ISRCTN91138792 https://doi.org/10.1186/ISRCTN91138792

The use of a bedside radar device in cystic fibrosis to detect changes in breathing rate during respiratory exacerbation

Submission date 06/04/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/05/2023	**Overall study status** Ongoing	
Last Edited 20/11/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
The aim of this study is to explore if the Circadia C100 Contactless Respiratory Monitoring System detects changes in respiratory rate during inpatient treatment for pulmonary exacerbation (chest infection) in adult patients with cystic fibrosis.

In a previous study (Project Breathe) in people who have Cystic Fibrosis we have shown that home monitoring (for example, lung function, weight, oxygen levels) can predict, using artificial intelligence, when a pulmonary exacerbation is developing before patients are aware of symptoms. We can therefore start treatment sooner and potentially reduce long term lung damage.

The Circadia Contactless Respiratory Monitor is a non-contact device that uses radar technology to monitor respiration, motion, and sleep. The basis for the technology is that ventilation causes mechanical displacement of the chest and abdomen. A radar sensor can thus be used to monitor a person's respiratory rate and respiration patterns by tracking such motion. Because respiratory rate is measured continuously, respiratory rate variation can also be determined, as can the rate of change over time.

If the system successfully detects changes in respiratory rate, we will then request ethical approval to do a larger study. This will be to evaluate if overnight contactless respiratory monitoring in the home setting improves an Artificial Intelligence derived predictive algorithm for pulmonary exacerbation in adults with cystic fibrosis.

Who can participate?
Adults who are 18 years old or over, who have a diagnosis of cystic fibrosis and are able to perform home monitoring. Participants must be able to provide written informed consent, being admitted to Royal Papworth Hospital to receive treatment for a pulmonary exacerbation and already using the Project Breathe remote monitoring kit.

What does the study involve
When a participant is admitted to hospital for the treatment of a pulmonary exacerbation the bedside radar device will be set up in their room. It sits on the bedside table and continuously records breathing. Participants will have routine observations (including respiratory rate) monitored by the ward nursing team as per standard of care. Patients will also be asked to score their level of breathlessness during the admission using the modified Borg scale.

What are the potential benefits and risks of taking part?
There are no potential immediate benefits to taking part however, 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 in Cambridge, UK.

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

Who is funding the study?
Cystic Fibrosis Trust and LifeArc (UK)

Who is the main contact?
Dr Charles Haworth, charles.haworth@nhs.net

Contact information

Type(s)
Principal Investigator

Contact name
Dr Charles Haworth

Contact details
Royal Papworth Hospital NHS Foundation Trust
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0AY
+44 1223 638000
charles.haworth@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294760

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 48560, IRAS 294760

Study information

Scientific Title
Continuous contactless respiratory monitoring in cystic fibrosis

Acronym
CCRM in CF

Study objectives
Does the Circadia C100 Contactless Respiratory Monitoring System show a change in respiratory rate in adult patients with cystic fibrosis (CF) during inpatient treatment for a pulmonary exacerbation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2021, West of Scotland REC 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140211; WoSREC1@ggc.scot.nhs.uk), ref: 21/WS/0025

Study design
Single centre prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
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
Detection of change in respiratory rate in adult patients with cystic fibrosis during inpatient treatment for a pulmonary exacerbation.

Interventions

Following study consent, participants will have respiratory rate and related respiratory metrics (including respiratory rate variability, duration of inhalation and exhalation, ratio between respiration and pause events, respiratory patterns) recorded by the Circadia C100 Contactless Respiratory Monitor while in bed for the duration of the admission. Participants will have routine observations (including respiratory rate) monitored by the ward nursing team as per standard of care. Participants will also be asked to score the level of breathlessness during the admission using the modified Borg scale.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Circadia C100 Contactless Respiratory Monitor

Primary outcome measure
Change in mean respiration rate (breaths per minute) during admission day 1 to day 14. The ward nurses will measure respiration rate by counting how many times the participants chest rises in a minute. This information will then be documented in the medical notes.

Secondary outcome measures
Change in respiratory rate variability using breaths per minute over day 1 to 14. The ward nurses will measure respiration rate by counting how many times the participants chest rises in a minute. This information will then be documented in the medical notes.

Overall study start date
23/03/2021

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Clinical diagnosis of Cystic Fibrosis and confirmed by genetic testing
2. Age >= 18 years of age at time of consent
3. Able to provide written informed consent
4. Admitted to Royal Papworth Hospital to receive treatment for a pulmonary exacerbation
5. Already using the Project Breathe remote monitoring kit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8

Total final enrolment
8

Key exclusion criteria
1. Patients unable to provide written informed consent
2. Lung transplant recipients

Date of first enrolment
19/07/2022

Date of final enrolment
25/01/2023

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
Cambridge Biomedical Campus
Cambridge
England
United Kingdom
CB2 0AY

+44 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
01/05/2025

Individual participant data (IPD) sharing plan
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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No