

Cognitive behavioural therapy for persistent insomnia - a randomised controlled trial

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

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

1. Sleep onset
2. Total sleep time
3. Wake time after sleep onset
4. Pittsburgh Sleep Quality Index
5. Disability days and service use

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

Dorset HealthCare NHS Foundation Trust (UK)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes