

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

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

Quarry House
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United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

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?
Results article	results	01/12/2003		Yes	No
Other publications	HTA monograph	01/02/2004		Yes	No