ISRCTN18384206 https://doi.org/10.1186/ISRCTN18384206

The relationship between insomnia, negative affect, and paranoia

Submission date
09/08/2016

Recruitment status
No longer recruiting

Registration date
11/08/2016

Overall study status
Completed

Last Edited
30/01/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Sleep problems and mental health complaints go hand-in-hand, with sleeping problems associated with many, if not all, mental health problems. This association is particularly apparent between insomnia (problems falling to sleep and staying asleep) and feelings of paranoia (when a person believes that harm is occurring, or is going to occur, to him or her, and that the persecutor has the intention to cause harm). Indeed, both sleeping problems and paranoid thinking are relatively common in both those with a clinical diagnosis and in the general population. This association raises an intriguing possibility that the present study aims to explore: can interventions for insomnia lead to improvements in paranoia? To answer this question, the aim of this study is to test the impact of a self-help intervention designed to improve insomnia on paranoia and associated experiences such as depression, stress and anxiety. The prediction is that by improving insomnia and helping people sleep better, they will also experience less paranoia alongside reduced feelings of depression, stress and anxiety.

Who can participate?
Anyone over the age of 18

What does the study involve?
Participants are randomly allocated to one of three groups: the intervention group, a sleep diary group, and a waiting list group. Participants in the intervention group are asked to log into the intervention website and follow the instructions presented to them. They complete six modules over 6 weeks, each offering information and practical exercises to help them to sleep better. These participants are also asked to complete a daily sleep diary to record the times that they go to bed and get up each day, the number of times that they wake each night, how they feel in the morning (ranging from 1 – 'very tired' to 5 – 'very refreshed'), and their caffeine consumption. Participants who complete the daily sleep diary can access their responses on the intervention website in a section called 'Sleep Stats'. Here their responses are displayed using graphs, tables and charts so that participants can track their progress throughout the study. Participants in the sleep diary group complete the same sleep dairy for 6 weeks, but do not have access to any other aspect of the intervention. Participants in the waiting list group receive no intervention in the first instance so that we can compare the effects of the intervention to doing nothing at all. However, after the study has finished, participants in the waiting list group are offered access to

the full intervention. Levels of insomnia, paranoia, depression, stress and anxiety are measured before the intervention started, immediately after the intervention, and 4- and 18-weeks after the intervention.

What are the possible benefits and risks of participating?
Participants benefit from receiving an online insomnia intervention for free, which may help them to improve their sleep and access information about their sleep. Participants also benefit from contributing to research that may help patients in the future. There are no risks involved in this study.

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

When is the study starting and how long is it expected to run for?
April 2014 to August 2015

Who is funding the study?
Investigator funded

Who is the main contact?
Dr Alexander Scott

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

The relationship between insomnia, negative affect, and paranoia: a parallel-group randomised controlled trial

Study objectives
An online, cognitive behavioural therapy based intervention for insomnia will lead to reductions in negative affect and paranoia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee in the Department of Psychology at the University of Sheffield, 15/01/2014

Study design
Parallel-group randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia, paranoia, negative affect

Interventions
Participants are randomised into three groups: the intervention group; a group who completed only a daily sleep diary (active control); and a wait-list control group who received nothing. All participants in each group were in the trial for a total of 24 weeks (6 week intervention delivery period followed by follow-up points at 4-weeks and 18-weeks post intervention)

The intervention group received the full, 6-week CBT intervention designed to target factors that contribute to the formation and maintenance of insomnia, adapted from that developed by Lancee, van den Bout, van Straten and Spoormaker (2012). The intervention was self-administered via a website (i.e., did not involve any contact with the researchers) and provided psychoeducational materials detailing good sleep hygiene practices and information about sleep, as well as exercises based on the principles of CBT that aimed to challenge common misconceptions and maladaptive thought processes about sleep. Participants in this group also completed a daily sleep diary documenting how they slept the previous night. The diary asked them to record the times that they went to bed and got up each day, the number of times that they woke each night, how they felt in the morning (ranging from 1 – 'very tired' to 5 – 'very refreshed') and caffeine consumption. Participants who completed the daily sleep diary were able to access their responses on the intervention website in a section called 'Sleep Stats'. Here their responses were collated and visualised (e.g., using graphs, tables, charts etc.) so that participants could track their progress throughout the trial.

The sleep diary group completed only the sleep diary aspect of the intervention described above. They did not have access to sleep hygiene information or the CBT content.

The wait-list control group received no intervention whatsoever (however they were offered access to the full intervention after the final follow-up point).

Intervention Type
Behavioural

Primary outcome(s)
Sleep-50 insomnia sub-scale: assessing aspects of insomnia (both falling asleep and staying asleep)

Each of the outcome measures were completed by all participants before the intervention started (baseline), immediately after the intervention (post-intervention), 4-weeks after the intervention and finally 18 weeks after the intervention

Key secondary outcome(s))
1. Depression, Anxiety, and Stress Scale-21 (DASS-21): the shortened form of DASS-21 assessing feelings of depression, anxiety and stress, collectively referred to as negative affect
2. Green Paranoid Thoughts Scale part B (GPTS-B): measuring levels of paranoid thinking

Each of the outcome measures were completed by all participants before the intervention started (baseline), immediately after the intervention (post-intervention), 4-weeks after the intervention and finally 18 weeks after the intervention

Completion date
17/08/2015

Eligibility

Key inclusion criteria
Participants must be over the age of 18

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
348

Key exclusion criteria

1. Under the age of 18
2. Insomnia due to a physical complaint (e.g. back pain)
3. On medication for a mental health problem or sleep complaint
4. Currently receiving psychological therapy

Date of first enrolment
11/04/2014

Date of final enrolment
20/02/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Sheffield
United Kingdom
S10 2TP

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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?
Results article	results	19/10/2017	30/01/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes