

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

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## Scientific summary

### The Healthy Lifestyles Programme (HeLP)

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# Scientific summary

## Background

The Healthy Lifestyles Programme (HeLP) was a school-based intervention designed to prevent overweight and obesity in children. The intervention was developed using intervention mapping (involving extensive stakeholder involvement) and was guided by the information, motivation and behavioural skills (IMB) model. The intervention has four phases and runs over three school terms with 9- to 10-year-old children. HeLP aims to engage children, parents and schools through a mixture of educational activities, drama, goal-setting and reinforcement activities to help children to increase healthy behaviours and reduce the risk of overweight and obesity.

## Objectives

To estimate the effectiveness and cost-effectiveness of HeLP in preventing overweight and obesity in children.

## Specific objectives

1. To assess the effectiveness of HeLP in children aged 9–10 years by comparing between intervention and control schools:
  - body mass index (BMI) standard deviation score (SDS) at 24 months (primary outcome)
  - BMI SDS at 18 months
  - waist circumference SDS at 18 and 24 months
  - percentage body fat SDS at 18 and 24 months
  - proportion of children classified as underweight, overweight and obese at 18 and 24 months
  - physical activity [time, in average minutes per day, spent in sedentary, light, moderate, moderate to vigorous or vigorous physical activity, and the average volume of physical activity in milligravity (mg) units] at 18 months
  - food intake (number of energy-dense snacks, healthy snacks, negative and positive food markers) at 18 months.
2. To estimate the costs associated with the delivery of the HeLP intervention and its cost-effectiveness versus usual practice.
3. To conduct a mixed-methods process evaluation and a mediational analysis to explore the way in which the programme worked (i.e. how it was delivered, taken up and experienced, and the possible mediators of change).

## Methods

We undertook a cluster randomised controlled trial with follow-up at 18 and 24 months post baseline (6 and 12 months post intervention) in 32 primary schools in Devon that had at least 20 pupils in Year 5 (aged 9–10 years). We aimed to recruit half of the schools with  $\geq 19\%$  pupils eligible for free school meals (the national average in 2012). Schools were randomised post collection of baseline measures. Schools allocated to receive HeLP started the programme in the spring term of Year 5 with phase 1 activities to create a receptive context in the school and to engage the children and their families. Phases 2 and 3 (healthy lifestyles week and goal-setting) took place in the summer term of Year 5 and reinforcement

activities (phase 4) took place in the autumn term of Year 5. Schools allocated to the control group continued with their standard syllabus. For practical reasons, the trial was run over two cohorts (each with 16 schools). The primary outcome was BMI SDS at 24 months post baseline. The secondary outcomes were BMI SDS at 18 months, waist circumference SDS and percentage body fat SDS, weight status category at 18 and 24 months, accelerometer-assessed physical activity and child-reported consumption of food and drink (averaged across the week, as well as for weekday and weekend separately). Children had 18-month measures taken at the end of Year 6 (aged 10–11 years) and in the autumn term of Year 7 (aged 11–12 years) when the children had moved to secondary school.

Potential mediators were assessed using a bespoke questionnaire that was underpinned by the IMB model and was developed to capture knowledge, cognitions and behaviours that we anticipated would be related to changing diet and physical activity and, hence, weight status. An exploratory factor analysis generated four composite variables: 'confidence and motivation', 'peer norms', 'family approval/behaviours and child attitudes' and 'behaviours and strategies'. These, as well as 'knowledge', were used in the subsequent mediational analysis. We collected details on the cost of the intervention and developed a framework for estimating the cost-effectiveness of the intervention. Questionnaires, focus groups and interviews were conducted with parents, teachers, head teachers and children, and observations of intervention delivery were conducted to assess how HeLP was delivered and received, as well as the experience of being part of the programme.

## Results

We recruited 32 schools and 1324 children. Only 34 eligible children opted out of the study and we had a rate of 94% follow-up for our primary outcome at 24 months. No difference was found between children in the intervention schools and children in the control schools at 24 months for BMI SDS [mean difference (intervention minus control)  $-0.02$ , 95% confidence interval (CI)  $-0.09$  to  $0.05$ ] for any anthropometric measure (all adjusted for baseline values) at 18 or 24 months or for physical activity at 18 months.

Children in the intervention schools reported eating significantly fewer energy-dense snacks per day ( $-0.37$ , 95% CI  $-0.66$  to  $-0.07$ ) and fewer negative food markers per day ( $-0.47$ , 95% CI  $-0.91$  to  $-0.02$ ) than children in the control schools, when these were averaged across the week. These differences were also evident for weekday, but not weekend, reporting of energy-dense snacks and negative food markers. The intervention increased children's knowledge, cognitions and behavioural skills. The effect of the intervention on reported weekday negative food markers was fully mediated ( $p = 0.059$ ) by three composite variables, confidence and motivation, family approval/behaviours and child attitudes and behaviours and strategies, as well as knowledge. The intervention effect on weekday energy-dense snacks was partially mediated ( $p = 0.041$ ) by the same variables, apart from behaviours and strategies.

The cost of implementing the intervention was estimated at approximately £210 per child. Costs were predominantly those associated with the time inputs for the HeLP co-ordinator and drama components of the programme. Given the lack of effectiveness, the programme is not cost-effective compared with the control group; results are unambiguous, with no expected health gains and schools' usual practice being less costly.

The process evaluation showed that the programme was delivered with a high degree of fidelity in respect of both the components of the intervention and the manner in which the components were delivered. Over 95% of children took part in at least 8 of the 10 sessions of healthy lifestyles week and set goals. Over 90% of children were considered to be actively engaged with the programme according to prespecified criteria, with no differences across socioeconomic groups. Similarly, 75% of parents were considered engaged, and all but three of the schools were deemed to be very engaged and enthusiastic. Parents and children reported changes that they had made to diet and activity, and the majority of barriers to and/or facilitators of achieving goals were related to parental support or lack of it.

## Limitations

We had a low response rate (25%) to the parental questionnaire that was part of the process evaluation. The schools involved in the trial were broadly similar to those in the south-west and England in terms of socioeconomic deprivation, class sizes and both rural and urban settings, but not in terms of ethnicity.

## Conclusions

HeLP is neither effective nor cost-effective in affecting BMI SDS or preventing overweight and obesity in 9- to 10-year-olds, nor is it effective in increasing physical activity. There is weak evidence of effectiveness in reducing the consumption of unhealthy foods (negative food markers and energy-dense snacks).

## Future research

Our findings show that, although it is an intensive intervention that was able to engage schools, children and their families, HeLP did not affect objectively measured physical activity or weight status. Schools are an obvious location for health promotion programmes but we consider it unlikely that any school-based programme that is not part of a wider co-ordinated whole-systems approach will be able to prevent overweight and obesity in a single age group. Research should address the effectiveness of programmes that incorporate whole-systems approaches.

The failure of this intensive intervention, with high levels of engagement, to have a sufficient impact on objectively measured behaviours in children aged 9–10 years still leaves open questions about whether or not it is possible to design effective interventions aimed at very young children whose behaviours may be more malleable or at older children who may have greater autonomy than younger children in making healthy choices.

## Trial registration

The trial is registered as ISRCTN15811706.

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