

# Snuggledown - Use of sensory blankets for children with autistic spectrum disorder

<b>Submission date</b> 10/08/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/06/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

**Study website**  
<http://www.researchautism.net/snuggledown>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Gringras

**Contact details**  
Paediatric Neurology, 6th Floor  
Evelina Children's Hospital  
Lambeth Palace Road  
London  
United Kingdom  
SE1 7EH

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
10090

# Study information

## Scientific Title

Snuggledown - The use of sensory weighted blankets in children with autistic spectrum disorders and poor sleep: a randomised crossover study

## Study objectives

The objective of this trial is to confirm (or refute) that a specially designed weighted blanket is effective in improving total duration of night-time sleep compared to a similar but non-weighted blanket in children with autistic spectrum problems

No randomised clinical trials (RCT) have been published. Previous studies of weighted jackets have not reported any side effects. Care is required to ensure that the child is free to move /remove blanket at any point.(MCF, 2008)

Anecdotal parent reported benefits include a reduced sleep latency time (ie: reduced time to fall asleep) and reduced number of awakenings throughout the night (ie: increased periods of continuous, un-interrupted sleep throughout the night).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South East London REC2, 24/08/2010, ref: 10/H0802/57

## Study design

Randomised interventional treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Sleep disorders in paediatrics

## Interventions

Sensory blanket (Southpaw Sensory Integration blanket)

## Intervention Type

Other

**Phase**

Not Applicable

**Primary outcome measure**

Total sleep time based on actigraphy two weeks after each cross-over period

**Secondary outcome measures**

1. Sleep latency and efficiency (actigraphy)
2. Total sleep time and sleep latency by sleep diary
3. Parental assessment of sleep according to composite sleep disturbance index
4. Changes in behaviour (Aberrant Behaviour Checklist questionnaire)
5. Child's Visual Analogue Scale (VAS) perspective of sleep quality and acceptability of blanket
6. Sensory Behaviour Questionnaire (Green 2009)

**Overall study start date**

01/04/2011

**Completion date**

01/10/2012

## **Eligibility**

**Key inclusion criteria**

1. Children aged 5 to 15 years and 10 months with a diagnosis of an autistic spectrum disorders (ASD), diagnosed by a community paediatrician, paediatric neurologist or paediatric neurodisability consultant
2. No plans to commence new medication known to influence behaviour or sleep
3. Diagnosis of impaired sleep as defined by a) not falling asleep within one hour of 'lights off' or 'snuggling down to sleep' at age-appropriate times and/or b) less than 7 hours of continuous sleep in 3 out of 5 nights
4. A total score of <4 on questions 18 to 20 on the Children's Sleep Habits Questionnaire indicating the likely absence of sleep apnoea
5. Parental English language sufficient to read and complete questionnaires and sleep diaries
6. Ability to start each night's sleep in own bed
7. Male and female participants

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

15 Years

**Sex**

Both

### **Target number of participants**

Planned Sample Size: 100; UK Sample Size: 100

### **Key exclusion criteria**

1. Children who are using a weighted blanket
2. Children whose parents are unlikely to be able to use the actigraph or complete sleep diaries or both
3. Children where there may be a problem of major non-concordance with blanket or actigraph
4. Currently participating in a conflicting clinical study
5. Epilepsy (uncontrolled or medication changes)
6. Cerebral palsy

### **Date of first enrolment**

01/04/2011

### **Date of final enrolment**

01/10/2012

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**Evelina Children's Hospital**

London

United Kingdom

SE1 7EH

## **Sponsor information**

### **Organisation**

Guy's and St.Thomas' NHS Foundation Trust (UK)

### **Sponsor details**

4th Floor

Thomas Guy House

Lambeth Palace Road

London

England  
United Kingdom  
SE1 7EH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.guysandstthomas.nhs.uk/>

**ROR**

<https://ror.org/00j161312>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Research Autism (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2014		Yes	No