

A randomised controlled trial of sleep problems for children with autism

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

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

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