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Healthy and Active Parenting Programme for early Years (HAPPY) - A pilot RCT to evaluate a parenting intervention to prevent childhood obesity in a bi ethnic population

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
07/03/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A multi-disciplinary team has developed an intervention [HAPPY - Healthy and Active Parenting Programme for early Years] aimed at reducing the risk of obesity in children of over weight and obese mothers. There are number of issues which need to be addressed before the HAPPY intervention can be evaluated for effectiveness and cost-effectiveness in a study. The acceptability and feasibility of implementing and evaluating such as intervention within this diverse population is unclear. The study aims to assess the results of a feasibility study exploring issues surrounding the recruitment of women to such a study, and the acceptability and feasibility of the HAPPY intervention both to individual participants, and to the local services who would deliver the intervention if it were to be incorporated into usual practice.

Who can participate?
All overweight (defined as body mass index of ≥25) pregnant mothers aged 18 years and over who attend a clinic appointment at the Bradford Royal Infirmarys Womens and Newborn Unit are eligible to take part. Further inclusion criteria include the ability to attend intervention sessions at a location close to their home address, and the ability to understand intervention sessions delivered in the English Language. Mothers to be excluded if they have a pre-existing serious physical or mental health disorder self-reported pre-existing serious physical or mental health condition, a foetal abnormality or multiple pregnancies.

What does the study involve?
Those mothers who accept a screening at the maternity unit will be given participant information sheet and called to book an appointment. A researcher working on the study will visit the mother in the home setting (or hospital if preferred). A questionnaire will be completed and height and weight measurement will be taken. The mother will then be randomly allocated to either attend the HAPPY intervention or receive usual care only.
The HAPPY intervention consists of six group antenatal and six group postnatal sessions. The content is integrated into an existing parenting programme (Family Links Nurturing Programme:

FLNP). The FLNP programme is one of the preferred parenting programmes in Bradford and aims to enhance parents understanding of themselves, of their childrens emotional as well as physical needs and which develops self-esteem and self-efficacy of parents. All participants will be followed up at when their child is aged 6 months and 12 months. A purposively selected sample of mothers will be invited to attend qualitative interviews to gain feedback on trial participation.

What are the possible benefits and risks of participating?
There may be no direct benefits to anyone taking part in this study; however, we hope that taking part in this study will lead to a better general level of health for participating mothers and their babies. The results of the study may benefit other mothers and their babies in the future. We do not foresee any risks to either women or their babies that taking part in the study.

Where is the study run from?
The study is part of the Born in Bradford Project and is run from the Bradford Institute for Health Research at Bradford Teaching Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
Recruitment to the study started in March 2012 and is expected to run until the children in the study are aged one year of age. The study end date is July 2014, including analysis of data collected and final reports.

Who is funding the study?
The study is part of the Born in Bradford Programme grant funded by the National Institute for Health Research.

Who is the main contact?
Dr Rosie McEachan - Programme Manager for Born in Bradford Project
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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
12027

Study information

Scientific Title
Healthy and Active Parenting Programme for early Years (HAPPY) - A pilot RCT to evaluate a parenting intervention to prevent childhood obesity in a bi ethnic population

Acronym
HAPPY

Study objectives
The UK is experiencing a major obesity epidemic that threatens the capacity of the NHS. Existing clinical trials of interventions to tackle obesity have shown disappointing results. Possible reasons for this include insufficient consideration of existing evidence, failure to understand and target key behaviours, lack of attention to early design and testing and implementation of interventions too late in childhood.

We propose to evaluate an exploratory randomised controlled trial (RCT) in Bradford which will inform a definitive RCT focussing on working with families ante natally and the first year of life which can be implemented within the NHS. We will play particular attention to cultural adaptation of the intervention to address the potential differences in lifestlye,dietary habits and family dynamics between ethnic groups. Early evaluation will help to refine and optimise the interventions in partnership with families and professionals. We will describe the feasibility and acceptability of the interventions for different communities; eligibility, consent and recruitment rates; acceptability of randomisation process; follow up rates.

The outcomes will inform the components and delivery of the interventions as well as estimate the effect size (account and test and validate the primary and intermediate outcome measures).

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=12027

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & the Humber - Bradford Research and Ethics Committee, 08/02/2012, ref: 11/YH/0458

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

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
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics/ Childhood obesity

Interventions
60 participants will be randomised to the receive the intervention and 60 to the control (routine care).

The HAPPY trial intervention consists of 12 sessions delivered by trained facilitators (six antenatal and six postnatally) aimed to prevent unhealthy weight gain in children born to the mothers recruited to the study.

Follow Up Length: 12 months

Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Child weight gain

Potential primary outcomes will be collected to inform which will be most sensitive to change, and will include:
1. The proportion of children who cross two centile bands (1.33 SD) for weight age 1 year.
2. The proportion of children who cross one centile (0.67SD) for weight at age 1 year
3. Weight age and sex adjusted z-score (observable on growth trajectory charts) at one year
4. Proportion of children aged 1 with weight > 85th centile

Secondary outcome measures
Secondary outcomes will explore the extent to which behaviours targeted in the intervention have been modified. These will be assessed by completing questionnaires at child age 6 and 12 months.

The outcome measures include:
1. Mothers body mass index (BMI)

2. Child height and length
3. Maternal diet
4. Environment (foods in the home)
5. Breastfeeding and weaning
6. Infant diet, infant feeding styles, infant development
7. Maternal and child physical activity, sedentary behaviours and beliefs and health behaviours

Overall study start date
26/03/2012

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Women will be eligible if they are booked in to have their baby at Bradford Royal Infirmary Maternity Unit.
2. All mothers with a BMI >=25 aged over 18 years willing and able to attend sessions at a pre-specified venue near to where they live will be approached.
3. Capability to give consent is assessed by the research midwives and community research administrators at the time of recruitment. This adheres to the Mental Capacity Act 2005 where women are deemed capable of consent unless otherwise demonstrated as per section 30-34

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 120; Description: Study participants will be allocated to one of the two arms of the trial.

Key exclusion criteria
1. Pre-existing serious physical or mental health disorder
2. Multiple pregnancy or fetal abnormality

Date of first enrolment
26/03/2012

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Health Research
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Bradford Institute for Health Research (UK)

Sponsor details
Bradford Institute for Health Research (UK)
c/o Jane Dennison
Research Governance Manager
Research Support & Governance Office
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Sponsor type
Hospital/treatment centre

Website
http://www.bradfordresearch.nhs.uk/

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Programme Grants for Applied Research; Grant Codes: RP-PG-0407-10044

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	01/03/2016		Yes	No