

Sleep Matters Trial

Submission date 09/04/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Dr Dalena van Heugten

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

10/04/2015

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 \geq 18 years (no upper limit), any gender

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

85

Key exclusion criteria

None

Date of first enrolment

20/04/2015

Date of final enrolment

25/02/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Oxford, Nuffield Department of Clinical Neurosciences

Headley Way, John Radcliffe Hospital

Level 6 West Wing

Oxford

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Sponsor information**Organisation**

University of Oxford

Sponsor details

Nuffield Department of Clinical Neurosciences

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England

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Sponsor type

University/education

Website

<http://www.ndcn.ox.ac.uk/>

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

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available