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

Submission date
04/07/2023

Registration date
18/07/2023

Last Edited
26/01/2026

Recruitment status
No longer recruiting

Overall study status
Ongoing

Condition category
Respiratory

[_] 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

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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

316930

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

AI_AWARD02259

Central Portfolio Management System (CPMS)

55288

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 >=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/01qbebb31

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?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes