

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

Submission date 10/11/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/10/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

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Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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)

ROR

<https://ror.org/00v4dac24>

Funder(s)

Funder type

Industry

Funder Name

Gilead Sciences Ltd (UK)

Results and Publications

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