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Uptake, retention and engagement of children participating in the cluster randomised controlled trial of the Healthy Lifestyles Programme (HeLP)

In 2013, we presented the development of a novel, school-located obesity prevention programme called the Healthy Lifestyles Programme (HeLP) (Wyatt & Lloyd, 2013). At this time we had just embarked on the 5-year definitive trial to assess the effectiveness and cost effectiveness of HeLP in 32 schools across Devon (funded by the National Institute for Health Research Public Health Research Programme). The current paper is an update of our progress to date and will provide a brief overview of the programme and the trial and present data on child recruitment and follow up as well as uptake and engagement of children and parents receiving the HeLP programme.

Conceptualisation of the Healthy Lifestyles Programme (HeLP)

A crucial focus for us in developing an obesity prevention programme was to promote engagement of schools, children and their families throughout the intervention as we believed this to be essential for behaviour change to occur. In line with the WHO's Health Promoting Schools framework (Langford et al., 2011), we took a whole school approach and aimed to develop activities that were compatible with the existing school curriculum. We promoted messages in a manner that would impact the wider school culture, as well as specific behaviours of children and their families. First and foremost; we sought to build supportive and trusting relationships with teachers, children and their families. We employed coordinators with specific skills and competences, using the initial phase of the intervention to create a receptive context for the Programme and by using

engaging delivery methods to try and increase uptake of HeLP. Previous research into preventing childhood obesity has found it difficult to engage parents in order to affect change within the family (Hesketh et al., 2005; Sonnevile et al., 2009), thus we believed that the delivery methods needed to be sufficiently dynamic, creative and empowering to motivate the children to talk about the activities at home with their parents and encourage them to come into the school to attend key events. Most school-based obesity prevention interventions to date have used traditional delivery methods such as education lessons to teach children about the importance of healthy nutrition and physical activity as opposed to methods where the child actively engages with the messages (Khambalia et al., 2012). In developing HeLP we were mindful that the children themselves, if sufficiently motivated, were a key resource in taking messages home to their families, encouraging their parents to attend activities and in affecting change at home. This thinking led us to explore the use of interactive drama as it has shown promise in promoting positive attitudes towards a number of health behaviours (Joronen et al., 2008), and was a means of delivering a range of behaviour change techniques.

The Healthy Lifestyles Programme:

The Healthy Lifestyles Programme is a multi-component school-based obesity prevention intervention delivered to all Year 5 children (9-10 year olds) within a school. It consists of 4 phases delivered over three school terms, which have been ordered to enable and support behaviour change (Lloyd and Wyatt, 2015).

HeLP delivers a general healthy lifestyle message, encouraging a healthy energy balance with a focus on three specific behaviours relating to energy intake and energy expenditure; decreasing the consumption of sweetened fizzy drinks; increasing the ratio of healthy to unhealthy snacks consumed and reducing screen-based activities. The delivery methods used are highly interactive and encourage identification with, and ownership of, the healthy lifestyle messages so that children are motivated to take them home to their parents and effect change within the family. A key delivery method we use is drama which 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*, *Active Amy* and *Snacky Sam*.

Each school has one key contact person called the HeLP Coordinator (HC) who liaises with school staff and parents. They are also involved in delivering aspects of the intervention and liaising with other delivery personnel. Table 1 (page 90) shows each phase of HeLP, their function, the behaviour change techniques (BCTs) used as well as the delivery method and personnel.

The Trial

The cluster randomised controlled trial assesses effectiveness and cost effectiveness of HeLP in preventing overweight and obesity in children (Wyatt et al., 2013). The primary outcome is change in body mass index standard deviation scores (BMI SDS), which represent age and gender-standardised BMI, at 24 months post-randomisation. The trial started in 2012 and involves 32 schools (1324 children) across Devon. Schools were recruited via the Devon Association of Primary School Heads (DAPH) and local learning community meetings. All state primary and junior schools with children in single year 5 groups of 20 or more children were eligible to participate. Ethical approval was obtained from the University Ethics Committee in March 2012.

Sixteen of the schools recruited had >19% pupils eligible for free school meals, which represented the national average at the start of the trial. Half of the schools were randomised to receive HeLP and half are acting as control schools. Schools were randomly allocated to intervention or control, stratified by the proportion of children eligible for free school meals (< 19%, ≥ 19%) and class size

(one year 5 class, > 1 year 5 class). For practical reasons half of the schools entered the study in 2012 (8 intervention, 8 control), and the other half in 2013. Children were recruited using an 'opt out' system in which detailed information about the trial was sent directly home to parents via the school with parents returning an 'opt out' form if they did not wish their child to participate. Parents were able to speak to the class teacher or the HC at any time if they required further information. Children had measures taken at baseline (before group allocation was revealed to schools and research staff) and then at 18 and 24 months post baseline. At 12 months (following the intervention for programme schools), all children complete the *My Lifestyles Questionnaire*, developed by the research team to assess knowledge, individual motivations and cognitions, parental behaviours, child use of behaviour change techniques and specific behaviours that mediate levels of physical activity and food intake in children (Wyatt et al., 2013).

Outcome Measures

Anthropometric outcomes

Height was measured using a SECA stadiometer (Hamburg, Germany), recorded to an accuracy of 1mm. Weight was measured using the Tanita Body Composition Analyser SC-330 (U.K. Ltd., Middlesex, U.K.). Weight was recorded to within 0.1kg and children are asked to take off their shoes and socks. BMI is calculated and converted to centiles using the software package LMS, developed by Cole (Cole, 1990).

Percent body fat was estimated from leg-to-leg bioelectric impedance analysis (Tanita Body Composition Analyser SC-330) and converted to centiles using the LMS software (Cole, Freeman and Preece, 1995). Waist circumference was measured using a non-elastic flexible tape measure, 4cm above the umbilicus. In order to put children at ease and minimise any possible stigmatisation of overweight or sensitive children, these measurements formed part of a specially designed lesson which was based around measuring in general and how information can be presented. The HC led the lesson (for baseline measures only) so that they got to know the children. Each child, one at a time, left the classroom to go to a private room and have their height, weight, waist circumference and bio-electrical impedance measured by two trained researchers.

Table 1 Intervention phases, function, BCTs, delivery methods and personnel

Intervention Phase	Function	Behaviour Change techniques (BCTs)	Component (Frequency and Duration)	Agent of delivery
Phase 1 Creating a supportive context Spring term (Yr 5) Jan-March	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 (1x20 mins) Newsletter article Literacy lesson (to create HeLP rap.poem) (1x1 hour) Activity workshops (2x1.5 hours) Parent assembly (1x1 hour) involving child performances	HeLP Coordinators HeLP Coordinators Class teacher Professional sportsmen/dancers Class teachers/ HeLP Coordinator /Drama group
Phase 2 Intensive Healthy Lifestyles Week – one week Summer term (Yr 5) April-June	<ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> Provide information on health behaviour link Problem solving/barrier identification Modelling/demonstrating behaviour Prompt identification as a role model Communication skills training Teach to use prompts and cues 	Education lessons (5x1 hour) (morning) Drama (5x2 hours) (afternoon) (forum theatre; role play; food tasting, discussions, games etc.).	Class teacher Drama group
Phase 3 Personal Goal Setting with Parental Support- goals set during week following drama Summer term (Yr 5) June-July	<ul style="list-style-type: none"> Increase awareness of own behaviour Increase self-efficacy for change Develop planning skills Increase parental support 	<ul style="list-style-type: none"> 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 (1x40 mins) Goal setting sheet to go home to parents to complete with child (1x10 mins) 1:1 goal setting interview (1x10 mins) (goals sent home to parents) Forum theatre assembly (1x1 hour)	HeLP Coordinator HeLP Coordinator /Parents HeLP Coordinator HeLP Coordinator /Drama group
Phase 4 Reinforcement Activities Autumn term (Yr 6) Sept-Dec	<ul style="list-style-type: none"> Increase self-awareness and prioritise healthy goals. Consolidate social support. Develop self-monitoring and coping skills Increase parental support 	<ul style="list-style-type: none"> Provide information on health behaviour link Modelling/demonstrating behaviour Prompt identification as a role model Provide social approval Prompt self-monitoring Prompt intention formation Follow up prompts Prompt review of behavioural goals Prompt barrier identification and resolution Coping plans 	Education lesson (1x1 hour) Drama workshop (1x1 hour). Followed by a class delivered assembly about the project to rest of school (1x20 mins). 1-to-1 goal supporting interview to discuss facilitators/barriers and to plan new coping strategies (1x10 mins) (renewed goals sent home to parents)	Class teacher Drama group HeLP Coordinator HeLP Coordinator

For the subsequent 18 and 24 month follow up measures, children came out of their classroom to have the same measures taken by trained researchers. The HC was always present to keep the children at ease and ensure the process went as smoothly as possible.

Behavioural outcomes

Physical activity was assessed using a GENEActiv accelerometer. Pupils in one randomly selected class from each school were asked to wear a [GENEActiv accelerometer](#) - a device worn like a watch around the wrist during waking and sleeping hours over-seven consecutive days. Information packs were sent directly home to parents one week before the children came home with the watches, so that they were aware of all the procedures discussed with the children on the day of 'hook up'. On the day of 'hook up' the HC spoke to 10 children at a time about the watches and ensured that all understood how to comply with procedures.

Food intake was assessed using the adapted version of the validated *Food Intake Questionnaire* (FIQ) (Johnson and Hackett, 1997). The FIQ asks children about the food and beverages they consumed the previous day and allows an estimation of the number of healthy and unhealthy food and drink items consumed per day. Children complete the FIQ twice in order to obtain a weekday and weekend food intake. The HC led the two lessons required for the children to complete the questionnaires. Children were arranged in literacy tables to ensure that help could be given as efficiently as possible. Another researcher and the class teacher and teaching assistant (TA) provided support.

The *My Lifestyle Questionnaire* was more difficult to understand than the FIQ. The HC led its completion as a whole class activity ensuring that children with additional learning needs completed it in another room supported closely by another researcher and/or the TA.

Baseline characteristics of recruited schools and child demographics

Table 2 presents the demographics of recruited schools and children at baseline (numbers and percentages unless otherwise specified).

Table 2: Demographics of recruited schools and children at baseline

School Characteristics	Cohort 1	Cohort 2	Total
Number of Participating Schools	16	16	32
Number of Year 5 Classes	24	23	47
Mean (sd) [range] Percentage of Free School Meals	20.3 (9.8) [6.1 – 37.8]	19.6 (13.5) [5.3 – 52.8]	20.0 (11.6) [5.3 – 52.8]
Median (IQR) Percentage of Free School Meals ²	20.4 (10.7 – 26.7)	15.8 (10.5 – 2.5)	17.3 (10.7 – 26.7)
Child demographics			
Number of Participating Children	658	666	1324
Gender:			
Female	50.8 (334)	51.5 (343)	51.1 (677)
Male	49.2 (324)	48.5 (323)	48.9 (647)
Mean (sd) [range] of Age (years)	(n=655) 9.8 (0.3) [9.2 – 10.8]	(n=659) 9.8 (0.3) [9.2 – 10.3]	(n=1314) 9.8 (0.3) [9.2 – 10.8]

Recruitment and follow up

A total of 44 schools expressed an interest, of which 36 were eligible. Four schools were randomly selected to go on our wait list, thus 32 schools with a total of 1324 children participated in the trial; 16 schools with 658 children entered the study in 2012 (cohort 1) and 16 schools with 666 children entered the study in 2013 (cohort 2) (Wyatt et al., 2013). Thirty four children opted out prior to baseline measures (17 in cohort 1 and 17 in cohort 2). Figure 1 (page 92) shows the flow of children through the trial with the completeness of follow-up data at each time point.

Intervention uptake (child and parent)

Across both cohorts 677 children were randomised to receive the intervention; delivery of the intervention was between January 2013–November 2013 for Cohort 1 and January 2014 – November 2014 for Cohort 2 (Table 3 below). Child attendance registers were kept for each component in each phase and parental attendance was documented for all parental engagement activities.

Table 3: Percentage of children participating in each phase of the HeLP intervention and the total percentage of children receiving key components

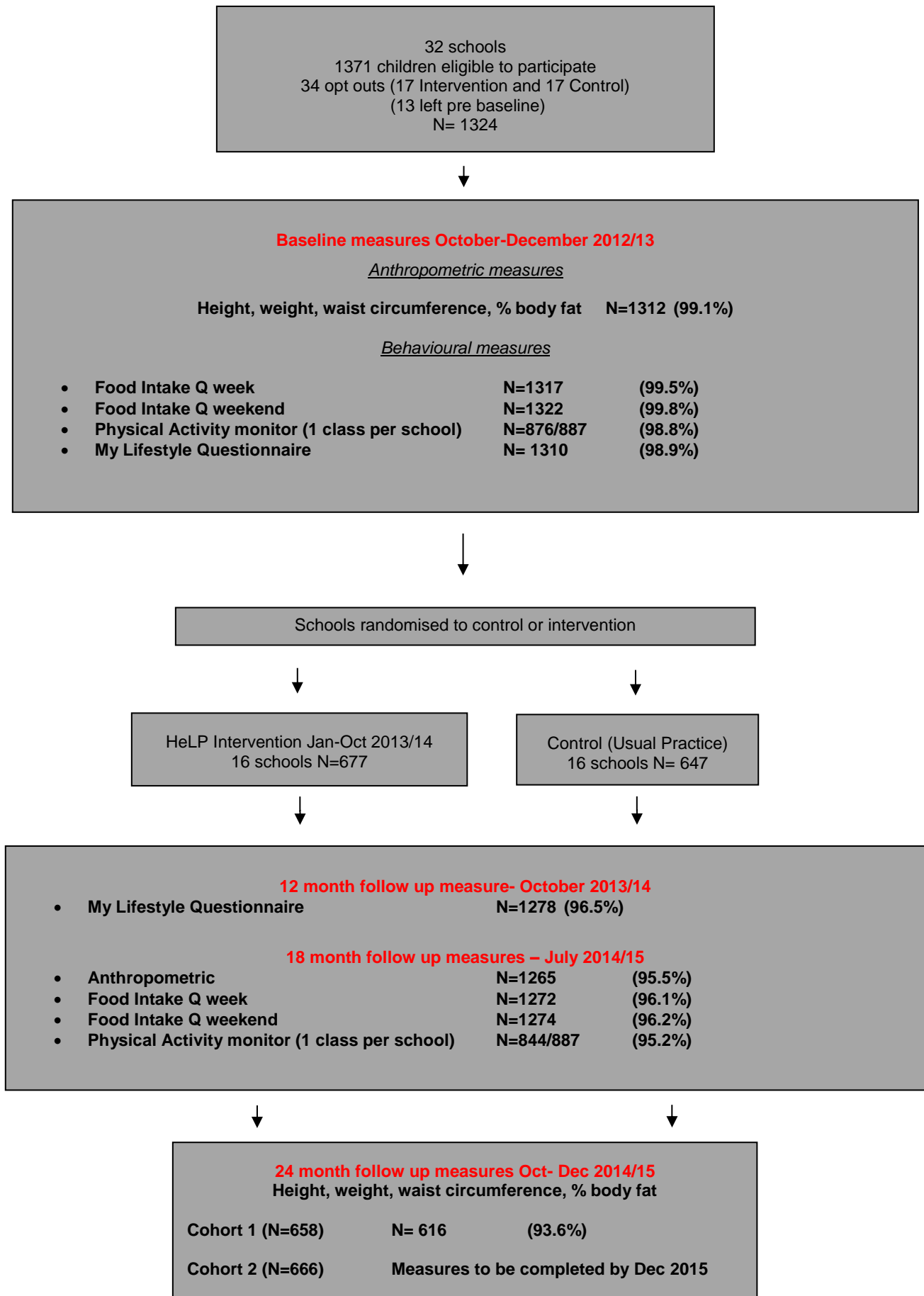
	Phase 1	Phase 2	Phase 3	Phase 4	Total*
Cohort 1	91.2%	94.2%	91.0%	92.2%	93.7%
Cohort 2	94.7%	93.7%	92.9%	91.4%	92.7%
Total	93.4%	93.9%	92.2%	91.7%	93.1%

* Total no. of children receiving 4 drama sessions (phase 2) and the goals setting (phase 3)** delivered in the 'spirit of HeLP***

** Dose of HeLP deemed to be essential for behaviour change

*** Enthusiatic delivery, open body language, responsive to child/school needs, clear and friendly communication.

Figure 1: Recruitment and follow up of children in the HeLP trial



Across the programme, there are six invitations for parents and carers to come into the school and take part in the programme. These included the parent assembly and observation of the two activity workshops in phase 1, observation of work in progress in the final two drama sessions of the Healthy Lifestyle Week in phase 2 and the forum theatre assembly in phase 3 (See Table 1 page 90). Approximately half of children, 52% (354/677), had family attending at least one parent invitation.

Engagement with the intervention (child and parent and school)

All children had a 1-1 discussion with the HC in phase 3 about their goals. It was during this interaction that the HC gave each child an engagement score between 0 and 3 (0=disinterested/unaware goals needed to be set; 1=reluctant/needs a lot of prompting; 2=enthusiastic and happy to chat about goals and how they will achieve them; 3=very enthusiastic, has discussed them at home and has clear strategies for achieving them). By the time the HC sees the children for this discussion they know the children well, having been working closely with them for 10 months. These engagement scores were then dichotomised to create two groups (≤ 1 = less engaged children and > 1 = engaged children). 96% (653/677) of children set goals with the HC in phase 3 and of these children 63% (412/653) had parental support which was indicated by a parent signature on the goal setting sheet and/or written comments regarding how the parent would support the child in achieving their goals. Overall, 92% (603/653) of children were deemed to be engaged with the HeLP programme. Chi-squared tests showed no difference in individual IMD rank spread between the engaged and less engaged children, suggesting that HeLP was able to engage across the social spectrum.

Parental engagement was measured using two sources of data; attendance at one or more parent events and/or signature on the goal setting sheet. A score between 0 and 2 is given to each child's parent (0=did not attend/did not sign; 1=attended or signed the goal setting sheet (but not both); 2=attended one or more events and signed the sheet. As with child engagement these scores were dichotomised to create two groups (≥ 1 =engaged, < 1 =not engaged). 77% (521/677) of

parents were deemed to be engaged with HeLP. Chi squared tests showed no difference in IMD rank spread between the two groups, suggesting that HeLP was able to engage parents across the social spectrum.

School engagement was assessed using three scores based on the HC's interaction with the head teacher, the year 5 teacher(s) and the support staff. A score between 0 and 3 is given to each group (0=unengaged/uncooperative, 1=supportive, 2=enthusiastic and supportive, 3=very enthusiastic and used HeLP in other aspects of teaching/school activities). These scores were aggregated and then dichotomised into two groups (0-3=less engaged school and 4-9= engaged school). Out of 16 schools, only three were categorised as less engaged.

Discussion

We are now in the final stages of the trial, collecting 24 month anthropometric data from cohort 2 children. Results will be available in the summer of 2016. We also have a detailed process evaluation running alongside the trial in order to provide insight into the way the programme works. This includes collecting data on the delivery and uptake of HeLP, the engagement of teachers, children and parents, how HeLP was experienced and the school context. We are capturing these characteristics using a number of data collection methods including registers, questionnaires, focus groups, interviews and field notes.

The average rate of attrition in health behaviour change trials is 20% (Crutzen et al., 2013) and this can lead to bias in the findings with 'differential attrition' (i.e. differences between follow in the control and intervention groups) threatening the internal validity of a study (Crutzen et al., 2013). The HeLP trial has an attrition rate of 4% and 6% at 18 and 24 month follow-up respectively, with no differences between the control and intervention groups at both time points. This level of retention is almost unheard of in trials of this size and nature. We believe this can be attributed to the high level of stakeholder involvement in both the design of the trial and the intervention.

From the outset we worked with a group of teachers, head teachers, parents and children who came forward from the early piloting of HeLP (Wyatt, Lloyd, Creanor, and Logan, 2011)

and who subsequently became our Project Advisory Group (PAG). Our PAG members has advised us on; what was feasible and acceptable when taking behavioural and anthropometric measures from 9-10 year old children, how to communicate with parents about the research process so that they a) would receive the information, b) understand it and c) feel they were able to engage with the researchers if they had any concerns or queries. In addition, it was important for us to understand how to recruit schools and engage teachers. The head teacher from an early pilot suggested we recruit schools via the DAPH during one of their briefing sessions and a teacher involved in the exploratory trial (Lloyd, Wyatt, and Creanor, 2012) offered to talk to heads about her experiences of being involved in the programme during this session.

Teachers and parents from our PAG were invited to be partners on our research bids and both our funded exploratory (Lloyd, Wyatt, and Creanor, 2012) and definitive trial (Wyatt et al., 2013) had a Year 5 teacher and a parent as a co-applicant. Members from the PAG also assisted in the recruitment of the HeLP Coordinators, assessing how they delivered the messages and whether they had the necessary qualities to build relationships with schools children and their families.

Our PAG also provided invaluable feedback on possible intervention activities and delivery methods that were acceptable and feasible for schools, children and their families. It was important that any intervention we developed did not widen existing health inequalities and had the potential to engage children and their families from across the socio-economic spectrum. We wanted to develop a programme which affected both upstream and downstream influences on health behaviours and encouraged children to identify with and take ownership of the healthy lifestyle messages (Lloyd and Wyatt, 2015). The use of the interactive drama in which the children identify with characters has motivated the children to take the messages on board and engage the family in change (Lloyd and Wyatt, 2014). Our delivery personnel (the HeLP Coordinators and the actors) were carefully selected and trained to ensure they had the necessary skills and competencies to build relationships. In pilot work, teachers and parents have commented that having one key contact

person (the HC), who was both accessible and approachable, was crucial in feeling supported throughout the duration of the programme (Lloyd and Wyatt, 2015).

At present our PAG are helping us with understanding the possible enablers and barriers to implementation of HeLP should it prove to be effective. We are organising a stakeholder workshop to engage schools across the South West in this research as well as Public Health and other relevant local authority bodies. This wider stakeholder engagement is intended to support the development of relationships and an understanding of the school and public health context which in turn will support future work and possible roll out of HeLP.

Conclusion

Data from the National Childhood Measurement Programme (NCMP) for 2013-2014 show that over a fifth of children entering primary school are overweight or obese and this rises to over a third when they leave (Public Health England, 2014). Public Health England recognise the need to go beyond information, education and health marketing to tackle the epidemic, however, there is a paucity of evidence regarding how best to engage and support children and families to make small sustainable changes to their eating and activity behaviours. At present, there is no healthy schools programme in Devon, yet schools are coming under increasing pressure to help prevent childhood obesity. The School Food Plan, which provides a guide and support for head teachers to create a school culture promoting the pleasures of growing, cooking and eating proper food is mandatory and OFSTED have now developed specific criteria to assess the extent schools are implementing the plan. Following the results of the HeLP trial, we will continue to work with our PAG, Public Health Devon, the Local Authority and advisors for the School Food Plan to see how best to implement HeLP across primary schools in Devon and beyond.

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