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HELP trial: Healthy Eating Lifestyle Programme for adolescents

Submission date	Recruitment status
21/01/2011	No longer recruiting
Registration date	**Overall study status**
21/01/2011	Completed
Last Edited	**Condition category**
23/08/2018	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The Healthy Eating and Lifestyle Programme (HELP) has shown promising results in an initial hospital-based study and this is now the main study. The treatment uses motivational and solution focused psychological techniques, combined with up-to-date information on nutrition and lifestyle. HELP was developed in consultation with healthcare professionals from multi-disciplinary backgrounds and in response to specific feedback from young people and health care workers who took part in the HELP initial study.

Who can participate?
Young people aged 12 to 19 struggling with overweight in London and surrounding boroughs

What does the study involve?
Young people are randomly allocated to one of two methods of managing weight:
1. Intervention (HELP): 12 x 45-minute solution-focused, motivational interviewing sessions with a trained health care worker and delivered in the young person's community.
2. Control: 1 x 45-minute educational session based upon current Department of Health guidelines regarding healthy lifestyle, delivered by a practise nurse at the young person's GP surgery.
All young people in the study are seen at regular intervals at the Great Ormond Street Hospital (GOSH) Clinical Research Facility for psychological and physical assessment (including fasting blood tests). During these assessments, any significant medical or mental health issues are referred on appropriately if identified. Researchers do not know which group the young people are in. Everyone involved with running the study receives safety and child protection training and has been CRB checked.

What are the possible benefits and risks of participating?
Possible benefits include weight maintenance or loss, improved fitness and increased self-confidence. HELP focuses on motivating and empowering young people to find change from within, listening to their thoughts and ideas about weight and lifestyle, with an emphasis on harnessing existing strengths and skills in the management of their overweight. Participating is

free to the young people involved: public transport expenses to and from sessions are covered and the young people are given a £40 iTunes or high street store voucher as a thank you for participating.

Where is the study run from?
UCL Institute of Child Health (UK)

When is the study starting and how long is it expected to run for?
January 2011 to September 2014

Who is funding the study?
National Institute of Health Research Programme Grants for Applied Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9623

Study information

Scientific Title
HELP trial: randomised controlled trial of the Healthy Eating Lifestyle Programme for adolescents

Acronym
HELP

Study objectives

Aim:
To improve management of adolescent obesity by conducting an efficacy trial of the Healthy Eating Lifestyle Programme (HELP) within primary care.

Hypotheses:
1. Primary: That a motivational and solution-focused family-based weight management programme (the Health Eating Lifestyle Programme: HELP) individually delivered over 6 months is more efficacious in improving body mass index (BMI) in obese adolescents than enhanced standard care
2. Secondary: That the HELP intervention over 6 months is more efficacious in improving quality of life, reducing waist circumference and cardiovascular risk factors and improving psychological function in obese adolescents than enhanced standard care

Design:
MRC complex intervention phase III efficacy randomised clinical trial. Subjects will be individually randomised to receiving either the HELP intervention or enhanced standard care for 6 months. Subjects will be aware of allocation status but assessments will be undertaken blind to allocation status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London Research Ethics Committee 3, 27/08/2010, ref: 10/H0706/54

Primary study design
Interventional

Study design
Single-centre randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Intervention (87 subjects):
HELP programme: A solution-focused and motivational weight management programme. Young people and families will attend twelve 40 - 45 minute sessions over 6 months. HELP has 4 components:
1. Modifying eating behaviours and encouraging regular eating patterns
2. Decreasing sedentary behaviour and increasing lifestyle and programme activity
3. Reducing intake of energy dense foods, and increasing healthy nutritional choices
4. Addressing emotional eating triggers
The intervention duration is 6 month (12 sessions).

Control (87 subjects):
As the trialists want the controls to represent, as closely as possible, the current standardised care in the United Kingdom, they will offer the control group a single education session provided by the young person's GP Practice nurse.

Assessment for control and intervention groups at 0, 13, 26, 52 weeks (follow up assessment).
End of recruitment July 2013

Intervention Type
Behavioural

Primary outcome(s)
BMI (kg/m2), measured at 0, 13, 26, 52 weeks (follow-up assessment)

Key secondary outcome(s)
Current secondary outcome measures as of 06/10/2015:
1. Health-related quality of life (HR-QOL) assessed using one measure: An obesity-specific QOL instrument. The Impact of Weight on Quality of Life (IWQOL)-Kids is a 27-item instrument consisting of four scales: physical comfort (six items), body esteem (nine items), social life (six items), and family relations (six items). It has excellent psychometric properties (0, 26, 52 weeks)
2. Anthropometric measures (0, 13, 26, 52 weeks)
3. Psychological factors: Assess the impact of the intervention on psychological function and enable examination of pathways by which the intervention may influence QOL and BMI change (0, 26, 52 weeks)
4. Lifestyle (0, 26, 52 weeks)
5. Cardiometabolic risk factors (0, 26 weeks)
6. Health economic assessment data (0, 13, 26, 52 weeks)

Previous secondary outcome measures:
1. Health-related quality of life (HR-QOL) assessed using two measures (0, 26, 52 weeks)
2. Anthropometric measures (0, 13, 26, 52 weeks)
3. Psychological factors: Assess the impact of the intervention on psychological function and enable examination of pathways by which the intervention may influence QOL and BMI change (0, 26, 52 weeks)
4. Lifestyle (0, 26, 52 weeks)
5. Cardiometabolic risk factors (0, 26 weeks)
6. Health economic assessment data (0, 13, 26, 52 weeks)

Completion date
01/09/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 13/07/2012:
1. Young people aged 12 - 19 years, either sex
2. Obese (body mass index [BMI] greater than 95th centile for age and sex)

Previous inclusion criteria until 13/07/2012:
1. Young people aged 13 - 17 years, either sex
2. Obese (body mass index [BMI] greater than International Obesity Task Force [IOTF] thresholds for age and sex)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
19 Years

Sex
All

Key exclusion criteria
Current exclusion criteria:
1. Participants with significant mental health problems or undergoing mental health treatment
2. Other chronic illness, known secondary obesity, monogenic obesity syndrome or use of medications known to promote obesity. Added 06/10/2015: Young people with asthma will be included in the study so long as they have not had more than one course of oral steroids in the preceding 3 months (where course is less than or equal to 5 days), or are on more than the first starting dose of inhaled steroids as per British Thoracic Society Guidelines.
3. Participants with significant learning disability
4. Participants with lack of command of English sufficient to render them unable to participate effectively in the planned intervention. The great majority of eligible young people from black or minority ethnic groups in this population have good command of English. Given the importance of standardising the intervention, it will not be possible to use interpreters to enable parents with poor English to participate. To allow as many young people as possible to participate while maintaining the external validity of the study, we will allowing another relative with good English to participate alongside the young person (if they wish it).
5. Participation in behavioural weight management programmes in the past 12 months. This does not include participation in commercial programmes such as Weight Watchers.
6. Young people with BMI greater than or equal to 45 kg/m2. We exclude this group as the evidence suggests they are unlikely to benefit from a community based intervention such as HELP.

Previous exclusion criteria until 13/07/2012:
6. Young people with BMI greater than or equal to 40 kg/m2. We exclude this group as the evidence suggests they are unlikely to benefit from a community based intervention such as HELP.

Date of first enrolment
05/01/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Child Health
London
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Sponsor information

Organisation
Institute of Child Health (ICH) (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research (PGfAR) (ref: RP-PG-0608-10035)

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

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?
Results article	results	01/08/2017		Yes	No
Results article	results	15/02/2018		Yes	No
Protocol article	protocol	16/11/2011		Yes	No