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

1. Background:

1.1. Existing research

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.

1.2. Risks and benefits

This proposal addresses the commissioned call of weight loss services for men and targets obese men as well as also addressing the current NIHR PHR call for interventions for parents or carers to promote healthy behaviours in children and young people (15/01).

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.

1.3. Rationale for current study:

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.

2. Research objectives:

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

WP1a: CULTURAL ADAPTATION OF EXISTING PROGRAMME:

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 acceptable in a UK multi-ethnic population.

To achieve this, specific objectives are:

1.1 To explore cultural (ethnic, religious, socio-economic) acceptability of the programme elements and proposed questionnaires with fathers from a range of ethnic, religious and socio-economic groups.

1.2 To increase the cultural acceptability of the programme using theoretically informed adaptations so that it is acceptable and accessible to the full ethnic, religious and socio-economic diversity of the UK population.

WP1b: FEASIBILITY OF DELIVERING ADAPTED HDHK PROGRAMME:

1.3 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 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.

3. Research design and theoretical framework:

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]

This proposal involves 2 phases: (i) cultural adaptation of the Healthy Dads, Healthy Kids (HDHK) programme[5,6,27]; (ii) feasibility RCT.

4. Setting/context

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. The proposed study will take place in Birmingham; a super-diverse city with 47% of the population non-white British (Pakistani, Indian, Black Caribbean, Eastern European) and about one third non-white ethnicity (compared to 13% for England). It will also take place in at least one other local authority area in the West Midlands.

5. The existing Healthy Dads, Healthy Kids (HDHK) programme

The proposed 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. Mothers/partners are invited to attend 2 sessions, fathers attend all 9, and the children attend 7. In the joint sessions, the children and fathers separate for 20-25 minutes for a discussion session followed by a 1 hour joint physical activity session. 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 (see Appendix 1). 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

Sess-ion	Dads sessions	Kids sessions	Attend-ees
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	**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
4	**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.*	**(Dads only session)**	Dads
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.*	**(Dads only session)**	Dads
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.*	Dad, Mum & Kids

Need for further study of the HDHK programme

The programme has been compared to wait-list controls (which may over-estimate effect sizes compared to a 'placebo' comparator group[32]), with short follow-up against a comparator (14 weeks in main RCT). In addition, it has not been tested in an ethnically diverse population and the programme uses Australian examples and terminology.

The PPI group consulted in the development of this proposal identified the need for adaptations. Recent interviews about weight management groups for children with parents of Pakistani and Bangladeshi ethnicity in Birmingham has highlighted the importance of family group programmes being delivered close to home, the preference for interactive sessions rather than classroom style, a need to promote free physical activities and a preference for Saturday classes because of attendance at Mosque after school [unpublished].

6. WP1 Cultural adaptation of the Healthy Dads, Healthy Kids programme

(i) Make UK appropriate changes to the terminology within the HDHK programme

The current HDHK programme will be adapted to include examples and terms that are UK focussed and consider super-diversity. For example, we will use UK rates of obesity and physical activity levels and change any language or terms that are not used in the UK e.g. use of kilojoules, Australian slang terms.

(ii) Qualitative data collection from fathers from ethnic minority groups

The aims of the qualitative research are described in objectives 1.1 and 1.2 (page 4).

From the research team's local knowledge and from our initial public participation work we have identified certain cultural barriers to engagement with behaviour change activities in some MEGs. For example, participation in sports and physical activity outside of the home may be prohibited among girls, and cultural dress codes can restrict physical activity.

We plan to hold up to five focus groups (FGs) with fathers and family members from the Bangladeshi and Pakistani communities and fathers from socio-economically deprived communities (e.g. white British, African Caribbean and other ethnic groups), supplemented with up to 15 one to one interviews purposively selected to ensure a sample that represents a range of socioeconomic, age, geographical neighbourhoods, family types and ethnic groups. We are focusing on these Bangladeshi/Pakistani ethnic groups because of particularly high rates of obesity in the adults and children from these communities[13] together with low attendance of members of these ethnic groups at weight management programmes for adults and children. Participants will be identified through community networks.

We will develop semi-structured topic guides for the FGs and interviews, informed by the typology of cultural adaptation,[26] literature on facilitators and potential barriers of men and children to attending weight management programmes, research team knowledge and experience, and our PPI advisors. The FGs and interviews will be undertaken by our qualitative researcher in conjunction with a community researcher if required. The University of Birmingham has a network of community researchers as part of its super diversity research network. Research questions are likely to explore family and community attitudes to girls taking part in a group-based healthy-lifestyles programme, the cultural acceptability of girls and their fathers partaking in 'rough and tumble' and other physical activities together, acceptable locations and timing of sessions, cultural issues related to fathers

being more involved in food preparation, how fathers would like to be invited to take part, including the 'hook' that would encourage them to take part (personal weight loss, health, role modelling to improve children's health, time with children) and any potential barriers to changes in diet and physical activity. The use of two different qualitative data collection methods will help to facilitate the collection of interactional data (FGs) as well as providing an opportunity to explore participants' views in more depth (interviews). Overall, it will help us to triangulate our findings and enhance the richness of the dataset.[33]

It may be beneficial to undertake second interviews or a follow-up focus group to explore issues in more depth. At the end of the interview or focus group we will ask if any participants would be willing to contribute a second interview should the need arise.

Interviews and FGs will be audio-recorded and transcribed clean verbatim for analysis. A thematic analysis of content will be informed by the Framework analytical approach. Following initial familiarisation with the interview and FG data, development of thematic frameworks and data coding will proceed in an iterative manner. Thematic charts / grids will be used to aid interrogation of patterning within the qualitative data and to explore potential similarities and differences between groups of interest (e.g. MEGs/SES). Analysis and discussion within the experienced qualitative team and in partnership with the PPI group will provide multiple perspectives on the data during the analysis phase. Data collection and analysis will run concurrently so that emergent analytical themes can inform further data collection.

(iii) Application of principles for adapting behavioural interventions for minority ethnic groups

Based on our experience of health service development for MEGs[34] and the comprehensive evidence synthesis review on the adaptation of health promotion programmes for MEGs (undertaken by Liu et al[26]), we will apply the principles for adapting behavioural interventions for MEGs to guide the intervention development process. These include approaches to increase accessibility, addressing barriers to participation, strategies to improve communication, and working with cultural or religious values that could contribute to behaviour change.[35,36] Specifically, the information from the described qualitative work will be mapped to the 46-item typology of health promotion intervention adaptation for MEGs, developed by Liu and colleagues.[26] This will enable specific opportunities for adaptation to be identified from the qualitative findings.

The programme theory of adapted health promotion interventions [26] will be used to guide the adaptation process throughout. This programme theory provides an initial framework to support a systematic approach to the adaptation of health promotion interventions, and will ensure that all aspects of the programme have been taken into consideration during the adaptation process. The programme theory describes the processes within the health promotion intervention cycle: conception/planning, promotion, recruitment, implementation, retention, evaluation, outcome, and dissemination (appendix 2). The 46-item typology can be mapped to these programme theory processes, thus the opportunities for adaptation identified by application of the typology to the qualitative findings will be aligned to the stages in the programme theory. Any further opportunities for adaptation will then be identified.

(iv) Expected outputs

The HDHK programme will undergo modifications specified by the processes described above to produce a new, culturally adapted HDHK programme appropriate for a diverse UK population. The delivery of the HDHK sessions will be adapted to fit with the learning styles and health literacy levels

of a socio-economically and ethnically diverse population. HDHK manuals for facilitators, fathers and children and resources will be adapted with the objective that they are relevant to a diverse cultural population, but not focussed exclusively on any particular groups (e.g. by including materials with data referring to a range of ethnic groups, activities and dietary advice with wide cultural appeal, appropriate communication/ language that will not exclude any group). The programme theory of adapted health promotion interventions[26] will also be used to guide manual adaptation, so that opportunities for tailoring within each stage of the intervention cycle (described above) are included within the manuals. We will also adapt the HDHK training programme for staff who will be delivering the newly adapted programme.

(v) Feasibility and acceptability of amended programme

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

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 focus groups/interviews with the facilitators and participants to explore acceptability of the intervention, timing and location as well as training of the facilitators.

Fathers will be approached through primary schools, community groups, large employers, religious institutions and any other community organisations identified by the qualitative study participants. These organisations will send an invitation letter, summary leaflet, reply slip and freepost envelope to potential participants. Advertisements with study contact details will also be placed in locations/organisations identified the qualitative study participants.

Interested people will be sent the participant information sheet (PIS) and the children's PIS 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.

Follow-up will take place at the final session, as this stage is focussing on the acceptability of the intervention, rather than trial processes. Outcomes measures are the same as those for WP2.

Any participant who ceases to attend will be invited to undertake a telephone interview to explore why they failed to attend. The qualitative interviews/focus groups 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.

7. WP2: Feasibility randomised controlled study of the UK culturally adapted HDHK programme

Design

The two primary aims are to assess the feasibility of the intervention and trial components and to test the intervention in an RCT to determine the feasibility of undertaking a future fully powered RCT. Participants will be randomised to intervention and comparator arms using block randomisation with 2:1 randomisation in favour of the HDHK intervention. The randomisation list will be developed by an independent statistician in the Primary Care Clinical Research and Trials Unit (PC-CRTU) and held in a secure database.

Young and middle aged men are low users of health services. We propose to recruit fathers through a range of pathways. We have experience of working with families through primary schools in the West Midlands, where we have recruited over 1400 children from 54 schools as part of the WAVES childhood obesity prevention study[37]. Unpublished data from the WAVES childhood obesity prevention study[37] shows that over 50% of fathers of primary school aged children are overweight or obese. We have also recruited 550 fathers to HDHK in Australia.

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. Baseline measurements will be taken after consent and prior to randomisation.

Fathers will be randomised to the HDHK intervention or control group over the telephone/web to ensure allocation concealment, stratifying for father's ethnicity (white British or Irish/other ethnic group).

Data collection:

Follow-up data will be collected by a project officer not involved in randomisation or delivery of the intervention and stored on a secure password-protected database. To minimise unblinding where possible, participants will be instructed to keep their allocation status a secret from the project officer, including not wearing HDHK tee-shirts, pedometers or having HDHK materials in the vicinity if follow-up is done at a home visit.

Study population:

The study will take place in Birmingham which is the city with the highest prevalence of obesity in the European Union, high proportions of non-white British and high levels of deprivation. At least one other area will be selected from Wolverhampton and Sandwell (see letters of support). Their details are in the table below:

Area	% non-white British	Rank for deprivation[1]	% of local population living in most deprived LSOAs in country
Birmingham	47%	10	55
Sandwell	34%	6	57
Wolverhampton	35%	18	50

[1]Denominator 326 local authority areas; LSOA: local super-output areas

The intervention will take place in community venues close to where people live. These will include local leisure centres and schools. These venues were identified as most suitable by the PPI group and will be informed by the qualitative work in WP1. The feasibility study will explore recruitment from fathers in the more socio-economically disadvantaged localities and the acceptability of programme delivery in different community facilities.

Inclusion criteria

Obese men who are fathers/step-fathers of primary school aged children (4-11 years). Men must be aged between 18-65 years with a BMI of 30-40kg/m^2 (27.5-40kg/m^2 for MEGs) and want to lose weight. Fathers do not have to be resident in the same household as their child/ren to take part.

Exclusion criteria are selected to ensure safety of participants, as the intervention group will be undertaking exercise in a community setting: 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 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.

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. The focus groups and interviews in WP1 will explore recruitment methods and locations that are acceptable to people from diverse communities. 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.

Planned interventions:

The intervention will be a UK adapted version of the Healthy Dads, Healthy Kids (HDHK) programme[5,6,27] (details above). Each father can bring all their primary school aged children (4-11 years) to participate in the programme. We propose to run four HDHK groups: one in Wolverhampton, one in Sandwell and two in Birmingham.

Facilitators

In Australia the facilitators were largely teachers of physical education or personal, health and social education. We will explore options for facilitators from different backgrounds to deliver the joint programme to the fathers and children.

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 content and delivery style. Training will last for 2 days (10-12 hours). Professor Phil Morgan, who developed the HDHK programme, is a co-applicant and will share experience and initially train the trainers from the Fatherhood Institute. These trainers will then train the facilitators. Quality assurance will be achieved through videoing the sessions and providing constructive feedback to trainers if appropriate.

The intervention will be commissioned and paid for by the local authorities (see letters of support).

Control group

The control intervention is designed to try to reduce loss to follow-up in this group. Participants will be provided with details about local opportunities for physical activity. For example, in Birmingham a free Be Active programme is available in leisure centres at particular times of the day to all Birmingham residents who register with the service [38]. A family voucher to attend a leisure centre for swimming or other family activity will be provided free for one occasion.

Give a brief explanation of the methods proposed.

In the Australian evaluation of the HDHK programme there was 70% attendance at the programme sessions. Loss to follow-up at 6 months in the pilot evaluation was 17% and it was <30% at 12 months in the community trial. Loss to follow-up in disadvantaged communities can be high so we will put in place measures to maximise follow-up (see 'assessment and follow-up' below). This feasibility study would provide estimates of follow-up rates to inform a definitive trial.

Proposed outcome measures:

Feasibility outcomes:

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

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

The feasibility of collecting educational attainment data from schools will be explored (we are currently doing this within our NIHR HTA funded WAVES study).

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 questionnaires. (See section 9 for criteria for progression to a full trial).

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.

Secondary outcomes of a full effectiveness trial include:

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

Children's BMI z-score change, % body fat, % categorised as overweight or obese, objectively measured physical activity (eldest child), parent-reported dietary behaviours for eldest child (using the same measures as for the fathers), and attainment data collected from schools.

Weight (Tanita bio-impedance BF-522W analyser scales), and height (using Leicester height measure) will be assessed objectively to allow BMI to be calculated. Objective physical activity will be measured using GENEactiv accelerometers over a consecutive 7 day period in all fathers and their eldest child.

Utility-based quality of life (QOL) will be measured in the fathers using the EQ-5D to calculate QALYs. To measure a broader sense of health with a focus on general wellbeing in a definitive trial, we will also collect data from fathers using the ICECAP instrument. We will also collect quality of life information from the child using the CHU-9D, a validated paediatric QOL instrument. In a subsequent full effectiveness trial, this would allow the cost-effectiveness analysis to go beyond the conventional perspective by considering outcomes of the family members and outcomes that go beyond the traditional health focus. The health service costs associated with delivering the intervention will be collected using standard resource use collection methods. To determine the feasibility of an analysis from a wider perspective, resource use will also be collected from fathers and the family members.

Assessment and follow up:

Follow-up will take place at 3 months and 6 months post-randomisation to get a measure of likely drop-out. Loss to follow-up in community weight management trials is often high[2]. To minimise loss to follow up we will have a procedure of letters, phone calls and text reminders running up to the assessment points to reduce non-attendance. We will hold follow-up sessions in soft play areas to provide an enjoyable experience for the children, also offer home follow-up and offer £10 and £15 shopping vouchers on completion of follow-up at 3 and 6 months.

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.

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.

Assessment of harms:

Adverse events resulting from the study will be recorded. These will be collected at the HDHK sessions, but also directly asked about at the follow-up assessments. Participants will be asked when the adverse event occurred in relation to physical activity. Further details will be sought from their GP if needed. Serious related adverse events will be reported to the ethics committee and sponsor. All adverse events will be reported in a blinded manner to the SSC/DMEC.

Proposed sample size:

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%.

*Statistical analysis***:**

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.

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.

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. 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; fidelity of the intervention will be above 75% of the sessions observed; attendance: 70% attending at least 5/9 of the planned sessions, >70% follow up at 3 and 6 months.

The fidelity of the intervention 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

Progression criteria based on differences in weight: as it would be inappropriate to be undertaking between group analyses in a feasibility study, we have included weight change within the fathers from baseline to end of programme (3 months follow-up). We propose a mean difference of 3kg weight loss would be evidence of a likely beneficial effect.

Recruitment targets based on weight: we propose that all the fathers should be in the obese range (BMI of ≥30kg/m^2 for white British) and as previously stated that we would expect to recruit at least 75% of the target number.

9. Ethical arrangements:

Ethical approval will be sought from the University of Birmingham Research Ethics Committee (REC), as the participants will not be identified via the NHS and the intervention will be delivered by non-NHS personnel. Ethical approval will be sought at the start of the study and if changes are required prior to the feasibility trial, then a substantial amendment will be submitted to the REC before WP2.

WP1: Informed consent will be obtained from fathers and others participating in interviews.

WP2: Informed consent will be obtained from fathers participating in the trial and by a parent on behalf of the children. Regarding the interviews and possible FGs, informed consent will be obtained from group facilitators, fathers and mothers. For the participating children, parental consent and children's assent will be obtained for participation in interviews.

Throughout the study the University of Birmingham's data protection policies and procedures will be followed. All data will be kept strictly confidential. Audio-files created during the qualitative elements of the study will be kept in a secure place until the study is completed. Audio files will be transcribed by a specialist external company who will sign confidentiality agreements and will be required to store data appropriately. Transcripts of interviews and FGs will have all identifying information removed.

10. Research Governance:

The trial will form part of a portfolio of studies hosted and managed by the Primary Care Clinical Research Trials Unit, University of Birmingham.

The University of Birmingham is the nominated sponsor for this study. Research governance approval will be sought from Birmingham City Council.

A Study Steering Committee (SSC) will be convened to provide overall supervision of the feasibility trial and ensure its conduct is in accordance with the principles of GCP and the relevant regulations. The SSC will agree the study protocol and any protocol amendments, including at the end, whether the criteria for progression to a main phase III trial have been met and advising on potential modifications. Furthermore the SSC will provide advice to the investigators on all aspects of the trial. The SSC will be chaired by Prof Pat Hoddinott, University of Stirling. Three additional independent members will be invited to join the SSC, including a statistician and a lay representative. In addition, Mr A. Entwistle will join the SMG as the PPI representative. 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.

The intervention will adhere to Birmingham City Council's policies and quality standards.

11. Project timetable and milestones

A detailed project timetable is appended. Project commence 1 May 2016, with regulatory approvals applied for prior to start. Initial changes to HDHK materials, recruitment to qualitative research, interviews, FGs and analysis: months 1-6; cultural adaptation to HDHK months 4-7; finalise manual

month 8, facilitator training month 9; uncontrolled feasibility trial intervention delivery months 10-12; amend materials and train facilitators months 13-14; feasibility trial recruitment months 14-16; HDHK delivery 17-19; process evaluation 17-19; 3m follow-up and qualitative interviews 20-21; 6m follow-up and qualitative interviews 23-24; qualitative analysis 17-25; data entry completion 25; statistical analysis 22-26; report writing 11-13 and 21-27.

12. Expertise:

The study team involves researchers and health professionals of international standing from different disciplines including public health (KJ, PA, MP), health psychology (AD, MY), physical activity (PM, AD), nutrition (CC, EM), primary care (KJ, AD), health economics (EF), qualitative research (LJ, MP, KJ), clinical trials (AR, KJ, PA, AD, PM, CC) education (PM) and statistics (AR). Members of the study team have previously and currently work together on a number of trials in adults and children. We have been awarded funds to conduct several weight management trials in adults and children. We have a track record of publishing our studies in highly rated general and specialist journals

Contributions of the research team in the proposed study

KJ (PI) will lead and manage the project, develop methodology, liaise with other co-investigators and stakeholders.

Peymane Adab will advise on engagement with schools for recruitment and on cultural adaptation of the intervention from the perspective of the children, using her experience from the BEACHeS and WAVES trials of childhood obesity prevention

Miranda Pallan leads an HTA funded study of a cultural adaptation of a children's weight management programme (12/137/05). This study has included qualitative interviews with the parents of overweight children from the Pakistani and Bangladeshi communities and has provided insights into delivering programmes for children from minority ethnic groups. She has also been adapting the intervention using the toolkit recommended by the Board in point 6 (Liu et al ref 26 of proposal). She will provide advice on the cultural adaptation and will lead on this element with KJ.

Laura Jones is qualitative and mixed methods researcher and is experienced at designing and conducting qualitative research within feasibility studies. She will lead the qualitative research elements.

Amanda Daley is a health psychologist; she will advise on physical activity measurement and will work on the cultural training in relation to ensuring that the psychological constructs of the intervention remain central to the adapted intervention.

Adrienne Burgess will work in collaboration with the research team at UoB to adapt the HDHK programme and will lead the training of the facilitators. Using her experience as Director of the Fatherhood Institute, she will advise on ways to engage fathers in research studies and on the dissemination of the findings.

Phil Morgan designed the original HDHK programme. He will advise on practical aspects encountered in the previous evaluations in Australia and on developing a maintenance element. He will also ensure that the essence of the HDHK programme remains. With MY he will train the Fatherhood Institute to train the facilitators.

Clare Collins is a professor of nutrition who developed the dietary element and assessments for the HDHK programme and the subsequent evaluations. She will ensure that any changes suggested in the cultural adaptation are coherent with the underlying model of HDHK and will advise on the dietary assessments.

Myles Young will train the Fatherhood Institute to train facilitators and will work with PM and KJ on developing a maintenance element.

Andrea Roalfe will provide advice on statistical aspects of the study (including study design and analysis)

Manbinder Sidhu will be the research fellow managing the study on a day-to-day basis, supported and mentored by KJ. He will undertake much of the qualitative research. This would be his first involvement as a co-applicant on a large funded study and will provide him with extensive learning opportunities to develop new skills.

Emma Frew is a health economist. She will advise on developing economic evaluation methodology for a future trial and on the data collection of resource use for the feasibility study.

Mark Roscoe (collaborator) is the commissioning lead for lifestyles at Birmingham City Council and will ensure that the perspective of the commissioners is considered and he will be the link between the research team and service commissioners.

Eleanor McGee (collaborator) is the public health nutrition lead at Birmingham Community Health Care Trust. She will advise on measurement of nutrition in the local ethnically diverse population and will bring her experience of tailoring and delivering nutrition and weight management interventions in these populations.

13. Partner Collaboration

This research is a proposal in collaboration with Birmingham City Council, who will fund the HDHK intervention. Mark Roscoe will represent BCC on the study management group and is responsible for commissioning such services in Birmingham. Other local authorities who have expressed an interest in collaborating are Wolverhampton and Sandwell. In addition we are linking with the Fatherhood Institute, a third sector organisation.

14. Copyright

15. References

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