

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

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 01/09/2009	Condition category Mental and Behavioural Disorders	☐ 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
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.

Primary study design

Interventional

Study design

Pragmatic cluster randomised controlled trial

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