

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

Submission date 12/06/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/01/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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 stay 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 IAPT 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 IAPT 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