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Treatment for insomnia in Improving Access to Psychological Therapies (IAPT) services

Submission date	Recruitment status	[X] Prospectively registered
12/06/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2018	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Sleep is an essential requirement for life, and is vital for people to be able to function. Insomnia is a common sleep disorder, where the sufferer finds it difficult to get to sleep and/or sty asleep. It can cause great distress, affecting mood, concentration and quality of life. While sleeping pills offer a short term solution, they cannot be used in the long term as they are highly addictive and eventually lose their effectiveness. The recommended treatment for insomnia is a form of therapy called cognitive behavioural therapy for insomnia (CBT-I). This involves teaching the sufferer ways to recognise and change the thoughts and beliefs that are preventing them from sleeping, such as “racing thoughts”. This therapy is not always available to people suffering from insomnia, as it is a specialised technique which requires extensive training. Many people with insomnia do not have access to this type of therapy and so use the Improving Access to Psychological Therapies (IAPT) services in the UK. IAPT services are designed to provide help to people suffering from anxiety or depression. The usual treatment given by IPAT for insomnia is giving advice and written information about how to improve sleep practices. The aim of this study is to compare the effectiveness of CBT-I and IAPT services for treating insomnia.

Who can participate?
Adults who report difficulty getting to sleep and/or staying asleep for at least three months.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the first group attend weekly sessions of CBT-I for a total of five weeks. Those in the second group receive the standard advice and treatment for insomnia that is routinely provided by IPAT services. Before treatment, after treatment and then at a 20 week follow up, participants complete questionnaires about their sleeping habits and general mental health.

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

Where is the study run from?
St Pancras Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2011 to September 2013

Who is funding the study?
Camden and Islington NHS Foundation Trust (UK)

Who is the main contact?
1. Professor John Cape
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of cognitive behavioural therapy (CBT) groups for insomnia delivered by IAPT low intensity workers compared to treatment as usual: a randomised controlled pragmatic trial

Study objectives
What is the effectiveness of cognitive behaviour therapy for insomnia (CBT-I) groups compared to treatment as usual in treating insomnia in routine Improving Access to Psychological Therapies (IAPT) Services?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City Road & Hampstead REC approved on 27th July 2011 (Ref No:11/LO/0989)

Study design
Pragmatic two-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Insomnia

Interventions
1. Patients randomised to group CBT-I will attend 5 weekly 90 minute sessions in a class of up to 16 participants. The group CBT-I intervention will follow a manualised treatment protocol used in three previous treatment trials and will include education about sleep and common CBT-I components such as stimulus control, sleep restriction, and cognitive therapy strategies delivered by the IAPT low intensity workers.
2. Patients randomised to treatment as usual will receive advice and treatment for insomnia routinely provided within primary care and IAPT services

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sleep efficiency at end of treatment. This is calculated as the percentage time in bed that is reported by the patient as spent asleep.

Secondary outcome measures
1. Sleep efficiency at 20 week follow-up. This is calculated as the percentage time in bed that is reported by the patient as spent asleep.

2. Total Sleep Condition Indicator (SCI) score, and response and remission on the SCI post-treatment
3. Patient Health Questionnaire Depression Scale (PHQ-9) scores at post-treatment and follow-up
4. Patient Health Questionnaire Generalised Anxiety Disorder Scale (GAD-7) scores at post-treatment and follow-up
5. Work and Social Adjustment Scale (WASAS) at post-treatment and follow up
6. Satisfaction post-treatment with the treatment and service received for insomnia

Overall study start date
01/09/2011

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Self-reported concern about difficulty getting to sleep and/or staying asleep of at least 3 months duration
2. Age 18 or over
3. Good enough understanding and use of English to be able to benefit from a psychoeducational group delivered in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Untreated major physical or mental illness, including untreated major depressive disorder or an anxiety disorder (patients with major illness may be included if they are being treated)
2. Untreated substance misuse
3. Excessive daytime sleepiness suggestive of sleep apnoea, narcolepsy or other specific sleep disorder
4. Contraindication to treatment in a group

Date of first enrolment
01/09/2011

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Wing
London
United Kingdom
NW1 0PE

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust (UK)

Sponsor details
St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
Camden and Islington NHS Foundation Trust (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?
Results article	results	01/04/2016		Yes	No