ISRCTN10460064 https://doi.org/10.1186/ISRCTN10460064

Feasibility of a brief weight loss intervention for women following childbirth, delivered within the national child immunisation programme

Submission date
05/08/2015

Recruitment status
No longer recruiting

Registration date
28/08/2015

Overall study status
Completed

Last Edited
08/06/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
It has been found that one year after giving birth up to 25% of women keep more than 4kg of the weight that they have gained during their pregnancy. This excess weight can increase the risk of developing diseases later in life. It has been suggested that additional interventions (i.e. programmes or treatments) can be included as part of existing public health appointments to tackle this issue for women after having a baby very cheaply. This study aims to include an intervention for women who have gained weight during their pregnancy into the national child immunisation programme, in order to test whether or not women feel this would be an appropriate measure to take and would help them to lose weight after having had their baby.

Who can participate?
Women who have given birth within the last four and eight weeks with a BMI of over 25kg/m2, and have not yet attended their first child immunisation visit.

What does the study involve?
Participants who have volunteered for the study are visited at home to measure their weight and gather personal information. They are then randomly allocated into one of two groups. All women are asked to weigh themselves weekly and record this on a record card attached the child's 'red book' and aim for 0.5-1kg weight loss per week. Women in the first group are provided with a leaflet on healthy living, but otherwise no additional advice or assistance. For women in the second group, nurses make recommendations for healthier lifestyle choices and they are also advised to use an online weight loss programme. At each child immunisation (2, 3, 4 months old), nurses weigh the women to check their progress. A final weight measurement is then taken three months after women start the study. Women and nurses in the trial are then interviewed for feedback about what they think of the intervention.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study include weight loss and improved self-

management of weight. There are no potential risks of the intervention to individual participants. However, we will be monitoring immunisation and breastfeeding rates to investigate if the intervention has an impact on these behaviours.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2016 to February 2019 (as of 22/10/2018)

Who is funding the study?
University of Birmingham (UK)

Who is the main contact?
Ms Janice Ferguson
j.a.ferguson@bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/bctu/trials/primary-care/pimmswl/index.aspx

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility and acceptability of a routine weight management intervention for postnatal women embedded within the national child immunisation programme

Acronym
PIMMS

Study objectives
A brief routine weight management intervention for women in the postnatal period that promotes self-management through self-monitoring and signposting to an online weight management programme and is embedded within the child immunisation programme may be feasible and acceptable both to patients and health care professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands- Black Country Research Ethics Committee, 17/02/2016, ref: 15/WM/0445

Study design
Single-centre cluster feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Postnatal weight gain and obesity

Interventions
Intervention Group: The intervention is embedded within pre-existing immunisation contacts, when babies are two, three and four months old. The intervention involves nurses encouraging women in the postnatal period to make healthier lifestyle choices though self-monitoring of weight and signposting to a female specific online weight management programme.

Comparison Group: Women will receive a healthy lifestyle leaflet and no other intervention.

Women will be asked to weigh themselves weekly and record this on a record card attached to the child's red book, with a goal of losing 0.5kg per week. The practice nurse will weigh the women at each child immunisation to assess their progress against their weight loss goal. Follow-up of weight will be three months after randomisation. Semi-structured interviews with both participants and nurses will be carried out at the end of the trial to obtain their views of the intervention.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of the intervention

Secondary outcome measures
1. Mean difference in weight change between groups
2. Breastfeeding rates
3. Immunisation rates
4. Recruitment rate
5. Adherence to intervention
6. Self-reported physical activity
7. Contamination rate
8. Diet quality
9. Body image
10. Depression scores

Overall study start date
01/01/2016

Completion date
28/02/2019

Eligibility

Key inclusion criteria

1. Women who have given birth between four and eight weeks ago
2. Have not yet attend the first immunisation visit
3. Aged 18 or over
4. BMI 25kg/m2 or more
5. Considered suitable to participate by their GP

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

Total final enrolment
28

Key exclusion criteria
1. Dependency on insulin
2. Using illicit drugs or alcohol
3. Experiencing serious mental health difficulties (e.g. postnatal psychosis) or known history of eating disorders
4. Mothers in contact with social services because of concerns relating to safeguarding and/or domestic violence
5. Mothers whose babies have been removed from their care at birth
6. Mothers whose babies have died

Date of first enrolment
01/01/2016

Date of final enrolment
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

School of Heath and Population Sciences
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B152TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
C block, Aston Webb Building, University of Birmingham, Edgbaston
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University Of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to publish the results in a peer reviewed journal such as the British Journal of General Practice and will also present the results at appropriate national and international conferences (such as the European Congress on Obesity or UK Society for Behavioural Medicine annual meeting) as well as to primary care and public health professionals.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study are available upon request from Professor Amanda Daley, A.Daley@lboro.ac.uk, on reasonable request. Access to anonymised data may be granted following review of the request. Exclusive use will be retained until the publication of major outputs.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/02/2020	08/06/2021	Yes	No
Results article		01/12/2020	08/06/2021	Yes	No
HRA research summary			28/06/2023	No	No