

# The nightmare intervention study

<b>Submission date</b> 19/11/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Nightmares are disturbing dreams which leave an individual feeling distressed when they wake up. Nightmares are a common experience for people who have persecutory fears or hear voices (symptoms of psychosis\*). However, despite being distressing, they are rarely the focus of treatment. Previous research with people without psychosis has shown that nightmares can be reduced through offering cognitive behavioural (talking) therapy (CBT), specifically targeting nightmares. The key technique in this therapy is called Imagery Rehearsal and involves practicing an alternative and less distressing ending to the original nightmare 'script'. However, people experiencing symptoms of psychosis have typically been excluded from these studies and hence we do not know if the therapy is effective for this group. The aim of this study is to find out whether CBT for nightmares is acceptable and feasible to offer to people who experience persecutory fears. The study will also look into whether the therapy improves nightmares as well as mood, fears, emotional wellbeing and other distressing or unusual experiences.

\*Psychosis describes a range of symptoms such as hearing voices or experiencing fears of being harmed/persecuted by other people. In their most severe form, fears of other people are described as persecutory delusions.

### Who can participate?

Adult patients who experience regular nightmares, persistent persecutory delusions and have a diagnosis of non-affective (not related to disturbance of mood) psychosis (e.g. schizophrenia).

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given individual sessions of CBT for nightmares over the course of 4 weeks, in addition to all of their standard NHS care. The length of these sessions and how many they have are decided based on the individual patients' needs. Those in the second group continue with all their standard NHS care alone throughout the course of the study, however they are offered the full CBT for nightmares therapy at the end of the study. Participants complete a range of questionnaires and interview assessments at the start of the study, and then again at 4 and 8 weeks. Participants who receive the CBT for nightmares immediately will be invited to take part in an interview to find out about their experience of nightmares, the therapy and any changes they've noticed over the 8 weeks of the study.

What are the possible benefits and risks of participating?  
Participants may benefit from a decrease in the frequency of their nightmares as a results of the CBT. There are no known risks of taking part in the study.

Where is the study run from?  
Oxford Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?  
November 2015 to October 2016

Who is funding the study?  
Wellcome Trust (UK)

Who is the main contact?  
Dr Bryony Sheaves

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Bryony Sheaves

**Contact details**  
Department of Psychiatry  
Warneford Hospital  
Warneford Lane  
Headington  
Oxford  
United Kingdom  
OX3 7JX  
+44 1865 226486  
bryony.sheaves@psych.ox.ac.uk

## Additional identifiers

**Protocol serial number**  
20020

## Study information

**Scientific Title**  
The Nightmare Intervention Study: A pilot randomised controlled trial of a brief cognitive behavioural therapy for nightmares for patients with persecutory delusions

**Acronym**  
NlTeS

**Study objectives**

The aim of this study is to assess the acceptability and feasibility of cognitive behavioural therapy for nightmares, delivered to patients experiencing persecutory delusions.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

South Central – Oxford C Research Ethics Committee, 29/09/2015, ref: 15/SC/0502

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Topic: Mental Health; Subtopic: Psychosis; Disease: Psychosis

### **Interventions**

Participants will be randomly allocated to one of two groups.

Group 1: Participants will receive individual sessions of CBT for nightmares, delivered over a period of four weeks. The length and number of therapy sessions will be decided based upon patient choice and clinical need. The key therapy techniques will include Imagery Rehearsal training (re-scripting the content of the nightmare) and techniques to better manage nightmare related distress (for example compassion and grounding techniques). All participants in this group will continue with all standard NHS care.

Group 2: This control group will not receive any CBT sessions over the 8 week course of the study, but will continue with all standard NHS care. The CBT for nightmares therapy will then be delivered to these participants at the end of the study.

All participants will complete questionnaire assessments of nightmares, sleep and other daytime psychiatric symptoms. These will be at 0 weeks (baseline), 4 weeks (end of therapy) and 8 weeks (follow up). All participants in the immediate intervention group will be invited to complete a qualitative interview to find out more about their experience of nightmares, of the therapy and any changes they notice over the eight week therapy period.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. To assess trial methodology including the acceptability and feasibility of the intervention and recruitment and retention rates. This will be measured by the number of sessions used, uptake of therapy, sessions required, participant satisfaction and trial dropout rates.
2. Nightmare severity will be measured using the Distressing Dreams and Nightmare Severity Index measured at baseline, 4 and 8 weeks

**Key secondary outcome(s)**

1. Psychological wellbeing will be measured using the Warwick Edinburgh Mental Wellbeing Scale measured at baseline, 4 and 8 weeks
2. Persecutory beliefs will be measured using the Green Paranoid Thoughts Scale at baseline, 4 and 8 weeks
3. Hallucinatory experiences will be measured using the Cardiff Anomalous Perceptions Scale at baseline, 4 and 8 weeks
4. Affect will be measured using the Depression Anxiety and Stress Scale - 21 item version measured at baseline, 4 and 8 weeks
5. Symptoms of insomnia will be measured using the Sleep Condition Indicator at baseline, 4 and 8 weeks
6. Sleep quality will be measured using the Pittsburgh Sleep Quality Index measured at baseline, 4 and 8 weeks
7. Dissociative symptoms will be measured using the Brief Dissociative Experiences Scale at baseline, 4 and 8 weeks

**Completion date**

01/10/2016

**Eligibility****Key inclusion criteria**

1. Currently experiencing one or more nightmares per week
2. A current persecutory delusion, as defined by Freeman and Garety (2000)
3. A cut off of 33 or above on part A or B on the Green Paranoid Thoughts Scale (Green et al., 2008).
4. Nightmares are at least moderately distressing (on a 7 point Likert scale, scoring at least 4).
5. Nightmares have been present for at least three months (i.e. chronic).
6. Aged between 18 and -65 years
7. A clinical diagnosis of non-affective psychosis (schizophrenia, schizo-affective disorder, delusional disorder or psychosis not otherwise specified)
8. Stable medication (both drug and dose) for at least four weeks and no planned medication changes. Where medication changes are planned, the patient will wait until medication has been stable before entering the trial.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

24

**Key exclusion criteria**

1. Screen positive for sleep apnoea with no history of having received a full assessment and / or treatment. If receiving optimal treatment for sleep apnoea, the patient will be invited to take part.
2. Primary diagnosis of personality disorder, alcohol or substance dependency
3. An organic syndrome or learning disability
4. A command of spoken English inadequate for completing questionnaire measures, or engaging in therapy
5. Currently receiving cognitive behavioural therapy or due to commence within the time frame of the trial
6. Nightmares that are considered to be a side effect of medication by the treating psychiatrist

**Date of first enrolment**

04/01/2016

**Date of final enrolment**

01/10/2016

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Warneford Hospital**

Department of Psychiatry  
Warneford Lane  
Oxford  
United Kingdom  
OX3 7JX

**Sponsor information****Organisation**

University of Oxford

**ROR**

<https://ror.org/052gg0110>

# Funder(s)

## Funder type

Charity

## Funder Name

Wellcome Trust

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

International organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

## 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="#">Results article</a>		26/05/2019	07/01/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes