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Light therapy exploratory trial: investigating the effectiveness and feasibility of home use light therapy for the management of depression

Submission date
25/06/2015

Recruitment status
No longer recruiting

Registration date
02/02/2016

Overall study status
Completed

Last Edited
20/11/2023

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
The environmental day/night cycle plays a key role in stabilising mood by regulating our internal rhythms. The 'clock', located in the brain, is responsible for regulating biological rhythms, such as hormone levels and sleep patterns. This 'clock' relies heavily on the ability of the eye to detect and interpret light to synchronise our body processes to the day and night. When these rhythms are not in sync with the day/night cycle, patients can experience symptoms of depression. By introducing light therapy (LT), the 'clock' receives an enhanced daytime cue to resynchronise these biological rhythms, thus relieving symptoms. The aim of this initial study is to assess whether LT can treat mild to moderate depression in primary care and whether a larger study could take place in the future.

Who can participate?
Adults diagnosed with mild to moderate depression, recruited through standard GP consultation or advert shared by mental health charities/support groups to their members.

What does the study involve?
Participants receive a recruitment pack providing study information and a mood questionnaire to assess eligibility. They receive monitored usual care for week 1 of the study and week 6. For weeks 2-5, participants are randomly allocated to one of two groups. Those in group one are given an active bright LT (10,000lux) to use in their home for 30 minutes every morning. . Those in group 2 are given a control dim red LT (<100lux) to be used in their home for 30 minutes every morning. All participants are asked to fill in questionnaires to assess their mood and side effects every week and other questionnaires about expectation, quality of life and seasonality at the beginning of the study. Participants wear an Actiwatch, designed to monitor activity/sleep patterns and light exposure, and complete a diary throughout the study. They are also asked to produce 8 saliva samples before and after the study. Melatonin and cortisol hormone levels are analysed to identify people most likely to benefit from LT. Follow up assessments include telephone interview and 6 month postal questionnaire to explore participant experience and their opinions of LT.

What are the possible benefits and risks of participating?
Participants will not be paid to complete this study. There are no personal benefits from participating in this research, other than the chance to try light therapy as part of the study. However, participation may provide researchers with a better understanding of light therapy including its effectiveness, usability, how it affects sleep and it may lead to a method of identifying people who would benefit most from light therapy. As far as risks to participant in this research, studies on light therapy that have taken place in hospitals and clinics have shown that light therapy is very well tolerated and has few side-effects. The most common of these side effects include improved mood, eye irritation and headaches. Side effects will be closely monitored throughout the study use of light therapy. Before and during the trial, depression will be closely monitored using questionnaires. In an event where a participant's mood worsens above the maximum score of the trial's inclusion criteria, or if there are concerns about general mental health, the participant will be advised to make an appointment to see their GP. The research team will also contact the GP to inform them that the participant's depression symptoms have become more severe, for safety reasons.

Where is the study run from?
GP surgeries in the Chatham/Rochester area (UK)

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

Who is funding the study?
Medway School of Pharmacy (UK)

Who is the main contact?
Jacqueline Walsh

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ResGov 297

Study information

Scientific Title
Light therapy: a double-blind placebo-controlled exploratory trial investigating the effectiveness and feasibility of light therapy for the management of mild-moderate depression in primary care

Study objectives
The environmental day/night cycle plays a key role in stabilising mood by regulating our internal rhythms. The ‘clock’, located in the brain, is responsible for regulating biological rhythms, such as hormone levels and sleep patterns. This ‘clock’ relies heavily on the ability of the eye to detect and interpret light to synchronise our body processes and daily routines to the day and night. When these rhythms desynchronise with the day/night cycle, patients can experience symptoms

of depression including mood and sleep disturbances. By introducing light therapy (LT), the 'clock' receives a very strong daytime cue to resynchronise the biological rhythms, relieving these symptoms.
Therefore the objectives of this trial are:
1. Pilot the methodologies proposed in this study, and assess suitability for a full-scale trial.
2. To evaluate the feasibility of using light therapy devices in the home for patients with depression
3. To measure the participants' depression score in response to light therapy use.
4. To determine if melatonin and cortisol concentrations, as measured by salivary sampling, can be used as an indicator to predict a positive response to light therapy
5. To monitor participants' behavioural rhythms at baseline, during intervention and post-treatment to determine the impact light therapy has on the activity and sleep patterns/quality of the participants, as measured by the Actiwatch device (wrist watch device measuring levels of activity and levels of light).
6. Calculate the economic benefit of light therapy as a potential treatment for depression in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Brighton & Sussex, 27/04/2015, ref: 15/LO/0418

Study design
Multicentre interventional randomized-controlled parallel-group double-blind pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mild - moderate depression

Interventions
Active group: Standard light box device administering 10,000lux white light - to be used 30 minutes in the morning, within ten minutes of waking before midday.

Control group: Altered standard light box device administering >100lux red light - to be used 30 minutes in the morning, within ten minutes of waking before midday.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Light box

Primary outcome measure
Response to treatment at four weeks of the intervention as compared to baseline, measured by the Structured Interview Guide for the Hamilton Depression Rating Scale – Seasonal Affective Disorder version Self-rated (SIGH-SAD-SR).

The resulting SIGH-SAD score will be treated in two ways. A total SIGH-SAD-SR score of less than or equal to 50% of the baseline total score will be used to define "response". A total SIGH-SAD-SR score less than or equal to 50% of the baseline total score, and a total score of less than or equal to 8 will be used to define "remission". These parameters provide a quantitative measurement of improvement and estimate participant recovery.

Secondary outcome measures
1. Response to intervention defined by a change in depression score as measured by the Patient Health Questionnaire 9 (PHQ-9), an established primary care depression assessment tool. This measurement will be used to investigate the suitability of this questionnaire to measure response of a patient using light therapy in primary care, by comparing with SIGH-SAD-SR scores which are collected concurrently.
2. Measurement and comparison of total weekly SIGH-SAD-SR scores of the active and control intervention arms, collected from weeks 1 to 4 of the trial, as compared to baseline SIGH-SAD-SR score.
3. To investigate the relationship between the global seasonality score (GSS), collected for each participant at baseline by the SPAQ, and the difference between the total SIGH-SAD-SR score measured at baseline and after 4 weeks of the intervention.
4. Comparison of the phase angle between time to peak of cortisol concentration and dim-light melatonin onset (DLMO), between participants who responded and did not respond to active light therapy intervention. DMLO will be determined through analysis of the evening saliva samples. It is defined as the interpolated clock time at which melatonin concentration reaches 20pg/ml.
5. Compare active and control intervention groups' behavioural activity profiles (actigraphy) by analysing duration of sleep, sleep efficiency (percentage of actual sleep between sleep onset and final awakening) and sleep onset latency in response to intervention, and one week post-intervention.
6. The feasibility of using light therapy in patients own homes will be evaluated using the adherence data gathered by Actiwatch data, participant diary entries, and post-trial semi-structured interviews. The relationship between self-efficacy and social support, two factors which have shown to be potential key determinants of adherence to light therapy in a previous study (Roecklein et al., 2012) will be explored through the expectation questionnaires.
7. Investigate health related quality of life using the SF-36 pre and post intervention. The data collated from this questionnaire can be used in order to calculate quality-adjusted life-year (QALY) combined with the cost of providing an intervention. This results in the additional costs required to generate a year of perfect health (one QALY). These measurements will give an

indication of the economic benefits of recommending light therapy in primary care practice
8. Suitability of the methodologies employed within the exploratory trial, for use in a future larger/full-scale randomised controlled trial, will be evaluated by comparing recruitment methods, observing retention rates, testing procedures, calculation of appropriate sample sizes, and through qualitative interviews with the participants on completion of the trial.

Overall study start date
01/05/2015

Completion date
01/05/2016

Eligibility

Key inclusion criteria
1. Aged 18 to 64 years old
2. Current diagnosis of mild-moderate depression defined via a PHQ-9 score of 5 to 14
3. Ability to provide informed consent for randomisation, treatment and follow up, including a good command of the English language
4. Ability to access their general practice surgery / University campus at Medway for assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Pregnant/planning pregnancy or breastfeeding
2. Alterations to participant antidepressant treatment, including medication and counselling /talk therapy, in the previous four weeks of trial commencement or during the trial
3. Current treatment with antipsychotic drugs
4. Previous use of light therapy, including use of light boxes, light visors and dawn simulation lamps. This does not include the use of seasonal affective disorder (SAD) alarm clocks
5. History of or current substance/drug abuse
6. History or current diagnosis of; psychosis, severe depression, bipolar disorder, Parkinson’s, dementia or Alzheimer’s disease.
7. A history of light-induced migraine or epilepsy

8. A history of traumatic brain injury (TBI)
9. Presence of ocular disorders including retinal blindness, cataract, retinal diseases of the eye and glaucoma.
10. Current oral diseases, such as candidiasis, or inflammation or lesions within the mouth
11. Is currently or has recently been involved in any research prior to this study

Date of first enrolment
01/05/2015

Date of final enrolment
15/04/2016

Locations

Countries of recruitment
England

United Kingdom

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University/education

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
University/education

Funder Name
Medway School of Pharmacy

Results and Publications

Publication and dissemination plan
Data collection was planned until May 2016, however we are in the process of applying for an amendment to extend this time to March 2017. We plan to disseminate the findings of the study through publication in relevant peer reviewed journals by early-mid 2017.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

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