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A RANDOMIZED, CONTROLLED TRIAL OF BRIGHT LIGHT THERAPY FOR AGITATED BEHAVIORS IN DEMENTIA PATIENTS RESIDING IN LONG-TERM CARE

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ABSTRACT

Background. Agitated behaviors are common in dementia patients residing in chronic care settings. Their occurrence may be associated with lack of adequate exposure to sunlight and with circadian rhythm disturbances.

Objective. Prior research has suggested that bright light therapy (BLT) may reduce agitated behaviors in dementia patients. The aim of this study was to test the efficacy of BLT in a randomized, controlled, crossover clinical trial.

Method. Fifteen patients with dementia and agitated behaviors residing in a chronic care facility were randomized in a crossover design to morning BLT for 1 hour per day or to a control condition with dim light exposure. Patients were treated in either condition for 4 weeks, followed by 1 week on no treatment, prior to being crossed over to the other condition.

Results. Eight out of 15 patients completed the entire study. The rest completed at least 2 weeks of study. Patients randomized to the BLT condition exhibited a statistically significant improvement in nocturnal sleep from a mean of 6.4 hours/night to 8.1 hours/night 4 weeks later ($p < 0.05$). The sleep of patients in the control condition did not improve significantly. There were no other significant differences between baseline and follow-up, nor between BLT and control treated patients on the other outcome measures, which included the Behavioral Pathology in Alzheimer Disease scale (Behave-AD) and the Cornell Scale for Depression in Dementia.

Conclusion. Patients with dementia in chronic care who exhibit agitated behaviors sleep more hours at night when administered morning BLT. However, BLT does not lead to improvements in agitated behaviors in institutionalized patients with dementia with non-disturbed sleep–wake cycles.

KEY WORDS—dementia; agitation; bright light therapy; nursing home

Dementia is associated with a range of agitated behaviors that are particularly common in later stages of the disease and in institutional settings, such as nursing homes (Lyketsos *et al*., 1999). These disturbances have considerable impact on patients and caregivers, including mental suffering, injury, use of restraints, use of medications and others (Lyketsos *et al*., 1999; Finkel, 1996). Their etiology is complex and likely includes interactions of genetic factors and brain damage from the underlying dementing disease, as well as environmental causes (Lyketsos *et al*., 1999). Evidence has suggested that 'agitated behaviors' in chronic care may in part be due to circadian dysrhythmias (Satlin *et al*., 1988) or to limited sunlight exposure (Campbell *et al*., 1995). Circadian rhythm disturbances and limited sunlight exposure in the nursing home are more common among dementia patients than among other elderly patients (Ancoli-Israel *et al*., 1997).

Several papers have reported on efforts to correct circadian dysrhythmias and limitations in light exposure among dementia patients in institutional settings by using bright lights or increased ambient lighting. Satlin *et al*. (1992) and Mishima *et al*. (1994) reported the results of open trials in which dementia patients showed improvement in sleep and/or a reduction in behavioral disturbance after exposure to bright light therapy. Van Someren *et al*.

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(1997) also reported improvement in agitated behaviors in 22 patients with dementia exposed to increased daytime environmental illumination. A fourth uncontrolled community study using 2000 lux full spectrum bright light for 2 hours each morning in community-residing Alzheimer disease patients showed *no* improvements in sleep time, although there was a resetting of the biological clock (Colenda *et al*., 1997).

In the only randomized controlled clinical trial that could be located, Lovell *et al*. (1995) reported on the use of 2500 lux bright lights used for 2 hours in the morning in six demented elderly nursing home residents. They noted significant reductions in agitated behaviors only during the days when patients were exposed to bright light therapy. However, the sample size was small. Additional controlled trials of the efficacy of BLT for agitated behaviors in dementia patients are necessary before the widespread use of BLT, given that agitated behaviors might improve with increasing nursing staff attention (Campbell *et al*., 1991).

In this study we report findings of a randomized, controlled, crossover clinical trial of morning BLT for the treatment of agitated behaviors in patients with dementia residing in a chronic care setting.

METHOD

Participants

Fifteen residents of Copper Ridge, a chronic care residence for patients with dementia, participated in this study. All met DSM-IV criteria for dementia and scored greater than four points on the Behavioral Pathology in Alzheimer Disease scale (Behave-AD; 13). Patients were excluded if they suffered from a major depressive episode, delusions, hallucinations, manic syndrome, or were bed-bound, blind, or in some other way unable to participate in bright light therapy. Patients who had been treated with medications for problem behaviors or sleep disturbance were only enrolled in the study if they had been on a stable dose of these medicines for 1 week prior to enrollment and continued to meet inclusion criteria (ie the behavior disturbance had not stabilized sufficiently). Given that agitated behaviors in patients with and without sleep–wake cycle disturbances might have a different etiology (with the agitation more likely linked to the sleep disturbance in the former), patients with sleep–wake cycle disturbances by DSM-IV criteria were excluded so as to assess the benefits of BLT for agitated behaviors specifically in the absence of sleep–wake cycle disturbance.

Design

This was a randomized, controlled, crossover trial with two conditions: bright lights and control. Patients were randomized to one or the other condition and spent 4 weeks in that condition. Subsequently, they received no treatment for 1 week and a second baseline was taken. They were then treated in the other condition for an additional 4 weeks.

Bright lights condition

Bright light therapy was administered for 1 hour every morning using a 10,000 lux full spectrum lamp at 3 feet. This intensity of lights was chosen to ensure adequate administration of light therapy to persons with dementia, who have difficulty sitting still. This intensity of lights was also shown to be effective in reducing the symptoms of seasonal affective disorder. Patients were positioned at a distance of 3 feet from the lamp. They were instructed every 15 minutes to keep their eyes open and in the direction of the light source. A nursing staff member supervised the light bathing in a quiet room. Patients were allowed to participate concurrently in other activities such as reading, watching television, listening to music or eating, although they had to have their face within 3 feet of and directed towards the light during the entire treatment.

Control condition

The control condition was identical to the above except that a dim, digital, low-frequency blinking light positioned in the middle of the active bright light therapy was used. This is a standard control condition used in studies of bright light therapy for seasonal affective disorder. The 10,000 lux light bulb was off during the control condition treatments.

Outcome assessment

Outcome ratings were carried out by staff who were blind as to condition assignment. Outcome measures were: (1) a sleep log for hours of sleep between 8 pm and 8 am, reported as the mean nocturnal hours of sleep in the past week assessed

at baseline and at weeks 2 and 4 in each condition; (2) the Behavioral Pathology in Alzheimer Disease scale (Behave-AD; 13), rated at baseline and at weeks 2 and 4 in each condition; and (3) the Cornell Scale for Depression in Dementia (CSDD; 14) to investigate effects of BLT on mood, rated at baseline and at week 4 in each condition.

Analyses

Data from the same patients in each condition were handled as unique observations (as if they were different patients) to create a single dataset of 30 study participants with 15 assigned to each condition. The assumption was made that there would be no carryover effects from one condition to the next given the intervening no-treatment week. Analyses were all 'intent-to-treat', based on initial condition assignment and using the last observation carried forward (LOCF) method. Eight participants completed the entire trial. An additional three completed the first condition, the no-treatment week and 2 weeks of the second condition. Two other participants only completed the first condition and the final two only completed the first 2 weeks in the first condition. Of the seven who dropped out early, two (one in each condition) did so at the request of their legally representative family member due to lack of efficacy and desire for a medication treatment trial for agitation. The other five (four in bright lights, one in control) were removed by the study principal investigator due to worsening of their agitation. Dropout was comparable between those randomized to each condition ($p < 0.05$).

The effect of treatment within conditions was assessed by comparing baseline to follow-up measures at each point in follow-up, on each outcome measure, using repeated measures (paired) *t*-tests. The effect of treatment between conditions was assessed after 2 or 4 weeks of treatment on all outcome measures using *t*-tests. We also analyzed the data sequentially and with or without the last observation carried forward method and had similar findings.

RESULTS

Study participants had a mean age of 80.8 years (SD 8.7). Fourteen of 15 were female and they had a mean education of 12.6 years (SD 4.2). All were white (there was no effort to select for whites). Twelve of 15 met DSM-IV criteria for Alzheimer disease and the other three met criteria for vascular dementia. On study entry, the mean MMSE score was 6.4 (SD 6.8). Participants in the two conditions were compared on age, sex, education, race, diagnosis and baseline scores on the Behave-AD, CSDD and total hours of sleep in the last week. At baseline, there were no significant differences (in all cases $p > 0.10$) between the lights and control conditions on any of these measures. All participants scored above zero on the Behave-AD agitation/aggression items.

Fig. 1 shows the mean hours of nocturnal sleep (8 pm–8 am) in the two conditions at baseline, weeks 2 and week 4. Those receiving bright lights were sleeping an average of 6.4 hours per night (SD 2.07) for the week before treatment. Two weeks into treatment they were sleeping an average of 7.6 hours every night (SD 1.93), and 4 weeks into treatment they were sleeping an average of 8.1 hours (SD 1.93) at night. The improvement in nocturnal sleep between baseline and week 2 was not statistically significant. The improvement between baseline and 4 weeks was statistically significant (repeated measures, two-tailed, $t(df, 14) = -2.37$, $p < 0.05$).

Participants in the control condition were sleeping an average of 6.0 hours per night (SD 2.28) in the week prior to treatment. By week 2 they were sleeping an average of 6.2 hours (SD 2.14) and by week 4 an average of 7.3 hours (SD 1.78) every night. None of the changes across time in the control condition were statistically significant ($p > 0.05$).

The difference between the control and active treatment groups at 2 weeks was of borderline significance ($t(df, 28) = 1.823$, $p = 0.08$). The difference between the two groups at week 4 was not statistically significant ($t(df, 28) = 1.158$, $p = 0.257$).

Fig. 2 shows means on the Behave-AD total score in the two conditions, at baseline and at weeks 2 and 4. In the BLT condition, the baseline mean was 14.9 (SD 3.83); at week 2 it was 13.1 (SD 6.09); and at week 4 it was 12.6 (SD 4.79). For the patients randomized to the control condition, the baseline Behave-AD mean was 13.7 (SD 3.49); the week 2 mean was 13.5 (SD 6.28); and the week 4 mean was 10.7 (SD 4.85). Differences between baseline and follow-up and differences between conditions at each time point on the total Behave-AD were not statistically significant (in all cases, $p > 0.05$).

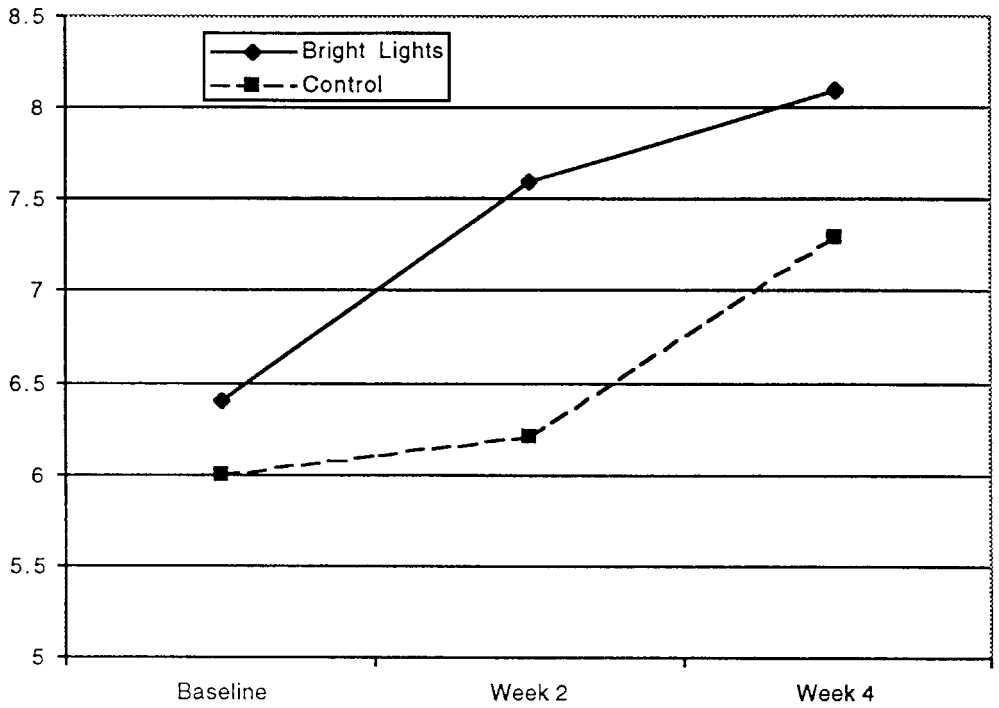

Fig. 1. Mean hours of sleep at night (in the past week) in the BLT or control condition at baseline, at week 2 and at week 4

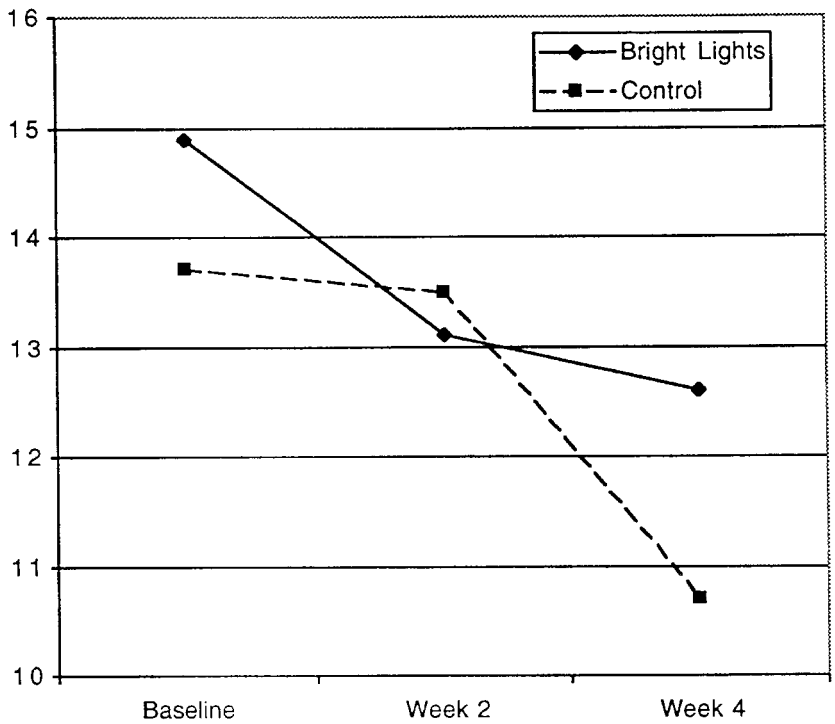

Fig. 2. Mean total score on the Behave-AD in the BLT or control condition at baseline, at week 2 and at week 4

Similarly, when Behave-AD 'global disruptiveness' scores, or scores on subscales for 'activity', 'aggression', 'diurnal rhythm', 'affective' and 'anxiety', were compared between baseline and follow-up and between conditions, no significant differences were found ($p > 0.05$ in all cases).

When Cornell Scale for Depression and Dementia scores were compared between baseline and follow-up in each condition and between conditions at each time point, there were also no significant differences ($p > 0.05$).

DISCUSSION

We report findings from a randomized, controlled, crossover clinical trial of bright light therapy versus a control condition in institutionalized patients with dementia. Our findings indicate that improvements in nocturnal sleep hours are possible for patients treated with bright light therapy. However, improvements in sleep may have been due to factors other than light treatment. In addition, we found no significant benefit of BLT for behavior or mood.

These findings are different from those of previous uncontrolled research (Satlin *et al*., 1992; Mishima *et al*., 1994; Van Someren *et al*., 1997) and of a smaller randomized clinical trial (Colenda *et al*., 1997) which supported the use of bright light therapy for agitated behaviors in institutionalized patients with dementia. They are more in line with those of Colenda *et al*. (1997), who reported no significant benefit from bright light therapy other than mild stabilization of the circadian cycle.

All patients in the study, including those assigned to the control treatment, showed slight improvements in nocturnal sleep as well as in mean scores on the Behave-AD, although these changes were not statistically significant. These improvements may have been related to the fact that all patients received a considerable amount of attention from study staff, and also practiced better sleep hygiene since they had to get up early every morning in order to sit in front of the 'light box' in both conditions. (In the control condition, the 'light box' was not turned on.)

There are several possible reasons which might explain a lack of efficacy in this study. One is the fact that the sample size was small. Another is that we may have used the wrong timing of treatment, and that we should have administered bright lights in the evening. However, previous studies reported efficacy with either morning or evening bright light therapy. The timing of BLT administration intended to stabilize a circadian dysrhythmia is best chosen based on whether the circadian cycle is phase-advanced or phase-delayed (Campbell *et al*., 1991). A third is that we did not include in the study patients with a clearly demonstrated 'off-phase' sleep/wake cycle disturbance, in whom the benefits of bright light therapy might be expected to be greater. Finally, 4 weeks may not have been long enough for bright lights to have an effect on agitation. Regardless, these findings are valuable in that they suggest a lack of efficacy of BLT for agitated behaviors in institutionalized dementia patients in the absence of a sleep/wake cycle disorder.

We conclude that bright light therapy may not be an effective treatment for agitated behavior in institutionalized dementia patients with non-disturbed sleep–wake cycles. However, it may be a useful means of improving or stabilizing sleep disturbances. There is need for a larger, randomized controlled clinical trial to conclusively answer these questions.

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