

# Sleep Matters Trial

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

**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  $\geq$  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

Level 6 West Wing

Oxford

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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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes