

Cognitive behavioural therapy for persistent insomnia - a randomised controlled trial

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/09/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stuart Purcell

Contact details
St Ann's Hospital
69 Haven Road
Canford Cliffs
Poole
United Kingdom
BH13 7LN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0321179916

Study information

Scientific Title

Cognitive behavioural therapy for persistent insomnia - a randomised controlled trial

Study objectives

To evaluate the clinical effectiveness of a manualised multifaceted CBT intervention administered on an individual basis to patients with persistent insomnia who present with their insomnia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled 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

Mental and Behavioural Disorders: Insomnia

Interventions

1. Treatment group
2. Deferred treatment group

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Sleep onset
2. Total sleep time
3. Wake time after sleep onset

4. Pittsburgh Sleep Quality Index
5. Disability days and service use

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2004

Completion date

01/08/2005

Eligibility

Key inclusion criteria

Patients referred by their GP, aged between 18 and 65 and needed to meet the APA criteria for insomnia

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

Total sample size target is 70 (35 per comparison group).

Key exclusion criteria

1. Psychosis
2. Significant cognitive impairment
3. Affective disorders of moderate to severe severity as diagnosed by ICD10
4. Insomnia secondary to medical illness requiring specific treatments

Date of first enrolment

01/10/2004

Date of final enrolment

01/08/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Ann's Hospital

Poole

United Kingdom

BH13 7LN

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Dorset HealthCare 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