

Child weight management for Ethnically diverse communities study (CHANGE)

Submission date 10/05/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/07/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Overweight and obese children are at risk of poor health both in childhood and adulthood. As well as physical ill health, being overweight or obese can also impact on a child's social and emotional wellbeing. Some South Asian children are at greater risk of becoming overweight or obese in childhood and South Asians are also more susceptible to some of the health consequences of obesity, such as heart disease and diabetes. In Birmingham (a large ethnically diverse city), a weight management programme for children and their families is available for all overweight and obese children. It has been found that Bangladeshi and Pakistani families are willing to start the programme but then drop out before they have completed it. Therefore the main aim of this study is to develop and assess the feasibility and acceptability of a weight management programme for children aged 4-11 years and their families, tailored to be culturally relevant to Bangladeshi and Pakistani communities, but also suitable for delivery to an ethnically diverse population.

Who can participate?

The study has two phases: development of a culturally adapted children's weight management programme and a study to test the feasibility and acceptability of the adapted programme. In the first phase, the study will recruit 40-60 Bangladeshi and Pakistani parents and carers of overweight or obese children aged 4-11 years who have been offered the local children's weight management programme. In the second phase, the study will recruit 120 overweight/obese children aged 4-11 years and families who have been referred to the Birmingham children's weight management service (60% of families will be Bangladeshi or Pakistani and 40% will be from other ethnicities).

What does the study involve?

In the first phase we will explore the reasons why Bangladeshi and Pakistani families do not finish the existing children's weight management programme, and make changes to try and make sure that families feel more able to continue to the end of the programme. First we will look at the results of previous research to identify what has worked well in other children's weight management programmes. Then we will find out from parents themselves what they thought by inviting them to take part in interviews or focus groups with researchers from their own communities. We will explore reasons why they did or did not attend or complete the

programme, and their ideas on how it could be improved. Third we will use our previous experience, together with what is already known about adapting health promotion services for minority ethnic groups, to develop a modified children's weight management programme that is relevant to Bangladeshi and Pakistani communities, but also suitable to be delivered in a diverse population. In the second phase we will test the modified programme's feasibility to deliver and acceptability to families, and we will also test methods for use in a future study to find out the programme's effectiveness and its value for money. As the existing programme is available to all children, the new programme will be tested in children and families from all ethnic backgrounds. In this way we can explore whether the new programme is acceptable to Bangladeshi and Pakistani families, and also to families of other ethnicities. Children and families taking part in this phase will be randomly allocated to the modified or existing programme. We will calculate and compare the proportions of families completing the adapted programme and the existing programme. We will also take measurements from children and parents before they start the programme, immediately after the programme finishes, and 6 months after the programme. Measurements include measures of weight and body fat, food intake, physical activity levels, psychological assessments and assessments of parental behaviours.

What are the possible benefits and risks of participating?

There will be no immediate benefit to those participating in interviews or focus groups in the first phase of the study. The information resulting from the interviews and focus groups will potentially benefit future recipients of children's weight management programmes. It is anticipated that the risk of harm to these participants is minimal. All participants in the second phase study will receive a weight management programme, either the standard programme or the newly adapted programme. As the weight management programmes focus on changing lifestyle behaviours, the risk of harm to participants is very low. Psychosocial assessments will be undertaken during the study to monitor for any adverse impact on children's emotional and social wellbeing.

Where is the study run from?

This study is run from Birmingham Community Healthcare NHS Trust, Birmingham, UK.

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

The study will start in September 2014 and will run for 30 months.

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?

Dr Miranda Pallan

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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

HTA 12/137/05

Study information

Scientific Title

Development of a culturally adapted weight management programme for children of Pakistani and Bangladeshi origin

Acronym

CHANGE

Study objectives

Data from locally provided children's weight management services indicate that Bangladeshi and Pakistani families are initially willing to engage with the children's weight management programme offered, but are then less likely to complete the programme than families of other ethnicities. We hypothesise that the development of a programme that is more culturally relevant to Bangladeshi and Pakistani communities will ensure higher rates of completion of the programme in these families.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/1213705>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Edgbaston Research Ethics Committee, 28/07/2014, REC ref: 14/WM/1036

Study design

Development and feasibility study of a complex behavioural intervention, taking place in a single centre

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Childhood obesity

Interventions

Children and families are randomised to two groups:

1. Intervention: an adapted children's weight management programme will be developed in the first phase of the study. This will be group based and delivered over approximately 8 weeks. It will include elements to address eating and physical activity behaviours and will incorporate techniques to support behaviour change by families. Following the 8-week programme there will be a programme of longer term support for families.

2. Comparator: the existing children's weight management programme. Parents attend seven weekly daytime sessions (1-1.5 hours duration each), with children attending the first and last sessions with their parents. Sessions are interactive and practical covering nutrition education, physical activity promotion and behaviour change. Following the 7-week programme, children and parents are invited to attend follow up events every 3 months. These are 1.5-hour sessions that consist of a 1-hour physical activity session, family activities to reinforce healthy eating messages, and measurement of children's height and weight.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Percentage of Bangladeshi and Pakistani families completing the adapted children's weight management programme.

Secondary outcome measures

The proportion of all families completing the adapted children's weight management programme and all families completing the standard programme will be calculated.

Other secondary outcome measures for the feasibility study are:

1. Height and weight (to calculate BMI); waist circumference; bioimpedance analysis (to derive percentage body fat)
2. Usual patterns of dietary intake (assessed using the Children's Dietary Questionnaire, which will be adapted for use in the study population)
3. Physical activity (objectively measured with an Actigraph accelerometer over a 5-day period, including a weekend)
4. Parent-reported sedentary activities
5. Health-related quality of life (assessed using the PedsQL)
6. A health utility measure (CHU 9D)
7. Body image (assessed using the Figure Rating Scale, adapted for use in the study population)
8. Constructs of self-concept (assessed using the Pictorial Scale of Perceived Competence and Social Acceptance for the Young for ages 4-7, and the Self-Perception Profile for Children for ages 8-11).

These measures will be undertaken at three time points: baseline, after the weight management programme is completed, and 6 months after programme completion.

Overall study start date

01/09/2014

Completion date

28/02/2017

Eligibility

Key inclusion criteria

Phase 1: Bangladeshi and Pakistani parents and carers of overweight/obese children aged 4-11 years who have been offered the existing children's weight management service.

Phase 2: overweight/obese children aged 4-11 years and their families who have been referred to the Birmingham children's weight management service.

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

Phase 1: 40-60 parents/carers; Phase 2: 120 children and families

Total final enrolment

92

Key exclusion criteria

Phase 2: Families who self-refer to the service but do not have an overweight or obese child (defined as 91st centile or above) aged 4-11 year will be excluded from the study.

Date of first enrolment

01/09/2014

Date of final enrolment

28/02/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Public Health Building

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

University of Birmingham (UK)

Sponsor details

c/o Dr Sean Jennings

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Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK); ref: HTA 12/137/05

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?
Results article	results	01/07/2019	15/07/2019	Yes	No
HRA research summary			28/06/2023	No	No