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

Katrina Wyatt,1* Jenny Lloyd,1 Siobhan Creanor,2 Colin Green,1 Sarah G Dean,1 Melvyn Hillsdon,3 Charles Abraham,1 Richard Tomlinson,4 Virginia Pearson,5 Rod S Taylor,1 Emma Ryan,6 Adam Streeter,2 Camilla McHugh,1 Alison Hurst,1 Lisa Price,3 Louise Crathorne,1 Chris Krägeloh,7 Richard Siegert7 and Stuart Logan1

1Institute for Health Research, University of Exeter Medical School, South Cloisters, St Luke’s Campus, Exeter, UK
2Peninsula Clinical Trials Unit and Medical Statistics, Plymouth University Peninsula Schools of Medicine & Dentistry, Plymouth, UK
3Sport and Health Sciences, College of Life and Environmental Sciences, University of Exeter, Exeter, UK
4Royal Devon & Exeter NHS Foundation Trust, Exeter, UK
5Devon County Council, Public Health Directorate, Exeter, UK
6Isca Academy, Exeter, UK
7Health Sciences, Auckland University of Technology, Auckland, New Zealand

*Corresponding author k.m.wyatt@exeter.ac.uk

Declared competing interests of authors: Stuart Logan reports grants from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health, Research and Care. He also reports a grant from the NIHR Public Health Research programme during the conduct of the study. Colin Green served as a member of the funding panel for the NIHR Programme Grants for Applied Research programme from 2009 to 2013. Colin Green (2007–13) and Siobhan Creanor (2013–present) served as members of the NIHR Research Funding Committee for the South West Region of the Research for Patient Benefit Programme. Intervention costs for this study were paid for by the Peninsula College of Medicine and Dentistry. Stuart Logan (NF-SI-0515–10062) and Rod Taylor (NF-SI-0514–10155) are NIHR senior investigators. This study was undertaken in collaboration with the Peninsula Clinical Trials Unit (CTU), a UK Clinical Research Collaboration-registered CTU in receipt of NIHR CTU support funding. None of the funders had any involvement in the Trial Steering Committee, data analysis, data interpretation, data collection or writing of the report.
Scientific summary

The Healthy Lifestyles Programme (HeLP)
Public Health Research 2018; Vol. 6: No. 1
DOI: 10.3310/phr06010

NIHR Journals Library www.journalslibrary.nihr.ac.uk
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 ≥ 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.

Funding

Funding for this project was provided by the Public Health Research programme of the National Institute for Health Research.
Public Health Research

ISSN 2050-4381 (Print)
ISSN 2050-439X (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PHR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/phr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Public Health Research journal

Reports are published in Public Health Research (PHR) if (1) they have resulted from work for the PHR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in Public Health Research are termed ‘systematic’ when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

PHR programme

The Public Health Research (PHR) programme, part of the National Institute for Health Research (NIHR), evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad, covering a range of interventions that improve public health. The Public Health Research programme also complements the NIHR Health Technology Assessment programme which has a growing portfolio evaluating NHS public health interventions.

For more information about the PHR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/phr

This report

The research reported in this issue of the journal was funded by the PHR programme as project number 10/3010/01. The contractual start date was in March 2012. The final report began editorial review in November 2016 and was accepted for publication in February 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health.

© Queen’s Printer and Controller of HMSO 2018. This work was produced by Wyatt et al. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).
Public Health Research Editor-in-Chief

Professor Martin White  Director of Research and Programme Leader, UKCRC Centre for Diet and Activity Research (CEDAR), MRC Epidemiology Unit, Institute of Metabolic Science, School of Clinical Medicine, University of Cambridge; Visiting Professor, Newcastle University, and Director, NIHR Public Health Research Programme

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May  Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson  Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

Dr Catriona McDaid  Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie  Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross  Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood  Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk