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Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): A novel school-based obesity prevention programme

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ABSTRACT

Objectives*:* To assess the effect of a novel school-based obesity prevention programme on behavioural and weight status outcomes in English primary school children

Design*:* Exploratory cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP), involving 4 schools with children aged 9-10 years (n=202). Baseline, 18 and 24 month post intervention height, weight, waist circumference, % body fat, objective physical activity using accelerometry, food intake and TV viewing/screen based activity were assessed. Intention to treat regression analyses (n=187) allowing for clustering were undertaken.

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 and support schools, children and their families in healthy lifestyle behaviours.

Results*:* At 18 months follow-up, intervention children had fewer 'negative food markers', consumed less energy dense snacks and more healthy snacks, had more 'positive food markers', had lower mean TV/screen time and spent more time doing Moderate-Vigorous Physical Activity each day than children in the control schools. Intervention children had lower anthropometric measures at 18 and 24 months than control children, with larger differences at 24 months than at 18 months for all measures except percentage body fat sds.

Conclusion: Results from this exploratory trial show consistent positive changes in favour of the intervention across all targeted behaviours which, in turn, appear to affect weight status and body shape. A definitive trial is now warranted.

Article focus

- To present behavioural and weight status outcomes from an exploratory cluster randomised controlled trial of a novel school-based obesity prevention programme with English primary school children
- To present sample size estimates required for a definitive trial of the Programme based on outcome results, attrition rates and estimates of the intraclass correlations of the outcome measures

Key messages

- HeLP has been developed using behaviour change theory and extensive stakeholder involvement to engage and support children and their families in healthy lifestyles
- Behavioural and weight status outcomes at 18 and 24 months from this exploratory trial (Phase 3 pilot) show consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'
- Results from the exploratory trial have provided sufficient evidence to support the evaluation of HeLP in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process using research evidence, behavioural 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. The exploratory trial presented in this paper (phase 3 pilot), has demonstrated that not only is the design of the trial feasible, with outcome data obtained from 92% of the original cohort

at 24 months after transition to secondary school, but also that behavioural and weight status outcome measures at 18 and 24 months show consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'. This shows that a definitive trial of HeLP is both necessary and feasible.

Limitations: The study was based in the South West of England which is predominantly white, and although, there are areas of deprivation, none of the 4 schools, had ≥ 25% of children eligible for free school meals (the national average of proportion of children eligible for free school meals). However, the intervention has been developed to allow the flexibility and adaptation to ensure it is recognising and responding to the local needs of children and families from different socio-economic and ethnic groups whilst still maintaining fidelity. Food intake [1] and TV viewing/screen time [2] were self report and, although children were asked to sit in their literacy tables so that appropriate support could be provided to each child during completion, the information children are able to provide is limited. We did, however, go to great lengths to ensure that the questionnaires were simple and presented in such a way so as to trigger recall.

INTRODUCTION

During the last three decades, the prevalence of obesity in children in Europe has risen dramatically [3]. In the UK ,The Health Survey for England reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and 33% of boys were overweight or obese [4]. The National Child Measurement Programme in England (NCMP) reported that by age 10-11 years, one in three children were either overweight or obese [5]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes and musculo-skeletal and psychological problems [6]. A recent systematic review showed that the risk of overweight children becoming overweight adults was at least twice as high as for normal weight children [7] and more contemporary data, from a large prospective cohort of children born in the South-West of England in 1991/1992 (ALSPAC), showed that the four year incidence of obesity was higher between the ages of 7 and 11 years than between 11 and 15 years, suggesting that mid to late childhood (around 7-11 years) may merit greater attention in future obesity prevention interventions [8].

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 [9]. There are also strong associations between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [10]. 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 [11]. In addition, the National

Travel Survey [12] has shown that, since the 1970s, children's transport activity has been in decline.

Evidence about the relationship between physical activity, sedentary behaviours and childhood obesity is scarce with reviews of physical activity and obesity prevention reporting inconsistent results [13, 14]. Using data from the Avon Longitudinal Study of Parents and Children (ALSPAC), Riddoch and colleagues found strong associations between children's fat mass at age 14 and their physical activity at age 12 [15]. Compared to previous generations, children in the UK spend more time participating in sedentary activities; with research suggesting that children spend an average of 4.5 hours in screen time a day [16]. Some studies have reported an association between time spent watching television and obesity [17]. Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [18] and the consumption of snack foods [19].

Schools have the potential to play a critical role in the prevention of overweight and obesity and the more recent development of community-wide multisite approaches often use school-based interventions as part of the overall programme of events [20, 21]. Schools' existing organisational, social and communication structures provide opportunities for regular health education and for the creation of a health enhancing environment and, if school-based interventions are developed in a systematic way involving stakeholders and appropriate piloting phases, they have the potential to reach children and their families across the social spectrum. The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which aim to increase activity and

reduce sedentary behaviour and affect diet may be more effective in preventing children becoming overweight in the long term [22].

The Healthy Lifestyle Programme (HeLP) is an innovative school-based intervention that aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. The Programme takes a population approach, seeking to change behaviour at a family as well as at an individual and school level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [23] involving careful theoretical derivation of behaviour change techniques [24] and three phases of iterative pilot work [25]. Phase 3 was the exploratory randomised controlled trial, to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the intervention and of future trial outcomes measures, and facilitators and barriers to uptake of the intervention. In addition, data from this trial would help us in calculating the sample size required for a full scale trial. Here we present the behavioural and weight status outcomes from the exploratory randomised controlled trial and the estimation of the sample size required for a definitive evaluation of the Programme.

METHODS

Study design

An exploratory cluster randomised controlled trial of the HeLP intervention, in Exeter (a city in the South West of England) involving 202 9-10 year old children. There is little ethnic mix in the South West, with the majority of the population being 'white'. Although overall socio-economic status for the area is higher than average, within Exeter there are some areas with

quite severe deprivation. All state Primary and Junior schools in Exeter were eligible to take part if they had at least one single age year 5 group (9-10 year olds) (i.e. not mixed classes, 8-10 or 9-11 year olds). Schools were recruited via the local network of Primary school head teachers. Of the 11 eligible schools in Exeter, eight expressed an interest from which four schools (with a total of 7 Year 5 classes) were randomly selected to participate. Baseline measures were taken prior to schools being randomised to control or intervention. Randomisation was undertaken by a researcher independent to the study.

Intervention

HeLP is a multi-component 4 phase programme delivered to 9-10 year olds over 3 school terms (Spring and Summer term of year 5 and Autumn term of year 6). The Programme is based on the Information, Motivation and Behavioural Skills Model [26] and aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. Within this context, three key behaviours are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks to unhealthy snacks consumed, and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the UK NICE guidance on the prevention of overweight and obesity in adults and children [27].We hypothesise that targeting information, motivation and behavioural skills will lead to improvements in diet and physical activity thus preventing excessive weight gain. This process of change may be moderated by gender, weight status, socio-economic circumstances and school size. Figure 1 presents a schematic map of the proposed change processes.

Insert Fig 1

An Intervention Mapping (IM) approach [28], involving considerable stakeholder consultation and pilot work, was undertaken to link theory to specific behaviour change techniques (BCTs) and methods of delivery [24] that were suitably engaging and compatible with the existing school curriculum (Table 1).

Insert table 1

Outcome measures

Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity were collected at the start of the school year, in the Autumn term (October/November, 2008) prior to randomisation of schools. These same measures were then collected 18 months post baseline (June/ July 2009) and anthropometric measures only were collected 24 months post baseline (October/November 2010), after the children had moved to secondary school.

Anthropometric

All anthropometric measures were taken by an independent assessor blind to allocation. 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.

Behavioural

Food intake was assessed using the adapted version of the validated Food Intake Questionnaire (FIQ) [1], a recall method which asks whether specific foods were consumed

the previous day. Children completed the FIQ twice, during school hours, 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 (HS), energy dense snacks (EDS); positive (PM) and negative (NM) foods consumed each day. TV viewing/screen based usage was assessed using the adapted version of the validated Children's TV Viewing Habits Questionnaire [2]. 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. Additional information on the number and location of TV sets and rules in the home regarding TV viewing and screen based usage was also collected.

Questionnaires were completed during class time, where children were asked to sit in their literacy groups. JL instructed the class on how to complete the questionnaires and, with the class teacher, learning support assistant and an additional researcher, assisted individual children where necessary. Physical activity was measured in one randomly selected class per school using a GT1M Actigraph (Actigraph LLC, Pensacola, FL:http://www.theactigraph.com) which children were asked to wear around their waist during waking hours over seven consecutive days (5 weekdays and one weekend).

Data management

Anthropometric and questionnaire data were entered into a specifically designed database. 10% of entries (using a random number generator) were subsequently checked by a second researcher.

The raw accelerometry data from the pre and post time points was processed using kinesoft software (version 3.3.55) and quality control checks carried out. To be included in the analysis, participants had to have at least 10 hours of wear time a day on 3 week days and one weekend day. Days were counted if participants accrued 10 hours of wear time each day. Periods of non-wear time were classified as 30 mins of 0 counts. Those that failed to meet the inclusion criteria were excluded from subsequent analysis.

Eligible days of data were organised into time spent in each activity intensity per day. Activity intensity categories were classified using the following previously published cut points (sedentary: 0 to 299; light: 300 to 3580; moderate: 3581 to 6129; vigorous: ≥6130) [29].

Statistical analysis

As this was an exploratory study we sought to utilise the results, including the attrition rates and estimates of the intraclass correlations of the outcome measures, to help us plan a definitive cluster randomised controlled trial, including estimating the sample size needed for such a definitive trial.

The main analysis of the effect of the exploratory trial was undertaken on an intention-to-treat basis. As there was only a small number of missing data for some of the outcomes, the analysis was based on all the available data, with no imputation for missing data. Given there were only four schools participating in this exploratory trial, only cluster level analyses were undertaken [30, 31]; this meant that the analyses could not be adjusted for individual-level covariates (e.g. baseline measures). As there were varying numbers of children in each school, the analyses were weighted by cluster size [31, 32]; inverse variance weighting was

not used, given the uncertainties in estimating the intraclass correlation coefficients. Differences between the intervention and control groups are presented, together with 95% confidence intervals. Unadjusted results (i.e. without clustering being taken into account) are also presented, in order to allow comparison of the precision of the estimates of the effect of the intervention. Intraclass correlation coefficients (and 95% confidence intervals) were calculated for selected outcomes. All analyses were undertaken in STATA version 11.1.

RESULTS

Recruitment and participant characteristics at baseline

Figure 2 shows the flow of participants through the trial [33] and follow up of anthropometric measures at 18 and 24 months. The intervention group consisted of two primary schools, one with 170 children on the school roll (13% eligible for free school meals (FSM) and one larger primary school with 384 children on the roll (2.6% FSM). The control group consisted of two primary schools, one with 317 on roll (14% FSM) and the other with 364 on roll (6% FSM).

Table 2 shows that the intervention and control groups were generally comparable at baseline with the percentages of children overweight/obese being 24% and 26% respectively [34]. Whilst there was higher percentage of obese and a higher percentage body fat (≥85th and < 95th centile) in the control schools, the continuous measurements had very similar means and ranges. Food intake on all categories were similar for both control and intervention groups, with an approximate ratio for HS:EDS and PM:NM of 1:1. Children's mean TV viewing/screen time was 2.6 hours a day, which mirrors national data for 4-15 years [16], however the percentage of children who had televisions in their bedrooms and no rules regarding the amount of TV/screen time was higher in the control

group compared to the intervention group. Both groups spent a similar amount of time per day in sedentary activities but differed slightly in time spent in MVPA, however this varied greatly between children (range; 13.7-104 mins). Mean sedentary time for all children was 16.2 hours/day.

Insert Fig 2

Insert Table 2

Intervention and control group comparisons at follow-up

Anthropometric

Anthropometric follow up data was collected for 193 and 187 participants at 18 and 24 months respectively (94% and 92% of the original cohort of 202 children).

Table 3 shows the comparisons of the main outcomes at 18 and 24 month follow-ups between the children in the intervention schools and control schools. Children in the intervention schools typically fared better than those in the control schools having, on average, lower anthropometric measures at 18 and 24 months with larger differences at 24 months than at 18 months for all measures except percentage Body Fat sds. 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. The waist circumference data show similar proportions at baseline (≥ 85th centile) shifting to an 8.7 % difference in favour of the intervention at 24 months.

Behavioural

At 18 months follow-up, children in the intervention schools had fewer 'negative food markers', consumed less energy dense snacks and more healthy snacks, had more 'positive food markers', had lower mean TV/screen time and on average spent more time doing Moderate-Vigorous Physical Activity each day than children in the control schools.

As expected, the 95% confidence intervals were narrower for all outcomes in the unadjusted results, when the clustering within schools was (incorrectly) not accounted for in the analyses.

Estimation of intraclass correlation coefficients

The intraclass correlation coefficient (ICC) for BMI at 24 months for this exploratory trial was estimated to be 0.04 (95% CI: 0.00 to 0.15) and for BMI sds at 24 months was 0.06 (0.00 to 0.19). As four clusters are insufficient to precisely estimate the intraclass correlation coefficients, we have looked at the effect of using a range of ICCs, based on both our pilot data and other published data in this field [35-37] in our sample size calculations for a definitive randomised controlled trial (see Table 4).

Estimation of sample size required for definitive trial

Statistical efficiency will be maximised in a full trial by analysing BMI sds and adjusting for baseline values, which will reduce the standard error of the estimates of the difference between intervention and control. In this exploratory trial, the correlation between baseline and 24 month BMI sds was 0.93 (95% CI: 0.92 to 0.96).

The sample size estimates shown are based on recruiting 26 schools, each with an average of 50 children. Using BMI sds as the primary outcome measure at 24 months follow-up,

Table 4 shows possible sample sizes required for a definitive trial, for a number of possible scenarios (varying possible effect sizes and ICCs). All sample size calculations are two-sided, significance level of 5%, with an adjustment for a more conservative reduction in variability (assuming a correlation between baseline and 24 month measures of 0.8) and assuming a loss to follow-up of 20%.

A difference in BMI sds of 0.25 has been shown to be a meaningful change, impacting on improvement on adiposity and metabolic health [38]. Using a significance level of 5%, we would need to recruit 1267 children from 26 schools to be able to detect a true difference of at least 0.25, with 90% power, allowing for a conservative attrition rate of 20%, assuming an ICC of 0.03.

DISCUSSION

We have shown over three phases of piloting that HeLP is feasible and acceptable to schools, children and their families [25] and that the study design is feasible for a definitive evaluation. We were able to recruit and retain schools and children throughout the study, obtaining follow up data from 92% of the original cohort at 24 months, after the children had moved on to secondary school. In addition, we obtained useable accelerometry data from 85% of the children at 18 months. We are aware that with a sample size of 202 children and only 4 schools, the trial was not powered to be able to provide precise estimates of the effect of the intervention. Analyses were undertaken at cluster-level only, thus unable to be adjusted for individual-level covariates (such as measures at baseline), however, both behavioural and anthropometric outcome measures at 18 and 24 months

showed consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'.

Although estimates of the differences between intervention and control schools were imprecise, it is encouraging to see that there was a consistent positive impact on the behaviours targeted (snacking, screen time and physical activity) and on anthropometric values. When we began the development of this Programme back in 2005, we believed that the cumulative effect of making small, sustainable changes in multiple behaviours related to the energy balance had the potential to significantly impact on weight status. Interestingly, there were larger differences at 24 months than at 18 months for all measures except percentage body fat sds, which is encouraging, suggesting the potential of the Programme to support children and their families to sustain these lifestyle changes in the longer term.

Further evidence of 'proof of concept' is shown by looking at the weight status proportions. Whilst the proportion of overweight and obese were similar at baseline in both groups, in the control schools, this increased to 32% at 18 months (matching our national data for children of the same age) but remained at baseline levels in the intervention schools at both the 18 and 24 month follow up, suggesting that the intervention may have the effect of preventing the shift from normal to overweight or overweight to obese that occurs during this time. These results are supported by recent tracking data from England showing that the greatest increases in weight in a non obese sample are between the ages of 7 and 11 years [8]. Our waist circumference data is particularly striking, showing a reduction of almost 10% in those with a waist circumference greater than the 85th centile in the intervention group at 24 months, whilst remaining at baseline levels in the control group.

In the planned definitive RCT, more sophisticated statistical analyses will be able to be undertaken at the individual level and, by incorporating individual level covariates, the precision of effect of the intervention will be further improved. Despite being unable to do this for the current study, the data obtained from this study has enabled us to calculate a likely sample size required for the definitive evaluation.

CONCLUSION

Situating an intervention within a school is not sufficient within itself to generate sustained behaviour change. It is critical to engage and motivate children and to generate a supportive social context involving the whole school as well as children's parents [39]. HeLP is unique in that it uses highly inclusive and interactive delivery methods for a range of behaviour change techniques to encourage identification with and ownership of the key messages, ensuring that children have the information, motivation, behavioural skills and support necessary to initiate and sustain change. Results from this exploratory trial show positive changes in favour of the intervention across all targeted behaviours (snacking, screen time and physical activity). Furthermore, these changes appear to have a sustained effect on children's weight status and body shape. A definitive trial is now warranted.

Table 1 Intervention phases, change targets, BCTs and the method and agent of delivery.

Intervention Phase	Change targets	Behaviour change techniques	Method (Frequency) and agent of delivery	
Phase 1	Establish relationships with schools, children and families	Provide information Creating social norms	Whole school assembly (1)	HeLP Coordinators
Creating a supportive context	Raise awareness and increase knowledge	Exchange information	Newsletter articles (3)	HeLP Coordinators
Spring term (Yr 5)	Promote positive attitudes and norms towards healthy eating and physical activity	Communicate messages implying positive evaluations and norms.	Activity workshops (2) (parents observe)	Professional sportsmen/dancers
	Increase self efficacy for behaviour change	Role modelling Skill building	Parents' evening (1) involving child performances	Class teachers/ HeLP Coordinator /Drama group
Phase 2	Strengthen relationships with schools, children and families	Exchange information	*PSHE lessons (5) (morning)	Class teacher
Intensive Healthy Lifestyles Week – one week Summer term (Yr 5)	Increase knowledge Increase self awareness Increase self efficacy Develop communication and problem solving skills Increase social support (school, peer and family)	Decision balance Problem solving tasks Modelling/demonstrating behaviour Providing role models Communication skills training	§Drama (5) (afternoon) (forum theatre; role play; food tasting, discussions, games etc)	Drama group
Phase 3	Increase awareness of own behaviour	Self monitoring	Self reflection questionnaire (1)	HeLP Coordinator/ Class teacher
Personal Goal Setting with Parental Support- goals set during week following drama	Increase self efficacy for change Develop planning skills Increase parental support	Identification and resolution of barriers Provide models of others setting goals Prompt intention and specific goal formation Problem solving Behavioural contract	Goal setting sheet to go home to parents to complete with child. 1:1 goal setting interview (1) (goals sent home to parents)	HeLP Coordinator /Parents HeLP Coordinator
Summer term (Yr 5)		Prompt identification as a role model	Parent's evening (1) (child involvement – Forum Theatre)	HeLP Coordinator /Drama group
Phase 4	Increase self awareness and prioritise healthy goals.	Prompt self monitoring and practice	Newsletter articles (2)	HeLP Coordinator
Reinforcement Activities	Consolidate social support.	Provide social approval.	Whole school assembly (1)	Drama group
	Develop monitoring and coping skills Increase parental support	Prompt self monitoring Prompt intention formation Follow up prompts	Drama workshop (1) *PSHE lesson (1)	Drama group Class teacher
Autumn term (Yr 6)		Prompt practice	Class to deliver assembly about the project to rest of school (1) (parents invited to attend)	Children to all other year groups in the school
		Prompt review of behavioural goals Prompt barrier identification and resolution Coping plans	1-to-1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (renewed goals sent home to parents)	HeLP Coordinator

* PSHE – Personal, Social and Health Education

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

Table 2 Baseline characteristics of children allocated to the intervention and control

	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	 50.0 (40) 50.0 (40)	 50.0 (61) 50.0 (61)	 50.0 (101) 50.0 (101)
Total % of all children in the schools eligible for free school meals	5.7	9.7	7.9
Anthropometric Measures			
% (n) Overweight (≥85th and < 95th centile)[a]	10.5 (8)	7.6 (9)	8.7 (17)
% (n) Obese (≥95th centile)	13.2 (10)	18.5 (22)	16.4 (32)
% (n) Underweight (≤2nd centile)	1.3 (1)	0.0 (0)	0.5 (1)
% (n) with Bodyfat (≥85th and < 95th centile)[b]	5.3 (4)	11.8 (14)	9.2 (18)
% (n) with Bodyfat ≥95th centile	11.8 (9)	10.1 (12)	10.8 (21)
% (n) with Bodyfat ≤2nd centile	19.7 (15)	14.3 (17)	16.4 (32)
% (n) with Waist Circumference (≥85th and < 95th centile)[c]	21.3 (17)	21.3 (26)	21.3 (43)
% (n) with Waist Circumference ≥95th centile	21.3 (17)	21.3 (26)	21.3 (43)
Mean (sd) BMI [range]	17.4 (2.6) [13.3 to 25.4]	17.8 (2.8) [13.7 to 25.1]	17.6 (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]
Mean (sd) % Bodyfat [range]	19.3 (6.8) [3.0 to 37.4]	20.0 (6.7) [7.6 to 36.8]	19.71 (6.8) [3.0 to 37.4]
Mean (sd) % Bodyfat sds [range]	-0.9 (3.4) [-25.8 to 2.3]	-0.5 (1.7) [-6.5 to 2.4]	-0.6 (2.5) [-25.8 to 2.4]
Mean (sd) Waist Circumference (cm) [range]	62.0 (6.5) [50 to 81]	62.6 (7.0) [52 to 83]	62.3 (6.8) [50 to 83]
Mean (sd) Waist circumference sds [range]	0.8 (1.0) [-1.9 to 3.0]	0.91 (1.0) [-1.2 to 3.2]	0.9 (1.0) [-1.9 to 3.2]
Food Intake*(sd)			
Mean (sd) Energy Dense Snacks (EDS) [range]	4.2 (2.2) [0.0 to 10.7]	4.1 (2.1) [0.3 to 11.2]	4.2 (2.1) [0.0 to 11.2]
Mean (sd) Healthy Snacks (HS) [range]	3.2 (1.6) [0.3 to 8.4]	3.4 (1.7) [0.0 to 8.0]	3.4 (1.7) [0.0 to 8.4]
Mean (sd) Positive Food Markers (PM) [range]	7.3 (2.9) [2.6 to 15.0]	7.6 (3.3) [2.3 to 20.3]	7.5 (3.1) [2.3 to 20.3]
Mean (sd) Negative Food Markers (NM) [range]	6.8 (3.3) [1.4 to 16.6]	6.8 (3.2) [0.3 to 20.2]	6.8 (3.2) [0.3 to 20.2]
TV/screen viewing			
Mean (sd) TV/screen viewing (hours/day) [range]	2.5 (1.7) [0.1 to 7.9]	2.7 (1.7) [0.3 to 8.4]	2.6 (1.7) [0.1 to 8.4]
% (n) with TV in bedroom	45.6 (36)	59.8 (73)	54.2 (109)
% (n) with no rules re TV/screen time	39.2 (31)	33.9 (40)	36.0 (71)

Physical activity (mean time/day)			
Moderate-Vigorous PA/day (mins) [range]	36.7 (12.0) [13.7 to 70.0]	49.5 (20.0) [18.1 to 104.4]	43.6 (17.9) [13.7 to 104.4]
Sedentary Activities/day (hours) [range]	16.2 (1.6) [9.8 to 18.7]	16.4 (1.9) [10.6 to 19.2]	16.2 (1.9) [9.3 to 19.2]

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

a [34]

b [40]

c [41]

Table 3: Difference in outcomes at 18 and 24 months follow up of children allocated to the intervention and control groups.

	Mean difference (Intervention minus Control) (95% CI)			
	18 months		**24 months**	
Outcome	**Unadjusted**	**Adjusted for clustering**	**Unadjusted**	**Adjusted for clustering**
BMI	-0.95 (-1.88 to -0.02)	-0.95 (-3.79 to 1.90)	-1.16 (-2.15 to -0.18)	-1.16 (-3.82 to 1.49)
BMI sds	-0.38 (-0.74 to -0.02)	-0.38 (-1.65 to 0.89)	-0.45 (-0.82 to -0.08)	-0.45 (-1.71 to 0.81)
%Body fat	-0.83 (-3.01 to 1.36)	-0.83 (-6.26 to 4.60)	-1.28 (-3.60 to 1.05)	-1.28 (-8.69 to 6.14)
%Body fat sds	-0.33 (-1.04 to 0.38)	-0.33 (-2.52 to 1.85)	-0.21 (-0.85 to 0.42)	-0.21 (-2.45 to 2.03)
Waist circumference (cm)	-2.01 (-4.23 to 0.21)	-2.01 (-9.54 to 5.52)	-2.97 (-5.36 to -0.59)	-2.97 (-10.30 to 4.35)
Waist circumference sds	-0.32 (-0.63 to -0.01)	-0.32 (-1.52 to 0.87)	-0.46 (-0.79 to -0.13)	-0.46 (-1.72 to 0.80)
% with BMI ≥85th centile	-7.6 (-20.5 to 5.3)	-7.6 (-49.4 to 34.2)	-9.7 (-22.4 to 3.1)	-9.7 (-27.8 to 8.5)
% with %Body fat ≥ 85th centile obese	-5.5 (-15.6 to 4.6)	-5.5 (-31.8 to 20.9)	-6.4 (-17.8 to 5.1)	-6.4 (-34.9 to 22.1)
% with Waist circumference ≥ 85th centile	-5.9 (-20.1 to 8.3)	-5.9 (-50.7 to 39.0)	-8.7 (-22.9 to 5.4)	-8.7 (-58.9 to 41.4)
Energy dense snacks (EDS)	-0.28 (-0.83 to 0.27)	-0.28 (-0.83 to 0.27)	-	-
Healthy snacks (HS)	0.47 (0.02 to 0.92)	0.47 (-1.29 to 2.23)	-	-
Positive food markers (PM)	0.38 (-0.37 to 1.13)	0.38 (-1.55 to 2.31)	-	-
Negative food markers (NM)	-0.69 (-1.52 to 0.15)	-0.69 (-1.70 to 0.33)	-	-
Duration of TV viewing (hours/day)	-0.41 (-0.91 to 0.09)	-0.41 (-1.28 to 0.46)	-	-
Sedentary Activities/day (hours)	-0.04 (-1.09 to 1.01)	-0.04 (-1.91 to 1.84)	-	-
Moderate-Vigorous PA/day (mins)	5.67 (0.20 to 11.15)	5.67 (-12.59 to 23.93)	-	-

Table 4: Sample size calculations for a definite RCT with primary outcome of BMI sds at 24 months under different assumptions

	80% Power			90% Power		
	Minimum Difference Detectable			Minimum Difference Detectable		
ICC	**0.25**	**0.30**	**0.50**	**0.25**	**0.30**	**0.50**
0.01	571	397	145	764	531	193
0.03	947	658	240	1267	880	320
0.06	1511	1050	383	2021	1404	511
0.10	2262	1572	573	3027	2103	765

[1]All numbers are the total number of children required to be recruited, assuming 50 children per school and a loss to follow up at 24 months of 20%.
[2]The calculations take into account the reduction in variability associated with adjusting for baseline BMI sds, conservatively assuming the correlation between baseline and 24 months data to be 0.8 (in our pilot study this correlation was 0.93).
[3]This is the sample size required to detect a true minimal difference in BMI sds of 0.25, 0.3 or 0.5, assuming the standard deviation is 1.3 (based on our pilot data).

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Competing interests: None

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Author contribution*:* JL drafted the manuscript with KW and SC providing critical revision. SC carried out the statistical analysis and drafted this section of the manuscript. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention and the collection of measurements at baseline, 18 and 24 months. JL, KW and SL designed the study and obtained funding. JL will act as guarantor of the paper

References

1. Johnson B, Hackett AF. Eating habits of 11–14-year-old schoolchildren living in less affluent areas of Liverpool, UK. *J Hum Nutr Diet* 1997;**10**:135-44.
2. Owens J, Maxim R, McGuinn M, et al. Television-viewing Habits and Sleep Disturbance in School Children. *Pediatrics* 1999;**104**:e27.
3. Jackson-Leach R, Lobstein T. Estimated burden of paediatric obesity and co-morbidities in Europe. Part 1. The increase in the prevalence of child obesity in Europe is itself increasing. *Int J Pediatr Obes* 2006;**1**:26-32.
4. The NHS Information centre. Health Survey for England - 2008 Trend Tables. London: 2009.
5. National Child Measurement Programme. Results from the School Year 2009/10 Oxford: 2010.
6. Gunnell DJ, Frankel SJ, Nanchahal K, et al. Childhood obesity and adult cardiovascular mortality: a 57-y follow-up study based on the Boyd Orr cohort. *Am J Clin Nutr* 1998;**67**:1111-8.
7. Singh AS, Mulder C, Twisk JWR, et al. Tracking of childhood overweight into adulthood: a systematic review of the literature. *Obes Rev* 2008;**9**:474-88.
8. Hughes AR, Sherriff A, Lawlor DA, et al. Incidence of obesity during childhood and adolescence in a large contemporary cohort. *Prev Med* 2011;**52**:300-4.
9. Lake JK, Power C, Cole TJ. Child to adult body mass index in the 1958 British birth cohort: associations with parental obesity. *Arch Dis Child* 1997;**77**:376-80.
10. Li L, Law C, Lo Conte R, et al. Intergenerational influences on childhood body mass index: the effect of parental body mass index trajectories. *Am J Clin Nutr* 2009;**89**:551-7.
11. Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA* 2003;**289**:450-3.
12. National Travel Survey. Trends in personal travel trips, distance travelled and time taken per person per year: Great Britain, since 1972/73. London: 2010.
13. Molnár D, Livingstone B. Physical activity in relation to overweight and obesity in children and adolescents. *Eur J Pediatr* 2000;**159**:S45-S55.
14. Wareham N. Physical activity and obesity prevention. *Obes Rev* 2007;**8 Suppl 1**:109-14.

15. Riddoch CJ, Leary SD, Ness AR, et al. Prospective associations between objective measures of physical activity and fat mass in 12-14 year old children: the Avon Longitudinal Study of Parents and Children (ALSPAC). *BMJ* 2009;**339**.
16. Childwise. The Childwise Monitor Trends report 2010/11. Norwich: 2011.
17. Marshall SJ, Biddle SJ, Gorely T, et al. Relationships between media use, body fatness and physical activity in children and youth: a meta-analysis. *Int J Obes Relat Metab Disord* 2004;**28**:1238-46.
18. Wiecha JL, Peterson KE, Ludwig DS, et al. When Children Eat What They Watch: Impact of Television Viewing on Dietary Intake in Youth. *Arch Pediatr Adolesc Med* 2006;**160**:436-42.
19. Halford JCG, Gillespie J, Brown V, et al. Effect of television advertisements for foods on food consumption in children. *Appetite* 2004;**42**:221-5.
20. de Silva-Sanigorski A, Bolton K, Haby M, et al. Scaling up community-based obesity prevention in Australia: Background and evaluation design of the Health Promoting Communities: Being Active Eating Well initiative. *BMC Public Health* 2010;**10**:1-7.
21. de Silva-Sanigorski AM, Bell AC, Kremer P, et al. Reducing obesity in early childhood: results from Romp & Chomp, an Australian community-wide intervention program. *Am J Clin Nutr* 2010;**91**:831-40.
22. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;**10**:110-41.
23. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.
24. Lloyd JJ, Logan S, Greaves CJ, et al. Evidence, Theory and Context - Using intervention mapping to develop a school-based intervention to prevent obesity in children. *Int J Behav Nutr Phys Act* 2011;**8**:73.
25. Wyatt KM, Lloyd JJ, Creanor S, et al. The development, feasibility and acceptability of a school-based obesity prevention programme: results from three phases of piloting. BMJ Open 2011. http://bmjopen.bmj.com/content/early/2011/05/23/bmjopen-2010-000026.abstract (accessed 13 September 2011).
26. Fisher JD, Fisher WA. The information-motivation-behavioral skills model. In: DiClemente R, Crosby R, Kegler M, eds. Emerging theories in health promotion practice and research. San Fransisco: Jossy-Bass 2002:40-70.
27. NICE. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. London: NICE 2006.
28. Bartholomew LK. Planning health promotion programs: an intervention mapping approach. San Francisco: Jossey-Bass 2006:171-459.
29. Stone MR, Rowlands AV, Eston RG. Characteristics of the activity pattern in normal weight and overweight boys. *Prev Med* 2009;**49**:205-8.
30. Kerry SM, Bland JM. Trials which randomize practices I: how should they be analysed? *Family Practice* 1998;**15**:80-3.
31. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. London: Arnold 2000:1-178.
32. Bland JM, Kerry SM. Weighted comparison of means. *BMJ* 1998;**316**:129.
33. Campbell M, Elbourne D, Altman D. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;**328**:702 - 8.
34. Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Arch Dis Child* 1995;**73**:25-9.
35. Taylor RW, McAuley KA, Barbezat W, et al. APPLE Project: 2-y findings of a community-based obesity prevention program in primary school age children. *Am J Clin Nutr* 2007;**86**:735-42.

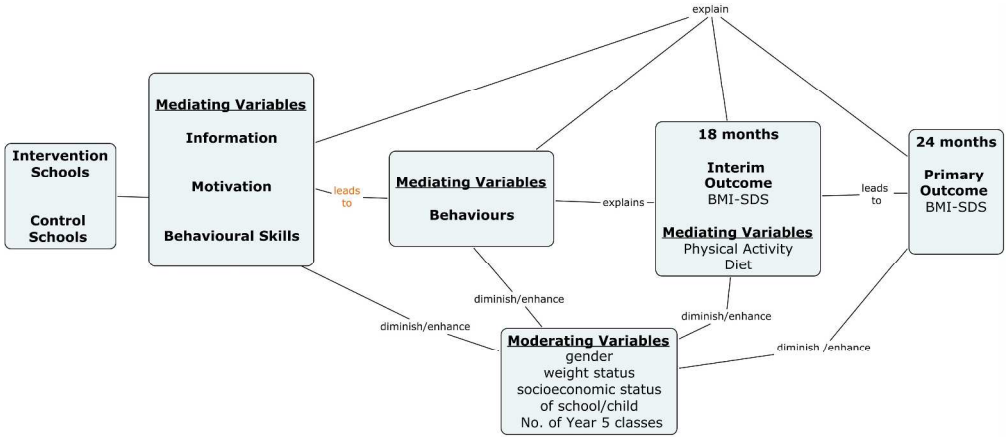
36. Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Arch Pediatr Adolesc Med* 1999;**153**:409-18.
37. Caballero B, Clay T, Davis SM, et al. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr* 2003;**78**:1030-8.
38. Ford AL, Hunt LP, Cooper A, et al. What reduction in BMI SDS is required in obese adolescents to improve body composition and cardiometabolic health? *Arch Dis Child* 2009.
39. Foresight. Tackling obesities: future choices-project report. London: The Stationery Office 2007.
40. McCarthy HD, Cole TJ, Fry T, et al. Body fat reference curves for children. *Int J Obes* 2006;**30**:598-602.
41. McCarthy HD, Jarrett KV, Crawley HF. The development of waist circumference percentiles in British children aged 5.0-16.9 y. *Eur J Clin Nutr* 2001;**55**:902-7.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-6
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	9-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	n/a
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	n/a
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	n/a
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

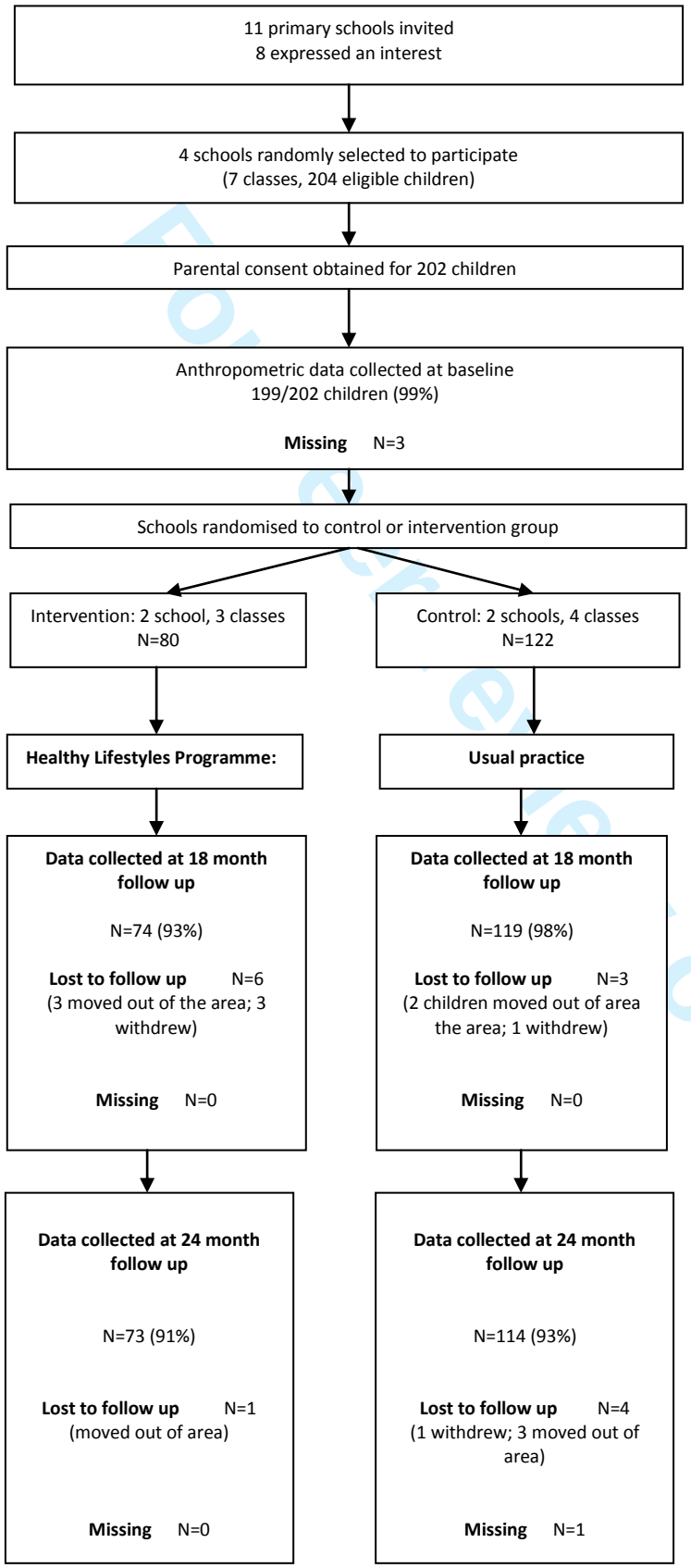
		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12 and Fig 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Fig 2
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	19 Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13 & 20 Table 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	4
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-16
Other information			
Registration	23	Registration number and name of trial registry	n/a
Protocol	24	Where the full trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



Schematic map of the proposed change processes for 'HeLP'
1252x542mm (72 x 72 DPI)

Figure 2: Flow chart of participants through the trial and numbers of children from which anthropometric measures were collected.



Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): A novel school-based obesity prevention programme

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Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): A novel school-based obesity prevention programme

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Key words

Obesity; Prevention; Intervention; Drama; Schools; Children; Exploratory trial

Word count 3,802

ABSTRACT

Objectives: To assess the effect of a novel school-based obesity prevention programme on behavioural and weight status outcomes in English primary school children

Design: Exploratory cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP), involving 4 schools with children aged 9-10 years (n=202). Baseline, 18 and 24 month post ~~intervention~~ baseline height, weight, waist circumference, % body fat, objective physical activity using accelerometry, food intake and TV viewing/screen based activity were assessed. Intention to treat regression analyses (n=187) allowing for clustering were undertaken.

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 and support schools, children and their families in healthy lifestyle behaviours.

Results*:* At 18 months follow-up, intervention children had fewer 'negative food markers', consumed less energy dense snacks and more healthy snacks, had more 'positive food markers', had lower mean TV/screen time and spent more time doing Moderate-Vigorous Physical Activity (MVPA) each day than children in the control schools. Intervention children had lower anthropometric measures at 18 and 24 months than control children, with larger differences at 24 months than at 18 months for all measures except percentage body fat standard deviation scores (sds).

Conclusion: Results from this exploratory trial show consistent positive changes in favour of the intervention across all targeted behaviours which, in turn, appear to affect weight status and body shape. A definitive trial is now ~~warranted~~justified.

Comment [j1]: R2, comment 2.2

Comment [j2]: R1, comment 1.1

Comment [j3]: R1, comment 1.1

Comment [j4]: R2, comment 2.4

Article focus

- To present behavioural and weight status outcomes from an exploratory cluster randomised controlled trial of a novel school-based obesity prevention programme with English primary school children
- To present sample size estimates required for a definitive trial of the Programme based on outcome results, attrition rates and estimates of the intraclass correlations of the outcome measures

Key messages

- HeLP has been developed using behaviour change theory and extensive stakeholder involvement to engage and support children and their families in healthy lifestyles
- Behavioural and weight status outcomes at 18 and 24 months from this exploratory trial (Phase 3 pilot) show consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'
- Results from the exploratory trial have provided sufficient evidence to support the evaluation of HeLP in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process using research evidence, behavioural 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. The exploratory trial presented in this paper (phase 3 pilot) has demonstrated that not only is the design of the trial feasible, with outcome data obtained from 92% of the original cohort

at 24 months after transition to secondary school, but also that behavioural and weight status outcome measures at 18 and 24 months show consistency in the direction of effects (although the differences are relatively small), all in favour of the intervention, demonstrating 'proof of concept'. This shows that a definitive trial of HeLP is both justifiednecessary ~~and~~ feasible and justified.

Comment [j5]: R2, comment 2.3

Comment [j6]: R2, comment 2.4

Limitations: The study was based in the South West of England which is predominantly white, and although, there are areas of deprivation, none of the 4 schools had ≥ 25% of children eligible for free school meals (the national average of proportion of children eligible for free school meals). However, the intervention has been developed to allow the flexibility and adaptation to ensure it is recognising and responding to the local needs of children and families from different socio-economic and ethnic groups whilst still maintaining fidelity. Food intake [1] and TV viewing/screen time [2] were self report and, although children were asked to sit in their literacy tables so that appropriate support could be provided to each child during completion, the information children are able to provide is limited. We did, however, go to great lengths to ensure that the questionnaires were simple and presented in such a way so as to trigger recall.

INTRODUCTION

During the last three decades, the prevalence of obesity in children in Europe has risen dramatically [3]. In the UK ,The Health Survey for England reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and 33% of boys were overweight or obese [4]. The National Child Measurement Programme in England (NCMP) reported that by age 10-11 years, one in three children were either overweight or obese [5]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes and musculo-skeletal and psychological problems [6]. A recent systematic review showed that the risk of overweight children becoming overweight adults was at least twice as high as for normal weight children [7] and more contemporary data, from a large prospective cohort of children born in the South-West of England in 1991/1992 (ALSPAC), showed that the four year incidence of obesity was higher between the ages of 7 and 11 years than between 11 and 15 years, suggesting that mid to late childhood (around 7-11 years) may merit greater attention in future obesity prevention interventions [8].

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 [9]. There are also strong associations between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [10]. 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 [11]. In addition, the National

Travel Survey [12] has shown that, since the 1970s, children's transport activity (e.g. walking or cycling to school) has been in decline.

Comment [j7]: R2, comment 2.8

Evidence about the relationship between physical activity, sedentary behaviours and childhood obesity is scarce with reviews of physical activity and obesity prevention reporting inconsistent results [13, 14]. Using data from the Avon Longitudinal Study of Parents and Children (ALSPAC), Riddoch and colleagues found strong associations between children's fat mass at age 14 and their physical activity at age 12 [15]. Compared to previous generations, children in the UK spend more time participating in sedentary activities; with research suggesting that children spend an average of 4.5 hours a day looking at a ~~in~~ screen ~~time a day~~ [16]. Some studies have reported an association between time spent watching television and obesity [17]. Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [18] and the consumption of snack foods [19].

Comment [j8]: R2, comment 2.9

Schools have the potential to play a critical role in the prevention of overweight and obesity and the more recent development of community-wide multisite approaches often use school-based interventions as part of the overall programme of events [20, 21]. Schools' existing organisational, social and communication structures provide opportunities for regular health education and for the creation of a health enhancing environment and, if school-based interventions are developed in a systematic way involving stakeholders and appropriate piloting phases, they have the potential to reach children and their families across the social spectrum. The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which aim to increase activity and

reduce sedentary behaviour and affect diet may be more effective in preventing children becoming overweight in the long term [22].

The Healthy Lifestyle Programme (HeLP) is an innovative school-based intervention that aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. The Programme takes a population approach, seeking to change behaviour at a family as well as at an individual and school level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [23] involving careful theoretical derivation of behaviour change techniques [24] and three phases of iterative pilot work [25]. Phase 3 was the exploratory randomised controlled trial, to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the intervention and of future trial outcomes measures, and facilitators and barriers to uptake of the intervention. In addition, data from this trial would help us in calculating the sample size required for a full scale trial. Here we present the behavioural and weight status outcomes from the exploratory randomised controlled trial and the estimation of the sample size required for a definitive evaluation of the Programme.

METHODS

Study design

An exploratory cluster randomised controlled trial of the HeLP intervention, in Exeter (a city in the South West of England) involving 202 9-10 year old children. There is little ethnic mix in the South West, with the majority of the population being 'white'. Although overall socio-economic status for the area is higher than average, within Exeter there are some areas with

quite severe deprivation. All state Primary and Junior schools in Exeter were eligible to take part if they had at least one single age year 5 ~~group~~ class (9-10 year olds) (i.e. not mixed classes, 8-10 or 9-11 year olds). Schools were recruited via the local network of Primary school head teachers. Of the 11 eligible schools in Exeter, eight expressed an interest from which four schools (with a total of 7 Year 5 classes) were randomly selected to participate and randomly allocated to intervention or control using a telephone based randomisation service ~~used by~~involving a~~n independent~~ statistician independent of the research. ~~to participate~~All parents of children were sent an information pack with an opportunity to opt out of the study. If the opt out form was not returned within 2 weeks consent was inferred. The class teacher gave daily reminders to the children to ensure that they and their parents had read the information sheet. Baseline measures were taken prior to schools being randomised to control or intervention groups.

Comment [j9]: R2, comment 2.10

Comment [j10]: R1, comment 1.2

Comment [j11]: R2, comment 2.1

Intervention

HeLP is a multi-component 4 phase programme delivered to 9-10 year olds over 3 school terms (Spring and Summer term of year 5 and Autumn term of year 6). The Programme is based on the Information, Motivation and Behavioural Skills Model (IMB) [26] which proposes that adequate information, motivation and behavioural skills are essential to behaviour change. IMB has been demonstrated to provide an effective basis for behaviour change interventions in other domains [27, 28] and aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. Within this context, three key behaviours are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks to unhealthy snacks consumed, and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the UK NICE guidance on the prevention of overweight and obesity

Comment [j12]: R1, comment 1.3

in adults and children [29]. We hypothesise that targeting information, motivation and behavioural skills will lead to the adoption of mediating behaviours which will, in turn, lead to improvements in diet and physical activity thus preventing excessive weight gain. These mediating variables and behaviours will interact to strengthen the engagement of children and their parents throughout the course of the intervention. Figure 1 provides a representation of this process indicating the feedback loops. ~~This process of change may be moderated by gender, weight status, socio-economic circumstances and school size. Figure 1 presents a schematic map of the proposed change processes.~~

Insert Fig 1

An Intervention Mapping (IM) approach [30], involving considerable stakeholder consultation and pilot work, was undertaken to link theory to specific behaviour change techniques (BCTs) [31] and methods of delivery [24] that were suitably engaging and compatible with the existing school curriculum. Table 1 shows each phase of HeLP, the targets of change, the BCTS used and the method and agent of delivery. Key to engaging and motivating the children are the highly inclusive and interactive drama activities, which are built around 4 characters (Disorganised Duncan, Football Freddie, Snacky Sam and Active Amy) with whom the children identify. During the Healthy Lifestyles Week (Phase 2) children work closely with the character most like them to help them to change their behaviours. In Phase 3, the children reflect on their own lifestyle behaviours around diet and activity and set simple goals with their parents. The Programme has been specifically designed so that the *function* of each phase is clearly defined and delivered appropriately while the precise content can be adapted to relate to children from differing ethnic and social backgrounds.

Comment [j13]: R2, comment 2.11

Comment [j14]: R1, comment 1.4

Comment [j15]: R1, comment 1.5

Comment [j16]: R1, comment 1.5. More information about the intervention.

During the drama workshops children cocreate scenes with the actors and provide their own ideas and solutions to problems faced by the characters.

Comment [j17]: R1, comment 1.9

Insert table 1

Outcome measures

Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity were collected at the start of the school year, in the Autumn term (October/November, 2008) prior to randomisation of schools. These same measures were then collected 18 months post baseline (June/ July 2009) and anthropometric measures only were collected 24 months post baseline (October/November 2010), after the children had moved to secondary school.

Anthropometric

All anthropometric measures were taken by an independent assessor who was blinded to each child's allocated group.~~ion.~~ 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.

Comment [j18]: Unsure what additional information is required R1, comment 1.11

Behavioural

Food intake was assessed using an ~~the~~ adapted version of the validated Food Intake Questionnaire (FIQ) [1], a recall method which asks whether specific foods were consumed the previous day. Children completed the FIQ twice, during school hours, in order to obtain

Comment [j19]: R2, comment 2.12

a weekday and weekend food intake. These results were then combined and weighted to calculate the mean number of different healthy snacks (HS), energy dense snacks (EDS), positive (PM) and negative (NM) foods consumed each day. TV viewing/screen based usage was assessed using an ~~the~~ adapted version of the validated Children's TV Viewing Habits Questionnaire [2]. 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. Additional information on the number and location of TV sets and rules in the home regarding TV viewing and screen based usage was also collected.

Comment [j20]: R2, comment 2.12

Questionnaires were completed during class time, where children were asked to sit in their literacy groups (table groupings based on their ability in literacy). JL instructed the class on how to complete the questionnaires and, with the class teacher, learning support assistant and an additional researcher, assisted individual children where necessary. Physical activity was measured in one randomly selected class per school using a GT1M Actigraph (Actigraph LLC, Pensacola, FL:http://www.theactigraph.com), attached to a flexible elastic belt fastened securely round the waist, which children were asked to wear ~~around their waist~~ during waking hours over seven consecutive days (5 weekdays and one weekend). As the device is not waterproof children were instructed to remove it for water-based activities and record on their log sheet the reason for removal and the duration of this non-wear time.

Comment [j21]: R1, comment 1.8

Comment [j22]: R1, comment 1.6

Data management

Anthropometric and questionnaire data were entered into a specifically designed database. 10% of entries (using a random number generator) were subsequently checked by a second researcher revealing only two data entry errors.

Comment [j23]: R2, comment 2.13

The raw accelerometry data from the pre and post time points was processed using kinesoft software (version 3.3.55) and quality control checks carried out. To be included in the analysis, participants had to have at least 10 hours of wear time a day on 3 week days and one weekend day. Days were counted if participants accrued 10 hours of wear time ~~each~~ during the day. Periods of non-wear time were classified as 30 mins of zero counts. Those that failed to meet the inclusion criteria were excluded from subsequent analysis. Useable accelerometry data was obtained for 104/111 (95%) and 95/111 (85%) of participants at baseline and 18 months follow-up respectively.

Comment [j24]: R2, comment 2.14

Comment [j25]: R1, comment 1.7

Eligible days of data were organised into time spent in each activity intensity per day. Activity intensity categories were classified using the following previously published cut points (sedentary: 0 to 299; light: 300 to 3580; moderate: 3581 to 6129; vigorous: ≥6130) [32].

Statistical analysis

As this was an exploratory study we sought to utilise the results, including the attrition rates and estimates of the intraclass correlations of the outcome measures, to help us plan a definitive cluster randomised controlled trial, including estimating the sample size needed for such a definitive trial.

The main analysis of the effect of the exploratory trial was undertaken on an intention-to-treat basis. As there was only a small number of missing data for some of the outcomes (see Figure 2), the analysis was based on all the available data, with no imputation for missing data. As this was an exploratory trial involving only four schools, only cluster level analyses were undertaken [33, 34]; this meant that the analyses could not be adjusted for individual-level covariates (e.g. baseline measures). As there were varying numbers of children in each school, the analyses were weighted by cluster size [34, 35]; inverse variance weighting was not used, given the uncertainties in estimating the intraclass correlation coefficients.

Comment [j26]: R3, comment 3.1

Differences between the intervention and control groups are presented, together with 95% confidence intervals. Unadjusted results (i.e. without clustering being taken into account) are also presented, in order to allow comparison of the precision of the estimates of the effect of the intervention. Intraclass correlation coefficients (and 95% confidence intervals) were calculated for selected outcomes. All analyses were undertaken in STATA version 11.1.

RESULTS

Recruitment and participant characteristics at baseline

Figure 2 shows the flow of participants through the trial [36] and follow-up of anthropometric measures at 18 and 24 months. The intervention group consisted of two primary schools, one with 170 children on the school roll (13% eligible for free school meals (FSM) and one larger primary school with 384 children on the roll (2.6% FSM). The control group consisted of two primary schools, one with 317 on roll (14% FSM) and the other with 364 on roll (6% FSM).

Table 2 shows that the intervention and control groups were generally comparable at baseline with the percentages of children overweight/obese being 24% and 26% respectively [37]. Whilst there was higher percentage of obese and a higher percentage body fat (≥85th and < 95th centile) in the control schools, the continuous measurements had very similar means and ranges. Food intake on all categories were similar for both control and intervention groups, with an approximate ratio for HS:EDS and PM:NM of 1:1. Children's mean TV viewing/screen time was 2.6 hours a day, which mirrors national data for 4-15 year olds~~s~~ [16]. The percentage of children who had televisions in their bedrooms ~~and no rules regarding the amount of TV/screen time~~ was higher in the control group compared to the intervention group, however, the percentage of children who had no rules regarding screen time was higher in the intervention group compared to the control group. Both groups spent a similar amount of time per day in sedentary activities but differed slightly in time spent in MVPA, however this varied greatly between children (range; 13.7-104 mins). Mean sedentary time (including sleep time) for all children was 16.2 hours/day.

Comment [j27]: R2, comment 2.15

Comment [j28]: R2, comment 2.16

Comment [j29]: R1, comment 1.7

Insert Fig 2

Insert Table 2

Intervention and control group comparisons at follow-up

Anthropometric

Anthropometric follow-up data was collected for 193 and 187 participants at 18 and 24 months respectively (94% and 92% of the original cohort of 202 children). Table 3 shows the comparisons of the main outcomes at 18 and 24 month follow-ups between the children in the intervention schools and control schools. Children in the intervention schools typically

fared better than those in the control schools having, on average, lower anthropometric measures at 18 and 24 months with larger differences at 24 months than at 18 months for all measures except percentage Body Fat sds. 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. The waist circumference data show similar proportions at baseline (≥ 85th centile) shifting to an 8.7 % difference in favour of the intervention at 24 months.

Comment [j30]: Compared to baseline has not been inserted as suggested by R2 comment 2.17 as given there were only 4 schools only cluster level analyses were appropriate.

Behavioural

At 18 months follow-up, children in the intervention schools had fewer 'negative food markers', consumed less energy dense snacks and more healthy snacks, had more 'positive food markers', had lower mean TV/screen time and on average spent more time doing Moderate-Vigorous Physical Activity each day than children in the control schools.

As expected, the 95% confidence intervals were narrower for all outcomes in the unadjusted results, when the clustering within schools was (incorrectly) not accounted for in the analyses.

Estimation of intraclass correlation coefficients

The intraclass correlation coefficient (ICC) for BMI at 24 months for this exploratory trial was estimated to be 0.04 (95% CI: 0.00 to 0.15) and for BMI sds at 24 months was 0.06 (0.00 to 0.19). As four clusters are insufficient to precisely estimate the intraclass correlation coefficients, we have looked at the effect of using a range of ICCs, based on both our pilot

data and other published data in this field [38-40], in our sample size calculations for a definitive randomised controlled trial (see Table 4).

Comment [j31]: R2, comment 2.18

Estimation of sample size required for definitive trial

Statistical efficiency will be maximised in a full trial by analysing BMI sds and adjusting for baseline values, which will reduce the standard error of the estimates of the difference between intervention and control. In this exploratory trial, the correlation between baseline and 24 month BMI sds was 0.93 (95% CI: 0.92 to 0.96).

The sample size estimates shown are based on recruiting 26 schools, each with an average of 50 children. Using BMI sds as the primary outcome measure at 24 months follow-up, Table 4 shows possible sample sizes required for a definitive trial, for a number of possible scenarios (varying possible effect sizes and ICCs). All sample size calculations are two-sided, significance level of 5%, with an adjustment for a more conservative reduction in variability (assuming a correlation between baseline and 24 month measures of 0.8) and assuming a loss to follow-up of 20%.

A difference in BMI sds of 0.25 has been shown to be a meaningful change, impacting on improvement on adiposity and metabolic health [41]. Using a significance level of 5%, we would need to recruit 1267 children from 26 schools to be able to detect a true difference of at least 0.25, with 90% power, allowing for a conservative attrition rate of 20%, assuming an ICC of 0.03.

DISCUSSION

We have shown over three phases of piloting that HeLP is feasible and acceptable to schools, children and their families [25] and that the study design is feasible for a definitive evaluation. We were able to recruit and retain schools and children throughout the study, obtaining follow-up data from 92% of the original cohort at 24 months, after the children had moved on to secondary school. In addition, we obtained useable accelerometry data from 85% of the children at 18 months. We are aware that with a sample size of 202 children and only 4 schools, the trial was not powered to be able to provide precise estimates of the effect of the intervention. Analyses were undertaken at cluster-level only, thus unable to be adjusted for individual-level covariates (such as measures at baseline), however, both behavioural and anthropometric outcome measures at 18 and 24 months showed consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'.

Although estimates of the differences between intervention and control schools were imprecise, it is encouraging to see that there was a consistent positive impact on the behaviours targeted (snacking, screen time and physical activity) and on anthropometric values. When we began the development of this Programme back in 2005, we believed that the cumulative effect of making small, sustainable changes in multiple behaviours related to the energy balance had the potential to significantly impact on weight status. Interestingly, there were larger differences at 24 months than at 18 months for all measures except percentage body fat sds, which is encouraging, suggesting the potential of the Programme to support children and their families to sustain these lifestyle changes in the longer term.

Further evidence of 'proof of concept' is shown by looking at the weight status proportions. Whilst the proportion of overweight and obese were similar at baseline in both groups, in the control schools, this increased to 32% at 18 months (matching our national data for children of the same age) but remained at baseline levels in the intervention schools at both the 18 and 24 month follow-up, suggesting that the intervention may have the effect of preventing the shift from normal to overweight or overweight to obese that occurs during this time. These results are supported by recent tracking data from England showing that the greatest increases in weight in a non obese sample are between the ages of 7 and 11 years [8]. Our waist circumference data is particularly striking, showing a reduction of almost 10% in those with a waist circumference greater than the 85th centile in the intervention group at 24 months, whilst remaining at baseline levels in the control group.

In the planned definitive RCT, more sophisticated statistical analyses will be able to be undertaken at the individual level and, by incorporating individual level covariates, the precision of effect of the intervention will be further improved. Despite being unable to do this for the current study, the data obtained from this study has enabled us to calculate a likely sample size required for the definitive evaluation.

CONCLUSION

Situating an intervention within a school is not sufficient within itself to generate sustained behaviour change. It is critical to engage and motivate children and to generate a supportive social context involving the whole school as well as children's parents [42]. HeLP is unique in that it uses highly inclusive and interactive delivery methods for a range of behaviour change techniques to encourage identification with and ownership of the key messages,

ensuring that children have the information, motivation, behavioural skills and support necessary to initiate and sustain change. Results from this exploratory trial show positive changes in favour of the intervention across all targeted behaviours (snacking, screen time and physical activity). Furthermore, these changes appear to have a sustained effect on children's weight status and body shape. A definitive trial is now ~~warranted~~justified.

Comment [j32]: R2, comment 2.19

Table 1 Intervention phases, change targets, BCTs and the method and agent of delivery.

Intervention Phase	Change targets	Behaviour change techniques	Method (Frequency and duration) and agent of delivery	
Phase 1 **Creating a supportive context** Spring term (Yr 5)	Establish relationships with schools, children and families Raise awareness and increase knowledge Promote positive attitudes and norms towards healthy eating and physical activity Increase self efficacy for behaviour change	Provide information Creating social norms Exchange information Communicate messages implying positive evaluations and norms. Role modelling Skill building	Whole school assembly (1) (20 mins) Newsletter articles (3) (Over the Spring term) Activity workshops (2) (parents observe) (1.5 hours) Parents' evening (1) involving child performances (1 hour)	HeLP Coordinators HeLP Coordinators Professional sportsmen/dancers Class teachers/ HeLP Coordinator /Drama group
Phase 2 **Intensive Healthy Lifestyles Week –** one week Summer term (Yr 5)	Strengthen relationships with schools, children and families Increase knowledge Increase self awareness Increase self efficacy Develop communication and problem solving skills Increase social support (school, peer and family)	Exchange information Decision balance Problem solving tasks Modelling/demonstrating behaviour Providing role models Communication skills training	*PSHE lessons (5) (morning) (1 hour) §Drama (5) (afternoon) (forum theatre; role play; food tasting, discussions, games etc) (2 hours)	Class teacher Drama group
Phase 3 **Personal Goal Setting with Parental Support-** goals set during week following drama Summer term (Yr 5)	Increase awareness of own behaviour Increase self efficacy for change Develop planning skills Increase parental support	Self monitoring Identification and resolution of barriers Provide models of others setting goals Prompt intention and specific goal formation Problem solving Behavioural contract Prompt identification as a role model	Self reflection questionnaire (1) (40 mins) Goal setting sheet to go home to parents to complete with child (1) (10 mins) 1:1 goal setting interview (1) (goals sent home to parents) (10 mins) Parent's evening (1) (child involvement – Forum Theatre) (1 hour)	HeLP Coordinator/ Class teacher HeLP Coordinator /Parents HeLP Coordinator HeLP Coordinator /Drama group
Phase 4 **Reinforcement Activities** Autumn term (Yr 6)	Increase self awareness and prioritise healthy goals. Consolidate social support. Develop monitoring and coping skills Increase parental support	Prompt self monitoring and practice Provide social approval Prompt self monitoring Prompt intention formation Follow up prompts Prompt practice Prompt review of behavioural goals Prompt barrier identification and resolution Coping plans	Newsletter articles (2) (over the Autumn term) Whole school assembly (1) (20 mins) Drama workshop (1) (1 hour) *PSHE lesson (1) (1 hour) Class to deliver assembly about the project to rest of school (1) (20 mins) (parents invited to attend) 1-to-1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (1) (10 mins) (renewed goals sent home to parents)	HeLP Coordinator Drama group Drama group Class teacher Children to all other year groups in the school HeLP Coordinator

Comment [j33]: R1, comment 1.5

* PSHE – Personal, Social and Health Education

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

Table 2 Baseline characteristics of children allocated to the intervention and control

	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	 50.0 (40) 50.0 (40)	 50.0 (61) 50.0 (61)	 50.0 (101) 50.0 (101)
Total % of all children in the schools eligible for free school meals	5.7	9.7	7.9
Anthropometric Measures			
% (n) Overweight (≥85th and < 95th centile)[a]	10.5 (8)	7.6 (9)	8.7 (17)
% (n) Obese (≥95th centile)	13.2 (10)	18.5 (22)	16.4 (32)
% (n) Underweight (≤2nd centile)	1.3 (1)	0.0 (0)	0.5 (1)
% (n) with Bodyfat (≥85th and < 95th centile)[b]	5.3 (4)	11.8 (14)	9.2 (18)
% (n) with Bodyfat ≥95th centile	11.8 (9)	10.1 (12)	10.8 (21)
% (n) with Bodyfat ≤2nd centile	19.7 (15)	14.3 (17)	16.4 (32)
% (n) with Waist Circumference (≥85th and < 95th centile)[c]	21.3 (17)	21.3 (26)	21.3 (43)
% (n) with Waist Circumference ≥95th centile	21.3 (17)	21.3 (26)	21.3 (43)
Mean (sd) BMI [range]	17.4 (2.6) [13.3 to 25.4]	17.8 (2.8) [13.7 to 25.1]	17.6 (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]
Mean (sd) % Bodyfat [range]	19.3 (6.8) [3.0 to 37.4]	20.0 (6.7) [7.6 to 36.8]	19.71 (6.8) [3.0 to 37.4]
Mean (sd) % Bodyfat sds [range]	-0.9 (3.4) [-25.8 to 2.3]	-0.5 (1.7) [-6.5 to 2.4]	-0.6 (2.5) [-25.8 to 2.4]
Mean (sd) Waist Circumference (cm) [range]	62.0 (6.5) [50 to 81]	62.6 (7.0) [52 to 83]	62.3 (6.8) [50 to 83]
Mean (sd) Waist circumference sds [range]	0.8 (1.0) [-1.9 to 3.0]	0.91 (1.0) [-1.2 to 3.2]	0.9 (1.0) [-1.9 to 3.2]
Food Intake*(sd)			
Mean (sd) Energy Dense Snacks (EDS) [range]	4.2 (2.2) [0.0 to 10.7]	4.1 (2.1) [0.3 to 11.2]	4.2 (2.1) [0.0 to 11.2]
Mean (sd) Healthy Snacks (HS) [range]	3.2 (1.6) [0.3 to 8.4]	3.4 (1.7) [0.0 to 8.0]	3.4 (1.7) [0.0 to 8.4]
Mean (sd) Positive Food Markers (PM) [range]	7.3 (2.9) [2.6 to 15.0]	7.6 (3.3) [2.3 to 20.3]	7.5 (3.1) [2.3 to 20.3]
Mean (sd) Negative Food Markers (NM) [range]	6.8 (3.3) [1.4 to 16.6]	6.8 (3.2) [0.3 to 20.2]	6.8 (3.2) [0.3 to 20.2]
TV/screen viewing			
Mean (sd) TV/screen viewing (hours/day) [range]	2.5 (1.7) [0.1 to 7.9]	2.7 (1.7) [0.3 to 8.4]	2.6 (1.7) [0.1 to 8.4]
% (n) with TV in bedroom	45.6 (36)	59.8 (73)	54.2 (109)
% (n) with no rules re TV/screen time	39.2 (31)	33.9 (40)	36.0 (71)
Physical activity (mean time/day)			
Moderate-Vigorous PA/day (mins)	36.7 (12.0)	49.5 (20.0)	43.6 (17.9)

[range]	[13.7 to 70.0]	[18.1 to 104.4]	[13.7 to 104.4]
Sedentary Activities/day (hours)	16.2 (1.6)	16.4 (1.9)	16.2 (1.9)
[range]	[9.8 to 18.7]	[10.6 to 19.2]	[9.3 to 19.2]

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

a [37]

b [43]

c [44]

Table 3: Difference in outcomes at 18 and 24 months follow-up of children allocated to the intervention and control groups.

	Mean difference (Intervention minus Control) (95% CI)			
	18 months		24 months	
Outcome	Unadjusted	Adjusted for clustering	Unadjusted	Adjusted for clustering
BMI	-0.95 (-1.88 to -0.02)	-0.95 (-3.79 to 1.90)	-1.16 (-2.15 to -0.18)	-1.16 (-3.82 to 1.49)
BMI sds	-0.38 (-0.74 to -0.02)	-0.38 (-1.65 to 0.89)	-0.45 (-0.82 to -0.08)	-0.45 (-1.71 to 0.81)
%Body fat	-0.83 (-3.01 to 1.36)	-0.83 (-6.26 to 4.60)	-1.28 (-3.60 to 1.05)	-1.28 (-8.69 to 6.14)
%Body fat sds	-0.33 (-1.04 to 0.38)	-0.33 (-2.52 to 1.85)	-0.21 (-0.85 to 0.42)	-0.21 (-2.45 to 2.03)
Waist circumference (cm)	-2.01 (-4.23 to 0.21)	-2.01 (-9.54 to 5.52)	-2.97 (-5.36 to -0.59)	-2.97 (-10.30 to 4.35)
Waist circumference sds	-0.32 (-0.63 to -0.01)	-0.32 (-1.52 to 0.87)	-0.46 (-0.79 to -0.13)	-0.46 (-1.72 to 0.80)
% with BMI ≥85th centile	-7.6 (-20.5 to 5.3)	-7.6 (-49.4 to 34.2)	-9.7 (-22.4 to 3.1)	-9.7 (-27.8 to 8.5)
% with %Body fat ≥ 85th centile obese	-5.5 (-15.6 to 4.6)	-5.5 (-31.8 to 20.9)	-6.4 (-17.8 to 5.1)	-6.4 (-34.9 to 22.1)
% with Waist circumference ≥ 85th centile	-5.9 (-20.1 to 8.3)	-5.9 (-50.7 to 39.0)	-8.7 (-22.9 to 5.4)	-8.7 (-58.9 to 41.4)
Energy dense snacks (EDS)	-0.28 (-0.83 to 0.27)	-0.28 (-0.83 to 0.27)	-	-
Healthy snacks (HS)	0.47 (0.02 to 0.92)	0.47 (-1.29 to 2.23)	-	-
Positive food markers (PM)	0.38 (-0.37 to 1.13)	0.38 (-1.55 to 2.31)	-	-
Negative food markers (NM)	-0.69 (-1.52 to 0.15)	-0.69 (-1.70 to 0.33)	-	-
Duration of TV viewing (hours/day)	-0.41 (-0.91 to 0.09)	-0.41 (-1.28 to 0.46)	-	-
Sedentary Activities/day (hours)	-0.04 (-1.09 to 1.01)	-0.04 (-1.91 to 1.84)	-	-
Moderate-Vigorous PA/day (mins)	5.67 (0.20 to 11.15)	5.67 (-12.59 to 23.93)	-	-

Table 4: Sample size calculations for a definite RCT with primary outcome of BMI sds at 24 months under different assumptions

	80% Power			90% Power		
	Minimum Difference Detectable			Minimum Difference Detectable		
ICC	**0.25**	**0.30**	**0.50**	**0.25**	**0.30**	**0.50**
0.01	571	397	145	764	531	193
0.03	947	658	240	1267	880	320
0.06	1511	1050	383	2021	1404	511
0.10	2262	1572	573	3027	2103	765

[1]All numbers are the total number of children required to be recruited, assuming 50 children per school and a loss to follow-up at 24 months of 20%.
[2]The calculations take into account the reduction in variability associated with adjusting for baseline BMI sds, conservatively assuming the correlation between baseline and 24 months data to be 0.8 (in our pilot study this correlation was 0.93).
[3]This is the sample size required to detect a true minimal difference in BMI sds of 0.25, 0.3 or 0.5, assuming the standard deviation is 1.3 (based on our pilot data).

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Competing interests: None

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Ethics approval: Ethical approval was granted from the Peninsula College of Medicine and Dentistry Ethics Committee in 2008.

Comment [j34]: Not sure whether adding ethical procedures is necessary R1, comment 1.13

Author contribution*:* JL drafted the manuscript with KW and SC providing critical revision. SC carried out the statistical analysis and drafted this section of the manuscript. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention and the collection of measurements at baseline, 18 and 24 months. JL, KW and SL designed the study and obtained funding. JL will act as guarantor of the paper

References

1. Johnson B, Hackett AF. Eating habits of 11–14-year-old schoolchildren living in less affluent areas of Liverpool, UK. *J Hum Nutr Diet* 1997;**10**:135-44.
2. Owens J, Maxim R, McGuinn M, et al. Television-viewing Habits and Sleep Disturbance in School Children. *Pediatrics* 1999;**104**:e27.
3. Jackson-Leach R, Lobstein T. Estimated burden of paediatric obesity and co-morbidities in Europe. Part 1. The increase in the prevalence of child obesity in Europe is itself increasing. *Int J Pediatr Obes* 2006;**1**:26-32.
4. The NHS Information centre. Health Survey for England - 2008 Trend Tables. London: 2009.
5. National Child Measurement Programme. Results from the School Year 2009/10 Oxford: 2010.
6. Gunnell DJ, Frankel SJ, Nanchahal K, et al. Childhood obesity and adult cardiovascular mortality: a 57-y follow-up study based on the Boyd Orr cohort. *Am J Clin Nutr* 1998;**67**:1111-8.
7. Singh AS, Mulder C, Twisk JWR, et al. Tracking of childhood overweight into adulthood: a systematic review of the literature. *Obes Rev* 2008;**9**:474-88.
8. Hughes AR, Sherriff A, Lawlor DA, et al. Incidence of obesity during childhood and adolescence in a large contemporary cohort. *Prev Med* 2011;**52**:300-4.
9. Lake JK, Power C, Cole TJ. Child to adult body mass index in the 1958 British birth cohort: associations with parental obesity. *Arch Dis Child* 1997;**77**:376-80.
10. Li L, Law C, Lo Conte R, et al. Intergenerational influences on childhood body mass index: the effect of parental body mass index trajectories. *Am J Clin Nutr* 2009;**89**:551-7.
11. Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA* 2003;**289**:450-3.
12. National Travel Survey. Trends in personal travel trips, distance travelled and time taken per person per year: Great Britain, since 1972/73. London: 2010.
13. Molnár D, Livingstone B. Physical activity in relation to overweight and obesity in children and adolescents. *Eur J Pediatr* 2000;**159**:S45-S55.
14. Wareham N. Physical activity and obesity prevention. *Obes Rev* 2007;**8 Suppl 1**:109-14.
15. Riddoch CJ, Leary SD, Ness AR, et al. Prospective associations between objective measures of physical activity and fat mass in 12-14 year old children: the Avon Longitudinal Study of Parents and Children (ALSPAC). *BMJ* 2009;**339**.
16. Childwise. The Childwise Monitor Trends report 2010/11. Norwich: 2011.
17. Marshall SJ, Biddle SJ, Gorely T, et al. Relationships between media use, body fatness and physical activity in children and youth: a meta-analysis. *Int J Obes Relat Metab Disord* 2004;**28**:1238-46.

18. Wiecha JL, Peterson KE, Ludwig DS, et al. When Children Eat What They Watch: Impact of Television Viewing on Dietary Intake in Youth. *Arch Pediatr Adolesc Med* 2006;**160**:436-42.
19. Halford JCG, Gillespie J, Brown V, et al. Effect of television advertisements for foods on food consumption in children. *Appetite* 2004;**42**:221-5.
20. de Silva-Sanigorski A, Bolton K, Haby M, et al. Scaling up community-based obesity prevention in Australia: Background and evaluation design of the Health Promoting Communities: Being Active Eating Well initiative. *BMC Public Health* 2010;**10**:1-7.
21. de Silva-Sanigorski AM, Bell AC, Kremer P, et al. Reducing obesity in early childhood: results from Romp & Chomp, an Australian community-wide intervention program. *Am J Clin Nutr* 2010;**91**:831-40.
22. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;**10**:110-41.
23. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.
24. Lloyd JJ, Logan S, Greaves CJ, et al. Evidence, Theory and Context - Using intervention mapping to develop a school-based intervention to prevent obesity in children. *Int J Behav Nutr Phys Act* 2011;**8**:73.
25. Wyatt KM, Lloyd JJ, Creanor S, et al. The development, feasibility and acceptability of a school-based obesity prevention programme: results from three phases of piloting. BMJ Open 2011. http://bmjopen.bmj.com/content/early/2011/05/23/bmjopen-2010-000026.abstract (accessed 13 September 2011).
26. Fisher JD, Fisher WA. The information-motivation-behavioral skills model. In: DiClemente R, Crosby R, Kegler M, eds. Emerging theories in health promotion practice and research. San Fransisco: Jossy-Bass 2002:40-70.
27. Fisher JD, Fisher WA, Amico KR, et al. An Information-Motivation-Behavioral Skills Model of Adherence to Antiretroviral Therapy. *Health Psych* 2006;**25**:462-73.
28. Fisher JD, Fisher WA, Williams SS, et al. Empirical Tests of an Information-Motivation-Behavioral Skills Model of AIDS-Preventive Behavior With Gay Men and Heterosexual University Students. *Health Psych* 1994;**13**:238-50.
29. NICE. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. London: NICE 2006.
30. Bartholomew LK. Planning health promotion programs: an intervention mapping approach. San Francisco: Jossey-Bass 2006:171-459.
31. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol* 2008;**27**:379-87.
32. Stone MR, Rowlands AV, Eston RG. Characteristics of the activity pattern in normal weight and overweight boys. *Prev Med* 2009;**49**:205-8.
33. Kerry SM, Bland JM. Trials which randomize practices I: how should they be analysed? *Family Practice* 1998;**15**:80-3.
34. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. London: Arnold 2000:1-178.
35. Bland JM, Kerry SM. Weighted comparison of means. *BMJ* 1998;**316**:129.
36. Campbell M, Elbourne D, Altman D. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;**328**:702 - 8.
37. Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Arch Dis Child* 1995;**73**:25-9.
38. Taylor RW, McAuley KA, Barbezat W, et al. APPLE Project: 2-y findings of a community-based obesity prevention program in primary school age children. *Am J Clin Nutr* 2007;**86**:735-42.

39. Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Arch Pediatr Adolesc Med* 1999;**153**:409-18.
40. Caballero B, Clay T, Davis SM, et al. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr* 2003;**78**:1030-8.
41. Ford AL, Hunt LP, Cooper A, et al. What reduction in BMI SDS is required in obese adolescents to improve body composition and cardiometabolic health? *Arch Dis Child* 2009.
42. Foresight. Tackling obesities: future choices-project report. London: The Stationery Office 2007.
43. McCarthy HD, Cole TJ, Fry T, et al. Body fat reference curves for children. *Int J Obes* 2006;**30**:598-602.
44. McCarthy HD, Jarrett KV, Crawley HF. The development of waist circumference percentiles in British children aged 5.0-16.9 y. *Eur J Clin Nutr* 2001;**55**:902-7.

Figure 1: The HeLP Process Model

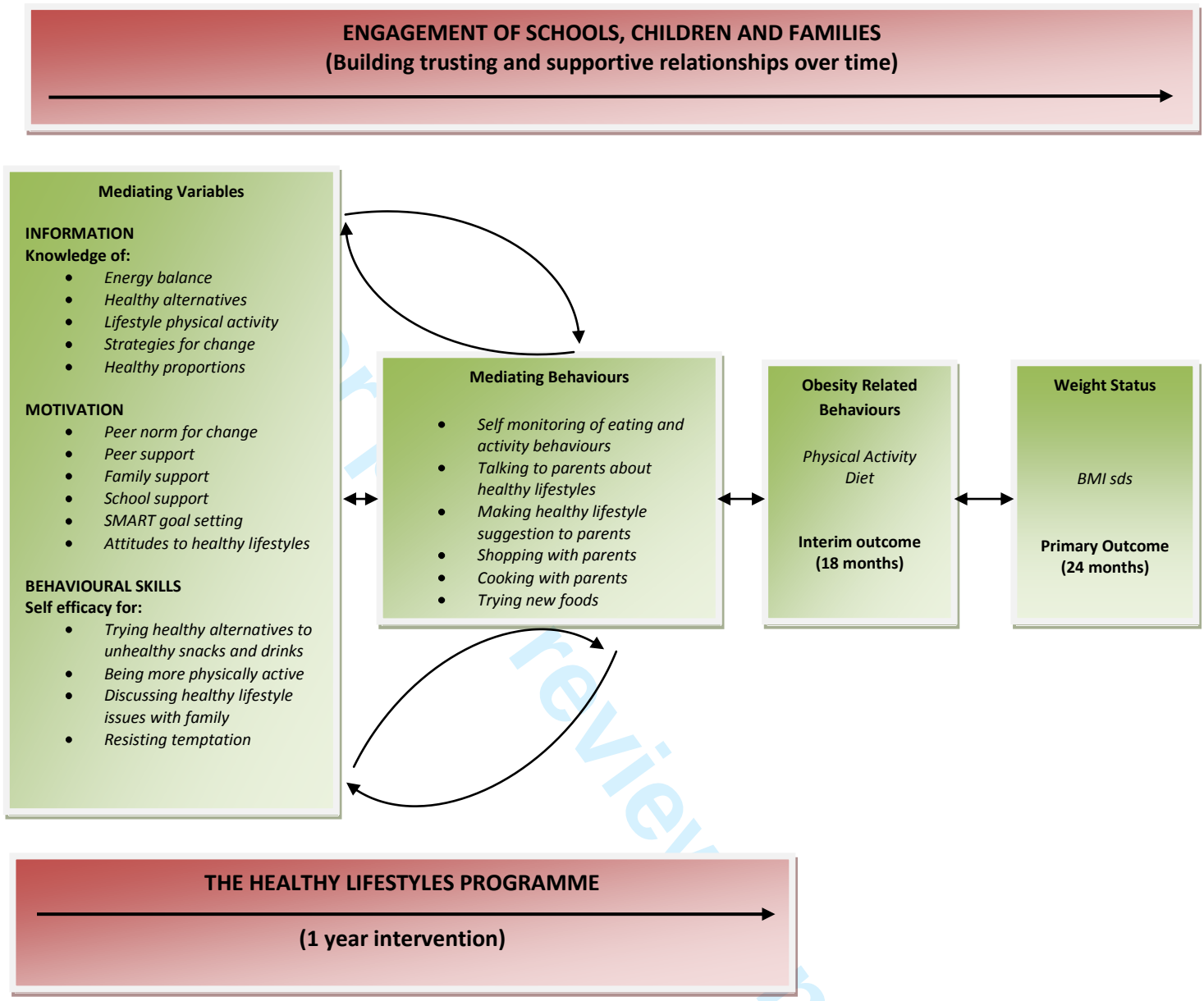
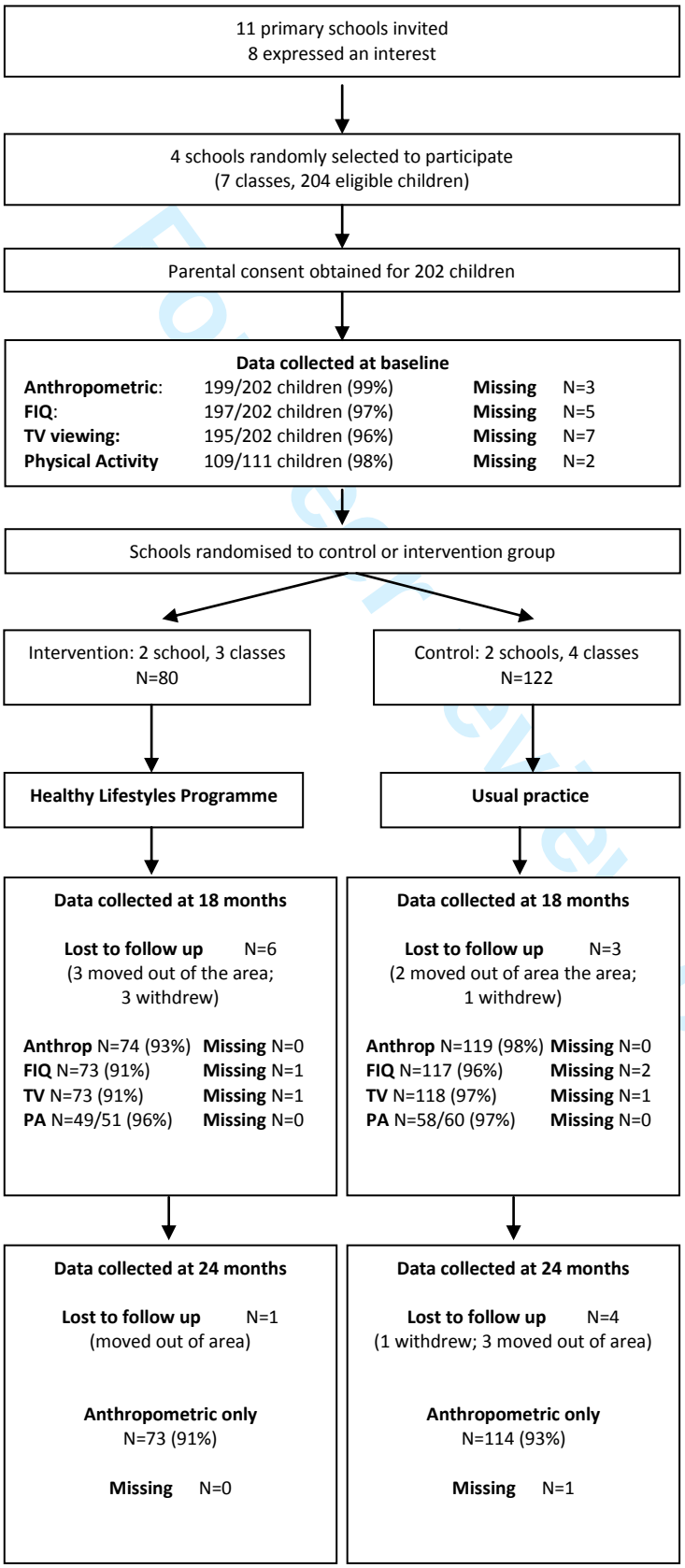


Figure 2: Flow chart of participants through the trial and numbers of children from which measures were collected.



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Methods			
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	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
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Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-10 Table 1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	n/a
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
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Sequence generation	8a	Method used to generate the random allocation sequence	n/a
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Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10

		assessing outcomes) and how	
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Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12-13
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Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13 and Fig 2
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Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): A novel school-based obesity prevention programme

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Primary Subject Heading:	Public health
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Keywords:	PUBLIC HEALTH, PREVENTIVE MEDICINE, Community child health < PAEDIATRICS

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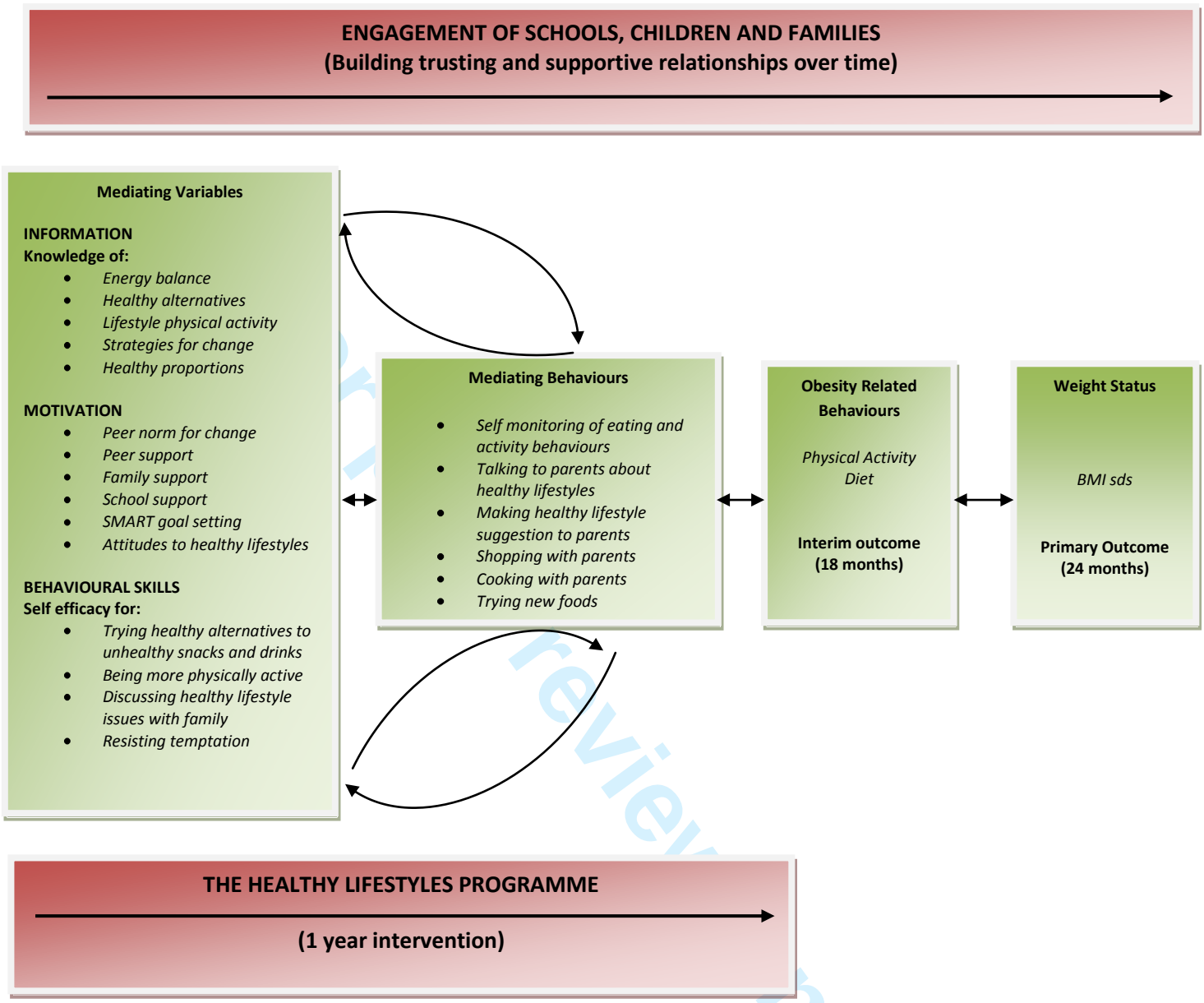

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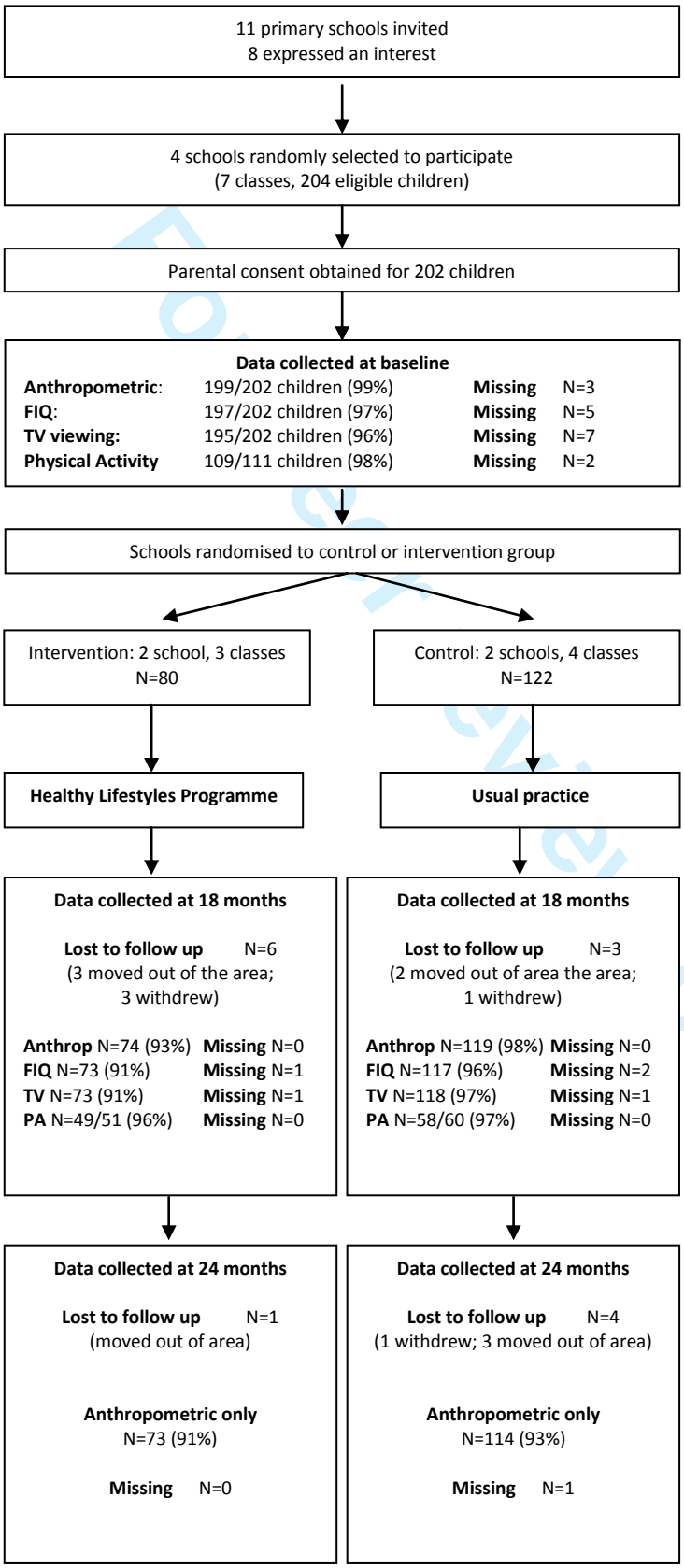

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Behavioural and weight status outcomes from an exploratory trial of the Healthy Lifestyles Programme (HeLP): A novel school-based obesity prevention programme

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Key words

Obesity; Prevention; Intervention; Drama; Schools; Children; Exploratory trial

Word count 3,815

ABSTRACT

Objectives: To assess the behavioural and weight status outcomes in English children in a feasibility study of a novel primary school-based obesity prevention programme.

Design: Exploratory cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP).

Setting: Four city primary schools (2 control, 2 intervention) in the South West of England.

Participants: 202 9-10 year old children, of which 193 and 188 were followed up at 18 and 24 months respectively. No child was excluded from the study; however, to be eligible, schools were required to have at least one single Year 5 class.

Intervention: Four phase multi-component programme using a range of school-based activities including lessons, assemblies, parents' evenings, interactive drama workshops and goal-setting to engage and support schools, children and their families in healthy lifestyle behaviours. It runs over the spring and summer term of Year 5 and the autumn term of Year 6).

Primary and secondary outcomes: Weight status outcomes were BMI, waist circumference and body fat sds at 18 and 24 months and behavioural outcomes were physical activity, TV viewing/screen time and food intake at 18 months.

Results: At 18 months follow-up, intervention children , consumed less energy dense snacks and more healthy snacks, had fewer 'negative food

markers', more 'positive food markers', lower mean TV/screen time and spent more time doing Moderate-Vigorous Physical Activity (MVPA) each day than children in the control schools. Intervention children had lower anthropometric measures at 18 and 24 months than control children, with larger differences at 24 months than at 18 months for nearly all measures.

Conclusion: Results from this exploratory trial show consistent positive changes in favour of the intervention across all targeted behaviours which, in turn, appear to affect weight status and body shape. A definitive trial is now justified.

Article focus

- To present behavioural and weight status outcomes from an exploratory cluster randomised controlled trial of a novel school-based obesity prevention programme with English primary school children
- To present sample size estimates required for a definitive trial of the Programme based on outcome results, attrition rates and estimates of the intraclass correlations of the outcome measures

Key messages

- HeLP has been developed using behaviour change theory and extensive stakeholder involvement to engage and support children and their families in healthy lifestyles

- Behavioural and weight status outcomes at 18 and 24 months from this exploratory trial (Phase 3 pilot) show consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'
- Results from the exploratory trial have provided sufficient evidence to support the evaluation of HeLP in a full scale trial

Strengths and Limitations

Strengths: The HeLP intervention has undergone a systematic development process using research evidence, behavioural 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. The exploratory trial presented in this paper (phase 3 pilot) has demonstrated that not only is the design of the trial feasible, with outcome data obtained from 92% of the original cohort at 24 months after transition to secondary school, but also that behavioural and weight status outcome measures at 18 and 24 months show consistency in the direction of effects (although the differences are relatively small), all in favour of the intervention, demonstrating 'proof of concept'. This shows that a definitive trial of HeLP is both feasible and justified.

Limitations: The study was based in the South West of England which is predominantly white, and although, there are areas of deprivation, none of the 4 schools had ≥ 25% of children eligible for free school meals (the national average of proportion of children eligible for free school meals). However, the intervention has been developed to allow the flexibility and adaptation to ensure it is recognising and responding to the local needs of children and

families from different socio-economic and ethnic groups whilst still maintaining fidelity. Food intake [1] and TV viewing/screen time [2] were self report and, although children were asked to sit in their literacy tables so that appropriate support could be provided to each child during completion, the information children are able to provide is limited. We did, however, go to great lengths to ensure that the questionnaires were simple and presented in such a way so as to trigger recall.

INTRODUCTION

During the last three decades, the prevalence of obesity in children in Europe has risen dramatically [3]. In the UK ,The Health Survey for England reported that 19% of girls and 18% of boys aged 11-15 were obese and 34% of girls and 33% of boys were overweight or obese [4]. The National Child Measurement Programme in England (NCMP) reported that by age 10-11 years, one in three children were either overweight or obese [5]. Being overweight in childhood is associated with adverse consequences including metabolic abnormalities, increased risk of Type II diabetes and musculo-skeletal and psychological problems [6]. A recent systematic review showed that the risk of overweight children becoming overweight adults was at least twice as high as for normal weight children [7] and more contemporary data, from a large prospective cohort of children born in the South-West of England in 1991/1992 (ALSPAC), showed that the four year incidence of obesity was higher between the ages of 7 and 11 years than between 11 and 15 years, suggesting that mid to late childhood (around 7-11 years) may merit greater attention in future obesity prevention interventions [8].

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 [9]. There are also strong associations between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors [10]. 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 [11]. In addition, the National

Travel Survey [12] has shown that, since the 1970s, children's transport activity (e.g. walking or cycling to school) has been in decline.

Evidence about the relationship between physical activity, sedentary behaviours and childhood obesity is scarce with reviews of physical activity and obesity prevention reporting inconsistent results [13, 14]. Using data from the Avon Longitudinal Study of Parents and Children (ALSPAC), Riddoch and colleagues found strong associations between children's fat mass at age 14 and their physical activity at age 12 [15]. Compared to previous generations, children in the UK spend more time participating in sedentary activities; with research suggesting that children spend an average of 4.5 hours a day looking at a screen [16]. Some studies have reported an association between time spent watching television and obesity [17]. Not only is television viewing a sedentary activity but it is also positively correlated with total calorific intake [18] and the consumption of snack foods [19].

Schools have the potential to play a critical role in the prevention of overweight and obesity and the more recent development of community-wide multisite approaches often use school-based interventions as part of the overall programme of events [20, 21]. Schools' existing organisational, social and communication structures provide opportunities for regular health education and for the creation of a health enhancing environment and, if school-based interventions are developed in a systematic way involving stakeholders and appropriate piloting phases, they have the potential to reach children and their families across the social spectrum. The most recent systematic review (2008) of controlled trials of school-based interventions concluded that interventions which aim to increase activity and

reduce sedentary behaviour and affect diet may be more effective in preventing children becoming overweight in the long term [22].

The Healthy Lifestyle Programme (HeLP) is an innovative school-based intervention that aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. The Programme takes a population approach, seeking to change behaviour at a family as well as at an individual and school level. The development of HeLP followed the MRC guidance for the development and evaluation of complex interventions [23] involving careful theoretical derivation of behaviour change techniques [24] and three phases of iterative pilot work [25]. Phase 3 was the exploratory randomised controlled trial, to assess, for schools, children and their families: recruitment and retention in control and intervention schools; feasibility and acceptability of the intervention and of future trial outcomes measures, and facilitators and barriers to uptake of the intervention. In addition, data from this trial would help us in calculating the sample size required for a full scale trial. Here we present the behavioural and weight status outcomes from the exploratory randomised controlled trial and the estimation of the sample size required for a definitive evaluation of the Programme.

METHODS

Study design

An exploratory cluster randomised controlled trial of the HeLP intervention, in Exeter (a city in the South West of England) involving 202 9-10 year old children. There is little ethnic mix in the South West, with the majority of the population being 'white'. Although overall socio-economic status for the area is higher than average, within Exeter there are some areas with

quite severe deprivation. All state Primary and Junior schools in Exeter were eligible to take part if they had at least one single age year 5 class (9-10 year olds) (i.e. not mixed classes, 8-10 or 9-11 year olds). Schools were recruited via the local network of Primary school head teachers. Of the 11 eligible schools in Exeter, eight expressed an interest from which four schools (with a total of 7 Year 5 classes) were randomly selected to participate and randomly allocated to intervention or control using a telephone based randomisation service involving a statistician independent of the research. All parents of children were sent an information pack with an opportunity to opt out of the study. If the opt out form was not returned within 2 weeks consent was inferred. The class teacher gave daily oral reminders to the children over this 2 week period to ensure that they and their parents had read the information sheet. Baseline measures were taken prior to schools being randomised to control or intervention groups.

Comment [j1]: R1, more information added

Intervention

HeLP is a multi-component 4 phase programme delivered to 9-10 year olds over 3 school terms (Spring and Summer term of year 5 and Autumn term of year 6). The Programme is based on the Information, Motivation and Behavioural Skills Model (IMB) [26] which proposes that adequate information, motivation and behavioural skills are essential to behaviour change. IMB has been demonstrated to provide an effective basis for behaviour change interventions in other domains [27, 28] and aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. Within this context, three key behaviours are emphasised: a decrease in the consumption of sweetened fizzy drinks; an increase in the proportion of healthy snacks to unhealthy snacks consumed, and a reduction in TV viewing and other screen-based activities. These messages are consistent with the strategies suggested in the UK NICE guidance on the prevention of overweight and obesity

in adults and children [29]. We hypothesise that targeting information, motivation and behavioural skills will lead to the adoption of mediating behaviours which will, in turn, lead to improvements in diet and physical activity thus preventing excessive weight gain. These mediating variables and behaviours will interact to strengthen the engagement of children and their parents throughout the course of the intervention. Figure 1 provides a representation of this process indicating the feedback loops.

Insert Fig 1

An Intervention Mapping (IM) approach [30,], involving considerable stakeholder consultation and pilot work, was undertaken to link theory to specific behaviour change techniques (BCTs) [31, 32] and methods of delivery [24] that were suitably engaging and compatible with the existing school curriculum. Table 1 shows each phase of HeLP, the targets of change, the BCTS used and the method and agent of delivery. Key to engaging and motivating the children are the highly inclusive and interactive drama activities, which are built around 4 characters (Disorganised Duncan, Football Freddie, Snacky Sam and Active Amy) with whom the children identify. During the Healthy Lifestyles Week (Phase 2) children work closely with the character most like them to help them to change their behaviours. In Phase 3, the children reflect on their own lifestyle behaviours around diet and activity and set simple goals with their parents. The Programme has been specifically designed so that the *function* of each phase is clearly defined and delivered appropriately while the precise content can be adapted to relate to children from differing ethnic and social backgrounds. During the drama workshops children cocreate scenes with the actors and provide their own ideas and solutions to problems faced by the characters.

Comment [j2]: R1. Reference to the new taxonomy. Michie et al., 2011

Insert table 1

Outcome measures

Baseline height, weight, waist circumference, % body fat, food intake, TV viewing/screen-based activity and physical activity were collected at the start of the school year, in the Autumn term (October/November, 2008) prior to randomisation of schools. These same measures were then collected 18 months post baseline (June/ July 2009) and anthropometric measures only were collected 24 months post baseline (October/November 2010), after the children had moved to secondary school.

Anthropometric

All anthropometric measures were taken by an independent assessor who was blinded to each child's allocated group. 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.

Behavioural

Food intake was assessed using an adapted version of the validated Food Intake Questionnaire (FIQ) [1], a recall method which asks whether specific foods were consumed the previous day. Children completed the FIQ twice, during school hours, 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 (HS), energy dense snacks (EDS), positive (PM) and negative (NM) foods consumed each day. TV viewing/screen based usage

was assessed using an adapted version of the validated Children's TV Viewing Habits Questionnaire [2]. 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. Additional information on the number and location of TV sets and rules in the home regarding TV viewing and screen based usage was also collected.

Questionnaires were completed during class time, where children were asked to sit in their literacy groups (table groupings based on their ability in literacy). JL instructed the class on how to complete the questionnaires and, with the class teacher, learning support assistant and an additional researcher, assisted individual children where necessary. Physical activity was measured in one randomly selected class per school using a GT1M Actigraph (Actigraph LLC, Pensacola, FL:http://www.theactigraph.com), attached to a flexible elastic belt fastened securely round the waist, which children were asked to wear during waking hours over seven consecutive days (5 weekdays and one weekend). As the device is not waterproof children were instructed to remove it for water-based activities and record on their log sheet the reason for removal and the duration of this non-wear time.

Data management

Anthropometric and questionnaire data were entered into a specifically designed database. 10% of entries (using a random number generator) were subsequently checked by a second researcher revealing only two data entry errors.

The raw accelerometry data from the pre and post time points was processed using kinesoft software (version 3.3.55) and quality control checks carried out. To be included in the analysis, participants had to have at least 10 hours of wear time a day on 3 week days and one weekend day. Days were counted if participants accrued 10 hours of wear time during the day. Periods of non-wear time were classified as 30 mins of zero counts. Those that failed to meet the inclusion criteria were excluded from subsequent analysis. Useable accelerometry data was obtained for 104/111 (95%) and 95/111 (85%) of participants at baseline and 18 months follow-up respectively.

Eligible days of data were organised into time spent in each activity intensity per day. Activity intensity categories were classified using the following previously published cut points (sedentary: 0 to 299; light: 300 to 3580; moderate: 3581 to 6129; vigorous: ≥6130) [33].

Statistical analysis

As this was an exploratory study we sought to utilise the results, including the attrition rates and estimates of the intraclass correlations of the outcome measures, to help us plan a definitive cluster randomised controlled trial, including estimating the sample size needed for such a definitive trial.

The main analysis of the effect of the exploratory trial was undertaken on an intention-to-treat basis. As there was only a small number of missing data for some of the outcomes (see Figure 2), the analysis was based on all the available data, with no imputation for missing data. As this was an exploratory trial involving only four schools, only cluster level analyses were undertaken [34, 35]; this meant that the analyses could not be adjusted for individual-

level covariates (e.g. baseline measures). As there were varying numbers of children in each school, the analyses were weighted by cluster size [35, 36]; inverse variance weighting was not used, given the uncertainties in estimating the intraclass correlation coefficients.

Differences between the intervention and control groups are presented, together with 95% confidence intervals. Unadjusted results (i.e. without clustering being taken into account) are also presented, in order to allow comparison of the precision of the estimates of the effect of the intervention. Intraclass correlation coefficients (and 95% confidence intervals) were calculated for selected outcomes. All analyses were undertaken in STATA version 11.1.

RESULTS

Recruitment and participant characteristics at baseline

Figure 2 shows the flow of participants through the trial [37] and follow-up of anthropometric measures at 18 and 24 months. The intervention group consisted of two primary schools, one with 170 children on the school roll (13% eligible for free school meals (FSM) and one larger primary school with 384 children on the roll (2.6% FSM). The control group consisted of two primary schools, one with 317 on roll (14% FSM) and the other with 364 on roll (6% FSM).

Table 2 shows that the intervention and control groups were generally comparable at baseline with the percentages of children overweight/obese being 24% and 26% respectively [38]. Whilst there was higher percentage of obese and a higher percentage body fat (≥85th and < 95th centile) in the control schools, the continuous measurements had very similar means and ranges. Food intake on all categories were similar for both control and intervention groups, with an approximate ratio for HS:EDS and PM:NM of 1:1.

Children's mean TV viewing/screen time was 2.6 hours a day, which mirrors national data for 4-15 year olds [16]. The percentage of children who had televisions in their bedrooms was higher in the control group compared to the intervention group, however, the percentage of children who had no rules regarding screen time was higher in the intervention group compared to the control group. Both groups spent a similar amount of time per day in sedentary activities but differed slightly in time spent in MVPA, however this varied greatly between children (range; 13.7-104 mins). Mean sedentary time (including sleep time) for all children was 16.2 hours/day.

Insert Fig 2

Insert Table 2

Intervention and control group comparisons at follow-up

Anthropometric

Anthropometric follow-up data was collected for 193 and 187 participants at 18 and 24 months respectively (94% and 92% of the original cohort of 202 children). Table 3 shows the comparisons of the main outcomes at 18 and 24 month follow-ups between the children in the intervention schools and control schools. Children in the intervention schools typically fared better than those in the control schools having, on average, lower anthropometric measures at 18 and 24 months with larger differences at 24 months than at 18 months for all measures except percentage Body Fat sds. At 18 months, the proportion of overweight and obese children had increased by 6%in the control schools (from 26% (31/122) to 32% (38/119)) whilst remaining at baseline levels in the intervention schools (24% (18/74)).. At 24 months the proportion of overweight/obese children remained at 32% (36/114) in the

Comment [j3]: R2. Wording changed to make it clearer

control schools and decreased slightly to 22% (16/73) in the intervention schools. The waist circumference data show similar proportions at baseline (≥ 85th centile) shifting to an 8.7 % difference in favour of the intervention at 24 months.

Behavioural

At 18 months follow-up, children in the intervention schools had fewer 'negative food markers', consumed less energy dense snacks and more healthy snacks, had more 'positive food markers', had lower mean TV/screen time and on average spent more time doing Moderate-Vigorous Physical Activity each day than children in the control schools.

As expected, the 95% confidence intervals were narrower for all outcomes in the unadjusted results, when the clustering within schools was (incorrectly) not accounted for in the analyses.

Estimation of intraclass correlation coefficients

The intraclass correlation coefficient (ICC) for BMI at 24 months for this exploratory trial was estimated to be 0.04 (95% CI: 0.00 to 0.15) and for BMI sds at 24 months was 0.06 (0.00 to 0.19). As four clusters are insufficient to precisely estimate the intraclass correlation coefficients, we have looked at the effect of using a range of ICCs, based on both our pilot data and other published data in this field [39-41], in our sample size calculations for a definitive randomised controlled trial (see Table 4).

Estimation of sample size required for definitive trial

Statistical efficiency will be maximised in a full trial by analysing BMI sds and adjusting for baseline values, which will reduce the standard error of the estimates of the difference between intervention and control. In this exploratory trial, the correlation between baseline and 24 month BMI sds was 0.93 (95% CI: 0.92 to 0.96).

The sample size estimates shown are based on recruiting 26 schools, each with an average of 50 children. Using BMI sds as the primary outcome measure at 24 months follow-up, Table 4 shows possible sample sizes required for a definitive trial, for a number of possible scenarios (varying possible effect sizes and ICCs). All sample size calculations are two-sided, significance level of 5%, with an adjustment for a more conservative reduction in variability (assuming a correlation between baseline and 24 month measures of 0.8) and assuming a loss to follow-up of 20%.

A difference in BMI sds of 0.25 has been shown to be a meaningful change, impacting on improvement on adiposity and metabolic health [42]. Using a significance level of 5%, we would need to recruit 1267 children from 26 schools to be able to detect a true difference of at least 0.25, with 90% power, allowing for a conservative attrition rate of 20%, assuming an ICC of 0.03.

DISCUSSION

We have shown over three phases of piloting that HeLP is feasible and acceptable to schools, children and their families [25] and that the study design is feasible for a definitive evaluation. We were able to recruit and retain schools and children throughout the study, obtaining follow-up data from 92% of the original cohort at 24 months, after the children

had moved on to secondary school. In addition, we obtained useable accelerometry data from 85% of the children at 18 months. We are aware that with a sample size of 202 children and only 4 schools, the trial was not powered to be able to provide precise estimates of the effect of the intervention. Analyses were undertaken at cluster-level only, thus unable to be adjusted for individual-level covariates (such as measures at baseline), however, both behavioural and anthropometric outcome measures at 18 and 24 months showed consistency in the direction of effects, all in favour of the intervention, demonstrating 'proof of concept'.

Although estimates of the differences between intervention and control schools were imprecise, it is encouraging to see that there was a consistent positive impact on the behaviours targeted (snacking, screen time and physical activity) and on anthropometric values. When we began the development of this Programme back in 2005, we believed that the cumulative effect of making small, sustainable changes in multiple behaviours related to the energy balance had the potential to significantly impact on weight status. Interestingly, there were larger differences at 24 months than at 18 months for all measures except percentage body fat sds, which is encouraging, suggesting the potential of the Programme to support children and their families to sustain these lifestyle changes in the longer term.

Further evidence of 'proof of concept' is shown by looking at the weight status proportions. Whilst the proportion of overweight and obese were similar at baseline in both groups, in the control schools, this increased to 32% at 18 months (matching our national data for children of the same age) but remained at baseline levels in the intervention schools at both the 18 and 24 month follow-up, suggesting that the intervention may have the effect of

preventing the shift from normal to overweight or overweight to obese that occurs during this time. These results are supported by recent tracking data from England showing that the greatest increases in weight in a non obese sample are between the ages of 7 and 11 years [8]. Our waist circumference data is particularly striking, showing a reduction of almost 10% in those with a waist circumference greater than the 85th centile in the intervention group at 24 months, whilst remaining at baseline levels in the control group.

In the planned definitive RCT, more sophisticated statistical analyses will be able to be undertaken at the individual level and, by incorporating individual level covariates, the precision of effect of the intervention will be further improved. Despite being unable to do this for the current study, the data obtained from this study has enabled us to calculate a likely sample size required for the definitive evaluation.

CONCLUSION

Situating an intervention within a school is not sufficient within itself to generate sustained behaviour change. It is critical to engage and motivate children and to generate a supportive social context involving the whole school as well as children's parents [43]. HeLP is unique in that it uses highly inclusive and interactive delivery methods for a range of behaviour change techniques to encourage identification with and ownership of the key messages, ensuring that children have the information, motivation, behavioural skills and support necessary to initiate and sustain change. Results from this exploratory trial show positive changes in favour of the intervention across all targeted behaviours (snacking, screen time and physical activity). Furthermore, these changes appear to have a sustained effect on children's weight status and body shape. A definitive trial is now justified.

Table 1 Intervention phases, change targets, BCTs and the method and agent of delivery.

Intervention Phase	Change targets	Behaviour change techniques	Method (Frequency and duration) and agent of delivery	
Phase 1 **Creating a supportive context** Spring term (Yr 5)	Establish relationships with schools, children and families Raise awareness and increase knowledge Promote positive attitudes and norms towards healthy eating and physical activity Increase self efficacy for behaviour change	Provide information on behaviour-health link Provide information on health behaviour link Modelling/demonstrating behaviour Prompt identification as a role model Provide information on behaviour-health link Skill building	Whole school assembly (1) (20 mins) Newsletter articles (3) (Over the Spring term) Activity workshops (2) (parents observe) (1.5 hours) Parents' evening (1) involving child performances (1 hour)	HeLP Coordinators HeLP Coordinators Professional sportsmen/dancers Class teachers/ HeLP Coordinator /Drama group
Phase 2 **Intensive Healthy Lifestyles Week –** one week Summer term (Yr 5)	Strengthen relationships with schools, children and families Increase knowledge Increase self awareness Increase self efficacy Develop communication and problem solving skills Increase social support (school, peer and family)	Provide information on health behaviour link Problem solving/barrier identificationModelling/demonstrating behaviour Prompt identification as a role model Communication skills training Teach to use prompts and cues	*PSHE lessons (5) (morning) (1 hour) §Drama (5) (afternoon) (forum theatre; role play; food tasting, discussions, games etc) (2 hours)	Class teacher Drama group
Phase 3 **Personal Goal Setting with Parental Support-** goals set during week following drama Summer term (Yr 5)	Increase awareness of own behaviour Increase self efficacy for change Develop planning skills Increase parental support	Self monitoring Goal setting (behaviour) Problem solving/barrier identification Plan social support Provide information on where and when to perform a behaviour Agree behavioural contract Prompt identification as a role model	Self reflection questionnaire (1) (40 mins) Goal setting sheet to go home to parents to complete with child (1) (10 mins) 1:1 goal setting interview (1) (goals sent home to parents) (10 mins) Parent's evening (1) (child involvement – Forum Theatre) (1 hour)	HeLP Coordinator/ Class teacher HeLP Coordinator /Parents HeLP Coordinator HeLP Coordinator /Drama group
Phase 4 **Reinforcement Activities** Autumn term (Yr 6)	Increase self awareness and prioritise healthy goals. Consolidate social support. Develop monitoring and coping skills Increase parental support	Provide information on health behaviour link Prompt self monitoring Prompt intention formation Follow up prompts Prompt practice Prompt review of behavioural goals	Newsletter articles (2) (over the Autumn term) Whole school assembly (1) (20 mins) Drama workshop (1) (1 hour) *PSHE lesson (1) (1 hour) Class to deliver assembly about the project to rest of school (1) (20 mins)	HeLP Coordinator Drama group Drama group Class teacher Children to all other year groups in the school

Comment [j4]: R1 BCTs now map against descriptions from the new taxonomy (Michie et al., 2011)

		Prompt barrier identification and resolution Coping plans	(parents invited to attend) 1-to-1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (1) (10 mins) (renewed goals sent home to parents)	HeLP Coordinator

* PSHE – Personal, Social and Health Education

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

Table 2 Baseline characteristics of children allocated to the intervention and control

	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	 50.0 (40) 50.0 (40)	 50.0 (61) 50.0 (61)	 50.0 (101) 50.0 (101)
Total % of all children in the schools eligible for free school meals	5.7	9.7	7.9
Anthropometric Measures			
% (n) Overweight (≥85th and < 95th centile)[a]	10.5 (8)	7.6 (9)	8.7 (17)
% (n) Obese (≥95th centile)	13.2 (10)	18.5 (22)	16.4 (32)
% (n) Underweight (≤2nd centile)	1.3 (1)	0.0 (0)	0.5 (1)
% (n) with Bodyfat (≥85th and < 95th centile)[b]	5.3 (4)	11.8 (14)	9.2 (18)
% (n) with Bodyfat ≥95th centile	11.8 (9)	10.1 (12)	10.8 (21)
% (n) with Bodyfat ≤2nd centile	19.7 (15)	14.3 (17)	16.4 (32)
% (n) with Waist Circumference (≥85th and < 95th centile)[c]	21.3 (17)	21.3 (26)	21.3 (43)
% (n) with Waist Circumference ≥95th centile	21.3 (17)	21.3 (26)	21.3 (43)
Mean (sd) BMI [range]	17.4 (2.6) [13.3 to 25.4]	17.8 (2.8) [13.7 to 25.1]	17.6 (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]
Mean (sd) % Bodyfat [range]	19.3 (6.8) [3.0 to 37.4]	20.0 (6.7) [7.6 to 36.8]	19.71 (6.8) [3.0 to 37.4]
Mean (sd) % Bodyfat sds [range]	-0.9 (3.4) [-25.8 to 2.3]	-0.5 (1.7) [-6.5 to 2.4]	-0.6 (2.5) [-25.8 to 2.4]
Mean (sd) Waist Circumference (cm) [range]	62.0 (6.5) [50 to 81]	62.6 (7.0) [52 to 83]	62.3 (6.8) [50 to 83]
Mean (sd) Waist circumference sds [range]	0.8 (1.0) [-1.9 to 3.0]	0.91 (1.0) [-1.2 to 3.2]	0.9 (1.0) [-1.9 to 3.2]
Food Intake*(sd)			
Mean (sd) Energy Dense Snacks (EDS) [range]	4.2 (2.2) [0.0 to 10.7]	4.1 (2.1) [0.3 to 11.2]	4.2 (2.1) [0.0 to 11.2]
Mean (sd) Healthy Snacks (HS) [range]	3.2 (1.6) [0.3 to 8.4]	3.4 (1.7) [0.0 to 8.0]	3.4 (1.7) [0.0 to 8.4]
Mean (sd) Positive Food Markers (PM)	7.3 (2.9)	7.6 (3.3)	7.5 (3.1)

[range]	[2.6 to 15.0]	[2.3 to 20.3]	[2.3 to 20.3]
Mean (sd) Negative Food Markers (NM) [range]	6.8 (3.3) [1.4 to 16.6]	6.8 (3.2) [0.3 to 20.2]	6.8 (3.2) [0.3 to 20.2]
TV/screen viewing			
Mean (sd) TV/screen viewing (hours/day) [range]	2.5 (1.7) [0.1 to 7.9]	2.7 (1.7) [0.3 to 8.4]	2.6 (1.7) [0.1 to 8.4]
% (n) with TV in bedroom	45.6 (36)	59.8 (73)	54.2 (109)
% (n) with no rules re TV/screen time	39.2 (31)	33.9 (40)	36.0 (71)
Physical activity (mean time/day)			
Moderate-Vigorous PA/day (mins) [range]	36.7 (12.0) [13.7 to 70.0]	49.5 (20.0) [18.1 to 104.4]	43.6 (17.9) [13.7 to 104.4]
Sedentary Activities/day (hours) [range]	16.2 (1.6) [9.8 to 18.7]	16.4 (1.9) [10.6 to 19.2]	16.2 (1.9) [9.3 to 19.2]

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

a [38]

b [44]

c [45]

Table 3: Difference in outcomes at 18 and 24 months follow-up of children allocated to the intervention and control groups.

	Mean difference (Intervention minus Control) (95% CI)			
	18 months		24 months	
Outcome	Unadjusted	Adjusted for clustering	Unadjusted	Adjusted for clustering
BMI	-0.95 (-1.88 to -0.02)	-0.95 (-3.79 to 1.90)	-1.16 (-2.15 to -0.18)	-1.16 (-3.82 to 1.49)
BMI sds	-0.38 (-0.74 to -0.02)	-0.38 (-1.65 to 0.89)	-0.45 (-0.82 to -0.08)	-0.45 (-1.71 to 0.81)
%Body fat	-0.83 (-3.01 to 1.36)	-0.83 (-6.26 to 4.60)	-1.28 (-3.60 to 1.05)	-1.28 (-8.69 to 6.14)
%Body fat sds	-0.33 (-1.04 to 0.38)	-0.33 (-2.52 to 1.85)	-0.21 (-0.85 to 0.42)	-0.21 (-2.45 to 2.03)
Waist circumference (cm)	-2.01 (-4.23 to 0.21)	-2.01 (-9.54 to 5.52)	-2.97 (-5.36 to -0.59)	-2.97 (-10.30 to 4.35)
Waist circumference sds	-0.32 (-0.63 to -0.01)	-0.32 (-1.52 to 0.87)	-0.46 (-0.79 to -0.13)	-0.46 (-1.72 to 0.80)
% with BMI ≥85th centile	-7.6 (-20.5 to 5.3)	-7.6 (-49.4 to 34.2)	-9.7 (-22.4 to 3.1)	-9.7 (-27.8 to 8.5)
% with %Body fat ≥ 85th centile obese	-5.5 (-15.6 to 4.6)	-5.5 (-31.8 to 20.9)	-6.4 (-17.8 to 5.1)	-6.4 (-34.9 to 22.1)
% with Waist circumference ≥ 85th centile	-5.9 (-20.1 to 8.3)	-5.9 (-50.7 to 39.0)	-8.7 (-22.9 to 5.4)	-8.7 (-58.9 to 41.4)
Energy dense snacks (EDS)	-0.28 (-0.83 to 0.27)	-0.28 (-0.83 to 0.27)	-	-
Healthy snacks (HS)	0.47 (0.02 to 0.92)	0.47 (-1.29 to 2.23)	-	-
Positive food markers (PM)	0.38 (-0.37 to 1.13)	0.38 (-1.55 to 2.31)	-	-
Negative food markers (NM)	-0.69 (-1.52 to 0.15)	-0.69 (-1.70 to 0.33)	-	-
Duration of TV viewing (hours/day)	-0.41 (-0.91 to 0.09)	-0.41 (-1.28 to 0.46)	-	-
Sedentary Activities/day (hours)	-0.04 (-1.09 to 1.01)	-0.04 (-1.91 to 1.84)	-	-
Moderate-Vigorous PA/day (mins)	5.67 (0.20 to 11.15)	5.67 (-12.59 to 23.93)	-	-

Table 4: Sample size calculations for a definite RCT with primary outcome of BMI sds at 24 months under different assumptions

	80% Power			90% Power		
	Minimum Difference Detectable			Minimum Difference Detectable		
ICC	**0.25**	**0.30**	**0.50**	**0.25**	**0.30**	**0.50**
0.01	571	397	145	764	531	193
0.03	947	658	240	1267	880	320
0.06	1511	1050	383	2021	1404	511
0.10	2262	1572	573	3027	2103	765

[1]All numbers are the total number of children required to be recruited, assuming 50 children per school and a loss to follow-up at 24 months of 20%.
[2]The calculations take into account the reduction in variability associated with adjusting for baseline BMI sds, conservatively assuming the correlation between baseline and 24 months data to be 0.8 (in our pilot study this correlation was 0.93).
[3]This is the sample size required to detect a true minimal difference in BMI sds of 0.25, 0.3 or 0.5, assuming the standard deviation is 1.3 (based on our pilot data).

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Author contribution*:* JL drafted the manuscript with KW and SC providing critical revision. SC carried out the statistical analysis and drafted this section of the manuscript. JL developed and supported the design and production of the intervention materials, coordinated the implementation of the intervention and the collection of measurements at baseline, 18 and 24 months. JL, KW and SL designed the study and obtained funding. JL will act as guarantor of the paper. All authors approved the final version of the manuscript to be published.

References

1. Johnson B, Hackett AF. Eating habits of 11–14-year-old schoolchildren living in less affluent areas of Liverpool, UK. *J Hum Nutr Diet* 1997;**10**:135-44.
2. Owens J, Maxim R, McGuinn M, et al. Television-viewing Habits and Sleep Disturbance in School Children. *Pediatrics* 1999;**104**:e27.
3. Jackson-Leach R, Lobstein T. Estimated burden of paediatric obesity and co-morbidities in Europe. Part 1. The increase in the prevalence of child obesity in Europe is itself increasing. *Int J Pediatr Obes* 2006;**1**:26-32.
4. The NHS Information centre. Health Survey for England - 2008 Trend Tables. London: 2009.
5. National Child Measurement Programme. Results from the School Year 2009/10 Oxford: 2010.
6. Gunnell DJ, Frankel SJ, Nanchahal K, et al. Childhood obesity and adult cardiovascular mortality: a 57-y follow-up study based on the Boyd Orr cohort. *Am J Clin Nutr* 1998;**67**:1111-8.
7. Singh AS, Mulder C, Twisk JWR, et al. Tracking of childhood overweight into adulthood: a systematic review of the literature. *Obes Rev* 2008;**9**:474-88.
8. Hughes AR, Sherriff A, Lawlor DA, et al. Incidence of obesity during childhood and adolescence in a large contemporary cohort. *Prev Med* 2011;**52**:300-4.
9. Lake JK, Power C, Cole TJ. Child to adult body mass index in the 1958 British birth cohort: associations with parental obesity. *Arch Dis Child* 1997;**77**:376-80.
10. Li L, Law C, Lo Conte R, et al. Intergenerational influences on childhood body mass index: the effect of parental body mass index trajectories. *Am J Clin Nutr* 2009;**89**:551-7.
11. Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA* 2003;**289**:450-3.
12. National Travel Survey. Trends in personal travel trips, distance travelled and time taken per person per year: Great Britain, since 1972/73. London: 2010.
13. Molnár D, Livingstone B. Physical activity in relation to overweight and obesity in children and adolescents. *Eur J Pediatr* 2000;**159**:S45-S55.
14. Wareham N. Physical activity and obesity prevention. *Obes Rev* 2007;**8 Suppl 1**:109-14.
15. Riddoch CJ, Leary SD, Ness AR, et al. Prospective associations between objective measures of physical activity and fat mass in 12-14 year old children: the Avon Longitudinal Study of Parents and Children (ALSPAC). *BMJ* 2009;**339**.
16. Childwise. The Childwise Monitor Trends report 2010/11. Norwich: 2011.

17. Marshall SJ, Biddle SJ, Gorely T, et al. Relationships between media use, body fatness and physical activity in children and youth: a meta-analysis. *Int J Obes Relat Metab Disord* 2004;**28**:1238-46.
18. Wiecha JL, Peterson KE, Ludwig DS, et al. When Children Eat What They Watch: Impact of Television Viewing on Dietary Intake in Youth. *Arch Pediatr Adolesc Med* 2006;**160**:436-42.
19. Halford JCG, Gillespie J, Brown V, et al. Effect of television advertisements for foods on food consumption in children. *Appetite* 2004;**42**:221-5.
20. de Silva-Sanigorski A, Bolton K, Haby M, et al. Scaling up community-based obesity prevention in Australia: Background and evaluation design of the Health Promoting Communities: Being Active Eating Well initiative. *BMC Public Health* 2010;**10**:1-7.
21. de Silva-Sanigorski AM, Bell AC, Kremer P, et al. Reducing obesity in early childhood: results from Romp & Chomp, an Australian community-wide intervention program. *Am J Clin Nutr* 2010;**91**:831-40.
22. Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;**10**:110-41.
23. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.
24. Lloyd JJ, Logan S, Greaves CJ, et al. Evidence, Theory and Context - Using intervention mapping to develop a school-based intervention to prevent obesity in children. *Int J Behav Nutr Phys Act* 2011;**8**:73.
25. Wyatt KM, Lloyd JJ, Creanor S, et al. The development, feasibility and acceptability of a school-based obesity prevention programme: results from three phases of piloting. BMJ Open 2011. http://bmjopen.bmj.com/content/early/2011/05/23/bmjopen-2010-000026.abstract (accessed 13 September 2011).
26. Fisher JD, Fisher WA. The information-motivation-behavioral skills model. In: DiClemente R, Crosby R, Kegler M, eds. Emerging theories in health promotion practice and research. San Fransisco: Jossy-Bass 2002:40-70.
27. Fisher JD, Fisher WA, Amico KR, et al. An Information-Motivation-Behavioral Skills Model of Adherence to Antiretroviral Therapy. *Health Psych* 2006;**25**:462-73.
28. Fisher JD, Fisher WA, Williams SS, et al. Empirical Tests of an Information-Motivation-Behavioral Skills Model of AIDS-Preventive Behavior With Gay Men and Heterosexual University Students. *Health Psych* 1994;**13**:238-50.
29. NICE. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. London: NICE 2006.
30. Bartholomew LK. Planning health promotion programs: an intervention mapping approach. San Francisco: Jossey-Bass 2006:171-459.
31. Michie S, Ashford S, Sniehotta FF, et al. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. *Psychol Health* 2011;**26**:1479-98.
32. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychol* 2008;**27**:379-87.
33. Stone MR, Rowlands AV, Eston RG. Characteristics of the activity pattern in normal weight and overweight boys. *Prev Med* 2009;**49**:205-8.
34. Kerry SM, Bland JM. Trials which randomize practices I: how should they be analysed? *Family Practice* 1998;**15**:80-3.
35. Donner A, Klar N. Design and analysis of cluster randomization trials in health research. London: Arnold 2000:1-178.
36. Bland JM, Kerry SM. Weighted comparison of means. *BMJ* 1998;**316**:129.

37. Campbell M, Elbourne D, Altman D. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;**328**:702 - 8.
38. Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Arch Dis Child* 1995;**73**:25-9.
39. Taylor RW, McAuley KA, Barbezat W, et al. APPLE Project: 2-y findings of a community-based obesity prevention program in primary school age children. *Am J Clin Nutr* 2007;**86**:735-42.
40. Gortmaker SL, Peterson K, Wiecha J, et al. Reducing obesity via a school-based interdisciplinary intervention among youth: Planet Health. *Arch Pediatr Adolesc Med* 1999;**153**:409-18.
41. Caballero B, Clay T, Davis SM, et al. Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren. *Am J Clin Nutr* 2003;**78**:1030-8.
42. Ford AL, Hunt LP, Cooper A, et al. What reduction in BMI SDS is required in obese adolescents to improve body composition and cardiometabolic health? *Arch Dis Child* 2009.
43. Foresight. Tackling obesities: future choices-project report. London: The Stationery Office 2007.
44. McCarthy HD, Cole TJ, Fry T, et al. Body fat reference curves for children. *Int J Obes* 2006;**30**:598-602.
45. McCarthy HD, Jarrett KV, Crawley HF. The development of waist circumference percentiles in British children aged 5.0-16.9 y. *Eur J Clin Nutr* 2001;**55**:902-7.