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Examining the efficacy of attentional bias re-training in reducing pre-sleep cognitive arousal and insomnia symptoms

Submission date
14/05/2018

Registration date
05/06/2018

Last Edited
29/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with insomnia display a tendency to show increased attention towards cues which are related to sleep (i.e. sleep-related cues). These can be internal in nature (e.g. bodily sensations whilst trying to sleep) or external (checking the clock/time whilst trying to fall asleep). This behaviour in turn leads people with insomnia to feel more anxious about sleep and can actually make the sleep disturbance worse. This study aims to use a computer-based task delivered online (i.e. attentional bias modification) to train such attention away from sleep-related cues.

Who can participate?
Adults with insomnia

What does the study involve?
Participants are randomly allocated to either online attentional bias modification training, or to a standard online attentional bias task (non-treatment). All participants allocated to the non-treatment are offered the attentional bias modification training once the study is complete. The total duration of treatment is 9 days, with follow-up on the 9th and the 16th day (one week after treatment is complete).

What are the possible benefits and risks of participating?
This study has the potential benefit of reducing symptoms of insomnia and the amount of time it takes to fall asleep. No major risks are anticipated with participation in this study. Whilst the experimental computer based task is relatively short, some may find this uncomfortable (e.g. experience of eye strain) due to its repetitive nature.

Where is the study run from?
Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?
May 2018 to February 2019

Who is funding the study?
Sheffield Hallam University (UK)

Who is the main contact?
Dr Umair Akram
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Contact information

Type(s)
Scientific

Contact name
Dr Umair Akram

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ER5451619

Study information

Scientific Title
A randomised controlled trial to examine the therapeutic potential of attentional bias modification training for insomnia

Acronym
N/A

Study objectives
This study will examine the efficacy of using attentional bias modification to reduce symptom severity, pre-sleep arousal and sleep onset latency in insomnia. As research in this area is limited,

with the evidence based mixed, the trialists offer no a priori hypothesis. Despite the lack of hypothesis, this exploratory study could show therapeutic potential of attentional bias modification for insomnia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sheffield Hallam University Research Ethics Committee, 19/04/2018, ref: ER5451619

Study design
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 disorder

Interventions
This study will use a simple randomisation with an allocation ratio of 1:1 which will be carried out by the automated online system. Participants will be randomised to an online attentional bias modification training condition, or to a standard attentional bias task (non-treatment) control condition. Both conditions will be delivered online by a web platform. All participants allocated to the non-treatment control group will be offered ABM training once the study is complete.

Total duration of treatment: 9 days, with follow-up 1 being on the 9th day, follow-up 2 on the 16th (one week after experimental protocol is complete).

Intervention Type
Other

Primary outcome measure
Primary outcome measure as of 25/09/2018:
1. Sleep-related attentional bias (i.e. vigilance, disengagement) assessed using a dot-probe task consisting of sleep-negative and neutral words at baseline (day1) and then again on day 9
2. Insomnia severity measured by the Insomnia Severity Index at baseline (day 1), on completion of experimental protocol (day 9), and on day 16

3. Sleep onset latency measured by a sleep diary at baseline (day 1) and on completion of experimental protocol (day 9)
4. Pre-sleep cognitive arousal measured by the Pre-Sleep Cognitive Arousal Scale prior to sleep on days where the experiment will be administered (days 3-7)

Previous primary outcome measure:
1. Sleep-related attentional bias (i.e. vigilance, disengagement) assessed using a dot-probe task consisting of sleep-negative and neutral words at baseline (day1) and then again on day 9
2. Insomnia severity measured by the Insomnia Severity Index at baseline (day 1), on completion of experimental protocol (day 9), and on day 16
3. Sleep onset latency measured by a sleep diary at baseline (day 1) and on completion of experimental protocol (day 9)
4. Pre-sleep cognitive arousal measured by the Pre-Sleep Cognitive Arousal Scale prior to sleep on days where the experiment will be administered (day 3, 5 and 7)

Secondary outcome measures
Safety and monitoring behavior, assessed using the SAMI at baseline (day 1), 9 and 16

Overall study start date
10/05/2018

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Adult members from the general population who meet the DSM-5 criteria for Insomnia Disorder
2. Dissatisfaction with sleep characterized by either a difficulty initiating or maintaining sleep or early morning awakenings
3. Insomnia should be present for three or more nights per week, for at least three months, and cause significant daytime impairment
4. These conditions must be met despite an adequate opportunity to sleep

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Symptoms of a sleep/wake disorder other than insomnia
2. Existing psychiatric illness

3. Central nervous system disorder
4. Use of medication that may affect sleep
5. Prior head injury
6. Current shift-work

Date of first enrolment
10/05/2018

Date of final enrolment
05/02/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Hallam University
Sheffield
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s10 2bp

Sponsor information

Organisation
Sheffield Hallam University

Sponsor details
Department of Psychology, Sociology and Politics
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Sponsor type
University/education

ROR
https://ror.org/019wt1929

Funder(s)

Funder type
University/education

Funder Name
Sheffield Hallam University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Protocol to be submitted with all additional information to the Journal Trials following registration. Planned publication of the study results in a high-impact peer reviewed journal approximately six months following completion of data collection.

Intention to publish date
02/08/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Umair Akram (u.akram@shu.ac.uk, u.akram@outlook.com). Data will become available after publication of the final outcomes. This will be in the form of raw data scores for each participant. Participant demographics will be available, however no identifying information will be provided.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/10/2018		Yes	No