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The Effects of Sleep Improvement on Emotion Regulation

Submission date	Recruitment status	[X] Prospectively registered
16/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/07/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Insomnia refers to persistent problems with falling asleep or staying asleep. Insomnia can have a significant effect on health and daily life. People with insomnia are at increased risk for depression, and the two disorders often occur together. Mood problems are a common complaint in insomnia patients, particularly difficulty managing emotions.
Digital Cognitive Behavioural Therapy for Insomnia (dCBTi) is a proven treatment for insomnia that is delivered to patients online, with 6 weekly, tailored sessions with a virtual animated therapist, online tools such as a sleep diary and audio help, and an online community of people also using the dCBTi.
The aim of this study is to test whether dCBTi is also effective in improving mood problems and depressive symptoms in patients who have symptoms of both depression and insomnia.

Who can participate?
People aged 25-65 who are currently experiencing both sleep difficulties and low mood.

What does the study involve?
We will provide participants with access to either a digital sleep improvement programme, which is completed over 6 weeks (sleep programme 1) or a website containing advice about how to improve sleep (sleep programme 2). We will randomly allocate paticipants to one of the two sleep programmes. At the end of the study (16 weeks) participants will be provided with access to the alternative sleep programme. All participants will complete a series of questionnaires, assessing sleep and mood, alongside computerised tasks at regular assessment points (0 weeks, 5 weeks, 10 weeks, 16 weeks).

What are the possible benefits and risks of participating?
Participants may benefit from improved sleep as a result of taking part, and contribute to research that may help to develop better treatments for people suffering from insomnia. There are no known risks to participants taking part in this study; however, involvement will involve answering questions about sensitive and potentially upsetting questions, and any changes in sleep pattern may be associated with a short-term increase in sleepiness.

Where is the study run from?
Sleep and Circadian Neurosciences Institute at the University of Oxford (UK)

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

Who is funding the study?
National Institute of Health Research (NIHR) Oxford Biomedical Research Centre (BRC) (UK)
Dr Mortimer and Theresa Sackler Foundation (UK)

Who is the main contact?
Matthew Reid
01865618656

Study website
https://ndcn.eu.qualtrics.com/jfe/form/SV_5t2PhfXYbLStSa9

Contact information

Type(s)
Scientific

Contact name
Mr Matthew Reid

Contact details
Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
Sir William Dunn School of Pathology
University of Oxford
South Parks Road
Oxford
OX1 3RE
United Kingdom
+44 (0)1865 618656
Oxford
United Kingdom
OX1 3RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R55815

Study information

Scientific Title
The Effects of SLEEP improvement on Emotion Regulation and processing: randomised controlled trial of digital CBT for insomnia versus sleep hygiene education in participants with comorbid insomnia and depression

Acronym
SLEEPER

Study objectives
Evidence suggests that sleep disturbance may be a causal factor in the development and maintenance of depressive symptoms. The aim of this study is to test whether a proven intervention for insomnia (dCBTi) is also effective in improving depressive symptoms in patients with comorbid depression and insomnia, and to further test the potentially causal relationship by assessing whether changes in emotion regulation mediate the change in these depressive outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Oxford Central University Research Ethics Committee, 28/03/2018, R55815

Study design
Interventional UK-based online randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
https://ndcn.eu.qualtrics.com/CP/File.php?F=F_efGPbO5GWTTIfIh

Health condition(s) or problem(s) studied
Insomnia

Interventions
This study will use stratified randomisation with an allocation ratio of 1:1 according to gender (Male, Female), age (25-44, 45-65) depression (PHQ-9 Scores: ≤19 : ≥20) and insomnia (ISI scores ≤19 : ≥20). On completion of baseline measures each subject will be randomly assigned by online software (ePRO system) to either digital Cognitive Behavioural Therapy for Insomnia (dCBT-I) via

Sleepio or Sleep Hygiene Education (SHE) delivered by a dedicated website. Participants will undergo treatment for 10 weeks, with a 6 week follow up period.

Intervention Type
Behavioural

Primary outcome measure
Depression severity assessed using the 9 item Patient Health Questionnaire (PHQ-9) after 10 weeks. This test will be completed online.

Secondary outcome measures
The following tests will be completed online:
1. Self-reported emotion regulation deficits, assessed using the Difficulty with Emotion Regulation Scale after 0 weeks, 5 weeks, 10 weeks and 16 weeks
2. Worry, assessed using the Penn State Worry Questionnaire after 0 weeks, 5 weeks, 10 weeks and 16 weeks
3. Rumination assessed using the Ruminative Response Scale after 0 weeks, 5 weeks, 10 weeks and 16 weeks
4. Perseverative thinking assessed using the Perseverative Thinking Questionnaire at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
5. Mediation effect of emotion regulation (DERS, PSWQ, RRS & PTQ scores) variables (dCBT-i over SHE) at week 5 on depressive symptoms (PHQ-9) at week 10
6. Objective biases in negative emotional processing assessed using the Facial Expression Recognition Task at 0 weeks, 5 weeks, 10 weeks, 16 weeks:
6.1. Accuracy and reaction times in response to sad facial expressions
6.2. Accuracy and reaction times in response to happy facial expressions
7. Mediation effect of emotion processing variables (FERT: Changes in recognition accuracy for happy and sad facial expressions) at week 5 on depressive symptoms (PHQ-9) at week 10.
8. Digit Symbol Substitution Task (DSST) performance (number of correctly matched digit-symbol pairs in 90 seconds) at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
9. Insomnia Severity Index (ISI Scores) at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
10. Total time in bed, sleep-onset latency, total sleep time, and sleep efficiency, assessed using Pittsburgh Sleep Quality Index items 1-4 (PSQI) at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
11. MEQ Scores a 0 weeks, 5 weeks, 10 weeks and 16 weeks
12. Anxiety Severity (GAD-7 Scores) at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
13. Mood instability at 0 weeks, 5 weeks, 10 weeks and 16 weeks.
14. Cognitive complaints (BC-CCI Scores) at 5 weeks, 10 weeks and 16 weeks.
15. Adverse events at 5 weeks and 10 weeks

Overall study start date
01/11/2017

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Aged 25-65
2. A positive screen for probable DSM-5 insomnia disorder using items from the Sleep Condition Indicator (SCI):

2.1. Scoring ≤2 on item 1 (sleep latency) or item 2 (wakefulness during the night)
2.2. Scoring ≤2 on item 3 (frequency of disturbance)
2.3. Scoring ≤1 on item 4 (sleep quality)
2.4. Scoring ≤2 on daytime functioning items 5 or 6
2.5. Scoring ≤2 on item 8 (chronicity of problem))
3. Endorsement of depressive symptoms in the probable "caseness" range (PHQ score ≥ 10)
4. Access to a laptop or desktop computer and reliable internet access either at home or work
5. Able to read and understand English
6. Currently living in the UK

Participant type(s)
Other

Age group
Adult

Sex
Not Specified

Target number of participants
200

Total final enrolment
344

Key exclusion criteria
1. Engaged in psychotherapy for insomnia or depression
2. Previous participation in online sleep treatments
3. Hypnotic, psychotropic or antiepileptic medications
4. Psychiatric comorbidities:
4.1. Psychosis
4.2. Bipolar disorder
5. Diagnosis of epilepsy or other neurological disorders
6. Diagnosis of mild cognitive impairment of dementia
7. Symptoms of a probable additional sleep disorder (e.g. possible obstructive sleep apnea, restless legs syndrome)
8. Serious physical health concerns necessitating surgery or with a survival prognosis of < 6 months
9. Habitual night shift, evening, or rotating shift-workers
10. Suicidal ideation with intent, history of recent suicide attempt (< 2 months)
11. Psychiatric hospital admission in the past month, or crisis team support within the past month
12. Alcohol misuses and dependency or recreational/illicit drug use

Date of first enrolment
19/07/2018

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sleep and Circadian Neuroscience Institute (SCNi)
Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
Sir William Dunn School of Pathology
University of Oxford
South Parks Road
Oxford
OX1 3RE
United Kingdom
+44 (0)1865 618656
SLEEPER@NDCN.OX.AC.UK
Oxford
United Kingdom
OX1 3RE

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services
University Offices
Wellington Square
Oxford
OX2 2JD
United Kingdom
Oxford
England
United Kingdom
OX2 2JD

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

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

Funder Name
Dr Mortimer and Theresa Sackler Foundation

Results and Publications

Publication and dissemination plan
The trialists will publish their primary findings in high-impact, peer reviewed journals. They will send trial participants a summary of study outcomes and present their findings at national (e.g. British Sleep Society), and international (e.g. SLEEP, World Sleep, European Sleep Research Society) conferences.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Simon Kyle (simon.kyle@ndcn.ox.ac.uk). Other data sharing details will become available when the study has all the required approvals in place.

IPD sharing plan summary
Available on request