ISRCTN14464661 https://doi.org/10.1186/ISRCTN14464661

CFHealthHub Data Observatory

Submission date
26/07/2017

Recruitment status
No longer recruiting

Registration date
02/08/2017

Overall study status
Completed

Last Edited
01/09/2026

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cystic Fibrosis (CF) is an inherited disease affecting 10000 people in the UK with an average age at death of 28 years in 2012. The lungs of people with CF (PWCF) are prone to infections. Daily physiotherapy and inhaled medications are needed to stay healthy. Around £30 million is spent annually on inhaled therapy but average adherence has been shown to be only 36%. Data suggest that adherence is better in younger children but of the most of the PWCF are now adults. PWCF who collect less than 50% of their medication cost the healthcare system significantly more than PWCF who collect more than 80% and most of the additional cost results from unscheduled emergency care and hospital admission. This unscheduled emergency care is distressing for PWCF and their families. Current research investigating whether adult PWCF can build successful, self-management, treatment habits using dose-counting nebulisers to collect adherence data, displaying this data on a website (CFHealthHub) and using a behaviour change toolkit, supported by a health professional, is ongoing. The aim of this study and the CFHealthHub is to help facilitate quality improvement projects using data from CFHealthHub about participants adherence and participant's relationship with the team. The study also aims to build an understanding of the process of implementing CFHH into routine practice.

Who can participate?
Adults aged 16 and older who are diagnosed with CF and use a nebuliser.

What does the study involve?
Participants receive a new chipped nebuliser, or have their existing nebuliser adapted to communicate with CFHealthHub. They are given a log in to the CFHealthHub system and shown how to use their device and the CFHealthHub website, by a member of their care team. This includes how to turn on and off data sharing with their clinical team. Participants are then able to use their nebuliser as normal, with the support of CFHealthHub. CFHealthHub automatically collects data on the participants' use of their chipped nebuliser, specifically the time of use and duration of inhalation. The data is stored in the secure CFHealthHub server. To provide a tailored CF toolkit participants will periodically complete a questionnaire about the challenges of taking their medication.

What are the possible benefits and risks of participating?
Participants may benefit from participating as the data could lead to changes in their CF care at their own health centre. Participants may find feedback available in the CFHealthHub useful to

understand their condition or form habits to take their medication. Participants may benefit from the treatment or therapy offered. There are no notable risks with participants, however, participants may have to give up some time to complete the consent visit.

Where is the study run from?
This study is being run by the University of Sheffield (UK) and takes place across seventeen hospitals in the UK.

When is the study starting and how long is it expected to run for?
January 2017 to March 2025

Who is funding the study?
NHS England CQUIN (UK)

Who is the main contact?
1. Sophie Farrell
sophie.farrell3@nhs.net
2. Dr Martin Wildman
martin.wildman3@nhs.net

Contact information

Type(s)
Public

Contact name
Ms Sophie Farrell

Contact details
Clinical Trials Research Unit
ScHARR (School of Health and Related Research)
University of Sheffield
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 114 222 4027
sophie.farrell3@nhs.net

Type(s)
Scientific

Contact name
Dr Martin Wildman

Contact details
Honorary Senior Clinical Lecturer Health Services Research, ScHARR, University Sheffield
Clinical Lead in Service Improvement
Consultant Respiratory Medicine & Adult CF
Sheffield Adult CF Centre

Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Type(s)
Public

Contact name
Ms India Davids

ORCID ID
https://orcid.org/0000-0003-4900-7695

Contact details
Sheffield Clinical Trials Research Unit, ScHARR
The University of Sheffield
Room 2.15, Innovation Centre
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 222 0843
i.davids@sheffield.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
216782

Study information

Scientific Title
CFHealthHub Data Observatory: A Quality Improvement project and Trials within Cohort platform for Cystic Fibrosis

Study objectives
Current study hypothesis as of 11/02/2020:
The aim of CFHealthHub data observatory is to explore the use of adherence data for quality improvement and as behavioural data within a cohort for future CF studies. The study also aims to build an understanding of the process of implementing CFHealthHub into routine clinical practice.

Previous study hypothesis:
The aim of CFHealthHub data observatory is to explore the use of adherence data for quality improvement and as behavioural data within a cohort for future CF studies.

Ethics approval required

Old ethics approval format

Ethics approval(s)
London-Brent Research Ethics Committee, 06/04/2017, ref: 17/LO/0032

Primary study design
Observational

Study design
Current study design as of 11/02/2020:
A pragmatic development study which consists of an observational cohort study and a platform for quality improvement projects across the NHS.

A mixed-methods process evaluation that will be repeated yearly from 2018 to 2020 and will follow MRC process evaluation guidelines to explore the activities and outputs documented on the logic model, specifically to identify the barriers and pathways to implementation.

Previous study design:
A pragmatic development study which consists of an observational cohort study and a platform for quality improvement projects across the NHS.

Study type(s)
Other

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

Interventions
CFHealthHub is an online portal which displays adherence data and provides behaviour change resources and tools for people with Cystic Fibrosis (PWCF), these tools used alongside trained CF health professionals support changes in patient self-management (nebuliser adherence). It is available on-line via computers, tablets or mobile phones. Previous research has focused on the development of an adherence intervention for PWCF (CFHealthHub) and is subject to ongoing evaluation. These work packages have been supported by an NIHR applied programme grants (Reference RP-PG-1212-20015).

The Data Observatory facilitates quality improvement projects, which act as an intervention within the CF team. These QI projects utilise the Clinical Microsystem methodology developed by the Dartmouth Institute, USA (Nelson, Bataldan and Godfrey 2007) and adopted by the Sheffield Microsystem Coaching Academy (MCA). The Sheffield MCA (http://www.sheffieldmca.org.uk) approach advocates that complex health systems can be reduced to smaller building blocks called ‘microsystems’ where multidisciplinary teams deliver healthcare to patients. At each microsystem a number of QI projects may occur but the implementation requires the completion of four phases; Assessment, Diagnose, Treatment and Standardise, where tools such as assessment using the 5 P’s (Purpose, Patients, Professionals, Processes, Patterns) process mapping, time series measurements, Plan Do Study Act (PDSA) cycles are utilised until the change idea has been adapted or has become embedded into the microsystem.

Participants who consent to take part in the study will receive a new chipped nebuliser, or have their existing nebuliser adapted to communicate with CFHealthHub. They will be given a log in to the CFHealthHub system and shown how to use their device and the CFHealthHub website, by

a member of their care team. This includes how to turn on and off data sharing with their clinical team. Participants will then be able to use their nebuliser as normal, with the support of CFHealthHub.
CFHealthHub automatically collects data on the participants use of their chipped nebuliser, specifically the time of use and duration of inhalation. The data is stored in the secure CFHealthHub server.

To provide a tailored CF toolkit participant's periodically complete a questionnaire about the challenges of taking their medication, which is entered by a member of staff into CFHealthHub, at a clinic appointment or review.

Members of the CF team will be able to view the adherence data for participants who have data sharing switched on, and identify if any participants could benefit from the behavioural intervention that is currently being tested in an RCT. The Data Observatory will not be measuring the effectiveness of this intervention. Instead, CFHealthHub will help facilitate quality improvement projects using data from CFHealthHub about participants adherence and participant's relationship with the team.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 11/02/2020:
Objective nebuliser adherence measured using adherence information stored in the CFHealthHub system. Three-monthly and annual adherence for each individual will be calculated as unadjusted adherence, normative adherence (Hoo, 2016) and total nebuliser used per week.

Previous primary outcome measure:
Sophisticated normative adherence as defined by Hoo (2016)

Key secondary outcome(s)
Current secondary outcome measures as of 13/02/2020:
1. Lung function assessed by FEV1 captured on CFHealthHub at baseline and every clinical encounter
2. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub at baseline and every clinical encounter
3. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

Previous secondary outcome measures as of 11/02/2020:
1. Lung function assessed by FEV1 on spirometry
2. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub
3. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

Previous secondary outcome measures:
1. Unadjusted adherence is measured using adherence information stored in the CFHealthHub system
2. Simple normative adherence is measured using the CFHealthHub system
3. Process data (prescription checks, duration of inhalation) is measured using data recorded on CFHealthHub
4. The rate of consent as measured by the number of completed consent forms. Rate of follow up is measured by the number of completed follow-up questionnaires, data sharing is available by extracting the number of participants with data sharing switched on or off on the CFHealthHub system.

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Diagnosed with CF and with data within the CF registry
2. Aged 16 years and above
3. Taking inhaled mucolytics or antibiotics via a chipped nebuliser (e.g. eTrack or I-Neb) or able and willing to take via eTrack or I-Neb

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Lacking in capacity to give informed consent

Date of first enrolment
25/05/2017

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Sheffield Teaching Hospital NHS Foundation Trust
Cystic Fibrosis Centre
Northern General Hospital
Herries Rd
Sheffield
England
S5 7AU

Study participating centre
Nottingham University Hospital NHS Trust
East Midlands Cystic Fibrosis Adult CF Centre
Nottingham University Hospitals NHS Trust City Hospital campus
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
University Hospital Southampton NHS Foundation Trust
Adult cystic fibrosis service
level C,
West Wing
Southampton General Hospital
Tremona Rd
Southampton
England
SO16 6YD

Study participating centre

Frimley Park Hospital
Frimley Health NHS Foundation Trust
Portsmouth Rd
Frimley
Camberley
England
GU16 7UJ

Study participating centre
The Royal Victoria Infirmary
Cystic Fibrosis Department, Respiratory Medicine
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Rd
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
Norfolk and Norwich University Hospital
Respiratory Medicine
East Block
Level 3
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
England
NR4 7UY

Study participating centre
Royal Stoke University Hospital
North West Midlands Cystic Fibrosis Centre
Children's Outpatients Department
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

Study participating centre
John Radcliffe Hospital
Oxford Adult Cystic Fibrosis Centre (OACFC)
Ward 5D
Level 5

John Radcliffe Hospital
Headley way
Headington
Oxford
England
OX3 9DU

Study participating centre
St Bartholomew's Hospital
Ward 4E
Cystic Fibrosis Unit
Department of Respiratory Medicine
4th Floor
KGV Building
West Smithfield
London
England
EC1A 7BE

Study participating centre
Royal Cornwall Hospital
The Lighthouse
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
England
TR1 3LQ

Study participating centre
Royal Devon and Exeter Hospital
Q235
Level 2
Royal Devon and Exeter Hospital NHS Foundation Trust
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Heartlands Hospital
Ward 26
University Hospitals Birmingham NHS Foundation Trust
Bordesley

Green East
Birmingham
England
B9 5SS

Study participating centre
Bristol Royal Infirmary
Medical Research Unit
Zone B501
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
England
BS2 8HW

Study participating centre
Glenfield Hospital
Respiratory Bioemedical Research Unit 3
University Hospitals of Leicester NHS Foundation Trust
Groby Rd
Leicester
England
LE3 9QP

Study participating centre
Derriford Hospital
Chest Clinic
Level 6
University Hospitals Plymouth NHS Trust
Plymouth
England
PL6 8DH

Study participating centre
University Hospital Llandough (UHL)
The All Wales Cystic Fibrosis Centre
University Hospital of Wales
Penlan Road
Llandough
Cardiff
Wales
CF64 2XX

Study participating centre
York Hospital
Learning and Research Centre
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
England
YO31 8HE

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NHS England CQUIN funding

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Martin Wildman (Chief Investigator), martin.wildman3@nhs.net. The data-sets are available throughout the duration of the Data Observatory. Data available will include real-time adherence data. At present the study team are refining what information will be helpful for future research, therefore contacting the study team to discuss any requests is advised. Data will only be available from participants who have consented to participate in the trials within cohorts platform. All future research using the Data Observatory platform must be ethically approved. The Data Observatory is suitable for future randomised controlled trials. However, there are two levels of consent for the trials within cohorts platform, consent to:
1. Pseudonymised data within CFHealthHub to be used for future research related to CF which has been ethically approved
2. Be included for selection in future research studies which have been ethically approved. If the participant meets the desired characteristics for the study they may be selected by chance to

receive a new treatment. If they are not selected to receive the new treatment then they consent to sharing pseudonymised data without further notification. If they are selected to receive the new treatment they understand that they will be contacted and will have the opportunity to decline participation in the new study.

Previous publication and dissemination plan:
Planned publication in a high-impact peer reviewed journal. Additional documentation is available to download from the study website https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub/dataobservatory

IPD sharing statement:
The datasets generated during and/or analysed during the current study will be available upon request from Dr Martin Wildman (Chief Investigator), martin.wildman@sth.nhs.uk. The data-sets are available throughout the duration of the Data Observatory. Data available will include real-time adherence data. At present the study team are refining what information will be helpful for future research, therefore contacting the study team to discuss any requests is advised. Data will only be available from participants who have consented to participate in the trials within cohorts platform. All future research using the Data Observatory platform must be ethically approved. The Data Observatory is suitable for future randomised controlled trials. However, there are two levels of consent for the trials within cohorts platform, consent to:
1. Pseudonymised data within CFHealthHub to be used for future research related to CF which has been ethically approved
2. Be included for selection in future research studies which have been ethically approved. If the participant meets the desired characteristics for the study they may be selected by chance to receive a new treatment. If they are not selected to receive the new treatment then they consent to sharing pseudonymised data without further notification. If they are selected to receive the new treatment they understand that they will be contacted and will have the opportunity to decline participation in the new study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		10/07/2019	01/09/2026	No	No
HRA research summary			28/06/2023	No	No
Other publications		08/02/2022	01/09/2026	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version v9.0	19/03/2020	01/06/2020	No	No
Study website		11/11/2025	11/11/2025	No	Yes