ISRCTN17706836 https://doi.org/10.1186/ISRCTN17706836

Sleep, wake and light therapy for depression

Submission date
02/01/2018

Recruitment status
No longer recruiting

Registration date
22/01/2018

Overall study status
Completed

Last Edited
09/12/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depression is a state of low mood and aversion to activity that can affect a person's thoughts, behavior, feelings, and sense of well-being. The aim of this study is to determine if altering sleep patterns combined with light therapy in the morning can speed up the treatment of depression.

Who can participate?
People aged 18-65 with depression

What does the study involve?
Participants are randomly allocated to one of two treatments: Wake and Light Therapy or Sleep and Light Therapy. In the Wake and Light Therapy group, participants are helped to change the pattern of their sleep by depriving them of sleep for one night. On Day 1 they are supported to stay up all night and the following day at the Hospital. They can go to bed by 5pm at their home on Day 2. They need to get up by about 1am and return to the hospital to be supported to stay awake. They then go to bed at 7pm on Day 3. They are asked to sleep until 3am and then stay awake at home until bed at 9pm on Day 4. They then get up by 5am on Day 5 and stay awake until 11pm to resume a normal sleep routine waking by 7am on Day 6. They are also given a light box to use each morning. They are asked to sit about one foot away from a light box. They are free to have breakfast, read or use a computer while facing towards the light. Treatment with a light box lasts 30 minutes. In the Sleep and Light Therapy group, participants are given information and advice on how to get a good night's sleep. They are also given a light box to use in the morning for 1 week as described above. All participants complete various questionnaires and are seen by the research team after 1, 2, 4, 8 weeks and at 6 months after the treatment commences. Both groups may continue with other treatments such as medication or talking therapies. If they are taking anti-depressant medication, there should be no plans by their doctor to change the dose of any medication or to start additional medication for depression in the next 6 months.

What are the possible benefits and risks of participating?
It is not known whether this treatment will help for certain, but it may help some people with depression. Information from this study will help researchers better understand whether it can be a practical treatment in the community and whether it is worth doing a larger study. One of the possible disadvantages may be the time and burden to complete the questionnaires and attend the research interview. The only potential risk of treatment is of triggering an episode of

mania, but this should be a rare occurrence as people with bipolar disorder are excluded from this study.

Where is the study run from?
South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to August 2019

Who is funding the study?
King's Health Partners (UK)

Who is the main contact?
Dr Clara Humpston
Clara.Humpston@kcl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Clara Humpston

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D2017/096

Study information

Scientific Title

Sleep, wake and light therapy for depression: a randomised parallel trial

Study objectives
To compare the rate of recruitment and adherence to the treatments in both groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Bromley Research Ethics Committee, 02/12/2017, ref: 17/LO/1567

Study design
Multicentre randomised parallel-group single-blind interventional study

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Unipolar major depression

Interventions
Method of randomisation: stratified block randomisation with fixed block sizes stratified by Season of the Year.

Wake and Light Therapy:
Participants will be helped to change the pattern of their sleep by depriving them of sleep for one night. On Day 1 they will be supported to stay up all night and the following day at the Hospital. They can go to bed by 5pm at their home on Day 2. They will need to get up by about 1am and return to the hospital to be supported to stay awake. They will then go to bed at 7pm on Day 3. They will be asked to sleep until 3am and then stay awake at home until bed at 9pm on Day 4. They will then get up by 5am on Day 5 and stay awake until 11pm to resume a normal sleep routine waking by 7am on Day 6. They will also be given a light box to use each morning. For the light box, they will be asked to sit about one foot away from a light box. They will be free to have breakfast, read or use a computer while facing towards the light. Treatment with a light box will last 30 minutes. They may continue to have treatment as usual.

Sleep and Light Therapy:
Participants will be given information and advice on how to get a good night's sleep. They will be

also given a light box to use in the morning for 1 week. For the light box, they will be asked to sit about one foot away from a light box. They will be free to have breakfast, read or use a computer while facing towards the light. Treatment with a light box will last 30 minutes when you get up. They may continue to have any treatment as usual (for example medication or talking therapies).

As part of the research, participants will need to complete various questionnaires and be seen by the research team after 1, 2, 4, 8 weeks and at 6 months after the treatment commences.

Intervention Type
Behavioural

Phase
Phase II

Primary outcome measure
Number of participants recruited per month/adherence to the protocol, measured during Week 1

Secondary outcome measures
1. Depressive symptom severity, assessed using Hamilton Depression Rating Scale – observer rated at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
2. Overall clinical impression, assessed using Clinical Global Impression and Improvement Scale (Guy, 1976) – observer rated at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
3. Subjective feelings of depression, assessed using Quick Inventory of Depressive Symptomatology - self rated version (Triveni et al, 2004) at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
4. Tendency to engage in ruminative thoughts, assessed using the Brief Ruminative Response Scale (Topper et al, 2014) – self rated at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
5. Sleep quality, assessed using the Pittsburgh Sleep Index (Bysse et al, 1999) – self rated at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
6. General health, assessed using Euroquol 5D (EQ5-D) (1990) – self rated at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
7. Amount of anti-depressant drugs (in mg of anti-depressant equivalents) (Hayasaka et al, 2015) or benzodiazepine drugs (in mg of diazepam equivalents) at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
8. Amount of Cognitive Behaviour Therapy or any other counselling or psychotherapy (number of hours) at baseline, 1, 2, 4, 8 weeks and 6 months post-randomisation
9. Total sleep time, measured using a daily sleep diary at 3 days pre-randomisation and 7 days post-randomisation
10. The credibility of the intervention and expectation of whether their mood will improve rapidly (Devilly, 2000), measured at baseline
11. Sleep/wake activity, measured with wrist actigraph from GeneActiv daily at 3 days pre-randomisation and 7 days post-randomisation
12. DSM-IV diagnoses, assessed using MINI International Neuropsychiatric Interview Version 5.0 – observer rated at baseline
13. Morning/evening preference, assessed using Morning and Evening Questionnaire – self rated at baseline

Overall study start date
08/01/2017

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Diagnosis of Depressive Episode (ICD10 F32) or Recurrent Depressive Disorder (F33)
2. Minimum score of 8 or more on the Hamilton Depression Rating Scale (6 item) (Range 0-22) (Bech,1981)
3. Age 18-65
4. Able to give informed consent
5. Women of child bearing age may be included and no methods of contraception is required to enable inclusion into the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
93

Key exclusion criteria
1. Current diagnosis of Seasonal Affective Disorder
2. Current diagnosis of anorexia nervosa or bulimia
3. Current diagnosis of an obsessive compulsive or related disorder
4. Current diagnosis of post-traumatic stress disorder
5. History of schizophrenia, schizoaffective disorder or bipolar disorder
6. Severe cognitive impairment, dementia, intellectual disability or organic brain disorder
7. History of stimulant or hallucinogenic misuse, alcohol or substance misuse or dependence in past 3 months
8. Borderline Personality Disorder or other personality disorder considered to be the main problem
9. Duration of depression more than 2 years
10. Significant risk of suicide that requires hospitalisation
11. Severe eye disease or cataracts or traumatic injury or visual impairment affecting both eyes
12. History of epilepsy, uncontrolled severe headaches, or stroke as this may lower seizure

threshold through sleep deprivation
13. Unstable medical condition that would make wake therapy intolerable
14. Untreated sleep disorder such as obstructive sleep apnoea or narcolepsy
15. Use of photo-sensitizing drugs
16. Current night-shift work
17. Non-English speaker

Date of first enrolment
08/01/2018

Date of final enrolment
22/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South London and Maudsley NHS Foundation Trust
Institute of Psychiatry, Psychology and Neuroscience
King's College London
16 De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
Joint R&D Office of South London and Maudsley NHS Foundation Trust
and Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
Box P005, Institute of Psychiatry, Psychology & Neuroscience (IoPPN)
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Sponsor type

University/education

ROR
https://ror.org/015803449

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King's Health Partners

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol with statistical analysis plan will be made available on request. Publications in peer-reviewed journals planned for 2019, approximately one year after the trial's completion. Results disseminated at national and international conferences in 2019.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Prof. David Veale (david.veale@kcl.ac.uk). Anonymised data (with consent from participants) will be shared with researchers from Universities and not the general public for secondary analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	24/11/2021	09/12/2021	Yes	No
HRA research summary		28/06/2023	No	No