

HELP trial: Healthy Eating Lifestyle Programme for adolescents

Submission date 21/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/08/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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?
Anne Mathiot
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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
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

Study design

Single-centre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

05/01/2011

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

Age group

Child

Lower age limit

12 Years

Upper age limit

19 Years

Sex

Both

Target number of participants

Planned sample size: 155; Final sample size: 174

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 allow 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

England

United Kingdom

Study participating centre

Institute of Child Health

London

United Kingdom

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Sponsor information

Organisation

Institute of Child Health (ICH) (UK)

Sponsor details

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Sponsor type

Research organisation

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

Publication and dissemination plan

HELP study main paper to be submitted for publication end of November 2015

Intention to publish date

01/11/2015

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