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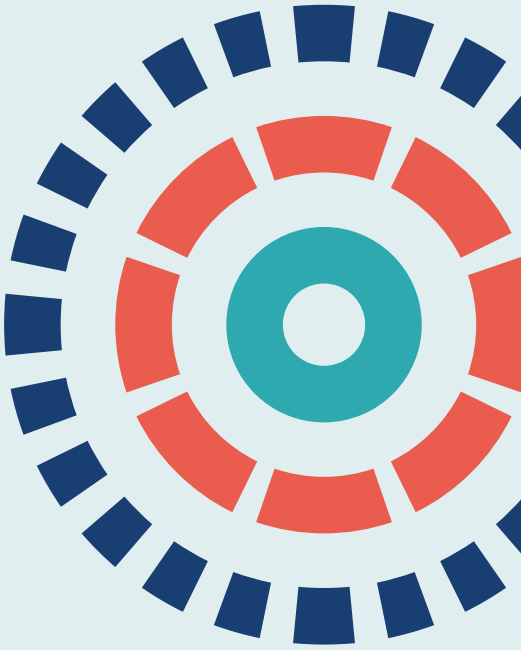

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An online family-based self-monitoring and goal-setting intervention to improve children's physical activity: the FRESH feasibility trial and three-arm pilot RCT

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Abstract

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

Esther MF van Sluijs,[1*] Helen E Brown,[1] Emma Coombes,[2] Claire Hughes,[3] Andrew P Jones,[2] Katie L Morton[1] and Justin M Guagliano[1]

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Background: Family-based physical activity promotion presents a promising avenue for promoting whole-family physical activity, but high-quality research is lacking.

Objectives: To assess the feasibility, acceptability and preliminary effectiveness of FRESH (Families Reporting Every Step to Health), a child-led online family-based physical activity intervention; and to identify effective and resource-efficient family recruitment strategies.

Design: The project consisted of (1) a randomised feasibility trial, (2) a randomised controlled pilot trial and (3) a systematic review and Delphi study.

Setting: Norfolk/Suffolk counties, UK.

Participants: Families, recruited from schools, workplaces and community settings, were eligible to participate if one child aged 7–11 years and one adult responsible for their care provided written consent; all family members could participate.

Interventions: The FRESH intervention, guided by self-determination theory, targeted whole families and was delivered via an online platform. All family members received pedometers and were given website access to select family step challenges to 'travel' to target cities around the world, log steps, and track progress as they virtually globetrotted. Families were randomised to FRESH intervention, pedometer-only or control arm.

Main outcome measures: Physical (e.g. blood pressure), psychosocial (e.g. family functioning) and behavioural (e.g. device-measured family physical activity) measures were collected at baseline and at 8- and 52-week follow-up. A mixed-methods process evaluation assessed the acceptability of the intervention and evaluation.

Data sources review: Systematic search of four databases (Cochrane Library, PubMed, PsycINFO and SCOPUS).

Review methods: Articles were screened in duplicate, and data extraction was fully checked. Academic experts participated in the three-round Delphi study. Data were combined to identify effective and resource-efficient family recruitment strategies.

Inclusion criteria: Included generally healthy school-aged children and at least one adult; intervention attempted to change physical activity, sedentary behaviour, screen use, diet, or prevent overweight/obesity in multiple family members; presented relevant measure of effect in children and adults.

Results: The feasibility study (12 families, 32 participants; 100% retention at 8 weeks) demonstrated the feasibility and acceptability of FRESH, but highlighted that adaptations were required. Of 41 families recruited in the pilot study (149 participants), 98% and 88% were retained at the 8-week and 52-week follow-up, respectively. More children in the FRESH arm self-reported doing more family physical activity, and they thought that FRESH was fun. There were no notable between-group differences in children's outcomes. Change in moderate to vigorous physical activity at 8 weeks favoured FRESH intervention adults [vs. control: 9.4 minutes/week (95% confidence interval 0.4 to 18.4) vs. pedometer only: 15.3 (95% confidence interval 6.0 to 24.5)], and was stronger in fathers, but this was not maintained. In 49 included studies, apart from recruitment settings and strategies used (reported in 84% and 73% of the studies, respectively), recruitment details were scarce. School-based recruitment was predominant. The Delphi study identified a wide range of recruitment settings and strategies.

Limitations: Recruitment was the main limitation of the FRESH studies; generalisability of the proposed recruitment strategies may be limited.

Conclusions: This study has demonstrated the feasibility and acceptability of the FRESH intervention. However, we failed to recruit the target sample size and were unable to demonstrate a signal of effectiveness. Future research should employ a multifaceted recruitment approach.

Future work: Further refinements to intervention delivery and recruitment methods should be investigated.

Study registration: Current Controlled Trials ISRCTN12789422 and PROSPERO CRD42019140042.

Funding: This project was funded by the National Institute for Health Research (NIHR) Public Health Research programme and will be published in full in *Public Health Research*; Vol. 9, No. 9. See the NIHR Journals Library website for further project information.

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List of abbreviations

BMI	body mass index
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
FRESH	Families Reporting Every Step to Health
GPS	Global Positioning System
IQR	interquartile range
LMVPA	light, moderate and vigorous physical activity
MRC	Medical Research Council
MVPA	moderate to vigorous physical activity
NIHR	National Institute for Health Research
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomised controlled trial
SD	standard deviation
SDT	self-determination theory
SEM	socioecological model
SSC	Study Steering Committee
TIDieR	Template for Intervention Description and Replication

Plain English summary

Project aim

This project aimed to refine and test the FRESH (Families Reporting Every Step to Health) programme, which was developed to increase physical activity in 7- to 11-year-old children and their families.

Background

- A low level of physical activity raises the risk of obesity, mental health problems and poor bone development.
- Children's physical activity levels are low and decline as they get older. Physical activity declines mostly outside school, yet physical activity promotion focuses mainly on schools.
- Family-based physical activity promotion has potential, but it rarely targets the whole family.

Programme

- FRESH was developed with families. This pedometer-based programme included goal-setting and rewards, and encouraged family relations by getting families to be active together.
- Children (and their families) virtually travelled across the world by accumulating steps throughout the week. They had access to a website to help set goals, received rewards for achieving goals, and unlocked fun facts about the places visited and novel activity challenges.

Findings

- We tested FRESH in two studies, recruiting 53 families and 181 participants across studies.
- Families enjoyed taking part in FRESH, enjoyed wearing the pedometers and said that the website was easy to use. Parents and children reported that they were more active together and would like to continue with FRESH.
- We saw little change in physical activity in most participants, apart from a short-term positive change among fathers.
- The main difficulty in the studies was recruiting families to take part. Additional consultation with international experts helped us find new ways of recruiting families. The top recommended approach was to speak with parents while they were waiting for their children to complete an activity, such as swimming.

Conclusion

The FRESH programme is feasible and acceptable, but it did not promote physical activity in families. Further work should refine the programme and its evaluation.

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 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 adaptions 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 (≈ £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.

Funding

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Chapter 1 Introduction

Benefits of physical activity

Regular physical activity in children is positively associated with a wide range of health benefits.[1,2] This includes favourable associations with cardiovascular and metabolic,[3–6] skeletal[7] and mental[8,9] health. Improved cognitive and academic performance has also been shown to be associated with regular physical activity engagement.[10] Furthermore, harmful effects have been reported of excessive or uninterrupted sedentary behaviour, especially screen time.[11,12] Given that children and adolescents have been reported to engage in sedentary behaviours for between 6–9[13,14] and 5–8 hours per day,[15,16] respectively, this is a particularly concerning issue. Inactivity in childhood tracks into adulthood,[17] increasing the risk of diabetes, cancer and mortality.[4] The development of interventions to promote and maintain children's physical activity levels is, therefore, a public health priority.

Children's levels of physical activity and interventions

The UK's Chief Medical Officers recommend that children and adolescents engage in an average of 60 minutes of moderate to vigorous physical activity (MVPA) per day.[18] The number of children meeting this guideline dropped between 2008 and 2012,[19] and the most recent reports suggest that that around one-fifth of English children and youth aged 5–17 years met the recommended physical activity guidelines.[20] Using device-measured physical activity, Steene-Johansen *et al.*[21] reported that, across Europe, only 29% of children and adolescents were sufficiently active. Observational data show that children are less active after school and at weekends than during school time,[22–24] and that as children enter adolescence their levels of MVPA decline steeply,[25] particularly at weekends.[24] Last, physical activity levels vary by children's home location, with indications not only that rural 9- to 10-year-old children are less active than their suburban counterparts,[26] but also that their 4-year decline in minutes per week spent in MVPA is higher than that among children living in suburban or urban environments.[24]

The issue of declining levels of physical activity is even more concerning when young people's physical activity levels are examined separately by sex. Girls are less active than boys throughout childhood[21] and their participation in physical activity declines more precipitously than that of boys during the transition to adolescence.[27] Therefore, it is critical for young people to develop positive physical activity habits, as an active childhood can track into adulthood.[17,28]

An effort to, at a minimum, maintain sufficient physical activity levels should be considered a public health priority. Therefore, intervening in children's physical activity before they reach adolescence may be an important strategy.[29,30] To date, the majority of research on young people's physical activity promotion has focused in and around school time. For instance, a considerable amount of attention has been given to general school-based interventions,[31–34] active transport to and from school,[35] activity at recess,[36] physical activity during physical education lessons[37,38] and activity generated through after-school programs.[39] Focusing in and around the school setting is understandable because of near-universal attendance rates and the large portion of young people's waking hours that are spent at school, which makes school an ideal place to target physical activity interventions. However, the effectiveness of school-based physical activity promotion has been limited,[31–34] and out-of-school approaches should be explored.

Parents, the family environment and children's physical activity

The socioecological model (SEM) of health[40] posits that individual behaviour is influenced by factors operating at different levels of influence, including individual, intrapersonal and institutional. 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 receive from their parents, and modelled on their parents' own behaviour, which is in turn affected by, for example, the time that parents have available for such pursuits, and access to recreational facilities.[41] Indeed, family factors consistently exhibit positive associations with children's physical activity, particularly parental support and parental modelling.[42,43]

The importance of positive parental role-modelling and direct parental involvement in/support (e.g. transport, co-participation and encouragement) of young people's physical activity is well known.[29,43–47] A recent cohort study by Abbott *et al.*[48] reinforced the importance of parental role modelling for both physical activity and sedentary behaviour, demonstrating significant associations between preschool children's behaviours and their parents' behaviours. In addition, the authors observed a potentially important role of same- and mixed-sex parent–child relationships.[48] Furthermore, family support has been shown to be associated with physical activity at weekends,[23,46] when young people are known to be less physically active than on weekdays.[49,50]

Parents may also influence their children's health behaviours through a variety of other mechanisms, including their general parenting style, their parenting practices (e.g. rule-setting, behavioural consequences, establishing behavioural expectations) and their control of the home environment.[51,52] Interventions that target both the child and the family are particularly effective,[29,53,54] and without the involvement of family members it is unlikely that a change in children's physical activity levels will be maintained long term.[44,55,56] Thus, targeting whole families may create a more supportive, synergistic environment for the promotion of healthy behaviours,[29,57] from which wider family members may also be able to benefit.[42]

Together, this evidence highlights the need for the promotion of young people's physical activity to target the family, where wider family members may also be able to benefit.[42] That said, little is known about how best to engage families.[29,44,52] This is highlighted by Tremblay *et al.*,[58] who state that 'the role of peers and parents in creating supportive environments for physical activity is unequivocal' but conceded that they could not draw any firm conclusions from their 38-country comparison.

Previous evidence on family-based physical activity promotion

Family-based physical activity promotion has received less attention than the promotion of young people's physical activity in other settings. In 2016, investigators on the current project published a systematic review, including a meta-analysis and a realist synthesis, in which we included 40 family-based physical activity studies.[29] 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; focusing on changing the family psychosocial 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. In addition, this review highlighted the generally low quality of the evidence base (including self-reported physical activity, small sample sizes and 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 review also highlighted that most studies focus only on promoting child physical activity, rather than considering the family as a unit that may work as a team to change behaviour.[59] Intergenerational,

family-based programmes targeting, for example, early literacy or prosocial development have shown positive effects, and highlight the potential benefit of including multiple family members in an intervention to improve child health outcomes.[60]

Theoretical background

In conceptualising an intervention to improve physical activity in children and families, the investigator team used a socioecological approach.[40] Specifically, the SEM provided a framework for the intervention components. Within this framework, behaviour change strategies were guided by self-determination theory (SDT).[61] Brief descriptions of the theories guiding intervention development and evaluation are provided in the following sections.

Socioecological model

The SEM of health[40] 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,[62] showing that a multitude of factors are associated with children's physical activity levels. Family factors, in particular, consistently exhibit positive associations with children's physical activity.[42,43,46] The family environment is most certainly an important influence on children's physical activity;[63] thus, efforts to increase children's physical activity should target the whole family.[64] In fact, the involvement of family members may be crucial for long-term physical activity change.[55,56]

Self-determination theory

Self-determination theory is a motivational theory that has received significant empirical support in the context of health behaviour change[61,65] and in the physical activity context specifically.[66–68] SDT makes a distinction between intrinsic and extrinsic forms of motivation. Intrinsically motivated individuals engage in a behaviour for its own sake (i.e. for the challenge or enjoyment). On the other hand, those motivated by extrinsic regulations engage in an activity to satisfy external demands that can be experienced as controlling or autonomous to varying degrees.[69] SDT posits that individuals move along a continuum as their extrinsic motives or reasons become more internalised they become more autonomous (or self-determined) to engage in behaviours over time (*Figure 1*).

According to SDT, social environments that support individuals' basic psychological needs (i.e. autonomy, relatedness and competence) are assumed to foster more autonomous motivational patterns.[71] When individuals are more autonomously motivated or self-determined, 'they experience volition, or a self-endorsement of their actions'.[69] The highest level of self-determination is intrinsic motivation, whereby

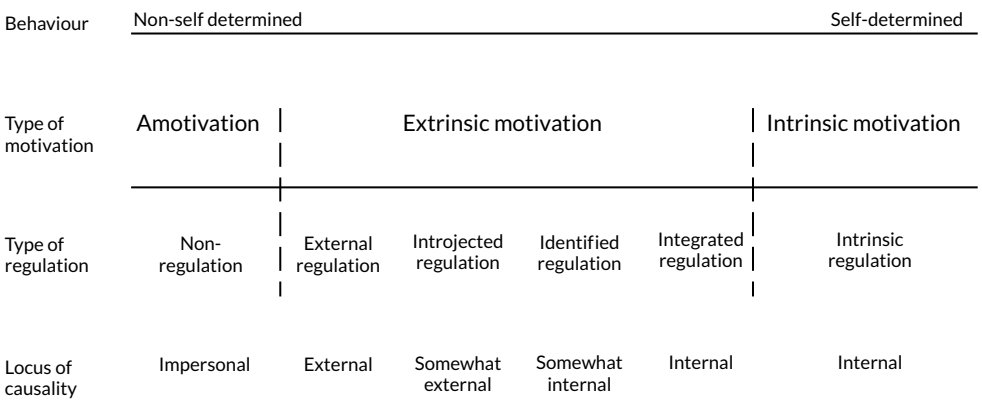

FIGURE 1 The self-determination continuum, showing the motivational, self-regulatory and perceived locus of causality from Deci and Ryan.[70] From 'The "what" and "why" of goal pursuits: human needs and the self-determination of behavior', Deci EL, Ryan RM, *Psychological Inquiry*, 1 October 2000, Taylor & Francis, reprinted by permission of the publisher (Taylor & Francis Ltd, http://www.tandfonline.com).

behaviours, such as physical activity, are performed for their own inherent rewards, such as enjoyment or challenge.[70]

Specifically, SDT argues that there are basic psychological needs for autonomy, competence and relatedness, all of which are critical and universal among individuals for psychological health and to move towards autonomous motivation.[70] Satisfaction of these basic needs results in increased feelings of vitality and well-being.[72] Thus, Deci and Ryan's concept of need support is what is thought to explain individual differences in the development of motivation across the lifespan.[70] Consequently, behaviour change interventions, including those in the area of physical activity, that enhance the satisfaction of participants' basic needs may be particularly effective.[73,74]

In summary, the broad purpose of SDT interventions is to assist individuals' progress on the continuum towards more autonomous forms of motivation. Overall, when the complete SDT causal sequence (*Figure 2*) is used, it creates an intervention outline that has the potential to be quite powerful.[71]

Summary and rationale for the FRESH project

The above literature highlights the importance of physical activity promotion in young people. This was echoed by an international expert panel, who concluded that developing effective and sustainable interventions to increase physical activity among young people is a key research priority in children's physical activity.[75] In addition, the National Institute for Health and Care Excellence[76] in the UK has identified 'The effect of community and family interventions on young people's physical activity levels' (p. 28) as an evidence uncertainty requiring further primary research.

Much of youth physical activity promotion has been predominantly targeted in and around the school setting; however, this project focuses on the important intrapersonal domain of the SEM. Moreover, most studies focus only on promoting child physical activity, instead of considering the family as a unit that may work together to change behaviour,[59] despite the known potential benefit of including multiple family members in an intervention to improve child health outcomes.[60] The Families Reporting Every Step to Health (FRESH) intervention, based on extensive prior work, including input from families themselves, will target the whole family and will be able to investigate whether or not this approach is more effective than solely targeting the child. The project was proposed 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.

The FRESH project received funding from the National Institute for Health Research (NIHR) Public Health Research programme in 2015 and commenced in late 2016. FRESH consisted of two phases: (1) intervention optimisation and feasibility testing, and (2) pilot testing. Both phases are described in

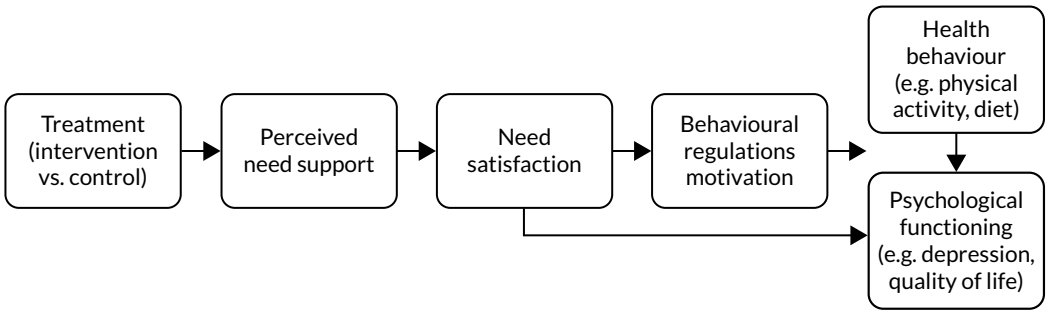

FIGURE 2 The SDT process model for health behaviour change in intervention research from Fortier *et al.*[71] Reproduced with permission. This article is published under license to BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

this report, as is an additional project aimed at optimising family recruitment. As per NIHR definitions,[77] 'a feasibility study asks whether something can be done, should we proceed with it, and if so, how'. Feasibility studies are used to estimate important parameters that are needed to design the main study, but do not evaluate the outcome of interest. 'A pilot study asks the same questions but also has a specific design feature: in a pilot study a future study, or part of a future study, is conducted on a smaller scale'.[77]

Study aims and objectives of FRESH feasibility and pilot project

The investigator team identified several strategic and practical uncertainties that needed to be dealt with before a definitive evaluation of the FRESH intervention could commence. The project reported on here consisted of the feasibility and pilot phases of the FRESH trial to reduce these uncertainties. The results of this project were to inform the decision whether or not to proceed with a definitive trial. As stated in the original funding application, the overall aim of a future definitive trial would be 'to establish the long-term effectiveness and cost-effectiveness of the family-based FRESH interventions to promote MVPA in 8-10 year-old children and their families living in rural Norfolk'.

The aim of the FRESH feasibility and pilot project was to assess the feasibility of delivering the FRESH intervention and its accompanying evaluation. The specific objectives are listed in *Box 1*.

BOX 1 Objectives of FRESH project

Objectives related to intervention optimisation and delivery

1. To further develop and optimise the content and delivery of the FRESH interventions (child-only, family) in collaboration with families and stakeholders.
2. To demonstrate feasibility and acceptability of delivery of the FRESH interventions in a short-term feasibility study.

Objectives related to recruitment, retention and adherence

3. To examine the feasibility and relative efficacy of different recruitment strategies and to 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 the recruitment and retention rate in a long-term pilot evaluation.

Objectives related to measurement and (cost-)effectiveness

7. To demonstrate the feasibility and acceptability of measurement procedures.
8. To assess the effect size and 95% confidence interval for the proposed primary outcome measure.
9. To test methods of assessing family physical activity and establish an intraclass correlation coefficient.
10. To examine participants' experience of the intervention and trial participation through questionnaires and interviews.
11. To develop and pilot a family physical activity-related expenditure questionnaire.
12. To model the 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 on the feasibility of a definitive FRESH trial and prepare a grant application, if relevant.

The four main research questions addressed were:

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 into obesity prevention programmes?

Progression criteria

The FRESH progression criteria were pre-defined at the grant application stage. The following parameters were to 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 uploading steps at least six times in the first 3 months of the pilot study)
- demonstrable feasibility of recruiting 20 families per month (based on pilot and accounting for increased staffing in a future definitive trial) and retaining 75% of index children at 1 year
- intervention optimisation feasible (identified adaptations are practical, affordable and acceptable)
- evidence to suggest that an adequately powered trial would require a feasible number of participants ($n = 250$ is considered logistically feasible and to provide sufficient power)
- discontinuation of trial arm based on evidence of harm or limited acceptability/feasibility
- positive expected net gain of sampling from definitive trial.

FRESH project study management

The overall FRESH project was managed by the FRESH project group, which was chaired by the principal investigator and consisted of all applicants, research associates working on the project, the study co-ordinator and a local stakeholder. Depending on the project phase, the project group met once every 1–3 months. Operational management was led by the FRESH operational group, consisting of the principal investigator, the study co-ordinator and the main research associate appointed on the grant.

At the start of the project, the FRESH Study Steering Committee (SSC) was established, consisting of seven independent members and the principal investigator. The independent members represented various scientific disciplines (young people's physical activity promotion, public health, family-based interventions, health economics, physical activity measurement, feasibility and pilot trials) and included stakeholders (public health) and members of the public (including with expertise in web-design). The FRESH SSC met once or twice each year. Its stated role was to:

- oversee the development and co-ordination of research activities
- act as a sounding board and provide advice on research matters to ensure the long-term health, development and scientific value of the project
- advise on the continuation of the project after the completion of a pilot study.

At its first meeting, the SSC agreed that, in addition to the pre-established progression criteria, it would consider 'changes in MVPA' as 'evidence of promise' to inform progression to a full trial.

Chapter 2 The development, trial design and methods of the FRESH feasibility trial

Introduction

Previous evidence indicates that home-based physical activity interventions are potentially more effective than those that require the family to travel to community or other intervention locations.[63,79] Furthermore, it is unlikely that any change in children's physical activity levels will be sustained long term without the active involvement of wider family members.[44,55,56] Many previous studies, however, focus only on promoting children's physical activity instead of considering the family as a unit that may work together to change behaviour.[59] Calls for physical activity research in young people and families highlight the dearth of research in this area[76] and the need to develop and evaluate innovative interventions targeting children and families.

Responding to this challenge, we sought to identify and develop a family-based physical activity intervention and evaluation. In this chapter, we describe the development of the FRESH intervention and recruitment strategy, and the protocol of the FRESH feasibility study. The aims of this study were to (1) assess the feasibility and acceptability of the FRESH recruitment strategy, intervention (including intervention fidelity) and accompanying outcome evaluation; and (2) explore how FRESH could be optimised through a mixed-methods process evaluation.

Methods

Overview of study design

The reporting of this study was guided by the Consolidated Standards of Reporting Trials (CONSORT) extension to randomised pilot and feasibility trials guidelines[80] and the Template for Intervention Description and Replication (TIDieR).[81] This feasibility study received ethics approval from the Ethics Committee for the School of the Humanities and Social Sciences at the University of Cambridge and was prospectively registered (ISRCTN12789422).

We conducted a 6-week, two-arm, parallel-group, randomised feasibility study, using a 1 : 1 allocation ratio, aiming to recruit 20 families with an 'index child' aged 8–10 years. The study focused on this age group, as these are the ages when physical activity starts to decline more steeply,[25] and it was anticipated that children of in this age group could be engaged effectively with intervention implementation. After measurements were completed at baseline, families were randomly assigned to one of two intervention arms. In the 'child-only' arm, the index child was the focus of the intervention, with family members simply providing support. By contrast, in the 'family' arm, all participating family members received the FRESH intervention (described in *Description of the FRESH feasibility study intervention*).

An independent statistician performed the randomisation procedure in Stata® (version 14; Stata Corp LP, College Station, TX, USA) using a computer-generated algorithm and a randomised block design (blocks of four) to ensure equal numbers in each condition and enrolment in both conditions at similar time points and rates.

Eligible participants

Families were eligible to participate when at least one child aged 8–10 years (hereafter referred to as index children) and at least one adult responsible for their care and living in their main household provided consent. Participants also needed to be able to take part in light-intensity physical activity (e.g. walking), have access to the internet and have a sufficient understanding of the English language. No restrictions were placed on family type (e.g. single parent, inclusion of grandparents, siblings). All other family members living in the index child's main household were invited to participate, but their participation was not required. In addition, intervention and evaluation participation were separate; family members could take part in the intervention irrespective of whether they participated in the accompanying evaluation, and vice versa. Specific exclusion criteria applied only to the evaluation of this study, and these are outlined below.

Study setting

Families were recruited from rural Norfolk, a county in East Anglia, UK (*Figure 3*). Norfolk has an area of 2074 square miles and an estimated population of 898,400.[82] About half of the population live rurally;[83] rural–urban disparities in physical activity have been reported.[24,26] In accordance with the Office for National Statistics[84] classification, 'rural' was defined as having a postcode falling in a small town, village, hamlet or dispersed settlement.

FIGURE 3 Map of England showing study location of FRESH feasibility and pilot studies (note that the feasibility study was conducted in Norfolk only).

Recruitment method

Formative work informing the development of the FRESH recruitment strategy

The recruitment of families is known to be particularly challenging and there is little evidence to suggest how best to engage families in physical activity research.[44,52] To inform recruitment and retention, prior to the start of the FRESH project, we conducted focus groups with 17 families (82 participants, consisting of 2–6 family members).[30] The findings of these led to the following recommendations for effective recruitment: (1) using a multifaceted recruitment strategy (i.e. through different setting and different methods) and (2) highlighting the wide range of benefits of research and physical activity participation (particularly social, health and educational outcomes). The findings explicitly contributed to the planned recruitment strategies for the current study, where we planned school- and community-based (e.g. Brownies/Cubs, community centres, general practitioner clinics) recruitment, and highlighted the benefits of spending time together as a family in our recruitment material.

Recruitment protocol

To recruit schools and community-based organisations, we first contacted lead personnel (e.g. head teachers, physical education co-ordinators and heads of community-based organisations) by sending an information pack that included information sheets and a leaflet describing the purpose of the study and what it would involve for schools, parents and children. We followed this up with a telephone call if no response was received. Verbal or written approval was sought from the gatekeeper (e.g. Brownies leader, head teacher) prior to family recruitment. Gatekeepers were asked to send home study leaflets with children, circulate our leaflet to parents online (i.e. via Parentmail or an equivalent system) and send an online reminder to parents approximately 2 weeks later. From schools, we also sought permission to present the study to Year 3–5 students at a scheduled assembly.

Interested parents were asked to contact the study team by e-mail or Freephone, after which their eligibility was assessed and they were e-mailed the study information. Following this, a baseline assessment appointment was made with those families still interested in participating. At the start of the visit, written informed consent was obtained for participating adults, and written parental consent and child assent for each participating child.

Intervention selection and development

Building on previous evidence

As described in *Chapter 1*, we previously conducted a systematic review and meta-analysis to study the effectiveness of family-based physical activity promotion on children's levels of physical activity.[29] The meta-analysis showed a small, but significant, effect favouring the experimental groups of family-based interventions compared with controls [Cohen's $d = 0.41$, 95% confidence interval (CI) 0.15 to 0.67]. However, it also highlighted the scarcity of family-based intervention studies that (1) clearly indicated intended behaviour change mechanisms, (2) employed objective measures of physical activity, (3) engaged with/assessed intervention effects on wider family members and (4) were theory-based. The development of the FRESH intervention was informed by a programme theory for family-based physical activity interventions, developed as part of this review.[29] This programme theory highlighted the value of (1) using goal-setting combined with reinforcement in the context of family constraints (e.g. lack of time or scheduling difficulties), (2) focusing on changing the family psychosocial environment (e.g. using the child as agent/instigator of change) and (3) focusing on something other than the health benefits of physical activity (e.g. spending time together as a family). These collective findings were considered in the development of the FRESH intervention.

Intervention selection through public involvement

The research team developed four potential intervention concepts based on their previous work.[29,30] The four concepts were:

1. Buddy scheme – families would be paired or grouped to facilitate peer support for physical activity.
2. Small changes – providing a resources toolkit to each family, containing information on making small changes to increase physical activity (e.g. active travel suggestions, such as getting off the bus a stop early).
3. Sports equipment library – a 'travelling library' of a large range of sporting equipment would move through a community once per week, allowing families to borrow equipment.
4. Family challenge – families would be framed as a 'team' working towards a common goal (e.g. an overall step count to 'walk around the world').

These four concepts were then brought to families during a university-run community engagement event. At this event, children acted as researchers to identify which intervention concept their family would enjoy most. Based on the feedback, the most popular concepts were further refined during meetings with stakeholders (i.e. parents, teachers, family health practitioner). This led to the selection of an intervention that allowed families to work as a 'team', tracking their efforts towards a common goal and receiving small rewards for progress (the family challenge described above). This initial input from families and stakeholders was used as a starting point from which develop FRESH in its current form.

Description of the FRESH feasibility study intervention

In brief, FRESH was primarily a goal-setting and self-monitoring intervention aimed at increasing physical activity in whole families. The SEM (individual and interpersonal levels)[40] and family systems theory[85] provided a framework for the intervention components. Within this framework, behaviour change strategies were guided by SDT.[61] A detailed description of the FRESH intervention components and associated behaviour change techniques,[86] targeted SDT constructs and hypothesised mediators is provided in *Table 1*. In addition, the FRESH feasibility study logic model can be found in *Figure 4*.

TABLE 1 Summary of the FRESH feasibility study intervention components, their proposed frequency and their theoretical basis

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
1. 'Family time'	Minimum once per week, 10–20 minutes	'Family time' provided an opportunity for index children[a] and family members to plan PA, monitor their week's steps, discuss any potential PA barriers and strategies to overcome them by logging in their family action planners.[27] Regular 'family time' was hypothesised to provide index children with: • A consistent (re)structured environment, where family members supported index children in choosing an optimally challenging and realistic goal (reflected as an easy, moderate, or difficult challenge on the FRESH website), breaking down goals into proximal (daily) and distal (weekly) step count targets, and providing praise and positive feedback on progress towards those goals. These strategies provide direct support for participants' perceived competence[32]	Goal-setting Self-monitoring Positive feedback on progress Social support Praise Positive reinforcement	Perceived competence Perceived relatedness Perceived autonomy	Family social norms for PA PA awareness Basic needs satisfaction PA motivation

TABLE 1 Summary of the FRESH feasibility study intervention components, their proposed frequency and their theoretical basis (*continued*)

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
		• Consistent parental involvement which directly facilitates relatedness.[32] Parental involvement (via co-participation in PA) may also positively affect family connectedness[33] • An opportunity for consistent autonomy support. Autonomy support has been shown to directly support participants' autonomy and indirectly support their basic needs for competence and relatedness[34] Additionally, index children were named their family's team captain (i.e. change agent) where they were in charge of initiating 'family time'. Evidence suggests that children may elicit changes to the psychosocial environment;[28] therefore, promoting the index children to the role of family 'team captain' may strengthen child buy-in, perceived autonomy, and improve intervention fidelity			
2. FRESH website	Minimum once per week, 5–20 minutes	The FRESH website facilitated self-monitoring of step counts, and goal-setting through selecting challenges. Specifically, the FRESH website allowed families to choose one of three target cities to 'walk to' weekly, with the aim to eventually 'walk' around the world. Each week, families chose an easy, moderate or difficult challenge, which represented a 0%, 5% or 10% increase, respectively, relative to the average steps they had taken in preceding weeks. Increases were adjusted to 0%, 2.5% and 5% once adults and children accumulated an average of 10,000 and 12,000 steps per day, respectively. Families also had access to a general resources area that provided suggestions of activities that families could do together and a map to give a visual representation of the locations families had travelled to	Goal-setting Self-monitoring Positive feedback on progress Rewards	Perceived competence Perceived relatedness Perceived autonomy	Social support Family social norms for PA PA awareness Basic needs satisfaction PA motivation
3. Pedometry	Throughout intervention (6 weeks)	Participants were provided with pedometers for self-monitoring and immediate feedback. Pedometers are simple to use and convenient and are associated with effective interventions for increasing parent–child physical activity.[35] Index children logged their steps (and their family members' steps) into the FRESH website and/or onto the family action planners, which allowed participants to view their progress towards their proximal and distal step goals	Self-monitoring Immediate feedback	Perceived competence Perceived autonomy	Social support Family social norms for PA PA awareness Basic needs satisfaction PA motivation

continued

TABLE 1 Summary of the FRESH feasibility study intervention components, their proposed frequency and their theoretical basis (*continued*)

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
4. Virtual rewards/ competence reinforcement	Approximately once per week (6 weeks)	To praise effort (i.e. competence reinforcement), participants received supportive messages, virtual passport stamps (i.e. virtual rewards) and access reinforcement materials (i.e. interactive multimedia information about the cities they have visited) on the FRESH website as they completed challenges to various cities around the world. Participants received 2–4 passport stamps for completed challenges (i.e. as difficulty increased, more stamps were awarded) and one passport stamp for an incomplete challenge	Feedback on progress Rewards	Perceived competence	Basic needs satisfaction PA awareness

PA, physical activity.
a The index child is the child aged 8–10 years in the family.

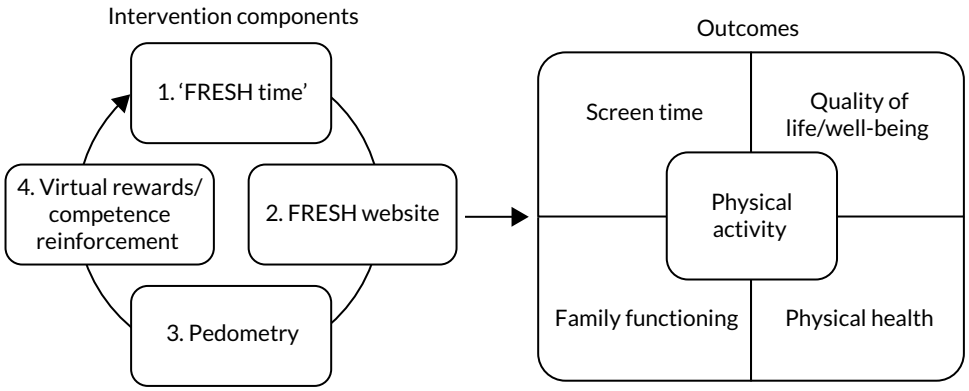

FIGURE 4 The FRESH feasibility study logic model.

To initiate intervention participation, a facilitator visited all families a week after baseline assessments for a 'kick-off' meeting to introduce the families to the intervention components and accompanying materials (e.g. family action planner). The main purpose of this meeting was to familiarise families with the website and prompt them to schedule regular 'family time' meetings (a suggested minimum of one per week) during which they would review and update their family action planner. All meetings occurred in participating families' homes and lasted approximately 1 hour. Participant-initiated distant support was available for the duration of the intervention.

A detailed description of the FRESH intervention components can be found in *Table 1*. At the start of each new weekly challenge, families had 'family time', during which they selected a challenge on the FRESH website and filled in their action planners. The FRESH website allowed families to choose one of three target cities to 'walk to' each week, with the aim of eventually 'walking' around the world. The FRESH website primarily facilitated the self-monitoring of step counts and goal-setting through selecting challenges of varying difficulty. In both study conditions, children were allocated the role of 'team captain', leading on destination selection and uploading steps online. Families were to wear their pedometers for as long as possible daily to capture their steps and were asked to upload their step counts at least once weekly. After completing a challenge, families received effort-praising messages and virtual rewards (i.e. virtual passport stamps) and were able to track their progress around the

world and access reinforcement materials on the FRESH website (i.e. interactive information about the cities they had walked past and reached during their challenge). If a family did not complete a challenge, to praise their effort, they progressed to a hidden city along their challenge route and still received a supportive message, a virtual passport stamp and access to reinforcement materials. Completing a challenge (or the week coming to an end) initiated the next 'family time' meeting, when the above cycle was repeated (see the cycle in *Figure 4*).

FRESH child-only condition

The child-only condition was essentially the same as described above, but in this condition only the index child received a pedometer and was able to record their steps on the FRESH website. All other components were kept the same.

Refining the prototype FRESH intervention

The initial FRESH intervention was developed further through public involvement activities. We sought input from children ($n = 7$) through a talk-aloud session regarding the layout and design of the FRESH website and also from families ($n = 2$) who pilot-tested the intervention protocol described above. Overall, the FRESH intervention was well received, children found the website easy to navigate, and no changes were made to the protocol. However, based on participants' suggestions, minor changes were made to the intervention website. For example, participants found it discouraging when they participated in activities that could not be captured by their pedometers (e.g. swimming). Therefore, we added a 'step calculator' to the website that enabled participants to estimate the number of steps that various activities, such as swimming, would give them, using data from a readily available online activity-to-step converter.[87]

Outcome evaluation measures

As part of this feasibility study, we aimed to assess the feasibility and acceptability (i.e. not the effectiveness) of the planned outcome evaluation. Therefore, here we briefly describe the measures included to provide an overview of what the outcome evaluation entailed. *Table 2* outlines the measures taken, including the order of assessments and the estimated duration of each. Data collection was carried out by two trained research staff in participating families' homes. Outcomes were assessed at baseline (prior to randomisation) and at follow-up (at 6 weeks) for all participating family members (excluding children aged ≤ 2 years). All consenting family members took part in measurements, irrespective of their intervention allocation and participation.

TABLE 2 Order of measures and estimated duration of data collection for each time point[a]

Measure	Duration
1. Anthropometric measures (height, weight, waist circumference)	5 minutes per person
2. Questionnaires[b]	20 minutes per family
3. Blood pressure	10 minutes per person
4. Step test (aerobic fitness)	Preparation: 5 minutes per person
	Test: 8 minutes per family
5. Accelerometer and GPS explanation	5 minutes per family
6. Fictional Family Holiday (family functioning)	10 minutes per family
Total duration of measurements	Minimum of 73 minutes
Total duration of visit (including consent process)	Minimum of 88 minutes

GPS, Global Positioning System.
a Estimate based on a three-person household; total time increases by ≈ 30 minutes per additional family member.
b Questionnaires completed during data collection included a child or parent questionnaire (per person), a family out-of-pocket physical activity expenditure questionnaire (per family) and a child or adult process evaluation questionnaire (per person; follow-up only).

Physical activity assessment

To assess individual physical activity, and family co-participation in physical activity, participants were asked to simultaneously wear an ActiGraph GT3X+ triaxial accelerometer (ActiGraph LLC; Pensacola, FL, USA) and QStarz Travel Recorder BT1000X Global Positioning System (GPS) monitor (QStarz; Taipei, Taiwan). Participants wore the monitors affixed at each hip on an elastic belt during waking hours for 7 consecutive days. The monitors where then picked up by a member of the study team, or participants were asked to return the monitors to the study office in a prepaid enveloped. Accelerometer data were downloaded and processed. A valid week was defined as $\geq$ 600 minutes per day from 3 weekdays and 1 weekend day during the 7-day measurement period.[88] Non-wear was defined as $\geq$ 90 minutes' consecutive zeros using vector magnitude. ActiGraph accelerometers have been shown to be valid and reliable devices for the measurement of physical activity levels in children and adults;[89–91] the GPS monitor used has been shown to have high static and dynamic validity in a variety of settings.[92]

Combined GPS and accelerometer data were collected to enable the assessment of family co-participation in physical activity (i.e. family members being active in proximity to each other). Accelerometer and GPS data were matched using Java; after this, data points that had a time difference of $\leq$ 30 seconds between the accelerometer timestamp and that of its matched GPS location were considered valid for inclusion. Matched data points with a time difference greater than this, for example when the GPS had been switched off or had lost signal, were considered as missing location information because the participant might have moved to a new, unrecorded, location. From the matched data, we computed the minutes per day for which the GPS had maintained a signal, and had therefore recorded the participants' location, as an indicator of data completeness. Only wear time data will be presented as part of the feasibility study; therefore, we have only provided information relevant to estimating wear time using both monitors.

Health outcomes

Aerobic fitness was measured using an 8-minute submaximal step test.[93] Children aged $<$ 8 years were excluded from the aerobic fitness test because of the height of the step. Older children and adults were all asked to complete the step test. Height, weight, waist circumference and blood pressure [using an OMRON 705IT digital blood pressure monitor (OMRON Healthcare UK Ltd, Milton Keynes, UK)] were measured in accordance with standardised operating procedures. Body mass index (BMI) was calculated and was converted into age- and sex-specific percentiles using standard growth charts for children using LMSgrowth Program version 2.77 (Child Growth Foundation, London, UK).[94]

Behavioural and psychosocial measures

Questionnaires assessed behavioural and psychosocial measures: adult and child screen-use time;[95–98] quality of life;[99–102] family co-participation in physical activity;[98] physical activity awareness;[103,104] family social norms for physical activity;[105,106] family support;[105] children's and adult's motivation for physical activity;[107,108] and children's perceived autonomy, competence, and relatednesss.[108] *Table 3* provides an overview of the measures used with children and adults. Children aged $\leq$ 4 years did not complete this questionnaire. Research assistants were available to answer questions during completion.

Fictional Family Holiday

The Fictional Family Holiday paradigm, a 10-minute video-recorded activity where families were asked write out a week-long holiday itinerary with unlimited budget, was used to assess family functioning via family relationships[109] and connectedness.[110] This is because the activity requires 'power sharing' (i.e. taking turns) and prompts the viewpoints of all family members on the topic, eliciting both individuality (through suggestions for destinations/activities or disagreements) and connectedness (through agreements, questions, or initiating compromise), contributing to the family's final plan.[109]

TABLE 3 Description of the questionnaire-assessed behavioural and psychosocial measures

Measure	Assessment method§
Screen time	*Adult:* two items from the Recent Physical Activity Questionnaire[95]
	Child: parent proxy using one item from the Children's Physical Activity Questionnaire[96]
Family co-participation in screen time	Four items derived from the SPEEDY study questionnaire
Screen-based restriction	Restricting access to screen-based activities was measured with two versions (parent-report and child-report versions) of the Activity Support Scale for Multiple Groups[97]
Quality of life	*Adult:* EQ-5D-5L[99,100] The EQ-5D-5L asks respondents to describe their health today using five dimensions, each at five levels. The dimensions are mobility, self-care usual activities, pain/discomfort and anxiety/depression
	Child: CHU-9D.[101,102] The CHU-9D asks respondents to rate their health today using nine dimensions, for example pain and usual activities, school work/homework, tired and sleep. Algorithms exist based on population preferences for both scales to be converted into a 'health state utility', an index relative to two anchor points of 0 (dead) and 1 (perfect health). Integrating these over time allows the calculation of QALYs
Physical activity awareness	*Adult*: self-report whether or not they achieve enough MVPA to meet national guidelines, as used previously[104]
	Child: one item on the child and parent questionnaire from Corder *et al.*[103]
Family social norms for PA	*Adult*: single item using previously used question[105]
	Child: four items from previously used questionnaires[106]
Family support	*Adult and child:* six items using previously used questionnaires[105]
Motivation for PA	*Adult*: BREQ-2, developed by Markland and Tobin[107]
	Child: questionnaire developed by Sebire *et al.*[108]
Basic psychological needs satisfaction	Children's perceived autonomy, competence, and relatedness will be assessed in child participants only, using a questionnaire developed by Sebire *et al.*[108]

BREQ-2, Behavioural Regulation In Exercise Questionnaire; CHU-9D, Child Health Utility 9D; PA, physical activity; QALY, quality-adjusted life-year.

Family out-of-pocket expenditure for physical activity

Information on family expenditure related to physical activity was collected using a questionnaire that was developed and tested for the current study. This was completed by one adult for their whole family. The questionnaire consisted of two questions about expenditure related to membership fees and subscriptions (e.g. for sports clubs, fitness centres) and sports equipment (e.g. sportswear, gadgets).

Process evaluation

A mixed-methods process evaluation was conducted at the end of the 6-week intervention. In questionnaires, adults self-reported their overall opinion of FRESH, their opinion of the intervention components and measurements, and suggestions for improvement using open-ended and 5-point Likert-scale questions (1 = strongly disagree, 5 = strongly agree). Children also self-reported on the above topics, responding to dichotomous 'yes/no' questions. In addition, we conducted semistructured focus groups with 11 out of 12 families (one family declined to participate), focusing on families' perceived acceptability of the individual FRESH intervention components, intervention fidelity, challenges/barriers to engaging with FRESH, and suggested improvements. The mean duration of focus groups was 34 minutes [standard deviation (SD) 10 minutes; range 17–50 minutes]. All focus groups were audio-recorded and transcribed verbatim.

Data analysis

Quantitative data

Frequencies, percentages, means and SDs were calculated to describe the data related to recruitment, retention, fidelity, intervention optimisation, website engagement and outcome measures.

Qualitative data

Using a long-table approach, a content analysis was conducted using existing guidelines.[111] Specifically, the analysis was conducted in two separate phases. During the data organisation phase, text from each transcript was divided into segments (i.e. meaning units) to produce a set of concepts that reflected meaningful pieces of information.[111] Tags were then assigned to each meaning unit. Tagging was performed by one researcher, with a second double-tagging approximately 25% of the transcripts. In the data interpretation phase, the inventory of tags from all transcripts was examined by two researchers, which led to the emergence of themes and subthemes within each overarching category.

Chapter 3 FRESH feasibility trial findings

The FRESH feasibility study was conducted in May–August 2017, in accordance with the protocol described in *Chapter 2*. This chapter describes the findings of this study, which had the following aims: (1) to assess the feasibility and acceptability of the FRESH recruitment strategy, intervention (including intervention fidelity) and accompanying outcome evaluation; and (2) to explore how FRESH could be optimised through a mixed-methods process evaluation.

Recruitment and retention

Owing to intervention development delays, we were only able to deploy school recruitment strategies. Of 11 schools approached, three declined (too busy, $n = 2$; doing enough physical activity promotion already, $n = 1$), and three did not respond. Five schools with an estimated 437 eligible students in Years 3–5 agreed to disseminate the FRESH recruitment material (reach).

Figure 5 shows the flow of participants from the number of families assessed for eligibility through to the number analysed. Of those families reached, 6.4% (i.e. 28 families) expressed interest; initial interest came from 23 mothers and 5 fathers. Expressions of interest occurred at a rate of three or four families per week or five or six families per school assembly conducted. Fewer than half of the families expressing interest in participation subsequently signed up to participate in FRESH ($n = 12$ families), and these were enrolled at a rate of one or two families per week. All families were retained at the 6-week follow-up.

Of the 12 families enrolled, four were whole families and six were dyads (i.e. one parent and one index child); 32 family members participated overall. About two or three family members took part per family (range 2–4 family members); four families had an additional eligible adult, three families had an additional eligible child and one family had both. *Table 4* describes the participant characteristics.

In focus groups, families were asked about the perceived challenges to recruitment, which revealed four challenges to be considered for optimising future recruitment. A brief description of the challenges is provided below, with supporting quotations in the first part of *Table 5*.

Children trying to convey what FRESH was to parents

Delivering school assemblies emerged as an effective strategy for captivating children's interest in FRESH. The children's interest in FRESH following assemblies appeared to be the main reason parents expressed interested in participating. However, children struggled, or were unable, to explain to their parents what FRESH involved, which is likely to have had an impact on the likelihood of recruiting the family unit.

Participation would be time-consuming

Parents suggested that one of the main barriers was the perception that participation in FRESH would be burdensome and time-consuming. However, participating parents reported that FRESH participation did not impede their normal daily activities.

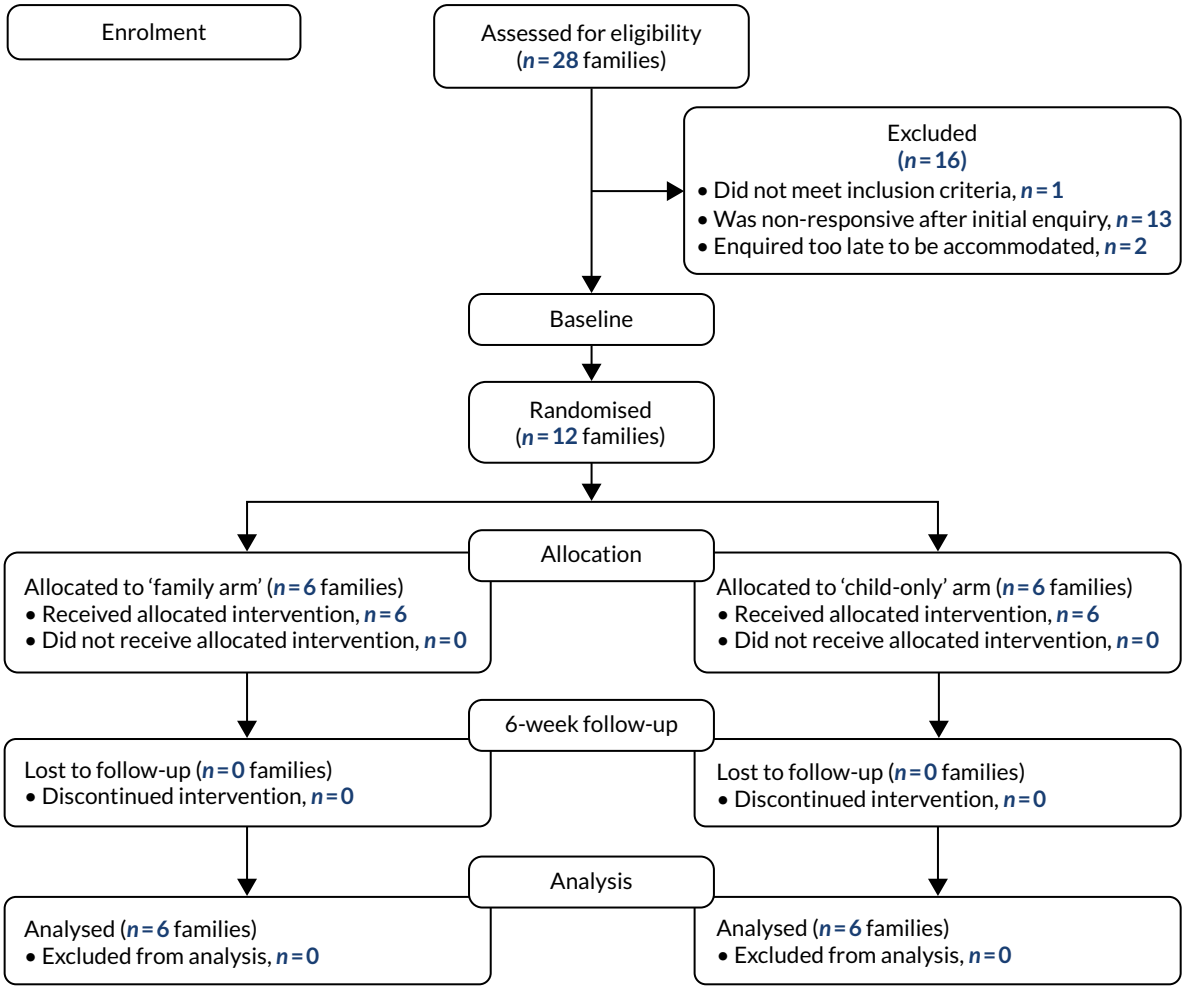

FIGURE 5 Flow of participants in the FRESH feasibility study.

TABLE 4 Individual characteristics of FRESH feasibility study participants at baseline

Variable	Adults ($n = 18$)	Children ($n = 14$)
Sex (% male)	38.9	50.0
Age (years), mean (SD)	39.8 (8.2)	8.3 (1.7)
Height (cm), mean (SD)	168.6 (8.6)	133.6 (12.7)
Weight (kg), mean (SD)	74.7 (15.9)	32.5 (10.8)
BMI (kg/m^2), mean (SD)	26.3 (5.8)	N/A
BMI z-score, mean (SD)	N/A	0.5 (1.1)
Waist circumference (cm), mean (SD)	92.0 (12.7)	66.6 (12.3)
Blood pressure (mmHg), mean (SD)		
Systolic	127.8 (16.2)	110.0 (105)
Diastolic	72.6 (9.1)	64.6 (7.2)
Pulse rate	68.3 (7.1)	81.0 (7.8)

N/A, not applicable.

TABLE 5 Supporting quotations from FRESH feasibility study family focus groups

Subheading	Supporting quotations
Findings related to recruitment and retention	
Children trying to convey what FRESH was to parents	*I guess because you did it in assemblies, I wasn't sure what he was going on about. It wasn't till [a mother of a participating family] had obviously been in touch with you that we found out more. But going back to the whole thing of trying to then explain [FRESH], if the kids can't do it, it becomes sort of Chinese whispers between the parents, doesn't it?* *Mother 7, family arm*
Participation would be time-consuming	*I think people have misconceptions . . . I think they just heard the words research project and thought, 'oh no, we're going to have to do a load of stuff' '. . . but you don't have to do anything, just wearing this [pedometer] and going about what I do normally and log on the website every night or a couple of times a week and have a look at how we're doing. I didn't think it was a hassle at all* *Father 5, child-only arm*
Lack of confidence for physical activity	*Exercise is a funny thing, you know . . . Like if they're overweight or they don't eat healthy . . . they may think they're being judged by it and actually they're not being judged by it at all. That's not what this was about . . . but there's a fear factor when it comes to exercise for some people . . . And given that I think obesity levels are pretty high around here for the national average, I think West Norfolk's one of the fatter areas, people may be a bit . . . I don't know, possibly there was lack of confidence about signing up to something like this* *Mother 5, child-only arm*
Reluctance to be measured	*It was the measurements, I would've done the other stuff . . . I think with some people that just puts you off straightaway. I think it did for me . . . I was like 'no, I don't want to do that' and I'm sure others felt the same. Luckily [father] didn't mind because she really wanted to do this* *Mother 12, family arm*
Findings related to intervention feasibility, acceptability, fidelity and optimisation	
Feasibility and acceptability of FRESH	*Definitely more aware, I underlined that [on the process evaluation questionnaire] because I think in terms of our awareness, it has made us a lot more aware of the steps that we are doing. I really, really liked that, for me that has been the best thing* *Father 6, family arm* *. . . you [speaking about index child] wanted to walk more didn't you, like if we were going to nursery you were like, 'can I walk because I want to get more steps'. I noticed that on a few things, whereas before she would have been like, 'oh, can we go in the car?'* *Mother 12, family arm* *I do think if you'd given step counters to everyone in the family it gives us more onus to do it. Once you'd gone, it was all about him and no one else in the family, I felt like I'd done my bit and it was all down to just him and his step counter; whereas, if I'd have had a step counter . . . for the 6 weeks I probably would have been more aware about how active I was, and not necessarily competed with you, but just the fact that I had my own one to keep an eye on how active I'd been, then I'd have probably felt more involved* *Father 8, child-only arm*
'Family time'	*We would actually compare on a daily basis . . . we'd be like 'who's done the most steps today?' and you know, 'oh, you've done more than you normally do, [index child]' or 'you have done less then you normally do'. So, we were able gauge, 'oh, it's been a slow day, why has been it slow day? What have you been doing at school today?'* *Father 6, family arm* *We had the planner out the whole time in the kitchen, so it was easier to fill in. [Index child] was involved with it because, at the end of the day, I would say,' have you written your log?' And before bed she would have a look and she would write her number down and [father] and I would shout our numbers to her and say, 'oh this is mine, put mine in'* *Mother 6, family arm*

continued

TABLE 5 Supporting quotations from FRESH feasibility study family focus groups (*continued*)

Subheading	Supporting quotations
FRESH website	*We pretty much just went on [the website] to log [steps] . . . I think we found that hardest thing, we would fall out over whose going to log [on the website] . . . so that wasn't that helpful for the family dynamic [laughs]* *Father 6, family arm*
	Well I'd like to have a leaderboard, that shows everyone doing it and it says, 'you've got to beat this person and their name', like it says on my football game *Boy 5, child-only arm*
	Yeah, a family one would be good. That would spur us all on wouldn't it! It would spur us all on massively, yeah *Father 5, child-only arm*
Rewards	*He enjoyed that [virtual badges], but . . . maybe do a certificate or stickers or something, you know, even if you posted one to them, so they receive the post and we could be like 'oh yeah, look what you've done!' and . . . especially if you named it to them personally, so they actually got the physical post . . . 'I've got a letter, I get to open that, wow, got my certificate in it!* *Mother 3, family arm*

Lack of confidence about physical activity

One family said that a major challenge in recruiting families in their county might be a high prevalence of obesity, and they suggested that families would be reluctant to register for a physical activity intervention owing to a lack of confidence.

Reluctance to be measured

It was also confirmed that some family members chose not to participate in FRESH at all because they did want to participate in measurement sessions.

Family focus groups also revealed suggested strategies for improved recruitment. This included a return visit to schools to give parents an opportunity to hear about FRESH and ask questions; exploring recruitment strategies that targeted adults through formal (e.g. employers) or informal settings (e.g. clubs, local fetes, shopping centres); using social media, such as Facebook or Twitter; and providing endorsements from previous participants or familiar organisations.

Intervention feasibility, acceptability, fidelity and optimisation

Feasibility and acceptability of FRESH

All children reported that they liked taking part in FRESH and thought that it was fun. *Table 6* shows adults' overall perceptions of FRESH. Scores were generally positive. In particular, adults agreed that FRESH was fun, encouraged their family to do more physical activity, and made their family more aware of the amount of physical activity they did, which was confirmed in focus groups (see *Table 5*). Goal-setting also emerged as a major theme, particularly in those randomised to the 'family' arm. Participants (adults and children) were aware of the daily step counts required to complete their weekly challenge and were able to identify ways to accumulate additional steps to meet the daily targets (e.g. active travel; see *Table 5*). Participants also reported receiving socioemotional (e.g. feeling 'closer' as a family) and perceived cognitive benefits (e.g. to the index child's maths ability) as a result of their participation. Last, all six families allocated to the child-only arm demonstrated a clear preference for the whole family to be involved in FRESH. This finding was particularly evident among fathers (see *Table 5*).

TABLE 6 Summary process evaluation findings for adult participants assessing the acceptability of the FRESH intervention (feasibility study)

	Overall	Family arm ($n = 8$ adults)	Child-only arm ($n = 6$ adults)
The FRESH study …			
… was fun for my family and me	4.2 (0.8)	4.3 (0.7)	4.2 (1.0)
… encouraged my family and me to do more physical activity	3.9 (0.8)	4.0 (0.6)	3.8 (1.0)
… has led my family and me to do more physical activity than we did before FRESH	3.5 (1.0)	3.6 (0.7)	3.2 (1.3)
… has led my family and me to do more activities (other than physical activity) together than we did before FRESH	3.4 (0.7)	3.3 (0.7)	3.5 (0.8)
… has made my family and me more aware of the amount of physical activity we do	4.6 (0.5)	4.7 (0.5)	4.6 (0.5)
… is something my family and I would like to continue to be part of	3.8 (1.3)	4.3 (0.8)	3.4 (1.5)
Regarding 'family time', to what extent do you agree or disagree with the following?			
It was easy to schedule 'family time'	3.1 (1.1)	3.1 (1.4)	3.1 (0.8)
My family consistently scheduled 'family time'	3.1 (1.2)	3.1 (1.4)	3.2 (1.0)
My child reminded us about 'family time'	2.9 (1.6)	3.0 (1.7)	2.7 (1.5)
My child led/initiated 'family time'	2.6 (1.4)	2.7 (1.5)	3.0 (1.5)
Regarding the FRESH website, to what extent do you agree or disagree with the following?			
It was easy to use	3.6 (1.3)	3.6 (1.4)	3.5 (1.4)
I enjoyed using it	3.6 (0.9)	3.6 (1.1)	3.7 (0.8)
My child/children enjoyed using it	4.0 (1.2)	3.9 (1.3)	4.2 (1.0)
I thought the website was appealing	3.7 (0.9)	3.6 (0.8)	3.8 (1.0)
I liked that there were varying degrees of difficulty with the challenges	4.3 (0.9)	4.3 (1.1)	4.3 (0.8)
I enjoyed the information about the cities	3.9 (1.1)	3.6 (1.3)	4.3 (0.8)
My child/children enjoyed the information about the cities	3.8 (1.1)	3.4 (1.3)	4.3 (0.8)
The step converter was useful (e.g. converting swimming to steps)	3.3 (1.3)	2.8 (1.2)	4.0 (1.2)
The resources page was useful	3.2 (1.1)	3.0 (1.2)	3.5 (1.0)
I enjoyed the recipes	3.3 (0.9)	3.1 (1.1)	3.5 (0.8)
My child/children enjoyed the recipes	3.4 (1.0)	3.1 (1.1)	3.7 (1.0)
Logging our steps was easy	3.7 (1.5)	3.9 (1.7)	3.5 (1.4)
Regarding the step counter we gave out to log your steps, to what extent do you agree or disagree with the following?			
I didn't mind wearing it	4.0 (1.2)	4.0 (1.2)	N/A
My child/children didn't mind wearing it	3.9 (0.9)	3.9 (1.1)	4.0 (0.6)
It was easy to use	4.5 (0.7)	4.6 (0.5)	4.3 (0.8)
I thought it was reasonably reliable at counting steps	4.3 (0.7)	4.6 (0.5)	3.8 (0.8)
I used the memory feature to go back and look at the number steps my family and/or I took	4.6 (0.5)	4.6 (0.5)	4.5 (0.5)

N/A, not applicable.

Note
Participants responded on a 5-point Likert scale for each question (1 = strongly disagree; 5 = strongly agree). All values are mean (SD).

Intervention acceptability and fidelity

Kick-off meeting

Using a five-point Likert-scale (1 = strongly disagree, 5 = strongly agree), all families felt that the 'kick-off' meeting was useful (family vs. child only: mean 4.4, SD 0.8, vs. mean 4.5, SD 0.8) and appreciated the fact that it was a face-to-face meeting as opposed to a telephone or video meeting. Most families felt that they had enough technical support (mean 3.9, SD 1.5; mean 4.2, SD 1.0), and the majority of families stated that a single meeting was enough for them to understand the protocol and how to use the intervention website and materials. However, two families would have liked a follow-up meeting the following week.

'Family time'

Overall, adults disagreed that children led or reminded them of 'family time' (see *Table 6*). In line with the adult data, the majority of children did not view themselves as their family's team captain to lead on 'family time'. Several children said that they forgot they were team captain or they could not be bothered to be the team captain. There was also evidence to suggest that some parents took over the team captain role.

Overall, adults reported that it was not particularly easy for their family to schedule 'family time' or to have it consistently. Most families claimed they either rarely or never had 'family time'. A lack of time was the most commonly cited challenge to having 'family time'. In addition, some parents' work schedules (i.e. shift work) made it difficult to organise 'family time' with all family members present. However, focus group evidence shows that some families were discussing physical activity in a manner that would have been unlikely prior to FRESH (see *Table 5*).

Generally, families used their action planners only to log daily step counts and not to plan weekly activities or anticipate barriers to meeting step goals. Most families preferred to write their step counts out on their paper-based action planners and transfer them to the FRESH website once, near the end of their weekly challenge (see *Table 5*).

FRESH website

Compared with the child-only arm, the family arm exhibited greater website engagement, as they travelled to more cities (mean 36, SD 11, vs. mean 13, SD 8) and failed fewer challenges (mean 1.5, SD 1, vs. mean 3, SD 1). All children in the family arm and most (≈ 80%) children in the child-only arm wanted to continue using the FRESH website. Children in the family arm also found it easier to use the website than those in the child-only arm (83% vs. 60%). Overall, adults' mean scores were generally positive in relation to the FRESH website (see *Table 6*), although more critical opinions were voiced during the focus groups. For the majority of families, the extent of their website engagement entailed selecting challenges and logging steps, which was normally a task performed reluctantly by parents (see *Table 5*). Many adults and children were unaware of or had not used several of the website elements (e.g. step calculator, parent resources, virtual rewards). Others stated that children had been interested in the website (e.g. information about cities) but that their interest wore off and only an interest in accumulating steps remained.

Technical issues arose with the website, particularly with the algorithm that calculated the number of steps that families needed to accumulate to complete their challenge. This might have negatively affected some participants' experiences. Aside from technical bugs that needed resolving, families provided input on other potential improvements that could be made to the website. Almost unanimously, families wanted an element of competition on the website. It was evident from numerous focus groups that within-family competition occurred throughout the intervention period. However, the ability to compete against other families was also suggested in several focus groups (see *Table 5*). Other suggested website improvements included (1) adding a step history page to enable families to view progression over the intervention period; (2) providing more feedback/praise from the research team; (3) providing more flexibility in challenge destinations; (4) sending a text or e-mail reminder to log steps, and (5) improving the website design.

Pedometers

Overall acceptability of the pedometers was high among adults in both arms (see *Table 6*). Generally, adults stated that it became 'routine' or 'second nature' to wear pedometers, although some would have preferred wrist-worn pedometers. The most frequently cited reason children gave for wanting to participate in FRESH was to receive a pedometer. Families reported that there were few settings where children were not allowed to wear their pedometers, with the most cited setting being during physical education. Wearing the pedometer was more acceptable to children in the family arm than to those in the child-only arm (≈ 80% vs. 60%).

Rewards

Overall, parents moderately agreed that their child enjoyed receiving virtual rewards (mean 3.5, SD 1.2), with slightly higher scores in the child-only arm than in the family arm (mean 3.8, SD 1.0 vs. mean 3.1, SD 1.3). Children's responses in the focus group generally supported parents' perceptions that the virtual rewards were not particularly of long-term interest to them. Most parents suggested that a small, tangible reward, such as a posted certificate or stickers, would appeal to their child more than a virtual reward. Other suggestions included vouchers, clothing or equipment that encouraged physical activity (see *Table 5*).

Risk of contamination

Focus groups revealed that children were aware of other FRESH participants in their school and that some families did indeed communicate among each other about FRESH, with some even revealing their allocated condition. One family allocated to the child-only arm disclosed that they had purchased a set of pedometers.

Findings related to feasibility of outcome evaluation

Data collection took a mean of 91.1 (SD 27.7) minutes per family at baseline and 77.1 (SD 24.5) minutes per family at follow-up. Overall, adults disagreed that there were too many measures and that data collection took too long. All children self-reported that they 'liked' being measured. With the exception of accelerometer/GPS and step test assessment (one refusal each), all participants completed all measures at baseline. At follow-up, 91% of participants accepted an accelerometer/GPS and completed the step test; 94% of participants completed all other measures.

At baseline, mean valid accelerometer wear time was 851.5 (SD 54.1) minutes for adults and 755.7 (SD 29.7) minutes for children. At follow-up, mean wear time was 843.1 (SD 78.6) for adults and 742.3 (SD 56.4) for children. The GPS provided a location for a mean of 750.6 (SD 191.4) (adults) and 646.2 (SD 189.0) (children) minutes at baseline and for a mean of 720.0 (SD 237.6) (adults) and 586.8 (SD 262.8) (children) at follow-up. Valid data (600 minutes) on ≥ 4 days (including one weekend day) was available for 83% of adults at both baseline and follow-up; this was slightly lower for children, at 75% and 67%, respectively. A visual inspection of wear-time data revealed a tendency for children to remove their devices at around dinner time, for parents to remove their devices after their child had gone to bed, and for families to put on their devices much later in the day at the weekend than on weekdays.

An initial assessment of family functioning via the video-recorded Fictional Family Holiday activity showed poor to moderate data quality, as discussions were limited and cursory. Three factors may have affected data quality: (1) most families enrolled were dyads, limiting opportunities for whole-family discussion; (2) providing families with a planner to write out their itinerary may have shifted the emphasis away from open-ended discussion; and (3) the activity was completed at the end of the visit, when participants may have been fatigued from data collection.

The physical activity-related expenditure questionnaire developed for this study appeared to have appropriate face validity and was capable of providing rich data related to membership fees and subscriptions (e.g. for sports clubs, fitness centres, after-school clubs) and sports equipment (e.g. sportswear, gadgets).

Chapter 4 Lessons learned from the FRESH feasibility study

The FRESH feasibility study described in *Chapters 2* and *3* provides a response to calls for the need for innovative interventions targeting young people and families.[76] To our knowledge, FRESH is among the first physical activity interventions to specifically target whole family engagement, helping to create supportive, synergistic environments for the promotion of healthy behaviours and long-term change.[29,57,59] We assessed the feasibility and acceptability of the FRESH intervention and accompanying evaluation to inform future research. Our findings showed that it was feasible and acceptable to deliver and evaluate a family-targeted physical activity promotion intervention with generally high acceptability from participating families. This feasibility study, however, also revealed areas for improvement.

Optimising recruitment

Previous literature has identified family-based recruitment as being particularly difficult.[44,112] Our formative work[30] and other studies (see a review by Morgan *et al.*[52]) recommend a multifaceted recruitment strategy in family-based research. Owing to unforeseen delays, we were unable to employ our planned multifaceted recruitment strategy, which likely contributed to our under-recruitment of families (60% of targeted 20). Of the families enrolled, only one-third included all family members. There was some suggestion that this may have been because of either a lack of confidence in physical activity or a reluctance to be measured. Improved messaging is, therefore, required early in the recruitment process to reassure low-active families, and individual family members, that FRESH is tailored to their activity levels and to highlight that they have the option of opting out of (parts of) the measurements. Allowing family members to be involved in the intervention, regardless of their participation in the evaluation, as was done in FRESH, may improve effectiveness and long-term behaviour change.[44,55,56,59]

Interestingly, our findings showed that fathers appeared to be interested in participating in FRESH, but only 5 out of 28 expressions of interest were initiated by fathers. This may be because, among heterosexual parents, tasks such as making telephone calls (e.g. to express interest) or family event preparation (e.g. study participation) are more likely to be performed by mothers than fathers.[113] Therefore, recruiting whole families, whereby any parent can initiate an expression of interest, may be an important catalyst for the inclusion of more fathers in family-based research.

Other key areas of improvement to recruitment include optimising the conversion from children reached to families expressing an interest (e.g. extending the age range of index children to cover the whole of UK Key Stage 2 (Years 3–6, covering ages 7–11 years); reducing the burden on children to explain FRESH to their parents (e.g. by directing parents to a video); targeting adults directly via community- and employer-based recruitment or social media; and obtaining recruitment support from local organisations.

Optimising the FRESH intervention

FRESH was designed as a goal-setting and self-monitoring intervention, aimed at increasing family physical activity. Encouragingly, these behaviour change techniques resonated with most families and align with recommendations to increase family physical activity.[29] Participants reported being aware of what their daily step goals needed to be in order to complete their weekly challenges. Interestingly, the challenge context did not seem to be important to participating families (i.e. choosing challenge cities to walk to virtually). Instead, focus group interviews revealed that meeting daily step goals, completing weekly challenges and intrafamily competition appeared to be the key drivers motivating families throughout the intervention period.

We found that families did not implement all of the intervention components as intended, and strategies may be needed to improve intervention delivery and families' fidelity to the intervention protocol. For instance, most families did not select new challenges on the FRESH website together during 'family time', and families used their action planners only to log their steps and not to also identify family activities or upcoming challenges for the week ahead. This may be resolved by the facilitator placing a greater emphasis on 'family time' and helping the family to schedule this at the 'kick-off'. Facilitators are critical to the delivery of interventions, and a recent review found that facilitators have an important moderating influence on the effectiveness of any programme.[114] Ongoing follow-up with the facilitator would also support this. Other strategies to improve intervention fidelity include sending e-mail reminders to log steps, adding competition elements to the website (e.g. a leaderboard), providing more regular feedback/praise from the research team, and including small, tangible rewards.

Although the FRESH intervention was well received overall, in our focus groups it was evident that families, and in particular fathers in the child-only arm, would have preferred to have their whole family involved in FRESH. Consideration, therefore, should be given to discontinuing the child-only arm. Furthermore, the finding that fathers were particularly interested in having their whole family participate in FRESH is noteworthy. Fathers have an independent influence on their children's health and development[115] and are an important influence on children's physical activity,[116–118] but they are very under-represented in family-based interventions.[119] Fathers' engagement with FRESH is consistent with recent evidence that fathers are more willing to participate in family-based interventions when the focus is on their children,[120] and as a result reported newfound enjoyment for family-based physical activity and a desire to be a positive role model.[121] The online delivery of FRESH may have also appealed to some fathers.[120]

Optimising measurement

The duration of data collection at both time points was in line with our estimates, and acceptability of the duration and number of measures was high among both adults and children. Nevertheless, the duration of the data collection process may have acted as a barrier to participation. Minor adjustments are needed to improve the quality of data from the Fictional Family Holiday, and monitor wear time. For example, for the Fictional Family Holiday paradigm, a greater emphasis on recruiting whole families, removal of the written aspect of the activity and shifting the order of measures, so that the assessment occurs earlier during data collection, might improve the quality of the family functioning data. To improve monitor wear time, emphasis should be placed on participants wearing the monitors for as long as possible from the time that *they* wake up until the time that *they* go to sleep, as opposed to going by their children's bedtime. In addition, reminders (e.g. e-mail, telephone) could improve wear time,[122] particularly at the end of the week to improve weekend wear.

Study strengths and limitations

This study is among the first physical activity interventions that aim to target and measure whole families, providing novel evidence in an area where more primary research is needed.[76] The phased approach of assessing feasibility and acceptability to inform refinement for pilot study is in accordance with established guidelines.[86] Public involvement was used extensively to inform development and refinement of FRESH, as suggested previously.[123,124] Furthermore, our use of a mixed-methods design provides unique insight and context for our quantitative findings, assisting in identifying strategies to further optimise FRESH. Limitations include that we were unable to fully employ our recruitment strategy and did not have the opportunity to test the efficacy of recruiting families through community-based recruitment. In addition, only one-third of families enrolled in FRESH included all family members.

Conclusions FRESH feasibility study

This study demonstrates feasibility and acceptability of the family-targeted FRESH intervention and provides valuable suggestions for further optimisation. This work informs a future pilot trial testing the impact of these adaptations and the preliminary effectiveness of FRESH on family physical activity. The findings of our upcoming pilot trial will inform sample size/power calculations for a future definitive trial, should the pilot study findings suggest that a definitive trial is warranted.

Chapter 5 Trial design and methods for the FRESH pilot trial

Introduction

The feasibility study described in *Chapters 3* and *4* was among the first physical activity interventions to specifically target whole family engagement. The findings showed that it was feasible and acceptable to deliver and evaluate a family-targeted physical activity promotion intervention with high acceptability from participating families. However, as described in *Chapter 4*, multiple areas for further improvement of the intervention and its evaluation procedures were identified. This chapter describes the protocol of revised FRESH interventions and evaluation, evaluated in a pilot randomised controlled trial (RCT).

The primary aim of the FRESH pilot trial was to assess the feasibility and acceptability of the revised recruitment strategy, intervention and outcome evaluation. The secondary aims were (1) to explore the preliminary effectiveness of the intervention on potential outcomes of interest and (2) to assess whether or not prespecified criteria were sufficiently met to warrant progression to a full-scale definitive trial.

Trial design

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[80] was used to guide the reporting of this study. We also used TIDieR[81] to guide our description of the intervention. All protocol amendments from the FRESH feasibility study described below were made following consultation with the FRESH SSC and the funder (the NIHR Public Health Research programme).

The FRESH pilot study was a three-arm, parallel-group, randomised controlled pilot trial using a 1 : 1 : 1 allocation ratio with follow-up assessments at 8 and 52 weeks post baseline (*Figure 6*). Following baseline assessment, families were randomly allocated to one of three arms: (1) FRESH arm, (2) pedometer-only arm or (3) no-treatment control arm. All family members in the pedometer and FRESH arms received

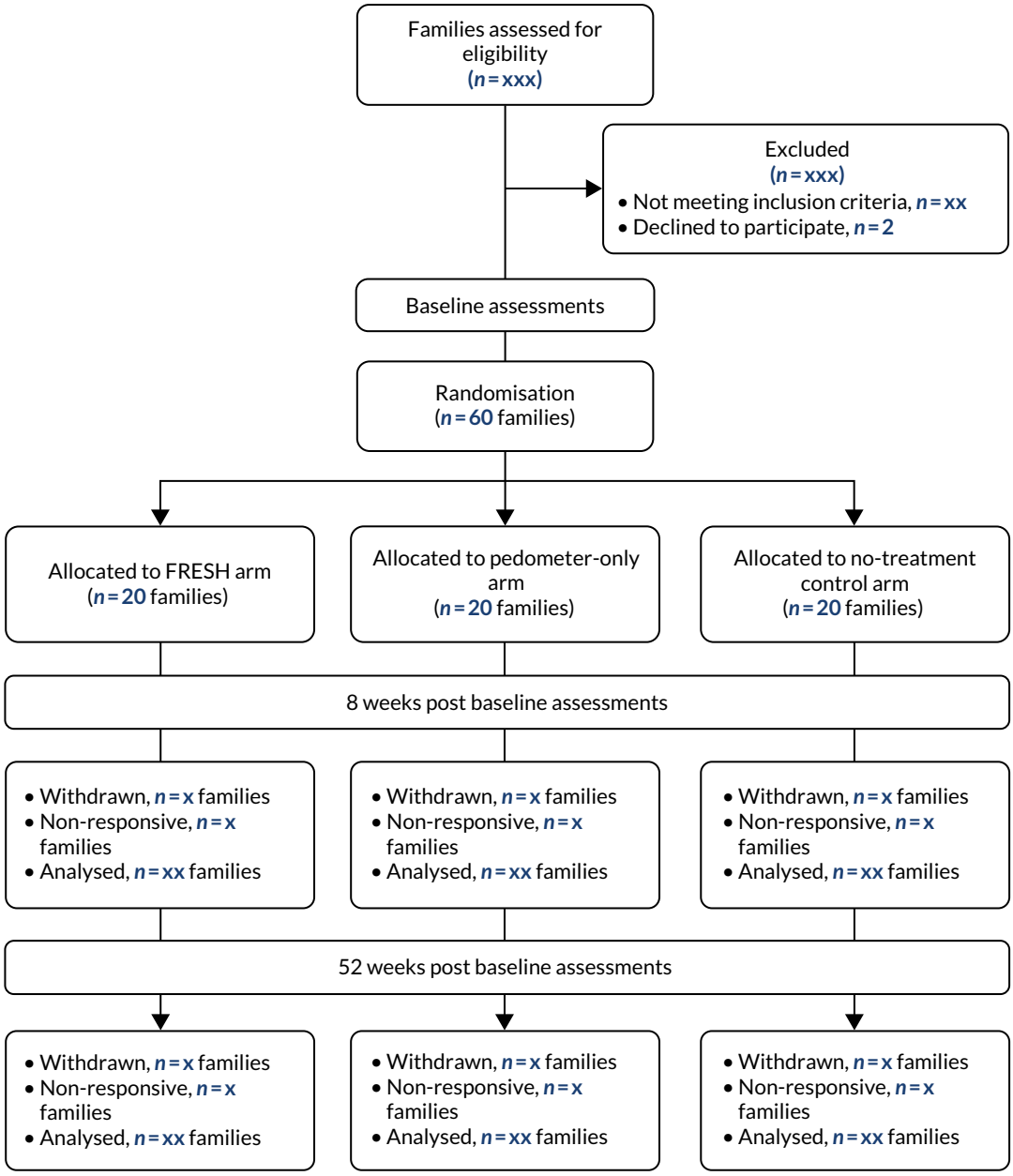

FIGURE 6 Flow chart of process of the FRESH pilot study.

pedometers and generic family physical activity promotion information. The FRESH arm additionally received access to the intervention website. Those in the control arm were asked to carry on as normal.

Participants

Families were deemed eligible to participate in this study if there was consent from at least one child in school years 3–6 (aged 7–11 years, hereafter referred to as the index child) and at least one adult responsible for the index child. The adult had to live with the index child in the main household (i.e. the index child's primary residence as indicated by the parent). No restrictions were placed on family type (e.g. single parent, shared parenting, inclusion of extended family living in the main household) and there was no maximum number of participants per family. If requested, we also enabled the inclusion of parents or siblings who lived outside the main household, or extended family members (e.g. grandparents) living in or outside the index child's main household. All participants needed to be

able to perform light-intensity physical activity (e.g. walking), have access to the internet and understand the English language sufficiently well to provide informed consent. Family members were able to take part in the intervention irrespective of their participation in the accompanying evaluation and vice versa. Exclusion criteria related to participation in specific assessments are outlined below.

The eligible age range of the index child was expanded to reflect the age range of children attending Key Stage 2 in UK primary schools, which meant that all children attending assemblies about the FRESH project were eligible to take part.

Setting

Families were initially recruited from rural Norfolk and Suffolk, counties in East Anglia, UK (see *Figure 3*). Norfolk is 2074 square miles in size and had a total estimated population of 898,400 in 2017 (most recent estimate)[82] and Suffolk is 1466 square miles and had a total estimated population of 756,978 in 2017 (most recent estimate).[127] According to Norfolk and Suffolk County Councils,[128,129] approximately 53% and 42% of the Norfolk and Suffolk populations, respectively, are classified as living in a rural area. Based on the Office for National Statistics[84] classification, 'rural' will be defined as having a postcode falling in a small town, village, hamlet or dispersed settlement. In both counties, existing inequalities have been identified, including physical activity, obesity and other indicators of child ill health, school readiness and attainment.[24,26,130] Following recruitment challenges, the requirement for participating families to live in a rural location was dropped after consultation with, and approval from, the FRESH SSC and the funder.

Recruitment

To overcome the challenges encountered in the FRESH feasibility study, in the pilot study we used a multifaceted recruitment strategy, including targeting adults (parents) directly, and messaging that focused on the wider benefits of research participation (e.g. spending more time together as a family) as opposed to solely focusing on increasing physical activity or obesity prevention.[30] Recruitment was scheduled to be undertaken over an estimated 3 months (with a recruitment rate of $\approx$ 20 families per month), using two main strategies that target adults and children, as summarised in *Figure 7*. The first strategy involved recruitment in the school setting and the second in employer-based and community-based settings (e.g. Brownies/Cubs, community centres, GP surgeries). Alternative recruitment settings were also explored (e.g. online/traditional media) as needed, following the same procedure as in the second strategy. For logistical purposes, we aimed to find recruitment settings located roughly within an hour's drive of Cambridge, UK.

Recruitment protocol

To recruit schools, employers and community-based organisations, we first contacted those in leadership positions (e.g. head teachers, human resources, health and well-being leaders, heads of community-based organisations). An information pack detailing the purpose of the study and all procedures was included in our correspondence with the individual identified. This included a link to a recruitment video, which was developed with families following the suggestion of participants in the FRESH feasibility study (URL: www.youtube.com/watch?v=UxUHN1JsjUM; accessed 19 July 2021, also see below). For school-based recruitment, verbal or written approval was sought from the school to send home study leaflets with children, to circulate our leaflet to parents online, and to send an online reminder to parents approximately 2 weeks later. We also sought permission to present the study to Key Stage 2 students (Years 3–6; aged 7–11 years) at a scheduled school assembly. Similarly, for employer- and community-based recruitment, we sought approval to circulate our study information to employees or members either online or as a hard copy. In all cases, similar to the feasibility study, interested parents were asked to express their interest by contacting the study team by e-mail or a free-to-call telephone number, after which eligibility was assessed and further detailed study information was e-mailed. A baseline

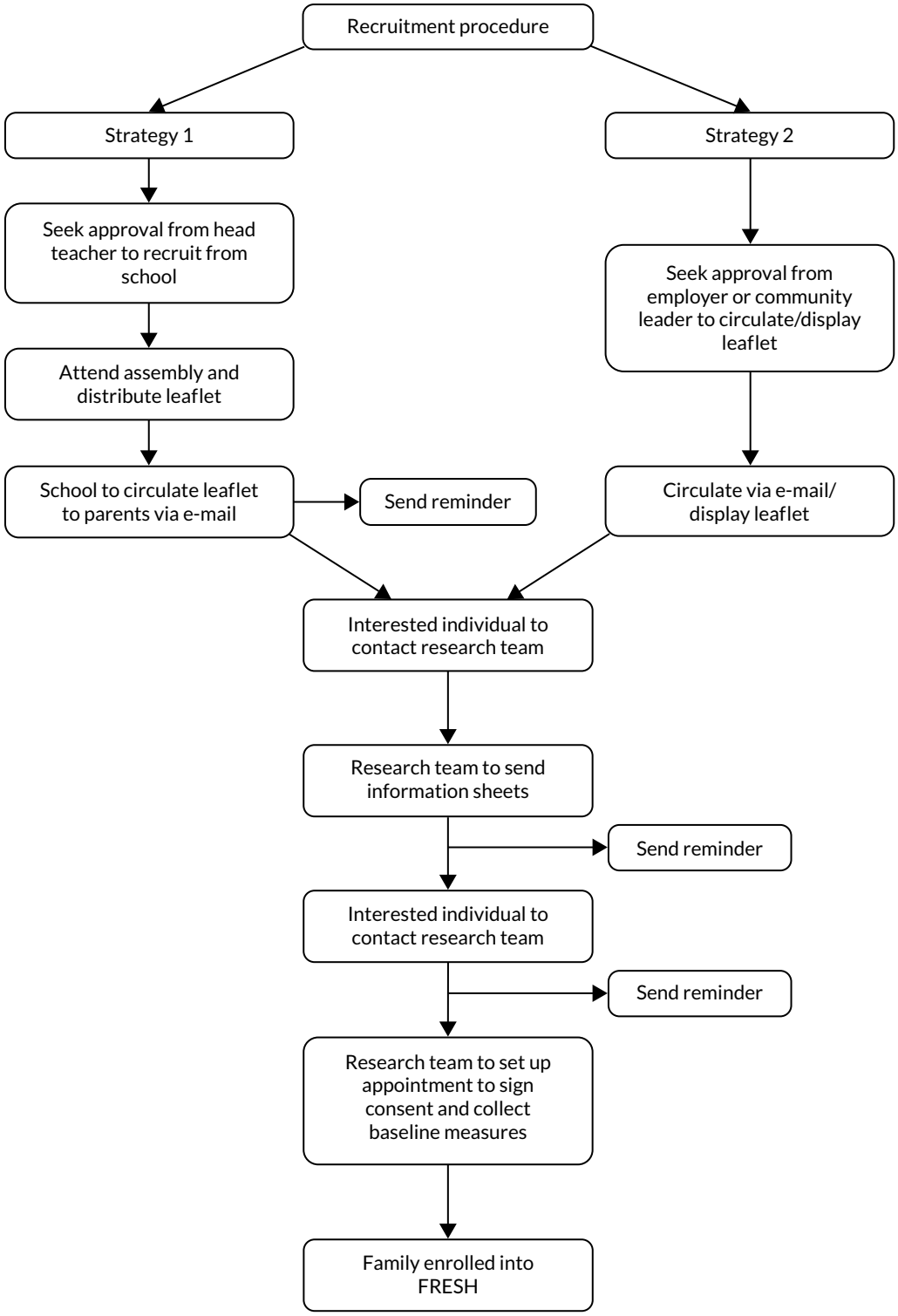

FIGURE 7 Overview of recruitment methods in the FRESH pilot RCT.

assessment appointment was made with families who were still interested in participating. Written informed consent was obtained for all participating adults and written parental consent and child assent was obtained for each participating child during this appointment, prior to the baseline assessments.

To inform the assessment of the progression criteria (see *Chapter 1*, *Progression criteria*), recruitment success and rate were monitored closely by the study team. Information was tracked regarding source of recruitment, conversion from expressing interest to participation, the family member expressing interest, and the number and type of family members participating.

Retention

To encourage retention, we remained in regular contact with all participating families (through the intervention website, newsletter/holiday cards), and offered measurement incentives and study feedback. Each individual participant (adults and children) received a £5 voucher on return of the accelerometer and GPS monitors at each measurement time point (maximum £15 per participant over 1-year follow-up). To inform assessment of the progression criteria (see *Chapter 1*, *Progression criteria*), retention was monitored closely by study group and demographic characteristics to observe whether or not differences in retention occurred.

Randomisation

Randomisation occurred after the baseline assessments were completed; the unit of randomisation was at the family level (i.e. the index child and all participating family members). Families were randomised in blocks of six by an independent statistician using a computer-generated algorithm produced with Stata version 14 and stratified by county (i.e. Norfolk or Suffolk). This strategy ensured that families were randomised to the three different groups at an equal rate, and that similar numbers of families were allocated to each arm within the two counties. The random allocation sequence was implemented via a database created in-house on Microsoft Access by independent data management staff. A study co-ordinator used the database after baseline to determine which study arm a family was allocated to. No one directly involved in the evaluation had access to the allocation code or complete sequence.

Interventions

FRESH arm

As in the FRESH feasibility study, the intervention the FRESH arm received is primarily a goal-setting and self-monitoring intervention, delivered online, aimed at increasing physical activity in whole families. The intervention used concepts from the SEM[40] and family systems theory[85] and operationalised constructs from SDT[61] to inform behaviour change strategies. The full FRESH logic model can be found in *Figure 8*.

As in the feasibility study, 1 week after baseline measures, each family allocated to the FRESH arm had an hour-long kick-off meeting, which took place in the family home with a facilitator (who was a member of the study team). The facilitator introduced families to the intervention components and the accompanying materials (e.g. family action planner) and distributed pedometers. In the pilot study, families also received their first of four pieces of generic walking information, similar to the pedometer-only arm (described in *Protocol for pedometer and control families*). The main goals of this meeting were to familiarise families with the intervention website and their pedometers and to prompt weekly 'FRESH time' meetings (described in *Table 1*; rebranded from 'family' time, following feasibility evaluation) during which they were to complete their action planners and select a new challenge city to 'walk to' on the FRESH intervention website. All families received a follow-up telephone call 1 week after their kick-off meeting so that they could discuss any issues and ask any clarifying questions. Participant-initiated distant support continued to be available, whereby participants could contact the research team with questions or to report issues (e.g. website bugs, pedometer issues).

Table 7 provides a detailed description of the FRESH pilot intervention components and highlights where changes were made from our feasibility study. In each family, the index child (or children, if multiple) were designated 'team captain(s)', which involved taking the lead in selecting challenges and uploading steps online. Evidence suggests that children may act as change agents to elicit changes to the psychosocial environment;[29] therefore, promoting the index children to the role of family 'team captain(s)' may strengthen child buy-in and perceived autonomy, and improve intervention fidelity. All family members were given pedometers with instructions to wear them for as long as possible daily so that their steps would be captured during challenges. The team captain(s) led weekly 'family time' meetings. During these meetings, families completed family action planners and accessed the FRESH website,

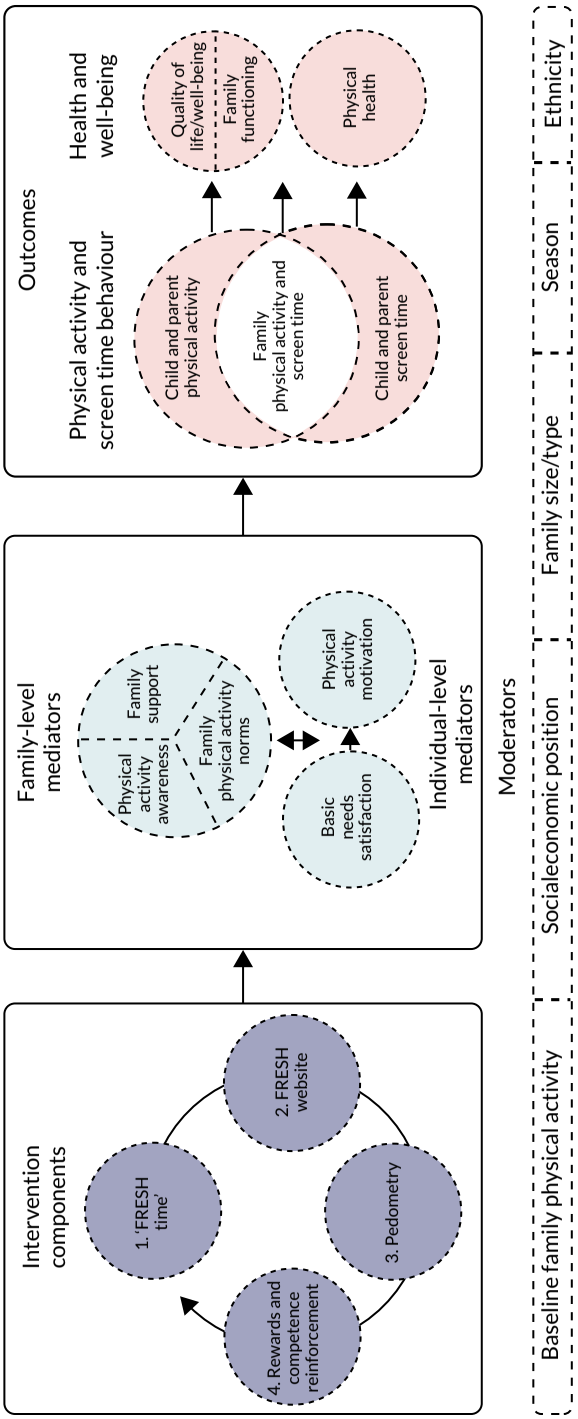

FIGURE 8 FRESH logic model (expanded version of logic model shown in *Figure 4*).

TABLE 7 Summary of FRESH pilot trial intervention components

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
1. 'FRESH time'	Minimum once per week, 10–21 minutes	'FRESH time' was expected to provide a weekly (at minimum) opportunity for index children[a] and family members to review, revise, and update their family action planners. Family action planners prompt families to plan PA, monitor weekly steps, discuss any potential upcoming PA barriers and strategies to overcome them. Index children will be allocated as their family's 'team captain' leading in challenge selection and uploading steps on the FRESH website	Goal-setting Self-monitoring Positive feedback on progress Social support Praise Positive reinforcement	Perceived competence Perceived relatedness Perceived autonomy	Social support Family social norms for PA PA awareness Basic needs satisfaction PA motivation
2. FRESH website	Minimum once per week, 5–20 minutes	The FRESH website provided a place for families to self-monitor their step counts and set goals by selecting challenges of varying difficulty. Specifically, the website allowed families to 'walk' around the world by choosing one of three target cities to 'walk to' weekly. The challenges were framed as easy, moderate or hard, which represented a 0%, 5% or 10% increase, respectively, relative to the average steps they took in preceding weeks. Once adults and children accumulated an average of 10,000 and 12,000 steps per day, the step challenge increases were reduced to 0%, 2.5% and 5%, respectively Families also had access to: • A general resources area with suggestions for activities that families could do together • A map for a visual representation showing the locations families travelled to • A step calculator that converted activities not captured by pedometers to steps (e.g. swimming)	Goal-setting Self-monitoring Positive feedback on progress Rewards	Perceived competence Perceived relatedness Perceived autonomy	Social support Family social norms for PA PA awareness Basic needs satisfaction PA motivation

continued

TABLE 7 Summary of FRESH pilot trial intervention components (*continued*)

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
		• Their families' **step history** by challenge • A **leaderboard**. Families opted in to being included in a leaderboard that was updated weekly; families got points for selecting a challenge, uploading steps, completing a challenge, accumulating a family average of 10,000 steps/day over the week, increasing steps from the previous week, and going on streaks (e.g. five completed challenges in a row) Families with an ongoing challenge received **e-mail reminders** to log steps 3 days and 1 day before an impending challenge ends			
3. Pedometry	Throughout intervention (8 weeks)	All family members received pedometers to enable self-monitoring and provide immediate feedback. To allow families to view their progress towards their proximal and distal step goals, they were encouraged to log their steps on the FRESH website and/or in the family action planners	Self-monitoring Immediate feedback	Perceived competence Perceived autonomy	Social support Family social norms for PA PA awareness Basic needs satisfaction PA motivation
4. Competence reinforcement/ rewards	Approximately once per week (8 weeks)	After completing a challenge or if the challenge week ended, to praise effort (i.e. competence reinforcement) children received **personalised supportive letters in the post** and messages on the FRESH website They also received small online and **tangible rewards** • Online rewards included virtual passport stamps (i.e. virtual rewards) and access to reinforcement materials (i.e. interactive information about the cities they walked past during their challenge)	Feedback on progress Rewards	Perceived competence	Basic needs satisfaction PA awareness

TABLE 7 Summary of FRESH pilot trial intervention components (*continued*)

Intervention components	Dose	Description	Behaviour change techniques	Targeted SDT constructs	Hypothesised mediators
		• **Tangible rewards** were in the form of collectable FRESH cards, which displayed the city names corresponding with the families' challenge. The cards also enabled families to play a card game version of 'rock, paper, scissors' Children received two to four passport stamps/cards for completed challenges (i.e. as difficulty increased, more stamps were awarded) and one passport stamp/card for an incomplete challenge			

PA, physical activity.
a The index child refers to the child aged 7–11 years in the family.
Text in **bold** indicates new elements added for the FRESH pilot trial, i.e. post feasibility study.

which enabled them to choose weekly step challenges. Family action planners prompted families to plan weekly family physical activities to help them meet their step challenge for a given week. It was intended that families would plan activities they would do together; however, participants had the flexibility to also set individual goals. The action planners also prompted families to monitor weekly step counts, and discuss any potential upcoming barriers for physical activity and strategies to overcome them. Pedometers are simple to use, convenient and associated with effective interventions for increasing parent–child physical activity.[131]

After a challenge week was over, whether or not a family had completed their challenge, they received personalised competence reinforcement messages praising their effort online. In response to the feedback from the feasibility study, reinforcement messages were also sent in hard-copy letters (addressed and mailed to all participating children in the family). In addition, both online and tangible rewards were given to participating children after a challenge week. The tangible rewards were sent to each participating child in the family and consisted of playing cards representing the cities the families had visited, which could also be used to play rock, paper, scissors. If a family did not complete a challenge, they still progressed to a hidden city along their challenge route, as opposed to the city they had chosen, and received the accompanying reinforcement message and reward, as described above. In the pilot study, we also implemented reminders as requested by some families in the feasibility study: families with an ongoing challenge would receive e-mail reminders to log steps 3 days and 1 day before a challenge ended. After every challenge week, the above cycle would be repeated, starting with the next 'FRESH time' meeting. Following the assessments at 8 weeks post baseline, families retained access to the website and their pedometers, and were able to continue using these for as long as they liked. There was also continued support in terms of website updates (e.g. leaderboard and parental resource updates) and participants continued to receive competence reinforcement letters and rewards.

Protocol for pedometer and control families

Following less positive feedback during the FRESH feasibility study, the study team decided to drop the child-only arm (see *Chapter 4*). In consultation with the FRESH SSC, the study team decided to replace this with a pedometer arm to assess whether or not access to the FRESH website provided additional benefits over and above family pedometer-wear. Families allocated to the pedometer arm were mailed pedometers and the same generic family physical activity promotion information as FRESH families received. This information was produced by Walk4Life, a sub-brand of Change4Life (www.nhs.uk/change4life). Information continued to be e-mailed to families (in the pedometer and FRESH arms) fortnightly on four occasions. The information provided families with tips to get walking daily and games that can be played while walking.

Control families were asked to carry on as normal and did not receive access to the intervention website, pedometers or any generic information.

Outcome evaluation measures

Table 8 outlines a summary of the measures taken as part of the FRESH pilot study, including the order of assessments and the estimated duration of each prior to data collection. Data collection was carried out by two trained research staff and occurred in participating families' homes. Outcomes were assessed at baseline (prior to randomisation; April–August 2018), at 8 weeks post baseline (June–November 2018) and at follow-up (52 weeks post baseline; May–October 2019) for all consenting family members.

Accelerometer and global positioning system assessment protocol

To assess physical activity, a similar protocol to that applied in the feasibility study was used. All participants were asked to simultaneously wear an ActiGraph GT3X+ triaxial accelerometer (ActiGraph LLC; Pensacola, FL, USA) and a QStarz Travel Recorder BT1000X GPS monitor [QStarz; Taipei, Taiwan (Province of China)]. The accelerometer was initialised to record data at a sampling rate of 50 Hz, and the GPS was set to

TABLE 8 Order of measures and estimated duration of FRESH pilot study data collection[a]

Measure	Duration
Anthropometric measures (height, weight, waist circumference)	5 minutes per person
Questionnaire	20 minutes per family
Blood pressure[b]	10 minutes per person
Step test (aerobic fitness)	Preparation: 5 minutes per person
	Test: 10 minutes per family
Accelerometer and GPS explanation	5 minutes per family
Fictional Family Holiday (family functioning)	10 minutes per family
Total duration of baseline measurement session (includes consent/assent process)	120 minutes
Total duration of subsequent measurement sessions	105 minutes

a Estimate based on a four-person household; total time increases by ≈ 30 minutes per additional family member.
b Duration is halved when calculating total duration because multiple monitors will be used to enable two family members to be measured simultaneously.

record a location every 10 seconds. Participants were instructed to wear the devices on each hip during waking hours for 7 consecutive days. Following evaluation of the feasibility study data, participants were clearly instructed to wear the monitor during their waking day to maximise wear. All monitors were picked up by a member of the study team or mailed back in a prepaid envelope.

Defining participant physical activity

For accelerometer data, a valid week was defined as a minimum of 420 minutes per day from 3 days (including 1 weekend day) over the 7-day measurement period. Non-wear was defined as ≥ 90 minutes consecutive zeros using the vector magnitude. Raw accelerometer counts were downloaded and integrated into 5-second epochs to enable application of prespecified cut-off points. Evenson *et al.*[132] cut-off points have been recommended for estimating physical activity intensity in youth[90,133] and Troiano *et al.*[134] cut-off points have been recommended for this in adults; these cut-off points were used in this study.

Defining family co-participants in physical activity

A novel methodology was developed to establish times when family members were physically active in each other's proximity. Data from the accelerometers were downloaded and interpolated to a 10-second epoch using the ActiLife software. Data from the GPS devices were downloaded and entered into the ArcGIS v10.3 (Esri Inc., Redlands, CA, USA) Geographical Information System, and then longitude and latitude values were converted to easting and northing values, respectively, in accordance with the British National Grid co-ordinate reference system.[135]

The accelerometer and GPS data were then integrated based on their date and time stamps using bespoke software written in Java. After the accelerometer and GPS data had been matched, data points that had a time difference of ≤ 30 seconds between the accelerometer time stamp and that of its matched GPS location were considered valid for inclusion in the study. Matched data points with a time difference greater than this, for example where the GPS had been switched off or had lost signal, were considered as missing location information because the participant might have moved to a new unrecorded location since the last locational data were available. The data were also cleaned to remove GPS locations with low location confidence, in accordance with the protocol of Schipperijn *et al.*[136] This resulted in the removal of just 0.8% of data points.

All accelerometer-derived measures of physical activity were calculated for valid days (i.e. those on which there were at least 10 hours' wear time). To maximise the available data, participants with at least 1 day of valid wear time for the accelerometer were included for analysis. As it was not possible to differentiate times when the GPS had no signal because it was indoors from times when it had no signal because it had been switched off, no minimum wear-time requirements were set for the GPS.

Periods when the accelerometer was continuously recording zero acceleration for ≥ 90 minutes were excluded from analysis, as these were considered to be times when the accelerometer was not worn.[137] The remaining data points were then classified into four physical activity intensity categories (sedentary, light, moderate or vigorous activity), using the widely adopted Evenson *et al.*[132] cut-off points for children and the Troiano *et al.*[134] cut-off points for adults. These categories were then used to generate a binary variable for every child and adult that indicated whether or not they were undertaking light, moderate or vigorous physical activity (LMVPA) during any given 10-second interval. We focused on LMVPA rather than solely higher-intensity activity to ensure that we captured a range of activities from walking to more vigorous ones such as running.

To compute individual measures of time spent with and without other family members present, a script was written in Stata (version 16; StataCorp LLC, College Station, TX, USA) that calculated the straight-line distance between each participant and every member of their family for all 10-second intervals, based on each participant's easting and northing locations. This produced a matrix that depicted the straight-line distance in metres between all possible family dyad combinations. This matrix was then

used to compute a binary variable for every child and adult that indicated whether or not they were located within ≤ 50 m (which was taken as indicative of being at the same location) of other members of their family during any given 10-second interval. A distance of ≤ 50 m was selected because this is approximately equivalent to a ball court (e.g. tennis, basketball) or a large residential garden.[138]

Finally, we generated measures for each participant of the time they spent undertaking LMVPA in the same location as other members of their family. This was computed for all possible family dyad combinations by summing the binary variables for LMVPA for each pair of family members along with the binary variable indicating whether the pair were within the target distance of ≤ 50 m, with the resulting variable indicating for any given 10-second interval whether or not the family was were being physically active in the same location. For each participant, all times spent doing dyad-based LMVPA were summed to obtain the outcome measures used.

Health outcomes

Aerobic fitness was measured using an 8-minute submaximal step test (with 2-minute rest), which provides an individual calibration of heart rate to work rate (energy expenditure per unit time) to predict a fitness estimate of a participants' heart rate recovery index.[93,139] Children outside the age range for eligible index children (i.e. aged < 8 years) were excluded from the aerobic fitness test. To improve measurement efficiency, the study team conducted the step test with up to four family members simultaneously, using a maximum of two steps.

Height and weight were measured once with a Leicester portable stadiometer and a Seca 877 digital scale, respectively. Waist circumference was measured at least twice, using a non-elastic tape measure. A third measure was taken if the first two measures differed by ≥ 3 cm, and the mean of these measures was used in analyses. BMI was calculated [(height in cm)/(weight in kg)^2], and converted into age- and sex-specific percentiles using standard growth charts for participants aged < 18 years using LMSgrowth Program.

Behavioural and psychosocial measures

Behavioural and psychosocial measures were assessed using questionnaires distributed to adults and children (participants aged ≤ 4 years did not complete questionnaires). The questionnaires were largely unaltered from the feasibility study (see *Table 3*). These measures included adult and child screen-use time;[95–98] quality of life;[99–102] family co-participation in physical activity;[98] physical activity awareness;[103,104] family social norms for physical activity;[105,106] family support;[105] children's and adult's motivation for physical activity;[107,108] and children's perceived autonomy, competence and relatedness.[108]

Family functioning

The Fictional Family Holiday Paradigm was used to assess family functioning via family relationships[109] and connectedness.[110] In this observational paradigm, each family was asked to spend 10 minutes planning and discussing a week-long holiday itinerary with unlimited budget. The video-recorded activity was then transcribed and coded by two to four trained research assistants per time point for 'power sharing' (i.e. taking turns); positive talk (e.g. expressions of amity, elicitation of family members' viewpoints, agreement, compromise)[110] and discussions that revolve around physical activity.

Family out-of-pocket expenditure for physical activity

Physical activity-related expenditure for each family member was collected using a questionnaire that was developed and refined following our feasibility study.[78] Refinement focused on amending the layout of the questionnaire to improve ease of completion. The questionnaire comprised two questions about expenditure related to membership fees and subscriptions (e.g. for sports clubs, fitness centres) and sports equipment (e.g. sportswear, gadgets) and was completed by the same adult at each time point for their whole family. Baseline expenditure covered the 3 months prior to study participation. At the follow-ups, participants were asked to record their expenditure during the first 8 weeks of the study and then until 1 year after randomisation.

Process evaluation

A mixed-methods process evaluation was conducted after assessments 8 weeks post baseline. Using open-ended and four-point Likert-scale questions (with 1 = strongly disagree and 4 = strongly agree), adults self-reported their overall opinion of FRESH, the intervention components (FRESH arm only; Pedometer arm adults responded to pedometer-related questions only) and the measurements and suggestions for improvement. Children also self-reported on the above topics, responding to dichotomous 'yes/no' questions. In addition, semistructured focus groups were planned to be conducted online with 10 out of 20 FRESH arm families and 5 out of 20 families from each of the other two arms (i.e. pedometer and control). Focus groups focused on families' experiences of taking part in the trial, perceived acceptability of individual intervention components, intervention fidelity, challenges/barriers encountered and suggested improvements, as appropriate based on study arm allocation. All focus groups were transcribed verbatim. We also explored families' engagement with the intervention website (e.g. page views, challenges accepted/completed) and aspects of the recruitment process (e.g. recruitment duration, resources used, comparisons of recruitment strategies).

Patient and public involvement

FRESH was developed with substantial input from children and families from the public, as detailed in *Chapter 2*. Since the completion of the FRESH feasibility study, families from the public have been further involved with the optimisation of FRESH in a number of ways. As mentioned earlier, we sought the involvement of families from the public to develop a recruitment video; these families helped develop the script and acted in the video, which can be viewed at www.youtube.com/watch?v=UxUHN1JsjUM. We also asked two families to engage with the FRESH website and provide feedback to inform modifications that could be made.

Sample size considerations

As this was a pilot study, a sample size calculation was not performed. We planned to recruit a sample of 60 families, with a sample size of ≈ 180–240 participants, based on three or four members per family. Our estimated sample size is based on previous study experience[30] and on sample sizes of previous pilot studies.[140,141]

Progression criteria assessment

The prespecified criteria used to inform progression to a definitive trial have been outlined in *Chapter 1*, *Progression criteria*. Where applicable, quantitative and qualitative findings were taken into account to assess whether or not a criterion had been met. As detailed in *Chapter 1*, *FRESH project study management*, on the recommendation of the SSC, 'changes in MVPA' as 'evidence of promise' was to be considered in addition to the pre-established progression criteria to inform progression to a full trial.

Data analysis

A prespecified data analysis plan was approved by the FRESH SSC before the start of the analyses.

Quantitative data

Descriptive statistics are provided for all process evaluation and outcome measures at all relevant time points. Statistical analyses of the physical activity variables were conducted using analysis of covariance (adjusting for baseline values) in Stata (version 15; StataCorp LP, College Station, TX, USA), stratified by age group (adults and children). Participants with missing values at baseline were included in the analysis using the missing indicator method.[142] An estimate of effect and 95% CI were calculated for primary and selected secondary outcomes; no *p*-values were calculated.

To inform one of the progression criteria, post hoc sample size calculations were carried out to provide 80% power to detect a difference of 10 minutes in MVPA in index children ($p < 0.05$), using a SD of 16.3 minutes of MVPA and a pre–post correlation of 0.63 (values obtained from the 52-week follow-up).

To estimate the intraclass correlation coefficient of MVPA within families, a base model was created, with participants nested within families. Intraclass correlation coefficients were calculated for each time point. As different accelerometer cut-off points were applied to children's and adults' data, intraclass correlation coefficients were calculated using both (whereby all participants had their level of MVPA estimated using the same cut-off point).

Economic analyses

In a change to the published protocol, agreed with the funder, the aim of the health economic analysis was to investigate the incremental cost of the FRESH intervention, focusing on the intervention cost per family and family expenditures on physical activities. A full economic evaluation was not warranted, given the findings from the main study in terms of the lack of a treatment effect and recruitment difficulties. The following approach was applied.

Intervention and follow-up cost

The intervention costs were calculated by deploying a micro-costing approach. The cost components associated with the interventions were retrieved from the published protocol.[125] The unit costs used in the micro-costing process were obtained from either publicly available resources or personal communications for market prices. *Table 9* reports the resources used per family, and the monetary value of these resources, alongside the subsequent cost per item. All families, irrespective of trial arm, were assumed to incur the same intervention cost, except the pedometers. The cost of pedometers was calculated considering the number of participants in each family. The reported family physical activity expenditure was summed to produce the mean cost per family at each time point.

TABLE 9 Intervention cost components and cost per item per family

Item	Resource use	Unit cost (£)	Cost per item (£)	Source
FRESH intervention				
Kick-off meeting	75 minutes[a]	0.33	25	Protocol,[125] personal communication
Accompanying booklet	12 pages	0.20	2.40	Protocol,[125] personal communication[143]
Pedometers	1 pedometer per study participant	4.00	4	Protocol,[125] personal communication
Personalised messages	118 minutes[b]	0.33	39.30	Protocol,[125] personal communication
Online and tangible rewards	5 cards	0.20	1	Protocol,[125] personal communication[143]
FRESH intervention total cost	–	–	71.70	
Pedometer-only intervention				
Pedometers	1 pedometer per study participant	4.00	4	Protocol,[125] personal communication
Accompanying booklet	12 pages	0.20	2.40	Protocol,[125] personal communication[143]
Pedometer-only total cost	–	–	6.40	

a Kick-off meeting duration: 60 minutes; travelling time: 15 minutes.
b The personalised messages were posted for 11 weeks, which required an average of 10.72 minutes per week per family.

Descriptive statistics for resource consumption were calculated for all available families at each time point as counts and proportions. The mean cost per family and the 95% CI around the mean were estimated at each time point. The average costs of the intervention components, such as the pedometers and other activities costs, were also estimated.

We conducted a *comparative analysis* based on the complete-case data set at 1 year. A linear regression was used to estimate the between-group differences in mean costs per family; unadjusted and adjusted differences were estimated. The adjusted estimates accounted for the cost at baseline.[144] The 95% CIs of both the adjusted and the unadjusted estimates were constructed by resampling the data set 5000 times, performing a non-parametric bootstrap with replacement.

Qualitative data

A content analysis was conducted using existing guidelines[111] to explore the feasibility and acceptability of the revised FRESH intervention, the outcome evaluation and suggestions for further intervention optimisation using family focus groups. The approach to data-analysis was the same as that taken in the FRESH feasibility study. Specifically, the analysis was conducted in two separate phases. During the data organisation phase, text from each transcript was divided into segments (meaning units) to produce a set of concepts that reflected meaningful pieces of information.[111] Tags were then assigned to each meaning unit. Tagging was performed by one researcher, with a second researcher double-tagging $\approx$ 25% of transcripts. For the data interpretation phase, the inventory of tags from all transcripts were examined by two researchers, which led to the emergence of themes and subthemes within each overarching category.

Chapter 6 FRESH pilot trial findings

Recruitment and retention

Table 10 provides a summary of the recruitment sources used in this study and *Figure 9* shows the recruitment flow. Owing to under-recruitment, the recruitment period was extended from 12 to 24 weeks. Expressions of interest occurred at a rate of four or five families per week over the 24-week recruitment period. Approximately 77% of families expressing interest were eligible for participation and 48% of eligible families were enrolled with an enrolment rate of one or two families per week.

Of the 41 families enrolled, 73% were whole families ($n = 30$ families) and ≈10% ($n = 4$ families) were dyads of one parent and one index child. The remaining families either only included index parent–child dyads ($n = 4$ families) or the index parent, index child, and an additional parent and/or children ($n = 7$ families); however, in all cases there were additional adults and/or children living with the index child that chose not to participate in the study. We did not recruit any extended family members or any family members that lived outside the index child's main household. Consent was obtained for 149 participants, averaging four members per family (range 2–6 family members) and included

TABLE 10 Sources of recruitment in the FRESH pilot study

Recruitment stage	Schools	Employers	Community[a]	Traditional media[b]	Social media[c]	Referral	Unknown	Total
Approached	87	102	56	N/A	12	N/A	N/A	257
Agreed	16	10	7	N/A	5	N/A	N/A	38
Families reached	≈ 1641	≈ 8761	≈ 1740	≈ 2371	24,333	N/A	N/A	≈ 38,846
Expressions of interest	42	11	26	22	1	4	6	112
Eligible	41	9	22	7	1	4	2	86
Families enrolled	23	7	4	4	0	3	0	41
Enrolment (%)	56	17	10	10	–	7	–	100

N/A, not applicable.
a Included settings such as parkrun, community centres, swimming pools, Scouts/Cubs/Guides, shopping centres and local community events.
b Included a story highlighting the study on a local television news programme.
c Included parent websites or groups on Facebook and Twitter.

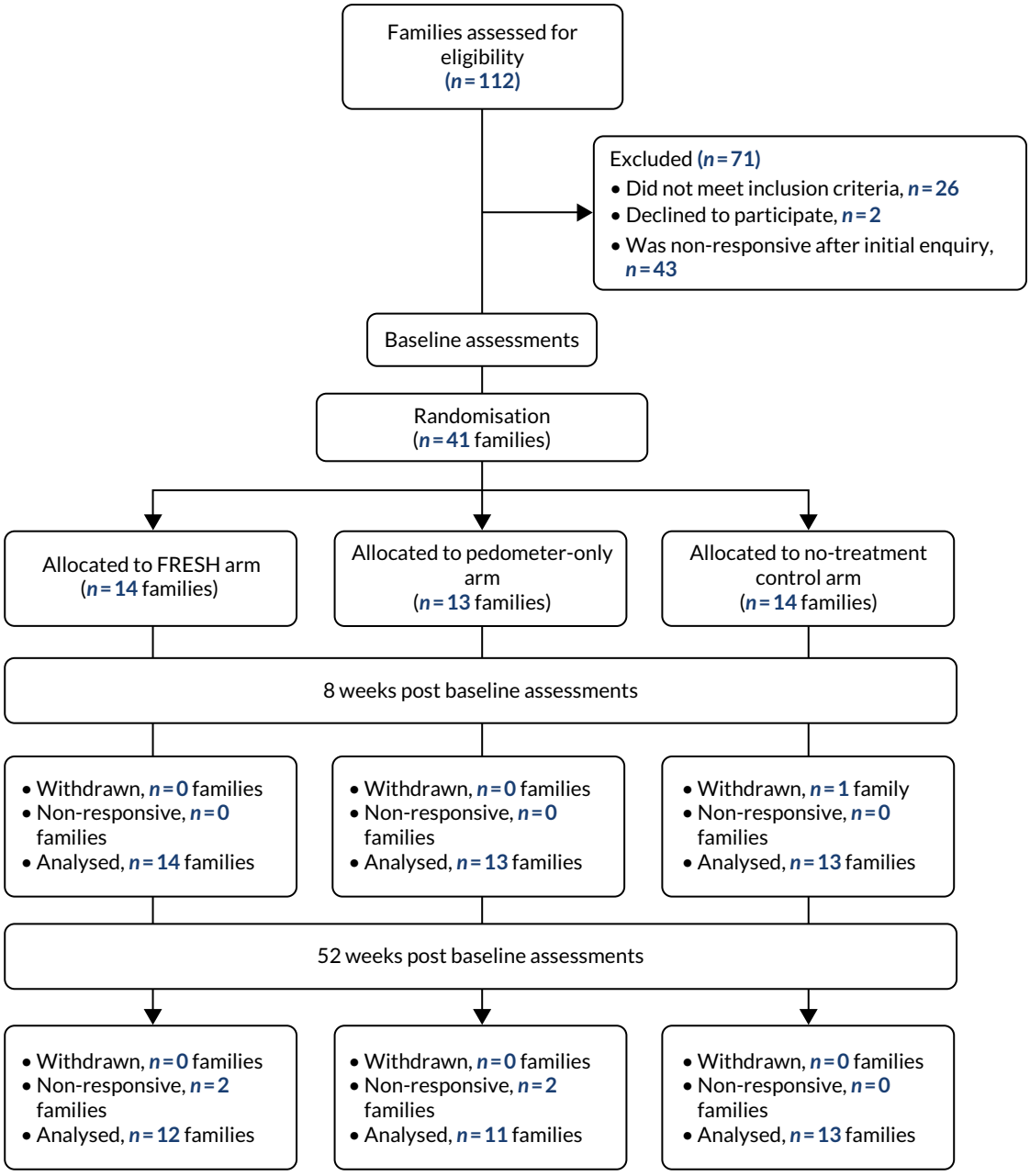

FIGURE 9 Flow chart of recruitment and retention in the FRESH pilot study.

39 mothers (95%), 31 fathers (76%) and 41 siblings (from 32 families with an eligible sibling; 78%). Eleven siblings were younger than the index child (i.e. aged < 7 years), 15 were in the same age category as the index child (aged 7–11 years) and 15 were older than the index child (aged > 11 years). *Table 11* describes the participant characteristics at baseline. Notably, children in the family arm were older than children in the other two arms (FRESH, mean 10.1 years, SD 2.8 years; pedometer only, mean 8.6 years, SD 1.9 years; control, mean 8.9 years, SD 2.7 years) and fewer girls were allocated to the pedometer arm (FRESH, 50.0%; pedometer only, 17.4%; control, 48.3). Approximately 92% of adults reported being married or living as married, 94% of adults reported their ethnicity as white, and the mean age at which adults had finished full-time education was 20.5 (SD 3.5) years.

At the 8- and 52-week assessments, 98% and 88% of families were retained (family dropout: FRESH, $n = 2$; pedometer only, $n = 2$; control, $n = 1$). Participant loss to follow-up at 52 weeks comprised nine adults (FRESH, $n = 4$; pedometer only, $n = 3$; control, $n = 2$) and 11 children (FRESH, $n = 4$; pedometer only, $n = 3$; control, $n = 4$).

TABLE 11 Individual participant baseline characteristics in the FRESH pilot study

	Overall		FRESH		Pedometer		Control	
Variable	Adults ($n = 67$)	Children ($n = 82$)	Adults ($n = 21$)	Children ($n = 30$)	Adults ($n = 24$)	Children ($n = 23$)	Adults ($n = 22$)	Children ($n = 29$)
Sex (% female)	56.7	40.2	54.2	50.0	50.3	17.4	57.1	48.3
Age (years)	41.3 (5.8)	9.3 (2.6)	42.7 (5.3)	10.1 (2.8)	39.0 (6.2)	8.6 (1.9)	42.2 (5.7)	8.9 (2.7)
Height (cm)	171.8 (9.1)	136.3 (15.6)	172.4 (8.8)	140.4 (14.8)	172.8 (9.6)	135.1 (11.7)	170.0 (9.0)	132.9 (18.4)
Weight (kg)	78.1 (14.2)	32.5 (9.6)	81.3 (13.8)	35.2 (9.1)	76.5 (13.0)	31.4 (7.8)	76.3 (15.7)	30.7 (10.9)
BMI (kg/m^2)	26.5 (4.6)	17.1 (2.4)	27.5 (5.0)	17.6 (2.4)	25.6 (3.4)	16.9 (2.3)	26.3 (5.3)	16.8 (2.5)
BMI z-score	N/A	0.1 (1.1)	N/A	0.2 (1.1)	N/A	0.3 (1.1)	N/A	0.0 (1.1)
Waist circumference (cm)	89.1 (12.2)	61.0 (8.0)	93.4 (12.0)	62.4 (9.1)	86.6 (12.5)	62.0 (5.8)	86.9 (11.3)	59.0 (8.2)

N/A, not applicable.
Values are mean (SD) unless stated otherwise.

Intervention feasibility, acceptability, fidelity and optimisation

Most children reported that they liked taking part in the study (> 90%) and thought that it was fun (> 80%). Compared with the pedometer (45%) and control (39%) arms, a higher percentage of children in the FRESH arm (81%) reported doing more activities with their family at the 8-week follow-up. *Table 12* shows adults' overall perceptions of FRESH. Scores were generally positive and favoured the FRESH arm over the pedometer arm. In particular, adults agreed that FRESH encouraged their family to do more physical activity and made their family more aware of the amount of physical activity that they did. Themes related to family physical activity, physical activity awareness and parental modelling also emerged in our focus groups:

> *It was really fun, it pushed us to get our steps in and do more activities and sports together, you know. I never really thought about how many steps or exercise I've done to be honest, so since these [step] counters, I just look and go '3000 [steps] only? I have to do something'. So sometimes they [her three sons] come home and they see me . . . dancing, doing something, or skipping, they say, 'what are you doing, Mum?' [laughs] and I say, 'I'm just putting effort in to get my steps' and then they join me, you know. It just made your more aware . . . I even started walking for small shopping instead of driving just to get my steps up [laughs] . . . small things, you know, it just made you aware.*
>
> *Mother 127, FRESH arm*

TABLE 12 Summary of pilot study process evaluation findings for adult participants assessing the acceptability of the FRESH intervention

Questionnaire item	FRESH arm ($n = 25$ adults)	Pedometer-only arm ($n = 21$ adults)
(a) The FRESH study . . .		
. . . was fun for my family and I	3.2 (0.7)	3.1 (0.5)
. . . encouraged my family and I to do more physical activity	3.2 (0.7)	2.7 (0.8)
. . . has led my family and I to do more physical activity than we did before FRESH	3.0 (0.8)	2.4 (0.8)
. . . has led my family and I to do more activities (other than physical activity) together than we did before FRESH	2.6 (0.8)	2.2 (0.5)
. . . has made my family and I more aware of the amount of physical activity we do	3.6 (0.6)	3.2 (0.7)
. . . is something my family and I would like to continue to be part of	3.3 (0.9)	3.2 (0.6)
(b) Regarding the step counter we gave out to log your steps, to what extent do you agree or disagree with the following?		
I didn't mind wearing it	3.4 (1.0)	3.1 (1.1)
My child/children didn't mind wearing it	3.2 (1.0)	3.2 (0.9)
It was easy to use	3.1 (0.9)	3.6 (0.5)
I thought it was reasonably reliable at counting steps	2.8 (1.0)	3.0 (0.6)
I used the memory feature to go back and look at the number steps my family and/or I took	3.0 (1.1)	2.0 (1.1)
(c) Regarding 'family time', to what extent do you agree or disagree with the following?		
It was easy to schedule 'family time'	3.0 (1.0)	N/A
My family consistently scheduled 'family time'	2.4 (1.0)	N/A
My child reminded us about 'family time'	3.0 (0.9)	N/A
My child led/initiated 'family time'	3.1 (0.8)	N/A

TABLE 12 Summary of pilot study process evaluation findings for adult participants assessing the acceptability of the FRESH intervention (*continued*)

Questionnaire item	FRESH arm ($n = 25$ adults)	Pedometer-only arm ($n = 21$ adults)
(d) Regarding the FRESH website, to what extent do you agree or disagree with the following?		
It was easy to use	3.8 (0.7)	N/A
I enjoyed using it	3.4 (0.8)	N/A
My child/children enjoyed using it	3.4 (0.8)	N/A
I thought the website was appealing	3.5 (0.7)	N/A
I liked that there were varying degrees of difficulty with the challenges	3.5 (0.8)	N/A
I enjoyed the information about the cities	3.5 (0.8)	N/A
My child/children enjoyed the information about the cities	3.4 (0.8)	N/A
The step converter was useful (e.g. converting swimming to steps)	3.6 (0.8)	N/A
The resources page was useful	3.5 (1.0)	N/A
I enjoyed the recipes	3.6 (1.4)	N/A
My child/children enjoyed the recipes	3.6 (1.4)	N/A
Logging our steps was easy	3.5 (0.9)	N/A

N/A, not applicable.
Participants responded on a four-point Likert scale for each question (1 = strongly disagree; 4 = strongly agree).
Values are mean (SD).

The overall acceptability of the pedometers was fairly high among adults in both the FRESH and the pedometer arms (see *Table 12*). Families in both groups reported that wearing the pedometers had become habitual. One parent stated:

> *I think it's become quite habitual now, we pick them up first thing in the morning and take them off last thing at night and they [her children] were quite happy to do that, so that was good from a parent point of view.*
>
> *Mother 125, FRESH arm*

A greater percentage of pedometer-only children than FRESH children self-reported that they liked wearing their pedometer (86% vs. 62%, respectively). In addition, compared with our previous feasibility study, we replaced a greater number of malfunctioning pedometers (despite using the same make and model of pedometers in both studies) and families' preference for wearing wrist-worn pedometers was emphasised more strongly during focus group discussions.

Adults in the FRESH arm found the kick-off meeting useful (3.6 ± 1.0) to help them get started, felt that they had enough technical support if needed (3.9 ± 0.6) and found it feasible to schedule 'family time', albeit not consistently (see *Table 12*). The focus groups revealed that families rarely used their action planners. One parent said, 'we probably didn't fill that [action planner] in as much as we should've … we use that [action planner] more to actually record our steps' (father 146, FRESH arm).

The majority of children in the FRESH arm found the website easy to use (93%), wanted to keep using the website (81%), enjoyed being their family's team captain (70%) and did not find it too difficult to reach their step goals (65%). Overall, adults' mean scores in relation to the intervention website were generally positive (see *Table 12*). In particular, adults strongly agreed that the website was easy to use and found various website elements useful (e.g. the step converter). Parents agreed that their child enjoyed receiving rewards and competence reinforcement after each challenge week (3.5 ± 1.2).

When asked in focus groups about suggestions for improvement, families in the pedometer-only arm suggested elements that were delivered to the FRESH arm. For example:

> *I think if you can walk so many steps and it gets you to a place, like a country or something like that. So maybe there could be mini challenges like you walk to London or walk to Paris, you know, or something. Yeah, something like that would be probably quite good for you guys [referring to her children]. [. . .] We haven't been around the world, but we'd like to go around the world. [. . .] I think that's something you can add to this [study].*
>
> *Mother 114, pedometer-only arm*

Google Analytics data indicated that 59 users accessed the website (≈ 4 users/family), with a median of 2 [interquartile range (IQR) 1–5] sessions per user viewing about 5 (IQR 2–11) pages per session for approximately 7 (IQR 3–12) minutes per session. The most common behaviour flow was to log on, access the challenge page (to select a new challenge) and then access the steps page (to add steps to complete the challenge). Families selected an average of 11 challenges and completed nine of those. During a challenge, families uploaded steps at least once 86% of the time.

Findings related to the feasibility and acceptability of the outcome evaluation

Data collection took an average of 119.5 (SD 26.4) minutes per family at baseline and 95.0 (SD 16.7) and 82.3 (SD 35.8) minutes per family at the 8- and 52-week follow-ups, respectively. Overall, adults disagreed that there were too many measures [mean values of answers on a 4-point Likert scale, 1.5 (SD 0.7)] and that data collection took too long [mean values of answers on a 4-point Likert scale, 1.7 (SD 0.8)]. In the focus groups, families mentioned the convenience of home-based data collection and, in some cases, said that this had been essential to their participation. One parent said:

> *. . . it was a lot more convenient you coming to us and you guys being quite flexible in offering us multiple dates and times you could come . . . if you hadn't come to us, we probably wouldn't have participated.*
>
> *Father 125, FRESH arm*

In addition, > 80% of children reported that they 'liked' the measurement sessions. At each time point, > 90% of eligible adults and children completed all measures, except for the submaximal step test (86%) and the video-recorded activity assessing family functioning (89%).

Mean valid accelerometer wear time was 835.6 (SD 76.5) and 734.9.4 (SD 62.7) minutes for adults and children across time points, respectively. Valid accelerometer data on ≥ 3 days (including 1 weekend day) were available for 82% of adults and 77% of children at all three assessment points. On average, across time points, the GPS provided a location for 757.0 (SD 126.3) minutes and 541.6 (SD 200.3) minutes for adults and children, respectively.

Preliminary effectiveness

Children's and adults' levels of MVPA and sedentary behaviour at all time points are presented in *Table 13*. Subgroup analyses are given in *Tables 14* and *15* and the data on family co-participation in physical activity are available in *Table 16* and *Figure 10*. Children and adults either met or were close to meeting the recommended levels of MVPA at baseline, with the exception of children in the FRESH arm, who accumulated notably less MVPA than children in the pedometer and control arms. Within-family intraclass correlation coefficients ranged from 0.42 to 0.52 and were largely similar at the two cut-off points applied.

TABLE 13 Children's and adults' mean (SD) daily minutes in MVPA and sedentary time

										Adjusted difference between arms,[a] mean (95% CI)					
	FRESH			Pedometer			Control			FRESH vs. control		FRESH vs. pedometer		Pedometer vs. control	
Outcome variable	T1	Change T1 to T2	Change T1 to T3	T1	Change T1 to T2	Change T1 to T3	T1	Change T1 to T2	Change T1 to T3	Mean change T1 to T2	Mean change T1 to T3	Mean change T1 to T2	Mean change T1 to T3	Mean change T1 to T2	Mean change T1 to T3
Children															
n	24	15	15	24	18	15	25	23	22						
MVPA	48.4 (15.8)	−8.0 (13.1)	−14.8 (17.4)	60.5 (22.5)	−7.3 (14.2)	−6.4 (16.4)	54.2 (20.4)	−4.7 (10.3)	−8.4 (14.6)	−3.1 (−9.9 to 3.8)	−3.9 (−13.7 to 5.9)	0.0 (−8.2 to 8.1)	−3.1 (−9.2 to 15.4)	−3.0 (−10.1 to 4.1)	−0.8 (−10.8 to 9.3)
SED	552.3 (59.1)	−2.6 (62.9)	−28.6 (59.2)	469.1 (56.5)	−1.6 (78.1)	46.5 (52.5)	524.6 (70.1)	−4.2 (56.1)	2.4 (62.3)	7.1 (−18.0 to 32.2)	12.3 (−12.3 to 36.8)	8.5 (−21.2 to 38.3)	10.1 (−21.0 to 41.2)	−1.5 (−27.5 to 24.5)	2.2 (−23.3 to 27.6)
Adults															
n	21	16	15	21	17	13	17	19	18						
MVPA	52.0 (17.7)	2.1 (14.8)	−4.6 (16.3)	52.0 (19.2)	−12.9 (17.7)	−0.9 (10.5)	47.8 (16.3)	−7.1 (11.3)	0.7 (17.6)	9.4 (0.4 to 18.4)	−5.7 (−16.7 to 5.3)	15.3 (6.0 to 24.5)	1.2 (−11.7 to 14.2)	−5.8 (−15.1 to 3.3)	−6.9 (−19.3 to 5.5)
SED	647.3 (92.6)	−17.3 (86.5)	−49.2 (45.9)	604.3 (70.9)	6.8 (65.7)	19.9 (55.1)	648.1 (55.4)	18.4 (50.1)	−39.5 (68.4)	−17.2 (−41.3 to 7.0)	7.5 (−17.2 to 32.3)	−8.6 (−33.9 to 16.7)	−6.3 (−23.2 to 35.8)	−8.6 (−33.0 to 15.9)	13.8 (−14.1 to 41.7)

SED, sedentary time; T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline.
a Adjusted for baseline MVPA or sedentary time, wear time, sex and age.

TABLE 14 Children's mean (SD) daily minutes in MVPA and sedentary time by subgroup

Outcome variable	FRESH			Pedometer			Control		
	T1	Change T1 to T2[a]	Change T1 to T3[a]	T1	Change T1 to T2[a]	Change T1 to T3[a]	T1	Change T1 to T2[a]	Change T1 to T3[a]
Boys									
n	11	5	9	17	15	12	14	12	13
MVPA	50.3 (18.2)	−0.7 (11.1)	−12.5 (18.3)	62.8 (23.9)	−9.2 (14.5)	−7.3 (16.9)	60.2 (22.6)	−2.3 (10.3)	−6.8 (15.6)
SED	569.9 (70.0)	−47.5 (38.8)	−41.5 (67.7)	469.5 (61.5)	−1.6 (83.8)	48.3 (53.9)	520.2 (68.8)	−12.5 (71.4)	3.7 (67.3)
Girls									
n	13	10	6	4	3	3	11	11	9
MVPA	46.8 (18.2)	−11.7 (13.0)	−18.4 (17.1)	50.9 (12.8)	2.2 (9.8)	−2.8 (16.9)	46.5 (17.8)	−7.3 (10.0)	−10.8 (13.5)
SED	537.5 (45.2)	19.9 (61.7)	−9.1 (41.4)	467.4 (32.6)	−1.3 (51.8)	39.4 (56.6)	530.2 (74.7)	4.9 (33.6)	0.6 (63.6)
Index child									
n	11	7	8	12	11	8	14	13	13
MVPA	51.6 (9.7)	−9.8 (11.7)	−13.5 (17.4)	63.0 (23.0)	−10.0 (14.5)	−8.9 (16.3)	56.2 (23.9)	−2.5 (10.9)	−5.6 (16.0)
SED	537.0 (64.9)	−17.4 (54.4)	−32.5 (54.8)	470.9 (62.0)	2.1 (89.2)	52.3 (43.2)	532.9 (72.3)	−12.5 (65.0)	3.0 (43.7)
Additional child									
n	12	7	6	9	7	7	11	10	9
MVPA	45.9 (20.5)	−4.1 (14.3)	−16.2 (20.5)	57.3 (22.7)	−3.2 (17.3)	−3.6 (17.3)	51.6 (15.4)	−7.5 (9.2)	−12.4 (11.9)
SED	565.9 (54.9)	−0.6 (68.4)	−24.8 (74.4)	466.6 (51.6)	−7.4 (63.0)	39.9 (64.5)	514.0 (67.8)	6.7 (42.7)	1.6 (89.4)
Less deprived									
n	10	7	3	15	14	12	14	14	13
MVPA	41.6 (9.0)	−12.0 (14.2)	−11.4 (5.3)	56.2 (23.5)	−5.9 (13.4)	−1.9 (14.3)	50.5 (17.3)	−5.5 (9.8)	−5.5 (9.8)
SED	533.7 (49.6)	36.6 (51.2)	19.4 (64.4)	477.2 (41.8)	6.8 (61.4)	43.9 (46.8)	517.5 (74.8)	−8.1 (63.2)	3.5 (78.4)
More deprived									
n	14	8	12	6	4	3	11	9	9
MVPA	53.4 (18.0)	−4.5 (11.9)	−15.7 (19.4)	71.5 (16.6)	−12.5 (18.0)	−24.4 (12.2)	58.8 (23.8)	−3.4 (11.5)	−8.9 (18.0)
SED	565.6 (63.4)	−36.9 (52.8)	−40.6 (54.0)	448.6 (84.6)	−30.9 (129.4)	57.0 (83.8)	533.5 (66.1)	2.1 (45.6)	0.8 (40.2)

SED, sedentary time; T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline.
a Adjusted for baseline MVPA or sedentary time, wear time, sex and age.

TABLE 15 Adults' mean (SD) daily minutes in MVPA and sedentary time

Outcome variable	FRESH			Pedometer			Control		
	T1	Change T1 to T2[a]	Change T1 to T3[a]	T1	Change T1 to T2[a]	Change T1 to T3[a]	T1	Change T1 to T2[a]	Change T1 to T3[a]
Men									
n	10	7	7	9	7	5	6	8	7
MVPA	55.0 (23.1)	2.3 (21.3)	0.4 (11.3)	61.3 (18.5)	−23.5 (19.4)	3.7 (11.1)	42.9 (18.4)	−11.8 (7.7)	7.3 (17.1)
SED	642.8 (108.4)	2.8 (88.61)	−23.4 (30.0)	612.9 (60.5)	1.9 (82.1)	−16.1 (55.1)	661.7 (44.4)	14.6 (68.6)	−54.7 (62.5)
Women									
n	11	9	8	12	10	8	11	11	11
MVPA	49.3 (11.5)	2.0 (8.4)	−9.0 (19.4)	45.0 (17.2)	−5.5 (12.5)	−3.8 (9.8)	50.5 (15.2)	−3.8 (12.6)	−3.5 (17.4)
SED	651.3 (81.0)	−33.0 (86.6)	−71.8 (46.9)	597.8 (79.9)	10.3 (56.2)	42.4 (44.5)	640.7 (61.3)	21.1 (34.7)	−29.9 (73.0)
Index parent									
n	12	10	8	13	11	8	13	13	13
MVPA	47.7 (11.8)	0.8 (14.9)	−6.4 (18.3)	46.0 (16.8)	−8.7 (15.9)	−3.8 (9.8)	46.2 (17.6)	−4.1 (11.7)	1.1 (19.5)
SED	653.0 (99.6)	−13.5 (92.1)	−56.6 (44.8)	591.8 (79.8)	19.1 (60.8)	42.4 (44.5)	640.4 (61.2)	11.8 (51.6)	−34.3 (67.5)
Additional parent									
n	9	6	7	8	6	5	4	6	5
MVPA	57.8 (23.1)	4.4 (15.7)	−2.5 (14.9)	61.9 (19.7)	−20.7 (19.6)	3.7 (11.1)	52.9 (11.1)	−13.8 (7.0)	−0.3 (13.3)
SED	639.6 (87.7)	−23.7 (84.0)	−40.7 (49.2)	624.4 (52.1)	−15.6 (74.1)	−16.1 (55.1)	673.3 (16.6)	33.6 (47.7)	−53.2 (76.5)
Less deprived									
n	6	4	2	13	12	9	10	10	10
MVPA	50.4 (4.4)	−4.0 (14.7)	−7.0 (7.4)	52.4 (19.8)	−12.2 (13.2)	−3.0 (10.2)	47.3 (16.8)	−4.9 (12.6)	3.9 (0.1)
SED	547.8 (69.5)	97.5 (40.2)	11.0 (2.8)	616.6 (80.6)	6.5 (61.1)	3.5 (53.5)	622.1 (55.9)	5.3 (55.9)	−46.8 (86.6)
More deprived									
n	15	12	13	8	5	4	7	9	8
MVPA	48.5 (16.7)	4.2 (14.9)	−4.2 (17.4)	51.5 (19.4)	−14.6 (27.8)	3.8 (11.1)	48.5 (16.7)	−9.7 (9.7)	−3.3 (14.3)
SED	687.0 (67.8)	−55.6 (58.0)	−58.5 (42.0)	584.2 (50.1)	7.5 (83.8)	56.9 (43.5)	685.2 (27.9)	32.9 (41.0)	−30.5 (39.2)

SED, sedentary time; T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline.
a Adjusted for baseline MVPA or sedentary time, wear time, sex and age.

TABLE 16 Mean (SD) minutes of family co-participation in LMVPA

Outcome variable	FRESH			Pedometer			Control		
	T1	Change T1 to T2	Change T1 to T3	T1	Change T1 to T2	Change T1 to T3	T1	Change T1 to T2	Change T1 to T3
Children									
n	22	13	16	14	13	12	22	19	20
Child–child LMVPA	90.4 (59.0)	−58.5 (67.4)	−38.9 (77.0)	117.1 (69.6)	−55.0 (110.0)	−75.4 (68.0)	80.2 (49.3)	−31.5 (68.0)	−28.4 (54.3)
n	22	19	18	18	19	17	23	23	22
Adult–child LMVPA	46.0 (35.7)	−27.5 (46.3)	−9.1 (39.4)	40.0 (22.5)	−3.4 (33.8)	−10.0 (36.4)	55.0 (42.4)	−28.2 (49.0)	−18.6 (53.5)
Adults									
n	14	12	16	16	16	14	8	12	12
Adult–adult LMVPA	19.4 (14.0)	−1.1 (6.1)	−6.7 (22.1)	13.7 (10.6)	−1.3 (17.6)	−0.7 (13.5)	25.0 (19.0)	−10.4 (11.5)	−7.8 (9.7)
n	21	18	16	18	18	15	19	19	18
Adult–child LMVPA	53.4 (62.0)	−37.0 (77.1)	−29.8 (22.8)	54.9 (28.6)	−12.3 (30.4)	−29.8 (22.8)	58.6 (47.0)	−22.2 (57.6)	−14.6 (61.9)

T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline.

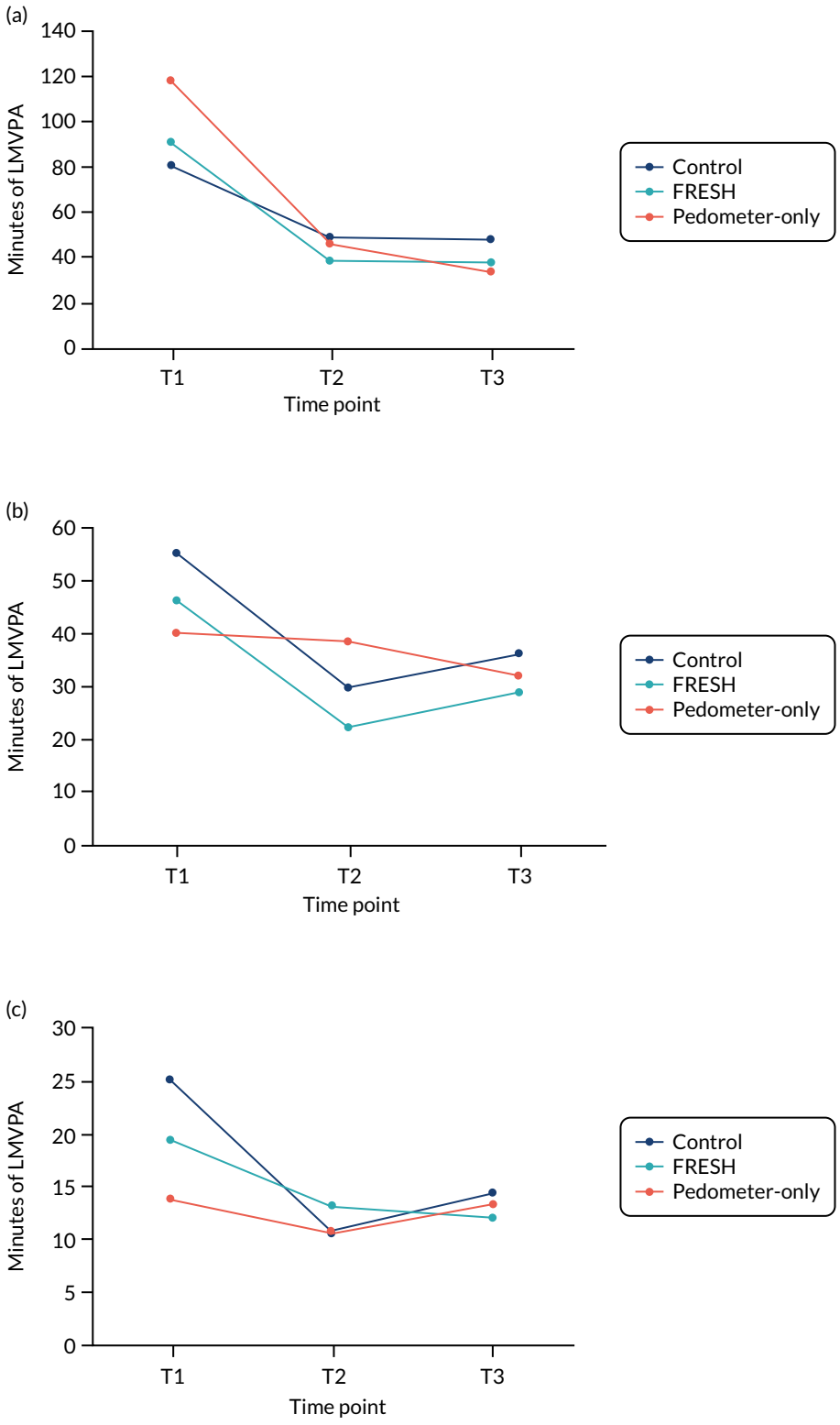

FIGURE 10 Mean minutes of family co-participation in LMVPA (T1, baseline; T2, 8 weeks post baseline; T3, 52 weeks post baseline). (a) Child with sibling; (b) child with parent; (c) parent with other parent; and (d) parent with child. (*continued*)

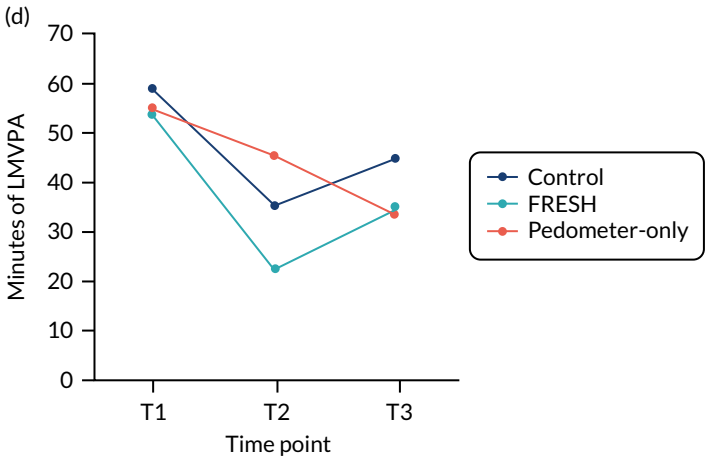

FIGURE 10 Mean minutes of family co-participation in LMVPA (T1, baseline; T2, 8 weeks post baseline; T3, 52 weeks post baseline). (a) Child with sibling; (b) child with parent; (c) parent with other parent; and (d) parent with child.

Among children, no notable between-group differences were found in minutes of MVPA, time spent sedentary or co-participation in physical activity with family members at either of the follow-up time points. However, at 12 weeks a sizeable difference in change of 9.4 (95% CI 0.4 to 18.4) and 15.3 (95% CI 6.0 to 24.5) minutes in MVPA was found for adults in the FRESH arm compared with those in the pedometer or control arm, respectively. Adults in the FRESH arm also increased their activity with other family members (co-participation) more than those in the control and pedometer arms (10.0, 95% CI 2.9 to 17.1 minutes, and 10.6, 95% CI −3.6 to 17.6 minutes, respectively). No between-group group differences were found for time spent sedentary among adults.

Exploratory subgroup analyses (see *Tables 13* and *14*) showed a greater decline in MVPA among FRESH girls and FRESH children from less deprived areas than among their counterparts. The latter group also showed a greater increase in sedentary behaviour than those in the other groups. By contrast, FRESH adults, in particular men, showed a greater increase in MVPA at 8 weeks than the other groups.

Tables 17–19 display the findings for children and adults for all other outcomes. No notable or consistent between-group or subgroup differences were found for any other outcome measured at 8 or 52 weeks for children or for adults.

Evaluation of costs

The proportion of families who bought any sports items was materially unaltered throughout the study. *Table 20* reports the costs incurred by families and the intervention cost (incurred by local authority budgets). There was no difference across groups in the cost observed at baseline. The summation of the costs from randomisation until 1 year showed that for families enrolled in the FRESH arm expenditure was on average £157.92 (95% CI −£154.76 to £484.79) more than the no treatment group. The majority of this cost difference is accounted for by cost of the intervention. Conversely, the cost incurred by the families receiving only the pedometers tended to be smaller than that incurred by the families randomised to the control arm (B: −£90.50, 95% CI −£301.30 to £104.45). Adjusting these differences by the cost at baseline did not qualitatively change the findings.

Assessment against progression criteria

Table 21 outlines the prespecified progression criteria, whether or not the study team considers that the specific criterion was met, and the evidence to support that assessment.

TABLE 17 Secondary outcomes for children in FRESH pilot study

Outcome variable	FRESH				Pedometer				Control			
	n	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3
Weight (z-score)	30	0.27 (0.85)	0.04 (0.18)	0.11 (0.22)	22	0.64 (0.86)	0.00 (0.14)	−0.06 (0.28)	29	0.01 (1.0)	0.06 (0.11)	0.04 (0.27)
WC (z-score)	30	0.57 (1.33)	0.14 (0.64)	0.04 (0.66)	22	1.17 (0.94)	−0.21 (0.61)	−0.41 (0.57)	29	0.37 (1.21)	0.13 (0.71)	−0.01 (0.59)
BMI (z-score)	30	0.16 (1.09)	0.01 (0.26)	0.08 (0.25)	22	0.29 (1.07)	−0.06 (0.27)	−0.14 (0.36)	29	−0.02 (1.12)	0.03 (0.15)	−0.01 (0.34)
Predicted VO_2max	25	41.3 (4.1)	−1.0 (3.3)	1.2 (4.7)	17	43.8 (5.6)	0.3 (4.0)	1.9 (3.1)	18	42.4 (5.2)	−0.7 (3.5)	0.4 (3.5)
Quality of life	26	0.93 (0.03)	−0.02 (0.08)	−0.07 (0.12)	19	0.89 (0.11)	0.01 (0.08)	0.04 (0.17)	22	0.92 (0.06)	−0.03 (0.05)	0.02 (0.08)
TV viewing (minutes/week)	23	609.1 (309.2)	−200.9 (281.5)	−221.1 (423.1)	22	525.0 (380.0)	−26.8 (290.7)	−130.6 (453.2)	18	406.7 (212.4)	63.5 (292.0)	−35.3 (303.8)
Video games (minutes/week)	21	217.1 (347.5)	−91.4 (264.0)	−112.9 (408.4)	22	278.2 (434.8)	−48.6 (308.2)	−15.9 (273.7)	18	91.2 (255.9)	−18.5 (158.3)	87.6 (226.8)
Computer use (minutes/week)	23	469.6 (420.9)	−103.0 (273.7)	−187.9 (363.3)	22	288.2 (292.3)	26.4 (265.9)	32.4 (357.6)	18	257.5 (316.5)	12.5 (195.7)	30.8 (194.7)
Phone use (minutes/week)	23	133.0 (280.2)	−93.6 (269.9)	−48.3 (125.7)	22	78.2 (145.9)	5.0 (139.1	10.6 (166.0)	19	0.5 (2.3)	26.3 (47.2)	24.7 (61.3)

T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline; VO_2max, maximal oxygen consumption; WC, waist circumference. Values are mean (SD) unless stated otherwise.

TABLE 18 Secondary outcomes for adults in FRESH pilot study

	FRESH				Pedometer				Control			
Outcome variable	*n*	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3
Weight (kg)	23	81.3 (13.8)	−0.1 (1.3)	−1.4 (2.8)	21	76.5 (13.0)	0.3 (1.3)	0.3 (2.3)	21	76.3 (15.7)	0.3 (1.1)	1.4 (2.2)
WC (cm)	23	93.4 (12.0)	−1.3 (5.3)	−2.2 (5.5)	21	86.6 (12.5)	−1.3 (4.4)	−8.4 (30.8)	21	86.9 (11.3)	1.4 (3.9)	2.4 (4.4)
BMI	23	27.5 (5.0)	0.1 (0.7)	−0.5 (1.0)	21	25.6 (3.4)	0.1 (0.6)	−2.1 (8.7)	20	26.3 (5.3)	0.0 (0.4)	0.5 (0.7)
Predicted VO_2max	22	33.2 (4.7)	1.2 (3.0)	1.4 (1.7)	21	37.0 (4.8)	0.9 (3.5)	1.3 (2.8)	20	35.8 (6.1)	−0.2 (2.8)	0.3 (5.3)
Quality of life	23	75.4 (14.0)	2.0 (10.3)	6.5 (11.4)	22	82.7 (11.1)	−0.2 (12.8)	1.3 (7.9)	19	86.5 (8.3)	−2.2 (11.8)	−2.8 (10.0)

T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline; VO_2max, maximal oxygen consumption; WC, waist circumference.
Values are mean (SD) unless stated otherwise.

TABLE 19 Scores for family functioning in the FRESH pilot study

	FRESH				Pedometer				Control			
Time	*n*	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3	*n*	T1	Change T1 to T2	Change T1 to T3
Mean turns	6	82.5 (21.3)	10.6 (6.3)	13.4 (8.7)	5	76.6 (9.9)	−12.6 (20.9)	2.4 (25.2)	5	82.8 (20.7)	1.5 (14.8)	29.0 (22.4)
Positive talk/turn	14	0.06 (0.06)	−0.01 (0.05)	0 (0.03)	12	0.09 (0.05)	−0.03 (0.03)	−0.03 (0.04)	13	0.07 (0.04)	−0.01 (0.03)	−0.02 (0.03)
Activity talk/turn	14	0.10 (0.08)	−0.02 (0.07)	0.01 (0.04)	12	0.06 (0.05)	0.02 (0.05)	0.02 (0.06)	13	0.11 (0.12)	−0.01 (0.03)	−0.06 (0.11)

T1, baseline; T2, time 2 assessments 8 weeks post baseline; T3, time 3 assessments 52 weeks post baseline.
Values are mean (SD) unless stated otherwise.

TABLE 20 Baseline and follow-up average costs aggregated at family level

Cost/time	No treatment, average cost (£) (95% CI) [*n* (%)]	FRESH intervention, average cost (£) (95% CI) [*n* (%)]	Pedometer-only intervention, average cost (£) (95% CI) [*n* (%)]
Baseline	200.86 (130.96 to 270.76) [13 (100%)]	195.05 (110.22 to 279.88) [14 (100%)]	183.09 (118.08 to 248.10) [13 (100%)]
Intervention	0 (–) [13 (100%)]	89.97 (84.54 to 95.40) [14 (100%)]	24.55 (19.03 to 30.07) [13 (100%)]
Other components	0 (–) [13 (100%)]	67.69 (–) [14 (100%)]	2.40 (–) [13 (100%)]
Pedometers	0 (–) [13 (100%)]	22.29 (16.86 to 27.72) [14 (100%)]	22.15 (16.63 to 27.67) [13 (100%)]
8 weeks	115.56 (65.27 to 165.85) [13 (100%)]	89.79 (33.90 to 145.68) [14 (100%)]	104.92 (39.90 to 169.94) [13 (100%)]
52 weeks	322.22 (171.43 to 473.01) [13 (100%)]	409.76 (137.58 to 681.94) [12 (85.71%)]	239.52 (112.03 to 367.01) [11 (84.62%)]
Total cost – 1 year	437.78 (275.89 to 599.67) [13 (100%)]	595.7 (307.5 to 883.90) [12 (85.71%)]	347.29 (216.31 to 478.27) [11 (84.62%)]
Unadjusted differences[a]	Reference	157.92 (–154.76 to 484.79)	–90.5 (–301.3 to 104.45)
Adjusted differences[b]	Reference	191.45 (–62.5 to 506.32)	–55.65 (–250.07 to 143.61)

n, number of respondents; %, percentage of respondents out of the whole sample.
a CIs were calculated using 5000 non-parametric bootstrap replicates.
b The differences were adjusted for cost at baseline.

TABLE 21 Descriptions and study team's assessments of prespecified criteria used to inform progression to a definitive trial

Description	Criterion met?	Assessment
1. > 75% of families upload steps at least six times in the first 3 months of pilot study	Yes	• 86% of families uploaded steps > 6 times in first 3 months [mean 11 (SD 4) uploads]
2. Demonstrable feasibility of recruiting 20 families per month (accounting for increased staffing in future definitive trial) and retaining 75% of index children at 52-week follow-up	Partially	• The average recruitment rate was approximately $\approx 7 \pm 5$ families/month (range 2–15 families/month) • 88% of index children were retained at 52-week follow-up
3. Intervention optimisation feasible (identified adaptations are practical, affordable, acceptable)	Yes	• Focus groups revealed few suggested changes to the website; however, some families indicated a preference for the intervention to be delivered through a mobile phone app rather than a website • Many families suggested receiving wrist-worn pedometers

4. Evidence to suggest an adequately powered trial would require a feasible number of participants ($n = 250$ is considered to be logistically feasible and provide sufficient power)	Yes	• Post hoc sample size calculations were performed and to provide 80% power to detect a difference of 10 minutes in MVPA in index children, 27 index children/family are needed, using a SD of 16.3 minutes of MVPA and a pre–post correlation of 0.63:
		  ○ With three arms: 27 index children × 4 people/family × 3 arms; $N = 81$ families ($\approx$ 324 total participants)
		  ○ With two arms: 27 index children × 4 people/family × 2 arms; $N = 54$ families ($\approx$ 216 total participants)
		• Therefore, to conduct an adequately powered trial with a feasible number of participants will necessitate a two-armed study

5. Discontinuation of trial arm based on evidence of harm or limited acceptability/feasibility	Yes	• There were no reports of harm, however, during the focus groups some pedometer only-armed families unknowingly indicated that they would have liked to receive several elements that were delivered to families in the family-arm (e.g. step challenges). This finding provides some evidence to suggest that the pedometer-only arm could be discontinued in future
6. Preliminary effectiveness on MVPA[a]	No	• There was no indication of a positive signal of changes in children's MVPA over time. There was evidence of a short-term positive change over time for participating adults, particularly men, but this was not maintained at 1-year follow-up

a This criterion was an additional consideration added on request of the FRESH SSC.

Note
The criterion 'positive expected net gain of sampling from definitive trial' was dropped following consultation with the funder as a definitive trial had been decided against following an assessment of the other criteria.

Discussion of the FRESH pilot study results

Our findings show that it was feasible to deliver and evaluate a family-targeted physical activity promotion intervention with generally high acceptability from participating families. In addition, each of the prespecified progression criteria was met at least partially (see *Table 21*). However, we found a favourable indication of effectiveness only for adults and not for children, that is, a sizeable positive change in MVPA for adults in the FRESH arm compared with the other arms. The between-group difference found for adults' time spent in MVPA was not maintained at the 52-week follow-up, and we also found no notable between-group differences for any other outcome measured at either time point.

Family recruitment posed a substantial challenge, and this progression criterion was not entirely met (i.e. recruiting 20 families/month). Our average recruitment rate was ≈ 7 families/month (range 2–15 families/month), despite using a multifaceted recruitment strategy that targeted adults and children, included a wide range of settings, and used direct and indirect recruitment strategies. A review of 73 publicly funded trials in the UK (through the NIHR) found that only 55% recruited 100% of their target sample size within their pre-agreed timescale and nearly 45% received an extension of some kind.[145] There is little evidence of major improvement in recruitment into experimental research over time.[146] Several studies have reported that the recruitment of families is particularly challenging,[44,52] and we have described specific recruitment challenges that we have encountered previously.[78] Little methodological research is currently available to support the optimisation of family recruitment methods. Therefore, further research into how to recruit families to family-based research is needed.

In terms of recruitment, 94% of adults reported their ethnicity as white. Although this figure is reflective of the population of the counties where recruitment occurred,[82] the potential effectiveness of this intervention on minority families is unclear. Several studies have acknowledged the under-representation of minority groups in trials.[147,148] Therefore, further research to better establish how to recruit families in family-based research is needed, and in particular, greater consideration should be given to recruiting families from ethnic minority groups. Targeting specific recruitment settings and tailoring messaging on recruitment materials are strategies that could be used.[148,149]

An extensive measurement protocol was applied in the FRESH studies, and it is not possible to disentangle whether the challenges of recruiting families were because families lacked interest in increasing their physical activity or in FRESH in particular, or that the commitment to three rounds of home-based assessment of all family members was a barrier. Families in both the FRESH feasibility and the pilot studies indicated that the level of measurement was acceptable to them, but this is likely to have been a biased perception of a group of families that had made the commitment to take part in the FRESH study. Further research is needed to identify whether families may not be interested in physical activity promotion per se, or whether the research commitment required poses a barrier. With this in mind, researchers and funders should carefully balance the scientific need for detailed data collection (driven, for example, by questions around how interventions work, and impacts on important physical health outcomes beyond the target behaviour) with the burden on participants and the impact that it has on the recruitment of a representative sample of participants.

Encouragingly, we found evidence of preliminary short-term effectiveness for adults and, in particular, for fathers in the FRESH arm. Similar interventions with mothers have resulted in positive physical activity promotion.[150] However, the effect on fathers may be noteworthy as evidence indicates that fathers have an independent influence on their children's health and development[115] and an important influence on children's physical activity.[116–118]

We did not find evidence of preliminary effectiveness for children or for co-participation in physical activity between parents and their children in this study. This may be for a number of reasons. First, our process evaluation and focus groups revealed that family planning time was not being implemented as intended. In a family-based physical activity intervention that included a similar planning component, the authors found that children's MVPA significantly increased in the short term compared with a condition that received education only.[151] Therefore, without implementing the planning component in our study, the step challenges alone may have not been enough to change children's MVPA. There were also group differences in children's sex and age, with fewer girls in the pedometer-only arm and more older children in the FRESH arm. Observational data reveal that children's physical activity declines with age,[22–24] girls accumulate less physical activity than boys throughout childhood,[134,152] and girls' physical activity declines more precipitously than boys' with age.[49,153,154] These differences may have affected preliminary intervention effectiveness on MVPA, but this issue would likely be resolved through randomisation in an adequately powered trial. Last, there may have been a healthy volunteer bias, as participants across groups were generally already meeting the physical activity recommendations at baseline. In future, excluding families that are sufficiently active could be considered.

Delivery of the FRESH intervention was estimated to cost £90 per family (≈ £15 per participant), including pedometers for all family members, the face-to-face kick-off meeting and personalised follow-up support. The last of these accounted for ≈ 55% of the costs. These costs could be reduced in future, as this part of the intervention delivery had not been automated but was processed manually by research staff. The automation of these processes will help reduce delivery costs, and make it more attractive to funding agencies to consider delivering FRESH as part of their portfolio of physical activity interventions, if it is proven effective. Previous work has estimated the cost of delivering a multicomponent school-based physical activity intervention at ≈ £190 per participant,[155] and an after-school intervention at £51 per participant,[156] suggesting that cost of delivering the FRESH intervention is low in comparison. However, the definitions, scope and perspectives of the costs considered across studies were quite different, making comparison difficult. Moreover, little is known about how much local authorities or other delivery agents are willing to pay, and future research should explore this.

Strengths and limitations of the FRESH pilot trial

This study has several noteworthy strengths, which include its randomised design, high retention rates, device-measured physical activity, a measure of family functioning, and a long-term follow-up assessment (i.e. 52 weeks post baseline). There were also some limitations. Despite bolstering our recruitment strategy after our feasibility study, we were still unable to recruit the desired number of families into this study; therefore, further optimisation regarding recruitment in family-based research appears prudent. In addition, the children and adults who participated in this pilot study were generally sufficiently physically active at baseline, which may have affected the potential of the intervention. The populations of Norfolk and Suffolk are not representative of the wider UK population, and the potential feasibility of FRESH in other locations should be tested. The assessment of cost was focused on intervention implementation as these would be the costs directly incurred by local providers such as local authority. Costs of longer-term maintenance and implementation (including website updates) were not included. The analyses presented do not account for the clustering of participants within families. Within-family intraclass correlation coefficients for MVPA ranged between 0.42 and 0.52, and this level of clustering should be taken into account in the design and analyses of future family-based physical activity studies. Last, randomisation did not lead to balanced groups as there were large differences in sex and age among children across groups, with noticeably fewer girls in the pedometer group and fewer older children in the FRESH arm. This may have affected our findings for preliminary intervention effectiveness. The randomisation procedure is likely to have been affected by small sample size and the use of a stratified randomisation procedure by county owing to funding. There is no indication that this issue would also affect an adequately powered trial; however, stratifying randomisation by child sex and/or age could also be considered.

Conclusion

In conclusion, this study demonstrates feasibility and acceptability of the family-targeted FRESH intervention, as well as satisfying all progression criteria, at least partially. However, we failed to recruit the target sample size and did not find a signal of effectiveness on MVPA particularly long term or in children. Therefore, further refinements around intervention delivery and recruitment may be required prior to progressing to a full-scale trial.

Chapter 7 A systematic review with expert opinion assessing effective and resource-efficient strategies for recruiting families to physical (in)activity, nutrition and obesity prevention research

Introduction

As described before, physical activity promotion interventions targeting families may be a valuable way to increase physical activity among children.[158,159] However, the study team's experience in the FRESH feasibility and pilot studies demonstrated that effective strategies are needed to overcome barriers to recruitment.

As noted earlier in this report, recruitment of participants into intervention research is notoriously difficult.[160,161] Two reviews of publicly funded trials in the UK (through the NIHR) found that only about half of the included trials recruited 100% of their target sample size within their pre-agreed timescale.[146,162] The overall start to recruitment was delayed in 41% of trials, early recruitment problems occurred in 63% of trials,[146] and just over one-third of trials received an extension of some kind.[146,162] There is little evidence that recruitment into experimental research is improving over time.[146,160] The recruitment of multiple family members to research projects is particularly challenging.[29,30,44,52] We have described specific recruitment challenges that we have encountered previously,[78,125,126] but there has not been a comprehensive assessment of how to recruit families to family-based health promotion research.

The aim of this study was, therefore, to systematically identify effective and resource-efficient strategies for recruiting families into intervention research aimed at improving physical activity or nutrition or reducing levels of sedentary behaviour (including screen time) and overweight/obesity. Our objectives were to (1) describe procedures used and outcomes related to recruitment (e.g. recruitment duration, strategies used, recruitment settings, reach, expressions of interest, enrolment rates); and (2) determine the most optimal family-based recruitment strategies.

Methods

This study was conducted in two phases:

1. a systematic review of family recruitment methods
2. a Delphi consensus study.

Both phases examined the settings (i.e. where recruitment occurred) and the strategies (i.e. how recruitment was implemented) used by researchers conducting family-based intervention research with outcomes related to physical activity, sedentary behaviour (including screen time), nutrition, and obesity prevention. Details of the protocol for this study were registered on PROSPERO (CRD42019140042) and can be accessed at www.crd.york.ac.uk/prospero/display_record.php?RecordID=140042.

Phase 1: systematic review

Search strategy overview

Reporting of the systematic review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[163] In short, we identified relevant intervention studies through a systematic search of published reviews on the relevant topic. Intervention studies were then extracted from those included reviews. Subsequently, a forward search of the included intervention studies identified more recently published studies that had not been captured in the included reviews.

Eligibility criteria

Systematic reviews

All types of reviews describing the results of family-based experimental studies with outcomes related to physical activity, sedentary behaviour, nutrition or obesity prevention were eligible for inclusion.

Intervention studies

Intervention studies were eligible for inclusion if they met the following inclusion criteria:

- Participants. Generally healthy school-aged children and young people *and* at least one adult primarily responsible for their care. Studies focused on preschool or post-secondary-aged youth samples were excluded, as were those with clinical populations (e.g. populations with any illness, disorder or disability) or those exclusively targeting overweight/obese children and youth.
- Interventions. Interventions that deliberately attempted to implement a change in physical activity, sedentary behaviour, screen time use or diet or prevent overweight/obesity were included. No restriction was placed on the type of comparison. Treatment interventions (e.g. weight management interventions) were excluded.
- Study type. All experimental (e.g. RCTs, crossover designs) and quasi-experimental designs were included. Cross-sectional and cohort studies were excluded. No limitations were set on the duration of the intervention or the follow-up period.
- Types of outcome measures. Studies could be included if they had employed any outcome measure related to physical activity, sedentary behaviour, screen-use time, diet, or overweight/obesity prevention. However, outcomes must have been measured in at least one child and at least one adult primarily responsible for their care.

For both reviews and intervention studies, we set no limits on the earliest publication date. We included English-language, peer-reviewed full-text articles that reported primary data or protocols and had been published by February 2019. Forward searching was conducted in August 2019.

Search strategy

We conducted a systematic search for review articles in Cochrane Library, PubMed, PsycInfo and Scopus. The search included keywords related to the population ('children/young people' and 'parents'), interventions ('physical activity', 'diet', etc.) and study type (e.g. 'review'), *Box 2* provides an example of the full search strategy. Identified references were imported into EndNote reference manager and duplicates were removed. Titles and abstracts were screened by a single reviewer, with a second reviewer double-screening a random 10% as a check. Full-text papers were screened by two reviewers independently, with any discrepancies resolved by discussion. Reasons for exclusion were identified at this full-text screening stage. Reference lists of included reviews were reviewed in duplicate, and references of potentially relevant studies were extracted into EndNote. Following deduplication, two reviewers independently screened the titles/abstracts and then the full-text versions of additional interventions studies identified. Any disagreements were discussed by the two reviewers until a consensus was reached.

BOX 2 SCOPUS search terms

((TITLE-ABS-KEY (child* OR boy* OR girl* OR teen* OR adolesc* OR youth OR young* OR dyad*)) AND (TITLE-ABS-KEY (parent* OR mom* OR mum* OR dad* OR mother* OR father* OR famil* OR dyad*))) AND (TITLE-ABS-KEY (trial* OR intervention* OR experiment*)) AND (TITLE (review OR "meta-analys*")) AND (((TITLE-ABS-KEY ("physical activit*" OR exercis* OR sport* OR fitness OR "activity intens*" OR "activity level*" OR movement)) OR (TITLE-ABS-KEY (overweight OR obesity OR adipos* OR "body mass" OR "body weight" OR "waist circumference" OR "weight loss")) OR (TITLE-ABS-KEY ("healthy eat*" OR "healthy snack*" OR beverage* OR diet* OR nutrition OR vegetable* OR fruit* OR "energy intake" OR "energy balanc*" OR "soft drink*" OR soda OR sugar*))) OR (TITLE-ABS-KEY (sedentar* OR screen* OR game* OR computer* OR television OR tv OR tablet*))) AND (LIMIT-TO (DOCTYPE, "re") OR LIMIT-TO (DOCTYPE, "ar") OR LIMIT-TO (DOCTYPE, "ip")) AND (LIMIT-TO (LANGUAGE, "English")).

The same key words were used in our searches of the other three databases (Cochrane Library, PubMed and PsycInfo).

Data extraction

The following data were extracted from each intervention study: characteristics of study design and sampling, recruitment duration and strategies used, recruitment settings, and information about reach, expressions of interest and enrolment. We sent the extracted data to the first and last authors of studies published within the last 5 years (i.e. since 2014), inviting them to check the extracted data for accuracy and to add any missing information, if possible. We only contacted authors of articles published within the last 5 years as we believed that this was a reasonable time period for which their records would be available and they were likely to have adequate recall of the study.

Risk of bias in individual studies and across studies

We were only interested in examining the strategies used for recruiting families into family-based intervention research, which does not inherently affect the internal validity (risk of bias) of a study. Therefore, we decided not to include a risk-of-bias (quality) assessment.

Summary measures and synthesis of results

As indicated above, only family-based recruitment strategies were of interest in this study and not the main outcome findings of an included study; thus, we present findings descriptively only.

Phase 2: Delphi consensus study

Study design

The Delphi procedure or technique is a group process involving the interaction between the researcher and a group of identified experts on a specified topic.[164] This procedure is appropriate for research questions which cannot be answered with complete certainty, but rather by the subjective opinion of a collective group of informed experts.[165] Here, we used a Delphi procedure to determine, through the consensus of experts, the most effective and resource efficient strategies for recruiting families into intervention studies. Our protocol was guided by a similar published study.[75] Ethics approval for the study was obtained in July 2019 through a Medical Research Council (MRC) Epidemiology Unit departmental ethics review.

Study procedures

Two groups of experts were invited by e-mail: (1) all first and senior authors of the intervention studies identified in phase 1, and (2) known experts in the field identified by the study team. Participants were also permitted to suggest other experts for invitation. All participants were asked to complete an informed consent online prior to the start of the study.

The Delphi study included three rounds using an online questionnaire created in Qualtrics (Provo, UT, USA), a web-based survey tool. To start each round, participants were sent an e-mail containing a direct link to the online questionnaire, which they were given 1–2 weeks to complete. One reminder was sent 3 days before the deadline. After each round, a summary of the findings was fed back to the participants.

In round 1, participants responded to questions related to the most recent family-based study they had conducted (e.g. about recruitment strategies, recruitment duration, sample size), and to provide their top two strategies for recruiting families in intervention studies (*Box 3* lists the questions asked). Following the deadline, the study team reviewed the panel's responses to their top strategies. We then collated responses into overarching themes based on the setting in which recruitment occurred (e.g. schools) and then organised similar recruitment strategies used under each overarching theme.

In round 2, participants reviewed the recruitment strategies put forward in round 1 and rated how effective and resource-efficient they believed each strategy to be separately on two different four-point Likert scales (4 = very effective/resource-efficient, 1 = not effective/resource-efficient). To rank strategies, summary scores were created in which scores for effectiveness were weighted by a factor of 2. Therefore, the weighted scores for effectiveness ranged between 2 and 8 and the scores for resource efficiency ranged between 1 and 4. Effectiveness was weighted more than resource efficiency as we believed that effectiveness was a more important factor related to recruitment strategies. The top 10 recruitment strategies were then taken forward to round 3.

In the final round (round 3), participants were asked to rank the top 10 recruitment strategies into their individual top 10. Following completion, all rankings were summed to determine the overall rank of each strategy (i.e. a lower score indicated a higher rank).

BOX 3 Questions asked in round 1 of the Delphi procedure

1. Was the most recent family-based experimental study that you conducted a pilot/feasibility trial or full-scale trial?
2. How many families did you aim to recruit in the study?
3. How many families were enrolled in the study?
4. How much time (in weeks) was allotted for recruitment?
5. Was this enough time to recruit the number of families you aimed to recruit?
6. Was the recruitment period extended?
7. How much additional time (in weeks) was allotted for recruitment?
8. In your opinion, what are the top two recruitment strategies that you have used in the family-based experimental research that you have conducted?
9. Please provide a detailed description of the recruitment strategies.
10. Whom did you find to be the best contact person when initiating the recruitment strategies?
11. How effective were the recruitment strategies the most recent time you used them?
12. What resources were required with the recruitment strategies the most recent time you used it?
13. Are there any recruitment strategies that you have used in previous studies that you have stopped or plan to stop using?
14. Are there any recruitment strategies that you would like to try but have not yet used?

Results

Findings of phase 1: systematic review

Phase 1: systematic review findings

Figure 11 shows the study selection process. Fifty-five relevant reviews met the inclusion criteria; from these, 360 references to potentially relevant intervention studies were extracted and 50 were included. An additional 14 intervention studies were identified through forward searching, and, therefore, a total of 64 articles, describing 49 intervention studies, met the inclusion criteria. The study characteristics are detailed in *Table 22*. Of the 49 separate studies, the majority were undertaken in the USA (57%), were pilot or feasibility studies (43%), aimed to improve physical activity only (37%) and recruited parent–child dyads (53%). Publication dates ranged from 1983 to 2019, with 27% of the included articles published in the last 5 years (i.e. since 2014; 17 of 64 articles). After attempting to contact the authors of the 17 studies published in the last 5 years, we received responses for seven of the 17 studies. Modifications were made or additional information was provided for five out of these seven studies.

Table 23 provides the details of all relevant recruitment data. Overall, a target sample size was presented a priori in 33% of studies, with a median target sample size of 120 (IQR 65–182) participants. Actual sample size was reported in 98% of studies and included a median of 100 (IQR 53–304) participants. Of the 16 studies in which target and actual sample sizes were provided, 56% recruited a sufficient number of participants. The duration of recruitment was reported in 33% of studies, and this was a median of 10 (IQR 8–36) weeks. Few studies reported figures on reach (18%), expressions of interest (33%), expressions of interest rate (16%), who initiated an expression of interest (< 1%) and enrolment rate (22%). Where reported, the median estimated reach was 437 (IQR 350–864) families, of whom 122 (IQR 92–174) expressed interest. The single study describing who expressed initial interest showed that in 82% (23/28) of the cases these were mothers. The median weekly expression of interest rate was 14 (IQR 11–21) families per week, with median enrolment rate at about 5 (IQR 2–11) families/dyads per week.

Details on family recruitment settings and strategies were reported in 84% and 73% of studies, respectively. On average, researchers recruited from 2.2 $\pm$ 1.9 different settings and used 2.7 $\pm$ 1.2 recruitment strategies per study; there was no difference between full-scale trials, pilot/feasibility or quasi-experimental trials in the number of recruitment settings or strategies used. School-based recruitment was the most common recruitment setting, with community-based recruitment second. Community-based recruitment settings included churches, recreation centres, play groups, libraries, fairs/fetes, sports clubs, 4-H, day cares, preschools, tutoring programs, malls, grocery stores, farmers' markets, cafes, trailer parks and laundromats. Recruitment also occurred through employers, primary care (e.g. general practitioners, health centres, other health-related businesses), and print/electronic media.

Across settings, the most commonly used recruitment strategies included disseminating study information through leaflets, posters or newsletters. School-based recruitment had the most recruitment strategies specific to the setting and included leaflets, posters, newsletters, letters from the head teacher (principal), research teams presenting study information to students and parents at assemblies, research teams presenting study information at other school events (e.g. parent–teacher association meetings), and research teams approaching parents during pick-up/drop-off times. Local newspapers and referral-based recruitment (e.g. word-of-mouth) were also popular recruitment strategies. Less commonly reported recruitment strategies included using: electronic/digital media (e.g. television, radio, social media, Google AdWords, Craigslist), face-to-face recruitment (e.g. home visits, community demonstrations), mail, telephone calls and distribution lists (e.g. via marketing companies).

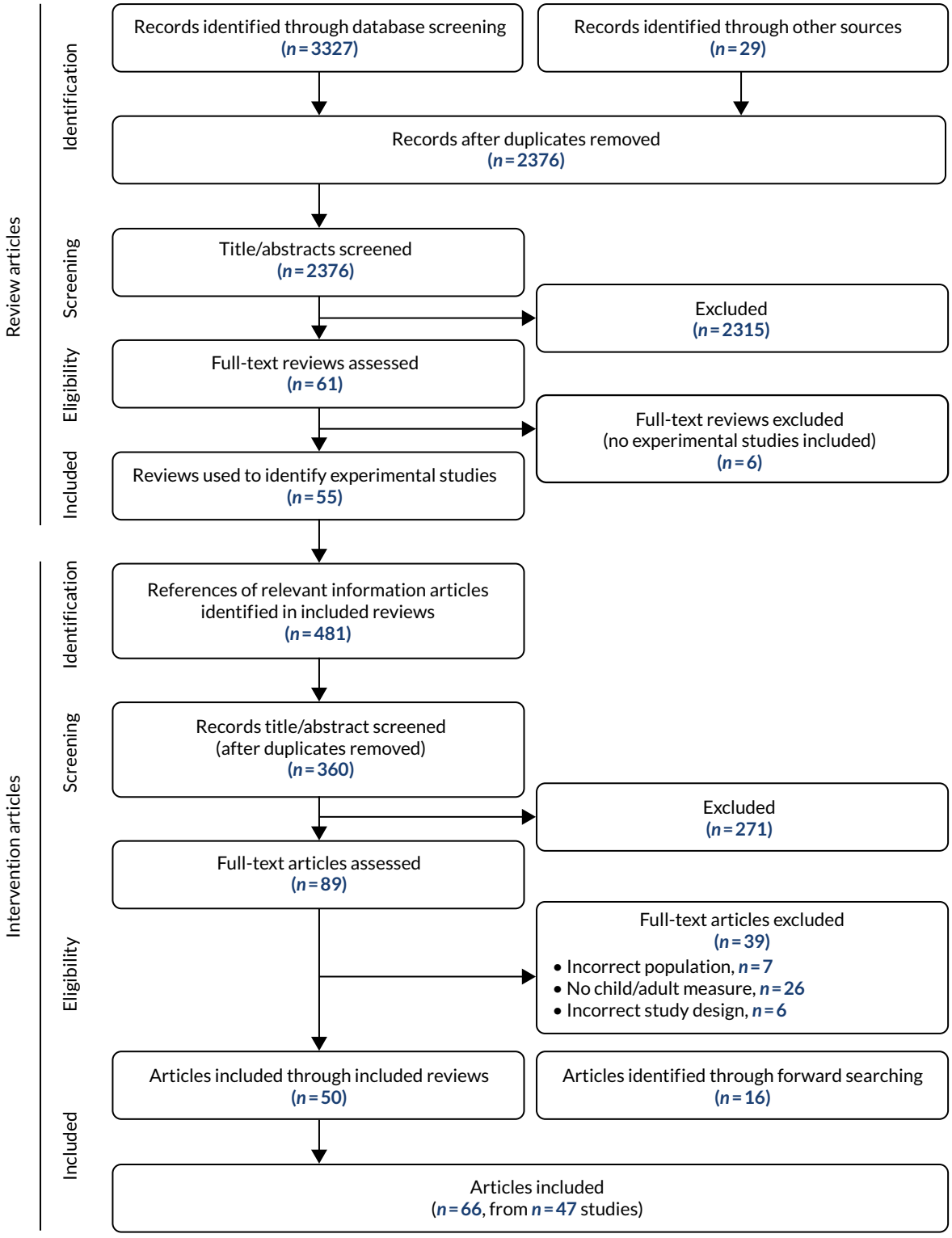

FIGURE 11 Flow chart of identification of family-based intervention studies for systematic review.

Phase 2: Delphi study

We invited 107 experts, representing all inhabited continents, to participate in the Delphi study. Twenty-three experts actively declined as they were no longer conducting family-based research ($n = 3$) or did not have the time ($n = 2$), or gave no reason ($n = 18$). Six e-mail invitations bounced back and no other e-mail addresses were identified for these experts. Thirty-five experts participated in at least one round of the study; only 13 completed all rounds. Most participants were experienced

TABLE 22 Study characteristics of studies included in systematic review

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
No intervention name, Alhassan, 2018, USA[166]	**Pilot RCT** (pre and 2 post measures) **Study arms:** child–mother, child alone or control **Aims/objective:** to examine the feasibility and efficacy of a mother–daughter intervention on African American girls' physical activity	**Recruitment target:** African American mother–daughter dyads **Target sample size:** 60 dyads (20 dyads/group) **Actual sample size:** 76 dyads (child–mother, $n = 28$; child alone, $n = 25$; or control, $n = 23$) **Family characteristics:** children: 8.3 (1.3) years (100%); adults: 37.4 (7.7) years (100%)	**Duration:** not reported **Setting:** not reported **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** 125 dyads **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
SHARE-AP ACTION, Anand, 2007, Canada[167]	**RCT** (pre and 2 post measures) **Study arms:** experimental or usual care control **Aims/objective:** to determine if a household-based lifestyle intervention was effective at reducing energy intake and increasing energy expenditure	**Recruitment target:** families on a Six Nations Reserve (minimum parent–child dyad required) **Target sample size:** not reported **Actual sample size:** 57 families (intervention, $n = 29$; control, $n = 28$) **Family characteristics:** children: experimental – 10.9 (2.9) years (62.5%), control – 9.9 (3.2) years (60.5%); adults: experimental – 41.3 (9.0) years (not reported), control – 37.2 (8.8) years (not reported) 57 families (participants: intervention, $n = 88$; control, $n = 86$); average three participants/family	**Duration:** 48 weeks **Setting:** not reported **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Arredondo, 2014, USA[168]	**Pilot trial** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to examine the acceptability, feasibility and preliminary efficacy of an intervention on physical activity and correlates of physical	**Recruitment target:** Latina mother–daughter dyads **Target sample size:** 11 dyads **Actual sample size:** 11 dyads **Family characteristics:** children: 9.6 (1.1) years (100%); adults: 36.7 (6.2) years (100%)	**Duration:** 8 weeks **Setting:** church (approached, $n = 1$; agreed, $n = 1$) **Strategies:** Announcements in Spanish from the pulpit; flyers distributed by study staff and church leaders	**Reach:** ≈ 864 parishioners (the church had 1800 enrolled parishioners and 48% were Latino) **Expressions of interest:** not reported

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
	activity of Latina preadolescents and their mothers			**Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Baranowski, 1990, USA;[169] Baranowski, 1990, USA[170]	**Randomised controlled feasibility study** (pre and post measures) **Study arms:** experimental or no treatment control **Aims/objective:** to reduce sodium, saturated fat and total fat, and to increase aerobic activity	**Recruitment target:** families who self-identified as Black American (minimum parent–child dyad required) **Target sample size:** not reported **Actual sample size:** 96 families (intervention, $n = 50$; control, $n = 46$) **Family characteristics:** children: experimental – 10.6 years (51.6%), control – 10.0 years (66.1%); adults: experimental – 31.8 years (79.4%), control – 32.9 years (88.2%) 96 families (participants: $n = 63$ adults and 64 children intervention; $n = 51$ adults and 56 children intervention)	**Duration:** not reported **Setting:** schools only (number not reported) **Strategies:** mail, telephone calls and home visits (up to five visits) of all Black-American students identified in listings in the public or private school systems	**Reach:** 728 Black-American families identified **Expressions of interest:** N/A. This was not a sample of self-presenting volunteers **Initiated expression of interest:** N/A **Expressions of interest rate:** N/A **Enrolment rate:** not reported
Mothers and Daughters Exercising for Life (MADE4LIFE), Barnes, 2015, Australia[171]	**Pilot RCT** (pre and 2 post measures) **Study arms:** experimental or 6-month wait-list control **Aims/objective:** to evaluate the feasibility and preliminary efficacy of a mother–daughter programme to improve physical activity	**Recruitment target:** mother–daughter dyads **Target sample size:** 40 dyads **Actual sample size:** 40 dyads (mothers, $n = 40$; daughters, $n = 48$) **Family characteristics:** children: 8.5 (1.7) years (100%); adults: 39.1 (4.8) years (100%)	**Duration:** ≈ 3 weeks **Setting:** schools (n = not reported) **Strategies:** media releases, school newsletter advertisements, school presentations to students and parents, local newspapers and local television news	**Reach:** not reported **Expressions of interest:** 122 families **Initiated expression of interest:** not reported **Expressions of interest rate:** ≈ 40–41 families/week **Enrolment rate:** ≈ 13 families/week

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Family Affair, Barr-Anderson, 2014, USA[172]	**Pilot trial** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to test the feasibility and acceptability of an intervention designed to impact obesity-related behaviours (physical activity, healthy eating and sedentary behaviour) among African American adolescent girls and their mothers	**Recruitment target:** African American mother-daughter dyads **Target sample size:** not reported **Actual sample size:** 18 dyads **Family characteristics:** children: 12.4 ± 1.3 years (100%); adults: 36.9 ± 5.7 years (100%)	**Duration:** not reported **Setting:** not reported **Strategies:** radio advertisements, flyers and recruitment letters sent to or posted at youth- and family-serving organisations, health-related businesses, churches, social and professional organisations; e-mail distribution lists; Facebook posts; word-of-mouth	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Healthy Kids & Families study, Borg, 2019, USA[173]	**Quasi-experimental protocol** (pre and 4 post measures) **Study arms:** experimental or attention-control **Aims/objective:** to test the effectiveness of an intervention to promote a healthier lifestyle and to prevent childhood obesity among low-income and minority families	**Recruitment target:** parent–child dyads **Target sample size:** 240 dyads **Actual sample size:** 247 dyads (intervention, $n = 121$; attention-control, $n = 126$) **Family characteristics:** children: 7.8 (2.1) years (49%); adults: 36.2 (7.4) years (92%)	**Duration:** not reported **Setting:** schools only ($n = 9$ schools) **Strategies:** letter from the school principal placed in child's backpack by school staff; automated telephone messages from principals; research staff presented study at school events (e.g. parent nights, family events, parent–teacher organisation meetings); interactions with parents at school drop-off/pick-up and after-school programmes	**Reach:** not reported **Expressions of interest:** 605 parents **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Back-to-Basics Healthy Lifestyle program, Burrows, 2013, Australia[174]	**Pilot trial** (pre and post measure) **Study arm:** experimental arm only **Aims/objective:** to assess the feasibility and acceptability of an after-school obesity prevention strategy for families	**Recruitment target:** parent–child dyads **Target sample size:** 10 dyads **Actual sample size:** 10 dyads **Family characteristics:** children: 7.3 (3.8) years (80%); adults: 31.0 (7.2) years (100%)	**Duration:** 2 weeks **Setting:** schools only ($n = 1$) **Strategies:** study flyers; word-of-mouth by school staff	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** 5 dyads/week
No intervention name, De Bourdeaudhuij, 2002, Belgium[175]	**Quasi-experimental** (pre and post measure) **Study arms:** family arm, individual arm (adolescents) or individual arm (parents) **Aims/objective:** to explore the differences between a family- and an individual-based tailored nutrition education programme on fat reduction	**Recruitment target:** parent–child dyads **Target sample size:** not reported **Actual sample size:** family condition: $n = 55$ dyads ($n = 110$ participants); individual condition (adolescents): $n = 71$ adolescents; individual condition (parents): $n = 47$ parents **Family characteristics:** children: range 15–18 years (not reported); adults: not reported	**Duration:** not reported **Setting:** schools only ($n = 52$ classes from two secondary schools) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
MOVE/me Muevo Project, Elder, 2014, USA[176]	**RCT** (pre and 2 post measures) **Study arms:** experimental or control **Hypotheses:** (1) children in the experimental arm would have lower BMI z-scores than control children after 2 years; (2) children in the experimental arm spend more time in MVPA and less time sedentary, eat fewer high-fat foods and sugary beverages, and have more fruits, vegetables and water vs. control children	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 541 families **Family characteristics:** children: 6.6 (0.7) years (55%); adults: not reported	**Duration:** not reported **Setting:** schools, libraries, street fairs, recreation centres ($n =$ not reported) **Strategies:** targeted telephone calls using telephone numbers obtained from a research marketing company ($n = 8600$); families contacted via school- and community-based recruitment efforts ($n = 1000$)	**Reach:** 9607 families **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
No intervention name, Epstein, 2001, USA[177]	**Randomised trial** (pre and post measures) **Study arms:** increase fruit and vegetable (FV) intake treatment condition or decrease high-fat/high-sugar intake (FS) treatment condition **Aims/objective:** to evaluate the effect of a parent-focused intervention on parent and child eating changes and on the percentage of overweight changes in families	**Recruitment target:** families (minimum parent–child dyad required) **Target sample size:** not reported **Actual sample size:** 30 families (FV: $n = 13$ parents and $n = 13$ children; FS: $n = 12$ parents and $n = 13$ children) **Family characteristics:** children: FV – 8.8 (1.8) years (54%), FS – 8.6 (1.9) years (77%); adults: FV – 39.1 (4.1) years (92%), FS – 42.2 (4.8) years (92%)	**Duration:** not reported **Setting:** physician practices ($n =$ not reported) **Strategies:** physician referrals, posters, newspapers, and television advertisements	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Fitzgibbon, 1995, USA[178]	**Pilot trial** (pre and post measures) **Study arms:** experimental or control **Aims/objective:** to examine the effects of an obesity prevention programme on eating-related knowledge and behaviour of low income, Black American girls and their mothers	**Recruitment target:** Black American mother–daughter dyads **Target sample size:** not reported **Actual sample size:** 20 dyads (10 dyads/group) **Family characteristics:** children: experimental – 11.0 (1.0) years (100%), control – 11.0 (1.0) years (100%); adults: experimental – 31.0 (10.0) years (100%), control – 33.0 (5.0) years (100%)	**Duration:** not reported **Setting:** tutoring programme ($n = 1$) **Strategies:** advertisements in tutoring newsletter	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Children First Study, Fornari, 2013, Brazil[179]	**RCT** (pre and post measures) **Study arms:** experimental or control **Aims/objective:** to evaluate whether or not an educational programme for children could improve cardiovascular risk in parents	**Recruitment target:** children and their parents **Target sample size:** 150 parents per group **Actual sample size:** 197 children and 323 parents (intervention: $n = 105$ children, $n = 162$ parents; control: $n = 92$ children, $n = 161$ parents) **Family characteristics:** children: experimental – 8.2 (1.5) years (50%), control – 9.0 (1.5) years (51%); adults: experimental – 38.3 (6.0) years (55%), control – 39.3 (6.7) years (53%)	**Duration:** not reported **Setting:** schools only ($n = 1$) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Active Families in the Great Outdoors, Flynn, 2017, USA[180]	**Feasibility trial** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to determine whether changes could be observed in duration, frequency and type of outdoor physical activities performed by families; parent social cognitive outcomes and physical activity support behaviours	**Recruitment target:** families (minimum parent–child dyad required) **Target sample size:** not reported **Actual sample size:** 16 families ($N = 52$ participants: parents, $n = 25$; children, $n = 27$) **Family characteristics:** children: 10.7 (3.3) years (52%); adults: 41.5 (7.9) years (60%)	**Duration:** not reported **Setting:** not reported **Strategies:** flyers, e-mail, word-of-mouth	**Reach:** not reported **Expressions of interest:** 38 families **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Take Action, French, 2011, USA[181]	**CRCT** (pre and post measures) **Study arms:** experimental or control **Hypothesis:** the experimental group would gain less weight and increase healthful behaviours related to energy balance over 1 year compared with the control group	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 90 households ($n = 45$ households/group) **Family characteristics:** children, not reported; adults, 41.0 years (93%) ≈ 4 members per family (≈ 2 adults and ≈ 2 children/family)	**Duration:** 32 weeks **Setting:** libraries, worksites, schools, day-care centres, health clinics, religious institutions, park and recreation centres, grocery stores, and food co-ops (number not reported) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** 723 households **Initiated expression of interest:** not reported **Expressions of interest rate:** 22 or 23 households per week **Enrolment rate:** 2 or 3 households per week
Families Reporting Every Step to Health (FRESH), Guagliano, 2019, UK	**Feasibility trial** (pre and post measures) **Study arms:** 'child-only' or 'family' **Aims/objectives:** to describe intervention and recruitment strategy; assess the feasibility and acceptability of the FRESH recruitment strategy, intervention and outcome evaluation; explore options for optimisation	**Recruitment target:** families (minimum parent–child dyad required) **Target sample size:** 20 families **Actual sample size:** 12 families (children, $n = 14$; adults, $n = 18$) **Family characteristics:** children: 8.3 (1.7) years (50%); adults: 39.8 (8.2) years (61%) Whole families 4, parent–child dyads 6,	**Duration:** 8 weeks **Setting:** schools only. $N = 11$ schools approached, $n = 5$ agreed, $n = 3$ declined, $n = 3$ no response. Recruitment from community-based organisations planned, but not implemented **Strategies:** assembly delivered to students; study	**Reach:** ≈ 437 students **Expressions of interest:** 28 families **Initiated expression of interest:** 23 mothers, 5 fathers **Expressions of interest rate:** 3 or 4 families per week, 5 or 6 families per

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
		families with an additional adult or child 2; 2 or 3 members per family (range 2–4 members per family)	leaflets given to students to bring home and emailed to parents from schools; reminder e-mail sent from schools to parents 2 weeks after assembly	school assembly **Enrolment rate:** 1 or 2 families per week
Scouting Nutrition and Activity Program+ (SNAP+), Guagliano, 2012, USA[182]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental arm only **Aims/objectives:** to evaluate a physical activity promotion intervention with a channel of communication to parents	**Recruitment target:** Girl Scouts troops and their parents **Target sample size:** not reported **Actual sample size:** three troops (children, $n = 32$; adults, $n = 26$) **Family characteristics:** children: 9.5 (1.4) years (100%); adults: 37.1 (5.4) years (92%)	**Duration:** not reported **Setting:** Girl Scouts troops ($n = 3$ troops invited and agreed) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Active 1 + FUN, Ha, 2019, Hong Kong[183]	**RCT protocol** (pre and 2 post measures) **Study arms:** experimental or control **Aims/objective:** to evaluate the effectiveness of a family-based intervention on parents and their children's physical activity	**Recruitment target:** students and their parents (minimum parent–child dyad required) **Target sample size:** 204 children **Actual sample size:** 187 children **Family characteristics:** children: 9.8 (1.2) years (41%); adults: unknown (78%)	**Duration:** ≈ 4–6 weeks **Setting:** Schools only ($n = 100$ invited; $n = 9$ responded and agreed; $n = 1$ dropped out) **Strategies:** written information was circulated to parents; face-to-face parent–researcher sessions	**Reach:** unknown **Expressions of interest:** ≈ 229 **Initiated expression of interest:** unknown (not collected) **Expressions of interest rate:** unknown (researchers only received a confirmed list from schools) **Enrolment rate:** unknown (researchers only received a confirmed list from schools)

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Abriendo Caminos, Hammons, 2013, USA[184]	**Pilot trial** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to test the effectiveness of a family-based healthy eating programme aimed to reduce obesogenic behaviours among Latino parents and children	**Recruitment target:** Latino families; only 1 target child (5–13 years) and 1 parent measured **Target sample size:** not reported **Actual sample size:** 73 families **Family characteristics:** children: 8.5 years (49%); adults: 34.4 years (100%) ≈ 4 family members per family (range 2–9)	**Duration:** 104 weeks **Setting:** trailer park ($n = 1$) and elementary school ($n = 1$) with known Latino population **Strategies:** flyers, announcements, and word-of-mouth. Project co-ordinators were Latino and fluent Spanish speakers	**Reach:** unknown **Expressions of interest:** unknown **Initiated expression of interest:** unknown **Expressions of interest rate:** unknown **Enrolment rate:** < 1 family per week
Fit 'n' Fun Dudes Programme, Hardman, 2009, UK[185]	**CRCT** (pre and 2 post measures) **Study arms:** experimental or control **Aims/objective:** to increase daily step counts of girls with the support of their parents to maintain increases over time	**Recruitment target:** parent–daughter dyads **Target sample size:** not reported **Actual sample size:** $n = 32$ children (intervention, $n = 14$ children; control, $n = 18$ children) **Family characteristics:** children: 10.6 (0.7) years (100%); adults: 41.0 (4.7) years (83%)	**Duration:** not reported **Setting:** not reported **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Hopper, 1992, USA[186]	**CRCT** (pre and 2 post measures) **Study arms:** school-and-home treatment condition, school-only treatment condition, and standard treatment control condition **Aims/objective:** to compare the effect of including versus not including a family participation component in a school-based programme to develop children's heart-healthy exercise and nutrition habits	**Recruitment target:** parents and children or children only **Target sample size:** not reported **Actual sample size:** school-and-home condition, $n = 45$ children and 42 parents; school-only condition, $n = 43$ children; control condition, $n = 44$ children **Family characteristics:** children: 11.6 (0.7) years (not reported); adults: 37.8 (6.8) years (74%)	**Duration:** not reported **Setting:** not reported **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Teamplay, Jago, 2013, UK[187]	**Randomised controlled feasibility trial** (pre and 2 post measures) **Study arms:** experimental or no treatment control **Aims/objectives:** six specific aims related to feasibility of recruitment, retention and data collection; intervention development and optimisation; estimating effect sizes of outcomes of interest (e.g. physical activity, screen viewing) and sample size for definitive trial	**Recruitment target:** parents of children aged 6–8 years **Target sample size:** between 80 and 340 participants **Actual sample size:** 48 participants (intervention, $n = 25$; control, $n = 23$) **Family characteristics:** children: experimental – 6–8 years (62%), control – 6–8 years (69%); adults: experimental – age not reported (100%), control – age not reported (96%)	**Duration:** not reported **Setting:** schools, coffee shops, children's centres, play groups, school playgrounds (number not reported) **Strategies:** leaflets, advertisements, face-to-face recruitment	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Motivating Families with Interactive Technology (mFIT), Jake-Schoffman, 2018, USA[188]	**Pilot trial** (pre and post measures) **Study arms:** tech or tech+ **Aims/objective:** to test the feasibility, acceptability and preliminary effectiveness of two family-based programs targeting improvements in parent–child dyad's physical activity and healthy eating and delivered remotely	**Recruitment target:** parent–child dyads **Target sample size:** not reported **Actual sample size:** 33 dyads (tech+, $n = 17$; tech, $n = 16$) **Family characteristics:** children: 11.0 (0.9) years (64%); adults: 43.0 (5.8) years (88%)	**Duration:** not reported **Setting:** not reported **Strategies:** e-mail announcements, flyers posted in community settings, paid newspaper ads, direct mail postcards	**Reach:** not reported **Expressions of interest:** 98 **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Childhood and Adolescence Surveillance and Prevention of Adult Non communicable disease (CASPIAN) Study, Kargarfard, 2012, Iran;[189] Kelishadi, 2010, Iran[190]	**Non-RCT** (pre and 2 post measures) **Study arms:** mother/daughter arm or student-only arm **Aims/objective:** to examine the effect of a physical activity programme for high-school girls and their mothers	**Recruitment target:** mother–daughter dyads or students only **Target sample size:** not reported **Actual sample size:** mother/daughter group ($n = 206$ girls and $n = 204$ mothers); student-only group ($n = 60$ girls) **Family characteristics:** children: 15.8 (1.0) years (100%) in mother/daughter group; 15.9 (1.3) years	**Duration:** not reported **Setting:** schools (number not reported) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
		(100%) in student-only group; adults: age not reported (100%) in either group		**Enrolment rate:** not reported
4-Health, Lynch, 2012, USA[191]	**Pilot RCT protocol** (pre and 2 post measures) **Study arms:** experimental or 'best practices' control **Aims/objective:** to develop, implement and evaluate a parent-centred obesity prevention programme for rural families	**Recruitment target:** children and their parents **Target sample size:** 75 participants per group **Actual sample size:** unknown **Family characteristics:** unknown	**Duration:** not reported **Setting:** 4-H ($n = 25$ 4-H extension agents) **Strategies:** announcements and information at county fairs, announcements in 4-H newsletters, electronic and/or printed announcements to 4-H clubs, e-mails to 4-H listservs, and telephone calls to 4-H leaders	**Reach:** unknown **Expressions of interest:** unknown **Initiated expression of interest:** unknown **Expressions of interest rate:** unknown **Enrolment rate:** unknown
No intervention name, Mark, 2013, Canada[192]	**Pilot RCT** (pre and post measure) **Study arms:** GameBike (experimental) or traditional stationary bike (control) **Aims/objective:** primarily, to compare usage of a GameBike with that of a traditional stationary bike placed in front of the television among parents and children	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 30 families (adults, $n = 59$; children, $n = 38$) **Family characteristics:** children: experimental – 6.0 (2.1) years (42%); control – 5.4 (1.7) years (42%); adults: experimental – 37.1 (6.6) years (52%), control – 36.6 (6.1) years (50%)	**Duration:** not reported **Setting:** health-care centres, recreation centres, day cares, preschools and shopping malls (number not reported) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** 58 families **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Kick Start Your Day, Mohammad, 2012, USA[193]	**Pilot trial** (pre and post measure) **Study arms:** experimental or control **Aims/objective:** to evaluate a family-based nutrition and physical activity programme targeting	**Recruitment target:** Latino families **Target sample size:** not reported **Actual sample size:** 56 parents (intervention, $n = 25$; control, $n = 31$) and their children ($n =$ not reported) **Family characteristics:** children: range 6–12 years	**Duration:** not reported **Setting:** community centre ($n = 1$) and clinic ($n = 1$) **Strategies:** flyers and brochures written in English and Spanish, presentation delivered at a	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
	low-income Latino families	(not reported); adults: 37.0 (7.0) years (not reported)	parent–teacher association meeting and community leader forum	**Expressions of interest rate:** not reported **Enrolment rate:** not reported
Children, parents and pets exercising together (CPET), Morrison, 2013, UK;[194] Yam, 2012, UK[195]	**Randomised controlled feasibility trial** (pre and post measure) **Study arms:** experimental or no treatment control **Aims/objectives:** to assess the feasibility and acceptability of the CPET intervention and trial, preliminary evidence of its potential efficacy, planning and powering a future intervention, and to improve understanding of the frequency, intensity and duration of dog walking among dog-owning families in Scotland	**Recruitment target:** families with dogs **Target sample size:** 40 families **Actual sample size:** 28 families (experimental, $n = 16$ families; control, $n = 12$ families) **Family characteristics:** children: 10.9 years (76%), adults: 44.8 years (82%)	**Duration:** not reported **Setting:** primary schools (approached, $n = 37$; agreed, $n = 35$) **Strategies:** invitation letters sent to dog-owning parents with children attending primary schools in one local authority area	**Reach:** 350 letters sent **Expressions of interest:** 127 families **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Dads and Daughters Exercising and Empowered (DADEE), Morgan, 2019, Australia[131]	**RCT** (pre and 2 post measures) **Study arms:** experimental or wait-list control **Aims/objective:** to evaluate a programme designed to improve father–daughter physical activity and daughters' fundamental movement skill competency; fathers', daughters' screen-time; fathers' physical activity parenting practices	**Recruitment target:** fathers and their daughters **Target sample size:** 86 fathers and 134 daughters **Actual sample size:** 115 fathers and 153 daughters (DADEE: fathers, $n = 57$; daughters, $n = 74$; wait-list control: fathers, $n = 58$; daughters, $n = 79$) **Family characteristics:** children: 7.7 (1.8) years (100%); adults: 41.0 (4.6) years (0%)	**Duration:** 11 weeks **Setting:** not reported **Strategies:** university media release picked up by local television, radio, newspaper news outlets	**Reach:** not reported **Expressions of interest:** 160 **Initiated expression of interest:** not reported **Expressions of interest rate:** 14 or 15 families per week **Enrolment rate:** ≈ 10 families per week

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Healthy Dads, Healthy Kids, Morgan, 2014, Australia;[196] Morgan, 2011, Australia[197,198] Williams, 2018, Australia[199]	**Community RCT** (pre and post measures) **Study arms:** experimental or a wait-list control **Aims/objective:** to evaluate the Healthy Dads, Healthy Kids intervention when delivered by trained local facilitators in the community	**Recruitment target:** fathers and their children **Target sample size:** 50 fathers and their children **Actual sample size:** 93 fathers and 132 children **Family characteristics:** children: 8.1 (2.1) years (45%); adults: 40.3 (5.3) years (0%)	**Duration:** ≈ 8 weeks **Setting:** schools (*n* not reported) **Strategies:** school newsletters, school presentations, interactions with parents at school pick-up, local media, and flyers distributed through local communities	**Reach:** not reported **Expressions of interest:** 116 **Initiated expression of interest:** not reported **Expressions of interest rate:** ≈ 14–15 families per week **Enrolment rate:** ≈ 11–12 families per week
Healthy Dads, Healthy Kids, Morgan, 2011, Australia[197,198] Lubans, 2012, Australia;[117] Burrows, 2012, Australia[200]	**RCT** (pre and 2 post measures) **Study arms:** experimental or a wait-list control **Aims/objective:** to evaluate the feasibility and efficacy of Healthy Dads, Healthy Kids to help fathers lose weight and model positive health behaviours to their children	**Recruitment target:** fathers and their children **Target sample size:** 44 fathers and their children **Actual sample size:** 53 fathers and 71 children **Family characteristics:** children: 8.1 (2.1) years (45%); adults: 40.3 (5.3) years (0%)	**Duration:** ≈ 8 weeks **Setting:** schools (*n* not reported) **Strategies:** school newsletters, local media	**Reach:** not reported **Expressions of interest:** 107 **Initiated expression of interest:** not reported **Expressions of interest rate:** ≈ 13 families per week **Enrolment rate:** ≈ 6 or 7 families per week
The San Diego Family Health Project, Nader, 1989, USA;[201] Nader, 1992, USA;[202] Nader, 1983, USA;[203] Patterson, 1988, USA[204]	**CRCT** (pre and 3 post measures) **Study arms:** Mexican American experimental, Anglo-American experimental, Mexican American control, or Anglo-American control **Aims/objective:** to decrease consumption of high-salt, high-fat foods; and increase frequency and	**Recruitment target:** families (only up to two children and two adults measured) **Target sample size:** not reported **Actual sample size:** 206 families **Family characteristics:** Mexican American experimental: children: 12.1 (1.7) years (55%); adults: 37.1 (6.8) years (88%)	**Duration:** not reported **Setting:** primary schools (*n* not reported) **Strategies:** newspaper articles, Parent–Teacher Association meetings, community groups and a family fun night (covered by a local TV station)	**Reach:** ≈ 6000 children **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
	intensity of physical activity	Anglo-American experimental: children: 12.1 (1.9) years (38%); adults: 39.4 (7.1) years (62%) Mexican American control: children: 12.0 (1.7) years (49%); adults: 35.6 (6.9) years (75%) Anglo-American control: children: 11.8 (1.4) years (48%); adults: 36.9 (5.1) years (58%)		**Enrolment rate:** not reported
Behavior Opportunities Uniting Nutrition, Counseling, and Exercise (BOUNCE), Olvera, 2010, USA;[205] Olvera, 2008, USA[206]	**CRCT** (pre and post measures) **Study arms:** experimental or control **Aims/objective:** primarily, to assess the efficacy of the BOUNCE intervention for improving physical fitness and activity in Latino mother–daughter pairs	**Recruitment target:** Latino mother–daughter dyads **Target sample size:** 50 dyads **Actual sample size:** 46 dyads (experimental, $n = 26$; control, $n = 20$) **Family characteristics:** children: experimental – 9.9 (1.1) years (100%), control – 10.4 (1.1) years (100%); adults: experimental – 33.3 (4.6) years (100%), control – 38.2 (10.6) years (100%)	**Duration:** not reported **Setting:** not reported **Strategies:** flyers mailed to homes of Latino families	**Reach:** not reported **Expressions of interest:** 57 parents **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Owens, 2011, USA[207]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental or control **Aims/objective:** to examine changes in physical activity and fitness in families after 3 months of home use of the Wii Fit	**Recruitment target: families** **Target sample size:** not reported **Actual sample size:** 8 families ($n = 21$ participants) **Family characteristics:** children: 10.0 (1.6) years (50%); adults: 37.8 (4.9) years (78%)	**Duration:** not reported **Setting:** not reported **Strategies:** local newspaper advertisement	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

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TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Etude Longitudinale Prospective Alimentation et Santé (ELPAS) study, Paineau, 2008, France[208]	**RCT** (pre and post measures) **Study arms:** group A (experimental), group B (experimental) and group C (no-treatment control) **Hypothesis:** family dietary coaching would improve nutritional intakes and weight control in free-living children and parents	**Recruitment target:** families (parent–child dyad minimum) **Target sample size:** 295 families per experimental group and 420 families in the control group **Actual sample size:** 1013 families (Group A, *n* = 297 families; Group B, *n* = 298 families; Group C, *n* = 418 families) **Family characteristics:** children, 7.7. years (52%); adults, 40.5 (82%)	**Duration:** 16 weeks **Setting:** schools only (*n* = 54) **Strategies:** mailed study information	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Y Living, Parra-Medina, 2015, USA[209]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to examine the impact of the Y Living Program on the weight status of adult and child participants	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 242 adults, 106 children **Family characteristics:** children, 12 (interquartile range 10–14) years (49%); adults, 41 (interquartile range 33–53) (81%)	**Duration:** not reported **Setting:** churches, schools (number not reported) **Strategies:** organisational newsletters, neighbourhood newspapers, word-of-mouth	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Choosing 5 Fruits and Veg Every Day, Pearson, 2010, UK[210]	**Pilot trial** (pre and 2 post measures) **Study arms:** experimental or no treatment control **Aims/objective:** to evaluate the feasibility and effectiveness of a family-based newsletter intervention to increase fruit and vegetable consumption among adolescents	**Recruitment target:** parent–adolescent dyads **Target sample size:** not reported **Actual sample size:** 49 dyads **Family characteristics:** children: experimental – 12.6 (1.0) years (44%), control – 12.3 (0.7) years (42%); adults: experimental – 44.4 (5.3) years (71%), control – 43.9 (3.6) years (75%)	**Duration:** 16 weeks **Setting:** schools, universities, factories, warehouses, clubs/societies (number not reported) **Strategies:** newspaper and website advertisements, posters in workplaces (universities, factories, warehouses), and letters through schools and activity clubs/societies	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
Daughters and Mothers Exercising Together (DAMET), Ransdell, 2004, USA;[211] Ransdell, 2003, USA;[212] Ransdell, 2001, USA[213]	**Pilot trial** (pre and post measures) **Study arms:** community-based or home-based experimental arms **Aims/objective:** to assess the effectiveness of home- and community-based physical activity interventions that target mothers and daughters to increase physical activity and improve health-related fitness	**Recruitment target:** mother–daughter dyads **Target sample size:** not reported **Actual sample size:** 20 dyads **Family characteristics:** children: community-based – 15.2 (1.2) years (100%), home-based – 15.7 (1.5) years (100%); adults: community-based – 46.0 (8.5) years (100%), home-based – 44.0 (6.1) years (100%)	**Duration:** not reported **Setting:** not reported **Strategies:** newspaper articles, local Girl Scout troop announcements, referral	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Generations Exercising Together to Improve Fitness (GET FIT), Ransdell, 2004, USA;[214] Ornes, 2005, USA[215]	**Pilot trial** (pre and post measure) **Study arms:** experimental or no treatment control **Aims/objective:** to compare a 6-month home-based physical activity intervention with a control condition for physical activity and health-related fitness in three generations of women	**Recruitment target:** grandmother–mother–daughter triads **Target sample size:** not reported **Actual sample size:** 17 triads **Family characteristics:** children: experimental – 10.8 (1.4) years (100%), control – 9.4 (1.5) years (100%); mothers: experimental – 37.8 (4.2) years (100%), control – 36.6 (4.2) years (100%); grandmothers: experimental – 60.7 (4.3) years (100%), control – 62.9 (4.5) years (100%)	**Duration:** not reported **Setting:** not reported **Strategies:** newspaper, e-mail and flyer advertisements, word-of-mouth	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Rhodes, 2019, Canada;[151] Quinlan, 2015, Canada[216]	**RCT** (pre and 3 post measures) **Study arms:** physical activity education + planning (experimental) or physical activity education (control) **Aims/objective:** to evaluate whether or not a planning condition improves regular physical activity compared with an education-	**Recruitment target:** families (minimum parent–child dyad required) **Target sample size:** 160 families **Actual sample size:** 102 families **Family characteristics:** children: intervention – 8.8 (2.3) years (50%), control – 9.1 (1.9) years (54%); adults: intervention – 42.2 (5.7) years (76%) intervention, control – 43.0 (5.7) years (83%)	**Duration:** not reported **Setting:** schools, recreation centres, health-care centres, children's recreation classes, shopping malls and outdoor markets (number not reported) **Strategies:** newspaper advertisements. Snowball recruitment was	**Reach:** not reported **Expressions of interest:** 188 parents **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
	only control condition among families	Dual-parent families, 52%; single families, 44%; families with siblings, 29%	also used, whereby families received a CA$25 grocery store gift card if they referred another family Recruitment was conducted by stratifying the city into regions to ensure diversity of families	**Enrolment rate:** not reported
No intervention name, Rhodes, 2010, Canada[141]	**Pilot RCT** (pre and post measures) **Study arms:** standard intervention or standard intervention + planning **Aims/objective:** to examine the effect of a planning intervention compared with a standard condition on intergenerational physical activity in families	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 85 families **Family characteristics:** children: standard – range 4–10 years (not reported) standard+ – range 4–10 years (not reported); adults: standard – 38.6 (5.30 years (79%), standard+ – 39.0 (5.2) years (90%)	**Duration:** 52 weeks **Setting:** day cares, recreation centres, preschools, primary schools (number not reported) **Strategies:** flyers, poster advertisements	**Reach:** not reported **Expressions of interest:** 107 families **Initiated expression of interest:** not reported **Expressions of interest rate:** ≈ 2 families per week **Enrolment rate:** ≈ 1 or 2 families per week
Scouting Nutrition & Activity Program, Rosenkranz, 2010, USA;[217] Rosenkranz, 2009, USA[218]	**CRCT** (pre and post measure) **Study arms:** experimental or standard-care control **Aims/objective:** to evaluate an intervention designed to prevent obesity by modifying Girl Scout troop meeting environments, and by empowering girls to improve the quantity and/or quality of family meals in their home environments	**Recruitment target:** Girl Scout troops and their parents **Target sample size:** 8 troops with 20 girls per troop **Actual sample size:** 7 troops (mean 11 girls per troop) **Family characteristics:** children: experimental – 10.6 (1.1) years (100%), control – 10.5 (1.3) years (100%); adults: experimental – age and % female not reported, adults: control – age and % female not reported	**Duration:** not reported **Setting:** Girl Scouts troops ($n = 7$ troops) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
No intervention name, Salimzadeh, 2010, Iran[219]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to evaluate the effectiveness of an exercise programme on the body composition and physical fitness of mothers and daughters	**Recruitment target:** mother–daughter dyads **Target sample size:** not reported **Actual sample size:** 35 dyads **Family characteristics:** children: 15.0 (1.6) years (100%); adults: 40.0 (3.8) years (100%)	**Duration:** not reported **Setting:** schools only ($n = 5$) **Strategies:** not reported	**Reach:** 300 students **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
No intervention name, Schwinn, 2014, USA[220]	**Pilot trial** (pre and 2 post measures) **Study arms:** experimental or control **Aims/objective:** to improve the well-being of girls living in public housing by improving dietary intake, increasing physical activity and reducing drug use risks	**Recruitment target:** mother–daughter dyads **Target sample size:** not reported **Actual sample size:** 67 dyads (intervention, $n = 36$; control, $n = 31$) **Family characteristics:** children: 11.9 (0.9) years (100%); adults: 36.2 (6.2) years (100%)	**Duration:** 4 weeks **Setting:** public housing development ($n = 1$) **Strategies:** Google AdWords, public housing development newspapers, Facebook and Craigslist advertisements	**Reach:** not reported **Expressions of interest:** 86 **Initiated expression of interest:** not reported **Expressions of interest rate:** 21 or 22 families per week **Enrolment rate:** 16 or 17 families per week
Brighter Bites, Sharma, 2016, USA[221]	**Quasi-experimental** (pre and post measures) **Study arms:** Brighter Bites (experimental) or school health programme (control) **Aims/objective:** to evaluate the effectiveness of a school-based food co-op programme to increase fruit and vegetable intake, and home nutrition environment among low-income children and their parents	**Recruitment target:** parent–child dyads **Target sample size:** not reported **Actual sample size:** 717 dyads (intervention, $n = 407$; control, $n = 310$) **Family characteristics:** children: 6.2 (0.4) years (52%); adults: 34.3 (7.4) years (90%)	**Duration:** 2 school years **Setting:** schools only ($n = 12$) **Strategies:** not reported	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** 358 or 359 dyads per school year

continued

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
No intervention name, Stolley, 1997, USA[222]	**Pilot trial** (pre and post measures) **Study arms:** experimental or control **Aims/objective:** to assess the effectiveness of an obesity prevention programme on pre-adolescent girls and their mothers	**Recruitment target:** mother–daughter dyads **Target sample size:** not reported **Actual sample size:** 65 dyads **Family characteristics:** children: intervention – 9.9 (1.3) years (100%), control – 10.0 (1.5) years (100%); adults: intervention – 31.5 (3.4) years (100%), control – 33.7 (6.8) years (100%)	**Duration:** not reported **Setting:** tutoring programme ($n = 1$) **Strategies:** advertisement in tutoring newsletter, letters sent to mothers of children registered in tutoring programme, presentation delivered to parents at tutoring programme orientation	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
One Body, One Life, Towey, 2011, UK[223]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to evaluate a family-based programme designed to prevent obesity	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 272 children and 182 parents. **Family characteristics:** children: 8.0 years (50%); adults: age not reported (87%)	**Duration:** not reported **Setting:** neighbourhood groups, local fetes, community groups, general practitioner surgeries, libraries, children's centres, print media, schools (number not reported) **Strategies:** flyers, posters, newsletters, word-of-mouth, referrals from health-care professionals and local newspapers, and making team members visible in the community (e.g. attending events, delivering 'taster sessions')	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported
Family Eats, Cullen, 2017, USA[224]	**RCT** (pre and 2 post measures) **Study arms:** experimental or control **Aims/objective:** to improve parent and child fruit and vegetable intake	**Recruitment target:** families **Target sample size:** not reported **Actual sample size:** 126 families ($n = 92$ intervention; $n = 34$ control) **Family characteristics:** children: age not reported (55%); adults: 59% aged < 40 years (98%)	**Duration:** not reported **Setting:** schools, churches, health fairs, community centres (number not reported) **Strategies:** flyers, radio advertisements	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported

TABLE 22 Study characteristics of studies included in systematic review (*continued*)

Intervention name, study (first author, year of publication, country)	Study design (assessments), study arms, aims/objectives	Families/participants [recruitment target; target and actual sample size; mean (SD) years of age at baseline; % female]	Recruitment (duration; settings; strategies used)	Reach, expressions of interest and enrolment
				Expressions of interest rate: not reported **Enrolment rate:** not reported
No intervention name, Ziebarth, 2012, USA[225]	**Quasi-experimental** (pre and post measures) **Study arms:** experimental arm only **Aims/objective:** to evaluate a family intervention programme designed to decrease overweight and obesity in Hispanic families	**Recruitment target:** Hispanic families **Target sample size:** not reported **Actual sample size:** 47 families (adults, $n = 57$; children, $n = 54$) **Family characteristics:** children: age and % female not reported, adults: age 32 years (not reported)	**Duration:** not reported **Setting:** local churches, medical clinics, schools, self-service laundries and community programmes (number not reported) **Strategies:** posters, announcements, word-of-mouth	**Reach:** not reported **Expressions of interest:** not reported **Initiated expression of interest:** not reported **Expressions of interest rate:** not reported **Enrolment rate:** not reported

CRCT, cluster randomised controlled trial; N/A, not applicable.

TABLE 23 Summary of recruitment figures from intervention studies included in the systematic review

	Overall	Number of studies with relevant data ($n = 49$ studies)
Target sample size (participants)	120 (65–182)	16
Actual sample size (participants)	100 (53–304)	48
Recruitment duration (weeks)	10 (8–36)	16
Reach	437 (350–864)	9
Expressions of interest	119 (95–167)	16
Initiated expression of interest	82% mothers	1
Expressions of interest rate (per week)	14 (11–21)	8
Enrolment rate (families per week)	5 (2–11)	11
Percentage of studies with under-recruitment	44%	N/A

N/A, not applicable.
Median (IQR) values are presented unless indicated otherwise.

researchers (full/associate/assistant professors, lecturers/senior lecturers; 82.8%), and most were from North America (71.4%), followed by Europe (11.4%), Australia/Oceania (8.6%), Asia (5.7%) and South America (2.9%).

Round 1: overview of experience with recruitment settings and strategies

Twenty-one participants provided information in round 1. *Table 24* summarises the median (IQR) duration of recruitment and the sample sizes of the participants' family-based studies. The participants recommended 36 different recruitment strategies, which fell into six overarching themes: school-based strategies ($n = 14$ Delphi participants recruited in schools), print and electronic media strategies ($n = 8$), community settings-based strategies ($n = 7$), primary care-based recruitment strategies ($n = 4$), employer-based strategies ($n = 3$) and referral-based recruitment ($n = 3$). *Table 25* provides an overview of the 36 recruitment strategies described.

TABLE 24 Summary of Delphi participants' responses to recruitment experiences

	Overall	Feasibility/pilot trials	Full-scale trials
Studies (*n*)	21	11	10
Target sample size	80 (60–210)	60 (45–70)	225 (170–486)
Actual sample size	79 (41–180)	41 (37–65)	190 (131–375)
Initial recruitment duration (weeks)	12 (7.5–52)	8.5 (6–12)	52 (10–68)
Percentage of studies in which recruitment was extended	33	36	30
Recruitment extension duration (weeks)	20 (8–37.5)	8 (8–11)	48 (37.5–50)
Enrolment rate (families per week)	4 (2–9)	3 (2–6)	8 (2–18)
Percentage of studies with under-recruitment	62	55	70

Median (IQR) values are presented unless indicated otherwise.

TABLE 25 Overview of experts' top recruitment strategies and mean ratings for each strategy's effectiveness and resource efficiency

Category	Strategy	*n*	Mean	SD
Referral	Word-of-mouth	23	4.8	1.8
Schools	Letter about the study from head teacher to parents on behalf of research team	25	4.4	1.7
Media (print and electronic)	Social media posts (e.g. Facebook, Twitter)	22	4.3	1.7
Employers	Study information emailed to employees from within organisation on behalf of the research team (e.g. an e-mail sent from HR to employees within an organisation)	24	4.2	1.4
Schools	Assembly delivered to parents by research team	25	4.2	2.0
Primary care	Letters sent from GPs or health-care providers on behalf of research team	23	4.2	1.8
Community	Research team speaking to parents while waiting for their children (e.g. during their child's swimming lesson)	24	4.1	2.0
Primary care	Letters from research team directly to potential participants	23	4.0	1.8
Schools	Research team attending parent meetings (e.g. orientation meetings, Parent Teacher Association meetings)	25	4.0	1.9
Media (print and electronic)	Television (local news story promoting study)	22	4.0	2.0

TABLE 25 Overview of experts' top recruitment strategies and mean ratings for each strategy's effectiveness and resource efficiency (*continued*)

Category	Strategy	*n*	Mean	SD
Media (print and electronic)	E-blasts (e.g. university news, third-party media groups, corporate mailing lists)	22	4.0	1.6
Media (print and electronic)	Electronic newsletter mailing list	22	3.9	1.4
Schools	Leaflets via e-mail (e.g. ParentMail) or other third-party companies (e.g. Peachjar)	25	3.9	1.5
Community	Research team speaking to parents during pick-up time (e.g. at the end of an after-school programme or a summer camp day)	24	3.9	2.0
Schools	Research team attending school events (e.g. sports day)	25	3.8	1.9
Media (print & electronic)	Radio (ads or story promoting study)	23	3.8	1.9
Schools	Study information in school newsletter (hard copy)	25	3.8	1.4
Community	Hard-copy leaflets to parents	24	3.7	1.6
Primary care	Telephone calls from research team directly to potential participants	23	3.7	2.1
Schools	Assembly delivered to students by research team	25	3.7	1.5
Media (print and electronic)	Print – newspaper (advertisements or story promoting study)	23	3.6	1.6
Primary care	Pull-tab poster displays in GP clinic	22	3.6	1.1
Schools	Hard-copy leaflets to parents via children	25	3.6	1.7
Schools	Study information written in students' diary/agenda	25	3.6	1.5
Primary care	Hard-copy leaflets displayed in GP clinic	23	3.5	1.1
Employers	Hard-copy leaflets displayed in employee common areas (e.g. kitchen)	24	3.5	1.3
Media (print and electronic)	Print – other local publications (advertisements or story promoting study)	23	3.4	1.3
Community	Electronic neighbourhood bulletin boards	23	3.4	1.1
Community	Pull-tab poster displays	23	3.4	1.1
Schools	Research team hosting parent/researcher night to discuss study	25	3.4	1.7
Community	Pop-up stands disseminating study information directly (e.g. at local market)	24	3.4	1.7
Media (print and electronic)	Craigslist (an American classified advertisement website)	20	3.4	1.5
Media (print and electronic)	Print – magazines (advertisements or story promoting study)	23	3.4	1.3
Schools	Research team speaking to parents during 'pick-up' time	25	3.3	2.0
Schools	Research team hosting after school 'drop-in' sessions for parents	25	3.1	1.6

GP, general practitioner.

Notes
Experts rated each strategy using a four-point Likert scale (4 = very effective/resource-efficient, 3 = effective/resource-efficient, 2 = slightly effective/resource-efficient and 1 = not effective/resource-efficient). Scores for effectiveness were weighted more heavily, by a factor of 2, than scores for resource efficiency.

School-based recruitment

School-based recruitment strategies included study information distributed by: hard copy leaflets to parents via children, school newsletters, letters from head teachers on behalf of research team, leaflets by e-mail (e.g. ParentMail) or via other third-party companies (e.g. Peachjar), assemblies with students and/or parents, students' diary/agenda, research team attending parent meetings (e.g. orientation meetings, Parent–Teacher Association meetings) or other school events (e.g. sports day), hosting parent/researcher nights or after school 'drop in' sessions, speaking to parents during pick up time.

Generally, most Delphi study participants were successful at gaining approval from someone at most schools that they approached to distribute study information. However, gaining approval could be time-consuming and included multiple e-mails, telephone calls and/or face-to-face meetings (e.g. with head teachers, physical education co-ordinators, parent representatives). Some reported that, in future, they planned to either stop recruiting in schools or stop using passive recruitment strategies in schools (e.g. sending hard copy leaflets home with children to give to their parents). Staff time was considered a major resource requirement for recruiting in schools (e.g. searching for schools, visiting schools, travel time, assemblies/meetings preparation). In addition, many reported having to make multiple e-mails, phone calls and/or face-to-face meetings for permission to distribute study information. Other resource requirements reported for school-based recruitment were travel costs (e.g. petrol, car hire), printing costs and postage costs.

Print and electronic media-based recruitment

Participants reported using advertisements or stories about their study printed in magazines, newspapers, or other local publications as effective print-based recruitment strategies. Regarding recruitment strategies using electronic media, Delphi participants reported the following strategies as their most effective: social media posts (e.g. Twitter, Facebook, Instagram) radio, television news, e-blasts (e.g. via university news, third party media groups, corporate mailing lists), and electronic newsletters.

Disseminating study information through social media was the strategy that the most participants planned to implement in future. They reported that print and electronic media were wide-reaching and generally inexpensive to use. However, those with experience with this recruitment strategy reported low and slow response rates. Creating regular content on social media platforms or newsletters (e.g. update posts, quarterly newsletter, blogs) was considered more beneficial than one-off posts, advertisements, or newsletters. Caution was raised that some media-driven strategies can be less targeted than others (e.g. posts in social media groups, television advertisements/stories), which can lead to a lot of interest from ineligible participants (and increased staff requirements). Staff time was considered the greatest resource requirement (e.g. searching for online groups/communities, creating content, increased eligibility checking).

Community setting-based recruitment

The strategies applied in community setting-based recruitment were hard-copy leaflets or pull-tab posters, speaking to parents during pick-up time after community clubs, using pop-up stands at local events to speak to families, and using electronic neighbourhood bulletin boards. A wide variety of recruitment settings were reported, including churches, local museums, summer camps, Scouts/Guides, YMCA/YWCA, after-school programs, swimming pools, local events, local markets, Parkrun, newsagents, shopping centres, community centres, electronic neighbourhood bulletins and local businesses.

Generally, reports indicated that recruiting from community settings was unpredictable, with high yields at some events and no interest at others. It was reported to be very time-consuming to find appropriate places to recruit and stay on top of upcoming local events (and gaining approval to be at those events to recruit). Having staff attend events (e.g. local market, shopping centre) was also time-consuming and generally occurred outside normal working hours. Some participants planned to stop recruiting in some settings, specifically newsagents, community centres, and shopping centres because of the time investment required and poor yield. However, under some circumstances, community

settings-based recruitment was suggested to be particularly effective, especially if the intervention is directly or partly tied to the recruitment setting. Some suggested that having outgoing staff could be important for engaging families and it may be beneficial to target parents while they are waiting for their children to complete an activity (e.g. during swimming lessons). Again, staff time was the biggest resource requirement (finding appropriate locations to recruit and events to attend, gaining approval to attend, and attending and distributing recruitment material). Other resource requirements reported for community settings-based recruitment were costs associated with printing, postage, travel, and equipment (e.g. pop-up gazebo, banners).

Employer-based recruitment

Employer-based recruitment strategies included displaying hard-copy leaflets in employee common areas (e.g. staff kitchen) or e-mails being sent to employees from within an organisation on behalf of the research team (e.g. an e-mail sent from human resources to employees within an organisation).

Generally, most participants found employer-based recruitment very time-consuming and had low levels of success at reaching and gaining approval from someone within an organisation to distribute study information. Recruitment in this setting allows a researcher to directly expose family decision-makers (i.e. parents) to study information; however, it is quite untargeted as many will be ineligible. Staff time was considered the major resource requirement for recruiting employers as many participants reported having to make multiple e-mails and telephone calls (mostly to generic email addresses or telephone numbers) for permission to distribute study information. Costs associated with travel, printing and postage need to be considered.

Primary care-based recruitment

Recruitment strategies used during primary care-based recruitment included displaying hard-copy leaflets in general practitioners' offices, general practitioners or health-care providers sending letters on behalf of the research team, health-care providers making telephone calls on behalf of the research team and the research team sending letters or making telephone calls directly to potential participants.

Gaining access to electronic health records was considered a very effective way of identifying potential participants, but not necessarily of reaching participants, as their contact information was sometimes not current. Approaches that were deemed minimally effective included letters about the study sent from health-care providers to potential participants. It was cautioned that primary care-based recruitment can be very expensive (e.g. to access electronic medical records, time/reimbursement of the health-care provider or general practitioners) and technically challenging.

Referral-based recruitment

Referral-based recruitment (i.e. word of mouth) was usually not a method that was explicitly used by participants, but they reported that a modest number of enrolled families in their studies had been recruited through word of mouth (≈ 10–30% of their total sample). One Delphi study participant reported that referral-based recruitment was particularly effective in studies that had multiple waves of recruitment.

Round 2: effectiveness and resource efficiency of recruitment strategies

Table 25 shows the mean ratings of 25 participants for each recruitment strategy suggested in round 1 based on its perceived effectiveness and resource efficiency.

Round 3: ranking recruitment strategies

The 10 highest scoring strategies were ranked by 17 participants in round 3. *Table 26* shows participants' rankings of the top 10 most effective and resource efficient strategies for recruiting families into intervention studies. Findings between the top-rated strategies in round 2 and the final ranking of the top 10 strategies in round 3 were largely similar, apart from 'speaking to parents' and 'attending parent meetings', which were rated higher in the final ranking, and 'word of mouth' and 'social media posting', which were rated lower.

TABLE 26 Delphi participants' ranking of the top 10 recruitment strategies in family-based experimental research

Rank	Recruitment source	Recruitment strategy	Total[a]	Top rank[b]
1	Community	Research team speaking to parents while they are waiting for their children (e.g. while waiting during their child's swimming lesson)	64	4
2	School	Letter sent from head teacher to parents on behalf of research team	77	1
3	School	Research team attending parent meetings (e.g. orientation meetings)	79	2
4	Employer	Study information emailed to employees from within organisation on behalf of the research team (e.g. from human resources)	86	3
5	Primary care	Letters sent from general practitioner or health-care providers on behalf of research team	86	3
6	School	Assembly delivered to parents by research team	96	2
7	Referral	Word of mouth	97	1
8	Primary care	Letters sent directly to potential participants from research team	98	0
9	Media	Social media posts (e.g. Facebook, Twitter, Instagram)	106	1
10	Media	Television (e.g. local news story promoting study)	146	0

a Sum of rankings (lower sum = higher ranking).
b Count of number 1 rankings each strategy received.

Discussion

The aim of this study was to systematically identify effective and resource-efficient strategies for recruiting families into physical activity, sedentary behaviour/screen time, diet and obesity prevention intervention research. Our systematic review showed that, despite being checklist items on the Consolidated Standards of Reporting Trials,[80,226] data related to recruitment strategies and their effectiveness were scarcely reported among the included studies. Moreover, most studies applied similar recruitment strategies, predominantly through schools, despite the known challenges of recruiting families through school settings. Overall, a multisetting and multistrategy approach may be most effective, and the top 10 identified strategies may help researchers allocate limited resources effectively.

The data shown here indicate that researchers conducting family-based intervention studies were unable to attract sufficient expressions of interest, let alone recruit target sample sizes. We extracted very little information from the included studies related to expressions of interest and enrolment, which was similar to another review.[193] In particular, only one study reported which parent (i.e. mother or father) initiated an expression of interest.[78] That study found that 82% of the parents who initiated an expression of interest were mothers; however, once enrolled, fathers were enthusiastic about and benefited from their family's participation in the study. The fact that most parents who expressed interest were mothers may not come as a surprise as, historically, mothers have been more likely than fathers to be their family's social agent and lead on tasks such as family event preparation.[113,227] It may be prudent to consider this in the recruitment of families in two ways. First, recruitment materials that target mothers and their family may be the most efficient method of attracting expressions of interest; and it may also be an important catalyst for the inclusion of more fathers in family-based research. Second, separate recruitment materials that explicitly target fathers may also be useful and should be considered; Morgan and colleagues[52,119,228] have written extensively on recruiting and engaging with fathers in family-based research.

Related to target sample size, we found that only 38% and 56% of the studies included in our Delphi study and review, respectively, recruited their target sample size. Similarly, other reviews of publicly funded trials have found that only 33–50% of included trials recruited 80–100% of their target sample size within their pre-agreed timescale.[145,146,162,229] Few studies reported on reach and representativeness, but, generally, healthy and affluent families were recruited. Only one study, as far as we are aware, described formative work in which families were consulted to inform the development of the recruitment strategy.[78] Although the target sample size was not achieved in that study, public involvement should be encouraged and has been highlighted as a good method for helping with participant recruitment, engagement and retention.[230] It is also possible that the chance of being randomly allocated into a study arm that was not a family's preferred study arm may have negatively affected recruitment;[231] however, no study reported that the randomisation procedure hindered their recruitment.

Analogous to our Delphi study findings, one-third of trials received an extension of some kind because of recruitment-related issues.[146,162] Our findings showed the planned median recruitment duration to be about 10–11 weeks and when recruitment extensions were implemented recruitment was extended for an additional 20 weeks, which would have a substantial impact on a study's timeline. A recent survey on research priorities related to the methodology of trials among directors of the Clinical Trials Units registered with the NIHR Clinical Research Network in the UK identified the recruitment of participants in trials as among the top three priorities for improvement;[232] overall, our findings reinforce these concerns.

The majority of included studies reported the settings from which they recruited participants, and our findings indicate that researchers recruited in about two settings per study, on average. In both our review and our Delphi study, we found that the two most common recruitment settings were schools and the community. Other recruitment settings included primary care settings, employers and social media. Although it was positive to find that recruitment occurred in multiple settings, as recommended by others,[29,30,233] usually it was not possible to discern what proportion of a study's sample had been recruited by setting.

On average, researchers used about three recruitment strategies per study. As in other studies,[233,234] the most commonly used recruitment strategies for family-based recruitment included disseminating study information through leaflets, posters or newsletters. Placing advertisements in local newspapers, using electronic media (e.g. social media platforms, radio, television) and referral-based recruitment (e.g. word-of-mouth) were also popular. Considering that school-based recruitment was the most used recruitment setting, it was unsurprising that this setting had the greatest number of recruitment strategies. Generally, recruitment strategies were only listed in study manuscripts and not described in any great detail, particularly in terms of how and by whom these strategies were actually implemented. However, among the few studies that recruited a sufficient sample size, many included strategies that targeted adults and children and often while they were together.[204,205,207,208] For example, interacting with parents and children at school drop-off/pick-up, giving study presentations at school events (e.g. parent nights) or making announcements from the pulpit are some of the strategies used in the studies that recruited their target sample size. Furthermore, based on the top 10 recommended recruitment strategies identified here, it appears that leveraging familiar, and perhaps trusted, relationships would be beneficial. For example, disseminating study information in correspondence from head teachers, general practitioners and human resources staff and by word of mouth (e.g. through family friends) are strategies that generally assume that potential participants would have at least some familiarity with the person disseminating the information. Even those Delphi participants who were most enthusiastic about recruiting through social media platforms appeared to be trying to build rapport with their followers (i.e. potential participants). Delphi participants recommended that creating regular content on social media platforms or newsletters (e.g. update posts, quarterly newsletter, blogs) would be more beneficial than one-off posts, advertisements or newsletters. The top 10 strategies also include several face-to-face recruitment strategies (e.g. delivering assemblies, attending parent–teacher meetings). Although face-to-face recruitment can be extremely time (and resource) consuming, studies that included this type

of recruitment were more likely to achieve close to their target sample size.[229] In addition, face-to-face recruitment allows for quick rapport-building and gives potential participants the ability to receive responses to their questions about the study in real time, while they are still interested.[235]

Strengths and limitations

As far as we are aware, this study is the first comprehensive assessment of recruitment in family-based intervention research. We conducted a systematic review of the available evidence, and the inclusion of the Delphi procedure provides additional credibility and insight to the findings of the review. In addition, our Delphi procedure had several strengths, including participant blinding, iterative data collection, controlled feedback and purposive sampling. Despite these strengths, there are some limitations that should be considered. We conducted a comprehensive literature search but cannot rule out that we may have missed some publications. The data available related to recruitment duration, reach, expressions of interest, expressions of interest rate and enrolment rate were scant, and details about the implementation of recruitment strategies were often vague. Although we made efforts to contact authors for this information (if available), few authors responded to our e-mails. In addition, we had a low and variable response rate to our Delphi study. Generally, Delphi study participants reported recruitment strategies that they perceived to be effective and resource efficient; therefore, self-report could be considered a limitation. Moreover, the majority of included studies and Delphi study participants were from North America and Europe. Optimum recruitment strategies and setting may differ by context, and we recognise the lack of a global perspective on how best to recruit families and that some recommended recruitment strategies may not be feasible or appropriate everywhere. Last, our review was limited to articles published in English and our Delphi study was also limited to researchers who were competent in English.

Concluding remarks

In conclusion, this study highlights that (1) under-recruitment is a major issue in family-based trials and (2) there is a clear need to improve reporting related to recruitment, for example by following the checklist items in the Consolidated Standards of Reporting Trials.[80,226] Improved reporting on the effectiveness of recruitment will give future researchers the ability to better budget their time and resources, as well as provide them with greater confidence that they will meet their target sample size. Our findings suggest that researchers should employ a multifaceted recruitment approach that targets adults and children and provides potential participants with repeated exposure to study information. This study also provides experts' recommendations for recruitment strategies; future research should investigate the effectiveness of these strategies in different settings. In future, analyses should be conducted to estimate the cost of recruiting families into trials. Future research should explore more sophisticated and innovative research strategies, which may include, for example, consultation with experts in data science, marketing, graphic design or social media.

Chapter 8 Recommendations for research

Recommendations for research have been discussed in the discussion sections of the chapters included in this report. They are summarised here for ease of reference.

- Future research should continue exploring ways of engaging whole families in physical activity. The FRESH project demonstrates that family-based physical activity promotion is feasible and acceptable, but the intervention generally had limited effectiveness. The findings and experiences reported here should be used as building blocks to help researchers identify novel avenues for intervention and evaluation. This may include, for example, capitalising on the active engagement of fathers in the FRESH intervention following sign-up by mothers.
- Recruiting whole families, where any parent could initiate an expression of interest, may be an important catalyst for the inclusion of more fathers in family-based research. It is important that researchers consider this in the recruitment of families in two ways. First, recruitment materials that target mothers and their family may be the most efficient method of attracting expressions of interest. Second, separate recruitment materials that explicitly target fathers should be considered.
- The FRESH study included an extensive outcome assessment protocol. The duration of data collection was broadly in line with a priori estimates, and the acceptability of the duration and number of measures was high among both adults and children. Nevertheless, the duration and number of measures may have acted as a barrier to participation. Researchers and funders should, therefore, carefully balance the scientific need for extensive data collection (driven, for example, by questions around how interventions work, and impacts on important physical health outcomes beyond the target behaviour) with the burden of data collection on participants and the impact it has on recruitment of a representative sample of participants.
- Methodological research is required to support the optimisation of family recruitment methods. This should focus on the cost and effectiveness of diverse recruitment strategies in different settings, and should consider the impact on recruiting hard-to-reach populations.
- Future family-based physical activity promotion research should explore the potential of compensatory effects on children's physical activity behaviours, whereby increased physical activity with family members replaces physical activity otherwise done in other settings and with other co-participants (e.g. friends).
- Device-based assessment of family co-participation in physical activity is feasible and provides objectively-assessed insights into the context of children's and adults' physical activity behaviour. Future research should continue to explore the utility of combined accelerometry and GPS data for understanding the social context of physical activity behaviour, accounting for clustering of physical activity behaviours within families.
- Future family-based physical activity promotion research should consider conducting exploratory cost-effectiveness analyses. This could focus on the cost per quality-adjusted life-year gained and/or the cost of improving an additional unit of MVPA. Future research should also explore how much local authorities or other delivery agents are willing or able to pay for children's physical activity interventions in general and for family-based physical activity in particular.
- Research into family-based physical activity promotion may benefit from focusing intervention efforts on low-active families. These families may have more to gain from intervention engagement and this could represent a more targeted use of scarce resources.
- Researchers are encouraged to provide more detail in relation to family recruitment strategies and their effectiveness in published documents, as included in relevant CONSORT statements. This should include, for example, information on who led on recruitment, the methods and materials used, the time to recruit the target population, reach, expressions of interest and the demographic characteristics of the population recruited. A more detailed account of recruitment efforts and their effectiveness will help researchers to better plan and resource future studies.

- Researchers are encouraged to apply a multisetting and multistrategy approach targeting both adults and children to family recruitment and to test the effectiveness of the top 10 strategies identified in this project in different contexts.
- Future research should consider more sophisticated and innovative recruitment strategies, which may include, for example, consultation with experts in data science, marketing, graphic design or social media.

Chapter 9 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 the 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, whereas change in children's MVPA at long-term follow-up was the prespecified main outcome measure for a potential future full-scale trial. We successfully demonstrated the potential for device-based assessment of family physical activity, which we recommend for use in future studies. We also show that future family-based research would benefit from 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 planning with families, efficient online delivery and capitalising on the involvement of fathers) and recruitment methods should be implemented.

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Publications

Guagliano JM, Brown HE, Coombes E, Haines ES, Hughes C, Jones AP, *et al.* Whole family-based physical activity promotion intervention: the Families Reporting Every Step to Health pilot randomised controlled trial protocol. *BMJ Open* 2019;**9**:e030902.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following favourable review of a research proposal.

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