings as the recent 6-week Tucker et al. study had in regard to sleep health behavior change.[5, 23] Therefore, a 4-week, home-based, technology-supported program targeting sleep hygiene will be conducted among 80 CDOA, ages 50-80 using a 30-minute educational video. Eighty participants is based off of the systematic review performed by Murawski et al. which reviewed sleep health intervention research studies which had participant sizes ranging from 19 to 391 with a median of 84.[5] Taking into account a potential dropout rate of 20%, the initial total number of participants to be recruited will be 100. Similar studies performed in younger populations have shown 4-weeks is an effective time frame to implement sleep hygiene education. This in combination from data from the Murawski review which showed an average study duration of 5-weeks with a mode of 4-weeks, therefore 4-weeks was chosen for our study duration.[5] During the 4-week study, several physiological markers will be taken. These markers will be taken from data collected on the FitBit Inspire HR device and will include sleep efficiency, time in bed, time actually sleeping, sleep midpoint, and time spent at each stage of sleep. FitBit was the device chosen to track these markers due to its efficacy and comparability to the Actigraph device along with FitBit's usability.[32] Of the several wearable devices that track sleep on the market, FitBit is used in more biomedical clinical research than any other consumer wearable.[33] The FitBit Inspire HR 2 was specifically chosen given its ability to track sleep along with it aligning most closely with

the FitBit Alta (now out of stock with FitBit) that was proven comparable and slightly more accurate to actigraphy as researched by Chinoy et al. in 2020.[30]

Experimental design: The proposed 3-year pilot study will begin in the fall (September 2022) and conclude before the end of the academic year (May 2025). This proposal design outlines the first year of this 3-year study. The first step in the experimental process will be the creation of a 30-minute sleep hygiene education video that will be provided to participants to watch on either a smartphone or computer. The video will be created by the PI and student researcher(s) and reviewed and modified based on feedback from the mentors. This video will include tips to improve sleep hygiene and habits. The video will provide education on the value of having a consistent time of going to sleep and waking up in the morning, setting the bedroom up so that it is a comfortable temperature, dark, quiet, and relaxing. The video will also include information regarding the value of removing electronic devices from the bedroom, the importance of exercise, along with avoiding caffeine, alcohol and large amounts of food prior to going to bed.[34] The principal investigator and student researcher(s) will recruit participants through flyers and word of mouth. Flyers will be placed at senior centers, community centers, and medical centers in Rapid City, SD. Interested participants will email or call Dr. Ashley Pfeiffer to enroll in the study. Dr. Ashley Pfeiffer will meet with the participant to determine eligibility status for the study. Due to the use of human subjects in this study, the research protocol will be approved by the University of South Dakota, Black Hills State University institutional review boards, and the National Institutes of Health prior to participant recruitment. Participant inclusion criteria will include participants ages 50-80, own a smartphone with the capability of receiving text messages. Exclusion criteria: a diagnosed sleep disorder such as insomnia or obstructive sleep apnea, and inability to wear any sleep tracking device on their wrist. During the initial visit, participants will read through and sign informed consent explaining the procedures and expectations of them during the study. The participants will then complete the following questionnaires related to the primary objectives of the study: the Ru-SATED questionnaire which includes the Sleep diary (based on the Consensus Sleep Diary) and Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, and the Sleep Hygiene Index. Participants will also complete the Perceived Stress Scale, Numeric Pain Rating Scale, and Patient Specific Functional Scale as secondary outcomes. Initial data collection will consist of taking anthropometric measurements and vital signs (Figure 1), with the assistance of the student researcher. The anthropometric measurements will include the following: body weight, height, and body mass index (BMI). BMI will be calculated by the standard method (body weight [kg]/ height [m]2) from weight and height measurements. The vital signs assessed will be resting blood pressure, heart rate, and respiratory rate. Following anthropometric data collection and vital signs, the participants will be instructed on the use of the wearable sleep tracker and provided assistance with setting up and charging the device. Participants will be instructed to contact the PI with any questions throughout the study by email or phone. The participants will then watch the sleep hygiene education video created by the research team.

Following the initial meeting with the PI, the participants will wear the sleep tracker on their wrist during the day and night for 4 weeks. The sleep tracker will monitor the physiological markers of sleep provided by wearable technology on sleep efficiency, time in bed, time actually sleeping, sleep midpoint, and time spent at each stage of sleep. Within the first week of participating in the study, student researcher(s) will contact the participant and perform a short 5- minute qualitative interview on the participants understanding and comprehension of the educational video along with a satisfaction survey (using a 5-point Likert scale). At the end of

the 4-week study period, the PI and/or student researcher(s) will once again meet with each participant. The participant will complete the following questionnaires once again: Sleep diary, Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, Sleep Hygiene Index, Perceived Stress Scale, Numeric Pain Rating Scale, and Patient Specific Functional Scale. Acceptability will be again assessed using a satisfaction survey (5-point Likert scale) and qualitative interview. Anthropometric data collection and vital signs will be reassessed, and the sleep tracker will be returned to the PI. Pre/post measurements will be compared and data analyses will be conducted using a 2x2 mixed factorial repeated measures ANOVA test. The PI will be assisted in the stats process by her mentor, Dr. Siengsukon along with her peer in the psychology department at her university.
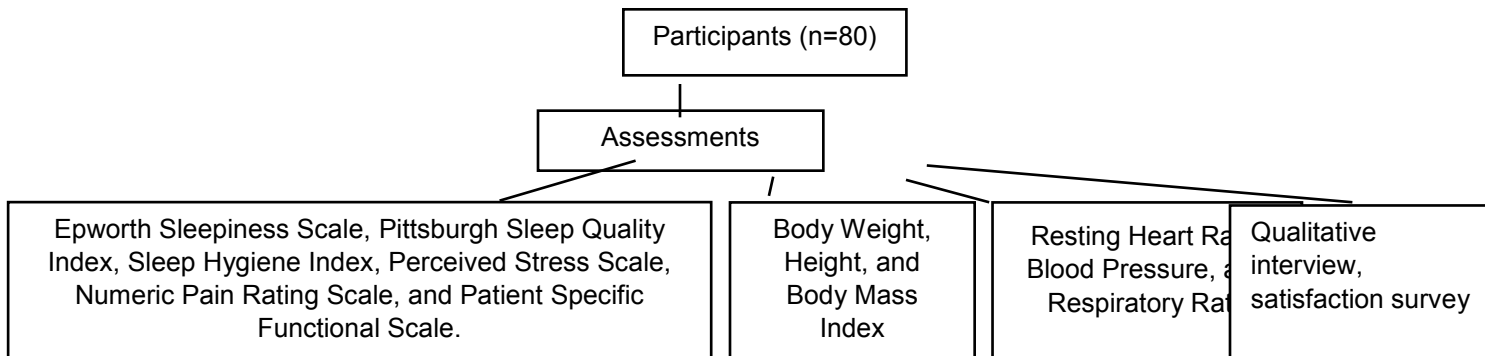
During the first year of this study, when in the treatment development phase, our primary outcomes for feasibility will be the following: recruitment (people enrolled from people contacted), retention and attrition (participants who complete the study and number who drop out), adherence (number of sessions attended and adherence to intervention protocol). Acceptability will be assessed using the satisfaction survey (5-point Likert scale) and qualitative interview. This information will be used to tailor the intervention to CDOA to further assess treatment effect in year two and three.

Assessing overall sleep health is relatively new and therefore there is no established gold standard, however the Ru-SATED questionnaire (Table 1) has been shown to be a reliable and valid measure of sleep health.[35] We will use this in combination of objective data from the FitBit device to measure sleep health. Each sleep health domain will be dichotomized using the cut-off points in Table 1 with 0 = poor sleep health and 1 = good sleep health. The domains will be summed to create the composite sleep health score ranging from 0 - 6 with a higher score indicating better sleep health.

Table 1 Sleep Health Composite			
Sleep health domain	**Source**	**Operational definition**	**Cut-off for good sleep health**
Regularity	FitBit	Standard deviation of sleep midpoint, which is calculated as [sleep onset + (wake time – sleep onset/2)]	<60 min
Satisfaction	Sleep Diary	The sleep diary includes an item to rate "restedness upon awakening" with 0 = "not at all", 1 = "somewhat", 2= "moderately", 3 = "quite a bit", and 4 = "extremely". Satisfaction will be operationalized as the average "restedness" score	Average of ≥3
Alertness	Epworth Sleepiness Scale	Epworth Sleepiness Scale which consists of 8-items of various activities (ie. sitting and reading, watching TV, etc) answered using a 4-point Likert Scale with 0 = "would never nod off" to 3 = "high chance of nodding off"	≤10
Timing	FitBit	Average sleep midpoint	2am-4am

Efficiency	FitBit	Average total minutes of sleep divided by time in bed multiplied by 100	>85%
Duration	FitBit	Average total minutes of sleep	6-8 hours

Table 1: Sleep Health Composite

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                    │   Participants (n=80)    │
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                    │      Assessments         │
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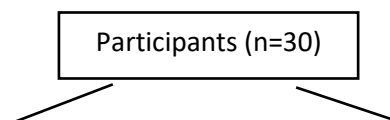| Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, Sleep Hygiene Index, Perceived Stress Scale, Numeric Pain Rating Scale, and Patient Specific Functional Scale.	Body Weight, Height, and Body Mass Index	Resting Heart Rate, Blood Pressure, and Respiratory Rate	Qualitative interview, satisfaction survey

Figure 1: Study design for Specific Aim 1.

Specific Aim 2: Assess the ability of daily automated text messaging in CDOA to serve as an effective augmentation for sleep hygiene education.

Rationale: Our second aim is to study the effectiveness of sending automated text messaging as an effective augmentation for sleep hygiene education in CDOA. With the promising short term results of a one-time sleep hygiene education session in young adults and the working adult population, we want to test if reinforcing the education daily through the use of a simple text message over the course of 4 weeks provides even greater and more sustainable results on changing people's sleep behaviors. The expansion of smartphone technology combined with the abundance of services offering bulk messages to be sent out automatically provides an opportunity to reinforce the initial education with continual reminders of good sleep habits that an individual can practice over the course of 4-weeks. Given that 86% of adults over 50 now consistently use text messaging; it is safe to say this is an easy way to provide daily education and reminders on good sleep habits to this population.[28] If a new habit can be solidified during this timeframe, perhaps we will see long-term changes in sleep that will greatly improve overall health and wellness. For these reasons, we want to explore using automated text messaging as a supplement to our 30-minute educational video for sleep hygiene education.

Experimental design: Following anthropometric data collection and vital signs, as well as having the participants watch the sleep hygiene education video created by the research team, the participants will be randomly assigned to one of two groups (Figure 2). The intervention group will receive daily automated text messages scheduled for 8:00 pm every evening. The text messages will include a variety of sleep hygiene behavioral tips for the participant to try (Table 2). The participants will receive the text messages for a total of 4 weeks. The control group will not receive any intervention during this time frame. Following the 4 weeks, PI and student researcher(s) will meet again with the participants to collect the same data that was collected at the initial visit. Each participant will have a total of 2 sessions to complete with each session taking approximately 45-60 minutes to complete.

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                    │   Participants (n=30)    │
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Sleep Hygiene Education Video Group (n=15)	Sleep Hygiene Education Video Plus Daily Automated Text Messaging Group (n=15)

Figure 2: Study design for Specific Aim 2.

Day	Daily Text
1 & 16	Go to sleep and wake up at the same time every day. This will help set your natural biological clock.
2 & 17	Exposure to bright natural light when you first wake up is also helpful to set your natural biological clock.
3 & 18	Use your bed for only sleep and sexual activity to help train your brain that if you are in your bed, you should be sleeping. Do not eat, work, or watch TV in bed. Do these activities outside of the bedroom.
4 & 19	Leave bed if unable to fall asleep within 20 minutes and return when sleepy. If unable to leave the bed due to limited mobility or safety concerns, do something relaxing (ie, relaxation techniques) until sleepy and able to fall to sleep.
5 & 20	Develop a relaxing bedtime routine. This may include taking a warm bath, reading a book, meditation, or stretching. Avoid stimulating activities right before bedtime, including watching TV or discussing a stressful topic.
6 & 21	Avoid moderate to vigorous exercise at least 2-3 hours before bedtime. Exercising immediately before bedtime stimulates your body and brain, making it hard to fall asleep. There is evidence however that doing regular (preferably moderate to vigorous) exercise improves your sleep at night. Talk to your physical therapist about an appropriate exercise program.
7 & 22	Avoid caffeinated foods and drinks at least 4 hours before bedtime (includes most tea, coffee, chocolate, and soft drinks). Check the presence of caffeine in your drink or food by reading the label. Caffeine can cause difficulty falling asleep and increase the number of times you wake up during the night.
8 & 23	Refrain from drinking alcohol or smoking at least 3 to 4 hours before bedtime. Although people may think drinking alcohol causes relaxation before bedtime it can actually increase the number of times you wake up during the night and can cause you to wake up early. Nicotine in cigarettes acts as a stimulant that can cause difficulty falling asleep.
9 & 24	Do not take unprescribed or over-the-counter sleeping pills.
10 & 25	Avoid daytime napping so that you are tired at night and can fall asleep easily. If you feel you need to take a nap, limit the nap to 30 minutes and avoid napping in the evening.
11 & 26	Make your sleeping environment comfortable and relaxing. This includes avoiding too much light and disturbing noises. Stop using light emitting electronics (ie, television, computer, smartphone) at least 30 minutes before bedtime as the blue light that is emitted can disrupt sleep by suppressing melatonin production. Use ear plugs, light-blocking curtains, or an eye mask if needed.
12 & 27	Keep the temperature comfortable. Being too warm or cold may disturb your sleep. Also, use a comfortable and supportive pillow and mattress.
13 & 28	Avoid eating a large meal or spicy food 2-3 hours before going to bed. Your digestive system slows down while you are sleeping, which can stimulate acid secretions that cause heartburn. A light snack may be helpful if you are hungry. Avoid excessive liquid 2-3 hours before bedtime.
14 & 29	Eat nutritious, well balanced meals. Avoid eating a large amount of highly processed and sugary foods as these can disrupt the hormones that help regulate your sleep patterns. Instead try to make a habit of eating whole foods whenever possible.
15 & 30	Talk to your doctor or health professional if you still have trouble sleeping.

Table 2: Sleep hygiene tips that will be sent out through text messaging