

# Developing and testing a toolkit of interventions to improve adherence to non-invasive ventilation in children: a mixed methods study (The SPIRITUS study)

<b>Submission date</b> 26/09/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/12/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Children and young people (CYP) with breathing difficulties during sleep, known as sleep-disordered breathing (SDB), can suffer from hyperactivity and/or lack of energy, poor concentration, repeated admissions for respiratory infections and poor growth and development. NIV is a method of helping children's breathing via a face mask over their nose and/or mouth and a breathing machine. It can have positive short and long-term effects on the child's health, behaviour and school participation (called outcomes). However, it can be uncomfortable and cause facial skin damage and other problems. The aim of this study is to produce a toolkit of interventions that address the barriers to NIV use and discover what outcomes from NIV are important to CYP and parents.

### Who can participate?

Children and young people (aged 0-18 years) who have been diagnosed with sleep-disordered breathing, are being treated by the study site and have used NIV for more than 3 months, their parents and staff at the study site who provide care for patients who use NIV.

### What does the study involve?

Phase 1: The researchers will look at all the previous NIV studies on ways to help families and outcomes. They will host online/in-person workshops (8-12 parents, 8-12 CYP, 8-10 HCPs and NIV equipment industries representatives). The researchers will share their previous study findings and others' research and ask what interventions and outcomes they should test.

Phase 2: The researchers will look at all the research on these interventions and outcomes. They will host further workshops to finalise a list of outcomes and interventions.

Phase 3: 10-12 CYP and parents will choose and test an intervention and outcome for 2 weeks to see if they are practical and acceptable. Parents will keep a diary and CYP will wear an Actiwatch. Afterwards, parents and CYP will talk about their experience. Data will be collected from the ventilator and questionnaires completed before and afterwards.

What are the possible benefits and risks of participating?

There are no direct benefits to taking part but it is hoped that participants will find it worthwhile to help the scientific community to understand more about potential ways to help children use NIV. Taking part will mean participants giving up some time. Although the researchers do not think that participating in discussions will be distressing, should any participant become upset and want to talk to someone the researchers can arrange that for them.

Where is the study run from?

Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

January 2023 to October 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

Jessica Russell, [jessica.russell@gosh.nhs.uk](mailto:jessica.russell@gosh.nhs.uk)

## Contact information

### Type(s)

Principal Investigator

### Contact name

Ms Jessica Russell

### ORCID ID

<http://orcid.org/0000-0003-3194-412X>

### Contact details

Great Ormond Street Hospital NHS Foundation Trust

Barclay House

37 Queen Square

London

United Kingdom

WC1N 3BH

+44 (0)7716111173

[jessica.russell@gosh.nhs.uk](mailto:jessica.russell@gosh.nhs.uk)

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

325870

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IRAS 325870, CPMS 56256

# Study information

## Scientific Title

Developing and testing a toolkit of interventions to improve adherence to non-invasive ventilation in children: a mixed methods study (The SPIRITUS study)

## Acronym

SPIRITUS

## Study objectives

This study aims to identify and assess for feasibility and acceptability the components of a toolkit of interventions to address some of the barriers to adherence of non-invasive ventilation for sleep disordered breathing in children and young people.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 05/06/2023, The West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, East Midlands REC Centre, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 1048191; solihull.rec@hra.nhs.uk), ref: 23/EM/0102

## Study design

Mixed methods feasibility acceptability study

## Primary study design

Interventional

## Secondary study design

Mixed methods feasibility acceptability study

## Study setting(s)

Home, Hospital

## Study type(s)

Other

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Sleep disordered breathing in children and young children

## Interventions

Phase 1:

The researchers will look at all the previous NIV studies on ways to help families and outcomes.

They will host online/in-person workshops, (8-12 parents, 8-12 CYP, 8-10 HCPs and NIV equipment industries representatives). They will share their previous study findings and others' research and ask what interventions and outcomes they should test.

#### **Phase 2:**

The researchers will look at all the research on these interventions and outcomes. They will host further workshops to finalise a list of outcomes and interventions.

#### **Phase 3:**

Phase 3 will comprise a toolkit of interventions to address some of the barriers to adherence to non-invasive ventilation. 10-12 CYP and parents will choose and test an intervention and outcome for 2 weeks to see if they are practical and acceptable. Parents will keep a diary and CYP will wear an Actiwatch. Afterwards, parents and CYP will talk about their experience. Data will be collected from the ventilator and questionnaires completed before and afterwards.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Delivery of Phase 3 of the study:

1. Feasibility is measured by fidelity to study design and procedures, including any adaptations made during the study period
2. Acceptability is measured by the invitation and response and retention rates:
  - 2.1. Invitation rate: recorded as the number of potentially eligible participants invited to participate in the study during the recruitment period
  - 2.2. Response rate: recorded as the number of eligible participants who consent to participate during the recruitment period.
  - 2.3. Retention rates: recorded as the number of eligible participants who consent to participate, engage in a clinical session in which they choose an intervention from the toolkit, test the intervention for a period of 2 weeks and take part in at least one debrief activity with the researcher at the end of the intervention

### **Secondary outcome measures**

1. Feasibility of toolkit components measured by parent and child self-report post-intervention
2. Acceptability of toolkit components measured by:
  - 2.1. Uptake of toolkit components by families during the study period
  - 2.2. Retention rate: recorded as the number of eligible participants who test the intervention for a period of 2 weeks and take part in at least one debrief activity with the researcher at the end of the intervention

### **Overall study start date**

11/01/2023

### **Completion date**

25/10/2025

## **Eligibility**

### **Key inclusion criteria**

Phases 1, 2 and 3:

Children and young people:

1. Age 0-18 years
2. Diagnosis of sleep disordered breathing
3. Have been prescribed NIV >3 months prior to recruitment
4. Under the care of the study site NIV team

Parents and carers:

1. Parents/carers (adults with parental responsibility) of the above children

Staff

1. Study site staff who provide NIV care (medical, nursing, allied health professionals, health care assistants, sleep-unit technicians, physiologists)

**Participant type(s)**

Patient, Employee, Other

**Age group**

Child

**Lower age limit**

0 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

46

**Key exclusion criteria**

Phases 1 and 2:

1. Children and young people
2. Medically dependent on NIV
3. Receiving NIV for palliation
4. Use of NIV for <3 months
5. Weaning off NIV

Parents:

Parent members of the SPIRITUS Study Steering Group

Staff:

Study Site staff who do not work in Study Site NIV service

Phase 3:

Children and young people:

1. Medically dependent on NIV
2. Receiving NIV for palliation
3. Use of NIV for <3 months
4. Weaning off using NIV

Parents and carers:

1. Parents who do not consent for their child's participation (even if they consent for their own)
2. Parents of children who do not want to take part
3. Parents in the PPI Study Steering Group
4. Parents who took part in Phases 1 and 2
5. Any families involved in intervention development (either PPI activities or the creation of the intervention e.g. a video)
6. Parents who have already tested one intervention

**Date of first enrolment**

03/07/2023

**Date of final enrolment**

30/09/2023

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Great Ormond Street Hospital**

Great Ormond Street

London

United Kingdom

WC1N 3JH

## **Sponsor information**

**Organisation**

Great Ormond Street Hospital for Children NHS Foundation Trust

**Sponsor details**

Division of Research & Innovation

Joint R&D Office for GOSH/ICH

UCL Great Ormond Street Institute of Child Health

30 Guilford Street

London

England

United Kingdom

WC1N 1EH

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research.governance@gosh.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

<https://ror.org/03zydm450>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health and Care Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

The researchers will disseminate the results of this study through international peer-reviewed journals and at national and international conferences. A final report will be published on the funder's website and a report of the study findings will be sent to participants in a range of accessible formats. The researchers will discuss alternative dissemination routes with the Research Communications Officer at the study site, including the Trust's website and social media channels.

**Intention to publish date**

01/04/2025

**Individual participant data (IPD) sharing plan**

Data from the study will not be made available: the participants of this study did not give written consent for their data to be shared publicly, so due to the sensitive nature of the research supporting data are not available. All paper data will be stored in a locked filing cabinet, which is located in a research office at Great Ormond Street Hospital only accessible by a swipe card. Personal identifiable data and consent forms will be stored separately from research data. Electronic data (such as audio recordings and Zoom/MS Teams recordings) is stored on password-protected servers accessed by Trust devices. At the end of the study personal data will only be stored and accessed for up to 6 months. Research data will be stored for 20 years or in accordance with GOSH Trust policies.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		28/11/2024	02/12/2024	Yes	No