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Empowering Parents to Prevent Obesity at Weaning

Submission date	Recruitment status
19/05/2010	No longer recruiting
Registration date	**Overall study status**
19/05/2010	Completed
Last Edited	**Condition category**
23/11/2010	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4880

Study information

Scientific Title

Empowering Parents to Prevent Obesity at Weaning - Exploratory Research: Royal College of Paediatrics and Child Health (RCPCH) pilot and feasibility study

Acronym
EMPOWER

Study objectives
This is a Department of Health funded study to test the feasibility of a programme designed to prevent obesity at weaning (EMPOWER). The study is being conducted by researchers at the Universities of Warwick and Leeds.

The aims are as follows:
1. To pilot an intervention developed by the Royal College of Paediatrics and Child Health and the Child Health Obesity Group
2. Ascertain the feasibility and acceptability of the intervention and prepare for a randomised controlled trial (RCT) to determine clinical effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Ethics Committee approved on the 1st June 2007 (ref: 07/Q2707/114)

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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, Primary Care Research Network for England; Subtopic: Not Assigned, Generic Health Relevance (all Subtopics); Disease: All Diseases, Public Health Research

Interventions
Pilot study (9 months, n = 16):
The pilot will take place at two locations: Leeds and Warwick and will be delivered by two specially trained health visitors. The aim will be for each health visitor to work with 8 families at

each site. The outcome measures provisionally selected for use in the feasibility trial will be administered at baseline and at 6 months, by the health visitor. In-depth interviews will be conducted with the health visitors, service providers and participating families twice during the pilot phase and will explore user and provider satisfaction; perceptions about the acceptability of the intervention, its content, its usefulness and the quality of the resources; and the outcome measures. This data will be used to modify and enhance the programme. Process data will also be collected regarding recruitment, number of sessions received by each participant etc. The results of this analysis will contribute to an understanding of the acceptability and feasibility of the intervention, and will also help shape the recruitment strategy for the feasibility trial.

Exploratory trial (24 months, n = 64):
This stage of the study will involve and assessing the feasibility of conducting a randomised controlled trial. Of the intervention by delivering the intervention to a group of 32 infants and 32 control infants (at the above two locations) The following data will be collected:
1. Process data - qualitative and quantitative data from participating families concerning the intervention such as number of sessions received by each participant, drop-out, satisfaction with the intervention etc
2. Quantitative data
3. Qualitative data - in-depth interviews with families and service providers
4. Cost data

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Recruitment rate and acceptability of randomisation
2. Acceptability of the trial methodology

Data collection periods are at baseline (when the infant is 4 - 6 weeks old), when the infant is 9 months old, and again at 18 months of age. The primary outcomes will be assessed quantitatively at recruitment as well as qualitatively at the end of the trial.

Secondary outcome measures
Infant outcomes:
1. Infant weight gain on scales
2. Infant diet: diet and eating behaviour questionnaire
3. Eating pattern

Parental outcomes:
1. Maternal weight and body mass index (BMI)
2. Maternal and family diet: food frequency questionnaire

Data collection periods are at baseline (when the infant is 4 - 6 weeks old), when the infant is 9 months old, and again at 18 months of age. The secondary outcomes will be analysed against baseline at the two timepoints mentioned above.

Overall study start date
01/09/2007

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Women with a pre-pregnancy body mass index (BMI) of greater than or equal to 35 kg/m^2
2. Aged 16 years or over
3. Able to understand and communicate in English
4. Live within the Primary Care Trusts (PCT) area recruiting for the study (namely Leeds PCT and Heart of Birmingham PCT)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned sample size: 64

Key exclusion criteria
1. Obesity has a medical cause
2. Develop pre-eclampsia or gestational diabetes during their pregnancy
3. Baby is born with any birth defects
4. Infant is on the child protection register
5. The woman has learning difficulties and is unable to fully understand the requirements of the study, or the woman's comprehension of English is insufficient to enable her to fully understand the study requirements

Date of first enrolment
01/09/2007

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Policy Research Programme
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NS

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - National Service Framework (NSF) for Children, Young People and Maternity Services

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 of programme acceptability study	01/11/2010		Yes	No