

## Effects of non-pharmacological interventions for insomnia in children with Autistic Spectrum Condition

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### Citation

Sophie Keogh, Ffion Curtis, A. Niroshan Siriwardena, Amulya Nadkarni, Mithilesh Jha, Christopher Bridle. Effects of non-pharmacological interventions for insomnia in children with Autistic Spectrum Condition. PROSPERO 2017 CRD42017081784 Available from:

[http://www.crd.york.ac.uk/PROSPERO/display\\_record.php?ID=CRD42017081784](http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017081784)

### Review question

Effects of non-pharmacological interventions for insomnia in children with autistic spectrum condition.

### Searches

The following databases will be searched for completed and ongoing trials: MEDLINE, PsycINFO, CINAHL, ScienceDirect, Web of Science, Autism Data, Cochrane Central Register of Controlled Trials (CENTRAL), ClinicalTrials.gov and Current Controlled Trials.

All databases will be searched from inception. Database searches will be supplemented with internet searches (i.e. Google Scholar), searches of The Conference Proceedings Index for unpublished materials and forward and backward citation tracking from included studies and review articles.

### Types of study to be included

Studies will be considered for inclusion if they are randomised controlled trials that included randomisation of participants at an individual or cluster level, or quasi-randomised method.

### Condition or domain being studied

Autism Spectrum Condition (ASC) is the name for a range of similar conditions that affect a person's social interaction, communication, interests and behaviour. In most cases many of the features of Autism can be recognised during early childhood. It is estimated that about 1 in every 160 children has an Autism Spectrum Condition (World Health Organisation). Further to this it is thought that between 40-80% of children with Autism have difficulties relating to sleep (Polimeni et al., 2005). Such sleep problems have been linked to a range of serious implications for the child's wellbeing.

### Participants/population

Children (aged 0-18 years) with co-morbid Autistic Spectrum Condition and Insomnia.

### Intervention(s), exposure(s)

Any type of non-pharmacological sleep based intervention (i.e. behavioural interventions, educational, sleep hygiene, alternative therapies).

### Comparator(s)/control

Comparators will be those used within the individual studies (i.e. usual care, alternative intervention).

### Primary outcome(s)

Any changes in insomnia (sleep problem) following a sleep based intervention.

### Secondary outcome(s)

Quality of life, medication use, other (behavioural) difficulties associated with ASC and outcomes for parents/carers.

### Data extraction (selection and coding)

Titles and abstracts will be screened independently by two reviewers, against the inclusion criteria. For

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studies that are not excluded on the basis of the title/abstract, full text papers will be requested and assessed by two reviewers. Any discrepancies will be resolved through discussion, and if required, a third reviewer. Papers will be compiled using Endnote referencing software.

Data extraction will take place using an adapted Cochrane Data Extraction Template for interventions. One reviewer will undertake data extraction for each study, to be cross-checked by a second reviewer.

The following key data will be extracted:-

Study Details: Date of study, title, author and study aim.

Methods: Study design, intervention, unit of allocation, primary outcome, potential confounders and any other outcomes.

Participants: Population demographics (age, gender, diagnosis, severity, co-morbidities), inclusion and exclusion criteria and total number randomised.

Intervention/Comparators: Number randomised to groups, description of intervention and comparator (delivery, content, frequency, duration and provider).

Outcomes: Outcome name and definition, outcome type, how it is measured/reported, missing data and reasons for missing data.

### Risk of bias (quality) assessment

Two reviewers will independently assess risk of bias within the included studies using the Cochrane Tool for Risk of Bias, the following domains will be evaluated: selection bias, performance bias, detection bias, attrition bias and reporting bias. These domains will be categorised as high, low or unclear risk of bias. Each domain will be classified as adequate, unclear or inadequate with the risk of bias for each study classified using the following criteria:

- a) Low risk of bias (all criteria deemed adequate)
- b) Moderate risk of bias (one criterion graded as inadequate or two rated as unclear)
- c) High risk of bias (more than one criterion is deemed inadequate or more than two graded as unclear)

Any discrepancies between reviewers will be resolved through discussion, and if required, a third reviewer will be consulted.

### Strategy for data synthesis

We will create a narrative synthesis of the findings from the included studies, structured around the type of intervention, target population characteristics, type of outcome and intervention content. Due to a range of different interventions and outcomes measured and reported across existing trials there may be a limited scope for meta-analysis. However, where studies overlap in terms of interventions and outcome measures, we will bring these together using a random-effects meta-analysis, with mean or standardised mean differences for continuous outcomes, rates and rate ratios, and dichotomous data as risk ratios. Data will not be pooled if heterogeneity is moderate ( $I^2$  statistic greater than 40%). If heterogeneity is identified, potential causes will be explored (e.g. clinical and/or methodological diversity). We will try to clarify heterogeneity via subgroup analysis, but if it cannot be explained (i.e. there is considerable variation in the results, particularly inconsistency in the direction of the effect), then a narrative approach will be taken and a meta-analysis will not be performed.

We will exclude studies with a moderate or high risk of bias to determine the extent to which the synthesised results are sensitive to risk of bias.

### Analysis of subgroups or subsets

We plan to carry out subgroup analysis on the primary outcomes using the following:

- Grouping studies based on participant age
- Intervention characteristics (type/duration)

### Contact details for further information

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### Organisational affiliation of the review

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Lincolnshire Partnership Foundation Trust

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#### Anticipated or actual start date

06 September 2017

#### Anticipated completion date

30 March 2018

#### Funding sources/sponsors

Research Department, Lincolnshire Partnership Foundation Trust (LPFT)

National Institute for Health Research Clinical Research Network East Midlands (NIHR CRN EM)

#### Conflicts of interest

#### Language

English

#### Country

England

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