

A randomised controlled trial of sleep problems for children with autism

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
30/09/2004	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
30/09/2004	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
19/02/2014	Nervous System Diseases	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N0584127466

Study information

Scientific Title

Study objectives

Is behavioural treatment for sleep problems effective in treating sleeplessness in children with autism? If so, are there any associated effects on the children's behaviour and the parents' well being?

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

Interventions

Patients are randomised to behavioural treatment or care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Children's sleep patterns (assessed by diary, interview and activity monitors)
2. Child behaviour (parent and teacher questionnaire report)
3. Parental well being (self report questionnaire)

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/08/2004

Eligibility

Key inclusion criteria

1. Formal diagnosis of autism according to internationally accepted International Statistical Classification of Diseases and Related Health Problems, tenth revision (ICD 10) criteria as applied by local specialised childhood autism service
2. Aged between 5 and 11 years old

3. Have severe bedtime settling and/or troublesome night waking problems of at least 12 months duration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

11 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2001

Date of final enrolment

31/08/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Psychiatry, University section

Oxford

United Kingdom

OX3 7LQ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Charity

Funder Name
The Shirley Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration