

Using a Wireless Controller to Deliver a Lighting Intervention to Persons With Dementia

PI: Mariana Figueiro, PhD

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Salmon Health Medway – Tailored Lighting Intervention Study Protocol

Objectives/Specific Aims

Objectives

This study is designed to investigate the impacts of a lighting intervention on depression and nighttime sleep measures of persons with Alzheimer's disease or related dementia (ADRD) living in long-term memory care settings. The subjects will undergo a prescribed tailored light treatment designed to increase their circadian entrainment and activity consolidation.

Purpose/Specific Aims

The proposed study proceeds from preliminary data showing that light that is carefully designed and delivered so that it maximally affects the circadian system and can improve sleep (measured with sleep questionnaire and actigraphy), mood, and behavior in Alzheimer's disease and related dementia (AD/ADRD) patients living in controlled environments. Our premise is that AD/ADRD patients living in nursing homes are in continuous dim light and that a tailored lighting intervention (TLI) that can deliver the correct light dose can have a significant impact on sleep, mood, and behavior in this population. The field study will demonstrate how, when measured and delivered appropriately, a TLI can be incorporated into memory care facilities.

In addition to the aims stated above, this project will evaluate the feasibility and utility of both wearable and room-mounted light sensor devices calibrated to monitor the subjects' exposure to circadian stimulus (CS) throughout the course of their enrollment in the study. These data will be instrumental in assessing the performance and overall impacts of the tailored lighting intervention in terms of circadian stimulation.

Background

Older Americans (65+) numbered 44.7 million in 2013, representing 14.1% of the U.S. population, and by 2030 this older population is estimated to grow to about 72 million. Furthermore, this population is living longer; people reaching age 65 have an average life expectancy of an additional 19.3 years. Of the 65+ population, 3.4% lived in nursing homes in 2013. If current trends continue, by 2030 this number will rise to about 10%. Dementia is a progressive, degenerative disease of the brain. There is no known cure, and there are very few effective treatments. Alzheimer's disease (AD), the most common form of dementia, is the sixth-leading cause of death in the U.S. and the fifth-leading cause of death for those over the age of 65. It is projected that 13.8 million Americans will have AD or a related dementia disorder (ADRD) by 2050. More than 70% of people with this disease live at home, and family members and friends provide almost 75% percent of the required care. As the disease progresses, families are often forced to move loved ones from home to assisted living facilities. Often, the precipitating factor



is disturbed sleep-wake (circadian) cycles, where the person with AD/ADRD is awake at night, causing stress and fatigue to caregivers. Light therapy has shown great promise as a nonpharmacological treatment in helping to regulate sleep and in improving cognition in older adults with AD/ADRD. Studies have demonstrated that daytime light exposure can consolidate and increase nighttime sleep efficiency, while increasing daytime wakefulness and reducing evening agitation.

Hypotheses / Research Question(s)

Light therapy has shown great promise as a nonpharmacological treatment in helping to regulate sleep and in improving cognition in older adults with AD/ADRD. This proposed project will field-test a permanently installed architectural lighting system controlled to deliver the circadian stimulus (CS) for Alzheimer disease (AD) and Alzheimer-disease-related dementia (ADRD) patients in a long-term memory care facility. Human biology has evolved to have two distinct optical systems: the visual system, by which we see and process images, and the circadian system, which regulates our biological clock and associated biological systems. While a broad and growing body of research has documented the impacts the circadian system has on human health, including regulating sleep and improving cognition in AD/ADRD patients, research on the CS experienced by AD/ADRD patients is extremely limited. Most lighting systems are designed and installed in buildings with consideration only given to the photopic (visual) system and light meters used to characterize lighting in buildings are calibrated to measure photopic light, not CS.

Preliminary Data

This project builds on our previous research concerning the effectiveness of tailored lighting interventions in long-term care facilities on patients with ADRD. Our previous studies have utilized various forms of light delivery systems from free-standing plug-in luminaires installed in patients' rooms, to self-luminous light tables and light trays installed in communal dining and activity spaces. Such lighting interventions have been shown to be effective at improving sleep quality, mood, and agitation in Alzheimer's Disease patients over a period of several months, with the magnitude of the effects increasing over time. In this project, we will be investigating the impacts of permanently installed ceiling and wall mounted luminaires in a long-term care facility in order to demonstrate similar benefits of lighting systems that are part of the overall facility lighting design.

Study Design

Thirty participants with AD/ADRD will be recruited to participate in this controlled, cross-over designed study. The aim of the project is to field-test the circadian-effective tailored lighting intervention in two communal dining/activity spaces of similar layout and configuration. The lighting in each space will be controlled by a programmable digital



system that can be configured to deliver the “active” CS schedule throughout the day, with high CS delivered in the morning/daytime hours (until 6pm), and low CS levels in the evening/nighttime. The lighting in each space will be programmed either with the “active” CS schedule, or a “control” schedule wherein the lighting is set to be below the threshold for circadian activation throughout the daytime and nighttime. Participants of the study will be exposed to both lighting intervention conditions in a counter-balanced cross-over design in order to assess the impacts of the systems both within and between subjects. Data collection will be obtained through use of questionnaires designed to assess changes in sleep quality, depression, and cognition, and the use of actigraphs to assess sleep and activity. Subject light exposure data will be collected through a combination of the worn and room-mounted measurement devices.

Research Procedures

All data collection and assessments will take place at the participant’s care facility. Eligible participants will be moderate to severe AD/ABRD patients with a Mini Mental Score Examination (MMSE) score between 0 and 19, who have sleep disturbances and reside in long term care. Once consent has been obtained, baseline screening will be administered by the research coordinator or study RN using the following questionnaires: Cornell Scale for Depression in Dementia (CSDD) and the Pittsburgh Sleep Quality Index (PSQI) and The Sleep Disorders Inventory (SDI). The questionnaires will take approximately ten minutes to complete. If the participants are not able to self-complete these questionnaires, we will work with the charge nurse or social worker at the facility to have a staff member most familiar with the participants sleep and behavior complete the questionnaires. We will ask the same staff member to complete the questionnaires each time during the protocol.

Participants will be asked to wear a wrist actigraph for one week to obtain baseline data on rest/activity patterns and sleep quality. Following this initial baseline collection, the lighting intervention, either active or placebo control, will be initiated in the dining areas where the participants spend the majority of their time on a typical day. The active lighting intervention will deliver high circadian stimulus (CS) during the day produced by ceiling and wall mounted light sources tuned to the sensitivity of the circadian system. By combining spectrum and light level, the TLI will allow us to use a light source that will stimulate the circadian system and will be delivered at the times when the residents need light exposure to promote entrainment. The circadian-effective lighting will be delivered from wake time to 6:00 pm each day for participants exposed to the active condition. Each lighting intervention (active and control) will start upon completion of baseline assessment, which occurs in Week 1 and will be presented for eight weeks with a four-week washout period between the active and control interventions. In a crossover design, half of the subjects will start the study with the TLI and the other half will start with the placebo control lighting condition. Each subject will participate in the study for a total of 22 weeks. In addition, half of the subjects in each lighting intervention



group will receive the intervention during the winter months and the other half during the summer months. This will allow us to counterbalance data collection within seasons.

In order to identify the dining rooms in which the lighting intervention is implemented, a sign will be placed at the entry of the space describing the intervention and providing study and contact information.

Data Points

All assessments will be completed during the baseline (Week 1) and repeated at Weeks 9, 14 and 22; see Figure 1 below for the data collection protocol.

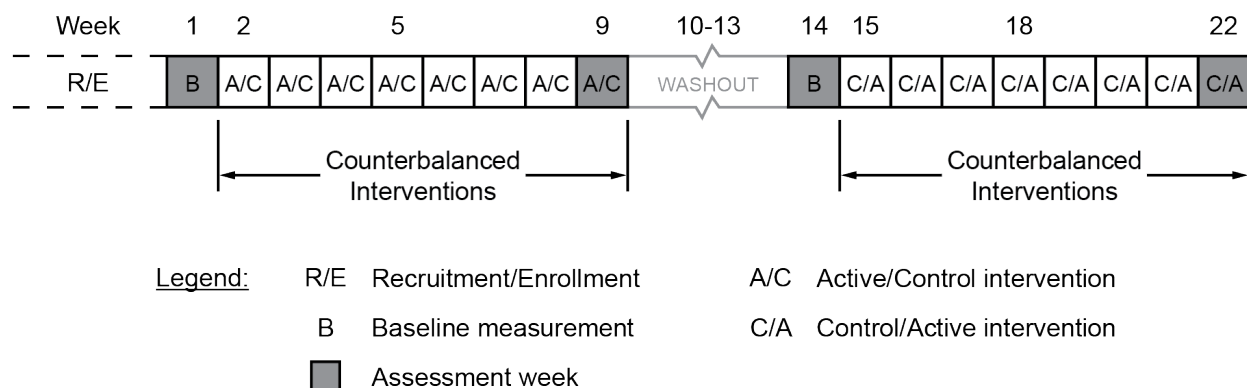


Figure 1: Study data collection protocol.

Questionnaires

The Mini Mental Score Examination MMSE: The MMSE is a one-page, 30-point test that can be administered in 10 minutes. It is widely used for cognitive screening in research and in clinical practice. It assesses 5 areas of cognitive function: orientation, registration, attention and calculation, recall, and language. While the sensitivity of other screening measures like the MOCA may be higher, those have other limitations such as significant floor effects with more advanced dementia.

Cornell Scale for Depression in Dementia (CSDD): The CSDD is a 19-item tool designed to rate symptoms of depression in persons with dementia. This tool evaluates the presence and extent of mood-related signs (anxiety, sadness, irritability), behavioral disturbances (agitation, loss of interest), physical signs (loss of appetite, weight loss), and cyclic functions (mood variation, sleep quality).

The Pittsburgh Sleep Quality Index (PSQI): The PSQI is a tool that can be used to measure sleep quality in clinical populations. It is composed of 19 items that generate seven component scores (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction). The sum of the seven component scores yields one global score. A



person with a global score above 5 is considered to have sleep disturbances. The PSQI is a well validated scale and has been used previously in patients with Alzheimer's disease.

Sleep burden using The Sleep Disorders Inventory (SDI): The SDI is an expanded version of one item of the Neuropsychiatric Inventory (NPI). It describes the frequency, severity, and caregiver burden of sleep-disturbed behaviors. The SDI is a simple and short instrument that can be administered multiple times during a study protocol. Validity of using the sleep questions of the SDI as an independent instrument in sleep research requiring a caregiver's report of sleep symptoms by showing good correlation, but not redundancy, with quantitative sleep measurements was shown.

Wrist actigraph: Participants will be asked to wear the actigraphs for 7 days during the assessment weeks. Actigraphic monitoring employs an accelerometer the size of a small watch (Philips Respironics Actiwatch-2), which will be worn on the nondominant wrist of each study participant. Actigraphy has been demonstrated in prior studies to be well tolerated by older adults with ADRD, and it is strongly correlated with polysomnography (PSG) and sleep logs.

Tailored Lighting Intervention (TLI)

The TLI will provide high CS during the day produced by light sources that provide moderate light levels of spectra that are tuned to the sensitivity of the circadian system. A circadian-ineffective lighting intervention will be used as a control. TLI quantities are based on calculations made using the mathematical model developed by Rea et al., which provides a method for determining the CS for any light source and light level. A light source that strongly affects the circadian system will be used in new ceiling and wall mounted luminaires installed in two similar dining areas where the participants will spend much of their time on a daily basis. These lights use light emitting diodes (LEDs) and are very energy efficient. The building lighting control system will control the TLI to provide the ideal dosage of CS and to automatically turn on the lights at participants' breakfast times (but no later than 09:00 am). TLI will remain on during the day and will dim automatically at 6:00 pm. Each lighting intervention will be in place for eight weeks.

Study Duration

The overall study duration is two years and the study duration for each participant is 22 weeks.

Data Analysis

Rest-activity rhythms before and after the TLI will be measured using the actigraph (rest-activity) data. The following measures will be calculated: (1) interdaily stability (IS), a ratio indicating the strength of coupling between the light-dark cycle and rest-activity rhythm over a 24-hour period; (2) intradaily variability (IV), an indication of the fragmentation of the rest-activity rhythm (i.e., the frequency of the transitions between rest and activity); (3) RA of the rest-activity rhythm, calculated as the difference between



the means of the most active 10-hour period (M10) and the least active 5-hour period (L5) in the 24-hour pattern; and (4) measures of nighttime sleep (minutes of sleep, sleep onset latency, and sleep efficiency). Photopic light levels (lux) and CS values will be calculated from the light-dark data collected by the wearable and room-mounted light measurement devices. Increases in IS and RA and a decrease in IV will be considered an improvement in rest-activity patterns. We will also evaluate the change in these variables from baseline to the end of each intervention period. Questionnaires will allow us to evaluate depression, and sleep quality. In our current studies, we have not encountered any issues recruiting males and females. The relatively small sample size proposed for this research study ($n=30$) will make it impossible to match sex, but every attempt to recruit both sexes will be made. The study will have enough power to detect treatment differences. Data from our past grant using a similar protocol provides measures of variability for our primary outcome measures (actigraphy and questionnaires). In particular, a planned sample size of 30 patients (with 30% attrition rate) will provide 80% power, using two-sided $\alpha = 0.05$ significance tests, to detect statistically significant differences in the means between two treatment conditions that are 66% the SD.