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Better Sleep Trial

Submission date	Recruitment status	[X] Prospectively registered
26/09/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2015	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12766

Study information

Scientific Title
Better Sleep Trial: a pilot randomised controlled trial for patients with delusions and/or hallucinations

Study objectives
Patients with psychosis frequently report difficulties getting or staying asleep (insomnia). Dissatisfaction with sleep is high. Insomnia should be treated in this group, but typically it is not even assessed. Importantly, recent evidence indicates that insomnia triggers and exacerbates delusions and hallucinations. The clinical implication is that if insomnia is treated then the psychotic symptoms will significantly lessen too. In a recent case series with fifteen patients with persecutory delusions resistant to previous treatment this is exactly what we found: Cognitive Behavioural Therapy for Insomnia (CBT-I) led to large clinically significant reductions in the insomnia and the delusions. It was also a highly popular intervention with patients. The clear next step is a pilot randomised controlled test. The clinical aim is to test whether CBT-I can reduce both insomnia and psychotic symptoms (establishing treatment effect sizes). It will inform decisions for a definitive large-scale evaluation. We will carry out a randomised controlled trial with 60 patients with distressing delusions and/or hallucinations in the context of a schizophrenia spectrum diagnosis. Half of the participants will be randomised to CBT-I, in addition to their standard treatment, which will be carried out over three months. Half of the participants will continue with treatment as usual. Blind assessments will take place at 0 months, 3 months (post-treatment) and 6 months (follow-up). This will be the first controlled test of CBT-I for patients with delusions and hallucinations. It will provide significant evidence for an easily administered intervention likely to prove very popular with patients experiencing the difficult to treat problems of delusions and hallucinations.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12766

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 23/04/2012, ref: 12/SC/0138

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Psychosis

Interventions
CBT-I, The insomnia intervention will be provided in up to eight sessions over 12 weeks. The twelve week window will allow some flexibility for appointment times (DNAs are quite common in this group) and the extension of intervals between the final two sessions.
The main techniques, standard for CBT sleep interventions, are taken from four main sources:
Espie (2006)
Freeman & Freeman (2010)
Harvey et al. (2007)
Meir & Kryger (2004).

The intervention is written in a manual, which we will develop further. Followed up at 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Insomnia Severity Index measured at 0,12, and 24 weeks

Secondary outcome measures
Psychotic Symptoms Rating Scale measured at 0,12, 24 weeks

Overall study start date
01/11/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. A current delusion and/or hallucination; scoring at least 2 on the distress scale of the PSYRATS for either a delusion or hallucination
2. The delusion and/or hallucination has persisted for at least three months
3. Clinical diagnosis of schizophrenia, schizoaffective disorder or delusional disorder (i.e. diagnosis of nonaffective psychosis (F2) in the International Classification of Diseases and Diagnostic and Statistical Manual IV)
4. Sleep difficulties lasting one month or longer and an Insomnia Severity Index score of 15 or above
5. Aged between 18 and 65
6. Where changes in medication are being made, entry to the study would not occur until at least a month after stabilisation of dosage
7. Male or female participants

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 60

Key exclusion criteria
1. Sleep apnoea
2. A primary diagnosis of alcohol or substance dependency
3. Organic syndrome or learning disability
4. A command of spoken English inadequate for engaging in therapy
5. Currently having individual CBT (though previous CBT experience is not an exclusion criterion)

Date of first enrolment
01/11/2012

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Nuffield Department
Obstetrics and Gynaecology
Division of Medical Sciences
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England
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme ref: PB-PG-0211-10007 (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	11/07/2013		Yes	No
Results article	results	01/11/2015		Yes	No