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Adherence to treatment in adults with cystic fibrosis

Submission date	Recruitment status	[X] Prospectively registered
18/05/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Genetic Diseases	

Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is an inherited condition which causes the lungs and digestive system to become blocked with mucus. It is caused by a faulty gene, which is responsible for controlling the movement of water and salts in and out of cells. This leads to a buildup of sticky mucus which clogs the lungs and airways causing breathing difficulties and lung infections, and the digestive system which affects the way food travels through and the ability to absorb nutrients from it. Most people with CF experience problems with lung function and usually are treated with a combination of physiotherapy and inhaled medications to prevent lung infections and the buildup of mucus that causes damage. Around £30 million is spent every year on inhaled therapy but average adherence has been shown to be only 36%. Data suggest that adherence is better in younger children (71% in under-12s, falling to 50% in teenagers) but of the 10000 UK people with CF (PWCF) almost 6000 are now adults. PWCF who collect less than 50% of their medication cost the healthcare system significantly more in terms of unscheduled emergency care and hospital admission. This study is looking at a new programme which has been designed to help adults with CF to monitor their medication usage, by using dose-counting nebulisers to collect data and send it to a website where it can be displayed. The aim of this study is to find out whether a large-scale study looking at the whether this program is feasible and acceptable to PWCF.

Who can participate?
Patients aged 16 years and over with CF who are within a CF registry and are taking medication via a chipped nebulizer.

What does the study involve?
Participants are randomly allocated to one of two groups. Both groups have a short period of two to four weeks when data is collected through their nebulisers and fed back to the website. Following this, those in the first group are given access to their data so that they can manage their treatment habits. This involves a combination of at least three face-to-face/telephone /email contact sessions with trial staff and using the program independently over five months. Those in the second group continue as normal, whilst having their usage data recorded

continually. At the start of the study and after five months, the health and medication usage and behaviour patterns of participants in both groups are determined using the data collected by the dose-counting nebulisers.

What are the possible benefits and risks of participating?
Participants with access to the program may benefit from improvements to the way they take their medication. There are no notable risks involved with participating.

Where is the study run from?
1. Wessex Adult Cystic Fibrosis Service - Poole (UK)
2. Wessex Adult Cystic Fibrosis Service - Southampton (UK)
3. Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2016 to April 2017

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
20849

Study information

Scientific Title
Development and evaluation of an intervention to support Adherence to treatment in adults with cystic fibrosis: A feasibility study comprised of an external pilot randomised controlled trial and process evaluation (WP 3.1)

Acronym
ACtiF

Study objectives
The aim of the study is to determine the feasibility of conducting a full-scale randomised controlled trial investigating the acceptability of the CFHealthHub intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC London - Brent Research Ethics Committee, 11/03/2016, ref: 16/LO/0356

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Other diseases of the respiratory system

Interventions
Study participants will be randomised to either the intervention arm (CFHealthHub) or control arm (usual care). Participants in both groups will contribute adherence data to CFHealthHub but only those randomised to the intervention arm will have access to interact with CFHealthHub to manage their treatment habits. This will be 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. Although it is anticipated that there will be a minimum of 3 sessions during the follow up period, further sessions will be tailored to each participants individual needs.

Intervention Type
Other

Primary outcome(s)
Number of pulmonary exacerbations of cystic fibrosis is measured using the modified Fuchs Criteria at baseline and 5 (+/- 1) months

Key secondary outcome(s))

1. Generic health status is measured using the EQ5D5L at baseline and 5 (+/- 1) months
2. Assessment of patient knowledge, skill, and confidence for self-management is measured using the Patient Activation Measure -13 at baseline and 5 (+/- 1) months
3. Life chaos is measured using the Confusion, Hubbub And Order Scale -6 at baseline and at 5 +/- 1 months
4. Habit-based behaviour patterns are measured using the Self-Reported Behavioural Automaticity Index at baseline and 5 (+/- 1) months
5. Disease specific health-related quality of life is measured using the Cystic Fibrosis Questionnaire-Revised at baseline and 5 (+/- 1) months
6. Depressive disorder severity is measured using the Patient Health Questionnaire depression scale -8 at baseline and 5 (+/- 1) months
7. Medication adherence is measured using the Medication Adherence Data -3 at baseline and 5 (+/- 1) months
8. Anxiety severity is measured using the General Anxiety Disorder -7 at baseline and 5 (+/- 1) months
9. Perceived necessities and concerns for nebuliser treatment are measured using the Capability Opportunity Motivation–Beliefs about Medicines Questionnaire at baseline and 5 (+/- 1) months
10. Resource use data is collected using the resource use form developed for the study at 5 (+/- 1) months
11. Acceptability of the intervention is determined through qualitative interviews with patients and members of the multidisciplinary CF team at 5 (+/- 1) months
12. Condition severity is measured using FEV1/FVC at routine clinic visits from baseline to study end

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Diagnosed with CF and within 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
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
61

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
13/06/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wessex Adult Cystic Fibrosis Service (Southampton)
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Wessex Adult Cystic Fibrosis Service (Poole)
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Nottingham University Hospitals NHS Trust
City Hospital campus
Hucknall Road
Nottingham

United Kingdom
NG5 1PB

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/02/2019	08/05/2019	Yes	No
Results article	results	06/10/2020	24/07/2020	Yes	No
Results article		01/10/2021	10/07/2023	Yes	No
Results article		27/10/2020	10/07/2023	Yes	No
Results article		11/04/2019	10/07/2023	Yes	No
Basic results		18/09/2018	18/09/2018	No	No
HRA research summary			28/06/2023	No	No
Protocol (other)		11/04/2019	10/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes