Methodological challenges in studies of bright light therapy to treat sleep disorders in nursing home residents with dementia

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Aim: Numerous studies have explored the effectiveness of bright light therapy as a treatment of sleep disorders in nursing home and long-stay geriatric hospital residents, most of whom have dementia. A recent Cochrane Collaboration meta-analysis of 10 selected studies concluded that there was insufficient evidence to assess its therapeutic efficacy as most available studies had methodological problems. We sought to remedy this situation by developing proposals to guide research methods in future studies.

Methods: Based on the literature and our own clinical and research experience, we developed a series of proposals relating to study design, participant selection, light delivery modalities and outcome measures that we believe will maximize the chances of identifying a bright light treatment effect. We then checked adherence to these proposals in all relevant published experimental studies.

Results: Of the 18 studies published in the last two decades that met our selection criteria, only half the studies had selected participants with a sleep disorder. Eleven studies excluded people with severe vision loss; seven included a clinical rating of sleep, and five measured baseline lighting levels. Most checked psychoactive medication prescriptions but few reported changes in prescriptions over the course of the study. Most also checked treatment adherence and included some control for differences in amount of social contact.

Conclusions: Evidence for the effectiveness of bright white light treatment in people residing in nursing homes is equivocal. We anticipate that the quality of this evidence will be improved if researchers refine their study methods and adopt a more uniform approach.

Key words: dementia, nursing homes, phototherapy, research design, sleep disorder.
cycle is required to maintain appropriate circadian entrainment. The circadian pacemaker is located in the hypothalamic suprachiasmatic nuclei (SCN), which send multiple efferent signals to other brain areas to synchronize physiological, metabolic and behavioral functions. With ageing, there is a reduction in SCN cell numbers and neuronal activity, resulting in a loss of the robustness of circadian rhythms as shown by a lower oscillation amplitude and reduced sensitivity to Zeitgebers, particularly light. SCN neurons might simply become inactive, rather than defunct, as studies of aged rats found that exposure to bright light appeared to reverse age-related circadian rhythm disturbances and prevent age-related reductions in the numbers of vasopressin-secreting cells. The same mechanisms might operate in humans.

Other factors that could contribute to the breakdown of 24-h sleep–wake rhythms in older people include: (i) reduced exposure to light–dark cycles because of physical immobility and restricted access to daylight; (ii) intrinsic changes in optical, photoreceptor and neuronal functioning leading to a diminished retinal sensitivity to light; (iii) yellowing of the lens; and (iv) a smaller pupil diameter meaning that less light is transmitted to the retina. People aged over 75 years retain only 20% of a 10-year-old child’s photoreceptive capacity and therefore require 5 times brighter light to maintain optimal circadian rhythms.

Generally speaking, the elderly need more and brighter light to reset their circadian rhythms but, once admitted to nursing homes and other long-stay settings, their exposure to light is often reduced. As an example, in 29 Japanese aged-care facilities, the average light intensity was 300 lux by day and 200 lux at night, blurring differences between day and night. In Belgium, lighting levels in eight nursing homes met national standards in only one of the homes on sunny days and in none on cloudy days. Similarly, 77 aged-care residents in a US study had a median daytime light exposure of only 52 lux.

Numerous studies have explored the effectiveness of bright light therapy to strengthen the circadian rhythm and improve sleep patterns in older people in nursing homes and long-stay hospital wards. Bright white light has been delivered either by seating participants in front of a light box or by substituting standard wall or ceiling light fittings with bright light tubes in selected areas. The intensity of the light intervention varied greatly between studies. The results have been mixed and a Cochrane Collaboration meta-analysis of 10 reports that met strict inclusion criteria concluded that there was insufficient evidence to assess the value of light therapy for people with dementia as too few of the studies were of high methodological quality.

In contrast to the Cochrane review, which synthesized the results of a small number of randomized controlled trials, we set out to enumerate the methods employed in studies of the effects of bright light therapy on the sleep patterns of aged residents of nursing homes and long-stay hospitals. Prior to conducting the review, we developed a series of recommendations regarding study design features that might, we believe, maximize researchers’ chances of detecting the benefits of bright light treatment, assuming that such benefits exist. These recommendations were then mapped against the methods employed in studies that met basic inclusion criteria with the goal of promoting discussion and encouraging a greater uniformity of approach in future studies. We chose not to focus on elements like randomization and blinding that are addressed in standard checklists of clinical trial integrity but to concentrate instead on issues particular to the study of sleep disorders in people with dementia.

**METHODS**

**Selection of studies**

To qualify for inclusion in the review, experimental studies were required to have: (i) been published in English; and (ii) tested bright light using a light box, wall- or ceiling-mounted lighting installations, or outdoor light in (iii) a long-term care setting where all, or almost all, participants had dementia, (v) using a rating or measure of activity, rest or sleep, with (vi) statistical analyses that (vii) partialled out outdoor light in (iii) a long-term care setting where all, or almost all, participants had dementia, (v) using a rating or measure of activity, rest or sleep, with (vi) statistical analyses that (vii) partialled out the benefits of bright light therapy in the event that more than one intervention was tested.

After a search of PubMed and EMBASE literature databases using the terms (‘aged’ or ‘nursing homes’) and (‘circadian rhythm’ or ‘sleep disorder’) and ‘humans’ and ‘phototherapy’, followed by checks of references from earlier reviews, 24 studies appeared to meet the stated criteria. Of these, six reports were excluded for the following reasons: two presented preliminary data that were described in greater detail elsewhere, two included no statistical analyses, one tested low intensity dawn–dusk simula-
tion;22 and one was conducted in a non-residential setting.23 This left 18 papers for consideration, only six of which had also been included in the Cochrane meta-analysis.24–29

Methodological proposals

We developed a series of recommendations drawn from the literature and our own clinical and research experience that we hope will maximize researchers’ chances of detecting treatment effects. These proposals concern the selection of study participants, treatment delivery modalities and outcome measurement. Both authors checked each of the selected reports and noted whether the eight recommended strategies had or had not been included in the methodology. If a clinical characteristic or strategy was not mentioned explicitly, it was rated as ‘absent’ or ‘not done’.

1. Study sample

1a. Dementia

Bright light therapy could be of benefit to many nursing home residents but interest to date has focused on those with dementia given the association between dementia and sleep and behavioral disorders. It is advisable therefore to confirm the diagnosis of dementia using an internationally accepted glossary. In studies in which all residents of a facility are exposed to an intervention, for example ceiling-mounted bright lights, cognitive function and dementia diagnoses should be mapped to ascertain their associations with treatment outcomes.

1b. Sleep disorder

To show that bright light therapy leads to improved sleep quantity and/or quality, participants in clinical trials should have some pre-existing sleep disorder, such as delayed sleep onset, multiple awakenings or daytime sleepiness. While dementia is often accompanied by changes in the rest–activity cycle, they may not always be clinically significant. If there is no problem to solve, no treatment can be shown to be effective.

1c. Vision loss

For bright light therapy to reset the rest–activity cycle, it is critical that light reaches the retina.10 Participants should be able to perceive light but measuring visual acuity in people with advanced dementia is sometimes difficult. As a minimum safeguard, people known to have an ophthalmic abnormality that greatly impedes light perception (e.g. dense bilateral cataracts) should be excluded from studies.

1d. Psychoactive medication checks

Medications including antipsychotics, antidepressants and benzodiazepines are commonly prescribed in nursing homes to relieve agitation and improve mood.30 Many of these medications are sedative and changes in prescribing patterns during the course of a study, or the use of medications on an occasional basis, may confound the results, especially in studies that last for several weeks. Researchers should therefore exclude residents with unstable psychotropic dosing regimens and report changes in medications over the course of the study.

2. Treatment design

2a. Baseline lighting

To induce clinically significant change, an intervention should increase the amount, intensity and/or duration of available light. While lighting levels are often low, conditions in summer months in the southern hemisphere, for example, may be very different from those in winter in the northern hemisphere. Available light levels should be measured, therefore, in the parts of the residence or ward where participants spend most time and at the time of day when treatment is actually delivered.

2b. Adherence checks

Individuals with severe dementia are at risk of agitated behaviors like incessant pacing. These behaviors will interfere with treatment protocols if participants cannot remain still in front of a light source for the specified periods, usually 1–2 h. Researchers should therefore ensure adherence to treatment protocols. Adherence might also be an issue in studies of wall- or ceiling-mounted light fittings if participants repeatedly leave the treatment area or spend much of their day elsewhere.

2c. Control condition

If light therapy is administered or supervised by a nurse or researcher, their presence close to partici-
pants can help shape the outcome. In the case of people with dementia, social contact greatly reduces levels of motor agitation and promotes better quality sleep, making it necessary to employ a control condition that tests another type of light or offers an equivalent amount of social interaction. This may not be an issue in studies of wall- or ceiling-mounted light fixtures where no special supervision is required (though the times spent in brightly lit areas should still be recorded).

3. Outcome measures

3a. Measures

Sleep is best assessed outside laboratories through a combination of clinical observations and actigraphic monitors that detect the occurrence and degree of movement-induced acceleration. Nurses tend to overestimate sleep time while actigraphy, when used alone, cannot discern if a participant is sleeping or just sitting or lying quietly. This is a particular issue for physically incapacitated residents who spend most of the day sitting in a chair. It is desirable, therefore, to combine actigraphy with a clinical rating of sleep when assessing daytime and night-time sleeping patterns.

RESULTS

The selected studies are summarized in Table 1. In addition to basic details (study type, participant numbers, light source, light intensity, treatment duration), the Table shows if researchers had specified: (1b) the presence of a sleep disorder of any type, determined by any means; (1c) if people with severe vision loss were excluded; (1d) checks of psychoactive medications; (2a) baseline light levels; (2b) a check of treatment adherence; (2c) some means to control for participant–researcher interaction where this was not held constant across study arms; and (3) the use of observational and/or actigraphic outcome measures. Finally, the Table indicates if sleep was significantly improved in the bright light condition relative to baseline or the control condition.

The 18 selected studies were conducted in five countries with eight from the USA, five from Japan, two from the Netherlands, two from Norway and one from the UK. All were published in the last two decades.

Eight studies had employed a before–after design comparing bright light with usual light levels; seven were randomized controlled trials, and three used a cross-over design in which participants were switched from one experimental condition to another in random order. Two studies added sleep hygiene and melatonin to the treatment condition and two others used multiple experimental arms to test for any additional, independent effects on sleep of melatonin and vitamin B12.

With respect to other conditions of interest, one study also focused on neuropsychiatric symptoms, cognition and activities of daily living. Other studies also focused on agitation, mood, and cognition.

The number of participants per study ranged from 10 to 189 with a mean of 47.3. Five studies were very small with fewer than 20 participants. In the largest study, standard ceiling light fittings were replaced with bright lights with the aim of irradiating large areas within the nursing homes for many hours each day. The study ran for over 2 years but participant numbers declined steadily over this period, falling from 189 to 48.

The bright light treatments varied in intensity from 1000 to 10 000 lux with a mean of about 4400 lux. The levels emanating from wall- or ceiling-mounted fittings were typically lower than those from light boxes with a mean of about 2700 lux when measured near participants’ faces.

Bright lights were applied for 1 h or less daily in six studies; for 2 h daily in nine studies; for between 4 and 13 h in different arms in one study, and for all or most of the day and evening in two. Treatment was applied in the morning in 11 studies; in the evening in one study, in the morning or evening or both in different arms in four studies and throughout the day using wall- or ceiling-mounted fixtures in two.

With respect to the recommended strategies, 10 of the 18 studies selected participants on the basis of disordered sleep patterns. One required a degree of agitation but made no reference to sleep disorder and seven required neither. Criteria were mostly couched in general terms, such as ‘various sleep disturbances’. One study required ‘sleep disruption at least two nights per week’ and the conditions themselves were specified in more detail in two others, for example, ‘frequent night-time awakenings, wandering at night, unusually early morning awakenings, sundowning and excessive daytime sleepiness’.

Only one study required participants to have delayed
Table 1. Details of studies and adherence to recommended methods

<table>
<thead>
<tr>
<th>Study type</th>
<th>Participants numbers</th>
<th>Light source</th>
<th>Mean light (lux)</th>
<th>Study length (weeks)</th>
<th>Hours of light/day</th>
<th>Time of day</th>
<th>1b: Sleep disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancoli-Israel (2002)</td>
<td>R 77</td>
<td>B</td>
<td>2 500</td>
<td>2</td>
<td>2</td>
<td>M,E</td>
<td>No</td>
</tr>
<tr>
<td>Ancoli-Israel (2003)</td>
<td>R 63</td>
<td>B</td>
<td>2 500</td>
<td>2</td>
<td>2</td>
<td>M,E</td>
<td>No</td>
</tr>
<tr>
<td>Burns (2009)</td>
<td>R 48</td>
<td>B</td>
<td>10 000</td>
<td>2</td>
<td>2</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Dowling (2005)</td>
<td>R 70</td>
<td>I</td>
<td>2 500</td>
<td>10</td>
<td>1</td>
<td>M,E</td>
<td>Yes</td>
</tr>
<tr>
<td>Dowling (2008)</td>
<td>R 50</td>
<td>B + O ± M</td>
<td>6 200</td>
<td>10</td>
<td>1</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Fetter (2003)</td>
<td>B 11</td>
<td>B</td>
<td>7 000</td>
<td>1</td>
<td>2</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Kobayashi (2001)</td>
<td>B 10</td>
<td>I</td>
<td>8 000</td>
<td>3</td>
<td>1</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Lyketsos (1999)</td>
<td>X 15</td>
<td>B</td>
<td>10 000</td>
<td>4</td>
<td>1</td>
<td>M</td>
<td>No</td>
</tr>
<tr>
<td>Martin (2007)</td>
<td>R 108</td>
<td>O + I</td>
<td>&gt;1 000</td>
<td>1</td>
<td>0.5</td>
<td>M</td>
<td>Yes</td>
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<tr>
<td>Mishima (1994)</td>
<td>B 24</td>
<td>B</td>
<td>4 000</td>
<td>4</td>
<td>2</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Mishima (1998)</td>
<td>X 22</td>
<td>B</td>
<td>6 500</td>
<td>2</td>
<td>2</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Riemersma (2008)</td>
<td>R 189</td>
<td>I</td>
<td>1 000</td>
<td>104</td>
<td>All</td>
<td>All</td>
<td>No</td>
</tr>
<tr>
<td>Ito (2001)</td>
<td>B 10</td>
<td>B</td>
<td>1 750</td>
<td>1</td>
<td>2</td>
<td>E</td>
<td>Yes</td>
</tr>
<tr>
<td>Lyketsos (1999)</td>
<td>B 11</td>
<td>B</td>
<td>6 500</td>
<td>4</td>
<td>0.75</td>
<td>M</td>
<td>Yes</td>
</tr>
<tr>
<td>Sloane (2007)</td>
<td>X 66</td>
<td>I</td>
<td>2 500</td>
<td>3</td>
<td>4–13</td>
<td>M,E</td>
<td>All</td>
</tr>
<tr>
<td>Van Someren (1997)</td>
<td>B 22</td>
<td>I</td>
<td>1 136</td>
<td>4</td>
<td>All</td>
<td>All</td>
<td>No</td>
</tr>
<tr>
<td>Yamadera (2000)</td>
<td>B 27</td>
<td>B</td>
<td>3 000</td>
<td>4</td>
<td>2</td>
<td>M</td>
<td>No</td>
</tr>
</tbody>
</table>

1c: Excluded severe vision loss
1d: Medication reported
2a: Baseline light measured
2b: Adherence constant or controlled
2c: Social contact measured
3: Outcome measure
Activity–rest change
Comment

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sleep latency and subsequent periods of wakefulness verified using actigraphy.35

People with severe vision loss were excluded in 11 of the 18 studies. Exclusion criteria included ‘cataracts’,36 ‘substantial cataracts’,40 ‘cloudy optical media’,24 ‘moderate to severe visual impairment’,37 ‘severe visual impairment’,41 an inability ‘to perceive light’25 and ‘blindness’.27

Fifteen reports made some reference to the numbers of participants taking psychoactive medications at treatment outset but only four mentioned changes in prescriptions over the course of the study.29,37,40,42

Only five reports included measures of baseline lighting levels in the study settings.

Treatment adherence was promoted in eight of the 12 light box studies, usually by an attending nurse. In studies of wall or ceiling installations, checks of attendance in specially lit areas were recorded in three of the five cases.25,39,43 In the remaining two studies, common living areas were brightly illuminated for the whole of the day and the researchers assumed that participants spent most of their time there.5,29

To minimize differences in the levels of social contact, control conditions were employed in five of the 12 light box studies in the form of a dim or dimmer light,24,41,44 a standard light,36 and a blinking light.27 In the light installation studies, participants were free to move about and their social contacts and participation in activities were judged to be similar in the experimental and control conditions, making it unnecessary to control for differences.

With respect to outcome measures, 11 studies relied on actigraphic recordings alone; two used some sort of clinical observation, and five used a combination of actigraphy and observation. The observations were mostly described just as sleep charts or sleep logs. In two studies, nurses completed simple sleep–wake scales.37,43 Frequencies and intervals were typically not reported.

Outcomes were mostly positive. In four studies, rest–activity cycles were described as consolidated or stabilized based on actigraphic recordings. Participants were judged to have slept more, or been less active, at night in six studies and to have slept less, or been more active, during the day in five studies. Night-time sleep was reduced relative to baseline actigraphic recordings in one of the lighting installation studies.29 Differences were mostly very modest. However, in one light box study, the proportion of total daily activity occurring between 23.00 hours and 07.00 hours fell from 18.4% on average in the baseline week to 11.6% in the intervention week.40 In another light box study, there were 18.1 awakenings per night during the baseline week compared with an average of 13.9 during the 4-week intervention period.38

**DISCUSSION**

There is certainly some evidence that bright lighting improves sleep in nursing home and long-stay hospital ward residents with dementia but the evidence is contradictory and incomplete. For example, of the studies that had applied five or more of our eight suggested methodological strategies, two had negative results29,36 while three reported improvements in actigraphic rest–activity patterns.26,37,40

This lack of consistent evidence helps to explain why bright light therapy has not been adopted as a mainstream treatment of sleep disorders in people with dementia, notwithstanding the prevalence of these conditions and their onerous consequences for caregivers. Light boxes require constant staff supervision in the case of residents who are mobile and physically agitated and this adds greatly to the treatment’s expense.5 It is unlikely, therefore, that residential facilities will invest in their use until the evidence base is more persuasive.

It might be helpful if future researchers remedied some of the methodological shortcomings identified in this paper. If bright light therapy is conceptualized as a treatment of frequent night-time awakenings and nocturnal restlessness, for example, it makes sense to choose participants with these problems but only half the studies completed to date have done so. Doses of psychoactive medications were mostly held constant but just over half used actigraphy as the sole measure of daytime and night-time activity where inactivity is presumed to represent sleep, perhaps incorrectly.

Inserting special bright light tubes into the existing wall- and ceiling-mounted fixtures of nursing homes and long-stay hospital wards may provide an affordable, practicable solution to bringing greater illumination to many residents simultaneously, provided they spend time in the specially lit areas. Bright lights are acceptable to staff, have no clear adverse effects29 and have the added potential benefits of improving mood and preventing falls.15 While it is difficult to reach gaze levels of 2500 lux, the accepted intensity
for treatment of seasonal affective disorder, this can certainly be achieved.\textsuperscript{41} In any case, the lights are left on all day and the cumulative daily dose is actually very high.\textsuperscript{5} This treatment modality warrants further investigation.

There is no certainty that the results of further studies will be favorable but a more uniform methodology should prove helpful and assist in subsequent meta-analyses. We cannot demonstrate that our recommended strategies will boost the chances of meta-analyses. We cannot demonstrate that very high.\textsuperscript{5} This treatment modality warrants further investigation.

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