ISRCTN17117237 https://doi.org/10.1186/ISRCTN17117237

Emotional processing in insomnia

Submission date
17/03/2021

Recruitment status
No longer recruiting

Registration date
23/03/2021

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Research suggests that disturbed sleep can cause people to experience low mood and may lead to feelings of depression. Studies have shown that improving sleep using digital cognitive behavioural therapy can improve depressive symptoms but how this change comes about is not clear. The main focus of the EPIC study is to investigate if digital cognitive therapy for sleep problems (CBT-I) can improve emotional processes, that are thought to underlie the development of depressive symptoms.

Who can participate?
Adults who report clinically-significant insomnia and depressive symptoms. Participants will have to live in the UK, have access to a computer, and be aged between 25 and 65 years.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants will receive either a digital CBT-I treatment or a control treatment with sleep hygiene advice for a 10-week period. Participants will be asked to complete online questionnaires and standardized tasks before the study begins (week 0), mid-treatment (week 5), and after treatment (week 10) to measure emotional functions. All contact with participants will be online and through phone calls (before the study begins and after 2 weeks).

What are the possible benefits and risks of participating?
Participants may benefit from improved sleep from taking part in this study and will be provided with evidence-based treatment for insomnia. Participants will also be reimbursed for participating in the week 5 and week 10 assessments.

There are no risks associated with taking part in the study anticipated. However, involvement in the study will involve answering questions about sensitive and potentially upsetting topics. Changes to sleep patterns, as part of the treatment, may also be associated with a short-term increase in sleepiness.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
From January 2020 to April 2022

Who is funding the study?
The Biomedical Research Centre Oxford (UK) and The Swedish Brain Foundation (Sweden)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number

EPIC01

Study information

Scientific Title
Emotional Processing in Insomnia Co-occurring with low mood (EPIC)

Acronym
EPIC

Study objectives
Primary hypothesis:
1. Digital cognitive therapy for insomnia (dCBT-I) will improve objective biases in negative emotional processing of faces relative to Sleep Hygiene Education (SHE) (5 and 10 weeks post-randomisation), reflected in:
1.1. Reduced recognition accuracy in response to sad facial expressions in the Facial Emotional Recognition Task (FERT)
1.2. Increased recognition accuracy in response to happy facial expressions in the FERT

Secondary hypotheses:
1. dCBT-I will improve objective negative biases in categorisation of emotional self-descriptors (5 and 10 weeks post-randomisation) relative to SHE, reflected in decreased reaction time to identify positive compared with negative characteristics in Emotional Categorisation Task (ECAT)
2. dCBT-I will increase positive emotional memory bias relative to SHE (10 weeks post-randomisation), reflected in increased memory for positive compared with negative words in the Emotional Memory Task (EMEM)
3. dCBT-I will reduce self-reported emotion regulation deficits (Difficulty with Emotion Regulation Scale, DERS), worry (Penn State Worry Questionnaire, PSWQ), and perseverative thinking (Perseverative Thinking Questionnaire, PTQ) (5 and 10 weeks post-randomisation) relative to SHE
4. dCBT-I will reduce self-reported depression severity (Patient Health Questionnaire, PHQ-9) (5 and 10 weeks post-randomisation) relative to SHE
5. dCBT-I will reduce insomnia severity (Insomnia Severity Index, ISI) (5 and 10 weeks post-randomisation) relative to SHE
6. Change in emotional perception of faces (FERT: Changes in recognition accuracy for happy and sad facial expressions) at week 5 will mediate change in depressive symptoms (PHQ-9) at week 10
7. Change in emotion processing (ECAT: reaction times for positive compared with negative words) at week 5 will mediate change in depressive symptoms (PHQ-9) at week 10
8. Change in self-rated emotion regulation, worry, and preservative thinking (reductions in DERS, PSWQ, and PTQ scores) at week 5 will mediate the effect of dCBT-i over SHE on depressive symptoms (PHQ-9) at week 10
9. dCBT-I will advance midpoint of sleep period on work-free days, sleep corrected, (MSF SC, Munich ChronoType Questionnaire, MCTQ) (10 weeks post-randomisation) relative to SHE
10. dCBT-I will reduce social jetlag (SJL, Munich ChronoType Questionnaire, MCTQ) (10 weeks post-randomisation) relative to SHE
11. dCBT-I will increase positive affect (Positive and Negative Affect Schedule Short Form - Positive affect, PANAS-SF: PA) and reduce negative affect (Positive and Negative Affect Schedule Short Form - Negative affect, PANAS-SF: NA) (5 and 10 weeks post-randomisation)

relative to SHE
12. Change in mood (PANAS-SF: PA and NA) at week 5 will mediate change in depressive symptoms (Patient Health Questionnaire, PHQ-9) at week 10

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2020, amendment approved 10/02/2021, The Medical Sciences Interdivisional Research Ethics Committee (MS IDREC) (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: R72715/RE001, amendment ref: R72715/RE002

Primary study design
Interventional

Study design
Parallel-group superiority randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Investigating emotional processing in patients with insomnia co-occurring with low mood.

Interventions
This study will use stratified randomisation with an allocation ratio of 1:1 to either digital cognitive behavioural therapy for insomnia (dCBT-I) or Sleep Hygiene Education (SHE). Randomisation will be conducted by the ePRO system with stratification according to sex (male, female), age (25-44, 45-65), depression severity (PHQ-9 scores: ≤15, ≥16) and insomnia severity (ISI scores ≤19, ≥20).

dCBT-I will be delivered using the Sleepio® programme (www.sleepio.com and associated Sleepio® app).

Sleep hygiene education (SHE) will be provided to those in the control group as a minimal treatment control and delivered via a dedicated webpage.

Participants will be assessed at baseline and 5 and 10 weeks post-randomisation. The primary outcome will be assessed using the Facial Expression Recognition Task (FERT). Faces with seven different expressions (happiness, fear, anger, disgust, sadness, surprise, neutral) are displayed on a screen and participants are required to indicate the expression on the face by selecting a corresponding button. The task takes approximately 15-20 min to complete and assesses the following dependent variables: Emotion Accuracy, Emotion Misclassifications, and Emotion Reaction time. Emotion Accuracy for sad and happy faces is the primary variable of interest, but accuracy, misclassification, and reaction times will be reported for all expressions.

Intervention Type
Behavioural

Primary outcome(s)

1. Emotion accuracy, emotion misclassifications, and emotion reaction time measured using the Facial Expression Recognition Task (FERT) at baseline, 5 and 10 weeks

Key secondary outcome(s)
1. Self-reported emotion regulation measured using the Difficulties in Emotion Regulation Scale (DERS), the Penn State Worry Questionnaire (PSWQ), and the Perseverative Thinking Questionnaire (PTQ) at baseline, 5 and 10 weeks
2. Mood instability measured using one item (self-rated) from the Structured Clinical Interview for DSM-IV at baseline, 5 and 10 weeks
3. Insomnia symptoms measured using the Insomnia Severity Index (ISI) and supplemented with four items from the Pittsburgh Sleep Quality Index (PSQI) at baseline, 5 and 10 weeks
4. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 5 and 10 weeks
5. Chronotype measured using the Munich Chronotype Questionnaire (MCTQ) at baseline, 5 and 10 weeks
6 Positive and Negative Affect measured using the Positive and Negative Affect Schedule – Short Form (PANAS-SF) at baseline, 5 and 10 weeks
7. Emotional bias for words measured using the Emotional Categorisation Task (ECAT) at baseline, 5 and 10 weeks
8. Emotional memory measured using the Emotion Recognition Memory Task (EMEM) at baseline, 5 and 10 weeks
9. Engagement with mental health services and sleep medication measured using the following three questions: " Since your last study assessment, have you taken any medication for your sleep problems?" (Yes/No), "Since your last study assessment, have you undergone any additional psychological therapies for your sleep problems?" (Yes/No), and "Since your last study assessment, have you received treatment for your mental health, for example, medication, counselling, or other psychological therapies?" (Yes: Psychological Therapies/Yes: Medication /Yes: Counselling/Yes: A combination of the above/No) at baseline, 5 and 10 weeks
10. Device use measured using Device Monitoring Questions (as control variables) at 5 and 10 weeks

Completion date
11/04/2022

Eligibility

Key inclusion criteria
1. Positive screen for probable DSM-5 insomnia disorder using the following items from the Sleep Condition Indicator (SCI):
1.1. Scoring ≤2 on item 1 (sleep latency) or item 2 (wakefulness during the night)
1.2. Scoring ≤2 on item 3 (frequency of disturbance)
1.3. Scoring ≤1 on item 4 (sleep quality)
1.4. Scoring ≤2 on daytime functioning items 5 or 6
1.5. Scoring ≤2 on item 8 (chronicity of problem)
2. Endorsement of depressive symptoms in the probable “caseness” range (PHQ score ≥10)
3. Aged 25-65 years
4. Access to a laptop or desktop computer and a phone and reliable internet access either at home or work
5. Being able to read and understand English
6. Currently living in the UK

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
211

Key exclusion criteria
1. Engaged in psychotherapy for insomnia or depression
2. Previous participation in online (or face to face) sleep treatments
3. Hypnotic, psychotropic, or antiepileptic medications
4. Psychiatric comorbidities of psychosis or bipolar disorder
5. Diagnosis of epilepsy or other neurological disorder
6. Diagnoses of mild cognitive impairment or 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 (assessed during last month)
10. Suicidal thoughts (Score >1 “yes” on C-SSRS suicide item 2), history of recent suicide attempt (<12 months)
11. Psychiatric hospital admission in the past year, or crisis team support within the past year
12. Alcohol misuse & dependency or recreational/illicit drug use

Date of first enrolment
01/04/2021

Date of final enrolment
24/01/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sleep and Circadian Neuroscience Institute (SCNi)
Nuffield Department of Clinical Neurosciences
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
Hjärnfonden

Alternative Name(s)
Swedish Brain Foundation, Brain Foundation

Funding Body Type
Private sector organisation

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

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/02/2025	28/02/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes