Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances Associated with Alzheimer Disease

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BACKGROUND

In 1996, 29 million people world-wide suffered from dementia (Vink 2002). As world populations age, and specifically as the 'baby boomers' reach old age, this number will significantly increase. Alzheimer disease represents 64% of all cases of dementia (CSHAWG 1994). Cognitive impairment is the central defining feature of Alzheimer disease (Harper 1999) and sleep disruptions, behavioural disturbances, sundowning, and depression are commonly associated with Alzheimer disease (Harper 2001; Johnson 2002; Liu 2000; Moe 1995).
The term 'sundowning' refers to exacerbation of agitation during the early evening or nocturnal hours (McGaffigan 1997). All of these reduce the quality of life of the individual with Alzheimer disease, while sleep disruptions and behavioural disturbances contribute to the burden on informal and formal caregivers. The stress that such disturbances place on informal caregivers is an important factor in the decision to institutionalize people with dementia (Ancoli-Israel 1994; Gallager-Thompson 92; Pollak 1991; van Someren 1993). In addition, there are cost implications for both unpaid caregivers and health care systems (Fast 1999; Johnson 2002)

A decreased ability to maintain a stable circadian pattern of daytime arousal and nocturnal quiescence may contribute to cognitive dysfunction, behavioural disturbances, sundowning, sleep disruptions, and depression associated with Alzheimer disease (Haffmans 2001; Mishima 1999; Satlin 1992). The rest-activity and sleep-wake cycles are controlled by the endogenous circadian rhythm generated by the suprachiasmatic nuclei (SCN) of the hypothalamus (Harper 2001). The SCN, considered to function as a biological clock, synchronizes internal rhythms with the environmental light-dark cycles predominantly by responding directly to retinal input (van Someren 1996; van Someren 1999). Light impinging on the retina is transduced into neural activity that reaches the SCN through the retinohypothalamic and the geniculo-hypothalamic tracts. Light leads to changes in the firing rates of specialized neurons in the SCN that in turn affect circadian rhythms (Chesson 1999).

With normal ageing, there is functional deterioration of the SCN and circadian rhythms are phase-advanced leading to an altered relationship between the timing of nocturnal sleep and these rhythms (Campbell 1998; van Someren 1993). Over half of the population over 65 years of age experience sleep changes such as fragmented nocturnal sleep, multiple and prolonged awakenings in the second half of the night, and increased daytime napping (Campbell 1998). These abnormalities appear to be even more pronounced in elderly people with Alzheimer disease (Bliwise 1993) reported lower amplitude and delayed acrophase (time of peak daily activity) of the circadian rhythm in individuals with Alzheimer disease than in healthy elderly people. Other evidence of disordered circadian rhythmicity in individuals with Alzheimer disease emerges from studies of rhythms of sleep and endocrine secretion (Ancoli-Israel 1997; Prinz 1982; Touitou 1982). Neuropathological studies have noted loss of vasopressin-secreting neurons in the SCN of the hypothalamus (Liu 2000; Swaab 1985). However, Liu 2000 emphasize that the loss of vasopressin-secreting neurons in the SCN does not necessarily mean that the neurons have died; they may still be present but inactive.

Reactivation of SCN cells was shown to be possible in studies of aged rats. These studies revealed that exposure to bright light appeared to reverse age-associated disturbances of circadian sleep-wake rhythm (Witting 1993) and to prevent the age-associated decrease in the number of vasopressin-secreting neurons in the SCN (Lucassen 1995). In humans, the neurons in the SCN decrease during ageing and even more so in individuals with Alzheimer

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disease. As in the studies of aged rats, stimulation with light might reactivate the SCN neurons in humans.

As well as the internal regulatory loss, elderly people (especially those with Alzheimer disease) experience a reduction in sensory input because they are visually less sensitive to light, and have less exposure to bright environmental light. They also, typically, have fewer social contacts. Reduced sensory input is likely to lower the 'general level of excitement' that is thought to play an important role in the entrainment of circadian rhythms (van Someren 1993).

Several studies have examined the effectiveness of light therapy in managing disturbances of sleep, behaviour, mood, and cognition of individuals with Alzheimer disease (e.g., Colenda 1997; Gasio In press2002; Graf 2001; Ito 2001; Lovell 1995; Lyketsos 1999; Mishima 1994; Mishima 1998; Satlin 1992; Thorpe 2000; van Someren 1997). The light sources were usually a light box placed approximately one meter away from the subjects at a height within their visual fields, or a light visor worn on their heads, 3 to 4 cm. from their eyes. A more acceptable source of light to the subjects was the more recent 'naturalistic' light therapy, known as dawn-dusk simulation, that mimics outdoor twilight transitions. A computer algorithm drives an electronic controller connected to a halogen lamp placed behind a diffusing membrane near the subject's bed (Gasio In press2002). The intensities of the light sources varied greatly from 210 to 10,000 lux. The subjects were exposed to the bright light for half an hour to two hours per day in the morning and/or evening, over periods of three days to eight weeks. The minimum and optimum intensities and durations of light therapy that best manage disturbances of sleep, behaviour, mood, and cognition associated with Alzheimer disease are unknown. While organizations such as the American Academy of Sleep Medicine have drawn up practice recommendations in a number of areas of sleep medicine, there are currently no practice recommendations with regard to people with Alzheimer disease (Chesson 1999).

There is preliminary evidence from these studies that light therapy improves nocturnal sleep (Gasio In press2002; Lyketsos 1999), providing support for the hypothesis that degenerative changes in the SCN are the biological basis of circadian disturbances in people with Alzheimer disease, and that they may be reversed by stimulation of the SCN by light (Liu 2000). There is therefore a need for a systematic review of studies that have examined the efficacy of bright light therapy in managing disturbances of sleep, behaviour, mood, and cognition associated with Alzheimer disease. The findings of the review will be useful to clinicians and informal caregivers who care for people with Alzheimer disease and in guiding researchers in their pursuit of knowledge.

OBJECTIVES

The objectives of the systematic review are:

- To assess the relevance and quality of studies that measure the efficacy of light therapy in managing disturbances of sleep, behaviour, mood, and cognition associated with Alzheimer disease.
- To determine the efficacy of light therapy in managing disturbances of sleep, behaviour, mood, and cognition associated with Alzheimer disease.
- To make recommendations to consumers, practitioners, and researchers regarding the efficacy of light therapy in managing disturbances of sleep, behaviour, mood, and cognition associated with Alzheimer disease.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomized controlled trials (RCTs) in which light therapy of any intensity or duration is compared with placebo or alternative therapy for the management or prevention of disturbances of sleep, behaviour, mood, and/or cognition associated with Alzheimer disease will be considered for inclusion. Since the intervention consists of bright light, single-blind RCTs will be expected; double-blind RCTs would be impossible. Other designs such as cohort, case-control, before-and after studies and case series studies may be described but will not be included.

Types of participants

Participants will reside in a long-term care facility or in their own homes and may attend a day care or outpatient setting. Participants will have a diagnosis of mild, moderate or severe Alzheimer disease according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R, DSM-IV) (APA 1995), the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) (McKhann 1984), or the ICD-10 (WHO 1992). Severity of dementia will be assessed by the use of standardized instruments such as the Mini-Mental Status Examination (Folstein 1975).

Types of intervention

The intervention will be bright light (photo) therapy. The bright light may be in the form of indirect (e.g., ceiling mounted) or direct bright light (e.g., light box, light visor, dawn-dusk simulation) and administered at a wide range of intensities, duration, number of treatment sessions, and time of day. The light therapy will be compared with a control treatment (placebo or alternative therapy).

Types of outcome measures

Outcomes that could demonstrate the efficacy of light therapy in managing disturbances of sleep, behaviour, mood or cognition as-

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sociated with Alzheimer disease will be considered. These measures may be obtained at baseline, during the light therapy, immediately following, and at any interval of time after the treatment. Both dichotomous and continuous data will be used. Outcome measures must assess at least one of the following:

- Changes in the incidence, severity or frequency of sleep-wake disturbances
- Changes in the incidence, severity or frequency of behavioural disturbances (e.g. sundowning, agitation, aggression)
- Changes in mood (e.g. depression)
- Changes in cognition (e.g. memory)
- Changes in rate of institutionalization
- Impact on cost of care

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: search strategy

See: Collaborative Review Group search strategy. The following strategies will be completed to identify relevant studies:

- The Cochrane Dementia and Cognitive Impairment Group (CDCIG) Specialized Register, which includes records from medical databases such as MEDLINE, EMBASE, CINAHL, PsycINFO, LILACS, SIGLE and many trials databases will be searched by the Trial Search Coordinator.
- The Librarian reviewer will search Biological Abstracts and the Web of Science.
- The reviewers will check the reference lists of all relevant studies.
- Key researchers and research centres will be contacted for information on unpublished or 'in press' studies.

METHODS OF THE REVIEW

1. Searches will be conducted as described above and information about the searches will be documented (e.g., data base searched, controlled vocabulary used, date).
2. Hard copies of the articles will be retrieved.
3. Two reviewers will independently assess relevance of the retrieved articles. The relevance criteria comprise the following questions:

- Does the article describe an evaluation of the efficacy of bright light (photo) therapy in managing disturbances of sleep, behaviour, mood, and/or cognition associated with AD using a randomized controlled design?
- Does the study measure at least one of the following patient/resident outcomes: sleep-wake disturbances, agitated behaviour, aggressive behaviour, sundowning behaviour, mood, cognition, or cost?
- Does the study incorporate measures of the frequency or severity of behaviour, or change in mood, cognition, or cost of care?
- All relevant criteria must be met for the study to be included in the next stage of assessment. Disagreements will be resolved where possible by discussion. A third reviewer will adjudicate persisting differences. Percent agreement beyond chance (kappa) between the reviewers will be calculated.

4. Two reviewers will independently assess the selected studies for methodological quality using criteria adapted from Forbes (1998). The following criteria will be assessed: type of study design and concealment to treatment allocation, level of agreement to participate, attrition rate, potential confounders controlled, blinding for data collection and outcome measures, presence of point estimates, and measures of variability for the outcome measures.
5. Two reviewers will independently extract data from the studies selected for inclusion. Information regarding the publication date, authors, country, study design, characteristics of the study population including ethnicity, setting, credentials of those who provided the treatment, type, duration, intensity, frequency, and time of day of light therapy, control intervention, concurrent interventions, changes in the care environment, and measures of outcomes will be extracted, recorded, and entered into RevMan.
6. The first step in the analyses will be to prepare tabular summaries of the data. As well, a Continuous Data Table (number of participants in each group, means and standard deviations for the outcomes in each group), and a Dichotomous Data Table (number of participants who experienced a change in each comparison group, the total number of participants in each group, and the odds ratio or relative effect), and a table comprising all of the data will be developed. Attempts will be made to collect missing data from the investigators. Each study will be summarized using a measure of effect (e.g., odds ratio, relative risk) and if appropriate the results of a group of studies will be combined and a relative measure (odds ratio, relative effect, weighted mean difference, standardized mean difference) will be reported. Whether the results will be combined depends on the degree of heterogeneity. Statistical heterogeneity will be assessed using the chi-square test for heterogeneity and visual inspection of graphs such as Forest, funnel, and L'Abbe plots. A significance level of less than 0.10 will be interpreted as evidence of heterogeneity. Heterogeneity may be related to differences in the participants (e.g., severity of AD), intervention (e.g., degree of exposure to the light therapy), and methodological quality of the studies. Subgroup analyses will be conducted to explore these differences, if they exist. Both the fixed-effects and random-effects models will be used. However, if the test for heterogeneity is significant and the differences are of practical importance then

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more weight will be given to the random-effects model. Lastly, sensitivity analyses will be conducted to determine how sensitive the results of the analyses are to changes in the way they were conducted. For example, analyses will be conducted with and without the weaker studies included.

7. The reviewers will discuss and reach consensus on the interpretation of the results. The consumer editor and other reviewers will review the draft review prior to submitting it to the CDCIG.

POTENTIAL CONFLICT OF INTEREST

None known

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COVER SHEET

Title	Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances Associated with Alzheimer Disease
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