

Development of effective primary care treatment of severe sleep disorders in children with a learning disability; a randomised controlled trial

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

SPGS756

Study information

Scientific Title

Study objectives

What is the relative efficacy of briefer treatment for sleep problems in children with learning disabilities for use in the primary care setting? What are the effects of these briefer treatments on maternal mental health and child behaviour?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Sleep disorders; learning disability

Interventions

3 groups

1. Conventional behavioural techniques

2. Written information

3. Control group (no info or support)

Each for 6 weeks duration

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Sleep diary
2. Activity monitors

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/1998

Completion date

01/02/2000

Eligibility**Key inclusion criteria**

1. Children age 2-5 years
2. Male or female
3. Severe learning disability
4. Severe sleep disorder present >3 months with the following characteristics
 - 4.1. Night waking >3x/week disturbing parents
 - 4.2. Taking >1 hr to settle child >3x/week

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

66 (added 25/01/10; see publication)

Key exclusion criteria

Sleep problems thought to be due to physical discomfort

Date of first enrolment

01/08/1998

Date of final enrolment

01/02/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Department of Psychiatry**

Oxford

United Kingdom

OX3 7LQ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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79 Whitehall

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United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (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	01/02/2004		Yes	No