Study Protocol

Effects of Sleep hygiene Education on Sleep Health in Adults Ages 50 -80

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Experimental design: The two-year randomized control trial will begin in the fall (September 2023) and conclude before the end of the academic year (May 2025). 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 the 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 before participant recruitment. Participant inclusion criteria will include participants ages 50-80, who own a smartphone with the capability of receiving text messages. Exclusion criteria: an untreated 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, and the Numeric Pain Rating Scale as secondary outcomes. Initial data collection will consist of taking anthropometric measurements and vital signs, 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 assisted 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.

A total of 120 participants will be recruited with 40 participants per group. The 40 participants per group are based on recently performed studies related to text messaging and sleep health. Participants will be randomly assigned to one of three groups. The three groups will consist of a control group in which no intervention will be performed, a one-time educational group that will watch a sleep hygiene video on behavior changes related to healthy sleep, and the third group will get the one-time educational video plus daily automated text messages reinforcing education learned in the video.

Following the initial meeting with the PI, all participants will wear the sleep tracker on their wrist for 2 weeks to collect preliminary data and then 4 additional weeks following their intervention for a total of 6 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. At the end of the 6-week study period, the PI and/or student researcher(s) will again meet with each participant. The participant will again complete the following questionnaires: Sleep diary, Epworth Sleepiness Scale, Pittsburgh Sleep Quality Index, Sleep Hygiene Index, Perceived Stress Scale, and Numeric Pain Rating Scale. Anthropometric data collection and vital signs will be reassessed. Pre/post measurements will be compared and data analyses will be conducted using a 2x2 mixed factorial repeated measures ANOVA test.

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(26). 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

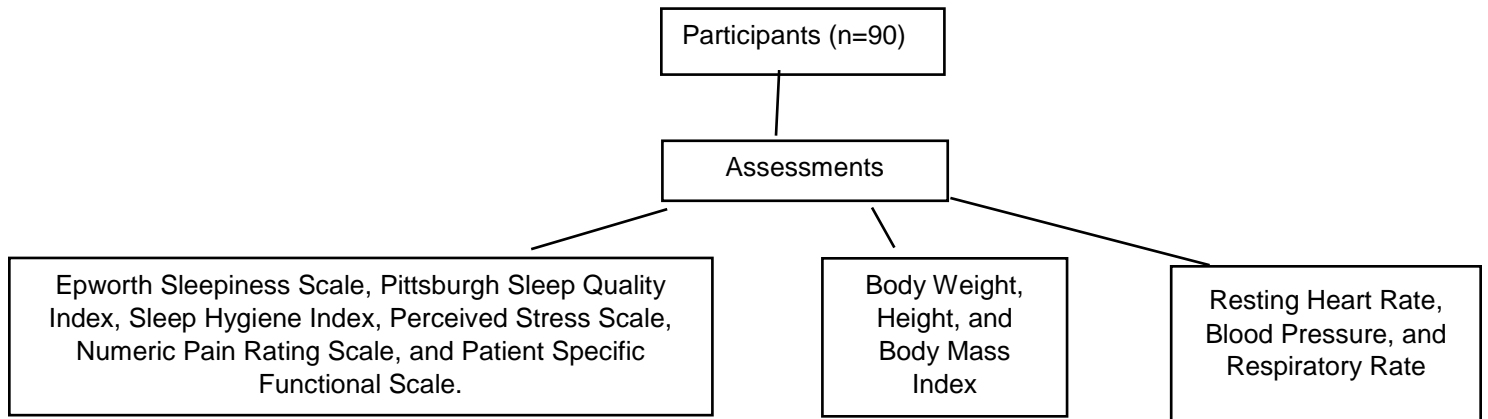**Table 1: Sleep Health Composite**

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. Several research studies have shown that a one-time sleep hygiene education session have improved sleep health in younger adults and working individuals(4, 27). With the promising results of a one-time education on short term progress, we want to test if longer-term reminders outside the initial training would provide even more sustainable results. The expansion of smartphone technology opens up an opportunity to reinforce the initial education with continual reminders of good sleep habits. A recent survey demonstrated that 86% of Americans over 50 utilize text messaging(28). In addition, one study showed text messaging significantly improved exercise rates in older adults(25). For this reason, we want to explore using automated text messaging for sleep hygiene education. *We hypothesize that automated text messaging will enhance the treatment effect of a one-time educational session on sleep health in CDOA.*

Experimental design: Following anthropometric data collection and vital signs, the participants will be randomly assigned to one of three groups (Figure 2). The third group, a one-time education plus automated text messaging, 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 and the one-time educational group will not receive any intervention during this time frame. Following the 4 weeks, PI and student researcher(s) will meet again with all 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.
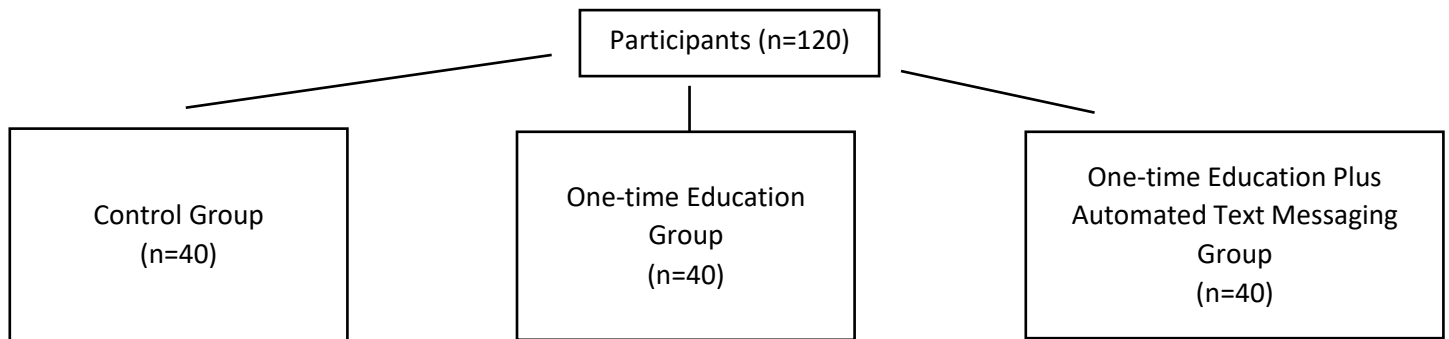


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                          Participants (n=120)

Control Group          One-time Education        One-time Education Plus
(n=40)                 Group                     Automated Text Messaging
                       (n=40)                    Group
                                                 (n=40)
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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

Health Relevance: The main goal of this project is to develop an understanding of effective sleep hygiene education methods in CDOA and their possible effect on sleep health. A long-term goal is to create an easy sleep hygiene education system that can be implemented by all healthcare practitioners to improve sleep health, which potentially could reduce the risk of developing chronic disease.