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# Effect of home-based light treatment on persons with dementia and their caregivers

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## Abstract

Sleep disorders are problematic for persons with dementia and their family caregivers. This randomized controlled trial with crossover evaluated the effects of an innovative blue-white light therapy on 17 pairs of home-dwelling persons with dementia and their caregivers. Subjects with dementia received blue-white light and control (‘red-yellow’ light) for six weeks separated by a four-week washout. Neither actigraphic nor most self-reported sleep measures significantly differed for subjects with dementia. For caregivers, both sleep and role strain improved. No evidence of retinal light toxicity was observed. Six weeks of modest doses of blue-white light appear to improve sleep in caregivers but not in persons with dementia. Greater or prolonged circadian stimulation may be needed to determine if light is an effective treatment for persons with dementia.

## 1. Introduction

Sleep disorders are particularly common in persons with Alzheimer’s disease and related dementias, leading to adverse effects for individuals and their caregivers. Compared with other older adults, persons with dementia demonstrate lower sleep efficiency and more frequent arousals, with the severity of the sleep disturbance paralleling the level of dementia.[1,2] For persons with dementia who live at home, these sleep disorders can be

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disruptive for family caregivers. Disturbed sleep has been associated with caregiver stress, functional decline and depression. Further, disturbed sleep is often given as a reason for nursing home placement.[2–5]

Medications, while frequently prescribed for sleep problems, have low effectiveness[6,7] and are associated with adverse effects, such as worsening confusion, falls and hip fractures.[8–13] Indeed, a meta-analysis of sedative/hypnotic medications for older people with insomnia concluded that 'in people over 60, the benefits of these drugs may not justify the increased risk, particularly if the patient has additional risk factors for cognitive or psychomotor adverse events'.[14] Valerian root and kava are herbal sleep aids that are sometimes used for disturbed sleep. However, their effectiveness has not been established and they too pose dangers. Delirium and liver toxicity have been reported with valerian root, and dangerous drug interactions have been reported with kava.[15] Melatonin appears to be safe and has some effect on circadian patterns in adults who do not have dementia; however, four randomized trials have failed to demonstrate its effectiveness in dementia patients.[16–19] Thus, an effective, safe alternative to medications would constitute a significant advance in the care of persons with dementia who have disturbed sleep.

Bright light therapy is one such alternative that has promise, and its theoretical basis is well-established. In healthy persons, cyclical changes in light exposure across the 24-hour day synchronize a circadian pacemaker in the suprachiasmatic nuclei in the hypothalamus. That, in turn, regulates the timing of sleepiness, wakefulness, melatonin and cortisol secretion and core body temperature. Impairment of these circadian rhythms is characteristic of persons with dementia and contributes to the high prevalence of sleep disturbance.[20–23] In addition, frail older persons, especially those with dementia, spend increasingly less time outdoors, which deprives them of the body's primary circadian stimulus (CS) – a regular light/dark exposure pattern. Therefore, therapies that specifically target delivering a robust diurnal light/dark exposure to the circadian system could constitute a physiological method of treating many sleep disorders in persons with dementia.

Prior work has shown that exposure to bright white light – at least 2500 lux and as high as 8000 lux at the cornea – for at least one hour in the morning for a period of at least two weeks consolidates the sleep of persons with dementia.[24,25] Greater sleep efficiency at night has been associated with decreased sleep during daytime hours and, in some cases, reduced agitated behaviour.[26–34] In other work, light exposure during the day consolidated rest/activity rhythms in persons with dementia and increased their sleep times at night.[35] Moreover, a five-year, placebo controlled, randomized trial in 189 patients with dementia showed that bright light (approximately 1000 lux at the cornea) attenuated cognitive deterioration, ameliorated depression symptoms and attenuated the increase in functional limitations.[36]

However, other studies of light therapy for sleep disturbances in persons with dementia have failed to yield consistent results, and many of those studies have suffered from methodological issues. A 2009 Cochrane review excluded 33 trials for methodological reasons and concluded that the five remaining studies failed to demonstrate adequate evidence of an impact of light therapy on sleep in persons with dementia.[37] As was

emphasized by the Cochrane reviewers, the inconsistent research results may be due, in part, to methodological problems. These problems include (a) poor tolerance of protocols that required persons with dementia to sit for long periods in front of a light box (the most commonly used intervention); (b) the use of white light, a nonspecific stimulus that is uncomfortably bright, heat-producing and inefficient as a CS (i.e. recent research demonstrates that the human circadian system responds more favourably to short wavelength (blue) light, with a peak sensitivity close to 460 nanometres (nm))[38–41] and (c) the use of unselected target populations rather than persons meeting specified thresholds for disturbed sleep.[37,42]

To address these issues, we exposed community-dwelling persons with dementia and disturbed sleep to daily (from the time of awakening until 18:00) therapeutic levels of blue-white lighting in commonly used living areas. The study's goals were to test the study protocol's ability to identify, recruit and follow through to study completion persons with dementia who reside with a family caregiver in a private home or apartment; to test the delivery, fidelity, acceptability and safety of the intervention and to gather data on outcomes. The use of a light source emitting more short-wavelength radiation allowed for a reduction in the light level compared to white light, thereby decreasing glare and power consumption. The application of light in commonly used living areas eliminated the requirement that persons with dementia sit in front of a light box. The primary hypothesis was that lower levels of a blue-white light (300–400 lux at the cornea) would improve sleep as measured subjectively and objectively. Outcomes were measured using actigraphy and caregiver reports, while fidelity to light exposure was measured directly with a device worn by study participants. To address the theoretical possibility of retinal toxicity from blue light,[43] all subjects underwent dilated ophthalmologic examination, visual acuity testing and cross-sectional retinal imaging.

## 2. Methods

### 2.1. Experimental design

The study was a randomized clinical trial with crossover. All participants received both the experimental (blue-white light) and control (red-yellow light) intervention. To determine the intervention order, a stratified permuted block randomization scheme was used that employed a block size of four participants early in the study and two later in the study, with stratification by participant gender.

### 2.2. Participants

Potential study participants were volunteers recruited from dementia clinics, caregiver support groups, senior centres and by posting notices in local newspapers and on university email list servers. For persons with dementia, eligibility criteria included a diagnosis of dementia documented by a physician (a precise diagnosis was not required, as nonspecific diagnoses are common in community populations); residence in a private home or apartment with a family caregiver; and having a sleep disturbance as reported by the individual and/or family caregiver and verified by a score of 6 or greater on the Pittsburgh Sleep Quality Index (PSQI).[27] Potential participants were excluded if they scored 26 (females) or 29

(males) or higher on the sleep apnea scale of the Sleep Disorders Questionnaire;[28] if they had a history of severe photosensitivity dermatitis, a progressive retinal disease or a permanently dilated pupil; if their primary physician made recommendations against their participation (physicians were notified about the study as part of our protocol); or if they were identified during a screening eye exam as having moderate or severe macular degeneration. Subject dyads were excluded if the caregiver showed evidence of cognitive impairment (defined as a score of 24 or less on the Mini-Mental State Examination (MMSE))44 or reported a history of severe photosensitivity dermatitis, a permanently dilated pupil or moderate or severe macular degeneration.

### 2.3. Lighting conditions

For the intervention condition, 13,000K (blue-white) compact fluorescent light bulbs (Philips Lighting, Eindhoven, NL) were placed in table and floor lamps added to the participant's home in the area where the participant spent most of his/her time. As an adjunct, a light-emitting diode (LED) light box (goLITE P2, Philips Respironics, Amsterdam, the Netherlands) was placed in the area where the individual ate breakfast and lunch. The goLITE P2 is a 6 × 6 inch (15 × 15 cm) device containing an array of 66 LEDs with a peak wavelength at approximately 470 nm (full width at half maximum (FWHM) = 20 nm).

For the control condition, 2700K (yellow-white) compact fluorescent light bulbs (Philips Lighting, Eindhoven, NL) were placed in the table and floor lamps and used during the day, and a red LED light box was used at breakfast and lunch. The same goLITE device was used, but the 470-nm peaking LEDs were replaced with 638-nm peaking LEDs (FWHM = 15 nm).

The blue-white light source was expected to stimulate the circadian system more than five times as much as the yellow-white light source at the same light level (i.e. 400 lux at the cornea). The blue LED light box was expected to stimulate the circadian system over one thousand times more than the red LED at the same light level (100 lux) at the cornea. These circadian-to-visual ratios were calculated using the mathematical model developed by Rea *et al.*[45,46]

To individualize the placement of floor and table lamps for each participant, the study coordinator visited each participant's home after enrollment, drawing a floor plan, gathering light measurements, taking photographs and ascertaining the spaces where the subject spent most of the time; this information was then sent to the study's lighting expert (M.F.), who developed a plan designed to provide at least 300–400 lux at the cornea of the participants. The floor and table lamps were turned on from the caregiver-reported usual awakening time until 18:00, as had been determined to have the most favourable effect on sleep in persons with dementia during a previous study.[35] The two study conditions were applied for six weeks to each participant, with a four-week wash-out period in between.

### 2.4. Measures

The primary outcomes of interest were measures of sleep quality. As a direct measure, wrist actigraphy was used among study participants with dementia. Using a wrist-watch-like accelerometer (Actiwatch-L®) worn around the wrist, we sought to record actigraphic data continuously during the week prior to each condition's initiation, and during weeks two and six of each condition, for a total of six weeks per subject.

Caregiver informants reported subjective sleep quality for both themselves and the person with dementia using (a) the PSQI, a 19-item measure that generates one global score and seven subscores (the PSQI global index and sleep efficiency score are presented herein);[27] (b) the Medical Outcomes Study (MOS) sleep scale, a 12-item measure that measures overall sleep problems and that creates four subscales (sleep disturbance, four items; sleep adequacy, two items; day-time somnolence, three items and a sleep problems index, nine items)[47] and (c) the Epworth Sleepiness Scale, an eight-item scale that rates the likelihood of falling asleep during a variety of daytime conditions.[48] These data were collected at baseline and follow-up of both period one and period two (a total of four times).

Caregivers reported information to assess secondary outcomes, which for subjects with dementia included depressive symptoms and quality of life. Depressive symptoms were assessed using the Cornell Scale for Depression in Dementia (CSDD)[49] and the depression instrument (the PHQ-9) from the Patient Health Questionnaire of the PRIME-MD.[50,51] The CSDD is a 19-item questionnaire that assesses the presence and severity of depressive symptoms in individuals with dementia over the previous seven days; scores range from 0 to 38 and higher scores indicate worse depression.[49] The PHQ-9 contains nine items that sum to create a score of 0–27, and again, higher scores reflect more depressive symptoms; it shows good sensitivity and specificity (88%) in normal adult populations.[50,51] Quality of life was assessed using a modification of the Quality of Life in Alzheimer's disease (QOL-AD) instrument; modified QOL-AD scale scores range from 15 to 60, with higher scores indicating better quality of life.[52.53]

Secondary outcome measures for the family caregiver subjects included the PHQ-9[50,51] as well as measures to assess caregiving hassles and burden. Caregiving hassles were assessed using 30 items from three subscales (measuring hassles related to assisting with activities of daily living, the subject's cognitive status and the subject's behaviour) of the Caregiving Hassles Scale (CHS); using these three subscales, CHS scores can range from 0 to 120, with higher scores reflecting greater caregiving hassle.[54] Caregiving burden was measured using the Zarit Burden Interview (ZBI).[55,56] The ZBI contains two subscales – one measuring psychological distress (termed Personal Strain, comprising 12 items) and the other measuring the impact of caregiving (termed Role Strain, comprising six items).[57]

We also collected information about the subject's demographic characteristics (e.g. age, race/ethnicity and educational level), activities of daily living (ADLs, e.g. independence in bathing, dressing and toileting),[58] instrumental activities of daily living (IADLs, e.g. ability to use the telephone or take medications)[59] and cognitive status. To assess cognitive status, all subjects completed the MMSE[44] and the Saint Louis University Mental Status (SLUMS)

examination.[60] Like the MMSE, theoretical SLUMS scores range from 0 to 30, and higher scores reflect greater cognitive impairment.[60]

To determine whether and to what extent medication changes may have affected study results, we obtained full medication lists at baseline and at the end of study participation (four months later) and evaluated them for changes in analgesic, antipsychotic, sedative/hypnotic and cognitive enhancement medications.

### 2.5. Protection of human subjects

All study materials and procedures were reviewed and approved by the Biomedical Committee of the Institutional Review Board of the University of North Carolina at Chapel Hill. Informed consent was obtained from all participants after full explanation of the procedures, in accordance with the Helsinki Declaration of 1975.[60]

### 2.6. Power

The study's planned sample size of 18 was selected to provide 80% power, using two-sided alpha = 0.05 significance tests, to detect statistically significant differences in the means between treatment and control conditions for the amount of night-time sleep (one of the primary outcomes) as small as 0.28 hours (17 minutes).

### 2.7. Fidelity

To evaluate the study's ability to deliver a CS level of light that differed between the intervention and control conditions, each study participant wore a circadian light meter pinned to their clothing for three to five days during each of the two study conditions. The circadian light meter is a small device that contains two sensors that record and store data.[61–63] Data from the two photosensor channels were downloaded, and after visually inspecting the data and checking the logs provided by caregivers, periods clearly showing poor quality data (i.e. device not worn, obviously covered or broken) were removed; if more than one-third of a day's data were removed, that day was not used in the analyses. A total of 81 of the 111 files (73%) were used in the analysis.

As a secondary measure of intervention exposure, the research assistant recorded the light levels in the location where the intervention was implemented using a standard illuminance meter. Additionally, caregiver subjects maintained logs to document time spent outside of the home, away from the light intervention and instances of light malfunction.

### 2.8. Evaluation for potential retinal adverse effects

Because of theoretical concerns about potential retinal effects of blue light (the 'blue light hazard'),[43] all participants were evaluated by a retina specialist prior to and at the end of study participation. The examination included visual acuity, Amsler Grid evaluation (grid of horizontal and vertical lines used to monitor a person's central visual field) and a dilated eye exam. In addition, the study sought to evaluate all participants before and after the study period using high-resolution optical coherence tomography (OCT) to assess central retinal anatomy and multi-focal electroretinography (mfERG) to assess central retinal function. OCT generates a high-resolution (3–5 micron axial resolution) anatomic map of the retinal

cell layers of the macula; it requires pupillary dilation and one to two minutes of patient cooperation to image each eye. The mfERG measures electrical activity from the central retina, primarily the cone photoreceptors and is a high-resolution measure of the central retinal function. To obtain the mfERG, a local anaesthetic drop is administered to each eye, a contact lens is placed on the cornea, and the study participant must fixate on a target for several minutes during the procedure and may not rub the eye for a period afterwards. Due to difficulties tolerating the procedures, only 10 participants contributed both baseline and follow-up OCT data. MfERG testing was discontinued early in the trial because several participants were unable to follow procedure and safety protocols. To address the theoretical concern that the blue light hazard is a bigger concern for patients who have had cataract surgery (since the native yellow lens acts as a 'blue blocker'), analyses were conducted for the group overall and separately for the eyes that had undergone cataract surgery.

### 2.9. Analysis

The following summary outcome measures were calculated from the raw actigraphic data: total sleep time during the six-hour period after bedtime (for days when bedtime was recorded by the caregiver informant) or during the usual sleep time (for days when bedtime was not recorded); sleep latency; sleep efficiency during the six-hour sleep analysis period; number of sleep bouts (i.e., 1 + (the number of wakefulness episodes recorded by the actigraph using a standard algorithm)); inter-daily stability (a measure of the consistency of circadian rhythms from day to day) and intra-daily variability (a measure of the difference in activity between day and night, i.e. of circadian rhythmicity).[29,39]

Because the subjective data were collected four times within a crossover design, we were able to estimate six effects of interest: the period effect, the effect of the intervention compared to the usual light (the lighting at baseline), the effect of the control condition compared to the usual light, the carryover for the intervention condition, the carryover for the control condition and the intervention condition effect minus the control condition effect, which is the effect of primary interest. A linear mixed model was created for each outcome with independent variables coded to test for these six fixed effects. A random effect for participant was included to account for intra-participant correlation of the outcome. Analyses of actigraphic and subjective data were conducted using SAS for Windows 9.1 software.

Regarding fidelity, illuminance, circadian light ($CL_A$) and CS levels were calculated from the circadian light meter data. $CL_A$ is a measure of circadian effective light; it is based on the model of phototransduction by Rea *et al.*[45,46] The values of $CL_A$ are scaled so that 1000 lux of CIE Illuminant A (incandescent source at 2856 K) is equivalent to 1000 units of $CL_A$. CS values are transformed CLA values and correspond to relative melatonin suppression after one hour of light exposure for a 2.3-mm diameter pupil during the midpoint of melatonin production. Since CS is defined in terms of the circadian system's input–output relationship, including threshold and saturation, it is considered a better measure of the circadian effectiveness of light than either lux or $CL_A$.[61]

## 3. Results

Participants were enrolled between March 2009 and September 2010. Of the 67 participant pairs who contacted the project office about the study, 49 (73%) were ineligible. Reasons for ineligibility included: absence of a sleep problem, defined as a PSQI score of less than 6 (33%); living outside the project area (12%); inability to complete the required ophthalmologic examination (12%; note that our initial protocol required the study participants with dementia to complete the entire ophthalmologic examination; however, this requirement was later modified due to the inability of many subjects to complete the mfERG component); absence of dementia (10%); participant with dementia not at home during the day to receive the intervention (8%); a history of retinal or macular disease (4%); no live-in caregiver (5%) or obstructive sleep apnea (2%). An additional 14% of subjects were marked as ineligible because their eligibility could not be confirmed; these individuals were largely lost to follow-up.

Of the 18 eligible participant pairs, 17 enrolled in the project. One (6%) pair declined participation. In terms of subject retention, of the 17 pairs, one completed the first study period (in this case, the control period) but not the second (the intervention); another completed the first three weeks of the first study period (the intervention period) and then discontinued participation. In both cases, the participant with dementia moved to a more supportive setting (in one instance, a different daughter's home, and in another, an assisted living community).

Most participants with dementia were over age 80 (65%), female (65%), white (82%), had some college education (71%) and represented a wide range of cognitive impairment (MMSE mean 12.7, SD 9.1). The caregivers were primarily white (82%), either the participant's spouse (35%) or daughter (47%), not working outside the home (59%) and cognitively intact (mean MMSE score = 28.9). Table 1 profiles the care recipients and caregivers who participated in the trial.

### 3.1. Circadian light exposure

Analysis of output from the circadian light meter indicated that for the control condition, the median daily $CL_A$ was 118, and the median daily CS was 0.145. During the experimental condition, the median $CL_A$ was 239, and the median CS was 0.230. Therefore, subjects were exposed to greater circadian light during the intervention weeks than during the control weeks.

### 3.2. Outcomes for participants with dementia

**3.2.1. Actigraphic measures of sleep quality—**As shown in Table 2, no significant differences in actigraphic sleep measures were noted. The mean sleep latency was 23.3 minutes under the intervention condition and 24.6 minutes under the control condition. Total sleep time (246 vs. 248 minutes) and sleep efficiency (68% vs. 69%) were also similar across the two conditions. Computed measures of circadian rhythmicity were not significantly different across the two conditions; inter-daily stability averaged 0.41 during

both conditions and intra-daily variability averaged 1.21 during the experimental condition and 1.20 during the control condition.

**3.2.2. Reported sleep quality—**For all eight measures of sleep quality reported by family caregivers, scores recorded during the intervention condition were better than those recorded under the control condition (Table 3). However, the differences were modest, and overall, the p-values did not approach statistical significance. The one exception was the sleep efficiency subscale of the PSQI, for which the intervention condition was superior to usual light ($p = 0.045$), and the difference between intervention and control, though not significant ($p = 0.17$), trended in the same direction. In addition, the carryover effect for the intervention condition was significant ($p = 0.026$), while the carryover effect for the control condition was not ($p = 0.52$).

**3.2.3. Other outcomes—**For the IADL scale (Table 3), participants with dementia experienced a statistically significant decline in the intervention condition relative to the control condition ($p = 0.02$). For both the CSDD and the PHQ-9, however, the intervention condition was associated with a statistically significant improvement compared to usual light ($p = 0.011$ and $p = 0.038$, respectively), but the contrasts of intervention condition to control condition were not significant ($p = 0.26$ and $p = 0.82$ respectively). No significant carryover effects were observed.

### 3.3. Outcomes for family caregivers

**3.3.1. Reported sleep quality—**As shown in Table 4, the effects of intervention compared to control conditions were statistically significant for the PSQI Sleep Index ($p = 0.013$), the MOS Sleep Adequacy subscale ($p = 0.046$), the MOS Sleep Problems scale ($p = 0.011$) and the MOS Sleep Index ($p = 0.012$), with all effects representing improved sleep. In addition, the intervention condition had significantly better outcomes compared to usual light for the MOS Sleep Problems scale ($p = 0.009$), the MOS Sleep Disturbance subscale ($p = 0.009$) and the MOS Sleep Index ($p = 0.023$). For the MOS Sleep Disturbance scale, carryover for the control condition and global carryover were statistically significant ($p = 0.013$ and 0.041, respectively).

**3.3.2. Other outcomes—**For the Zarit Role Strain subscale, family caregivers experienced a statistically significantly improvement during the intervention condition relative to usual light ($p = 0.037$), but not relative to the control condition ($p = 0.06$). No statistically significant effects were found in comparison of intervention to control conditions or usual light in terms of caregiver hassles, the Zarit Personal Strain subscale or depression scores on the PHQ-9. Neither period nor carryover effects were identified for these outcomes.

**3.3.3. Ophthalmic effects—**No eye-related symptoms were reported by caregivers during the control period, whereas a few were reported during the intervention period (i.e. eyestrain and eye fatigue during 1% of intervention weeks and glare during 3% of intervention weeks). These differences were not statistically significant.

There was no significant change in visual acuity before and after the intervention, nor was there change based on the dilated retinal examination. OCT qualitative and quantitative measures such as retinal thickness and volume before and after the intervention were essentially unchanged. The mean central (subfield = 1 mm) retinal thickness in the right eye for nine subjects with both baseline and follow-up data was 273.1 microns (SD 81.5 microns) at baseline and 274.7 microns (SD 77.5 microns) at follow-up, and the mean central subfield thickness in the left eye for 10 subjects with data for both periods was 253.3 microns (SD 21.1 microns) at baseline and 264.7 microns (SD 49.3 microns) at follow-up. None of these differences were statistically significant.

The 15 eyes with prior cataract extraction were evaluated separately; there were no significant differences between baseline and follow-up values for visual acuity, central subfield thickness or volume ($p > 0.47$ for all).

**3.3.4. Medication use—**Of the 17 participants, 10 had no changes in psychotropic or cognitive enhancement medications during the study period; 3 had medications discontinued (1 each of memantine, eszopiclone and risperidone); 3 had medications added (1 each of memantine, escitalopram and risperidone) and 1 had risperidone increased (by 0.125 mg/day).

## 4. Discussion

This study sought to determine, on a preliminary basis, whether moderate levels of blue-white light would improve sleep in community-dwelling persons with dementia and their caregivers. The overall hypothesis was that, because the circadian system is maximally sensitive to short-wavelength light (peak close to 460 nm), a light source with more short-wavelength (blue) content would more positively impact objective and subjective sleep measures in persons with dementia than light sources commonly used in light therapy devices. Our results showed that 300–400 lux of blue-white light at the cornea, delivering a median CS value of approximately 0.23, did not significantly change objective and subjective sleep parameters in persons with dementia, but did significantly improve the subjective sleep of family caregivers. In addition, this level of short-term blue light exposure was not associated with any measurable adverse ophthalmic effects, even among persons who had undergone cataract surgery.

Most proxy measures of sleep reported by caregivers about the study participants with dementia failed to improve (Table 3), and none of the actigraphic measures changed (Table 2). Some modest evidence suggested that light stimulation levels achieved in the study may have had some effect, albeit minor, on sleep patterns. For example, the treatment condition was associated with a significant carryover effect ($p = 0.026$), whereas the control condition was not ($p = 0.52$). Furthermore, medication changes were negligible and therefore would not have affected the results. Thus, the overall results suggest that the levels of light exposure used in this study were not sufficient to change sleep parameters in subjects with dementia. In fact, the robust consistency of the actigraphic measurements is remarkable, suggesting that an effective intervention, once found, may have pervasive success. On the other hand, secondary outcomes of IADL scores worsened, suggesting that some non-

circadian effect – such as the progressive deterioration of dementia – may have been present and possibly counteracting some of the positive effects of the light treatment. Depression did improve, however, possibly indicating that this outcome is more sensitive to the treatment and/or at lower levels.

In contrast to the persons with dementia, caregivers showed improvement in multiple indicators of sleep quality (Table 4). Both the PSQI Sleep Index and the MOS Sleep Index were significantly better during the blue light condition than the red light control condition. Furthermore, virtually, all measures of sleep were in a positive direction when treatment results were compared with controls. These results suggest that the treatment condition did improve sleep in the caregivers, while not having a similar effect on persons with dementia.

The most likely reason for this disparity in results between persons with dementia and their caregivers is that the light levels achieved in our study had a more powerful effect on the caregivers (who are neurologically normal) than on the persons with dementia (who are not). As was revealed by our measurement using the circadian light meter, light-exposure rates achieved in the study resulted in a CS value of 0.23, which corresponds to an estimated 23% melatonin suppression. This relatively low dose may have been enough to affect normal caregivers but not people with dementia, whose neuronal systems are damaged. Also, given that we observed a strong carryover effect, it is possible that the circadian systems of persons with dementia need more time to respond to the light. In fact, van Someren *et al.* showed that the positive effect of bright light on sleep parameters in persons with dementia was only observed after six months of treatment.[64] There was no positive effect after six weeks of treatment, which was the length of our study. Thus, future work should consider a longer treatment period, 24-hour monitoring of light exposure and adequate subjects to allow separate analysis of treatment response by dementia severity.

Approximately five million persons in the United States currently suffer from dementia, most of whom are cared for at home and that number is anticipated to more than double by 2050.[65] Sleep disturbances affect the majority, which lead to further functional impairment and increased risk of placement in nursing homes and residential care/assisted living. Sleep disturbances among persons with dementia also have a negative impact on the mental health, sleep patterns and physical health of family caregivers. Medications, while widely used, are well-recognized as only marginally effective and as having significant side effects. Therefore, if light could be administered in a manner that would improve sleep, it would be a significant treatment advance. It is recommended that another study with longer exposure durations and higher light levels be conducted to determine if a stronger CS can improve sleep in this population. Furthermore, the finding of improved sleep among caregivers is intriguing and deserves replication, suggesting that with more intensive light levels, perhaps both caregiver and care recipient can benefit from such an intervention.

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**Table 1**

Characteristics of study participants

| Characteristic | N | % |
|---|---|---|
| *Participants with dementia (N = 17)* | | |
| Age | | |
| 65–79 | 6 | 35 |
| 80+ | 11 | 65 |
| Female gender | 11 | 65 |
| White race | 14 | 82 |
| Educational status | | |
| ≤12 years | 5 | 29 |
| >12 years | 12 | 71 |
| Functional status | | |
| Need assistance in bathing | 7 | 41 |
| Need assistance in locomotion | 4 | 24 |
| Need assistance in eating | 2 | 12 |
| Urinary incontinence | 4 | 24 |
| Needs assistance in toileting | 5 | 29 |
| Need assistance in dressing | 6 | 35 |
| | Mean | SD |
| Mini-Mental State Examination Score (range, 0–25) | 12.7 | 9.1 |
| St. Louis University Mental Status Score (range, 5–26) | 13.8 | 6.1 |
| *Family caregivers (N = 17)* | | |
| Age | | |
| 18–44 | 3 | 18 |
| 45–59 | 7 | 41 |
| 60+ | 7 | 41 |
| Female gender | 13 | 77 |
| White race | 14 | 82 |
| Educational status | | |
| ≤12 years | 4 | 24 |
| >12 years | 13 | 77 |
| Relationship to the person with dementia | | |
| Spouse | 6 | 35 |
| Daughter | 8 | 47 |
| Daughter-in-law | 1 | 6 |
| Grandson | 2 | 12 |
| Employment | | |
| Not working for pay | 10 | 59 |
| Working part-time for pay | 2 | 12 |
| Working full-time for pay | 5 | 29 |
| | Mean | SD |

| Characteristic | N | % |
|---|---|---|
| Mini-Mental State Examination Score (range 26–30) | 28.9 | 1.5 |

**Table 2**

Actigraphic sleep measures, by condition

| Measure | Condition | | | | | | Difference (intervention–control) (N = 14)[b] | |
|---|---|---|---|---|---|---|---|---|
| | Usual light (N = 17) | | Intervention (N = 15)[a] | | Control (N = 16) | | | |
| | Mean | SD | Mean | SD | Mean | SD | Mean (95% CI) | p-value[c] |
| Time asleep (minutes) | 248.3 | 70.2 | 246.3 | 77.9 | 248.2 | 73.3 | −0.23 (−12.75, 12.28) | 0.99 |
| Sleep latency (minutes) | 20.9 | 16.8 | 23.3 | 25.1 | 24.6 | 30.7 | −3.72 (−9.54, 2.10) | 0.19 |
| Sleep efficiency | 69.0 | 19.5 | 68.4 | 21.6 | 68.9 | 20.3 | 0.003 (−3.45, 3.45) | 0.99 |
| Number of sleep bouts | 15.8 | 5.2 | 14.9 | 6.5 | 15.9 | 6.8 | −0.81 (−2.64, 1.03) | 0.36 |
| Interdaily stability | 0.56 | 0.17 | 0.41 | 0.17 | 0.41 | 0.16 | 0.004 (−0.05, 0.05) | 0.87 |
| Intra-daily variability | 1.16 | 0.30 | 1.21 | 0.30 | 1.20 | 0.27 | 0.049 (−0.11, 0.21) | 0.52 |

[a] N is 14 for inter-daily stability and intra-daily variability, 15 for all other measures for the blue light condition.

[b] N is 13 for inter-daily stability and intra-daily variability, 14 for all other measures for the paired differences.

[c] Paired t-test.

**Table 3**

Baseline, intervention and control condition outcomes for persons with dementia

| Measure* | Possible range and valence | Mean value by condition | | | Mean difference (p-value) | |
|---|---|---|---|---|---|---|
| | | Usual light (baseline) | Intervention condition | Control condition | Intervention minus usual | Intervention minus control |
| Quality of night-time sleep | | | | | | |
| PSQI Sleep Efficiency[a] | % of 100, higher is better | 73.4 | 81.8 | 76.7 | 8.4 (0.045) | 5.1 (0.17) |
| PSQI Sleep Index[b] | 0–21, lower is better | 6.6 | 5.6 | 5.6 | −1.0 (0.18) | 0.04 (0.94) |
| MOS Sleep Adequacy | 0–100, higher is better | 65.6 | 67.3 | 66.4 | 1.7 (0.84) | 0.9 (0.90) |
| MOS Sleep Problems | 0–100, lower is better | 31.7 | 27.5 | 30.7 | −4.2 (0.24) | −3.2 (0.32) |
| MOS Sleep Disturbance | 0–100, lower is better | 20.0 | 19.8 | 23.9 | −0.2 (0.96) | −4.1 (0.40) |
| MOS Sleep Index | 0–100, lower is better | 30.1 | 25.8 | 29.3 | −4.3 (0.23) | −3.5 (0.28) |
| MOS Somnolence | 0–100, lower is better | 60.6 | 51.9 | 56.5 | −8.7 (0.21) | −4.6 (0.47) |
| Daytime sleepiness | | | | | | |
| Epworth Sleepiness Scale | 0–24, lower is better | 12.6 | 12.2 | 12.1 | −0.4 (0.58) | 0.1 (0.90) |
| Other measures | | | | | | |
| ADLs[b] | 0–24, higher is better | 17.4 | 17.7 | 17.0 | 0.3 (0.50) | 0.7 (0.17) |
| IADLs | 0–9, higher is better | 2.6 | 2.3 | 2.9 | −0.3 (0.25) | −0.6 (0.02) |
| CSDD | 0–38, higher more depressed | 9.8 | 6.3 | 7.7 | −3.5 (0.011) | −1.4 (0.26) |
| PHQ-9 | 0–27, higher more depressed | 9.0 | 6.5 | 6.8 | −2.5 (0.038) | −0.3 (0.82) |
| QOL-AD | 15–60, higher is better | 37.1 | 35.2 | 35.2 | −1.9 (0.19) | −0.02 (0.98) |

*ADL = Activity of Daily Living; CSDD = Cornell Scale for Depression in Dementia; Epworth = Epworth Sleepiness Scale; IADL = Instrumental Activities of Daily Living; MOS = Medical Outcomes Study sleep measures; PHQ-9 = Patient Health Questionnaire, depression measure; PSQI = Pittsburgh Sleep Quality Index; QOL-AD = Quality of Life in Alzheimer's Disease, modified.

Note: Mixed model with fixed effects for intervention condition, control condition and carryover plus a random effect for participant.

[a]Carryover for the intervention condition is statistically significant (p = 0.026).

[b]Period effect is statistically significant.

**Table 4**

Baseline, intervention and control condition outcomes for family caregivers of persons with dementia

| Measure* | Possible range and valence | Mean value, by condition | | | Mean difference (p-value) | |
|---|---|---|---|---|---|---|
| | | Usual light (baseline) | Intervention condition | Control condition | Intervention minus usual | Intervention minus control |
| Quality of night-time sleep | | | | | | |
| PSQI Sleep Efficiency | % of 100, higher is better | 85.3 | 87.4 | 82.1 | 2.1 (0.68) | 5.3 (0.24) |
| PSQI Sleep Index | 0–21, lower is better | 4.6 | 3.7 | 5.4 | −0.9 (0.19) | −1.7 (0.013) |
| MOS Sleep adequacy | 0−100, higher is better | 65.6 | 68.4 | 54.2 | 2.8 (0.71) | 14.2 (0.046) |
| MOS Sleep problems | 0–100, lower is better | 25.2 | 16.0 | 24.2 | −9.2 (0.009) | −8.2 (0.011) |
| MOS Sleep disturbance[a] | 0–100, lower is better | 27.0 | 9.0 | 17.1 | −18.0 (0.002) | −8.1 (0.10) |
| MOS Sleep Index | 0–100, lower is better | 24.2 | 16.3 | 24.3 | −7.9 (0.023) | −8.0 (0.012) |
| MOS Somnolence | 0–100, lower is better | 20.2 | 18.2 | 23.4 | −2.0 (0.55) | −5.2 (0.09) |
| Daytime Sleepiness | | | | | | |
| Epworth Sleepiness Scale | 0–24, lower is better | 4.1 | 3.0 | 3.7 | −1.1 (0.08) | −0.7 (0.22) |
| Other measures | | | | | | |
| Caregiver Hassles Scale | 0–120, lower is better | 21.4 | 17.0 | 18.5 | −4.4 (0.23) | −1.5 (0.65) |
| Zarit Role Strain | 0–24, lower is better | 9.9 | 8.4 | 9.6 | −1.5 (0.037) | −1.2 (0.06) |
| Zarit Personal Strain | 0–48, lower is better | 16.9 | 16.2 | 18.4 | −0.7 (0.66) | −2.2 (0.13) |
| Zarit total | 0–88, lower is better | 32.4 | 29.8 | 33.7 | −2.6 (0.25) | −3.9 (0.06) |
| PHQ-9 | 0–27, lower is better | 2.7 | 1.8 | 2.5 | −0.9 (0.24) | −0.7 (0.33) |

*Epworth = Epworth Sleepiness Scale; MOS = Medical Outcomes Study sleep measures; PHQ-9 = Patient Health Questionnaire, depression measure; PSQI = Pittsburgh Sleep Quality Index.

Note: Mixed model analysis with fixed effects for intervention condition, control condition and carryover plus a random effect for participant.

[a]Carryover for control condition (p = 0.013) and global carryover (p = 0.041) are statistically significant.