ISRCTN49949826 https://doi.org/10.1186/ISRCTN49949826

The use of a smartphone app to detect changes in health from voice recordings of people with cystic fibrosis

Submission date
05/05/2023

Recruitment status
No longer recruiting

Registration date
15/08/2023

Overall study status
Ongoing

Last Edited
19/12/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Sonde Health is a health technology company with a platform that provides voice-enabled health detection and monitoring capabilities for brain, respiratory and muscular impairment. Analysis of vocal biomarkers can give early insight into health and wellness. Sonde enables most companies and developers with Android or iOS mobile applications to integrate health condition detection and monitoring capabilities powered by voice.
Royal Papworth Hospital has demonstrated that daily recordings of a range of physiological parameters (e.g. spirometry, pulse oximetry, activity, heart rate, etc) in combination with self-reported survey responses (e.g. general wellness, cough, sleep quality) in people with cystic fibrosis (CF) holds promise to more accurately track fluctuations in health condition, in particular the start of pulmonary exacerbations. These data are collected remotely at the study participant' s home using remote/virtual online tools, as part of a larger effort to take a more virtual approach to clinics. Smartphone-based collection of voice samples for vocal biomarker analysis is a natural extension of this approach.
The aim of this study is to explore the potential of vocal biomarkers to assist in or improve the detection of health conditions in people with CF. The emphasis is on identifying the onset and progression of pulmonary exacerbations.

Who can participate?
Patients who are 18 years old or over who have a diagnosis of cystic fibrosis, are able to perform home monitoring and are already using the Project Breathe remote monitoring kit

What does the study involve?
Participants will be asked to do a daily voice recording of an 'ahhh' sound twice into an app downloaded onto a personal smartphone. They will also need to continue to use the Project Breathe home monitoring kit, which includes weighing scales, lung function spirometer, activity watch and recording self-reported measures of coughing and wellness. Participants will be enrolled for 1 year and it will have no impact on usual care.

What are the possible benefits of participating?
There are no potential immediate benefits to taking part but if the study proves successful it has the potential to improve the early diagnosis of pulmonary exacerbations at home. There are no known risks to taking part.

Where is the study run from?
Royal Papworth NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2026

Who is funding the study?
1. Cystic Fibrosis Trust (UK)
2. LifeArc (UK)

Who is the main contact?
Prof. Andres Floto, arf27@cam.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Andres Floto

ORCID ID
http://orcid.org/0000-0002-2188-5659

Contact details
Royal Papworth Hospital
Papworth Road
Cambridge
United Kingdom
CB2 0AY
+44 (0)1223 638000
arf27@cam.ac.uk

Type(s)
Public

Contact name
Mrs Lucy Gale

ORCID ID
http://orcid.org/0000-0002-5697-810X

Contact details
Royal Papworth Hospital
Papworth Road
Cambridge

United Kingdom
CB2 0AY
+44 (0)1223638000
lucy.gale1@nhs.net

Type(s)
Scientific

Contact name
Mrs Lucy Gale

Contact details
Royal Papworth Hospital
Papworth Road
Cambridge
United Kingdom
CB2 0AY
+44 (0)1223 638000
lucy.gale1@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289665

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P02706, IRAS 289665

Study information

Scientific Title
VOICE-CF: Vocal Biomarker Analysis for Health Condition Detection in People with Cystic Fibrosis

Acronym
VOICE-CF

Study objectives
The aim of this study is to explore the potential of vocal biomarkers to assist in or improve the detection of health conditions in people with cystic fibrosis. The emphasis is on identifying the onset and progression of pulmonary exacerbations and to evaluate whether daily respiratory symptom risk monitoring can assist the remote care of patients with cystic fibrosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2021, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048285; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 21/NE/0013

Study design
Single-centre observational prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home, Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
Participants will complete two daily voice recordings on the Sonde app using a personal smartphone. Each daily voice sample will take approximately 1 minute to complete a 6-second held vowel “ahhh.” Participants will also continue with usual home monitoring such as weight, lung function, activity and self-reported measures as part of the Project Breathe study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sonde smartphone app

Primary outcome measure
The accuracy of the Sonde predictive algorithm to predict when antibiotics will be required to treat an acute pulmonary exacerbation. This will be from the sensitivity and specificity of the predictive algorithm when compared to the Project Breathe predictive algorithm over a 12-month period.

Secondary outcome measures

The accuracy of the Sonde predictive algorithm to substitute for spirometry and pulse oximetry. This will be from the sensitivity and specificity of the Sonde predictive algorithm when compared to spirometry and pulse oximetry over a 12-month period.

Overall study start date
18/01/2021

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Diagnosis of cystic fibrosis based on genetic testing and/or sweat chloride levels
2. Age between >/= 18 to </= 65 years of age at time of consent
3. Able to provide written informed consent
4. Patients who are currently undertaking home monitoring/virtual clinics
5. Patients who have the use of a smartphone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100 then interim analysis with option to increase to 300

Total final enrolment
41

Key exclusion criteria
1. Patients unable to provide written informed consent
2. Patients who are currently not undertaking home monitoring/virtual clinics
3. Lung transplant recipients

Date of first enrolment
21/06/2021

Date of final enrolment

25/02/2022

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Royal Papworth NHS Foundation Trust

Sponsor details
Papworth Road
Cambridge
England
United Kingdom
CB2 0AY
+44 (0)1223 638000
victoria.hughes1@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://royalpapworth.nhs.uk/research-and-development

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Trust

Alternative Name(s)
Cystic Fibrosis, CF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
LifeArc

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Participants will be informed of the results by newsletter.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date. The datasets generated and/or data analysed during the current study are not expected to be made available until the end of all of the home monitoring studies that are currently underway/planned by this group.

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?
Protocol file	version 3.0	19/03/2021	17/05/2023	No	No
HRA research summary			20/09/2023	No	No