Family-based physical activity promotion: findings from the Families Reporting Every Step to Health (FRESH) feasibility study and pilot RCT

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Scientific summary

Background

Across the globe, including in the UK, children are insufficiently physically activity 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 [MVPA] 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 to promote children's activity, however, high-quality intervention research is lacking. Limitations of the existing evidence base include: the use self-report physical activity, small sample sizes, lack of longer-term 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. 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 commencing a definitive evaluation of the FRESH intervention. 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 whether to proceed to a definitive trial of the long-term effectiveness and cost-effectiveness of FRESH to promote MVPA in 7-11 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 do 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 into 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 globetrot. 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 (FAM) or child-only condition (C-O). Families in both conditions received access to the FRESH website but only index children (8-10 years) wore pedometers in C-O. In the FAM condition, all family members wore pedometers and worked towards collective goals. Outcome data were collected on all participating family members at baseline and 8-week follow-up. This feasibility trial informed adaptions to the intervention and evaluation protocol, which were subsequently tested in a three-armed, 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 FAM, pedometer-only (PED) or control condition (CON). All family members in PED received pedometers and generic walking information (similar to FAM); CON families received no treatment. All family members were eligible to participate in the evaluation.

Participant recruitment: Families were recruited via school, workplace and community recruitment settings, using a range of strategies (including school assemblies, stands at events, community advertising, and dissemination of recruitment materials via email). 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 monitors to enable assessment of family co-participation in physical activity. A mixed-methods process evaluation was conducted (questionnaires and family focus groups) assessing acceptability of the intervention and evaluation, and exploring FRESH families' website engagement. Data on cost of intervention delivery and families' expenditure was collated.

Data analyses: Descriptive statistics were calculated. Preliminary effect on change in the proposed primary outcome (index child's average daily MVPA) was estimated using ANCOVA; no p-value was calculated. Focus groups interviews were transcribed verbatim

and coded by two independent researchers. The results were assessed against pre-specified progression criteria focussed on recruitment, intervention delivery, and feasibility of future research, in consultation with the FRESH Study Steering Committee.

Trial registration: The FRESH studies were prospectively registered 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. Additionally, 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 into intervention research.

Inclusion criteria: Intervention studies were eligible for inclusion if they (a) included generally healthy school aged children and youth and at least one adult primarily responsible for their care, (b) described the effect of interventions that deliberately attempted to implement a change in multiple family members in physical activity, sedentary behaviour, screen time use, diet, or prevent overweight/obesity, (c) included a measure of effect on any outcome measure related 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 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 8-week follow-up. Parents enjoyed FRESH and all children found it fun. More FAM children wanted to continue with FRESH, found the website easy to use, and enjoyed wearing pedometers. FAM children also found it easier to reach goals. Most C-O families would have preferred whole family participation. Compared to C-O, FAM exhibited greater website engagement as they travelled to more cities (36 ± 11 vs. 13 ± 8) and failed fewer challenges (1.5 ± 1 vs. 3.0 ± 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: 2.4 ± 1.3) or that data collection took too long (overall: 2.2 ± 1.1). Of 41 families recruited in the *pilot study* (149 participants; 4.0 ± 1.0 (mean ± SD) people/family), 40 (98%) and 36 (88%) were retained at 8-week and 52-weeks follow-up, respectively. Although mothers tended to sign up families, the mixed-methods process-evaluation showed that fathers appeared most engaged. Compared to CON and PED, a greater percentage of FAM children self-reported doing more family physical activity (CON: 35%, PED: 45%, FAM: 83%) and found FRESH fun (CON: 93%, PED: 81%, FAM: 94%). Higher mean (±SD) scores were reported by parents in FAM for improved physical activity awareness (3.6 ± 0.6 vs. 3.2 ± 0.7) and increased self-reported family physical activity (3.0 ± 0.8 vs. 2.5 ± 0.8) compared to PED. Approximately 82% of FAM children wanted to keep using the FRESH website and 93% found it easy to use. Focus groups revealed FAM families enjoyed choosing weekly step challenges and were capable of identifying ways of meeting daily steps goals. In children, there were no notable between-

group differences found for minutes in MVPA, time spent sedentary, or co-participation in physical activity with family members at 8- or 52-weeks. In contrast, change in MVPA minutes differed between adults in the FAM group and those in PED or CON groups (FAM vs CON: 9.4 [95%CI: 0.4, 18.4]; FAM vs PED: 15.3 [95%CI: 6.0, 24.5]; PED vs CON: -5.8 [95%CI: -15.1, 3.3]). This effect appeared stronger for fathers than for mothers. There were no substantive difference in family co-participation in physical activity for adults. Delivery costs were estimated at £90 per family (~£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, regarding who or how these 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 6 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 MVPA. This was particularly the case at the long-term assessment and in children, which was the pre-specified 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. We additionally 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.