ISRCTN55504164 https://doi.org/10.1186/ISRCTN55504164

A randomised controlled trial and parallel process evaluation to determine whether CFHealthHub, an intervention to help CF patients build better treatment habits, offers any benefit over usual care to adults with CF

Submission date
17/07/2017

Recruitment status
No longer recruiting

Registration date
12/10/2017

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Respiratory

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

Plain English summary of protocol
Background and study aims
Cystic Fibrosis (CF) is a genetic condition that causes the lungs and digestive system to be clogged with mucus. It affects 10000 people in the UK. The lungs of people with CF (PWCF) are prone to infections and require daily medication to stay healthy. Average adherence to medication has been shown to be only 36%. Poor adherence is associated with poor clinical outcomes including distressing unscheduled hospitalisations. Researchers have designed an intervention that will feedback adherence data to PWCF using chipped nebulisers displaying real-time treatment use on smartphones and the website (CFHealthhub). Feedback is a powerful support to habit formation and the use of the CFHealthHub and a behaviour change manual to support PWCF in building successful treatment habits. The aim of this study is to assess whether the use of the CFHealthHub intervention, which includes the toolkit and website, reduces the amount of unscheduled emergency care PWCF require compared to those receiving standard care.

Who can participate?
Aged 16 years and older who are diagnosed with CF and are willing to take inhaled mucolytics or antibiotics via a chipped nebuliser.

What does the study involve?
Participants are randomly allocated to groups. Those in the first group receive their usual care. Those in the second group receive the CFHealthHub and behaviour change manual to support them in building successful treatment habits. Participants are followed for 12 months and data is collected about their exacerbations and their adherence in treatment.

What are the possible benefits and risks of participating?
Participants may benefit from being able to access their CFHealthhub group and a record of

their nebuliser use. Participants may find feedback treatment useful in making treatments a regular and routine part of life. The main risk/disadvantage to participation is giving up time to attend the appointments. Appointments will vary from 10 minutes (over the phone) to up to one hour when more data is collected.

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

When is the study starting and how long is it expected to run for?
January 2019 to December 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Chin Maguire
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Study website
http://www.sheffield.ac.uk/scharr/sections/dts/ctru/actif

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 33345

Study information

Scientific Title
Development and evaluation of an intervention to support Adherence to treatment in adults with Cystic Fibrosis: A randomised controlled trial and parallel process evaluation

Acronym
ACtiF

Study objectives
The aim of this study is to assess whether use of the CFHealthHub intervention, which includes the toolkit and website, reduces the amount of unscheduled emergency care PWCF require compared to those receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC London - Brent Research Ethics Committee, 02/03/2017, ref: 17/LO/0035

Study design
Randomized; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Device, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Congenital Disorders/ Congenital malformations of the respiratory system

Interventions
The study is a mixed method study comprising a Quantitative component (parallel group, open labelled, external RCT) and a Qualitative component (audio recordings of consultations and interviews). Both quantitative and qualitative data will contribute to the process evaluation. The main aims of the study are to determine whether the intervention offers any benefit over usual care in adult patients with CF.

Once consent and eligibility for the study have been determined, study participants are randomised to either the intervention arm (CFHealthHub) or control arm (usual care) via the Sheffield Clinical Trials Research Unit web randomisation system. Participants in both groups contribute adherence data to CFHealthHub but only those randomised to the intervention arm have access to interact with CFHealthHub to manage their treatment habits. This is done via a combination of face to face (or telephone/email contact sessions) with the trial interventionists and using CFHealthHub as a tool independently between sessions.

The mean number of Pulmonary Exacerbations (PE) per patient in the 12-month post-consent follow-up as determined by the Fuch's criteria is assessed. Each participant is followed up for 12 months. Research data is collected at a number of time points including baseline, standard clinic visits, during intervention sessions and at 12 months. Exacerbation data is collected at each point of an exacerbation. Data relating to intervention delivery are also collated during the course of the trial. Qualitative data are collected during interviews with interventionists and intervention arm participants to determine the acceptability of CFHealthHub. Audio recordings from each intervention delivery session are used to assess the fidelity of the intervention.

Beyond the 12 month visit, participants continue to contribute adherence data to CFHealthHub till 30/6/2019. During this period, those in the intervention arm can continue to receive support from the interventionists or use CFHealthHub independently.

Intervention Type
Other

Primary outcome measure
Number of exacerbations are measured based on the modified Fuch's criteria and determined by a combination of hospital and participant input at baseline to June 2019.

Secondary outcome measures
1. Patient knowledge, skills, and confidence for self-management is measured using Patient Activation Measure (PAM-13) at baseline and 12 months
2. Life chaos is measured using Assessment of routine at baseline and 12 months
3. Generic health status is measured using the EuroQuol (EQ5d-5L) at baseline, 12 months and around points of exacerbations
4. Habit based behavioural patterns are measured using Self-Report Behavioural Automaticity Index (SRBAI) at baseline and 12 months
5. Disease specific quality of life is measured using Cystic Fibrosis Questionnaire-Revised (CFQ-R) at baseline and 12 months
6. Depression severity is measured using the Patient Health Questionnaire depression scale (PHQ-8) at baseline and 12 months
7. Medication adherence is measured using MAD (Medication Adherence Data-3 items) at baseline and 12 months
8. Anxiety severity is measured using the General Anxiety Disorder 7-item anxiety scale (GAD-7) at baseline and 12 months

9. Beliefs about medication (specifically nebuliser use) is measured using The Capability Opportunity Motivation Behaviour Beliefs Questionnaire (COM-BMQ) at baseline and 12 months
10. Behaviour is measured using Behavioural question and questionnaire at baseline and 12 months
11. Clinical measures is measured using Medical adherence questions, BMI FEV1/FVC at baseline to end of study
12. Resource use is measured using questionnaire at 12 month visit

Overall study start date
01/09/2017

Completion date
30/12/2019

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 566; UK Sample Size: 556

Total final enrolment
608

Key exclusion criteria
1. Post-lung transplant
2. People on the active lung transplant list
3. Patients receiving palliative care, with palliative intent, for whom trial participation could be a burden
4. Participants who lack capacity to give informed consent
5. Participants using dry powder devices to take antibiotics or mucolytics

Date of first enrolment
02/10/2017

Date of final enrolment
30/05/2018

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Staffordshire
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Papworth Hospital
Papworth Everard
Cambridge

United Kingdom
CB23 3RE

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
St Bartholomew's Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Bristol Royal Infirmary
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
King's College Hospital
Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre
Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Royal Brompton Hospital
Sydney Street
Chelsea
London
United Kingdom
SW3 6NP

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
Cardiff and Vale University Health Board
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Western General Hospital
Crewe Road S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green E
Birmingham

United Kingdom
B9 5SS

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LQ

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Sheffield Teaching Hospitals NSH Foundation Trust

Sponsor details
Sheffield Teaching Hospitals NHS Foundation Trust
D Floor
Clinical Research Office
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The main study report will be published within the NIHR Journals Library (Programme Grants for Applied Research). Other study publications will be published in peer-reviewed journals.
The CFHealthHub RCT website has links to the Protocol and PIS
https://www.sheffield.ac.uk/scharr/sections/dts/ctru/cfhealthhub

Intention to publish date

31/01/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Amanda Loban, Data Manager (a.loban@sheffield.ac.uk). A formal request will need to be submitted and reviewed by the Study Trial Management group. The group will consider, at the time of the request, the type of data, any restrictions on this and the mechanism by which this will be shared on a case-by-case basis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		30/09/2020	01/10/2020	No	No
HRA research summary			28/06/2023	No	No
Results article		23/09/2021	08/11/2023	Yes	No
Results article		01/10/2021	08/11/2023	Yes	No
Other publications	fidelity assessment	21/03/2024	30/06/2025	Yes	No