

RESEARCH PROTOCOL

Scientific title

Development of a culturally adapted weight management programme for children of Pakistani and Bangladeshi origin

Public title

Child weight mANaGement for Ethnically diverse communities study (CHANGE)

Summary of the research

We will undertake two work packages (WPs), informed by the MRC complex interventions framework.^{1,2}

WP1 (Theoretical and modelling phase): Development of a children's weight management programme that is culturally adapted for Bangladeshi and Pakistani (BP) families, but is suitable to be delivered in a diverse community encompassing multiple ethnic groups.

WP2 (exploratory phase): A feasibility study to evaluate the acceptability of the developed weight management programme and to assess the feasibility of a future definitive trial.

The setting for the study is Birmingham; a diverse city with 44% of children from minority ethnic groups (MEGs), and 20% from BP communities. The NHS offers a group-based community weight management programme for parents of overweight/obese children aged 4-11 years (First Steps), targeting all ethnic groups. Parents are invited to attend 7 sessions, with the children attending the first and last sessions. Sessions are interactive and practical covering nutrition education, behaviour change and physical activity promotion. After completion, families are invited to attend quarterly follow up events. Currently, initial uptake of the programme by BP families is high, but completion rates are lower than in other ethnic groups. The programme is delivered by Birmingham Community Healthcare NHS Trust, and is commissioned by Birmingham City Council. This existing infrastructure will be used for the study.

WP1 consists of three strands of work to inform development of the culturally adapted children's weight management programme.

- 1) We will review the existing programme against the current evidence for effective children's weight management interventions and identify common behaviour change techniques included in effective programmes using the CALO-RE taxonomy for behaviour change techniques.³
- 2) We will recruit three groups of BP parents to participate in interviews and FGs to explore barriers and facilitators to participation in the existing programme and potential modifications to enhance participation and sustained engagement. These groups will comprise parents/carers who were offered the First Steps programme but declined to attend (n=15), parents/carers who attended but did not complete the programme (n=15), and parents/carers who completed the programme (n=20-30).
- 3) We will use our previous experience, existing literature and a framework for the adaptation of health promotion interventions for MEGs⁴ to guide the programme adaptation process.

Accompanying manuals will be developed for the adapted programme. Much of the content will be generic but will include tailored content specific to BP families. The tailored content will provide a template for adaptation to other communities, enabling future transferability and tailoring to different populations.

In WP2 we will undertake a feasibility study with the primary aim of assessing the proportion of BP families completing the adapted intervention programme. We will also assess the proportion of families of all ethnicities completing the adapted programme. In addition the feasibility study will inform design of a future RCT to determine effectiveness of the modified programme.

Study population: Families in Birmingham with an overweight/obese child aged 4-11years. Families referred to the existing service will be invited to participate. Purposive sampling will be undertaken to achieve over representation of BP families (60% of the study sample)

Health technology: The culturally adapted weight management programme for children aged 4-11years, modified from the existing First Steps programme. Structure, content and delivery will be determined in WP1. The programme will be delivered over 7-8 weeks, followed by post-intervention support.

Study design: Programmes (which typically contain 10 families) will be randomised to intervention or standard care arms with a 2:1 ratio. Families will choose to attend a programme based on a location and timing that is convenient to them, without knowledge of the randomisation allocation.

Outcome measures: For the primary outcome measure we will estimate the proportion of BP families completing the programme in the intervention arm. We will assess intervention acceptability and success of programme adaptation. Interviews, FGs and questionnaires will be used to explore the views of programme providers, children and parents in relation to the adapted programme, and reasons for non-completion.

Sociodemographic data will be collected and measures taken on children and parents at baseline. Follow up measures will be taken immediately post-intervention and 6 months after the intervention. Data will be collected by researchers through home visits (with interpreters if required). Anthropometric, diet, physical activity and psychosocial outcomes will be collected and compared between the two groups. Methods for collecting resource use data for the intervention and standard care will be developed to inform a future economic evaluation.

Sample size: We will recruit 80 families (60% BP). Programme randomisation will be undertaken with a 2:1 ratio. We will randomise 24 programmes. We expect approximately 54 participants in the intervention arm and 26 in usual care arm.

The project length will be 30 months in total.

Background and Rationale

Epidemiology of childhood overweight and obesity

The prevalence of childhood overweight/obesity in England is currently 23% in 4-5 year olds, rising to 34% in 10-11 year olds⁵, and is forecast to continue rising.⁶ Among minority ethnic groups, South Asian children have a higher prevalence of obesity compared to white children (23% vs. 18% in 10-11 year olds).⁵ Pakistani boys, and Bangladeshi children have higher overweight/obesity levels (39% and 34% respectively) than the general UK population (30%).⁷ Obesity is associated with a range of physical, psychological and social consequences in childhood.⁸ Furthermore, up to 80% of obese children will become obese adults.⁹ Obesity in adulthood is a risk factor for a wide range of health consequences, including certain cancers, cardiovascular disease and type 2 diabetes.^{10;11} It is therefore a major contributor to morbidity and premature mortality.

South Asians (persons originating from the Indian subcontinent) comprise the largest minority ethnic population in the UK and are a vulnerable group with regard to obesity and its health consequences. South Asians tend to have higher body fat and central obesity compared to white European populations.¹² In addition, South Asians are more vulnerable to the cardiometabolic consequences of obesity than other ethnic groups in the UK¹³, and have markers of increased cardiovascular risk, even in childhood.¹⁴

Given the high prevalence of childhood overweight and obesity in the UK, together with the high likelihood of this tracking into adulthood and the severity of the associated health consequences, effective interventions to treat childhood obesity are required. South Asians represent a particular target group for obesity intervention at all ages, due to their high cardiometabolic risk.

Effectiveness of current programmes for addressing overweight and obesity in children

Despite the pressing need for intervention, evidence for effective childhood obesity treatment programmes is limited. A Cochrane review of childhood obesity treatment RCTs has been undertaken and was last updated in 2009.¹⁵ This included 64 studies, 54 of which were on lifestyle intervention programmes, and 34 of which were studies in children under the age of 12 years. A significant issue with childhood obesity intervention research is the limited quality of the majority of studies. In the Cochrane review Luttikhuis et al. highlighted particular methodological issues such as insufficient power, lack of allocation concealment, high attrition rates, and lack of intention to treat analysis, which makes it difficult to draw firm conclusions from the existing evidence. Despite this, meta-analyses of the higher quality studies showed that lifestyle intervention programmes do have a small but clinically meaningful effect on weight status at 6 months follow up (0.06 and 0.14 reductions in BMI z-scores compared to standard care in the preadolescent and adolescent age groups respectively). In adolescents (but not in preadolescent children) the effect appears to be sustained at 12 months.

More recent RCTs of community-based childhood obesity treatment programmes have also reported clinically meaningful effects on weight status. Examples include an RCT of the MEND programme (a community-based multi-component programme targeting nutrition and physical activity, incorporating individual behaviour change techniques) undertaken in 8-12 year olds and their families in the UK (n=116). A clinically meaningful reduction in BMI and waist circumference was reported at 6 and 12 months in the intervention group compared to controls.¹⁶ Another recent RCT of a family-based childhood obesity intervention targeting 8-12 year old children and families in the US (n=192) reported a clinically meaningful reduction in percent overweight in the intervention arm compared to controls at 6 months, but this was not sustained at 12 or 18 months. Again, the intervention programme addressed diet, physical activity and sedentary behaviour, and incorporated individual behaviour change techniques.¹⁷ The absence of cost-effectiveness evaluations of childhood obesity treatment interventions has been highlighted.^{15;18}

Critical elements of effective programmes

The limitations of the existing evidence for effective interventions to treat childhood obesity mean that the most effective intervention components are as yet undetermined. Luttikhuis et al. highlighted the requirement for process measurement to assess implementation and adherence to interventions in future trials in order to interpret effects on outcomes in a more meaningful way. In their review, Luttikhuis and colleagues concluded that the most effective studies addressed both diet and physical activity, and included behavioural elements. In addition, parental involvement in the intervention was an important feature in the preadolescent age group.¹⁵ A recent review on behalf of the American Heart Association also suggests that greater parental involvement in

childhood obesity intervention programmes leads to better long term weight outcomes, although the specific nature of this parental engagement still needs to be determined.¹⁹

Evidence of the effectiveness of overweight and obesity management programmes in minority ethnic children

There is a paucity of studies evaluating the effectiveness of childhood obesity treatment programmes in minority ethnic populations. Most work has been done in the US; some interventions have targeted specific ethnic groups (e.g. African-Americans²⁰ or Chinese Americans²¹), and others have targeted ethnically diverse populations.²² Cultural adaptation for the target populations has mainly involved delivery of materials in different languages, tailoring of nutritional content, and ethnically matched programme providers. Similar to the main body of childhood obesity intervention research, findings from these studies are inconclusive. A small RCT (n=67) of a behavioural intervention addressing diet and physical activity, targeting Chinese American children aged 8-10 years reported a reduction in BMI in the intervention group compared to the control group. This was sustained over 8 months follow up but the effect was marginal.²¹ An RCT of a culturally adapted behavioural modification programme targeting a mixed Hispanic, black and white population of children aged 8-16 years in the US (n=206) again showed a small reduction in BMI z-score in the intervention group compared to controls, which was sustained at 2 years follow up.²²

UK evidence for childhood obesity treatment interventions targeting minority ethnic groups is even more limited. Croker and colleagues undertook an RCT of a family-based behavioural treatment programme (originally developed for a US population²³) in an ethnically and socioeconomically diverse population of 8-12 year old children (n=72, 43% non-white European).²⁴ The intervention programme had been found to be feasible and acceptable to deliver to a diverse UK population in a prior feasibility study²⁵, and no specific cultural adaptations were made. However findings of the RCT showed no difference in weight status outcomes between intervention and control groups.²⁴

To date, there has been a lack of theoretical approaches to the cultural adaptation of childhood obesity treatment programmes.²⁰ A further gap in the research is the lack of studies that specifically evaluate the success of the cultural adaptation of a programme. In their evidence synthesis review on adaptation of health promotion programmes for minority ethnic groups, Liu and colleagues emphasised the requirement for future trials comparing culturally adapted programmes to standard programmes.⁴

Existing provision of a children's weight management programme to an ethnically diverse population in Birmingham, UK

A children's weight management programme for 4 -11 year olds is currently available to overweight/obese children in Birmingham. The programme has developed and evolved over time, based on available evidence and service provider experience, and has been successful in achieving weight status reduction in those who participate and complete the programme. Participants are referred through health professionals, schools, the National Child Measurement Programme (NCMP), or are self-referred. Referral to the programme across ethnic groups reflects the ethnic make-up of the overweight/obese population of children in Birmingham, with over a third of participants from Bangladeshi/Pakistani (BP) families. However, BP families are less likely to complete the programme than other ethnic groups. The proportion of families completing the programme is 50% overall, but in BP families, this is less than 40% (compared to 65% in white British and African-Caribbean ethnic groups).

Our previous childhood obesity prevention research in South Asians highlights the importance of considering cultural context in intervention design.²⁶ We therefore hypothesise that a major contributor to the lower completion rates is that aspects of the current programme are not

culturally relevant to BP families. We propose to explore the reasons for this and adapt the programme to ensure more cultural relevance to these groups, and thus higher completion rates. However, for reasons of equity, the NHS programme commissioners stipulate that the modified service must also be inclusive of families from other ethnicities as the existing provision covers the ethnically diverse population of Birmingham. Therefore we must ensure that modifications to the programme do not have the unintentional effect of reducing completion rates in other ethnic groups. To assess this we propose a feasibility study of the modified intervention in all ethnic groups, primarily to assess the impact of the modified programme on the proportion of families completing the programme (both BP and non-BP families), and the reasons for these effects. We will also explore the feasibility of a randomised controlled study design and collect data to inform parameters for a definitive RCT. In this study we intend that the programme will be modified in such a way that it could be easily transferred and tailored for use in populations with a different ethnic makeup. Therefore we will focus on BP families as a case study for cultural adaptation of the existing children's weight management programme.

Study aims

Work package 1

Aim: To develop a weight management programme for children aged 4-11 years and their families, tailored to be culturally relevant to specific communities. The programme will be developed by adapting an existing programme, and using Bangladeshi and Pakistani families as a case study, but inclusive of and appropriate for families from all ethnic communities.

Objectives:

- Explore facilitating factors and barriers to participation in and completion of existing childhood obesity treatment programmes among BP families
- Use resulting information, together with existing research evidence, to develop a modified and culturally tailored treatment programme that:
 - incorporates behaviour change techniques that have been identified to maximise effectiveness in previous research studies
 - incorporates theoretically informed adaptations to ensure cultural relevance to BP families.

Work package 2

Aim: To undertake a feasibility study of the culturally adapted intervention programme.

Objectives:

- Assess the proportion of BP families completing the culturally adapted intervention programme, and assess the proportion of families from all ethnic groups completing the programme
- Assess the feasibility of delivery of the new programme
- Assess acceptability of the newly modified programme and barriers to participation/engagement for BP families, and families from other ethnic groups
- Assess the feasibility of recruitment, randomisation and follow up to inform a future definitive RCT
- Assess the feasibility and acceptability of outcome measures to inform a future definitive RCT
- Collect data to inform parameters of a future definitive RCT to assess effectiveness and cost-effectiveness.

Guiding framework

The framework guiding this study is the UK Medical Research Council (MRC) framework for the development and evaluation of complex health interventions.^{1;2} Work package (WP) 1 will address the theoretical and modelling phases of complex intervention development, ensuring that adaptation of the existing First Steps weight management programme is informed by:

- Evidence for effective childhood weight management intervention
- Experiences and perceptions of BP families who have participated in and also those who have declined to participate in the current First Steps programme
- Relevant theory relating to the cultural adaptation of health promotion programmes for minority ethnic groups.

We will address phase 2 of the MRC complex intervention framework by undertaking a feasibility study of the newly adapted programme in WP2. This will yield valuable information on the acceptability of the new programme to BP and other families, the barriers to uptake, completion and sustained engagement with the programme, and key parameters required for the planning of a future effectiveness and cost-effectiveness evaluation.

Study Setting

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 diverse than ever before. This has resulted in a new kind of diversity described as 'super-diversity', 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).^{27;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 society. The proposed study will take place in Birmingham; a super-diverse city with 44% of children from minority ethnic groups (MEGs), and 20% from BP communities.

The First Steps children's weight management programme is commissioned by Birmingham City Council Public Health and is delivered by Birmingham Community Healthcare NHS Trust. All families of children who are of primary school age (4-11 years) and who are clinically overweight or obese (defined as greater than 91st centile and greater than 98th centile for BMI on the UK 1990 growth reference charts²⁹ respectively) are eligible to attend the First Steps weight management programme. Referral pathways to the programme include self-referral, health professional referral, school referral, and identification and invitation to attend First Steps through the National Child Measurement Programme (NCMP). The programme is delivered to groups of parents/carers and children in community venues.

The First Steps children's weight management programme

This existing childhood weight management service infrastructure will be used for the study. Participants for both WPs will be recruited from those referred to the existing First Steps programme.

The First Steps programme has been delivered to overweight/obese children and families in Birmingham for the last two and a half years. Prior to this established child weight management programmes developed in other settings, such as MEND¹⁶ and Watch It³⁰, had been commissioned and delivered to children and families in Birmingham. However, these programmes were not suited to the local population. The specific issues with these previous programmes were the intensity and duration of the courses which resulted very low uptake rates, and high dropout rates, and the lack of

flexibility to change the structure and content of the programmes to accommodate cultural and language requirements.

In order to address these issues, the First Steps programme was developed, informed by the experiences of the local children's weight management service providers. The structure, timing, duration and content of First Steps has been designed to be more acceptable to the local population. Examples of this include a greater focus on parental engagement, timing of sessions so that they do not coincide with religious commitments, inclusion of different cultural foods within the nutritional activities and resources, greater interactive and visual programme content, and the provision of interpreters. Given that there is evidence to support the effectiveness of the MEND and Watch It programmes in achieving weight reduction in children^{16,30}, the elements of the programmes that worked were retained in First Steps (specific behaviour change strategies, emphasising the roles of parents, and some content relating to nutrition and physical activity). Subsequent childhood weight management intervention research also supports the approaches incorporated in the First Steps programme (e.g. the emphasis on parental participation, and the use of behaviour change techniques^{15,19}).

Given that this existing programme 1) goes some way to addressing the needs of a diverse population, 2) is informed by the evidence base, 3) is established and successfully running in the local area, and 4) is achieving weight reduction in those completing the programme that is comparable with effect sizes reported in clinical trials, it is an appropriate programme on which to base the development of a tailored programme designed to be delivered within a super-diverse population but with a particular focus on cultural relevance to BP families.

Structure and content of the First Steps programme

Currently, parents are invited to attend 7 weekly daytime sessions (1-1.5 hours duration each), with children attending the first and last sessions with their parents. Sessions are interactive and practical covering nutrition education, behaviour change and physical activity promotion (see Table 1 for further details of session content). After completion families are invited to attend quarterly follow up events. These are 1.5 hour sessions that consist of 1 hour of structured physical activity, measurement of children's height and weight, and self-directed family activities to reinforce healthy eating messages. The programme is delivered by Birmingham Community Healthcare NHS Trust support workers who have received specialist training on delivery of the programme.

Table 1: First Steps programme session content

Session	Attending	Content
1	Parents and children	Introduce structure and content of the programme; initial height and weight measurement of children; discuss the commitment required by families throughout the programme and beyond; exercise to raise awareness of the fat and sugar content of foods; set goal to swap snacks high in sugar and fat to a healthier alternative.
2	Parents	Review families' achievements of the goals set in week 1; exercises based on the Eatwell plate to raise awareness of what constitutes a balanced diet and impart key healthy eating messages; discuss healthy portion sizes and frequency of food intake; discuss ways of increasing fruit and vegetable intake to meet Five-a-day requirement; set goal to increase children's fruit and vegetable intake.
3	Parents	Discuss the parents'/carers' role in creating an environment that supports healthy eating and physically active lifestyles for children (positive relationships with children, parents as facilitators and role models, boundary setting); identify solutions to problematic family behaviour patterns; introduce the setting of SMART goals within the family.
4	Parents	Discuss importance of regular healthy meals; identify the recommended frequency of snacks and give ideas for healthy snacks, identify strategies to deal with persistent requests for food.
5	Parents	Facilitate parents to analyse size of portions given to all family members; identify appropriate portion sizes for children and adults; discuss strategies to reduce portion sizes; support parents to develop the necessary skills to interpret food labels and be able to identify foods that are high or low in sugar/fat.
6	Parents	Discuss the requirement to balance energy intake with energy expenditure; identify recommended physical activity levels for children and adults; emphasise the health and wellbeing benefits of physical activity; identify opportunities for families to increase physical activity and reduce sedentary activity within their day; identify strategies to motivate and sustain family members in undertaking physical activity.
7	Parents and children	Review the previous sessions; identify participants' achievements, develop plans for maintaining behaviour change; discuss coping strategies for when family members do not maintain healthy behaviours; measure height and weight of children.

Work package 1: Adaptation of the First Steps children's weight management programme

There will be three strands to the development of a culturally adapted children's weight management programme:

1. Review of the existing programme against the current literature

We will review structure, content and delivery of First Steps against the current evidence for effective weight management programmes (including the NICE guidelines for lifestyle weight management services for overweight and obese children, due to be published in October 2013³¹) to ensure that approaches that have been identified as effective are incorporated into the developed programme. To assist this review process we will apply the taxonomy of behaviour change

techniques promoting changes in eating and physical activity (CALO-RE taxonomy³) to studies to identify specific behaviour change content of effective interventions and the First Steps programme.

2. Qualitative data collection from BP parents of overweight/obese children

Three groups of BP parents who are eligible to attend the First Steps weight management programme will be recruited to participate in this qualitative part of the study: 1) those who were offered the First Steps programme but declined to attend (n=15), 2) those who attended but did not complete the programme (n=15), and 3) those who completed the First Steps programme (n=20-30). We will aim to recruit parents from a range of geographical areas and socioeconomic backgrounds.

Potential participants will be initially approached by a telephone call from the First Steps programme staff. If they agree to be contacted by the research team, they will be sent a participant information leaflet in the post, and the research team will follow this up with a telephone call. If the person agrees to participate, researchers will arrange a time and place for the interview or focus group. Consent forms will be signed by participants and researchers on the day of the interview or focus group.

The first two groups of parents will be invited to participate in semi-structured interviews. The research team recognise that recruiting these parents will be particularly challenging. Based on our team's previous experience of recruiting such participants, we have opted to undertake individual interviews (rather than FGs) to maximise participation. We will also employ other strategies to encourage participation, including engaging Community Researchers (see section 2) to assist in recruiting participants and undertake the interviews in the participant's preferred language, and offering a range of venues or the option of telephone interviews.

Parents in the 3rd group (who completed the First Steps programme) will be invited to attend FGs (3-5 FGs with 6-8 parents in each group). We recognise that even within families who complete the programme, engagement in the different aspects of the programme may vary considerably. Therefore, we will purposively sample parents in this group to reflect a range of levels of engagement with the programme. We propose to undertake FGs with this group of parents as this method explicitly uses group interaction as a way of stimulating discussion, resulting in richer data being collected. Participants respond not only to the researcher, but also to each other, producing new ideas, questions and priorities. Views and perspectives change and develop during discussions leading to the generation of critical comments and potential solutions to problems.³² However, from our past research experience in South Asian communities, we are aware that FGs are challenging to undertake. Participants are often reluctant to visit unfamiliar venues, and also there will be a variety of language requirements among participants. Therefore, if FGs prove too logistically challenging in this group and attendance is very low, we will conduct one-to-one interviews with these participants in the same way as with the other two groups of participants.

We will develop semi-structured topic guides for the interviews and FGs, informed by the literature on potential facilitators of and barriers to childhood weight management programmes, our PPI advisors and our Community Researchers. The interviews and FGs will be undertaken by our Community Researchers, under the supervision of LG. The Community Researchers will conduct the interviews/FGs in the preferred language of participants. When this is another language, such as Urdu, Punjabi, Pashto, Bengali, Sylheti or Mirpuri (languages spoken in Pakistan and Bangladesh), the Community Researcher will conduct the interview or FG in the preferred language and transcribe and translate it into English so it can be added to the data set and analysed. Community Researchers' observations and reflections on the interview/FG will be incorporated into the data set and will supplement the analysis. These are likely to be related to cultural understandings and references which traditional academics are unlikely to have access to.

Research questions to be explored in interviews with parents who did not attend or complete the programme include:

- What are the barriers to attending and completing the programme?
- Which aspects of the structure, content and delivery of the programme are perceived as problems?
- What information, content or format would increase the appeal of the programme?
- What might need to change about the current programme to ensure its cultural relevance?

In the FGs or interviews with parents who have completed the programme we will explore the above research questions, and in addition the following questions:

- What are facilitators of participation and completion?
- What aspects of the structure, content and delivery of the programme are valued?

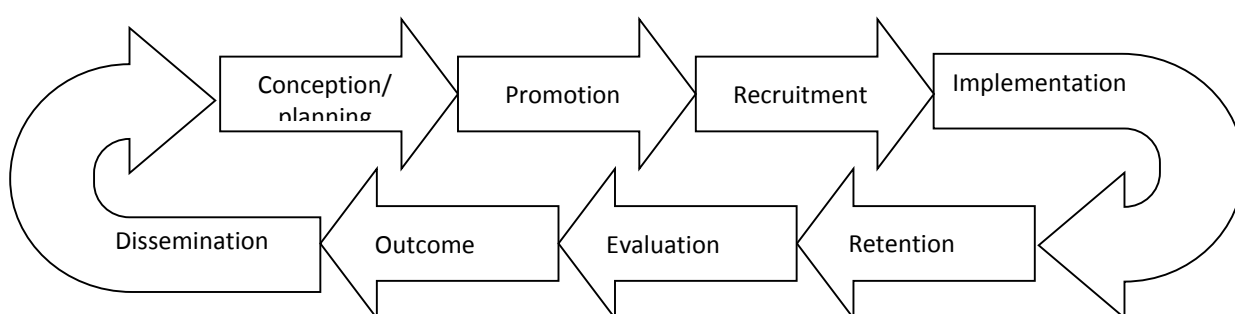
Interviews and FGs will be audio-recorded and transcribed for analysis. We will adopt a systematic and iterative approach to data analysis based on the constant comparative method.³³ Open coding of a selection of transcripts will be undertaken to identify initial key themes and emerging patterns. Thus a coding frame will be developed, refined and subsequently applied to the full dataset.

3. Application of principles for adapting behavioural interventions for minority ethnic groups (MEGs)

Based on our experience of health service development for MEGs²⁶ and the comprehensive evidence synthesis review on the adaptation of health promotion programmes for MEGs (undertaken by Liu and colleagues⁴), 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.^{34;35} 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.⁴ This will enable specific opportunities for adaptation to be identified from the qualitative findings.

The programme theory of adapted health promotion interventions (Liu et al.⁴) 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 (see Figure 1). 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.

Figure 1: Programme theory of adapted health promotion interventions developed by Liu et al.⁴



For each stage in the programme theory we will identify potential programme elements to be adapted that have been identified from the evidence review and qualitative data, and identify the potential types of adaptation from the 46-item typology of adaptations. We will also consult with the local children's weight management service providers to gain their perspective on potential development and adaptation of the existing programme elements. Some examples of programme elements that could potentially be adapted, and examples of the types of adaptation are shown in Table 2 below.

Table 2: Examples of cultural adaptations to the existing children's weight management programme

Programme Theory stage	Programme element to be adapted	Types of adaptation*	Method through which the adaptation opportunity is identified
Promotion	Advertising and referral avenues for the children's weight management service	Utilise ethnically/culturally appropriate formal and informal networks Use ethnically and culturally appropriate media sources	Qualitative data from BP parents
Recruitment/Engagement	Initial communication to give information on the programme	Reflect target population's preferred method of communication Cross-cultural training for staff	Qualitative data from BP parents Local service provider experience
Recruitment/Engagement	Structure and content of the introductory session	Intervention content targets populations social and cultural values	Qualitative data from BP parents Local service provider experience
Implementation	Timing of sessions	Utilise appropriate incentives and timing of programme Consider target population's employment situations	Qualitative data from BP parents Local service provider experience
Implementation	Techniques to change eating and physical activity behaviour	Intervention content targets population's social and cultural values Address emotional barriers and stressors	Evidence review Qualitative data from BP parents
Implementation	Programme tasks and goals	Intervention goals and outcomes are culturally appropriate	Evidence review Qualitative data from BP parents Local service provider experience
Retention	Whole family involvement	Encourage/involve social support	Qualitative data from BP parents
Retention	Timing, structure and frequency of post-programme follow up	Utilise appropriate incentives and timing of programme Provide ethnically and	Qualitative data from BP parents Local service provider

Programme Theory stage	Programme element to be adapted	Types of adaptation*	Method through which the adaptation opportunity is identified
		culturally appropriate activities	experience
Evaluation	Monitoring of behavioural and obesity outcomes	Utilise appropriate evaluation instruments and tools Cross-cultural training for staff	Evidence review Qualitative data from BP parents

*From the typology of adaptation of health promotion interventions for minority ethnic groups (Liu et al., 2012)

The potential adaptation opportunities within the programme that are identified in this way will be reviewed by the PPI panel, and the panel will submit comments and recommendations relating to these identified adaptation opportunities.

Outputs from work package 1

A new programme, adapted to be culturally appropriate for BP families (but suitable for families of all ethnicities) will be developed in discussion with the local children's weight management service providers and commissioners to ensure that it is feasible to deliver within the local funding constraints. Final agreement on the adapted programme will be obtained from the study co-investigator team. Manuals will be developed for weight management service providers, parents and children. The manuals will be designed to be transferable to any population, i.e. they will have largely generic content, but will include sections particularly relevant to BP communities that can be adapted to make them relevant to other local communities (e.g. by including materials with ethnic specific data, culturally appropriate activities and dietary advice, culturally appropriate goals, appropriate communication/language etc.). The programme theory of adapted health promotion interventions will also be used to guide manual design, so that opportunities for tailoring within each stage of the intervention cycle (see Figure 1) are included within the manuals. In this way the programme and manuals will provide a template that can be easily adapted for use in any population. We will also develop a training programme for staff who will be delivering the newly adapted programme. Nominated facilitators will be invited to attend the training programme, which will cover the background and rationale for the adaptations and the content and structure of the new programme, as well as familiarising them with the new manuals.

Work package 2: Cluster-randomised feasibility study of the culturally adapted programme

Design

The primary aim is to assess the impact of programme adaptation on the proportion of families completing the programme. To assess completion rates and acceptability of the programme, and also to determine the feasibility of undertaking a future definitive trial and estimate parameters for this, a small scale cluster-RCT will be undertaken. In order to provide choice and convenience to participants in terms of timing and location of programmes, a cluster-design will be used whereby all programmes delivered within the study period are randomised to intervention or comparator arms. This will mean that families referred to the children's weight management services who are not study participants may also attend an adapted programme, depending on which is the most convenient location for them. We have agreement from the commissioners of the service to provide

a mixture of existing and adapted courses for all families attending the programmes in the study period, regardless of whether or not they are a study participant. A 2:1 (intervention to comparator) randomisation ratio will be used. The aim of the 2:1 randomisation ratio is to ensure that there are a sufficient number BP families in the intervention arm to enable calculation of the primary outcome (see below). In order for the programme providers to plan delivery of the programmes, randomisation will be undertaken by Birmingham Primary Care Clinical Research & Trials Unit at the beginning of the feasibility study. Programme providers will be informed of the allocation of programmes to intervention and comparator arms but this information will not be shared with any members of the University of Birmingham research team so no researchers undertaking baseline measures will be aware of which study arm the participant is in. During the study period, there will be 24 programmes randomised to intervention or study arms.

Study population

Families in Birmingham with a primary school-aged overweight or obese child (defined as greater than 91st centile and greater than 98th centile for BMI on the UK 1990 growth reference charts²⁹ respectively), who are referred to the existing children's weight management service will comprise the study population. From existing programme data we expect 40% of referrals to be BP families. We will purposively sample from all families referred to the existing service through any referral pathway to achieve a sample with 60% BP families. To reduce the risk that non-BP families will not want to participate, potential participants will be informed that the study is comparing the existing standard children's weight management programme to a new programme that has been developed to be more relevant to the diverse local population of Birmingham. Families who decline to participate will have access to the standard treatment programme. We will make interpreter services available to all families who are approached to participate in the feasibility study.

All potential participants will be those referred to the existing children's weight management service. The NHS provider team will send potential participants the standard letter inviting them to attend a weight management programme along with an invitation letter and participant information leaflet for the CHANGE study. The NHS team will follow up their letter with a phone call to book the parent/carer and child onto a programme of their choice. They will ask at this time if they are willing to participate in the study. If the participant agrees, their details will be passed onto the research team who will contact them to arrange a home visit to collect baseline data. If it is identified that a parent requires information in another language, we will arrange for an interpreter to call them and verbally translate the study information. At the beginning of the home assessment, the researcher will ask the parent participant to sign the consent form, and ask for verbal assent from the child participant if under the age of 8 years, and written assent from child participants 8 years and over. Interpreters will be made available to families if necessary.

Intervention

Families in the intervention arm will receive the weight management programme for children aged 4-11 years that has been culturally adapted for BP families. Structure, content and delivery of this programme will be determined in WP1. It is anticipated that the programme will be delivered over 7-8 weeks, followed by sustained post-intervention support.

Comparator arm

Families in the comparator arm will receive the existing First Steps children's weight management programme. To avoid contamination between the two arms, the standard and adapted programmes will be delivered by different NHS staff.

Data collection: outcome measures

We will assess acceptability and success of the programme adaptation primarily through the proportion of BP families completing the programme. We will estimate: 1) proportion of BP families completing the adapted programme; 2) proportion of families from all ethnic groups completing the adapted programme; and 3) sustained engagement of families following programme completion (both in BP families and overall).

We will undertake a range of other outcome measures to assess their feasibility and thus inform design of a definitive effectiveness and cost-effectiveness evaluation. Measures undertaken on participating children will comprise measures of adiposity, measures of food intake and physical activity, and a range of psychosocial assessments (to assess the wider outcomes of intervention, as this is indicated as a research gap in the Cochrane review¹⁵). Specifically these will be: height and weight (to calculate BMI); waist circumference; bioimpedance analysis (to derive percentage body fat); usual patterns of dietary intake (assessed using the Children's Dietary Questionnaire³⁶, which will be adapted for use in the study population); physical activity (objectively measured with an Actigraph or Genactiv accelerometer over a 5 day period, including a week-end); parent-reported sedentary activities; health-related quality of life (assessed using the PedsQL³⁷); a health utility measure (CHU 9D³⁸); and body image (assessed using the Figure Rating Scale³⁹, adapted for use in the study population). We will also conduct an assessment of pubertal status, so that this can be taken into account in the study analyses. A simple visual assessment of puberty based on the Tanner breast development scoring system will be undertaken in girls aged 8 years and above. Observers will classify females into 2 categories: no development or some development. If breast development is noted, parents will be asked if the child has started menstruating. This enquiry will be conducted with sensitivity and if it is felt that it is not appropriate, the researcher will omit this question. In boys, it will be noted whether or not there is pubertal facial hair growth.

We will also undertake a number of outcome measures with parents/carers and other family members to test feasibility and acceptability of measures to assess potential effects of the modified intervention on family members and the family environment. These will be: height, weight and bioimpedance analysis of parents/carers and other family members in the household (to calculate BMI); family eating and physical activity habits (assessed using the Family Nutrition and Physical Activity screening tool⁴⁰); parental child feeding practices (assessed using the Comprehensive Feeding Practices Questionnaire⁴¹); parental self-efficacy (assessed using the Parental Locus of Control scale⁴²); and parenting styles (assessed using the Parenting Styles and Dimensions Questionnaire⁴³).

Measurements will be undertaken on children and parents/carers at baseline by trained research staff. Researchers and families will be blind to their treatment allocation at the time of baseline measures. Follow up measures will be taken post-intervention. Further follow up measures will be taken 6 months after the end of the intervention, which will give an indication of likely attrition rates in a future full scale trial.

Data collection from children and parents at baseline and follow up 2 will be undertaken by researchers through home visits. Data collection at the post-intervention follow up will be undertaken at the last session of the programme, or through home visits for those who do not attend this session. Visits will take place out of school hours. We have proposed this approach for data collection as it should in theory facilitate more complete data collection and less attrition. If required, interpreters will be available to participating families whose preferred language is not English. The feasibility of this data collection approach will be assessed in this study and will inform a future trial.

Other data collection

Sociodemographic data will be collected from all participants, including sex, age, ethnicity, migration history, religious beliefs/practices, home postcode (which will be mapped to Index of Multiple Deprivation scores), parental occupation, and parental education level.

Methods for collecting data on intervention costs will be developed to inform a future economic evaluation. In particular, we will explore methods to measure costs from a societal perspective so as well as intervention-specific costs we will include items such as parent productivity costs (time off work to attend the intervention sessions), associated childcare costs, and changes to weekly food bill. The focus will be on the assessment of the wording of these questions to assess the acceptability and feasibility of collecting this data in a future definitive trial.

Evaluating the success of adaptation

During the feasibility study we will undertake a range of methods to explore the success of the cultural adaptation of the programme. We will assess implementation of the adapted programme components, and how well the identified barriers have been addressed. We will conduct interviews with staff delivering the modified programme to explore their experiences. The interview guide will be informed by the cultural adaptation typology and programme theory framework used in WP1.

We will undertake FGs with BP and non-BP parents/carers completing the modified programme (n=4-6 FGs with 6-8 participants in each FG) to explore the success of the overall programme adaptation, the success of each adapted component, and the barriers and facilitators to engagement with the programme. Again, we will purposively sample parents to reflect a range of levels of engagement with the adapted programme. As in WP1, if FGs prove too logistically challenging in this group and attendance is very low, we will conduct one-to-one interviews with these participants. We will also explore the success of adaptation by undertaking interviews with BP and non-BP parents/carers who did not complete the programme (n=10-12), specifically exploring the reasons for non-completion. To maximise participation, parents will be given the option of a telephone interview if they decline a face-to-face interview. As in WP1 qualitative work will be undertaken by Community Researchers in the participants' preferred languages where appropriate, and will be audio-recorded, transcribed and translated.

In addition we will undertake interviews with BP and non-BP children completing the modified programme to explore their experiences and engagement with the programme as a whole and the specific culturally adapted elements (n=10).

Process evaluation

We will undertake process measures to assess the degree to which the intervention was delivered and adhered to as intended, as the need for this has been highlighted by systematic reviews of previous childhood obesity treatment research.¹⁵ We will finalise process evaluation methods, informed by the evaluation planning framework for public health interventions and research⁴⁴, for use in a future definitive trial. We will use a variety of methods. We will use the planned FGs and interviews with parents/carers who participate in the programme (see evaluating the success of adaptation above) to explore their experience of the different components and whether any behavioural changes were made as a result of their participation. We will also ask programme providers return information on family attendance, withdrawals, and also to note any changes or adaptations that are made to any sessions, and why. In addition we will directly observe a sample of sessions to assess fidelity of implementation.

Sample size

In this feasibility study the main outcome of interest is an estimate of the proportion of BP families completing the adapted children's weight management programme. To calculate this we will use anonymised data on completion that is routinely collected by the children's weight management service. From existing service data we expect approximately 70 BP families to start attending the adapted programme within the study period. This will allow estimation of the proportion of BP families completing the programme to within 26% precision. For example, if 65% of BP families complete the adapted programme, the 95% confidence interval of the estimate of completion will be 52-78%. To estimate the width of this confidence interval we have inflated the variance we would expect under individual randomisation by the typical variance inflation factor for cluster trials (with an additional inflation of 12% to account for the varying cluster sizes⁴⁵). We have assumed an ICC of 0.05, which is conservative, and a cluster size of 5.

[*Technical note:* The width of the 95% CI before inflation is 11.2 either side of the mean (i.e. from 53.8% to 76.2%). The conventional variance inflation factor (VIF) for a parallel cluster trial is 1.2 ($=1+(5-1)*0.05$). We have inflated this by 12% to allow for varying cluster size, so the VIF increases to 1.34, and the square root of this is 1.16. The width of the CI adjusting for clustering (either side of the mean is $1.16*11.2=13.0$].

A secondary outcome will be the proportion of families completing the adapted programme overall, so that we can ensure that there has been no adverse impact of the programme adaptation on the likelihood of programme completion by other families. A further secondary outcome will be the comparison of the proportion of families completing the programme in the two study arms.

To test recruitment and data collection methods and gain an estimate of recruitment and attrition rates to inform a future trial we plan to recruit at least 80 children and families into the study.

A sample size of 80 will also enable estimation of key parameters required for a definitive sample size calculation⁴⁶, including standard deviation or prevalence, and correlation between baseline and follow up values of the primary outcome. We will also estimate the intra-cluster correlation (ICC), along with a 95% confidence interval, which will be needed for the sample size calculation of a definitive trial. With 24 clusters we should be able to do this with reasonable accuracy.

Data analysis

The primary analysis for the feasibility study will be estimation of the proportion of BP families completing the adapted intervention programme and 95% confidence intervals. Completion will be defined as attending at least 60% of the programme. Secondary analyses will include estimation of the proportion of families completing the adapted programme overall and 95% confidence intervals, and a comparison of proportion of families completing the programme in the intervention and usual care arms.

We will report the number of assessments attempted for each outcome and the number (and proportion) of complete assessments made. This will inform which outcomes can feasibly be measured and which cannot be in a future definitive trial.

Descriptive statistics will be used to describe the outcomes deemed to be feasible outcome measures, reporting means and SDs, medians and IQRs or numbers and proportions as appropriate. We will also estimate correlations between baseline and follow-up BMI z-scores. This will provide information on baseline event rates (for dichotomous outcomes), and SDs and correlations (for continuous outcomes) for sample size calculations for a definitive trial. All analyses will be intention to treat. We will summarise the outcomes (i.e. proportion completing) by arm providing a

confidence interval which allows for the clustered nature of the data. The confidence interval will be estimated from the appropriate mixed effects model.

Although this trial is not sufficiently powered to compare clinical outcomes between intervention arms, estimates of differences between arms will be calculated. The sample size in the feasibility study is such that in the event of a large effect of the intervention, the study will have sufficient power to detect this, and it is important to not miss such large effect sizes if they exist. As height and weight data are routinely collected from children at the beginning and end of the weight management programmes, we plan to obtain this data in an anonymised format and use it in an additional analysis to give us a further indication of BMI z-score outcomes in the intervention and control arms.

Analyses will be by mixed effects methods, adjusting for clustering and baseline measures. 95% confidence intervals will be reported and differences deemed significant at the 5% level. This model will also provide an estimate of the ICC and 95% confidence interval, which will be needed to inform the definitive trial.

Outputs from work package 2

- 1) Information gained from the process evaluation will be used to further refine the intervention programme and manuals so that they are ready to be definitively evaluated in a full scale trial.
- 2) Study procedures, outcome measures, and health economic evaluation methods will be determined for a future full scale trial.
- 3) The prevalence or standard deviation of the primary outcome for a future definitive trial will be estimated.
- 4) The effect of the modified programme on the outcome measures will be estimated.

Progression to a definitive RCT to evaluate effectiveness and cost-effectiveness of the modified intervention programme.

To determine whether to proceed to a proposal for a definitive trial we will consider:

- 1) The estimate of the proportion of families completing the modified programme (BP and overall)
- 2) The feasibility and acceptability of the culturally adapted components of the programme to the ethnically diverse study sample
- 2) The feasibility and acceptability of trial processes (recruitment, randomisation etc.)
- 4) The feasibility and acceptability of outcome measures and other evaluation methods
- 5) The identification of appropriate methods for an economic evaluation in a full scale trial.

Project timetable

The project timetable is shown in the Gantt Chart below. In the feasibility study participants will be recruited as they are referred into the service. Participants will be randomly allocated to intervention or standard care arms following baseline assessment, and will then attend the relevant programme. Groups will be run within school term times to facilitate participation. All intervention and standard care programmes in the feasibility study will take place over two school terms.

	2014				2015												2016												2017			
	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb		
Work package 1																																
Review of programme against evidence for effective obesity interventions	█	█	█																													
Recruit participants for interviews and FGs		█	█	█	█																											
Conduct and analyse interviews and FGs		█	█	█	█	█	█																									
Programme adaptation guided by cultural adaptation typology and programme theory framework							█	█	█	█																						
Finalise modified programme and manuals											█	█																				
Work package 2																																
Participant recruitment												█	█	█	█	█	█															
Baseline measurements													█	█	█	█	█															
Randomisation													█	█	█	█	█															
Delivery of intervention programme														█	█	█	█	█	█													
Process evaluation questionnaires/interviews/FGs															█	█	█	█	█													
Post-intervention measurements																█	█	█	█	█	█											
Second follow up measurements																					█	█	█	█	█	█	█					
Data entry completion																													█			
Data analysis and report writing																														█	█	

Project management

The University of Birmingham is the nominated sponsor of the study. The study will have an externally appointed study steering committee (SSC) that will include a lay member and subject experts. The SSC will meet twice a year or as deemed necessary to monitor study progress. The co-investigator team will meet regularly (2-4 times) per year to oversee the study. Day to day management of the study will be undertaken by the appointed research fellow. MP (Principal Investigator), EL (co-investigator) and PA (co-investigator) will form a senior project management team, which will oversee the day to day management undertaken by the project research fellow. Representatives from the commissioning and provider organisations of the children's weight management programme are on the co-investigator team. There will be close liaison between the study research team, the NHS staff delivering the children's weight management programme and the commissioners, which will be facilitated by the relevant co-investigators.

Patient and Public Involvement

We will convene a reference panel of parents of primary school-aged children from Bangladeshi and Pakistani communities. The panel will be consulted at crucial stages to enable them to bring values to the project that may otherwise remain unaddressed. This will ensure that the development of the programme, outcome measures and research procedures are culturally appropriate. Timing of the panel meetings will be dictated by the stage of the project. The objectives for each meeting will be specified by the research team. A panel chair will be appointed and will be the primary point of liaison between the panel and the research team.

Data management

Throughout the study the University of Birmingham 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. Transcripts of interviews and FGs will have all identifying information removed. Data from the feasibility study will be entered into a secure database which will be developed and maintained by Birmingham Primary Care Clinical Research Trials Unit.

Ethical Issues

In this study we are adapting a weight management programme for children aged 4-11 yrs and their parents, and assessing the programme in a feasibility study. The intervention will have behavioural elements addressing diet and physical activity. With children we will undertake anthropometric measures, objective physical activity measurement with accelerometers over 5 days, and questionnaires measuring aspects of lifestyle and psychosocial functioning. We will undertake height, weight and questionnaire measures with parents. It is anticipated that there is minimal risk to participants.

In WP1 informed consent will be obtained from parents participating in FGs/interviews. In WP2 informed consent will be obtained from parents of participating children. Regarding qualitative elements of WP2, informed consent will be obtained from staff and parents participating in interviews/FGs. For children, parental consent and children's assent will be obtained for participation in interviews.

In both WPs, trained Community Researchers will undertake qualitative work and will be able to

converse with participants in their first language. In WP2, interpreters will be made available for participants who require them to facilitate the informed consent process and undertaking the measurements.

Throughout the study the University of Birmingham data protection procedures will be followed. All data will be kept confidentially. Audio-files will be kept in a secure place until the study is completed. Transcripts of interviews and focus groups will have all identifying information removed.

Ethical approval from an NHS Research Ethics Committee will be applied for at the beginning of the study for both WP1 and WP2. Given that the exact details and content of the culturally adapted children's weight management programme for the feasibility study (WP2) will be determined by the development work undertaken in WP1, a substantial amendment form will be submitted to the relevant Local NHS Research Ethics Committee in advance of WP2, when the modified programme has been fully developed.

WP1: Informed consent will be obtained from parents/carers participating in FGs and interviews.

WP2: Informed consent will be obtained from parents of participating children. Regarding interviews and FGs in WP2, informed consent will be obtained from staff delivering the programme and parents participating in interviews. For children, parental consent and children's assent will be obtained for participation in interviews.

In WPs 1 and 2, trained Community Researchers will undertake qualitative work with parents and will be able to converse with participants in their first language. In WP2, interpreters will be made available for all participants who require them to facilitate the informed consent process and undertaking the measurements.

Adverse Event Reporting

Reporting procedures

NHS staff delivering the intervention in the feasibility study will be asked to contact the study team within 5 working days if any untoward incident or adverse event (AE) occurs to child, parent/carer, or a member of staff, as a direct result of taking part in the study. In these cases, study specific adverse event/incident report forms will be used to record information on the event.

All adverse event/incident report forms will be discussed with the Principal Investigator to assess seriousness and to confirm causality. All AEs deemed to be 'serious' (SAE) will be reported to the Sponsor within 24 hours. Where the SAE is suspected to be related to the intervention and unexpected, i.e. a suspected unexpected serious adverse reaction (SUSAR), the Chair of the SSC and the REC will be notified within 15 days of the study team receiving the initial report.

Safety reporting definitions:

Untoward Incident

An untoward incident is something unintended or unplanned, that could have or did lead to harm.

Adverse Events

Adverse Events (AE): Any untoward medical occurrence in a study participant to whom the intervention has been delivered, including occurrences which are not necessarily caused by or related to that intervention.

Serious Adverse Events

Serious Adverse Events (SAEs) are any adverse event that:

- results in death
- is life-threatening
- results in persistent or significant disability/incapacity
- requires hospitalisation or prolongs a current hospitalisation
- results in a congenital anomaly or birth defect

Expected AEs/SAEs

There are no expected AEs/SAEs for this intervention. Any treatment received by a participant that was planned prior to the start of the study will not be considered an AE/SAE.

Adverse Reaction /Serious Adverse Reaction/Suspected Unexpected Serious Adverse Reaction

Adverse Reactions (ARs) and Serious Adverse Reactions (SARs) are AEs/SAEs that are thought to be related to the intervention. The intervention programme is aimed at changing dietary and physical activity behaviours, therefore it is unlikely that any AEs/SAEs will be directly related to its delivery. SAEs that are both unexpected and related to the intervention, are classed as SUSARs (suspected unexpected serious adverse reaction).

Dissemination and projected outputs of the study

Accessible, plain English written reports will be prepared after completion of each WP and sent to service commissioners, providers, parent participants and the funders. Reports will also be made available in other languages if required, and made publicly available through the project website. Findings of the study that have implications for wider health and social care (e.g. barriers to engagement with health promotion initiatives) will be publicised through the media.

We will submit a number of papers to peer reviewed academic journals and we will produce publications that target relevant audiences, including clinicians, public health professionals and policy makers.

Presentations will be delivered at relevant national and international conferences (e.g. UK Society for Behavioural Medicine, European Congress on Obesity, and International Society for Behavioural Nutrition and Physical Activity).

It is also intended that co-applicants and stakeholders (including our PPI parent panel and Community Researchers) will be involved in identification and facilitation of dissemination opportunities within local and national NHS and government organisations and networks, and within local communities. National and local commissioning organisations will also receive copies of the findings to highlight the ongoing developmental and evaluative work around childhood weight management programmes.

Dissemination in this way will alert NHS service commissioners, providers, and users to this ongoing developmental work relating to children's obesity services. Direct impact through roll out of a fully evaluated, culturally adaptable weight management programme will be the end outcome of a future definitive trial that aims to evaluate the programme developed in this study.

The key research outputs will be:

1. A manualised weight management programme for 4-11 year old children. The programme will be designed to allow tailoring to make it culturally relevant to different target populations.
2. Peer-reviewed publications including papers on:
 - The cultural adaptation process and use of the newly developed typology of cultural adaptations and programme theory of adapted health promotion interventions framework
 - The acceptability and success of the adapted programme in the feasibility study
 - Behavioural and anthropometric outcomes in the feasibility study.
3. Application for funding to evaluate effectiveness and cost-effectiveness of the developed programme on overweight and obese children's weight status in a future RCT.
4. Insights into cultural needs which will help inform other health promotion activities.
5. Development of skills of the research team relating to patient and public involvement in research.

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