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The effect of parental group sleep education in young children with Down syndrome: The REST-Ed study

Submission date	**Recruitment status**	☒ Prospectively registered
13/04/2018	Stopped	☐ Protocol
Registration date	**Overall study status**	☐ Statistical analysis plan
22/05/2018	Stopped	☐ Results
Last Edited	**Condition category**	☐ Individual participant data
26/02/2025	Genetic Diseases	☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Children with Down syndrome (a genetic condition typically causing some level of learning disability) experience sleep problems more often than typically-developing children. Untreated, this can lead to sleepiness, behavioural/emotional problems, cognitive impairment and reduced quality of life. Children's sleep problems also affect parental wellbeing, and parents caring for a child with a developmental disability may already experience poor sleep.
This study aims to test the effect of a sleep education package on the sleep and quality of life of young children (aged 6 months - 5 years) with Down syndrome and their parents/carers.

Who can participate?
Child aged 0.5-5 years with down syndrome and parent/carer

What does the study involve?
Participating children and their parents/carers are randomly allocated to one of two groups. Those in the first group receive the education package (intervention group) which includes a short film, colour booklet and talk, all of which include basic information on sleep and good sleep practices. It is delivered in a small group setting in venues across Scotland.
Those in the second group receive a short talk on another topic (control group).
Sleepiness, behaviour and quality of life of children and parents/carers is assessed using questionnaires at the start of the study and at 4 weeks, 6 month and 12 month follow-up visits. Sleep quality will be measured using a wrist-worn device called an actigraph, again at 4 week, 6 month and 12 month intervals.
Participants in the control group are offered the education package at the end of the study, with 4 week, 6 month and 12 month follow-up if they wish.

What are the possible benefits and risks of participating?
All parents and carers receive the study education package which may help prevent or improve sleep problems in the children taking part. If it is shown to be effective, it will be made freely available to help other children with Down syndrome and their families. At the end of the study, participants receive feedback on their child's study data, including detailed information on their

child’s sleep/wake patterns as measured using the actigraph. All children taking part in the study receive screening for breathing problems during sleep, meaning that these problems may be identified and treated earlier and potentially prevent longer- term health issues.
Possible disadvantages: Participants are enrolled in the study for a maximum of 15 months, during which time they are expected to attend 8 visits. This may involve travelling some distance from their home, although we aim to minimise this by offering locations across Scotland. Reasonable travel expenses are paid during the study period. Participants are required to return some equipment by post, however, the study team cover Royal Mail postage costs for this. The education pack includes some techniques to improve sleep which require commitment and persistence by the parent. Some families may find this challenging but the study team provides support and guidance. It is possible that we may discover a significant sleep disorder during study testing. In this case, we inform the parent/carer and also contact the child’s GP.

Where is the study run from?
Royal Hospital for Sick Children (UK)

When is the study starting and how long is it expected to run for?
November 2016 to June 2025

Who is funding the study?
Edinburgh Children’s Hospital Charity (UK)

Who is the main contact?
Dr Florian Gahleitner
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
227772

Study information

Scientific Title
A randomised, parallel groups evaluation of a parental group sleep education intervention in young children with Down syndrome: The REST-Ed study

Acronym
REST-Ed

Study objectives
Research questions:
1. Does a parental group education package improve sleep and quality of life for young children with Down syndrome?
2. Does a parental group education package improve sleep and quality of life for the parents of young children with Down syndrome?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/07/2019, East of Scotland Research Ethics Service (Tayside Academic Health Sciences Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital& Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383848; TAY.eosres@nhs.scot), REC ref: 19/ES/0058

Primary study design
Interventional

Study design
Single-centre randomized design

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Down syndrome; Sleep disorders

Interventions

Parents /carers of children aged 6 months - 5 years with Down Syndrome living in Scotland are invited to take part. All children taking part have a sleep study at home to test for breathing problems during sleep. If a sleep breathing problem is found, the child leaves the research study and is sent for further assessment and treatment locally.
The parents of the remaining children are chosen at random using balanced blocks to receive the education package (intervention group) or a short talk on another non-sleep-related topic (control group).
The intervention is a sleep education package, based on the package evaluated by Stores & Stores (Stores, R. and Stores, G. (2004), Evaluation of Brief Group-Administered Instruction for Parents to Prevent or Minimize Sleep Problems in Young Children with Down Syndrome). This study evaluates a modified version of the Stores and Stores package, including a DVD, booklet and talk delivered in a small-group setting.
Sleepiness, behaviour and quality of life of children and parents/carers is assessed using questionnaires at the start of the study and at 1 month, 6 month and 12 month follow-up visits. Sleep quality is measured using a wrist-worn device called an actigraph, again at 1, 6 and 12 month intervals.
Participants in the control group are offered the education package at the end of the study, with 1 month follow-up if they wish.

Intervention Type

Behavioural

Primary outcome(s)

1. Sleep disturbance is measured using Composite Sleep Disturbance Score at baseline and 4wk post-intervention.
2. Total sleep time and sleep efficiency are assessed by actigraphy at baseline and 4wk post-intervention.

Key secondary outcome(s)

1. Prevalence of sleep-disordered breathing (SDB) is assessed using a sleep study at home at the start of the study
2. Composite sleep score at baseline, 6m and 12m post-intervention
3. Total sleep time and sleep efficiency are assessed by actigraphy at baseline, 6m and 12m post-intervention
4. Child quality of life is measured using Infant and Toddler Quality of Life questionnaire (47-item short form) at baseline, 4wk, 6m and 12m post-intervention
5. Child behaviour is measured using the Child Behaviour Checklist at baseline, 4wk, 6m and 12m post-intervention
6. Parental quality of life is measured using GHQ-12 at baseline, 4wk, 6m and 12m post-intervention
7. Parental sleepiness is measured using pictorial Epworth Sleepiness Scale at baseline, 4wk, 6m and 12m post-intervention

Completion date

30/06/2025

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Inclusion criteria:
1. Child has known diagnosis of Down syndrome (trisomy 21, mosaic or translocation karyotype)
2. Child aged 0.5 - 5.0 years at baseline visit
3. Child and parent/carer resident in Scotland for the study duration
4. Parent able and willing to comply with protocol

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0.5 Years

Upper age limit
5 Years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Child has a previous diagnosis of sleep-disordered breathing (SDB), whether treated or untreated, or evidence of SDB on home cardio-respiratory polygraphy at screening (children showing evidence of SDB at screening will be signposted for further assessment/treatment as required via their local NHS pathway)
2. Child has severe or uncontrolled comorbidities affecting sleep or ability to participate, e.g. uncontrolled epilepsy, chronic lung disease, uncorrected congenital heart defects
3. Child is currently using medication which may affect sleep, e.g. melatonin, sedating antihistamines, benzodiazepines, chloral hydrate etc
4. Child has severe behavioural problems which would preclude compliance with home cardio-respiratory polygraphy or actigraphy
5. Not resident in Scotland for duration of study
6. Parent unable or unwilling to comply with protocol

Date of first enrolment
01/03/2022

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Department of Paediatric Cardiac, Respiratory and Sleep Physiology
Royal Hospital for Children and Young People
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Sponsor information

Organisation
Academic and Clinical Central Office for Research and Development (ACCORD)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Charity

Funder Name
Edinburgh Children's Hospital Charity (ECHC)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from:
Dr Florian Gahleitner

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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No