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## Katrina Wyatt and Jennifer Lloyd

### Development of a novel, school located, obesity prevention programme, the Healthy Lifestyles Programme (HeLP)

The obesity epidemic is rapidly and constantly growing and affects all socio-economic levels and ethnicities (Kriemler & Zahner et al., 2010). In 2010, 43 million children were estimated to be overweight and obese across the world (de Onis, Blossner & Borghi, 2010). The most recent Health Survey for England (NHS Information Centre, 2011a) reports that 16.1% of boys and 15.3% of girls aged 2-15 were obese with 15.4% of boys and 12.9% of girls classified as overweight. The National Child Measurement Programme (NHS Information Centre, 2011b) data report that more than one in five 5-6 yr olds and one in three 10-11 year olds are either overweight or obese. Childhood obesity is associated with serious emotional and physical health problems (Bibbins-Domingo & Coxson et al., 2007) and is an independent risk factor for adult obesity (Singh & Mulder et al., 2008). Given the significant short- and long-term health and social consequences, treatment and prevention of obesity is of utmost importance.

Obesity occurs as a result of an incorrect energy balance; however, there are a multitude of interrelating behavioural, environmental, social and genetic factors which can contribute to excessive weight gain (McPherson, Marsh & Brown, 2007). Epidemiological studies suggest a number of risk factors, the strongest of which is having one or more overweight parents (Lake, Power & Cole, 1997) and there are also strong associations, between the risk of overweight and socio-economic status, diet, physical activity levels and other lifestyle factors (Li & Law et al., 2009). 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 (Nielsen & Popkin, 2003).

The association with overweight and obesity and physical activity is not clear with cross-sectional studies showing a reduction in levels and intensity of physical activity in children and an increase in percentage body fat (Jiménez-Pavón, Kelly & Reilly, 2010). Longitudinal studies looking at this relationship suggest that fitness leads to a reduction in physical activity rather than the other way round (Metcalf & Hosking et al., 2010); however, the relationship is likely to be bidirectional. Some studies have reported an association between time spent watching television and obesity (Marshall & Biddle et al., 2004). Not only is television viewing a sedentary activity, but it is also positively correlated with total calorific intake (Wiecha & Peterson et al., 2006) and the consumption of snack foods (Halford & Gillespie et al., 2004).

Although the prevalence of childhood obesity has trebled in the last three decades there is little evidence regarding effective obesity prevention programmes (Foster & Linder et al., 2010; Singh & Chin et al., 2009). A systematic review of controlled trials of school-based interventions concluded that interventions which increase activity and reduce sedentary behaviour may help children to maintain a healthy weight, although results were short-term and inconsistent (Brown & Summerbell, 2008). The reviewers also suggested that a combined approach may be more effective in preventing children becoming overweight in the long term.

We sought to develop a school-located obesity prevention programme which used creative delivery methods to engage and support schools children and their families in adopting sustainable changes to their lifestyles. The Healthy Lifestyle Programme (HeLP) seeks to deliver healthy lifestyle messages and provide simple individually-tailored strategies to assist

change relating to healthy activity and eating. HeLP takes a population approach seeking to change behaviour at a family as well as at an individual and institutional level.

### **The Healthy Lifestyles Programme (HeLP)**

The Healthy Lifestyles Programme was developed with extensive stakeholder support (teachers, sports partnership and healthy schools coordinators, public health personnel, behavioural scientists, epidemiologists, paediatricians and drama experts) and further refined in two schools in Devon, involving 200 children, teachers and headteachers to determine the most appropriate age and the most engaging delivery methods to create supportive environments for healthy behaviours.

HeLP is a multi-component four-phase programme which takes place over three school terms (the spring and summer term of Year 5 and the autumn term of Year 6) and aims to deliver a general healthy lifestyle message encouraging a healthy energy balance, with a focus on three specific evidence-based behaviours: a decrease in the consumption of sweetened fizzy drinks; an increase in the ratio of healthy to unhealthy snacks consumed and a reduction in screen-based activities. Throughout the programme the children are encouraged to find acceptable activity and dietary replacements in order to maintain a healthy energy balance. Piloting has demonstrated that it was helpful for children and their parents to frame these behaviours around the 80:20 concept, suggesting we should eat healthily and be active 80% of the time. This message was easy to remember and provided room for negotiation for both child and parent. Piloting across three age groups (Year 4, 8-9 year olds, Year 5, 9-10 year olds and Year 6, 10-11 year olds) also showed that Year 5 were the most appropriate Year group for the Programme as they engaged to a very high level and, crucially, were most effective in taking the messages home and in initiating change within the family.

Each phase of the Programme has a specific function and has been ordered to enable and support lifestyle change as shown in the box below.

#### **HeLP programme phases 1-4**

- Phase 1 - Creating a Supportive Context, aims to establish relationships and raise awareness of the Programme using a number of introductory activities.
- Phase 2 - The Healthy Lifestyles Week aims to strengthen relationships, build motivation, increase knowledge and build skills and confidence using education sessions and interactive drama.
- Phase 3 - Personal goal setting with parental support aims to increase self awareness, develop planning skills and increase parental support using a self reflection questionnaire and 1-1 goal setting.
- Phase 4 - Reinforcement Activities - aims to reinforce programme messages, develop self-monitoring and coping skills and increase parental support using a range of activities.

HeLP includes a range of behaviour change techniques (BCTs) designed to enhance relevant information, motivation and behavioural skills (Abraham, 2012; Abraham & Michie, 2008). The Programme utilises accessible and engaging delivery methods that are compatible with the existing school curriculum as well as providing several opportunities for parental engagement. Table 1 (below) shows each phase of HeLP, their function, the BCTs used as well as the method and agent of delivery.

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

Intervention Phase	Change targets (function)	Behaviour change techniques	Method (Frequency and duration)	Agent of delivery
Phase 1  Creating a supportive context  Spring term (Yr 5)	Establish relationships with schools, children and families	Provide information on behaviour-health link	Whole school assembly (1x20 mins)	HeLP Coordinator
	Raise awareness and Increase knowledge	Provide information on behaviour-health link	Newsletter articles (3)(Over the Spring term)	HeLP Coordinator
	Promote positive attitudes and norms towards healthy eating and physical activity	Modelling/demonstrating behaviour Prompt identification as a role model	HeLP messages rap lesson (1x1 hour) Activity workshops (2x1.5 hours) (parents observe)	Class teacher Professional sportsmen/dancers
	Increase self efficacy for behaviour change	Provide information on behaviour-health link Skill building	Parents' evening (1x1 hour) involving child performances	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	Provide information on behaviour-health link	PSHE lessons (Personal, Social and Health Education) (5x 1 hour) (am)	Class teacher
	Increase knowledge, self awareness and self efficacy	Problem solving/barrier identification Modelling/demonstrating behaviour	Drama (5x2 hours) (pm) (forum theatre; role play; food tasting, discussions, games etc)	Drama group
	Develop communication and problem solving skills	Prompt identification as a role model Communication skills training		
	Increase social support (school, peer and family)	Teach to use prompts and cues		
Phase 3  Personal Goal Setting with Parental Support- goals set during week following drama  Summer term (Yr 5)	Increase awareness of own behaviour	Self monitoring Goal setting (behaviour)	Self reflection questionnaire (1x40 mins)	HeLP Coordinator/ Class teacher
	Increase self efficacy for change	Problem solving/barrier identification Plan social support	Goal setting sheet to go home to parents to complete with child (1x10 mins)	HeLP Coordinator /Parents
	Develop planning skills Increase parental support	Provide information on where and when to perform a behaviour Agree behavioural contract	1:1 goal setting interview (1x10 mins) (goals sent home to parents) Parent's evening (1) (child involvement – Forum Theatre) (1x1 hour)	HeLP Coordinator HeLP Coordinator /Drama group
		Prompt identification as a role model		
Phase 4  Reinforcement Activities  Autumn term (Yr 6)	Increase self awareness and prioritise healthy goals. Consolidate social support.	Provide information on behaviour-health link Prompt self monitoring	Newsletter articles (1) Whole school assembly (1x 20 mins)	HeLP Coordinator Drama group
	Develop monitoring and coping skills Increase parental support	Prompt intention formation Follow up prompts	Drama workshop (1x1 hour) PSHE lesson (1x1 hour) Class to deliver assembly about the project to rest of school (1x20 mins)	Drama group Class teacher Children to all other year groups
		Prompt practice 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 (1x10 mins) (renewed goals sent home to parents)	HeLP Coordinator

Our hypothesis is that targeting information, motivation and behavioural skills, whilst building supportive and trusting relationships at the level of the school, child and family will lead to improvements in diet and physical activity thus preventing excessive weight gain.

Key to engaging the children are the interactive drama activities in phase 2 in which the children identify with and take ownership of the healthy lifestyle messages. In order to promote this, the drama has been built around a framework of characters, each represented by an actor whose attributes relate to the healthy lifestyle messages. The characters are *Disorganised Duncan*, *Football Freddie*, *Snacky Sam* and *Active Amy*. Children choose which character they feel they most resemble and work very closely with them to help them change their behaviours. The children, therefore, co-create scenes with the actors and are actively involved in all decision making. Other activities during these sessions include food tasting, making smoothies, role playing temptations and overcoming barriers and forum theatre.

### **Proof of Concept**

An exploratory trial of HeLP to determine the acceptability and feasibility of the programme, taking anthropometric and behavioural measures as well as all the processes associated with conducting a trial of HeLP, was conducted with four schools, including seven Year 5 classes and 203 children. Baseline measures (height, weight, waist circumference and body fat, objectively measured physical activity, food consumption using the Food Intake Questionnaire (Johnson & Hackett, 1997) and screen time, assessed using screen time viewing habits questionnaire (Owens & Maxim et al., 1999) were taken on 201 children who consented to participate. Schools were then randomised to receive the HeLP Programme or to be 'control' schools. The measures were repeated at 18 months, on all children, when they were in Year 6 and height and weight, waist circumference and body fat measures were taken again at 24 months when the children had moved to secondary school. The

results showed that schools, children and their families found the trial design and the intervention feasible and acceptable with only three children not consenting to participate in the research. Over the course of the study a further eight children were lost to follow up (three withdrew and five moved out of the area). 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 to vigorous physical activity each day than children in the control schools. The percentage of children classified as overweight or obese at baseline was similar for both intervention and control at baseline (24% and 26% respectively) but this had increased to 32% at 18 and 24 month follow up in the control children whilst remaining at baseline levels in the intervention children. Overall, 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 summed difference score (Lloyd, Wyatt & Creanor, 2012).

### **Cluster randomized controlled trial to determine the effectiveness and cost effectiveness of HeLP in preventing childhood obesity**

Funding was secured from NIHR-PHR in January 2012 to conduct a 32-school trial involving *circa* 1300 Year 5 children and their families in the Healthy Lifestyles Programme.

Figure 1 (page 95) shows the proposed flow of the trial as well as the details of the measures to be taken.

### **Recruitment of schools**

Schools have been recruited through presentations at local meetings of the SW Association of Primary Heads and at the individual local learning community meetings for head teachers. Further presentations were made at the county conferences for deputy head teachers and primary school leads for Personal, Social and Health Education (PSHE). All state

primary and junior schools with children in single year 5 groups, based in the South West of England were eligible to participate. We have ensured that at least half of the schools we recruit have 19% or more pupils eligible for free school meals, to reflect the national average.

For practical reasons, half of the control schools have been randomised into cohort 1 and baseline measures taken in 2012, and schools randomised to be in cohort 2 and will enter the study in 2013. The random sequence of allocation of schools to intervention or control has been computer-generated and stratified by (i) the proportion of children eligible for free school meals (<19%, ≥19%) and (ii) school size (one Year 5 class, >1 Year 5 class).

### **Ethical approval and consent**

Ethical Approval was obtained from the Peninsula College of Medicine and Dentistry in March 2012.

*Families* - Information sheets are sent to parents directly from the school and include the rationale for the study and emphasise the importance of healthy growth. The information sheet explains that if parents want to opt their child out of the programme, they need to return a form within two weeks, otherwise consent will be inferred. This 'opt out' approach has been used in other cluster randomised clinical trials (Junghans & Feder et al., 2005) and was agreed to by the Ethics Committee on the basis of the low risk of adverse effects of the intervention. Alternative arrangements for children not participating are made in consultation with the teacher and parents, based on what would be best for that child.

*Children* - When the anthropometric measures (height, weight, waist circumference, body fat) are taken the children have the option to decline if they so wish at the time of measurement. At baseline and 18 months, measurements are carried out during a general maths lesson on measurement. During this lesson, children are taken out of the class one at a time for the measures in private. Measurements are carried out by a trained outcome assessor who is 'blind' to group allocation.

The scales used to weigh and calculate percent body fat give a print out of the readings, thereby ensuring that children are not able to read and, therefore, possibly discuss, their own results. As the children are at secondary school at the time of the 24-month measures, individual arrangements will be made with each child regarding their measures being taken.

### **Progress to date**

Forty five schools expressed a willingness to participate, of which nine were ineligible due to mixed year groups and small numbers of Year 5 pupils. Four schools agreed to go on a waiting list (should any Cohort 2 schools drop out before baseline measures). There are 1380 pupils in the 32 schools who are participating (678 in cohort 1 and 702 in cohort 2). Only 17 out of 678 pupils opted out of cohort 1 and baseline measures have been taken on 658 children.

Intervention activities are underway with the eight schools receiving the programme in cohort 1 and baseline measures will be taken in all schools in Cohort 2 in October 2013.

The results from this trial (available in October 2016) will provide evidence regarding the effectiveness and cost effectiveness of HeLP. Should the programme prove to be both effective and cost effective, in supporting children and their families to make small lifestyle changes that affect children's weight status, the next phase of research will involve how best to implement HeLP on a wider scale. We will work closely with the local education authority and public health to build capacity and assess feasibility.

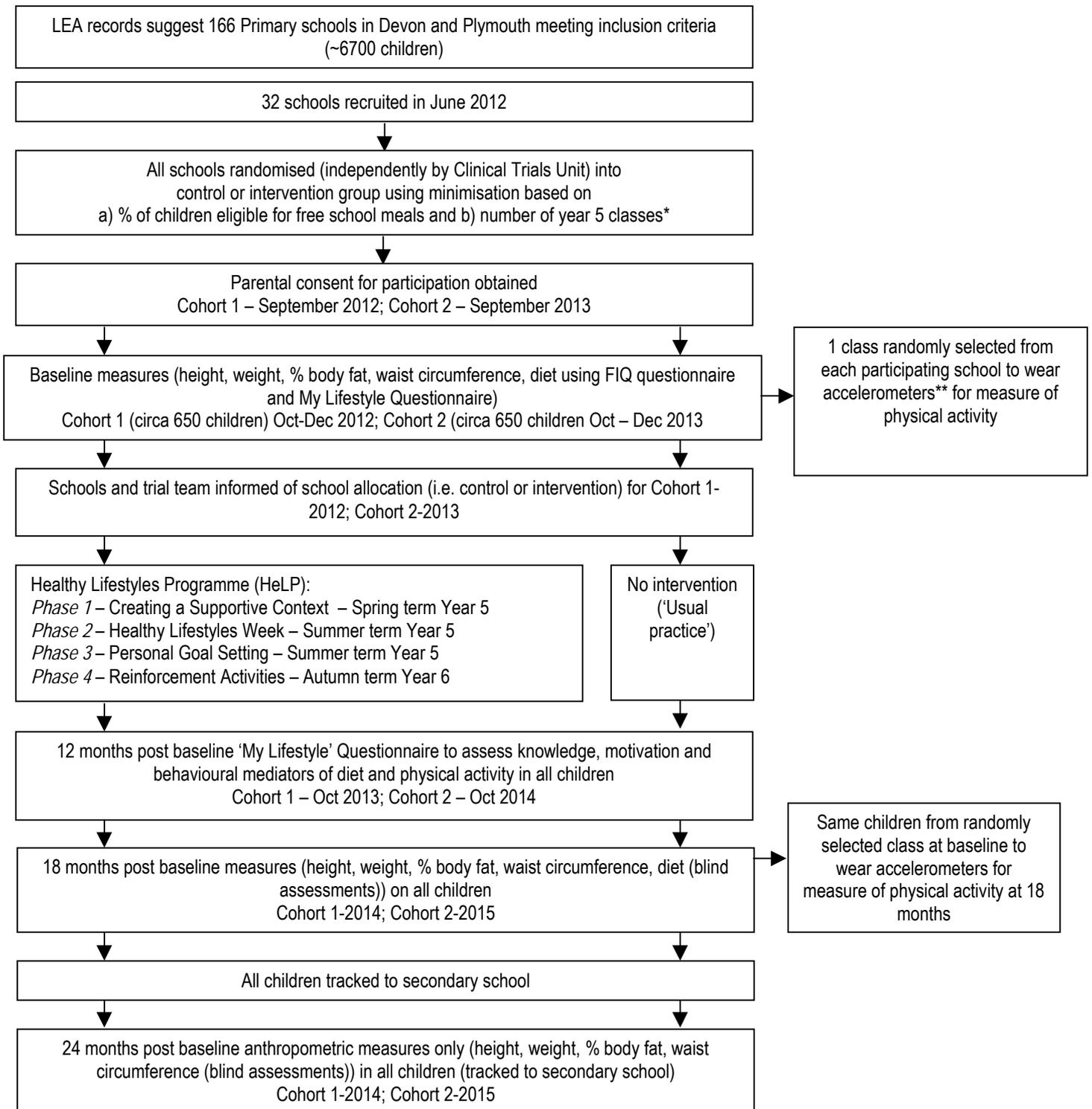
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See page 95 for Figure 1: Flow diagram of participants in the cluster RCT of the Healthy Lifestyles Programme to prevent obesity in school children

**Figure 1: Flow diagram of participants in the cluster RCT of the Healthy Lifestyles Programme to prevent obesity in school children**



\* For practical reasons 16 schools will enter the study in Year 1 and 16 in Year 2. Randomisation will be performed by the CTU immediately after all schools have been recruited (2012) but allocation (intervention or control) will not be communicated to the schools, parents or researchers until *after* baseline measures have been taken in each cohort (2012 for cohort 1 and 2013 for cohort 2). The CTU will ensure that equal numbers of control and intervention schools are in the 1<sup>st</sup> and 2<sup>nd</sup> time period.

\*\* Accelerometers are worn continuously by the children for a week to determine their total daily volume of physical activity and mean daily time spent in sedentary, low, moderate and vigorous intensity physical activity.