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Testing an early online intervention for the treatment of disturbed sleep during the COVID-19 pandemic

Submission date
01/04/2020

Recruitment status
No longer recruiting

Registration date
08/04/2020

Overall study status
Completed

Last Edited
13/05/2024

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
Stressful life events can cause a short-term disruption to sleep. This can cause people to try and compensate for the sleep disruption. For example, people might then spend too long in bed, or become preoccupied with the daytime consequences of this poor or disturbed sleep. Over time, we know that this can create long-term sleep problem such as insomnia.
Previous research studies have shown that stressful major events, in the form of natural disasters such as earthquakes, can disrupt sleep. The ongoing COVID-19 (coronavirus) pandemic might therefore cause people to develop sleep problems. However, by intervening early, we think that short-term sleep disruption can be stopped. This is likely to prevent short-term sleep disruption from becoming a long-term problem.
The aim of this study is to use an online treatment, in the form of sleep education, to try and treat short-term sleep problems in people who have recently reported having poor sleep, particularly as a result of the ongoing COVID-19 pandemic. This involves being provided with an online version of a leaflet which suggests ways in which people can change their behaviour to avoid poor sleep from becoming a problem. We have previously used a version of this leaflet with people who have long-term sleep problems (insomnia) and it has been effective.
We are also looking for people who do not have sleep problems to take part in this study because we want to understand if this intervention can prevent sleep problems from happening in the first place. We also need people who do not have sleep problems to take part so that we can measure whether or not the treatment is effective for people who do have sleep problems. We also want to understand if the intervention is effective in the short-term, and long-term, by following participants up 1 week, 1 month and 3 months after receiving the treatment.

Who can participate?
Adults over 18 years, who are having problems sleeping, or who are good sleepers.

What does the study involve?
This study will be conducted entirely online (https://nupsych.qualtrics.com/jfe/form/SV_blyyHjB71JWEa9f) and participants will not need to visit Northumbria University at any point.

The first part of the study involves completing some questionnaires about sleep habits and sleep quality, stress levels and general mood. Participants will also be asked some questions in relationto the ongoing COVID-19 pandemic, and brief questions about health and employment. This will take approximately 30 to 45 minutes to complete.
The researchers will then ask participants to keep a daily log of their sleep for 1 week, by completing what is known as a 'sleep diary'. This takes less than 5 minutes to complete each day and involves noting down details including what time people went to sleep, how long they slept for, and whether they woke up during the night or not. This will be done using an online link that participants can complete on their computer, tablet, or mobile phone.
The next step of the study will depend on which group participants are in. This study is a type of study called a randomised controlled trial. This means that some participants will receive the treatment, and some people will not receive the treatment.
The treatment is an online version of a leaflet which the researchers have previously used in face-to-face studies with people who have clinical sleep problems. This involves being told about various different practical behaviours which participants can do to help improve sleep. This leaflet has been shown to be effective and the researchers want to see if the online version is also effective, because this will allow us to deliver this very cheaply and reach lots of people at once.
Poor sleepers will be randomly placed into one of two groups. Participants in the first group will receive the treatment after keeping a sleep diary for a week. Participants in the second group will be asked to wait for a month before being asked to repeat some of the questionnaires taken at the start of the study, and will receive the treatment after keeping a sleep diary for a week. This delay of 1 month means that we can measure whether or not the treatment works, but still make sure that everyone who might benefit from the treatment does receive it.
Both groups of poor sleepers will be asked to keep sleep diaries for another week after receiving the treatment. At the end of this week, they will be asked to complete some of the same questions that were completed at the start of the study. This means that the research team can check how effective the treatment is in the short-term.
Poor sleepers will also be asked to repeat these questions 1 month and 3 months after receiving the treatment. This allows the research team to see if the treatment is effective over a longer time period.
Participants who are good sleepers will be randomly placed into one of two groups. The first group will complete sleep diaries for a week before receiving the treatment. The second group will not receive the treatment. This is because we are interested in monitoring the sleep of individuals who do not have sleep problems, as this might help us to develop new behavioural treatments for poor sleep. We also want to see if this treatment might be able to prevent sleepproblems from developing in the first place.
Both groups will complete sleep diaries for another week, before completing follow-up questions 1 week after receiving the treatment (or at the same time point for those good sleepers who do not receive the treatment) and also 1 and 3 months later. This will allow the research team to see if the treatment is effective over short and long time periods.
E-mail links will be sent to all participants at each relevant point of the study.

What are the possible benefits and risks of participating?
In terms of direct advantages, the potential advantages of taking part in this study are that participants may receive treatment that might help current sleep problems, or that may prevent future sleep problems from developing. If participants do not receive the treatment, they will not receive any direct advantage but will be helping to improve treatments for sleep problems. There are very unlikely to be any disadvantages of taking part in this study. The researchers have used this treatment in the past, in multiple face-to-face research studies with people who have long-term sleep problems, and there have not been any side effects.

Where is the study run from?
Northumbria Sleep Research Laboratory, Northumbria University (UK)

When is the study starting and how long is it expected to run for?
August 2020 to April 2022

Who is funding the study?
Northumbria University (UK)

Who is the main contact?
Dr Greg Elder
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Study website
https://nupsych.qualtrics.com/jfe/form/SV_blyyHjB71JWEa9f

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1.0 (20 July 2020)

Study information

Scientific Title
Testing an early online intervention for the treatment of disturbed sleep during the COVID-19 pandemic (Sleep COVID-19)

Acronym
Sleep COVID-19

Study objectives
Current study hypothesis as of 22/12/2021:
The intervention will reduce insomnia severity in poor sleepers.

Previous study hypothesis:
The intervention will reduce insomnia severity in poor sleepers relative to good sleepers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/04/2020, Northumbria University (Department of Psychology, Northumbria University, Newcastle-upon-Tyne, UK; no tel. provided; nick.neave@northumbria.co.uk), ref: 23377

Study design
Current study design as of 22/12/2021:
Online stratified randomised trial

Previous study design:
Interventional cluster randomized trial

Primary study design
Interventional

Secondary study design
Stratified randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
https://nupsych.qualtrics.com/jfe/form/SV_blyyHjB71JWEa9f

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

Interventions
Current interventions as of 28/07/2020:
This is an interventional study where poor sleepers will be recruited to receive the intervention, or will be recruited as a wait-list control, where they will receive the treatment after a delay of one month. Two groups of good sleeper participants will be recruited and will either receive the intervention, or will not. An equal number of participants will be recruited to each group and healthy good sleepers, and poor sleepers, will be recruited at a 1:1 ratio. The study is single-centre and the study will be run entirely online.

Participants who are in the intervention groups will be provided with an online version of a self-help leaflet. A printed version of this leaflet has been used in previous treatment studies conducted by our research group. Briefly, this self-help leaflet aims to improve sleep by identifying and addressing sleep-related dysfunctional thinking by providing education about sleep, providing techniques to distract from intrusive worrisome thoughts at night, and providing guidelines for sleep-related stimulus control.

The duration of treatment will be one week and the follow-up period is one week, one month and three months after receiving the treatment (or an equivalent time point for good sleepers who do not receive the treatment). Participants will be randomised using online software (where poor sleepers will be randomised to receive the treatment, or to the wait-list condition; good sleepers will be randomised to treatment or no treatment).

The study is single-centre and the study will be run entirely online.

Participants who are in the two intervention groups (poor sleep and wait-list control good sleepers) will be provided with an online version of a self-help leaflet. A printed version of this leaflet has been used in previous treatment studies conducted by our research group. Briefly, this self-help leaflet aims to improve sleep by identifying and addressing sleep-related dysfunctional thinking by providing education about sleep, providing techniques to distract from intrusive worrisome thoughts at night, and providing guidelines for sleep-related stimulus control.

The duration of treatment will be 1 week and the follow-up period is at the end of the treatment period. Participants will be randomised using online software (where good sleepers will be randomised to treatment or no treatment).

Previous interventions:
This is an interventional study where good sleepers will be recruited as a wait-list control, where they will receive the treatment after a delay of one week. An additional group of good sleeper participants will be recruited who will not receive the intervention. An equal number of participants will be recruited to each group and healthy good sleepers and individuals with sleep problems will be recruited at a 2:1 ratio (estimated n = 40:20 participants).

The study is single-centre and the study will be run entirely online.

Participants who are in the two intervention groups (poor sleep and wait-list control good sleepers) will be provided with an online version of a self-help leaflet. A printed version of this leaflet has been used in previous treatment studies conducted by our research group. Briefly, this self-help leaflet aims to improve sleep by identifying and addressing sleep-related dysfunctional thinking by providing education about sleep, providing techniques to distract from intrusive worrisome thoughts at night, and providing guidelines for sleep-related stimulus control.

The duration of treatment will be one week and the follow-up period is at the end of the treatment period. Participants will be randomised using online software (where good sleepers will be randomised to treatment or no treatment).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 28/07/2020:
Insomnia severity measured using the Insomnia Severity Index prior to the intervention and 1 week, 1 month and 3 months post-intervention, relative to baseline

Previous primary outcome measure:
Insomnia severity measured using the Insomnia Severity Index at one week post-intervention

Secondary outcome measures
Current secondary outcome measures as of 28/07/2020:
1. Subjective mood measured using the PHQ-9 and GAD-7 immediately prior to the intervention, 1 week, 1 month and 3 months post-intervention, compared to baseline
2. Sleep continuity measured using sleep diaries 1-week pre-intervention and 1-week post-intervention

Previous secondary outcome measures:
1. Sleep continuity from sleep diaries throughout the intervention
2. Subjective mood measured using the PHQ-9 and GAD-7 at 1-week post-intervention

Overall study start date
25/03/2020

Completion date
06/04/2022

Eligibility

Key inclusion criteria
All participants must:
1. Be aged 18 years and above
2. Have a sufficient level of English comprehension to understand and complete questionnaires

Poor sleepers:
1. Must have difficulties in falling asleep, staying asleep, or awakening too early at least three nights per week, for a time period of between two weeks and three months
2. Must have distress or impairment caused by sleep loss
3. Both 1. and 2. must occur despite the individual having an adequate opportunity for sleep

Good sleepers:
1. No current sleep problems

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
124 (31 poor sleepers who will receive the intervention; 31 poor sleeper wait-list participants who will receive the intervention after a delay; 31 good sleepers who will receive the intervention; 31 good sleepers who will not receive the intervention)

Total final enrolment
344

Key exclusion criteria
Current exclusion criteria as of 28/07/2020:
1. Individuals who report having chronic sleep problems (i.e. where they have existed for more than 3 months immediately prior to providing consent)
2. Those who are actively seeking treatment for their sleep problems, irrespective of how long they have had the sleep problem
3. Participants who have a self-reported history of head injury, or who have had a diagnosis of schizophrenia, epilepsy or personality disorder cannot take part as the distraction techniques involved in the intervention may increase rumination and this may influence the effectiveness of the intervention

Previous exclusion criteria:
Poor sleepers:
1. Long-term (i.e. chronic) sleep problems (> 3 months)

Date of first enrolment
17/08/2020

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria University
Northumbria Sleep Research Laboratory
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NE1 8ST

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/049e6bc10

Funder(s)

Funder type
University/education

Funder Name
Northumbria University

Alternative Name(s)
Northumbria University, Newcastle

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Dr Greg Elder (g.elder@northumbria.ac.uk) after a period of exclusive use (12 months). Our intended policy is that the research team will have exclusive use of the data for a period of 12 months from the end of the project, or until the data is published, if this is required alongside publications. Anonymised data will be provided and data will be made available upon application and the research team would control access in line with Northumbria University guidelines, however, data access will not reasonably be refused.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/08/2020	13/08/2020	Yes	No
Protocol article		11/12/2021	14/12/2021	Yes	No
Results article		02/03/2024	13/05/2024	Yes	No