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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
25/04/2003	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/04/2003	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
01/09/2009	Mental and Behavioural Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Nigel Mathers** 

#### Contact details

Institute of General Practice and Primary Care
University of Sheffield
Community Sciences Centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU
+44 (0)114 271 5922
n.mathers@sheffield.ac.uk

# Additional identifiers

Protocol serial number

HTA 95/30/02

# 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

# Study type(s)

**Not Specified** 

# 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(s)

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

## Key secondary outcome(s))

Not provided at time of registration

#### 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** 

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

## 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

**United Kingdom** 

England

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

# Sponsor information

# Organisation

Department of Health (UK)

#### **ROR**

https://ror.org/03sbpja79

# Funder(s)

# Funder type

Government

#### Funder Name

NIHR Health Technology Assessment Programme - HTA (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	results	01/12/2003		Yes	No
Other publications	HTA monograph	01/02/2004		Yes	No