TRIAL PROTOCOL

The HDHK UK study

Healthy Dads, Healthy Kids UK: a cultural adaptation and feasibility study of a weight management programme for fathers of younger children

Version number: 4.0

version date: 12 July 2017

Protocol Amendments

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
1	*3 Feb 2017*	*3.0*	*Major*	*Change to inclusion criteria for phase 1b*
2	*12 July 2017*	*4.0*	*major*	*Change to inclusion criteria of WP2 2* *Clarification of progression criteria* *Change to stratification of randomisation of WP2*

PROTOCOL SIGN OFF

The table below should be signed by the CI to confirm approval of the protocol.

CI Signature Page	
This protocol has been approved by:	
Trial Name:	
Protocol Version Number:	Version: __ __
Protocol Version Date:	__ __ / __ __ / __ __ __ __
CI Name:	
Trial Role:	Chief Investigator
Signature and date:	_____ __ __ / __ __ / __ __ __ __
Sponsor statement: By signing the IRAS form for this trial, University of Birmingham, acting as sponsor of this trial confirm approval of this protocol.	

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ABBREVIATIONS AND DEFINITIONS:

Term	Description
Policies	Policies are developed to describe the approach of the UoB on areas that heavily regulated. Policies may also be developed when there is ambiguity in how regulatory requirements should be implemented in the QMS or when procedures to be captured in the QMS address areas controversial within the UoB at the time of implementation. Policies explain why the UoB has its procedures, especially when they seem to deviate from the regulatory requirements. Policies should be read in conjunction with the relevant SOP. Policies that are not part of a Quality Manual are coded up as 'POL'.
QCD	See "Quality Control Documents"
QMS	Quality Management System
Quality Control Documents (QCD)	Quality Control Documents can be instructions, forms, templates or checklists. They are developed to share best practices, promote standardisation to guarantee quality standards are maintained and reduce resources otherwise needed to develop similar documents. Unless indicated otherwise in the relevant SOP, QCDs are not mandatory and are designed to be an optional aid to UoB staff.
Quality Management System (QMS)	A Quality Management System (QMS) is a system that includes procedures and policies to describe how certain tasks should be performed and that encapsulate any standards and/or regulatory requirements that may apply to those tasks. By adhering to the Quality Management System, the user and the UoB will be assured that applicable regulations are adhered to.
SOP	See "Standard Operating Procedures"
Standard Operating Procedures (SOP)	Standard Operating Procedures are detailed written instructions to achieve uniformity in the performance of a specific function. They define tasks, allocate responsibilities, detail processes, indicate documents and templates to be used and cross-reference to other work instructions and guidance or policy documents. They are standards to which the UoB may be audited or inspected.
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical trial subject participating in the trial which does not necessarily have a causal relationship with the treatment received. Comment: An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory findings), symptom or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.
Related Event	An event which resulted from the administration of any of the research procedures.
Serious Adverse Event (SAE)	An untoward occurrence that: • Results in death • Is life-threatening* • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity

	• Consists of a congenital anomaly/ birth defect • Or is otherwise considered medically significant by the Investigator** Comments: The term severe is often used to describe the intensity (severity) of a specific event. This is not the same as serious, which is based on participants/event outcome or action criteria. * Life threatening in the definition of an SAE refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe. ** Medical judgment should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should be considered serious
Unexpected and Related Event	An event which meets the definition of both an Unexpected Event and a Related Event
Unexpected Event	The type of event that is not listed in the protocol as an expected occurrence.
Source data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial
BCTU	The co-ordinating centre for the trial.

TRIAL SUMMARY

Title: Healthy Dads, Healthy Kids UK: a cultural adaptation and feasibility study of a weight management programme for fathers of younger children

Trial Design

Two phase feasibility study informed by the MRC complex interventions framework.

WP1b: Single arm non-randomised feasibility trial.

WP2: Feasibility two arm prospective randomised controlled trial (RCT) with parallel process evaluation

Objectives

The overall aim is to modify an existing weight management and healthy lifestyle programme for fathers and their children (aged 4-11 years) so that it is culturally acceptably in a UK multi-ethnic population. Adaptation is part of a separate protocol.

WP1b: Uncontrolled feasibility study

The objectives of the uncontrolled feasibility study are to explore the acceptability of the adapted programme and research methods.

WP2: FEASIBILITY RANDOMISED CONTROLLED TRIAL (RCT)

The aim is to assess the feasibility of delivering the adapted intervention and the feasibility of recruitment and follow-up.

Objectives:

In obese fathers of primary school aged children:

2.1 To assess the acceptability of a UK adapted weight management and healthy lifestyle programme in an ethnically diverse population and make refinements to the programme based on facilitator and participant feedback.

2.2 To determine levels of adherence to the programme.

2.3 To assess fidelity of intervention delivery and feedback from facilitators and modify the facilitator training programme if required.

2.4 To assess whether participants are willing to be randomised.

2.5 To assess whether the expected recruitment rate for a subsequent full scale RCT is feasible and to identify successful recruitment strategies.

2.6 To explore ability to obtain educational attainment data for children.

2.7 To explore participants' and facilitators' perceptions of the intervention, trial participation and processes.

2.8 To provide estimates of the variability in the primary outcome.

Participant Population and Sample Size

Obese fathers (BMI≥25kg/m^2/23kg/m^2 for minority ethnic groups or waist circumference of 94cm (37 inches) or more) of children (aged 4-11) identified through schools, religious

organisations, jobcentres and workplaces.
WP1B: NON-RANDOMISED TRIAL: N=30 FATHERS AND THEIR CHILDREN

WP2: RCT: 90 FATHERS AND THEIR CHILDREN;

Outcome Measures

Feasibility of delivering the research and research methods;
OUTCOMES OF DEFINITIVE RCT INCLUDING WEIGHT CHANGE AT 3 AND 6 MONTHS IN FATHERS.

Eligibility Criteria

Phase 1b: Overweight and obese men who are fathers/step-fathers/father figures of primary school aged children (4-11 years). Men must be aged between 18-65 years with a BMI of at least 25kg/m^2 (23kg/m^2 for minority ethnic groups) and want to lose weight.

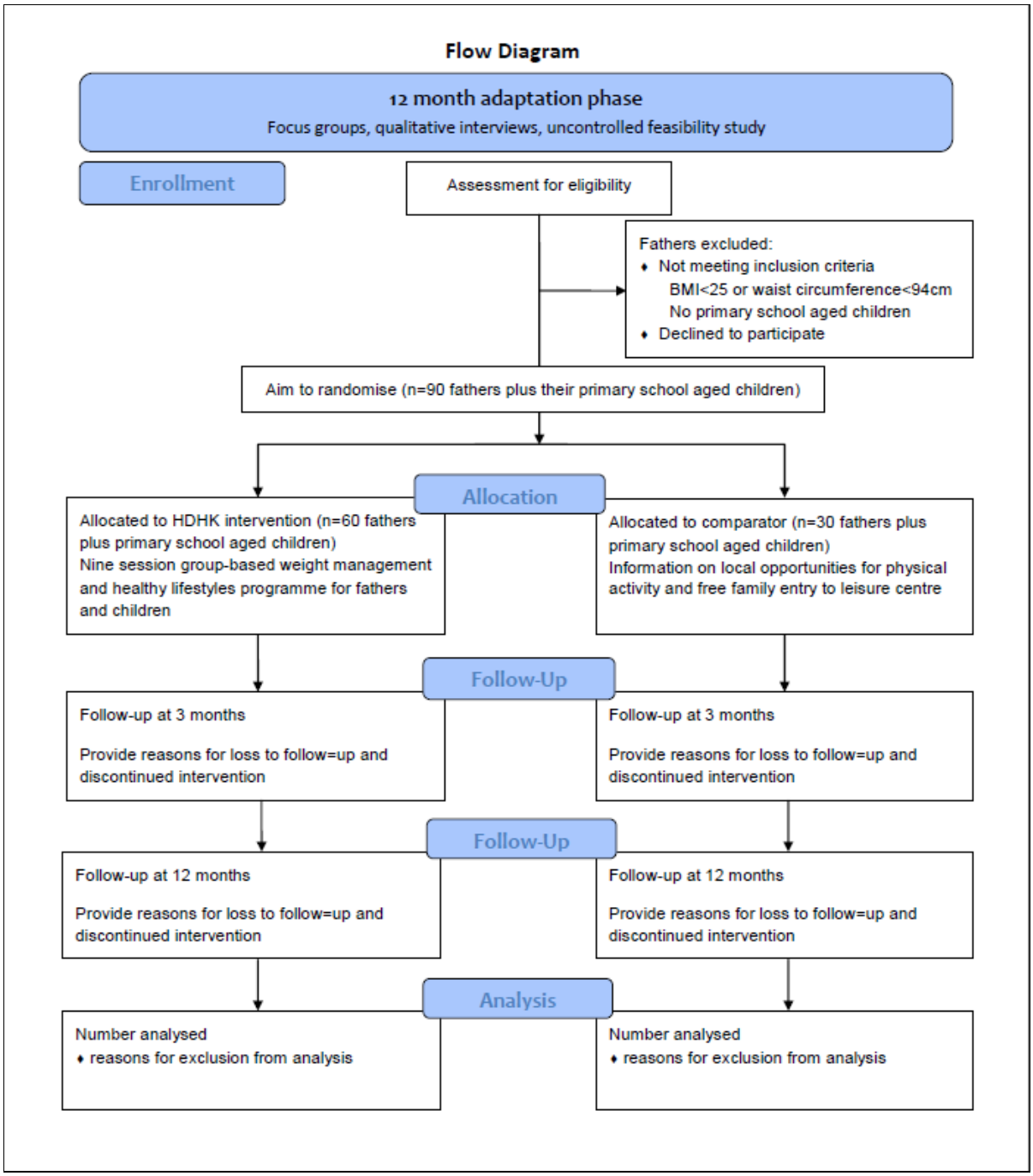
Phase 2: Overweight and obese men who are fathers/step-fathers/father figures of primary school aged children (4-11 years). Men must be aged between 18-65 years with a BMI of at least 25kg/m^2 (23kg/m^2 for minority ethnic groups) or waist circumference of 94cm (37 inches) or more) and want to lose weight.

Fathers do not have to be resident in the same household as their child/ren to take part.

Treatment Allocation

Feasibility RCT: 2:1 randomisation to (i) HDHK UK; (ii) information about local opportunities for physical activity plus voucher for family to attend leisure centre.

Trial Schema


Flow Diagram
12 month adaptation phase
Focus groups, qualitative interviews, uncontrolled feasibility study
Enrollment
Assessment for eligibility
Fathers excluded:
Not meeting inclusion criteria
BMI<25 or waist circumference<94cm
No primary school aged children
Declined to participate
Aim to randomise (n=90 fathers plus their primary school aged children)
Allocation
Allocated to HDHK intervention (n=60 fathers plus primary school aged children)
Nine session group-based weight management and healthy lifestyles programme for fathers and children
Allocated to comparator (n=30 fathers plus primary school aged children)
Information on local opportunities for physical activity and free family entry to leisure centre
Follow-Up
Follow-up at 3 months
Provide reasons for loss to follow=up and discontinued intervention
Follow-up at 3 months
Provide reasons for loss to follow=up and discontinued intervention
Follow-Up
Follow-up at 12 months
Provide reasons for loss to follow=up and discontinued intervention
Follow-up at 12 months
Provide reasons for loss to follow=up and discontinued intervention
Analysis
Number analysed
reasons for exclusion from analysis
Number analysed
reasons for exclusion from analysis

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1. BACKGROUND AND RATIONALE

1.1. Background

The epidemiology of overweight and obesity in men

Overweight and obesity are major public health challenges. Obesity is associated with increased risk of diseases including type II diabetes, cardiovascular disease, cancers (e.g. colon) and osteoarthritis.[9] It is also associated with higher rates of depression.[10] For each increase in BMI of 5kg/m^2, mortality increases by 30%, and median survival reduces by 2-4 years for people of BMI 30-35kg/m/^{2} compared to those of BMI 22.5-25kg/m^2.[1] Due to the associations with many long-term medical conditions, the cost of obesity is very high. The tackling Obesity Foresight project reported that, by 2015, costs to the NHS could reach £9.7 billion per year.[11]

Men are at a higher risk of overweight and obesity than women.[12] The proportion of men who are overweight or obese increases from 54% of 25-34 year olds, to 72% of 35-44 year olds and reaches a peak of 81% of men aged 45-54 years.[12] Inequalities are evident with a higher proportion of men in the lowest income quintile having a raised waist circumference (>102cm) (36% vs 31% in highest income quintile)[11]. In addition, compared to white Europeans, people of South Asian ethnicity living in England tend to have a higher percentage of body fat at the same BMI and more features of the metabolic syndrome at the same waist circumference.[3] Men of South Asian ethnicity also have higher waist–to-hip ratios compared to men from other ethnic groups.[13]

In conjunction with the high rates of overweight and obesity, men have become less physically active. In 2008, the Health Survey for England undertook objective measurement of physical activity; only 5% of men aged 35-64 years achieved the recommended activity level.[14]

Evidence of the effectiveness of weight management programmes in men

In a series of systematic reviews, Robertson and colleagues reviewed the evidence base for the management of obesity in men.[15] Fewer men than women join weight management programmes, but once they join they have higher retention rates and similar or greater percentage weight loss compared to women. Whilst the evidence is limited, it appears that the most effective programmes for men included reduced dietary intake, physical activity and behavioural change strategies. A meta-analysis of male-only weight loss interventions revealed a significant difference in weight change favouring interventions over no-intervention controls at the last reported assessment (-5.66 kg, 95% CI -6.35, -4.97).[16]

Successful men-only weight loss programmes have been run in football clubs[7] and workplaces[4], tapping into a shared identity. A similar shared identify may be experienced by fathers with similar aged children, who may be attending the same school and living in a similar locality.

Robertson et al's review[15] identified no eligible studies looking at how to increase engagement of men in weight management interventions. However, many men expressed that a health concern motivated them to lose weight, rather than a concern about their appearance. The qualitative review [15] identified that men felt an individual responsibility for their weight gain, and that men from socio-economically disadvantaged communities were often constrained by economic circumstances from healthy eating and exercise. To date, no studies have explored the beliefs of men from minority ethnic groups in the UK. The qualitative review also identified the features associated with successful weight loss

programmes in men. These included group-based programmes and social support, promoting engagement with the use of humour, accountability and adherence, and goal setting.[15] Men valued a personalised approach that took account of their individual needs. In HDHK in Australia, men described the motivation provided by a pedometer. All of these factors are features of our proposed intervention for fathers and their children.

The Healthy Dads, Healthy Kids (HDHK) intervention

The HDHK programme was developed in Australia by co-applicants (PM, CC, MY) and is described in detail below. In brief, it was developed to address weight management in fathers, but in the context of their families, such that changes in their health behaviours would positively impact on their children. A highly novel aspect to the intervention was that children also play a major role in helping their father to maintain his behaviour change.

Risks and benefits

The potential benefits to the men are weight loss, improved physical activity levels and improved diet quality, which would result in a reduction in risk for a wide range of health conditions including type II diabetes, cardiovascular disease, cancers and arthritis and other musculoskeletal symptoms.[17] Increased physical activity is associated with mental wellbeing[18] and undertaking activities with their children may result in closer relationships and bonding.[19] For the children, there are the benefits of healthier eating patterns and increased physical activity resulting in a lowered risk of developing obesity[20], potentially improved attention and outcomes at school[21], improved social-emotional well-being and shared activity with their father leading to a closer relationship.[22]

The risks to the participants are low and outweighed by the considerable potential health benefits. The suggested dietary changes are all within national recommendations and goals are set individually. Risks of minor musculoskeletal injury are reduced by appropriate warm ups and careful selection of practical activities.

1.2. Study Rationale

1.2.1. **Justification for participant population**

By recruiting fathers with their children and involving mothers/partners in the intervention, meaningful health gains are possible for the whole family. There is also potential for sustained behaviour change as a result of family behaviour change, which would help to break the cycle of intergenerational obesity. In the UK, 22% of 4-5 year and 33% of 10-11 year old children are overweight or obese[23], demonstrating the importance of intervention in primary school aged children to prevent obesity.

HDHK has been rigorously evaluated by RCT in Australia, reporting a difference in weight in the fathers of 3.4kg (95%CI 2.1, 4.7) in favour of the intervention at 14 weeks, compared to a wait list control, a significant reduction in the BMI z-score of the children and increases in children's physical activity levels and improvement in diet quality compared to a wait-list control group [6]. A larger-scale community roll out has demonstrated clinically meaningful weight loss sustained to one year in fathers (4kg loss; 95%CI 3.0, 5.0) and significant mean reduction in BMI z-score (-0.13, 95% CI-0.20,-0.05) in children. Positive effects reported via qualitative research were improved family relationships and involvement of the father and children in joint activities.[24] The intervention may also lead to improved educational or behavioural outcomes for children, which will be explored in the proposed study. Whilst the intervention has been tested in Australia, its transferability to a multi-ethnic UK setting needs testing.

1.2.2. **Justification for design**

The frameworks guiding this study are the UK Medical Research Council (MRC) framework for the development and evaluation of complex health interventions[25] and Liu at al's Typology of Adaptation of health promotion interventions to meet the needs of ethnic minority groups.[26]

1.2.3. **Choice of treatment**

The intervention is a UK culturally adapted version of the Healthy Dads, Healthy Kids (HDHK) programme for fathers and their primary school aged children.[5,6,27] HDHK has the primary aim of weight loss in fathers. The Australian programme has been modified since the first evaluation. It now has nine sessions of 90 minutes duration delivered at weekly intervals. Mother/partners are invited to attend a single session; fathers and children attend all 9. Each session begins with fathers and children together for 15 minutes setting/reviewing weekly goals, then 30 minute separate fathers session and children's session run in parallel, concluding with a 45 minute physical activity session (fathers and children together). The physical activity sessions are interactive, highly active, fun and focus on elements associated with optimal child development outcomes across physical, cognitive and social-emotional domains. This includes fundamental movement skills, health-related fitness-based activities and rough-and-tumble play.

The HDHK programme is based on Social Cognitive Theory (SCT)[29] and Family Systems Theory(FST).[30] SCT constructs targeted in HDHK are self-efficacy, goals/intention, outcome expectations, perceived facilitators and barriers to changes and social support. The FST postulates a framework of reciprocal relationships between family members. Thus when a father changes his dietary behaviours and physical activity levels, this will be reflected in his children's behaviour.[31]

The HDHK programme aims to provide fathers with the knowledge and skills for long-term behaviour change. It teaches fathers about the importance of engaging with their children and uses healthy eating and physical activity as media to engage fathers with their children. The children's engagement and enthusiasm for the HDHK father-child activity aims to reinforce the change in family lifestyle. During the program fathers come to understand the profound influence that their parenting, actions, behaviours, and attitudes have on their children – this realization becomes a driving force behind their motivation to get fit and become more engaged in their children's lives.

2. AIMS, OBJECTIVES AND OUTCOME MEASURES

2.1 Aims and Objectives

The aims outlined below will be addressed in 2 work packages (WP).

WP1b: FEASIBILITY OF DELIVERING ADAPTED HDHK PROGRAMME:

Objectives:

To explore the acceptability of the adapted programme in an uncontrolled feasibility study

WP2: FEASIBILITY RANDOMISED CONTROLLED TRIAL (RCT)

The aim is to assess the feasibility of delivering the adapted intervention and of recruitment and follow-up.

Objectives:

In obese fathers (father figures) of primary school aged children:

2.1 To assess the acceptability of a UK adapted weight management and healthy lifestyle programme in an ethnically diverse population and make refinements to the programme based on facilitator and participant feedback.

2.2 To determine levels of adherence to the programme.

2.3 To assess fidelity of intervention delivery and explore feedback from facilitators and modify the facilitator training programme if required.

2.4 To assess whether participants are willing to be randomised.

2.5 To assess whether the expected recruitment rate for a subsequent full scale effectiveness RCT is feasible and to identify successful recruitment strategies.

2.6 To explore ability to obtain educational attainment data for children.

2.7 To explore participants' and facilitators' perceptions of the intervention, trial participation and processes.

2.8 To provide estimates of the variability in the primary outcome.

2.9 To test the components of the proposed RCT to determine the feasibility of the protocol.

2.2 Outcome Measures

Our main outcomes are to assess the feasibility of delivering the intervention and the research methods:

(i) The feasibility of delivery of the adapted HDHK programme will be assessed by

- ability to recruit and train facilitators;
- (ii) ability to deliver sessions at a time and location convenient for participants, which will be determined through interviews with participants who drop-out of the programme and those who remain, as well as attendance records;
- (iii) acceptability to participants, ascertained by qualitative interviews with fathers, mothers/partners and children;
- (iv) fidelity of delivery, assessed through structured observation of sessions to determine whether the key tasks are delivered as planned, as well as whether good practice in terms of mode and degree of participant-centred delivery are achieved.

(ii) The feasibility of collecting educational attainment data from schools will be explored.

(iii) The feasibility of a future definitive trial will be assessed by:

- recruitment rates
- participants' willingness to be randomised
- follow-up rates at 3 and 6 months and level of completion of questionnaire.

(iv) Outcomes of a definitive trial – measures included in feasibility trial

The feasibility RCT will also assess whether the whole trial can be run as planned and therefore will also collect all the outcome measures that a full effectiveness trial would collect. Particular attention will be paid to levels of missing data. In a definitive trial the

primary outcome would be weight change in fathers at 12 months follow-up, this trial will have final follow-up at 6 months.

Secondary outcomes of a full effectiveness trial in *fathers*:

- Fathers' weight change at 3 months,
- % losing ≥5% body mass,
- waist circumference
- % body fat
- self-reported physical activity measured by the IPAQ-short[39]
- objectively measured physical activity measured by a GENEactiv accelerometer,
- self-reported dietary intake using sub-scales of FFQs (e.g. for fruit and vegetables, sugar sweetened beverage consumption)
- father involvement using the Parent-Child Relationships Questionnaire [40]
- parenting for physical activity using the physical activity items from the 'Parenting Strategies for Eating and Activity Scale' [41]

Secondary outcomes of a full effectiveness trial in *children*:

- Children's BMI z-score change (Weight and height)
- % body fat
- % categorised as overweight or obese,
- objectively measured physical activity (eldest child),
- parent-reported dietary intake for eldest child using sub-scales of FFQs (e.g. for fruit and vegetables, sugar sweetened beverage consumption)
- strengths and difficulties questionnaire.

Health economics measures:

Fathers: EQ-5D and ICECAP

Children: CHU-9D

Health service utilisation and resource use in fathers and children

Assessment of harms:

Adverse events resulting from the study will be recorded.

3. STUDY DESIGN AND SETTING

3.1 Study Design

Two phase feasibility study informed by the MRC complex interventions framework.

WP1b: Single arm non-randomised feasibility trial with process evaluation.

WP2: Feasibility two arm prospective randomised controlled trial (RCT) with parallel process evaluation.

3.2 Study Setting

Community facilities (non-NHS) in the UK. Potential facilities include schools and leisure centres.

As a result of changes in migration patterns over the last 20 years, urban populations such as that of Birmingham have become more complex and 'super-diverse'. Super-diversity' is characterised by overlapping variables including country of origin, ethnicity, language, religion, regional/local identities, migration history and experience (influenced by sex, age, education, specific social networks, economic factors) and immigration status (encompassing a variety of entitlements and restrictions).[28] Such complexity in the population has created unique challenges with regard to how we identify and respond to the health needs of all members of a super-diverse society.

Socioeconomic position and inequalities:

The cultural adaptation will ensure that the programme content and materials are accessible to participants from a range of ethnic groups and varying literacy levels. Given the focus on fathers with children at primary school, it is likely that some programmes will be held in primary schools. We are mindful of the importance of keeping programmes local, to reduce travel costs and travel times. We plan to focus recruitment in local areas and can thus focus the study in the more socio-economically disadvantaged areas. The three areas selected for the feasibility study have at least a third of the population of non-white British ethnicity. We do not propose to set targets for the inclusion of particular ethnic groups, but would expect about a third to be from a minority ethnic group and thus reflect the local population.

WP1a Cultural adaptation of the Healthy Dads, Healthy Kids programme

This is subject to a separate protocol and ethics approval – 0237-RG_15-197).

WP1b: Feasibility and acceptability of amended programme

The adapted programme will be delivered in Wolverhampton and Sandwell (and possibly in Birmingham, if intervention funds can be identified). The group facilitators will be trained using the materials developed by the HDHK team in Australia, with any adaptations to ensure that the intervention is culturally appropriate for a UK multi-ethnic population both in both content and delivery style. Training will last for 2 days (10-12 hours).

During the programme, two members of the research team will observe sessions and do structured 20 minute telephone interviews with the facilitators and participants to explore acceptability of the intervention, timing and location as well as training of the facilitators.

Recruitment methods will follow the methods outlined in WP2. We will recruit overweight and obese fathers to this uncontrolled study. Follow-up will take place at the final session, as this stage is focussing on the acceptability of the intervention, rather than trial processes.

Any participant who ceases to attend will be invited to undertake a telephone interview to explore why they failed to attend. The qualitative telephone interviews will be audio recorded, but will not be formally transcribed, but comprehensive notes and reflections will be made straight after the observations/focus groups. These will feedback into changes to the programme.

(vi) Further changes made to adapted HDHK programme

Any additional changes to the programme materials or delivery will be made before proceeding to WP2. An additional training session for the facilitators will be delivered as part of WP2.

FEASIBILITY STUDIES' METHODS

3.3 Identification of participants

We will work with schools, religious institutions, job centres, children's centres and large employers as well as using social and other media to identify and invite obese fathers to take part.

Interested fathers will be asked to attend a baseline recruitment session with their children, or be assessed at home.

Non-randomised study (WP1b) sample size:

Total sample size 30 fathers plus their children.

Two HDHK programmes with up to 15 fathers in each will explore the acceptability of the amended HDHK programme and trial processes.

Feasibility RCT (WP2) sample size:

Total sample size 90 fathers plus their children.

Each HDHK programme will aim to recruit 15 fathers, thus we aim to randomise 60 fathers to the HDHK groups and 30 to the control group. The sample size has been chosen to enable estimation of the feasibility outcomes with reasonable precision. We will be able to estimate the recruitment, follow-up and questionnaire completion rates to within +/- 10% with 95% confidence, based on a worst case estimate of 50%.

Qualitative research sample size:

WP1b: 2 focus groups (n=6-8 per group) with fathers who participated, individual interviews with fathers who drop-out of the programme before completion; interviews with the group facilitators (n=4).

WP2: Interviews will be undertaken with fathers who drop-out during the intervention (up to n=10), participants who complete the programme, and who have a range of socio-demographic characteristics and family structures as well as their partners and child/ren (independently from the fathers where possible). We will interview up to 20 family groups on two occasions at 3 and 6 months ensuring that they are sampled from across the different HDHK programmes delivered. We will also undertake one to two focus groups (or interviews if FGs not feasible) with programme facilitators at the end of the programmes with the aim of exploring experiences and perspectives of the trial. We will also interview up to 10 fathers who were randomised to the control group to ascertain their experiences and identify any behaviour change made as a family after joining the study.

4. ELIGIBILITY

4.1 Inclusion Criteria

- Overweight and obese men who are fathers/step-fathers/father figures of primary school aged children (4-11 years). (Fathers do not have to be resident in the same household as their child/ren to take part).
- aged between 18-65 years
- Phases 1b and 2: BMI of ≥25kg/m^2 (23kg/m^2 for minority ethnic groups) or or waist circumference of 94cm (37 inches) or more)
- willing to lose weight.

4.2 Exclusion Criteria

- angina or other cardiovascular disease
- orthopaedic or joint problems that would be a barrier to vigorous physical activity
- weight loss of 3kg or 7lbs in previous 3 months
- Fathers with diabetes who are not confident in managing their condition during exercise.
- Adults who are unable to speak and/or understand English
- Families involved in ongoing custody or access disputes and/or any contexts with a risk of domestic violence

Fathers will be asked to complete the physical activity readiness questionnaire (PAR-Q) which screens for conditions that might preclude safe exercise. If any question responses are positive they will be referred to alternative local weight management pathways. Fathers with insulin dependent diabetes will be asked to sign a 'health commitment statement' taking personal responsibility for their condition and ability to self-manage their diabetes with increased exercise.

5. CONSENT

It will be the responsibility of the Investigator to obtain written informed consent for each participant prior to performing any trial related procedure. This responsibility will be delegated to the study research fellow and study co-ordinator after appropriate training and this delegation will be captured on the Site Signature and Delegation Log.

A Participant Information Leaflet (PIL) for the 'fathers' will be provided to facilitate this process. The PIL will explain what is involved for both the father and for their child/ren. There are different PIL and consent forms for the two phases of the study (1b and 2). Investigators or delegate(s) will ensure that they adequately explain the aim, trial intervention, anticipated benefits and potential hazards of taking part in the trial to the participant. They will also stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the trial at any time. The participant will have adequate time to read the PIL and to discuss their participation with others outside of the site research team. The participant will be given the opportunity to ask questions. If the participant expresses an interest in participating in the trial they will be asked to sign and date the latest version of the Informed Consent Form (ICF).

An age appropriate PIL will be produced for the children aged 7 years or more. Investigators or delegate(s) will ensure that they adequately explain the aim, trial intervention, anticipated benefits and potential hazards of taking part in the trial to the children. They will also stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the trial at any time. If the child (aged approximately 8 or more and depending on the child's understanding) is willing to take part in the trial they will be asked to sign and date the latest version of the Informed Assent Form (IAF-C). A parent with parental responsibility for the child will be asked to sign and date the latest version of the Informed Consent Form for children (ICF-C).

The Investigator or delegate(s) will then sign and date the form. A copy of the ICF will be given to the participant, and the original returned to BCTU to be placed in the Investigator Site File (ISF), as will the ICF-C and IAF-C. Once the participant is entered into the trial, the participant's trial number will be entered on the Informed Consent Form maintained in the ISF. In addition, if the participant has given explicit consent a copy of the signed Informed Consent Form will be sent to the BCTU trials team for review.

At each follow-up assessment the participant's willingness to continue in the trial will be ascertained and documented in the CRF. Throughout the trial the participant will have the opportunity to ask questions about the trial. Any new information that may be relevant to the participant's continued participation will be provided. The participant's right to withdraw from the trial will remain.

Electronic copies of the PIL and ICF will be available from the Trials Office and for UK trials will be printed or photocopied onto the headed paper of the local institution. Details of all participants approached about the trial will be recorded on the Participant Screening/Enrolment Log.

Separate consent will be sought from the participants invited to take part in a qualitative interview as part of the randomised feasibility study (phase 2). Children will be asked to provide written assent before each qualitative interview.

6. ENROLMENT AND RANDOMISATION

6.1 Enrolment

In WP1b non-randomised trial the study team may approach fathers through primary schools, community groups, large employers, religious institutions and any other community organisations identified in WP1a. These organisations will send a summary leaflet, reply slip and freepost envelope to potential participants. Advertisements with study contact details will also be placed in locations/organisations.

Interested people will be sent the PIL and the children's PIL and an appointment made for a home visit to discuss the study, answer questions and take the children's assent and father's consent and consent on behalf of child participants. Options for alternative locations for recruitment such as a community venue will also be considered. Following informed consent the study measurements will be taken, CRF and questionnaires completed and eligibility checked. All participants will be invited to the HDHK programme.

In WP2 feasibility RCT the study team may approach fathers through primary schools, community groups, large employers, religious institutions and any other community organisations identified by WP1 participants. These organisations will send a summary

leaflet, reply slip and freepost envelope to potential participants. Advertisements with study contact details will also be placed in locations/organisations identified in WP1.

Interested people will be sent the PIL and the children's PIL and an appointment made for a home visit to discuss the study, answer questions and take the children's assent and father's consent and consent on behalf of child participants by a parent with parental responsibility. Options for alternative locations for recruitment such as a community venue will also be considered. Following informed consent the study measurements will be taken, CRF and questionnaires completed and eligibility checked. Randomisation will be undertaken by a member of the study research team using a secure, web-based randomisation website designed and maintained by CTU data programmers. The randomisation list will be developed by the trial statistician and held in a secure database. The study research fellow will inform the father of their family's allocation by telephone call and letter.

Families will be randomised 2:1 to intervention and control group with stratification for the father's ethnicity (white British or Irish / other ethnic group) and site (Wolverhampton or Sandwell).

6.2 Blinding

Trial participants cannot be blinded as to their study group allocation, however, we will attempt to ensure that the person doing the follow-up assessments is blinded to allocation status. The statistician undertaking the data analysis will not be able to blinded because of the 2:1 allocation.

7. TRIAL TREATMENT / INTERVENTION

7.1 Intervention Schedule

The intervention is a UK culturally adapted version of the Healthy Dads, Healthy Kids (HDHK) programme for fathers and their primary school aged children.[5,6,27] HDHK has the primary aim of weight loss in fathers. The Australian programme has been modified since the first evaluation. It now has nine sessions of 90 minutes duration delivered at weekly intervals. Mother/partners are invited to attend a single session; fathers and children attend all 9. Each session begins with fathers and children together for 15 minutes setting/reviewing weekly goals, then 30 minute separate fathers session and children's session run in parallel, concluding with a 45 minute physical activity session (fathers and children together). The physical activity sessions are interactive, highly active, fun and focus on elements associated with optimal child development outcomes across physical, cognitive and social-emotional domains. This includes fundamental movement skills, health-related fitness-based activities and rough-and-tumble play.

The HDHK programme is based on Social Cognitive Theory (SCT)[29] and Family Systems Theory(FST).[30] SCT constructs targeted in HDHK are self-efficacy, goals/intention, outcome expectations, perceived facilitators and barriers to changes and social support. The FST postulates a framework of reciprocal relationships between family members. Thus when a father changes his dietary behaviours and physical activity levels, this will be reflected in his children's behaviour.[31]

The HDHK programme aims to provide fathers with the knowledge and skills for long-term behaviour change. It teaches fathers about the importance of engaging with their children and uses healthy eating and physical activity as media to engage fathers with their children.

The children's engagement and enthusiasm for the HDHK father-child activity aims to reinforce the change in family lifestyle. During the program fathers come to understand the profound influence that their parenting, actions, behaviours, and attitudes have on their children – this realization becomes a driving force behind their motivation to get fit and become more engaged in their children's lives. A logic model of the intervention theory is appended.

The individual session content is in the table below. Resources include a facilitator's manual, manuals for fathers and children, log book, website for self-monitoring and instruction guide. A maintenance element will include monthly emailed/posted ideas for family activities, encouragement to continue goal setting, self-monitoring and planning for overcoming barriers.

HDHK programme and session outline

Session	Dads sessions	Kids sessions	Attendees
1	**Dads matter in children's health** *Highlights the unique influence of dads in contributing to the physical and mental health of children.*	**Rough 'n' tumble fun** *Kids learn about their mission to 'get dad fit and healthy' and are taught about rough and tumble activities.*	Dads & Kids
2	**Weight management for men** *Explores the challenges of healthy eating in the modern world, outlines the mathematics of weight loss and setting SMART goals to achieve activity and dietary ambitions.*	**Turning Dad into a healthy eater** *Through fun activities, kids learn about 'sometimes' foods and 'anytime' foods and how they can encourage dad to eat more healthily.*	Dads & Kids
3	**Being a healthy dad– Strategies to enhance you and your family's life** *Highlights the 8 weight loss tips for men, tells dads how to 'stay on track' and provides advice on sustainable approaches to weight loss.*	**Helping dad to stay healthy**	Dads & Kids
4	**Healthy eating for families** *Provides advice on appropriate portion sizes for the whole family, discusses strategies for implementing the trust paradigm to encourage their children to eat healthily at home.*	**The HDHK rainbow plate** *Through fun activities, kids learn about different fruits and vegetables and are challenged to make their plates 'rainbows' with a variety of healthy fruits and vegetables.*	Dad, Mum & Kids
5	**The unique and powerful influence of fathers** *Explains to dads why they have such a powerful influence over their kids, the importance of being a good role model and outlines the most effective parenting style.*	**Quality time with Dad** *Kids are given activities to help them think about games they can play with dad to spend quality time together.*	Dads & Kids
6	**Raising active kids in an inactive world** *Explains the growing issues of childhood obesity and why physical activity is so important for kids, highlights key strategies for dads to be physical activity leaders.*	**Trying a new physical activity/sport!**	Dads & Kids
7	**'Switching on' your child's mind by 'Switching off'** *Highlights the physical and mental health issues created by excessive screen time and provides strategies for 'switching off'.*	**Helping Dad 'Switch off'** *Kids think about activities they could enjoy from dad instead of playing on the computer or watching TV.*	Dads & Kids
8	**'Healthy' fathering in a busy world** *Encourages discussion of barriers and solutions for achieving SMART goals, highlights opportunities to create family traditions and maximize the time dads can spend with their kids.*	**Becoming Dad's personal trainer** *Kids develop an activity board with games and exercises the family can complete at home.*	Dads & Kids
9	**Continuing the 'Healthy Dad' journey** *Reviews the key messages of the program, provides tips for staying on track after the program, awards kids with their certificates and awards dads with card.*	**Helping Dad stay on track** *Kids review the program and receive their HDHK Certificates for achieving their mission to get dad fit and healthy. Dads receive card off kids for their commitment to the program.*	Dads & Kids

7.2 Contraindications

Participants with diabetes must be confident in managing their diabetes when exercising.

Participants who have a positive response to the PAR-Q will be signposted to alternative weight management pathways.

Participants will be excluded if they have angina or other cardiovascular disease, orthopaedic or joint problems that would be a barrier to vigorous physical activity, weight loss of 3kg or 7lbs in previous 3 months.

7.3 Accountability Procedures

Adherence to the HDHK programme will be monitored by an attendance register at the sessions. With prior approval, group facilitators will text or email fathers if they miss a session.

7.4 Withdrawal of Treatment

Participants may withdraw from the interview or trial at any time if they choose not to continue. There are no clinical criteria for withdrawal from the HDHK programme. In the event of injury the father can attend the talks and undertake modified activities or the children's mother can attend to do the activities with the children.

8. TRIAL PROCEDURES AND ASSESSMENTS

8.1 Summary of assessments for phase 2

Visit	Screening	Baseline	Month 3 -30d to +30days	Month 6 -30d to +60days
Eligibility check	x			
Valid informed consent	x	x		
Relevant medical history taken	x			
Randomisation		x		
Weight measurement	X		X	X
Height measurement	X			
Fathers				
Waist circumference		X	X	X
% body fat using Tanita Scales		X	X	X
Physical activity: IPAQ-short		X	X	X
Physical activity: accelerometry		X	X	X
Dietary questionnaires		X	X	X
Parent-child relationship questionnaire [40]		X	X	X
Parenting strategies for Eating and Activity Scale – physical activity items [41]		X	X	X
EQ-5D-5L		X	X	X
ICECAP		X	X	X
Health service utilisation		X	X	X
Children				
% body fat using Tanita Scales		X	X	X
Physical activity: accelerometry (eldest)		X	X	X
Parent reported dietary questionnaire(eldest)		X	X	X
Quality of Life – CHU-9		X	X	X
Health service utilisation		X	X	X

Parent reported Strengths and difficulties questionnaire		X		X

8.2 Study Procedures

Weight will be measured on Tanita bio-impedance BF-522W analyser scales. Each participant will be weighed without shoes and wearing light indoor clothes.

Height will be measured using a Leicester height measure without wearing shoes.

Weight and height will be used to calculate the BMI in adults and BMI Z-score in children.

Objective physical activity will be measured using GENEActiv accelerometers over a consecutive 7 day period in all fathers and their eldest child. This will be set-up and worn according to a SOP.

SCREENING: Please note, details of the screening assessment have been described earlier in section 6.1.

8.3 Schedule of Assessments

QoL Questionnaire(s)

During the Baseline visit the participant will complete the QoL questionnaire after consent but prior to randomisation.

Three QoL questionnaires are available a CHU-9D (child version), a CHU-9D (parent version) and EQ-5D-5L. The father will complete the EQ-5D-5L. A parent will complete the CHU-9D (parent's version for children under the age of 7 years) and child's version for children aged 7-11 years). The same CHU-9D will be completed at follow-up as at baseline, even if the child reaches the age of 7 years during the study.

Participant Health Resource Use Questionnaire

The fathers will be given the Participant Health Resource Use Questionnaire to complete at each follow-up point. The form will capture many aspects of costs incurred by the participant including attendance at primary care and hospital, time lost from work and transportation costs. A parent will complete an identical questionnaire on behalf of each child.

Physical activity Questionnaire - IPAQ short

The researcher will ensure that the father is aware that walking is collected separately and should not be included in the moderate or vigorous activities.

Dietary questionnaire

The food frequency questions from the community roll out trial of HDHK in Australia are used, with minor adaption to UK terminology.

Parental questionnaire reporting children's dietary intake

A parent will complete the dietary questionnaire for the eldest child taking part. The food frequency questions from the community roll out trial of HDHK in Australia are used, with minor adaption to UK terminology.

Parental completion of the Strengths and Difficulties Questionnaire

A parent will complete the Strengths and Difficulties Questionnaire for the eldest child taking part.

Questionnaire completion

Each form should be checked for missing data whilst the trial participant is still present. If missing data are identified the participant should be notified and provided an opportunity to complete the question(s). If a participant chooses not to complete particular questions where possible the reasons should be documented.

8.4 Evaluating the success of adaptation

Semi-structured interviews in the feasibility trial will purposively select fathers who drop-out during the intervention (within 3 weeks of leaving the programme) (up to n=10), participants who complete the programme, and who have a range of socio-demographic characteristics and family structures as well as their partners and child/ren (independently from the fathers where possible). We will interview up to 20 family groups on two occasions at 3 and 6 months ensuring that they are sampled from across the different HDHK programmes delivered. We will also undertake one to two focus groups (or interviews if FGs not feasible) with programme facilitators at the end of the programmes with the aim of exploring experiences and perspectives of the trial. As part of these interviews and FGs we will explore the adaptation of all processes including: invitation methods, location of the programme, barriers/facilitators to participation, acceptability of content and delivery, ability to sustain behaviour change, changes to food purchasing and cooking practices and family relationships. With facilitators we will also explore delivery of the intervention and their skills development. We will also interview up to 10 fathers who were randomised to the control group to ascertain their experiences and identify any behaviour change made as a family after joining the study.

8.5 Process evaluation

A comprehensive process evaluation running in parallel to the feasibility study will measure (i) reach using data from expressions of interest and baseline characteristics of participants; (ii) reasons for opting out during the programme ascertained from interviews with participants leaving the programme, interviews with coaches and attendance records; (iii) programme fidelity determined from observations of sessions, focus groups with the facilitators and interviews with participants; (iv) participants experiences of taking part from qualitative interviews at 3 months with fathers, mothers and children (independently where possible); (v) facilitators experiences of the HDHK training and delivery of the programme from focus group/s or interviews with the facilitators; (vi) participant's experiences of maintaining changes from qualitative interviews at 6 months with fathers, mothers and children, as family groups.

The fidelity of the HDHK delivery will relate to checklist items of activities and content included in the session plan. For one session this might include:

(i) all powerpoint slides presented; (ii) fathers and children complete all session-related log book and handbook activities; (iii) fathers and children select homework item; (iv) physical activities delivered including options for children of all ages and those requiring cultural adaptations; (v) engagement by fathers and children in proposed activities.

8.6 Qualitative research methods

Observations of the HDHK sessions: 3 per programme; interviews with fathers who drop-out of the intervention; interviews with up to 20 family groups at 3 and 6 months with fathers interviewed separately from the children/mothers where possible; focus groups (with interviews if unable to attend) with HDHK facilitators. Separate consent will be sought for the qualitative aspects of the randomised study (Phase 2). Written assent will be sought from children aged 8 or more before any qualitative interview in phase 2.

Discussion guides will be refined by PPI input and data from the qualitative research in WP1 with subsequent presentation and discussion of the qualitative results with the PPI panel. As highlighted previously, interviews/FGs will be audio recorded, data collection and analysis will run in parallel, and a framework method will be used to facilitate a systematic and flexible approach to the analysis.

8.7 Participant Withdrawal

There are two different types of withdrawal:

- The participant would like to withdraw from the randomised treatment allocation (or intervention in the case of the non-randomised trial), but is willing to be followed-up according to the trial protocol (i.e. has agreed that follow-up data can be collected)
- The participant is not willing to be followed up for trial purposes at any further visits (i.e. has agreed that any data collected prior to the withdrawal of consent can be used in the trial final analysis)

There are three different types of withdrawal from the Qualitative Research:

- The participant does not wish to participate in the interview.
- The participant does not wish to participate in the interview(s) but has agreed to continue in the trial.
- The participant does not wish to participate in the interview(s) and does not want to participant in any further study activities.

9. ADVERSE EVENT REPORTING

9.1 Reporting Requirements

The collection and reporting of Adverse Events (AEs) will be in accordance with the Research Governance Framework for Health and Social Care and the requirements of the National Research Ethics Service (NRES). Definitions of different types of AEs are listed in the table of abbreviations and definitions. The Investigator should assess the seriousness and causality (relatedness) of all AEs experienced by the trial participant this should be documented in the CRF with reference to the protocol.

9.2 Adverse Events (AE)

Only injuries requiring medical attention which occur at HDHK sessions will be reported.

9.3 Serious Adverse Advents (SAE)

9.3.1 Events that require expedited (immediate) reporting

Investigators will report all AEs that meet the definition of an SAE immediately and within 24 hours of being made aware of the event.

Only overnight admissions to hospital due to injury or sudden illness during an HDHK session will be reported as an SAE.

9.4 Reporting period

Adverse events will be collected during the intervention period, then at each follow-up visit.

9.5 Reporting Procedure

9.5.1 Adverse Events

AEs should be collected on an AE Form. An AE Form should be completed at each follow-up point and returned to the trials office in person or posted promptly.

9.5.2 Serious Adverse Events

AEs defined as serious and which require reporting as an SAE should be reported on an SAE Form. When completing the form, the CI will be define the causality and the severity of the AE.

On becoming aware that a participant has experienced an SAE, the CI (or delegate) must complete, date and sign an SAE Form as soon as possible and no later than 24 hours after first becoming aware of the event. The form will be retained at the BCTU.

On receipt the BCTU trials team will allocate each SAE a unique reference number. If confirmation of receipt is not received within 1 working day please contact the BCTU trials team. The SAE reference number should be quoted on all correspondence and follow-up reports regarding the SAE and filed with the actual SAE in the Site File.

9.5.3 Provision of follow-up information

Participants should be followed up until resolution or stabilisation of the event. Follow-up information should ideally be provided on a new SAE Form.

9.6 Reporting Procedure – BCTU

On receipt the PC-CRTU trials team will allocate each SAE a unique reference number. The SAE reference number will be quoted on all correspondence and follow-up reports regarding the SAE and filed with the actual SAE in the TMF.

On receipt of an SAE Form seriousness and causality will be determined by the CI. An SAE judged by the CI to have a reasonable causal relationship with the trial intervention will be regarded as a related SAE. If the event is unexpected (i.e. is not defined in the protocol as an expected event) it will be classified as an unexpected and related SAE.

9.7 Reporting to the Competent Authority and main Research Ethics Committee

9.7.1 Unexpected and Related Serious Adverse Events

BCTU will report all events categorised as Unexpected and Related SAEs to the main REC and RGT within 15 days.

The main REC and RGT will be notified immediately if a significant safety issue is identified during the course of the trial.

9.10 Data Monitoring Committee

The independent Data Monitoring Committee (DMC)/TSC will review all SAEs.

10. DATA HANDLING AND RECORD KEEPING

10.1 CRF Completion

All missing and ambiguous data will be queried. Staff delegated to complete CRFs will be trained to adhere to the CRF completion guidelines as documented below:

- CRF completion and corrections – The CRF will be completed by the researcher . Any corrections will be crossed through and the researcher will sign and date the change.
- Date format and partial dates – Dates are to be completed as set-out in the CRF (DD-MMM-YYYY). If the actual date of birth is unknown, but month and year are known, the
- *Time format and unknown times*

Rounding conventions –If participant height falls either side of 0.5cm – two body fat measures should be taken, rounding one up and one down; e.g. a man whose height is recorded as 173.4 cm and 173.6cm would need a Tanita measure using height as 173cm and also as 174cm

- Which forms to complete and when – At the baseline assessment the CRF should be completed and the father asked to complete the father's baseline questionnaire and the child/ren with help from a parent should complete the children's baseline questionnaire. Further questionnaires and measures for fathers and children should be completed at 3 months and 6 months follow-up as detailed in section 8.1.
- What to do in certain scenarios, for example when a subject withdraws from the trial
- Missing/incomplete data
- Completing SAE forms and reporting SAEs
- Protocol and GCP non-compliances

The completed originals will be submitted to the BCTU trials team.

10.2 Participant completed Questionnaires

Quality of life (QOL) questionnaires will be administered and completed by the participants (fathers and children) at baseline and each follow-up point. QoL questionnaire completion and training will be overseen by a named individual who can answer any questions the participant may have regarding the rationale and method of assessment. The participant will be asked to complete the questionnaire during the follow-up appointments. Ideally the questionnaire should be completed by the participant alone (without assistance from friends, family or the clinical or research team). Any assistance or proxy completion will be recorded and flagged to the trials office. On completion, the QoL questionnaires will be checked on site by a member of the research team for missing data. The participant will be given the opportunity to complete any missing data. If for any reason, the participant is unable to complete the QoL questionnaires during the appointment, they will be offered the opportunity to complete it over the telephone at a convenient time (within a 2 week period).

Staff delegated to administer QOLs will be trained to adhere to the following QOL completion guidelines in addition to the CRF completion guidelines provided above:

- QoL questionnaires to be completed in accordance with completion instructions.
- Participants will be encouraged to answer all questions when completing the CRFs and the QoL questionnaires.
- QoL questionnaires will be checked for missing data and where feasible participants will be given the opportunity to complete any missing data.

10.3 Data Management

All data will be handled in accordance with the UK Data Protection Act 1998.

The CRFs will not bear the participant's full name. The participant's initials, date of birth and trial number, will be used for identification.

The CRFs will comprise, but will not necessarily be limited to, the following forms

Form name	**Schedule for submission**
Screening Log	At baseline
Randomisation Form	Collected at randomisation
Baseline	As soon as possible after visit
Follow Up questionnaires (Months 3 and 6)	As soon as possible after each visit
Serious Adverse Event (SAE) Form	Faxed/delivered within 24hrs of research staff becoming aware of event
Health Resource Utilization Questionnaire	As soon as possible after each visit

Questionnaires must be completed, signed/dated and returned to the HDHK Study Office by the PI or an authorised member of the site research team (as delegated on the HDHK Study Signature & Delegation Log) within the timeframe listed in the table above. Any errors on questionnaires should be crossed out with a single stroke, the correction inserted and the change initialled and dated. If it is not obvious why a change has been made, an explanation should be written next to the change. If information is not known, this must be clearly indicated on the CRF or questionnaire. All sections should be completed; all missing and ambiguous data will be queried. In all cases it remains the responsibility of the PI to ensure that the CRF has been completed correctly and that the data are accurate.

10.4 Archiving

Archiving will be authorised by the BCTU on behalf of the Sponsor following submission of the end of trial report. All essential documents will be archived for a minimum of 5 years after completion of trial. Destruction of essential documents will require authorisation from the BCTU on behalf of the Sponsor.

11. QUALITY CONTROL AND QUALITY ASSURANCE

11.1 Monitoring

11.1.1 Central Monitoring

Trials staff will be in regular contact with the research team to check on progress and address any queries that they may have. Trials staff will check incoming Case Report Forms for compliance with the protocol, data consistency, missing data and timing. Researchers will be sent Data Clarification Forms requesting missing data or clarification of inconsistencies or discrepancies. Copies of signed Informed Consent Forms will be brought in-house for review and storage for all participants providing explicit consent.

11.2 Audit and Inspection

Notification of Serious Breaches

The sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with that trial or the protocol relating to that trial. Researchers are therefore requested to notify the Trials Office of any suspected trial-related serious breach of GCP and/or the trial protocol. Where the Trials Office is investigating whether or not a serious breach has occurred researchers are also requested to cooperate with the Trials Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

12.0 END OF TRIAL DEFINITION

The end of trial will be the date of the last data capture (follow-up visit or qualitative interview). The BCTU trial team will notify the main REC and RGT that the trial has ended and a summary of the study report will be provided within 12 months of the end of study.

A copy of the end of study notification as well as the summary report is also sent to the University of Birmingham Research Governance Team at the time of sending these are sent to the REC.

13. STATISTICAL CONSIDERATIONS

The data analysis plan will be reviewed and approved by the Study Steering Committee (SSC). Any amendments to the original plan will be approved, recorded and justified in any final report. Analysis of results will be performed by the trial statistician and will be based on treatment code only. The correspondence between actual treatment arm and the assigned code will be revealed only on completion of all analyses.

The trial will conform to CONSORT recommendations. Analysis will be on an intention-to-treat basis.

13.1 Analysis of Outcome Measures

Full details will be specified in a Statistical Analysis Plan but an outline of the plan will be given here.

Primary analyses for the feasibility study will be estimation of participant programme recruitment rates, completion rates and follow-up rates with 95% confidence intervals of these estimates.

Descriptive statistics will be used to describe the outcomes deemed to be feasible outcome measures (by satisfactory completion rates) reporting means and standard deviations, medians and IQRs or numbers and proportions as appropriate.

A confidence interval of the variability in father's weight change (proposed primary outcome for the definitive trial) will be obtained from repeated measures mixed modelling adjusting for baseline weight and ethnic group (stratification variable). Trial participants in the HDHK arm will receive the intervention in groups, we will therefore estimate the potential facilitator cluster effect with corresponding 95% confidence interval. These estimates of variability, together with the Australian data [5,6,27], will help to inform the power calculation for the definitive effectiveness trial.

The primary outcomes will not be analysed using hypothesis testing as this study is not formally powered to address these questions.

There are no stopping rules.

13.1.1. Planned Randomisation Methodology

After all eligibility criteria have been confirmed and informed consent has been obtained, the participants can be randomised into the HDHK UK trial.

The Birmingham Clinical Trials Unit (BCTU) will provide a third-party randomisation service on-line. Once eligibility criteria have been confirmed, consent has been obtained; and baseline measurements and questionnaires have been completed participants will be randomised online via a secure internet facility in a 2:1 ratio (intervention to control).

13.1.2. Power Calculations

Each HDHK programme will aim to recruit 15 fathers, thus we aim to randomise 60 fathers to the HDHK groups and 30 to the control group. The sample size has been chosen to enable estimation of the feasibility outcomes with reasonable precision. We will be able to estimate the recruitment, follow-up and questionnaire completion rates to within +/- 10% with 95% confidence, based on a worst case estimate of 50%.

14. TRIAL ORGANISATIONAL STRUCTURE

14.1 Sponsor

The University of Birmingham is the nominated sponsor for this study.

Coordinating Centre

14.2 Trial Management Group

The SMG will comprise the CI, other lead investigators and members of the BCTU. The SMG will be responsible for the day-to-day running and management of HDHK UK. It will convene at least once a month, and more frequently when required.

14.3 Trial Steering Committee

The Study Steering Committee (SSC) will provide the overall supervision of the trial. The SSC will monitor study progress and conduct and advise on scientific credibility. The SSC

will consider whether the trial needs a separate Data Monitoring Committee (DMC). The SSC will have responsibility for deciding whether the study needs to be stopped on grounds of safety or efficacy.

The SSC will chaired by Prof John Wright, Bradford Institute for Health Research. Academic members include Prof Pat Hoddinott, University of Stirling, Elaine Nicholls, University of Keele (statistician) and Mr Ray Fiveash (lay representative).

14.4 Data Monitoring Committee

We do not propose that a data monitoring and ethics committee would be useful as this is an unblinded study with no substantial risk and no early termination rules. The final decision will be made by the SSC.

14.5 Finance

This is a researcher-initiated and researcher-led study funded by the NIHR Public Health Research programme. The intervention will be funded by the local authorities where the services are provided (Wolverhampton and Sandwell Borough Councils).

14.6 Criteria for progression to a main trial

For the phase III trial to be considered the following criteria need to be met:

- Process evaluation suggests that the intervention is acceptable to a majority of fathers and families;
- Randomisation occurs and >80% of those assessed accept randomisation;
- Recruitment of at least 68 out of the planned 90 fathers (75%) within the 4 month time frame;
- Intervention implemented with fidelity in 75% of observations (see 'process evaluation' section above);
- Attendance 70% attending at least 5/9 of the planned sessions,
- More than 70% follow up at 3 and 6 months
- Mean weight loss in the intervention arm of ≥3kg.

15. ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, 1964, amended by the 48th WMA General Assembly, Somerset West, Republic of South Africa, 1996 (website: http://www.wma.net/en/30publications/10policies/b3/index.html).

The trial will be conducted in accordance with the Research Governance Framework for Health and Social Care, the applicable UK Statutory Instruments, (which include the Data Protection Act 1998) and the Principles of Good Clinical Practice (GCP) The protocol will be submitted to and approved by the main Research Ethics Committee (REC) prior to circulation.

Before any participants are enrolled into the trial, the Principal Investigator at each site is required to obtain local R&D approval/assurance. Sites will not be permitted to enrol participants until written confirmation of R&D approval/assurance is received by the BCTU trials team.

It is the responsibility of the Principal Investigator to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual clinicians' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.

16. CONFIDENTIALITY AND DATA PROTECTION

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 1998.

Participants will always be identified using only their unique trial identification number and date of birth on the Case Report Form and correspondence between the BCTU. Participants will give their explicit consent for the movement of their consent form, giving permission for BCTU to be sent a copy. This will be used to perform in-house monitoring of the consent process".

BCTU will maintain the confidentiality of all participants' data and will not disclose information by which participants may be identified to any third party other than organisations for which the participant has given explicit consent for data transfer (e.g. competent authority, sponsor). Representatives of the *HDHK UK* trial team and sponsor may be required to have access to participant's notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times.

Data will be stored according to the University of Birmingham's code of practice for Research. Data will be preserved and accessible for 10 years from the end of the study.

17.0 INSURANCE AND INDEMNITY

The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

18. PUBLICATION POLICY

The CI will coordinate dissemination of data from HDHK UK

Dissemination will focus on: the findings of the qualitative research on cultural adaptation of the HDHK programme; qualitative findings in relation to the successes and barriers to implementing the HDHK programme and the findings of the feasibility trial. The level of dissemination will be in keeping with that appropriate for a feasibility study.

A monograph with an accessible lay summary will be prepared for the NIHR. Results of this trial will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by the Professor Kate Jolly and authorship will be determined by mutual agreement.

Where journals have a maximum number of authors, the list of co-authors may need to be truncated and use of the text 'on behalf of the HDHK UK research team' used with a full listing of the other named contributors in the acknowledgements section of the publications.

Any secondary publications and presentations prepared by Investigators must be reviewed by the study investigators. Manuscripts must be submitted to the *NIHR* in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Authors must acknowledge that the trial was performed with the support of the NIHR and University of Birmingham. Intellectual property rights will be addressed in the project agreement between the University of Birmingham, Fatherhood Institute and University of Newcastle, New South Wales.

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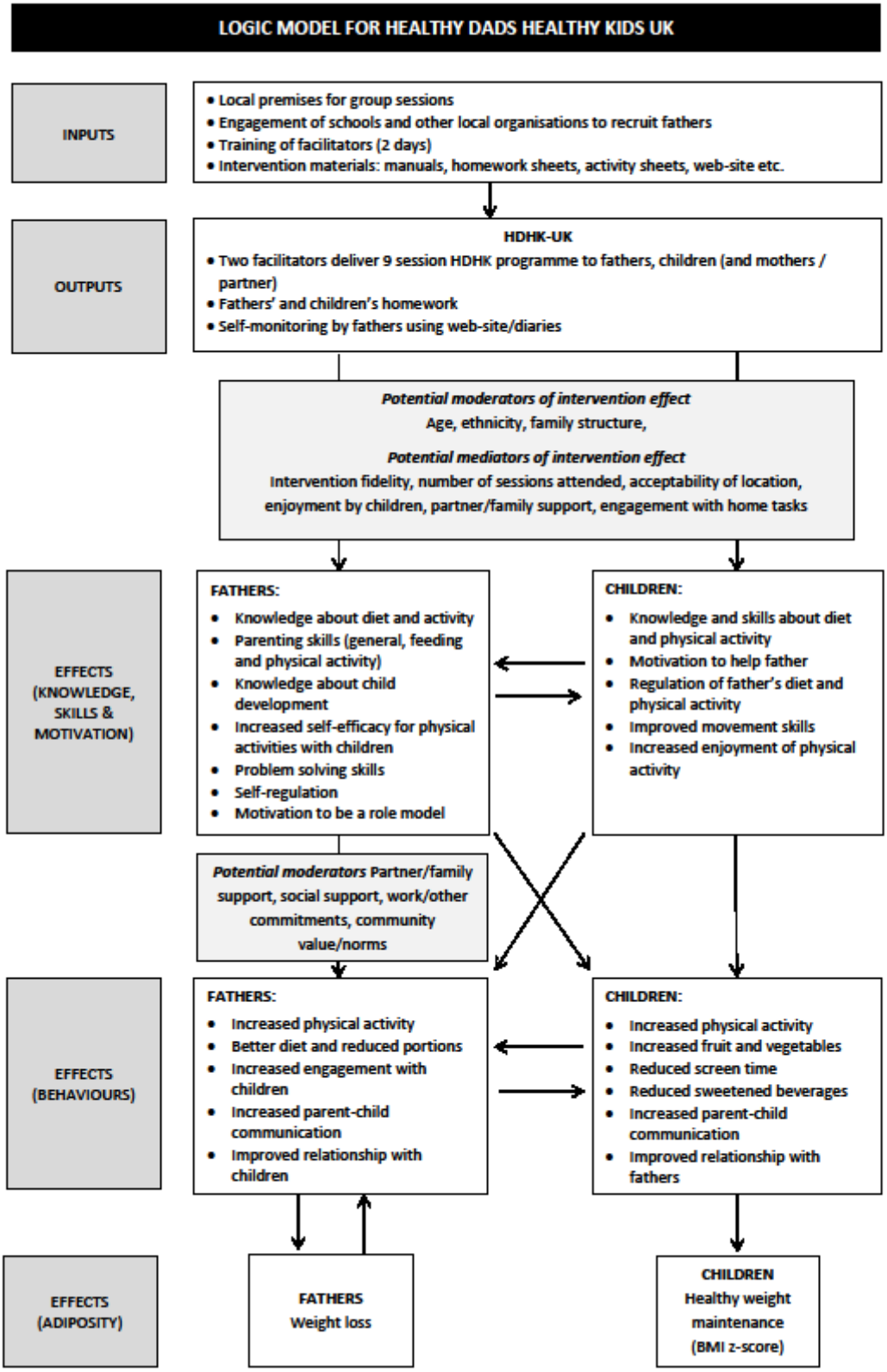
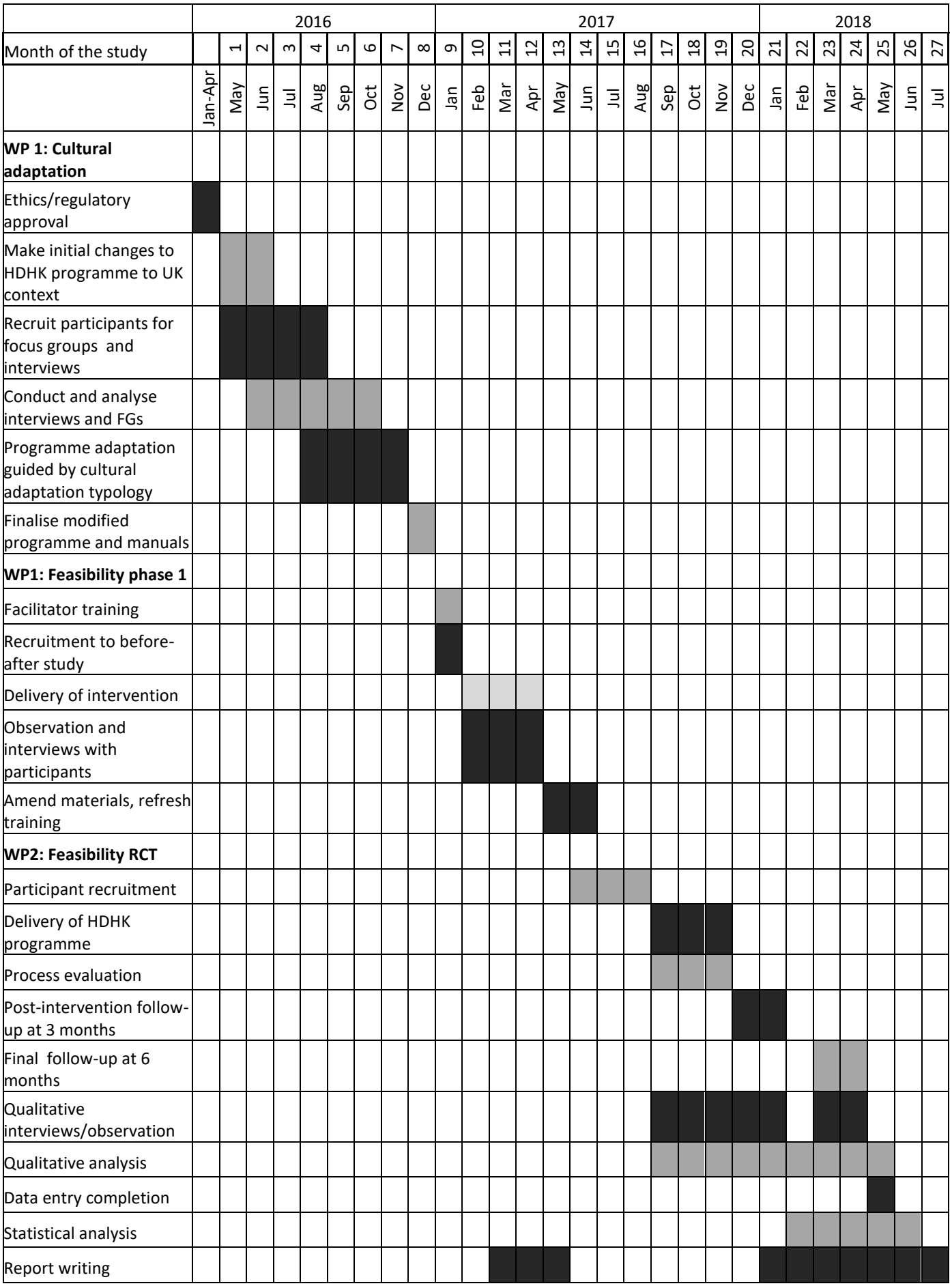
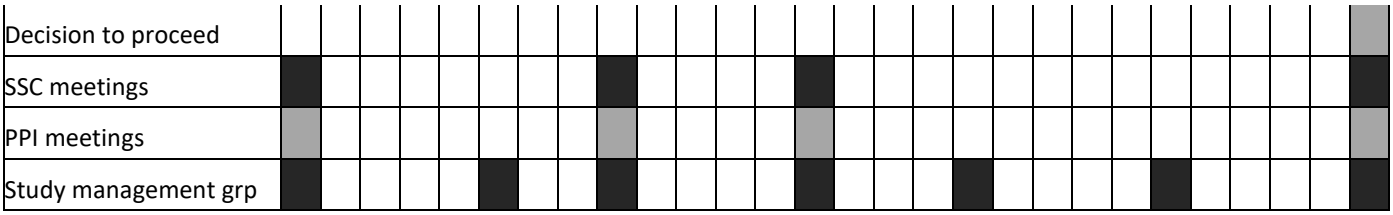
APPENDICES


LOGIC MODEL FOR HEALTHY DADS HEALTHY KIDS UK
INPUTS
• Local premises for group sessions
• Engagement of schools and other local organisations to recruit fathers
• Training of facilitators (2 days)
• Intervention materials: manuals, homework sheets, activity sheets, web-site etc.
OUTPUTS
HDHK-UK
• Two facilitators deliver 9 session HDHK programme to fathers, children (and mothers / partner)
• Fathers' and children's homework
• Self-monitoring by fathers using web-site/diaries
Potential moderators of intervention effect
Age, ethnicity, family structure,
Potential mediators of intervention effect
Intervention fidelity, number of sessions attended, acceptability of location, enjoyment by children, partner/family support, engagement with home tasks
EFFECTS (KNOWLEDGE, SKILLS & MOTIVATION)
FATHERS:
• Knowledge about diet and activity
• Parenting skills (general, feeding and physical activity)
• Knowledge about child development
• Increased self-efficacy for physical activities with children
• Problem solving skills
• Self-regulation
• Motivation to be a role model
CHILDREN:
• Knowledge and skills about diet and physical activity
• Motivation to help father
• Regulation of father's diet and physical activity
• Improved movement skills
• Increased enjoyment of physical activity
Potential moderators Partner/family support, social support, work/other commitments, community value/norms
EFFECTS (BEHAVIOURS)
FATHERS:
• Increased physical activity
• Better diet and reduced portions
• Increased engagement with children
• Increased parent-child communication
• Improved relationship with children
CHILDREN:
• Increased physical activity
• Increased fruit and vegetables
• Reduced screen time
• Reduced sweetened beverages
• Increased parent-child communication
• Improved relationship with fathers
EFFECTS (ADIPOSITY)
FATHERS
Weight loss
CHILDREN
Healthy weight maintenance
(BMI z-score)

Gantt chart for May 2016 start and 6 months follow-up: study milestones




Decision to proceed
SSC meetings
PPI meetings
Study management grp