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The effect of family-based physical activity promotion on child physical activity: an evaluation of the Families Reporting Every Step to Health (FRESH) programme

Submission date
16/03/2016

Recruitment status
No longer recruiting

Registration date
06/12/2016

Overall study status
Completed

Last Edited
20/01/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims

A low level of physical activity in children puts them at risk of obesity, mental health problems and poor development. It has been found that in general children's physical activity levels are low and get worse as they get older, particularly in rural areas. UK-based data shows that only half of 7-year olds meet physical activity guidelines, while in adolescence physical activity is estimated to decline by 7% per year. FRESH (Families Reporting Every Step to Health) is a family-based programme delivered via an online platform which was developed with families to improve physical activity levels. The programme uses goal setting and rewards in order to encourage family relations by getting families to be active together. It involves children and their families virtually travelling across the world by accumulating steps throughout the week. Each week children and/or families access the FRESH website to help them set goals, log their steps, and monitor their progress towards virtually reaching a new city. As they achieve their weekly goals they will receive rewards, which include fun facts about the cities they 'visit', virtual badges, collectable playing cards, and other activity challenges. The aim of this study is to investigate the effectiveness of an online delivered family-based physical activity promotion programme at promoting physical activities in children and their families living in Norfolk and Suffolk.

Who can participate?

Children in school years 3-6 who live in Norfolk/Suffolk and their families.

What does the study involve?

Feasibility study:

Participants are randomly allocated to one of two groups. For those in the first group, all participating family members are given pedometers (step counters) to wear to reach their goals using FRESH. For those in the second group, only children wear the pedometers and receive

support from their families to reach their goals. All participants (family members) in both groups are measured at the start of the study and followed up after eight weeks with accelerometers and a range of questionnaires and physical tests.

Pilot study:
Participants are randomly allocated to one of three groups:
1. Intervention website' arm – all participating family members will be given pedometers, have access to the FRESH website to help them work together towards their weekly goals.
2. Pedometer-only' arm – all participating family members will be given pedometers and readily available information leaflets (e.g., by NHS, Change4Life), but they do not receive access to the FRESH website.
3. Standard care control – these families receive no treatment.
All participants (family members) in all three groups are measured at the start of the study and followed up after eight weeks and ~1 year with accelerometers and a range of questionnaires and physical tests.

What are the possible benefits and risks of participating?
Participants may benefit from increasing their levels of physical activity, which could potentially have long term benefits to participants' health. There are no anticipated risks involved with participating.

Where is the study run from?
The study is run from University of Cambridge and takes place in the community (UK)

When is the study starting and how long is it expected to run for?
September 2016 to December 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The impact of a family-based physical activity promotion programme on child physical activity: feasibility and pilot of the Families Reporting Every Step to Health (FRESH) intervention

Acronym
FRESH

Study objectives
Current hypothesis:
The family-based FRESH interventions promotes moderate-to-vigorous physical activity in children and their families living in Norfolk/Suffolk.

Previous hypothesis:
The family-based FRESH interventions promotes moderate-to-vigorous physical activity in 8-10 year-old children and their families living in rural Norfolk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Feasibility study: University of Cambridge's School of Humanities and Social Sciences Ethics Committee, 21/02/2017
Pilot study: University of Cambridge's School of Humanities and Social Sciences Ethics Committee, 24/01/2018

Study design
Feasibility study: Randomised parallel-group feasibility study
Pilot study: Three-arm randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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
Prevention of disease

Interventions
Current interventions as of 13/02/2018:
Feasibility study:
A statistician will generate a randomisation list (stratifying by individual level socio-economic status) using Stata; research staff will use this to allocate eligible families to either family or child-only group using a 1:1 ratio:

Group 1 – 'Family': This involves all participating family members wearing pedometers and working together towards goals using the intervention website.
Group 2 – 'Child only': This involves only the child wearing a pedometer, setting individual goals, and receiving support from other family members using the intervention website.

All participants (family members) in both groups are followed up after eight weeks with accelerometers and a range of questionnaires and physical tests.

Pilot study:
A statistician will generate a randomisation list (stratifying by country) using Stata; research staff will use this to allocate eligible families to either the intervention website, pedometer-only, or standard care groups using a 1:1:1 ratio:

Group 1 - 'Intervention website' arm – all participating family members will be given pedometers, have access to the FRESH website to help them work together towards their weekly goals.
Group 2 - 'Pedometer-only' arm – all participating family members will be given pedometers and readily available information leaflets (e.g., by NHS, Change4Life), but they do not receive access to the FRESH website.
Group 3 - Standard care control – these families receive no treatment.

All participants (family members) in all groups are followed up after eight weeks and one year with accelerometers and a range of questionnaires and physical tests.

Previous interventions:
Feasibility study:
A statistician will generate a randomisation list (stratifying by individual level socio-economic status) using Stata; research staff will use this to allocate eligible families to either family or child-only group using a 1:1 ratio:

Group 1 – 'Family': This involves all participating family members wearing pedometers and working together towards goals using the intervention website.
Group 2 – 'Child only': This involves only the child wearing a pedometer, setting individual goals, and receiving support from other family members using the intervention website.

All participants (family members) in both groups are followed up after eight weeks with accelerometers and a range of questionnaires and physical tests.

Pilot study:
A statistician will generate a randomisation list (stratifying by individual level socio-economic status) using Stata; research staff will use this to allocate eligible families to either a family, child-only, or standard care group using a 1:1:1 ratio:

Group 1 – 'Family': This involves all participating family members wearing pedometers and working together towards goals using the intervention website.
Group 2 – 'Child only': This involves only the child wearing a pedometer, setting individual goals, and receiving support from other family members using the intervention website.
Group 3 – 'Control': This involves 'standard care'; no intervention will be implemented and participants receive no access to the intervention website.

All participants (family members) in both groups are followed up after eight weeks and one year with accelerometers and a range of questionnaires and physical tests.

Intervention Type
Behavioural

Primary outcome measure
Child's level of moderate-to-vigorous physical activity (MVPA) is measured using an accelerometer at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)

Secondary outcome measures
Current secondary outcome measures as of 13/02/2018:
All participating family members:
1. Daily average level of moderate-to-vigorous physical activity (MVPA) is measured in minutes using an accelerometer at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
2. Daily sedentary (SED) behaviour is measured in minutes using an accelerometer
3. Week/weekend MVPA/SED is measured using an accelerometer at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
4. Waist circumference is measured using measuring tape at baseline and 8wks later for the feasibility study and baseline, 8 weeks later, and ~1 year post baseline for pilot study.
5. Blood pressure is measured using blood pressure monitor (Omron) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
6. Aerobic fitness is measured using sub-maximal step test at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
7. Family co-participation in physical activity is measured using The Activity Support Scale for Multiple Groups (parent/child version) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
8. Activity location is measured using GPS (Waist-worn Qstarz BT-Q1000XT) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)

9. Family functioning is measured using the Fictional Family Holiday paradigm at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
10. Family social support is measured using The Activity Support Scale for Multiple Groups – parent/child version at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
11. Family social norms for physical activity is measured using The Activity Support Scale for Multiple Groups – parent/child version at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
12. Physical activity awareness is measured using the 'Meeting guidelines' self-report measure at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
13. Physical activity self-efficacy is measured using self-efficacy for physical activity Scale at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
14. Motivation for physical activity is measured using 12-item physical activity motivation questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
15. Quality of life is measured using EQ-5D & CHU-9D questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
16. Intervention delivery costs is measured using study billing records throughout the feasibility and pilot studies
17. Family out of pocket physical activity expenditure is measured using a questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)
18. Screen time is measured using a questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)

Participating children:
1. Executive function is measured using the Dimensional Change Card Sort and Flanker task at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study) (Outcome measure removed 08/11/2018)
2. Basic psychological needs are measured using a questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and ~1 year (pilot study)

Previous secondary outcome measures:
All participating family members:
1. Daily average level of moderate-to-vigorous physical activity (MVPA) is measured in minutes using an accelerometer at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
2. Daily sedentary (SED) behaviour is measured in minutes using an accelerometer
3. Week/weekend MVPA/SED is measured using an accelerometer at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
4. Waist circumference is measured using measuring tape at baseline and 8wks later for the feasibility study and baseline, 8wks later, and 1yr-post baseline for pilot study.
5. Blood pressure is measured using blood pressure monitor (Omron) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
6. Aerobic fitness is measured using sub-maximal step test at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
7. Family co-participation in physical activity is measured using The Activity Support Scale for Multiple Groups (parent/child version) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
8. Activity location is measured using GPS (Waist-worn Qstarz BT-Q1000XT) at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
9. Executive function is measured using the Dimensional Change Card Sort and Flanker task at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)

10. Family functioning is measured using the Fictional Family Holiday paradigm at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
11. Family social support is measured using The Activity Support Scale for Multiple Groups – parent/child version at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
12. Family social norms for physical activity is measured using The Activity Support Scale for Multiple Groups – parent/child version at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
13. Physical activity awareness is measured using the 'Meeting guidelines' self-report measure at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
14. Physical activity self-efficacy is measured using self-efficacy for physical activity Scale at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
15. Motivation for physical activity is measured using 12-item physical activity motivation questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
16. Quality of life is measured using EQ-5D & EQ5D-Y questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
17. Parenting behaviours is measured using Transformational Parenting Questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)
18. Intervention delivery costs is measured using study billing records throughout the feasibility and pilot studies
19. Family out of pocket physical activity expenditure is measured using a questionnaire at baseline and 8 weeks (feasibility study) and baseline, 8 weeks and 1 year (pilot study)

Overall study start date
01/09/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/02/2018:
1. Child between school years 3-6 living in Norfolk/Suffolk
2. Participation of index child and at least one adult responsible for their care and living in their main household is required (participation of the wider family is encouraged, but not required)
3. Sufficient understanding of the English language to understand recruitment/intervention materials, verbal description of procedures, and complete questionnaires
4. Index child able to take part in at least light physical activity
5. Internet access

Previous inclusion criteria:
1. Child age 8-10 years living in a rural location in Norfolk OR person living in the main household of the index child (irrespective of age or relationship)
2. Participation of index child and at least one adult responsible for their care and living in their main household is required (participation of the wider family is encouraged, but not required)
3. Sufficient understanding of the English language to understand recruitment/intervention materials, verbal description of procedures, and complete questionnaires
4. Index child able to take part in at least light physical activity

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
Approximately 80 (based on 20 families with 4 members per family) and 180-240 (based on 60 families with 3-4 members per family) participants for the feasibility and pilot studies, respectively.

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2017

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Cambridge
Cambridge Biomedical Campus
School of Clinical Medicine
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Cambridge

Sponsor details

School of Clinical Medicine
Addenbrooke's Hospital
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
University/education

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
Planned submission of papers on intervention development and feasibility; family physical activity assessment; context of family physical activity; and a grant and/or paper on pilot evaluation.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be shared with anyone outside of the study's research team. The data will be held at the MRC Epidemiology Unit at the University of Cambridge.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility study results	09/02/2019	25/02/2019	Yes	No
Results article	results	22/09/2020	24/09/2020	Yes	No
Protocol article	pilot study protocol	28/10/2019	22/10/2020	Yes	No
Results article		01/09/2021	20/01/2023	Yes	No