

Can live feedback and coaching improve the effectiveness of airway clearance treatments for children and young people with cystic fibrosis?

Submission date 30/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/10/2026	Overall study status Ongoing	☐ Protocol
Last Edited 30/10/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Cystic fibrosis is an inherited condition that affects the lungs and other organs. Airway clearance treatments (chest physiotherapy) are recommended to help clear mucus from the lungs and maintain respiratory health. Previous research has shown that airway clearance treatments can improve lung function when they are performed using the recommended breathing technique. However, many children and young people do not perform these treatments in the most effective way.

This study aims to investigate whether a novel breathing sensor and mobile application providing real-time feedback and coaching can improve the quality of airway clearance treatments performed by children and young people with cystic fibrosis. The study will also assess the feasibility and acceptability of this technology and generate information to support a future larger clinical trial.

Who can participate?

Children and young people aged 6 to 16 years with a confirmed diagnosis of cystic fibrosis who are prescribed regular airway clearance treatment and attend Great Ormond Street Hospital for Children NHS Foundation Trust.

What does the study involve?

Participants take part in a 3-month study using the ImpACT4CF breathing sensor and mobile application during their usual airway clearance treatments at home. The sensor records breathing information during treatment sessions and transfers the data securely for analysis. The study consists of six stages, during which participants experience different levels of feedback and coaching, ranging from monitoring alone to real-time feedback on breathing technique. Information collected by the sensor is used to assess the quality of airway clearance treatments and investigate whether feedback and coaching can help participants perform their treatments more effectively. Participants, parents and healthcare professionals are also asked to provide feedback on their experiences of using the system.

What are the possible benefits and risks of participating?

Participants may benefit from improved understanding of their airway clearance treatments and from the real-time feedback and coaching provided by the ImpACT4CF system. The information gained from this study may help improve airway clearance treatment support for children and young people with cystic fibrosis in the future.

The risks associated with participation are considered low. The study involves the use of a breathing sensor and mobile application during routine airway clearance treatments and does not require participants to change their prescribed clinical care.

Where is the study run from?

UCL Great Ormond Street Institute of Child Health (UK)

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

October 2025 to November 2026

Who is funding the study?

The study is funded by the Rosetrees Trust and the Stoneygate Trust (UK)

Who is the main contact?

Prof. Eleanor Main, e.main@ucl.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

350280

Study information

Scientific Title

ImpACT4CF: a pilot study of real-time feedback and coaching to improve airway clearance treatment quality in children and young people with cystic fibrosis

Acronym

ImpACT4CF

Study objectives

To determine whether real-time feedback and coaching delivered through the ImpACT4CF sensor and mobile application can improve the quality of airway clearance treatments performed by children and young people with cystic fibrosis.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/07/2025, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8150; riverside.rec@hra.nhs.uk), ref: 25/LO/0517

Primary study design

Observational

Secondary study design

Single-centre two-arm six-stage cohort pilot study with an interrupted time series design

Study type(s)**Health condition(s) or problem(s) studied**

Cystic fibrosis

Interventions

Participants will use the ImpACT4CF breathing sensor and mobile application during their usual airway clearance treatments at home over a 3-month period. The study comprises six sequential stages with increasing feedback and coaching support. Participants will experience different modes of feedback, ranging from monitoring alone to real-time coaching. During one study stage, participants will be allocated to different feedback approaches for comparison. Airway clearance treatment quality will be measured throughout the study using data recorded by the sensor. Participant, parent and healthcare professional experiences will also be collected to assess feasibility and acceptability and to inform the design of a future larger trial.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Puffin (ImpACT4CF breathing sensor and mobile coaching application)

Primary outcome(s)

1. Airway clearance treatment quality measured using objective measures of airway clearance treatment performance using data recorded by the ImpACT4CF breathing sensor and mobile application, including adherence to prescribed breathing patterns during airway clearance treatment, at throughout the 3month study period across all six study stages, with comparisons between baseline, feedback and coaching phases

Key secondary outcome(s)

Completion date

30/11/2026

Eligibility

Key inclusion criteria

1. Patients using a commonly available ACT device which is compatible with the clip fitting of the ImpACT4CF sensor (e.g., Acapella, Astratech PEP, Aerobika or Pari PEP)
2. Children and young people aged between 6 – 16 years
3. Currently under the care of Great Ormond Street Hospital CF Centre (GOSH-CF)
4. The participant or legally acceptable representative must be able to give informed consent

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Years

Upper age limit

16 Years

Sex

All

Total final enrolment

36

Key exclusion criteria

1. Medical, cognitive or behavioural factors that would prevent completion of study procedures
2. Inability to perform airway clearance treatment independently or with usual family support

Date of first enrolment

31/10/2025

Date of final enrolment

30/06/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Great Ormond Street Hospital for Children NHS Foundation Trust, London, United Kingdom

Great Ormond Street Hospital for Children NHS Foundation Trust

Great Ormond Street

London

WC1N 3JH

United Kingdom

London

England

WC1N 3JH

Sponsor information**Organisation**

UCL Great Ormond Street Institute of Child Health

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

Rosetrees Trust

Alternative Name(s)

Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Stoneygate Trust

Alternative Name(s)

The Stoneygate Trust

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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

Not expected to be made available