

# A randomised controlled trial of sleep problems for children with autism

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