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Is it feasible and acceptable to deliver HELPclinic (Healthy Eating Lifestyle Programme by Clinicians) in the medical office (outpatient) setting?

Submission date
20/08/2016

Recruitment status
No longer recruiting

Registration date
26/10/2016

Overall study status
Completed

Last Edited
30/01/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A programme called HELPclinic has been developed for young people aged 12 to 18 who are obese. It is designed to be used by doctors, nurses and dieticians to help young people control their weight by changing the way they eat and exercise. This programme has been developed using an existing programme called HELP. The aim is to test this intervention for the first time to see whether it is possible to recruit young people and their families to join the study, to see whether they are able to complete the whole study, and to find out whether is possible for doctors, nurses and dieticians to deliver this type of programme in the outpatient clinic.

Who can participate?
Patients aged 12-18 who are obese

What does the study involve?
At the start of the study participants undergo blood tests and blood pressure measurement and complete quality of life and psychological questionnaires. All participants in this study attend five sessions of the HELPclinic programme at monthly intervals. Participants are then invited for an interview one month later to find out what they and their families think about the study. The doctors and nurses in the clinic who have been trained to deliver the programme are also interviewed to find out their views. The participants' changes in weight and health are measured.

What are the possible benefits and risks of participating?
Possible benefits are the health benefits of having a healthy diet and increased levels of exercise. There are no anticipated risks associated with this study. The diet and lifestyle advice follows national recommendations and does not involve any unsafe diet or exercise plans.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2010 to March 2013

Who is funding the study?
Institute of Child Health, University College London (UK)

Who is the main contact?
Dr Billy White
billy.white@ucl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Billy White

ORCID ID
https://orcid.org/0000-0002-0109-6935

Contact details
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG
+44 (0)20 3447 9221
billy.white@ucl.ac.uk

Additional identifiers

Protocol serial number
10/H0706/53

Study information

Scientific Title
Healthy Eating Lifestyle Programme by Clinicians: a feasibility randomised control pilot trial

Study objectives
This feasibility study is part of a research program that will examine the following hypotheses:
1. A family--based lifestyle intervention, delivered by clinicians (doctors, nurses and dieticians) using two psychological techniques (solution-focused therapy and motivational interviewing) is efficacious in reducing body mass index.
2. The intervention is efficacious in improving quality of life, reducing waist circumference and cardiometabolic risk factors and improving psychological function in obese adolescents.

This study will:
1. Establish feasibility and acceptability of recruitment, randomisation and delivery of the

program.
2. To obtain estimates of outcomes to plan a full randomised control trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West London REC3 NRES Committee, 17/09/2010, ref: 10/H0706/53

Study design
Randomised control trial, subsequently adapted to a pre-post observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
All participants in this study undertake the HELPclinic intervention, a five-session individual lifestyle programme delivered at monthly intervals. The lifestyle intervention uses behavioural tools from motivational interviewing and solution-focused therapy to enable behaviour change aligned with contemporary dietary and exercise recommendations. It was originally planned to undertake a waiting-list control randomised control trial where half of the participants would wait 5 months to start the intervention. This was subsequently changed to an observational study where all participants undertake the study immediately at the time of entry into the study. All participants are invited for review one month after the intervention by their referring clinician.

Baseline measurements are taken at baseline to characterise the sample: cardio-metabolic measurements (HbA1c or oral glucose tolerance test, blood pressure measurement, lipids), quality of life and psychological function measurements (SDQ, PedsQL, RSE, EDEQ and DEBQ questionnaires) and auxology measurements (height and weight). Height and weight measurements are repeated at each session.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility - recruitment, attendance and attrition rates are continually monitored in order to test the ability to recruit and retain participants
2. Acceptability - qualitative interviews are performed with participants and clinicians after 6-12 months of study completion

Key secondary outcome(s))
Change in BMI over the course of the programme: height and weight are measured at each session and 1 month after completion of the programme

Completion date
01/03/2013

Eligibility

Key inclusion criteria
1. Aged 12-18 years
2. Male and female
3. BMI between 98th centile and 45kg/m2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Subjects with significant mental health problems or undergoing mental health treatment
2. Other chronic illness, monogenic obesity syndrome or use of medications known to promote obesity
3. Patients who have signs or symptoms which require them to have immediate investigations, e. g. diabetes
4. Participants with significant learning disability or 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. We will ensure that the external validity of the study is maintained by allowing another relative with good English to participate
5. BMI>45 kg/m2 as they are unlikely to respond to lifestyle changes alone
6. Participants who have been involved in a weight management research program greater than 12 months previously will be eligible but those who are actively involved in a weight management program will be excluded

Date of first enrolment
17/10/2010

Date of final enrolment

03/04/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London Hospital

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
Institute of Child Health, University College London

Alternative Name(s)
UCL Great Ormond Street Institute of Child Health, GOS ICH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.1	02/09/2010	26/10/2016	No	Yes
Participant information sheet	version v2.0	19/08/2010	26/10/2016	No	Yes