

The Oxford Access for Students Improving Sleep (OASIS) study

Submission date 15/01/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 29/01/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/09/2017	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Sleep is a common problem: around a third of the general population experience symptoms of insomnia. There is increasing recognition that poor sleep impacts on emotional wellbeing. This study investigates the role of sleep in emotional wellbeing. Students with sleep problems receive access to an evidence-based digital Cognitive Behaviour Therapy (CBT) sleep improvement programme for insomnia. CBT is a talking therapy that can help people manage their problems by changing the way they think and behave. This CBT treatment for insomnia should improve the sleep in the students. This study also tests the impact this has on mistrust of others, unusual perceptual experiences, anxiety, depression, elevated mood, nightmares and psychological well-being. The prediction is that treating sleep problems will improve these measures.

Who can participate?

Students aged 18 and over who experience symptoms of insomnia

What does the study involve?

Participants are randomly allocated to receive either an evidence-based sleep improvement programme (online CBT therapy for insomnia) or continue as usual. Participants complete a range of online assessments to measure insomnia, mistrust of others, unusual perceptual experiences, mood, nightmares, day to day functioning, and emotional wellbeing. At the end of the study, the group who did not receive the sleep help are also offered the full sleep improvement programme.

What are the possible benefits and risks of participating?

All participants are offered the sleep improvement programme, whether immediately or delayed.

No risks are expected for participants. The sleep improvement programme has already been shown to have a positive effect on sleep, and similar benefits are likely for participants.

Where is the study run from?

The running of the study is automated (delivered entirely online), allowing a large number of students to take part. The study is run by the University of Oxford, but students are recruited from several universities throughout the UK.

When is the study starting and how long is it expected to run for?

December 2013 to March 2017

Who is funding the study?

Wellcome Trust strategic grant awarded to the Sleep and Circadian Neuroscience Institute (SCNi), University of Oxford (UK)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

A randomised controlled trial testing the effects of cognitive behavioural therapy for insomnia on the mental health of university students

Acronym

OASIS

Study objectives

The primary hypotheses for the trial are:

1. Cognitive Behavioural Therapy for insomnia (CBTi) will reduce insomnia by the end of treatment.
2. CBTi will reduce psychotic-like experiences (paranoia and hallucinations) by the end of

treatment.

3. Changes in insomnia will mediate the changes in psychotic-like experiences.

The secondary hypotheses are:

1. CBTi will reduce levels of depression, anxiety, nightmares, and mania by the end of treatment.
2. CBTi will improve psychological well-being by the end of treatment.
3. The effects of CBTi will be maintained at follow-up.
4. CBTi will lead to the occurrence of fewer mental health disorders (ultra-high risk for psychosis, bipolar affective disorder, depression, anxiety, treatment by mental health services) during the period of the trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Sciences Division Interdisciplinary Research Ethics committee (MSD-IDREC), 29/10/2014,
Reference: MSD-IDREC-C2-2014-034

Primary study design

Interventional

Study design

Multicentre randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Insomnia in university students

Interventions

The treatment arm will receive digital Cognitive Behavioural Therapy for insomnia (in addition to treatment as usual). The control arm will continue with treatment as usual. Participants will not be recruited from clinical services, therefore most people will not be receiving any help for their sleep difficulties. The control group will be offered the full intervention at the end of the trial (22 weeks) as an ethical consideration.

Intervention Type

Behavioural

Primary outcome(s)

1. The Sleep Condition Indicator (SCI) will be used as the primary sleep outcome measure. It will be administered at weeks 0, 3, 10 and 22. Week 10 will be the primary endpoint
2. The Green Paranoid Thoughts Scale (GPTS) and the hallucinations subscale of the Specific Psychotic Experiences Questionnaire (SPEQ) will be administered at weeks 0, 3, 10 and 22. Both of these measures will be primary measures to assess sub-clinical levels of mistrust of others (paranoia) and abnormal perceptual experiences (hallucinatory experiences) which are common in the general population. Week 10 will be the primary endpoint

Key secondary outcome(s)

1. Depression, measured using the Patient Health Questionnaire 9-item version at weeks 0, 10, and 22 and 2-item version at week 3
2. Anxiety, measured using the Generalised Anxiety Disorder Questionnaire 7-item version at weeks 0, 10, and 22 and 2-item version at week 3
3. Mania, measured using the Altman mania scale at weeks 0, 3, 10 and 22
4. Nightmare severity, measured using the Disturbing Dream and Nightmare Severity Index at weeks 0, 10 and 22
5. Emotional wellbeing, measured using the Warwick-Edinburgh Mental Wellbeing scale at weeks 0, 10 and 22
6. Ultra high risk for psychosis, measured using the Prodromal Questionnaire at weeks 0, 10 and 22
7. Use of services for mental health problems

Completion date

01/03/2017

Eligibility

Key inclusion criteria

1. Students (undergraduate, post-graduate or other) screening positive for probable insomnia disorder, using the sleep condition indicator questionnaire (Espie et al., 2014)
2. All participants must be aged 18 or older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Under age 18

Date of first enrolment

01/03/2015

Date of final enrolment

01/03/2017

Locations

Countries of recruitment

United Kingdom

Study participating centre

University of Oxford

OX1 2JD

Study participating centre

Other UK universities - to be confirmed

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Sponsor information

Organisation

Medical Sciences Inter-Divisional Research Ethics Committee, University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

This study is supported by a Wellcome Trust Strategic Award (098461/Z/12/Z) to the Oxford Sleep and Circadian Neuroscience Institute (SCNi)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	01/10/2017	Yes	No
Protocol article	protocol	28/05/2015	Yes	No