

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

<b>Submission date</b> 07/08/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/11/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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](http://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(s)**

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.

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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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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**

United Kingdom

England

**Study participating centre**

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# Sponsor information

## Organisation

University of Oxford

## 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**

**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