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Cluster randomised controlled trial, economic and process evaluation to determine the effectiveness and cost effectiveness of a novel intervention (Healthy Lifestyles Programme, HeLP) to prevent obesity in school children

This study is a pragmatic; cluster randomised controlled trial (RCT) involving two arms: an *intervention arm* who will receive the **Healthy Lifestyles Programme (HeLP)** and a *control arm* who will receive the usual school curriculum. Parallel process and economic evaluations will also be described.

1. Aims/Objectives:

The proposed cluster RCT will assess the effectiveness and cost-effectiveness of the Healthy Lifestyles Programme (HeLP) compared to usual practice in preventing overweight and obesity in children.

***Specific objectives*:**

1. To assess the effectiveness of the Healthy Lifestyles Programme (HeLP), in children aged 9-10 years, by comparing in intervention and control schools (adjusting for baseline measures):
    i. Body Mass Index (BMI) standard deviation scores (SDS) at 24 months (primary outcome) and 18 months
    ii. Waist Circumference SDS at 18 and 24 months
    iii. % Body Fat SDS at 18 and 24 months
    iv. Proportion of children classified as underweight, overweight and obese at 18 and 24 months
    v. Physical activity (average time spent per day in sedentary, light, moderate, vigorous and total physical activity) at 18 months
    vi. Food intake at 18 months
2. To assess the costs of HeLP and cost-effectiveness versus usual practice
3. To conduct a mixed-methods process evaluation and mediational analysis to provide insight into the way the Programme worked (delivery, uptake, how it was experienced and what the behavioural mediators of change are).

2. Background:

Existing research

Over a short period of time, there has been a substantial increase in the proportion of children in the UK who are overweight or obese, with recent data from the Health Survey for England reporting that 34% of girls and 33% of boys aged 11-15 were either overweight or obese [1]. The National Child Measurement Programme (NCMP) 2009/10 reported that by age 10-11 years, one in three children was either overweight or obese [2]. Being overweight in childhood is associated with metabolic abnormalities, increased risk of Type II diabetes and musculo-skeletal and psychological problems [3]. According to the models in the Foresight report, two thirds of all children under 16 years will be overweight or obese by 2050, and overweight and obesity are predicted to have an annual cost of £50 billion to UK society and the NHS, if current trends continue [4].

Obesity results from an imbalance between consumption and expenditure of energy. Epidemiological studies suggest a number of risk factors, the strongest of which is having one or more overweight parents [5]. There are also strong associations between the risk of being overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [6]. At a population level, the consumption of processed and fast food, including sweetened fizzy drinks has increased while that of fruit and vegetables has declined and portion size in pre-packaged food has increased substantially [7]. The National Travel Survey has also shown that, since the

1970s, the number of children walking to school has substantially decreased [8]. Evidence about the direction of the relationship between physical activity, sedentary behaviours and childhood obesity is scarce with reviews of physical activity and obesity prevention reporting inconsistent results [9, 10]. However, compared to previous generations, children in the UK spend more time participating in sedentary activities with an average of 4.5 hours each day devoted to screen-based activity [11]. Some studies have reported an association between time spent watching television and obesity [12]: not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [13] and the consumption of snack foods [14]. Recent evidence also suggests
that most childhood weight gain occurs in mid-childhood (age 7-11 years) in UK children, although the underlying causes for this pattern are not clear [15].

To date, most childhood obesity prevention programmes have been school-based. A recent systematic review (2008) of controlled trials of such school-based interventions concluded that simultaneous targeting of increased physical activity, reduced sedentary behaviour and improved diet may be more effective in the long term than targeting only one behaviour [16]. For example, Planet Health [17], in the USA, targeted multiple behaviours and, at 2 years follow up, showed statistically significant reductions in the prevalence of obesity for girls – but not boys. An adapted version of Planet Health is currently being trialled in the UK [18]. The UK APPLES trial [19] was underpinned by a health-promoting schools philosophy. This programme was found to successfully change children's attitudes and school ethos. However, the trial was underpowered (only 5 schools in each arm) and, at one year follow up, there was no significant difference in BMI change between children in the intervention and the control schools. A further UK study (reported in the CHOPPS trial; [20]), focussed on reducing consumption of sweetened fizzy drinks. This was a low intensity intervention (one hour session per class per term) over one year (4 sessions in total). Although the prevalence of overweight and obesity *increased* by 7.5% in the control group at 12 months, compared with a statistically significant *decrease* of 0.2% in the intervention group, there was no significant difference between the groups in the change in BMI or BMI standard deviation score (SDS). Moreover, the difference in obesity prevalence between the control and intervention groups was lost at 3 year follow up. Despite these disappointing UK results, schools have the potential to play a critical role in the prevention of obesity and the recent community-wide multi-site approaches often incorporate school-based interventions [21, 22]. However, situating an intervention within a school is not sufficient in itself to generate sustained behaviour change. It is critical to ***engage and motivate children*** and to generate a **supportive social context** involving the whole school as well as children's parents [4]. To date interventions appear to have under-utilised creative delivery methods to promote engagement and empower children to actively involve their parents in supporting behaviour change. Most school-based interventions have used the traditional lesson format to '*teach'* children about healthy lifestyles as opposed to utilising highly interactive methods where the child actively engages with the messages. Moreover, due consideration has not been given to the range of prerequisite psychological changes required to generate behaviour change. Taking this into account, we have developed a theory-based intervention in which the method and agent of delivery is central to engaging the children, their parents and the school. We have also ensured that children have the information, motivation, skills and support necessary to initiate and sustain change. Initial results suggest that this approach is effective [23].

The Intervention

HeLP is a multi-component 4 phase programme that aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. It is delivered across 3 schools terms (Spring and Summer term of school year 5 and the Autumn term of school year 6). Although it is delivered specifically to year 5 children, activities have been developed to impact the whole school

environment. Piloting has demonstrated that the children found it useful to focus on **three specific behaviours related to energy intake and expenditure; a decrease in the consumption of sweetened fizzy drinks; increasing the ratio of healthy to unhealthy snacks and a reduction in screen-based activities.** Throughout the Programme the children are encouraged to find acceptable and affordable activity and dietary replacements in order to maintain a healthy energy balance. For example, children liked the "80/20" mnemonic which implies that they should maintain healthy behaviours "80%" of the time. This resonated with children and their parents as a clear and simple representation of a flexible approach to maintaining a healthy energy balance. HeLP includes a range of behaviour change techniques (BCTs) [24] delivered across four phases, using accessible and engaging delivery methods that are compatible with the existing school curriculum and create several opportunities for parental engagement. Table 1 shows each phase of HeLP, the targets of change, the BCTs used and the method and agent of delivery. We hypothesise that targeting information, motivation and behavioural skills will lead to improvements in diet and physical activity thus preventing excessive weight gain. This process of change may be moderated by gender, weight status, socioeconomic circumstances and school size.

HeLP has been specifically designed so that it can be adapted for use in different school environments and differing populations of children and be delivered within existing Public Health/Local Authority staff remits. An 'Intervention Manual' (for the delivery of each component of the Programme) and a 'HeLP Trainers Manual', to train personnel delivering the intervention (actors, drama facilitator, HeLP Coordinators), have been produced. This ensures that the function of each phase is clearly defined and delivered appropriately whilst the precise content can be adapted to local populations [25]. For example, the drama framework is built around four characters (Active Amy, Snacky Sam, Football Freddie and Disorganised Duncan) played by young actors, with whom the children can easily identify, and can be adapted to relate to children from differing ethnic and social backgrounds. During the drama workshops children co-create scenes with the actors and provide their own ideas and solutions to problems faced by the characters. This drama-based delivery is both engaging and flexible to differing needs.

Table 1

Intervention Phase	**Change targets**	**Behaviour change techniques**	**Method (Frequency and duration) and agent of delivery**	
Phase 1 **Creating a supportive context** Spring term (Yr 5)	Establish relationships with schools, children and families Raise awareness and increase knowledge Promote positive attitudes and norms towards healthy eating and physical activity Increase self efficacy for behaviour change	Provide information on behaviour-health link Provide information on health behaviour link Modelling/demonstrating behaviour Prompt identification as a role model Skill building Provide information on behaviour-health link	Whole school assembly (1) (20 mins) Newsletter articles (3) (Over the Spring term) Activity workshops (2) (parents observe) (1.5 hours) Parents' evening (1) involving child performances (1 hour)	HeLP Coordinators HeLP Coordinators Professional sportsmen/dancers Class teachers/ HeLP Coordinator /Drama group
Phase 2 **Intensive Healthy Lifestyles Week –** one week	Strengthen relationships with schools, children and families Increase knowledge Increase self awareness Increase self efficacy Develop communication	Provide information on health behaviour link Problem solving/barrier identification Modelling/demonstrating behaviour	*PSHE lessons (5) (morning) (1 hour) §Drama (5) (afternoon) (forum theatre; role play; food tasting,	Class teacher Drama group

Summer term (Yr 5)	and problem solving skills Increase social support (school, peer and family)	Prompt identification as a role model Communication skills training Teach to use prompts and cues	discussions, games etc) (2 hours)	
Phase 3 **Personal Goal Setting with Parental Support-** goals set during week following drama Summer term (Yr 5)	Increase awareness of own behaviour Increase self efficacy for change Develop planning skills Increase parental support	Self monitoring Goal setting (behaviour) Problem solving/barrier identification Plan social support Provide information on where and when to perform a behaviour Agree behavioural contract Prompt identification as a role model	Self reflection questionnaire (1) (40 mins) Goal setting sheet to go home to parents to complete with child (1) (10 mins) 1:1 goal setting interview (1) (goals sent home to parents) (10 mins) Parent's evening (1) (child involvement – Forum Theatre) (1 hour)	HeLP Coordinator/ Class teacher HeLP Coordinator /Parents HeLP Coordinator HeLP Coordinator /Drama group
Phase 4 **Reinforcement Activities** Autumn term (Yr 6)	Increase self awareness and prioritise healthy goals. Consolidate social support. Develop monitoring and coping skills Increase parental support	Provide information on health behaviour link Prompt self monitoring Prompt intention formation Follow up prompts Prompt practice Prompt review of behavioural goals Prompt barrier identification and resolution Coping plans	Newsletter articles (1) (over the Autumn term) Whole school assembly (1) (20 mins) Drama workshop (1) (1 hour) *PSHE lesson (1) (1 hour) Class to deliver assembly about the project to rest of school (1) (20 mins) (parents invited to attend) 1-to-1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (1) (10 mins) (renewed goals sent home to parents)	HeLP Coordinator Drama group Drama group Class teacher Children to all other year groups in the school HeLP Coordinator

* PSHE – Personal, Social and Health Education
§The drama framework includes 4 characters, each represented by one of the actors, whose attributes related to the three key behaviours. Children choose which of the characters they most resemble then work with that actor to help the character learn to change their behaviour.

3. Need:

The prevalence of childhood obesity has increased three-fold (from 5%-17%) in the last 30 years and is linked with increasing prevalence of type 2 diabetes, hypertension and atherosclerosis [3]. The current high prevalence of adult obesity suggests that all young people regardless of weight

status are at risk of adult obesity [26]. In England, one third of 10-11 year olds are overweight or obese and the distribution of BMI has shifted in a skewed fashion such that the heaviest children have become heavier [1, 2]. Childhood obesity has significant adverse physical and psychological effects in childhood and tracks strongly into adult life [27]. It is predicted that the burden of obesity related diseases will cost the NHS up to £50 billion by 2050, and this burden of disease and associated incapacity and reduction in quality of life, will be most widely felt by adults and children of lower socioeconomic status (25). Behavioural treatments of established obesity in both children and adults are generally of limited effectiveness and it is now recognised that early prevention to avoid unhealthy behaviours are critical for all children and adolescents not just those already overweight [28]. Inequalities in health across socioeconomic groups have continued to increase since the 1970s. There is a strong socioeconomic gradient associated with childhood obesity which not only translates into associated cardiovascular risk factors, but also tracks into adulthood and is believed to influence the adiposity of the next generation of children. Using entitlement to free school meals as a proxy for socioeconomic status (SES), we will ensure that the sample is weighted towards schools from more deprived areas. During pilot phases four schools received HeLP, three of which were from two of the most deprived wards in our region. Over 75% of parents attended one or more Programme-related school events. Feedback from these parents about the intervention supporting behaviour change at a family level was overwhelmingly positive, suggesting HeLP is feasible, acceptable and effective in areas of low socioeconomic status. The intervention has been developed and refined through three phases of piloting with considerable stakeholder involvement from Public Health, education, parents and teachers ensuring it is relevant and feasible for the end user. There is a clear public health need for evidence regarding obesity prevention in children and we believe that HeLP meets the value-of-information criteria suggested by Petticrew et al [29] because the proposed trial will not only determine intervention effectiveness but will also contribute to theoretical models related to behaviour change, hence assisting the development of future obesity prevention interventions.

4. Methods:

a. Setting

State run Primary/Junior schools Devon and Plymouth. Both of these are located in the South West of England

Inclusion criteria: Mainstream primary schools with at least one single year 5 class. If a school has enough children to make a single year 5 class, but have chosen to split them into two mixed year classes they would still be eligible if they run other activities as a single year 5 group and are happy to combine the year 5 children into one class for all intervention activities and for the taking of outcome measures. All Year 5 pupils are eligible and will be invited to participate. **125** schools in Devon and Plymouth meet the inclusion criteria, **40** of which meet the deprivation criteria ≥ 18% Free school meals (FSM).

Exclusion criteria: Schools that do not have enough children to make at least one single year 5 class and the schools who received the intervention in the pilot phases of the research.

b. Design

School-based cluster randomised controlled trial.

c. Recruitment and randomisation

All state primary or Junior schools in Devon and Plymouth will be invited to participate if they have at least one single year 5 class. The target is to recruit 32 schools by July 2012. Allocation of schools to intervention or control will be stratified by (i) the proportion of children eligible for free school meals (<18%, ≥ 18%) and (ii) school size (one Year 5 class, >1 Year 5 class). For practical

reasons half of the control schools will be randomised into cohort 1 who will enter the study in year 1(2012) and half will be randomised to cohort 2 who will enter the study in year 2 (2013). Group and cohort randomisation will be performed by a member of staff in the PenCTU who is not involved with the trial, immediately after all schools have been recruited**. Schools will be informed by the Trial Manager whether they are cohort 1 or 2 in July 2012.

Only after completion of baseline measures (Sept-Dec) for each cohort will the Trial Manager and HeLP Coordinators be informed whether the school will receive the Programme or be a control school. The HeLP Coordinators will then inform the schools, children and parents at the beginning of January 2013/14 for cohorts 1 and 2 respectively of their allocated group (i.e. intervention or control).

d. Data collection

Following recruitment, schools will be randomised into 2 cohorts in July 2012. Cohort 1 will enter the trial in September 2012 and Cohort 2 will enter the trial in September 2013. Children will be assessed on four occasions planned to be taken at the following times

1. Baseline, between Sept and Dec 2012/2013 for cohorts 1/2 respectively when the children are in school Year 5
2. 12 months post baseline in Nov 2013/2014 for cohorts1/2 (questionnaire to understand possible mediating variables)
3. 18 months post baseline, between June and July 2014/2015 for cohorts 1/2 respectively, when the children are in school Year 6
4. 24 month post baseline, between Sept and Dec 2014/2015 for cohorts 1/2 respectively, when the children are in school Year 7

The following outcomes will be measured/collected at the time points indicated in brackets

Anthopometric measures

BMI (baseline, 18 and 24 months)

Height will be measured using a SECA stadiometer (Hamburg, Germany), recorded to an accuracy of 1mm. Weight will be measured using the Tanita Body Composition Analyser SC-330 (U.K. Ltd., Middlesex, U.K.). Weight will be recorded to within 0.1kg and children are asked to take off their shoes and socks. BMI is calculated and converted to centiles using the software package LMS, developed by Cole [30].

Body fat (baseline, 18 and 24 months)

Percent body fat will be estimated from leg-to-leg bioelectric impedance analysis (Tanita Body Composition Analyser SC-330) and converted to centiles using the LMS software [31] and compared to percentiles for British children [32].

Waist circumference (baseline, 18 and 24 months)

Waist circumference will be measured using a non-elastic flexible tape measure, 4cm above the umbilicus [42]; converted to centiles using the LMS software and compared to the waist circumference percentiles for British children [33].

The anthropometric measures are taken individually in a private room and no child is told their height, weight, percentage body fat or waist circumference. We have developed a school lesson associated with the measures using the 'good practice' exemplar for taking anthropometric measures, developed by Birmingham PCT for the National Child Measurement Programme [34] to avoid any possible stigmatisation of sensitive children. The scales used to weight and calculate % body fat give a print out of the readings (seen only by the researchers), thereby ensuring that

children are not able to read and, therefore, possible discuss, their own results.

Behavioural measures

Physical activity (baseline and 18 months)
One randomly selected class from each school will be asked to wear a GENEActiv accelerometer (www.geneactiv.co.uk) a watch worn around the wrist during waking and sleeping hours over seven consecutive days. GENEActiv data will be uploaded onto a PC and analysed using the GENEActiv Software (www.activeinsights.co.uk). Output measures will include total daily volume of physical activity and mean daily time spent in sedentary, low, moderate and vigorous intensity physical activity, with thresholds for the classification of activity intensity taken from recent research undertaken using the GENEActiv accelerometers [35, 36]. How (sporadically or in bouts) and when activity is accumulated will also be determined. Where possible the GENEActivs will be charged and initialised on a Monday and given out to each child on a Tuesday and will be collected the following Wednesday. The GENEActivs will be shown to children in groups of 10 with verbal instructions given in these groups. The GeneActivs are waterproof and children will be asked to wear them all day and night.
Food intake (baseline and 18 months)
Food intake will be assessed using the adapted version of the validated Food Intake Questionnaire (FIQ) [37]. Children complete the FIQ twice in order to obtain a weekday and weekend food intake. Results are combined and weighted to calculate the mean number of healthy snacks, energy dense snacks, positive and negative foods consumed per day.

Mediators

Potential mediators will be assessed using a lifestyles questionnaire ('My Lifestyle Questionnaire') developed by the applicants as part of the process evaluation for the Exploratory Trial of HeLP based on the Information, Motivation and Behavioural skills Model [38] to capture possible regulatory processes which may mediate change in physical activity and diet. The items in the questionnaire assess (i) knowledge (ii) perceived environment and social support (iii) individual motivations and cognitions (iv) use of behaviour change techniques (BCTs) and (v) mediating behaviours that may affect levels of physical activity and diet. These include:

(i) **Knowledge** of the energy balance, healthy alternatives to unhealthy snacks/drinks, healthy proportions, lifestyle physical actvity and strategies for change
(ii) **Perceived environment and social support** - peer norm for change, peer approval, family approval and support.
(iii) **Individual motivation and cognitions** – attitudes towards healthy lifestyles, self efficacy (for: trying alternatives to unhealthy snacks and drinks, being more active, discussing healthy lifestyles with the family, persuading the family to make changes and resisting temptation
(iv) **Use of BCTS** - self monitoring, goal setting, behavioural contract, barrier identification.
(v) **Mediating behaviours** - talking to parents, making healthy suggestions to the family, food shopping with parents, cooking, trying new healthy foods

The 'My Lifestyle Questionnaire' has been developed using the process evaluation data from the exploratory trial and two validated scales. The first is the Social Support for Diet and Exercise Behaviours Questionnaire [39] which was developed and validated in the US to determine perceived social support for healthy diet and activity behaviours in children and the second is a validated self-efficacy scale for diet behaviours in US primary school children [40].These modified questions, specific to the HeLP intervention, have been piloted in the early stages of the project

and found to be feasible and acceptable to children and teachers in both control and intervention schools.
All questionnaires are delivered as a class activity led by the HeLP Coordinator and supported by the class teacher and Learning Support Assistants. Children sit in their literacy groups to ensure that appropriate help and guidance can be given as effectively as possible.

Moderators
Possible moderating variables (individual level SES, weight status, number of Year 5 classes and gender) will be taken from baseline data.

All baseline measures will be taken by the HeLP Coordinators prior to knowledge of group allocation. Both 18 and 24 month anthropometric measures will be made by an independent assessor, blind to the children's allocated group. All baseline physical activity measures will be collected between the beginning of September and the end of October.

Collection of information on resource use
Resource use related to the delivery of the HeLP intervention will be collected using within-trial report forms completed by those coordinating the delivery of the intervention (HeLP Coordinators). Resource use against the four phases of the intervention (Table 1) will be collected during each phase, within each school, for each of the specific component parts of the intervention, as set out in Table 1.These report forms will collect all time input, by type/grade of person, required for HeLP (incl. preparation and travel time), and any other resource use items (e.g. consumables, additional expenditure) associated with delivery of the HeLP intervention.

e. Data analysis
Primary analysis
The primary outcome is BMI SDS. Throughout the analysis, emphasis will be placed on estimation rather than hypothesis testing. Where hypothesis tests are carried out, these will be at the 5% level for primary and secondary outcomes, and the 1% level for interaction terms. No adjustment for multiple analyses will be made; as such adjustment methods are too conservative when outcomes are positively correlated, as they would be in this trial. However, all analyses will be planned *a priori* and reported in full.

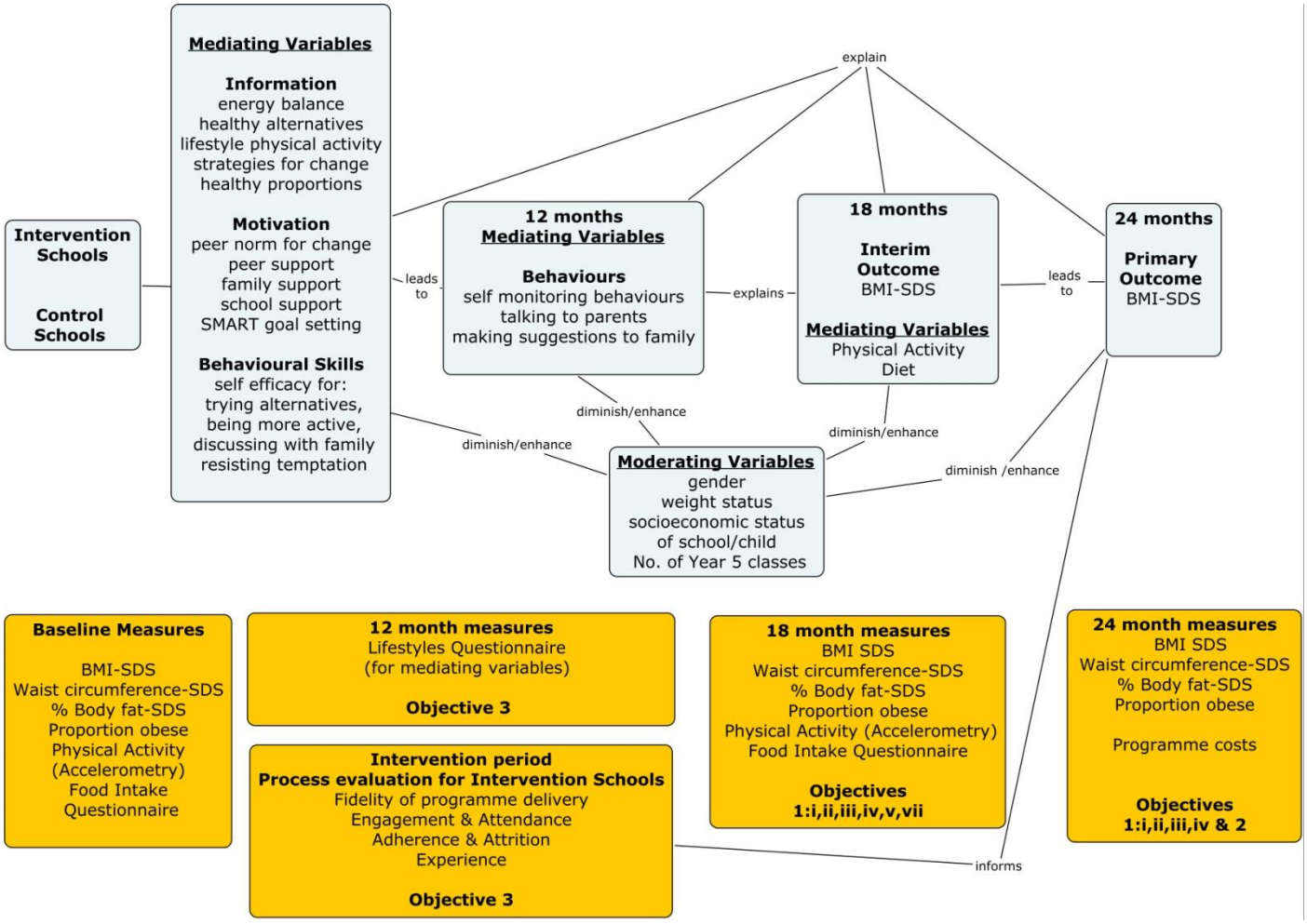
The reporting and presentation of this trial will be in accordance with the CONSORT guidelines for cluster randomised trials [41], with the primary comparative analysis being conducted on an intention-to-treat basis. Descriptive statistics will be used to assess any marked baseline differences in demographics or outcome measures between the two groups, taking clustering into account. Comparisons of outcome measures will be undertaken at 18 and 24 months for all available measures. Comparisons of binary outcomes will be expressed as odds ratios with 95% confidence intervals and comparisons of continuous outcomes as mean differences together with 95% confidence intervals. Between-group comparisons will be made using random effects regression analysis (weighted by clusters), taking account of the hierarchical nature of the study design and allowing for adjustment by eligibility to receive free school meals, a proxy for socio-economic class, and school size, as well as important individual level baseline covariates (e.g. age, sex) and baseline individual outcome values (where relevant). Sensitivity analysis, making different assumptions such as 'best' and 'worst' case scenarios, as well as imputation models of missingness, will be conducted to investigate the potential impact of missing data.

Secondary analyses

Although the trial is not powered to detect the influence of mediating and moderating factors on children's BMI, we will explore possible interactions in the following secondary analyses: (i) Interaction terms will be examined to investigate possible differences in intervention primary outcome effects by gender, SES, baseline BMI and number of Year 5 classes; (ii) individual child estimate of engagement with HeLP will be determined and a comparison between children who meet the criteria for engagement (see process evaluation) vs those who do not will be undertaken to assess 'per protocol' effectiveness; (ii) a mediational analysis, using the analytic framework recommended for RCTs [42], will explore whether the effect of the intervention on the primary and secondary outcomes is mediated by knowledge, attitudes, norms, self-efficacy, perceived environment, social support, use of regulation techniques and behaviours relating to physical activity and diet

Figure 1 below details the possible mediating and moderating variables and the measures and timing of their assessment.

Figure 1 Schematic Mapping of Proposed Change Processes and Corresponding Measures



Economic evaluation

A prospective economic evaluation will be undertaken to estimate the incremental cost-

effectiveness of HeLP compared to usual practice, from the perspective of the Third Party Payer (e.g. NHS), with other perspectives for the public sector, and the participants, explored in sensitivity analyses. Assessment of cost-effectiveness will involve a within-trial economic analysis and a model-based economic evaluation to assess the longer-term cost-effectiveness of HeLP. Within-trial analyses will provide a robust estimate of the resource use and costs associated with delivery of the HeLP intervention, based on regular reporting of resource use (e.g. trial report forms) by those hosting and delivering the intervention. Resource use data (in physical units, e.g. staff time, consumables) will be combined with appropriate unit costs, to estimate a mean incremental cost per school, and a mean incremental cost per child. Cost-effectiveness analysis (CEA) will be presented against effectiveness outcomes for the study (e.g. cost per unit change in BMI, cost per change in proportion of overweight/obese). Results from the trial-based CEA will be presented in a disaggregated way in a tabular format that is useful to decision-makers. Uncertainty in estimates will be explored using detailed sensitivity analyses.
The assessment of cost-effectiveness over a longer term time horizon will be via a model-based evaluation to explore the broader policy context of the effects of the intervention and to present a policy-relevant CEA (e.g. cost per life-year, cost per QALY). The modelling framework will link effectiveness outcomes to weight status over time (child to adult), and the impact of weight status to future health outcomes (e.g. prevention of adult overweight/obesity, diabetes, CHD), with costs and QALYs for health outcomes over time informing the CEA. Modelling methods will be transparent, will be informed by systematic review to populate the model, and will follow guidelines for good practice in modelling for health technology assessment [43].

Process evaluation

A process evaluation will be conducted in intervention schools to provide insight into the way HeLP worked: Information on intervention uptake, delivery and experience will be collected. Delivery and uptake will be determined by assessing child and parental attendance at events and adherence to, and engagement with, HeLP. Criteria for assessing engagement for each child are i) active participation in 90% of HeLP activities (observation); ii) parental agreement of goals (parental signature and indication of parental support); iii) Child understanding of energy balance concept ('My Lifestyle' Questionnaire'). We will triangulate approaches. Twenty percent of activities for each intervention school will be observed, and detailed field notes taken, to determine the 'intensity' of the intervention components delivered, 'engagement' of pupils, teachers and parents as well as how well the HeLP Coordinators and actors deliver the intervention. In addition, quantitative data on child and parental participation will be recorded. We will also conduct qualitative interviews and focus groups to identify barriers and facilitators to participation as well as understand experience of participating at an individual, family and school level. Schools or children who withdraw from the intervention will be invited to participate in an exit interview/debrief with K Wyatt (PI).

Purposeful sampling will be used to identify participants for focus groups and interviews. A sampling frame has been developed for children, families and schools, sampling by level of engagement (see above) and socioeconomic status. Focus groups will be held with the children and whilst we will not sample children by weight status (due to the ethics of such an approach) we know from pilot work that there will be children with varying weight status in the focus groups. Interviews will be conducted with parents and teachers. We have used this sampling frame in the pilot work and it was acceptable and feasible to children and families regardless of weight and socioeconomic status. We will conduct approximately 14 focus groups with children (up to eight per group) and between 24-40 interviews with parents and teachers. Up to 12 interviews will be conducted with personnel who deliver the intervention; they will also be asked to keep a detailed

field diary. Interviews and focus groups will ask open ended questions, informed by the mediating factors about the experiences of being in the study. Transcribed data will be managed using NVivo software which will also support the coding and analytical processes. As this process evaluation is partially driven by predetermined concepts a Framework Analysis approach [44] will be adopted for the analysis and interpretation of emergent themes.

The findings from the process evaluation will inform us about why the Programme worked, what parts are most important and how the Programme might be remodelled for a wider roll out.

5. Plan of Investigation:

2012 Months 1-5: Agree final protocol, seek ethical and research governance approval, attend Devon head teachers meetings, revise and agree standard operating procedures with PenCTU
2012 Months 3-6: Recruit and train staff, recruit schools and children to trial; randomise all schools
2012 Months 7-10: Gain consent, baseline measures in 1st cohort of schools; group allocation for cohort 1 revealed.
2013 Months 11-13: Phase 1; 'Creating a supportive context' activities in intervention schools. Submit interim project report to NIHR
2013 Months 14-16: Delivery of Phases 2 and 3 (Healthy Lifestyles week and Personal Goal Setting with Parental Support)
2013 Months 17-18: Input and clean baseline data
2013 Months 19-22: Gain consent, baseline measures in 2nd cohort of schools; group allocation for cohort 2 revealed; 'Reinforcement Activities' (Phase 4) in first cohort intervention schools; 'My Lifestyle' questionnaire to all children in cohort 1
2014 Months 23-25: Phase 1; 'Creating a supportive context' activities in intervention schools in 2nd cohort. Identify secondary school for all children in cohort 1; Submit interim project report to NIHR
2014 Months 26-28: Delivery of Phases 2 & 3 (Healthy Lifestyles week & Personal Goal Setting with Parental Support) to 2nd cohort
2014 Months 29: 18 month follow up measures in 1st cohort schools
2014 Months 30-31: Input and clean baseline data
2014 Months 31-34: Reinforcement activities in 2nd cohort; 'My Lifestyle' questionnaire to all children in cohort 2; gain consent from children 24 month measures in 1st cohort children
2014 Months 35-39: Data entry, data cleaning. Identify secondary school for all children in cohort 2; Submit interim project report to NIHR
2015 Months 40-42: 18 month measures in 2nd cohort schools; data entry; Submit interim project report to NIHR
2015 Months 43-46: 24 month measures in 2nd cohort
2016 Months 47-52: Data entry, checking, cleaning and analysis
2016 Months 53-56: Write report, feedback results to participants, write and submit articles to peer-reviewed journals. Policy and roll-out implications

6. Project Management:
The **Trial Manager** (Jennifer Lloyd) will be responsible for the day to day management of the study, including data collection, entry and analysis, intervention delivery and the project budget. She will be responsible for training the HeLP Coordinators who she will line manage along with the Trial Administrator and Data Coordinator.
The **Trial Administrator** will support the applicants and HeLP Coordinators with administrative tasks. They will organise appointments with schools, take minutes at meetings of the Trial Management Group, Project Advisory Group and Trial Steering Committee and will ensure all

information (electronic and paper) sources are appropriately labelled and stored
The **HeLP Coordinators** will be responsible for delivering components of the HeLP Programme, building relationships with the schools, children and their families, organising the delivery of intervention components with school staff and the drama group, ensuring teachers have all the necessary intervention resources and materials and collecting and inputting data. They will update SOPs as necessary, log any changes as data collection proceeds and collect information on resource use.

We are forming a **Trial Steering Committee (TSC)** which will include an independent chair and at least two other independent members with relevant experience, along with the Principal Investigator (Dr Katrina Wyatt) Trial Manager (Jennifer Lloyd), a teacher, a parent and representatives from the funding body. We do not propose convening a **Data Monitoring Committee (DMC)** to act in an advisory capacity to the TSC as we do not consider that an independent DMC is required for this study [45] since no interim analyses are planned. We will, however, review this decision with the TSC once the trial has completed its first year and in the event that any potentially serious issues are identified that may fall under the remit of a DMC. Adverse events will be reported to the Research Ethics Committee as well as the TSC.
A separate **Trial Management Group (TMG)** will be established to oversee the smooth running of the trial. The TMG will comprise the Principal Investigator (KW), Trial Manager (JL) and other co-applicants as necessary. A **Project Advisory Group (PAG)** will be established to assist and oversee the process evaluation. The PAG will comprise the PI, Trial Manager, a Head Teacher, Year 5 teachers, parents, the Devon Schools4Life Advisor and Public Health Policy personnel.

7. Service users/public involvement:
Schools, teachers, parents and children have been involved in the development, refinement and process of delivery of HeLP as well as the design of the evaluation. Methods of involvement have included initial workshops to determine the messages and possible modes of delivery, formal feedback through focus groups interviews and questionnaires with children, families and teachers in participating schools and the inclusion of a Year 5 teacher and a parent of a Year 5 pupil as co-applicants on this proposal. We have also consulted extensively with people in education and health whose role would be to decide policy and direct implementation should HeLP prove effective. During the trial a Project Advisory Group (see above), including parents and teachers will work with the researchers to help guide all aspects of study conduct but with particular responsibility for advising on the process evaluation and, if appropriate, advising on implementation.

We have a close working relationship with the Health Policy Unit (NHS Devon) who will support the dissemination of the findings to relevant stakeholders and discuss implications for policy at a local level.

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** Amendment to protocol (August 19th 2013)
Our successful recruitment strategy resulted in 36 schools indicating that they would like to participate. As our initial recruitment target was to recruit 32 schools, four schools agreed to go onto a waiting list. The remaining 32 schools, were randomised to intervention or control groups stratified by (i) the proportion of children eligible for free school meals (<=18%, > 18%) and (ii) school size (one Year 5 class, >1 Year 5 class). As previously stated and for practical reasons, 16

of the control schools were randomised into cohort 1 and entered the study in 2012 and 16 were randomised to cohort 2 to enter the study in 2013. Allocation was performed by a member of staff in the PenCTU who is not involved with the trial delivery and took place immediately after the 32 schools had been recruited, with the allocation kept concealed from all the trial staff until after baseline measures have been taken in each cohort. The 16 schools allocated to Cohort 2 were re-contacted in July 2013 at which time two schools indicated that their circumstances had changed and they were no longer able (or eligible) to participate. The four waiting list schools were therefore contacted to establish whether they were still willing and eligible to participate, of which two were. Given the possibility of selection bias in the two withdrawn schools and in terms of potential imbalance between intervention and control groups in school level cofounders (known and unknown), the 16 schools in cohort 2 (replacing the two withdrawn schools with the two waiting list schools) will be re-allocated to intervention or control group. This will be done using a minimisation approach, to ensure reasonable balance in stratification characteristics between groups across the combined two cohorts.

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the PHR programme or the Department of Health.

Healthy Lifestyles Programme Analysis Plan Version 5.0

The Healthy Lifestyles Programme (HeLP), a novel school-based intervention to prevent obesity in school children: a cluster randomised controlled trial

ISCRTN Number: 15811706

Siobhan Creanor, Rod Taylor, Colin Green, Jenny Lloyd, Charles Abraham, Sarah Dean, Melvyn Hillsdon, Stuart Logan, Katrina Wyatt

Signatures Page

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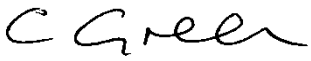
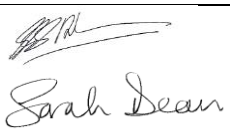
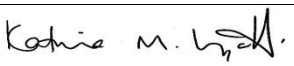
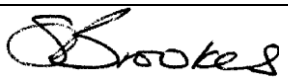
Statistical Analysis Plan Authored by:	Trial Statistician: Siobhan Creanor		06/10/2015
Cost and cost effectiveness Analysis Plan Authored by:	Colin Green		07/10/2015
Mediational Analysis Plan Authored by:	Sarah Dean Charles Abraham		07/10/2015
Process Evaluation Plan Authored by:	Jenny Lloyd Katrina Wyatt		05/10/2015
Approved by:	Chief Investigator: Katrina Wyatt		05/10/2015
	Independent Statistician (TSC): Sara Brookes		21/10/2105
	TSC Chair: Martin White		03/11/2015

Contents

ANALYSIS PLANS FOR HELP TRIAL

1.0 BACKGROUND

The Healthy Lifestyles Programme is a school-based intervention designed to prevent overweight and obesity in children. The intervention has been developed using intervention mapping (involving extensive stakeholder involvement) and has been guided by the Information, Motivation, and Behavioural Skills model. HeLP includes creating a receptive environment, drama activities, goal setting and reinforcement activities and runs over three school terms and involves children of 9-10 years of age. This cluster randomised trial will assess the effectiveness and cost-effectiveness of HeLP in preventing overweight and obesity in children. The primary outcome is change in body mass index standard deviation score (BMI SDS) at 24 months post-randomisation.

2.0 STUDY AIMS/OBJECTIVES

The aim of this cluster randomised controlled trial (RCT) is to determine the effectiveness and cost-effectiveness of the Healthy Lifestyles Programme (HeLP) in preventing overweight and obesity in children.

Specific objectives

1. To assess the effectiveness of the Healthy Lifestyles Programme (HeLP), in children aged 9 to 10 years, by comparing between intervention and control schools:

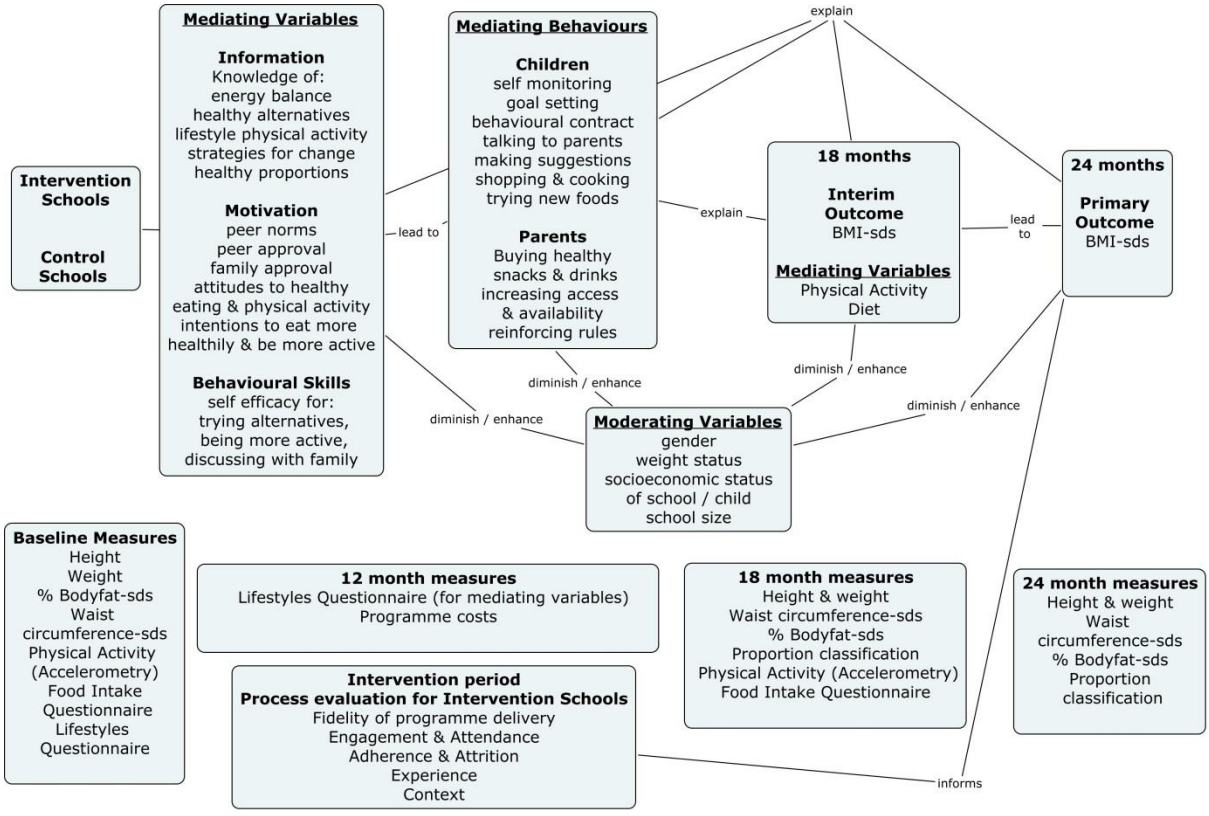
a. BMI SDS at 24 months (primary outcome)
b. BMI SDS at 18 months
c. Waist Circumference SDS at 18 and 24 months
d. Percentage Body Fat SDS at 18 and 24 months
e. Proportion of children classified as underweight, overweight and obese at 18 and 24 months
f. Physical activity (time spent in sedentary, light, moderate, moderate to vigorous and vigorous activity) and total volume (Gm) at 18 months

g. Food intake (number of energy dense snacks, healthy snacks, negative and positive food markers) at 18 months.

2. To estimate the costs associated with the delivery of the HeLP intervention and its cost-effectiveness versus usual practice.

3. To conduct a mixed-methods process evaluation and mediational analysis to explore the way the Programme worked (that is, how it was delivered, taken up, and experienced, and what the behavioural mediators of change are).

Figure 1: Diagrammatic representation of the HeLP trial



3.0 OUTCOME AND PROCESS MEASURES

See Appendix 1 for a full list of outcome and process measures, when the assessments are being made and by whom.

4.0 TRIAL DESIGN

4.1 General design

A cluster randomised controlled trial, allocating schools 1:1 to either HeLP or usual school practice. As the intervention was designed to be delivered in schools, a cluster design is appropriate. Individual measurements are collected at baseline, 12 (My Lifestyles Questionnaire (MLQ) only), 18 months and 24 months post-randomisation.

Given finite resources, it is necessary to run the trial in two cohorts, each cohort with the same number of intervention and control schools. All schools were recruited in spring 2012 and then allocated to Cohort 1 (commencing trial in 2012) or Cohort 2 (commencing trial in 2013).

Parents/carers of children within recruited schools had the opportunity to opt their child out of the study, prior to baseline measures being collected. At each time of collection of measures, children have the option to decline measurement if they so wish. Letters are sent home to parents prior to each set of measurements to remind them that measures are going to be taken.

A mixed methods process evaluation is incorporated into the trial design. The process evaluation has two levels; the first is conducted at the level of the trial and data will be collected on recruitment of schools and children in order to understand how generalisable the findings are likely to be, as well as child data on possible mediating variables associated with diet and physical activity behaviours; the second is conducted with intervention schools only and data are collected from teachers, children and their families to understand delivery, uptake, reach, context and experience of HeLP.

An economic evaluation will estimate the incremental cost-effectiveness of HeLP compared to control/usual school practice, from the perspective of the NHS/Third Party Payer (with other perspectives for the public sector, and the participants, explored in sensitivity analyses). Assessment of cost-effectiveness will involve a within-trial economic analysis and

the development of an economic model to assess the longer-term cost-effectiveness of HeLP.

4.1.1. *Blinding*

Due to the nature of the intervention, blinding of the children and those delivering the intervention is not possible. However, baseline anthropometric, physical activity, food intake and mediating variables measures are collected by HeLP Co-ordinators (HCs) and trained assessors prior to revealing schools' allocated trial groups. Blinded assessors are used for the collection of the 18 and 24 month measures. After each child's 24 month assessment, the blinded assessor will complete a simple form indicating whether or not the child revealed which group s/he had been allocated to.

4.1.2 *Randomisation and stratification variables*

All schools were initially randomly allocated to intervention or control by computer-generated sequence stratified by (i) the proportion of children eligible for free school meals (<19%, ≥19%; this represented the national average at the start of the trial) and (ii) school size (one Year 5 class, >1 Year 5 class). For practical reasons half the schools commenced the study in 2012 and the other half in 2013. Randomisation was performed by the UKCRC-registered Peninsula Clinical Trials Unit (PenCTU) immediately after all schools had been recruited (2012) but schools' allocation (intervention or control) was not communicated to the schools, parents or researchers until ***after*** baseline measures had been taken in each cohort (2012 for Cohort 1 and 2013 for Cohort 2). The PenCTU ensured that there are equal numbers of control and intervention schools in both cohorts, to facilitate trial delivery.

4.1.3 *Sample size justification*

There is little published consensus on what effect size might indicate a clinically important effect at an individual level and we could find no evidence of what a clinically relevant population shift in weight status might be. One study suggested that a difference of 0.25 units in BMI SDS at an individual level would have a meaningful change impacting on improvement in adiposity and metabolic health [1], this is one of the few studies to estimate what a clinically meaningful effect at an individual level might be. The exploratory trial of HeLP showed a mean between-group difference (intervention minus control) in BMI SDS of

~-0.2 units (95% confidence interval (CI): -0.5 to 0.1) at 24 months, suggesting that a difference in the region of 0.25 units in BMI SDS is plausible [2]. Therefore, the aim of this trial is to detect a between-group difference in BMI SDS of 0.25 units at 24 months, with 90% power and a two-sided type 1 error rate of 0.05. The standard deviation of BMI SDS was estimated from the exploratory trial to be 1.3 units [1]. To maximise statistical efficiency, BMI SDS at 24 months will be analysed including adjustment for baseline values. Although the correlation between baseline and 24 months BMI SDS was 0.93 (95% CI: 0.92 to 0.96) in the HeLP exploratory trial, a more conservative estimate of 0.8 was used in the sample size calculations. Similarly, whilst there was a low attrition rate of 8% in the exploratory trial, a conservative attrition rate of 20% was assumed for the definitive trial. Finally, given the clustered nature of this trial, an estimate of the likely school intra-class coefficient (ICC) was required for the sample size calculations. Based on data from approximately 35,000 NCMP records for year 6 children in Devon, the school intra-class correlation coefficient (ICC) was conservatively estimated as 0.02 (95% CI for ICC from NCMP records was 0.005 to 0.017).

Allowing for variable year 5 intake (mean=35 children, coefficient of variation=0.5) [3] and an ICC of 0.02, the design effect was estimated to be 1.86. To have 90% power, with two-sided 5% significance level, to detect a between-group difference in BMI SDS of 0.25 units at 24 months, assuming a standard deviation of 1.3 and adjusting for baseline BMI SDS (assuming within-person correlation of 0.8), and allowing for an attrition rate of 20%, required a total of 952 children to be recruited. Therefore the aim was to recruit 32 schools to ensure we had a minimum of 28 schools completing the trial, each with an average of 35 children, giving a recruitment target of approximately 980 children, and their families.

Table 1 illustrates the range of likely effect sizes detectable, based on recruiting 980 children, across plausible values for the ICC, correlation and attrition rates. Under these various scenarios, the target sample size would allow the detection of an effect size ranging at best from 0.14 standard deviation units to 0.25 standard deviation units at worst (i.e. the detection of a between-group difference in mean BMI SDS of 0.18 to 0.32).

Table 1: Sample size scenarios

	ICC	Within person correlation coefficient	Attrition rate	Effect size detectable	
				Number of SD units	Difference in BMI SDS[a]
Base case	**0.02**	**0.8**	**20%**	**0.19**	**0.25**
Vary ICC	0	0.8	20%	0.14	0.18
	0.02	0.8	20%	0.19	0.25
	0.05	0.8	20%	0.25	0.32
Vary correlation between baseline and 24 months BMI SDS	0.02	0.75	20%	0.21	0.27
	0.02	0.8	20%	0.19	0.25
	0.02	0.85	20%	0.17	0.22
	0.02	0.9	20%	0.14	0.18
Vary attrition rate	0.02	0.8	10%	0.18	0.23
	0.02	0.8	20%	0.19	0.25
	0.02	0.8	30%	0.20	0.26

[a]Between-group difference in BMI SDS at 24-month follow-up.

5.0 ANALYSIS POPULATIONS

5.1 Effectiveness:

The primary analysis will be undertaken on an 'intention-to-treat' (ITT) basis, i.e. participants will be analysed in the group that they were allocated to, regardless of compliance with the protocol. Whilst it is not anticipated that there will be many participants who cross-over their trial group (i.e. change from intervention to control, or vice-versa), any instances will be documented.

The full analysis population for the primary analysis will consist of all randomised participants for whom baseline anthropometric data was collected and for whom 24 month anthropometric data is available. If a participant moves to another school within the trial geographical area, s/he will be invited to continue with the data collection over the remaining period of the trial. Any participants who withdraw from the study will be asked whether their data can be used in the trial analyses.

As the full analysis population in the primary analysis will exclude a small number of children lost to follow-up (i.e. for whom 24 month BMI data is not available: in Cohort 1 this is 42/658), a sensitivity analysis will be performed to account for all randomised children (see section 7.1.3 below for details).

6.0 DATA SOURCES AND DATA HANDLING

6.1 Data sources and data entry

6.1.1 *Effectiveness*

The data analysed in this trial will come from a number of sources. Data collection for all sources follows a standard operating procedure (SOP). Anthropometric measures are captured on a specifically designed data collection form (see Appendix 2):

- BMI SDS
- Waist circumference SDS
- % body fat SDS
- Proportion classified underweight, normal, overweight and obese
- Food Intake Questionnaire
- Physical Activity behaviour
    - Time spent sedentary
    - Time spent in moderate to vigorous activity
    - Total volume (Gm)

The data will be entered by AH (Data Coordinator) and second entered by another member of the research team and stored on a secure purposively designed database. Data queries will be raised and resolved at data entry. Data discrepancies following second data entry will be discussed and resolved with the Trial Manager. Electronic data will be extracted from the database during the study for the purpose of checking (validating) and for study progress reports, as well as for the end-of-study statistical analyses.

6.2 Missing Data

6.2.1 *Effectiveness*

The reasons for missing outcomes will be documented. The primary outcome of BMI SDS may be missing for a number of reasons. For example:

a. Parent/carer opts child out of trial before follow-up data collection at either 18 or 24 months
b. Child refused to participate in collection of anthropometric measures at 18 months but remained in the trial
c. Child refused to participate in collection of anthropometric measures at 24 months
d. Child moved out of the County before follow-up data collection at either 18 or 24 months
e. Anthropometric data missing because the child was withdrawn (but not left the school) prior to that time point
f. Child absent on day of measurement and subsequent follow up visits

The recruitment target for this trial allowed for a conservative 20% attrition rate by 24 months, and substantially more children were recruited than the target, given the higher than expected number of recruited schools with more than one Year 5 class: 1371 children were recruited compared with the target of around 980, with 24 month data required from 760 children to achieve 90% power in the primary analysis.

Primary outcome measure: There is also no *a priori* reason to assume that children who are lost to follow-up are missing not at random. Therefore, for the primary analysis, no imputation of missing anthropometric data will be undertaken and this primary outcome analysis will be based on the complete case/observed outcomes data set [4]. A sensitivity analysis of the primary outcome will account for all children randomised (see section 7.1.3).

Secondary outcome measures: Various trial processes will be put in place to minimise missing data. For example, other missing data items, such as age, sex, etc., will be queried at the time of data entry. It is not anticipated that variables collected at time of recruitment/baseline will have many missing data. In the FIQ, where participants are missing

a subset of the items, the total score will be extrapolated based on the average scores across the four categories (Energy Dense Snacks, Health Snack foods, Negative Markers, Positive Markers, see Appendix 3).

For the MLQ dataset, each item will be examined for missing data which will be reported as a descriptive summary. To be included in the physical activity analysis participants need to comply with the required minimum continuous wear time of ≥10hours a day for 3 weekdays and 1 weekend day. Non-wear will be determined using procedures previously outlined [5]. To minimise missing data due to non-wear, each 15-minute period of device non-wear time will be replaced by the participant's own data from the same time of day, averaged across all other recorded days [6]. This approach provides a person-specific method for imputing missing data. Any time window with >50% non-wear will be treated as missing.

6.3 Derived variables

6.3.1 *Effectiveness*

- BMI for each child is calculated from height and weight. Height will be measured using a SECA stadiometer (Hamburg, Germany), recorded to an accuracy of 1 mm. Weight will be measured using the Tanita Body Composition Analyser SC-330 (U.K. Ltd., Middlesex, U.K.) and recorded to within 0.1 kg and children are asked to take off their shoes and socks. BMI is calculated and converted to centiles using the software package LMS, developed by Cole [7].
- Categorisations of underweight, normal, obese or overweight will be made based on the definitions from Cole *et al.* [8].
- Percent body fat will be estimated from leg-to-leg bioelectric impedance analysis (Tanita Body Composition Analyser SC-330) and converted to centiles using the LMS software and compared to percentiles for British children [9].
- Waist circumference will be measured using a non-elastic flexible tape measure, 4 cm above the umbilicus; converted to centiles using the LMS software and compared to the waist circumference percentiles for British children [10].
- Average time per day, during valid days (see section 6.2), in sedentary, light, moderate, vigorous and moderate to vigorous physical activity (MVPA) intensities will be calculated using published cut points for children at baseline and 18 months [11].

- Food Intake Questionnaires (number of energy dense snacks, healthy snacks, negative and positive food markers) at baseline and 18 months [12].
- My Lifestyle Questionnaire (knowledge, motivation and cognitions, attitudes and behaviours) at baseline and 12 months.

7.0 ANALYSIS

7.1 Effectiveness

The reporting and presentation of data from this trial will be in accordance with the CONSORT guidelines for cluster randomised trials [13], with the primary comparative analysis being conducted on an intention-to-treat basis, as described above. All comparative analyses will allow for the clustered nature of the data. Unadjusted between group differences will be presented for completeness [14]. Unless otherwise specified, all adjusted comparative analyses will be adjusted for the two stratification variables (proportion of children eligible for free school meals and number of year 5 classes) and baseline values for the outcome under consideration where available. In general, analyses will also be adjusted for gender and cohort. Ninety five percent confidence intervals for between-group comparisons will be calculated and presented wherever possible. Where given, p-values for statistical significance will be two-sided and the significance level set at ≤0.05. P-values will be reported and interpreted in terms of the amount of evidence they provide against the null hypothesis.

Adjustments will not be made for multiple tests undertaken as the primary outcome of interest is clearly defined. As this is a trial of a complex intervention the secondary outcomes are all potentially of interest and relevance to participants, parents and other stakeholders. Interpretation of the clinical significance of any differences between the two groups will acknowledge the range of variables being measured.

Summaries of continuous/measurement variables will usually comprise the number of schools or participants and either

i. the mean, standard deviation (SD), minimum and maximum, or
ii. the median, inter-quartile range (IQR), minimum and maximum

as appropriate for the distributional form of the data under consideration.

Summaries of categorical variables will usually comprise the number of schools or participants and the number and percentage of observations in each category.

Participating schools will be compared to state primary schools in Devon and England at the time of school recruitment into the trial (2012) in terms of the following characteristics:

- % of children eligible for free school meals
- Number of Year 5 classes/school size
- % of children achieving Level 4 at Key Stage 2
- Proportion of pupils with English as an Additional Language or non-white British

The recruitment, flow and follow-up of participants in the trial will be summarised, using the CONSORT-style flow-diagram. The extent and distribution of missing data for each variable will be assessed and dealt with as detailed in section 6.2. It is expected that the frequency of missing anthropometric data and other data will be reasonably balanced between allocated trial groups.

7.1.1 *Baseline characteristics*

Baseline characteristics, collected at the time of commencing the trial, will be cross-tabulated according to the randomised group (see Appendix 5) to check for appropriate balance and to provide an overview of the study population, both at the school and child levels. At the school level, this will include % of children eligible for free school meals, index of multiple deprivation score for the school's postcode, number of year 5 classes, % of pupils for whom English is an additional language and average educational attainment. At the child level, variables will include gender, age at baseline data collection, individual IMD values, baseline measures of all anthropometric measurements, physical activity, MLQ, FIQ.

It is expected that participants in both allocated groups will, on average, be similar, given the randomisation procedure. The formal statistical comparison at baseline of randomised groups is not good practice [15] and thus will not be undertaken – only descriptive data, as described above, will be presented. If substantial baseline imbalance between randomised

groups is identified in terms of any relevant variables not already being adjusted for in the primary analysis, additional adjusted sensitivity analyses may be performed, to allow for such variable(s), in addition to the pre-specified variables for adjustment, to assess the robustness of the primary analysis [15].

7.1.2 *Primary analysis of the primary outcome*

As described above, the primary analysis of the primary outcome, BMI SDS at 24 months, will follow an intention-to-treat approach, with children analysed according to the trial group their school was randomised. Comparisons between the two trial groups will be implemented using random effects regression, allowing for the clustered nature of the data. Analyses will include the two stratification variables as covariates as well as baseline BMI SDS, gender and cohort as outlined above. The means and standard deviations will be presented for each group, together with the mean difference between groups, 95% confidence interval for the mean difference and corresponding p-value. The ICC (with 95% confidence interval where possible) of BMI SDS will be reported.

The distribution of BMI SDS will be examined visually using boxplots, as will the model residuals, with a suitable transformation of BMI SDS considered if necessary. Should a transformation of BMI SDS be necessary, the p-value for the test of the between-group difference on the transformed scale will be presented, with consideration given to providing a boot-strapped 95% confidence interval for the between-group difference in mean BMI SDS.

7.1.3 *Secondary analyses of the primary outcome*

As described above, the primary analysis will utilise an intention-to-treat strategy of all observed 24 month BMI SDS data. A sensitivity analysis will be undertaken after imputing the missing BMI scores, to account for all randomised children. It is anticipated that multiple imputation will be used to impute the missing BMI scores based on the assumption of missing at random, see section 6.2.

In addition to the primary analysis, exploratory analyses of the following possible interactions will be undertaken to assess whether the effect of the HeLP intervention is modified by (i) gender (ii) baseline BMI SDS (iii) number of Year 5 classes within school (iv) socio-economic status. These subgroup analyses will be performed by adding the interaction term between allocated group and the subgroup variable into the regression model. A test of interaction will also be performed to assess whether there is evidence that the effect of the intervention differs across the two cohorts. As the study is not powered for these interaction analyses the results will be treated with caution; given the exploratory nature of these investigations, the emphasis will be on the interpretation of the corresponding confidence intervals for such sub-groups.

A repeated measures model will also be fitted to all the observed BMI SDS data at baseline, 18 months and 24 months, including effects of time and the interaction term between allocated group and time, to assess whether there is evidence that the effect of the intervention differs across time.

Given the small number of children who have 'switched' between allocated treatment groups (as at March 2015 four children have moved from control to intervention schools and one child has moved from intervention to control although this was after the intervention phase had been completed), a "per-protocol" analysis of *actual treatment received* is not likely to be informative. However, the primary analysis intention-to-treat strategy, whilst providing an unbiased estimate of the effect of randomising to intervention or control groups, may underestimate the effect of actually receiving HeLP. Therefore, further exploratory analyses of the primary outcome will be undertaken to estimate the complier average causal effect of treatment (CACE), as a potentially unbiased estimate of receiving HeLP. Compliers can only be observed amongst those randomised to receive HeLP and will be defined as those children who received >4 sessions of drama activities during healthy lifestyles week and who participated in 1: 1 goal setting in Phase 3; an indicator variable will be created to identify whether each child randomised to the intervention group complied. Compliers and non-compliers within the intervention group will be compared in terms of key baseline characteristics. The estimated CACE between-group difference will

then be obtained using instrumental variable regression including the same variables used in the primary analysis, together with randomised group as an instrumental variable for treatment received and including the indicator variable for compliance [16].

7.1.4 *Analysis of Secondary outcomes*

Secondary outcomes will be compared between groups based on the complete data only. Most of the secondary outcomes (see Appendix 1) are of a continuous nature and so comparative analyses will follow the approach detailed above for the primary outcome, using random effects regression, allowing for the clustered nature of the data and including the stratification factors, baseline value of the variable under consideration and gender and cohort. Binary outcomes (such as the proportion of children classified as obese at 24 months) will be analysed using binary logistic regression, allowing for the clustered nature of the data, and including the stratification factors, baseline BMI SDS and cohort. Multinomial outcomes e.g. categorisation of weight status, will be similarly analysed using multinomial regression. For all models, corresponding distributional assumptions will be investigated, with consideration given to providing boot-strapped confidence intervals for estimates of between-group differences.

7.1.5 *Interim analyses*

As agreed at the first TSC meeting, no interim analyses are planned for this study.

8.0 WITHDRAWAL FROM TRIAL AND ADVERSE EVENTS

If a child is withdrawn from participating in the intervention, s/he will be encouraged to continue with the data collection over the remaining part of the trial. Participants who discontinue completing the data collection prior to the end of the study period will be withdrawn but will remain in the full analysis population unless they specify otherwise. Every attempt will be made to find out why the child has withdrawn.

Appendix 6 defines what a serious adverse event is and the actions and notifications that are to be made.

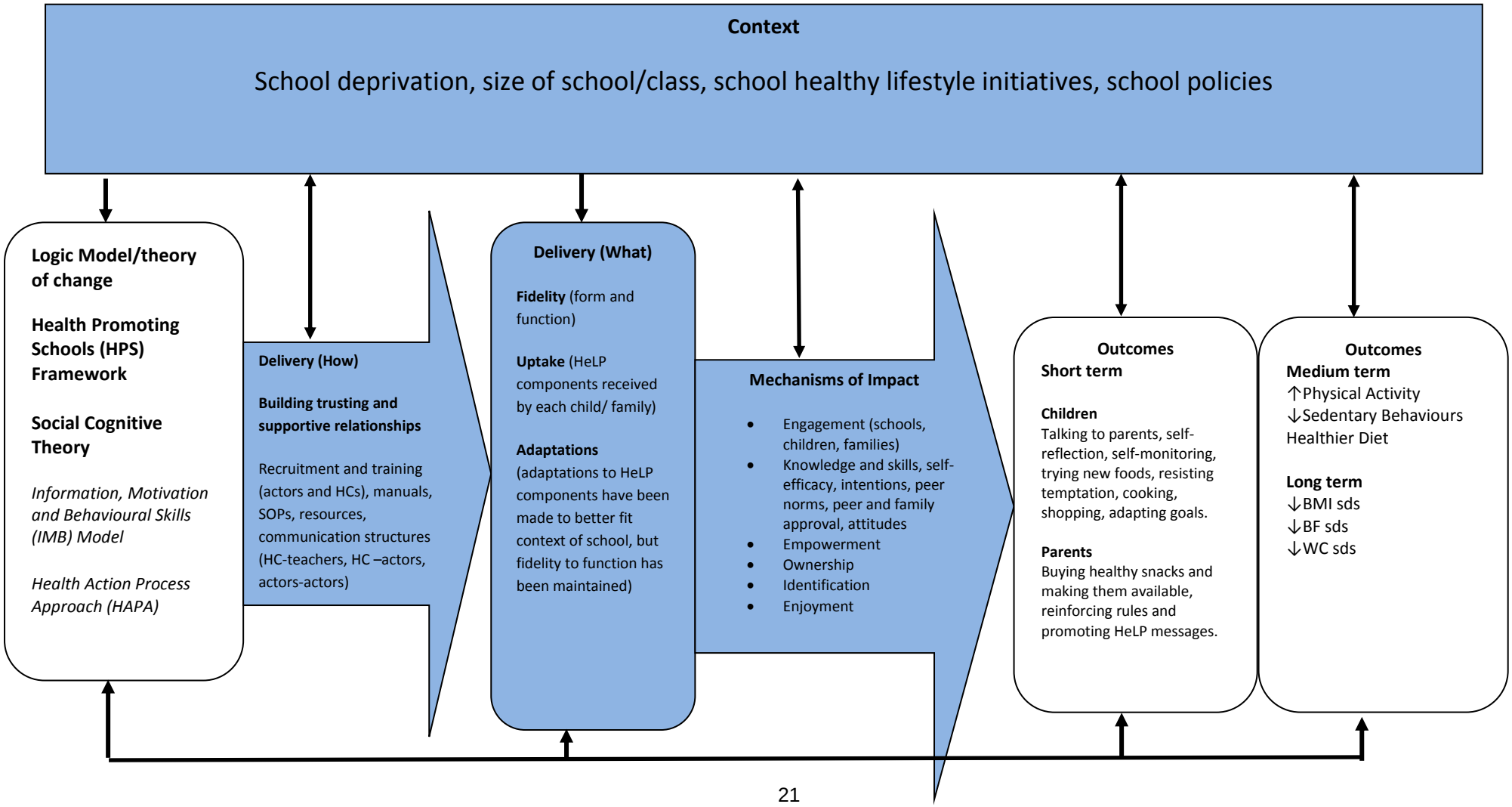
Numbers and percentages of adverse events and serious adverse events will be cross-tabulated with allocated group. Binary logistic regression may be used to estimate the odds ratio for the group effect, together with the corresponding 95% confidence interval and p-value, if there are sufficient numbers of adverse events (example Adverse events table in Appendix 6).

9.0 PROCESS EVALUATION

The overall aim of this HeLP process evaluation, including a behaviour change mediational analysis, is to provide insight into the way the Programme worked (delivery, uptake, participant response, how it was experienced, the context and what the behavioural mediators of change are). Process evaluations are recommended by the UK's Medical Research Council guidance [17] on developing and evaluating complex interventions so that any discrepancies between expected trial outcomes and observed trial outcomes can be explained, contextual factors can be analysed for their influence on outcomes and insights can be gained regarding further implementation of an intervention after the trial has concluded (if appropriate) [18]. Recently Grant and colleagues have proposed a framework for the design and reporting of the process evaluation for cluster-randomised trials of complex interventions; these authors note the importance of reporting findings at both the level of the cluster as well as at the level of the individual participant [19]. We have used this framework as well as those of Baranowski and Stables [20], Steckler and Linnan [21] and Dane and Schneider [22] to plan our process evaluation analysis. The structure of this analysis plan reflects that process evaluations distinguish between analyses that are designed to relate to the overall trial (section 1) and analyses that relate only to the intervention arm of the trial (section 2). For both, the overarching analytical approach will be one of hypothesis–raising, with the exception of the behaviour change mediational analysis which will incorporate some hypothesis testing. Mixed research methods will be used for reporting and analysing the data.

Figure 2 maps HeLP onto the key functions of a process evaluation of complex interventions as presented in the MRC guidance [17].

Figure 2: Key functions of the process evaluation for HeLP



9.1 Process evaluation at the level of the overall trial

Description of measures and data summaries

Description of measures – please see accompanying document 'HeLP Outcome and Process Measures Summary' document (Appendix 1).

Analysis

Descriptive summaries will be provided for all the trial measures at each time point for all data collected in intervention and control groups as well as by cohort:

Baseline: MLQ, Physical Activity (Moderate to Vigorous)/ time spent sedentary, FIQ, BMI SDS, % body fat, Waist circumference SDS

12 months: MLQ only

18 months: Physical Activity/ time spent sedentary; FIQ; BMI SDS, % body fat, Waist circumference SDS

24 months: BMI SDS, % body fat, Waist circumference SDS

9.1.1 Trial recruitment and retention

A description of the *process* of school and child recruitment and retention will be given. We will seek to document the processes which facilitated, or acted as barriers, to participation in order to understand how generalisable the findings are likely to be.

9.1.2 Mediational analysis

The mediational analysis aims to provide insight regarding behavioural mediators that may help explain the trial outcomes. We propose to undertake a mediational analysis using Structural Equation Modelling (SEM) and bootstrapping techniques. These procedures allow for a more nuanced and potentially robust analysis for the following reasons:

a. Identification of how well theory-based expectations and observations correspond [23] with SEM being a family of statistical techniques that allow you to assess the relationships among a set of variables (Tennant et al 2013*)

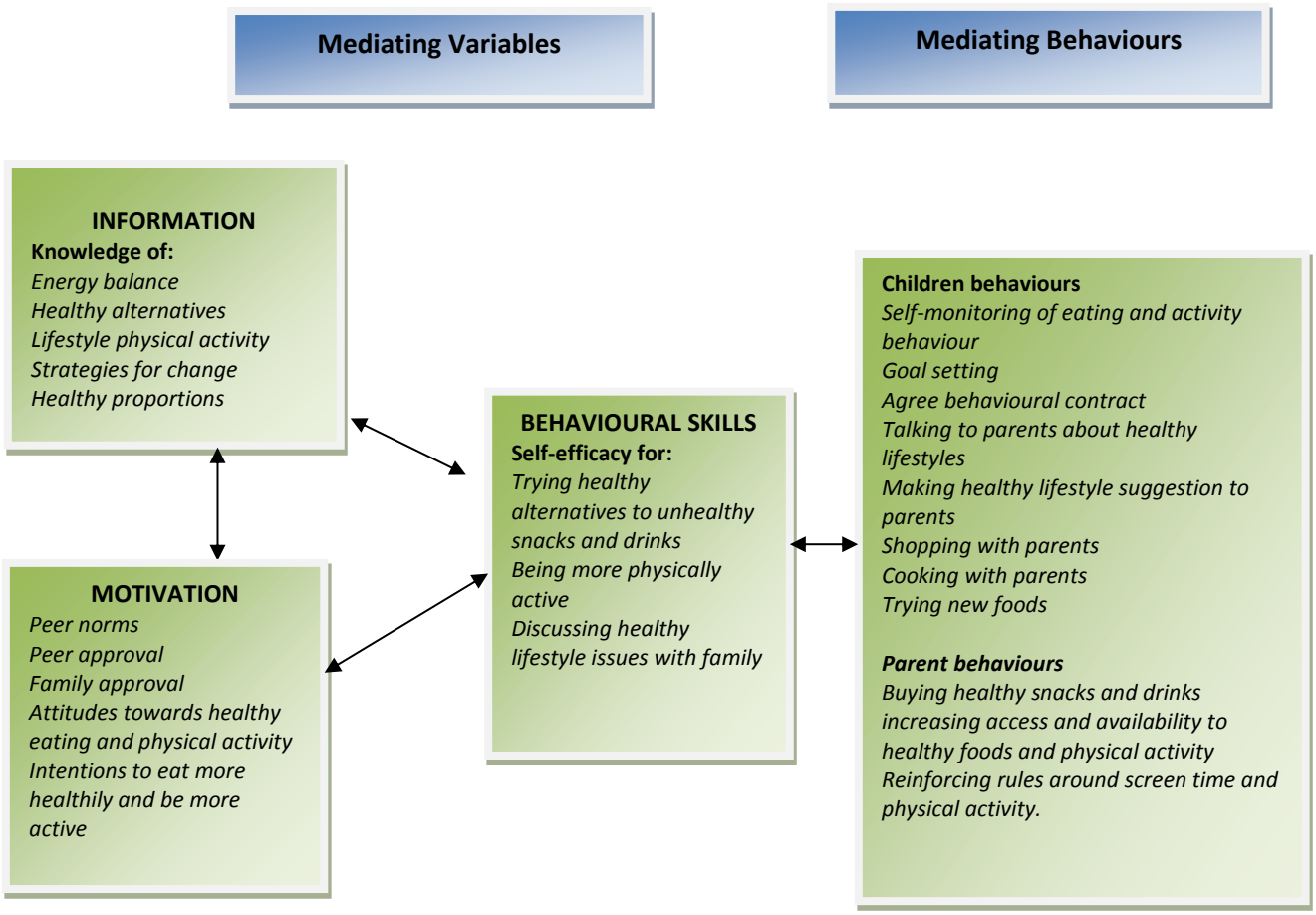
b. Potential mediators can be classified as either complementary, competitive or indirect as well as providing insight as to whether any direct effects are mediated by an omitted mediator

c. 'SEM models error in the measurement of mediators, allowing one to distinguish between 'true' direct effect from one that is an artefact of errors in variables'[24].

d. Multi-item scales, multiple variables and multiple outcomes can all be included in full structural models.

The development of HeLP was guided by the Information-Motivation-Behavioural Skills (IMB) model [25]using intervention mapping [26] and extensive stakeholder consultation. Based on data from the exploratory trial, we developed a model suggesting how the effects of HeLP on the primary and secondary outcomes may be mediated by knowledge, motivation, behavioural skills and behaviours, Figure 3.

Figure 3: Diagrammatic representation of Step 2 in the mediational analysis



The IMB framework elements are assessed by the My Lifestyles Questionnaire (MLQ) completed by the children at baseline and 12 months. The MLQ has been developed to capture data on the following constructs: knowledge (5 items), individual motivations and cognitions (23 items), parental mediating behaviours (4 items), child use of change techniques (10 items), child mediating behaviours (8 items).

9.1.3 Analysis procedure

Step 1 a) Provide a summary describing missing data for each item / construct.
b) In order to inform what the reliable scores are for the mediational analysis, the psychometric properties of the MLQ baseline and 12 month data will be examined and analysed using (a) confirmatory factor analysis and, if appropriate, (b) Rasch analysis.

Initial analysis of how the MLQ is performing will be undertaken; the data set from baseline will be divided into two sets (taking every other ID for each of the two groups to ensure an equal mix of both cohorts). The validation will be carried out on one of the data sets and the identification of possible unreliable constructs and items made. The validation process will then be rerun using the second half of the MLQ data with the removal of the constructs/items that did not perform well in the initial validation process. This procedure will be repeated with the 12 month MLQ data. The final set of constructs from the MLQ for the longitudinal analysis will consist of constructs that work best across both time points.

Data requirements will be the raw score data for MLQ at baseline and 12 month, once this data has been collected, entered and cleaned.

Reliability tests on the baseline MLQ data to ascertain the internal consistency of each construct. A judgement will be made as to which constructs are felt to be reliable enough to be used in the subsequent steps of the mediational analysis

Step 2: We will build parsimonious structural equation model(s) to answer pre-specified hypotheses such as:

Do changes in children's knowledge, motivation, behavioural skills, behaviours and parent behaviours (from MLQ), between baseline and 12 months explain children's diet (and physical activity behaviour) at 18 months?

Data required: all MLQ data and all 18 month PA and dietary behavioural data for children to be supplied after main trial SAP has been actioned. The data will be analysed by SEM steps using AMOS software:

i) Draw the input diagram (see Figure 4 for an example of a possible mediating pathway)

ii) Attach data file (tolerances for missing data will be determined and thresholds for each construct will be agreed)

iii) Specifiy the output

iv) Run the analyses

v) Evaluate the overall fit of the model

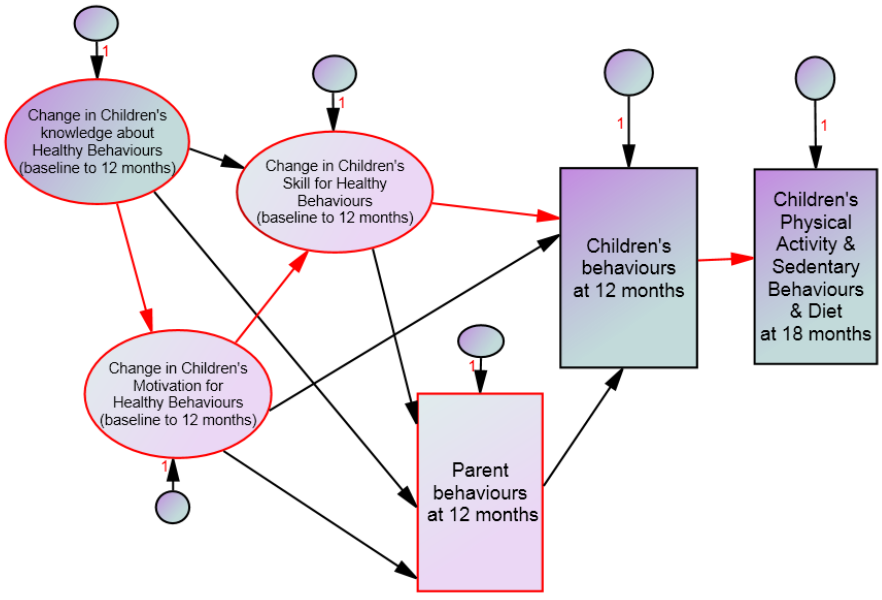
vi) Improving the model

vii) Modifying the diagram

viii) Retest the model (from Tennant et al., 2013*)

**From the course: 'An Introduction to Structural Equation Modelling (SEM) using AMOS Alan Tennant, Mike Horton and Julie Pallant 2013 Psychometric Laboratory for Health Sciences, University of Leeds.*

Figure 4: Representatin of a possible mediating pathway



Ovals = unobserved variables, rectangle = observed variables, circles = error, red arrow = causal pathway, black arrow = additional pathways

9.2 Process evaluation for intervention schools only

The dimensions to be included in the process evaluation of the intervention are defined in the table below, with selection being guided by the frameworks of Linnan and Steckler [21] and Dane and Schneider [22]. Specific questions have been mapped onto the different evaluation dimensions and a variety of methods have been selected from those commonly used in process evaluation. The purpose of the process evaluation that arises from intervention school data is to help explain the results of the trial primary and secondary analyses. Where possible, multiple methods are used to measure the same dimension so that findings can be triangulated.

Table 2: Summary of research questions assessed in the process evaluation for the intervention schools

Research Question	**Process Evaluation Dimension (HeLP terminology)**	**Process Evaluation Dimension (other terminology)**	**Data Source**
Do the children receive all of the HeLP components in the correct order?	Delivery - Fidelity to form	Fidelity [1] Dose delivered [1] Adherence [2]	Observation checklists
Is the programme delivered in the spirit of HeLP?	Delivery - Fidelity to function	Quality of delivery [2]	Observation checklists Field notes
How much of HeLP are children and families receiving?	Uptake	Dose received [1] Reach [1] Exposure [2]	Child and/or family registers for each component
How are schools, children and families responding to HeLP?	Reach (engagement) Experience	Participant responsiveness [2]	Observations Field notes Parental signature Parent questionnaire Qualitative evaluation (interviews and focus groups with teachers, children and parents)
Are there contextual and environmental factors which have the potential to influence delivery, reach and experience?	Context	Context [1]	Observations Field notes Qualitative evaluation (interviews and focus groups with teachers, children and parents) Parent questionnaire

[1] Based on process evaluation components outlined by Baronowski and Stables [20]and Linnan and Steckler [21]

[2] Based on implementation fidelity components outlined by Dane and Schneider [22]

This process evaluation will not ask the question 'are there intervention components which are more essential than others' (programme differentiation[2]) as HeLP was developed as a dynamic, evolving set of processes with reinforcing feedback loops between the school, child and family. It is believed that individual components within the programme continually interacted with each other over time to achieve the desired outcome, and that the deliverer is part of the intervention. Assessing the effect of any one component would be at odds with how HeLP was conceived and developed [27].

9.2.1 Delivery

This will assess whether HeLP was delivered in the way it was developed (i.e. did children receive all the components in the correct order?) to ascertain fidelity to content (or form/ structure of HeLP) and will also assess whether the Programme was delivered in the 'spirit of HeLP' to ascertain fidelity to function or purpose of each component.

Fidelity to content (form) will be assessed by observation using checklists for all components. Checklists are completed by the HeLP Co-ordinators (HCs) (see Appendix 1 for details). We will document the percentage of components delivered in the right order per school.

Fidelity to 'function' will be assessed using checklists for quality of delivery; this is to understand whether HeLP is being delivered in the 'spirit' in which it was developed. Spirit of HeLP is defined as enthusiastic delivery, open body language, responsive to child/school needs and clear and friendly communication, for observed key events; Parent assembly (Phase 1); Healthy Lifestyles Week (Phase 2); Parent assembly (Phase 3); Class delivered assembly (Phase 4).

These are completed by HeLP Coordinators for the Healthy Lifestyles week (Phase 2) and the Trial Manager for the two parent meetings (Phase 1 and 3) and class delivered assembly (Phase 4).

We will document the percentage of HeLP components delivered in the 'spirit' of HeLP per school. An average score of 8 or more out of 10(per component, as above) on quality of delivery would be classified as having been delivered in the spirit of HeLP (see Appendix 1 for details). For each school, the % of components delivered in the 'spirit of HeLP will be presented.

9.2.2 Uptake: Receipt of components (Dose)

This will be assessed using quantitative data from attendance registers for child and family by HeLP component.

Children: We will document the percentage of children in each school who received all of HeLP (we will descriptively present % attendance by individual component by each Phase).

Parents: We will document the percentage of parents per school attending one or more parental activity (this will be reported descriptively only).

9.2.3 Reach (engagement)

This will be assessed at the level of the school, child and parent/family.

School staff (HeLP Coordinator field notes from observations over the course of the intervention)

Criteria for engaged school staff:

0 = unengaged/ uncooperative

1 = supportive

2 = enthusiastic and supportive

3 = very enthusiastic - used HeLP in other aspects of teaching/school activities

A score between 0 and 3 for the head teacher, year 5 teachers, support staff per school will be given which will be aggregated into an overall score of 0-9 and then dichotomised into engaged/less engaged with 0-3 being less engaged and 4-9 being engaged.

Child (Engagement with the Goal Setting (GS) process during the 1-1 discussion in Phase 3)

Criteria for engagement with the GS process:

0 = disinterested/unaware goals needed to be set

1 = reluctant - needs a lot of prompting

2 = enthusiastic and happy to chat about goals and how they will achieve them

3 = very enthusiastic - have discussed at home – clear strategies for achieving them

This data will be reported at the level of the child and collapsed to engaged (score 2-3) /less engaged (0-1) and these dichotomised groupings will also be used for selection for the focus groups.

Parent/Family (Parental engagement is either attendance at one or more events and/or signature on goal setting sheet)

Criteria for parental engagement:

0 = did not attend / did not sign

1 = attended or signed the sheet (but not both)

2 = attended one or more events and signed the sheet

A score of ≥ 1 = engaged <1 = not engaged.

9.2.4 Experience of HeLP

This will be captured at the level of the school, child and parent/family.

Child - Focus groups conducted by HCs (2 per school) with a purposively sampled group of children, engaged vs less engaged, as determined for 'Reach' (section 2.3) using a pre-specified focus group schedule (Appendix 7);

Parent/Family – Parent questionnaire (Appendix 8) and self-selected parent interviews conducted by HCs/TM using a pre-specified interview schedule (Appendix 9);

Teachers – Year 5 teacher interviews conducted by TM/ PI (all year 5 teachers) using a pre-specified interview schedule (Appendix 10).

9.2.5 Context

This will assess whether there are any contextual and environmental factors which have the potential to influence delivery. Data will be collected using HeLP Coordinator observations and accompanying field notes, interviews and focus groups with teachers, children and parents, a parent questionnaire, a school characteristics and policies questionnaire (SCPQ). Data for the SCPQ (see Appendix 11) is collected at baseline and at 18 months post baseline by the HeLP Coordinator. Details of how the rest of the context data will be collected have already been outlined in the previous sub sections.

All focus groups and interviews will be recorded. Qualitative data will be managed using NVivo and analysed using Framework Analysis [28] with the aim of systematically describing and summarising the data. Transcripts will be read and re-read and an index of multiple emerging themes and sub themes will be constructed. Each interview and focus group transcript will be coded using the index and the data represented by each theme will be extracted and collated into charts to facilitate the organisation of the data. Each interview

or focus group transcript will be coded, with 20% double coded by JL, with KW/SD providing verification for half of those checked by JL. Emergent themes will be discussed and, if appropriate, refined before a summary of each theme will be derived from chart entries and direct quotations will be identified which will represent the range of views expressed in relation to each subtheme.

9.2.6 Triangulation

Each data set (interviews, focus groups, responses from parent questionnaire) will be analysed and the themes/findings reported. A convergence coding matrix will be produced detailing the findings from each set of data [29]. The resulting matrix will then be further analysed to look for agreement, partial agreement, silence or dissonance from the different data sets in order to build an insight into:

a) how schools children and families are responding to HeLP
b) The contextual and environmental factors influencing delivery, reach and experience of HeLP.

JL and KW will undertake the triangulation.

The data will be presented descriptively and used to produce hypotheses for future testing. The data will be analysed prior to the effectiveness results so as not to 'read in' explanations in to the data.

9.2.7 Unintended consequences

We will seek to identify both beneficial and negative, unintended consequences at the level of the school, child and their family using observation as well as questionnaire, interview and focus group data.

10.0 ECONOMIC ANALYSIS (OUTLINE)

The primary aim of the economic analyses within the HeLP research plan is to estimate the cost-effectiveness of the HeLP intervention versus usual practice, using the incremental cost per quality-adjusted life-year gained. In addition the analyses will report incremental cost per unit reduction (change) in BMI-SDS (at 24-months).

Economic analysis will estimate the additional resource use and related costs associated with the delivery of the HeLP intervention in practice.

There is no participant level data being collected within-trial on participant resource use (costs) in relation to wider use of health and/or social care (or wider participant level costs). The resource use data being collected within-trial are those data collected at the school-level required to inform an estimate of the resource use, and subsequent cost, of the HeLP intervention delivery.

Economic analyses will comprise two stages/components; 1 within-trial analyses, and 2 evidence synthesis and modelling.

10.1 Stage 1: Within-trial cost/cost-effectiveness analyses

This stage of the economic analyses includes (a) estimating the cost for delivery of the HeLP intervention, and (b) presenting within-trial cost-effectiveness (cost-consequences) analysis

(a) *The cost for delivery of the HeLP intervention*

The aim here is to provide a robust (and policy-relevant) estimate of the resource use and related cost associated with the future delivery of the HeLP intervention [applicable where it is considered to be an effective and cost-effective intervention].

10.1.2 Data

Based on development / pilot research the introduction of the HeLP intervention, in addition to usual practice, is expected to involve additional resource use related to (i) delivery of HeLP, (ii) training and set-up costs associated with the introduction of HeLP.

(i) Delivery of HeLP intervention includes staff/person time input

- HeLP Coordinator
- School staff (e.g. Teacher, Head Teacher)
- Other
- External input/externally contracted services

Data collection for (i): Data on these areas of resource use are being recorded at school-level by HeLP Coordinators, through a report form detailing each contact with the school, by type of activity, stage of HeLP, 'who' was involved (by type), for 'how long' (minutes), to include information on preparation time (where applicable), activity time, and travel time (where applicable).

For external input such as drama, and other externally facilitated/delivered activity sessions, the HeLP Trial coordinator will provided data on specific resource use/costs.

(ii) Training / Set-up resource use for introduction of HeLP intervention includes:

- Trainer time
- Trainee time
- Other (e.g. admin input, venue, consumables, travel)

An assessment / estimate of resource input for this area (ii) is to be provided by the Trial Coordinator based on experience within the trial. For example the structure of the training required; the ratio of trainer to trainee time, the numbers of Trainer/Trainee involved, and other resource inputs. An important additional data (parameter) requirement is on expected caseload, and longevity of training. For example will one HeLP Coordinator be expected to deliver HeLP to 8 schools (classes) per school year? And will training be expected to be consistent with a 3-year term for a HeLP Coordinator. Such data (estimates) are needed to distribute training input over a caseload/time period.

10.1.3 Unit Costs

Units of resource use will be combined with appropriate unit costs, typically taken from credible/national cost data (e.g. PSSRU report on unit costs for health and social care, national pay scales by type/grade).

Drama is a significant component of the HeLP intervention, and it is expected (anticipated) that the 'Provider' for the drama (within trial) will provide an estimated contract cost for provision of the drama input, together with manualised data on delivery requirements.

We will estimate the costs associated by resource use type, and will set out a profile reporting the estimated overall cost for delivery of the HeLP intervention. Primarily this will be an estimate of the additional cost per child, and thereafter per class, per school, and per geographic area (however best defined). The cost analyses will be from the perspective of the 'Third Party Payer' (i.e. NHS funded, or other).

Cost analyses aim to tell a plausible (transparent) story, using available data and reporting the best estimate of resource use and cost associated with the addition of the HeLP intervention to usual practice.

Cost estimates will involve assumptions, and uncertainty, and the analyses will include sensitivity and scenario analyses, to consider uncertainty in assumptions and in data inputs. Where possible (based on data collected) a simulation will be used to consider uncertainty in parameter inputs (level of resource use, by type), sampling probabilistically from an uncertain distribution, to provide a confidence statement on the mean estimated cost for the intervention.

Cost analysis will not be presented by study school setting (not by 'named' school). Estimates of resource use and costs will be based on an average level of reported resource use, and mean estimated costs, across the study schools (intervention schools). Where disaggregated data are presented (for discussion within study team) they will be given a site number and not identifiable at specific school level. *[this supports the accurate data collection process required within the cost analyses]*

(b) Trial-based cost-effectiveness (cost-consequences) analyses

The above estimate of incremental costs associated with delivery of the HeLP intervention will be presented alongside the effectiveness results from the RCT, in the form of the estimated incremental cost per unit change in primary outcome, i.e. change in BMI-SDS. Results for this trial-based CEA will be presented alongside other effectiveness data from

the trial -as a cost-consequences analysis (i.e. tabulated data on additional costs alongside other outcome/effectiveness results).

However, summary results reporting cost per unit change in BMI-SDS are not easy to interpret in a health policy context. Whilst clearly a good thing, what does a 1-point improvement in BMI-SDS represent, and how to compare such summary statistics in the context of broader NHS decisions on use of resources? Therefore, as stated in the original application and analysis plan, it is necessary to consider beyond the trial effectiveness data, and this is to be undertaken through modelling the potential impact of the effectiveness data from the HeLP RCT on longer term health outcomes, as summarised below (Stage 2).

10.2 Stage 2: Evidence synthesis - Modelling costs, outcomes, and the cost- effectiveness of the HeLP intervention

The aim here is to consider (combine) the relatively short-term costs associated with the HeLP intervention, compared with usual practice, with the expected longer term health gains associated with the effectiveness profile of HeLP as seen in (reported from/by) the HeLP RCT, in order to provide a policy-relevant estimate of the cost-effectiveness of the HeLP intervention.

10.2.1 Summary

- Economic endpoint: quality-adjusted life-year (QALY) / cost per QALY
- Time horizon: longer term, e.g. up to ages 65+
- Discounting: future costs and health gains to be discounted at 3.5% pa.
- Perspective: health outcomes to participants, and Third Party Payer perspective.
- Scope: limited to small number of core/major obesity related health events, including type two diabetes, CHD, stroke, colorectal cancer (proposal)
- QALY estimates/data from published literature (e.g. health state values for CHD)

10.2.2 Methods – Evidence synthesis and mathematical modelling

Framework: Two-stage mathematical model to predict adult weight status (BMI) as a function of adolescent weight status (BMI-SDS), and to predict health events in adult years (longer term health impacts) associated with predicted adult weight status.

Model: Simple Excel based spreadsheet model.

10.2.3 Evidence synthesis

Data - Effectiveness (HeLP)
From HeLP RCT (change in weight status, BMI-SDS, at participant level)

Data - predicting adult weight status from adolescent weight status (as above)
From observational/cohort data

Data - predicting health events from adult weight status (as predicted, above)
From published systematic review/meta-analyses/ obesity tracking cohort studies

Data - Costs and QALY weights for health events (e.g. T2 diabetes, CHD)
From the published literature (and NICE technology appraisal reports)

Assumption-based approach

Primary assumptions:

Weight status in adult years constant

Simple (restricted) modelling framework

Major restrictions:

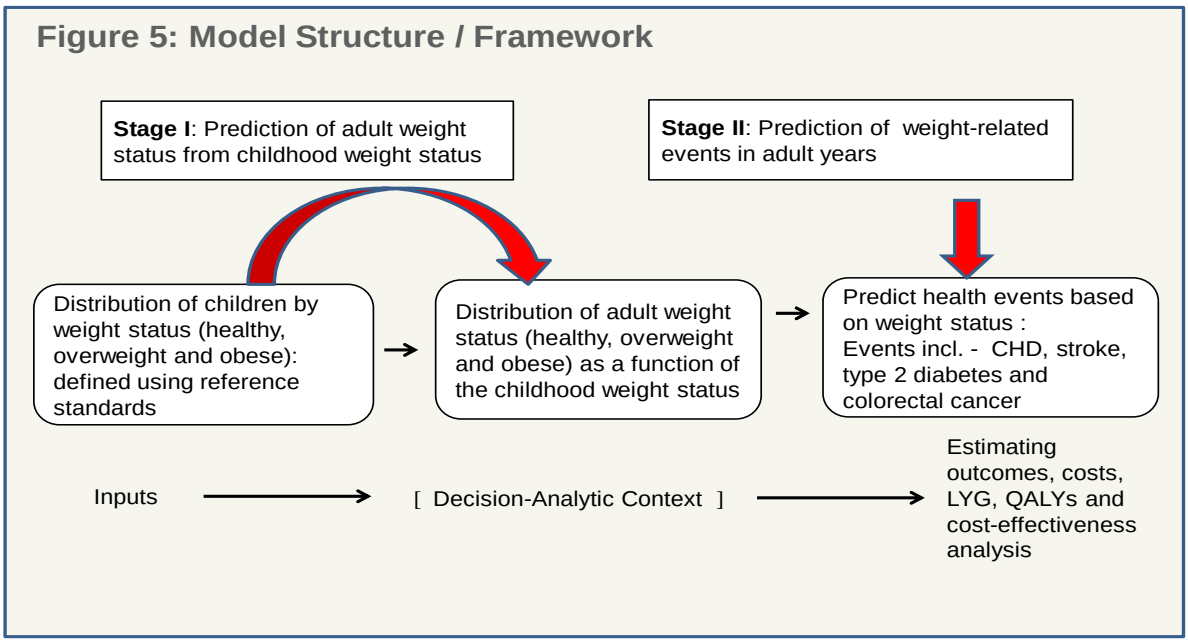
Focus is on predicting events (scope: 4 conditions) in adult years over set time horizon, and other impacts 'noise' not considered/captured.

Health effects estimated based on impact of major events (scope: 4 conditions), and other impacts of weight status / health not considered/captured.

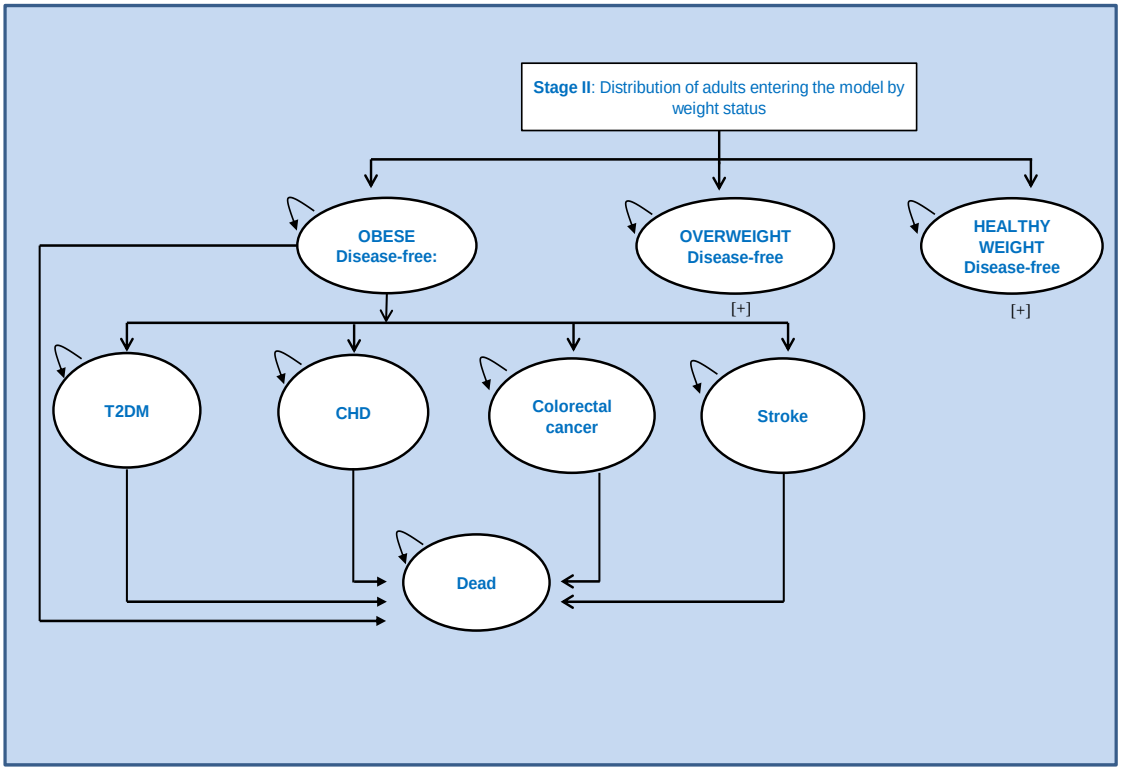
Rationale: Approach is not aiming (or pretending) to accurately 'describe/model/quantify' the impacts and experiences of people by weight status, simply seeking to identify health impacts in a restricted way in order to make a comparison between intervention (HeLP) and control cohort, and to make the case that the intervention is cost-effective (or not) within the modelling framework employed. If this approach does not make the case, then difficult to make the case! (to health care providers - in our opinion).

Some preliminary research/development on the proposed modelling framework in 2012/early 2013, but full development of the modelling (economic) framework planned over 2015-2016 (timeline to be developed).

See below copies of PowerPoint slides for outline information on modelling plans.



Stage 2: Markov Structure



Economic analyses will present results in the form of incremental cost effectiveness ratios (ICERs), using cost per QALY gained, as well as presenting dis-aggregated estimates of data on expected costs and outcomes over time.

Modelling methods will employ good practice guidelines for decision-analytic modelling in the HTA context (Philips et al, 2004), with all assumptions and data sources stated clearly and explicitly. Uncertainty in data (parameters) and structural assumptions will be explored using scenario and sensitivity analyses.

Please see Green et al (2013) which is a published abstract on the development work [30] (note data/numbers have changed since then – for illustration only).

11.0 CHANGES TO THE ANALYSIS PLAN

Any changes to the analysis plan will be summarised and documented in this section.

12.0 PROPOSED FORMAT OF FIGURES AND TABLES FOR REPORTING EFFECTIVENESS, COSTS AND PROCESS.

Proposed format for figures and tables for the primary publication are given in Appendix 5

Appendix 1: HeLP Outcomes and Mediators

Variable	Type	Units/categories	Collection time point and assessor	Comments
	Primary outcomes			
Body mass index (BMI)	Continuous	z(SD)-score	24 months Blind assessor	Age and gender standardised[1]
	Secondary outcomes			
Body mass index (BMI)	Continuous	z(SD)-score	18 months Blind assessor	Age and gender standardised
Waist circumference (WC)	Continuous	z(SD)-score	18 and 24 months Blind assessor	Age and gender standardised[2]
% Body Fat	Continuous	z(SD)-score	18 and 24 months Blind assessor	Age and gender standardised[3]
Proportion classified underweight/ overweight/obesity	Binary/ multinomial	No	18 and 24months Blind assessor	Derived from British Reference 1990 models[4]
Objectively measured Physical activity	continuous	Minutes	Baseline and 18months Help Coordinator / Physical activity Coordinator	Sedentary / light / Moderate / vigorous MVPA and total volume
Self-reported (validated questionnaire [12] used to measure change in dietary behaviours in 11-14 year olds) number of energy dense snacks/	Count	Servings (portion)	18 months HeLP Coordinator	Will be treated as a continuous variable

Variable	Type	Units/categories	Collection time point and assessor	Comments
day (including sweetened fizzy drinks)				
Self-reported (validated questionnaire) number of healthy snacks/ day (including healthy drinks)	Count	Servings/ Portion	18 months HeLP Coordinator	Will be treated as a continuous variable
	Potential mediators to be explored in mediational analyses			
Self-reported (questionnaire) knowledge (5 questions)	Score in whole numbers	Range 0-20	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) self-efficacy (3 questions)	Score in whole numbers	Range 3-12	12 months HeLP Coordinator	Will be treated as continuous variable
Self-reported (questionnaire) intentions (6 questions)	Score in whole numbers	Range 6-24	12 months HeLP Coordinator	Will be treated as continuous variable
Self-reported (questionnaire) peer-norms (3 questions)	Score in whole numbers	Range 3-12	12 months HeLP Coordinator	Will be treated as continuous variable
Self-reported (questionnaire) peer approval (5 questions)	Score in whole numbers	Range 5-20	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) family approval (3 questions)	Score in whole numbers	Range 3-12	12 months HeLP Coordinator	Will be treated as a continuous variable

Variable	Type	Units/categories	Collection time point and assessor	Comments
Self-reported (questionnaire) attitudes towards restrictions on unhealthy behaviours (3 questions)	Score in whole numbers	Range 3-12	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) parental provision and rules (4 questions)	Score in whole numbers	Range 4-16	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) child use of goal setting (6 questions)	Score in whole numbers	Range 6-24	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) self-monitoring (4 questions)	Score in whole numbers	Range 4-16	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) child discussion of healthy lifestyles with parents (3 questions)	Score in whole numbers	Range 3-12	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) child making suggestions to parents (2 questions)	Score in whole numbers	Range 2-8	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) child shopping with parent (1 question)	Score in whole numbers	Range 1-4	12 months HeLP Coordinator	Will be treated as a continuous variable

Variable	Type	Units/categories	Collection time point and assessor	Comments
Self-reported (questionnaire) child cooking with parents (1 question)	Score in whole numbers	Range 1-4	12 months HeLP Coordinator	Will be treated as a continuous variable
Self-reported (questionnaire) child trying new healthy snacks and drinks (1 question)	Score in whole numbers	Range 1-4	12 months HeLP Coordinator	Will be treated as a continuous variable
	Process evaluation measures for intervention schools only			
Delivery **Fidelity to Form**	Categorisation of key content for each component by observation	Yes/ No/Partial	Assessed for all components of HeLP HeLP Coordinator	% components delivered in complete form per school
Fidelity to Function	Score, in whole numbers, whether HeLP was delivered enthusiastically and responsively.	Range 1-10	Assessed during Parent Assembly (TM); Healthy Lifestyles Week (HC); Forum theatre assembly (TM); class delivered assembly (TM)	An average score/ school of $\geq$ 8 indicates fidelity to function (Spirit of HeLP) Fidelity to function defined as: Enthusiastic delivery; open body language; responsive to child/ school needs/ clear and friendly communication % components delivered in spirit of HeLP/ school

Variable	Type	Units/categories	Collection time point and assessor	Comments
Uptake	Binary (present/ absent)	% children attending in each school by Phase % parents attending one or more parental activity	Assessed for all components of HeLP HeLP Coordinator	The scores will be reported as % children/ school who received all of HeLP % parents attending one or more activity
Reach (engagement) **School**	Score in whole numbers	Range 0-9	Post intervention assessment by HeLP Coordinators based on field notes and observations	Aggregate score to engaged (4-9)/ less engaged (0-3) Individual scores (0=unengaged- 3 = very enthusiastic and HeLP +)
Reach (engagement) **Child**	Score in whole numbers	Range 0-3	Child level of engagement with goal setting process based on interaction with HeLP Coordinator	Engaged 2-3/ less engaged ≤1 (0= disinterested unaware goals need to be set – 3 = very enthusiastic, have discussed at home and clear strategies for achieving goals)
Reach (engagement) **Parent**	Binary (attendance at event and/ or signature on goal setting sheet)	Range 0-2		0= did not attend/ did not sign 1= signature or attendance but not both 2= both signature and attendance Score 0= not engaged; 1 or more = engaged
Experience **Teachers**	Qualitative (interviews)	Themes	Post Year 5 involvement with HeLP by TM	Framework analysis; data managed using NVivo

Variable	Type	Units/categories	Collection time point and assessor	Comments
Experience **Child**	Qualitative (focus groups)	Themes	Post intervention with HeLP coordinators	Two focus groups per school of approx. 6 children per FG (engaged vs less engaged)
Experience **Parent**	Qualitative (interviews) Parent Questionnaire	Themes Questionnaire responses	Post intervention with HeLP Coordinators Sent through the child to each parent	Self-selected group of parents who complete questionnaire and indicate that they would like to be interviewed.

1. Cole TJ. The LMS method for constructing normalized growth standards. Eur J Clin Nutr. 1990 Jan;44(1):45-60.
2. McCarthy HD, Cole TJ, Fry T, Jebb SA, Prentice AM. Body fat reference curves for children. Int J Obes. 2006;30(4):598-602.
3. 3 McCarthy HD, Jarrett KV, Crawley HF. The development of waist circumference percentiles in British children aged 5.0-16.9 y. Eur J Clin Nutr. 2001 Oct;55(10):902-7.
4. Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. Arch Dis Child. 1995 Jul;73(1):25-9.

Appendix 2: Anthropometric Data Collection Proforma

COHORT: 1

SCHOOL CODE - 01 - Seaton Primary School

TEACHER - Mr Ed Hunt - 5EH

Date of activity: (dd/mm/yyyy)
Activity Type: **MEASUREMENT**
Activity Name: **ANTHROPOMETRIC**
Time point:
Visit Notes:

REGISTER OF ATTENDANCE

Forename	Surname	Child ID	Date	Height	WC	Weight	BF	BMI

Appendix 3: FIQ Scoring

Energy dense snack foods (n=13)	FIQ Week question number	FIQ weekend question number	Healthy snack foods (n=10)	FIQ Week question number	FIQ Weekend question number
High sugar cereals	6	2	Brown/wholemeal bread	9	5
Plain biscuits	13	9	Malt/fruit bread	10	6
Chocolate biscuits	14	10	Breadsticks/crackers	11	7
Cakes	15	11	Unsalted nuts	34	30
Puddings	16	12	Fresh fruit	35	31
Boiled sweets	17	13	Dried fruit	36	32
Chocolate	18	14	Salad	37	33
Ice cream	19	15	Hard cheese	50	46
Crisps	27	23	Yoghurt	52	48
Salty nuts	33	29	Semi skimmed milk	59	55
Pies/pasties	44	40			
Processed cheese	51	47			
Sweetened fizzy drinks	55	51			

Negative marker foods (n=25)	FIQ Week question number	FIQ Weekend question number	Positive marker foods (n=22)	FIQ Week question number	FIQ Weekend question number
Sugar cereals	6	2	Low sugar cereals	7	3
Butter/marg	12	8	Brown/wholemeal bread	9	5
Biscuits	13	9	Malt/fruit loaf	10	6
Chocolate biscuits	14	10	Breadsticks/crackers	11	7
Cakes	15	11	Boiled potatoes	22	18
Puddings	16	12	Mashed potatoes	23	19
Boiled sweets	17	13	Baked potatoes	24	20
Chocolate	18	14	Pasta	28	24
Ice cream	19	15	Rice	29	25
Sugar added to drinks	20	16	Noodles	30	26
Sugar added to food	21	17	Homemade pizza	31	27
Roast potatoes	25	21	Unsalted nuts	34	30
Crisps	27	23	Fresh fruit	35	31
Chips	26	22	Dried fruit	36	32
Salted nuts	33	29	Salad	37	33
Fried vegetables	38	34	Vegetables	39	35
Shop bought burger	40	36	Homemade burgers	42	38
Shop bought sausage	41	37	Homemade sausages	43	39
Pies and pasties	44	40	Yogurt	52	48
Fried fish	46	42	No sugar squash	56	52
Fried egg	49	45	Semi skimmed milk	59	55

Processed cheese	**51**	**47**	Water	**60**	**56**
Takeaways	**53**	**49**			
Salt added to food	**54**	**50**			
Sweet fizzy drink	**55**	**51**			

FIQ calculations

Below is an example of how the EDS scores are calculated and the same principles and calculations apply to each of the four scores EDS, HS, NM, PM.

Step 1 - Values are calculated for the FIQ Week and FIQ Weekend questionnaires (2 values for each questionnaire);

- **EDS Total** this is the number of Yes responses for EDS foods.
- **EDS Nulls** this is the number of missing/invalid/illegible data responses for the EDS foods.

This results in four values for each child **FIQWk EDS Total**, **FIQWk EDS Nulls**, **FIQWkend EDSTotal**, **FIQWkend EDS Nulls**.

Step 2 - The EDS score for a weekday and for a weekend day are calculated, taking into account any missing data (**EDS Nulls**).

- If there is no missing data for the **FIQWk** or **FIQWkend** then the EDS score will be equal to the **FIQWk EDS Total** or **FIQWkend EDS Total** respectively.
- If there are more than three missing values for the EDS score then a NULL will be returned.
- If there are between 1 and 3 missing values then we work out an EDS score based on the number of responses we have. The formula for this:
  (**EDS Total** / (13 – **EDS Nulls**) * 13. We divide the number of Yes responses by the number of responses received. Then multiplying this by 13 gives a score out of 13 which can be used for analysis.

NB: 13 is the number of items that make up the EDS foods. The other scores HS,NM and PM have varying numbers of columns involved and also varying tolerances for missing data (i.e. PM score is made up of 28 foods and if more than 7 responses are missing then we treat it as null).*

This results in two values for each child **FIQWk EDS Score** and **FIQWkend EDS Score**.

Step 3 - A daily average is calculated, taking into account the weighting of weekdays to weekend days in a week. The formula for this:

(**FIQWk EDS Score**)*5 + (**FIQWkend EDS Score**)*2) / 7

This calculates the EDS total for an entire week – 5 lots of the FIQWk score and 2 lots of the FIQWkend score) – and then divides this by 7 to find the average daily EDS score.
NB: If one of the scores used in this step is NULL then the final output will also be NULL.
Other scores are calculated using the same method.

*Tolerances are given below:

- Energy Dense Snack foods (13 responses) – total score calculated only if at least 10 responses given
- Health Snack Foods (10 responses) – total score calculated only if at least 8 responses given
- Negative Markers (25 responses) – total score calculated only if at least 19 responses given
- Positive Markers (22 responses) – total score calculated only if at least 17 responses given

Appendix 4: My Lifestyle Questionnaire (MLQ) and Scoring system

Date: _____ Time point: _____

My Lifestyle Questionnaire

Child ID: _____

Child DOB: _____

School: _____

Class: _____

We are interested in finding out about your lifestyle. Please listen to the questions very carefully and answer as best you can. Please note that none of your answers will be shared.

High scores represent health promoting cognition, motivation, attitudes and behaviours

Section A

For questions 1 and 2 you are given 2 lists (A and B). You have to **match up the items in list B to list A** by writing in the correct number as shown in the example below.

E.g. Sport and equipment

Example

A—Sport		B—Equipment
Tennis	5	1. Goggles
Football	2	2. Boots
Snooker	4	3. Beam
Swimming	1	4. Cue
Gymnastics	3	5. Racquet

1. Unhealthy food and healthy replacement.

From list B, please choose what you believe to be the healthy alternative that **best matches** the unhealthy food item.

A – Unhealthy Food		B—Healthy Alternatives
Orange tango	_____	1. Portion of hard cheese
Packet of crisps	_____	2. Dried fruit e.g. apricots/raisins
Biscuits	_____	3. Ham sandwich (wholemeal bread)
Jelly sweets	_____	4. Bread sticks
Jam sandwich (white bread)	_____	5. Sweet oatcakes
Cheese strings	_____	6. Sugar free orange squash and fizzy water

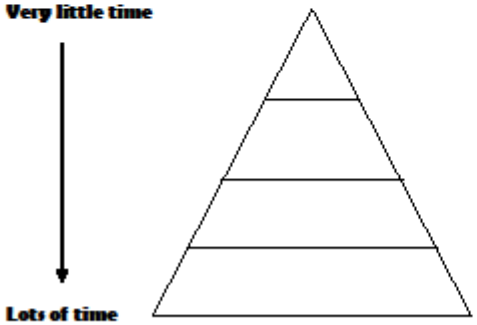
2. Food group and the percentage of each that should make up your diet.

From List B choose the correct percentage for each food group.
You may use a percentage more than once. Your answers should add up to 100%.

A		B	
Fruits and vegetables	_____%	12%	33%
Fatty and sugary foods	_____%	7%	11%
Meat, fish and alternatives	_____%	40%	15%
Milk and dairy products	_____%	50%	2%
Bread, other cereals and potatoes	_____%		

3. The activity triangle below has 4 levels to show very little time at the top with more time in each level as you go down. In the box to the right of the triangle there are 4 different types of activity. **Please write the letter linked to each activity type in one section of the triangle to show how much time you should spend on that type of activity.** You can only use each letter once and have one letter in each level of the pyramid.

Very little time



Lots of time

A	Games and activities that make the heart beat faster e.g. playing football/netball
B	Daily activities e.g. Walking
C	Not moving around for more than 2 hours in the day
D	Activities which involve stretching and building strength e.g. gymnastics, judo, weight training

4. What is the **smallest** amount of healthy foods we should be eating? What is the **largest** amount of unhealthy foods we should be eating?

Choose your answers from the list below and write your answer in the appropriate box. Your answer should add up to 100%.

15% 20% 25% 30% 35%

40% 45% 50% 55% 60%

65% 70% 75% 80% 85%

Healthy food	**to**	Unhealthy food
%		%

5. Imagine you have decided to reduce your screen time on a school day evening by playing outside instead. In the box below **write down 3 things that would help you to remember** to play outside.

1.

2.

3.

Section B

Questions 6-8 are statements about **how easy or hard it would be for you to do certain things.** You must TICK the box that shows how much you agree with the statement.

- *Unhealthy snacks include biscuits, cakes, crisps, sweets and sweetened fizzy drinks (e.g. coke, fanta, lemonade)*
- *Healthy snacks include fruit, crackers, breadsticks, oatcakes, dried fruit, carrot sticks, wholemeal bread*
- *Screen based activities include TV, computer, mobile phone, Xbox, Nintendo DS, Ipad etc.*

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
6	I would find it **very easy** to give up half of my screen based activities and swap them with being more active everyday				
7	I would find it **very easy** to eat only one unhealthy snack every day				
8	If offered my favourite unhealthy snack I would find it **very easy** to say 'no thanks'				

Questions 9-14 are statements **about whether you plan to do certain things in the next two weeks.**
You must TICK the box that shows how much you agree with the statement.

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
9	I plan to give up at least half of **my screen based activities** and replace them with **physical activity**				
10	I plan to only eat **one unhealthy snack** every day				
11	If offered my favourite unhealthy snack, I will say **'no thanks'**				
12	I plan to eat **new** healthy snacks				
13	I plan to talk to my parents about how the whole family can **eat more healthily**				
14	I plan to try to persuade my parents to be **more active**				

Questions 15-17 are statements **about how many of your friends do certain things.**
You must TICK the box which shows how many of your friends do these things.

No.	Question	None	A few	Lots	All
15	How many of your friends eat more than two **healthy** snacks at school each day?				
16	How many of your friends drink a fizzy drink (e.g. coke, lemonade , Fanta) **every day**?				
17	How many of your friends **play on a computer, mobile phone or watch TV** when they get home from school?				

Questions 18-22 are statements about **whether your friends think it's ok to do certain things**. You must TICK the box that shows how much you agree with the statement.

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
18	Most of my friends think it is ok to **play on the computer/mobile phone** for most of the time at home				
19	Most of my friends think it is ok to **help their parents cook a meal**				
20	Most of my friends think it is ok to **help their parents shop for healthy foods**				
21	Most of my friends think its ok to **watch TV** for most of the time at home				
22	Most of my friends think it is ok to **help their parents with the household chores** e.g. hoovering, laying the table, tidying their bedroom				

Questions 23-25 are statements **about whether your family think it is ok to do certain things**.
You must TICK the box which shows how much you agree with the statement.

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
23	Most of my family think it is ok for me to eat more than three **unhealthy** snacks (e.g. crisps, chocolate, biscuits, sweets) every day				
24	Most of my family think it is ok for me to drink more than two **sweetened fizzy drinks** each day				
25	Most of my family think it is ok for me to spend more than 2 hours each evening on **screen-based activities**				

Questions 26-28 are statements **about eating and activity**.
You must TICK the box which shows how much you agree with the statement.

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
26	If you want to eat lots of food high in salt, sugar and fat then you should be able to				
27	If you want to drink sweetened fizzy drinks then you should be able to				
28	If you want to spend more than 3 hours a day doing screen based activities then you should be able to				

Section C

Questions 29-32 are statements **about your home.**
You must TICK the box which shows how much you agree with the statement.

No.	Question	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
29	My parents/carers provide mostly **healthy snacks** for me at home				
30	My parents/carers provide mostly **unhealthy drinks** for me at home				
31	My parents/carers provide **many opportunities** for me to be physically active				
32	My parents/carers have **rules at home** to help me eat more healthily and to reduce my screen time e.g. I can only spend half an hour on a computer game each day or I am not allowed to help myself to crisps, chocolate, biscuits and sweets whenever I want.				

Section D

Questions 33-50 are statements **about what you do**.
You must tick the box which shows how often you do these things.

No.	Question	All of the time	Most of the time	Some of the time	Never
33	I set targets to help me cut down on the number of unhealthy snacks I eat				
34	I set targets to help me cut down on the number of sweetened fizzy drinks I have				
35	I set targets to help me cut down on my screen time				
36	I set targets to help me do more physical activity				
37	If I set a target, I write it down				
38	If I set a target, I tell/show my parents/carers and ask them to agree it				
39	I try to remember each type of food I eat to make sure I do not eat too many unhealthy snacks				
40	I try to remember each type of food I eat to make sure I eat enough healthy food				
41	I try to remember how much screen-based activity I do to make sure I don't do too much				
42	I try to remember how much physical activity I do to make sure I do enough				
43	I talk to my parents/carers about eating more healthily				
44	I talk to my parents/carers about increasing my physical activity				
45	I talk to my parents/carers about spending less time on screen-based activities				
46	I make suggestions to my parents/carers about how we can be more active as a family				
47	I make suggestions to my parents/carers about how we can eat more healthily				
48	I go food shopping with my parents/carers and help them choose healthy foods and drinks to buy				
49	I help my parents/carers to cook at home				
50	I try new healthy foods and drinks				

MLQ scoring

Section A – Knowledge (one point for each correct answer)

Answers
Q1
Orange tango – 6
Packet of crisps – 4
Biscuits – 5
Jelly sweets – 2
Jam sandwich – 3
Cheese strings - 1

Q2
Fruits and veg – 33%
Fatty foods and sugary foods – 7%
Meat, fish and alternatives – 12%
Milk and dairy products – 15%
Bread, other cereals and potatoes – 33%

Q3
From top of triangle to bottom
C
D
A
B

Q4
Healthy food – 80%
Unhealthy food – 20%

Q5
Each strategy listed below will be counted as 1 point. In order to score 3, there needs to be 3 separate strategies. For example if a child writes removing the X Box, removing the TV and hiding the remote control for her 3 strategies this will only count as 1 point.

Any answer indicating leaving a **note/reminders** to themselves *e.g. putting a post it note on the computer telling me to play outside instead*

Any answer suggesting they **write their goal** (of replacing screen time on a school day evening with playing outside instead) on a piece of paper. This would include getting their parents to sign their goal

Any answer suggesting a **stimulus cue** e.g. placing a football/kit/trainers etc in a place that reminds them they should play outside rather than do screen-based activity

Any answer suggesting **removing or hiding TV/computer/phone/Xbox/DS** from a room

Any answer suggesting getting **parents/friends/sibling to remind them** of their goals
Section B-D

Points	**4**	**3**	**2**	**1**
	Strongly agree	Slightly agree	Slightly disagree	Strongly disagree
	All	Lots	A few	None
	All of the time	Most of the time	Some of the time	Never

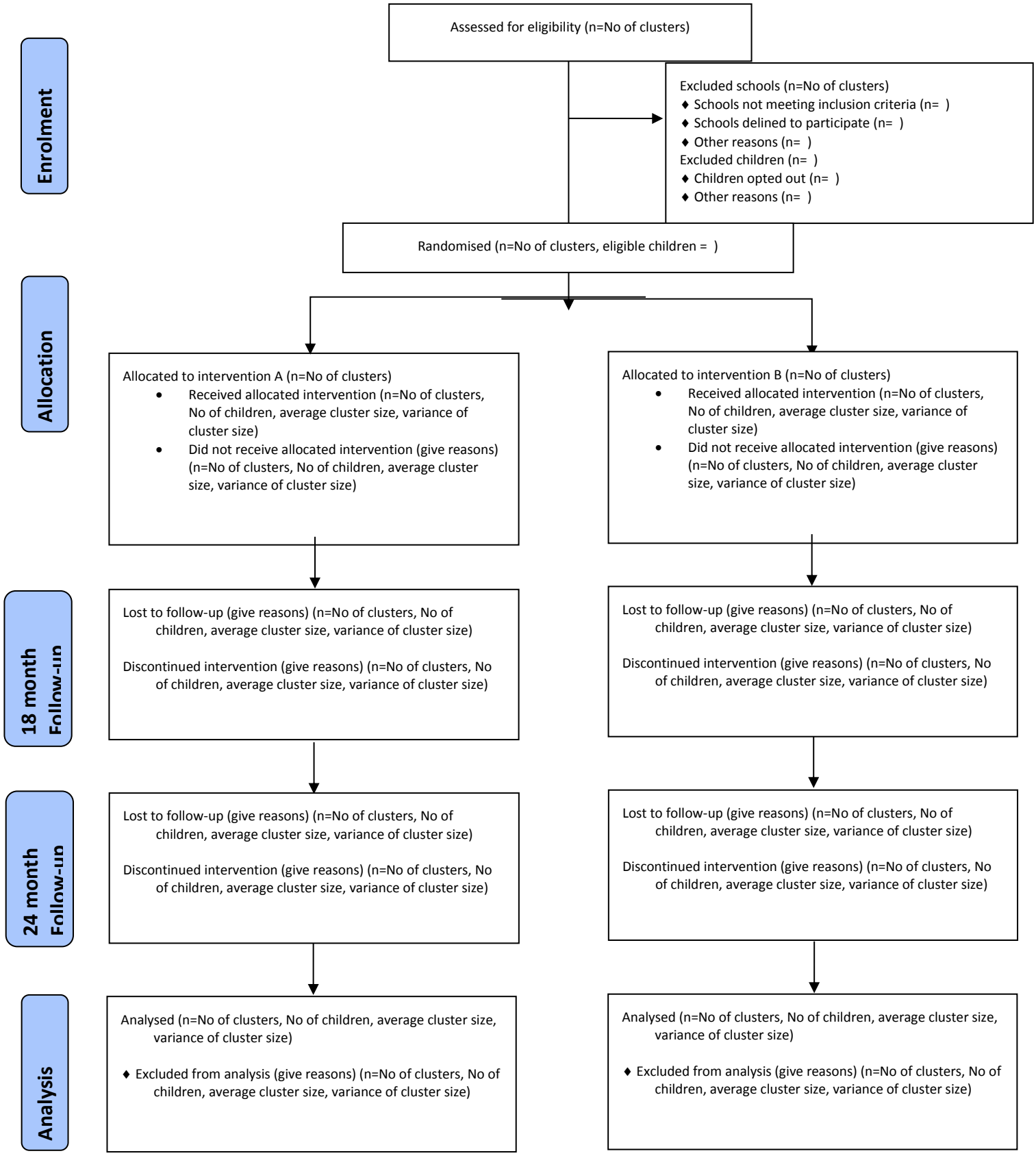
Reverse score items: 16, 17, 18, 21, 23, 24, 25, 26, 27, 28, 30

Range of possible scores and associated questions for each construct

Construct	**Minimum score**	**Maximum score**	**Questions**
Knowledge	0	20	1-5
Self-efficacy	3	12	6-8
Intentions	6	24	9-14
Peer norms	3	12	15-17
Peer approval	5	20	18-22
Family approval	3	12	23-25
Attitudes towards restrictions on behaviours	3	12	26-28
Parental provision and rules	4	16	29-32
Goal setting	6	24	33-38
Self-monitoring	4	16	39-42
Discussion with parents	3	12	43-45
Suggestions to parents	2	8	46-47
Child shopping	1	4	48
Child cooking	1	4	49
Child trying new healthy snacks	1	4	50

Appendix 5: Proposed Format of Figures and Tables for Primary Publication

Flow of schools and children through study



Demographic and baseline characteristics at individual child and school cluster levels. Values are percentages (numbers) unless stated otherwise

	Intervention (n=xxx children)	**Control (n=xxx children)**	**All (n=xxx children)**
Individual / child level			
Mean (sd) age (years)			
Gender:			
Female			
Male			
Ethnicity:			
White			
Other			
Eligible for free school meals			
?? Index of multiple deprivation			
Mean (sd) BMI sds			
Mean (sd) Waist circumference sds			
Mean (sd) % body fat sds			
% underweight			
% overweight			
% obese			
% overweight or obese			
Mean (sd) Physical activity sedentary			
Mean (sd) Physical activity light			
Mean (sd) Physical activity moderate			
Mean (sd) Physical activity vigorous			
Mean (sd) Physical activity MVPA			
Mean (sd) mG value *			
Mean (sd) Food Intake Energy dense snacks			
Mean (sd) Food Intake Healthy snacks			
Mean (sd) Food Intake Negative food markers			

	Intervention (n=xxx children)	**Control (n=xxx children)**	**All (n=xxx children)**
Mean (sd) Food Intake Positive food markers			
Cluster / school level			
Number of Year 5 classes:			
1 class			
≥2 classes			
Mean (sd) % of children eligible for free school meals			
% of children eligible for free school meals:			
<19%			
≥ 19%			
Index of multiple deprivation			

*GENEActiv measures the acceleration of movement at the wrist at provides the output as raw acceleration (milli-G, i.e. multiples of 0.00981 m/s^2). With previous monitors, raw acceleration data was converted into counts through a manufacturer-specific algorithm that wasn't disclosed preventing comparison between studies. The average acceleration for each child provides a measure of total movement per hour.

Primary outcome of BMI sds at 24 months. Values are means (95% confidence intervals) unless stated otherwise

	Intervention Group (xx schools)		Control Group (xx schools)		Adjusted analysis[1]				Unadjusted analysis	
	Number of children	Mean (sd) [range]	Number of children	Mean (sd) [range]	Number of children in adjusted analysis	Adjusted effect estimate[2] (95% CI)	p-value	Intraclass correlation coefficient (95% CI)	Unadjusted effect estimate (95% CI)[3]	p-value
Primary analysis:										
BMI SDS										
SENSITIVITY 1										
SENSITIVITY 2										
Exploratory analysis:										
e.g. No. year 5 classes										

[1] analysis adjusted for stratification variables (school size and %free school meals) and baseline BMI SDS and cohort

[2] adjusted difference for Intervention minus Control

[3] difference for Intervention minus Control

Secondary Outcomes. Values are means (95% confidence intervals) unless stated otherwise

	Intervention Group (xx schools)		Control Group (xx schools)		Adjusted analysis[1]				Unadjusted analysis	
	Number of children	**Mean (sd) [range]**	**Number of children**	**Mean (sd) [range]**	**Number of children in adjusted analysis**	**Adjusted effect estimate[2] (95% CI)**	**p-value**	**Intraclass correlation coefficient (95% CI)**	**Unadjusted effect estimate (95% CI)[3]**	**p-value**
18 month outcomes										
BMI sds										
Waist circumference sds										
% body fat sds										
% underweight										
% overweight										
% obese										
% overweight or obese										
Mean (sd) Physical activity sedentary										
Mean (sd) Physical activity light										
Mean (sd) Physical activity moderate										
Mean (sd) Physical activity vigorous										
Mean (sd) Physical activity MVPA										
Mean (sd) mG value										
Food Intake Energy dense snacks										
Food Intake Healthy snacks										
Food Intake Negative food markers										

	Intervention Group (xx schools)		**Control Group (xx schools)**		**Adjusted analysis[1]**				**Unadjusted analysis**	
Food Intake positive food markers										
24 month outcomes										
Waist circumference sds										
% body fat sds										
% underweight										
% overweight										
% obese										
% overweight or obese										

[1] analysis adjusted for stratification variables (school size and %free school meals) and baseline values where appropriate

[2] adjusted difference for Intervention minus Control for continuous outcome measures; adjusted odds ratios for Intervention:Control for binary outcome measures

[3] difference for Intervention minus Control for continuous outcome measures; odds ratios for Intervention:Control for binary outcome measures

Adverse Events. Values are percentages (numbers) unless stated otherwise

	Intervention (n=xxx children)	**Control (n=xxx children)**	**All (n=xxx children)**
Event A			
Event B			
Event C			
Event D			

Appendix 6: Standard Operating Procedure for reporting Serious Adverse Events

This Standard Operating Procedure (SOP) defines what a serious adverse event is, how it might be identified and what should happen as a result of one occurring during the HeLP trial.
In this trial, any of the following would constitute a serious adverse event:

1. Unusual dieting behaviours
2. Unusual physical activity behaviours
3. Stigmatisation of overweight/underweight children
4. Noticeable weight loss

IDENTIFICATION OF AN ADVERSE EVENT

All these adverse events could be observed and reported by either teachers, Learning Support Assistants, Meal Time Assistants, parents, HeLP Coordinators and actors.

REPORTING OF AN ADVERSE EVENT

1. Identification of adverse event by any means
2. Report adverse event to child's class teacher
3. Class teacher reports event to HeLP Coordinator (HC)
4. HeLP Coordinator to complete adverse event log sheet
5. HeLP Coordinator to inform Trial Manager (TM)
6. Trial Manager to inform Principal Investigator (PI)
7. Trial Management Group to be informed
8. Trial Steering Committee to be informed
9. Ethics Committee to be informed
10. Sponsor to be informed

ACTION TO BE TAKEN

1. The Principal Investigator, Trial Manager and HeLP Coordinator to consider the reasons for the adverse event occurring, using available information.
2. The HeLP Coordinator to liaise with the head teacher/class teacher and/or parents to discuss how best to proceed.
3. If necessary, parents will be offered a referral for the child to a community paediatrician (Dr Richard Tomlinson/Dr Stuart Logan, co applicants on the trial) if they feel their child is or has been exhibiting potentially harmful behaviours.
4. If a withdrawal follows, then parents/carers will be sent a withdrawal form by post with an SAE indicating whether they are happy for their child's data (collected to date) to be kept on the database or to be removed immediately.

Appendix 7: Focus Group Schedule

Thank you very much for taking part in this group discussion. Ideally we would love to talk to all the year 6's but sadly this is not possible, so we have selected names out of a hat and yours was one of them. As you know, last year you were involved in our Healthy Lifestyles Programme which ended in you setting goals based on our healthy lifestyle messages. The reason we have set up this group discussion is to find out what you remember about the Programme and how you felt about it. The feedback you give us will help us make the programme better before it goes into other schools. There are no right or wrong answers as it's very personal and we are going to make sure that each and every one of you has the opportunity to speak. To help us do that, you need to listen to each other, one at a time. Try not to make any personal comments if you don't agree - all your views are very important to us and we will get to you, if you wish to say something. Do you think that is fair? Good, we are glad you agree, which is why we know that you will listen to your class mates and respect their views.

Icebreaker snap shot: give the kids a post it note each and a pen, get them to think about HeLP and come up with 3 words that they would use to describe the whole experience to other children if it were coming to their school.

1. What do you remember about the HeLP Programme? (one thing from each child)

2. What do you think your parents/family think of HeLP? *Probe events they came to*

3. Did you talk about HeLP at home? *Probe what was said and with whom*

4. Did you talk about HeLP at school outside the HeLP activities? *Probe what was said and with whom*

5. Did you enjoy the Programme? *Probe why and which bits - if not already covered.*

6. Do you remember the HLW? What did you think about the drama and the other activities during this week? How about the year 6 activities? *(remind them and probe if 'feeling' is different)*

7. Was it different to what you usually do in school? *Probe why*

8. Who was your character?
    a. How easy was it to pick a character? *Draw out why they identified with their character*
    b. Did working with your chosen character help you to set goals? *Probe reasons why*

9. How did you find setting goals at home with your parents? *Probe reasons for their experiences*

10. What was it like trying to change your behaviours? (at home and at school). *Probe reasons for why it was difficult/easy*

11. Could you tell me anything you or others did to help you achieve your goals? (at home and at school). *Probe what they were*

12. Have you noticed any changes at home since the Programme? *Probe what they were*

13. Have you noticed any changes in yourself from being involved in the Programme? *Probe what they were*

14. Was there anything about the project you didn't enjoy so much? *Probe reasons why?*

15. Is there anything else you would like to say?

Appendix 8: Parent Questionnaire

The Healthy Lifestyles Programme

PARENTS/CARERS QUESTIONNAIRE

The Healthy Lifestyles Programme (HeLP) would like to hear about your personal experience of the Programme as a parent/carer and family. It is crucial in helping us to understand how HeLP affected you and your family. We would be grateful, therefore, if you can spare the time to complete the simple questionnaire below. Please return it in the envelope provided and it will be entered in the prize draw to win a £50 high street voucher!

1. How did you become aware of your child's involvement in the Healthy Lifestyles Programme?

2. Did you and your child talk about the Healthy Lifestyles Programme at all?

☐ A lot

☐ A little

☐ Not at all

3. What do you think the Programme was trying to do?

4. Part of the Programme was to encourage the children to make changes to some of their lifestyle behaviours and state what they were going to do differently. We called these their HeLP goals.

* Were you aware of these goals? ☐ Yes ☐ No

* How easy do you think it was for your child to make these changes?

☐ Easy ☐ Quite Easy ☐ Quite Difficult ☐ Difficult

5. Did you notice any change in your child's:

*Choice of snacks ☐ Yes ☐ No

*Choice of drinks ☐ Yes ☐ No

*Time spent doing screen based activities (e.g. computer, iPod, phone, iPad, TV) ☐ Yes ☐ No

*Time spent doing physical activity? ☐ Yes ☐ No

*Other (please specify below)

_____

_____

6. If you have said yes to any of the above, please could you write a little about the changes you noticed below:

7. If your child made some changes, have they managed to stick to any of them?

☐ Yes

☐ No

☐ Unsure

8. Have you or the rest of your family made any changes because of your child taking part in HeLP?

☐ No changes

☐ A few

☐ Lots

9. If any changes have been made (by you or the rest of the family) , please could you write what these are below:

10. If there is anything else you would like to add, please write it below:

11. If you are happy to talk and give more detail to you HeLP Coordinator we would love to hear your thoughts. Please provide your details below and we will be in touch shortly.

*Name _____

*Telephone number _____

*Email _____

*Child's name _____

*Child's school and class _____

*Best time for us to call you _____

Appendix 9: Parent interview schedule

Thank you so much for agreeing to participate in this interview in order to expand on your questionnaire responses, we really appreciate your time. The aim of the interview is to understand yours and your family's experience of HeLP and any impact if may have had so that we can learn for future development. We are happy to hear all types of feedback, so please feel free to express anything that you think we could have done differently to improve the Programme.

The interview will take around 15 minutes and will be audio taped to ensure that we do not miss anything. All information you provide will be anonymised. Before we begin please feel free to ask any further questions.

Once I switch the recorder on I will say your name and the date and then we can begin.

Questions

1. What were your overall views of the Programme? (probe whether they attended any parental engagement activities)
2. You mentioned that XXX talked about the Healthy Lifestyles Programme (a lot; a little); please could you expand on the sort of conversations you had.
3. We asked in the questionnaire about the HeLP goals, which were set around the three key messages of reducing fizzy drink consumption, replacing unhealthy snacks with healthy alternatives and reducing screen time. You thought that it was easy/quite easy/quite difficult/difficult for XX to make these changes. Would you be able to expand on the reasons for this?
4. You indicated that you noticed changes in XX choice of snacks/drinks/screen time/physical activity. Please could you tell me a little more about these changes?
5. Is XX managing to maintain these changes at all? (if so probe how; if not probe why this might be).
6. You mention that the family have made some changes as a result of HeLP, please could you expand on these.
7. Are the family/you managing to maintain these changes?
8. Is there anything else you would like to say about HeLP in particular or healthy lifestyles in general.

Appendix 10: Teacher interview schedule

Thank you for agreeing to give a brief interview on your experience of your involvement in HeLP. Understanding your experience of HeLP is vital to the further development of the programme, so please feel free to be as frank as you wish! This interview will be relatively unstructured to allow you to just talk about your views and experiences of participating in the Programme. So that I can concentrate on what you are saying is it ok for me to record this interview? All your comments will remain anonymous and will only be used for the purposes of this research project.

1. How did you feel when you heard that your Y5 class was going to receive the Healthy Lifestyles Programme?
    a. Was there anything that made you anxious?
    b. Was there anything that you were excited about?
    c. Is there anything we could have done to allay any fears in the first instance?

2. Do you think it is necessary to have programmes like HeLP given everything else going on in schools?
    a. Probe added value – what makes HeLP distinct

3. Having been through the whole year 5 programme could you give us some indication of the workload/hassle factor?
    a. Has it added to your workload and, if so, in what way?
    b. What could we do differently to alleviate your workload?
    c. Probe how the PSHE lessons were received
    d. How much do the HeLP activities overlap with the year 5 curriculum? (try and get teachers to give a percentage overlap)

4. One of the key roles of the HeLP Coordinator is to build relationships with schools, children and families and especially to support you.
    a. Did you feel supported?
    b. Was there more we could have done?

5. How do you think the children found the Programme?
    a. How many drama sessions did you observe and what did you think?
    b. Did you notice any impact at a class/individual child level?
        i. Probe possible reasons for teacher observations re whole class or individual children (need to tease out what is it about HeLP that led to certain behaviours – programme differentiation)
        ii.
6. Do you think HeLP is known/understood in the wider school context?
    a. Probe examples

7. Do you have any sense of how parents perceived the Programme?

8. Have you used any aspect of HeLP in your day to day teaching and/or interactions with the children?

9. Had HeLP had any effect on you personally?

10. Would you recommend HeLP to your colleagues or other schools?

11. Is there anything else you would like to say/comment on?

Appendix 11: School Characteristics and Policies Questionnaire (SCPQ)

School: _____

Timepoint: _____

School Characteristics	
Number of pupils on roll	
Number of pupils eligible for FSM	
Number of pupils with EAL	
Number of pupils with SEN (School Action, School Action Plus, Statement)	
Number of children NOT White British	
Number of children in care	
PE time (in hours/week)	
County wide meal provision	
Independent meal provision	
Playing Field	
Gym or Hall	
Healthy school standard/HCQM	
PEDPASS or Active Lifestyle Award	
Daily Take 10 or equivalent	
Breakfast club	
School travel plan	
Provision of space for wet play	
Play equipment freely available	
Number of after school Physical Activity clubs	

Policies and Initiatives	
School Physical Activity policies/initiatives	
School Nutrition policies/initiatives	
Other school policies related to healthy lifestyles	

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