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The Oxford Access for Students Improving Sleep (OASIS) study

Submission date
15/01/2015

Recruitment status
No longer recruiting

Registration date
29/01/2015

Overall study status
Completed

Last Edited
12/09/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Multicentre 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
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2013

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2614

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

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Sponsor type
University/education

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

Publication and dissemination plan
The trialists intend to submit an outcome paper to a peer reviewed journal within six months of data collection being complete (estimated 01/09/2017).

Intention to publish date
31/12/2017

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?
Protocol article	protocol	28/05/2015		Yes	No
Results article	results	01/10/2017		Yes	No