

A randomised controlled trial of sleep problems for children with autism

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Interventions

Patients are randomised to behavioural treatment or care as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2001

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

Age group

Child

Lower age limit

5 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre
Department of Psychiatry, University section
Oxford
United Kingdom
OX3 7LQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Charity

Funder Name
The Shirley Foundation (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