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Post natal weight loss study

Submission date
04/12/2017

Recruitment status
No longer recruiting

Registration date
10/01/2018

Overall study status
Completed

Last Edited
27/09/2022

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
Pregnancy and the postnatal period are vulnerable life stages for gaining excess weight. Many women have reported that pregnancy is an important factor that has led to weight problems later on in life. This can significantly increase the risk of obesity and other serious chronic illnesses including type 2 diabetes, heart disease and cancer. It is therefore important to find ways to help new mothers lose weight gained during pregnancy and return to their pre-pregnancy weight. The aim of this study is to assess the feasibility and acceptability of a brief routine weight management intervention for postnatal women, with the aim to then undertake a larger study to assess the effectiveness and cost effectiveness of the intervention in facilitating long term weight loss.

Who can participate?
Women aged 18 and older who are at least four weeks postnatal and have a BMI of 25 kg/m2.

What does the study involve?
General practices are randomly allocated to one of two groups. Those in the first group receive brief motivation and support by nurses at baby immunisation appointments at two, three, and four months to make healthier lifestyle choices though self-monitoring of weight and signposting to an online weight management programme (POWeR). Those in the second group receive brief written information about following a healthy lifestyle and no other intervention. The NHS EatWell guide leaflet is used. All women are followed up three months post-recruitment. Women and nurses are invited for an interview to gain their views on the intervention.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their BMI. There are no expected risks with taking part in the trial. The intervention is embedded into the national child immunisation programme and so no additional visits are required. If participants are interested in taking part in the trial, a member of the PIMMS-WL research team will arrange to visit them at home. Even if regular weighing helps individuals to control their weight, there may be concerns that it will have negative psychological consequences and that feedback about weight and body size may result in psychological distress or lead to the adoption of unhealthy weight control practices, but there is little objective evidence to support these concerns. We will be collecting data on these issues during the study. There may also be concerns that the intervention may have an effect on

breastfeeding or immunisation uptake rate. We will also be monitoring these behaviours during the study so that although we do not expect there to be any issues, should they occur we will be able to identify them.

Where is the study run from?
Birmingham Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2017 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Sarah Tearne
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Study website
www.birmingham.ac.uk/pimmswl

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36526

Study information

Scientific Title
Feasibility and acceptability of a brief routine weight management intervention for postnatal women embedded within the national child immunisation programme in primary care: Randomised controlled cluster feasibility trial with nested qualitative study

Acronym
PIMMS-WL

Study objectives
The primary objective is to produce evidence that a large-scale phase III cluster RCT of a weight management intervention where women engage in managing their own weight by self-monitoring their weight and by accessing an existing online weight loss programme (Positive Online Weight Reduction; POWeR) for support is feasible. The aim of the phase III cluster RCT would be to examine the effectiveness and cost effectiveness of the intervention in facilitating long term weight loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Black Country Research Ethics Committee – REC, 27/11/2017, ref: 17/WM/0399

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Dietary

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Women who are overweight after having given birth

Interventions
The PIMMS-WL trial is a randomised controlled cluster feasibility trial. First, a feasibility trial is run before undertaking a large-scale phase III RCT to assess the clinical and cost-effectiveness of this weight management intervention, as there is a need to assess the feasibility and acceptability of such a trial. The unit of randomisation is the GP practice (cluster). The GP practices are randomised in a 1:1 ratio to the weight management intervention or no intervention (comparator group).

80 participants are recruited from approximately 10-12 GP practices across the Birmingham area over 8 months. Potentially eligible participants are identified initially from medical records at the Birmingham Women's Hospital (BWH). BWH is Patient Identification Centre (PIC) and assists in the identification of patients. Medical records are screened by site staff to determine initial eligibility. This determines which participants can then be contacted about the trial and invited for further screening to determine full eligibility. An invitation letter and a patient information sheet are mailed to these women asking them to contact the PIMMS-WL researchers if they are interested in the trial. Women do not receive their letter of invitation until at least four weeks post-delivery.

Written informed consent into the PIMMS-WL trial is a 2-stage process. First written informed consent is sought for screening to confirm all eligibility criteria are met. Once all eligibility criteria have been confirmed, participants are then invited to give their written informed consent to be enrolled into the main PIMMS-WL trial. Written informed consent for each participant is obtained by a member of the PIMMS-WL research team in the patient's home at the baseline home visit.

Trial participants registered at GP practices randomised to deliver the intervention receive brief motivation and support by nurses to make healthier lifestyle choices though self-monitoring of weight and signposting to an online weight management programme (POWeR). The intervention takes place at the baby immunisation visits at two, three and four months.

Trial participants registered at GP practices randomised to the control arm receive brief written information about following a healthy lifestyle and no other intervention. The NHS EatWell guide leaflet is used.

All women are followed up at a home visit at 3 months post-recruitment. Women and nurses are also invited to participate in a qualitative study interview to obtain their views on the intervention and its acceptability.

For the phase III trial to take place there needs to be evidence from this feasibility trial of meeting pre-specified STOP-GO rules. The trial is too small to include meaningful and sensitive

STOP-GO criteria regarding the impact of the intervention on immunisation rates. However, we will check that the intervention has not adversely affected usual immunisation rates at each GP practice. The criteria to proceed to the phase III trial are therefore be based on three criteria; recruitment rate of eligible women; adherence to weekly self-weighing and registration with the online weight loss programme (POWeR) using a traffic light system.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcomes as of 24/01/2019:
1. The feasibility of a full-scale phase III cluster RCT. This decision will be based on the acceptability of the trial using a composite assessment of both quantitative and qualitative data and will include assessment of the following:
1.1. Whether the trial is appealing to women (via assessment of the recruitment rate to ensure a full phase III trial is feasible)
1.2. Whether the intervention is acceptable
1.3. Whether the intervention has any adverse impact on infant immunisation rates
1.4. The number of women who complete the trial and complete the trial questionnaires
2. The recruitment rate will be presented as the proportion of eligible participants who took part in the trial (i.e. the number of participants who agreed to enrol in the trial divided by the number of eligible participants invited to take part in the trial). BWH will provide data on the number of invitation letters sent, along with data on age, ethnicity and IMD score of women who were sent an invitation. Data on age and ethnicity will be provided in summary format. The IMD score will be calculated on the postcode of the participant and will be provided for each participant invited. These data will be used to calculate the recruitment rate so a comparison of the socio-demographics of participants recruited and those who did not respond to the invitation can be made.
3. The quantitative assessment of whether the intervention is acceptable will be based on the adherence of women to weekly self-weighing. The trial includes three sources of data regarding frequency of self-weighing; objective recording scales, self-reported in the red book and recordings using the POWeR programme. The objective recording of weight on the scales will be the authoritative source of data for frequency of self-weighing/adherence. If this is not available, the red book are authoritative source, and if this is not available then data from the POWeR programme will be used as the measure of intervention adherence.
4. To check that the intervention has no adverse impact on infant immunisation rates, the GP practices will provide data on all immunisation appointments attended during the trial. Babies are routinely immunised at two, three, four and twelve months of age. The trial is taking place over the first three of these immunisation appointments. The proportion of babies who attended all of these three immunisation appointments are reported for each practice (both intervention and control GP practices) and the rate compared with the normal immunisation rate for the practice. Reasons for missed appointments will be summarised descriptively.
5. Recruitment, adherence and immunisation rates are summarised as proportions with 95% confidence intervals

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1.1. Whether the trial is appealing to women (via assessment of the recruitment rate to ensure a full phase III trial is feasible)

1.2. Whether the intervention is acceptable
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2. The recruitment rate are presented as the proportion of eligible participants who took part in the trial (i.e. the number of participants who agreed to enrol in the trial divided by the number of eligible participants invited to take part in the trial). Birmingham Women's Hospital will provide data on the number of invitation letters sent, along with the age, postcode and ethnicity of women who were sent an invitation, so that the recruitment rate can be calculated, and so a comparison of the socio-demographics of participants recruited and those who did not respond to the invitation can be made.
3. The quantitative assessment of whether the intervention is acceptable will be based on the adherence of women to weekly self-weighing. The trial includes three sources of data regarding frequency of self-weighing; objective recording scales, self-reported in the red book and recordings using the POWeR programme. The objective recording of weight on the scales will be the authoritative source of data for frequency of self-weighing/adherence. If this is not available, the red book are authoritative source, and if this is not available then data from the POWeR programme will be used as the measure of intervention adherence.
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Secondary outcome measures

While this feasibility trial will not be powered to detect meaningful differences in outcome measures, it will give us the opportunity to ensure that there are no issues with the completion of these measures in preparation for the main trial.
1. Demographic, lifestyle and pregnancy related information will be collected using the PIMMS-WL baseline and follow-up health questionnaire as follows:
1.1. Marital status, employment status and financial status are using the PIMMS-WL baseline health questionnaire collected at baseline
1.2. Smoking status and alcohol consumption are measured using the PIMMS-WL baseline and follow-up health questionnaire at baseline and 3 months post baseline
1.3. Data relating to participants' type of delivery, pregnancy complications and how many children they have given birth to will be measured using the PIMMS-WL baseline health questionnaire at baseline
1.4. Attendance on any formal weight loss programmes during their involvement in the trial and any specific weight loss strategies or diets that participants might have used are measured using the PIMMS-WL baseline and follow-up health questionnaire at baseline and 3 months post baseline
1.5. Data relating to timing of cessation of breastfeeding, infant feeding practices and sleeping patterns of the mother are collected using the PIMMS-WL baseline and follow-up health questionnaire at baseline and 3 months post baseline
2. Weight, BMI and body fat are assessed using a Tanita SC-240MA analyser measured at baseline and at 3 months post baseline
3. Depression and anxiety will be measured using the Hospital Anxiety and Depression scale (HADS) at baseline and at 3 months post baseline

4. Self-reported physical activity are measured using the Pregnancy Physical Activity Questionnaire (PPAQ) at baseline and at 3 months post baseline
5. Body image are measured using the Body Image State Scale at baseline and at 3 months post baseline
6. Eating habits are assessed using the 3 Factor Eating Questionnaire (subscales: cognitive restraint of eating, emotional eating and uncontrolled eating) completed at baseline and at 3 months post baseline
7. Use of weight control strategies are measured using the Weight Controls Strategies Scale at 3 months post baseline
8. For the intervention group only, perception on regular self-weighing are measured using the Daily Self-weighing Perceptions questionnaire completed at 3 months post baseline
9. For the intervention group, trial acceptability is measured using the PIMMS-WL follow-up health questionnaire at follow-up at 3 months post baseline
10. To inform the design of the economic evaluation in the phase III trial, the acceptability of the ICECAP instrument is assessed using the rates of completion of the ICECAP at baseline and at 3 months post baseline
11. Views of women about the interventions and experiences of the practice nurses delivering the intervention are measured using semi-structured interviews after trial follow-up

Overall study start date
01/09/2017

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or more
2. Women who are at least 4 weeks postnatal and who have not yet attended the first child immunisation appointment
3. Planning to have their child immunised within the national immunisation programme
4. BMI 25 kg/m2 or more at the time of recruitment at the baseline home visit
5. Patient able and willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
28

Key exclusion criteria
Current exclusion criteria as of 24/01/2019:
1. Mothers whose babies have died or have been removed from their care at birth
2. Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
3. Unwilling to give consent to notify their GP
4. Women who have been diagnosed with a serious mental health difficulty requiring hospitalisation in the past two years or been diagnosed with anorexia and/or bulimia in the past two years

Previous exclusion criteria:
1. Mothers whose babies have died or have been removed from their care at birth
2. Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
3. Unwilling to give consent to notify their GP
4. Women who are using illicit drugs, alcohol dependant, experiencing serious mental health difficulties (e.g. postnatal psychosis) or known history of eating disorders

Date of first enrolment
10/07/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's Hospital
Birmingham Women's and Children's NHS Foundation Trust
Birmingham Women's Hospital
Mindelsohn Way
Edgbaston
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B15 2TG

Sponsor information

Organisation
University of Birmingham

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of this trial will be submitted for publication in a peer reviewed journal on completion of the trial.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the PIMMS-WL trial office (email: pimms-wl@trials.bham.ac.uk). Requests will be reviewed by Dr Amanda Daley and the PIMMS-WL Trial Management Group. The data will become available at the end of the trial once the main trial results have been accepted for publication.

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	01/09/2020	04/09/2020	Yes	No
Funder report results	results	01/08/2021	13/08/2021	Yes	No
Protocol article		16/02/2020	27/09/2022	Yes	No
HRA research summary			28/06/2023	No	No