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Sleep and cognition following digital cognitive behavioral therapy for insomnia (CBTi) - the SCOTIA study

Submission date
07/08/2019

Recruitment status
No longer recruiting

Registration date
08/08/2019

Overall study status
Completed

Last Edited
19/11/2021

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
Insomnia refers to frequent problems falling asleep and staying asleep. It affects about 10% of the population. People with insomnia also experience problems with cognitive function, such as poor concentration and memory. It is often the impact of poor nighttime sleep on daytime activities that leads people to seek help. We want to find out what effect a digital sleep improvement programme, called Cognitive Behavioural Therapy for insomnia (CBTi), has on sleep and cognitive functions (e.g. concentration, memory, emotion perception). CBTi involves changing thoughts and behaviours that maintain poor sleep. Using a digital CBTi programme called Sleepio™ we want to look at changes in sleep and cognitive function between people who receive the programme, versus those who do not. Participants will be allocated to the sleep treatment programme (group 1) or to a 'wait-list' (group 2). The wait-list group (group 2) will be given access to the sleep programme on study completion.

Who can participate?
Men and women aged 25 to 65 with poor sleep, who do not currently take medication for their sleep or mental health, are invited to take part in this study. Participants must have reliable access to the internet, be able to read and understand English, and are able to complete the study visits/procedures.

What does the study involve?
People who are interested in the study will be screened for suitability through
1. An online questionnaire;
2. A brief telephone interview with a member of the research team;
3. Monitoring of sleep using a diary and a wrist worn activity tracker; and
4. An overnight sleep recording in the sleep laboratory (called polysomnography).
Once eligibility for the study has been confirmed, participants will then attend another overnight sleep recording and complete a number of computerised tests and paper questionnaires. These are called baseline assessments. Following this overnight stay, participants will be assigned, by chance, to one of two treatment groups. These groups will be either (1) digital cognitive behavioral therapy (dCBT) or (2) a wait-list group (WLC). The dCBT will

be delivered through the programme, Sleepio™. The dCBT treatment involves 6 sessions, delivered weekly. Participants have 8 weeks to complete this. Both the dCBT and WLC groups will monitor their sleep over this period using sleep diaries and wrist worn activity trackers. At the end of the intervention period, participants will complete another overnight sleep recording and complete a number of computerized tests and paper questionnaires. Participants in the WLC group will then receive access to the dCBT programme.

What are the possible benefits and risks of participating?
All participants will receive free access to digital CBT treatment delivered by Sleepio™ and may, therefore, benefit from improved sleep. Furthermore, all participants who are interested in receiving a summary of the study findings will be sent a copy at the end of the study.
Participants will be reimbursed for their time via amazon vouchers (£100 in total) for completing specific phases of the study. The payment will be made at the end of participation in the study. If a participant is found to not be suitable for the study or decides to terminate the study early, they will be paid for the visits which they did attend.
There are no known serious side effects from taking part in this study, but any change in sleep patterns may be associated with a short-term increase in sleepiness. The sensors and electrodes for the PSG/EEG recordings are commonly used in sleep research and are non-invasive. They are temporarily attached to the skin of the participant using medical tape or a water-soluble paste. EEG is a procedure for measuring brain waves. It is harmless and painless and carries no significant risk to participants. EEG recording has been used safely for many years, and we are aware of no cases of adverse events however slight irritation and abrasion of skin can occur due to the cleaning and preparation required. The EEG equipment comes from certified suppliers of medical equipment, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-601).

Where is the study run from?
Sleep and Circadian Neuroscience institute, University of Oxford, UK

When is the study starting and how long is it expected to run for?
April 2018 to October 2020 (updated 13/04/2021, previously: April 2021)

Who is funding the study?
1. National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC)
2. Dr. Mortimer and Theresa Sackler Foundation
3. John Fell Fund, University of Oxford

Who is the main contact?
1. Dr Simon Kyle
simon.kyle@ndcn.ox.ac.uk
2. Dr Ximena Omlin
ximena.omlin@ndcn.ox.ac.uk
3. Dr Rachel Sharman
rachel.sharman@ndcn.ox.ac.uk
4. Prof. Colin Espie
colin.espie@ndcn.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Simon Kyle

ORCID ID
http://orcid.org/0000-0002-9581-5311

Contact details
Sleep and Circadian Neuroscience Institute
Sir William Dunn School of Pathology
South Parks Road
Oxford
United Kingdom
OX1 3RE
+44 (0)1865 618675
simon.kyle@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Ximena Omlin

ORCID ID
http://orcid.org/0000-0003-2508-9956

Contact details
Sleep and Circadian Neuroscience Institute
Sir William Dunn School of Pathology
South Parks Road
Oxford
United Kingdom
OX13RE
+44 (0)1865 618671
ximena.omlin@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Rachel Sharman

ORCID ID
http://orcid.org/0000-0002-1683-0477

Contact details
Sleep and Circadian Neuroscience Institute
Sir William Dunn School of Pathology
South Parks Road
Oxford
United Kingdom

OX1 3RE
+441865618665
rachel.sharman@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Prof Colin Espie

ORCID ID
http://orcid.org/0000-0002-1294-8734

Contact details
Sleep and Circadian Neuroscience Institute
Sir William Dunn School of Pathology
South Parks Road
Oxford
United Kingdom
OX13RE
+44(0)1865 618665
colin.espie@ndcn.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
R449862

Study information

Scientific Title
Sleep and COgnition following Therapy for Insomnia: A randomized controlled trial of digital cognitive behavioral therapy for insomnia (CBTi)

Acronym
SCOTIA

Study objectives
The primary hypotheses for the trial are:
1. Digital CBT will a) reduce insomnia severity at the end of treatment (week 10 post randomisation) relative to wait list control (WLC) and will b) increase objective sleep efficiency at the end of treatment (week 10 post randomisation) relative to WLC

Secondary hypotheses for the trial are:
2.1 Digital CBT will decrease objective sleep latency and improve sleep continuity at the end of treatment (week 10 post randomisation) relative to WLC
2.2 Digital CBT will improve objective sleep architecture (reduction of time spent in N1, increased time spent in N3, and reduction in sleep fragmentation) at the end of treatment (week 10 post randomisation) relative to WLC
2.3 Digital CBT will improve self-reported sleep continuity at the end of treatment (week 10 post randomisation) relative to WLC
2.4 Digital CBT will increase EEG delta power and slow wave activity at the end of treatment (week 10 post randomisation) relative to WLC
2.5 Digital CBT will reduce subjective and objective (cortical) arousal at the end of treatment (week 10 post randomisation) relative to WLC
2.6 Digital CBT will result in improvements in global sleep quality, cognitive impairment, fatigue, worry, rumination, emotion regulation, and sleep-related quality of life at the end of treatment (week 10 post randomisation) relative to WLC
2.7 Digital CBT will result in improvements in emotion processing (reduction in bias in emotion perception, memory and attention), overnight declarative memory consolidation and complex attention at the end of treatment (week 10 post randomisation) relative to WLC.
2.8 Digital CBT, relative to WLC, will decrease inter-daily stability of rest-activity rhythms and increase the relative amplitude of rest-activity rhythms (assessed during treatment phase)
2.9 Digital CBT, relative to WLC, will reduce objective-subjective sleep discrepancy during treatment phase and post-treatment
2.10 To compare CBT and WLC on self-reported adverse effects during treatment and at the end of treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/04/2017, The University of Oxford Central University Research Ethics Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD; 44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R49862

Study design
Single-centre parallel group interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Insomnia disorder

Interventions
Participants are block randomized (1:1) to one of two study arms. The sequence is generated using the website, www.sealedenvelope.com, and is stratified by sex (male/female) and age (25-44/45-65).

Treatment group (dCBT): Participants receive digital Cognitive Behavioural Therapy (dCBT) delivered via the Sleepio™ programme. This comprises of six weekly 15-20 sessions delivered by an animated virtual therapist. The Sleepio programme has been tested in multiple RCTs.

Control group (WLC): Participants are placed on a waiting list for 8 weeks.

During the 8-week period both groups record a sleep diary and wear an actigraph watch.

Intervention Type
Behavioural

Primary outcome measure
1. Insomnia severity will be measured through the Sleep Condition Indicator
2. Objective sleep efficiency will be measured with polysomnography (PSG) at baseline and post-treatment.

Secondary outcome measures
1. Objective sleep latency and sleep continuity will be measured through PSG and actigraphy (sleep onset latency, wake-time after sleep onset, and number of awakenings) at baseline and post-treatment.
2. Objective sleep architecture will be measured through PSG [duration in each sleep stage and sleep fragmentation (stage change index)] at baseline and post-treatment.
3. Subjective sleep continuity will be measured through a sleep diary (sleep onset latency, wake-time after sleep onset, number of awakenings, and sleep efficiency) at baseline and post-treatment.
4. Changes in EEG delta power and slow wave activity will be measured through whole night EEG spectral analysis (power in the delta frequency band and slow wave oscillation evaluations) at baseline and post-treatment.
5. Subjective and objective arousal will be measured through 1) questionnaires (Glasgow Content of Thoughts Inventory, the Sleep Interference Rating Scale and the Pre-Sleep Arousal Scale) and 2) pre/post sleep resting state EEG (assessed by EEG spectral power in the high frequency range) at baseline and post-treatment.
6. Global sleep quality (Pittsburgh Sleep Quality Index), cognitive impairment (British Columbia Cognitive Complaints Inventory), fatigue (Flinders Fatigue Scale), worry (Penn State Worry Questionnaire), rumination (Ruminative Responses Scale), emotion regulation (Difficulties in Emotion Regulation), and sleep-related quality of life (Glasgow Sleep Impact Index) will be measured at baseline and post-treatment.
7. Cognitive and emotional functioning will be measured using the Emotional Test Battery, word-pair memory task, and attention task at baseline and post treatment.
8. Inter-daily stability and relative amplitude of rest-activity rhythms (non-parametric circadian rhythm analysis) will be measured with actigraphy during treatment phase.
9. Objective-subjective sleep discrepancy will be computed from sleep diary and PSG for the laboratory nights (baseline and post treatment) and for sleep diary and actigraphy (baseline and

during treatment phase).
10. Self-reported adverse effects will be collected by questionnaire at mid-treatment and end of treatment

Overall study start date
01/06/2016

Completion date
23/10/2020

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 25-65 years
3. Screening positive for persistent insomnia disorder as indicated on the Sleep Condition Indicator
4. Average (over 7 nights) sleep onset latency of >30min and/or wake after sleep onset >30min (determined by actigraphy)
5. Typical sleep period takes place within the hours of 10pm – 9am
6. Can read and understand English
7. Regular access to the internet with a tablet, laptop or desktop computer
8. Normal or corrected to normal vision

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
60

Key exclusion criteria
Current exclusion criteria as of 10/03/2020:
1. Unstable physical or mental health problems that may explain sleep disturbance
2. Additional sleep disorders (e.g. sleep disordered breathing or periodic leg movements during sleep)
3. Habitual night shift, evening, or rotating shift-workers
4. Undergoing a psychological treatment programme for insomnia with a health professional
5. Central nervous system medications (including hypnotics)
6. Substance misuse
7. Pregnancy
8. Psychosis or epilepsies
9. A score within the clinical range for depression (>14) or anxiety (>14) on the Hospital Anxiety and Depression Questionnaire (HADS)
10. Learning disability

11. Skin allergies or very sensitive skin
12. Diagnosis of a neurological condition (e.g. epilepsy, stroke, multiple sclerosis)
13. Previously accessing a digital CBT sleep improvement programme

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Previous exclusion criteria as of 09/12/2019:
1. Unstable physical or mental health problems that may explain sleep disturbance
2. Additional sleep disorders (e.g. sleep disordered breathing or periodic leg movements during sleep)
3. Habitual night shift, evening, or rotating shift-workers
4. Undergoing a psychological treatment programme for insomnia with a health professional
5. Central nervous system medications (including hypnotics)
6. Substance misuse
7. Pregnancy
8. Psychosis or epilepsies
9. A score within the clinical range for depression (>10) or anxiety (>10) on the Hospital Anxiety and Depression Questionnaire (HADS)
10. Learning disability
11. Skin allergies or very sensitive skin
12. Diagnosis of a neurological condition (e.g. epilepsy, stroke, multiple sclerosis)
13. Previously accessing a digital CBT sleep improvement programme

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Previous exclusion criteria:
1. Unstable physical or mental health problems that may explain sleep disturbance
2. Additional sleep disorders (e.g. sleep disordered breathing or periodic leg movements during sleep)
3. Habitual night shift, evening, or rotating shift-workers
4. Undergoing a psychological treatment programme for insomnia with a health professional
5. Central nervous system medications (including hypnotics)
6. Substance misuse
7. Pregnancy
8. Psychosis or epilepsies
9. A score within the clinical range for depression (>7) or anxiety (>10) on the Hospital Anxiety and Depression Questionnaire (HADS)
10. Learning disability
11. Skin allergies or very sensitive skin
12. Diagnosis of a neurological condition (e.g. epilepsy, stroke, multiple sclerosis)
Added 21/08/2019:
13. Previously accessing a digital CBT sleep improvement programme

Date of first enrolment
01/04/2018

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sleep and Circadian Neuroscience institute, University of Oxford
Sir William Dunn School Of Pathology
South Parks Road
Oxford
United Kingdom
OX1 3RE

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services
University Offices
Wellington Square
Oxford
England
United Kingdom
OX22JD
+44 (0)1865 616577
ethics@medsci.ox.ac.uk

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC)

Funder Name
Dr. Mortimer and Theresa Sackler Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
John Fell Fund, University of Oxford

Alternative Name(s)
John Fell OUP Research Fund

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the results of this study, irrespective of magnitude or direction of effect, in peer-reviewed journals. Findings will also be presented at national and international scientific meetings. The results will be made available online wherever possible, if permitted by journal policies.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

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