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The Sleep Study

Submission date	Recruitment status	[X] Prospectively registered
23/09/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2019	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Many people who are admitted to hospital with mental health difficulties report sleep difficulties. The recommended treatment for persistent difficulties with getting to, or staying asleep is cognitive behavioural therapy, a talking therapy which involves working together with the individual to alter patterns of thinking and behaviour which keep the sleep problem going. This therapy has never been adapted, or tested in a psychiatric inpatient ward setting. This study has designed a therapy for sleep problems, specifically adapted for a ward setting. The therapy includes cognitive behavioural strategies and light therapy. Light therapy is used to re-align the body clock, which can often become out of sync when in hospital. The study will test whether this treatment is acceptable to patients, whether the trial is feasible to complete in a ward setting and also gather data on the impact that the therapy has on both sleep and emotional wellbeing.

Who can participate?
Male patients admitted to Vaughan Thomas ward (an adult psychiatric ward in Oxford Health NHS Foundation Trust) who experience symptoms of insomnia (difficulties getting to or staying asleep) and would like help to improve their sleep.

What does the study involve?
Each participant meets with a research assistant to complete a first assessment. This includes questionnaires and an interview about sleep and emotional wellbeing. After this assessment a computer program decides at random whether or not the participant receives the sleep therapy (in addition to all other standard ward care). Each person has equal chance of being in each group. For participants in the group which receives the sleep therapy, the clinical psychologist offers sessions of cognitive behavioural therapy for sleep problems and for some participants, light therapy. Sleep monitoring watches are offered which help the participants to self-monitor their sleep and activity levels. For participants who are not receiving the sleep therapy (the control group), they continue with all other standard ward care. They are be offered a session with the clinical psychologist at the end of the study (12 weeks) to consider some cognitive behavioural strategies to improve sleep. Every participant meets with the research assistant for further assessments (the same as the first assessment), two weeks after the first assessment, and again four weeks and 12 weeks after that.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Warneford Hospital, Oxford (UK)

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

Who is funding the study?
1. The Health Foundation (UK)
2. Wellcome Trust (UK)

Who is the main contact?
1. Dr Bryony Sheaves (Scientific)
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2. Dr Alvaro Barrera (Public)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital: A single blind, pilot randomised controlled trial

Acronym
OWLS (Oxford Ward sLeep Solution)

Study objectives
This is a pilot randomised controlled trial designed to assess trial procedures for a definitive large scale evaluation. The intervention is cognitive behavioural therapy for sleep problems, augmented with timed bright light therapy, adapted for patients admitted to an acute psychiatric inpatient ward.

The hypotheses are that cognitive behavioural therapy for sleep problems, augmented with timed bright light therapy will:
1. Reduce symptoms of insomnia
2. Improve psychological wellbeing when compared with treatment as usual.

This study will estimate confidence intervals and treatment effect sizes for the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester Central NHS Research Ethics Committee, 13/08/2015, ref: 15/EM/0341

Study design
Parallel-group pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Insomnia

Interventions
Fifty participants will be recruited and participant allocation will occur with a ratio of 1:1. Assessments will take place at weeks 0, 2, 4 and 12 weeks. The assessor will be blind to allocation, the participant and care team will know their allocation (single blind study). At week 12 all the control participants will be offered a one off session of CBTi for help with their sleep problems. The study will be set in an 18 bed male acute adult psychiatric inpatient ward (Vaughan Thomas ward, Oxford Health NHS Foundation Trust).
The treatment group will receive cognitive behavioural therapy for sleep problems adapted for a psychiatric
inpatient ward. In addition, timed bright light therapy will be used to treat circadian rhythm disruption and sleep monitoring devices will be used to inform the sleep care plan. The therapy will be delivered by a clinical psychologist. The majority of therapy will be delivered over the first fortnight, but with clinical flexibility depending on length of stay. The two week assessment is the
primary end point for the study. The duration of each session will be flexible, according to patient
preference. The intervention will be delivered in a manual, which we will develop further.
Both groups in the trial will be encouraged to continue with all standard care for the duration of the trial. This will typically include ward rounds with a multi-disciplinary team and medication, occupational therapy and other psychological therapy.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is measured by determining the percentage of participants admitted to the ward who are eligible and consent to take part in the study
2. Rate of uptake of therapy is measured by determining the percentage of participants who complete the intervention and percentage of sessions received from number of sessions offered
3. Accessibility of participant information sheet and informed consent is measure by patient feedback

Secondary outcome measures
1. Insomnia symptoms is measured using the Insomnia Severity Index questionnaire at weeks 0, 2, 4 and 12
2. Emotional wellbeing is measured using the Warwick Edinburgh Mental Wellbeing Scale at weeks 0, 2, 4 and 12
3. Psychiatric symptoms measured using the Positive and Negative Syndrome Scale and Young Mania Rating Scale at weeks 0, 2, 4 and 12
4. Suicidal ideation measured using the Beck Suicide Scale at weeks 0, 2, 4 and 12
5. Medication use and use of NHS care services is recorded using the Client Service Receipt Inventory at weeks 0, 2, 4 and 12
6. Health related quality of life is assessed using the EQ-5D at weeks 0, 2, 4 and 12
7. Global distress will be measured using the CORE-10 at weeks 0, 2, 4 and 12

Overall study start date
01/05/2015

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Male patients of an adult psychiatric inpatient ward
2. Self-reported symptoms of insomnia (Ie. a self-reported difficulty getting to or staying asleep)
3. Would like help to improve their sleep
4. Willing to allow his or her community care team to be notified of participation in the trial
5. Participant is willing and able to given informed consent to participate in the trial

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
50

Total final enrolment
40

Key exclusion criteria
1. If at the point of screening there are plans for the patient to move to an alternative ward within the following 14 days (prior to week 2 primary end point)
2. The patient lives outside of the region covered by Oxford Health NHS Foundation Trust
3. A command of the English language inadequate for engaging in psychological therapy and comprehending the assessment measures
4. A diagnosis of a learning disability or organic syndrome (e.g. dementia)

Date of first enrolment
05/10/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Vaughan Thomas ward, Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Oxford Health NHS Foundation Trust

Sponsor details
Warneford Hospital
Headington
Oxford
England
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OX3 7JX

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04c8bjx39

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

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
We intend to submit an outcome paper to a peer reviewed journal within six months of data collection being complete

Intention to publish date
01/02/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018	28/02/2019	Yes	No
HRA research summary			28/06/2023	No	No