1. 06/85/11: A cluster randomised controlled trial of the effectiveness and cost-effectiveness of an obesity prevention intervention in primary school age children

2. <u>How the project has changed since the original proposal was submitted:</u>

We have incorporated amendments agreed since the revised proposal was submitted, and the data from the National Prevention Research Initiative (NPRI) funded project (Birmingham healthy Eating Active lifestyle for CHildren Study – BEACHeS) which allows us to fully describe the intervention package. We have completed process measures of the intervention components, which provide evidence on the feasibility and acceptability of each intervention component. We also have preliminary data on outcome measures, which are favourable, and support the testing of the intervention in a randomised controlled trial. As a result, the main changes are:

a) ***Sample size:*** We have used data from our exploratory trial to inform the power calculation and sample size has been reduced from 64 to 44 schools. This section has been revised in line with further reviewer comments.

b) ***Randomisation:*** As requested, we will randomise schools AFTER baseline measures are undertaken

c) ***Intervention package***: the results of the exploratory trial have been used to inform and clearly define the intervention components. This is based mainly on the process measures that assessed the feasibility and acceptability of the components, and these are summarised in appendix 1. A summary of outcome measures from the exploratory trial are presented in appendix 2. The section on the planned intervention (section 3.4) is substantially amended, providing more detail based on the findings from the exploratory trial.

d) ***Outcome measure***: In addition to the primary binary outcome measure of overweight (including obese) versus normal, we will use the continuous outcome measure of BMI (and BMI z-score) in analyses.

e) ***Process measures***: More detail on this is provided.

f) ***Input from a Clinical Trials Unit***: As requested, we have sought input from the Birmingham Primary Care Clinical Research Trials Unit (PCCRTU), at the University of Birmingham. They will support the trial in terms of audit and monitoring, database development and support, providing support to the trial manager and co-ordinator, and advice on data monitoring and provision of archiving.

g) ***Increase in Health Economic component***: As requested and agreed, we have increased the health economic element of the application.

h) ***Costing***: We have updated the costing to be in line with a start date of September 2010. Also, in response to the correspondence, we have made a number of other changes. These include:
   1. The addition of resource to support the health economic component as requested
   2. Costs for the PCCTRU support
   3. The computer costs have been reduced as suggested.
   4. The costs for the Nutritional Epidemiology Unit at Leeds have been reduced as requested and broken down further.
   5. The salary costs for one of the investigators that had been queried has now been revised to separate out the salary from the indirect and estates cost components
   6. The NHS service support costs have been moved to research costs in line with discussions with Trudi Simmons.
   7. The intervention costs are now classified as NHS treatment costs.

i) ***Review point***: As requested, we have incorporated a review point at 21 months in the timeline of the study (Gantt chart).

In addition, we have provided a brief updated literature review, focusing on relevant systematic reviews published since the original proposal.

3. Planned investigation:

The aim of the trial is to prevent overweight and obesity in 6-7 year old children. The intervention takes a population approach, and whilst it may result in weight reduction among those who are overweight or obese, the primary aim is to prevent weight gain among those with normal weight.

3.1 Research Objectives

1) To compare the effectiveness of a theory based intervention package (BEACHeS intervention) delivered at school level, to prevent obesity in children aged 6-7 with usual care
2) To assess costs and compare cost-effectiveness of the intervention with no intervention from the societal perspective
3) To explore differences in outcomes, uptake and adherence to the intervention by gender, ethnicity, socioeconomic status, baseline BMI and rural/urban residence
4) Use qualitative approaches to describe the implementation of, uptake, motivation to participate and adherence to the intervention components

The study will seek to address the following research questions:

1. How effective is the BEACHeS intervention package, delivered through schools, in preventing overweight and obesity in children, compared to usual practice?
2. For how long do any observed effects persist, after active intervention has ceased?
3. What is the incremental cost associated with supplying the BEACHeS obesity prevention intervention?
4. What is the incremental benefit associated with supplying the BEACHeS obesity prevention intervention?
5. What is the incremental cost-effectiveness ratio of supplying the BEACHeS obesity prevention intervention?
6. How effective is the intervention package in improving diet and increasing physical activity, compared to usual practice?
7. Does the intervention package result in increased fitness levels in the children involved compared to usual practice?
8. What is the effect of the intervention on quality of life and perceived self worth?
9. Is there a trend in difference in outcomes by sex, ethnicity, social class or urban/rural living?

3.2 Existing research

3.2.1 The Problem

Overweight and obesity is an increasing global epidemic in both adults and children. The World Health Organisation estimated that worldwide 1.6 billion adults were overweight and 400 million were obese in 2005, with a projected increase of 44% and 75% respectively over the next decade[1]. In the UK the problem is also growing, with two thirds of men and over half of women in England estimated to be overweight or obese[2], and 28% of children aged 2 to 10 overweight or obese in 2003[3]. Furthermore childhood overweight and obesity rates increase both with age (3% and 10% for boys and girls respectively from the 6-10 to 11-15 age bands) and over time (projected increases of 1% and 10% for 6-10 year old boys and girls respectively from 2003-2010)[2]. The cost of overweight and obesity to the overall economy in England was conservatively estimated as £6.6-7.4 billion, based on 2002 figures[4].

Obesity is associated with several health consequences in adult life, including type 2 diabetes[5], cardiovascular disease[6] and some cancers[7]. Longitudinal studies have shown that childhood obesity is also independently associated with morbidity and mortality in adulthood[8-10]. Added to this, childhood obesity is associated with poor health in childhood, including hypertension, dyslipidaemia and psychosocial problems such as poor self-esteem, anxiety and depression[11-13].

Childhood obesity is strongly associated with adult obesity, with over 50% of obese children becoming obese adults[14]. Obesity that persists into adulthood is thought to be established before the age of 11[15], which highlights the need to target prevention strategies at younger children.

3.2.2 Existing research on childhood obesity prevention

There are numerous systematic reviews of childhood obesity prevention interventions. A Cochrane review, published in 2001 and updated in 2005 reviewed 22 prevention studies[16]. These included school, community and family-based studies that targeted a range of ages. Interventions were aimed at improving diet, increasing physical activity, or a combination of the two. Studies with both short and longer term follow up were included. Despite most studies showing a small improvement in diet and/or physical activity, many were of short duration and most were unable to demonstrate a convincing effect

on overweight status. None of the studies examined cost-effectiveness. The main recommendations arising from this review were the need for consideration to be given to sustaining behaviour change, and corresponding environmental change to support this, and the need for stakeholders, such as families, schools and local communities, to be involved in the decision making regarding potential intervention strategies.

The National Institute for Health and Clinical Excellence published a comprehensive guideline on obesity, including prevention in childhood[17]. A review of the evidence on childhood obesity prevention showed a dearth of UK based studies, with the majority being US based. School-based intervention studies were reviewed, and interventions aimed at diet, physical activity, and combined diet and physical activity were considered. In terms of weight outcomes, many studies failed to show a significant change. Only one dietary intervention study (with the aim of reducing carbonated drink consumption)[18], 4 of 10 physical activity intervention studies, and 4 of the 10 diet and physical activity intervention studies reported a significant reduction in weight outcomes. However the effects were often confined to sub-groups (e.g. girls only). Furthermore it is not clear why intervention components that seemed effective in some studies were not replicated in others. The populations targeted, components, duration and emphasis of intervention, the theoretical frameworks and duration of follow up varied widely between studies.

Since the publication of these reviews, the only study with some promising results was a non-randomised controlled trial in the US, involving 1178 children in 3 schools[19]. A multi-faceted community based environmental change intervention delivered over one school year resulted in a significant fall in BMI z-scores. Results from other reviews of interventions to modify diet and physical activity in children also suggest that positive behaviour change is more likely if interventions are multi-faceted[20], involve parents and consider the children's views[21;22]. The importance of targeting environmental change is also emphasised[23;24].

Updated literature review since initial proposal

Since our original proposal, there have been a few additional relevant papers published. A systematic review of behavioural intervention trials to prevent childhood obesity published up to 2006 found that overall such trials resulted in small changes in the target behaviours, but with negligible effect on BMI[25]. They also found that interventions tended to be more successful in reducing unhealthy behaviour (e.g. sedentary activity or high fat diet), than increasing healthy behaviour (e.g. physical activity or healthy dietary intake) and that overall, effects were greater in trials with >6 months intervention. Another systematic review of school-based physical activity interventions found no significant difference in BMI between children in the intervention compared to those in the control schools[26]. They also concluded that the 18 trials reviewed had many deficiencies in quality which need to be addressed in future trials. These included lack of assessment of adherence to study protocols, lack of objective assessment of physical activity and not always being powered sufficiently to detect clinically important changes.

In summary, whilst multifaceted school-based interventions have the potential to prevent weight gain and obesity in children, the results of previous studies are inconsistent and the combination of components most likely to be effective are not clear. Previous studies were not always adequately powered, the basis for interventions sometimes unclear, and long term outcomes were rarely assessed[17].

3.2.3 Summary of work from BEACHeS

For a complex intervention such as obesity prevention, which has several interconnecting components, a rigorous and iterative phased approach is required to improve study design, execution and generalisability of results. Our team, through funding by the NPRI, has carried out the phase I and II work in developing an intervention for childhood obesity prevention (BEACHeS), following the MRC framework for complex interventions[27]. An extensive, careful and detailed review of the literature was used to identify and separate out components from all interventions tested in previously published obesity prevention trials. We then used stakeholder meetings and focus groups to generate further ideas, to identify barriers and opportunities for intervention, and to inform the prioritisation of components for the intervention package, in terms of importance and changeability. The findings were fed back to an expert group, which helped in finalising the components for the intervention package. The research team then analysed the components further by outlining the theoretical pathways by which various intervention components could lead to obesity prevention, and the environments that they would impact upon. The environments were derived from the ANGELO (analysis grid for environments linked to obesity) framework[24], focusing on the four micro-environmental factors. These include the physical (what is available), economic (what are the costs), political (what are the rules)

and socio-cultural (what is the social and cultural background). Through this process a number of approaches clearly emerged as a focus for intervention.

First, schools were recognised as an important setting for education and influencing behaviour, and for identifying children. However a number of recent and ongoing national initiatives are already targeting school food provision, and curricular activity. The important gaps where intervention could be targeted were identified as interventions with families, and increasing the provision of physical activity for children in schools. Family interventions that are activity based (as opposed to providing written material), and aim to confer skills (in addition to knowledge) were particularly prioritised. Schools were thought to be a good base for co-ordinating and possibly hosting such activities, although individuals other than teachers were envisaged as the key people delivering such interventions. The main opportunities identified were that several agencies (including primary care trusts (PCT) and industries such as sports and voluntary organisations) involved with schools have similar goals, and have experience and resources that may be built upon.

Based on these findings, and taking account of available resources, we designed and tested a multi-faceted intervention package which targeted environmental change. This package was tested in an exploratory trial in around 600 children aged 5-7 at baseline from 8 primary schools, during which time the intervention components were refined and modified. The main aim was to assess the feasibility and acceptability of each intervention component, and inform the final intervention package that could be tested in a phase III cluster randomised controlled trial. We used a number of approaches to evaluate the way the intervention was delivered and a summary for each component is provided in appendix 1. Briefly we analysed data from tape-recorded interviews with school staff, self-administered questionnaires to children in participating schools and their parents, and observation of school playground activities to evaluate and decide on the final components for the intervention package. In addition, outcome measures, including BMI, dietary intake and physical activity levels, were compared between intervention and control children, adjusted for baseline measures. To date, this data has been collected and collated for around 400 children (6 out of 8 schools). The measures in the remaining two schools are ongoing and will be complete by mid-June 2009. Given that this was not a definitive trial, the outcome data needs to be treated with caution. The exploratory trial was not randomised, the intervention was constantly being modified, and measures are not complete. The dietary assessment instrument was developed and validated during this study, and has changed slightly from baseline to follow up as a result of this process. Nevertheless, we felt it was important to compare outcome measures in order to assess the direction of any effect and see whether a definitive trial is warranted. The results of the outcome assessment are in appendix 2, but briefly we found that at follow-up, children in the intervention schools had significantly lower BMI than those in the control schools.

3.3 Research methods

Design: This will be a cluster randomised controlled trial. Schools are a natural setting for accessing children to take part in a prevention trial. In order to minimise contamination, the unit of randomisation and analysis will therefore be schools rather than individual children.

Participants: All Local Education Authority (LA) maintained primary schools (s) across the West Midlands (n=1,829 in 13 LA's) will be eligible. This is a multi-ethnic region with wide socio-economic diversity. The schools will first be stratified by rural/urban location (at county level). In the rural counties, the proportion of children from ethnic minority groups is small (mean 5%, range 2-8%)[28]. Therefore schools in these counties will be stratified by level of socio-economic deprivation, based on median proportion of children eligible for free school meals (FSM). In urban counties schools will be stratified into two groups, based on the proportion of pupils from minority ethnic groups (at LA level: median = 26%, range 9-54%). Each group will be further stratified by level of deprivation, in the same manner as schools in rural counties. The median proportion of children eligible for FSM in rural counties is lower (11%) compared with schools in urban counties (26%). We extrapolated individual school level data confidentially supplied by Birmingham LA to nationally available LA level data[29] to estimate the number of schools (s) that are likely to be in each stratum (see flow diagram, section 7). These numbers will be refined by contacting each of the 13 LA in the W Midlands individually, if funding is approved.

Whilst randomisation will be at cluster level, eligible participants will be all children age 6-7 at baseline (Key stage 1, year 2; n~3840) from participating schools and their families. This is the age around which adiposity rebound occurs, and is a critical period for future adult obesity. Children from families where English is a second language will be included, and interpreters used if necessary. The mean number of eligible children per school is estimated to be 51 (range 30-69 across all LA's).

However average numbers are greater in urban schools, which will comprise a higher proportion of participating schools. Therefore in the final sample we estimate that the average number of children per school will be ~ 60. From our experience of working with a deprived, difficult to reach group of children in BEACHeS and other studies[30], we estimate that the participation rate would be about 70%.

Proposed practical arrangements for allocating clusters to trial groups
A computer generated randomisation table will be used to order all eligible schools within each stratum in a list. From each stratum, 10 schools will be invited to take part, with schools being invited sequentially from the list. If any school refuses to take part or is ineligible, the next one on the list will be invited. Once they have agreed and after baseline measures are undertaken, schools within each stratum will be randomly allocated to the control or the intervention arm. The identity of the schools will be removed during randomisation, so that the person in charge of allocation is blind to the actual schools. Participants (children in year 2 from selected primary schools) will be allocated to intervention or control based on their school (cluster).

Planned inclusion/exclusion criteria: Schools that accept will be assessed for eligibility by checking that data on FSM and ethnicity are correct. Schools that are in special measures, have a notice to improve or that have less than 18 pupils in the relevant year group will be excluded.

3.4 Planned interventions

3.4.1 Intervention arm

Children in the schools allocated to the intervention arm, and their families, will be offered the intervention package (see below). This will run over one school year, with half the intervention schools receiving the intervention in study year 2 and the other half in study year 3. The schools will be used to disseminate information, target intervention children and their families, and as the venue for some of the intervention components. Furthermore, tailoring of the intervention will be at school level, taking account of the individuals within it.

The intervention package
The intervention package was developed by combining evidence from the literature with views and ideas from key stakeholders (including parents, teachers, school nurses, dieticians, community leaders and school governors, retail and leisure representatives close to schools and some children) and a multi-disciplinary group of experts (the BEACHeS team). The ANGELO framework was used to conceptualise the determinants of behaviours leading to obesity, and thus model the effects of intervention components. The intervention package was tested and modified as part of the BEACHeS exploratory trial. The intervention package targets diet and physical activity behaviours, and each component has fixed parameters, as well as elements that allow tailoring to specific populations. Most components involve adaptations of existing structures and resources within the community, which allows rapid and feasible roll-out on a larger scale, should the intervention package be effective and cost-effective.

a) Increasing children's physical activity levels and promoting healthy eating through school
Evidence from several longitudinal studies suggest that lower levels of physical activity are associated with weight gain in children[31;32]. Data from our focus groups suggest that a variety of options have to be available to encourage all children to participate in physical activity, as interests, abilities and inclination varies. The environments targeted are mainly the physical environment, by providing structured organised activities. In addition, the socio-cultural environment is targeted through planning, goal setting and monitoring (cultural change), and use of "mentors" to encourage behaviour change. The political environment is targeted by working with schools to provide additional physical activity sessions.

- **Delivering structured physical activity sessions in the school day**

Theoretical pathway: Increasing opportunities for, and range of, physical activity available in the school day should increase energy expenditure and promote weight maintenance.
Details: The aim of this component is to build in at least an additional 30 minutes of moderate physical activity in the school day. This will be done by working with intervention schools to firstly assess existing initiatives and programmes of physical activity, the frequency and timing of their delivery, and the target groups. We will then offer them a menu of other potential approaches to increase this to the targeted level of activity. These approaches will consist of three elements:

i) Structured activity during lunch time: There is an existing national programme for training all lunch time supervisors in primary schools through a linked secondary school. The programme is being rolled out and will be a requirement in all schools over the next few years. However,

the extent to which it is adhered to and the way it is provided varies greatly. We will offer training and appropriate equipment to all schools, with the aim of involving all children in some form of physical activity during the lunch break.

ii) A number of programmes ("Wake-Up-Shake-Up"[33], "Activate" [34], or similar), that involve short bursts (5-10 minutes) of physical activity, either at the start of the school day, or between lessons are available. These are usually accompanied by music, and are used by teachers to increase concentration of children. However whether and to what extent these programmes are used, and which children are involved, varies greatly between schools. We will offer training in delivery of such programmes to teachers of target intervention classes, and encourage them to use this at least once a day in all intervention classes.

iii) "Take-10"[35] is a programme, initially developed for children in the US, and later adapted to the UK national curriculum[36] (specific to "Key Stages"), which provides lesson plans that include a physical activity element to deliver components of the curriculum

Intervention delivery: Intervention schools will be encouraged to introduce a structured rolling programme of physical games and activities to be delivered during lunchtimes, breaks and at the start and during lessons. Training will be provided for lunchtime supervisors, teachers and other school staff (e.g. support teachers) on delivery and how to motivate children and encourage universal participation. A member of the research team will monitor progress, and encourage trained staff to provide a programme which varies each day throughout the school year. The intervention is in keeping with national initiatives, and should help schools towards achieving national targets.

Tailoring: School facilities, size, staff involved and existing initiatives in the school will allow variation of the programme to build on what is already delivered (e.g. number, type, duration and timing of activities)

Modification of intervention based on lessons from BEACHeS

Each of the intervention schools in the exploratory trial started at least one of the initiatives outlined above, though no single programme was undertaken by all schools. Which programme was selected was dependent on the interests of teachers and who took responsibility for delivery. Thus it is important to offer schools a selection of programmes from which they can choose.

❖ **Villa Vitality: Healthy lifestyle training programme linking schools with the community**

Theoretical pathway: The emphasis in this component is the use of various "mentors" or role models to encourage healthy behaviours (increase physical activity and eat healthy diet). There is little research support for this component in the field of physical activity[37;38], but there is theoretical evidence to support such programmes, and many examples in the field of behaviour change. The importance of role models was discussed in our focus groups and in combination with other approaches, should increase exposure to opportunities for physical activity.

Details: The intervention is amended from a programme developed between Aston Villa Football Club (AVFC) and Birmingham PCT's. Children from intervention classes will have three contacts with the Club, the first and last being organised trips to AVFC during a school day, and the middle contact being a school-based session. On day one children will participate in a variety of activities based around healthy eating and exercise. This includes an interactive learning session on healthy eating using video, computers and a trained coach. To reinforce these messages the children will have the opportunity to go into a radio studio and role-play as radio presenters broadcasting healthy lifestyle messages. In addition, children will have a football skills session with a coach on this day. Between the first and last contacts the children will be expected to work on a healthy lifestyles project at school, including goal-setting. The second session (school visit) will take place between 2 and 4 weeks after the initial session. This will involve an hour long physical activity session run by a coach, who will also reinforce healthy lifestyle messages. Day three takes place about 6 weeks after the first session and again has a diet and physical activity component. The children will have a session in the specially adapted Club kitchen to prepare a healthy meal, which is then served and they eat at lunch time or as an afternoon snack. They will also participate in a group physical activity session, led by a gym instructor. On this day they have a chance to go into a television recording studio and present their project work in the form of a film. At the end of session 1, the group get a CD of the radio recording, and at the end of day 3, a video of the film produced, which they can then take away and revisit in their own time. The programme has been modified for the target age group as part of BEACHeS.

Intervention delivery: We have agreement in principal from AVFC to collaborate and provide this intervention component. They have experience in delivering this programme for over 3 years, including as part of BEACHeS.

Tailoring: The timing and actual content of the school-based session will be tailored to the school, linking with other ongoing school activities.

Modification of intervention based on lessons from BEACHeS

During BEACHeS, participants attended only a single day at Aston Villa, followed by follow-up material being provided to schools to deliver. Some schools also had a follow up session delivered by the research team, which was well received. However, wider experience from Villa suggested that schools rarely used the follow-up material, and that a one-off day session had short lasting effect. Since the end of the BEACHeS intervention period the programme has been modified to the above model, and successfully delivered for about 6 months.

b) Family educational activities, focusing on transferring skills

The intervention package is directed partly at families. Evidence from some research studies suggests that parental overweight and obesity may be an important risk factor for childhood obesity[39;40]. Furthermore there is evidence that interventions involving children are more likely to be successful if the family is involved[17], and this is also supported by information gathered from our focus groups. Each of the interventions below target the physical environment, by providing structured programmes. In addition, the socio-cultural environment is targeted by including techniques to encourage cultural change (e.g. planning, goal setting, reviewing to increase motivation) and the economic environment by offering activities at minimal cost to participants. The intervention components include:

- **Cooking skills workshops for children and their parents: "Cook with your kids"**

Theoretical pathway: There is evidence of a relationship between greater consumption of food high in fat (including high consumption of "junk food" and takeaways) and increasing BMI in children in longitudinal studies[31;40]. Data from our focus groups suggests that although the main messages about healthy eating are generally known, lack of cooking skills and knowledge about how to incorporate healthy foods in every day life is a key contributor to poor dietary habits. Furthermore there is evidence that "dietary advice" achieves small, positive changes in diet[41] and improving cooking skills improves nutritional intake[42-44]. The aim of this component is therefore to improve healthy cooking skills, and thus reduce high fat, energy dense food consumption by children at home.

Details: The programme consists of three sessions (one per term) held over the school year, supplemented by written material, recipes and "homework" for children. It is overseen by experienced dieticians and is designed to provide an interactive approach to conveying healthy eating messages. For each session parents will be invited to join their children to prepare one or more quick, easy, affordable, healthy dish using locally-available ingredients. Dishes are designed to be acceptable to children. During the sessions an overview will be provided of healthy eating as well as focusing on the importance of fruit and vegetables and of reducing fat, salt and sugar. The sessions will use a model that has been successfully implemented to involve parents in a teaching activity with their child (Inspire workshops). These workshops tend to have high parental uptake (75-100% for those run in Birmingham), and so have the potential of targeting most parents. After each session, children will have targeted homework to prepare another dish at home with their parents, using the information provided in that session. They will be asked to share the experience gained from this activity in the form of an essay, drawing or other action, decided with the class teachers. Parents will also be given written material to supplement the content of the session, and access to a "healthy recipe bank", with more recipes being shared via study newsletters.

Intervention delivery: Each intervention school will be asked to identify one teacher and a parent link worker to work with the research team and assist in parent recruitment and intervention delivery. A member of the research team will facilitate and run each session. Children in the intervention classes and their parents will be invited to take part, irrespective of whether they have consented to be included in the measurements.

Tailoring: The timing of sessions, recipes chosen and homework activity will be decided locally, in consultation with school staff and parents where relevant.

Modification of intervention based on lessons from BEACHeS

The evaluation of the exploratory trial suggested that involving children in these sessions improved attendance, and that 3 sessions was optimal. The model used in the exploratory trial had limited capacity and not all parents were able to participate. However findings from the teacher interviews and experience from our LEA expert suggests that using the Inspire Workshop model could improve

parental involvement (75-100% involvement in their experience). Sharing of healthy recipes through newsletters was popular with parents.

❖ **Signposting of family leisure activities**

Theoretical pathway: Lower levels of physical activity are associated with higher BMI. The neighbourhood and other environmental factors are increasingly suggested as contributors to physical activity levels. However a systematic review concluded that it was not particular environmental characteristics, but perceptions of the environment which predict levels of physical activity[45]. Results from our focus groups suggest that there are a number of services, facilities and activities in most communities which are conducive to physical activity, but are underutilised. Lack of signposting and low awareness, as well as inertia were thought to contribute to this underutilisation, and a poor perception of the local environment. Also, interests vary, and a range of activities need to be available to appeal to a large audience. Therefore the aim of this component is to signpost opportunities and services for leisure activities within the communities. This could encourage them to identify activities that appeal to them, and take these up on a more regular basis. The aim is also to improve perceptions of the local environment.

Details: Several resources and activities (e.g. parks and green spaces, swimming pools (often with special offers for families), gyms etc) are available in most areas. Details of all such facilities, with information on opportunities offered, suitability for children, opening hours, costs, directions and any other relevant information will be compiled and printed in an attractive, simply worded and practical format and distributed to parents of all children in intervention classes. In addition, special events and suggestions of season-specific activities will be publicised and distributed via newsletters.

Tailoring: The types of facilities and activities included will depend on the availability of services in the area and interests of the local population, and will be tailored accordingly.

Modification of intervention based on lessons from BEACHeS

The signposting of facilities was well received, popular and used by parents. The "taster sessions" were also popular for those who attended, and introduced participants to new activities that they had not previously undertaken. However the intense resource requirements and associated practical barriers do not justify this aspect of the intervention. Therefore only the signposting aspect is being retained.

c) Packaging the intervention

The intervention package is multifaceted and consists of a number of components. However based on evaluation of the BEACHeS intervention, it is important for all components to be brought together under a single banner and for a "school approach" to intervention delivery. We will do this by having a presence at all school-level events, such as parents' evenings, teacher training days, and meeting with school governors and school councils. We will also work with parent link workers and a member of the research team will attend and speak at some of the school assemblies, including any where parents are invited. We will also use regular (half-termly) newsletters to communicate with parents and keep them informed of the study and intervention components.

3.4.2 Control arm

The children in control schools will be offered no intervention in addition to usual practice. Schools participating in the BEACHeS exploratory trial accepted this, and it posed no difficulty in recruitment or maintenance.

3.5 Ethical arrangements

The study will involve questionnaires and measurements on children. The schools involved in the study will be approached and given sufficient information to allow them to decide on whether they will participate. Named data will be collected from children, but anonymised by linking with ID numbers. The linking information will be kept securely in a locked office, available only to the research team. Ethics committee and R&D approval will be sought. The team is familiar with the process and forms involved through experience with BEACHeS.

Risks and anticipated benefits: Previous obesity prevention interventions in school age children have reported no negative outcomes. One trial specifically demonstrated no increase in extreme dieting behaviours among intervention participants[17]. The only potential harm is that by participating in the intervention activities, participants may have reduced time for some core curricular components. However, this is minimal, in keeping with national initiatives, and benefits of increased physical

activity and healthy eating may increase concentration, interest and performance. There is some evidence, based on a systematic review, of at least short term cognitive benefits of physical activity during the school day[46]. This supports providing such interventions in favour of other academic subjects.

Informing potential trial participants of benefits and known risks: Participant information sheets will be provided (adapted from BEACHeS) to provide information to potential participants.

Obtaining informed consent: Letters will be sent out to all parents of the target children, and informed consent obtained (using adaptations of forms from BEACHeS) prior to including any child in the study. Children whose parents do not consent will not have measurements taken and will therefore not be included in the study outcomes.

Proposed time frame for retention of relevant trial documentation: 15 years

Compliance with Medicines for Human Use Regulations: NA

3.6 Proposed sample size:

The sample size estimate is based on analysis of data from children from 8 schools in BEACHeS, where baseline and follow up data was available. The planned sample size is based on recruiting 44 schools with on average 43 pupils per school (total n=1892), clustering within school. For the clinically meaningful binary outcome of overweight or obese, our estimate for the intraclass correlation coefficient is ICC=0; 95%CI (0, 0.02) (estimated by ANOVA[32]of final BMI measurements). Allowing for variable school size (mean=43, sd=23)[33] the corresponding design effect is 1 (1, 1.84). The observed difference of the outcome in BEACHES between treatment and control groups was 33% vs 27%. Our planned sample size of 44 schools of on average 43 pupils will provide 80% power of detecting a difference of this magnitude based on the observed ICC=0. If the design effect was 1.84, the power would reduce (to 54%), as would also occur should centres be lost.
Statistical efficiency can be gained by analysing BMI z-scores rather than those in particular categories, particularly if baseline values are adjusted for. In the BEACHES data the ICC for BMI z-scores was 0.02 (0 to 0.06) with a corresponding design effect of 1.84 (1, 3.52). The standard deviation of final z-scores was ~1.45. Adjusting for baseline z-score more than halved the standard error of treatment effect estimates, equivalent to the gain obtained by quadrupling the sample size. The combined effect of clustering and adjusting in our study of 44 centres provides the same degree of evidence as an unadjusted parallel group trial of 4200 participants. Thus we will have over 80% power to detect a difference of 0.125 z-score units, or 90% power for a difference of 0.15 z-score units for the BMI outcome. The difference observed in BEACHES was 0.3 z-score units.

3.7 Statistical analysis

Because randomisation will be at the school (cluster) level, we will analyse most measures by school as well as by individuals. The baseline characteristics will be summarised by school (cluster) and described by control and intervention group. These characteristics will also be explored with individuals grouped by ethnicity, rural/urban status and deprivation.

Analyses of outcomes will be by intention to treat. The difference in primary and other outcomes between schools in the intervention and control group will be described at one- and two-year follow up stages. The effects of the intervention will be estimated using multilevel modelling techniques, adjusting for clustering and baseline covariates where available. Outcomes are either binary (e.g. normal weight vs overweight (including obese)), or continuous (e.g. BMI z-score or energy expenditure). Statistical analysis will be undertaken by the medical statistics group led by Professor Jon Deeks.

Planned subgroup analyses: We will also examine whether any difference in outcomes between control and intervention arms varies by ethnicity, socio-economic and geographic factors. The significance of subgroup effects will be assessed by tests of interactions of covariates (at individual and cluster level) and the treatment effect. The study will have low power to detect all but the largest differences.

Planned recruitment rate
Once schools and children have consented to take part, we plan to recruit (baseline measures) ~90 children per week (2 teams measuring 15 children/day, 3 days/week). We will recruit in two waves; in year 2 half the children will be measured (including control and intervention schools), recruited over 12

weeks (allowing for school holidays and exam weeks). This will allow sufficient time for intervention delivery after baseline measures. The remaining schools and children will be enrolled the following year. The timetable is based on our experience from BEACHeS and allows a balance between staffing requirements and the constraints in time period for measurement and delivery of intervention within a school year.

Likely rate of loss to follow-up

Pupil turnover for primary school children is estimated to be between 10-12% per year on average (personal communication, Birmingham LA statistics department). Our experience from BEACHeS suggests that children, whose parents consent for them to take part, tend to be more likely to remain in the same school. After two years from baseline, approximately 15% of children have been lost to follow-up, which is lower than the expected 19-23% based on pupil turnover rates. We therefore anticipate that loss to follow-up will be similar, at around 15% in the proposed trial.

3.8 Proposed outcome measures

All children who are taking part in the trial will undergo baseline assessment. Follow-up measures will be taken at intervals following delivery of intervention, for a minimum of 2 years. In addition, parents of participating children will be asked to complete questionnaires at intervals.

Primary outcome measure

This will be the difference in percentage of children categorised as normal weight, overweight and obese in control compared to intervention schools. The categorisation will be based primarily on height and weight measures and defined by BMI using cut-offs at the 85th and 95th percentiles on the UK 1990 reference charts for BMI centiles for boys and girls. In addition, we will compare BMI z-scores (standardised deviation scores) in control and intervention schools at follow up, taking account of clustering, baseline levels and other relevant co-variates. BMI is the most widely used method of assessing overweight and obesity in children and is practical, objective and the measure is consistent with adult practice[49]. In addition it allows comparison with other studies and is consistent with recommended national guidelines for measurement of school children. However BMI has limitations as a measure of body composition in children, and the cut-offs for overweight and obesity are not appropriate for all children. We will therefore use other measures[50;51] in addition, which are likely to be more accurate for subgroups of the population and compare methods for categorising body weight. The additional measures include skinfold measures at 4 sites (biceps, suprailiac, subscapular and thigh), waist circumference, and assessment of body fat using bioimpedance.

Secondary outcome measures:

Diet – Dietary assessment will be undertaken using a validated simple tick list (CADET[52]), which has also been used in BEACHeS. This will be administered over one day for each measurement period, and completed by the research team at school, and parents at home. The tool will allow us to compare general eating patterns, and specific nutrient intake (e.g. % energy from macronutrients (protein, fat, carbohydrate) or different food groups (cereals, dairy, meat/fish, fruit/vegetables)). The absolute difference between control and intervention clusters in dietary energy intake (expressed as kJ per kg body weight per day) will be compared. In addition dietary fat, sugar and fruit and vegetable intake will be compared between control and intervention clusters. Additional outcome measures will be whether any changes in diet occurred during or after school time, during weekdays or weekend days or both.

Physical activity (PA) levels – PA will be assessed objectively at baseline, follow 1 and follow up 2 using a monitor that combines heart rate and accelerometry (Actiheart), and has been shown to provide a more precise estimate of PA energy expenditure than other measures[53]. Our experience of using Actiheart in 600 children in BEACHeS has shown high compliance, and a high rate of usable data. This is in comparison to relatively poor compliance with less accurate methods of measurement. In addition, the use of Actiheart has generated interest and raised participation rates in some schools. The absolute difference between control and intervention clusters in physical activity energy expenditure (expressed as kJ per kg body weight per day, measured by combined heart rate and movement sensing) will be compared. In addition time spent doing sedentary activities (min/day), and time spent at light, moderate and vigorous intensity activity (min/day) will be compared between control and intervention clusters. Additional outcome measures will be whether any changes in activity levels occurred during or after school time, during weekdays or weekend days or both. An interviewer administered self-report tool will be used at follow up 3 and for some children at follow up 2.

Other measures:

Quality of life is an important global measure, which has been associated with measures of body composition. By including this measure, we will be able to consider the wider effects of the

intervention, either beneficial or potentially harmful. Children's quality of life will be assessed directly, using the Pediatric Quality of Life Inventory (PedsQL)[54], which is a validated instrument for children of this age, and has been successfully used in BEACHeS. In addition, parents will be asked to complete an assessment of the child's quality of life using the EQ-5d.

Physical fitness Several different tests will be used to measure physical fitness: a 6 minute continuous run will be used to assess aerobic fitness; grip strength; catching and throwing tests will be used to assess motor skills; muscle strength will be determined through the measurement of distance achieved for a power throw and also a standing jump; flexibility will be considered through a sit and reach test. These tests have been selected as previous studies have shown them both to provide a good indicator of fitness levels and also to be feasible in the relevant age groups. The fitness data will be used to investigate both the relationship between physical fitness and body composition and also physical fitness and weight status. In addition for children in phase 2 schools the change in fitness levels from baseline to first follow up will be considered separately for control and intervention schools to determine whether or not the WAVES study intervention programme impacts upon the fitness levels of the children involved.

Puberty For the third set of follow-up measurements, when the participating children will be aged 9 to 10 years, a simple visual assessment of puberty based on the Tanner breast development scoring system will be undertaken in the girls. They will be in light clothing and observers will classify females into 2 categories: no development or some development. This will enable pubertal status to be taken into account in some study analyses. No puberty assessment will be undertaken in the boys as they would not be expected to enter puberty until a later age.

Process measures The purpose of undertaking process measures is to answer a critical question: HOW HAS the interventional package prevented / not prevented inappropriate weight gain. We have indicated that the development of the interventions has been theoretically-informed not only from the literature but also from the experiential knowledge collected from key stakeholders in the original BEACHeS study, where pilot work has further guided the interventions' development. However, the effectiveness of even well-developed theoretically-informed and evidence-based interventions may be adversely affected by factors associated with implementation and local context. Thus, in addition to the collection of end-point outcome data, it is necessary to identify intermediate intervention-specific process measures that allow us to understand why / why not desired outcomes have been reached. In essence, we are required to get inside 'the black box' of the intervention package and to understand why we might expect some outcomes and not others to be realised in all or some of the schools.

An evaluative framework that enables such an approach to understanding the process of implementation is the 'Theory of Change' (TOC). Here, participants involved in a change process (i.e. the implementation of the intervention/s) articulate theories of how and why they think the actions they are taking / responding to, will lead to the outcomes the intervention aims to achieve. In the context of complex initiatives such as the one we propose, such theories are likely to have multiple strands, operating at many levels. The articulation of such theories identifies the assumed pathways of change. This, in turn, starts to define the type of data to be collected to establish whether those implementation pathways are being followed and whether expected short and medium term outcomes are observed.

The precise methods that can be used to surface change theories and to collect data relevant to them vary according to the change context. We will use methods developed by us in the successful evaluation of other national policy initiatives (for example the New Deal for Communities urban regeneration scheme; the National Expansion of Medical Education in England and Wales; and the National Implementation of the Health Trainers Initiative in England which have used the TOC Framework. Our methods will include documentary analysis (e.g. minutes of relevant meetings; checklists); analysis of quantitative data (e.g. attendance records), interviews with key stakeholders, and direct observation of selected components.

Our team has experience in administering all the above measures, and have developed standard operating procedures and protocols which were used in measurement of 600 children in BEACHeS.

Economic evaluation:
Comparisons will be made between the situation of supplying the intervention package and a situation where no intervention is in existence (i.e. usual current practice).

These questions will be answered in the context of a decision-analytic framework. This provides a rigorous methodology for combining information from a variety of sources. Cost data will be collected from two sources. First, once the evidence has been synthesised for the obesity prevention intervention, relevant studies will be examined for their data on costs and resource use. These data will be subject to relevant quality criteria. Additional cost data will be available from other sources such as the National Schedule for Reference Costs. It is anticipated however that cost data for the obesity prevention intervention may not be directly available. Associated costs may therefore have to be estimated from first principles ('bottom-up' costing) and/or based on expert advice (e.g. what components have gone into an intervention package e.g. time for training teachers, cost of additional staff and extra-curricular activities and any use of health care services by participants). Costs will be assessed from a societal perspective and thus include costs to the participants and families (such as time and travel costs) as well as the actual cost of running the obesity prevention programme. Expertise exists within the team for measuring this type of cost.

The decision-analytic model will allow a prediction of outcomes in terms of cost per 'case of overweight/obesity prevented' which will act as the main measure of cost-effectiveness. Other analyses will include change in percentage of body fat (measured indirectly by waist circumference and skin-fold thickness), diet (24-hour tick list), physical activity levels (Actiheart monitor) and perceived quality of life (Peds-QL). Quality of life will also be measured using parental report with EQ-5D and by using a child-version of EQ-5D. This will enable the construction of Quality-Adjusted Life Years (QALYs) which will also be used within the economic model. In addition, a combination of qualitative and quantitative approaches will be used to test the feasibility of various instruments that have either been developed to measure economic outcomes within a childhood population (CHU-9D, EQ-5D-Y) or designed to measure outcomes that go beyond health whilst still being amenable for use within economic evaluation (ICECAP). The results from this pilot work in year 1 will be used to inform choice of economic outcome measure to be put in place for first baseline measurement in year 2. Depending on the results of the pilot work we may choose to use more than one economic outcome measure. Ultimately the results from the full trial, in terms of costs and outcomes (measured using various methods) will be integrated into the final economic model which will be developed in year 5 once all data has been collected.

The modelling approach to be adopted will either be a Markov or a decision-tree approach, as required. Expertise exists within the group in assessing the appropriate type of model to use, and in constructing such models. Extensive sensitivity analysis will be carried out, to test for the robustness of the conclusions to assumptions made in the modelling, and to sampling variation in the data used in the construction of the model. Costs and benefits will be discounted at the standard rate (3.5%).

How will the results of this trial be used?

Once the effectiveness of the intervention package has been established and quantified, we would seek to implement the intervention more widely and continue to assess its impact. The intervention package builds mainly on existing structures, which will enable rapid and pragmatic roll-out on a larger scale. We have support from the Regional Director of Public Health in the West Midlands, who will facilitate this, with the help of the NHS and local authority. We also propose to seek funding to further develop the health economic model. This will take account of the likely long-term effects of the intervention, building on the methods used by Wang et al[55] and the model outlined in the NICE guideline[56]. This will enable subgroup analysis to be undertaken from a long-term perspective and thus lead to the evaluation of the cost-effectiveness of the intervention amongst groups within society that have variable rates of risk of developing chronic disease conditions (such as coronary heart disease, type 2 diabetes etc).

3.9 Research governance

The University of Birmingham will act as sponsors for this trial.

Trial steering committee (TSC): Three individuals who are independent of this study will be approached to form the TSC together with the lead investigator (PA) and members from the HTA. The independent members will have the following skill mix and experience: trial statistician (chair), exercise and health scientist with trial experience, person with nutritional research experience, or with childhood obesity research expertise. The committee will consider whether a Data Monitoring and Ethics Committee (DMEC) is needed, and if so, propose the membership.

4. Project Timetable and milestones:

Year	**1. 2010/11**				**2. 2011/12**				**3. 2012/13**				**4. 2013/14**				**5. 2014/15**			
Time periods: 1= Sept-Dec; 2= Jan-March, 3= April-June 4= July-August	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Staff recruitment																				
Contacting 13 LA's to identify schools																				
Develop protocols, training manuals, databases																				
Identification/recruitment of schools (Waves I and II, 44 schools), school visits, identification of school links																				
Identification of local services, Planning for intervention delivery, and opportunities for tailoring intervention (Wave I schools)																				
Baseline Measures (22 Wave I schools)																				
Implementation of tailored intervention (Wave I schools)																				
Process measures of intervention delivery and implementation (Wave I schools)																				
Review point by HTA																				
Identification of local services, Planning for intervention delivery, and opportunities for tailoring intervention (Wave II schools)																				
Baseline Measures (22 Wave II schools)																				
Follow up 1 of Wave I schools																				
Implementation of tailored intervention (Wave II schools)																				
Process measures of intervention delivery and implementation (wave II schools)																				
Assessment of ongoing intervention effects (wave I schools)																				
Follow up 1 of Wave II schools																				
Follow up 2 of Wave I schools																				
Assessment of ongoing intervention effects (Waves I and II schools)																				
Follow up 3 of Wave I schools																				
Follow up 2 of Wave II schools																				
Analysis of trial results. Economic analysis, report writing and dissemination																				

5. Expertise

All but two of the collaborators (Frew and Deeks) are investigators or collaborators for BEACHeS and therefore have been involved in the process of development of the intervention and the exploratory trial. The study has a multidisciplinary research team, with relevant and complementary skills and methodological approaches. This includes those with experience in clinical trials, behavioural epidemiology, programme evaluation, community child health, dietetics, exercise scientists, health psychology and school health education, ethnicity research. Several of the applicants, including the principal, are undertaking projects on childhood obesity prevention in the UK and other countries. *Adab* and *Pallan* jointly oversee and manage all aspects of the BEACHeS project. *Cheng* leads a number of international epidemiological research projects, including clinical trials, and is experienced

in large collaborations and epidemiological methods. *Cade* has an established record in nutritional epidemiology research, and a co-investigator in the only trial of childhood obesity prevention published from the UK. *Ekelund* leads on research related to assessment of PA in children. *Deeks* has expertise in trial statistics. *Frew* has expertise in health economics, particularly in relation to obesity prevention. *Gill* provides a link with the Primary Care Research Network, has expertise in cardiovascular disease prevention and ethnic minority health. *Barrett* has expertise in obesity research in children and leads a number of research studies in this area. *Bhopal* has expertise in cardiovascular and metabolic syndrome prevention, minority ethnic health and approaches to body fat measurement. *Daley* has research experience in PA promotion and lifestyle interventions with a range of populations, including clinically obese children. *Duda*'s expertise is in PA and motivational processes in children. *Parry* leads one of the largest Health Impact Assessment (HIA) units in the UK, and has experience in qualitative methods and evaluation and analysis of the health effects of policies in non-health sectors. *Mcgee* provides a link with NHS dietetics, and has experience in development and running of aspects of the proposed intervention. *Passmore* provides a link with the LA, and has vast experience in working with schools and running health education interventions in schools.

6. Justification of support required

This proposal takes forward our ongoing work with BEACHeS, in line with the MRC framework for complex interventions, to tackle a major public health problem in the UK. Given the complexity of obesity prevention, with both individual and environmental components, the proposed budget is modest compared to most phase III trials for pharmaceutical interventions. The costs include:

Staff costs: The research fellow (full time, 5 years) will be in charge of project co-ordination, managing staff timetables, school liaison, overseeing data collection and management. Additional support from a full time research assistant (RA) will be required for years 2-5, when data collection and intervention delivery take place. Another RA will be required in years 2-3, to focus on and oversee intervention delivery. A fulltime administrator through the study period will provide office support, telephone calls, photocopying, typing and data entry, as well as assisting during school visits. During the period of data collection and intervention delivery, an additional assistant will be needed to share this work, and to accompany one of the two teams during school visits. Two technical grade staff are required to assist in undertaking measurements, intervention monitoring and delivery. For school measurements, two teams of 3 staff are needed on 3 days per week. Technical grade staff, the RA and school nurses (casual staff) will undertake this task. Our estimates are based on our current experience in BEACHeS. Nine months equivalent full time RF is required for statistical support and 27 months (15 at the start, and 12 at end) for health economic analysis, over the trial period. Baseline and follow up assessments will require input from trained NHS staff (school nurses and NHS dieticians) who will be employed as casual research staff. In addition, we are requesting a small amount of staff time for the support offered from the PCCRTU (data monitoring and database support).

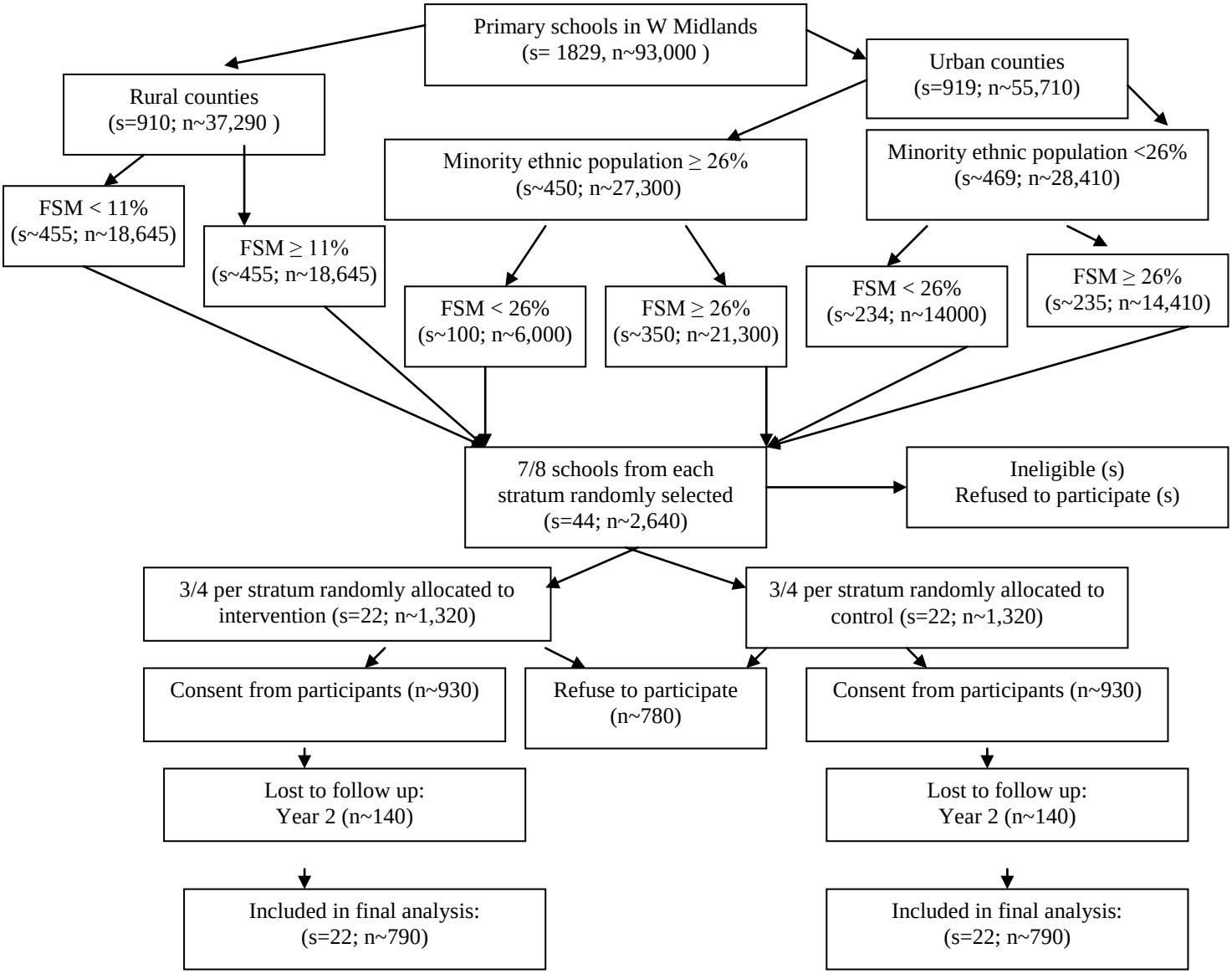
Equipment costs: Computers and printers are required for everyday work for the main project staff. In addition, we need laptops to take into schools for use with the Actiheart monitors. The measurement instruments are needed for baseline assessment. We need two sets of instruments (one for each team). However one set is available from BEACHeS, and so we are only requesting costs for a second set.

Travel costs: The trial will recruit schools from across the W Midlands, which will mean travelling for research staff from Birmingham. Based on our experience with BEACHeS, we have estimated the number of trips for engaging with the school and parents, undertaking measures and monitoring and delivering intervention. We also have collaborators from different parts of the country, who will need to travel to take part in collaborator meetings. The TSC and DMT will also have meeting and travel costs.

Consumables: In order to assess PA, we plan to hire 150 Actiheart units for each measurement period. The total time for measurements will be equivalent to 2 years. The equipment also requires USB readers, chargers, cables and software. Other associated costs are for electrodes to attach the monitors, and paper towels for skin preparation. Stationery, photocopying and library costs are calculated, based on experience from BEACHeS. All staff undertaking measurements in schools will need CRB checks annually. Schools will be paid a small amount in recognition of the time they devote to taking part in the trial. The children will undergo up to 30 minutes of measurements on 3 to 4 occasions, and from experience with BEACHeS, their participation is enhanced by small incentives. Use of the PedsQL incurs a licence cost. The intervention delivery will also have associated costs, related to arrangements for training, and costs of materials and consumables for specific components.

Other costs: We have requested costs for staff (nutritionist, data analyst) and database support from the Nutrition Epidemiology Group to develop and maintain a database, generate analyses on dietary intake and train staff on administration of the CADET tick list. Also £18,000 will be allocated for database support and analysis of the physical activity data, and for training research staff in the use of Actihearts. Finally, the CTU have requested an amount for data archiving.

7. Flow diagram: Proposed selection and anticipated flow of participants during the trial



s = number of schools (cluster level)
n = number of children
FSM = %eligible for free school meals (proportions based on medians)

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