

# An online family-based self-monitoring and goal-setting intervention to improve children's physical activity: the FRESH feasibility trial and three-arm pilot RCT

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## Scientific summary

FRESH feasibility and three-arm RCT

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# Scientific summary

## Background

Across the globe, including in the UK, children are insufficiently physically active to obtain the mental and physical health benefits associated with regular physical activity. The UK government recommends that children and adolescents engage in 60 minutes of moderate to vigorous activity daily. Physical activity levels decline throughout childhood and adolescence, and this decline is most pronounced during out-of-school time. Family-based physical activity interventions, therefore, present a promising avenue for promoting children's activity; however, high-quality research on such interventions is lacking. Limitations of the existing evidence base include the use of self-report physical activity, small sample sizes, a lack of longer-term post-intervention follow-up, issues with selection bias, recruitment and retention, and the lack of knowledge about how and why interventions may or may not work. This project addressed these limitations and assessed the feasibility, acceptability and preliminary effectiveness of FRESH (Families Reporting Every Step to Health), a child-led family-based physical activity intervention delivered online, and systematically identified effective and resource-efficient strategies for recruiting families to prevention research.

## Objectives

Several strategic and practical uncertainties were identified that needed to be dealt with before a definitive evaluation of the FRESH intervention could commence. The project reported here consisted of the feasibility and pilot phases of the FRESH project to reduce these uncertainties. The results were to inform the decision about whether or not to proceed to a definitive trial of the long-term effectiveness and cost-effectiveness of FRESH to promote moderate to vigorous activity in 7- to 11-year-old children and their families.

The overall aim of the FRESH feasibility and pilot project was, therefore, to assess the feasibility of delivery of the FRESH intervention and its accompanying evaluation. We addressed the following main research questions:

1. In what ways does the FRESH 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 are the most effective and resource-efficient methods for recruiting families to obesity prevention programmes?

## Methods

### *FRESH studies*

### **Intervention**

The theory-based FRESH intervention was guided by self-determination theory and was delivered via an online platform and targeted increases in physical activity in all family members. All family members enrolled in the FRESH intervention received pedometers and generic physical activity promotion

information and were given access to the intervention website. Here participants could select step challenges to 'travel' to target cities around the world, log steps and track progress as they virtually globetrotted. Families were able to continue engaging with the intervention following assessments. Intervention delivery was funded by local authority budgets.

### Study design

In 2017, we conducted a randomised feasibility trial, aiming to randomise 20 families to the family or child-only condition). Families in both conditions received access to the FRESH website, but only index children (aged 8–10 years) wore pedometers in the child-only arm. In the family arm, all family members wore pedometers and worked towards collective goals. Outcome data were collected for all participating family members at baseline and at the 8-week follow-up. This feasibility trial informed adaptations to the intervention and evaluation protocol, which were subsequently tested in a three-arm, parallel-group, randomised controlled pilot trial using a 1 : 1 : 1 allocation ratio (conducted in 2018/19). The aim was to recruit 60 families, with follow-up assessments at 8 and 52 weeks post baseline. Families were randomised to the family, pedometer-only or control arm. All family members in the pedometer-only arm received pedometers and generic walking information (similar to those in the family arm); families in the control arm received no treatment. All family members were eligible to participate in the evaluation.

### Participant recruitment

Families were recruited from school, workplace and community recruitment settings, using a range of strategies (including school assemblies, stands at events, community advertising, and the dissemination of recruitment materials by e-mail). Families living in the UK counties of Suffolk and Norfolk were eligible to participate if a minimum of one child in school Years 3–6 (aged 7–11 years) and at least one adult responsible for that child were willing to participate. Family members could take part in the intervention irrespective of their participation in the accompanying evaluation, and vice versa. Written informed consent was obtained for all participating family members prior to baseline measurement; children additionally provided written assent.

### Measurements

Physical (e.g. fitness, blood pressure), psychosocial (e.g. social support, family functioning) and behavioural (e.g. device-measured family physical activity) measures were collected from all participating family members at each time point. Family members simultaneously wore accelerometers and GPS (Global Positioning System) monitors to enable family co-participation in physical activity to be assessed. A mixed-methods process evaluation was conducted (using questionnaires and family focus groups) assessing the acceptability of the intervention and evaluation, and exploring FRESH families' engagement with the website. Data on the cost of intervention delivery and families' expenditure were collated.

### Data analyses

Descriptive statistics were calculated. The preliminary effect on change in the proposed primary outcome (i.e. the index child's average daily moderate to vigorous activity) was estimated using analysis of covariance; no *p*-value was calculated. Focus groups interviews were transcribed verbatim and coded by two independent researchers. The results were assessed against prespecified progression criteria focused on recruitment, intervention delivery and feasibility of future research, in consultation with the FRESH Study Steering Committee.

### Trial registration

The FRESH studies were registered prospectively on 16 March 2016 and given an International Standard Randomised Controlled Trials Number (ISRCTN12789422).

## Family recruitment review

### Study design

Four electronic databases (Cochrane Library, PubMed, PsycInfo and Scopus) were searched in February 2019 for reviews that included family-based intervention studies. Intervention studies were then extracted from those included reviews, and screened for inclusion by two independent reviewers. In addition, a Delphi study consisting of three rounds with feedback after each round was conducted with experts in family-based research. We assessed extracted data from our review and Delphi participants' opinions to identify effective and resource-efficient strategies for recruiting families to intervention research.

### Inclusion criteria

Intervention studies were eligible for inclusion if they (1) included generally healthy school-aged children and young people and at least one adult primarily responsible for their care, (2) described the effect of interventions that deliberately attempted to implement a change in multiple family members in physical activity, sedentary behaviour, screen time use or diet, or prevent overweight/obesity, or (3) included a measure of effect on any outcome measure related to physical activity, sedentary behaviour, screen time use, diet or overweight/obesity prevention in at least one child and at least one adult primarily responsible for their care. We included English-language, peer-reviewed full-text articles that reported primary data or protocols and had been published by August 2019. For the subsequent Delphi study, academic experts were identified as first or last authors of an included paper, or known experts in the field.

### Registration

This protocol for the review was prospectively registered (PROSPERO CRD42019140042) on 25 June 2019.

## Results

### FRESH studies

In the feasibility study we recruited 12 families, with 32 participants; all were retained at the 8-week follow-up. Parents enjoyed FRESH and all children found it fun. More children in the family arm wanted to continue with FRESH, found the website easy to use and enjoyed wearing pedometers. Children in the family arm also found it easier to reach goals. Most families in the child-only arm would have preferred whole-family participation. Compared with those in the child-only arm, families in the family arm exhibited greater website engagement, as they travelled to more cities (mean 36, standard deviation 11, vs. mean 13, standard deviation 8) and failed fewer challenges (mean 1.5, standard deviation 1, vs. mean 3.0, standard deviation 1). Focus groups also revealed that most families wanted elements of competition. All children enjoyed being part of the evaluation, and adults disagreed that there were too many intervention measures (overall: mean 2.4, standard deviation 1.3) or that data collection took too long (overall: mean 2.2, standard deviation 1.1). Of 41 families recruited in the pilot study (149 participants; mean 4.0, standard deviation 1.0, people per family), 40 (98%) and 36 (88%) were retained at the 8-week and 52-week follow-up, respectively. Although mothers tended to sign up families for the study, the mixed-methods process evaluation showed that fathers appeared more engaged. Compared with those in the control and pedometer arms, a greater percentage of children in the family arm self-reported doing more family physical activity (control, 35%; pedometer, 45%; family, 83%) and found FRESH fun (control, 93%; pedometer, 81%; family, 94%). Higher mean (standard deviation) scores were reported by parents in the family arm for improved physical activity awareness (mean 3.6, standard deviation 0.6, vs. mean 3.2, standard deviation 0.7) and increased self-reported family physical activity (mean 3.0, standard deviation 0.8, vs. mean 2.5, standard deviation 0.8) than by parents in the pedometer-only arm. Approximately 82% of children in the family arm wanted to keep using the FRESH website and 93% found it easy to use. Focus groups revealed that families in the family arm enjoyed choosing weekly step challenges and were capable of identifying ways of meeting daily steps goals. Among children, there

were no notable between-group differences found for minutes in moderate to vigorous physical activity, time spent sedentary or co-participation in physical activity with family members at 8 or 52 weeks. By contrast, change in moderate to vigorous physical activity minutes differed between adults in the family arm and those in the pedometer or control arm (family vs. control 9.4, 95% confidence interval 0.4 to 18.4; family vs. pedometer, 15.3, 95% confidence interval 6.0 to 24.5; pedometer vs. control -5.8, 95% confidence interval -15.1 to 3.3). This effect appeared stronger for fathers than for mothers. There were no substantive differences in family co-participation in physical activity for adults. Delivery costs were estimated at £90 per family ( $\approx$  £15 per participant).

### Family recruitment review

A total of 64 articles ( $n = 49$  studies) were extracted from 55 reviews or through forward searching. Data related to recruitment duration (33%), target sample size (32%), reach (18%), expressions of interest (33%), who initiated expressions of interest rate (< 1%), expressions of interest rate (16%), and enrolment rate (22%) were scarcely reported among the included studies. The reporting of recruitment settings and strategies used were available in the majority of studies, 84% and 73%, respectively. However, the details were often vague, particularly for recruitment strategies in terms of who was recruited and how the strategies were actually implemented. Moreover, most studies applied similar recruitment strategies (predominantly through schools). The Delphi study identified a wide range of recruitment settings and strategies, which fell into six overarching themes: school-based strategies, print and electronic media strategies, community settings-based strategies, primary care-based recruitment strategies, employer-based strategies and referral-based recruitment.

## Conclusions

The FRESH project demonstrates the feasibility and acceptability of the family-targeted FRESH intervention, satisfying the majority of progression criteria set a priori. However, in both the feasibility and pilot study we failed to recruit the target sample size. Moreover, in the pilot study we were unable to demonstrate a signal of effectiveness on time spent in moderate to vigorous activity. This was particularly the case at the long-term assessment and in children, which was the prespecified main outcome measure for a potential future full-scale trial. There was some evidence of successful engagement of fathers. We successfully demonstrated the potential for device-based assessment of family physical activity, which we recommend for use in future studies. In addition, we show that future family-based research should employ a multifaceted recruitment approach that targets adults and children and provides potential participants with repeated exposure to study information. Prior to progressing to a full-scale trial of the FRESH family-based physical activity intervention further refinements around intervention delivery (particularly family planning, efficient online delivery, and capitalising on father involvement) and recruitment methods should be implemented.

## Study registration

This study is registered as ISRCTN12789422 and PROSPERO CRD42019140042.

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