Detailed Project Description

1. Project title

A randomised controlled trial evaluating the effectiveness and cost-effectiveness of 'Families for Health', a family-based childhood obesity treatment intervention delivered in a community setting for ages 7 to 11

2. Planned investigation

Research question:

What is the effectiveness and cost-effectiveness of the 'Families for Health' (FFH) programme in the treatment of overweight and obesity in 7-11 year olds compared to usual care, as measured by reduction in BMI z-scores at one year post recruitment?

Research objectives

To undertake a randomised controlled trial to assess the effectiveness and cost-effectiveness at 12 months of the 'Families for Health' programme delivered within the NHS.

Our objectives are to:

- Assess the effectiveness of the 'Families for Health' programme in reducing BMI z-score in children aged 7 to 11 who are obese.
- Evaluate the cost-effectiveness and cost-utility of the 'Families for Health' programme.
- Investigate parents' and children's views of the programme and their observations on approaches to maximising impact.
- To investigate facilitators' views of the programme and their observations on approaches to maximising impact.

Existing research

The prevalence of obesity in children aged 2-15 in England rose from 11.7% in 1995 to 16.8% in 2007, although the trend may now be flattening it remains too high (NHS Information Centre 2009a). Obesity in childhood increases the risk of poor physical health in childhood, including type-2 diabetes and cardiovascular risk-factors, particularly when obesity is severe (Lobstein 2006). Psychological well-being is impaired in children attending for treatment of obesity, showing low self-esteem and depression (Wardle and Cooke 2005), and studies in both clinical and population samples show that quality of life is impaired in children who are obese. A recent epidemiological study indicates that a higher proportion of children whose parents are obese are 'very over-fat' at age 7, and were more likely to remain so to age 11 (Wright et al 2010). A key question for the NHS is whether childhood obesity affects adult health. There is some evidence from longitudinal studies that a higher BMI in childhood or adolescence increases morbidity and mortality from coronary heart disease in adulthood (e.g. Must 1992, Baker 2007) and is associated with adverse socio-economic outcomes in women (e.g. Sargent 1994, Viner 2005). A serious consequence of obesity in childhood is also that 40% to 70% of obese children become obese adults (Reilly 2003), with the associated risks to adult health.

The prevention and management of childhood obesity is now a public health priority. There are an estimated 0.75 million children aged 2-10 in England who are obese (Department of Health 2006). Effective interventions are needed to treat these children, in order to reduce the ill-health they experience as children and to reduce the proportion whose obesity tracks to adulthood. The 'Healthy Weight, Healthy Lives' strategy requires Primary Care Trusts to derive a care-pathway

for the weight management of young people (Department of Health 2008).

A Cochrane systematic review of interventions to treat obesity identified 64 RCTs, of these only two were from the UK (Oude Luttikhuis 2009). 37 studies were lifestyle interventions in children <12 years (4 dietary, 9 physical activity, 24 behavioural). Results from four behavioural interventions were pooled, with the mean difference in BMI z-score favouring the behavioural intervention over 'standard care' at 6-months (-0.06, 95% CI -0.12 to -0.01), but no benefit at 12-months. They concluded it is difficult to recommend any particular intervention, but indicated that family-based lifestyle interventions combining dietary, physical activity and behavioural components can produce 'a significant and clinically meaningful reduction in overweight'(p2). Parental involvement was identified as useful with children under 12. NICE (2006) and Oude Luttikhuis (2009) both point to the paucity of cost-effectiveness studies.

Recent UK research on interventions targeting obese junior school children has covered a variety of approaches. Of these, MEND (mind, exercise, nutrition and do it!), a 9-week family-based community programme, is most similar to Families for Health. An RCT of MEND with 116 children (8-12years) showed a difference in the BMI z-score at 6-months follow-up from baseline between the randomised groups of -0.24 (95% CI: -0.34 to -0.13, p<0.0001, n=82) in favour of MEND over a waiting list control (Sacher 2010). Within group differences for MEND showed a change in BMI z-score of -0.30 at 6 months (95% CI: -0.36 to -0.23, p<0.0001, n=71) and -0.23 at 12 months (95% CI: -0.33 to -0.13, p<0.0001, n=42). A further RCT compared one-to-one behavioural approach with a paediatric dietitian (5hrs) with standard dietetic care (1.5hrs) in 134 children (5-11years) (Hughes et al 2008). No significant differences were found between treatments in the change in BMI z-score at 6 or 12 months. A third study piloted the community-based WATCH IT programme, which is delivered by health trainers, which showed a small change in BMI z-score of -0.07 for 48 children at 6-months (p<0.01) (Rudolf 2006). An RCT of WATCH IT is underway. A fourth study is assessing Epsteins' 'family-based behavioural treatment' in a clinical setting, including the traffic light diet. A pilot with 33 families (8-13 years) showed an 8.4% reduction in BMI at 3-months (Edwards 2006).

Details on the 'Families for Health' intervention that we will test

'Families for Health' is a manualised group-based family intervention for the treatment of children aged 7-11 years who are obese, which could be an option in the care pathway as a targeted 'early intervention' service. The programme was developed at Warwick University, supported by a Department of Health career development award to the PI. The programme differs from other interventions being researched in the UK by offering a greater emphasis on parenting skills, relationship skills and emotional and social development, combined with information about lifestyle. Parents and children attend separate groups, meeting mid-way for a healthy snack and activity. The groups are led by two trained facilitators.

The development and evaluation of this new programme has followed the MRC framework for complex interventions (Craig 2008). A pilot in Coventry of 27 children showed that mean reductions in children's BMI z-scores from baseline were sustained at 9-months (-0.21, 95% CI -0.35 to -0.07, p=0.007) (Robertson 2008) and 2-years (-0.23, 95% CI -0.42 to -0.03, p=0.027). There were also other health-related improvements. Interview data showed that parents found the parenting approach helpful, providing the tools to become 'agents of change' in the family. NHS costs to deliver the programme were £517 per family or £402 per child. Pilots have also been run in Warwickshire and Portsmouth. 'Families for Health' appears comparable with and better than other interventions, with the results at 2-years indicating a sustained effect (Robertson, In Press).

The evaluation of the pilot suggested the need for minor modifications to the programme including more physical activity, removal of some unnecessary material, a reduction in the number of sessions and addition of follow-up sessions. These changes to the intervention may increase effectiveness.

The proposed research will provide evidence of effectiveness and cost-effectiveness of a family based programme with an emphasis on parenting alongside healthy lifestyle as an alternative approach for the treatment of obesity management in under 12s.

Research methods

Design: The trial will evaluate the effectiveness of 'Families for Health' in comparison to usual care in children aged 7-11 years who are overweight or obese. The design of the trial is a multi-centered, randomised parallel group controlled trial with economic analysis, with 12-month follow-up. The unit of randomisation will be the family, stratified by site. Participants will be randomised to two arms:-

1. 'Families for Health' intervention (60 families)
2. Control group receiving 'usual care' (60 families)

Outcomes will be assessed at baseline, end of programme (3 months) and 12 months, reflecting the short-term and sustained effects. Mixed-methods evaluation will run in parallel to the trial. See Appendix I for the flow diagram of families in the trial.

Randomisation, allocation concealment and masking: The random allocation sequence will be generated by an independent statistician using a random number generator, and implemented by a central telephone registration and randomisation service at the Warwick Clinical Trials Unit. Randomisation will be stratified by site. Researchers will register participants after confirming eligibility and obtaining consent, but before randomisation, to ensure allocation concealment. Neither the providers of 'Families for Health' (group facilitators) nor families can be masked to treatment allocation. Every effort will be made to ensure that study personnel involved with data management and analysis remain masked until the analysis is complete. We will assess the success of masking.

Planned interventions

'Families for Health' intervention: *'Families for Health'* is a family-based intervention aimed at the treatment of children (7-11yrs) who are overweight or obese. The programme focuses on parenting combined with social and emotional development, as well as lifestyle change. Delivery is group-based with up to 10-12 families, with children and parents attending parallel groups and meeting mid-way for a healthy snack and activity. The programme is manualised, with detailed handbooks available to facilitators, parents and children. (i) When? - The programme will be run at a weekend, comprising 2½ hours per week for 10 weeks. Follow-up sessions will be held at 1 and 3 months post-intervention. Piloting has shown that delivery at a weekend was more acceptable to families. (ii) Where? - The intervention will be delivered in a community setting (leisure centre, school or children's centre), to enhance access and ensure adequate space and facilities for physical activity. Access to physical activity opportunities, which could be sustained once the programme has finished, is important. (iii) By whom? - Four facilitators are required to run each programme (2 each for the children's and parents' groups). Facilitators will be identified from the local NHS or other services, and selected on the basis of personal attributes including empathy for families with obese children and previous relevant experience. Professional backgrounds may include community nursing, teaching, youth work, leisure services and dietetics. Some facilitators who have already run the programme in Coventry and Warwickshire may be available.

For families allocated to the intervention arm, both parents will be invited, together with non overweight siblings in the target age range. Families in the intervention arm will be eligible for usual care interventions in addition to attendance at the programme. Any 'usual care' they receive will be documented.

Training of Facilitators: Facilitators will attend a 4-day training course provided by Family Links, who developed the Nurturing Programme on which the parenting aspects of the programme are based. The training will be supported by Rebecca Lang (co-applicant and nutritionist) and Wendy Robertson (expertise in physical activity). The circle time element in the

children's programme also has parallels with the Nurturing Programme for schools. Family Links are highly regarded as deliverers of training for parent group and school leaders. (www.familylinks.org.uk/index.htm).

'Usual Care' Control Group: Families assigned to the 'control' arm will not be offered an intervention, but can receive the 'usual care' available in their area. This care will be documented.

Planned Eligibility Criteria

Inclusion criteria:

Potential participants will be eligible for inclusion if they meet each of the following criteria:

- Families with at least one overweight (≥91st centile for BMI) or obese* (≥98th centile for BMI) child aged 7-11 years.
- At least one parent/guardian and child willing to take part.

NB. *In the information to participants the term 'very overweight' will be used instead of 'obese', inline with the National Child Measurement Programme.

Exclusion criteria:

- Parent or child with insufficient command of English, who would find it difficult to participate in the group.
- Metabolic or other recognised medical cause of obesity
- Children with severe learning difficulties and/or behavioural problems.

Proposed Sample Size

For power calculations we assumed that 60% of participating families have one obese child and 40% have two. Allowing for clustering effects by family and for group effects in the intervention arm, a sample size of 6 groups of 10 families (60 families) in the intervention arm and 60 families in the control arm gives a power of 94%. These calculations were based on an intervention effect of 0.2 in BMI z-scores, a residual standard deviation of 0.22, a standard deviation of the random family effects of 0.14, an intra-cluster correlation of 0.1 in the intervention groups, and a two-sided significance of 5%. If 30% of families drop out, the study retains power of 88%. The power values were simulated and are based on 10,000 simulated trials. Calculations were informed by estimates from the pilot (Robertson 2008).

Setting

We have identified and agreed collaborations with three Primary Care Trusts within the West Midlands - NHS Coventry, NHS Warwickshire, Wolverhampton City PCT. They will offer 'Families for Health' as part of their care-pathway for the treatment of childhood obesity.

Key people to support the delivery at the sites are:

NHS Warwickshire: Helen King, Deputy Director of Public Health (also co-applicant on the bid)

Fran Poole, Health Development Manager, Public Health

NHS Coventry: Berni Lee, Consultant in Public Health (also co-applicant on the bid)

Kate Reddington, Health Weight Coordinator – Obesity, Public Health

Wolverhampton City Primary Care Trust:

Dr Adrian Phillips, Director of Public Health (also co-applicant on the bid)

Gloria Rye, Health Improvement Specialist

Recruitment

40 families will be recruited from each of the three Primary Care Trusts. Each Trust will run two 'Families for Health' programmes. Randomisation will be stratified by centre to ensure viable attendance numbers for each programme (max 12; min 8 families). Families will be recruited via referral from local health services, via the National Child Measurement Programme and from self-referral following publicity in the local media:

(a) *Local Health Services*: Referral from primary care (GPs, School Nurses) and secondary care (Dietitians, Paediatricians) will be invited. The local PCRN for Central England (West Midlands South) will be asked to support recruitment.

(b) *National Child Measurement Programme* (NCMP): The NCMP involves the annual measurement of BMI of children in Reception and Year 6 in maintained primary schools. PCTs are now expected to send results to parents and follow-up children who were underweight, overweight (BMI $\geq$91st centile) and obese ($\geq$ 98th centile for BMI) (Cross Government Obesity Unit 2009). Participating PCTs will offer participation in this trial via the letters to parents who have a child in Year 6 who is obese.

(c) *Media*: Press releases will be prepared and interviews undertaken with local newspaper and radio reporters and if possible local television. Experience in Coventry suggests that the media are engaged with the childhood obesity agenda and that free coverage is likely to be achieved to aid recruitment.

Participant pool: Data from the National Child Measurement Programme 2008/9 estimates the pool of potential participants, which is in excess of 600 children in each of Warwickshire, Coventry and Wolverhampton in Year 6 alone who are obese defined by the 95th centile for BMI (Table 1).

Table 1: Prevalence of Obesity (≥95th centile) in Year 6 (age 10-11) for the proposed study recruitment sites

	No. Eligible	No. Measured	Participation Rate	Prevalence of Obesity (95% CI)	Year 6 Children Obese (n)
NHS Warwickshire	5,548	4,584	82.6%	15.1% (14.1 to 17.2)	692
NHS Coventry	3,477	3,152	90.7%	19.4% (18.0 to 21.3)	611
Wolverhampton City PCT	2,827	2,649	93.7%	23.5% (21.9 to 25.5)	623
West Midlands SHA	62,526	55,993	89.6%	19.8% (19.5 to 20.8)	
England	558,633	497,680	89.1%	18.3% (18.2 to 19.1)	

Source: *NHS Information Centre (2009) (National Child Measurement Programme 2008/9)*

Measurement of Quantitative Outcomes

Measurements of outcomes will be made at baseline, the end of the 10 week programme and at 12 months post randomisation.

Primary outcome measure:
Change in children's BMI z-score at 12 months. Weight will be measured using Tanita scales, and height measured by a Leicester stadiometer. BMI (kg/m^2) will be converted into standard deviation scores (z) from 1990 UK growth reference curves (Cole 1995).

Secondary outcomes:
By measurements with children:

- Change in children's BMI z-score at end of programme.
- waist circumference (z-score) (McCarthy et al 2001), using a Seca 200 tape
- % body fat with Tanita body composition analyser
- habitual activity, using a 7-day accelerometer recording (Actigraph) with step-count function, to give minutes per day spent doing moderate/vigorous physical activity (Puyau 2002) and steps per day. NB. This outcome will only be measured at baseline and 12 months in order to minimise seasonal effects (Riddoch 2007).

By three validated questionnaires completed by children:

- children's quality of life (PedsQL) (Varni 1998)
- children's fruit and vegetable consumption using 'Day in the Life' (Edmunds 2002)
- EuroQol EQ-5D-Y health state valuation (Ravens-Sieberer et al, 2010)

By measurement with parents:

- BMI: Height recorded using Leicester stadiometer and weight with Tanita scales.

By six validated questionnaires completed by parents:

- 'Family Eating and Activity Questionniare': reports of activity of parents and children, and family eating environment (Golan 1998)
- children's quality of life from parents' perspective (PedsQL) (Varni 1998)
- parent's report of the quality of parent-child relationships (Pianta 1992)
- parenting style:'Parenting Styles and Dimensions Questionnaire' (Robinson 2001)
- EuroQol EQ-5D health state valuation – parent's own (Dolan 1997)
- EuroQol EQ-5D-Y health state valuation of the child by parent (Ravens-Sieberer 2010)
- Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) for parents (Tennant 2007)

Statistical Analysis

As indicated above, the primary endpoint for the statistical analysis will be the change in BMI z-score after 12 months of follow-up. It is anticipated that these data will be correlated within family level in both study arms and possibly correlated both within groups and centres in the FFH intervention arm, so that the analysis must allow for this multi-level clustering. The primary statistical analysis will use hierarchical mixed effect modelling to allow for the clustering. This will enable estimation of the effect of the FFH intervention together with calculation of 95% confidence intervals for this estimate. The model will also adjust for important baseline factors such as baseline BMI z-score and gender. Analyses of the secondary endpoints listed above will also be conducted using hierarchical models or marginal modelling in a similar way to that for the primary endpoint, possibly after transformation to ensure approximate normality. Analysis will be conducted using SAS or MLwiN as considered most appropriate. All main analyses will be conducted on an intention-to-treat basis.

The primary analysis will be conducted at the conventional (two-sided) 5% level. In order to minimise the risk of false positive results from the statistical analyses performed on the large number of secondary endpoints, hypothesis tests for these endpoints will be conducted only if a statistically significant result is obtained from the primary analysis. It is not proposed to formally adjust for multiple testing amongst the secondary endpoints as these are likely to be highly correlated so that adjustment techniques such as the Bonferroni method are likely to be conservative. The number of analyses conducted will, however, be informally considered when interpreting the results of these statistical analyses.

A fully specified data analysis plan will be developed in the early phases of the trial and approved by the Trial Steering Committee. Data will be summarised and reported in accordance with CONSORT guidelines for randomised controlled trials (Shultz et al 2010). No interim analyses are anticipated.

Economic evaluation

The economic evaluation will be conducted from the recommended NHS and Personal Social Services perspective (NICE, 2008). Data will be collected on all significant resource inputs used in the care of each family during the period between randomisation and one year post-randomisation. These data will be collated through the trial data collection forms, observational research methods and economic questionnaires families will be asked to complete at baseline, the end of the programme and at twelve months post-randomisation. A particular focus of the economic evaluation will be a full assessment of the cost of delivering the intervention in community settings, including the costs of training and developing facilitators, staff-related expenses, and revenue and capital overheads. The unit costs of each resource item will be valued using both primary research, based on established accounting methods, and data collated from secondary national tariff sets.

The results of the baseline economic evaluation will be expressed in terms of incremental cost per quality-adjusted life year (QALY) gained. QALY data will be estimated using responses to the EQ-5D-Y (EQ-5D youth version), with evidence of its feasibility, reliability and validity recently reported in the literature (Ravens-Sieberer et al, 2010). Both the parents and children will be asked to independently complete the EQ-5D-Y at each time point of assessment (baseline, the end of the programme and at twelve months post-randomisation). Each parent will be asked to complete the EQ-5D-Y as he/she would expect the child to respond (as opposed to asking the parent to rate the child's health from his/her perspective).

A *de novo* decision-analytic model will also be developed in order to estimate the lifetime clinical and economic consequences of the 'Families for Health' intervention. The model will be informed both by data collated by the family-completed economic questionnaires, but also by data extracted from secondary sources. The model will be structured using published evidence on the epidemiology and natural history of childhood obesity, and will be informed by guidance from clinical advisors, to reflect the natural course of childhood obesity and the impact of alternative interventions. Accepted guidelines for good practice in decision-analytic modelling and the

general principles outlined in the NICE 'reference case' will be followed (Philips et al., 2004; NICE, 2008). In developing and populating the model, three issues will be considered of central importance to the approaches and methods employed: (i) the need to develop an evidence network that facilitates direct and indirect comparisons between interventions; (ii) the requirement to extrapolate outcomes beyond the time horizon of the main RCT, to ensure that differences in costs and QALYs are appropriately quantified; and (iii) the need to ensure that the data inputs and assumptions are relevant to informing current NHS practice.

Long term costs and health consequences will be discounted to present values using discount rates recommended for health technology appraisal in the United Kingdom (NICE, 2008). We shall use non-parametric bootstrap estimation to derive 95% confidence intervals for mean cost differences between the trial groups and to calculate 95% confidence intervals for incremental cost effectiveness ratios (Barber and Thompson, 2000). A series of multi-way and probabilistic sensitivity analyses will be undertaken to explore the implications of uncertainty on the incremental cost-effectiveness ratios and to consider the broader issue of generalisability of the study results. This will include a sensitivity analysis that assesses the potential impact of adopting a societal perspective for the economic evaluation using data on informal and indirect costs provided by parents in the economic questionnaires. In addition, cost-effectiveness acceptability curves will be constructed using the net benefits approach (Stinnett and Mullahy 1998).

Process evaluation

Issues to be addressed by the process evaluation are:

1. What is the best method to recruit families? Specifically, what is the uptake of the invitation to participate through the National Child Measurement Programme?
2. Which, if any, aspects of a healthier lifestyle does the Families for Health programme enable? Which of these are sustainable to the 12 month follow-up?
3. What are the families (parent and child) experience of the 'Families for Health' programme, and how can we improve this?
4. Acceptability of the physical activity component across the age range of children (7-11 years)

We will also assess the delivery of the programme and how it is received by families as implementation takes place, using the framework of Linnan (2002), see Table 2.

Table 2 - Framework for the Process Evaluation

Component	Definition	How Assessed in Evaluation
Recruitment	Success of methods used to approach and recruit participants.	Baseline questionnaire asking parents how they heard about the trial and whether they were referred or self-referred.
Reach	Degree to which an *intended* audience participates in an intervention.	Baseline questionnaire with parents asking about socio-demographic characteristics, to define if participants reflect the site populations and if any sub-groups were more or less likely to participate.
Dose delivered	The 'amount' of intervention provided by the intervention team.	(1) Facilitators will keep notes about unavoidable changes to the programme enabling assessment of the number of sessions delivered as planned. (2) Facilitators' weekly evaluation forms. (3) Recording of additional interventions or care accessed by both groups.
Dose received	Extent of engagement with the intervention by the target population.	(1) Facilitators will log attendance by families, including withdrawals. (2) Parents' weekly evaluation questionnaires of the sessions. (3) Parents end-of-programme questionnaire and interviews, reporting changes made.
Fidelity	The extent to which the intervention was delivered as planned i.e. quality & integrity of intervention.	(1) For 4 sessions (randomly selected) on each programme fidelity will be addressed indirectly from: - flip-charts used and developed during the session; - parents end of session evaluation i.e. were the session's topics mentioned, perception of facilitators & programme; - facilitators weekly log of their delivery of the programme, recording how it went and any variations; - discussion (recorded) with the facilitators at the end of the session. (2) Parents' end-of-programme questionnaire.

An important aspect of the process evaluation is to assess the ease to which the trial recruits, and the effectiveness of the various methods of recruitment. 'Active' recruitment methods, such as referral by a doctor or targeted mail shots to families with children who are obese, have been found to be more effective than 'passive' recruitment (e.g. articles in media) in enrolling and randomising families into an RCT, although 'passive' recruitment methods were shown to be better at retaining families from enrollment to randomisation (Raynor 2009). We have previously found in the pilot in Coventry that self-referral following articles in the local media led to more successful recruitment and higher completion rates than recruitment via health professionals (Robertson 2008). We now have the opportunity to assess targeted recruitment via the National Child Measurement Programme.

Qualitative research will capture participants' views of the programme, of the changes they have made (or otherwise) and on facilitating or inhibiting factors they experienced. Interviews will be undertaken at the end of the programme and at 12 months with up to 24 children and 24 parents. Facilitators will be interviewed at the end of the programme. Purposive sampling will include representation of all 'Families for Health' groups, aim for diversity of age and gender of the children, family size and whether they completed the intervention or not. We will aim to

interview at least one parent of each interviewed child for triangulation of data. Children will be interviewed in pairs and interviews will include write and draw techniques as well as discussion about the programme. Parents and facilitators will usually be interviewed individually. All interviews will be digitally recorded and transcribed. The outline interview schedules below have been developed from pilot study data.

The interview schedule for parents will include:-

- Feelings when first approached to take part in the study
- Issues motivating parents/children to take part in study, and expectations
- Perceptions of the programme e.g. venue, session structure, topics, group etc
- Aspects/topics they had found useful / not useful
- Any changes made as a result of attending FFH and any difficulty with this
- Any changes in family functioning
- How could the programme be improved?
- How does the Families for Health intervention compare with other support?
- Exploration of reasons for dropping out.

The interview schedule for children will include:-

- Could you make a drawing of the 'Families for Health' programme. Tell me what you have drawn.
- Now could you make me a drawing of something you liked about the programme; and then something you didn't like.
- Sensitive questions will aim to probe why children came on the programme.
- Any changes that they or their families have made as a result of coming on the programme.

The interview schedule for facilitators will include:-

- What aspects they felt worked and didn't work on the programme and why
- What were the main facilitators and barriers to change in the families
- How were the group dynamics
- Whether they felt the training equiped them to deliver the programme

Analysis of initial interviews will inform development of the interview schedule for further interviews. NVivo software will be used for data handling and coding. Initial coding will be thematic, based on the interview schedule with the addition of emergent themes. The team overseeing the qualitative study will meet regularly to review the interviews, develop coding and discuss analysis. The quantitative data collected from each of the parent/child interviewees will provide background data for the analysis, with triangulation of qualitative and quantitative data sources. Final qualitative analysis will be of two forms. For all interviews, thematic analysis will be undertaken (Green 2004). Where there are interviews from parent and child, these interviews will be linked and each analysed as a unit particularly examining contrasts and similarities in what they report and the dynamics in their relationship with each other and in the groups.

Ethical arrangements

The study will obtain all necessary ethical permissions and NHS Research and Development approvals before commencing. All data will be stored securely and anonymised in accordance with Data Protection Act, and the trial will be conducted in compliance with the principles of MRC GCP guidelines, the Declaration of Helsinki and other requirements as appropriate.

Obtaining informed consent: The initial approach to potential families may come from the family's responsible clinician or other member of the healthcare team, such as the school nurse. Parents who provide outline permission will be contacted by a researcher, who will assess eligibility and obtain consent. Other families may come directly to the research team.

Researchers will use a three step procedure to obtain informed consent, giving parents/children time to consider whether they wish to participate. Each potential participant will be given or sent by post information sheets about the trial (children and parents versions). After a minimum of 3 days, parents will be contacted by telephone to answer any questions. A researcher will then visit the parent(s) and child(ren) at their home, and obtain the parents written consent, and the child's verbal assent.

All researchers will be trained in informed consent, including methods for assessing competence for consent, agreement to participate and obtaining assent from children.

Risks and benefits: All participants will have access to usual care, and thus no treatment will be withheld from trial participants. A possible disadvantage is the amount of time the 'Families for Health' intervention takes: the information sheet will clearly outline that attendance is a weekly commitment for 10 weeks.

Intervention participants may benefit from 'Families for Health' by helping families with their child(ren)'s weight management. The programme also provides the opportunity for families with similar issues to meet, and focuses on the skills needed to make and maintain lifestyle change in the family. A successful trial will also yield substantial benefits for others. Either we will demonstrate that 'Families for Health' is clinically effective and that wider implementation would benefit other families with children who are obese, or we will demonstrate that 'Families for Health' is ineffective or not cost-effective, thus allowing NHS resources to be re-directed to other more effective interventions.

Informing potential participants of risks and benefits: The information leaflets for parents will provide potential participants with information about the possible risks and benefits of taking part. Families will be given the opportunity to discuss the trial with the researcher. We will inform parents, managers of participating PCTs and GPs or consultants if new information comes to light that could affect their willingness to participate in the trial.

Research Governance

The trial will be sponsored by Warwick University, with co-sponsoring arrangements with participating sites. It will be conducted in accordance with the Standard Operating Procedures of Warwick Clinical Trials Unit. A Trial Steering Committee (TSC) will be convened, which will have at least 2 independent members, and one lay member with relevant experience of the *'Families for Health'* intervention.

3. User Involvement

A parent who attended a pilot group has agreed to be a member of the Trial Steering Committee. They will advise on the changes to the programme and the research measurements.

We undertook a process evaluation as part of piloting the 'Families for Health' intervention (Robertson 2010). Interviews of parents and children who attended the pilot groups assessed the acceptability of the intervention and the research measurements and found that the intervention was very well received by families. Some changes to the programme were indicated, including a greater focus on physical activity particularly for the children and the inclusion of follow-up sessions to improve sustainability. Parents also mentioned that some children did not want to wear the accelerometers because they were obtrusive (Robertson et al 2011). We are considering how to make the accelerometers more acceptable.

It is likely that the views of the world from the perspective of an adult will differ radically from that of the younger population. To access the views of children we have enlisted the support of Claire Callens and Carly Tibbins from the User Involvement team of the West Midlands Medicines for Children Research Network (WM MCRN). This team has a wealth of experience and strong links with schools within the West Midlands. In collaboration with the research team, they will access school children in the target age range (7-11 years) during their Personal and Social Health Education lessons, and will also access an existing group of children who attend a paediatric clinic for type 2 diabetes. The User Involvement Team will facilitate discussion about the content of the programme, including their preferred means of follow-up, and what physical activity taster sessions they would like in the programme, and what they think about the research measurements, for example about the acceptability of wearing accelerometers and alternative ways to attach them.

4. Project timetable

This project will require 36 months (Table 3). On notification of the award, we will obtain ethics approval and complete R&D registration with each PCT. We will make necessary amendments to the intervention, derived from our experience of delivering the intervention and recent literature. The user involvement study at a school in the West Midlands will be carried out early in the project in order to inform the intervention and the research measurements. The first six-months will be spent organising the venues and facilitators at the sites. The trial will recruit participants from months 6 to 14. Each site will run two groups consecutively, with both groups being completed by month 20. Programmes need to be run in school term times. Our timetable has a few months contingency if delays are incurred. Final 12 month follow up will be completed on both groups by month 30. Qualitative data analysis will commence from Month 15 after the interviews from the first groups have been completed. Statistical analysis and economic appraisal with be from month 30 onward.

The study protocol will be submitted to an open access journal. Summary results will be presented to Trial Steering Committee for comment, a full report will be prepared and submitted to HTA. Results will be presented at key national and international conferences and published in peer review journals and other dissemination activities will be undertaken. During the trial we will produce a regular newsletter which will be sent to all families, facilitators and key personnel in the PCTs involved in the trial.

5. Expertise / Responsibilities

The trial team comprises senior investigators with experience of leading trials of complex interventions in primary care. The expertise and responsibilities of each co-applicant are:

Robertson has been responsible for the evaluation to date of the 'Families for Health' intervention being tested in this trial, using a mixed-methods study design. She will be the chief investigator, responsible for the overall conduct of the trial.

Stewart-Brown conceived the 'Families for Health' programme and was closely involved in its development. She brings expertise in parenting and parenting interventions including running trials of group-based parenting programmes. She is facilitating links with Family Links the training organization. She will provide support and advice to the PI and research team throughout the trial.

Petrou is a health economist with expertise in health economic evaluation, and will be responsible for the parallel economic evaluation.

Stallard is an experienced statistician, who has previously undertaken analyses of group based interventions for HTA trials. He will be responsible for the statistical analysis.

Thorogood is an expert in the evaluation of health promotion interventions and has overseen process evaluation in HTA trials. She will advise on the process and outcome evaluation.

Lang is a nutritionist, with expertise in interventions for the prevention and treatment of childhood obesity. She will advise on the components of the intervention relating to healthy eating and on tools to measure change in nutritional intake.

Lee, King and Phillips bring experience of the delivery of childhood obesity interventions within Primary Care Trusts, and have knowledge of the National Child Measurement Programme at a local level in order to facilitate the recruitment of families through this avenue.

Griffiths is an expert in qualitative methods and mixed-methods research, and will also provide a general practice perspective.

Simkiss will contribute paediatric input and safeguarding expertise to ensure children's welfare, and has experience of running a randomised controlled trial of a parenting programme in South Wales (alongside Stewart Brown).

The trial will receive support with randomisation and programming from the fully accredited Warwick Clinical Trials Unit at Warwick Medical School.

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Table 3. Project timetable

	Trial Month												
Project Activity	<0	3	6	9	12	15	18	21	24	27	30	33	36
Ethics approval	*												
R&D Registration with PCTs	*												
Modify FFH intervention	*	*											
Recruit research staff	*	*											
User study–children(MCRN)	*	*											
Organise Venues at Sites		*	*										
Recruit / train FFH facilitators		*	*										
Organise Recruitment Strategies		*	*										
Trial at 3 sites													
Recruitment /randomisation			*	*	*	*							
Run Group 1			*	*	*								
Run Group 2					*	*	*						
12-month follow-up Group 1							*	*	*				
12-month follow-up Group 2									*	*	*		
Statistical analysis		*								*	*	*	*
Economic appraisal										*	*	*	*
Qualitative analysis						*	*	*	*	*	*	*	*
Steering Committee meeting		*		*			*			*			*
Monitoring reports			*			*			*			*	*
Writing of Reports / Papers											*	*	*

Appendix I: Flow Diagram: 09/127/41: A randomised controlled trial evaluating the effectiveness and cost-effectiveness of Families for Health (FFH), a family-based childhood obesity management intervention delivered in a community setting for ages 7 to 11