ISRCTN21222766 https://doi.org/10.1186/ISRCTN21222766

Feasibility of providing digital physical activity promotion materials for young people with cystic fibrosis

Submission date
06/10/2022

Recruitment status
Stopped

Registration date
07/11/2022

Overall study status
Stopped

Last Edited
03/05/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a feasibility trial of a digital physical activity intervention for young people living with cystic fibrosis (CF). CF is the most common inherited condition in the UK and is caused by a faulty gene. Physical activity is recommended in managing CF to counter the physical and psychological effects of the condition. Despite the benefits of regular physical activity, it is often reported that engagement in physical activity is poor. Physical activity levels among those with CF decrease during adolescence and remain low during adulthood, which can have long-term health consequences for people with CF impacting their quality of life. Intervening during adolescence is therefore critical.

We have developed a digital physical activity intervention that considers unique barriers experienced by young people with CF to motivate and support engagement in physical activity and to increase their quality of life. The aim of the current study is to help establish whether digitally delivering (e.g., online) physical activity promotion material is accessible, usable, and engaging in supporting young people with CF to be more physically active.

Who can participate?
Young people aged between 12 and 18 years old with CF

What does the study involve?
The total time commitment for participation is 6 months. Access to digitally delivered physical activity promotion material will be provided throughout this period. The trial will involve completing questionnaires, taking part in interviews (optional), and wearing activity monitors at different times over the course of the trial.

What are the possible benefits and risks of participating?
Access to digital physical activity promotion material may lead to participants increasing their levels of physical activity. The type of activity undertaken is of the participant's own choosing (i.

e., non-prescriptive). While increased levels of physical activity may lead to several health benefits, one issue is that it may also lead to increased injury risk. This is viewed as a minor risk of participating.

Where is the study run from?
This trial is being sponsored by the Royal Devon & Exeter NHS Foundation Trust (UK) and will be delivered by researchers based at the University of Exeter (UK) and the University of Bristol (UK)

When is the study starting and how long is it expected to run for?
July 2020 to August 2023

Who is funding the study?
National Institute of Health and Care Research (NIHR) Research for Patient Benefit (RFpB) (UK)

Who is the main contact?
Dr Robert Mann
robert.mann@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Robert Mann

ORCID ID
http://orcid.org/0000-0003-3704-6881

Contact details
Children's Health and Exercise Research Centre
Baring Court
St Luke's Campus
University of Exeter
Heavitree Road
Exeter
United Kingdom
EX1 2LU
+44 (0)1392724752
robert.mann@exeter.ac.uk

Type(s)
Principal Investigator

Contact name
Dr Samantha van Beurden

ORCID ID
http://orcid.org/0000-0001-7848-2159

Contact details

Research Fellow
University of Exeter
Primary Care Research Group
Smeall Building
University of Exeter Medical School
College of Medicine and Health
St Luke’s Camp
Heavitree Road
Exeter
United Kingdom
EX1 2LU
+44 (0)1392 726440
S.B.vanBeurden@exeter.ac.uk

Type(s)
Scientific

Contact name
Prof Craig Williams

ORCID ID
http://orcid.org/0000-0002-1740-6248

Contact details
Children’s Health and Exercise Research Centre
Baring Court
St Luke’s Campus
University of Exeter
Heavitree Road
Exeter
United Kingdom
EX1 2LU
+44 (0)1392724890
c.a.williams@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
308638

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53342, IRAS 308638

Study information

Scientific Title
Feasibility randomised controlled trial of digital physical activity promotion materials for young people with Cystic Fibrosis

Acronym
Digi PA for Youth CF – Feasibility

Study objectives
We expect to learn about:
1. The feasibility of conducting a full-scale randomised controlled trial
2. The feasibility and acceptability of digital physical activity promotion materials
3. Potential mechanisms of action
4. Moderators to be investigated as part of a (future) full-scale randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2022, West Midlands - Solihull Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 104 8191, (0)207 104 8269; solihull.rec@hra.nhs.uk), ref: 22/WM/0156

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Process evaluation

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
Respiratory

Interventions
The study design is a two-arm feasibility randomised controlled trial with nested mixed-methods process evaluation. Participants will be randomly allocated in a 1:1 ratio to receive one of two types of digital physical activity promotion materials. Both groups will also receive usual care as per clinical practice guidelines for the treatment of patients with CF. Data is collected at baseline, 1-month, and 6-month follow-up. All data collection and access to digital PA materials

will take place online.
Having enrolled in the trial (i.e., completed the screening process and returned consent/assent forms), all participants will be asked to provide data at three time points (baseline, 1-month follow-up, and 6-month follow-up). All data collection will take place remotely. The assessments that participants will complete at each timepoint are as follows:
BASELINE:
All participants will need to complete a set of questionnaires related to: (1) health and demographic information; (2) health-related quality of life; (3) physical activity behaviour; and (4) health and social care resource use and economic impact. All participants will also be required to wear an activity monitor for a period of 7-days, alongside completing a short log about their activity and a physical activity questionnaire.
1-MONTH FOLLOW-UP
All participants will need to complete a set of questionnaires related to: (1) health-related quality of life and (2) physical activity behaviour. All participants will also be required to wear an activity monitor for a period of 7-days, alongside completing a short log about their activity and a physical activity questionnaire. All participants in the intervention group will also need to complete a questionnaire about the usability and acceptability of the intervention. A sub-sample of participants will also be invited to take part in a semi-structured interview.
6-MONTHS FOLLOW-UP
All participants will need to complete a set of questionnaires related to: (1) health-related quality of life; (2) physical activity behaviour; and (3) health and social care resource use and economic impact. All participants will also be required to wear an activity monitor for a period of 7-days, alongside completing a short log about their activity and a physical activity questionnaire. All participants will also need to complete a questionnaire about their trial satisfaction. A sub-sample of participants will also be invited to take part in a semi-structured interview.
In addition to the data provided by participants, data related to trial feasibility (e.g., participant enrolment, willingness to be randomised, participant retention) and usual care (e.g., understanding level of physical activity advice provided by participant's usual CF care team) will also be collected. Trial feasibility data will also be recorded as part of trial procedures. Usual care data will be reported by a relevant member of each participant's CF clinical care team.
In combination, these data will allow for the completion of a nested mixed-methods process evaluation and economic evaluation. The process evaluation will focus on assessing the feasibility and acceptability of the digital physical activity promotion materials. The economic evaluation will focus on establishing: (1) the digital physical activity promotion material delivery costs; (2) the most appropriate way to collect health economics data in a full-scale trial; and (3) to set out an appropriate framework for health economic evaluation as part of a full-scale trial.

Intervention Type
Behavioural

Primary outcome measure
Feasibility of enrolling participants measured using patient logs throughout the trial:
1. The average number of participants enrolled into the trial per month, including details of their recruitment pathway/route
2. The eligible population, as indicated by the number of eligible participants invited
3. Recruitment (where possible), indicated by the number of participants who submit an Expression of Interest
4. Enrolment/uptake, indicated by the number of participants enrolled

Secondary outcome measures

1. Retention rates measured using a Trial Process Log throughout the 6-month trial recruitment and follow-up data collection periods
2. Trial assessment completion rates measured as part of the Trial Process Log for each participant at each of the trial data collection timepoints
3. Drop-out rates measured using a Trial Process Log throughout the 6-month trial recruitment and follow-up data collection periods
4. Usage of digital physical activity promotion materials measured using online metrics (e.g., total time spent using digital physical activity materials) throughout the 6-month follow-up data collection period
5. Feasibility of use and trial satisfaction measured using the User Version of the Mobile Application Rating Scale (uMARS) questionnaire after 1-month follow-up and qualitative interviews after 1-month and 6-months of follow-up in a sub-sample of participants. Trial satisfaction will also be recorded via the Trial Satisfaction Questionnaire (at 6-month follow-up) or Trial Withdrawal Questionnaire (at the point of trial withdrawal).
6. Describing usual care in relation to physical activity will be measured by the completion of an online form by each participant's CF Care Team at the baseline data collection timepoint

Overall study start date
01/07/2020

Completion date
24/08/2023

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of cystic fibrosis
2. Aged between 12 and 18 years old
3. Able to access the internet via any electronic device

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
0

Key exclusion criteria
1. Presence of an existing severe co-morbidity limiting mobilisation and/or participation in physical activity (e.g., orthopaedic, cardiac, or neurological condition)
2. Current (i.e., within the last month) lung function (forced expiratory volume in one second) is below 40% predicted
3. Currently pregnant
4. Inability to understand verbal and/or written English
5. Participation in a concurrent study for which eligibility precludes them from engaging in another research study and/or study focused on physical activity
6. Participation in a Patient and Public Involvement Advisory Group and/or research study that has directly informed the design of the present feasibility trial

Date of first enrolment
24/10/2022

Date of final enrolment
09/05/2023

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Royal Devon University Healthcare NHS Foundation Trust

Sponsor details
C/o Alison Kerridge
Bowmoor House
Barrack Road
Exeter

England
United Kingdom
EX2 5DW
+44 (0)1392 403055
alison.kerridge@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication
6. Submission to regulatory authorities

Access to raw data and right to publish freely by all investigators in the study or by Independent Steering Committee on behalf of all investigators

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
Some of the data collected and created (e.g., anonymised questionnaire data) will be suitable for sharing for research and teaching. Other trial data (e.g., fidelity data) will be trial specific and not suitable for sharing. Only fully anonymised data will be shared at the end of the project. Potential users will find out about data availability/access via our initial publications and a trial-specific University of Exeter website. Initially, data will be embargoed (i.e., not publicly accessible via the open-access data repository) until the publication of all intended academic papers/reports. Until then, the Trial Management Group will have exclusive use of the data. Following this period, data will be made available via a suitable open-access data repository (e.g., Open Science Framework). Please note that access to this data will require the approval of the PIs in each instance and will require adherence to a strict licence that includes a confidentiality agreement.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No