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Healthy Lifestyles Programme to prevent childhood obesity

Submission date
14/03/2012

Recruitment status
No longer recruiting

Registration date
01/05/2012

Overall study status
Completed

Last Edited
13/09/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The proportion of children who are obese has doubled in England in the last ten years and currently one third of 10-11 year olds are overweight or obese. Childhood obesity is associated with health issues in childhood as well as reduced self-esteem and quality of life. Obese children are also likely to become obese adults and experience significant health issues because of their weight. As current behavioural obesity treatments for children appear to have little effect, preventing children from becoming obese is an important issue for the Health Service. There is currently no good evidence to suggest which obesity prevention programmes are effective or how to engage schools, children and their families sufficiently to affect obesity-related behaviours. We have worked with schools, children and their families over five years to develop and refine a novel, inclusive, drama-based, healthy lifestyles programme called HeLP. The programme is delivered specifically to Year 5 (9-10 year old) children in the primary school setting but it also seeks to impact the whole school environment to create a supportive social context at the level of the school and family. HeLP combines education sessions, interactive drama workshops and goal setting, all with parental involvement, to promote and support sustainable changes in diet and physical activity.

HeLP aims to deliver a general healthy lifestyle message for the whole year group around the energy balance with a focus on three specific behaviours: to reduce the consumption of sweetened fizzy drinks, to increase the proportion of healthy to unhealthy snacks consumed and to reduce screen time. HeLP avoids creating special or discriminating treatment for those who are overweight. The main focus of the programme is a week of drama-based activities led by actors from a local theatre group. Four characters have been created with positive and negative lifestyle behaviours. Participating children select which character they most resemble and work with that character throughout the week, suggesting ways in which the character can alter their behaviours. The following week the children set goals with their families and the researchers, suggesting three behaviours they will target for improvement.

We have developed and tested HeLP in six schools including 398 children and their families. At each stage of the pilot work we have sought to understand whether the activities are acceptable and feasible for schools, children and their families. Three of the schools involved in the development were in the more deprived parts of the area, ensuring that the programme was acceptable and feasible to all socioeconomic groups. Extensive interviews with children, parents and teachers showed that children, parents and schools were happy to participate in all

intervention activities. Parents were adamant their childrens diet and activity choices were their responsibility but felt that school was a good place to reinforce these messages. Following delivery of HeLP, parents reported greater acceptance of rules relating to screen-time activities and healthy eating by their child as well as their child initiating discussion with other family members around healthy lifestyles and making suggestions to get the whole family involved in eating more healthily and being more active. Teachers agreed Year 5 was the right target group as children are gaining independence whilst still amenable to the messages. Some commented that the intervention had boosted the childrens self-esteem, had a positive effect on the class socially and created additional opportunities to link with parents. Teachers felt using young actors to deliver the messages was the key to achieving engagement with this age group. Children were unanimous in their enjoyment of the drama activities.

Who can participate?
Schools are eligible to participate if they are mainstream state-run primary schools and have at least one single Year 5 class (i.e. not Year 4/5 or 5/6 mixed classes).

What does the study involve?
We want to test HeLP with about 1000 children (9-10 year olds) from 32 schools; half of the schools (about 500 children) will be randomly selected to receive HeLP and they will be compared with the 16 schools (about 500 children) that do not. The success of the Programme will be judged by comparing measures of weight, physical activity and dietary behaviours between the groups of children at 18 and 24 months.

What are the possible benefits and risks of participating?
HeLP has the potential to improve participating childrens physical activity levels and dietary behaviours. Taking body measurements from children of this age could lead to stigmatising the overweight child; however, we have ensured that these are taken in a friendly, private and non-threatening environment. No child, teacher or parent in three phases of piloting has made any negative comments regarding these measures. Indeed, in focus groups, children did not spontaneously comment on the weighing and measuring and when this was highlighted the children dismissed these measurements as fine.

Where is the study run from?
The study will be run from the Peninsula College of Medicine and Dentistry in Exeter in the South West of England (UK).

When is study starting and how long is it expected to run for?
March 2012 to October 2016

Who is funding the study?
National Institute for Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/3010/01

Study information

Scientific Title
Cluster randomised controlled trial, 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

Acronym
HeLP

Study objectives
A novel school-based programme of activities will engage school children and their families sufficiently to affect dietary and activity behaviours and prevent excessive weight gain in 9-10 year olds.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Peninsula College of Medicine & Dentistry Research Ethics Committee, ref: 12/03/140

Study design
Cluster randomised controlled trial with economic and process evaluation

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Public health

Interventions
HeLP is a multi-component four phase programme which takes place over three school terms and aims to deliver a general healthy lifestyle message encouraging a healthy energy balance. Piloting has demonstrated that the children found it useful to focus on three specific behaviours related to energy intake and expenditure:
1. A decrease in the consumption of sweetened fizzy drinks
2. Increasing the ratio of healthy to unhealthy snacks
3. 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. HeLP includes a range of behaviour change techniques (BCTs) and accessible and engaging delivery methods which are compatible with the existing school curriculum, as well as providing several opportunities for parental engagement. Our hypothesis is that targeting information, motivation and behavioural skills will lead to improvements in diet and physical activity thus preventing excessive weight gain and that these processes may be moderated by gender, weight status, socioeconomic circumstances and school size.

Schools in the comparison arm will receive no intervention. Usual practice will be characterised using a pre-determined checklist of potential school level mediators. After completion of 24 month outcome measures, control schools will be offered £1000 to acknowledge their participation in the trial.

Intervention Type
Behavioural

Primary outcome measure
Body Mass Index (BMI) Standard Deviation Score (SDS) measured at baseline, 18 and 24 months which will be compared between the control and intervention groups

Secondary outcome measures
1. Weight Status Proportions (underweight, normal, obese or overweight) measured at baseline, 18 and 24 months

2. Percent body fat measured at baseline, 18 and 24 months
3. Waist circumference measured at baseline, 18 and 24 months
4. Accelerometer assessed moderate/vigourous physical activity/sedentary behaviour measured at baseline and 18 months
5. Mean number of healthy snacks, energy dense snacks, positive and negative foods consumed per day measured at baseline and 18 months
6. Mediating variables to assess knowledge, motivation and behaviours relating to the physical activity and diet measured at baseline and 12 months

Overall study start date
01/03/2012

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. State Primary/Junior schools in Devon and Plymouth
2. Year 5 children (9-10 year olds)

Participant type(s)
Other

Age group
Child

Lower age limit
9 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
32 schools including 1000 9-10 year olds

Total final enrolment
1324

Key exclusion criteria
Schools which received the intervention in the pilot phases and schools who do not have a single Year 5 group

Date of first enrolment
01/07/2012

Date of final enrolment

30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Peninsula College of Medicine & Dentistry
Exeter
United Kingdom
EX2 4SG

Sponsor information

Organisation
Royal Devon and Exeter NHS Foundation Trust (UK)

Sponsor details
c/o Mr Chris Gardner
Noy Scott House
Barrack Road
Devon
Exeter
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United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Public Health Research Programme ref: 10 /3010/01

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/04/2013		Yes	No
Statistical Analysis Plan	statistical analysis plan	15/12/2016		No	No
Results article	baseline results	04/04/2017		Yes	No
Results article	physical activity prevalence results	01/12/2018	02/07/2019	Yes	No
Results article	results	01/01/2018	13/09/2019	Yes	No