ISRCTN24468014 https://doi.org/10.1186/ISRCTN24468014

An electronic tool for the management of overweight children

Submission date
05/09/2012

Recruitment status
No longer recruiting

Registration date
10/09/2012

Overall study status
Completed

Last Edited
08/06/2017

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
The aim of this study is to test a new website to improve childhood obesity management in primary care and assess the need for a larger study. The website will guide a practice nurse or general practitioner (GP) through a consultation with an overweight child. It will prompt the health professional to collect information on the child and their lifestyle habits. The tool then uses this information to estimate a child's current risk of having cardiovascular (heart disease) risk factors and emotional/behavioural difficulties, and to provide tailored weight management advice.

Who can participate?
The study population will be children and parents with concerns about the child's weight (child age range: 5 to 18 years). We intend to recruit four GP practices in London, all of which will use the intervention.

What does the study involve?
Participants will attend a consultation with a health professional, who will use the website during the consultation. The health professional will take a few simple measurements from the child (height, weight and blood pressure) and will ask a series of questions regarding lifestyle habits. This information will be recorded by the tool, which will then identify children at an increased risk of having weight-related illnesses. The tool will also produce a weight and lifestyle management plan for the child. After the consultation is over, participants and health professionals will be asked to complete questionnaires about their experiences. In addition, individual interviews will be conducted with participants and health professionals to find out about their satisfaction with the consultation process and the acceptability of the website.

What are the possible benefits and risks of participating?
A potential benefit from taking part in this study is that participants will receive information about health risks and weight management that may help them make healthy lifestyle changes. A possible risk of study participation relates to risk predictions. Because the tool uses a prediction model to estimate a child's risk of having an illness, there is a chance for false positives (identifying a child as high risk when in fact the child is not at high risk) and false negatives (identifying a child as low risk when in fact the child is at high risk). This could lead to

unnecessary subsequent medical testing or consultations, or fail to identify a high-risk child, respectively.

Where is the study run from?
London School of Hygiene & Tropical Medicine (UK).

When is the study starting and how long is it expected to run for?
The study ran from September 2012 to February 2013.

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

Who is the main contact?
Áine Skow
aine.skow@lshtm.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Aine Skow

Contact details
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
-
aine.skow@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12831

Study information

Scientific Title
Evaluating a brief electronic tool to assist GPs and practice nurses in the identifying, managing and referring overweight children

Study objectives
The intended goal of this research is to aid in the management of childhood obesity by developing a simple electronic tool to assist primary care health professionals. This study will answer the question of whether an electronic tool for management of children with overweight is helpful to families and useful to health professionals. We hypothesise that patients and health professionals will be satisfied with consultations which employ the electronic childhood obesity management tool.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - West London, 07/06/2012, ref: 11/LO/2049

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

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

Interventions
The intervention is an electronic tool (website) which will guide a health professional through a consultation with an overweight child. The tool will prompt the health professional to take height and weight measurements and collect information on lifestyle behaviours. The tool then uses this information to:
1. Estimate a childs current risk of having certain cardiometabolic and mental health outcomes
2. Provide tailored weight management advice

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Family satisfaction with consultation will be assessed immediately after consultation is complete.

Secondary outcome measures
1. Acceptability of the tool to the family assessed at completion of the consultation
2. Acceptability of the tool to the health professional assessed at the completion of each consultation
3. Health professional satisfaction with the consultation process assessed at completion of each consultation

Overall study start date
01/09/2012

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. All families presenting to primary care with concerns over the childs weight will be eligible to partake in the study, if children are between the ages of 5 and 18 years
2. Male and female participants

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 40

Key exclusion criteria
1. Due to the nature of the intervention, families who are not able to read and understand English will not be eligible for inclusion in the trial.
2. Children already under primary or secondary care for weight management

Date of first enrolment
01/09/2012

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT

Sponsor type
University/education

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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