Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia (Review)

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[Intervention Review]

Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

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ABSTRACT

Background

Rest-activity and sleep-wake cycles are controlled by the endogenous circadian rhythm generated by the suprachiasmatic nuclei (SCN) of the hypothalamus. Degenerative changes in the SCN appear to be a biological basis for circadian disturbances in people with dementia, and might be reversed by stimulation of the SCN by light.

Objectives

The review assesses the evidence of efficacy of bright light therapy (BLT) in managing sleep, behaviour, mood, and cognitive disturbances associated with dementia.

Search strategy

The trials were identified from a search of the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group on 5 December 2005 using the terms "bright light*", "light box*", "light visor*", "dawn-dusk*", phototherapy (MESH), phototherapy, "photo therapy", "light therapy" "light treatment", light*.

Selection criteria

All relevant, randomized controlled trials in which BLT, at any intensity and duration, was compared with a control group for the effect on managing sleep, behavioural, mood, or cognitive disturbances (as well as changes in institutionalization rates or cost of care) on people with dementia of any degree of severity.

Data collection and analysis

Three reviewers independently assessed the retrieved articles for relevance and methodological quality, and extracted data from the selected studies. Statistically significant differences in changes in outcomes from baseline to end of treatment and from baseline to follow-up, between the light therapy and control groups, were examined. Each study was summarized using a measure of effect (e.g. mean difference). Owing to lack of homogeneity between studies, their results were not combined.

Main results

Five studies met the inclusion criteria. However, only three were included in the analyses because of inappropriate reported study analyses or inability to retrieve the required data from the investigators. This review revealed no adequate evidence of the effectiveness of BLT in managing sleep, behaviour, cognitive, or mood disturbances associated with dementia.

Authors' conclusions

There is insufficient evidence to assess the value of BLT for people with dementia. The available studies are of poor quality and further research is required.

PLAIN LANGUAGE SUMMARY

There is insufficient evidence to determine whether bright light therapy is effective in the management of sleep, behaviour, mood, or cognitive disturbances in dementia

Rest-activity and sleep-wake cycles are controlled by the endogenous circadian rhythm generated by the suprachiasmatic nuclei (SCN) of the hypothalamus. Degenerative changes in the SCN appear to be a biological basis for circadian disturbances in people with dementia, and might be reversed by stimulation of the SCN by light. The light sources in the included studies were: a light box placed approximately one metre away from the subjects at a height within their visual fields; a light visor worn on their heads; or a more acceptable 'naturalistic' light therapy, known as dawn-dusk simulation that mimics outdoor twilight transitions. Five studies met the inclusion criteria. However, only three were included in this analysis because of inappropriately reported analyses or inability to retrieve the required data from the original investigators. The three studies included in the analysis were of poor quality and revealed no adequate evidence of the effectiveness of bright light therapy (BLT) in managing sleep, behaviour, or mood disturbances associated with dementia.

BACKGROUND

Dementia affects approximately 8% of people aged 65 and over and between 25% and 30% of persons aged 80 and over. Alzheimer's disease is the commonest cause, accounting for 64% of all individuals with dementia (NACA 1999). Dementia with Lewy Bodies has been claimed to be the second most common cause of dementia and as common as Vascular Dementia in a general population aged 75 years and older (Rahkonen 2003). As world populations age, and specifically as the "baby boomers" reach old age, the number of people affected by dementia could triple by the year 2031 (NACA 1999). Dementia involves a global impairment of cognition (Harper 1999): sleep disruptions, behavioural disturbances, and depression are commonly associated features (Johnson 2002; Liu 2000; McCurry 2000). All of these reduce the quality of life of the individual with dementia, while sleep disruptions and behavioural disturbances also 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, sleep disruptions, and depression associated with dementia (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, synchronize 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 possibly 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 and decreased in amplitude, leading to an altered timing of nocturnal sleep (Campbell 1998; van Someren 1993). More than 50% of people aged 65 years and over experience sleep changes such as fragmented nocturnal sleep, multiple and prolonged awakenings in the second half of the night, and increased daytime napping (Campbell 1988). These

abnormalities appear to be even more pronounced in elderly people with Alzheimer's disease (McCurry 2000). In a comparison with healthy elderly people, Satlin 1991 reported lower amplitude and delayed acrophase (time of peak daily activity) of the circadian rhythm in individuals with Alzheimer's disease. Other evidence of disordered circadian rhythmicity in individuals with Alzheimer's 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). Vaspressin is one of the major neuropeptides in the SCN and is involved in the synchronization of the circadian rhythm. However, Liu 2000 emphasizes 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. The disorder of circadian rhythmicity common in non-Alzheimer's dementias is also likely to be due to deterioration of the SCN.

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 normal ageing and even more so in individuals with dementia. As in the studies of aged rats, stimulation with light might reactivate the SCN neurons in humans.

In addition to the internal regulatory loss, elderly people (especially those with dementia) 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 efficacy of light therapy in managing disturbances of sleep, behaviour, mood, and/or cognition in individuals with dementia (e.g. Ancoli-Israel 2003; Colenda 1997; Gasio 2003; 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 metre away from the subjects at a height within their visual fields; a light visor worn on their heads; or a more acceptable 'naturalistic' light therapy, known as dawn-dusk simulation, that mimics outdoor twilight transitions. Even if light therapy is efficacious, the minimum and optimum intensities and durations of light therapy that best manage disturbances of sleep, behaviour, mood, and cognition associated with dementia 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 dementia (Chesson 1999).

There is preliminary evidence from these studies that light therapy improves nocturnal sleep (Gasio 2003; Lyketsos 1999), consistent with the hypothesis that degenerative changes in the SCN are the biological basis of circadian disturbances in people with dementia, 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 examined the efficacy of BLT in managing disturbances of sleep, behaviour, mood, and/or cognition associated with dementia.

OBJECTIVES

The objectives of the systematic review were:

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

METHODS

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 dementia were included. Since the intervention consisted of bright light, single-blind RCTs were expected; double-blind RCTs would be impossible.

Types of participants

The participants in a study must have a diagnosis of dementia (Alzheimer's type, Lewy Bodies type, Vascular Dementia, or dementia due to other cause) according to accepted criteria such as those of 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 ICD-10 (WHO 1992). Severity of dementia should be assessed by the use

of standardized instruments such as the Mini-Mental State Examination (Folstein 1975). Level of severity of dementia, age, and sex were not inclusion criteria.

Types of interventions

Any form of intervention involving the use of bright light.

Types of outcome measures

Objective outcome measures sensitive to changes in sleep, behaviour, mood, or cognition were of interest to this review. These measures could be obtained at baseline, during the light therapy, immediately following, or at any interval of time after the treatment. Both dichotomous and continuous data were accepted. Outcome measures that assessed at least one of the following were included:

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

Search methods for identification of studies

The trials were identified from searches of the Specialized Register of the Cochrane Dementia and Cognitive Improvement Group (the last search was completed on 5 December 2005), using the terms "bright light" or "light box*" or "light visor*" or "dawn-dusk*" or phototherapy or "photo therapy" or "light therapy" or "light treatment" or light*.
The Specialized Register at that time contained records from the following databases:

- CENTRAL: July 2005 (issue 3);
- MEDLINE: 1966 to 2005/08, week 2;
- EMBASE: 1980 to 2005/08, week 2;
- PsycINFO: 1887 to 2005/07;
- CINAHL: 1982 to 2004/07;
- SIGLE (Grey Literature in Europe): 1980 to 2004/06;
- ISTP (Index to Scientific and Technical Proceedings): to May 2000;
- INSIDE (BL database of Conference Proceedings and Journals): to June 2000;
- Aslib Index to Theses (UK and Ireland theses): 1970 to March 2003;
- Dissertation Abstract (USA): 1861 to March 2003;
- http://clinicalstudies.info.nih.gov/;
- National Research Register (issue 3/2005)
- ClinicalTrials.gov: last searched 1 September 2005;
- LILACS (Latin American and Caribbean Health Science Literature): last searched April 2003
- http://www.forestclinicaltrials.com/: last searched 1 September 2005
- ClinicalStudyResults.org: last searched 1 September 2005
- http://www.lillytrials.com/index.shtml: last searched 28 August 2005
- ISRCTN Register: last searched 1 September 2005
- IPFMA Clinical trials Register: www.ifpma.org/clinicaltrials.html: last searched September 2005

The search strategies used to identify relevant records in MEDLINE, EMBASE, PsycInfo, CINAHL and LILACS can be found in the Group's module.
In addition, the reviewers checked the reference lists of all relevant studies, and key researchers were contacted for information on unpublished or 'in press' studies.

Data collection and analysis

1. Three reviewers (DF, DMO and SP) independently assessed the relevance of the retrieved articles. The relevance criteria consisted of 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 dementia 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, 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 had to be met for the study to be included in the next stage of assessment. Disagreements were resolved by discussion and agreement was reached.
2. Three reviewers (DF, DMO and SP) then independently assessed the selected studies for methodological quality using criteria adapted from Forbes 1998. The following factors were assessed: type of study design and concealment to treatment allocation, attrition rate, control of potential confounders, blinding for data collection and outcome measures, presence of point estimates, and measures of variability for the outcomes.
3. Three reviewers (DF, DMO and SP) independently extracted data from the studies selected for inclusion. Information regarding the publication date; authors; country; study design; characteristics of the study population including 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 were extracted, recorded, and entered into RevMan.

4. A Continuous Data Table (number of participants in each group, means and standard deviations for the outcomes in each group) was developed. Attempts were made to collect missing data from the investigators. Each study was summarized using a measure of effect (e.g., mean difference). The studies were examined for degree of heterogeneity, to determine the possibility of combining the results. Statistical heterogeneity was assessed using the I^2 test that measures the degree of inconsistency across studies (if I^2 equals 0% then there is no apparent heterogeneity. Larger values [70% and greater] indicate greater heterogeneity and caution should be used in interpreting the meta-analysis). The results from different studies were not combined because there were differences in the participants (e.g. types and severity of dementia) and extreme differences in the intervention (e.g. light intensity), and because the tools used to measure the outcomes were considered to be measuring different concepts. Unfortunately, the sample sizes were not large enough to conduct subgroup analyses to explore these differences. Both the fixed-effects and random-effects models were used. However, if the degree of heterogeneity was high and the differences were of practical importance, then more weight was given to the random-effects model. Lastly, sensitivity analyses would have been conducted to determine how sensitive the results of the analyses were to changes in the way they were conducted, if the number of included studies had been larger.

5. The three reviewers (DF, DMO and SP) discussed and reached agreement on the interpretation of the results. The consumer editor and other reviewers commented on the draft review prior to its submission to the CDCIG.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Please see Table *Characteristics of included studies*

Update 2005

The search strategy was last updated on December 5, 2005 and revealed one new incomplete RCT (Riemersma 2004, classification pending) and two non-RCTs (Fetveit 2003; Kobayashi 2001) that were not included in the updated review.

Following searches in MEDLINE, EMBASE, CINAHL, PsycINFO, Biological Abstracts, Web of Science, LILACS, SIGLE and many trials databases, fifty-two articles were retrieved and independently rated by two reviewers for relevance and validity. Five studies (six articles, as two were from the same study; Ancoli-Israel 2003) met the relevance and validity criteria (Ancoli-Israel 2003; Gasio 2003; Graf 2001; Lyketsos 1999; Mishima 1998).

The articles included in this review were published between 1998 and 2003. Two of the studies were conducted in the United States (Ancoli-Israel 2003; Lyketsos 1999), one was conducted in Japan (Mishima 1998), one in Switzerland (Gasio 2003), and one in Austria (Graf 2001). All of the participants were residents of long-term care facilities of varying descriptions: nursing homes (Ancoli-Israel 2003; Graf 2001), chronic care facilities (Lyketsos 1999), specialized wards (Mishima 1998), and nursing wings for residents with dementia (Gasio 2003).

Consent was obtained from the residents and/or from their relatives (Graf 2001; Mishima 1998) as well as from their physicians (Ancoli-Israel 2003; Gasio 2003). Consent was not mentioned in one study (Lyketsos 1999). The number of residents who agreed to participate in the included studies was relatively small, with a total of 165 subjects. Of these subjects, 132 to 133 completed the protocol (the range reflects the different outcomes measured in the same study; Ancoli-Israel 2003).

The participants met the DSM-IV or NINCDS-ADRDA criteria for Alzheimer's disease (Ancoli-Israel 2003; Mishima 1998), Vascular Dementia (VD) (Mishima 1998) or dementia (Lyketsos 1999). In one study, the participants were included only if their Mini-Mental State Examination (MMSE) score was no more than 23 (Graf 2001). In all studies, the MMSE was used to measure the severity of dementia at baseline. The mean MMSE scores of the participants in the included studies ranged from severe to moderate levels of dementia: 5.7 (SD 5.6) (Ancoli-Israel 2003), 6.4 (SD 6.8) (Lyketsos 1999), 8.45 (range 3-17) (Mishima 1998), 13.92 (SD 5.37) (Gasio 2003), and 15.9 (SD 5.90) (Graf 2001). In Graf 2001, subtypes of dementia were diagnosed by assessing whether the progress of the dementia was steady suggesting Alzheimer's disease, or was step-wise suggesting Vascular Dementia; and whether there was evidence of focal neurological deficits, essential hypertension, or vascular brain disease on computerized tomographic scan suggesting Vascular Dementia. In Mishima 1998 all subjects underwent brain magnetic resonance imaging (MRI) and computerized tomographic (CT) examinations; and residents with mixed type dementia (usually Alzheimer's disease with Vascular Dementia) were excluded from the study. Overall, 135 (82%) of the participants in the included studies were diagnosed with probable Alzheimer's disease. The remainder were diagnosed with either Vascular Dementia (n=29, 18%) or Dementia with Lewy Bodies (n=1, 1%).

Bright light therapy (BLT) was usually administered from a Brite-Lite^{TM} box (Apollo Light Systems, Orem, Utah) that was placed about 1 metre from the participant's head. The Brite-Lite^{TM} utilized cool-white fluorescent, non-ultra-violet, full-spectrum light bulbs. The treatment groups received BLT ranging from 2,500 to 10,000 lux and the control groups received dim red light or dim, low-frequency blinking light, less than 300 lux; either in the morn-

ing or evening, for one to two hours, for ten days to four weeks. The exception was the use of dawn-dusk simulation (maximum 400 lux) or placebo dim red light (< 5 lux) for approximately three weeks (Gasio 2003). The Dawn-Dusk Simulator^{TM} included a computer algorithm that drove an electronic controller connected to an overhead halogen lamp placed behind a diffusing membrane behind the participant's bed.

Each of the studies tested the efficacy of BLT in treating manifestations of dementia. Rest-activity cycles were documented using small wrist-mounted activity monitors such as the Actillume^{TM} (Ambulatory Monitoring, Inc., Ardsley, New York, cited in Ancoli-Israel 2003), Actigraph^{TM} (AMI, Ardsley, Inc. New York, cited in Mishima 1998) and the Actiwatch^{TM} (Cambridge Neurotechnologies, UK, cited in Gasio 2003). The Actillume^{TM}, for example, records activity level with a linear accelerometer and a microprocessor, and light exposure is collected via a photosensitive cell. Both activity and light data were sampled every 10 seconds and stored every minute on a 32 K byte memory chip. The reliability of the Actillume^{TM} for estimation of sleep and wake in nursing home residents has been found to be 0.81 ($p < 0.005$) for maximum activity and 0.91 ($p<0.001$) for mean activity levels (Ancoli-Israel 2003). In addition, sleep logs generated by nurses recorded hours of sleep (Gasio 2003, Lyketsos 1999).

Disruptive behaviours were measured by the Behavioral Pathology in Alzheimer Disease scale (Behav-AD) (Reisberg 1987) in Lyketsos 1999; Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield 1989) and Agitated Behavior Rating Scale (ABRS) (Bliwise 1993) in Ancoli-Israel 2003; and Neuropsychiatric Inventory (NPI) (Cummings 1994) in Gasio 2003. Mood was measured by the Cornell Scale for Depression in Dementia (Alexopoulos 1988) in Lyketsos 1999 and the Geriatric Depression Scale (GDS) (Sheikh 1986) in Gasio 2003. Memory, cognitive impairment, and progression of dementia were measured by the Consortium to Establish a Registry for Alzheimer's Disease (CERAD) (Morris 1989) in Gasio 2003 and the MMSE (Folstein 1975) in Gasio 2003 and Graf 2001. See Additional Table *Description of rating scales used in the included studies (*Table 1).

Table 1. Description of Rating Scales Used in the Included Studies

Scale	Abbreviation	Description	Reference
Behavioral Pathology in AD Scale, used in Lyketsos 1999 study	Behave-AD	25 item + global rating item, 4 point scale. Categories include paranoid and delusion ideation, hallucinations, activity disturbances, aggressiveness, & anxiety and phobias. Issues of validity or reliability were not addressed in the published article.	Reisberg 1987

Table 1. Description of Rating Scales Used in the Included Studies (*Continued*)

Cohen-Mansfield Agitation Inventory, used in Ancoli-Israel 2003 study	CMAI	29 item, 7 point scale. A maximum score of 203 indicates that the participant manifests agitated behavior on the average of 7 times per hour. Categories include aggressive behavior, physically nonaggressive behavior, verbal agitation, & a global rating of agitation. A caregiver's rating questionnaire that assesses the frequency of behaviour over the previous two weeks. Inter-rater agreement rates were calculated for each behavior on the CMAI (range r=0.88-0.92). No mention was made of the validity of the instrument.	Cohen-Mansfield 1989
Agitated Behavior Rating Scale, used in Ancoli-Israel 2003 study	ABRS	15 item, 4 point scale. Categories include agitation, manual manipulation, searching and wandering, escape behaviors, tapping and banging, & verbal agitation. The first four categories can be summarized into one physical agitation score. Higher scores indicate more frequent behaviour at high intensity. Content validity is established through the work of Cohen-Mansfield (1986), Cohen-Mansfield & Billig (1986), and Cohen-Mansfield, Marx & Rosenthal (1989). Data show high inter-rater reliability (coefficients not reported) for all components of rating scale.	Bliwise 1993
Neuropsychiatric Inventory, used in Gasio 2003 study	NPI	10 behavioral domains with 7-8 subquestions. Measures severity (3 point scale) and frequency (4 point scale). Categories include delusions, hallucinations, dysphoria, anxiety, agitation/aggression, euphoria, disinhibition, irritability/lability, apathy, & aberrant motor activity. A global score can be generated by summing the total scores (frequency multiplied by severity) of the individual subscales. Concurrent validity was determined by comparing the scores on the relevant subscales of the NPI with the appropriate scales of 2 instruments, BEHAVE-AD	Cummings 1994

Table 1. Description of Rating Scales Used in the Included Studies (*Continued*)

		and the Hamilton Depression Rating Scale (coefficients not reported). To establish content validity a delphi panel was developed and asked to rate the scale items. Inter-rater reliability was found to be very high (correlation not reported) and test-retest reliability was found to be 0.79 for frequency (p=0.0001) and 0.86 for sensitivity (p=0.0001).	
Cornell Scale for Depression in Dementia, used in Lyketsos 1999 study	CSDD	19 item, 3 point scale. Categories include mood related signs, behavioural disturbance, physical signs, cyclic functions, & ideational disturbance. The scale has adequate inter-rater reliability (kappa weighted = 0.67), internal consistency (coefficient alpha = 0.84) and sensitivity. Total scale scores were correlated with depressive subtypes of various intensity classified according to Research Diagnostic Criteria (r = 0.83).	Alexopoulos 1988
Geriatric Depression Scale, used in Gasio 2003 study	GDS	30 item, or short form 15 item, with 0 indicating no sign of depression and high score suggesting severe depression. Validation study compared the two forms and found both were successful in differentiating depressed from non-depressed subjects with high correlation (r =0.84, p< .001). No specific mention of the reliability of the study.	Sheikh 1986
Consortium to Establish a Registry for Alzheimer's Disease, used in Gasio 2003 study	CERAD	Batteries of clinical and neuropsychological tests that measure the primary cognitive manifestations of AD and detect deterioration of language, memory, praxis, & general intellectual status. The Clinical Assessment Battery includes semi-structured interviews with both the subject and informant, general physical, neurologic, and laboratory examinations, drug inventory, depression scale, and a general medical history. The Neuropsychological Assessment Battery includes Verbal Fluency: Animal Cat-	Morris 1989

Table 1. Description of Rating Scales Used in the Included Studies (*Continued*)

		egory, Modified Boston Naming Test, Mini-Mental State Examination, Word List Memory, Constructional Praxis, Word List Recall, and Word List Recognition. Inter-rater and test-retest reliabilities were substantial. Intraclass correlation coefficients for the tests ranged from 0.92 (Constructional Praxis) to 1.0 (Word List Recall). Test-retest correlations were comparable for both mild AD and moderate AD cases. Correlation for CDR1 ranged from r=0.52-0.89 and correlation for CDR2 ranged from r=0.43-0.90. Long-term observations are in progress to determine validity.	
Mini Mental State Examination, used in Gasio 2003 and Graf 2001 studies	MMSE	The MMSE was developed as a short test suitable for the elderly with dementia. It concentrates on the cognitive aspects of mental function: the five sections cover orientation, immediate recall, attention and calculation, delayed recall and language. A maximum score of 30 suggests normal function. Concurrent validity was determined by correlating MMS scores with the Wechsler Adult Intellegence Scale, Verbal and Performance scores. For Mini-Mental Status vs Verbal IQ, Pearson r=0.776 (p<0.001) and for Mini-Mental Status vs Performance IQ, Pearson r=0.660 (p<0.001). Test re-test reliability was determined by a single examiner 24 hrs. apart (r=0.887), by two different examiners 24 hrs. apart (r=0.827), and at 28 day re-test (r=0.988).	Folstein 1975

Risk of bias in included studies

Please see Additional Table *Description of Methodological Quality of Included Studies (*Table 2)

Table 2. Description of Methodological Quality of Included Studies

Study	Control Confounders	Attrition Rate	Compliance	Blinding of Assessor
Ancoli-Israel 2003	Age, Sex, Cognitive impairment, Education, Vision, Medication use	<10%	Treatment: Mean 92.1 BLT/120-min. BLT session, Actillumes worn by 93.3 - 100% of subjects	Deception of research & nursing staff
Gasio 2003	Age, Sex, Cognitive impairment, Mood, Vision, Medication use	>20%	Dawn-Dusk Simulation or Dim Red Light received by all participants. 5/20 residents withdrew due to noncompliance with actimeter.	Deception of residents & staff (unclear if assessor was blind to treatment)
Graf 2001	Age, Cognitive impairment, Mood, Acute medical illness, Medication use	>20%	Treatment/Control: 100% subjects	Rater blind to treament
Lyketsos 1999	Age, Sex, Cognitive impairment, Education, Vision, Race, Mood, Sleep, Behaviour, Medication use.	>20%	Treatment/Control: 100% subjects	Rater blind to treament
Mishima 1998	Age, Sex, Cognitive impairment, Physical function, Schedule, Medication use.	<10%	Treatment/Control: 100% subjects. Compliance with Actigraph unknown	Unknown

The process of randomization was assessed based on how the authors generated the allocation sequence of subjects to either a treatment or control group. Investigators who used a computer generated sequence program, random number tables, lot drawing, coin tossing, shuffling cards, or throwing dice were rated as 'adequate'. Those who used case number, date of birth, date of admission, or alternation were rated as 'inadequate'. If the randomization process was not adequately described in the article and the investigators did not respond to requests for clarification, then the study received an 'unclear' rating. The studies were also rated on concealment of allocation sequence. If the investigators used central randomization or envelopes that were sealed, opaque, and sequentially numbered, then the study was rated as 'adequate'. If open allocation sequence was used or the procedure was based on inadequate generation, then the study was rated as 'inadequate' for allocation concealment. If the process was not adequately described in the article and the investigators did not provide clarification, then the study received an 'unclear' rating. All but one of the authors of the included studies were contacted to determine the method of randomization and allocation concealment, as the description in the published articles was incomplete. One study utilized block-stratified randomization using pre-assignment by order of entry into strata; stratification was determined by sex and by quartiles of the categorical sleep spread score or by type of agitation (Ancoli-Israel 2003). This study was rated as 'inadequate' for randomization due to the potential for selection bias but 'adequate' for concealment of allocation sequence. Another study used date of admission to prospectively randomize subjects to either the treatment or control group (personal communication, Alexander Neumeister, August 5, 2003 regarding Graf 2001). This study was rated as 'inadequate' for generating an allocation sequence. A table of random numbers was used to select the subjects and a sealed envelope was used to conceal the allocation sequence in one study (Lyketsos 1999) and a random number generator was used in another study (personal communication, Anna Wirz-Justice, June 10, 2003 regarding Gasio 2003; further clarification requested on June 14, 2003 but to date not received). These two studies were rated 'adequate' for randomization and the Lyketsos 1999 study was also rated 'adequate' for concealment of allocation sequence. The process of ranomization and concealment of allocation sequence were not described in the Mishima 1998 study and the

authors have not responded to requests for this information that were made on May 29, 2003 and August 13, 2003. This study was rated as 'unclear' for both randomization and allocation concealment.

The exclusion criteria of the studies ensured that many of the potential confounders were eliminated. For example, residents who were blind or severely visually impaired or had severe motor symptoms or primary psychiatric disorders, were not included in the studies (Ancoli-Israel 2003; Graf 2001; Gasio 2003; Lyketsos 1999; Mishima 1998).

Participants' medications were stabilized for various periods of time prior to initiating the trials: 12 weeks (Mishima 1998), one month (Graf 2001), and one week (Lyketsos 1999). In addition Mishima 1998 excluded subjects who were taking sedatives, hypnotics or antipsychotics. Gasio 2003 kept the medications as constant as possible and listed each of the medications in a table. Ancoli-Israel 2003 did not report if and how medications were dealt with.

Four of the included studies had small sample sizes ranging from 13 to 23 participants at baseline, and 8 to 13 participants at completion (Gasio 2003; Graf 2001; Lyketsos 1999; Mishima 1998). The fifth study recruited 92 participants at baseline and 71-72 participants (sample size differed in two articles) completed the study (Ancoli-Israel 2003).

Attrition rates varied from 0% to 47% in the included studies. Often studies did not report whether the drop out rates related to the treatment or control groups. Compliance with the BLT and/or wearing the activity monitor was an issue in some of the studies. One study reported that participants received 77% of the BLT (Ancoli-Israel 2003). The range of compliance with wearing the activity monitors was 75% to 100% of the participants (Ancoli-Israel 2003; Gasio 2003). Mishima 1998 did not report compliance with the actigraph (information requested August 11, 2003).

Two studies reported that those who assessed the outcomes were blind to group allocation (Graf 2001; Lyketsos 1999). In other studies, nursing and research staff (Ancoli-Israel 2003) or residents and staff (personal communication, Anna Wirz-Justice, June 10, 2003 regarding Gasio 2003) were informed that both the white and red coloured light conditions were expected to show improvement and that the study was examining which colour was better.

Effects of interventions

Several outcomes were measured: sleep-wake disturbances, agitation, depression, and cognition (e.g. memory). These are each discussed in turn below.

Sleep

Three studies measured actual nocturnal sleep duration following 10 days (Ancoli-Israel 2003), three weeks (Gasio 2003), and four weeks of treatment (Lyketsos 1999) that consisted of BLT (>2500 - 10,000 lux) for one hour in the morning (Ancoli-Israel 2003; Lyketsos 1999), or evening (Ancoli-Israel 2003) or dawn-dusk simulation (400 lux) morning and evening (Gasio 2003). The treatment groups were compared with control groups who received dim light. Unfortunately, Ancoli-Israel 2003 reported only the combined findings of both the BLT and dim red light groups because there were no significant differences between the groups. On request, Ancoli-Israel provided the findings for each group for the treatment days (6-10 days) and follow-up, but so far we have not received the baseline data (requested July 27 and August 11, 2003). Thus the data from this study could not be included in the analysis. In addition, the study by Lyketsos 1999, which was a cross-over design, does not appear to have utilized analyses appropriate to a paired design. Group data prior to the cross-over were requested (August 12, 2003), but have not yet been provided. Thus, the findings from Lyketsos 1999 also had to be excluded from the analyses. Data from Gasio 2003 were analysed. No significant differences were found between the dawn-dusk simulation and dim red light groups in change in actual nocturnal sleep duration from baseline after three weeks of treatment (Weighted Mean Difference [WMD] 0.87, 95% confidence interval [CI] -711.60, 885.61) and after three weeks of follow-up (WMD 0.54, 95% CI -197.76, 305.76).

Three studies measured night-time activity counts (Ancoli-Israel 2003, Gasio 2003, Mishima 1998). Unfortunately, the findings from Ancoli-Israel 2003 cannot be included in the analyses for reasons described above. In addition, the study by Mishima 1998, which was a cross-over design, does not appear to have utilized analyses appropriate to a paired design. Group data prior to the cross-over were requested (August 13, 2003), but have not yet been provided. Thus, the findings from this study cannot be included in the analyses. In Gasio 2003, activity for each subject was averaged in one-hour bins and then over seven consecutive days of baseline, treatment, and follow-up. No significant differences were found between the dawn-dusk simulation and dim red light groups in change in night-time activity from baseline after three weeks of treatment (WMD -9.60, 95% CI -42.77, 23.57) and after three weeks of follow-up (WMD -13.70, 95% CI -48.52, 21.12).

Sleep latency, defined as the amount of time between reclining in bed and the onset of sleep (Davis 2001) was also measured. No effect was observed at the end of three weeks of treatment (WMD -85.00, 95% CI -347.45, 177.45) or on follow-up (WMD -68.00, 95% CI -244.57, 108.57) (Gasio 2003).

Agitation

Agitation was measured using several instruments, including the Behave-AD scale (Lyketsos 1999) and the NPI scale (Gasio 2003). For reasons cited above, the findings from Lyketsos 1999 could not be included in the analyses. Group data prior to the cross-over were requested on August 12, 2003, but have not yet been provided. Using data from the NPI in Gasio 2003, no significant differences were found between the dawn-dusk simulation and dim red light groups in change in agitation from baseline after three weeks of treatment (WMD -2.19, 95% CI -5.85, 1.47).

One study (Ancoli-Israel 2003) measured agitation using the CMAI and ABRS. Group data were provided for the ABRS Verbal Agitation during morning and evening shifts at baseline, treatment days (6-10), and follow-up and for the acrophase (defined as time of day of the peak of the function) of ABRS Physical Agitation at baseline, treatment days (6-10) and follow-up:

- When changes in ABRS Verbal Agitation scores were compared between those who received morning bright light vs those who received morning dim red light, there were no significant differences from baseline to end of treatment during the morning shift (WMD 0.09, 95% CI --0.35, 0.53) nor during the evening shift (WMD 0.14, 95% CI -0.34, 0.62); nor from baseline to follow up during the morning shift (WMD 0.01, 95% CI -0.39, 0.41) nor during the evening shift (WMD 0.10, 95% CI -0.37, 0.57).
- When changes in peak physical agitation, measured by the ABRS, were compared between those who received morning bright light vs those who received morning dim red light, there were no significant differences from baseline to end of treatment (135, 95% CI -36.90, 306.90) nor from baseline to follow-up (WMD 71, 95% CI -100.38, 242.38).
- When changes in ABRS Verbal Agitation scores were compared between those who received evening bright light vs those who received morning dim red light, there were no significant differences from baseline to end of treatment during the morning shift (WMD -0.08, 95% CI -0.54, 0.38) nor during the evening shift (WMD 0.16, 95% CI -0.33, 0.65); nor from baseline to follow up during the morning shift (WMD -0.06, 95% CI -0.51, 0.39) nor during the evening shift (WMD 0.10, 95% CI -0.38, 0.58).
- When changes in peak physical agitation, measured by the ABRS, were compared between those who received evening bright light vs those who received morning dim red light, there were no significant differences from baseline to end of treatment (16.00, 95% CI -167.07, 199.07) nor from baseline to follow-up (WMD 62.00, 95% CI -100.37, 244.37).

Cognition

Two studies used the MMSE to measure cognition (Gasio 2003; Graf 2001). Evening bright light (3,000 lux) was compared with evening dim light (100 lux) in Graf 2001; and dawn-dusk simulation with light (up to 400 lux) was compared with dawn-dusk simulation with dim red light (<5 lux) in Gasio 2003. Because the interventions were so different in terms of illumination intensity, the results could not be combined. The evening BLT was shown to have a significant effect in changing MMSE scores after 10 days of treatment from baseline (WMD 2.56, 95% CI 0.41, 4.71) (Graf 2001). The average MMSE score for the treatment group increased from a score of 15.2 (SD 4.8, n=11) at baseline to 18.1 (SD 4.5, n=9) following treatment, while the control group's score increased from 17.1 (SD 7.1, n=10) to 17.4 (SD 7.3, n=9). The effect of the dawn-dusk simulation in changing cognition was not significant after three weeks of treatment from baseline (WMD 0.93, 95% CI -7.30, 9.16) and after three more weeks of follow-up (WMD -0.03, 95% CI -7.05, 6.99).

Depression

Two studies measured depression: Gasio 2003 used the Geriatric Depression Scale (GDS) and Lyketsos 1999 used the Cornell Scale for Depression in Dementia (CSDD). Lyketsos 1999 reported that no significant differences in scores of depression were found between baseline and follow-up in each group and between groups at each time point. However, raw data were not reported and could not be retrieved as the data were archived (personal communication, Constantine Lyketsos, May 31, 2003). Analysis of the data provided by Gasio 2003 revealed no significant difference in change in depression scores between the dawn-dusk simulation and the dim red light groups from baseline to end of treatment (WMD 0.30, 95% CI -2.54, 3.14), and from baseline to follow-up (WMD -0.17, 95% CI -2.79, 2.45),

DISCUSSION

This review of the effects of BLT on sleep, behaviour, and mood disturbances associated with dementia revealed little significant evidence of benefit. Only one study (Graf 2001) demonstrated that evening BLT might improve cognition, as the treatment group's mean score on the MMSE increased by 3 points whereas the control group's mean score remained almost the same. However, Doody 2001suggests that a reliable indication of change requires a minimum of a 5-point difference in MMSE scores. This result must be viewed with caution also because the sample size was very small (n=23). No significant evidence was found that BLT increased nocturnal sleep time, decreased night-time activity, shortened sleep latency time, decreased agitation, or improved depression. However, given the methodological shortcomings in the published studies, they do not constitute good evidence that BLT is ineffective.

Most of the retrieved articles (n=52) did not meet the inclusion criteria of a randomized controlled trial (RCT). Only five studies were RCTs and included in the Review. However, none of these studies reported using a computer generated randomization technique, the only safe method of concealed allocation sequence. Inadequate concealment includes randomization by use of case record numbers, dates of birth, admission date, day of the week, and any procedure transparent before allocation such as an open list of random numbers (Wild 2003). Because selection bias is a concern, future research should use a randomized controlled de-

sign and ensure that participants are truly randomized by employing a computer generated randomization technique.

The non-significant results of the review may have been related to the small sample sizes of the included studies (n=13-23), with the notable exception of Ancoli-Israel 2003 that included 92 participants. Small sample sizes contribute to insufficient power to detect a difference, if one is present.

The participants within the studies were not homogeneous in terms of their diagnosis and severity of dementia except in Ancoli-Israel 2003 which included only participants with severe Alzheimer's disease. Individuals with Vascular Dementia have heterogeneous brain pathology; their response to light therapy may depend on the areas in which ischaemic damage has occurred.The response to BLT of individuals with scattered lesions of Vascular Dementia (Mishima 1998) or with frontotemporal degeneration (Harper 2001) may differ from that of people with Alzheimer's disease who commonly have damage to the hippocampi and medial temporal lobes of the brain. Investigators need to be sensitive to the importance of controlling for these differences in pathology and their severity when designing studies of light therapy.

One study (Gasio 2003) used dawn-dusk simulated light therapy that exposed the participants to natural amounts of light at dawn and dusk. This type of light therapy is less demanding of the residents than the traditional Brite-Lite^{TM} box used in the remaining studies. Use of a Brite Lite^{TM} box requires participants to sit in front of the box for approximately two hours, which they may find difficult, so noncompliance may be a problem. However, the intensity (<400 lux) and duration of the natural light at dawn and dusk may be insufficient to be effective in changing sleep, behaviour and/or mood disturbances. Bright light (> 2,000 lux) appears to synchronize circadian rhythms (Wever 1983). Healthy older adults on average were found to be exposed (naturally) to 60 minutes of bright light a day. People with Alzheimer's disease living at home were exposed to 29 minutes a day (on average) (Campbell 1988), while institutionalized residents with dementia spent a median of 10.5 minutes per day (mean=34 minutes, SD=63, range=0-314) exposed to light above 1000 lux and a median of 4 minutes (mean=19 minutes, SD=39, range=0-242) per day in light over 2000 lux (Shocat 2000). Further research that examines increasing natural ambient light exposure within nursing homes is needed (McCurry 2000).

The best time of day to offer BLT is not known. In older adults in general, circadian rhythms are phase-advanced (i.e., rhythms are shifted to an atypical early time resulting in falling asleep or waking up earlier than was habitual in earlier life) (Touitou 2000). However, individuals with Alzheimer's disease have been reported to have phase-delayed activity resulting in rhythms that are shifted to unusually late times (Satlin 2000). Exposure to morning bright light has been shown to advance circadian rhythms and thus normalize people with a phase delay, whereas evening bright light may delay circadian rhythms and normalize those with advanced rhythms (Campbell 1995). However, other studies (e.g. Ancoli-Israel 2002, Satlin 1992) have not supported the expected direction of change in individuals with Alzheimer's disease. Ancoli-Israel 2003, included in this Review, hypothesized that the timing of light required to achieve a phase advance or phase delay may be different in people with Alzheimer's disease owing to the advanced deterioration of the SCN, and recommends increasing light exposure throughout the day and evening. Clearly further research is required in this area.

Only three studies could be included in the analyses (Ancoli-Israel 2003; Gasio 2003; Graf 2001). Two other studies (Lyketsos 1999; Mishima 1998) used cross-over designs and did not conduct analyses appropriate to a paired design. Although participants received no light treatment for one week prior to being crossed over to the other group, it is not known if there is a carry-over effect from the two to four weeks of exposure to the light therapy. Some studies (e.g. Ancoli-Israel 2003) suggest that the effects of BLT on nocturnal sleep persist beyond the treatment, while McCurry 2000 concluded that the benefits to sleep from increased bright light decline almost immediately once exposure is discontinued. Until the evidence is stronger, participants should not be regarded as generating independent data in the two phases of a cross-over design.

The outcomes measured by the three studies included in the analyses were change in: sleep time (Gasio 2003), agitation using ABRS scores (Ancoli-Israel 2003) and NPI scores (Gasio 2003), depression (Gasio 2003), and cognition (Gasio 2003; Graf 2001). The results from the two studies (Gasio 2003; Graf 2001) that measured cognition using the MMSE could not be combined as the illumination intensity of the light therapy used in each study differed greatly (<400 and 3,000 lux respectively). Similarly, the results from the two studies that measured agitation (Ancoli-Israel 2003; Gasio 2003) were not combined as the instruments used in the studies measure different concepts related to agitation (see additional table *Description on rating scales used in included studies* - Table 1*)*. No RCT studies were retrieved that measured the other outcomes of interest, namely changes in rates of institutionalization or impact on cost of care. None of the studies identified potential adverse effects of BLT.

Clinical researchers need to make a practice of providing the information and data required for a systematic review in published articles or be willing to share this information with reviewers when contacted. In addition, data must be reported for each group and, if possible, for individuals within groups. For this Review, it was difficult to determine the process of randomization and concealment during assignment to groups, for most of the studies included.

The results and conclusions remain unchanged following the updated search on December 5, 2005 and the critique of retrieved

articles as no new trials were included in the review.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence of the efficacy of light therapy in managing sleep, behaviour, cognition or mood disturbances associated with dementia. Available studies are of poor quality.

Implications for research

As there is a possible rationale for light therapy in managing important manifestations of dementia, further and better-designed research is required.

Studies should incorporate:

1) a randomized controlled parallel-group design with statistically appropriate analysis,

2) a computer generated randomization technique,

3) a sample size with sufficient power to detect an effect of clinically significant magnitude, and

4) blinded and objective outcome ratings.

Further research is necessary to identify appropriate illumination intensity, frequency, interval, time of day and length of intervention for individuals with different types and severity of dementia. Exploring different BLT approaches (e.g., dawn-dusk simulation, light visors worn on heads, ambient light) is also required to ensure that the BLT is acceptable to the participants. Unless the participants are comfortable using BLT, there will be low compliance. Outcomes that contribute to the quality of life of those with dementia should be examined as well as potential adverse effects of BLT. The cost implications of light therapy also need to be examined.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ancoli-Israel 2003

Methods	Randomly assigned (although rated as inadequate) to morning bright light, evening bright light, or morning dim red light (control), single blind
Participants	Country: USA 92 nursing home residents (63 women, 29 men), mean age 82.3 years, MMSE 0-22 (mean=5.7, SD 5.6), NINCDS-ADRDA
Interventions	Apollo "Brite-Lite" box placed 1m from resident 1. Bright light > 2500 Lux: time of day 930-1130 or 1730-1930 2. Dim, red light < 300 Lux: time of day 930-1130 Received treatment daily Baseline data: 3 days Duration of treatment: 10 days Follow-up: 5 days post-treatment
Outcomes	Wake after sleep onset (WASO) Total sleep time (TST) Percent sleep Percent wake Number of nighttime awakenings Average length of nighttime awakenings Number of daytime naps Duration of naps Length of time between naps ABRS
Notes	

Gasio 2003

Methods	Randomly assigned to dawn-dusk simulation (DDS) light therapy or 'placebo' dim red light (DRL), single-blind
Participants	Country: Switzerland 13 nursing home residents, (12 women, 1 man) mean age 85.6 years. Dawn-Dusk Simulation Age mean 86.8 (SD 4.5) MMSE mean 13.8 (SD 5.9) Probable AD (n=7) Probable Vascular (n=2) Dim Red Light

Gasio 2003 (*Continued*)

	Age mean 83.0 (SD 5.2) MMSE mean 14.3 (SD 4.1) Probable AD (n=3) Lewy Body (n=1)
Interventions	Dawn-Dusk Simulation using an overhead halogen lamp placed behind a diffusing membrane behind the resident's bed simulating a naturalistic form of light therapy . 1. DDS max 400 Lux morning and evening 2. DRL < 5 Lux morning and evening Treatment time varied to mimic the duration and latitude of dawn and dusk. Baseline data: 3 weeks Duration of the treatment: 3 weeks Follow-up: 3 weeks post treatment
Outcomes	MMSE NPI-NH GDS CERAD Sleep logs: measured time of going to bed and getting up
Notes	

Graf 2001

Methods	Randomly assigned (although rated as inadequate) to dim light (control) or bright light (experimental), single-blind
Participants	Country: Austria 23 nursing home residents, (proportions of male and female not stated), mean age 81.6 years (range 65-94), diagnosed with AD (n=11) or Vascular Dementia (n=12)
Interventions	Bright light placed 90 cm from resident 1. Bright light = 3000 Lux: time of day 1700-1900 2. Dim, red dim light < 100 Lux: time of day 1700-1900 Received treatment daily. Baseline data: morning of initiation of study Duration of treatment: 10 days No follow-up
Outcomes	MMSE
Notes	

Lyketsos 1999

Methods	Randomized, single-blind, crossover design
Participants	Country: USA 15 nursing home residents (14 women, 1 man) mean age 80.8 (SD 8.7). DSM-IV criteria for AD (n=12) or Vascular Dementia (n=3) MMSE mean: 6.4 (SD 6.8) Behave-AD: > 4 points
Interventions	Bright light placed 3 feet from resident 1. Bright light = 10,000 Lux: time of day morning 2. Dim light = Lux not specified: time of day morning Received treatment daily for 1 hour. Baseline: 1 week Duration of treatment: 4 weeks Follow-up: one week postreatment Then received other condition for 4 weeks.
Outcomes	Behave-AD CSDD Mean hours of total nocturnal sleep
Notes	

Mishima 1998

Methods	Randomized (although process unclear), single-blind, crossover design
Participants	Country: Japan 22 nursing home residents, (13 women, 9 men) mean age 79.6 years MRI, CT, & DSM-IV criteria for AD (n=10; mean age: 78 years; MMSE: mean 9, range 3-17 or Vascular Dementia (n=12; mean age: 81 years; MMSE: mean 8, range 3-14)
Interventions	Bright light placed 90cm from resident 1. Bright light = 5,000-8,000 Lux: time of day 900-1100 2. Dim light = 300 Lux: time of day 900-1100 Received treatment daily. Baseline: 1 week Duration of treatment: 2 weeks. Follow-up: 1 week Interval between conditions: at least 4 weeks
Outcomes	Average daily total activity Average daytime activity Average nighttime activity Percentage of average nighttime activity to average daily total activity.
Notes	

Characteristics of excluded studies *[ordered by study ID]*

Abegg 1993	Not a randomized controlled design.
Ancoli-Israel 1997	Not a randomized controlled design.
Ancoli-Israel 2002	No published data on changes in sleep. Data requested from author but not provided.
Colenda 1997	Not a randomized controlled design.
Dawson 1999	Not a randomized controlled design.
Fetveit 2003	Not a randomized controlled design.
Haffmans 2001	Not a randomized controlled design.
Hozumi 1990	Not a randomized controlled design.
Ito 1999	Not a randomized controlled design.
Ito 2001	Not a randomized controlled design.
Kobayashi 2001	Not a randomized controlled design.
Koyama 1999	Not a randomized controlled design.
Lovell 1995	Not a randomized controlled design.
Mishima 1994	Not a randomized controlled design.
Mishima 2000	Not a randomized controlled design.
Okawa 1989	Not a randomized controlled design.
Okawa 1999a	Not a randomized controlled design.
Okawa 1999b	Did not measure severity of behaviour.
Okumoto 1998	Not a randomized controlled design.
Rheaume 1998	Not a randomized controlled design.
Riemersma 2001	Not a randomized controlled design.

(*Continued*)

Satlin 1992	Not a randomized controlled design.
Thorpe 2000	Not a randomized controlled design.
van Someren 1997	Not a randomized controlled design.
Yamadera 2000	Not a randomized controlled design. All participants received BLT.

Characteristics of ongoing studies *[ordered by study ID]*

Byrne 2000

Trial name or title	A randomised controlled trial of bright light therapy for agitation and sleep disturbance in symptoms of dementia
Methods	
Participants	Country: UK People with dementia in residential and nursing care
Interventions	1. Bright light therapy (dose to be determined)
Outcomes	Improvement in behavioural disturbances and sleep
Starting date	Ongoing in 2000
Contact information	Dr. J. Byrne South Manchester University Hospitals NHS Trust Dept of Mental Illness Withington Hospital Nell Lane Manchester M20 2LR E-mail: a-day@man.ac.uk
Notes	End date of trial was 31/12/2001 Study report requested June 4, 2003 and September 15, 2003, but to date no response.

Dimond 1999

Trial name or title	Light therapy and agitated behavior in dementia
Methods	
Participants	Country: USA 63 long-term care residents in 8 Special Care Units
Interventions	1. Bright light evening 2. Placebo Two week washout was followed by crossover to light or placebo Duration of treatment was 14 days
Outcomes	ABRS
Starting date	Unknown
Contact information	M. Dimond School of Nursing, University of Washington, Seattle, WA 98195-7266 Tel:+1 206 685 3778 Email: dimond@u.washington.edu
Notes	Author will submit final paper/report when completed.

Dowling 1999

Trial name or title	Light therapy in Alzheimer's disease
Methods	
Participants	Country: USA 25 institutionalized residents, mean age 87 years
Interventions	1. Bright light time of day: 900-1000 2. Placebo: usual light time of day: 900-1000 Received treatment daily Duration of treatment was 10 weeks
Outcomes	Sleep efficiency
Starting date	Unknown

Dowling 1999 (*Continued*)

Contact information	Glenna A. Dowling Director Institute on Aging Research Center 3330 Geary Blvd. San Francisco, CA 94118 Tel: 415 750 4180 ext. 170 E-mail: gdowling@ioaging.org
Notes	Author will submit final paper/report when completed.

Dowling 2000

Trial name or title	Light therapy for sleep-activity disruption in Alzheimer's disease
Methods	
Participants	Country: USA 40 institutionalized residents
Interventions	1. Bright outdoor light time of day: 930-1030 2. Placebo: usual indoor light time of day: 930-1030 Received treatment daily Duration of treatment was 10 weeks
Outcomes	Sleep efficiency Total nighttime activity
Starting date	Unknown
Contact information	As above
Notes	Author will submit final paper/report when completed.

Sloane 2003

Trial name or title	High intensity light therapy in Alzheimer's disease
Methods	

Sloane 2003 (*Continued*)

Participants	Country: USA Expected total enrolment: 180 Age: 60 years+, all in long term care, both genders
Interventions	High intensity light therapy
Outcomes	Sleep activity, mood and behaviour
Starting date	Still recruiting in 2003; expected completion date: September 2004
Contact information	John Umstead Hospital, Butner, North Carolina, 27514, USA. Recruiting :C. Madeline Mitchell (Madeline˙Mitchell@unc.edu)
Notes	Philip D Sloane is Principal Investigator. Study ID number: 1 R01 AT00212-01A1

DATA AND ANALYSES

Comparison 1. Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in sleep time (mins) at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	87.00 [-711.61, 885.61]
2 Change in sleep time (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	54.0 [-197.76, 305.76]
3 Change in nighttime activity counts (per night) at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-9.6 [-42.77, 23.57]
4 Change in nighttime activity counts/night at follow-up (3 weeks later after 3 weeks of treatment) from baselin	1	13	Mean Difference (IV, Fixed, 95% CI)	-13.70 [-48.52, 21.12]
5 Change in sleep latency (mins) at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-85.0 [-347.45, 177.45]
6 Change in sleep latency (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-68.0 [-244.57, 108.57]
7 Change in NPI at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-2.19 [-5.85, 1.47]
8 Change in MMSE at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	0.93 [-7.30, 9.16]
9 Change in MMSE at follow-up (3 weeks later after 3 weeks of treatment) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-7.05, 6.99]
10 Change in Geriatric Depression Scale at endpoint (3 weeks) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	0.30 [-2.54, 3.14]
11 Change in Geriatric Depression Scale at follow-up (3 weeks later after 3 weeks of treatment) from baseline	1	13	Mean Difference (IV, Fixed, 95% CI)	-0.17 [-2.79, 2.45]

Comparison 2. Morning bright white light vs morning dim red light

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 morning assessment	1	46	Mean Difference (IV, Fixed, 95% CI)	0.09 [-0.35, 0.53]
1.2 evening assessment	1	46	Mean Difference (IV, Fixed, 95% CI)	0.14 [-0.34, 0.62]
2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 morning assessment	1	46	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.39, 0.41]
2.2 evening assessment	1	46	Mean Difference (IV, Fixed, 95% CI)	0.1 [-0.37, 0.57]
3 Change in peak agitation time (mins) at endpoint (10 days) from baseline	1	46	Mean Difference (IV, Fixed, 95% CI)	135.0 [-36.90, 306.90]
4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline	1	46	Mean Difference (IV, Fixed, 95% CI)	71.0 [-100.38, 242.38]

Comparison 3. Evening bright white light vs morning dim red light

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 morning assessment	1	48	Mean Difference (IV, Fixed, 95% CI)	-0.08 [-0.54, 0.38]
1.2 evening assessment	1	48	Mean Difference (IV, Fixed, 95% CI)	0.16 [-0.33, 0.65]
2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 morning assessment	1	48	Mean Difference (IV, Fixed, 95% CI)	-0.06 [-0.51, 0.39]
2.2 evening assessment	1	48	Mean Difference (IV, Fixed, 95% CI)	0.1 [-0.38, 0.58]
3 Change in peak agitation time (mins) at endpoint (10 days) from baseline	1	48	Mean Difference (IV, Fixed, 95% CI)	16.0 [-167.07, 199.07]
4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline	1	48	Mean Difference (IV, Fixed, 95% CI)	62.0 [-100.37, 224.37]

Comparison 4. Evening bright light vs evening dim light

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Change in MMSE at 10 days from baseline	1	18	Mean Difference (IV, Fixed, 95% CI)	2.56 [0.41, 4.71]

Analysis 1.1. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 1 Change in sleep time (mins) at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

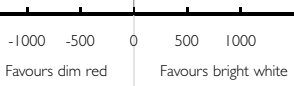
Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 1 Change in sleep time (mins) at endpoint (3 weeks) from baseline

Study or subgroup	DDS white light N	Mean(SD)	DDS dim red light N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Gasio 2003	9	23 (1170)	4	-64 (236)		100.0 %	87.00 [-711.61, 885.61]
Total (95% CI)	**9**		**4**			**100.0 %**	**87.00 [-711.61, 885.61]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.21 (P = 0.83)

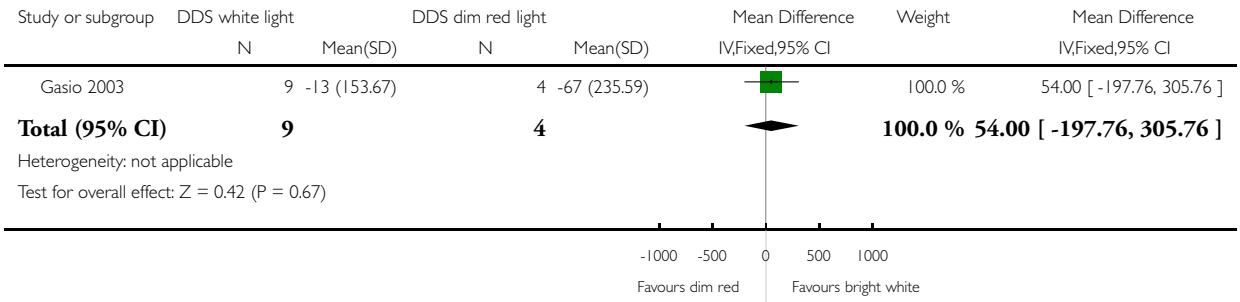


Analysis 1.2. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 2 Change in sleep time (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 2 Change in sleep time (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline

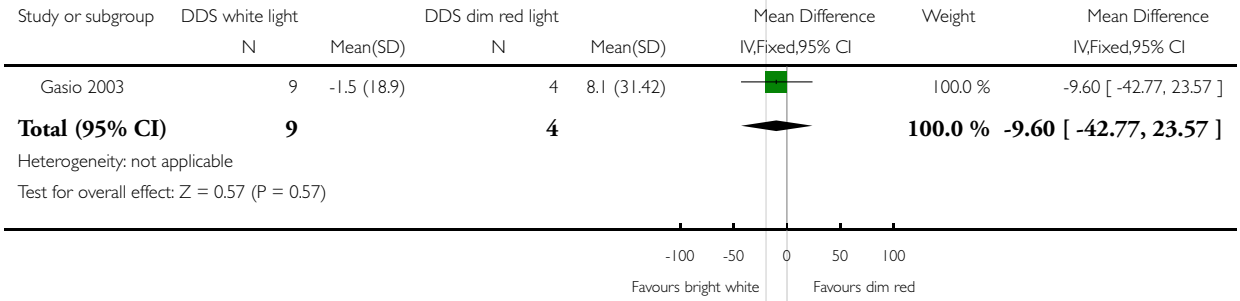


Analysis 1.3. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 3 Change in nighttime activity counts (per night) at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 3 Change in nighttime activity counts (per night) at endpoint (3 weeks) from baseline

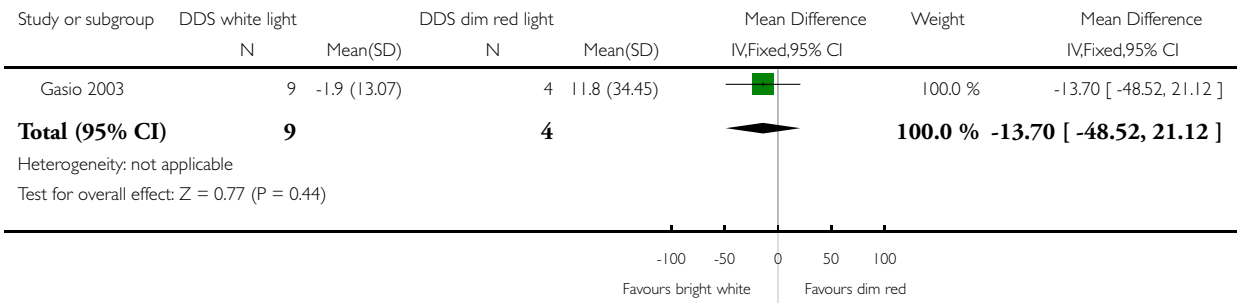


Analysis 1.4. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 4 Change in nighttime activity counts/night at follow-up (3 weeks later after 3 weeks of treatment) from baselin.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 4 Change in nighttime activity counts/night at follow-up (3 weeks later after 3 weeks of treatment) from baselin

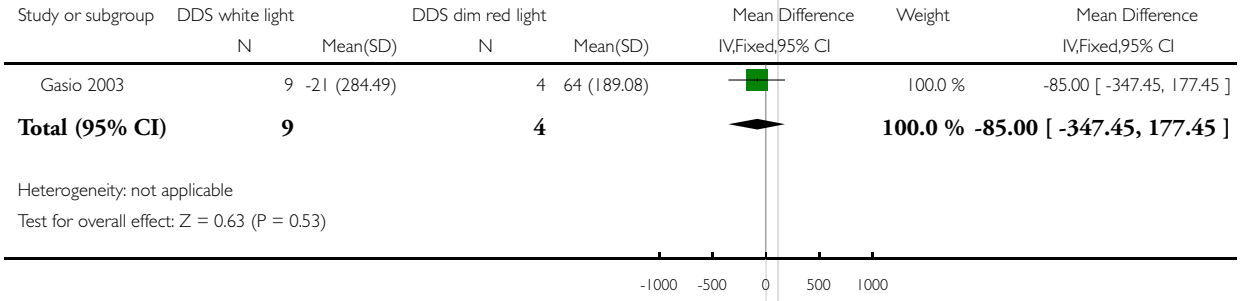


Analysis 1.5. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 5 Change in sleep latency (mins) at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 5 Change in sleep latency (mins) at endpoint (3 weeks) from baseline

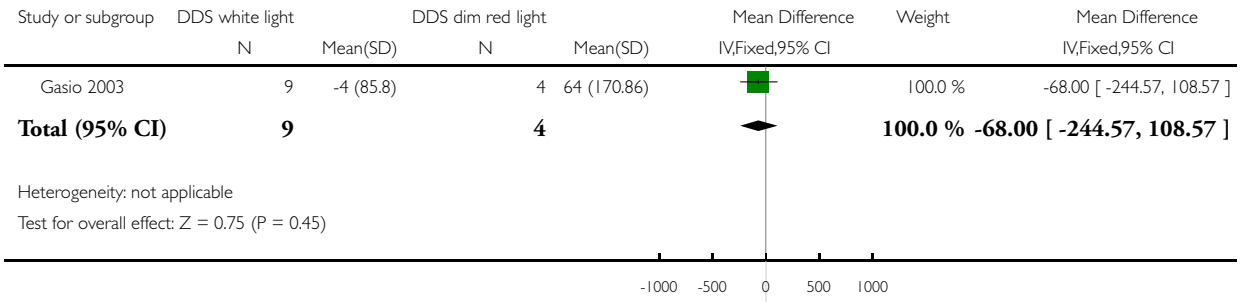


Analysis 1.6. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 6 Change in sleep latency (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 6 Change in sleep latency (mins) at follow-up (3 weeks later after 3 weeks of treatment) from baseline

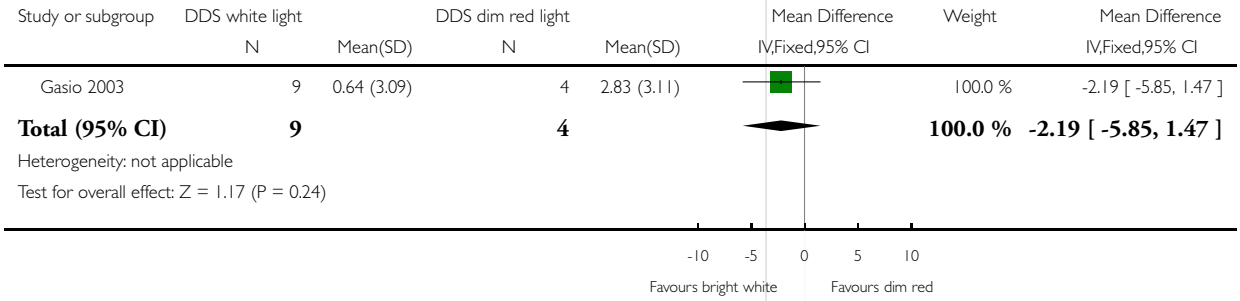


Analysis 1.7. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 7 Change in NPI at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 7 Change in NPI at endpoint (3 weeks) from baseline

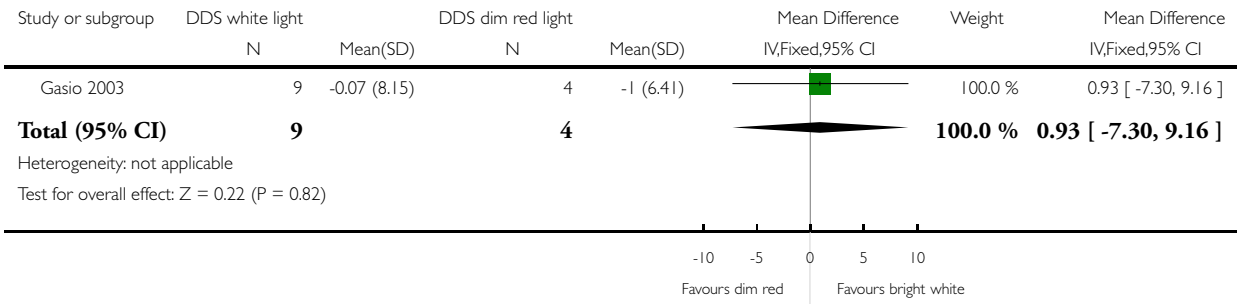


Analysis 1.8. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 8 Change in MMSE at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 8 Change in MMSE at endpoint (3 weeks) from baseline

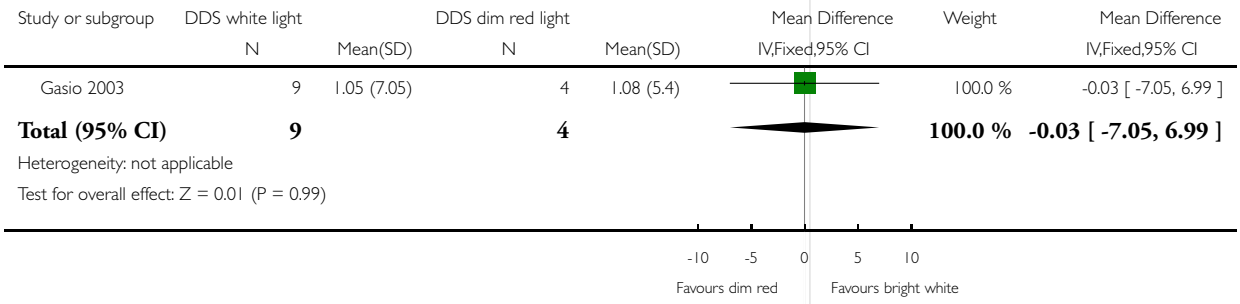


Analysis 1.9. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 9 Change in MMSE at follow-up (3 weeks later after 3 weeks of treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 9 Change in MMSE at follow-up (3 weeks later after 3 weeks of treatment) from baseline

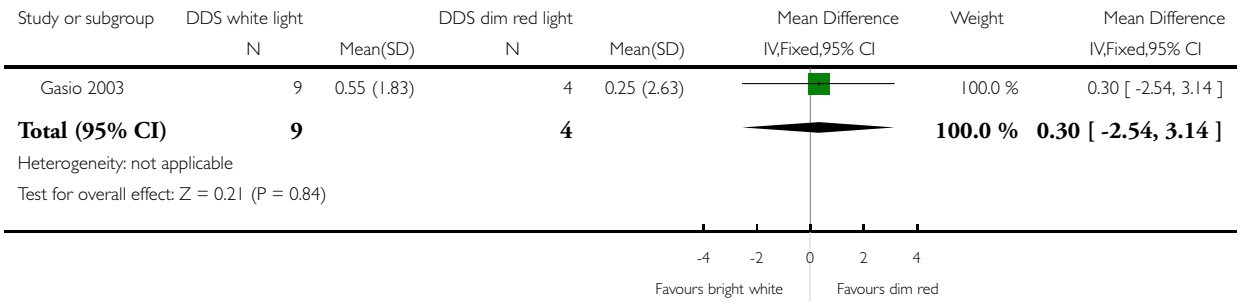


Analysis 1.10. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 10 Change in Geriatric Depression Scale at endpoint (3 weeks) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 10 Change in Geriatric Depression Scale at endpoint (3 weeks) from baseline

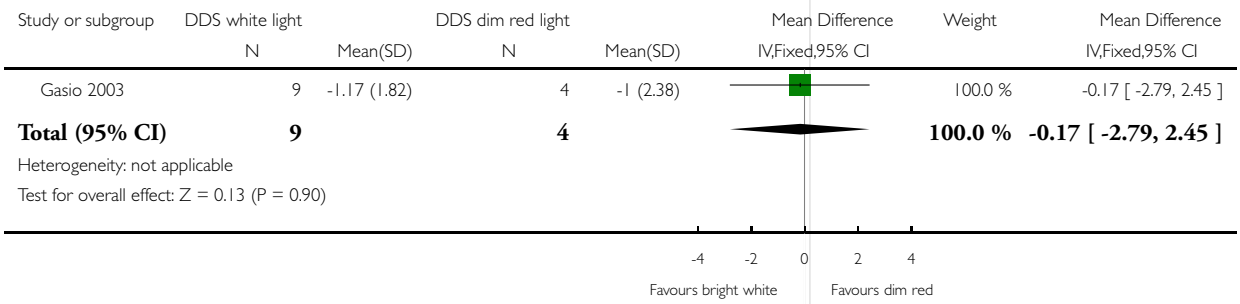


Analysis 1.11. Comparison 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light, Outcome 11 Change in Geriatric Depression Scale at follow-up (3 weeks later after 3 weeks of treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 1 Dawn-dusk simulation with bright white light vs dawn-dusk simulation with dim red light

Outcome: 11 Change in Geriatric Depression Scale at follow-up (3 weeks later after 3 weeks of treatment) from baseline

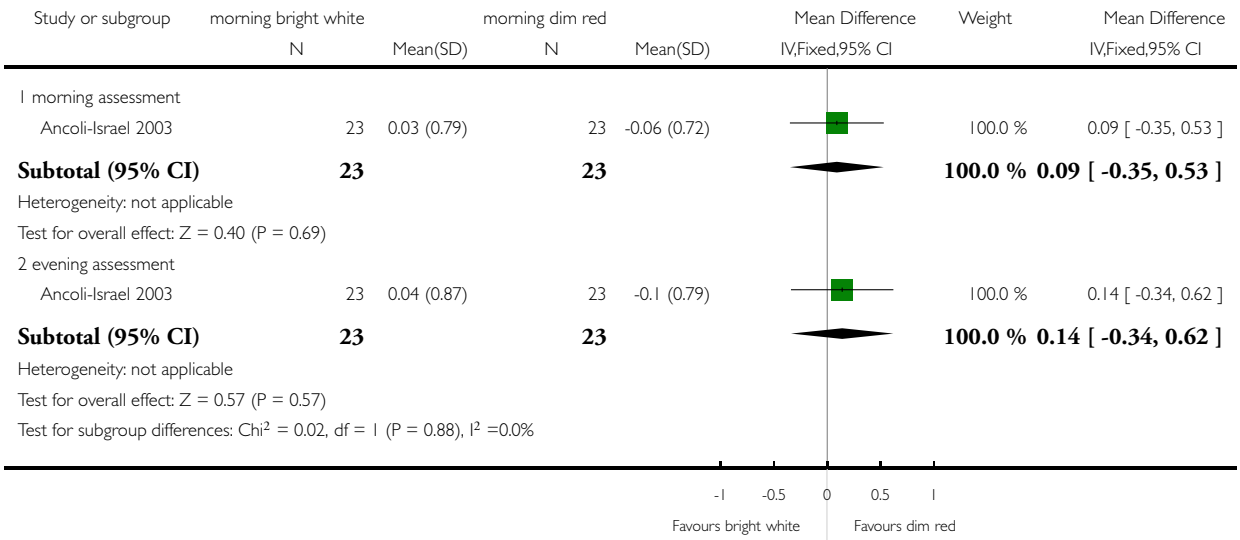


Analysis 2.1. Comparison 2 Morning bright white light vs morning dim red light, Outcome 1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 2 Morning bright white light vs morning dim red light

Outcome: 1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline

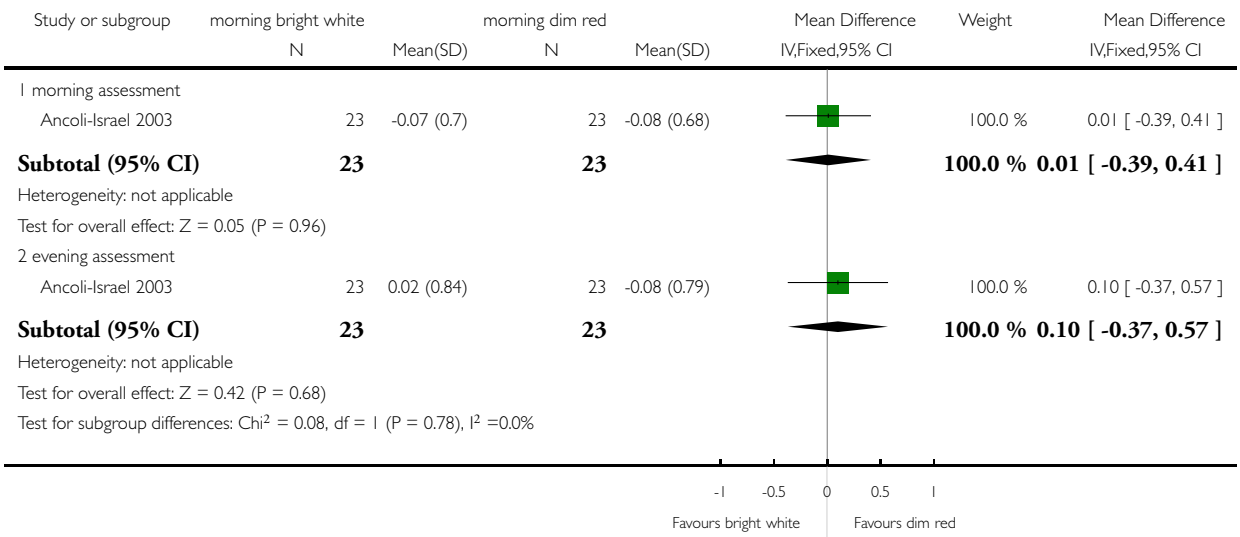


Analysis 2.2. Comparison 2 Morning bright white light vs morning dim red light, Outcome 2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 2 Morning bright white light vs morning dim red light

Outcome: 2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline

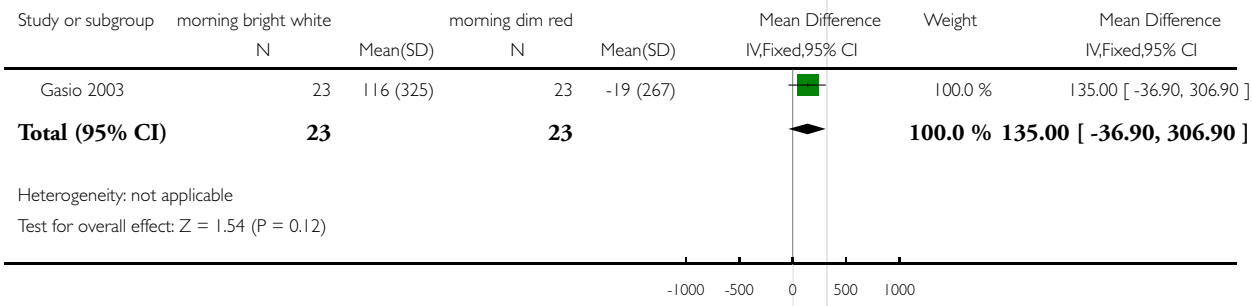


Analysis 2.3. Comparison 2 Morning bright white light vs morning dim red light, Outcome 3 Change in peak agitation time (mins) at endpoint (10 days) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 2 Morning bright white light vs morning dim red light

Outcome: 3 Change in peak agitation time (mins) at endpoint (10 days) from baseline

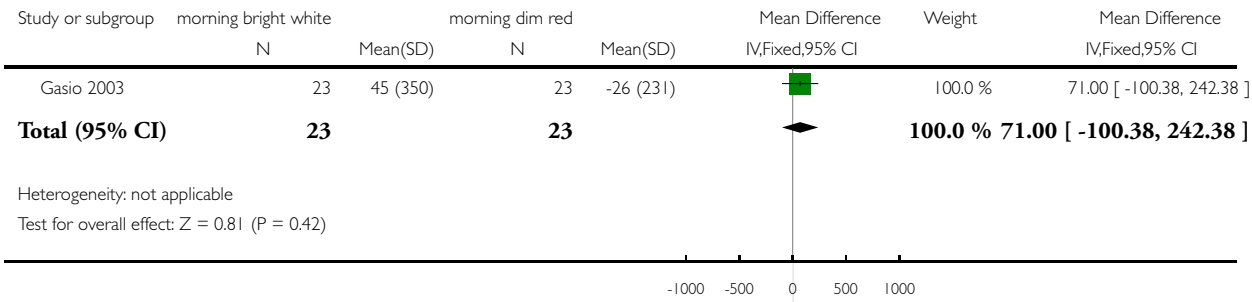


Analysis 2.4. Comparison 2 Morning bright white light vs morning dim red light, Outcome 4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 2 Morning bright white light vs morning dim red light

Outcome: 4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline

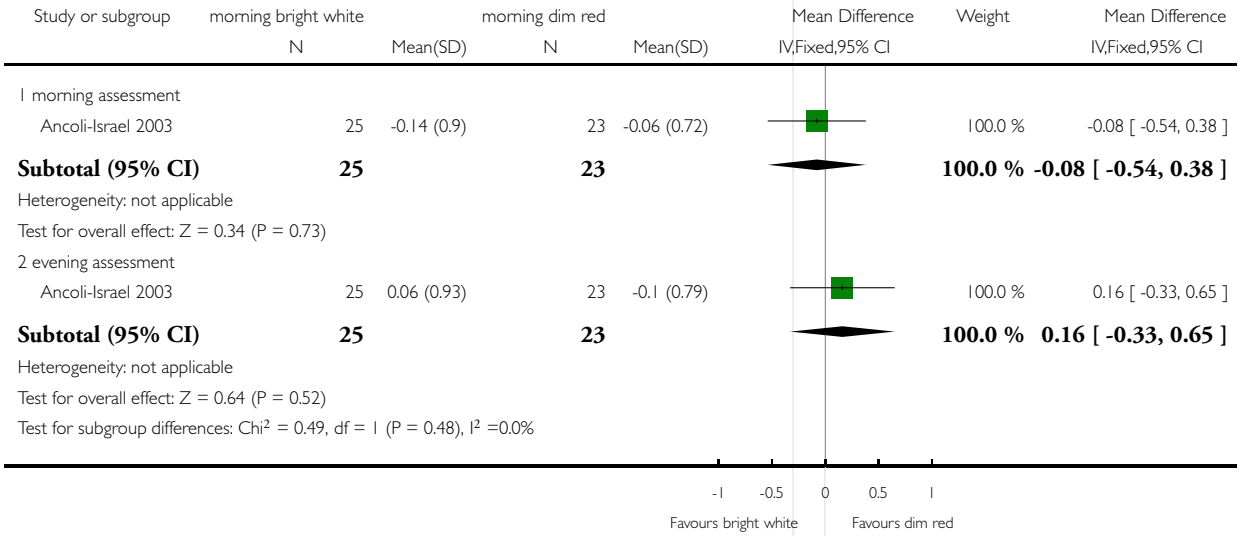


Analysis 3.1. Comparison 3 Evening bright white light vs morning dim red light, Outcome 1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 3 Evening bright white light vs morning dim red light

Outcome: 1 Change in ABRS Scores (Verbal Agitation) at endpoint (10 days) from baseline

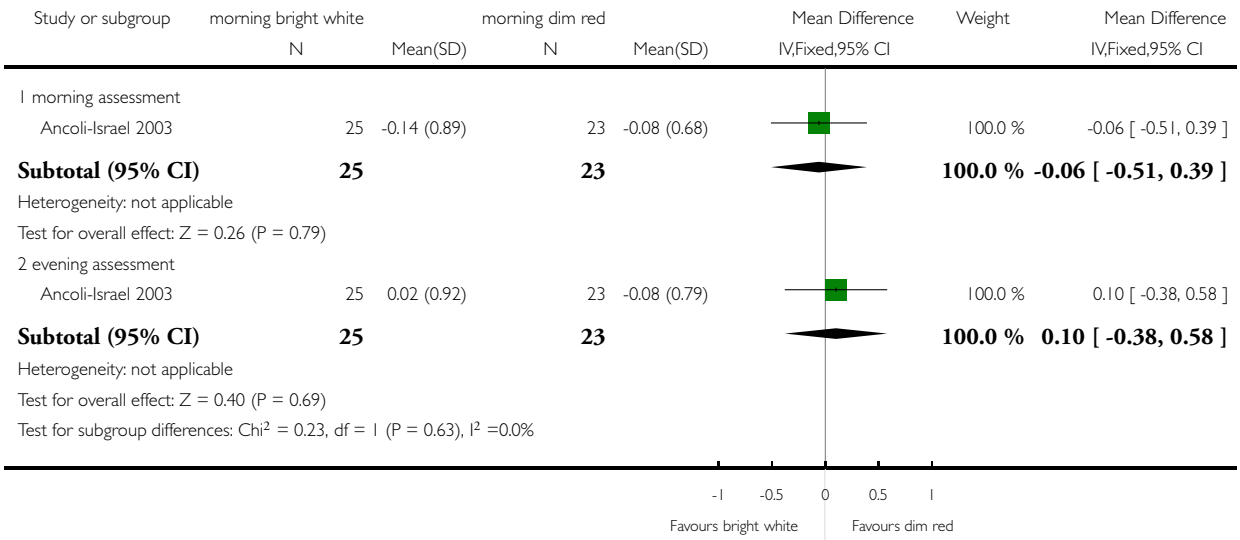


Analysis 3.2. Comparison 3 Evening bright white light vs morning dim red light, Outcome 2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 3 Evening bright white light vs morning dim red light

Outcome: 2 Change in ABRS Scores (Verbal Agitation) at follow-up (5 days later after 10 days treatment) from baseline

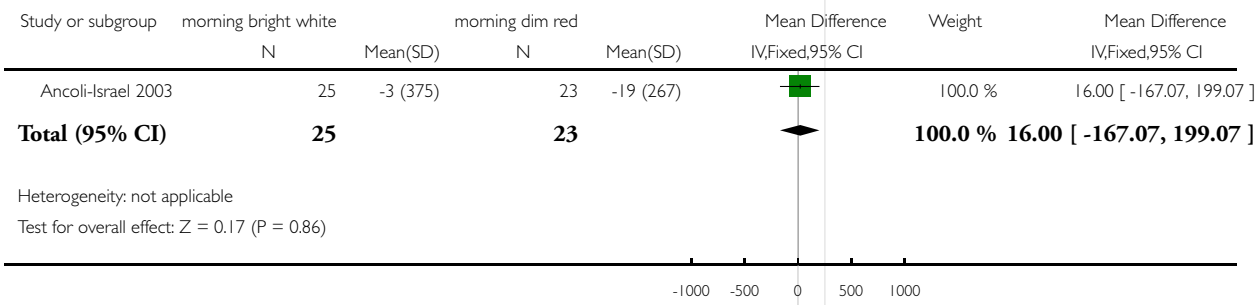


Analysis 3.3. Comparison 3 Evening bright white light vs morning dim red light, Outcome 3 Change in peak agitation time (mins) at endpoint (10 days) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 3 Evening bright white light vs morning dim red light

Outcome: 3 Change in peak agitation time (mins) at endpoint (10 days) from baseline

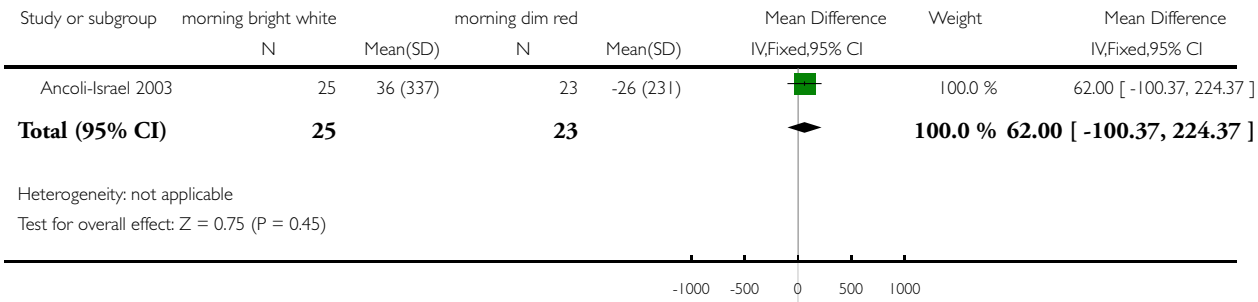


Analysis 3.4. Comparison 3 Evening bright white light vs morning dim red light, Outcome 4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 3 Evening bright white light vs morning dim red light

Outcome: 4 Change in peak agitation time (mins) at follow-up (5 days later after 10 days treatment) from baseline

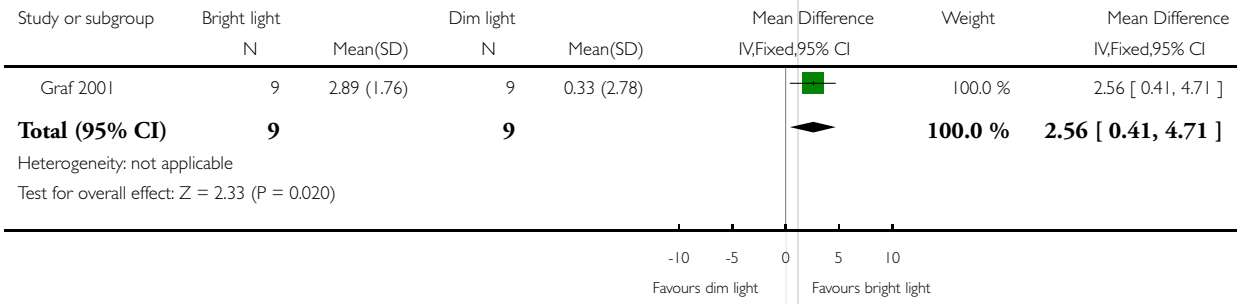


Analysis 4.1. Comparison 4 Evening bright light vs evening dim light, Outcome 1 Change in MMSE at 10 days from baseline.

Review: Light Therapy for Managing Sleep, Behaviour, and Mood Disturbances in Dementia

Comparison: 4 Evening bright light vs evening dim light

Outcome: 1 Change in MMSE at 10 days from baseline



WHAT'S NEW

Last assessed as up-to-date: 4 December 2005.

5 November 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 2002

Review first published: Issue 2, 2004

5 December 2005	New search has been performed	Update 2005: New searches revealed one incomplete trial and two non-RCTs. However, none met the inclusion criteria for this review. The Results and Conclusions of the review remain unchanged.
11 February 2004	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

-DF: All correspondence; drafting review versions; obtaining copies of reports; selection of trials; extraction of data; entry of data; interpretation of data analysis; writing review

-DMO: drafting review versions; selection of trials; extraction of data; interpretation of data analysis

-JBA: assisting with literature search

-SP: drafting review versions; selection of trials; extraction of data; entry of data; interpretation of data analysis

-JA: obtaining copies of reports; entry of data

-CDCIG contact editor: Linda Clare

-Consumer editor: Edith Sumner

This review has been peer reviewed anonymously

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- College of Nursing, University of Saskatchewan, Canada.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Phototherapy; Affect; Cognition Disorders [etiology; *therapy]; Dementia [*complications]; Depression [etiology; *therapy]; Psychomotor Agitation [etiology; *therapy]; Randomized Controlled Trials as Topic; Sleep Disorders [etiology; *therapy]

MeSH check words

Aged; Humans