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A feasibility randomised controlled trial of a novel postural management night-time intervention to improve respiratory health of children with complex neurodisability (ADAPT)

Submission date
09/06/2025

Recruitment status
Recruiting

Registration date
28/07/2025

Overall study status
Ongoing

Last Edited
23/10/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Children and young people with complex neurological conditions often experience recurrent chest infections, requiring frequent hospital stays and are the leading cause of premature death. A major cause of chest infections is aspiration, when saliva, food, liquid or stomach contents enter the lungs. Current recommendations advise children are positioned on their back at night to help with managing posture, but this position increases risk of aspiration. Our new approach, Breathe-Easy, involves children lying partway onto their front to drain secretions from the mouth.
We aim to investigate if:
• Breathe-Easy can be implemented by parents at home, guidance is clear, intervention is safe
• recruitment is possible to a trial where participants receive either Breathe-Easy or usual care
• health and well-being measures are appropriate to use in a subsequent, larger trial.

Who can participate?
Trial will involve 50 children. Children and young people are eligible if they:
• depend upon others to position and move their body
• have swallowing difficulties with high risk of aspiration
• are 2-18 years old
• use gastrostomy/jejunostomy (surgically placed long-term feeding tubes)
• have had a chest infection in the last 12 months.

What does the study involve?
Participants will be randomly allocated for 6 months to Breathe-Easy or usual night-time positioning.
Data collection at the start of the study, at 3 months and 6 months:
• Children's respiratory health, sleep, pain and quality of life using questionnaires.
• Use of antibiotics, X-rays and hospital admissions to treat chest infections from GP and hospital records.

We will ask children and young people, parents and healthcare staff about their experiences of the trial through surveys.

This study will tell us if parents and professionals are willing to trial Breathe-Easy, and if the trial design is feasible and safe. It will help develop a larger trial to test the effectiveness of Breathe-Easy.

What are the possible benefits and risks of participating?
This new intervention has the potential to improve breathing overnight and sleep. Research participants in both groups are likely to receive enhanced care compared to usual care in the community to monitor their lying position and sleep overnight. However, this sleep position may not be compatible with a child's individual needs. It may impact on either the child's or parental sleep or night-time routines.

Where is the study run from?
Sussex Community NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2025 to December 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333891

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58371, NIHR207188

Study information

Scientific Title
ADAPT - Airway Drainage And Positioning Night-Time

Acronym
ADAPT

Study objectives
The primary objective is to investigate the feasibility of conducting an RCT of novel night-time position intervention to improve the respiratory health of Children and Young People with Complex Neurodisability (CYPCN). The underlying hypothesis is that the novel intervention reduces “chest infections” and hospital admissions and improves quality of life for CYPCN.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2025, Yorkshire & The Humber - Leeds East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8357; leedseast.rec@hra.nhs.uk), ref: 25/YH/0064

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neurological and respiratory, other diseases of the respiratory system, other disorders of the nervous system

Interventions
The research physiotherapist employed at the local NHS site will collect baseline data about the CYPCN from the parents/guardians including medical history and current orthopaedic concerns, medication, sleep patterns, and use of sleep positioning equipment.

Intervention group:
The baseline data will identify any potential issues to implementation of the intervention so they can be addressed. Any medical concerns will be discussed with the respiratory and/or community paediatrician. The research team (CENTRAL OR LOCAL) will support the site research physiotherapists with any concerns or issues arising. Adoption of this new intervention changes usual practice in postural care positioning, and the research team will work closely with the site PI/site research physiotherapist, CYPCN’s physiotherapists and wider health team to support changes in practice, adapting existing night-time positioning and taking other needs into account.

The new intervention involves the child being positioned partway onto their front and supported by their usual night-time positioning equipment or pillows. Their stomach contents are drained overnight via their existing feeding tube to minimise the risk of reflux.

The site research physiotherapist and local physiotherapist, if required, will visit the CYPCN and their parents or carers in their usual home environment to set up the new intervention. Oxygen

saturations, heart and breathing rates will be taken for each child whilst in their usual sitting and sleep position, followed by the new position. This is to ensure that the new position does not cause any respiratory adverse effects.

CYPCN will then trial the new position at home during the day for a minimum of 1 hour per day for at least a week. This is to determine the safety and comfort of the new position, and effectiveness of upper airway drainage, prior to night-time implementation. Individualised written positioning guidance with photographs and training of parents or carers will be provided to support consistent overnight positioning.

When CYPCN, parents or carers, and site research physiotherapist are confident that the position is safe, comfortable and conducive to sleep, it will be trialled for the first part (initial 2–3 hours) of the CYPCN's night-time with the parents awake and able to monitor them.

Oxygen saturations and heart rate will be monitored overnight for 2 nights pre-implementation of Breathe-Easy and then 2 nights when Breathe-Easy is first implemented.

Sussex participants will also have the opportunity for more detailed monitoring of their breathing and heart rate, using Somnotouch (respiratory polysomnography) at 0 months (pre-intervention) and at 3 months for both intervention and control participants. This will involve wearing two soft elasticated bands around the chest and abdomen. As we would like to assess the acceptability and feasibility of using Somnotouch monitoring as a potential outcome measure, participants from SCFT only will additionally be asked for their consent to use this overnight. They may opt out of using Somnotouch but still be part of the trial.

Equipment and training will be provided to the parents/carers in liaison with the community nursing team, to drain the participant's stomach contents overnight via their gastrostomy using a bile bag and to replace fluid loss if required. A video will be provided for training.

The intervention will continue for six months from when the new intervention is first introduced at night-time. Weekly telephone contact between the site PI and parents/carers will be made for the first month to address any concerns or issues arising, provide further training if required, capture information about adherence to the protocol and any adaptations required. Following this, two to four weekly telephone or email contact will be made. Close contact between local teams and our expert training team will be maintained throughout; this team includes an experienced physiotherapist, paediatric respiratory consultant, dysphagia specialist and parent representative. Families can choose in consultation with their clinical team whether or not to adopt this new intervention as their usual practice at the end of this period.

Control group:
The site research physiotherapist and local physiotherapist, if required, will visit the CYPCN and their parents/carers in their usual home environment to investigate usual night-time positioning and collect baseline data. Oxygen saturations, heart and breathing rates will be taken for each child whilst in their usual sitting and sleep position. Oxygen saturation and heart rate will be recorded for 2 consecutive nights at this stage as for the intervention group.

No changes will be made to overnight positioning for CYPCN in this group for the duration of the trial. CYPCN will continue to receive their usual care with regards to night-time positioning for 6 months from date of baseline measures. To check for contamination, we will check individualised written positioning guidance to ensure that usual care is followed.

Both groups:
Health records for all participants will be accessed through community and GP records to collect data on respiratory health. Data will be collected by local teams retrospectively at 6 months for previous 12 months, with support from site level research delivery team.

Information on adherence to either the intervention or control group protocol will be captured by the site research physiotherapist through telephone calls or email contact with the parents.

Data will be collected at baseline, 3 and 6 months for both groups, on respiratory symptoms (BRSQ), sleep habits (CSHQ), health-related quality of life (CHU9D and EQ-5D-5L), pain or discomfort (rFLACC), respiratory polysomnography (SOMNOtouch) in Sussex only. We will also record data from 2 overnight recordings: one at baseline (pre-intervention in the intervention group) and one 3 months after the start of the trial.

After the intervention, a process evaluation will assess how the implementation of the Breathe-Easy intervention is achieved, the influence of contextual factors including randomisation and trial design, and the quality of implementation and acceptability.

An online survey will be sent to all parents and HCPs on trial completion to obtain their views and experiences of taking part.

The process evaluation eligibility criteria are:
- Parents whose CYPCN participated in the study (n=50)
- CYPCN between 5–18 years able to understand questions and communicate at least yes/no answers (n=10)
- HCPs involved in implementing the feasibility RCT intervention and control arms (n=50)

Families who declined or discontinued the intervention will be given the opportunity to provide feedback via an online questionnaire.

Intervention Type
Behavioural

Primary outcome(s)
Primary feasibility outcome measures:
1.1. Recruitment: Proportion of recruited children amongst eligible patients and reasons for not participating; measured using counts from screening and eligibility forms and logs at enrolment.
1.2. Retention: Proportion of participants that completed the feasibility trial out of the number randomised; measured using counts from the validated database records at the end of study (6-months).
2. Proportion of data collection complete per participant (candidate primary outcomes); measured using counts from the validated database records at the end of study (6-months).
3. Standard deviation of the candidate primary outcomes; estimated from the validated database records at the end of study (6-months).
4. Proposed design, sample size and number of centres for a definitive study; agreed at the end of study on discussion with joint TSC/DMEC.
5.1. Acceptability of intervention for participants: Number of nights in position for minimum of 4 hours measured from participant case records at the end of study (6-months).
5.2. Acceptability of intervention for families and healthcare staff: Acceptability measure from surveys of parents and HC professionals at the end of study (6-months).

Candidate primary outcome measures evaluated as part of primary feasibility outcome measures #2 and #3 above:
1. Proportion of CYPCN with 'chest infection' according to protocol definition amongst eligible patients at 6-months.
2. Time to first 'chest infection' from randomisation according to protocol definition.
3. Total time attending hospital in days.
4. Respiratory Health measured using the Bespoke Respiratory Symptom Questionnaire (BRSQ); at baseline, 3 and 6-months.

Key secondary outcome(s))
Candidate secondary outcome measures
1. Sleep behaviour measured using a validated questionnaire (CSHQ Abbreviated); at baseline, 3 and 6-months.
2. Health related quality of life of children measured using a paediatric generic preference-based measure instrument (CHU9D); at baseline, 3 and 6-months.
3. Health related quality of life of parents/guardians measured using a generic health related quality of life instrument (EuroQol - EQ-5D-5L); at baseline, 3 and 6-months.
4. Pain or discomfort of participating children measured using the Face Legs Activity Cry and Consolability (rFLACC) scale; at baseline, 3 and 6-months.
5. At the Sussex site only, sleep disordered breathing assessed at home using a portable respiratory polysomnography device (SOMNOtouchTM); at baseline and 3-months.

Secondary outcome measures for the process evaluation of the intervention
1. Talking Mats interview with children at 6-months.
2. Survey of parents/carers including trial factors experiences. After completion of participation: after consent, withdrawal from participation or end of study (6-months).
3. Discussion with families who decline intervention. Discussion takes place when families are approached to participate, after consent is declined.
4. Survey of Health Care Professionals at the end of study (6-months).

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Children will be invited to participate in the RCT if they meet the following criteria:
1. Dependent upon others to position/move their bodies (Gross Motor Function Classification System IV/V or equivalent)
2. High risk of aspiration linked to swallowing difficulties (Eating and Drinking Classification System IV/V)
3. Aged 2-18 years
4. Fed via gastrostomy/jejunostomy
5. At least one lower respiratory tract infection requiring antibiotics in past 12 months

For the surveys, stakeholders will be invited to participate if they are:
1. Parents of children in the RCT
2. Children in the intervention group
3. Healthcare professionals who have been involved in the RCT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. CYPCN using naso-gastric tube
2. CYPCN with overnight feeding via gastrostomy that cannot be altered to daytime only (jejunostomy feeds can continue overnight so considered safe)
3. CYPCN transitioning to adult care within trial period
4. CYPCN with planned orthopaedic surgery during trial period

Date of first enrolment
01/11/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Sussex Community NHS Foundation Trust

ROR
https://ror.org/04e4sh030

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	29/04/2025	11/07/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes