

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

Contact name

Prof Gregory Stores

Contact details

Department of Psychiatry
University Section
Park Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LQ
+44 (0)1865 226515

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

1. Sleep diary
2. Activity monitors

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

5 years

Sex

All

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

United Kingdom

England

Study participating centre

Department of Psychiatry
Oxford
United Kingdom
OX3 7LQ

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

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