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.

Lay title: FRESH

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1. **Project 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.

2. **Background:**

2.1. Existing research

Physical activity in children is favourably associated with multiple physical and mental health outcomes.[1,2] Many children are however insufficiently active[3] and levels decline into adolescence, particularly outside of school time and at weekends.[4,5] Inactivity in childhood tracks into adulthood[6] increasing the risk of diabetes, cancer and mortality.[7] The development of interventions to promote and maintain children's physical activity levels is therefore a public health priority.

The socio-ecological model (SEM) of health[8] posits that individual behaviour is influenced by factors operating at different levels of influence, including individual, intrapersonal and institutional. Reviews of determinants corroborate this assertion[9] showing that a multitude of factors are associated with young people's physical activity levels. Beyond individual-level variables, these include those related to the school, neighbourhood and family environment. For example, children's activity is influenced by the encouragement they received from their parents, and modelled upon their parents' own behaviour, which is in turn affected by, for example, the time parents have available for such pursuits, and access to recreational facilities.[10] Indeed, family factors consistently exhibit positive associations with children's physical activity, particularly parental support and parental modelling.[11–13] UK-based evidence from the applicants also shows that change in physical activity at the weekends is associated with family support.[14] Despite this evidence, youth physical activity promotion is still predominantly school-based, with limited effectiveness.[15] Involvement of family members has been suggested to be crucial for long term change in physical activity.[16,17] Together, this evidence highlights the need for youth physical activity promotion to target the family, where wider family members may be able to benefit as well.[12]

2.2 Existing research from applicants

The applicants have contributed extensively to existing observational evidence,[4,11,14,18–20] including on parental leadership and children's physical activity.[21] Recently, we expanded our previous review,[22] completing a meta-analysis and realist synthesis including 40 family-based physical activity studies (Brown et al, BMC PH 2015). The meta-analysis showed moderate efficacy in changing children's activity levels, but only one high quality trial was identified. Using a realist synthesis approach, it showed the value of: using combined goal-setting with reinforcement in the context of family constraints; focussing on changing the family psycho-social environment, for example through the child as agent of change; and drawing attention to additional (non-health) benefits of spending time, such as family time. This review (Brown et al, Obesity Rev 2015), additionally highlights the generally low quality of the evidence base (including self-report physical activity, small sample sizes, limited blinding), lack of post-intervention follow-up, issues with selection bias, recruitment and retention, and the lack of knowledge on how and why interventions may or may not work.

The applicants also recently completed a qualitative study with families, focussing on identifying suitable intervention and recruitment/retention strategies that would be attractive to families (Brown et al, BMC PH). Focus groups were conducted with 17 families (consisting of 2 to 6 family members). This work, currently under review at BMC Public Health, suggests using several recruitment strategies, including highlighting the wide range of benefits of research participation (particularly social, health and educational outcomes), and providing regular feedback. These lessons have explicitly contributed to the design of the recruitment strategies of the current project. Additionally, the project enabled identification of four potential strategies, from which this project was initiated following patient and public involvement (PPI) work with families.

2.3. Why is this research needed now?

The existing literature highlights the importance of youth physical activity promotion, which is echoed in the 2012 Chief Medical Officers report,[23] and by an international expert panel recently concluding that developing effective and sustainable interventions to increase physical activity among young people is the key research priority in children's physical activity.[24] More recently, NICE additionally

identified *"The effect of community and family interventions on young people's physical activity levels"* as an evidence uncertainty requiring further primary research.[25]

Whereas previous studies have predominantly targeted schools, this project focuses on the important intrapersonal domain of the SEM. Previous family-based physical activity intervention research shows potential, but has many methodological limitations. Moreover, most studies only focus on promoting child physical activity, instead of considering the family as a unit that may work as a team to change behaviour.[26] Inter-generational, family-based programmes targeting, for example, early literacy or pro-social development, have shown positive effects, and highlight the potential benefit of including multiple family members in an intervention to improve child health outcomes.[27] The intervention, based on extensive prior work including input from families themselves, will target the whole family and will be able to investigate whether this approach is more effective than solely targeting the child. The proposed project will be able to show whether this approach is feasible and acceptable, and potentially effective in changing whole day physical activity levels of the child and their family members, informing a potential definitive evaluation.

2.4. Addressing the remit of the commissioning brief.

This proposal directly addressing the remit of the commissioning brief:

- We aim to evaluate the effectiveness and cost-effectiveness of the interventions to promote overall physical activity in children in school Years 3-6 and their families.
- Evaluation of this web-delivered non-NHS intervention includes all family members. The potential of the 'two-generation approach' is supported by wider family-based research.[26]
- The control group receive usual practice.
- The proposed primary outcome is the child's objectively-assessed overall moderate-to-vigorous physical activity (MVPA); secondary outcomes include activity levels of the other family members, health and fitness indicators, psychosocial mediators, and assessment of the family social environment.
- Outcomes will be assessed at baseline, 8wk- and 1yr-post-baseline, with consent obtained for further long-term follow-up.
- The setting will focus on Norfolk and Suffolk, which has existing health inequalities. The impact of and on inequalities will be assessed, if possible.
- The interventions are evidence based and were developed with considerable input from the public; ongoing public engagement is planned.

Additional research questions will focus on assessing and understanding family-based physical activity, including family co-participation in physical activity and how this changes over time.

2.5. Risks and benefits

Benefits to health: Low physical activity is a risk factor for obesity and related metabolic disorders in youth[1], with a 10-minute difference in MVPA associated with smaller waist circumference (-0.52 cm) and lower fasting insulin (-0.028 pmol/L).[1] UK-based data shows that only half of 7-year olds meet physical activity guidelines,[28] while in adolescence physical activity is estimated to decline by 7% per year[5]. With low levels of physical activity likely to progress to adulthood inactivity,[6] with later health consequences, the period before transitioning into adolescence is critical in helping children increase or maintain their physical activity. This potentially has long term benefits to participants, but also to public health spending, as physical inactivity is estimated to cause 9% of premature mortality world-wide,[29] and to be responsible for twice as many total deaths as obesity.[30] With an estimated cost in England of £10.7 billion/year (incl. £2.5 billion/year for the contribution of inactivity to obesity),[31] efforts to increase physical activity may result in significantly reduced public spending.

Risks for participants: The interventions are designed with families, for families. They promote inclusivity (of all family members, allowing for adjustments for the inclusion of less abled family members), and focus on making small changes relative to the family's current activity level. Previous evidence shows that this can be achieved by all without harm.[32] During the intervention optimisation and feasibility testing phase, potential negative consequences will be established (e.g. injuries, family relationships, quality of life). Adaptations to the intervention and evaluation protocol will be implemented and monitored during the pilot phase. All measures have previously been applied in both adult and child populations and we will follow established standard operating procedures for

their use. Please see section 13 for a detailed consideration of the ethical implications and the provisions implemented to deal with potential issues.

3. **Research objectives**

3.1 Overall research objective

The overall aim of a future definitive trial will be "*to establish the long-term effectiveness and cost-effectiveness of the family-based interventions to promote moderate-to-vigorous physical activity in children in school Years 3-6 and their families living in Norfolk/Suffolk*". However, there are several strategic and practical uncertainties that need to be dealt with before we commence a definitive evaluation. The current application therefore seeks funding for a *feasibility and pilot phase* of the FRESH trial to reduce these uncertainties. The results of this phase will inform the decision whether to submit a separate application for definitive trial funding in 2019.

3.2 Research objectives of the current project proposed feasibility and pilot studies

Objectives related to intervention optimisation and delivery
1. To further develop and optimise the content and delivery of the interventions (Child-only, Family) in collaboration with families and stakeholders.
2. To demonstrate feasibility and acceptability of delivery of the interventions in a short-term feasibility study.
Objectives related to recruitment, retention and adherence
3. To examine feasibility and relative efficacy of different recruitment strategies and identify optimal recruitment strategies.
4. To describe the characteristics of families and individual participants recruited in the context of the eligible population.
5. To examine intervention uptake, adherence and maintenance in both intervention groups.
6. To estimate recruitment and retention rate in a long-term pilot evaluation.
Objectives related to measurement and (cost-)effectiveness
7. To demonstrate feasibility and acceptability of measurement procedures.
8. To assess effect size and 95% confidence interval for the proposed primary outcome measure.
9. To test methods of assessing family physical activity and establish intra-class correlation coefficient.
10. To examine participants' experience in intervention and trial participation through questionnaires and interviews.
11. To develop and pilot a family physical activity-related expenditure questionnaire
12. To model long-term intervention costs and outcomes to inform discussions with potential funders of the intervention, and to inform the likely efficiency of a future definitive trial.
13. To decide upon feasibility of definitive FRESH trial and prepare grant application, if relevant.

The main research questions that therefore will be addressed are:

1. In what ways do the intervention(s) need to be optimised prior to a definitive trial?
2. What is the feasibility and acceptability of the FRESH family-based physical activity promotion intervention and accompanying evaluation?
3. Which methods are valid and acceptable for measuring family physical activity?
4. What is the context of families' physical activity and does this appear to be affected by FRESH?

4. Research design

4.1 Summary of study design

The proposed project will consist of 2 phases:

- Phase 1: Intervention optimisation and feasibility testing (11M: Sep 2016 – Jul 2017):

Following further intervention refinement with PPI input, website development and development of delivery protocols (4M), we will run a two-group randomised feasibility study (7M) in which 20 families will be randomised to receiving either the child- or the family-targeted programme (measurements at baseline and 8wks later).

- Phase 2: Pilot testing (21M: Aug 2017 – Dec 2019):

We will conduct a pilot randomised controlled trial comparing two intervention groups (family-targeted with pedometers and access to the intervention website and family-targeted with pedometers and

readily available information leaflets) with a no-intervention control condition (N=60 families, measurements at baseline, and 8wks and 1yr-post baseline). Inclusion of 1-yr follow-up at pilot stage enables assessment of the potential for long-term effect (controlling for seasonal variation), and an accurate assessment of long-term participant retention, which is notoriously challenging in child-based research[33].

The last 4 months will be used for 'Evaluation and progression', in which we will evaluate the quantitative and qualitative pilot data, and present to the independent Study Steering Committee (SSC) for advice on progression to a definitive trial. In the case of a positive decision, a new protocol will be developed to inform a funding application for a definitive trial. Should the decision to progress be negative, we intend to use this time to write up the pilot work for dissemination.

4.2 Criteria for progression to definitive trial

The following parameters will be used to inform progression to a definitive trial, taking into account qualitative findings on the acceptability of trial procedures:

- Intervention adherence (>75% of families upload steps at least 6 times in the first 3 months of pilot study);
- Demonstrable feasibility of recruiting 20 families/month (based on pilot and accounting for increased staffing in future definitive trial) and retaining 75% of index children at 1-yr;
- Intervention optimisation feasible (identified adaptations are practical, affordable, acceptable);
- Evidence to suggest an adequately powered trial would require a feasible number of participants (N=250 is considered logistically feasible and providing sufficient power; see section 11 for provisional sample size calculations);
- Discontinuation of trial arm based on evidence of harm or limited acceptability/feasibility;
- Positive expected net gain of sampling from definitive trial.

Additionally, the Study Steering Committee will consider changes in MVPA as evidence of promise to inform progression to a full trial.

5. Study population

5.1 Overview

The FRESH interventions will target whole families and be delivered in the family home, using a web-based platform. Previous evidence indicates that home-based physical activity interventions are potentially more effective than those requiring the family to travel to community or other intervention locations.[22] In addition, observational data indicates that rural 9-10 year old children are not only less active than their suburban counterparts,[18] but also that their 4-year decline in minutes/week spent in MVPA is higher than children living in suburban or urban environments.[19] Given this inequality, we aim to predominately, but not exclusively, target families living in rural Norfolk and Suffolk. Existing inequalities have been identified, including obesity and other indicators of child ill health, school readiness, and attainment,[34] indicating that this area represents a worthwhile setting with needs that can be addressed by the proposed intervention.

5.1 Inclusion criteria

Our target population therefore is families living in Norfolk/Suffolk with at least one child in school Years 3-6 (the age when physical activity starts declining most rapidly). Irrespective of randomisation or intervention participation, we will invite all family members living in the child's main household to participate in the evaluation. No restrictions will be set on family type (e.g. single parent, inclusion of grandparents, siblings). Specific inclusion criteria are:

- Family with child in school Years 3-6 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).
- Living in Norfolk/Suffolk.
- Sufficient understanding of the English language to understand recruitment/intervention materials, verbal description of procedures, and complete questionnaires.
- Ability to take part in at least light physical activity.
- Access to the internet to be able to use the FRESH intervention website.

5.2 Exclusion criteria

We will seek to include participants from all ethnic and socio-economic backgrounds meeting the inclusion criteria and will seek to accommodate intervention participation for disabled family members. Family members not wishing to take part in the intervention will still be invited to take part in the evaluation and vice versa; the process evaluation will be designed to identify the extent of intervention participation of individual family members. Specific exclusion criteria are only related to the evaluation of FRESH and include:

- Children under 7 years can take part, but are excluded from taking part in the aerobic fitness measure.
- Children 6 years and under are also excluded from taking part in self-reported psychosocial and behavioural outcomes.
- Children 2 years and under are excluded from taking part in the evaluation.

6. Socioeconomic position and inequalities

As highlighted above, we are aiming to predominately, but not exclusively, target a population that is based in rural Norfolk and Suffolk. Socio-economic comparisons suggest that on average rural areas are better off than urban areas in relation to income, employment, education and crime, but not for some factors such as housing affordability and quality, fuel poverty access and cost of living. A 2006 report by OCSI concluded there was a significant problem of rural deprivation across Norfolk, with substantial numbers of deprived people living outside the main towns.[35] They argued that focusing only on the most deprived urban areas risked ignoring these groups. Moreover, our own previous research has shown that rural children tend to be less active than their suburban counterparts, and show a steeper decline in physical activity when transitioning into adolescence.[18,19] In the proposed project, we will establish the feasibility of recruiting a representative sample of varied socio-economic backgrounds and will explore differences in uptake, feasibility, acceptability, and effect by socio-economic status and sex.

The definitive trial results will allow us to draw robust conclusions about the effectiveness of FRESH to increase children's and families' physical activity. As we aim to recruit families of varied socioeconomic backgrounds, we can be relatively confident about the generalizability of the results (and possible impact on reducing inequalities), particularly to families living outside of the major cities. Differences in effect by socio-economic status and sex will be assessed. In the UK, there are no well researched, evidence-based, evaluated family-based physical activity interventions that can be 'pulled off the shelf' and used by practitioners; this project aids the development of a trial that could fill this evidence gap.

7. Planned interventions and control

The description provided below, based on the TIDieR guidance, describes the intervention prototype, which will be used as a starting point for the project under consideration. We anticipate further refinement during the intervention optimisation and feasibility phase, and intend to address key questions regarding the most acceptable incentives for children and other family members, the types of activities and/or information most valued and most appropriate means and frequency of communication. In the ongoing GoActive project (Corder, *BMJ Open* in press), we have shown that this process results in a more acceptable and effective intervention (NIHR-PHR 13/90/18). The control group will receive 'usual care', and no intervention will be implemented.

7.1 FRESH: Families Reporting Every Step to Health

Why: The FRESH interventions (where families have access to the intervention website) aim to increase physical activity through improved family functioning, and increased self-efficacy, motivation, and awareness (see Appendix for hypothesised logic model). The intervention is evidence-based and has been developed through extensive PPI and formative research with families. The interventions build on the following themes:

1. *Awareness:* A lack of awareness of activity level is associated with lower intention to increase physical activity; 80% of parents of inactive children overestimate their child's activity.[36] Self-monitoring and feedback may increase awareness,[37] and improve engagement and efficacy in physical activity interventions.[38]

   a. Participants wear pedometers and upload step counts online, enabling them to visually track their progression 'around the world'.
2. *Goal-setting and reinforcement:* Goal-setting is a strategy with substantial theoretical underpinning,[39] and, combined with reward (e.g. positive reinforcement), may be effective in increasing motivation and subsequently physical activity (Brown et al, Obes Rev 2015). Rewards may be extrinsic or intrinsic, with parental investment theory suggesting that parents engage in behaviours that benefit their offspring, regardless of the time or energy cost to themselves.[40]
   - Each week, families choose 1 of 3 target cities to walk to, representing an easy, moderate, or difficult challenge for their individual family. Progress is rewarded with information about the location reached, and incentives for children (e.g., collectable FRESH-branded playing cards).
3. *Family psycho-social environment:* Children's physical activity is associated with family cohesion,[20] and active parents are thought to affect family connectedness.[41] In line with Family Systems Theory, we hypothesise that a virtuous cycle may occur when one family member changes their behaviour, causing others to follow.[42]
   - In the 'Family' version (feasibility study) and 'intervention website' arm (pilot study), the family works as a team, planning for physical activity and setting goals *together*.
4. *Child as agent of change:* Review evidence suggests that the child may elicit changes to the psycho-social environment and subsequently, physical activity (Brown et al, BMC PH 2015).
   - Children are allocated the role as the 'team captain', entering steps and leading on destination selection.

What (materials/procedures): For the **feasibility study**, families will be randomised to a 'Child-Only' (the index child wears pedometer, sets individual goals, other family members provide support) or a 'Family' version (all participating family members wear pedometers and work together towards goals). Both groups get access to the FRESH intervention website.
For the **pilot study**, families will be randomised to the: 'intervention website' arm, 'pedometer-only' arm, or a standard care control. The differences between arms are:

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

In both conditions in the feasibility study and in the 'intervention website' arm of the pilot study, families have access to the intervention website and children are allocated the role as 'team captain', entering steps and leading on destination selection. The website will host a secure area, which facilitates the self-monitoring of step counts and goal-setting. Families also have access to a general resources area, offering ideas for improving family connectedness (not necessarily activity-focused, such as spending time outside or cooking together), suggestions of activities that families could do together, and local physical activity facilities.

A facilitator will visit the family in week 1 for a 'kick-off' meeting. During this kick-off meeting, family members will be introduced to the intervention, made familiar with the intervention materials and go through the first intervention steps (e.g. website registration) with a facilitator. The facilitator will also help plan their first week's goals and discuss initial action plans. In the following weeks, families are encouraged to upload weekly step counts and choose one of three target cities to 'walk to' in the upcoming week, representing a 'virtual' easy, moderate, or difficult challenge. In the 'Family' version (feasibility study) and

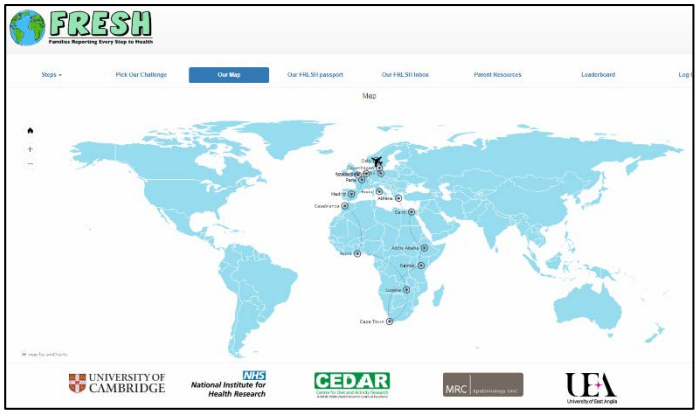

Figure 1: Screenshot of the virtual world map on the intervention website.

'intervention website' arm (pilot study), goals are scaled to the joint step count of all participating family members, irrespective of individual contributions. This encourages families to set joint goals, as opposed to individual goals. Individual and family totals are displayed visually to enable participants to track their progress 'around the world' (see Figure 1 for screenshot of example page). Progress across the world is rewarded with information about locations reached, and collectable incentives (e.g. FRESH-branded playing cards). Additional challenges are available for the child to select (e.g., walking up/around a famous local landmark). The website will additionally support problem solving, reinforcement via both visual and tangible rewards and contact with intervention facilitators for additional support where required.
In the 'pedometer only' arm (pilot study), all participating family members will receive pedometers and readily available information leaflets (e.g., by NHS or Change4Life), but they will not receive access to the FRESH intervention website.

When and how much?
In both arms of the feasibility study and the 'intervention website' arm of the pilot study, families are requested to upload step counts at least 1x/week. During this time, they can track their progress 'around the world', access reinforcement materials, and set their goal for the following week. Following the kick-off meeting, distant support will be provided for 6 weeks after which the families can continue engaging with the intervention. The families will retain the pedometers and the website will continue to be accessible, enabling families to choose how often, and for how long, they engage with the intervention materials. The platform hosting the website will record data to track the duration, frequency, and type of online activity by each family. As in the 'intervention website' arm and both feasibility study conditions, families in the 'pedometer only' arm will retain their pedometers.

Who provides the intervention, and where? As described above, FRESH will predominantly be delivered remotely, through web-based portals and online support. Previous evidence indicates that home-based physical activity interventions are potentially more effective than those requiring the family to travel to community or other intervention locations.[22] The initial kick-off meeting will be held in the family home or another convenient location for the family. For the current project (i.e. feasibility and pilot evaluation), intervention delivery will be led by a member of the wider project team, who will be separate from the measurement team in the pilot study. Should the agreed continuation criteria be satisfied (see 4.2) and a definitive trial be conducted, Active Norfolk and Suffolk County Council have agreed to fund intervention delivery in Norfolk and Suffolk, respectively.

8. Methods.

8.1 Intervention optimisation

Following initial development of intervention materials and prototype website, we will engage with our PPI panels to test materials and procedures. Through a 'Think Aloud' process, participants will be asked for feedback on content, design, clarity and attractiveness. A total of two testing sessions are planned, with feedback on the revisions provided in the second session.

8.2 Recruitment, randomisation, and retention for feasibility and pilot studies

Evaluation of previously conducted family-based physical activity promotion studies,[43] and our own work (Brown et al, BMC PH 2015), shows that a multi-facetted recruitment strategy is required. We will therefore seek to recruit through schools, employers, and community-based settings (e.g., Brownies, community centres, leisure centres). Advertisements, for example, in local newspapers, at GP surgeries, on local radio, and online (e.g., via social media) may also be explored. PPI advisors will support further development of recruitment materials. Full study information will be provided to all, seeking written (parental) consent and written child assent for participation in study measurements. We aim to recruit 20 families for feasibility and 60 families for pilot testing, at a rate of 10-20 families per month. Assuming 4 participating family members, we will therefore recruit 80 and 240 participants, respectively. As noted above, intervention and evaluation participation will be separate, and all family members can take part in the evaluation irrespective of intervention participation. We will register a family's method of recruitment in order to identify the most effective ones to be used in a potential definitive evaluation. A statistician will generate a randomisation list using Stata; research staff will use this to allocate eligible families to intervention or control groups. Randomisation will be

stratified by individual level socio-economic status (maternal education in 3 categories: GCSE or lower; up to A-level; higher education).

To encourage retention, we will remain in regular contact with all participating families (through study website, Twitter, newsletter, and birthday cards), and offer incentives and study feedback. Funds are requested to offer each participant a £5 voucher upon return of the accelerometer and GPS monitors with data. Retention will be monitored by study group and demographic characteristics to observe whether it may be differential.

8.3 Measurement procedures for feasibility and pilot studies

All outcomes will be assessed at (1) baseline, pre-randomisation, (2) week 8 (following supported intervention), and (3) 1yr post-baseline (pilot only). We will obtain written consent from all adults, and written parental consent and child assent for children prior to measurement. We will test the feasibility of using a drop-in format in local community centres and schools, (i.e. research staff will be available for an allocated day, to allow families or individual family members to attend when best suits them). If necessary, research staff will make individual visits to family homes. Two research staff will be present at all measurements. All participants will be asked to wear an ActiGraph accelerometer and GPS monitor for 7 days. Trained staff will follow standard operating procedures to additionally measure health outcomes and executive functioning; participants will independently complete a questionnaire about secondary outcomes and potential mediators/moderators. The Fictional Family Holiday paradigm, a 10-minute activity used to assess family functioning, will be introduced and recorded following standard protocols.[44] Individual participants will be able to opt out of participation in all or part of the measurements. In the pilot study, measurement staff will be separate from intervention delivery, blinded to the intervention condition and trained within the field epidemiology team at the MRC Epidemiology Unit.

8.4 Mixed-methods process evaluation in feasibility and pilot studies

A mixed-methods process evaluation will inform further intervention refinement, as well as evaluation optimisation and potential progression to a definitive trial.

- *Quantitative assessment:* 1) Evaluation-based measures will include source of recruitment, recruitment rate (families and number of participants per family), completion rate of measures at all assessments, risk of contamination, and reported acceptability of assessment procedures; 2) intervention-focussed measures will include website usage (i.e. frequency, duration, and type of visit), reported use, and acceptability, of intervention materials.
- *Qualitative assessment:* Towards the end of the feasibility project family focus groups will be conducted with 10 families (5 from each intervention group, purposively sampled for heterogeneity in socio-economic background) and an interview with the intervention facilitator to create an in-depth understanding of their intervention experience focussing on acceptability, barriers and facilitators to participation, and ideas for improvement. Similar data collection will follow the 8-wk assessment in the pilot study, with a total of 25 families (10 in each of the intervention groups and 5 in the control group, purposively sampled for heterogeneity in socio-economic background and website usage).

9. Proposed outcome measures

9.1. Outcomes related to feasibility and pilot project

Table 2 provides an overview of the data collected for the evaluation of the feasibility and effectiveness of the intervention.

TABLE 2: Data collected for evaluation of feasibility of definitive evaluation (continued on next page).

Outcome	Method of assessment
Recruitment & retention rate, recruitment method	N (families) reached/responded/assessed per wk, N retained, self-reported recruitment method
Feasibility/acceptability of intervention materials/delivery, intervention engagement	Mixed methods process evaluation (incl. focus groups, questionnaires, and website usage data)
Feasibility/acceptability of study procedures	Questionnaire

Outcome	Method of assessment
Completion rate of individual measures at all assessments	%participants & %families with valid data for each outcome measure
Effect size and 95% confidence interval for primary outcome measure	1-yr change in child objectively-measured MVPA, comparing joint intervention groups with control group
Representativeness of those recruited to the trial	Self-reported demographic data, publicly available data from Norfolk and Suffolk County Councils
Within-trial costs	Provider costs of intervention delivery (estimated from billing and trial records), and family out of pocket costs related to physical activity (questionnaire)
ICC for family physical activity and potential school-level clustering	Objectively-measured MVPA for all participating family members; school attended
Expected value of the definitive FRESH trial	Uncertainty in cost and outcomes at 1-yr will feed into a value of information analysis
Finalised cost for the definitive FRESH trial	Trial-related cost data (e.g. staff time, travel costs, incentives, number of equipment needed)

9.2. Outcomes related to evaluation

For a future definitive trial, the primary outcome measure will be 1-yr change in objectively-measured daily time spent in MVPA in the index child. Participants will be asked to wear an ActiGraph GT3X+ for 7 days which has validity to assess physical activity in children and adolescents,[45] and adults.[46] Table 3 describes the secondary outcomes, guided by the hypothesised logic model, and their assessment methods proposed. All will be assessed in both feasibility and pilot projects to assess acceptability and participant burden to inform definitive trial design.

TABLE 3: Proposed secondary outcomes and potential mediators

What	***Who***	***How***
Physical		
MVPA (daily average min)	All participants	ActiGraph GT3X+[45,46]
Sedentary (SED, daily average min)	All participants	ActiGraph GT3X+
Week/weekend MVPA/SED	All participants	ActiGraph GT3X+
Waist circumference	All participants	Measured (tape)
Blood pressure	All participants	Measured (Omron)
Aerobic fitness	Participants ≥8yr	Sub-maximal step test [47]
Family co-participation in PA	All participants	ACTS-MG – parent/child version[48]
Activity location	All participants	GPS[49] (Waist-worn Qstarz BT-Q1000XT)
Screen time	All participants	Recent Physical Activity Questionnaire[50], Children's Physical Activity Questionnaire[51]
Cognitive		
Executive function (not included)*	Child participants	DCCS and Flanker task[52,53]
Psycho-social		
Family functioning	All participants	Fictional Family Holiday paradigm[44]
Family social support	All participants	ACTS-MG – parent/child version[48]
Family social norms for PA	All participants	ACTS-MG – parent/child version[48]
PA awareness	All participants	'Meeting guidelines' self-report [54]
PA self-efficacy	All participants	Self-Efficacy for PA Scale[55,56]
Motivation for PA	All participants	12-item PA motivation questionnaire[57]
Quality of life	All participants	EQ-5D[58], CHU-9D[59,60]
Basic psychological needs satisfaction	Child participants	12-item PA motivation questionnaire[57]
Resource use and cost		
Intervention delivery costs (e.g. facilitator time/travel, materials (e.g. pedometers), website maintenance)	Intervention facilitator	Study billing records

Family out of pocket PA expenditure	All adult participants	Questionnaire, adapted from instrument currently used in ongoing trial[61]

[*]*Update April 2019:* The project team conducted an extensive search (including literature reviews, contacting experts and searching available toolkits) to identify a suitable EF test that was within budget and could be delivered to families in their homes. This highlighted the limited number of tests available to assess the components of EF we were interested in for the age group, the high cost relative to the number of tests we would conduct (licenses are paid on an annual basis, not per participant), and logistical challenges (including the need to purchase iPads and use of participants' internet connections to conduct the tests). In consultation with the SSC it was decided to not include the test in the pilot study, but to continue considering including it as an outcome for a potential full trial, where incorporation will be more cost-effective and assessment methods will likely have advanced.

As part of the preparatory work for a potential definitive trial, we will also monitor technological developments in assessment methods to improve feasibility and acceptability of study procedures.

10. Assessment and follow up

10.1. Assessment effectiveness

We intend to evaluate intervention effectiveness in a future definitive trial at 8-wk and 1-yr post baseline (main outcome assessment). Baseline assessment will be conducted prior to randomisation. Inclusion of a 1-yr follow up takes account of known seasonal variation in physical activity[62] and enables the assessment of effect on outcomes with longer lag-time (such as fitness and blood pressure). We will mimic this process in the pilot evaluation, to assess potential effectiveness and retention accurately. However, as the feasibility study is predominantly focussed on optimising the interventions and its delivery, we will only include the baseline and 8-wk post-baseline assessments (all evaluation outcomes to be included, see Tables 2 and 3).

10.2. Assessment of harm

Overall, the FRESH project is considered low-risk, with high potential benefits. The FRESH intervention encourages participants and families to take small steps in increase their physical activity, which poses limited risks to health. In the unlikely event of an incident, participants will be asked to inform the study team. In addition, as part of our evaluation of costs, we will ask participants to report health care use and to what extent this was related to intervention participation. In cases where this is reported, we will follow up with the relevant participants to obtain appropriate details.

The evaluation includes an assessment of potential harm and dis-benefit, including assessment of family functioning, and quality of life. Ethical concerns related to evaluation participation are discussed in section 13. Following established procedures at the MRC Epidemiology Unit, evaluation-related reports of harm will be followed up with a phone call with the participant (or their parents in case of an underage participant) and appropriate action will be taken. The role of the independent SSC (see section 14) will include the monitoring of potentially serious harm, advising on appropriate action and communicating concerns to the study sponsor and funder.

11. Proposed sample size

It is not appropriate to estimate a sample size for a feasibility or pilot study when the aims are to assess feasibility rather than demonstrate a treatment effect. We have estimated our recruitment of 20 families for feasibility and 60 families for pilot testing (estimated at up to 80 and 240 participants, respectively) based on our prior study experience (such as recruitment rate to our recent family-based focus group study (Brown et al, BMC PH 2015)) and sample sizes of previous pilot studies[32,63]

One of the reasons for conducting a pilot study is to estimate key parameters to inform a sample size calculation for a definitive trial. The aim would be to detect a clinically important intervention effect of 10 minutes as: 1) a 10-minute difference in MVPA has been associated with smaller waist circumference (-0.52 cm) and lower fasting insulin (-0.028 pmol/L)[1] and 2) this approximates the 3-yr change in MVPA observed in the rural children of the Norfolk-based SPEEDY cohort (9.0 mins).[19] In this context, it is important to consider the difference between clinically relevant changes at population and individual level. Whereas detecting smaller changes may be relevant at population level (such as for universally targeted interventions, e.g. school-based initiatives), the FRESH intervention, although scalable, has a more limited reach, and a relatively larger effect at individual level is therefore required for an intervention to be cost-effective. Provisional sample size calculations

have been conducted based on published data to provide an indication of sample size required for a definitive evaluation, accounting for inclusion of baseline physical activity in the analyses (Table 4).

TABLE 4: Sample size calculations (number of families) to detect 10-minute difference in change in MVPA/day (bold figures indicate variations to assumptions of main sample size calculation at top).

Power	SD[a]	Pre-post correlation[b]	N families/group	Recruited N/group[c]	Total N
80	22.4	0.60	51	68	204
80	***24.9***	0.60	63	84	252
85	22.4	0.60	59	79	237
80	22.4	***0.58***	53	71	213
80	***19.9***	0.60	41	55	165

[a]: Millennium Cohort Study (7y, SD:22.4)[28]; SPEEDY-1 (10y, SD:24.9)[64]; BProact1v (5/6y, SD:19.9)[65]; [b]: SPEEDY (10/11y; 1yr, unpublished data): 0.60; GoActive pilot trial (13y; 8wk, unpublished data): 0.58; [c]: estimated retention: 75%.

12. Data analysis

12.1. Analysis plan for feasibility and pilot studies

For the purpose of the feasibility and pilot project**,** statistical analysis will predominantly be descriptive and include investigation of relevant subgroup differences (sex, socio-economic background). For all outcome measures, effectiveness analyses will use an Intention-to-Treat (ITT) population, which includes all participants in the group to which they were randomised, regardless of the intervention received. We will compare effectiveness between intervention and control groups using analysis of covariance (ANCOVA), with adjustment for baseline MVPA. An estimate of the intervention effect and 95% confidence interval (but no p-value) will be calculated. Robust standard errors will be estimated where all participants are analysed simultaneously to account for the non-independence of individuals within families. Intervention groups will be compared with each other using the same method.

Economic analysis of the feasibility study will comprise descriptive evaluation of the physical activity expenditure questionnaire, and of study billing records (see Table 3). In the pilot study, resource use counts (e.g. time spent training families) will be converted to cost using unit costs from a common price year, and adjusted to the common price year using the consumer price index (CPI). Total cost per family will be the sum of intervention delivery and physical activity expenses in each arm. Incremental cost per family at 8wks and 1-yrwill be combined with change in MVPA to calculate a measure of cost-effectiveness. Analysis of uncertainty will include reporting 95%CIs around increments and the cost-effectiveness acceptability curve, showing the probability of cost-effectiveness as a function of willingness to pay for an hour of MVPA (taking account of dominance and extended dominance as appropriate). To predict the incremental cost per QALY of the FRESH interventions over a 10 year horizon, the pilot results will be inserted into a previously developed model (developed as part of NIHR Programme Grant RP-PG-0608-10079). The emphasis of these analyses will not be on the point estimate means, but on identifying the uncertainty in cost-effectiveness, informing a value of information analysis.[66] This latter analysis will be conducted on the 1-yr data to predict the efficient sample size the definitive FRESH trial as a function of *willingness to pay for an additional hour of MVPA*, and on the modelled results, showing the efficient sample size of the definitive FRESH trial as a function of *willingness to pay for a QALY*.

PPI discussions regarding intervention optimisation, focus groups and the 'Fictional Holiday' paradigm will be audio recorded and transcribed verbatim. Although the 'Fictional Holiday' paradigm is most commonly used to assess family functioning, it is also appropriate to code the content of the holiday plans,[44] and in this project we will focus on the content and social context of activity-related activities planned. Qualitative analysis will be undertaken using constant comparative analysis, facilitated by QSR NVivo. Coding will be inductive, incorporating emerging themes as well as topics presented a priori in the topic guide. Initial analyses will inform future quantitative data collection and analysis. Interim themes will be discussed by the research team to reach consensus.

Joint analysis of GPS and accelerometry data allows determination of the relative locations of family members' activity. This will enable an assessment of the volumes and activity intensity families do together, assessed using proximity measured from the GPS location.[49] In this preliminary study, we

will develop and test a protocol for management and analysis of the GPS data so that activity undertaken in the family context can be accurately and efficiently identified in a definitive trial.

12.2. Analysis plan for future definitive trial

- *Effectiveness analysis:* The primary analysis of effectiveness, intermediate and safety outcomes in a future definitive trial will also use an ITT population, a secondary analysis of efficacy and intermediate (i.e. potential mediators) outcomes will use a Per Protocol (PP) population. Inclusion in the PP population will be based on pilot study data. A similar analytical strategy as described above will be applied, with the exception that p-values will be calculated for the main evaluation and intervention group comparisons for the primary outcome only. Where baseline values of MVPA are missing, the missing indicator method will be used to enable these participants to be included in the analysis.[67] Analysis involving all family members will account for clustering within family; where appropriate, clustering by school will be taken into account.
- *Subgroup analysis:* Subgroup analyses by pre-specified moderators (sex, socio-economic status (using Index of Multiple Deprivation based on home postcode), and age (child/parent)) will be performed only for average daily minutes of MVPA. The interaction between randomised group and each moderator will be tested, and if the p-value is <0.05, the intervention effect (i.e. difference between intervention vs control and 95% confidence interval) will be estimated within each subgroup.
- *Mediator analysis:* The effect on potential mediating variables will initially be assessed as described above. We will subsequently conduct formal mediation analyses using the product of coefficient method[68] to assess the underlying causal effect of the intervention (guided by the logic model).
- *Economic analysis* We will estimate the short (i.e. within-trial) and long term (10-year) cost-effectiveness of the intervention arms vs control (no intervention) from the perspective of society. The longer term analysis will be decision-model based as previously described.

13. Ethical arrangements

Ethical approval will be obtained for feasibility and pilot studies, and will be sought from the Ethics Committee for the School of the Humanities and Social Sciences at the University of Cambridge prior to recruitment.

13.1 Recruitment procedures

- *Recruitment sites (including schools and scouting groups)* will be sent an information pack detailing all study procedures and the involvement asked from the staff and participating families. Verbal approval will be sought to contact potential participants through their setting.
- Depending on the setting, different *family* recruitment strategies will be applied. In schools and other community groups, children will be provided with a recruitment pack for their families, including appropriate information leaflets for parents and children. Where advertisements are used (such as on social media or in local shops, newspapers, GP surgeries, or community centres), those interested will be asked to contact the study team via email or Freephone, after which the same recruitment pack will be sent. All recruitment information will be made available online and an email address and Freephone number will be made available for questions.
- Those willing to take part will be asked to contact the study team to make an appointment for baseline assessment, at which written informed consent (and child assent) will be obtained by GCP-trained research assistants. Two reminders (2 weeks apart) will be issued if no response is received. Participants will be informed that they can opt out of parts of the evaluation of withdraw from the study at any stage. Measurements are unrelated to intervention participation and participants can choose to participate in neither the intervention nor evaluation, or either one separately.
- Recruitment to focus groups will follow similar procedures; only families participating in the feasibility/pilot study will be eligible for participation.

13.2 Other ethical considerations

We do not anticipate that participants in the FRESH project will experience any discomfort or inconvenience as a result of any of our measurements or procedures. As mentioned, participants are free to opt out of all or parts of the measurement process and this will be clarified both in written information and verbally on the measurement day. The measures included have been successfully and safely applied in a variety of populations; appropriate risk assessments will be conducted prior to

testing (such as screening prior to the sub-maximal step test using the Physical Activity Readiness – Questionnaire and Rose Angina tests for children and adults, respectively). In case of significantly elevated blood pressure relative to age, adults/parents will be notified by letter recommending that the participant has it checked by their GP. All measures will be conducted in light clothing by fully trained staff following standard operating procedures. All staff on this project will have an appropriate Disclosure and Barring Service check before the start of recruitment. Measurement by a same-sex individual will be accommodated if requested by the participant.

14. Research Governance

University of Cambridge sponsors the project and collaboration with UEA will occur under a formal collaboration agreement. Grant-administration and financial management will follow well-established processes at the MRC Epidemiology Unit; the PI and Finance Manager will review monthly budget updates. An independent Study Steering Committee (SSC) will be set up with the following responsibilities:

- To provide overall independent supervision of the project, and ensure that it is being conducted in accordance with the principles of Good Clinical Practice and the relevant regulations.
- To review protocol amendments, project progress, and provide advice on any aspect of the study.
- To make decisions about continuation or termination of the trial or substantial amendments to the protocol.
- To advise on the project continuation after completion of pilot evaluation, using pre-set criteria.

The SSC will consist of an independent chair, one independent expert, two lay representatives and at least two investigators. The study coordinator and a sponsor representative will be observers. The SSC will at least once per year, or more frequently if needed. The SSC is responsible for communicating any issues for concern to the Sponsor (in particular, where the issue could compromise the integrity of the study or data or participant safety).

15. Project timetable and milestones

This 3-year project will commence in Sep 2016. A detailed timetable is provided in the application and a flow chart and detailed Gantt chart are attached. Only key milestones are presented below:

Time*	Milestone
Mar 2017	FRESH interventions ready for feasibility testing
May/Jun 2017	Feasibility family recruitment (N=20), baseline data collection & randomisation
Jul/Aug 2017	Feasibility 6-wk follow-up data collection (incl. quantitative process evaluation)
Aug 2017	Feedback to feasibility participants
Aug/Dec 2017	Intervention optimisation with public involvement input
Feb/May 2018	Pilot family recruitment (N=60), baseline data collection & randomisation
May 2018	Submit paper intervention development and feasibility (Paper 1)
May/Aug 2018	Pilot 8-wk follow-up data collection (incl. quantitative process evaluation)
Feb 2019	Submit protocol paper pilot study (Paper 2)
Apr/Sep 2019	Pilot 1-yr follow-up data collection
May 2019	Submit family recruitment paper (Paper 3)
Aug 2019	Submit paper family physical activity assessment (Paper 4)
Sep 2019	Pilot participant feedback
Sep/Oct	T3 data cleaning and analysis completed
Oct/Nov 2019	Economic analysis of 1-yr data and value of information analysis
Dec 2019	Submit paper on context of family physical activity (Paper 5)
Nov/Dec 2019	SSC meeting to decide on progression
Dec 2019	Submit grant application or paper pilot evaluation (Paper 6, based on SSC decision)
Jan 2020	Submit NIHR final report

*Includes 4-month extension approved May 2019.

16. Expertise

16.1 Applicant team

This multi-disciplinary application brings together researchers from universities in Cambridge and Norwich. The project team spans the disciplines of epidemiology, family research, physical activity, social science, public health, geography, and health economics. Together, they bring expertise in

observational (EvS, AJ, CH) and intervention research (EvS, KM, HB, CH), intervention development (EvS, KM, HB), family-based research (CH, KM, HB), assessment of physical activity (EvS, HB, AJ), economic evaluation and efficient research design (EW), location assessment (AJ), social science research methods (KM, HB, CH), mixed-methods approaches (KM) and process evaluation (EvS). The team has ample experience in public involvement, including with children through the ACTIVE group and the CASE project (http://www.cedar.iph.cam.ac.uk/case/). The PI, Dr van Sluijs (MRC Epidemiology Unit and CEDAR, University of Cambridge) will have overall responsibility for project progress and direction. Dr van Sluijs developed and supervised the FRESH formative work undertaken by Dr Brown. She has substantial experience of recruitment/retention children in physical activity research, managing data collection, physical activity measurement, intervention development, evaluation and process evaluation. KM, CH, HB and AJ will advise on study procedures and evaluation from their respective disciplines; AJ will additionally lead the processing and analyses of the GPS data. EW will lead the economic analyses.

16.2 Wider research environment

The FRESH feasibility and pilot project will benefit from in-house knowledge of intervention development and optimisation, trial methodology, physical activity assessment, statistical analysis and knowledge translation. The project will be conducted through the infrastructure of the MRC Epidemiology Unit which has extensive experience of conducting trials, including the GoActive, FAB ADDITION, ProActive, DRCT, and Baby Milk Trials (www.mrc-epid.cam.ac.uk/research/studies). The Unit's expertise in trial methodology has been recognised and there are on-going discussions about the Unit being recognised as an affiliate of the Cambridge Clinical Trials Unit. Specifically, the Unit has developed a matrix management model where specialist teams (anthropometry, statistics, data management, study coordination, field epidemiology) operate across a range of different studies. The teams include core-funded specialists with expert knowledge of particular areas of research support who ensure that the methods used for data collection and analysis are at the forefront of their respective fields. Each of these teams operates a flexible staffing strategy allowing for the development of a highly professional core funded by the Unit with the ability to expand and contract the size of additional staff members with grant income according to need. We are able to draw upon this structure for the FRESH project, enabling costing for longer-term small contributions of existing members of staff. Moreover, the Unit has existing formal processes for monitoring study progress and recruitment targets (through monthly Science Operations Meetings). Stephen Sharp, senior statistician at the MRC Epidemiology Unit will prepare the randomisation lists, review the statistical analysis plan, and oversee the conduct of the trial analyses and their interpretation.

17. Partner Collaboration

Our Partner organisations are Active Norfolk and Suffolk County Council. They will support the research team in liaising with local organisations to aid recruitment and have provisionally offered funding for intervention delivery.

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Appendix: Hypothesised logic model for FRESH interventions where families have access to the intervention website.