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

Submission date 04/07/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/07/2023	**Overall study status** Ongoing	
Last Edited 17/02/2025	**Condition category** Respiratory	

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?
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Lucy Gale, lucy.gale1@nhs.net

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316930

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55288, AI_AWARD02259, IRAS 316930

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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.

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Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
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

Overall study start date
01/10/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

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
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Royal Papworth Hospital NHS Foundation Trust
Papworth Road
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0AY

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Kings College Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Southampton University Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

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

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

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

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust

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+44 1223 638000
victoria.hughes1@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.papworthhospital.nhs.uk/

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
LifeArc

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/09/2027

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?
HRA research summary			20/09/2023	No	No