

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

<b>Submission date</b> 13/04/2018	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/05/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/02/2025	<b>Condition category</b> Genetic Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Contact name

Dr Florian Gahleitner

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### Type(s)

Public

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

227772

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

Nil known

## **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

## **Study design**

Single-centre randomized design

## **Primary study design**

Interventional

## **Secondary study design**

Randomised parallel trial

## **Study setting(s)**

Community

## **Study type(s)**

Prevention

## **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

## **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 measure**

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.

### **Secondary outcome measures**

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

### **Overall study start date**

21/11/2016

### **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

### **Age group**

Mixed

### **Lower age limit**

0.5 Years

### **Upper age limit**

5 Years

**Sex**

Both

**Target number of participants**

60 (30 per group)

**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**

Scotland

United Kingdom

**Study participating centre**

**Department of Paediatric Cardiac, Respiratory and Sleep Physiology**

Royal Hospital for Children and Young People

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Edinburgh

United Kingdom

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**Sponsor information**

**Organisation**

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

**Sponsor details**

The Queen's Medical Research Institute  
47 Little France Crescent  
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EH16 4TJ

**Sponsor type**

Other

**Website**

<http://accord.scot/>

**ROR**

<https://ror.org/01x6s1m65>

**Funder(s)****Funder type**

Charity

**Funder Name**

Edinburgh Children's Hospital Charity (ECHC)

**Results and Publications****Publication and dissemination plan**

Abstract based on study design accepted for poster presentation at World Down Syndrome Congress, Glasgow 24-27/07/2018.

Abstract submitted for poster/oral presentation at European Sleep Research Society Congress, Basel 25-28/09/2018, to include interim results if available.

Abstracts based on interim results may be submitted to other international conferences in due course, e.g. ERS/ESRS Sleep and Breathing 2019, British Sleep Society Scientific Meeting 2019. It is anticipated that the final study results will be published in a high-impact, peer-reviewed journal thereafter.

**Intention to publish date**

30/06/2025

**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  
Primary Investigator  
Florian.Gahleitner@nhslothian.scot.nhs.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No