ISRCTN51624752 https://doi.org/10.1186/ISRCTN51624752

Project Fizzyo: Remote monitoring and gaming technology for children with cystic fibrosis

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
16/11/2018

Overall study status
Completed

Last Edited
03/11/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and Study Aims
Cystic Fibrosis (CF) is a chronic disease characterised by thick mucus in the lungs, causing recurrent lung inflammation, infection, permanent damage and early death. Airway clearance techniques (ACTs) and exercise can help this, but routine daily treatments are burdensome and adherence is low, causing conflict and stress within a family. Research has failed to produce credible evidence to guide physiotherapy practice.
We have worked with engineers and designers and UCL computer science students through the Industry Exchange Network (IXN) to develop an electronically chipped sensor for ACT devices. We have also developed a data transmission platform to facilitate automatic data transmission from the homes of children with CF to the clinicians and researchers caring for them. Industry partners (Microsoft) and UCL computer science experts and students have helped us develop computer games driven by breathing through an ACT device (to enhance treatment enjoyment and adherence).
The project will use this technology for the capture and transmission of data during ACTs, physical activity and exercise daily in children with CF over 16 months. This data, combined with individual demographic and clinical records, will be used to identify patterns of adherence and positive and negative clinical outcome predictors. Computer gaming will be introduced and removed (interrupted time series design) to evaluate the effect of gaming on ACT adherence and clinical outcomes during the study

Who can participate?
Children aged 6-16 years with a diagnosis of CF cared for at a participating centre, who carry out airway clearance using a compatible airway clearance device as part of their physiotherapy treatment

What does the study involve?
Participants will perform an exercise test, spirometry and complete CF-specific questionnaires at 3 time points. They will use a Fitbit activity tracker each day, a bespoke Fizzyo airway clearance sensor with each airway clearance session and a tablet computer once daily from their home to sync/send information about physiotherapy to the study team.

What are the possible benefits and risks of participating?
There are no direct benefits to CF participants, although they may find the computer games help them to enjoy and engage with airway clearance more effectively. This study will assist in developing more effective methods of personalising treatments for children with CF.
Risks may arise from potential infection from the sensor; however, cleaning instructions will be provided to prevent this. There is also a risk of malfunction of the tablet or chipped Fizzyo sensor; however, PAT testing will be undertaken to mitigate this, and tablets and Fizzyo sensors will be replaced if necessary.

Where is the study run from?
Three CF centres in hospitals in London, UK:
1. Great Ormond Street Hospital (lead centre)
2. Royal London Hospital
3. Royal Brompton Hospital

When is the study starting and how long is it expected to run for?
May 2018 to December 2020 (updated 11/11/2020, previously: November 2020) (updated 06/08/2019, previously: October 2020)

Who is funding the study?
1. Rosetrees Stoneygate Prize 2017 (UK)
2. The Cystic Fibrosis Trust (UK)
3. UCL Partners (UK)
4. HEFCE Higher Education Innovation Fund (UK)

Who is the main contact?
Emma Raywood
e.raywood@ucl.ac.uk
ICH.Fizzyo@ucl.ac.uk

Study website
https://www.cysticfibrosis.org.uk/news/project-fizzyo

Contact information

Type(s)
Public

Contact name
Ms Emma Raywood

ORCID ID
http://orcid.org/0000-0002-0993-5115

Contact details
Physiotherapy Research Group
RCCA Section
III Programme
UCL Great Ormond Street Institute of Child Health
4th Floor Welcome Trust Building
30 Guilford Street

London
United Kingdom
WC1N 1EH
02079052935
ICH.Fizzyo@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38779

Study information

Scientific Title
Project Fizzyo: Remote monitoring and gaming technology for improving physiotherapy prescription, adherence and prediction of clinical outcomes in children with cystic fibrosis

Acronym
Project Fizzyo

Study objectives
Children with better adherence to physiotherapy will have better clinical outcomes. Gaming during airway clearance may improve adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Bright and Sussex, 15/08/2018, 18/LO/1038

Study design
Interventional non-randomised 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 below to request a patient information sheet

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

Interventions
Staggered recruitment of the study population will occur over the first 6 months. Each child will participate in the study for at least 16-months following their recruitment. 160 children with cystic fibrosis from:
1. CF Centre A: (80 children) Great Ormond Street Hospital for Children NHS Foundation Trust
2. CF Centre B: (30 children) The Royal London Hospital (Barts Health NHS Trust).
3. CF Centre C: (50 children) Royal Brompton Hospital (Royal Brompton & Harefield NHS Foundation Trust)

After recruitment, participants from all centres will each be given a computer tablet (Linx 12X64 64 GB Tablet & Keyboard), a bespoke chipped ACT sensor and wearable activity monitor (Fitbit Alta HR) to use at home for 16 months. They will also be provided with careful verbal and written instructions related to the use, cleaning and data synchronisation of these devices. Participants will simply be expected to continue with their normal ACT, exercise and activity regimens at home during the study. They will have a person and number to call if they need any technical support with equipment during the study.

Daily airway clearance (breath count, length and pressure, treatment quality, count, length, profile and time) and physical activity data (heart rate and steps every 5 seconds) will be recorded and transmitted automatically once synchronised with the app on the computer tablet, from the devices to a secure cloud space (Microsoft Azure) and the Great Ormond Street Hospital Digital Research Environment (DRE).

ACT feedback (number and length of treatments per day, proportion of prescription completed etc), will be introduced after 2 months to see if this creates any change in ACT adherence, and if so whether the change is sustainable.

Optional ACT gaming (computer games driven by the electronic signal generated during breathing), will be introduced after a further 2 months, to see if this creates any change in ACT adherence, and if so whether the change is sustainable. Changes over time in gaming frequency and adherence will determine whether behaviour change is impacted by, or dependent on, sustained gaming access.

Participants will also have measures of lung function, exercise capacity and health related quality of life taken at the baseline, midpoint and end of study. All of these measures are routinely collected during hospital and 3 monthly clinic visits and we will try to ensure that no unnecessary hospital visits are required or measures duplicated. If any tests were not undertaken during a routine clinic appointment, additional testing would take no more than 90 minutes. If required, this testing would be scheduled on days when the children have pre-planned appointments at an outpatient clinic to minimise inconvenience to both children and parents.

All relevant routinely collected clinical records (lung function results, hospital admissions, microbiology results, antibiotic requirements, exercise capacity, quality of life, health economics, genotype, height, weight, sex etc.) collected clinically throughout the trial for each participant will be extracted from the electronic patient record (EPR) system, de-identified, and stored in the integrated DRE. This will be facilitated by the DRE and CF clinical teams. Any data encryption and transfer protocols to or from clinical / EPR systems and the data store meet with NHS

Information Governance standards, the NHS Information Governance Toolkit Level 2 and ISO27001. This data will be used in data modelling and analysis in conjunction with the adherence data.

Intervention Type
Other

Primary outcome measure
Adherence to home physiotherapy prescriptions for:
1. Airway clearance treatments (number of treatments, cycles, breaths per day). Adherence will be expressed as a proportion of personal prescription achieved and as a change from baseline measures in response to feedback or gaming.
2. Physical Activity (minutes per day of moderate to vigorous physical activity - calculated from heart rate and steps). This is usually defined as a percentage of the maximal heart rate achievable for a child of a particular age and gender (there are published normal tables for reference). Moderate physical activity might be considered as any activity at 55–70% of maximal heart rate, and vigorous physical activity, any activity at >70% of maximal heart rate. Cumulative minutes per day will automatically be calculated and expressed as a percentage of recommended levels.
The above will be measured using data from remote monitoring sensors used throughout the study compared to clinical physiotherapy prescription and clinical records for 16 months throughout the study.

Secondary outcome measures
1. Type of physiotherapy (type of airway clearance device, airway clearance and exercise prescription), collected by questionnaire at the baseline, midpoint and at the end of the study
2. The following airirway clearance session data, collected using bespoke Fizzyo sensor remote monitoring daily for 16 months:
2.1. Number of breaths per session
2.2. Frequency of session
2.3. Session breath profile
2.4. Session duration
3. Physical activity levels, assessed using Fitbit Alta HR remote monitoring, measurement of steps and heart rate, continuously for 16 months
4. Quality of Life, assessed using the Cystic Fibrosis Questionnaire Revised (CFQ-R)UK standardised questionnaire at the baseline, midpoint and at the end of the study
5. Lung function, assessed using spirometry testing at the baseline, midpoint and at the end of the study
6. Exercise capacity, assessed using the 10 m modified shuttle walk test at the baseline, midpoint and at the end of the study
7. The following clinical information collected throughout the study via clinical records:
7.1. Lung function results
7.2. Admissions
7.3. Medications
7.4. Infections
7.5. Comorbidities

Overall study start date
07/05/2018

Completion date

10/12/2020

Eligibility

Key inclusion criteria
1. Documented diagnosis of cystic fibrosis
2. Using an ACT suitable for the Fizzyo sensor (Acapella, Astratech PEP, Aerobika or Pari PEP) at least once per day as part of their routine treatment
3. Aged 6-16 years
4. Currently under the care of a participating London CF Unit
5. Legally acceptable representative must be able to give informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160

Total final enrolment
145

Key exclusion criteria
Patients who have had lung transplantation or have a clinically significant disease or medical condition other than CF or CF-related conditions that in the opinion of the MDT, would compromise the safety of the patient

Date of first enrolment
05/09/2018

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London
United Kingdom
WC1n 3JH

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Royal Brompton Hospital
Royal Brompton & Harefield NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
UCL Great Ormond Street Institute of Child Health

Sponsor details
Great Ormond Street
LONDON
England
United Kingdom
WC1N 3JH
+44 (0)20 7905 2669
research.governance@gosh.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zn2c847

Funder(s)

Funder type
Charity

Funder Name
Cystic Fibrosis Trust

Alternative Name(s)
Cystic Fibrosis, CF

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
THE TERESA ROSENBAUM GOLDEN CHARITABLE TRUST

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal by May 2022

Intention to publish date
07/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Eleanor Main (e.main@ucl.ac.uk) in the form of anonymised clinical records, and activity tracker and airway clearance sensor data. This is available throughout the study with the complete data set available from October 2020. This is held in the secure GOSH data research environment in perpetuity. Data access is restricted to GOSH staff and associated researchers who are directly involved with Project Fizzyo for analysis to answer the study

questions and objectives as is appropriate, using big data analytics and machine learning models. Parental consent was obtained and data will be de-identified before entry into the data research environment.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/10/2020	14/10/2020	Yes	No
Abstract results			14/11/2022	No	No
Other publications	Scoping review	01/03/2022	14/11/2022	Yes	No
Results article		07/10/2022	14/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		09/09/2023	03/11/2023	Yes	No