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Testing the efficacy of an early intervention for acute insomnia

Submission date
16/05/2014

Recruitment status
No longer recruiting

Registration date
28/05/2014

Overall study status
Completed

Last Edited
08/01/2015

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Acute insomnia, defined as a period of poor sleep between two weeks and three months, is a significant public health concern affecting millions of people worldwide each year. Despite considerable evidence that Cognitive Behavioural Therapy for Insomnia (CBT-I) works for people with chronic insomnia (persistent poor sleep for more than three months), it is not known whether it can also help people with acute insomnia. This study will examine whether a single session of CBT-I, with an accompanying self-help pamphlet, could prevent people with acute insomnia developing chronic insomnia.

Who can participate?
We are looking for adults who are at least 18 years of age and have acute insomnia.

What does the study involve?
There are two main stages to the study. In the first stage we examine whether the pamphlet alone does what we intend for it to do and how acceptable it is to people with acute insomnia. In the second stage we are going to do a trial of the single session of CBT-I with the pamphlet against no treatment to see how many people are successfully treated for insomnia in the treated group compared to the non treatment group. We will randomly assign people to the treatment group or the non-treatment group (control group) and will participants to monitor their sleep (with a sleep diary and a questionnaire) for a short amount of time. We will give those in the treatment group their session of CBT-I and the pamphlet. We will then ask people in both groups to complete a sleep diary and questionnaire again a month after the treatment. We will offer people in both groups further sessions of CBT-I should they wish on completion of the study.

What are the possible benefits and risks of participating?
The potential benefits of taking part are that participants will get a good understanding of their insomnia and, if successful, may see a reduction their symptoms. Additionally, at the end of the trial all individuals that take part will be offered a full course of Cognitive Behavioural Therapy for Insomnia. There are no known risks associated with participating in this study.

Where is the study run from?
Northumbria Centre for Sleep Research, Northumbria University, Newcastle-Upon-Tyne, UK

When is the study starting and how long is it expected to run for?
From start of June 2014 to end of May 2015

Who is funding the study?
Northumbria University, UK

Who is the main contact?
Professor Jason Ellis.
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RE-HLS-13-131030-527127509a78c

Study information

Scientific Title
Evaluating the effectiveness and efficacy of abbreviated cognitive behavioural therapy for insomnia within the context of acute insomnia

Study objectives
An abbreviated form of Cognitive Behavioural Therapy for Insomnia (CBT-I) which entails a single 60-70 minute session, with an accompanying booklet, would result in significantly higher levels of remission, as defined by follow-up caseness scores on the Insomnia Severity Index (ISI), compared to controls. The secondary hypotheses were that there would be significant reductions in insomnia symptoms, as measured through sleep diaries, for those in the treatment group compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northumbria University's Faculty of Health and Life Sciences ethics committee,19/11/2013, refs. RE24-06-12986 and RE-HLS-13-131030-527127509a78c

Study design
A pragmatic parallel group randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
A single session of cognitive behavioural therapy for insomnia (60-70 minutes) and an accompanying information pamphlet.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change scores from baseline to follow-up on the Insomnia Severity Index and numbers of individuals no longer meeting caseness for insomnia following the trial. The latter has been defined as scoring less than 11 on the Insomnia Severity Index (Morin et al, 2011).

Key secondary outcome(s))
Change scores from baseline to follow-up on self-reported sleep parameters (sleep onset latency, total sleep time, wake after sleep onset, time in bed, sleep efficiency and number of awakenings) and perceived arousal (cognitive and somatic).

Completion date
31/05/2015

Eligibility

Key inclusion criteria
A current diagnosis of acute insomnia (i.e. meeting criteria for the Diagnostic and Statistical Manual of Mental Disorders Fifth edition's - DSM-5 definition of Insomnia Disorder but lasting between two weeks and three months). The DSM-5 suggests there should be a problem getting to sleep, staying asleep or waking earlier than needed or wanted in the morning and this problem should occur at least three times a week and exist despite adequate opportunity for

sleep. Further, there should be at least one form of daytime dysfunction reported as a result of the poor sleep.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Over 65 or Under 18 years of age
2. An uncontrolled illness
3. Currently on sleep medication
4. A history or current diagnosis of sleep aponea, a parasomnia, or bi-polar disorder
5. Previous exposure to Cognitive Behaviour Therapy for Insomnia

Date of first enrolment
01/06/2014

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
407/408 Northumberland Building
Newcastle
United Kingdom
NE1 8ST

Sponsor information

Organisation
Northumbria University (UK)

ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
University/education

Funder Name
Northumbria University (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes