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The development, feasibility and acceptability of a school-based obesity prevention programme: Results from three phases of piloting.

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ABSTRACT

Objectives: To develop a school-based obesity prevention programme and evaluate the feasibility and acceptability of the intervention and the planned definitive cluster randomized trial.

Design: Three stage pilot involving six schools (395 children) in Southwest England, including an exploratory randomised controlled trial and qualitative interviews and focus groups with teachers, parents and children.

I**ntervention**: The Healthy Lifestyle Programme uses a range of activities including lessons, assemblies, parents' evenings, interactive drama workshops and goal setting to engage schools, children and their families.

Results: Of the 395 eligible children in the three pilot phases, only four opted out and a further three children withdrew from the exploratory trial. In the exploratory trial, baseline measures (anthropometric and behavioural) were obtained for 199/201 eligible children in 4 schools and both 18 and 24 month outcome measures for 193/199 participants and 190/193 respectively. Qualitative data show that delivery of the intervention is feasible within schools and acceptable to teachers, children and families. In the exploratory trial 17/77 (22%) in the intervention schools and 31/122 (25%) in the control schools were overweight or obese at baseline, increasing, at 18 months follow up, to 38/119 (32%) in the control schools compared with 18/74 (24%) in the intervention schools.

Conclusion: The Healthy Lifestyle Programme is feasible to deliver and acceptable to schools, children and their families. We recruited, retained and obtained outcome measures from virtually all eligible children in the exploratory trial, including measures taken after transition to secondary school suggesting that a definitive trial is likely to be deliverable.

Article focus

- To show the development and evaluation of a school-based obesity prevention programme through 3 stages of piloting
- To present evidence for the feasibility and acceptability of the HeLP Programme for schools, children and their families
- To present the evidence of the feasibility of the trial design and outcome measures through an exploratory trial involving 4 schools and 199 children.

Key messages

- The HeLP Programme has been systematically developed using an intervention mapping protocol and uses drama based activities to engage the school, children and their families
- The Programme has been piloted in six schools involving 395 children and results suggest that it is acceptable and feasible to schools, children and their families
- Results from the pilot phases have provided sufficient information to support the evaluation of the HeLP intervention in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process involving considerable stakeholder consultation and piloting. This has enabled the researchers to gain a deeper understanding of the context in which the intervention was to be delivered in order to maximize engagement at all levels. Preliminary results suggest the possibility that the Programme may affect behaviours associated with overweight and obesity.

Limitations: Interviews and focus groups were carried out by the lead researcher who had built up a relationship with the schools, children and their families. This may have affected responses as the participants might not have wanted to express negative opinions. However, the ongoing support and retention of the schools and children would suggest that if there was an effect, it was a very slight one.

Background

There has been a substantial increase in the proportion of children in the UK who are overweight [1]. The Health Survey for England (2007) reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and boys were overweight or obese [1]. The National Child Measurement Programme (2008/2009) reported that by age 10-11 years, school year 6, nearly one in three children were either overweight or obese [2]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes, and musculo-skeletal and psychological problems [3]. Over 50% of obese children become obese adults [4] with significant health consequences [5].

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 [6] and there are also strong associations, between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [7]. 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 [8].

The association with overweight and obesity and physical activity remains contested with cross sectional studies showing a reduction in levels and intensity of physical activity in children and an increase in % body fat [9]. Longitudinal studies are scarce, although recent data suggests that fatness leads to a reduction in physical activity rather than the other way round [10]. Some

studies have reported an association between time spent watching television and obesity [11]. Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [12] and the consumption of snack foods [13].

The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which increase activity and reduce sedentary behaviour may help children to maintain a healthy weight, although results were short-term and inconsistent [14]. The review also reported that trials of dietary interventions also produced inconsistent results, although the reviewers suggest that a combined approach may be more effective in preventing children becoming overweight in the long term.

The Healthy Lifestyle Programme (HeLP) is a school-based intervention which seeks to deliver healthy lifestyle messages and provide simple individually-tailored strategies to assist change relating to healthy activity and eating. HeLP takes a population approach seeking to change behaviour at a family as well as at an individual and institutional level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [15]; the stages of development were not linear, as each phase fed back into the development and refinement of the Programme. This paper reports on the iterative development and refinement of HeLP and presents results from, an initial development stage, a 'proof of concept' phase and preliminary results from an exploratory trial.

METHODS

The intervention: HeLP aims to deliver a general healthy lifestyle message relating to the energy balance. Within this context, three key messages are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks consumed and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the NICE guidance [16]. To avoid alienating families the messages are presented within an overarching "80:20 message", suggesting they should aim to maintain healthy behaviours "80%" of the time. An Intervention Mapping process [17] was undertaken to develop the individual components of the intervention and determine possible behaviour change techniques and implementation strategies, to be reported elsewhere.

Development and Evaluation Process

Phase 1 - Developing the intervention (2005-2006; One school; n=119 children, aged 8-11)

Following the Intervention Mapping process, we worked with children, parents and teachers from a single junior school to try candidate behaviour change approaches for different age groups. We delivered healthy lifestyle messages to three age groups, 8-9 year olds; 9-10 year olds and 10-11 year olds, using lessons and either drama or goal setting. Focus groups and semi-structured interviews were held with children and teachers. Parents were invited to complete a questionnaire about the study.

Phase 2 – Proof of Concept - Pilot of intervention and outcome measures (2006-2008; One school; n=77 children, aged 9-10)

Based on the results from the first phase, the intervention was further developed (figure 2) and evaluated in a second junior school, in an area of high social deprivation, with three Year 5 classes. Baseline and 6 week post-intervention height, weight, waist circumference, % body fat, objective physical activity, food intake and TV viewing/screen based activity were assessed. For the anthropometric measures children were asked to remove their shoes and socks. Height was measured using a portable SECA stadiometer (Hamburg, Germany) and recorded to an accuracy of 1mm. Weight and body fatness was measured using the Tanita SC330 portable body composition analyser (U.K. Ltd., Middlesex, U.K.).Weight was recorded to within 0.1kg. Body fatness was estimated from leg to leg bioelectrical impedance. Waist circumference was measured using a non-elastic flexible tape 4cm above the umbilicus.

Food intake was assessed using the adapted version of the Food Intake Questionnaire (FIQ) [18], an adapted recall method which asks whether specific foods were consumed the previous day. Children completed the FIQ twice in order to obtain a weekday and weekend food intake. These results were then combined and weighted to calculate the mean number of different healthy snacks, energy dense snacks; positive and negative foods consumed each day. TV viewing/screen based usage was assessed using the adapted version of the Children's TV Viewing Habits Questionnaire [19]. Participants were asked to record the time (in minutes) they usually spent watching TV or doing other leisure time screen-based activities on weekdays before school, before tea and after tea and on the weekend (Saturday and Sunday morning, afternoon and evening). The results were then combined and weighted to calculate the mean time spent watching TV/doing leisure time screen-based activities each day. To assess physical activity, children were asked to wear a GT1M Actigraph (Actigraph LLC, Pensacola,

FLhttp://www.theactigraph.com) during waking hours over seven consecutive days (5 weekdays and one weekend). Two focus groups (n=14) were held with children who 'engaged fully' (defined by enthusiasm for the study, desire to set and maintain goals) and a further focus group with those who appeared 'indifferent' to the study and the messages (n=4). Interviews were held with the staff and head teacher and parents of the children (n=7).

Phase 3 - Exploratory randomised controlled trial (2008-2010; 4 schools; n=201 children, aged 9-10)

Phase 3 sought to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the HeLP intervention and of future trial outcome measures and facilitators and barriers to the uptake of the intervention. All state Primary and Junior schools in Exeter were eligible to take part if they had at least one single age year 5 group (i.e. not year 4/5 or 5/6 mixed classes). Schools were recruited via the Devon Association of Primary Head teachers. Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity (as in phase 2) were collected prior to randomisation. These same measures were then collected 18 months post baseline and anthropometric measures only were collected 24 months post baseline which involved tracking the children to their secondary school. All anthropometric measures at each time point were taken by an independent assessor blind to allocation. Focus groups (children) and semi structured interviews (teachers and parents) have been conducted by the researchers in control and intervention schools.

RESULTS

Phase 1: Of the 120 children invited to participate, only one child opted out (Figure 1). Many parents reported in the questionnaire positive parent/family behaviour changes. Focus groups with children and teachers suggested that Year 5 (9-10 year olds) children were both receptive to the messages and more able and willing to translate them into possible behaviour changes and that drama and goal setting had the potential to work synergistically. Parents and children also highlighted the need for a greater variety of activities in the initial term.

Phase 2: The intervention was refined from the results of Phase 1 (Figure 2). No child opted out and no adverse events (e.g. feeling stigmatised) were reported by parents, teachers or children in questionnaires, focus groups or private discussions. Staff were enthusiastic about the Programme, in part because it met the National Curriculum guidelines for Personal Social Health Education (PHSE) and Citizenship, and importantly because they felt it promoted families' engagement with the school. Self-report questionnaires and accelerometry data suggested changes with respect to snacking and sedentary behavior. Detailed qualitative research (to be reported separately) with children and families suggested that they found the intervention acceptable, with a significant proportion of parents commenting that their family had made lifestyle changes. Teachers suggested additional activities for the next term to reinforce the messages and children suggested that they would like their parents to participate in the forum theatre.

Phase 3: The intervention was further refined (Figure 3). Eight schools expressed an interest in participating in this exploratory trial and four schools (seven classes) were randomly selected to take part.

Feasibility Measures

Of the 201 children eligible to participate, two opted out of the study. Baseline anthropometric measures, food intake and TV viewing/screen based activity were recorded for 199 children. We measured physical activity, using accelerometry, from one randomly selected class in each of the 4 participating schools. Measures were successfully obtained from 109/111. Numbers with useable data are presented in Table 1.

Prior to the 18 month post baseline measures, two children (control schools) had left the area and one child opted out (control school). Three girls in the same intervention school withdrew prior to the 18 month measures being collected; this coincided with the children being given a simple snacking and activity diary to complete over a 2 week period and feedback (teacher and parents) suggested this focused the girls too much on what they were eating and their parents felt they were restricting certain food groups.

Eighteen month post baseline measures have been collected from 193/199 children, with 107/111 children providing accelerometry data. Numbers with useable data are presented in Table 1. At collection of the twenty four month anthropometric data, one girl (control school) did not want to be measured and two children (both control schools) had moved out of the area, therefore data was obtained from 190/193 children (98%).

Baseline Data from the Exploratory trial

A quarter were classified as overweight or obese 22% (17/77) from the intervention school and 25% (31/122) from control schools. One child (intervention school) was classified as being underweight [20].

Food intake: The Food Intake Questionnaire data suggested that children consumed a mean of 4.15 (95% CI 3.85 to 4.44) different energy dense snacks (EDS) per day and a mean of 3.35 (95% CI 3.12 to 3.58) healthy snacks (HS). The mean number of different positive and negative food markers consumed each day was 7.45(95% CI 7.02 to 7.89) and 6.77(95% CI% 6.32 to 7.22) respectively.

TV viewing: Children's TV Viewing Habits questionnaire showed that mean daily time spent watching TV was 2.6 hours (95% CI 2.36-2.83). Fifty four percent of children had TVs in their bedrooms and 51% had no rules at home regarding the amount of TV/screen-based media they could watch/use.

Physical activity: Daily mean time spent in moderate to vigorous physical activity (MVPA) and sedentary activity was 43 minutes (95% CI 40.13-47.08) and 16 hours (95% CI 15.8-16.5) respectively.

Summary of 18 month post baseline data from the Exploratory trial

The proportion of overweight and obese children increased in the control schools from 25% (31/122) to 32% (38/119). The proportion of overweight and obese children in the intervention school rose very slightly from 22% (17/77) to 24% (18/74). Other anthropometric data and the

results from the questionnaires and accelerometry including 24 month follow up will be reported elsewhere.

Process evaluation

All children (n=77) in the intervention schools participated in the healthy lifestyle week and 90% set goals with their families around lifestyle change. Seventy five percent of parents have participated in one or more 'engagement' event. Detailed results from the interviews with parents (n=21) and teachers (n=11) and focus groups with the children (n=6) will be reported in detail elsewhere. In summary, parents were adamant their children's diet and activity choices were their responsibility but felt school was a good place to reinforce these messages. Parents reported a greater acceptance of rules relating to screen-time and healthy eating in their child as well as initiating discussion with other family members around healthy lifestyles.

Teachers agreed year 5 was the right target group as children are gaining independence whilst still amenable to the messages. Some commented that the intervention had boosted the children's self-esteem, had a positive effect on the class socially and created additional opportunities to link with parents. Teachers felt using young actors to deliver the messages was the key to achieving engagement with this age group. Children were unanimous in their enjoyment of the drama activities and equally unequivocal that these activities should be carried out by people external to the school. They did not comment on the weighing and measuring and when this was brought up in the focus groups, dismissed it as 'fine'. The key message the children remembered was the importance of replacing unhealthy snacks with more healthy alternatives and replacing screen-based activities with more active pursuits which they enjoy.

DISCUSSION

To date the evidence base for effective interventions to prevent and reduce childhood obesity is limited but suggests that a multi-component approach, addressing both sides of the energy balance and engaging families as well as the children, is more likely to be effective [14]. Using an intervention mapping protocol [17] we used a variety of methods (literature reviews, discussions with stakeholders and experts in behavioural science and obesity research) to create a programme of activities which aim to engage and change behaviours at a school, child and family level.

The Healthy Lifestyle Programme was further developed and refined through a series of pilot stages involving children, families and teachers. Throughout each pilot stage, qualitative and quantitative data was used to examine process as well as outcome. For each activity we attempted to assess the extent to which it promoted engagement of children and their families. Feedback in interviews as well as observation and informal discussions are strongly supportive of the Programme showing that the activities act synergistically to engage at all levels.

Finally we sought to determine whether our proposed trial design and the outcome measures are feasible and acceptable for the schools as well as the individual children and their families.

The baseline anthropometric data from Phase 3 is very similar to national figures reported in the Health Survey for England (2007) and the National Child Measurement Programme (NCMP) (2008/9). At 18 months, however, the percentage of overweight and obese children in the

control schools increased by 7%, mirroring the local NCMP data for 10-11 year olds in Exeter, whilst increasing by just 2% in the intervention schools. Although the exploratory trial was not powered to detect statistically significant differences between intervention and control schools, the finding that the proportions overweight and obese increased only slightly in the intervention schools is encouraging, particularly in light of recent tracking data showing a greatly increased odds of becoming obese in adolescence if the child was overweight in early childhood [21].

One of the key outcomes of interest was whether we had created a whole population approach and in particular whether overweight and obese children were happy and willing to participate. Only 4 of the 395 children invited to participate over the three phases of development opted out (two prior to baseline and one prior to the 18 month follow and one prior to the 24 month follow up measures). Two children had left the area prior to the 18 month and and further 2 had left the area prior to the 24 month follow up measures. Three girls from the same intervention class in phase 3 withdrew from the study. Prior to this no child had withdrawn. Following meetings with the class teacher and informal chats with parents we have decided to withdraw the food diary activity at the end of Year 6. This pilot work has, therefore, been invaluable in helping us understand the perspective of the school, child and family in developing the HeLP Programme.

Using the MRC framework for development and evaluation of complex interventions [15] we have developed a school-based programme to prevent and reduce obesity in children. We have demonstrated the feasibility and acceptability of the intervention and shown that it engages

children, schools and families. We have also demonstrated that we can recruit schools and children and collect baseline measures prior to randomisation. Retention of children has been excellent in all schools.

Results from these pilot stages have provided us with the necessary and sufficient information to suggest that the HeLP intervention should now be evaluated in a full-scale trial.

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Competing interests: None

Ethics approval: Ethical approval for each phase of the development and evaluation of the HeLP intervention was granted from the Peninsula College of Medicine and Dentistry Ethics Committee. This followed an approach to the NHS ethics committee who felt the study did not fall within their remit.

Author contribution: JL and KW drafted the manuscript with SC and SL providing critical revision. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention during pilot phases and conducted interviews with teachers and parents. JL and KW conducted the focus groups and with SL designed the study and obtained funding. KW will act as guarantor of the paper.

What is already known on this topic

There is little good quality evidence that existing interventions are effective in preventing and reducing childhood obesity

Interventions which aim to affect diet and activity seem to show more promise than those targeting either alone

What this study adds

The Healthy Lifestyle Programme is feasible to deliver and acceptable to children, their families and to teachers.

The intervention package engages staff, children and families and preliminary results suggest the possibility that it may affect behaviours associated with overweight and obesity.

The high levels of recruitment, retention and collection of outcome measures in the exploratory trial suggest that a definitive trial is deliverable.

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Table 1 – Feasibility Data (numbers of children (percentage))

Number of children participated/eligible	199/201 (98 %)
Baseline measures:	
Anthropometric	199/199 (100%)
Food Intake	199/199 (100%)
TV/screen viewing	199/199 (100%)
Physical activity (accelerometry)*	109/111 (98%)
Useable PA data – >=3 week days	104/111 (95%)
Complete useable PA data	93/111 (85%)
18 month follow-up:	
Lost to follow-up	3/199 (1.5%)
Withdrew	3/199 (1.5%)
18 month measures:	
Anthropometric	193/199 (97%)
Food Intake	193/199 (97%)
TV/screen viewing	193/199 (97%)
Physical activity (accelerometry)*	107/111 (96%)
Useable PA data – >=3 week days	95/107 (88%)
Complete useable PA data	83/107 (77%)
24 month follow up	
Lost to follow up	2/193 (1%)
Withdrew	1/193(0.5%)
24 month measures (only anthropometric taken)	
Anthropometric	190/193 (98%)

*One class randomly selected from each of the 4 schools

Table 2- Summary of Baseline Data

	All (n=199)	Male (n=100)	Female (n=99)
Anthropometric measures:			
% Overweight (≥85th and < 95th centile)[20]	8%	9%	6%
% Obese(≥95th centile)[20]	16%	18%	13%
% Overweight or Obese(≥85th centile)[20]	23%	27%	19%
% Underweight (≤2nd centile)[20]	0.5%	1%	0%
% with Bodyfat ≥85th centile[22]	-	21%	18%
% with Bodyfat ≥95th centile[22]	-	9%	11%
% with Bodyfat ≤2nd centile[22]	-	24%	18%
% with Waist Circumference ≥90th centile[23]	-	27%	34%
% with Waist Circumference ≥95th centile[23]	-	24%	24%
Mean (sd) BMI	17.6 (2.7)	17.5 (2.7)	17.8 (2.8)
Mean (sd) % Bodyfat	19.7 (6.7)	17.7 (6.4)	21.8 (6.5)
Mean (sd) Waist Circumference (cm)	62.3 (6.8)	62.6 (6.5)	62.3 (6.8)
Food Intake*(sd)			
Energy Dense Snacks (EDS)	4.15 (2.1)	4.02(2.1)	4.30 (2.0)
Healthy Snacks (HS)	3.35 (1.6)	3.29 (1.8)	3.41 (1.5)
Positive Food Markers (PM)	7.45 (3.1)	7.34 (3.0)	7.56 (3.2)
Negative Food Markers (NM)	6.77 (3.2)	6.72 (3.1)	6.81 (3.2)
TV/screen viewing (mean hours/day)			
TV viewing	2.6 (1.6)	2.49 (1.6)	2.7 (1.6)
% with TV in bedroom	54%	55%	53%
% with no rules re TV/screen	51%	52%	46%
Physical activity (mean time/day)			
Moderate-Vigorous PA/day (mins)	43 (17.8)	49.65 (17.0)	37.06 (16.5)
Sedentary Activities/day (hours)	16.2 (1.8)	16 (1.7)	16.4 (2.0)

*Refers to the number of different EDS/HS/PM/NM consumed in a day

Figure 1: Phase 1 – Development study (2005-2006).

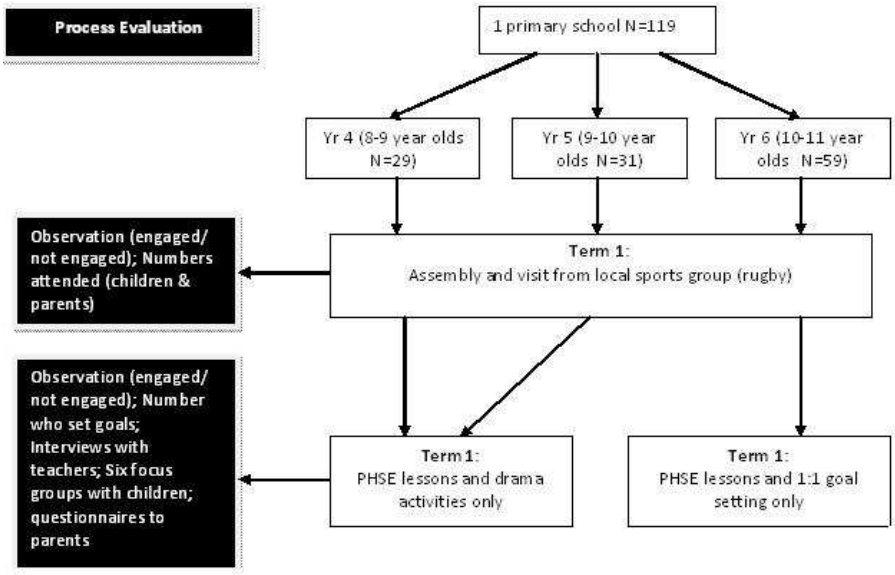


Figure 1
184x138mm (96 x 96 DPI)

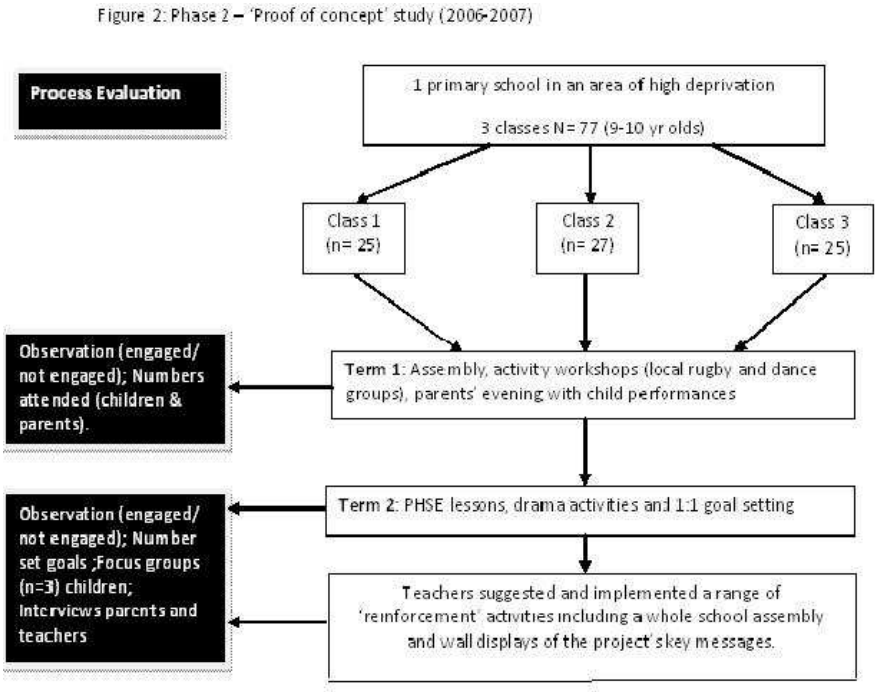
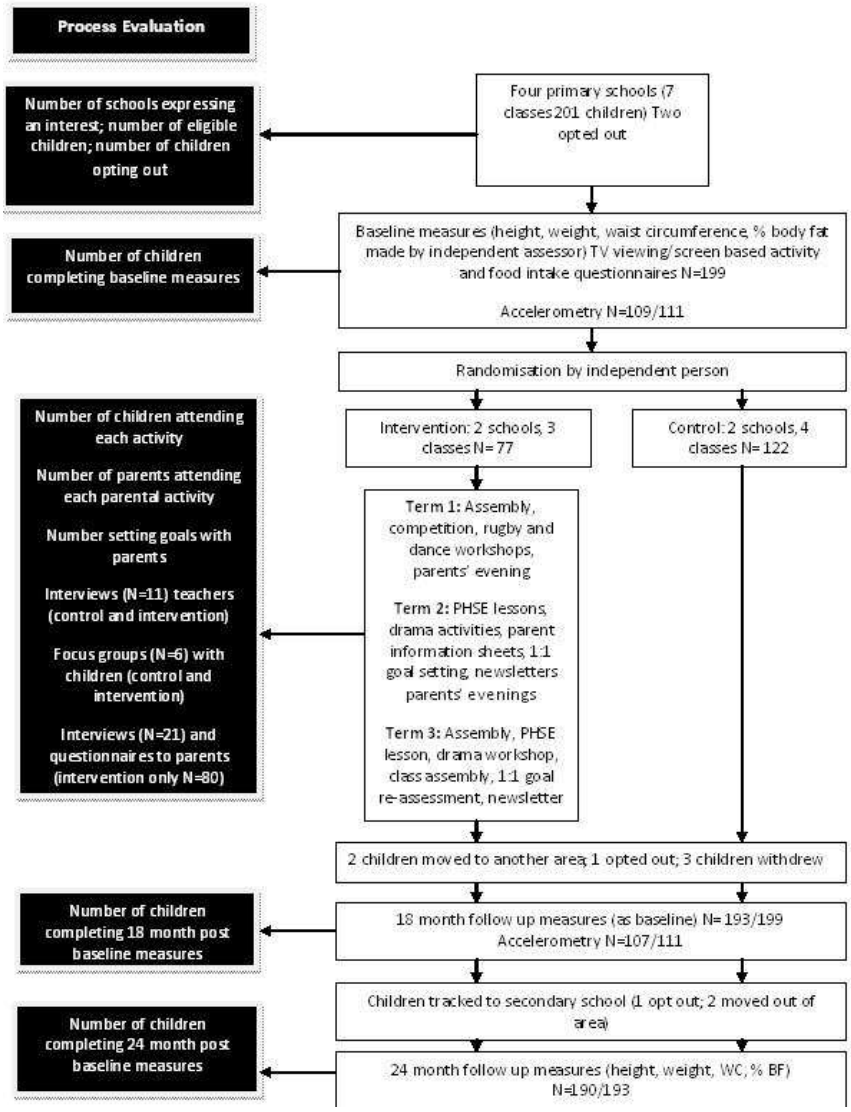


Figure 2
184x138mm (96 x 96 DPI)

Figure 3: Phase 3 – Exploratory trial 2008-2011



184x214mm (96 x 96 DPI)

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The development, feasibility and acceptability of a school-based obesity prevention programme: Results from three phases of piloting.

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ABSTRACT

Objectives: To develop a school-based obesity prevention programme and evaluate the feasibility and acceptability of the intervention and the planned definitive cluster randomized trial.

Design: Three stage pilot involving six schools (398 children) in Southwest England, including an exploratory randomised controlled trial and qualitative interviews and focus groups with teachers, parents and children.

I**ntervention**: The Healthy Lifestyle Programme uses a range of school-based activities including lessons, assemblies, parents' evenings, interactive drama workshops and goal setting to engage schools, children and their families.

Results: Of the 398 eligible children in the three pilot phases, only four opted out and a further three children withdrew from the exploratory trial. In the exploratory trial, baseline measures (anthropometric and behavioural) were obtained for 202/204 eligible children in 4 schools and both 18 and 24 month outcome measures for 193/204 participants and 187/204 respectively. Qualitative data show that delivery of the intervention is feasible within schools and acceptable to teachers, children and families. In the exploratory trial 18/80 children (24%) in the intervention schools and 31/122 (26%) in the control schools were overweight or obese at baseline, increasing, at 18 months follow up, to 38/119 (32%) in the control schools compared with 18/74 (24%) in the intervention schools. At 24 months the proportion of overweight and obese children in the control schools remained at 32% (36/114) whereas the proportion in the intervention schools decreased slightly to 22% (16/73).

Comment [j1]: Response to reviewer 3. Comment 3.3

Conclusion: The Healthy Lifestyle Programme is feasible to deliver and acceptable to schools, children and their families. We recruited, retained and obtained outcome measures from 92% of eligible children in the exploratory trial, including measures taken after transition to secondary school, suggesting that a definitive trial is likely to be deliverable.

Article focus

- To show the development and evaluation of a novel school-based obesity prevention programme through 3 detailed stages of piloting
- To present evidence for the feasibility and acceptability of the HeLP Programme for schools, children and their families
- To present the evidence of the feasibility of the trial design and outcome measures through an exploratory trial involving 4 schools and 202 children.

Key messages

- The HeLP Programme has been systematically developed and uses drama based activities to engage the school, children and their families in healthy lifestyle messages and activities
- The Programme has been piloted in six schools involving 398 children and results suggest that it is acceptable and feasible to schools, children and their families
- Results from the pilot phases have provided sufficient evidence to support the evaluation of the HeLP intervention in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process using research evidence, behavioral theory, stakeholder consultation and piloting. This has enabled the researchers to gain a deeper understanding of the context in which the intervention was to be delivered in order to maximize engagement at all levels. Preliminary results suggest the Programme may affect behaviours associated with overweight and obesity.

Limitations: Interviews and focus groups were carried out by the lead researcher who had built up a relationship with the schools, children and their families. This may have affected responses as the participants might not have wanted to express negative opinions. However, the ongoing support and retention of the schools and children would suggest that if there was such an effect, it was a very slight one. Piloting has taken place in schools in varying socioeconomic areas; and although, there is a limited ethnic mix of children in the South West of England, the drama framework has been specifically developed to allow flexibility and adaptation to ensure it is recognizing and responding to the needs of the children receiving it.

Comment [j2]: In response to comment from Reviewer 1.Comment 1.9

Background

There has been a substantial increase in the proportion of children in the UK who are overweight. The Health Survey for England (2007) reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and boys were overweight or obese [1]. The National Child Measurement Programme (2008/2009) reported that by age 10-11 years, school year 6, nearly one in three children in England were either overweight or obese [2]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes, and musculo-skeletal and psychological problems [3]. Over 50% of obese children become obese adults [4] with significant health consequences [5].

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 [6] and there are also strong associations, between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [7]. 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 [8].

The association with overweight and obesity and physical activity remains contested, with cross sectional studies showing a reduction in levels and intensity of physical activity in children and an increase in % body fat [9]. Longitudinal studies are scarce, although recent data suggests that fatness leads to a reduction in physical activity rather than the other way round [10]. Some studies have reported an association between time spent watching television and obesity [11].

Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [12] and the consumption of snack foods [13].

More recently community wide approaches to preventing and reducing obesity in children are being developed and evaluated [14, 15]. These initiatives take a multistrategy, multisite approach with school-based interventions forming part of the overall programme of events

Comment [j3]: Added in response to reviewer 1, comment 1.7 and reviewer 2, comment 2.2

The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which increase activity and reduce sedentary behaviour may help children to maintain a healthy weight, although results were short-term and inconsistent [16]. The review also reported that trials of dietary interventions also produced inconsistent results, although the reviewers suggest that a combined approach may be more effective in preventing children becoming overweight in the long term.

The Healthy Lifestyle Programme (HeLP) is a school-based intervention which seeks to deliver healthy lifestyle messages and provide simple individually-tailored strategies to assist change relating to healthy activity and eating. HeLP takes a population approach seeking to change behaviour at a family as well as at an individual and institutional level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [17]. This paper reports on the iterative development and refinement of HeLP, in accordance with the 'development' and the 'feasibility and piloting' processes of the MRC framework, and presents results from, an initial development phase, a 'proof of concept' phase and an exploratory trial.

Comment [j4]: Section strengethed in response to comments by reviewer 1, comment 1.9

Development, feasibility and piloting methods

The intervention was developed using an Intervention Mapping protocol [18] utilising research evidence, behavioural theory, extensive stakeholder consultation and piloting to develop key behavioural objectives for each target group (teachers, children and parents) and specific intervention techniques and strategies that linked directly to them. HeLP aims to deliver a general healthy lifestyle message relating to the energy balance and within this context, three evidence-based key messages are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks consumed and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the NICE guidance [19]. As a means of communicating these messages in a simple and easy to remember way we used a logo of '80/20', suggesting we should aim to eat healthily and be active 80% of the time. We hypothesised that this approach would enable children and their families to negotiate and have control over the choices they make; an important consideration in behaviour change [20]. Process evaluation methods during all three phases included semi structured interviews with staff and parents, focus groups with children, questionnaires responses from children and parents, documentation of child, parental and staff involvement and observation of intervention delivery.

Comment [j5]: Additional detail provided in response to Reviewer 1, comment 1.2

Comment [j6]: Additional detail provided in response to Reviewer 1 comment ,1.2 and reviewer 3, comments 3.5 and 3.6

Phase 1 - Assess range of delivery methods for key objectives identified in the intervention mapping process (2005-2006; One school; n=119 children, aged 8-11)

We worked with children, parents and teachers from a single primary school to try candidate behaviour change approaches for different age groups. We delivered healthy lifestyle messages

to three age groups, 8-9 year olds; 9-10 year olds and 10-11 year olds, using lessons and either interactive drama activities or goal setting (figure 1). Six focus gro two for each year group, n=33) were held with the children to ascertain views on activities and what messages and concepts they remembered. Children whose parents consented to the focus groups were randomly selected to participate. Semi-structured interviews were held with teachers (n=6) and parents were invited to complete a questionnaire about the study.

Comment [j7]: Further detail on numbers involved in the focus groups. Response to Reviewer 3, comment 3.1 and 3.5.

Phase 2 – Proof of Concept - Pilot of intervention and outcome measures (2006-2008; One school; n=77 children, aged 9-10)

Based on the results from the first phase, the intervention was further developed (figure 2) and evaluated in a second primary school, in an area of high social deprivation, with three Year 5 classes. Baseline and 6 week post-intervention height, weight, waist circumference, % body fat, objective physical activity, food intake and TV viewing/screen based activity were assessed. Food intake was assessed using the adapted version of the Food Intake Questionnaire (FIQ) [21], an adapted recall method which asks whether specific foods were consumed the previous day. Children completed the FIQ twice in order to obtain a weekday and weekend food intake.TV viewing/screen based usage was assessed using the adapted version of the Children's TV Viewing Habits Questionnaire [22]. To assess physical activity, children were asked to wear a GT1M Actigraph (Actigraph LLC, Pensacola, FLhttp://www.theactigraph.com) during waking hours over seven consecutive days (5 weekdays and one weekend). Two focus groups (a total of 14 children) were held with children who 'engaged fully' (defined by enthusiasm for the study, desire to set and maintain goals) and a further focus group with those who appeared

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'indifferent' (reluctant to take part in activities, needed several prompts regarding goals or did not want to set goals) to the study and the messages (n=4). Interviews were held with the staff (n=3) and head teacher (n=1) and parents of the children (n=5). Parents were also invited to complete a questionnaire about the study.

Comment [j8]: Additional information provided regarding the focus group. Response to Reviewer 3, comments 3.1, 3.5 and 3.10.

Phase 3 - Exploratory randomised controlled trial (2008-2010; 4 schools (7 classes); n=204 children, aged 9-10)

Phase 3 sought to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the HeLP intervention and of future trial outcome measures and facilitators and barriers to the uptake of the intervention. All state Primary schools in Exeter were eligible to take part if they had at least one single age year 5 group (i.e. not year 4/5 or 5/6 mixed classes). Schools were recruited via the Devon Association of Primary Head teachers. Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity (as in phase 2) were collected prior to randomization (two control and two intervention schools). These same measures were then collected 18 months post baseline and anthropometric measures only were collected at 24 months post baseline which involved tracking the children to their secondary school (figure 3). All anthropometric measures at each time point were taken by an independent assessor blind to allocation. Six focus groups across the 4 schools (a total of 38 children) were carried out from a selection of children whose parents gave consent (groups were purposefully sampled to reflect gender mix and weight status) and semi structured

interviews were conducted with staff (n=9) and parents (n=17) in control and intervention schools.

Comment [j9]: Additional information provided regarding the focus group. Response to Reviewer 3, comments 3.1, 3.5 and 3.10.

RESULTS

Phase 1: Of the 120 children invited to participate, only one child opted out (Figure 1).

Us[illegible]ws: Many parents reported in the questionnaire positive parent/family behaviour changes and qualitative data from teachers, children and their parents suggested that Year 5s (9-10 year olds) were more receptive to the messages and more able and willing than the year 4s and 6s to translate them into possible behaviour changes. In addition, it appeared that this year group engaged their families to the greatest extent. Teachers thought that the education lessons should be taught consecutively over one week to maintain momentum and that the drama and goal setting had the potential to work synergistically by engaging the children through the drama and following this up with encouraging the children, with their parents support, to make changes through setting simple goals. Parents and children also highlighted the need for a greater variety of activities to introduce the key messages and concepts in order to engage both boys and girls.

Implications: In order to build a trusting relationship, a range of activities were developed to introduce the school, children and their families to the project's key messages. A 'Healthy Lifestyles Week' was developed consisting of education lessons in the morning (delivered by teachers) which dovetailed with interactive drama activities in the afternoon (delivered by a local drama group). In order to guide the sequential development of the intervention components across the school year, key performance objectives, developed using an intervention mapping process [23], were mapped onto the Health Action Process Model (HAPA) of behaviour change that suggests behaviour change occurs through a sequence of adoption

(establish motivation), initiation (take action) and maintenance (stay motivated) processes [24]. The intervention components at this stage of development were: creating a receptive environment, a healthy lifestyles week and goal setting with year 5 children (9-10 year olds) as the target group.

Comment [j10]: More detail provided on the outcome of each phase and the implications for the subsequent phase. Response to reviewers 1, comment 1.1 and 1.3 and reviewer 3, comment 3.2.

Phase 2: No child opted out (figure 2) and no adverse events (e.g. child feeling stigmatised) were reported by parents, teachers or children in questionnaires, focus groups or individual discussions. Self-report questionnaires and accelerometry data from the children suggested changes with respect to snacking and sedentary behavior.

User views: Staff were enthusiastic about the Programme, in part because it met the National Curriculum guidelines for Personal Social Health Education (PHSE) and Citizenship, and importantly because they felt it promoted families' engagement with the school. Some teachers felt that the drama had a positive effect on the self esteem of the children, particularly those with additional learning needs. Some teachers suggested further activities for the subsequent term to reinforce the messages and refocus the children and their parents on their goals. Many parents reported that their family had made lifestyle changes and that their child was willing to try new foods. The children enjoyed the drama activities and felt that they could relate to the characters within the drama framework who made them more motivated to set their own goals. Some children reported that they had started going to more after school clubs.

Implications: An additional component was added to the intervention - 'reinforcement activities' to take place at the beginning of year 6, to motivate children to stick to their goals. In addition, minor refinements were made to the education lessons and the drama scripts to

enhance delivery and continuity. Table 1 shows the final intervention components, how they relate to the HAPA model with their associated methods and agents of delivery.

Comment [j11]: More detail provided on the outcome of each phase and the implications for the subsequent phase. Response to reviewers 1, comment 1.1 and 1.3 and reviewer 3, comment 3.2.

Phase 3: Eight schools expressed an interest in participating in this exploratory trial and four schools were randomly selected to take part.

Feasibility data

Of the 204 children eligible to participate, two opted out of the study (figure 3). Baseline anthropometric measures, food intake and TV viewing/screen based activity were recorded for 202 children. We measured physical activity, using accelerometry, from one randomly selected class in each of the 4 participating schools. Measures were successfully obtained from 109/111 with 95% (104/111) of children providing useable data (3 good weekdays and one weekend day). Prior to the 18 month post baseline measures, five (2 control and 3 intervention) children had left the area and one child opted out (control school). Three girls in the same intervention school withdrew prior to the 18 month measures being collected; this coincided with the children being given a simple snacking and activity diary to complete over a 2 week period and feedback (teacher and parents) suggested this focused the girls too much on what they were eating and their parents felt they were restricting certain food groups.

Eighteen month post baseline measures were collected from 193/204 children, with 107/111 children providing accelerometry data of which 85% (95/111) was useable. At collection of the twenty four month anthropometric data, one girl (control school) did not want to be measured

and five children (3 control, 2 intervention) had moved out of the area, therefore data was obtained from 187/204 children, 92% of the original cohort.

Summary of anthropometric baseline data from the exploratory trial

In the intervention schools, 24% (18/80) of children were classified as overweight or obese compared to 26% (31/122) in the control schools. One child (intervention school) was classified as being underweight [25]. Mean BMI was 17.6 (2.7) (95% CI 17.27 to 18.02). Almost 20% (39/202) had a % body fat ≥ the 85th centile [26] and 43% (86/202) had a waist circumference ≥ the 85th centile [27]. Table 2 summarizes child demographics and BMI status for the two groups.

Process evaluation of the Exploratory Trial

All children (n=80) in the intervention schools participated in the healthy lifestyle week and 90% set goals with their families around lifestyle change. Seventy five percent of parents participated in one or more programme activity.

User Views: Parents were adamant their children's diet and activity choices were their responsibility but felt school was a good place to reinforce these messages. Parents reported a greater acceptance of rules relating to screen-time and healthy eating in their child as well as initiating discussion with other family members around healthy lifestyles.

Teachers agreed year 5 was the right target group as children are gaining independence whilst still amenable to the messages. Some commented that the intervention had boosted the children's self-esteem, had a positive effect on the class socially and created additional

Comment [j12]: Amended in response to reviewer 1, comment 1.5.

Comment [j13]: Deleted in response to reviewer 1, comment 1.6

Deleted: *Food intake*: The Food Intake Questionnaire data suggested that children consumed a mean of 4.2 (95% CI 3.85 to 4.44) different energy dense snacks (EDS) per day and a mean of 3.4 (95% CI 3.12 to 3.58) healthy snacks (HS). The mean number of different positive and negative food markers consumed each day was 7.5 (95% CI 7.02 to 7.89) and 6.8 (95% CI 6.32 to 7.22) respectively. ¶
TV viewing: Children's TV Viewing Habits questionnaire showed that mean daily time spent watching TV was 2.6 hours (95% CI 2.36 to 2.83). Fifty four percent of children had TVs in their bedrooms and 51% had no rules at home regarding the amount of TV/screen-based media they could watch/use. ¶
Physical activity: Daily mean time spent in moderate to vigorous physical activity (MVPA) and sedentary activity was 44 minutes (95% CI 40.13-47.08) and 16 hours (95% CI 15.8 to 16.5) respectively

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opportunities to link with parents. Teachers felt using young actors to deliver the messages was the key to achieving engagement with this age group.

Children were unanimous in their enjoyment of the drama activities and equally unequivocal that these activities should be carried out by people external to the school. They did not comment on the weighing and measuring and when this was brought up in the focus groups, dismissed it as 'fine'. The key message the children remembered was the importance of replacing unhealthy snacks with more healthy alternatives and replacing screen-based activities with more active pursuits which they enjoy.

Implications: Following the withdrawal of 3 girls from an intervention class, the snacking and activity diary activity has been withdrawn from component 4 (reinforcement activities). The education lessons were refined to include more self monitoring activities for the children within the school and home environment in order keep the children focused on their goals in year 6.

Comment [j14]: Detail provided on the the implications from the exploratory trial Response to reviewers 1, comments 1.1 and 1.3 and reviewer 3, comment 3.2

Summary of 18 and 24 month post baseline anthropometric data from the Exploratory trial

At 18 months, the proportion of overweight and obese children increased in the control schools from 26% (31/122) to 32% (38/119) but remained at 24% (18/74) in the intervention schools. At 24 months the proportion of overweight/obese children remained at 32% (36/114) in the control schools and decreased slightly to 22% (16/73) in the intervention schools. Other anthropometric data and the results from the questionnaires and accelerometry will be reported elsewhere**DISCUSSION**

Comment [j15]: Substantial rewrite based on comments by reviewer 1 and 2 and 3.

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To date the evidence base for effective interventions to prevent and reduce childhood obesity is limited but suggests that a multi-component approach, addressing both sides of the energy balance and engaging families as well as the children, is more likely to be effective [16]. Using an intervention mapping protocol [18, 23] involving literature reviews, extensive stakeholder consultation, expert workshops and three stages of piloting, we have created a programme of activities to engage and change behaviours at a school, child and family level. Such an intervention could also form part of a wider community approach to tackling obesity such as the programmes described in 'Romp and Chomp' and 'Being Active, Eating Well' [15, 14]. Unlike previous school-based interventions [18, 29], HeLP activities have been ordered to promote and support behaviour change in children and their families using the HAPA model [24].Component 1 seeks to establish motivation and create a receptive context for the 'Healthy Lifestyles Week' (component 2). This component seeks to further motivate the children by building their confidence and skills and helping them make decisions. We worked closely with a local theatre company to design a drama framework built around 4 characters, each played by one of the actors whose attributes relate to our healthy lifestyle messages. Children have to choose which character they most resemble and then work with that character to help them change their behaviour. The actors became role models as they worked with the children in a range of interactive activities such as food tasting, making adverts, looking at ingredients and role play. The rationale for using the drama and the young actors as role models was to enthuse the children so much that they took the messages home to their parents and families and, crucially, encouraged them to come into the school and engage with the Programme. Previous research has suggested that low income parents may be more likely to attend an event in which their

Comment [j16]: Added in response to reviewer 2, comment 2.4.

children are participants than an educational event, (e.g. eating and joint parent-child classes) [30]. Qualitative data revealed that the dynamic nature of the drama and the use of the young actors did indeed engage the children to such an extent that they talked exuberantly about the Programme with their parents and siblings and encouraged them to attend events, particularly if they were going to be performing with the actors. Interestingly, it was the year 5s (9-10 year olds) who were best able to engage their families and translate the messages into possible behavior change which is why we decided to focus on this age group in subsequent pilots. The role play activities allowed us to teach the children how to communicate the healthy lifestyle messages to their family and seek their support in a subtle and positive manner. Component 3 moves the children on to helping them create an action plan and implement their goals with the support of their parents and component 4 helps them to remain motivated by delivering a range of reinforcement activities to monitor, assess and adapt their goals. Full details of each intervention component and their associated behaviour change techniques and methods of delivery are reported elsewhere [23].

Comment [j17]: Added in response to reviewer 1, comment 1.7 and reviewer 3, comment 3.7 and 3.9.

One of the aims of the intervention was to explicitly affect the whole school environment by engaging all staff using staff meetings, whole school assemblies, competitions and parents evenings. During the Healthy Lifestyles Week, the year 5 teachers delivered the pre prepared education lessons in the morning and then observed the theatre company deliver the interactive drama activities in the afternoon. Feedback from interviews and informal discussions with the teachers suggested that the observation of the drama led to an increase in their understanding and motivation which, in turn, led to greater support for, and involvement in, the Programme. After pilot 2, teachers and the head developed further activities relating to

the healthy lifestyle messages after we had trialled the original ideas, which lead to the addition of component 4. The HeLP intervention has been specifically designed so that it can be adapted for use in different types of schools, increasing its generalisability, whilst still remaining standardized enough to maintain fidelity. The activities within the Prograame dovetail with the National Curriculum objectives for this age group. The drama framework is based around 4 characters with whom the children identify and these can be adapted for schools in a variety of different settings. In addition, the children drive the drama scenes as this is key to engagement and encouraging ownership of the healthy lifestyle messages. HeLP has been piloted in a range of schools with children from different socio-economic groups and we have found no difference in the levels of engagement and parental involvement. One limitation, however, is that there is little ethic mix in schools in Exeter, but we would argue that the drama framework can be adapted to accommodate this.

Comment [j18]: Amended in response to reviewer 3, comment 3.4

Comment [j19]: Amended in response to reviewer 1, comment 1.8 and reviewer 3, comment 3.4.

Comment [j20]: Added in response to reviewer 1, comment 1.8.

As well as seeking to develop a novel and adaptable intervention that engages schools, children and their families we sought to determine whether our proposed trial design and outcome measures are feasible and acceptable for schools as well as individual children and their families. The baseline anthropometric data from Phase 3 is very similar to national figures reported in the Health Survey for England (2007) and the National Child Measurement Programme (NCMP) (2008/9). At 24 months, however, the percentage of overweight and obese children in the control schools increased by 6%, mirroring the local NCMP data for 10-11 year olds in Exeter, whilst decreasing by 2% in the intervention schools. Although the exploratory trial was not powered to detect statistically significant differences between intervention and control schools, the finding that the proportions overweight and obese remained at baseline

levels in the intervention schools is encouraging, particularly in light of recent tracking data showing that the greatest increases in weight in a non obese sample are between the ages of 7 and 11 years [31].

Comment [j21]: Clarified in response to reviewer 2, comment 2.1

Using the MRC framework for development and evaluation of complex interventions [17] we have developed and refined a novel school-based programme to prevent and reduce obesity in children. We have demonstrated the feasibility and acceptability of the intervention and shown that it engages children, schools and families. We have also demonstrated that we can recruit schools and children and collect baseline measures prior to randomisation. Retention of children has been excellent with very few losses to follow up at secondary school. Results from these pilot stages have provided us with the necessary and sufficient information to suggest that the HeLP intervention should now be evaluated in a full-scale trial.

Acknowledgements: The authors are very grateful to the participating schools, children and their families who gave up their time for the study. We would also like to acknowledge Sandy Akerman (Headbangers Theatre Company) who supported the design of the drama component of the intervention.

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expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests: None

Ethics approval: Ethical approval for each phase of the development and evaluation of the HeLP intervention was granted from the Peninsula College of Medicine and Dentistry Ethics Committee. This followed an approach to the NHS ethics committee who felt the study did not fall within their remit.

Author contribution: JL and KW drafted the manuscript with SC and SL providing critical revision. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention during pilot phases and conducted interviews with teachers and parents. JL and KW conducted the focus groups and with SL designed the study and obtained funding. KW will act as guarantor of the paper.

What is already known on this topic

There is little good quality evidence that existing interventions are effective in preventing and reducing childhood obesity.

Interventions which aim to affect both diet and activity seem to show more promise than those targeting either alone.

What this study adds

The Healthy Lifestyle Programme uses behavioural theory and novel interactive delivery methods to create the conditions to enable and support sustainable changes in behaviour for children and their families.

The Healthy Lifestyle Programme is feasible to deliver within the context of the National Curriculum at Key Stage 2 and acceptable to children, their families and schools.

Comment [j22]: Further developed in response to reviewer 2, comment 2.3.

The intervention package engages staff, children and families and preliminary results suggest the possibility that it may affect behaviours associated with overweight and obesity.

The high levels of recruitment, retention and collection of outcome measures in the exploratory trial suggest that a definitive trial is deliverable.

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Table Intervention components, processes of behaviour change and methods of delivery

Component	Process of Behaviour change	Method of delivery	Delivered by
Component 1 Engaging schools, children & families Spring term (Yr 5)	Establish motivation and create a receptive environment	Whole school assembly Activity workshops (parents observe) Parents' evening (involving performances by the children) Newsletter articles	Researcher Professional sportsmen/dancers Teachers/Researcher/Drama group Researcher
Component 2 Intensive Healthy Lifestyles Week – one week Summer term (Yr 5)	Establish motivation by developing children's confidence and skills and helping them make decisions	PSHE lessons (morning) §Drama (afternoon) (forum theatre; role play; food tasting, discussions, games etc)	Class teacher Drama group
Component 3 Goal Setting - goals set during week following drama Summer term (Yr 5)	Take action by helping children create an action plan and implement goals.	Questionnaire to enable children to reflect on snacking, consumption of fizzy drinks and physical activity. Goal setting sheet to go home to parents to complete with child. 1:1 goal setting interview (goals sent home to parents) Parent's evening (child involvement – Forum Theatre)	Researcher/class teacher Researcher/parents Researcher Researcher/Drama group
Component 4 Reinforcement activities Autumn term (Yr 6)	Stay motivated by helping children to monitor, assess and adapt goals	Whole school assembly followed by drama workshops to remind school/children of messages and to prepare class assembly PSHE lesson to remind children of messages and goals.	Drama group

		Children monitor goals on personalised chart Class to deliver assembly about the project to rest of school (parents invited to attend) 1:1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (renewed goals sent home to parents) Newsletter articles	Class teacher Class teacher provided prompts Children to all other year groups in the school Researcher Researcher

§The drama framework includes 4 characters, each represented by one of the actors, whose attributes related to the three healthy lifestlye messages (overall behavioural objectives). Children choose which of the characters they most resemble then work with that actor to help the character learn to change their behaviour

Comment [j23]: Table added to provide clarity on the components of the intervention, methods of delivery and who delivers them. Response to reviewers 1 and 3.

Table Baseline characteristics of children

	Intervention (n=80)	**Control** (n=122)	**Total** (n=202)
Demographics			
Age, years, mean (SD)	9.69 (0.3)	9.69 (0.3)	9.69 (0.3)
Sex % (n) Male % (n) Female	 50 (40) 50 (40)	 50 (61) 50 (61)	 50 (101) 50 (101)
Anthropometric Measures			
% (n) Overweight or Obese(≥85th centile)[20]	23.7 (18)	26.1 (31)	25.1 (49)
Mean (sd) BMI [range]	17.44 (2.6) [13.3 to 25.4]	17.89 (2.8) [13.7 to 25.1]	17.65 (2.7) [13.3 to 25.4]
Mean (sd) BMI sds [range]	0.3 (1.1) [-2.3 to 2.5]	0.4 (1.1) [-2.0 to 2.9]	0.3 (1.1) [-2.3 to 2.9]

Comment [j24]: Table altered in response to reviewer 1, comment 1.3.

March 9th 2011

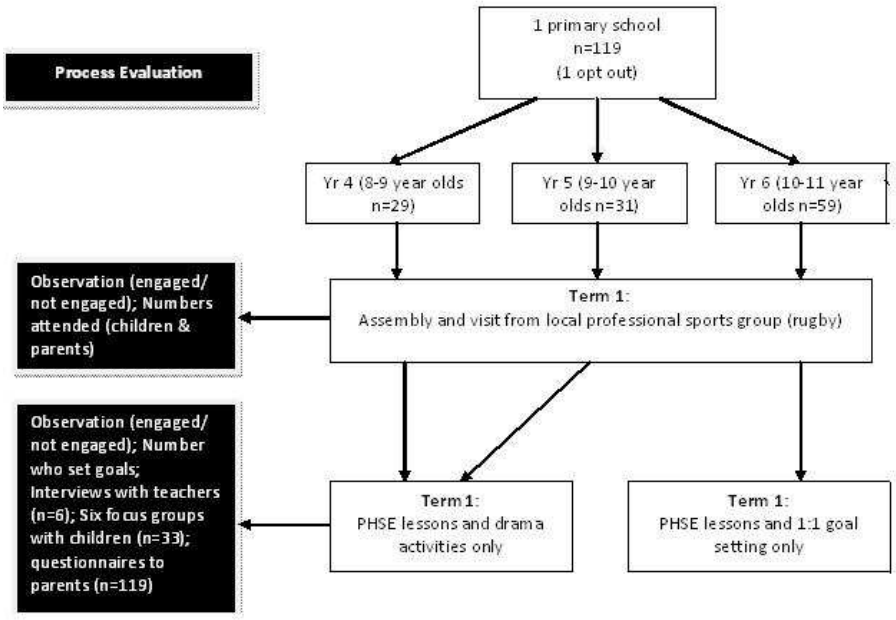
Dear Zara,

As yet, no appropriate checklist has been created for the reporting of studies showing the development, feasibility and acceptability of interventions. Even the STROBE checklist has many sections that are not applicable, so as you suggest, I have not uploaded a checklist from the ones provided.

Best Wishes

Jennifer Lloyd

Figure 1: Phase 1 – Development study (2005-2006).



Phase 1 - Development study (2005-2006)
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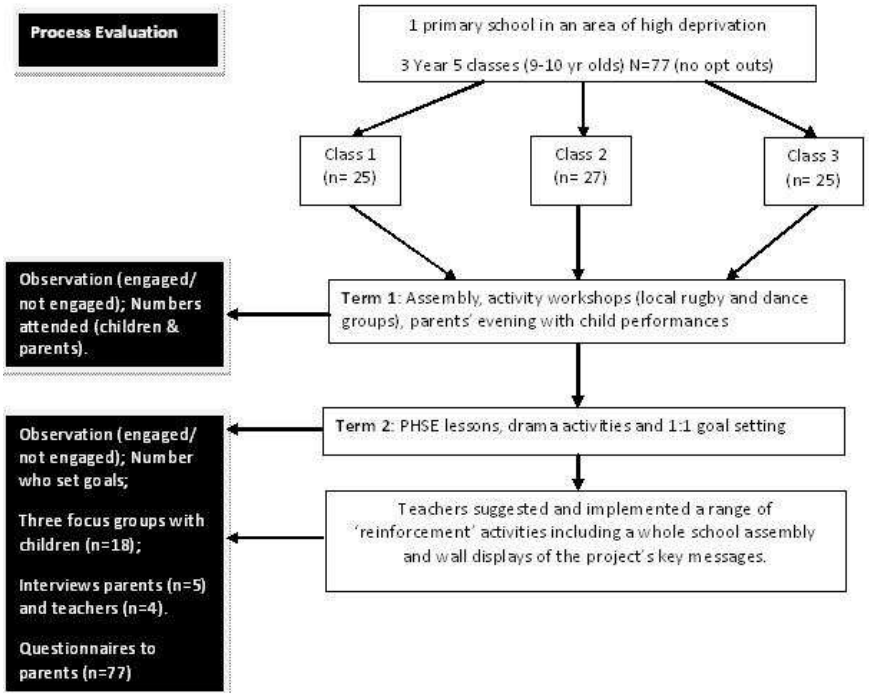
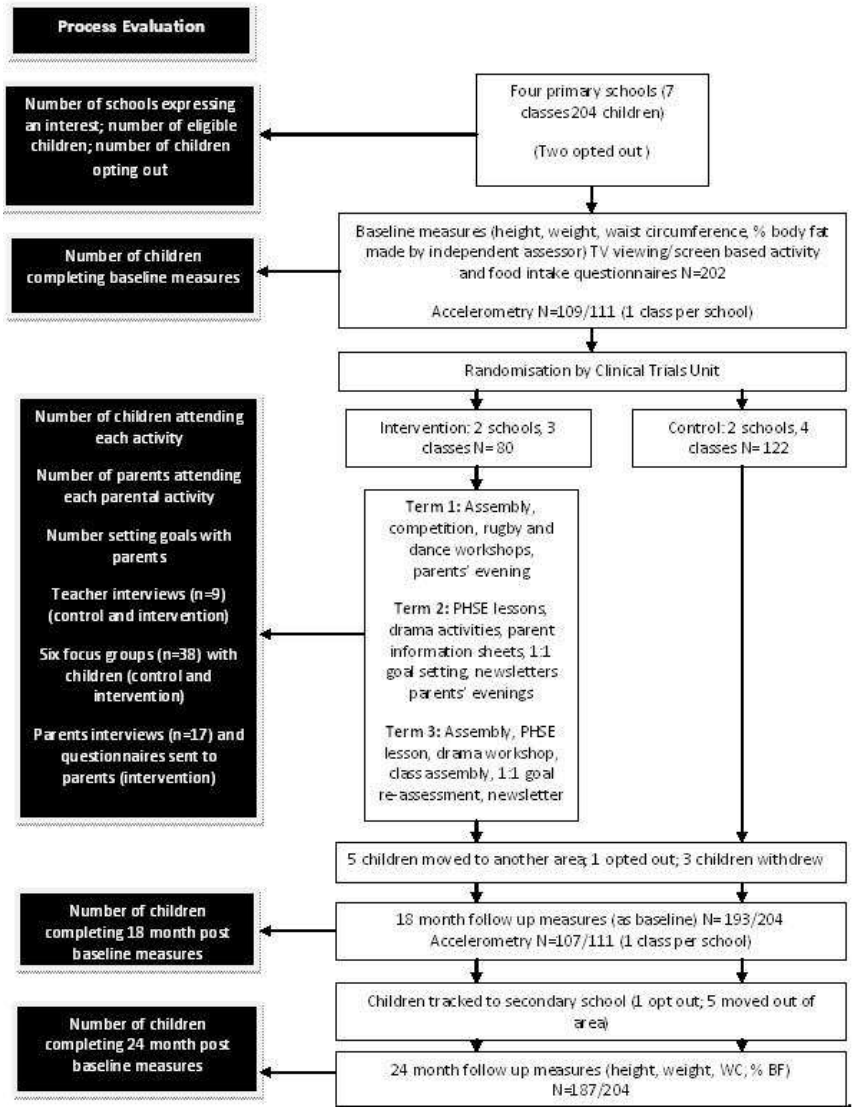
Figure 2: Phase 2 – 'Proof of concept' study (2006-2007)



Phase 2 - 'Proof of concept' study (2006-2007)
184x138mm (96 x 96 DPI)

Figure 3: Phase 3 – Exploratory trial 2008-2010



Phase 3 - Exploratory randomised controlled trial (2008-2010)
184x214mm (96 x 96 DPI)

BMJ open

The development, feasibility and acceptability of a school-based obesity prevention programme: Results from three phases of piloting.

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Subject Heading:	Public health
Keywords:	Child, Obesity, Intervention, Feasibility Study, Health Behaviours, Exploratory trial

The development, feasibility and acceptability of a school-based obesity prevention programme: Results from three phases of piloting.

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Key words: Child, obesity, intervention, feasibility study, health behaviours, exploratory trial

Word count: 3,736

ABSTRACT

Objectives: To develop a school-based obesity prevention programme and evaluate the feasibility and acceptability of the intervention and the planned definitive cluster randomized trial.

Design: Three stage pilot involving six schools (398 children) in Southwest England, including an exploratory randomised controlled trial and qualitative interviews and focus groups with teachers, parents and children.

I**ntervention**: The Healthy Lifestyle Programme uses a range of school-based activities including lessons, assemblies, parents' evenings, interactive drama workshops and goal setting to engage schools, children and their families.

Results: Of the 398 eligible children in the three pilot phases, only four opted out and a further three children withdrew from the exploratory trial. In the exploratory trial, baseline measures (anthropometric and behavioural) were obtained for 202/204 eligible children in 4 schools and both 18 and 24 month outcome measures for 193/204 participants and 187/204 respectively. Qualitative data show that delivery of the intervention is feasible within schools and acceptable to teachers, children and families. In the exploratory trial 18/80 children (24%) in the intervention schools and 31/122 (26%) in the control schools were overweight or obese at baseline, increasing, at 18 months follow up, to 38/119 (32%) in the control schools compared with 18/74 (24%) in the intervention schools. At 24 months the proportion of overweight and obese children in the control schools remained at 32% (36/114) whereas the proportion in the intervention schools decreased slightly to 22% (16/73).

Conclusion: The Healthy Lifestyle Programme is feasible to deliver and acceptable to schools, children and their families. We recruited, retained and obtained outcome measures from 92% of eligible children in the exploratory trial, including measures taken after transition to secondary school, suggesting that a definitive trial is likely to be deliverable.

Article focus

- To show the development and evaluation of a novel school-based obesity prevention programme through 3 detailed stages of piloting
- To present evidence for the feasibility and acceptability of the HeLP Programme for schools, children and their families
- To present the evidence of the feasibility of the trial design and outcome measures through an exploratory trial involving 4 schools and 202 children.

Key messages

- The HeLP Programme has been systematically developed and uses drama based activities to engage the school, children and their families in healthy lifestyle messages and activities
- The Programme has been piloted in six schools involving 398 children and results suggest that it is acceptable and feasible to schools, children and their families
- Results from the pilot phases have provided sufficient evidence to support the evaluation of the HeLP intervention in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process using research evidence, behavioral theory, stakeholder consultation and piloting. This has enabled the researchers to gain a deeper understanding of the context in which the intervention was to be delivered in order to maximize engagement at all levels. Preliminary results suggest the Programme may affect behaviours associated with overweight and obesity.

Limitations: Interviews and focus groups were carried out by the lead researcher who had built up a relationship with the schools, children and their families. This may have affected responses as the participants might not have wanted to express negative opinions. However, the ongoing support and retention of the schools and children would suggest that if there was such an effect, it was a very slight one. Piloting has taken place in schools in varying socioeconomic areas; and although, there is a limited ethnic mix of children in the South West of England, the drama framework has been specifically developed to allow flexibility and adaptation to ensure it is recognizing and responding to the needs of the children receiving it.

Background

There has been a substantial increase in the proportion of children in the UK who are overweight. The Health Survey for England (2007) reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and boys were overweight or obese [1]. The National Child Measurement Programme (2008/2009) reported that by age 10-11 years, school year 6, nearly one in three children in England were either overweight or obese [2]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes, and musculo-skeletal and psychological problems [3]. Over 50% of obese children become obese adults [4] with significant health consequences [5].

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 [6] and there are also strong associations, between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [7]. 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 [8].

The association with overweight and obesity and physical activity remains contested, with cross sectional studies showing a reduction in levels and intensity of physical activity in children and an increase in % body fat [9]. Longitudinal studies are scarce, although recent data suggests that fatness leads to a reduction in physical activity rather than the other way round [10]. Some studies have reported an association between time spent watching television and obesity [11].

Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [12] and the consumption of snack foods [13].

More recently community wide approaches to preventing and reducing obesity in children are being developed and evaluated [14, 15]. These initiatives take a multistrategy, multisite approach with school-based interventions forming part of the overall programme of events

The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which increase activity and reduce sedentary behaviour may help children to maintain a healthy weight, although results were short-term and inconsistent [16]. The review also reported that trials of dietary interventions also produced inconsistent results, although the reviewers suggest that a combined approach may be more effective in preventing children becoming overweight in the long term.

The Healthy Lifestyle Programme (HeLP) is a school-based intervention which seeks to deliver healthy lifestyle messages and provide simple individually-tailored strategies to assist change relating to healthy activity and eating. HeLP takes a population approach seeking to change behaviour at a family as well as at an individual and institutional level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [17]. This paper reports on the iterative development and refinement of HeLP, in accordance with the 'development' and the 'feasibility and piloting' processes of the MRC framework, and presents results from, an initial development phase, a 'proof of concept' phase and an exploratory trial.

Development, feasibility and piloting methods

The intervention was developed using an Intervention Mapping protocol [18] utilising research evidence, behavioural theory, extensive stakeholder consultation and piloting to develop key behavioural objectives for each target group (teachers, children and parents) and specific intervention techniques and strategies that linked directly to them. HeLP aims to deliver a general healthy lifestyle message relating to the energy balance and within this context, three evidence-based key messages are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks consumed and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the NICE guidance [19]. As a means of communicating these messages in a simple and easy to remember way we used a logo of '80/20', suggesting we should aim to eat healthily and be active 80% of the time. We hypothesised that this approach would enable children and their families to negotiate and have control over the choices they make; an important consideration in behaviour change [20]. Process evaluation methods during all three phases included semi structured interviews with staff and parents, focus groups with children, questionnaires responses from children and parents, documentation of child, parental and staff involvement and observation of intervention delivery.

Phase 1 - Assess range of delivery methods for key objectives identified in the intervention mapping process (2005-2006; One school; n=119 children, aged 8-11)

We worked with children, parents and teachers from a single primary school to try candidate behaviour change approaches for different age groups. We delivered healthy lifestyle messages

to three age groups, 8-9 year olds; 9-10 year olds and 10-11 year olds, using lessons and either interactive drama activities or goal setting (figure 1). Six focus groups (two for each year group, n=33) were held with the children to ascertain views on activities and what messages and concepts they remembered. Children whose parents consented to the focus groups were randomly selected to participate. Semi-structured interviews were held with teachers (n=6) and parents were invited to complete a questionnaire about the study.

Phase 2 – Proof of Concept - Pilot of intervention and outcome measures (2006-2008; One school; n=77 children, aged 9-10)

Based on the results from the first phase, the intervention was further developed (figure 2) and evaluated in a second primary school, in an area of high social deprivation, with three Year 5 classes. Baseline and 6 week post-intervention height, weight, waist circumference, % body fat, objective physical activity, food intake and TV viewing/screen based activity were assessed. Food intake was assessed using the adapted version of the Food Intake Questionnaire (FIQ) [21], an adapted recall method which asks whether specific foods were consumed the previous day. Children completed the FIQ twice in order to obtain a weekday and weekend food intake.TV viewing/screen based usage was assessed using the adapted version of the Children's TV Viewing Habits Questionnaire [22]. To assess physical activity, children were asked to wear a GT1M Actigraph (Actigraph LLC, Pensacola, FLhttp://www.theactigraph.com) during waking hours over seven consecutive days (5 weekdays and one weekend). Two focus groups (a total of 14 children) were held with children who 'engaged fully' (defined by enthusiasm for the study, desire to set and maintain goals) and a further focus group with those who appeared

Deleted:

'indifferent' (reluctant to take part in activities, needed several prompts regarding goals or did not want to set goals) to the study and the messages (n=4). Interviews were held with the staff (n=3) and head teacher (n=1) and parents of the children (n=5). Parents were also invited to complete a questionnaire about the study.

Phase 3 - Exploratory randomised controlled trial (2008-2010; 4 schools (7 classes); n=204 children, aged 9-10)

Phase 3 sought to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the HeLP intervention and of future trial outcome measures and facilitators and barriers to the uptake of the intervention. All state Primary schools in Exeter were eligible to take part if they had at least one single age year 5 group (i.e. not year 4/5 or 5/6 mixed classes). Schools were recruited via the Devon Association of Primary Head teachers. Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity (as in phase 2) were collected prior to randomization (two control and two intervention schools). These same measures were then collected 18 months post baseline and anthropometric measures only were collected at 24 months post baseline which involved tracking the children to their secondary school (figure 3). All anthropometric measures at each time point were taken by an independent assessor blind to allocation. Six focus groups across the 4 schools (a total of 38 children) were carried out from a selection of children whose parents gave consent (groups were purposefully sampled to reflect gender mix and weight status) and semi structured

interviews were conducted with staff (n=9) and parents (n=17) in control and intervention schools.

RESULTS

Phase 1: Of the 120 children invited to participate, only one child opted out (Figure 1).

User views: Many parents reported in the questionnaire positive parent/family behaviour changes and qualitative data from teachers, children and their parents suggested that Year 5s (9-10 year olds) were more receptive to the messages and more able and willing than the year 4s and 6s to translate them into possible behaviour changes. In addition, it appeared that this year group engaged their families to the greatest extent. Teachers thought that the education lessons should be taught consecutively over one week to maintain momentum and that the drama and goal setting had the potential to work synergistically by engaging the children through the drama and following this up with encouraging the children, with their parents support, to make changes through setting simple goals. Parents and children also highlighted the need for a greater variety of activities to introduce the key messages and concepts in order to engage both boys and girls.

Implications: In order to build a trusting relationship, a range of activities were developed to introduce the school, children and their families to the project's key messages. A 'Healthy Lifestyles Week' was developed consisting of education lessons in the morning (delivered by teachers) which dovetailed with interactive drama activities in the afternoon (delivered by a local drama group). In order to guide the sequential development of the intervention components across the school year, key performance objectives, developed using an intervention mapping process [23], were mapped onto the Health Action Process Model (HAPA) of behaviour change that suggests behaviour change occurs through a sequence of adoption

(establish motivation), initiation (take action) and maintenance (stay motivated) processes [24]. The intervention components at this stage of development were: creating a receptive environment, a healthy lifestyles week and goal setting with year 5 children (9-10 year olds) as the target group.

Phase 2: No child opted out (figure 2) and no adverse events (e.g. child feeling stigmatised) were reported by parents, teachers or children in questionnaires, focus groups or individual discussions. Self-report questionnaires and accelerometry data from the children suggested changes with respect to snacking and sedentary behavior.

User views: Staff were enthusiastic about the Programme, in part because it met the National Curriculum guidelines for Personal Social Health Education (PHSE) and Citizenship, and importantly because they felt it promoted families' engagement with the school. Some teachers felt that the drama had a positive effect on the self esteem of the children, particularly those with additional learning needs. Some teachers suggested further activities for the subsequent term to reinforce the messages and refocus the children and their parents on their goals. Many parents reported that their family had made lifestyle changes and that their child was willing to try new foods. The children enjoyed the drama activities and felt that they could relate to the characters within the drama framework who made them more motivated to set their own goals. Some children reported that they had started going to more after school clubs.

Implications: An additional component was added to the intervention - 'reinforcement activities' to take place at the beginning of year 6, to motivate children to stick to their goals. In addition, minor refinements were made to the education lessons and the drama scripts to

enhance delivery and continuity. Table 1 shows the final intervention components, how they relate to the HAPA model with their associated methods and agents of delivery.

Phase 3: Eight schools expressed an interest in participating in this exploratory trial and four schools were randomly selected to take part.

Feasibility data

Of the 204 children eligible to participate, two opted out of the study (figure 3). Baseline anthropometric measures, food intake and TV viewing/screen based activity were recorded for 202 children. We measured physical activity, using accelerometry, from one randomly selected class in each of the 4 participating schools. Measures were successfully obtained from 109/111 with 95% (104/111) of children providing useable data (3 good weekdays and one weekend day). Prior to the 18 month post baseline measures, five (2 control and 3 intervention) children had left the area and one child opted out (control school). Three girls in the same intervention school withdrew prior to the 18 month measures being collected; this coincided with the children being given a simple snacking and activity diary to complete over a 2 week period and feedback (teacher and parents) suggested this focused the girls too much on what they were eating and their parents felt they were restricting certain food groups.

Eighteen month post baseline measures were collected from 193/204 children, with 107/111 children providing accelerometry data of which 85% (95/111) was useable. At collection of the twenty four month anthropometric data, one girl (control school) did not want to be measured

and five children (3 control, 2 intervention) had moved out of the area, therefore data was obtained from 187/204 children, 92% of the original cohort.

Summary of anthropometric baseline data from the exploratory trial

In the intervention schools, 24% (18/80) of children were classified as overweight or obese compared to 26% (31/122) in the control schools. One child (intervention school) was classified as being underweight [25]. Mean BMI was 17.6 (2.7) (95% CI 17.27 to 18.02). Almost 20% (39/202) had a % body fat ≥ the 85th centile [26] and 43% (86/202) had a waist circumference ≥ the 85th centile [27]. Table 2 summarizes child demographics and BMI status for the two groups.

Process evaluation of the Exploratory Trial

All children (n=80) in the intervention schools participated in the healthy lifestyle week and 90% set goals with their families around lifestyle change. Seventy five percent of parents participated in one or more programme activity.

User Views: Parents were adamant their children's diet and activity choices were their responsibility but felt school was a good place to reinforce these messages. Parents reported a greater acceptance of rules relating to screen-time and healthy eating in their child as well as initiating discussion with other family members around healthy lifestyles.

Teachers agreed year 5 was the right target group as children are gaining independence whilst still amenable to the messages. Some commented that the intervention had boosted the children's self-esteem, had a positive effect on the class socially and created additional

opportunities to link with parents. Teachers felt using young actors to deliver the messages was the key to achieving engagement with this age group.

Children were unanimous in their enjoyment of the drama activities and equally unequivocal that these activities should be carried out by people external to the school. They did not comment on the weighing and measuring and when this was brought up in the focus groups, dismissed it as 'fine'. The key message the children remembered was the importance of replacing unhealthy snacks with more healthy alternatives and replacing screen-based activities with more active pursuits which they enjoy.

Implications: Following the withdrawal of 3 girls from an intervention class, the snacking and activity diary activity has been withdrawn from component 4 (reinforcement activities). The education lessons were refined to include more self monitoring activities for the children within the school and home environment in order keep the children focused on their goals in year 6.

Summary of 18 and 24 month post baseline anthropometric data from the Exploratory trial

At 18 months, the proportion of overweight and obese children increased in the control schools from 26% (31/122) to 32% (38/119) but remained at 24% (18/74) in the intervention schools. At 24 months the proportion of overweight/obese children remained at 32% (36/114) in the control schools and decreased slightly to 22% (16/73) in the intervention schools. Other anthropometric data and the results from the questionnaires and accelerometry will be reported elsewhere.

DISCUSSION

To date the evidence base for effective interventions to prevent and reduce childhood obesity is limited but suggests that a multi-component approach, addressing both sides of the energy balance and engaging families as well as the children, is more likely to be effective [16]. Using an intervention mapping protocol [18, 23] involving literature reviews, extensive stakeholder consultation, expert workshops and three stages of piloting, we have created a programme of activities to engage and change behaviours at a school, child and family level. Such an intervention could also form part of a wider community approach to tackling obesity such as the programmes described in 'Romp and Chomp' and 'Being Active, Eating Well' [15, 14]. Unlike previous school-based interventions [18, 29], HeLP activities have been ordered to promote and support behaviour change in children and their families using the HAPA model [24].Component 1 seeks to establish motivation and create a receptive context for the 'Healthy Lifestyles Week' (component 2). This component seeks to further motivate the children by building their confidence and skills and helping them make decisions. We worked closely with a local theatre company to design a drama framework built around 4 characters, each played by one of the actors whose attributes relate to our healthy lifestyle messages. Children have to choose which character they most resemble and then work with that character to help them change their behaviour. The actors became role models as they worked with the children in a range of interactive activities such as food tasting, making adverts, looking at ingredients and role play. The rationale for using the drama and the young actors as role models was to enthuse the children so much that they took the messages home to their parents and families and, crucially, encouraged them to come into the school and engage with the Programme. Previous research

has suggested that low income parents may be more likely to attend an event in which their children are participants than an educational event, (e.g. eating and joint parent-child classes) [30]. Qualitative data revealed that the dynamic nature of the drama and the use of the young actors did indeed engage the children to such an extent that they talked exuberantly about the Programme with their parents and siblings and encouraged them to attend events, particularly if they were going to be performing with the actors. Interestingly, it was the year 5s (9-10 year olds) who were best able to engage their families and translate the messages into possible behavior change which is why we decided to focus on this age group in subsequent pilots. The role play activities allowed us to teach the children how to communicate the healthy lifestyle messages to their family and seek their support in a subtle and positive manner. Component 3 moves the children on to helping them create an action plan and implement their goals with the support of their parents and component 4 helps them to remain motivated by delivering a range of reinforcement activities to monitor, assess and adapt their goals. Full details of each intervention component and their associated behaviour change techniques and methods of delivery are reported elsewhere [23].

One of the aims of the intervention was to explicitly affect the whole school environment by engaging all staff using staff meetings, whole school assemblies, competitions and parents evenings. During the Healthy Lifestyles Week, the year 5 teachers delivered the pre prepared education lessons in the morning and then observed the theatre company deliver the interactive drama activities in the afternoon. Feedback from interviews and informal discussions with the teachers suggested that the observation of the drama led to an increase in their understanding and motivation which, in turn, led to greater support for, and involvement

in, the Programme. After pilot 2, teachers and the head developed further activities relating to the healthy lifestyle messages after we had trialled the original ideas, which lead to the addition of component 4. The HeLP intervention has been specifically designed so that it can be adapted for use in different types of schools, increasing its generalisability, whilst still remaining standardized enough to maintain fidelity. The activities within the Prograame dovetail with the National Curriculum objectives for this age group. The drama framework is based around 4 characters with whom the children identify and these can be adapted for schools in a variety of different settings. In addition, the children drive the drama scenes as this is key to engagement and encouraging ownership of the healthy lifestyle messages. HeLP has been piloted in a range of schools with children from different socio-economic groups and we have found no difference in the levels of engagement and parental involvement. One limitation, however, is that there is little ethic mix in schools in Exeter, but we would argue that the drama framework can be adapted to accommodate this.

As well as seeking to develop a novel and adaptable intervention that engages schools, children and their families we sought to determine whether our proposed trial design and outcome measures are feasible and acceptable for schools as well as individual children and their families. The baseline anthropometric data from Phase 3 is very similar to national figures reported in the Health Survey for England (2007) and the National Child Measurement Programme (NCMP) (2008/9). At 24 months, however, the percentage of overweight and obese children in the control schools increased by 6%, mirroring the local NCMP data for 10-11 year olds in Exeter, whilst decreasing by 2% in the intervention schools. Although the exploratory trial was not powered to detect statistically significant differences between intervention and

control schools, the finding that the proportions overweight and obese remained at baseline levels in the intervention schools is encouraging, particularly in light of recent tracking data showing that the greatest increases in weight in a non obese sample are between the ages of 7 and 11 years [31].

Using the MRC framework for development and evaluation of complex interventions [17] we have developed and refined a novel school-based programme to prevent and reduce obesity in children. We have demonstrated the feasibility and acceptability of the intervention and shown that it engages children, schools and families. We have also demonstrated that we can recruit schools and children and collect baseline measures prior to randomisation. Retention of children has been excellent with very few losses to follow up at secondary school. Results from these pilot stages have provided us with the necessary and sufficient information to suggest that the HeLP intervention should now be evaluated in a full-scale trial.

Acknowledgements: The authors are very grateful to the participating schools, children and their families who gave up their time for the study. We would also like to acknowledge Sandy Akerman (Headbangers Theatre Company) who supported the design of the drama component of the intervention.

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expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests: None

Ethics approval: Ethical approval for each phase of the development and evaluation of the HeLP intervention was granted from the Peninsula College of Medicine and Dentistry Ethics Committee. This followed an approach to the NHS ethics committee who felt the study did not fall within their remit.

Author contribution: JL, KW and SC drafted the manuscript with SL providing critical revision. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention during pilot phases and conducted interviews with teachers and parents. JL and KW conducted the focus groups and SC performed the analyses on the anthropometric data. JL, KW and SL designed the study and obtained funding. KW will act as guarantor of the paper.

Comment [j1]: Clarification of SC's contribution.

What is already known on this topic

There is little good quality evidence that existing interventions are effective in preventing and reducing childhood obesity.

Interventions which aim to affect both diet and activity seem to show more promise than those targeting either alone.

What this study adds

The Healthy Lifestyle Programme uses behavioural theory and novel interactive delivery methods to create the conditions to enable and support sustainable changes in behaviour for children and their families.

The Healthy Lifestyle Programme is feasible to deliver within the context of the National Curriculum at Key Stage 2 and acceptable to children, their families and schools.

The intervention package engages staff, children and families and preliminary results suggest the possibility that it may affect behaviours associated with overweight and obesity.

The high levels of recruitment, retention and collection of outcome measures in the exploratory trial suggest that a definitive trial is deliverable.

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Table 1 Intervention components, processes of behaviour change and methods of delivery

Component	Process of Behaviour change	Method of delivery	Delivered by
Component 1 Engaging schools, children & families Spring term (Yr 5)	Establish motivation and create a receptive environment	Whole school assembly Activity workshops (parents observe) Parents' evening (involving performances by the children) Newsletter articles	Researcher Professional sportsmen/dancers Teachers/Researcher/Drama group Researcher
Component 2 Intensive Healthy Lifestyles Week – one week Summer term (Yr 5)	Establish motivation by developing children's confidence and skills and helping them make decisions	PSHE lessons (morning) §Drama (afternoon) (forum theatre; role play; food tasting, discussions, games etc)	Class teacher Drama group
Component 3 Goal Setting - goals set during week following drama Summer term (Yr 5)	Take action by helping children create an action plan and implement goals.	Questionnaire to enable children to reflect on snacking, consumption of fizzy drinks and physical activity. Goal setting sheet to go home to parents to complete with child. 1:1 goal setting interview (goals sent home to parents) Parent's evening (child involvement – Forum Theatre)	Researcher/class teacher Researcher/parents Researcher Researcher/Drama group
Component 4 Reinforcement activities Autumn term (Yr 6)	Stay motivated by helping children to monitor, assess and adapt goals	Whole school assembly followed by drama workshops to remind school/children of messages and to prepare class assembly PSHE lesson to remind children of messages and goals.	Drama group

		Children monitor goals on personalised chart Class to deliver assembly about the project to rest of school (parents invited to attend) 1:1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (renewed goals sent home to parents) Newsletter articles	Class teacher Class teacher provided prompts Children to all other year groups in the school Researcher Researcher

§The drama framework includes 4 characters, each represented by one of the actors, whose attributes related to the three healthy lifestlye messages (overall behavioural objectives). Children choose which of the characters they most resemble then work with that actor to help the character learn to change their behaviour

Table 2 Baseline characteristics of children

	Intervention (n=80)	**Control** (n=122)	**Total** (n=202)
Demographics			
Age, years, mean (SD)	9.69 (0.3)	9.69 (0.3)	9.69 (0.3)
Sex % (n) Male % (n) Female	 50 (40) 50 (40)	 50 (61) 50 (61)	 50 (101) 50 (101)
Anthropometric Measures			
% (n) Overweight or Obese(≥85th centile)[25]	23.7 (18)	26.1 (31)	25.1 (49)
Mean (sd) BMI [range]	17.44 (2.6) [13.3 to 25.4]	17.89 (2.8) [13.7 to 25.1]	17.65 (2.7) [13.3 to 25.4]
Mean (sd) BMI sds [range]	0.3 (1.1) [-2.3 to 2.5]	0.4 (1.1) [-2.0 to 2.9]	0.3 (1.1) [-2.3 to 2.9]

March 9th 2011

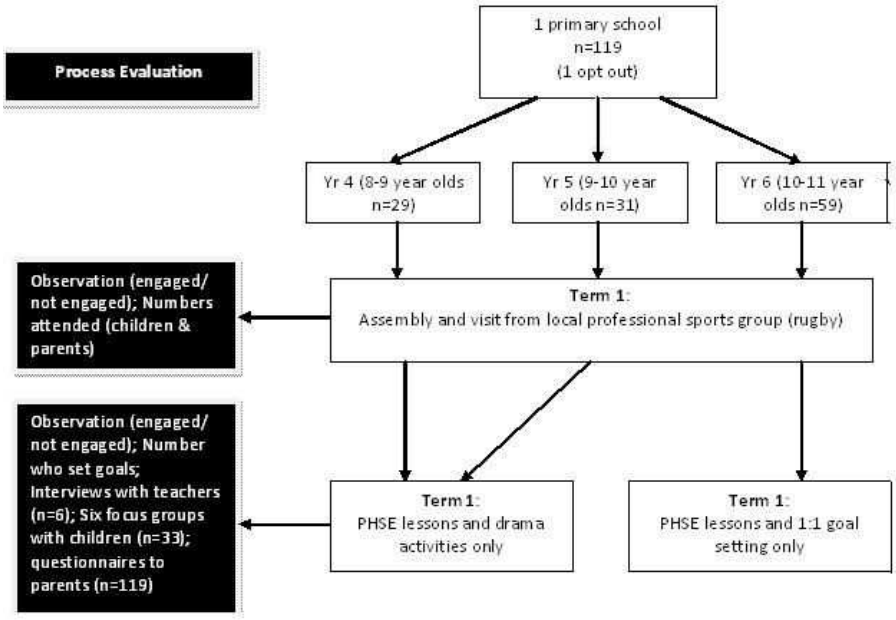
Dear Zara,

As yet, no appropriate checklist has been created for the reporting of studies showing the development, feasibility and acceptability of interventions. Even the STROBE checklist has many sections that are not applicable, so as you suggest, I have not uploaded a checklist from the ones provided.

Best Wishes

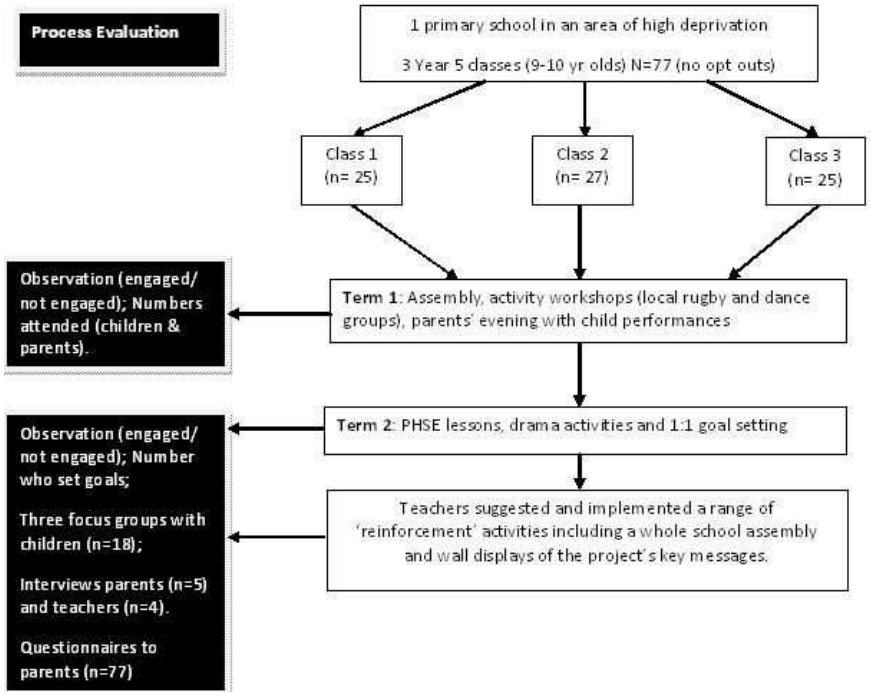
Jennifer Lloyd

Figure 1: Phase 1 – Development study (2005-2006).



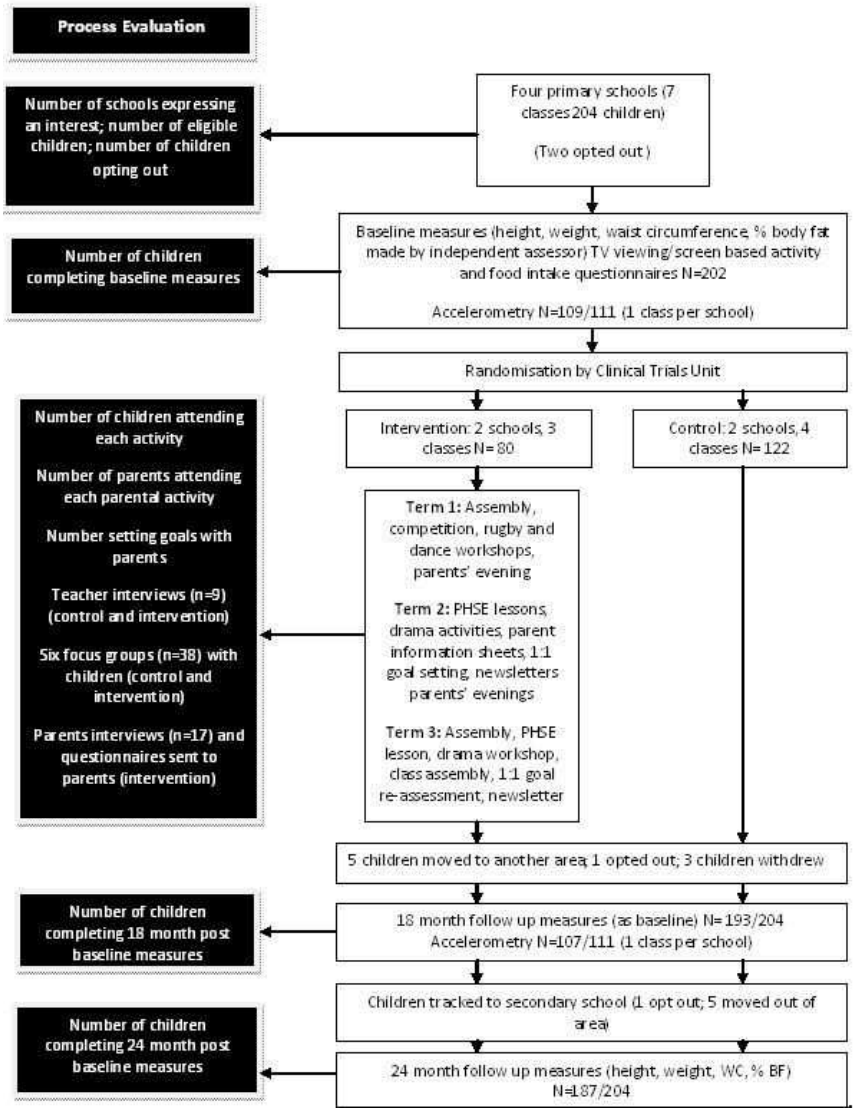
Phase 1 - Development study (2005-2006)
59x44mm (300 x 300 DPI)

Figure 2: Phase 2 – 'Proof of concept' study (2006-2007)



Phase 2 - 'Proof of concept' study (2006-2007)
59x44mm (300 x 300 DPI)

Figure 3: Phase 3 – Exploratory trial 2008-2010



Phase 3 - Exploratory randomised controlled trial (2008-2010)
59x68mm (300 x 300 DPI)