ISRCTN37959826 https://doi.org/10.1186/ISRCTN37959826

Randomised trial of a web-based intervention for adherence in cystic fibrosis

Submission date
10/11/2015

Recruitment status
No longer recruiting

Registration date
11/11/2015

Overall study status
Completed

Last Edited
28/10/2022

Condition category
Nutritional, Metabolic, Endocrine

[X] 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 in which the lungs and digestive system become clogged with thick sticky mucus. Non-adherence (when a patient does not continue treatment that a doctor has recommended) remains one of the biggest contributors to failure of treatment. Overall adherence rates have been reported as less than 50% for the disease but vary according to individual treatments and the measurement process used. Web-based intervention is one approach that has attracted increased interest as a means to update knowledge and encourage interaction and engagement with treatment. Online interventions have been shown to improve knowledge and behaviour for illnesses such as diabetes, asthma, arthritis and heart disease. Increased knowledge of medication, the purpose and side effects of treatment and self-monitoring have also been shown. Adherence programmes that use web-based interventions to improve adherence in CF are currently lacking. An early study has tested the use of a web-based intervention for improved adherence to nutritional treatment in children with CF, but there are none that have been tested in adults or within a UK population. This study aims to evaluate the use of a web-based intervention for adherence in adults with cystic fibrosis.

Who can participate?
Patients aged 16 - 60 with CF.

What does the study involve?
At the start of the study participants and their clinicians jointly identify one to three treatments to focus on for improved adherence from six areas of focus (i.e., nutrition, enzymes, liver medications, airways treatments, vitamins and antibiotics). Each participant is then randomly allocated either to receive information for the identified treatments online through the web, or to receive usual care. In the online group participants are provided with online information which shows how medications and treatments work, contains ‘patient video stories’ of their own treatment experiences, and asks participants to undertake specific tasks as they view the information, and to provide feedback and post questions prior to their planned two-monthly appointments. Feedback or questions can then be answered at the next two-monthly appointment. In the usual care group participants receive information from clinicians in the usual way, through individual discussion, fact sheets and clinician explanation. At the beginning and end of the 12-month period participants also complete a knowledge questionnaire for each of

their individual and agreed areas of focus, to assess change in knowledge. In total participants attend seven appointments at the start and after 2, 4, 6, 8, 10 and 12 months. At each of these appointments routine tests are carried out for lung function, weight and BMI. Some measures are additionally recorded at 0, 6 and 12 months, namely variation in lung function over previous 6 months, and a blood sample is taken to measure vitamin A, D and E levels.

What are the possible benefits and risks of participating?
This study will establish new ways of improving patient participation in care, and their feedback might benefit other CF patients. Potential risks/burdens include time spent accessing online knowledge and completing questionnaires, and an additional blood test.

Where is the study run from?
Leeds Adult Cystic Fibrosis Unit (UK).

When is the study starting and how long is it expected to run for?
February 2016 to February 2018.

Who is funding the study?
Gilead Sciences Ltd (UK).

Who is the main contact?
Dr Helen White
h.white@leedsbeckett.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Helen White

Contact details
Nutrition and Dietetic Group
Leeds Beckett University
Leeds
United Kingdom
LS1 3HE
+44 (0)113 812 4994
H.White@leedsbeckett.ac.uk

Type(s)
Scientific

Contact name
Prof Daniel Peckham

Contact details

University of Leeds and Leeds Teaching Hospitals Trust
Leeds
United Kingdom
LS9 7TF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IN-UK-205-1889

Study information

Scientific Title
Randomised trial of a web-based intervention for adherence in cystic fibrosis

Study objectives
Adherence programmes that use web-based interventions to improve adherence in cystic fibrosis are currently lacking. An early pilot RCT, the Be-In-CHARGE! Website Intervention, has tested the use of web-based intervention for improved adherence to nutritional treatment in children with cystic fibrosis and awaits evaluation, but there are none that have been implemented in adults or within a UK population. This study is the third phase of an ongoing programme of funded research which aims to evaluate the use of a web-based intervention for adherence in adults with cystic fibrosis.

Hypothesis: a web-based intervention improves adherence in adults with cystic fibrosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 18/01/2016, ref: 15/YH/0558

Study design
Interventional randomised controlled trial

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 below to request a patient information sheet

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

Interventions
Participants will complete two questionnaires at the beginning and end of the study. The first asks about the medications and treatments currently taken and any reasons they may have difficulty in taking prescribed treatments. The second asks about their quality of life. A blood sample will be taken at the start, middle and end of the study, to check fat soluble vitamin levels A, D and E. At baseline and end (12 months) their pharmacist will be contacted to provide details on how many prescriptions have been collected within the previous 6 months.

1-3 treatments for improved adherence will be identified jointly with the clinician at the start of the study from 6 areas of focus, i.e. nutrition, enzymes, liver medications, airways treatments, vitamins and antibiotics. Each participant will then be randomly allocated to receive information for the identified treatments, either online through the web (and through an electronic device) or to receive usual care. Computerised allocation will be used. In the treatment arm participants will be provided with online information which shows how medications and treatments work, contains ‘patient video stories’ of their own treatment experiences and is interactive, asking participants to undertake specific tasks as they view the information and to provide feedback and post questions prior to their planned two monthly appointments. Feedback or questions can then be answered at the next two monthly appointment. In the usual care arm participants will receive information from clinicians in the usual way, through individual discussion, and fact sheet and clinician explanation. At the beginning and end of the 12-month period participants also complete a knowledge questionnaire for each of their individual and agreed areas of focus, to assess change in knowledge.

In total participants will have 7 appointments according to existing defined standards of care at start, 2, 4, 6, 8, 10 and 12 months. At each of these appointments routine measures will be taken for lung function, weight and BMI. Some measures will additionally be recorded at 0, 6 and 12 months, namely coefficient variation in lung function over previous 6 months, and Vitamin A, D and E levels.

Intervention Type
Other

Primary outcome measure
Medication Possession Ratio (MPR) derived from two sources (self-report and pharmacy refill records) at baseline and 12 months

Secondary outcome measures
1. CF medication knowledge [time frame: baseline, 6 months, 12 months]
2. Health Related Quality of Life measured by the validated CF-QoL [time frame: baseline, 12

months]
3. Lung Function [time frame: baseline, 6 months, 12 months]. Forced expiratory volume in one second (FEV1) percent predicted and forced vital capacity (FVC) – used to calculate rate of decline for 1 year pre and 1 year post start intervention
4. BMI [time frame: baseline, 6 months, 12 months]
5. Vitamin A, D, E levels [time frame: baseline, 6 months, 12 months]
6. Coefficient of variation for lung function [time frame: baseline, 6 months, 12 months]. For each measure the coefficient of variation will be calculated from the variation of the highest and lowest values of lung function over the previous 6 months
7. Pulmonary exacerbation [time frame: number of exacerbations requiring intravenous therapy from 1 year prior to baseline until start; and from baseline to 1 year]
8. CF hospitalisations [time frame: 1 year prior to baseline until start; and from baseline to 1 year] – including iv treatment days

Overall study start date
01/02/2016

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of CF, attending Leeds Adult CF unit for their complete care
2. Male or female patients age 16 - 60 years old
3. Consecutive volunteers recruited at time of clinical stability [end of in-patient treatment or at out-patient clinic]
4. Patient must be prescribed a minimum of three specified medications (see below) for at least 6 months prior to signing the informed consent form: azithromycin hypertonic saline, TOBI®, Pulmozyme®, pancreatic enzyme replacement therapy, oral antibiotics, fat-soluble vitamins, insulin, inhaled compounded tobramycin, oral nutritional supplements, insulin, AZLI

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
99

Key exclusion criteria
1. Pregnancy
2. Acceptance on the lung transplant list (note: participation in this study will not delay or

exclude patients from being placed on the transplant list in the future or receiving a transplant once enrolled in the study)

Date of first enrolment
01/02/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Adult Cystic Fibrosis Unit
Ward J6
Gledhow Wing
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS6 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals Trust (UK)

Sponsor details
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Industry

Funder Name
Gilead Sciences Ltd (UK)

Results and Publications

Publication and dissemination plan
Dissemination will occur through:
1. Conference abstract submissions
1.1. Interim results European Cystic Fibrosis Conference June 2018 and North American Cystic Fibrosis Conference October 2018
1.2. Final results European Cystic Fibrosis Conference June 2019
2. Peer-reviewed journal submission August 2019
3. Dissemination to patients via Regional CF Unit newsletter and web site
4. ISRCTN website

Intention to publish date
30/03/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

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?
Abstract results	number 697, page 420	05/09/2019	28/10/2022	No	No
HRA research summary			28/06/2023	No	No