

# Psychological treatment in the regulation of long-term hypnotic drug use

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/09/2009	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

### Study objectives

In a randomised controlled trial the proposed study would evaluate the costs and consequences of using a structured "package" of psychological treatments for insomnia to promote and maintain low frequency, intermittent hypnotic drug consumption among those unwilling to discontinue their medication.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration.

### Study design

Pragmatic cluster randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

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

Mental and behavioural disorders: Other mental disorder

### Interventions

Structured package vs standard care

### Intervention Type

Other

### Phase

Not Specified

## Primary outcome measure

Main outcomes included: global sleep quality, as measured by the Pittsburgh Sleep Quality Index (PSQI); frequency of life (as measured by the SF-36); NHS service costs; and overall cost utility. For statistical analysis all non-categorical outcomes were modelled as baseline minus follow-up change scores

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/08/1998

### **Completion date**

31/07/2001

## **Eligibility**

### **Key inclusion criteria**

Patients aged 31-92 with chronic sleep problems who had been receiving repeat prescriptions for hypnotic drugs for at least one month

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

209

### **Key exclusion criteria**

Not provided at time of registration.

### **Date of first enrolment**

01/08/1998

### **Date of final enrolment**

31/07/2001

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Institute of General Practice and Primary Care**  
Sheffield  
United Kingdom  
S5 7AU

## **Sponsor information**

### **Organisation**

Department of Health (UK)

### **Sponsor details**

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### **Sponsor type**

Government

### **Website**

<http://www.dh.gov.uk/en/index.htm>

### **ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NIHR Health Technology Assessment Programme - HTA (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?
<a href="#">Results article</a>	results	01/12/2003		Yes	No
<a href="#">Other publications</a>	HTA monograph	01/02/2004		Yes	No