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A study to evaluate whether light therapy can help people with dementia to sleep better

Submission date
16/12/2015

Recruitment status
Stopped

Registration date
11/01/2016

Overall study status
Stopped

Last Edited
26/02/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Two out of three people with dementia have problems with sleep. This can cause stress and influence decisions to move the person into a care home. Medications prescribed for sleep disturbances may have negative side effects and we cannot be sure they work. Non-drug methods are recommended, but we are not sure they work either. A hormone released from the brain determines when people fall asleep. If someone is exposed to bright light, the brain stops the release of this hormone and this can disrupt sleep. Without this regular cue to stay awake, a person may naturally sleep at different times of the day. Exposure to enough light may become difficult with age and worsening dementia. Giving bright blue/white light to help people stay awake during the day may help reduce problems with sleep at night. There have been some studies, but because of weaknesses in the way the research has been carried out, they have not led to a conclusion on treatment.
We will test if a light box used during the day helps people with dementia sleep better at night. This is difficult research to carry out, but we think it can be done. Our group includes experts with experience in this type of research. However, we want to make absolutely sure that we can do the study in the way that we plan before we start. Therefore, we will start with a small study and ask only 6 people to take part. This will tell us whether we can recruit enough people, whether they use the light box in the way we prescribe and whether we can carry out all our planned assessments. After we have tried our plans in the small study we will not be able to comment on whether light treatment works, but we will be able to say whether it would be worthwhile to ask more people to take part. We will then finalise our plans for a larger study.

Who can participate?
People with Alzheimer's type dementia and an irregular sleep wake pattern.

What does the study involve?
Each participant is given a light box to use each day in their own home. Over the 9 weeks, the participants are given two different light boxes at two different times. One is an active bright blue/white light box and the other is an inactive dim red light box. The order in which the person receives the different light treatments is determined by chance. We compare how people sleep during the two periods to see if either of the light boxes is better. To measure sleep, participants wear a device that looks like a watch to record their movement in bed. This is a good

way of recording people's sleep behaviour. If the treatment works, we would expect people to sleep for longer at night during the period they are regularly using the bright blue/white light box, in comparison to the period they are using the dim red light box.

What are the possible benefits and risks of participating?
Participants may benefit from improvements of their sleep, mood, ability to think and remember clearly, quality of life, and feelings of self-determination. Participants may also experience improvement in their ability to go about their everyday activities, including social activities. Further benefits could include a reduced need for medication and less stress and distress. Aside from the time commitment of participating, potential side effects include headaches, dry mouth, mild agitation or irritability.

Where is the study run from?
Surrey & Borders Partnership NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
December 2015 to June 2016.

Who is funding the study?
University of Kent (UK).

Who is the main contact?
Dr David Lowery

Contact information

Type(s)
Public

Contact name
Dr David Lowery

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Contact details
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CT2 7NF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.6.2

Study information

Scientific Title
Disturbances of Sleep in Dementia (DOSID): a pilot randomized controlled cross-over trial to evaluate the efficacy and explore the mechanisms of bright full spectrum light as a therapy for sleep disturbances in people with dementia

Acronym
DOSID

Study objectives
Bright full spectrum light therapy will effectively improve objectively measured sleep behaviour (actigraphy). This hypothesis predicts light therapy will: increase total night time sleep (sleep duration); reduce the duration of time spent awake in bed after the initial onset of sleep (sleep efficiency) and reduce daytime napping.
Bright full spectrum light therapy will effectively improve subjective reported sleep quality (Leeds Sleep Evaluation Questionnaire [LSEQ]). This hypothesis predicts that participant's scores on the LSEQ will decrease with the use of light therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Bromley Research Ethics Committee under the auspices of the NHS Health Research Authority, 1. 20/11/2015, ref: 15/LO/1350

Study design
Randomised controlled double-blind cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Irregular sleep wake disturbance in people with dementia

Interventions
We will evaluate the efficacy of a full spectrum bright light box (~10,000 Lux; ~460nm) as a therapy for sleep disturbances within a cohort of community dwelling people with dementia by means of a randomised, controlled, double-blind, cross-over trial with two treatments: active bright light box (A), or a control dim red light box (B). In addition to treatment as usual, participants will be randomly allocated to one of two treatment sequences (AB or BA).

Intervention Type
Device

Primary outcome measure
Sleep behaviour (actigraphy), measured at Baseline, Week 3, Week 6 (Baseline 2), Week 9
*This study is a cross-over trial, so has two baseline assessments.

Secondary outcome measures
1. Dim Light Melatonin Onset (saliva)
2. Neuropsychiatric Inventory (NPI)
3. Mini-Mental State Evaluation (MMSE)
4. Leeds Sleep Evaluation Questionnaire (LSEQ)
5. Zarit Caregiver Burden Interview (ZBI)

Measured at Baseline, Week 3, Week 6 (Baseline 2), Week 9
*This study is a cross-over trial, so has two baseline assessments.

Overall study start date
01/12/2015

Completion date
01/06/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Alzheimer's type dementia
2. Irregular sleep wake pattern

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
6 (pilot only)

Key exclusion criteria
1. 'Severe' dementia
2. Sleep apnoea
3. Eye disease
4. Abnormal visual acuity
5. Parkinson's disease
6. Restless leg syndrome
7. Periodic limb movement
8. History of light-induced migraine or epilepsy
9. Using photosensitising medication
10. Trans-meridian travel or shift work
11. Bipolar affective disorder

Date of first enrolment
07/12/2015

Date of final enrolment
07/04/2016

Locations

Countries of recruitment
United Kingdom

Study participating centre
Surrey & Borders Partnership NHS Foundation Trust
United Kingdom
KT16 0 AE

Sponsor information

Organisation
University of Kent (UK)

Sponsor details
Registry
University of Kent
Canterbury
England
United Kingdom
CT2 7NZ

Sponsor type
University/education

Organisation
Surrey & Borders Partnership NHS Foundation Trust

Sponsor details
18 Mole Business Park
Randalls Road
Leatherhead
England
United Kingdom
KT22 7AD

Sponsor type
Hospital/treatment centre

Organisation
University of Kent

Sponsor details

Sponsor type
Not defined

Website
http://www.kent.ac.uk/

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
University/education

Funder Name
University of Kent

Alternative Name(s)
The University of Kent

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
In 2016 we plan to publish the protocol in a peer-reviewed journal.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No