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Sleep Matters Trial

Submission date	Recruitment status	[X] Prospectively registered
09/04/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/04/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When people suffer from a dissociative disorder, their sense of reality is changed. People with this mental health condition may suffer from memory loss, and feel that their body or the world around them is not real. Sometimes they are not certain of who they are and its possible that they will also develop multiple identities. In recent studies, we found evidence that dissociative symptoms are associated with a labile (unstable) sleep-wake cycle which leads to dreamlike phenomena invading the waking state, makes them absent-mindedness, and makes dissociative symptoms worse. This theory has the potential to inspire new treatments for dissociative symptoms, that is, treatments (or interventions) that help people to have a normal sleep-wake cycle. This is important as dissociative symptoms often do not respond well to drugs or psychotherapy. Here, we want to explore whether a treatment aimed at normalising sleep can alleviate dissociative symptoms. In a previous study, we found that sleep loss can result in dissociative symptoms. Following these findings, we would like to explore whether this relation will also hold in reverse; i.e., will sleep improvement lead to a decrease of dissociative symptoms? Therefore, we will use an evidence based digital cognitive behavioural therapy (CBT) for insomnia intervention to explore whether sleep improvement reduces dissociative symptoms.

Who can participate?
Adults (aged at least 18) with dissociative symptoms and insomnia.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given immediate access to the digital cognitive behavioural therapy (CBT) for insomnia programme. Those in group 2 are given the access to the programme 5 months later. The program can be accessed via the internet and smart phone. It consist of 6 weekly sessions which takes about 20 minutes to complete. All participants in the study are asked to complete a questionnaires to explore changes in sleep and emotional health at the start of the study, after 3 weeks, 10, weeks, 22 weeks, and 33 weeks. Participation in the study does not affect the participants normal medical treatment and they are asked to continue to take their existing medication and continue with routine medical appointments throughout the duration of the study

What are the possible benefits and risks of participating?
Previous research has shown that the treatment we are offering has a large effect on improving sleep. We do not anticipate that there are any risks in taking part.

Where is the study run from?
University of Oxford, Nuffield Department of Clinical Neurosciences (UK)

When is the study starting and how long is it expected to run for?
April 2015 to March 2017

Who is funding the study?
The study is funded by a NWO Rubicon grant from The Netherlands.

Who is the main contact?
Dr. Dalena van Heugten
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Sleep improvement and alleviation of dissociative symptoms: a randomised controlled trial of digital cognitive behavioural therapy for insomnia.

Study objectives
Sleep improvement will alleviate dissociative symptoms. A secondary aim is to assess whether the relation between improved sleep and reduced dissociation is mediated by a reduction in anxiety symptoms, as both insomnia and anxiety disorders are highly correlated with dissociation

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Oxford Central University Research Ethics Committee, 27/03/2015, ref: MS-IDREC-C2 2015-006

Study design
The study is a parallel-group, randomised controlled trial of digital cognitive behavioural therapy for insomnia in addition to treatment as usual (TAU) versus TAU alone. This is a single-centre trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
We are studying the relation between insomnia symptoms and dissociative symptoms.

Interventions
This study aims to explore the causal role of sleep disturbances in the development of dissociative symptoms and their concomitants through a randomised controlled trial. We will use a well-established digital CBTi application (Sleepio.com), which has proven its efficacy in improving sleep (Espie et al., 2012), to assess whether sleep improvement alleviates dissociative symptoms. We will compare treatment as usual (control condition) to digitalised cognitive behavioural therapy for insomnia in addition to treatment as usual (experimental condition).

Intervention Type
Behavioural

Primary outcome(s)
1. To test whether delivering digital CBTi improves insomnia symptoms. Outcome measure is the Sleep Condition Indicator, administered before, during, and after the intervention
2. To test whether sleep improvement (through digital CBTi) can reduce dissociative symptoms. Outcome measures are the Dissociative Experiences Scale, and the Clinician-Administered Dissociative States Scale, administered before, during, and after the intervention

Key secondary outcome(s))
1. To determine whether digital CBTi improves negative affect: depression, anxiety, and stress. Outcome measures are the Depression Anxiety Stress Scales (DASS) to measure depression, anxiety, and stress administered before, during, and after the intervention
2. To determine whether changes in anxiety symptoms mediate changes in dissociative symptoms. Current statistical techniques for mediation will be employed, using the primary outcome measures at all time points

Completion date
25/03/2017

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study.
2. Symptoms of insomnia, as indicated by the SCI
3. Medium-to-high level of dissociativity, as indicated by a score of 17 or more on the DES
4. Age >= 18 years (no upper limit), any gender

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
None

Date of first enrolment
20/04/2015

Date of final enrolment
25/02/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford, Nuffield Department of Clinical Neurosciences
Headley Way, John Radcliffe Hospital
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Organisation for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek; NWO), The Hague, The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available