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TITLE: Examining Health Effects of Daylight Exposure on Dementia Patients in Los Angeles Assisted Living Facilities

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Alhambra Dementia Care	1118 N. Stoneman Ave. Alhambra, CA 91801
Calabasas Memory Care Community	25100 Calabasas Rd Calabasas, CA 91302
Costa Mesa Dementia Care	350 W. Bay St. Costa Mesa, CA 92627
Los Angeles Dementia Care (Beverly Place)	330 N Hayworth Ave Los Angeles, CA 90048
Redondo Beach Dementia Care (Beach Cities)	514 N Prospect Ave Redondo Beach, CA 90277
San Juan Capistrano Memory Care Community	30311 Camino Capistrano, San Juan Capistrano, CA 92675
Sierra Vista Memory Care Community	125 W Sierra Madre Ave Azusa, CA 91702
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AMENDMENTS/REVISIONS: The original protocol was amended to change the scale used to assess depression from the Geriatric Depression Scale (GDS) to the Cornell Scale for Depression in Dementia (CSDD). (Approved 10/10/2016).

1.0 BACKGROUND INFORMATION

The Alzheimer's Association (2004) estimates that clinically significant depression occurs in about 20 to 40 percent of people with Alzheimer disease. The percentage increases to 70 to 80 percent for Alzheimer residents in assisted care facilities. Treatment of depression in Alzheimer disease can improve sense of well-being, quality of life, and individual function, even in the presence of ongoing decline in memory and thinking. In institutionalized settings, lack of sufficient exposure to bright light is considered one of the primary contributors to disruption of the circadian system, with cascading effects of sleep disruption, agitated behavior, depression, and cognitive decline (Day et al., 2000). Exposure to bright light (2500 - 10,000 lux) typically administered in the morning, has been shown through a large body of research to be an effective non-pharmaceutical treatment option for depression (Golden, et al., 2005). Light therapy has also been shown to be an effective treatment for sleep disturbances (Dowling, et al., 2005) and for ameliorating behavioral problems (Cohen-Mansfield, 2001) for people with Alzheimer disease. However, reliable and well-designed studies examining the efficacy of light therapy in treating depression among people with Alzheimer disease are extremely limited (Forbes et al., 2009). Moreover, the conventional approach to administering the bright light stimulus, through boxes containing arrays of fluorescent light fixtures, is problematic for people with Alzheimer disease due to reported side effects of headache, eye strain, nausea, and agitation (Labbate 1994; Terman, 1999). We hypothesize that exposure to sufficient daylight indoors can serve as an effective non-drug treatment option for people with Alzheimer disease and depression, with the potential to lead to fewer adverse effects than noted with light box treatments. Aside from the intervention, the residents and staff participating in this study will not experience any changes to their normal routine and duties. Staff supervised socialization can, but does not necessarily include interaction with other residents in the facility or engagement in "free time" activities such as watching TV. We are aware that any changes outside of the intervention, either with staff specified roles or residents could potentially interfere with the results of the study.

2.0 OBJECTIVES AND PURPOSE

This study is designed to test the hypothesis that an intervention increasing exposure to daylight will reduce depression and negative behaviors and increase cognitive function among Alzheimer patients in Los Angeles dementia care facilities.

3.0 STUDY DESIGN

The research will be conducted as a 12-week field study in eight Silverado dementia care facilities in Los Angeles and Orange County. Silverado is an assisted living service provider that delivers care for those with Alzheimer, dementia and other memory-impairing diseases. Data collection will occur twice during the study: baseline measures at the beginning of the study and outcome measures at the end of the study.

4.0 TREATMENT OF SUBJECTS

4.1 Intervention Group

At two facilities, the active light intervention will enlist staff to increase daylight exposure to Alzheimer residents by taking them to daylit perimeter room in the morning (8:00 - 10:00 AM) where vertical daylight illuminance at eye level exceeds 2500 lux and where direct sun exposure

can be avoided. The intervention will consist of two hours of daylight exposure administered beginning at 8:00 AM in the morning each day (7 days / week) over the 12-week study.

4.2 Control Group

Patients at the other two facilities will receive usual care. During the period from 8:00 AM to 10:00 AM each day, the control group of Alzheimer residents will be taken to a similar sized area indoors without daylight exposure for socialization under typical interior fluorescent lighting conditions.

4.3 Outcome Measures

The following outcome measures will be taken:

1. Patient outcomes will be completed at baseline and 12-weeks. For each of our major outcomes, we will use instruments that are well-validated for use in testing effects of short- to long-term interventions in AD:
    a. Depression: Cornell Scale for Depression in Dementia (CSDD)
    b. Neuropsychiatric Inventory Nursing Home Version (NPI-NH)
2. Trial conduct/methods outcomes:
    a. Facility and staff support and participation: facilitators and obstacles.
    b. Fidelity of light and control intervention: facilitators and obstacles.
    c. Data collection fidelity: patient outcomes and light measures.
    d. Estimates of subject recruitment, consent, and attrition rates: facilitators and obstacles.
    e. Estimates (and confidence intervals) for study/trial planning: intervention effect size, variance of outcome measures, within-facility correlation in outcome measures, within-patient correlation in outcome measures (repeated measures).

4.4 Lighting Measures

Physical lighting measurements will be recorded continuously at 1-minute intervals throughout the study using research grade photometric sensors and data logging equipment to establish 24-hour patterns of light / dark exposure. Additionally, in-situ measurements will be taken using a spectrometer to assess the spectral power distribution of light exposure at seated eye level.

5.0 SELECTION AND EXCLUSION OF SUBJECTS

5.1 Inclusion criteria for enrollment

The trial inclusion criteria is an AD diagnosis and no physical co-morbidities that preclude participation in the daily group intervention. Based on current facility records, we estimate the intervention and control groups will include approximately 160 Alzheimer disease participants total (20 patients per facility). Demographic information obtained during the study preparation phase (mean age, gender, type of dementia by diagnosis, depression level, length of time in facility, date of onset of dementia, ethnicity) will be obtained to show that the facilities are comparable.

5.2 Exclusion criteria for enrollment

Outcome measurements will be confined to those who meet the trial inclusion criteria (AD diagnosis, no physical co-morbidities that preclude participation in the daily group intervention).

6.0 STATISTICS

All analyses will include factors for facility and intervention (nested within facility). Baseline analyses will include descriptors of the study sample (age, gender, ethnicity, onset of Alzheimer's disease) as well as initial levels of the outcome measures (depression, cognition, behavior) and will utilize analysis of variance for continuous data and chi-square methods for categorical data to compare the intervention groups. If the intervention groups are found to differ on baseline levels of the outcome variables or other variables related to outcome, these variables will be included as adjusting covariates in the comparisons of 12-week outcomes. 12-week outcomes will be compared between intervention groups with analysis of variance (2-level factor for intervention, 8-level factor for facility, with intervention nested within facility). For planning of larger trials, the following estimates will be made (along with 95% confidence intervals) for each patient outcome: intervention effect size (mean group difference in outcome), variance in outcome (across patients, across facilities), within-facility correlation in outcomes (correlations in outcomes amongst patients within a facility), within-patient correlation in outcomes (repeated measures, baseline and 12-weeks).

6.1 Sample Size

As a pilot study, the planned sample size is not based on statistical power to detect specified effect sizes on intervention outcomes. Rather, the planned sample of 80 subjects per intervention group was selected in terms of pilot study feasibility. The planned sample is considered more than sufficiently adequate to address pilot trial questions related to feasibility (of study recruitment and conduct, delivery of intervention, data collection) and estimates of trial-related parameters, along with 95% confidence intervals (mean intervention effect size, variance in outcome measures in the study population, within-facility correlation in outcome measures, within-patient correlation in outcome measures). As pilot studies are well known to over-estimate intervention effect sizes and under-estimate measures of variance, it is crucial that confidence intervals (precision of the estimates) are also calculated and available for planning of larger studies.

7.0 ASSESSMENT OF SAFETY

The proposed study does not include any drug or device treatment and presents minimal (if any) risk to participants.

8.0 DISCONTINUATION OF THE STUDY

Participants do not have to remain in the intervention spaces if they do not want to while participating in the study. The informed consent form indicates to the Legally Authorized Representative (LAR) that he/she may withdraw his/her consent at any time and discontinue the participation of his/her family member without penalty.

9.0 ETHICS

All study staff are trained and credentialed to perform the duties assigned to them. In our proposed study, we are obtaining informed consent and HIPAA authorization from the legal representative of the participants in the study. All study staff have fulfilled the training mandated by their respective departments or institutions. Participant privacy and data confidentiality will be addressed via the following methods:

- Research procedures will be conducted in person in a private setting.
- Data will be captured and reviewed in a private setting.
- Only authorized research study personnel will be present during research related activities.
- The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.

10. DATA HANDLING AND RECORD KEEPING

All data will be coded and the key codes kept separately and securely. Research data will be protected against inappropriate use or disclosure via the following methods:

- Locked office
- Restricted access to authorized study personnel
- Secure computer/laptop
- Individual ID plus password protection
- Security software (firewall, antivirus, anti-intrusion) is installed and regularly
- updated in all servers, workstations, laptops, and other devices used in the study
- Restrictions on copying study related materials

11.0 REFERENCES

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