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# Effectiveness and cost-effectiveness of an educational intervention for practice teams to deliver problem focused therapy for insomnia: a pilot cluster randomised trial

**Submission date**
27/06/2008

**Recruitment status**
No longer recruiting

**Registration date**
31/07/2008

**Overall study status**
Completed

**Last Edited**
05/03/2014

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
N/A

# Study information

## Scientific Title

## Study objectives
Sleep problems are common, affecting two fifths of the population. Poor sleep (insomnia) is linked with psychological problems such as depression and physical problems such as high blood pressure, weight gain and heart disease. Many of those affected seek help from GPs whose response is often limited to sleep hygiene advice (a bedtime routine avoiding caffeine, alcohol, cigarettes or other stimulants) or prescription of sleeping pills (hypnotics) neither of which has been shown to be effective in the long term. Drugs for sleep difficulties are ineffective long term and probably do more harm than good, particularly in the elderly. Psychological /behavioural methods for managing sleep problems, termed cognitive behavioural therapy for insomnia (CBTi) have been shown to be effective and cost-effective when delivered by specialists but have not been fully evaluated in a general practice setting where they are most likely to be needed and most appropriately delivered.

Hypothesis:
Education for primary care teams in problem focused therapy for patients presenting to primary care with insomnia leads to better sleep outcomes for patients compared to treatment as usual with sleep hygiene up to three months from the beginning of treatment.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The North Nottingham Local Research Ethics Committee, approval received on the 16th September 2008 (ref: 08/H0406/128).

## Study design
Cluster randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Insomnia

## Interventions
We will undertake a pilot cluster randomised controlled trial (RCT) in which general practices are the unit of randomisation and where data will be collected from patients. Recruited general medical practices will be randomised to one of two arms; intervention consisting of education of primary care teams to use problem focused therapy for insomnia comprising sleep assessment tools (sleep diaries and Insomnia Severity Index) and modified cognitive behavioural therapy for insomnia (mCBTi); or a control arm using treatment as usual (TAU).

Patients will be involved in the study for a total of 13 weeks. Study outcomes will be measured at baseline, 4 weeks, 8 weeks and 13 weeks. Follow-up assessments will be performed using a telephone call at 2 weeks after the first treatment and self-completed postal questionnaires at all other timepoints. Non-responders will be telephoned 1 week after mailing the follow-up questionnaire on up to two occasions and posted a replacement questionnaire with a reminder letter if there is still no response at 2 weeks.

Please use the following contact details to request a patient information sheet:
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### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Global sleep quality as measured by PSQI at 0, 4, 8 and 13 weeks.

### Key secondary outcome(s))
Measured at 0, 4, 8 and 13 weeks:
1. The effect of the intervention on sleep outcome measures assessed with PSQI and sleep diaries:
1.1. Self reported sleep onset latency (SOL): how long it takes to fall asleep
1.2. Wake time after sleep onset (WASO): total hours awake at night after one has fallen asleep
1.3. Total time in bed (TIB)
1.4. Sleep efficiency (SE). Sleep efficiency, expressed as a percentage, is calculated as follows: SE = (100- [(SOL + WASO/TIB) x 100])
2. Daytime sleepiness (Epworth Sleepiness Scale)
3. Anxiety and depression using the generic Beck Depression Inventory
4. Health-related quality of life using EuroQol EQ-5D
5. Frequency of use and mean dose of hypnotic medication

Patients will also keep a Data Record Book (DRB) to record any adverse effects that participants might experience during the treatment period.

### Completion date
30/08/2009

## Eligibility

### Key inclusion criteria
1. At least 18 years old, either sex
2. Difficulty initiating and/or maintaining sleep for one month or more verified by Pittsburgh

Sleep Quality Index (PSQI) score of greater than or equal to 5
3. New presentations with insomnia and existing patients on long term hypnotics
4. Points 1 - 3 above and sleep disrupted by painful conditions
5. Points 1 - 3 above and moderate/mild depression measured by the Beck Depression Inventory (BDI) (score 11 - 30)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Current or previous illicit substance or alcohol abuse
2. Pregnant or planning pregnancy in the next 12 months
3. Psychotic illness and severe depression defined by a BDI score greater than or equal to 31
4. Documented or active symptoms of sleep disruptive comorbid conditions, e.g. restless legs syndrome and any type of parasomnia
5. Obstructive sleep apnoea
6. Terminal illness
7. Inability to consent

### Date of first enrolment
01/09/2008

### Date of final enrolment
30/08/2009

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Professor of Primary Care, University of Lincoln**
Lincoln
United Kingdom
LN6 7TS

# Sponsor information

### Organisation
Lincolnshire Primary Care Trust (UK)

# Funder(s)

### Funder type
Government

### Funder Name
The Health Foundation (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? |
|---|---|---|---|---|---|
| Results article | treatment fidelity results | 01/01/2014 | | Yes | No |
| Protocol article | protocol | 26/01/2009 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |