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

Submission date
26/09/2023

Recruitment status
No longer recruiting

Registration date
22/01/2024

Overall study status
Completed

Last Edited
02/12/2024

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325870

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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?
Protocol article		28/11/2024	02/12/2024	Yes	No