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

Submission date	Recruitment status	[ ] Prospectively registered
10/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/06/2015	Nervous System Diseases	

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
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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?
Results article	results	01/08/2014		Yes	No