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Exercise behaviours in children and young people with cystic fibrosis

Submission date
22/10/2018

Recruitment status
No longer recruiting

Registration date
14/11/2018

Overall study status
Completed

Last Edited
25/03/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Exercise has been found to help children and young people with cystic fibrosis (CF) but many people find it difficult to keep going. This research is finding out what children and young people with cystic fibrosis think and feel about exercise, and how much exercise they are doing. Then the researchers want to make a tool (a way of measuring something, like a questionnaire) that may help identify how to optimise and maintain healthy activity levels for individual children and young people with CF in the future.

Who can participate?
Children and young people aged 6-16 with CF

What does the study involve?
Each participant completes two questionnaires, one asking about that he/she thinks and feels about exercise and one asking about what exercise he/she has done in the last week. This takes about 20 minutes. The researchers then look at the information from each participants' Fitbit and bleep test collected during the first 2-3 months of Project Fizzyo, and use this information to explore the relationships between exercise activity patterns and what the participant thinks and feels about exercise. Each participant fills out a questionnaire asking about what her/she thinks and feels about exercise. If he/she answers differently to the other participants then the researcher shows him/her the new tool to see if it makes sense and is easy to use. This meeting is recorded so that the researcher can remember that the participant says. Each participant fills out the new tool and another questionnaire. They can either complete this when they are at the hospital for a routine clinic appointment, or complete at home and send back to the research team.

What are the possible benefits and risks of participating?
The participants will be helping the researcher to find out what children and young people with cystic fibrosis think and feel about exercise, and develop the new tool. This may help health professionals to understand how to help and support other young people with cystic fibrosis to keep exercising in the future, and therefore experience the health benefits from being fit and

active. It will take a bit of time to complete the questionnaires and/or interview, but the researchers will try and do these on a day when the participant is coming to the hospital for another appointment anyway.

Where is the study run from?
1. Great Ormond Street Hospital (UK)
2. Royal London Hospital (UK)
3. Royal Brompton Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2018 to June 2021

Who is funding the study?
Cystic Fibrosis Trust (UK)

Who is the main contact?
Ms Helen Douglas
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Study website
www.sshs.exeter.ac.uk/youthactivityunlimited/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40056

Study information

Scientific Title
Identifying predictors for maintenance of exercise participation in children and young people with cystic fibrosis

Study objectives
The hypotheses are that:
1. There are clusters of children and young people (CYP) with cystic fibrosis (CF) who will have similar exercise maintenance behaviours, and that these clusters will be identifiable by patterns in characteristics such as reported activity levels, actual activity levels, exercise capacity and self-efficacy for physical activity.
2. CYP with CF who report high levels of exercise engagement and maintenance will have high self-efficacy for exercise, high actual levels of exercise and higher physical exercise capacity than CYP with CF who report low levels of exercise engagement.
3. A tool will be developed that will identify those CYP with CF who require support to start and maintain exercise participation by recognising the predictors for exercise behaviour. This tool will be thorough but easy to administer, and demonstrate internal consistency (items measuring a similar concept) and initial evidence of construct validity (association with related measures).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East- Newcastle & North Tyneside 1 Research Ethics Committee, 12/10/2018, ref: 18/NE /0324

Study design
Non-randomised; Both; Design type: Screening, Active Monitoring, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

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

Cystic fibrosis

Interventions

Part A:
- Study design: Longitudinal observational cohort study to understand more about the relationships between the amount of activity and exercise CYP with CF say they do (HAES questionnaire), the amount they actually do (activity tracker), what they are capable of doing (exercise capacity test) and their self-efficacy for physical activity (CSAPPA questionnaire). Findings will help to identify characteristics that are predictive of exercise behaviour maintenance.
- Sample: up to 75 CYP with CF, aged 6-16 years old, will be recruited following their recruitment to Project Fizzyo (NREC 18/LO/1038, IRAS 228625). Each CYP will participate in this study for the first 2-3 months of their participation in Project Fizzyo.
- Methods: After recruitment, participants will complete the Children's Self-Perceptions of Adequacy in and Predilection for Physical Activity (CSAPPA) questionnaire (15 minutes). 2-3 months later, to be in line with a routine hospital clinic appointment, each participant will complete the Habitual Activity Estimation Scale (HAES).
- Analysis: Individual participants' questionnaire responses will be reconciled with activity tracker and exercise capacity test data collected as part of Project Fizzyo. Multiple regression modelling will be used to understand the relationships between reported activity levels, actual activity levels, exercise capacity and self-efficacy for physical activity.

A draft tool, identifying characteristics predictive of exercise maintenance behaviours in CYP with CF, will be developed based on:
- Results of Part A of this study
- Results of a literature review
- Consideration of existing tools or measures of exercise maintenance behaviours in CYP.

Consideration will also be given to:
- The reading age of the tool, inclusion of positively or negatively worded items, avoiding leading or double-barrelled questions or the creation of a response set
- Response categories

The draft tool will be shown to professionals working in CF exercise for their comments after which items may be amended.

Part Bi:
The tool will be piloted using cognitive interviewing with 8-12 CYP with CF. This will involve a one-to-one interview with the PhD researcher (about 30 minutes) carried out in NHS clinic offices. Participants will be asked to 'talk aloud' their answers to questions on the draft tool. They will be asked for their general comments on the tool (i.e. Do you think there are any relevant exercise maintenance attitudes and behaviours that are not being assessed on the tool?). Changes may be made based on participants' understanding of and responses to these questions.

Part Bii:
The final tool will be administered to a larger development sample of CYP with CF to explore reliability and construct validity. After consent/assent has been gained, participants will be asked to complete the tool and an appropriate similar measure or sub-scale if one is identified during the literature review process. Participation should take a maximum of 25 minutes. Participants will be required to read the instructions for each tool/measure and complete them independently. Participants can contact the PhD researcher if they require assistance. Participants recruited via a CF centre may complete the tool/measures before or after their

clinic appointment (in a hospital setting), or return them by post. For those recruited via social media platforms, the tool/measure will be sent by post, completed at home and returned by post.

Intervention Type
Behavioural

Primary outcome measure
Part A: maintenance of exercise participation. The definition of exercise maintenance for this study is achieving a daily average of 60 minutes of moderate or vigorous physical activity (defined as 'a noticeable increase in heart rate' by the World Health Organisation) for the study duration. Continuous (2-3 months) daily heart rate data will be available from the Project Fizzyo activity tracker dataset extracted for this work.

Part B: This part of the study is developing a new tool therefore does not require a primary outcome measure

Secondary outcome measures
Part A:
1. Self-efficacy for physical activity is measured using the Children's Self-perceptions of Adequacy in and Predilection for Physical Activity (CSAPPA) questionnaire at the end of 2-3 months of activity tracking
2. Reported activity levels are measured using the Habitual Activity Estimation Scale (HAES) at the end of 2-3 months of activity tracking
3. Actual activity levels are measured (continuous heart rate and step count data) using the Fitbit Alta HR activity tracker for 2-3 months duration (as part of Project Fizzyo) prior to recruitment to Part A
4. Exercise capacity is measured using the 10m-Modified Shuttle Walk Test (10mMSWT) 2-3 months prior to recruitment to Part A (as part of Project Fizzyo)

Part B:
This part of the study is developing a new tool therefore does not require a secondary outcome measure. If similar measures or subscales are identified during the literature review process then the most appropriate one will be administered alongside the new tool to support the initial construct validation process. This may act as a secondary outcome measure if appropriate.

Overall study start date
26/11/2018

Completion date
01/06/2021

Eligibility

Key inclusion criteria
Part A:
CYP participating in Project Fizzyo, and thus aged 6-16 years, diagnosed with CF, under the care of a participating London CF centre, and use a suitable airway clearance device for Project Fizzyo

Part B:
Confirmed diagnosis of CF, age 8-16 years, able to understand spoken and written English

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Planned Sample Size: 287; UK Sample Size: 287

Key exclusion criteria
Part A:
CYP unable to read, understand or complete questionnaires in written English

Part B:
Having received or on a waiting list for lung transplant, physical activity or exercise ability affected by a condition other than CF

Date of first enrolment
03/12/2018

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital (lead centre)
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

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

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

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research.governance@gosh.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Trust; Grant Codes: SRC 008

Alternative Name(s)
Cystic Fibrosis, CF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to report and disseminate the results of this study through PhD thesis, publication in high-impact peer reviewed medical and academic journals, and present at conferences, including but not limited to European Cystic Fibrosis Conference, North American Cystic Fibrosis Conference, UK Cystic Fibrosis Conference. No additional documents available at this stage - the protocol may be available in the near future.

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
HRA research summary			26/07/2023	No	No