

# Detection of respiratory exacerbations in adults with cystic fibrosis using artificial intelligence

<b>Submission date</b> 04/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/01/2026	<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

Cystic Fibrosis (CF) is a life limiting, inherited condition that causes a build up of thick, sticky mucus in the lungs and other organs that leads to severe and persistent bacterial infections. CF is characterised by periods of relative stability punctuated abrupt clinical deterioration known as acute pulmonary exacerbations (APEs.) APEs drive pulmonary inflammation, progressive lung damage and premature death. In preliminary studies we have shown that home monitoring empowers patients and can safely reduce routine outpatient hospital attendance by 50%. Breathe RM Signal is a smartphone app. It uses Bluetooth data from participants monitoring themselves at home with devices such a spirometer, heart rate monitor and weighing scales to see if they are stable or at risk of having an APE. After using their home monitoring equipment participants are able to see an easy-to-understand colour on the app with instructions of what they need to do. The app helps to detect the onset of an APE earlier than symptoms appear, which enables the infection to be treated earlier. This may reduce how much treatment is needed and how long it is needed for. Participants will also be asked to complete quality of life questionnaires during the study. The purpose of this study is to establish if Breathe RM Signal (developed from previous studies where participants monitored physiological parameters at home) improves quality of life, reliably predicts the onset of APEs and is safe to use in clinical practice.

### Who can participate?

Adults over 18 years with CF and suitable for home monitoring.

### What does the study involve?

All participants will be given an activity monitor, weighing scales, oxygen saturation monitor and spirometer (to measure lung function) to use at home. These devices connect to an app called Breathe RM via Bluetooth. They help to predict if a participant is at risk of an acute pulmonary exacerbation (APE). The results from these devices can then be seen by the participant and by their clinical team (if the participant agrees to this). Participants will be randomly allocated to be in one of two groups. There will be 200 participants in each group.

- Group 1. will see their data from home monitoring as usual (Breathe RM).
- Group 2. will see their data from home monitoring (Breathe RM) plus the Breathe RM Signal feature. Depending on the home monitoring data received the Breathe RM Signal predictor will

show the use a colour. –

o green, no sign of impending APE

o amber, health may be deteriorating. Optimise treatments and contact your clinical team if needed.

o red, signs that health is deteriorating and at risk of APE. Contact your CF team within the next 48 hours for review.

o white, not enough data has been entered into the system to provide a safe prediction. Please increase the amount of home monitoring you do.

Participants are advised that Breathe RM Signal is a guide and that if at any point they feel unwell they should contact their clinical team in the usual way.

Participants in both groups will be asked to complete a user acceptability questionnaire 3 monthly and a health-related quality of life questionnaire at the start of the study and then 3 monthly. Each questionnaire can be completed on paper or electronically and they take around 15 minutes to complete. Participants will be asked if they would like to participate in virtual (or one to one) discussions to give feedback regarding how they found using Breathe RM and/or Breathe RM Signal. People with CF have been involved in every stage of the design process and will continue to be involved throughout the study and dissemination of results.

A group of people with CF are involved in testing the user interface for the Breathe RM Signal App and ensuring that it is easy to use and understand.

What are the possible benefits and risks of participating?

Participants may feel empowered to take control of their health through home monitoring. If the Breathe RM Signal predictor detects an impending APE before symptoms start participants would benefit from earlier treatment options and therefore less long-term lung damage. Quality of life may be improved.

No risks.

Where is the study run from?

Papworth Hospital NHS Foundation Trust (UK)

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

October 2021 to April 2026

Who is funding the study?

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

2. LifeArc (UK)

Who is the main contact?

Prof Andres Floto, arf27@cam.ac.uk

Lucy Gale, lucy.gale1@nhs.net

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Type(s)**

Public

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**Additional identifiers****Integrated Research Application System (IRAS)**

316930

**Central Portfolio Management System (CPMS)**

55288

**Protocol serial number**

AI\_AWARD02259

**Study information****Scientific Title**

Artificial intelligence to control acute pulmonary exacerbations in cystic fibrosis

**Acronym**

ACE-CF

**Study objectives**

Visibility of Breathe RM Signal alongside home monitoring data will improve HRQOL (health related quality of life) and health parameters compared to visibility of home monitoring data alone.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 13/03/2023, East of England - Cambridge Central Research Ethics Committee (Equinox House City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8089; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0031

### **Study design**

Randomized; Both; Design type: Process of Care, Device, Cohort study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Cystic fibrosis

### **Interventions**

This is a one year randomised controlled trial. There will be 400 adult participants from 6 CF specialist centres across the UK. Potential participants will be approached regarding the study by the research team during their routine clinic appointments or inpatient stays. Potential participants may also be contacted by telephone, text, email or letter by the study team.

All participants will be given an activity monitor, weighing scales, oxygen saturation monitor and spirometer (to measure lung function) to use at home. These devices connect to an app called Breathe RM via Bluetooth. They help to predict if a participant is at risk of an acute pulmonary exacerbation (APE). The results from these devices can then be seen by the participant and by their clinical team (if the participant agrees to this). Participants will be randomly allocated to be in one of two groups. There will be 200 participants in each group.

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### **Intervention Type**

Other

### **Primary outcome(s)**

Quality of life using Cystic Fibrosis Revised Questionnaire (CFQR) at baseline and 12 months

### **Key secondary outcome(s)**

1. Lung function (FEV1 % predicted) at baseline and 12 months
2. Number of days requiring antibiotics for acute pulmonary exacerbation at baseline and 12 months

### **Completion date**

14/04/2026

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of Cystic Fibrosis based on genetic testing and/or sweat chloride levels
2. Age  $\geq$ 18 years of age
3. Able to provide written informed consent
4. Patients who are known to be suitable for home monitoring and able to manage the process or those currently undertaking home monitoring

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

257

**Key exclusion criteria**

1. Patients unable to provide written informed consent
2. Patients unwilling to consent to their link anonymized data from home monitoring being used for research
3. Patients unable to perform regular home monitoring
4. Lung transplant recipients
5. Patients participating in an interventional medicinal research study within the preceding 3 months

**Date of first enrolment**

12/07/2023

**Date of final enrolment**

28/02/2025

**Locations****Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**Royal Papworth Hospital NHS Foundation Trust**

Papworth Road

Cambridge Biomedical Campus

Cambridge

England

CB2 0AY

**Study participating centre**

**Belfast Health and Social Care Trust**

Trust Headquarters  
A Floor - Belfast City Hospital  
Lisburn Road  
Belfast  
Northern Ireland  
BT9 7AB

**Study participating centre**

**Cardiff & Vale University Lhb**

Woodland House  
Maes-y-coed Road  
Cardiff  
Wales  
CF14 4HH

**Study participating centre**

**Kings College Hospital**

King's College Hospital NHS Foundation Trust  
Denmark Hill  
London  
England  
SE5 9RS

**Study participating centre**

**NHS Greater Glasgow and Clyde**

J B Russell House  
Gartnavel Royal Hospital  
1055 Great Western Road Glasgow  
Glasgow  
Scotland  
G12 0XH

**Study participating centre**

**NHS Lothian**

Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
Scotland  
EH1 3EG

**Study participating centre**  
**Southampton University Hospital**  
Tremona Road  
Southampton  
England  
SO16 6YD

**Study participating centre**  
**University Hospital of South Manchester NHS Foundation Trust**  
Wythenshawe Hospital  
Southmoor Road  
Wythenshawe  
Manchester  
England  
M23 9LT

**Study participating centre**  
**Leeds Teaching Hospitals NHS Trust**  
St. James's University Hospital  
Beckett Street  
Leeds  
England  
LS9 7TF

**Study participating centre**  
**Nottingham University Hospitals NHS Trust - City Campus**  
Nottingham City Hospital  
Hucknall Road  
Nottingham  
England  
NG5 1PB

## **Sponsor information**

**Organisation**  
Papworth Hospital NHS Foundation Trust

**ROR**  
<https://ror.org/01qbabb31>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Central Commissioning Facility (CCF)

## Funder Name

LifeArc

# Results and Publications

## Individual participant data (IPD) sharing plan

### 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?
<a href="#">HRA research summary</a>			20/09/2023	No	No