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Improving Recognition of Childhood Overweight

Submission date	Recruitment status	[_] Prospectively registered
03/05/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/12/2018	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
One important step in decreasing the prevalence of children becoming overweight is to help families accurately recognise their childs weight status so they appreciate the need to take appropriate action or seek support. The clinical criteria for overweight are typically based on the body mass index (BMI) but evidence suggests that parents use visual methods rather than those based on BMI. This research team has developed a visual intervention tool which has age and gender-specific body image scales (ranges of images of body shapes of known BMI from underweight to obese) and supporting information about the health risks of childhood overweight (Map Me). A study will be conducted to find out if the Map Me intervention helps parents accurately identify their childs weight status, whether it influences knowledge and action taken. The study is entitled the 4 & UPP Study.

Who can participate?
Parents of school children aged 4-5 years (Reception) and 10-11 years (Year 6). The parents child will also be a participant. In cases where families have more than one eligible child, one will be selected at random by the study team.

What does the study involve?
Schools will be randomly allocated to: provision of Map Me in paper-based format; provision of Map Me in web-based format; or provision of no information (control). Comparison will be made between both intervention groups and the control group to determine effectiveness of the intervention.
Parents will complete a questionnaire with measures of their perception of their childs weight status and other aspects primarily about knowledge of the health consequences of childhood overweight and cognitive characteristics (child's development in terms of information processing, language learning, and other aspects of brain development) around facilitating weight control in their children. Parents in the intervention groups will have access to Map Me for one month prior to completing the questionnaire. The study team will work with National Child Measurement Programmes (NCMP), which measures the height and weight of Reception and Year 6 children and with parental consent will obtain the measures. The aim will be to obtain the questionnaire data for the study before parents receive the feedback letter from the NCMP informing them of the weight status of their child. Parents and children will be followed-up at 12 months; parents will be asked to complete a questionnaire similar to the first, and both parent and child will be measured by the study team for height and weight.

What are the possible benefits and risks of participating?
There is potential direct benefit to parents in the intervention groups in relation to perception of their childs weight status and health risks. Indirectly children may benefit due to increased parental awareness of childhood obesity. Those not in the intervention groups may be disadvantaged but will be given access to the intervention if it is shown to be effective and becomes publicly available (prior agreement confirmed with NHS Choices). There are no risks highlighted in taking part in the study.

Where is the study run from?
The study is run from the Institute of Health & Society at Newcastle University, England, UK.

When is study starting and how long is it expected to run for?
February 2013 to April 2015.

Who is funding the study?
The trial is funded by the National Prevention Research Initiative, website (http://www.npri.org.uk). The Funding Partners are: Alzheimer's Research Trust; Alzheimer's Society; Biotechnology and Biological Sciences Research Council; British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health and Social Care Research and Development Division of the Public Health Agency (HSC R&D Division); Medical Research Council; The Stroke Association; Wellcome Trust; Welsh Assembly Government; and World Cancer Research Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14008

Study information

Scientific Title
Cluster randomised trial on Improving Recognition of Childhood Overweight

Acronym
4 & UPP Study

Study objectives
4 & UPP Study - Understanding Parents Perceptions - children aged 4 and above

Preventing excess body weight in childhood is a public health priority. Parents are essential in achieving this but they often do not recognise when their child is overweight and consequently do not take action. Improving parental recognition of childhood overweight is essential to behaviour change. We have developed gender-specific body image scales of known body mass index for 4-5 and 10-11 year olds and supporting information about the health consequences of childhood overweight. This full cluster randomised trial (CRT) will test the developed tools designed to help parents identify their childs body weight status. The outcome measures are accuracy of parent perception of child weight status and change in child weight status over one year.

A minimum of 36 schools will provide a sample of parents (one parent per child) of 4-5 and 10-11 year children (target n=2160). The schools will be randomised to either: Intervention A-provided with paper-based tools and supporting information with techniques about identifying overweight in children and why it is important; Intervention B-the same but web-based; Control group. Parents in all arms will be asked to complete a questionnaire which includes assessment of their childs weight status, perceived behavioural control, action planning and related topics. Parent body measurements will be obtained. We will work with the National Child Measurement Programme (NCMP) in North of Tyne PCT which collects height and weight of Reception and Year 6 children. We will obtain these data to avoid duplicate measures of children, and crucially will provide the means to assess parents' accuracy of child weight status before parents receive the NCMP feedback letter informing them of their child's results (i.e. weight status). At 12 month follow-up parents will complete a postal questionnaire, and children's height and weight measured at school or home visit by the study team.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 2, First MREC approval date 21/11 /2012, 12/NE0409

Study design
Cluster randomised interventional trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format. The parents letter and information sheet can be requested from: Dr Kathryn Parkinson by emailing kathryn.parkinson@ncl.ac.uk or by telephone on +44 191 222 3828.

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Disease: Paediatrics / Childhood Overweight

Interventions
Parents of children in two age groups (4-5 years; 10-11 years). Their children will also be participants. The sample will be drawn from schools. A minimum of 36 schools with 120 children per school (2 classes of 30 in each of two year groups) will provide a sampling frame of 4320 children. Anticipating 50% agreeing to participate, provides a sample of 2160.

If some enrolled schools are smaller or take-up rate is lower than 50%, more schools will be enrolled.

Non-invasive information based, Delivery of body image scales and supporting information to parents to improve recognition of childhood obesity

Three study arms: delivery via web tool, paper-based and control.

The duration of the intervention is 30 days.

Intervention Type
Behavioural

Primary outcome measure
Change in parental perceptions of child body weight measured 1 month and 12 months post-intervention delivery

Secondary outcome measures
Child weight status at 12 months follow-up

Overall study start date
25/02/2013

Completion date

31/12/2013

Eligibility

Key inclusion criteria
1. The parent must have a child in Reception or Year 6 of a school enrolled to the study
2. Male & Female, lower age limit 4 years

Participant type(s)
Other

Age group
Child

Lower age limit
4 Years

Sex
Both

Target number of participants
UK Sample Size: 2160

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
25/02/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Health and Society
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle University (UK)

Sponsor details
Institute of Health and Society,
21-23 Claremont Place
Newcastle Upon Tyne
England
United Kingdom
NE2 4AA

Sponsor type
University/education

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

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) Grant Codes: MR/J00054X/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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	12/06/2015		Yes	No