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# Participatory feasibility study of an intervention and trial aimed at early prevention of obesity: protocol for Healthy Habits Happy Homes Scotland



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## ABSTRACT

*Introduction:*

Prevention of childhood obesity is an important public health objective. This study protocol outlines elements of participatory and co-production approaches utilised to test community involvement in a feasibility study to a) engage key stakeholders b) enable inclusive recruitment of participants and c) facilitate adaptation of study materials from the low cost and highly promising North American Healthy Habits, Happy Homes (4H) home based, pre-school childhood obesity prevention intervention to Scotland. Feasibility of translated version of 4H intervention will be tested in an exploratory randomised trial within a community experiencing health/social inequalities and high levels of deprivation in Dundee, Scotland.

*Methods and Analysis:*

4H for Scotland aims to recruit up to 40 participant families. A range of measures will be collected at baseline and again after 6 months. Intervention consists of 4 monthly visits to family home, adopting a motivational interviewing approach to support healthy family routines or Energy Balance- Related Behaviours (EBRB): bedtime routine / sleep duration; physical activity (active play); screen time; family meals eaten together. Control group will receive standard care healthy lifestyle information. Fidelity to intervention will be assessed using recordings from visits. Feasibility and acceptability of study design and components will be assessed through qualitative interviews and process evaluation of recruitment, retention rates; appropriateness, practicality of methods for obtaining outcome measures; duration, content, mode of delivery and associated costs. Participatory and co-production approach to translation of original intervention could support development of feasibility study design. Process evaluation may offer two future directions; advancement towards a definitive, larger trial or routine practice.

*Ethics and dissemination:*

Study was granted ethical approval by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Results will be disseminated through lay summaries to participants, workshops, publication in peer-reviewed journals and presentation at conferences.

**Trial registration:** ISRCTN13385965

**Article Summary**

*Strengths and limitations of this study*

- Participatory and co-production approach to engage and empower local people in research process within areas of high health and social inequality, poverty or deprivation.
- Testing the feasibility and cultural relevance of a home-based, pre-school childhood obesity prevention intervention which is low-cost and has shown efficacy in the USA.
- Translation of an existing intervention with families living in areas of high health and social inequality, poverty or deprivation.
- Use of both objectively measured Energy Balance Related Behaviours and qualitative approach to evaluate feasibility, with process evaluation on intervention design and components.
- Study may be limited by a short duration and a small number of participant families.

## Introduction

The global public health challenge presented by high levels of childhood obesity has been highlighted relentlessly for a number of years[1,2,3] and many nations now recognise that a whole system approach is required to tackle this complex and multifactorial issue[4,5,6]. Improving Energy Balance Related Behaviours (EBRB) in young children is one important area within a whole system approach because it offers a preventative public health strategy and a focus on early intervention, important not least because of the substantial amount of evidence highlighting that obesity and its health related consequences endure well into and beyond teenage years[7] and into adulthood[8]. The WHO Ending Childhood Obesity Report [2] and Ending Childhood Obesity Implementation Report[3] both emphasised the major opportunities for obesity prevention which exist in early life. Emerging data from Western nations suggest that the 'obesogenic' environment in which we live disproportionately impacts on those growing up and living in areas of deprivation, where there are high levels of health and social inequalities and this data, from across the UK, has shown that there is a persistent gap between those living in affluent versus deprived areas in relation to childhood

obesity[9]. In Scotland, this gap has widened so that, in 2016, obesity risk for children living in the most deprived areas was almost double that of those growing up in the least deprived areas[10,11] . A preventative and early intervention approach to improving EBRB in the pre-school years which targets children growing up in communities experiencing economic disparities is therefore critical to both early prevention and to the reduction of social inequalities in obesity risk.

In an attempt to examine the effectiveness of interventions to reduce socio-economic inequalities in obesity in children, a recent systematic review analysed evidence from 85 papers and found that targeted school-delivered, environmental and empowerment interventions to be the three most effective approaches[12]. Laws et al's systematic review on the impact of interventions to prevent obesity in young children highlighted common features of successful interventions for the pre-school age group (3-5years) including: focus on obesity prevention and household routines, weight screening, and an educational component for parents, although only 7 of the 32 included studies were based in the home and/or community (as opposed to pre-school education or care setting). Of the studies for children of pre-school age, interventions that included parental engagement, behaviour change techniques, skills acquisition, rewards and community based resources were most effective[13]. Although these strategies seem promising, this review also highlights the number of home based, early childhood interventions to be very limited.

The original Healthy Habits, Happy Homes (4H) randomised trial was interested in intervening to improve obesity related risk factors in early childhood. The study involved 121 racial/ethnic minority or low income families from Boston, USA who had a child aged 2-5 years. During the 6 month intervention, families were encouraged and supported to make changes to their EBRB's through telephone calls, text messages and monthly individualised support through motivational coaching with a councillor who met with them in their own home and targeted family routines. The trial demonstrated efficacy as children in the intervention group were found to have decreased BMI-for-age, increased sleep duration and reduced TV viewing on weekend days compared to control group participants who only received mailed health information[14, 15, ]. Efficacy in childhood obesity prevention interventions is scarce and difficult to achieve, and the 4H trial is notable for its evidence of efficacy, possibly because it targets key modifiable EBRBs which operate on both the energy intake and energy expenditure side of the energy balance equation. The 4H intervention is

also of note because it was a relatively low cost/low intensity intervention which might be particularly appropriate for groups at especially high risk of obesity and where households are busy and / or where parent availability is limited by time or other factors.

The desire to implement high quality, evidence based research findings into practice is balanced by the need for public health interventions that are inclusive, acceptable to the target population and are practical to deliver as soon as possible after their feasibility and efficacy has been demonstrated[12]. Therefore, translation of the original 4H study is considered necessary to reflect differences in the context within which it will be implemented. Indeed, recently an adapted version of 4H has been piloted in Guelph, Ontario, with participants in the Canadian version rating their satisfaction with the adapted intervention as high or very high[16]. The basis for this current research is to maximise 4H's cultural relevance for families living in Scottish communities experiencing health and social inequalities and economic deprivation by testing feasibility and acceptability in this setting and with this target group.

Participatory approaches offer a means to involve potential participants in study processes and provide insight into the context[17] in which the research outputs will be applied. Co-production can be drawn upon to ensure that the most important asset; that is the people themselves, are empowered and enabled to be involved[18]. The use of both participatory[19,20] and co-production[21,22] approaches reflect a recognisable shift in the type of research methodologies being used in the design and implementation of public health interventions for routine practice. Elements of each approach were utilised to support translation of the original 4H and for this 4H exploratory trial to be best suited to take place within the North East of Dundee, Scotland. Berge *et al* 2016 outlined the use and value of community based participatory research (CBPR) with 'play it forward' a childhood obesity prevention intervention which was co-created, implemented and evaluated with a community action group over a three year period, and offers a useful illustration of the merits associated with the use of this approach with families[23].

The present mixed methods feasibility study aims to describe how elements of co-production[21] and Community Based Participatory Research (CBPR)[19] were utilised to enable community involvement, in the translation of the adapted Scottish version of 4H and secondly to describe how we plan to test the feasibility and acceptability of the experimental randomised trial of 4H, Scotland in terms of intervention design and components. Factors such as recruitment and retention rates; appropriateness and practicality of methods for

obtaining outcome measures; duration, content and mode of delivery of the intervention and associated costs will be evaluated. If feasibility of the intervention was found to be acceptable, future developments would include either advancement towards a definitive Randomised Controlled Trial or direct testing in routine practice, e.g. as a home –based health service intervention delivered by community health workers.

**Methods and Analysis**

This Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement has been used in the preparation of this protocol.

*Patient and Public Involvement*

Member of the public, including community –based workers and a group of parents, were involved in the research process through participatory methods to support recruitment into the study, co-design of a study website and posters and with assistance in adapting existing intervention materials to be culturally relevant. Ongoing and continued contact with the public group is anticipated throughout the duration of this study and will allow suitable dissemination to workers and community groups and offer insights into the best format for summary results to be shared with participant parents.

*Aim, Design and Setting*

In order to translate the original 4H intervention for use in Scotland and test feasibility, features of both coproduction and CBPR were applied to engage and involve key stakeholders in the research process at a local level. Dundee was chosen as the Scottish test site due to the researcher's existing links with organisations and people and the high levels of socio-economic deprivation within the city. Based on the Scottish Index of Multiple Deprivation (SIMD), over 35 percent of the Dundee population live within the most deprived areas of Scotland (SIMD quintile 1)[24]. In Dundee, more than one quarter of children at primary 1 (age 4 - 5 years) were overweight or obese (i.e. had a BMI >85$^{th}$ percentile (UK 1990), higher than the Scottish average of 22% using measurements from more than 50,000 children as part of the national child health surveillance programme in 2016. Interestingly, children in the most deprived areas of Scotland were almost twice as likely to be obese (12.7%; obesity defined as being above the 95$^{th}$ centile for BMI relative to UK 1990

reference data) compared to those in the least deprived areas (6.6%), demonstrating a marked inequality[25].

An iterative process of dialogue and attendance at three meetings with multiagency workforce practitioners; gatekeepers into the local community took place. The aim was to identify a suitable location for the study and increase awareness of the study in that area. The North East area (made up of 5 neighbourhoods) was subsequently selected. Data from the most recent census demonstrates that 39% of households in the North East area lived in the 15% most income deprived areas in Scotland with figures for 2 of the neighbourhoods at 65% and 96% respectively. Profiles for the North East demonstrate the significant health and social inequalities experienced by the community with 58% of the population within one of the neighbourhoods living in the 15% most health deprived areas of Scotland, a domain that examines mortality rates, hospital stays related to drug and alcohol misuse, illness and prescription rates for certain conditions[24].

Five participatory meetings and workshops with an existing community group within the North East made up of local parent/carers and workers took place. The participatory meetings facilitated the co-production of a suitable study name, acceptable recruitment strategy, development of a study website and adaptation of existing intervention materials for feasibility testing in this exploratory, randomised trial, now called Dundee Family Health Study (DFHS).

*Participant Characteristics*

The study aims to recruit up to 40 participant families (with children aged 2.0-5.5years) who live in the North East area of Dundee City, Scotland. The sample size will be sufficient to measure important feasibility parameters in a sample of families, with pre-school children who live in communities experiencing health and social inequality (including high childhood obesity rates) and economic deprivation. This sample size is similar to a pilot of the 4H study which has recently taken place in the city of Guelph, Canada where 44 families were involved[16].

*Recruitment, Consent and Randomisation*

Informed by engagement with and insights offered by the community group and multiagency workforce recruitment will be inclusive; all families with a child aged 2-5.5 years, who live in the North East postcode area, will be eligible to sign-up and enrol in the study.

Recruitment will be through promotion and marketing of a co-designed study website, social media, leaflets, fliers and word of mouth. Interested families will make contact with the researcher via the website or by phone call, text message or email, with this contact initiating a home visit in order to obtain consent. This process offers an alternative recruitment methodology as compared to the original 4H which identified eligible families from 4 health centres serving racial/ethnic minorities and low income families. Families will be offered supermarket vouchers (£20) as an incentive for enrolling in the study and families who have provided written consent will be allocated a study code (a number assigned in sequential order as consent is obtained) and then have baseline measures taken. Participant families will then be randomised to receive either the control or intervention arm of the study. Randomisation will occur following completion of baseline data collection, and will be conducted using a sealed envelope system undertaken by a blinded independent researcher. The study researcher (JG) will be blinded to group randomisation until an envelope with the number corresponding to the study code is opened which identifies the family to be in either the intervention or control group.

An overview of the activities associated with each stage of the study process are outlined in DFHS logic model, adapted from NHS Health Scotland[26] shown in (Figure 1).

*Outcome Measures and Data Collection*

At baseline, objective measurements of EBRB's will include: time spent in physical activity, sedentary behaviour and sleep assessed using an activPAL accelerometer (PAL technologies, Glasgow, UK). Body Mass Index and BMI –z score will be determined through height (measured using rigid rule with T piece or stadiometer, Marsden Leicester height measure) and weight (measure using class III electronic scales, seca 875 model) and body composition (body fatness and lean body mass) estimated via supine arm-to-leg bioelectrical-impedence analysis (BIA) using Bodystat 1500. A parent/carer health questionnaire will offer subjective insight into family background, frequency of family meals eaten together, screen time, time spent being physically active, sleep routine and duration. The questionnaire was suitably adapted and shortened from one used in ToyBox, a multicomponent, evidence-and theory-based, family-involved intervention for pre-school and homes implemented across six European countries between 2012-2013[27, 28]. Health-related quality of life will be determined using PedsQL™ parent proxy questionnaire[29]. For reasons of pragmatism and consistency,

the study researcher will carry out all outcome measures at baseline and follow up. The researcher is experienced and trained in obtaining height, weight and questionnaire data from pre-school children and their families. Training in the use of activPAL and Bodystat 1500 will be undertaken. All measures will be repeated at 6month follow up. The change in outcome measures from baseline to follow-up between the intervention and control will be analysed using repeated measured two way anovas or other appropriate statistical tests depending on the distribution of the data.

*Intervention*

DFHS will balance the insights offered via participatory and co-production with adequate representation of the general principles and procedures of the original 4H intervention[15,16]. Adaptations of intervention components will be based on pragmatism, researcher (JG) experience and judgement in delivering interventions with families in this context. One researcher (JG) will deliver DFHS which provides both consistency and expertise in the approach, having extensive experience of delivering obesity treatment and prevention interventions with pre-school children and families using a Motivational Interviewing approach and having been trained on the specific 4H intervention from the original 4H researchers.

Families randomised to the intervention group will receive four visits to the family home over the course of six months with further contact every two weeks via SMS. The visits will use a motivational interviewing approach to support the families to make positive lifestyle changes linked to four EBRBs of sleep, physical activity, screen time and family meal routine. Families randomised to the control group will receive general healthy lifestyle information linked to sleep routine, family meals, physical activity and screen time each month mailed or emailed. This information includes materials issued routinely by primary care early years health workers in Scotland.

*Feasibility Study Process and Intervention Fidelity*

A summary of the intervention trial process is outlined in (Figure 2).

Intervention fidelity of Motivational Interviewing and use of behaviour change approach during intervention home visits will be assessed. For each participant family, documentation will enable the researcher to reflect on the appropriate use of and application of the behaviour change tools used in the home visits. A sample of home visits will be audio recorded and

analysed by a practitioner experienced and trained in the use of motivational interviewing skills and a behaviour change approach and who is independent to the research. A pre-defined checklist adapted from the Scottish Childhood Overweight Treatment Trial (SCOTT)[30] will be used. In addition the number of contacts made with participant families and number of visits attempted versus actual number of intervention visits completed will be carried out by reviewing researcher records and notes.

*Process Evaluation*

As this is a feasibility study, parameters such as recruitment and retention rates; appropriateness and practicality of methods for obtaining outcome measures; duration, content and mode of delivery of the intervention and associated costs will be evaluated using process evaluation. Intervention acceptability will be evaluated through intervention satisfaction questionnaires and semi-structured qualitative interviews conducted with a sample of parents post intervention. Interviews will take place with both intervention and control group families and will focus on participants experience of obtaining outcome measures, interaction with the intervention and study materials; barriers and facilitators to delivery; pro's, con's and areas for improvement. Insights on intended and unintended outcomes will also be achieved in this way by using open ended questions to understand a wide range of possible outcomes such as changes to family routines or behaviours outwith those linked to EBRB's. Interviews will be conducted by an interviewer either in the family home or by telephone with an interviewer who has experience of research interviewing and who is independent of the research. Each interview will be transcribed and analysis based on the Framework method of content matrix data analysis[30].

Recruitment, retention rates and cost of the intervention will be analysed. Cost parameters are based on an RCT of an obesity treatment intervention carried out in Scotland[31] and will include:

- Time spent by researcher in the lead up to the feasibility trial (engaging, participatory and co-production)
- Time spent by researcher / public health worker promoting and marketing the study
- Time spent by the researcher / public health worker arranging and scheduling home visits

- Time spent by the researcher / public health worker delivering intervention (including travel time)
- Training and salary cost for researcher / public health worker

The MRC guidance on process evaluation of complex interventions will support this assessment[32].

## Discussion

This paper provides a description of a participatory and co-production approach and protocol for a exploratory randomised controlled trial of a pre-school, home-based obesity prevention intervention and translation of the original 4H study for use in a Scottish setting. It is recognised that engaging people in delivering solutions is necessary for the future of public health interventions[3,4] and the importance of empowering interventions such as this has recently been highlighted[12]. Whilst a CBPR approach has been applied to childhood obesity prevention interventions before[23], none to date appear to have been carried out in the UK with families for the pre-school age group (2-5years), in the home environment.

A systematic review[13] recently highlighted that very few (less than 10%) high quality studies had looked at interventions to prevent obesity or improve obesity related behaviours in children from socioeconomically disadvantaged families and that, amongst other things, future studies should therefore develop and evaluate interventions with these groups, at particularly high risk of obesity. The review also recommended that objective measures should be used wherever possible and that an inclusive recruitment method could be helpful in making results more generalizable[13]. Hence the intention to do so in the DFHS is a strength and has the potential to reduce the marked socioeconomic inequalities in childhood obesity risk in the UK. An added strength of this study lies in the efficiency of translating an existing intervention which has demonstrated efficacy in a disadvantaged community, and which has a theoretical and empirical evidence base rather than developing a completely new intervention. Furthermore, a focus on early years, communities experiencing high levels of health and social inequality and a participatory approach is likely to be appealing to those working in routine practice. Therefore, the feasibility and acceptability of DFHS design and components will be tested in the hope that it is culturally relevant and suitable to inform either a larger scale trial in keeping with the MRC Framework on developing and evaluating complex interventions[33,34] or for direct testing in routine practice.

## Ethics and Dissemination

This study was granted ethical approval by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Any amendments to the study protocol will be submitted for ethical approval prior to implementation. Informed consent will be obtained from all participants via parental consent forms. Verbal agreement will be sought from children prior to their enrolment in the study. Findings of the study will be disseminated via summary reports/presentations/workshops to participant families, local people and workers and to public health staff and academics through publication in peer-reviewed journals and presentation at meetings and conferences.

*Data Management, Monitoring and Analysis*

This study has a data management plan. All data collection and storage procedures will be GDPR compliant. Only the immediate research team will have access to raw data. A unique identifier code will be assigned to each participant family and researcher notes will be held in locked filing cabinets and transported in secure backpacks. Data will be stored on the University of Strathclyde's centralised secure data storage system where it will be stored for a maximum of 5 years before being securely destroyed. Data from interviews will be deleted immediately from voice recorders after the transcription, with pseudonyms used in all reports in place of participant's names. Data will be available in anonymised format from the University of Strathclyde institutional repository.

*Trial status*

Study status as of 28/10/2018: Ethical approval has been granted for the study. All project funding is secured, and engagement, participatory and co-production approach is underway. Recruitment of participant families will be completed by October 2018. Baseline data collection will be completed by October 2018. The intervention will be ongoing until March 2019. Follow-up data collection will be complete by March 2019. There are no other publication s for DFHS, all analysis and write up will follow this protocol paper.

*Safety procedures*

Departmental risk assessment and lone working plans and procedures will be followed. No high-risk activities were identified by risk assessment during ethics application.

*Contributor ship Statement*

The principal investigators (AH, AMG, JJR) are responsible for overseeing the study. The study manager (JG) is responsible for liaising with study participants, co-ordinating data collection, and data management/storage. AH, AMG , JH, ET and JJR will advise on specific aspects of the study including recruitment, data analysis and process evaluation procedures. Any changes to the study protocol will be discussed before the trial registry is updated.

*Competing interests*

The authors have no competing interests.

*Funding Statement*

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*Data Sharing Statement*

The qualitative and quantitative data collected as part of this feasibility study will be stored anonymously on the University of Strathclyde institutional repository.

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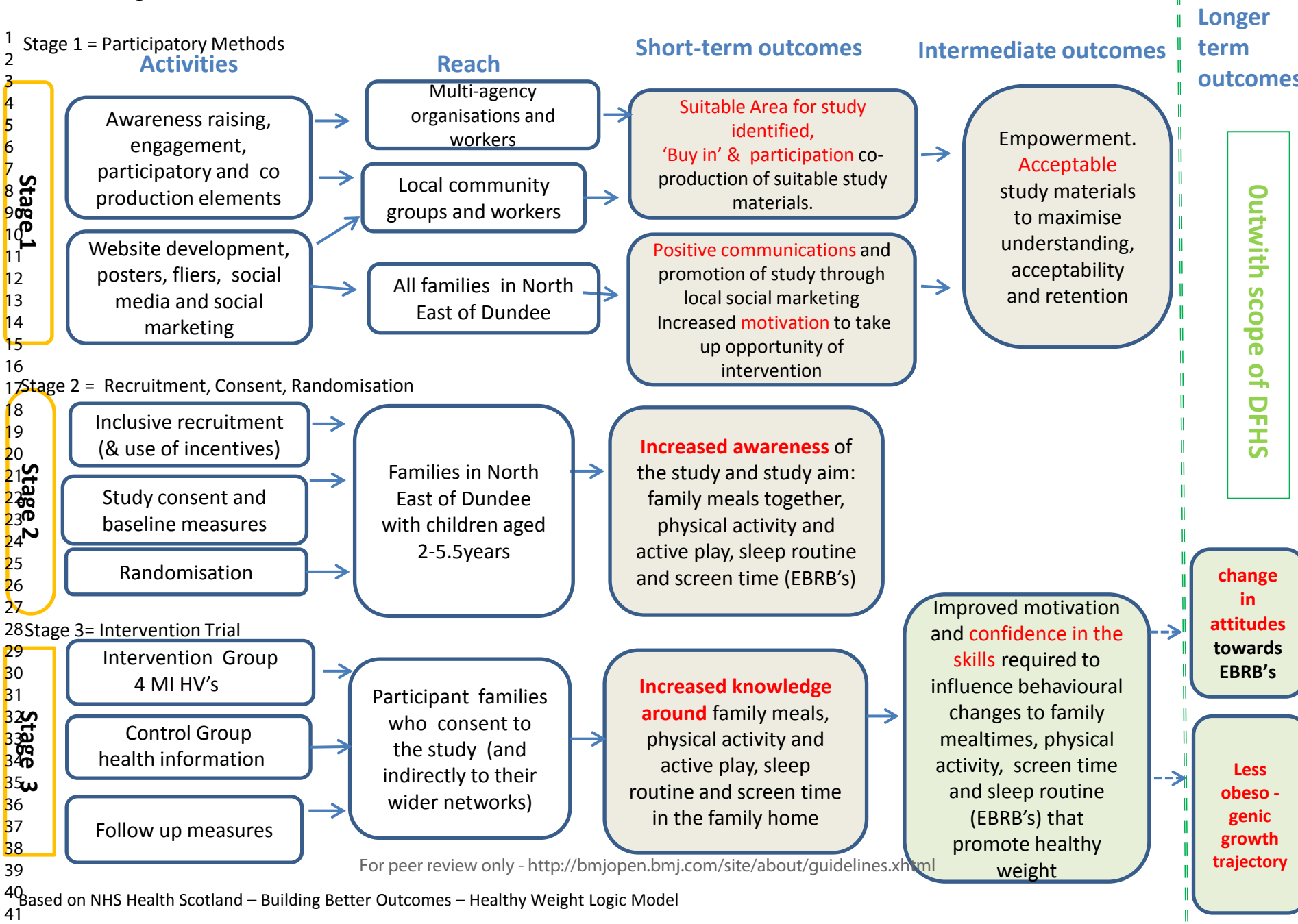
**Figure legends**

Figure 1. DFHS Logic Model

Figure 2. Feasibility Study Process

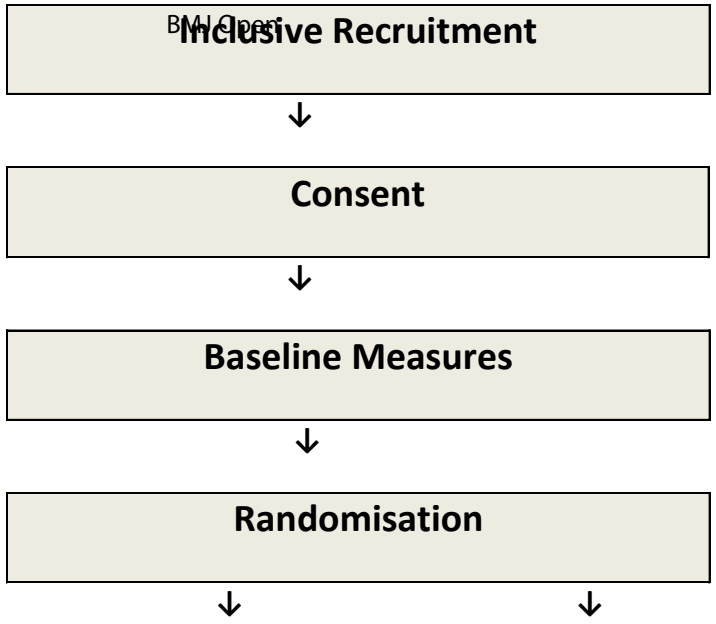
# DFHS Logic Model



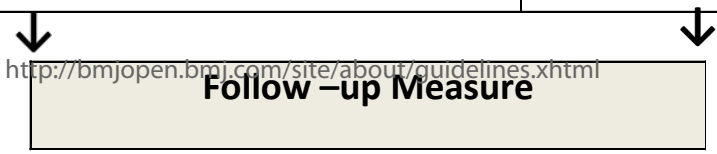



Based on NHS Health Scotland – Building Better Outcomes – Healthy Weight Logic Model

Figure 2 Feasibility Study Process




| INTERVENTION | | | | | | | CONTROL | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Month 1 | Week 6 | Month 2 | Week 10 | Month 3 | Week 14 | Month 4 | Month 1 | Month 2 | Month 3 | Month 4 |
| MI plus standard information issued at home visit | SMS or email | MI plus standard information issued at Home visit | SMS or email | MI plus standard information issued at home visit | SMS or email | MI plus standard information issued at home visit | Sedentary Behaviour / Screen Time Standard information | Healthy Eating standard information | Sleep Routine & duration standard information | Physical Activity & Active Play standard information |
| A range of behavioural tools used such as goal setting, self monitoring and individualised MI | | | | | | | Sent or emailed | Sent or emailed | Sent or emailed | Sent or emailed |



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 1 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | 1 |
| Protocol version | 3 | Date and version identifier | 12 |
| Funding | 4 | Sources and types of financial, material, and other support | 13 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1, 12 |
| | 5b | Name and contact information for the trial sponsor | 13 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 13 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | na |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | ___5_____ |
| | 6b | Explanation for choice of comparators | __8_____ |
| Objectives | 7 | Specific objectives or hypotheses | ___5_____ |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | _8,9, fig 2___ |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | __6,7_____ |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | __na_____ |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | _7,8,9,fig 2_____ |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | ____na_____ |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | ____na_____ |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | __12,13_____ |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | _8,9,10,fig 1__ |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | __fig 1, fig 2_____ |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 7 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 fig 1 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 6-10 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 6-10 |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 12 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 9 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 9 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 9 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 12 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 12 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 12-13 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | na |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 11-12 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 11-12 |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | _____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ____na_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _____y_____ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _____y_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | _____y_____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _____na____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____y_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____y_____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____na_____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | ____na_____ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____na_____ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

# Protocol for Healthy Habits Happy Homes Scotland. Feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity.

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| Primary Subject Heading: | Public health |
| Secondary Subject Heading: | Public health |
| Keywords: | feasibility, pre-school, inequalities, obesity prevention, Energy Balance Related Behaviours |
| | |

**Title:** Protocol for Healthy Habits Happy Homes Scotland. Feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity.

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## ABSTRACT

*Introduction:*

Prevention of childhood obesity is an important public health objective. Promoting healthful Energy Balance Related Behaviours (EBRB's) in the early years should be a key focus. In Scotland, 1 in 5 children are overweight or obese by age 5 years, with levels highest in deprived areas. This study protocol outlines the stages of a feasibility study to translate the highly promising North American Healthy Habits, Happy Homes (4H) home based, pre-school childhood obesity prevention intervention to Scotland (4H Scotland). Firstly, elements of participatory and co-production approaches utilised to a) engage key stakeholders b) enable inclusive recruitment of participants c) adapt original study materials. Secondly, 4H Scotland intervention will be tested within a community experiencing health/social inequalities and high levels of deprivation in Dundee, Scotland.

*Methods and Analysis:*

4H Scotland aims to recruit up to 40 families. Anthropometry, objective and subjective measures of EBRB's will be collected at baseline and at 6 months. The intervention consists of monthly visits to family home, using motivational interviewing and SMS to support healthful EBRB's: sleep duration; physical activity (active play); screen time; family meals. The Control Group will receive standard healthy lifestyle information. Fidelity to intervention will be assessed using recordings of intervention visits. Feasibility and acceptability of study design components will be assessed through qualitative interviews and process evaluation of recruitment, retention rates; appropriateness, practicality of obtaining outcome measures; intervention duration, content, mode of delivery and associated costs. Adaptation through participatory and co-production will support development of 4H Scotland. Process evaluation offers two future directions; advancement towards a definitive, larger trial or routine practice.

*Ethics and dissemination:*

Study was granted ethical approval by University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Results will be disseminated through lay summaries workshops, peer-reviewed publications and conference presentations.

**Trial registration:** ISRCTN13385965

## Article Summary

*Strengths and limitations of this study*

- Engaging and empowering local people in the research process within areas of high health and social inequality, poverty or deprivation.
- Feasibility testing of a low cost, culturally relevant a home-based, pre-school childhood obesity prevention intervention.
- Objectively measured Energy Balance Related Behaviours and qualitative approach utilised.
- Generalisability of study may be limited by a short duration and a small number of participant families.

## Introduction

The global public health challenge presented by high levels of childhood obesity has been highlighted relentlessly for a number of years[1,2,3] and many nations now recognise that a whole system approach is required to tackle this complex and multifactorial issue[4,5,6]. Improving Energy Balance Related Behaviours (EBRB) in young children is one important area within a whole system approach because it offers a preventative public health strategy and a focus on early intervention, important not least because of the substantial amount of evidence highlighting that obesity and its health related consequences endure well into and beyond teenage years[7] and into adulthood[8]. The WHO Ending Childhood Obesity Report [2] and Ending Childhood Obesity Implementation Report[3] both emphasised the major opportunities for obesity prevention which exist in early life. Emerging data from Western nations suggest that the 'obesogenic' environment [9] in which we live disproportionately impacts on those growing up and living in areas where there is health and social inequalities. Data from England, have also shown a persistent gap between those living in affluent versus deprived areas in relation to childhood obesity[10]. In Scotland, this gap has widened so that, in 2016, obesity risk for children living in the most deprived areas was almost double that of those growing up in the least deprived areas[11,12]. A preventative and early intervention approach to improving EBRB in the pre-school years which targets children growing up in communities experiencing economic disparities is therefore critical to both early prevention and to the reduction of social inequalities in obesity risk.

A recent systematic review of 85 papers found that targeted school-delivered, environmental and empowerment interventions to be the three most effective approaches in reducing socio-economic inequalities in obesity[13]. Laws *et al's* systematic review on the impact of interventions to prevent obesity in young children highlighted common features of successful interventions. For the pre-school age group (3-5years) focus on obesity prevention and household routines, weight screening, and an educational component for parents were promising, although only 7 of the 32 included studies were based in the home and/or community (as opposed to pre-school education or care setting). Interventions that included behaviour change techniques, skills acquisition such as cooking skills, rewards and community based resources were most effective. Elements deemed to be critical were those that were culturally appropriate and included parental engagement [14]. Although these strategies seem promising, this review also highlighted the number of home based, early childhood interventions was very limited.

The original 4H randomised trial was interested in intervening to improve obesity related risk factors in early childhood. The study involved 121 racial/ethnic minority or low income families from Boston, USA who had a child aged 2-5 years. During the 6 month intervention, families were encouraged and supported to make changes to 4 EBRB's (adequate sleep, family meals, limiting TV time and removing TV from bedroom) through telephone calls, text messages and monthly individualised support through motivational coaching with a counsellor who met with them in their own home and targeted family routines. The trial demonstrated efficacy as children in the intervention group had decreased BMI-for-age, increased sleep duration and reduced TV viewing on weekend days compared to controls[15, 16]. Efficacy in childhood obesity prevention interventions is scarce and difficult to achieve. The 4H trial is therefore notable, possibly because it targets key modifiable EBRBs which operate on both the energy intake and energy expenditure side of the energy balance equation. The 4H intervention was a relatively low cost/low intensity intervention which might be particularly appropriate for groups at especially high risk of obesity and where households are busy and / or where parent availability is limited by time or other factors.

The desire to implement high quality, evidence based research findings into practice is balanced by the need for public health interventions that are inclusive, acceptable to the target population and are practical to deliver in a timely manner after feasibility has been

demonstrated[12]. Therefore, adaptation of the original 4H study is considered necessary to reflect differences in the context within which it will be implemented. Indeed, recently an adapted version of 4H has been piloted in Guelph, Ontario, with participants in the Canadian version rating their satisfaction with the adapted intervention as high or very high[17].

Thus, the current research uses participatory approaches (i.e. co-production and Community Based Participatory Research) to adapt the original 4H study in order to maximise 4H's cultural relevance for families with pre-school children living in a Scottish community experiencing health and social inequalities and economic deprivation

Participatory approaches offer a means to involve potential participants in study processes and provide insight into the context[18] in which the research outputs will be applied. Co-production can be drawn upon to ensure that the most important asset; that is the people themselves, are empowered and enabled to be involved[19]. Features of both co-production and Community Based Participatory Research (CBPR) [20] were applied to engage and involve key stakeholders in the research process at a local level. A logic model (figure 1), adapted from NHS Health Scotland[21], was developed to provide an overview of the activities at 3 key stages; engagement of key stakeholders, enablement of inclusive recruitment of participants and adapting original study materials to ensure culturally relevant implementation of 4H Scotland within the North East of Dundee, Scotland.

The present mixed methods feasibility study aims to 1) describe the participatory process and methods utilised in stage 1 and 2 of the 4H Logic Model 2) describe elements of co-production and Community Based Participatory Research (CBPR) that were utilised to enable adaptations of the original 4H study 3) outline how the feasibility and acceptability of 4H Scotland will be tested and evaluated.

## Methods and Analysis

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement has been used in the preparation of this protocol.

### *Patient and Public Involvement*

Dundee was chosen as test site of 4H Scotland due to the researcher's existing links with organisations and people and the high levels of socio-economic deprivation within the city.

Based on the Scottish Index of Multiple Deprivation (SIMD), over 35 percent of the Dundee population live within the most deprived areas of Scotland (SIMD quintile 1)[22]. In Dundee, more than one quarter of children at primary 1 (age 4 - 5 years) were overweight or obese (i.e. had a BMI >85$^{th}$ percentile (UK 1990), higher than the Scottish average of 22% using measurements from more than 50,000 children as part of the national child health surveillance programme in 2016 [23].

Participatory approaches (CBPR and co-production) were used to adapt the original 4H study as they offer a useful approach when considering the cultural relevance of an intervention. CBPR promotes equitable involvement of members of the community, local organisations and researchers supports improved knowledge and understanding through 9 key principles [20]. Co-production is underpinned by key values of equal and reciprocal relationships, being assets based and 'doing with, not to' [19] which reflects the ethos of this study from the outset.

As shown in the logic model, at stage 1, these participatory approaches were utilised to support recruitment into the study, co-production of a study website and posters and adapting existing intervention materials to be culturally relevant. Ongoing and continued contact with a local community action group made up of members of the public, community-based workers and parents is anticipated throughout stage 2 and will allow suitable dissemination of study outcomes to workers and community groups and offer insights into the best format for results to be shared with participants following the intervention trial at stage 3.

*Design and Setting*

An iterative process of dialogue, correspondence via email and attendance at three meetings with multiagency workforce practitioners; gatekeepers into the local community took place. Meetings were held in community buildings with representatives from health and social care, education, third sector as members of an existing city wide, early years planning group. The aim was to identify a suitable location within Dundee for the study to take place and allow awareness raising and recruitment in that area.

Round table discussions at one planning group meeting identified the North East area as best suited (made up of 5 neighbourhoods) based on level of highest deprivation, perceived need for such an intervention, and absence of similar focussed work taking place. Data from the most recent census demonstrates that 39% of households in this area lived in the 15% most income deprived areas in Scotland with figures for 2 of the neighbourhoods at 65% and 96%

respectively. Profiles for the North East demonstrate the significant health and social inequalities experienced by the community with 58% of the population within one of the neighbourhoods living in the 15% most health deprived areas of Scotland, a domain that includes mortality rates, hospital stays related to drug and alcohol misuse, illness and prescription rates for certain conditions[22]

The researcher attended meetings with multiagency workforce practitioners who signposted to relevant community workers and a community action parent group who became integral to stage 1 and 2 of the study. Five participatory meetings and workshops with this local community action group (described in patient and public involvement section) took place in a health hub situated in the North East area. The participatory meetings facilitated the co-production of a suitable study name for 4H Scotland, acceptable recruitment strategy, development of a study website and adaptation of existing intervention materials for feasibility testing. Outcomes and results will be described in a future process evaluation.

*Participant Characteristics*

4H Scotland aims to recruit up to 40 participant families (with children aged 2.0-5.5years). The sample size will be sufficient to measure important feasibility parameters in a sample of families, with pre-school children who live in communities experiencing health and social inequality (including high childhood obesity rates) and economic deprivation. This sample size is similar to a pilot of the 4H study which has recently taken place in the city of Guelph, Canada where 44 families were involved[17] Data generated in this feasibility study could contribute to sample size and power calculations for subsequent definitive trials or offer insight for application in routine practice.

*Recruitment, Consent and Randomisation*

Informed by engagement and insights offered by the community group and multiagency workforce, recruitment will be inclusive; all families with a child aged 2-5.5 years, who live in the North East postcode area, will be eligible to sign-up and enrol in the study. Recruitment will be through promotion and marketing of a co-designed study website, social media, leaflets, fliers and word of mouth. Interested families will make contact with the researcher via the website or by phone call, text message or email, with this contact initiating a home visit to obtain consent. Families will be offered supermarket vouchers (£20) as an incentive for enrolling in the study and families who have provided written consent will be

allocated a study code (a number assigned in sequential order as consent is obtained) and then have baseline measures taken. Participant families will then be randomised to receive either the control or intervention arm. Randomisation will occur following completion of baseline data collection, using a sealed envelope system undertaken by a blinded independent researcher. The study researcher (JG) will be blinded to group randomisation until an envelope with the number corresponding to the study code is opened which identifies the family to be in either the intervention or control group.

*Outcome Measures and Data Collection*

Data collection will relate to outcomes linked to the adaptations made to original 4H study materials, website development and means of promoting the study that came from the participatory and co-production approach, as shown in stage 1 of the logic model. Stage 2 will have quantitative measure of recruitment and retention rates and a description of researcher views on approach to recruitment. The primary outcome measure related to the intervention trial at Stage 3 will be linked to acceptability and practicability of 4H Scotland. In order to understand more about the experiences of participants and to gain insight into the acceptability, a qualitative approach will be used whereby a sample of participants will be interviewed post intervention using a semi-structured interview. Interviews will be conducted with 50% of parents from both intervention and control group. Interviews will take place post intervention and will focus on participants experience of obtaining outcome measures, interaction with the intervention and study materials; barriers and facilitators to intervention delivery including duration, content and mode; pro's, con's and areas for improvement.

Insights on intended and unintended outcomes will also be achieved in this way by using open ended questions to understand a wide range of possible outcomes such as changes to family routines or behaviours outwith those linked to EBRB's. Interviews will be conducted by an experienced interviewer, independent of the research, either in the family home or by telephone. Each interview will be transcribed and analysis by the researcher using the Framework method of content matrix data analysis[24].

Quantitative methods will measure the number of contacts made with participant families, number of visits attempted versus actual number of intervention visits completed using researcher records and notes.

A range of secondary outcome measures related to EBRB's and BMI z-score will also be collected:

1. Child physical activity, sedentary behaviour and sleep: measured using the activPAL™ accelerometer at baseline and 6months.

2. Child screen time; measured at baseline and 6months (described below).

3. Family eating meals together: measured at baseline and 6months (described below).

4. Child BMI z-score: (height and weight measured at baseline and 6months) height (measured using rigid rule with T piece or stadiometer, Marsden Leicester height measure) and weight (measure using class III electronic scales, seca 875 model).

5. Child Health related Quality of Life (HRQOl) measured at baseline and 6months (determined using PedsQL™ parent proxy questionnaire)[25].

6. Child Body composition (bio-electrical impedance): measured at baseline and 6months. (body fatness and lean body mass) estimated via supine arm-to-leg bioelectrical-impedence analysis (BIA) using Bodystat 1500.

For reasons of pragmatism and consistency, the study researcher will carry out all outcome measures at baseline and follow up. The researcher is experienced in obtaining height, weight and questionnaire data from pre-school children and their families. Training in the use of activPAL and Bodystat 1500 will be undertaken. A parent/carer health questionnaire, adapted and shortened from one validated in a pre-school study across six European countries between 2012-2013 [26,27] will offer subjective insight into family background, frequency of family meals eaten together, screen time, time spent being physically active, sleep routine and duration.

Any changes in secondary outcome measures from baseline to follow-up between the intervention and control will be analysed using repeated measured two way anovas or other appropriate statistical tests depending on the distribution of the data. An estimate of associated costs related to the intervention could also be calculated. Further detail on assessment of outcome measures and cost will be described later in a process evaluation.

*Intervention*

4H Scotland will balance the insights offered via participatory and co-production in stage 1 and 2 with adequate representation of the general principles and procedures of the original 4H intervention[16, 17]. Adaptations of intervention components will be based on pragmatism, researcher (JG) experience and judgement in delivering interventions with families in this context. For example it will offer an alternative, inclusive recruitment methodology as compared to the original 4H which identified eligible families only from health centres. One researcher (JG) will deliver 4H Scotland which provides both consistency and expertise in the approach, having extensive experience of delivering obesity treatment and prevention interventions with pre-school children and families using a Motivational Interviewing (MI) approach and having been trained on the specific 4H intervention from the original 4H researchers.

Families randomised to the intervention group will receive monthly visits to the home over six months plus contact every two weeks via SMS. Families will be supported to make positive lifestyle changes towards meeting or exceeding UK guidelines or recommendations linked to four EBRBs of sleep, physical activity, screen time and family meal routine. The control group will receive general healthy lifestyle information linked to sleep routine, family meals, physical activity and screen time each month mailed or emailed. This information includes materials issued routinely by primary care early years health workers in Scotland.

*Feasibility Study Process and Intervention Fidelity*

A summary of the intervention trial process is outlined in (Figure 2).

Intervention fidelity to MI and behaviour change approach at home visits will be assessed. Documentation will enable the researcher to reflect on the appropriate use of and application of behaviour change tools used. A sample of home visits will be audio recorded and analysed by a practitioner experienced and trained in the use of motivational interviewing skills who is independent to the research. A pre-defined checklist adapted from the Scottish Childhood Overweight Treatment Trial (SCOTT) [28] will evaluate that the intervention was delivered within the spirit of MI.

*Process Evaluation*

As this is a feasibility study, parameters linked to the activities described in stage 1-3 of the logic model shown in Figure 1 and previously described in 'outcome measures and data collection section' will be assessed using process evaluation, supported by the MRC guidance on process evaluation of complex interventions[29]. Process evaluation of stage 1-2 will offer detail related to the participatory, co-production approach and adaptations that were made to the original 4H study design, procedures and methods. Stage 3 process evaluation will examine key features of the implementation of 4H Scotland within the North East of Dundee by considering the context, practicability and acceptability of delivery in this setting.

Cost parameters could also be analysed and would be based on those used in an RCT of an obesity treatment intervention carried out in Scotland [28] and would include: researcher time in lead up, promotion and delivery of intervention; travel; training.

**Discussion**

This paper uses a logic model to illustrate elements of participatory and co-production approaches (stage 1 and 2) utilised when adapting a pre-school, home-based obesity prevention intervention that originated in North America to a Scottish Setting. It also outlines the protocol for feasibility testing of the new 4H Scotland randomised controlled trial within Dundee City (stage 3).

It is recognised that engaging people in delivering solutions is necessary for the future of public health interventions[3, 4] and the importance of empowering interventions such as this has recently been highlighted[12]. This current study empowers through involving local people in the research process and using a MI approach to facilitate behaviour change. Berge *et al* 2016 outlined the use and value of community based participatory research (CBPR) with 'play it forward' a childhood obesity prevention intervention. The intervention was co-created, implemented and evaluated with a community action group over a three year period, and offers a useful illustration of the merits of using this type of approach with families[30]. Whilst this demonstrates that CBPR has been applied to childhood obesity prevention interventions before, it was not carried out in the UK with families for the pre-school age group (2-5years), in the home environment. Consideration must also be given to the potential barriers in utilising this approach namely major challenges related to extra cost and resource (time) required, building trust with the community, equitable participation, differing communication style and conflicting goals [20,31]. It is expected that many of these issues will be drawn out and reflected on as part of the later process evaluation of the current study.

A systematic review recently highlighted that very few (less than 10%) high quality studies had looked at interventions to prevent obesity or improve obesity related behaviours in children from socioeconomically disadvantaged families and that, amongst other things, future studies should therefore develop and evaluate interventions with these groups, at particularly high risk of obesity. The review also recommended that objective measures should be used wherever possible and that an inclusive recruitment method could be helpful in making results more generalizable[13]. Hence the intention to do so in 4H Scotland is a strength and has the potential to reduce the marked socioeconomic inequalities in childhood obesity risk in the UK.

An added strength of this study lies in the efficiency of adapting an existing intervention which has demonstrated efficacy in a disadvantaged community, and which has a theoretical and empirical evidence base, rather than developing a completely new intervention. Furthermore, a focus on early years, communities experiencing high levels of health and social inequality and a participatory approach is likely to be appealing to those working in routine practice. Therefore, the feasibility and acceptability of 4H Scotland design and components will be tested and assessed through process evaluation in the hope that it is culturally relevant and suitable to inform either a larger scale trial in keeping with the MRC Framework on developing and evaluating complex interventions[32, 33] or for direct testing in routine practice[34].

## Ethics and Dissemination

This study was granted ethical approval by the University of Strathclyde's School of Psychological Sciences and Health Ethics Committee. Any amendments to the study protocol will be submitted for ethical approval prior to implementation. Informed consent will be obtained from all participants via parental consent forms. Verbal agreement will be sought from children prior to their enrolment in the study. Findings of the study will be disseminated via summary reports/presentations/workshops to participant families, local people and workers and to public health staff and academics through publication in peer-reviewed journals and presentation at meetings and conferences.

### *Data Management, Monitoring and Analysis*

This study has a data management plan. All data collection and storage procedures will be GDPR compliant. Only the immediate research team will have access to raw data. A unique

identifier code will be assigned to each participant family and notes will be held in locked filing cabinets and transported in secure backpacks. Data will be stored on the University of Strathclyde's centralised secure data storage system where it will be stored for a maximum of 5 years before being securely destroyed. Data from interviews will be deleted immediately after the transcription, with pseudonyms used in all reports in place of participant's names. Anonymised data will be available from the University of Strathclyde institutional repository.

*Trial status*

Study status as of 28/10/2018: Ethical approval has been granted. All project funding is secured, engagement, participatory and co-production approach is underway. Recruitment of participant families and baseline data collection to be completed by October 2018. The intervention will be ongoing until March 2019. Qualitative and follow-up data collection to be complete by April 2019. Analysis and write up will follow this protocol paper.

*Safety procedures*

Departmental risk assessment and lone working plans and procedures will be followed. No high-risk activities were identified by risk assessment during ethics application.

*Contributor ship Statement*

The principal investigators (AH, AMG, JJR) are responsible for overseeing the study. The study manager (JG) is responsible for liaising with study participants, co-ordinating data collection, and data management/storage. AH, AMG, JH, ET and JJR will advise on specific aspects of the study including recruitment, data analysis and process evaluation procedures. Any changes to the study protocol will be discussed before the trial registry is updated.

*Competing interests*

The authors have no competing interests.

*Funding Statement*

This work was supported by The Hannah Dairy Research Foundation (HDRF)

*Data Sharing Statement*

Data collected as part of this feasibility study will be stored anonymously on the University of Strathclyde institutional repository.

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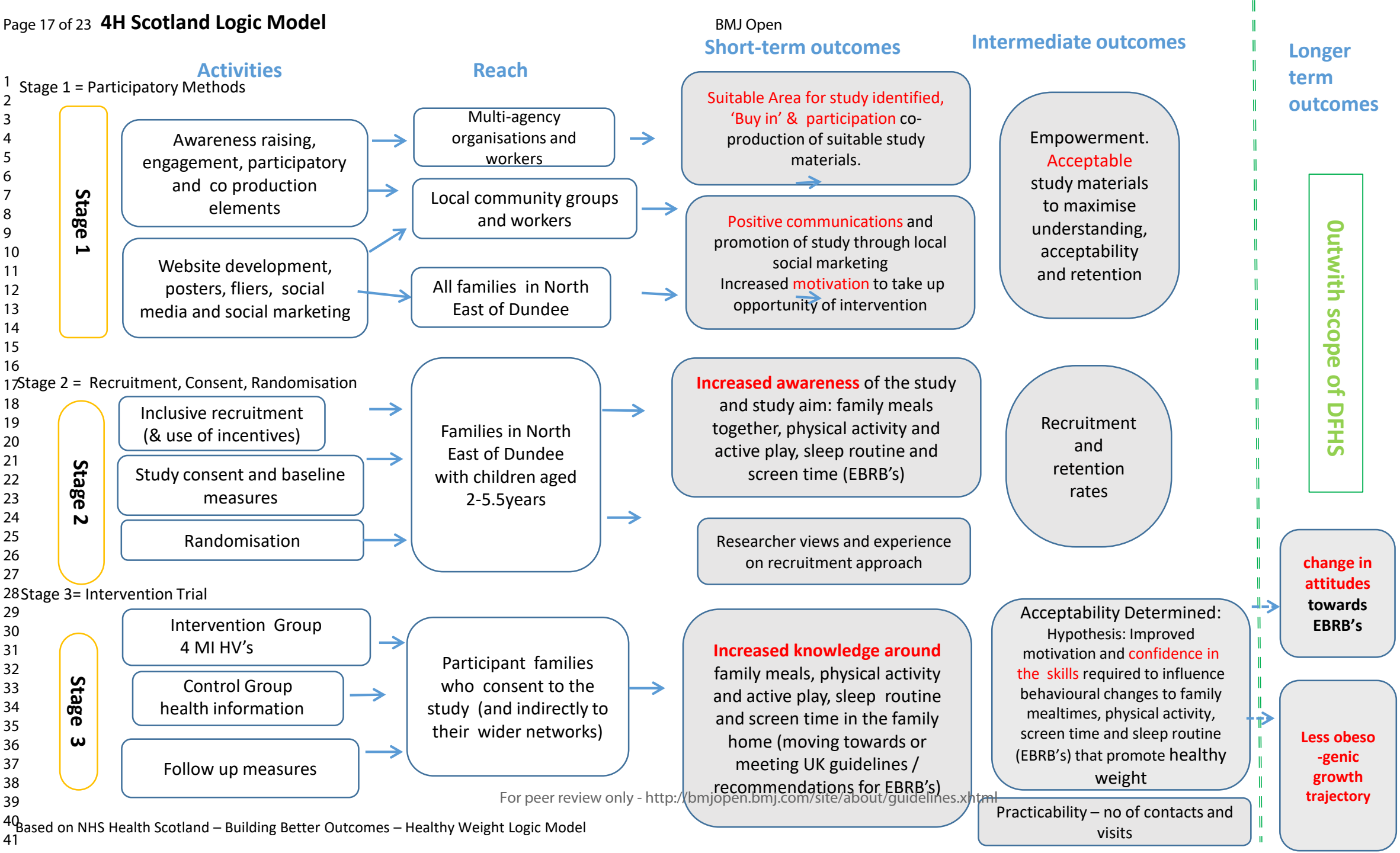
**Figure legends**

Figure 1. 4H Scotland Logic Model

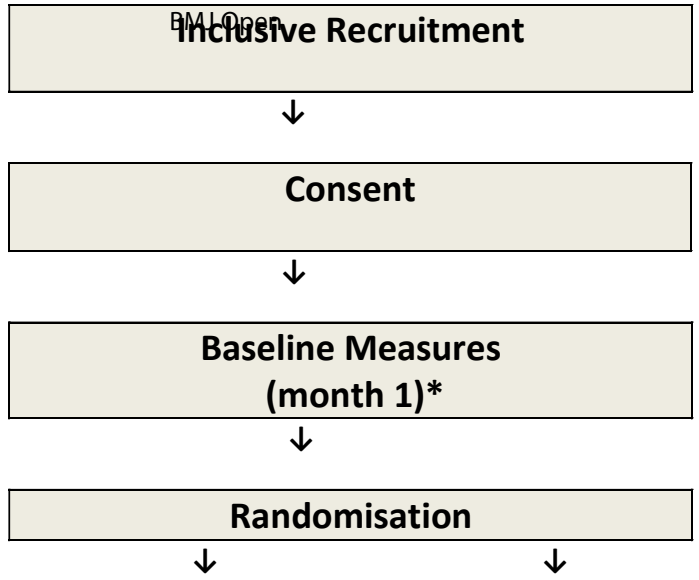
Figure 2. Feasibility Study Process






Based on NHS Health Scotland – Building Better Outcomes – Healthy Weight Logic Model

Figure 2 Feasibility Study Process




| INTERVENTION | | | | | | | CONTROL | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Month 2 | Between Month 2-3 | Month 3 | Between Month 3-4 | Month 4 | Between Month 4-5 | Month 5 | Month 2 | Month 3 | Month 4 | Month 5 |
| MI plus standard information issued at home visit | SMS or email | MI plus standard information issued at Home visit | SMS or email | MI plus standard information issued at home visit | SMS or email | MI plus standard information issued at home visit | Sedentary Behaviour / Screen Time Standard information | Healthy Eating standard information | Sleep Routine & duration standard information | Physical Activity & Active Play standard information |
| A range of behavioural tools used such as goal setting, self monitoring and individualised MI, height and weight measurements taken at each visit | | | | | | | Sent or emailed | Sent or emailed | Sent or emailed | Sent or emailed |

MI = motivational interviewing

* ActivPal
Parental questionnaire
Peds QL
Height, weight
Bio-electrica limpedance analysis



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 1 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | 1 |
| Protocol version | 3 | Date and version identifier | 12 |
| Funding | 4 | Sources and types of financial, material, and other support | 13 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1, 12 |
| | 5b | Name and contact information for the trial sponsor | 13 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 13 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | na |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | ___5_____ |
| | 6b | Explanation for choice of comparators | __8_____ |
| Objectives | 7 | Specific objectives or hypotheses | ___5_____ |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | _8,9, fig 2___ |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | __6,7_____ |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | __na_____ |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | _7,8,9,fig 2_____ |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | ____na_____ |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | ____na_____ |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | __12,13_____ |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | _8,9,10,fig 1__ |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | __fig 1, fig 2_____ |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 7 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 7 fig 1 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 6-10 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 6-10 |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 12 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 9 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 9 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 9 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 12 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 12 |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 12-13 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | na |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 11-12 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 11-12 |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | _____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ____na_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | _____y_____ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | _____y_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | _____y_____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | _____na____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____y_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____y_____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____na_____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | ____na_____ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____na_____ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.