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The nightmare intervention study

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
20/11/2015

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
NIteS

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
16/11/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

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
England

United Kingdom

Study participating centre
Warneford Hospital
Department of Psychiatry
Warneford Lane
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office
Block 60 Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LJ

Sponsor type
University/education

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

Publication and dissemination plan
Planned submission of an outcome paper to a peer reviewed journal within six months of the trial end date.

Intention to publish date
30/04/2017

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?
Results article		26/05/2019	07/01/2022	Yes	No
HRA research summary			28/06/2023	No	No