TRIAL PROTOCOL

PIMMS-WL

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.

Version Number: 7.0

Version Date: 5th November 2018

Protocol Development

Amendment number	Date of amendment	Protocol version number	Type of amendment
1.0	**5th Dec 2017**	**2.0**	**Substantial**

Summary of amendment

Substantial changes:

- Removal of the eligibility criteria screening for use of illicit drugs or alcohol dependence
- Clarification to the eligibility criteria screening for serious mental health difficulties and eating disorders
- Clarification of the recruitment process
- Clarification on the collection and analysis of the immunisation attendance data
- Clarification on safety reporting
- Addition to the instructions on the baseline questionnaire booklet front sheet
- Changes to the patient Invitation Letter
- Changes to the Participant Information Sheet and GP Poster
- Changes to the Screening Consent Form, Full Informed Consent Form A and Full Informed Consent Form
- Change to the Baseline Appointment Letter

Non-substantial changes:

- Minor changes to the baseline and follow-up questionnaire booklets
- Minor changes to the Weight Card
- Change to TSC contact details and change to the timings of TSC meetings
- Amended statement of activities and schedule of events
- Minor typographical corrections

Other modified documents approved	Previous version	New version
Invitation Letter and Reply Slip	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Participant Information Sheet	Version 2.0 (16th Nov 2017)	Version 3.0 (5th Dec 2017)
Screening Consent Form	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Full Consent Form A	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Full Consent Form B	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
GP Poster	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Baseline Appointment Letter	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Questionnaire Baseline	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Questionnaire Follow-up A	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Questionnaire Follow-up B	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Weight Card	Version 1.0 (12th Oct 2017)	Version 2.0 (5th Dec 2017)
Statement of Activities (BWH)	Version 1.0	Version 2.0
Statement of Activities (GPs)	Version 1.0	Version 2.0
Schedule of Events (BWH)	Version 1.0	Version 2.0
Schedule of Events (GPs)	Version 1.0	Version 2.0

Amendment number	Date of amendment	Protocol version number	Type of amendment
2.0	**1st Feb 2018**	**4.0**	**Substantial**

Summary of amendment

Substantial changes:

- Changes to the Participant Information Sheet as requested by the HRA
- Changes to section 8.6 and 16 of the protocol to reflect changes to the Participant Information Sheet
- Changes to the Full Consent Form B, Participant Interview Consent Form, Nurses Interview PIS and Nurses Interview Consent Form

Non-substantial changes:

- Change of CI title
- Addition of ISRCTN number to protocol and trial documentation
- Re-formatting of the Trial Number to incorporate site ID
- Addition of Trial Number and correction to the Weight Record card
- Correction to one question on Questionnaire Follow-up B
- Amended statement of activities and schedule of events as requested by the HRA

Other modified documents approved	Previous version	New version
Participant Information Sheet	Version 3.0 (5th Dec 2017)	Version 5.0 (1st Feb 2018)
Invitation Letter and Reply Slip	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Screening Consent Form	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Full Consent Form A	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Full Consent Form B	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
GP Letter	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
GP Poster	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Healthy Lifestyle Leaflet	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Baseline Appointment Letter	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Follow-up Appointment Letter	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Questionnaire Baseline	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Questionnaire Follow-up A	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Questionnaire Follow-up B	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Weight Record Card	Version 2.0 (5th Dec 2017)	Version 4.0 (1st Feb 2018)
Nurses Interview PIS	Version 3.0 (22nd Nov 2017)	Version 5.0 (1st Feb 2018)
Nurses Interview Consent Form	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Nurses Interview Schedule	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Participant Interview Consent Form	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Participant Interview Schedule	Version 1.0 (12th Oct 2017)	Version 3.0 (1st Feb 2018)
Statement of Activities (BWH)	Version 2.0	Version 3.0
Statement of Activities (GPs)	Version 2.0	Version 3.0
Schedule of Events (BWH)	Version 2.0	Version 3.0
Schedule of Events (GPs)	Version 2.0	Version 3.0

Amendment number	Date of amendment	Protocol version number	Type of amendment
3.0	**20th Mar 2018**	**5.0**	**Minor**

Summary of amendment

Non-substantial changes:

- Change to section 6.2. Clarification on the IMD score calculated for the GP practice.
- Change to section 13.2.1. Correction on the data collected on participants invited to participate.
- Amended statement of activities and schedule of events as requested by the HRA

Other modified documents approved	Previous version	New version
Statement of Activities (BWH)	Version 3.0	Version 4.0
Statement of Activities (BWH)	Version 4.0	Version 5.0
Statement of Activities (GPs)	Version 3.0	Version 4.0
Schedule of Events (BWH)	Version 3.0	Version 4.0
Schedule of Events (GPs)	Version 3.0	Version 4.0

Amendment number	Date of amendment	Protocol version number	Type of amendment
4.0	**10th May 2018**	**6.0**	**Substantial**

Summary of amendment

Substantial changes:

- Submission of participant POWeR registration card
- Submission of participant instructions for POWeR
- Submission of participant FAQs for POWeR
- Submission of participant instructions for BodyTrace weighing scales

Non-substantial changes:

- Addition of a 'date completed' to the Questionnaire Baseline
- Addition of a 'date completed' to the Questionnaire Follow-up A
- Addition of a 'date completed' to the Questionnaire Follow-up B

Other modified documents approved	Previous version	New version
Participant POWeR registration card	N/A	Version 1.0 (10th May 2018)
Participant Instructions for POWeR	N/A	Version 1.0 (10th May 2018)
Participant FAQs for POWeR	N/A	Version 1.0 (10th May 2018)
Participant Instructions for BodyTrace weighing scales	N/A	Version 1.0 (10th May 2018)
Questionnaire Baseline	Version 4.0 (1st Feb 2018)	Version 5.0 (10th May 2018)
Questionnaire Follow-up A	Version 4.0 (1st Feb 2018)	Version 5.0 (10th May 2018)
Questionnaire Follow-up B	Version 4.0 (1st Feb 2018)	Version 5.0 (10th May 2018)

Amendment number	Date of amendment	Protocol version number	Type of amendment
5.0	**5th Nov 2018**	**7.0**	**Substantial**

Summary of amendment

Substantial changes:

- Change of grant holder and CI employer from University of Birmingham to University of Loughborough
- Addition to TSC details
- Changes to the recruitment process
- Submission of a GP Flyer Cover Letter and GP Flyer
- Submission of a GP version of the Invitation Letter and Reply Slip

Non-substantial changes:

- Minor typographical corrections

Other modified documents approved	Previous version	New version
GP Flyer Cover Letter	N/A	Version 1.0 (5th Nov 2018)
GP Flyer	N/A	Version 1.0 (5th Nov 2018)
Invitation Letter and Reply Slip – GP Version	N/A	Version 1.0 (5th Nov 2018)

Funding and Support in Kind	
Funder	
Funding Organisation	National Institute for Health Research (NIHR)
Funding Scheme (if applicable)	Health Technology Assessment (HTA)
Funder's Reference Number	15/184/14
The funder of the trial has had no role in the trial design, data collection, data analysis or data interpretation.	

Protocol Sign-off

CI Signature Page

The undersigned confirms that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

This protocol has been approved by:

Trial Name:	**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.**
Protocol Version Number:	Version: 7.0
Protocol Version Date:	5th November 2018
CI Name:	Professor Amanda Daley
Trial Role:	Chief Investigator
Signature and Date:	_____ __ __ / __ __ / __ __ __ __

Sponsor Statement:

By signing the IRAS form for this trial, University of Birmingham, acting as Sponsor of this trial confirm approval of this protocol.

Reference Numbers	
EudraCT number	N/A
Sponsor number	RG_17-201
ISRCTN reference number	12209332
IRAS reference number	236462

PI Signature Page

The undersigned confirms that the following protocol has been agreed and accepted and that the Principal Investigator agrees to conduct the trial in compliance with the approved protocol.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

This protocol has been approved by:

Trial Name:	**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.**
Protocol Version Number:	Version: 7.0
Protocol Version Date:	5th November 2018
PI Name:	
Name of Site:	
Signature and Date:	_____ __ __ / __ __ / __ __ __ __

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As this is a feasibility trial, we do not propose to have a DMEC. Oversight will be provided by the Trial Steering Committee.

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Dr Dipesh Mistry	Warwick Clinical Trials Unit, University of Warwick
Mrs Eleanor McGee	Community Dietitian
Mrs Elizabeth Ketland	Patient Representative
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ABBREVIATIONS

Abbreviation	Term
AE	Adverse Event
BCTU	Birmingham Clinical Trials Unit
BMI	Body Mass Index
BWH	Birmingham Women's Hospital
CI	Chief Investigator
CI	Confidence Interval
CRF	Case Report Form
CTU	Clinical Trials Unit
DoH	Department of Health
DCF	Data Clarification Form
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HRA	Health Research Authority
HTA	Health Technology Assessment
ICF	Informed Consent Form
IMD	Index of Multiple Deprivation
ISF	Investigator Site File
NHS	National Health Service
NIHR	National Institute for Health Research
OR	Odds Ratio
PI	Principal Investigator at the General Practice
PIC	Participant Identification Centre
PIS	Participant Information Sheet
POWeR	Positive Online Weight Reduction
PPAQ	Pregnancy Physical Activity Questionnaire
RCT	Randomised Controlled Trial
REC	Research Ethics Committee

RGT	(University of Birmingham) Research Governance Team
SAE	Serious Adverse Event
SES	Socio-economic Status
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UoB	University of Birmingham
WP	Working Procedure

DEFINITIONS

Term	Abbreviation	Description
Policies	POL	Policies are developed to describe the approach of the University of Birmingham (UoB) on areas that are heavily regulated. Policies may also be developed when there is ambiguity in how regulatory requirements should be implemented in the QMS or when procedures to be captured in the QMS address areas controversial within the UoB at the time of implementation. Policies explain why the UoB has its procedures, especially when they seem to deviate from the regulatory requirements. Policies should be read in conjunction with the relevant SOP. Policies that are not part of a Quality Manual are coded up as 'POL'.
Quality Control Documents	QCD	Quality Control Documents (QCDs) can be instructions, forms, templates or checklists. They are developed to share best practices, promote standardisation to guarantee quality standards are maintained and reduce resources otherwise needed to develop similar documents. Unless indicated otherwise in the relevant SOP, QCDs are not mandatory and are designed to be an optional aid to UoB staff.
Quality Management System	QMS	A Quality Management System (QMS) is a system that includes procedures and policies to describe how certain tasks should be performed and that encapsulate any standards and/or regulatory requirements that may apply to those tasks. By adhering to the Quality Management System, the user and the UoB will be assured that applicable regulations are adhered to.
Standard Operating Procedures	SOP	Standard Operating Procedures (SOPs) are detailed written instructions to achieve uniformity in the performance of a specific function. They define tasks, allocate responsibilities, detail processes, indicate documents and templates to be used and cross-reference to other

		work instructions and guidance or policy documents. They are standards to which the UoB may be audited or inspected.
Adverse Event	AE	Any untoward medical occurrence in a participant or clinical trial subject participating in the trial which does not necessarily have a causal relationship with the intervention received.
Related Event		An event which resulted from the administration of any of the research procedures.
Serious Adverse Event	SAE	An untoward occurrence that: • Results in death • Is life-threatening • Requires hospitalisation or prolongation of existing hospitalisation • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly/ birth defect • Or is otherwise considered medically significant by the investigator
Unexpected and Related Event		An event which meets the definition of both an Unexpected Event and a Related Event.
Unexpected Event		The type of event that is not listed in the protocol as an expected occurrence.
Source data		All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.
Birmingham Clinical Trials Unit	BCTU	The coordinating centre for the trial.

TRIAL SUMMARY

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.
Trial Design	Randomised controlled cluster feasibility trial with nested qualitative study. GP practice (cluster) will be the unit of randomisation.
Objectives	• In women who have recently given birth, assess the feasibility of delivering an intervention to promote self-management of weight loss, by self-monitoring of weight and signposting to an online weight management programme by practice nurses as part of the UK child immunisation programme. • Assess recruitment to ensure a full-scale phase III trial is feasible. • Determine the extent of participant burden in completing the trial questionnaires. • Determine the potential risk for intervention contamination (whether women in the control group spontaneously access the online programme) to assess if the main trial sample size will need to be adjusted to account for this. • Determine levels of adherence to the intervention. • Collect data on immunisation uptake rates (to check there is no difference in rates in both groups, adjusted for the normal rate in the practice). • To provide estimates of the variability in the primary outcome (weight) to inform the sample size for the phase III trial. • Using semi-structured interviews explore practice nurses' views about delivering the intervention and explore any variation in intervention delivery to ascertain if any adjustments to nurse training are required. • Based on feedback from participants through interviews explore the acceptability of the intervention. • Assess the impact of the intervention on breastfeeding rates and psychological health in both groups. • Explore the acceptability/validity of the ICECAP (ICEpop CAPability measure for Adults) for the cost-effectiveness analysis in the phase III trial.
Participant Population and Sample Size	80 women who are at least four weeks postnatal will be recruited.
Eligibility Criteria	**Inclusion Criteria** • Aged 18 years or more • Women who are at least four weeks postnatal and who have not yet attended the first child immunisation appointment • Planning to have their child immunised within the national immunisation programme • BMI 25kg/m^2 or more at the time of recruitment at the baseline home visit • Patient able and willing to provide written informed consent

	Exclusion Criteria • Mothers whose babies have died or have been removed from their care at birth • Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight • Unwilling to give consent to notify their GP • 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
Intervention	**Treatment** In the GP practices randomised to deliver the intervention. Trial participants will receive brief motivation and support by nurses to make healthier lifestyle choices through self-monitoring of weight and signposting to an online weight management programme (Positive Online Weight Reduction; POWeR). **Comparator** In the GP practices randomised to the control arm. Trial participants will receive brief written information about following a healthy lifestyle and no other intervention. The NHS Eatwell guide leaflet will be used.
Outcome Measures	The primary aim of the trial is to assess the feasibility of undertaking a full-scale phase III cluster trial. 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: • whether the trial is appealing to women (via assessment of the recruitment rate to ensure a full-scale phase III trial is feasible); • whether the intervention is acceptable; • whether the intervention has any adverse impact on infant immunisation rates; • the number of women who complete the trial and complete the trial questionnaires. We also wish to measure the extent of any intervention contamination, obtain data to help inform the sample size calculations for the phase III trial and assess the acceptability/validity of the ICECAP for the cost-effectiveness analysis for the phase III trial.

TRIAL SCHEMA

Every two weeks Birmingham Women's Hospital (BWH) completes searches to identify women who have given birth in the last four weeks who are registered at GP practices participating in PIMMS-WL.

BWH sends invitation letter and patient information leaflet (PIS)

Women who have given birth and who are registered at GP practices participating in PIMMS-WL and have not yet attended the 2-month immunisation appointment are given an invitation letter and PIS directly from the GP or other health care professional at the GP practice

Interested women contact research team for initial screening and those eligible are booked a home visit for the baseline assessment. Women will not be entered into PIMMS-WL trial until at least four weeks post-delivery

Baseline home visit (about 6-7 weeks postnatal and prior to first immunisation visit). Written informed consent obtained. Height, weight and % body fat assessed and eligibility confirmed. Baseline questionnaires completed.

Inclusion Criteria:

- Aged 18 years or more
- Women who are at least four weeks postnatal and who have not yet attended the first child immunisation appointment
- Planning to have their child immunised within the national immunisation programme
- BMI 25kg/m^2 or more at the time of recruitment at the baseline home visit
- Patient able and willing to provide written informed consent

Exclusion Criteria:

- Mothers whose babies have died or have been removed from their care at birth
- Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
- Unwilling to give consent to notify their GP
- 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

Receive intervention according to treatment group GP practice (cluster) was randomised to deliver

Allocated to intervention

- Attends 2, 3, 4 month immunisation appointments
- Receive healthy lifestyles leaflet
- Encouraged to self-weigh weekly
- Weight checked by nurse and recorded on record card in child red book at start of each child immunisation visit
- Signposted to POWeR online weight loss programme

Follow up home visit of trial outcomes
3 months from recruitment (when baby 4-5 months old)

Semi-structured interviews with women and practice nurses who delivered the intervention

Allocated to comparator
Receive healthy lifestyle leaflet

Follow up home visit of trial outcomes
3 months from recruitment (when baby 4-5 months old)

TABLE OF CONTENTS

1. BACKGROUND AND RATIONALE

1.1. Background

Pregnancy is a vulnerable life stage for weight gain and the period after birth represents an important window for weight management intervention. Many women report pregnancy as the critical point for the onset of excess weight [1-2] which can significantly increase the risk of later obesity and serious chronic diseases including type 2 diabetes, heart disease and cancer. [3-4] The postnatal period is characterised not only by weight retention but also by susceptibility to further weight gain. [5] The NHS costs attributable to being overweight and obese are projected to reach £9.7 billion by 2050. [6] Prospective cohort studies have reported that among women who have a normal body mass index (BMI) prior to pregnancy, 30% are overweight 1 year after giving birth. Of women who are overweight prior to conception, 44% are obese by 1 year after giving birth, while 97% of women who are obese prior to pregnancy remain so at 1 year postnatally. It is estimated that on average women gain about 14-15 kg during pregnancy and at 1 year after birth 5-9 kg is retained with an average BMI of 29.4 kg/m^2. [2, 5-7] There is an association between postnatal weight retention and poor mental health, which is known to have negative consequences for the development of the infant and on the family as a whole. [8-10] There is a need, therefore, to intervene routinely and early in the postnatal period, to help women to manage their excess weight after having a baby and to minimise the long-term physical and mental health risks. This may have additional benefits by reducing weight at the start of subsequent pregnancies. Interventions to promote a healthy diet and physical activity may also raise awareness of the importance of healthy lifestyle habits which will be of benefit to the baby too.

1.1.1. Current Evidence and Why the Research Is Needed Now

Systematic reviews note that most trials in this population have recruited small sample sizes and/or tested interventions that have not been embedded within health systems. Several systematic reviews have identified the need for high-quality trials on how to best help women to lose weight after having a baby. [11-15] Within these reviews, the vast majority of studies have evaluated intensive physical activity and/or diet based interventions delivered by specialists; these types of interventions cannot be delivered to all the 820,000 women who give birth each year in the UK, 520,500 of whom will be overweight. [16] While the many systematic reviews to date have all had different study inclusion and exclusion criteria, they have each concluded that there are insufficient high-quality trials to assess the effectiveness of interventions to promote healthy weight loss after having a baby. Some reviews have noted that the vast majority of randomised controlled trials (RCTs) have been conducted outside of the UK in predominately advantaged women. [13]

1.1.2. Self-care and Self-management Strategies and Weight Loss

Trials of self-management interventions for weight loss can inform our knowledge about what types of self-directed weight loss strategies are most effective and which might be usefully highlighted to the public and policymakers as a scalable, low-cost intervention. One such intervention that has shown promise in helping people manage their weight is regular weighing, to check progress against a target, a form of self-monitoring. The potential efficacy of regular weighing (either by the individual or someone else) has been based on the principles of self-regulation theory. [17-18] Self-regulation has been described as a process that has three distinct stages; self-monitoring, self-evaluation and self-reinforcement. Self-monitoring is a method of systematic self-observation, periodic measurement and recording of target behaviours with the goal of increasing self-awareness. The awareness fostered during self-monitoring is considered an essential initial step in promoting and sustaining behaviour change. Strong evidence supports the role of self-monitoring as an effective strategy in the health behaviour change process. Reviews by Michie *et al*. of effective behavioural techniques for healthy eating, physical activity and reduction of alcohol consumption concluded that self-monitoring was

effective alone, but when combined with other techniques the effect size nearly doubled. [19-20] In a systematic review of RCTs to examine the effectiveness of self-weighing as a strategy for weight loss, one of the included studies examined self-weighing as a single strategy and it was ineffective (-0.5kg, 95% confidence interval (CI) -1.3 to 0.3), but adding self-weighing/self-regulation techniques to programmes resulted in a significant difference of -1.7 kg (95% CI -2.6 to -0.8). [21] Multi-component interventions including self-weighing compared to no/minimal control also resulted in mean differences of -3.7 kg (95% CI -4.6 to -2.9). [21]

In another systematic review of RCTs to determine the effectiveness of self-help interventions for weight loss, [22] self-help was defined as interventions that could feasibly be delivered without person-to-person support (including formats such as smartphone, web and print). Analyses showed self-help interventions that require no human input for delivery lead to small, but significantly greater weight loss than unsupported attempts to lose weight at six months compared with minimal interventions. However, results were variable and the reasons for this heterogeneity are unknown. In addition, in the small group of studies providing data at 12 months, weight loss was no longer significant; the effect size was comparable with that achieved at six months, suggesting that self-help interventions on their own, may not be useful for sustaining long-term weight loss, and that additional components, within weight loss interventions are required. Nonetheless, given the potential scalability and relatively low cost of this type of intervention, self-help programmes may be a useful component within a broader intervention to treat those who are overweight in primary care.

1.1.3. Accountability/Audit and Feedback

In the reviews of self-weighing and weight loss, there was some evidence to suggest that adding accountability to a self-weighing programme improves effectiveness. [21] In 13 trials, the intervention group asked to weigh themselves knew that they were accountable to a therapist/researcher, while this was not the case in two trials. There was a significant difference in mean weight loss between intervention and control for those trials with accountability compared with those without (-4.0kg, 95% CI -5.0 to -3.0kg versus -2.3kg, 95% CI -3.1 to -1.5kg; p=0.007). Participants in group weight loss programmes often report that it is the weekly weigh-in that is the most salient component of the programme that provides external accountability and keeps them committed to their diet and physical activity plan. [23] In practical terms, if a person knows their weight will be monitored they are more likely to make healthy lifestyle choices and therefore are more motivated to stick to their weight loss goals. Related to this, Gardner and colleagues have conducted a systematic review examining similar behaviour change techniques to accountability called audit and feedback. [24] They investigated whether audit and feedback changed healthcare professionals' behaviour and found a significant effect (Odds Ratio (OR)=1.43, 95% CI 1.28 to 1.61). Audit and feedback are similar to accountability in that participants are aware of being observed. Based on this evidence, it can reasonably be hypothesised that adding accountability/audit to self-help and self-monitoring interventions could further facilitate weight loss.

1.1.4. Potential Harms

Even if regular weighing helps people to control their weight, there may be concerns that it will have negative consequences and that feedback about weight and body size may result in psychological distress, or lead to the adoption of unhealthy weight control practices. [25-26] There is no evidence from RCTs that this is the case, but it is important to provide evidence of no harm. This will be assessed within this trial.

1.2. Trial Rationale

Given the consequences of obesity, the large numbers of women having babies each year and NHS resource implications of later health care needs, there is a need to evaluate pragmatic, low-cost

interventions that could facilitate postnatal weight loss at a population level. NICE have also highlighted the low quality of previous research as a limitation to developing clinical guidance in this area. [27] There is, therefore, a need for further research in this area.

We plan to assess the feasibility and acceptability of a brief routine weight management intervention for postnatal women in a randomised controlled cluster feasibility trial. The aim is to then undertake a large-scale phase III cluster RCT to assess the effectiveness and cost-effectiveness of the intervention in facilitating long-term weight loss.

The intervention will be delivered within the context of the national child immunisation programme in primary care to minimise the costs to the NHS and to avoid the need for additional contacts with health professionals at this busy time in women's lives. In the UK, infants are vaccinated four times in the first year of life as part of the child immunisation programme, which has a coverage rate of 94%. [28] We propose to embed a simple and brief intervention into this immunisation programme. The intervention does not require additional visits or expenses for the mother, thus the sustainability of the intervention is likely to be high and income and/or ethnicity will not be barriers to participation. This approach also provides the opportunity for early intervention, to reduce the possibility of women gaining further weight after childbirth. Although we expect our approach to result in a smaller effect than the intensive interventions described in section 1.1, because of its widespread applicability and scalability, it could have a larger population-level impact.

1.2.1. Justification for Participant Population

Pregnancy is a vulnerable life stage for weight gain. Prospective cohort studies have reported that among women who have a normal BMI prior to pregnancy, 30% are overweight 1 year after giving birth, and among women who are overweight prior to conception, 44% are obese by 1 year after giving birth. The period after childbirth represents an important window for weight management intervention, and there is a need for further research in this area to identify interventions that help women lose weight following childbirth. We will thus recruit women who have recently given birth into this trial.

1.2.2. Justification for Design

We have adopted a randomised controlled cluster feasibility trial design. We are undertaking a feasibility trial first, as before we can undertake a large-scale phase III cluster RCT to assess the clinical and cost-effectiveness of this weight management intervention, we need to assess the feasibility and acceptability of such a trial. While individually randomised trials can be less problematic and cheaper than cluster trials, a cluster design helps avoid the possibility of contamination in the comparator (control) group. In this trial, practice nurses will be trained in delivering the intervention. If we had used an individual randomisation design, nurses could potentially use aspects of their training with participants assigned to the usual care (control) group. It is also possible that women registered at the same practice or living near each other (by virtue of being registered at the same practice) could potentially share information or intervention resources. Cluster randomisation will help avoid the possibility of this contamination in the control group.

GP practices will be randomised to either the weight management intervention or comparator (control) trial group. To avoid the possibility of selection bias, which can be a concern in cluster trials, it is recommended that the randomisation of the clusters (in this case GP practices) occurs once the participants have been identified and recruited into the trial. In this trial, it is not possible to allocate GP practices to the trial groups after participants have been recruited because the required number of births per practice could occur over several months, meaning we will miss the immunisation visits where the intervention is being delivered. We have included a number of strategies to reduce the potential for selection bias. All women who give birth and who are registered at the participating GP

practices will be invited to take part in the trial and group allocation will be concealed from participants until baseline data has been collected.

2. AIMS AND OBJECTIVES

2.1. Aims and 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.

2.1.1. Objectives

- In women who have recently given birth, assess the feasibility of delivering an intervention to promote self-management of weight loss, by self-monitoring of weight and signposting to an online weight management programme by practice nurses as part of the UK child immunisation programme;
- Assess recruitment to ensure a full-scale phase III cluster trial is feasible;
- Determine the extent of participant burden in completing the trial questionnaires;
- Determine the potential risk for intervention contamination (whether participants in the control group have spontaneously accessed the online programme) to assess if the main trial sample size will need to be adjusted to account for this;
- Determine levels of adherence to the intervention;
- Collect data on immunisation uptake rates (to check there is no difference in rates in both groups, adjusted for the normal rate in the practice);
- To provide estimates of the variability in the primary outcome (weight) to inform the sample size for the phase III trial;
- Using semi-structured interviews explore practice nurses' views about delivering the intervention and to explore any variation in intervention delivery to ascertain if any adjustment to nurse training are required;
- Based on feedback from participants through interviews explore the acceptability of the intervention;
- Assess the impact of the intervention on breastfeeding rates and psychological health in both groups;
- Explore the acceptability/validity of the ICECAP (ICEpop CAPability measure for Adult) for the cost-effectiveness analysis in the phase III trial.

3. TRIAL DESIGN AND SETTING

3.1. Trial Design

This is a randomised controlled cluster feasibility trial to assess the feasibility, acceptability and the potential for intervention contamination of a weight management intervention in women who have recently given birth. The unit of randomisation is the GP practice. Eighty women will be recruited into the trial.

All women who have recently given birth and who are registered at a GP practice participating in the trial will be invited to take part. Group allocation will be concealed from participants until baseline data has been collected.

3.2. Trial Setting

This trial will take place in Birmingham where about one-third of the population are of non-white ethnicity (compared to 13% in England). Birmingham has high levels of deprivation, with 40% of the population living in Super Output Areas in the 10% most deprived areas in England. Collectively, these figures highlight that there is very high potential to recruit women from varied ethnic and socio-economic backgrounds. The initial identification of women will take place within the BWH and within participating GP practices, and the trial will take place within GP practices around the West Midlands. The baseline and follow-up assessments will be done in the participant's home and the University of Birmingham lone worker policy will be followed.

3.3. Identification of Participants

Computerised systems at BWH allow for systematic identification of all postnatal women who have recently given birth. Every two weeks BWH will complete searches of women aged ≥18 years who have recently given birth and who are registered at GP practices participating in the trial. A trial invitation letter and participant information sheet (PIS) will be mailed to these women from BWH asking them to contact the PIMMS-WL researchers at the University of Birmingham (UoB) if they are interested in the trial. Women will NOT receive their letter of invitation until at least four weeks post-delivery. This approach allows us to invite every woman aged ≥18 years who has given birth and who is registered with the participating GP practices, regardless of socio-economic status (SES) and ethnicity, and thereby reduce the risk of recruitment and selection bias.

If uptake in the feasibility trial is shown to be low in women of lower SES, BWH will conduct follow-up calls to women from practices serving socio-economically deprived populations to ask if they are interested in taking part. These women may respond better to a phone call where they can talk to someone regarding the trial, rather than by letter, particularly if there is low literacy.

If recruitment proves slower than anticipated, we will also attempt to recruit women directly from baby check clinics and postnatal check-ups in participating GP practices. We will also place trial adverts in participating GP practices.

3.4. Assessment of Risk

The assessment and management of risk is detailed in a separate PIMMS-WL risk assessment document. Risk will be continuously assessed throughout the trial.

This trial is categorised as:

- Type A = No higher than the risk of standard medical care

4. ELIGIBILITY

4.1. Inclusion Criteria

- Aged 18 years or more
- Women who are at least four weeks postnatal and who have not yet attended the first child immunisation appointment
- Planning to have their child immunised within the national immunisation programme
- BMI 25kg/m^2 or more at the time of recruitment at the baseline home visit
- Patient able and willing to provide written informed consent

4.2. Exclusion Criteria

- Mothers whose babies have died or have been removed from their care at birth
- Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
- Unwilling to give consent to notify their GP
- 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

4.3. Co-enrolment

Participants will not be permitted to co-enrol in other weight management trials. Participants will be permitted to take part in other non-interventional trials.

5. CONSENT

Written informed consent into the PIMMS-WL trial will be a 2-stage process. First written informed consent will be sought for screening to confirm all eligibility criteria are met. Once all eligibility criteria have been confirmed, participants will then be invited to give their written informed consent to be enrolled into the main PIMMS-WL trial.

Potential participants will be sent or given a trial invitation letter and a PIS. Women will be given ample time to read the PIS and to discuss their participation with others outside of the research team. The letter invites the women to contact the PIMMS-WL research team if they are interested in the trial. Participants responding to the invitation letter will be given the opportunity to ask questions, and if they are still interested, a baseline home visit with a member of the PIMMS-WL research team will be organised.

Written informed consent for each participant will be obtained by a member of the PIMMS-WL research team. This person will have undertaken Good Clinical Practice (GCP) training, have knowledge of the trial protocol and been delegated authority to obtain informed consent from the Chief Investigator (CI). Prior to enrolment into the trial, a member of the PIMMS-WL research team will ensure that they adequately explain the aims, trial interventions, anticipated benefits and potential hazards of taking part in the trial to the participant. They will also stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the trial at any time.

At the baseline home visit, participants will be given the opportunity to ask questions about the trial before signing and dating the latest version of the screening Informed Consent Form (ICF). A member of the PIMMS-WL research team will then sign and date the screening ICF. The participant will then have their height and weight measured to determine if they are eligible for the trial. If the

participant is eligible, they will then sign and date the main trial ICF. The PIMMS-WL research team will then also sign and date the main trial ICF. Once the participant is entered into the trial, the participant's trial number will be entered on each of the ICFs maintained in the ISF. A copy of each ICF will be given to the participant, a copy of each will be sent to the GP along with a copy of the PIS to be electronically scanned into the patient's GP medical records, and the original of each placed in the Investigator Site File (ISF) at the GP practice. In addition, once the participant has given explicit consent, a copy of the signed screening and main trial ICFs will be sent to the Birmingham Clinical Trials Unit (BCTU) for review by the PIMMS-WL trial team.

Participants who are eligible and agree to enter the trial must give explicit consent for the regulatory authorities, members of the research team and/or representatives of the Sponsor to be given direct access to the participant's medical records and those of their infant; this will be stated in the PIS and on each of the screening and main trial ICFs. Participants in the intervention group will also need to provide consent for all trial data collected by the POWeR online programme at the University of Southampton to be transferred to the research trial team at the University of Birmingham. Details of the informed consent discussions will be recorded in the GP letter and filed in the participant's medical notes. This will include the date of discussion and the name of the trial. A copy of the PIS given to the participant and signed copy of the main trial ICF will also be sent to the GP to be filed in the patient medical notes.

At the 3 month follow-up, visit the participant's willingness to continue in the trial will be ascertained and documented in the PIMMS-WL CRF. Throughout the trial, the participant will have the opportunity to ask questions about the trial. Any new information that may be relevant to the participant's continued participation will be provided. Where new information becomes available which may affect the participants' decision to continue, participants will be given time to consider and if happy to continue will be re-consented. Re-consent will be documented in the medical notes. The participant's right to withdraw from the trial will remain.

Electronic copies of the PIS and ICFs will be available from the Trials Office and will be printed onto the University of Birmingham headed paper. Details of all patients approached about the trial will be recorded on the Participant Screening Log at the Patient Identification Centre (PIC), the BWH.

6. RECRUITMENT, RANDOMISATION AND ENROLMENT

6.1. Recruitment

80 participants will be recruited from approximately 10-12 GP practices across the Birmingham area. It is expected that recruitment will take place over 8 months.

6.2. Randomisation

The unit of randomisation is the GP practice (cluster). Linked GP practices that share clinical staff will be considered a single practice (i.e. cluster). Linked GP practices that do not share staff will be considered as independent practices. Ten to twelve research active GP practices in Birmingham and Solihull will be invited to participate in the trial. The GP practices will be randomised in a 1:1 ratio to the weight management intervention or no intervention (comparator group) using minimisation for GP practice list size (large: 6000 or more; small: under 6000 patients) and Index of Multiple Deprivation (IMD) rank score. The IMD will be based on the postcode of the GP practice; the IMD rank score ranges from 1 to 32,844 and will be divided into tertiles of high, medium and low levels of deprivation. The BCTU will create the randomisation list to allocate GP practices to the two trial treatment groups. The randomisation list will be held securely at the BCTU who are managing the trial. Full details of the randomisation specification will be stored in a confidential document at the BCTU.

6.3. Enrolment and Screening

6.3.1. Screening via Birmingham Women's Hospital

Potentially eligible participants will be identified initially from medical records at the BWH. The BWH will be a PIC and will be engaged to assist in the identification of patients. Medical records will be screened by site staff to determine initial eligibility. This will determine which participants can then be contacted about the trial and invited for further screening to determine full eligibility. Initial screening of medical records at BWH will:

1. Confirm the participant is aged 18 years or over
2. Confirm the participant has given birth at least 4 weeks previously
3. Confirm the participant is registered at one of the PIMMS-WL participating GP practices
4. Exclude mothers whose babies have died or have been removed from their care at birth

A trial invitation letter will be posted to potentially eligible participants along with a PIS from BWH approximately 4 weeks postnatally. The invitation letter and PIS will include a telephone number which the potential participant can call if interested in the trial. Alternatively, potentially eligible participants may complete the PIMMS-WL screening reply slip and return it to the PIMMS-WL research team in the post. Participants will be requested to contact the PIMMS-WL research team within 10 days of receiving the invitation letter.

If women have not responded within 10 days of being sent the invitation letter and PIS, BWH will conduct up to two follow-up telephone calls to ask if they are interested in taking part. Some women may respond better to a phone call where they can talk to someone regarding the trial, rather than by letter.

6.3.2. Screening Prior to Baseline Home Visit

If a potential participant is interested in taking part in the trial, they may telephone the PIMMS-WL research team. Alternatively, upon receipt of the reply slip, a member of the PIMMS-WL research team will telephone the potential participant. During the telephone call, verbal permission will be requested to collect some screening information to establish eligibility to the trial. The member of the PIMMS-WL research team taking the telephone call will document and sign the PIMMS-WL screening CRF to confirm that verbal permission has been sought and agreed by the potential participant. Telephone screening will:

1. Reconfirm the participant is aged 18 years or over.
2. Reconfirm the participant has given birth at least 4 weeks previously.
3. Reconfirm the participant is registered at one of the PIMMS-WL participating GP practices.
4. Collect data on the participant height and weight to calculate BMI. This will be self-reported by the participant.
5. Confirm the participant is planning to have their child immunised within the national immunisation programme.
6. Confirm the participant has not yet attended the first child immunisation appointment.
7. Confirm the participant is not already actively involved in a weight loss programme or a weight management trial to lose weight.
8. Confirm the participant is willing to give consent to notify their GP of their participation in the trial.

For participants who fulfil the initial screening criteria and are interested in taking part in the trial, an appointment will be arranged for a member of the PIMMS-WL research team to visit their home for the baseline visit. Patient identifiable data and contact details will be collected and will include participant name, date of birth, address, postcode, home telephone number, mobile telephone

number, email address and main language spoken. The baseline visit will be arranged between 6-7 weeks postnatally (no earlier than 4 weeks and before the first immunisation visit at 2-months).

6.3.3. Advertising through GP Practices

A flyer advertising the PIMMS-WL trial will be posted with a flyer cover letter to potential participants from participating GP practices at approximately 36 weeks gestation. The flyer may also be given to potential participants registered at participating GP practices any time from approximately 36 weeks gestation up to time of birth. These may be given by their GP or other health care professional. The flyer will also be made generally available and prominently displayed in various areas within the participating GP practices. The flyer will give brief information about the PIMMS-WL trial informing women of their opportunity to participate in the trial after the birth of their baby.

Posters advertising the PIMMS-WL trial will be on display in waiting rooms at participating GP practices. Posters may also be made available for viewing on GP practice waiting room TV screens. Participants who hear about the trial through this route will be asked to telephone the PIMMS-WL research team for further information. During the telephone call, contact details will be collected to allow for a letter of invitation and PIS to be posted to the participant, if they have not already received one.

If, after having read the letter of invitation and PIS, a participant is still interested in taking part in the trial, they may contact the PIMMS-WL research team again. Alternatively, upon receipt of the reply slip, a member of the PIMMS-WL research team will telephone the potential participant. During this second telephone call, verbal permission will be requested to collect some screening information to establish eligibility to the trial. The member of the PIMMS-WL research team taking the telephone call will document and sign the PIMMS-WL screening CRF to confirm that verbal permission has been sought and agreed by the potential participant (see section 6.3.2 for screening criteria). If all initial screening criteria are met, an appointment can be made for a member of the PIMMS-WL research team to visit their home for the baseline visit.

6.3.4. Recruitment through GP Practices

Participants may also be informed about the trial directly from baby check clinics, postnatal check-ups or at any other appointment with the GP or other health care professional post-delivery and prior to the 2-month immunisation appointment in participating GP practices.

Participants may be given a letter of invitation and PIS directly from the GP or other health care professional at the GP practice.

Alternatively, a member of the PIMMS-WL research team may be available at the GP practice on specific clinic dates to help with recruitment into the trial. Participants may respond better to the personal approach from a member of the PIMMS-WL research team. The PIMMS-WL researcher will not be the first point of contact for participants about the PIMMS-WL trial. These participants will have already received at least one letter of invitation and PIS from their clinical care team, from the Birmingham Women's Hospital and/or a health care professional at their GP practice. The PIMMS-WL researcher may provide potential participants with the letter of invitation and PIS directly either to read at the GP practice or for the participant to take home. If, after having read the letter of invitation and PIS, a participant is interested in taking part in the trial, they may be screened at the GP practice by the PIMMS-WL researcher. The PIMMS-WL researcher will document and sign the PIMMS-WL screening CRF to confirm that verbal permission has been sought and agreed by the potential participant (see section 6.3.2 for screening criteria). If all initial screening criteria are met, an appointment can be made for a member of the PIMMS-WL research team to visit their home for the baseline visit. Otherwise the woman may contact the PIMMS-WL research team at a later date.

6.3.5. Screening at Baseline Home Visit

At the baseline home visit, prior to any trial measurements being undertaken, the PIMMS-WL researcher will obtain written informed consent for screening to collect further screening data to confirm eligibility for the trial. If the participant consents to screening, the PIMMS-WL researcher will measure the participant's height and weight to calculate the BMI and confirm the BMI eligibility criteria. We will also confirm the following eligibility criteria:

1. Confirm that the participant has not 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

We will obtain consent from participants not deemed eligible at the home visit to keep the trial data collected at screening.

Potential participants who have all eligibility criteria confirmed at the baseline home visit will then be asked if they consent to be enrolled into the main PIMMS-WL trial. The trial will be explained to them again verbally should further discussion be required and written informed consent will be obtained for enrolment into the trial.

After participant eligibility has been confirmed and written informed consent has been received, the participant will be registered and baseline assessments will be undertaken. The participant will then be notified of the treatment group of their GP practice.

Principal investigators will keep their own trial file log which links patients with their allocated trial number in the PIMMS-WL **Patient Recruitment and Identification Log**. The investigator must maintain this document, which is **not** for submission to the Trials Office. The PIMMS-WL **Participant Screening Log** will be kept by the PIC site, BWH, and should be available to be sent to the Trials Office upon request. The PIMMS-WL **Patient Recruitment and Identification Log** and PIMMS-WL **Participant Screening Log** should be held in strict confidence.

6.4. Informing the Participant's GP

Once the participant has consented to enter the trial, the participant's GP will be notified that they are taking part in PIMMS-WL trial, using the PIMMS-WL **GP Letter.**

6.5. Masking

It is not possible to mask participants or those providing the intervention to group allocation; however, the outcome assessor who performs the home visit to collect the follow-up data can and will be masked to group allocation. We have several strategies that we use in trials to ensure group allocation remains masked at follow-up home visits. Different researchers conduct the baseline and follow-up visits so that there is no prior knowledge of allocation. The home visit paperwork does not contain any information that would reveal group allocation so the person measuring weight will remain masked. The Case Report Form (CRF) is placed in a sealed envelope and is opened only after weight has been measured and recorded on a sticker on the front of the envelope. When booking the home visit, participants are told not to tell the person visiting which group they have been allocated to. We have used these approaches successfully in several of our funded trials.

7. TRIAL INTERVENTION

7.1. Trial Intervention

The intervention group will be offered brief support that encourages active self-management of weight in the postnatal period when they attend their practice to have their child immunised during the first year of life. In the first year, babies are routinely immunised at two, three, four and twelve months of age; we plan to embed the intervention within these pre-existing immunisation contacts so no additional visits by the women are required. The intervention involves motivation and support by nurses to encourage women in the postnatal period to make healthier lifestyle choices through self-monitoring of weight and signposting to an online weight management programme (POWeR). Nurses will NOT provide any lifestyle counselling; their role is simply to provide encouragement, regular external accountability (i.e. so women know their weight is being monitored by someone else) and to signpost women to using POWeR for weight loss information.

Women will be asked to weigh themselves weekly and record this on a weight record card that will be attached to the child health record 'red book' where infant immunisations are recorded or on the online programme. Women will be provided with brand new weighing scales for this trial. The scales will be calibrated and maintained by the PIMMS-WL research team at University of Birmingham. The intervention will run until the third immunisation (child is approximately 4 months old), with follow-up completed within one month thereafter. Women will be advised and encouraged to record their weight in their red book **AND** on the POWeR programme. This is because nurses will need to be able check that women are weighing themselves regularly and because the POWeR programme provides personalised information based on weight gain/loss progress.

7.1.1. Weight Loss Goals

No clinical guidelines exist that specify rates of healthy weight loss for postnatal women, but for the general population NICE recommend 0.5 to 1 kg per week. [29] Women will be advised to aim for 0.5 to 1 kg per week weight loss until they have achieved a BMI less than 25 kg/m^2 and are no heavier than their pre-pregnant weight.

7.1.2. Accountability

Practice nurses will not provide any counselling about diet/physical activity, they will simply weigh the women at each child immunisation visit and record this weight as a source of regular external accountability. An individual who is regularly weighed is more likely to maintain weight goals when they know their progress will be monitored.

7.1.3. Online Weight Loss Programme (POWeR: Positive Online Weight Reduction)

Nurses will signpost women to the POWeR online weight loss programme for weight loss support and assistance with goal setting, action planning and implementation of changes to their lifestyle. The website link is https://powerpimms.lifeguidehealth.org and women will be given their own unique username and password. The POWeR programme has been shown to result in clinically effective weight loss in overweight primary care patients when combined with brief nurse support. [30]

POWeR is a self-guided, online, theory- and evidence-based intervention to support weight management over one year and was subject to a feasibility trial. POWeR was designed to be appropriate for people in most situations, including postnatally. Participants choose either a low energy eating plan (a reduction of around 600 calories a day) or a low carbohydrate eating plan (a carbohydrate limit of 50g a day). Users are also encouraged to increase their physical activity levels by choosing either a walking plan or a self-selected mixture of other physical activities. POWeR focuses principally on fostering users' self-regulation skills for autonomously self-managing their

weight, rather than providing detailed dietetic advice. Users are taught active cognitive and behavioural self-regulation techniques ('POWeR tools') to overcome problems such as low motivation, confidence or relapse. Evidence is provided for the effectiveness of these techniques and examples given of how others have successfully used them ('POWeR stories'). POWeR emphasises forming healthy eating and physical activity habits that should become non-intrusive and require little effort to sustain. Information about breastfeeding and weight loss will be added to the programme for the purpose of this trial.

Participants are encouraged to continue to use the website weekly to track their weight, set and review eating and physical activity goals, and receive personalised advice. After entering their weight and whether they had achieved the goals they had set themselves the previous week, users receive tailored feedback giving encouragement if maintaining weight loss (e.g. reminders of health benefits accrued) and meeting goals. Weight gain and failing to meet goals triggers automated personalised advice such as appropriate goal setting and planning, boosting motivation, overcoming difficulties, recovering from lapses.

7.1.4. Training of Practice Nurses

All nurses who administer child immunisations at intervention practices will be trained to deliver the intervention following a standard protocol. We anticipate it will take about 20-25 minutes to train nurses given their involvement is very simple and brief, and there are already online training materials for nurses developed as part of the POWeR tool. We will also train the nurses in the research trial procedures. A training manual will be provided that contains information on the importance of adhering to the protocol, information on the consequences of postnatal weight retention, instructions about how to weigh and record weight in the appropriate place in the child health red book and tips and phrases for encouraging women to weigh themselves weekly. The nurse training will also address any concerns nurses may have about raising the topic of weight, although nurses deal with sensitive and difficult issues every day in their work so we anticipate that they will have the appropriate communication skills. Training logs will be maintained in the ISF.

7.1.5. Intervention Fidelity

The PIMMS-WL research team will observe and take consent to audio record two immunisation/intervention consultations per nurse, so that we can assess intervention fidelity against an intervention checklist criteria, and see how long the intervention takes nurses to deliver. This process will provide information from a practical and logistical perspective on how well our intervention fits within immunisation visits and will also inform nurse training for the main trial.

7.2. Usual Care Group

Women enrolled into the trial and registered at GP practices in the comparator (control) group will receive brief written information about following a healthy lifestyle and no other intervention at the baseline home visit. The NHS Eatwell guide leaflet will be used.

7.3. Post-trial Care

Participants in the intervention group will be able to access the POWeR online weight loss programme for one year from trial entry. No trial intervention will continue to be provided after the one year is completed. Participants will continue to receive standard care.

8. OUTCOME MEASURES AND TRIAL PROCEDURES

8.1. Primary Outcome

The primary aim of the trial is to assess the feasibility of undertaking 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:

- whether the trial is appealing to women (via assessment of the recruitment rate to ensure a full phase III trial is feasible);
- whether the intervention is acceptable;
- whether the intervention has any adverse impact on infant immunisation rates;
- the number of women who complete the trial and complete the trial questionnaires.

We also wish to measure the extent of any intervention contamination, obtain data to help inform the sample size calculations for the phase III trial and assess the acceptability/validity of the ICECAP for the cost-effectiveness analysis for the phase III trial.

8.2. Outcome Data

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. Weight will be objectively assessed. Body fat will be assessed using a Tanita SC-240MA analyser, this will be calibrated and maintained by the PIMMS-WL research team at the University of Birmingham. Depression, anxiety and self-reported physical activity will also be measured. [31-32] Body image will also be measured in both group which will provide the opportunity to assess whether the intervention had any negative effects on participants' feelings about their body. [33] Use of weight control strategies will also be measured in both groups at follow-up. [34] To inform the design of the economic evaluation in the phase III trial, we will explore the acceptability of the ICECAP instrument [35], a broader measure of health than the EQ-5D [36] that focuses on general wellbeing. This will be done by assessing rates of completion of the ICECAP and incorporating questions about the acceptability of the ICECAP into the qualitative interviews.

8.2.1. Demographic, Lifestyle and Pregnancy-related Information (Both Groups)

Information on age, ethnicity, pre-pregnancy weight, timing of cessation of breastfeeding, infant feeding practices and sleeping patterns of the mother will be collected. Some women resume smoking and alcohol consumption after pregnancy which might impact on weight and we will record these behaviours at baseline and follow-up. We will collect data on whether participants in both groups have attended any formal weight loss programmes during their involvement in the trial and collect data on any specific weight loss strategies or diets that participants might have used. Data relating to participants' type of delivery, pregnancy complications and how many children they have given birth to will be collected. We are collecting data on marital status to ascertain the general level of social support in participants' lives. Data on employment status and financial status is being collected to provide descriptive profile data on the type of women who are agreeing to participate in the trial.

8.2.2. Objective Assessment of Self-weighing/Adherence (Intervention Group)

As an objective measure of compliance, the intervention group will be given weighing scales (BodyTrace, USA) that objectively record weight every time participants weigh themselves and then this information is remotely transmitted back to the research team at the University of Birmingham by wireless transfer. The scales will be given to women at the baseline home visit by the PIMMS-WL researcher. These scales are only included as an objective process measure of adherence to the self-

weighing component of the intervention, and we will NOT provide any feedback to participants, nor will we monitor fluctuations or changes in weight during the trial.

8.2.3. Weight Record Cards (Intervention Group)

The intervention group will complete weight record cards and we will collect these from participants as a measure of intervention implementation at the end of the intervention. The record cards will also tell us how much of the intervention was delivered by practice nurses per protocol. We will obtain data from POWeR for participants who chose instead to record their weight on the online programme.

8.2.4. Perception on Regular Self-weighing (Intervention Group)

In the intervention group, we will use five items from Steinberg [37] to measure perceptions of regular monitoring of weight at follow-up.

8.2.5. Usage of the POWeR Online Programme (Both Groups)

Using participants email address the POWeR software automatically records participants' usage of the website and Apps (i.e. pages looked at/visited, when/for how long, goals and weights entered and dates).

8.2.6. Eating Behaviours (Both Groups)

There is evidence that a lower frequency of self-weighing is associated with increased disinhibition and our hypothesis is that regular self-weighing and monitoring of weight leads to the development of conscious cognitive energy restraint. [38] Using the revised three-factor eating questionnaire,[39] we will examine if feedback from self-weighing has led to the development of conscious cognitive energy restraint of eating (measured in both groups), and we will also measure uncontrolled eating and emotional eating at baseline and follow-up.

8.2.7. Weight Control Strategies (Both Groups)

Weight control strategies will be assessed at follow-up in both groups using the Weight Control Strategies Scale. As well as a total score, the domains of dietary choices, self-monitoring strategies, physical activity and psychological coping are measured. [34]

8.2.8. Attendance at Immunisation Appointments (Both Groups)

The intervention will be given at the immunisation appointments at 2, 3 and 4 months postnatally. These dates are sent automatically to the mother by the GP practice and may fall outside the usual time schedule due to the mother's circumstances (e.g. the baby may be ill on the appointment date and therefore the date changed). These are outside of the PIMMS-WL research team's control and will not be considered as protocol deviations.

Monitoring of immunisation uptake rates in the intervention group will be an explicit aim of the Trial Steering Committee (TSC). GP practices will be asked to provide data on all immunisations attended by the intervention group and any missed appointments will be investigated and a reason allocated. Intervention practices will provide this information when at least three participants have reached the 4-month immunisation appointments and again when all participants have reached follow-up. We will also collect patient-reported attendance at the immunisation appointments at the follow-up visit at 3 months.
In control practices, immunisation attendance data for participants will be collected at the end of the trial.

8.3. Schedule of Assessments

Visit	*Screening*	*Baseline Home Visit*	*Immunisation Visits at GP Practice (INTERVENTION GROUP ONLY)*			*Follow-up Home Visit*	*Post Follow-up*
	4 weeks postnatally (no earlier than 4 weeks/ no later than 6 weeks)	*6-7 weeks postnatally (no earlier than 4 weeks and before the first immunisation visit at 2 months)*	*2 months postnatally*	*3 months postnatally*	*4 months postnatally*	*3 months post-randomisation (-1 week/+4 weeks)*	
Identification of potential participants	x						
Eligibility check	x	x					
Valid informed consent for screening		x					
Height	x	x					
Weight	x	x	x	x	x	x	
% body fat		x				x	
BMI	x	x					
Valid informed consent for full trial		x					
Pregnancy and family details		x					
Feeding of baby		x				x	
Sleep patterns		x				x	
Marital status		x					
Employment status		x					
Financial status		x					
Smoking status		x				x	

Visit	*Screening*	*Baseline Home Visit*	*Immunisation Visits at GP Practice (INTERVENTION GROUP ONLY)*			*Follow-up Home Visit*	*Post follow-up*
	4 weeks postnatally (no earlier than 4 weeks/ no later than 6 weeks)	*6-7 weeks postnatally (no earlier than 4 weeks and before the first immunisation visit at 2 months)*	*2 months postnatally*	*3 months postnatally*	*4 months postnatally*	*3 months post-randomisation (-1 week/+4 weeks)*	
Alcohol consumption		**x**				**x**	
HADS Questionnaire		**x**				**x**	
ICECAP Questionnaire		**x**				**x**	
Eating Habits Questionnaire		**x**				**x**	
Body Image Questionnaire		**x**				**x**	
PPAQ Questionnaire		**x**				**x**	
Weight Control Strategies Scale						**x**	
Immunisation record from participant						**x**	
Weight loss resources used						**x**	
Intervention only – Self-weighing data						**x**	
Intervention only – BodyTrace weight data						**x**	
Intervention only – POWeR programme data						**x**	**x**
Intervention only – Trial Acceptability						**x**	
Immunisation records from GP							**x**
Qualitative Study Interviews							**x**

Table 1: Schedule of Assessments

8.4. Trial Procedures

8.4.1. Baseline and Follow-up Case Report Forms (CRF)

Height measurement

Height measurement will be taken using a Seca stadiometer. A Working Procedure (WP) will detail procedural instructions.

Weight, BMI and body fat measurement

Weight, body fat and BMI will be calculated using Tanita SC-240MA analyser.

Pregnancy, feeding and sleep

Questions in CRF

8.4.2. Baseline and Follow-up Questionnaires

A number of questionnaires will be used to assess depression, anxiety, self-reported physical activity, body image and eating habits:

- Anxiety and depression will be assessed using the Hospital Anxiety and Depression Scale (HADS)
- Self-reported physical activity will be measured using the Pregnancy Physical Activity Questionnaire (PPAQ)
- Body image will be assessed using the Body Image State Scale
- Eating habits will be assessed using the Three-Factor Eating Questionnaire (subscales: cognitive restraint of eating, emotional eating and uncontrolled eating)
- Self-weighing will be assessed using the Daily Self-weighing Perceptions (follow-up only)
- Weight control strategies will be assessed using the Weight Control Strategies Scale (follow-up only)

To assess the acceptability/validity of tools for the cost-effectiveness analysis for the phase III trial:

- ICECAP instrument

Marital status, employment status and financial status will be collected on the baseline health questionnaire. Smoking status and alcohol consumption will be measured at baseline and follow-up. For the intervention group, trial questions on acceptability will be asked at follow-up.

8.5. Schedule of Assessments

8.5.1. Baseline Home Visit

The baseline home visit will occur between 6-7 weeks postnatally and before the first immunisation visit at 2 months. The participant will be visited at home by a member of the PIMMS-WL research team.

- Screening consent obtained
- Height, weight, BMI, % body fat measured
- Eligibility (inclusion/exclusion criteria) reviewed
- Informed consent obtained for eligible participants
- Questions regarding participant's pregnancy, method of feeding, and sleep patterns completed

- Collect baseline health questionnaire. The baseline questionnaire will be posted to the participant prior to the baseline home visit to allow the participant to complete the questionnaire in their own time prior to the visit.
- Inform participant which group of the trial they are allocated to
- Usual care group
    - Issue Healthy Lifestyle leaflet
    - Advise that participant will receive usual care at immunisation appointments
- Intervention group
    - Issue Healthy Lifestyle leaflet
    - Attach weight record card to red immunisation book
    - A trial sticker will be placed on the front of the book
    - Issue BodyTrace scales and instruct participant on their use (issue instruction leaflet)
    - Women will be advised to aim for 0.5 to 1 kg per week weight loss until they have achieved a BMI less than 25 kg/m^2 and are no heavier than their pre-pregnant weight
    - Give details of the online POWeR programme – advise the women to use the website weekly to track their weight, set and review eating and physical activity goals, and receive personalised advice (https://powerpimms.lifeguidehealth.org)

8.5.2. Follow-up Home Visit

The 3-month follow-up visit will occur at 3 months post entry of the participant to the trial. The participant will be visited at home by a member of the PIMMS-WL research team. In order to maintain blinding, this will be a different member of the research team who conducted the baseline home visit.

- Confirmation of willingness to continue in the trial
- Weight, % body fat measured
- Collect follow-up questionnaires. Questionnaires will be posted to women 5-7 days in advance (for collection by the researcher at the follow-up visit)
- Confirmation of attendance at immunisation appointments obtained
- Questions regarding
    - method of feeding, duration of breastfeeding the baby and sleep patterns
    - weight loss and support
    - use of POWeR website
    - contamination
- Intervention group only
    - Willingness to participate in the qualitative study interview
    - Collect/photograph weight record card
    - Collect BodyTrace scales

To minimise loss to follow-up, a £20 gift voucher shall be offered to all participants as reimbursement for any inconvenience trial participation may have caused them. This shall be offered at the follow-up home visit once all follow-up CRF questions and questionnaires have been completed.

8.5.3. Child Immunisation Visits to the GP Practice

- The intervention contacts will be carried out at the child immunisation appointments
- Following recruitment, those participants in the intervention group will, at the start of each child immunisation appointment (when the baby is 2, 3 and 4 months), be weighed by the practice nurse
- The weight will be recorded on the weight record card attached to the red immunisation book by the researcher at the baseline home visit
- The nurse will check whether participants are weighing themselves weekly

- All participants in the intervention group will also be reminded:
  - of their weight loss goal
  - to use the POWeR website
  - to weigh themselves weekly and record their weight on the weight card
- Participants in the control group will receive usual care

8.6. Qualitative Study

We will use semi-structured interviews after trial follow-up to explore the views of women about the intervention and experiences of the practice nurses delivering the intervention. The topic guides will be informed by existing literature.

We will purposively sample up to 15 women (e.g. age, ethnicity, SES and BMI category at enrolment) and 8-10 practice nurses and ask them about their experiences of the trial to allow for theme saturation to be reached [40]. Interviews will be conducted using a topic guide which will explore the women's experiences of and attitudes to trial participation, their understanding and rating of the importance of postnatal weight management, strategies used for weight management and their use of the on line weight programme. Nurses who delivered the intervention will be invited to participate in individual semi-structured interviews after all the recruited women from their practice have undergone their final follow-up home visit for the trial. At least two nurses from each practice with more than one nurse delivering the intervention will be invited to be interviewed. For practice nurses, we will explore their experiences of delivering the intervention, barriers and facilitators, the content and phrasing of discussions with women about weight and views about the approaches that work best and least.

Before any interviews are conducted, topic guides with broad, open-ended questions will initially be piloted to ensure the questions are easily understood.

8.6.1. Objectives

- To explore whether the child immunisation appointments are an appropriate setting for postnatal mother's weight to be monitored;
- To capture mother's views on how useful the intervention was at helping them manage their weight;
- To determine what elements of the intervention facilitated and/or impeded its acceptability;
- Explore what participants found helpful and unhelpful;
- To investigate what aspects of the intervention were acceptable and unacceptable to participants and practice nurses, as well as the reasons for these feelings and opinions;
- To assess what components of the intervention may need to be amended, if any;
- To assess if the intervention leads to the mothers experiencing any anxiety or psychological harm relating to their weight;
- To capture nurse's views on the impact of delivering the intervention had on the structure and duration of the child immunisation appointment.

8.6.2. Recruitment of Participants to the Qualitative Study

During the follow-up home visit at 3 months post enrolment into the trial, participants in the intervention group will be asked if they would be willing to participate in the qualitative study interview to talk about their experiences of the trial. Those willing to participate will be asked to sign a separate consent form prior to the interview taking place.

At the end of their involvement in the study, practice nurses who delivered the intervention will be asked to participate in a semi-structured interview about their experiences. Practice nurses will be asked at the start of the trial whether they are willing to be approached later to participate in an

interview study. Practice nurses will be asked to provide written informed consent to participate in the interview.

It is anticipated that interviews will take place face-to-face, but it is possible for logistical reasons that some will need to take place by telephone. Any interviews that take place by telephone, participants will be verbally asked the questions on the consent form and asked to state their agreement with each statement and their responses will be audio recorded.

8.6.3. Analysis

Interviews will be recorded and transcribed with the permission of participants and thematically analysed using a constant comparative method. [41-42] Data management will be facilitated by the use of QSR NVivo 8. A list of overall and individual themes for women and practice nurses will be compiled to allow for cross-group/individual comparison. Data collection and analysis will be iterative, with new data being used to confirm or challenge the emerging concepts in order to detect similarities/differences between participants with different characteristics and lay and professional perspectives. A thematic analysis framework approach will be used to understand the data. This framework is very useful for answering questions related to people's experiences and perceptions. It is a thorough method of qualitative data analysis which creates a framework from which the data can be organised and then coded, enabling themes and sub-themes to emerge from the data.

All digitally recorded data that is collected during interviews will be recorded on an encrypted audio recording device. The audio recording will be securely transferred and stored at the University of Birmingham Clinical Trials Unit. The recording will be transcribed by an external company after which the audio recording will be destroyed. A confidentiality agreement between the University of Birmingham (as Sponsor) and the external transcription service will be put into place prior to any data being sent to them. The transcriptions will be anonymised and identifiable only with a participant identification number.

8.7. Participant and Cluster Withdrawal

8.7.1. Participant Withdrawal

Informed consent is defined as the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is a continuous and dynamic process and participants should be asked about their ongoing willingness to continue participation.

Participants should be aware at the beginning of the trial that they can freely withdraw (discontinue participation) from the trial (or part of) at any time.

Types of withdrawal as defined are:

- The participant would like to withdraw from trial treatment but is willing to be followed up in accordance with the schedule of assessments (i.e. the participant has agreed that data can be collected and used in the trial analysis)
- The participant would like to withdraw from trial treatment and is not willing to be followed up in any way for the purposes of the trial and for no further data to be collected (i.e. only data collected prior to the withdrawal can be used in the trial analysis)

or

- The participant wishes to withdraw completely (i.e. from trial treatment and all follow-up) and is not willing to have any of their data, including that already collected, to be used in any future trial analysis

The details of withdrawal (date, reason and type of withdrawal) should be clearly documented in the source data.

8.7.1. Cluster withdrawal

If a recruited GP practice withdraws from participation in the trial prior to randomisation, they may be replaced by another practice. If a practice withdraws after randomisation, consideration will be given to replacing with another practice.

9. ADVERSE EVENT REPORTING

9.1. Reporting Requirements

The collection and reporting of Adverse Events (AEs) will be in accordance with the Research Governance Framework for Health and Social Care and the requirements of the Health Research Authority (HRA). Definitions of different types of AEs are listed in the table of abbreviations and definitions. The investigator should assess the seriousness and causality (relatedness) of all AEs experienced by the trial participant and this should be documented in the source data with reference to the protocol.

No risks are expected to arise from taking part in the trial. There are no Investigational Medicinal Products being used as part of the PIMMS-WL trial. The intervention is considered low risk and consists of self-monitoring of weight, goal setting and using an online weight loss programme, all of which have been used in other populations and settings without evidence of harm. No serious adverse events (SAEs) are anticipated as a unique consequence of participation in PIMMS-WL, but reporting requirements are clearly outlined in this section. Safety will be assessed continuously throughout the trial.

9.2. Adverse Events

There may be certain AEs which are commonly expected in participants undergoing a weight management programme. However, as these events are well characterised it is highly unlikely that this trial will reveal any new safety information relating to this intervention. Therefore we will not be collecting adverse events for this trial. We will also not be collecting adverse events on the newborn baby.

9.3. Serious Adverse Events

For the purpose of the PIMMS-WL trial, the following are expected SAEs and should not be reported to the PIMMS-WL Trial Office as SAEs:

- SAEs that are related to a pre-existing condition;

  Pre-existing conditions are medical conditions that existed *before* entering the trial, as we intend to monitor the safety of the intervention, by capturing severe, *unexpected* occurrences, in relation to the intervention.

- Death as a result of a pre-existing medical condition*;

*All deaths should be reported to the PIMMS-WL Trial Office immediately on becoming aware so that no correspondence (patient questionnaires or queries) are sent to the participant or family.

Investigators should only report SAEs which are attributable to the trial intervention. The above events are not considered related to the trial intervention and are therefore excluded from notification

to the PIMMS-WL Trial Office as SAEs. These events should continue to be recorded in the medical records according to local practice.

9.4. Reporting Period

SAEs (except those listed above as expected) will be documented and reported from the date of consent into the PIMMS-WL trial until 30 days after 3-month follow-up visit. SAEs that are judged to be at least possibly related to the intervention must still be reported in an expedited manner irrespective of how long after the intervention they occurred.

9.5. Reporting Period – at Site

9.5.1. Adverse Events

See section 9.2. Adverse events will not be collected in this trial.

9.5.2. Serious Adverse Events

SAEs which do not meet the criteria of 'expected' (see section 9.3 above) and which require reporting as an SAE should be reported on an SAE form to the PIMMS-WL Trial Office **within 24 hours of becoming aware of the event**. On becoming aware that a participant has experienced a trial-related SAE, the Principal investigator (or delegate) must complete, date and sign the PIMMS-WL SAE form. The form should be faxed to the PIMMS-WL Trial Office using one of the numbers below. The Principal Investigator will also be asked to provide a categorisation of seriousness (mild, moderate or severe) and causality (see below table).

Category	Causality	Definition
Definitely related	Related	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out
Probably related		There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly related		There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the trial intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events)
Unlikely to be related	Unrelated	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatments)
Not related		There is no evidence of any causal relationship

Table 2: Categorisation of Causality and Relatedness

On becoming aware that a participant has experienced an SAE, the investigator (or delegate) should also report SAEs to their own Trust in accordance with local practice.

To report an SAE, fax the SAE form to:

0121 414 3050

On receipt of an SAE form, the BCTU trials team will allocate each SAE a unique reference number and return this via fax or email to the site as proof of receipt. If the site has not received confirmation of receipt of the SAE from the BCTU or if the SAE has not been assigned a unique SAE identification number, the site should contact the BCTU PIMMS-WL trial team within one working day. The site and the BCTU trials team should ensure that the SAE reference number is quoted on all correspondence and follow-up reports regarding the SAE and filed with the SAE in the site file.

Where an SAE form has been completed by someone other than the investigator, the original SAE form will be required to be countersigned by the investigator to confirm agreement with the causality and severity assessments.

9.5.3. Provision of Follow-up Information

Following reporting of an SAE for a participant, the participant should be followed up until resolution or stabilisation of the event. Follow-up information should ideally be provided on a new SAE form, using the SAE reference number provided by the BCTU trials team. Once the SAE has been resolved, all follow-up information has been received and the paperwork is complete, the original SAE form that was completed at site must be returned to the BCTU Trials Office and a copy kept in the site file.

9.6. Reporting Procedure – PIMMS-WL Trial Office

On receipt of a faxed SAE form from the site, the BCTU trials team will allocate each SAE form with a unique reference number and enter this onto the SAE form in the section for office use only. The SAE form (containing the unique reference number completed) will be forwarded to the site as proof of receipt within one working day. The SAE reference number will be quoted on all correspondence and follow-up reports regarding the SAE and filed with the SAE in the Trial Master File (TMF).

On receipt of an SAE form, the Chief Investigator (CI) (or delegate) will independently determine the seriousness and causality of the SAE. An SAE judged by the GP site PI or CI (or delegate) to have a reasonable causal relationship with the intervention will be regarded as a related SAE. The causality assessment given by the PI will not be downgraded by the CI (or delegate). If the CI (or delegate) disagrees with the PI's causality assessment, the opinion of both parties will be documented, and where the event requires further reporting, the opinion will be provided with the report.

The CI (or delegate) will also assess all related SAEs for expectedness. If the event is unexpected (i.e. is not defined in the protocol as an expected event) it will be classified as an unexpected and related SAE.

9.7. Reporting to the Research Ethics Committee

9.7.1. Unexpected and Related Serious Adverse Events

The PIMMS-WL Trial Office will report all events categorised as Unexpected and Related SAEs to the main Research Ethics Committee (REC) and the University of Birmingham Research Governance Team (RGT) within 15 days.

9.7.2. Other Safety Issues Identified During the Course of the Trial

The main REC and the University of Birmingham RGT will be notified immediately if a significant safety issue is identified during the course of the trial.

9.8. Investigators

Details of all Unexpected and Related SAEs and any other safety issue which arises during the course of the trial will be reported to CI. A copy of any such correspondence should be filed in the site file and TMF.

9.9. Data Monitoring and Ethics Committee

As this is a feasibility trial designed to test whether a definitive trial is feasible, no Data Monitoring and Ethics Committee (DMEC) will be established. Oversight of the trial will be provided by the TSC.

10. DATA HANDLING AND RECORD KEEPING

10.1. Source Data

In order to allow for the accurate reconstruction of the trial and clinical management of the subject, source data will be accessible and maintained.

Some data variables may be entered directly onto the PIMMS-WL CRFs and will be considered source data; these are identified and detailed below:

- Weight
- Height
- BMI
- Percentage body fat
- Pregnancy complications and mode of delivery
- Feeding practices
- Sleep quality
- Strategies used to lose weight
- Demographic data
- Objective recording of weight using the BodyTrace Scales
- Usage of POWeR programme

For all other data items, the source data will be collected in the trial questionnaire booklet. These being:

- Lifestyle behaviours (smoking and alcohol intake)
- Depression and anxiety through the HADS
- ICECAP
- Feelings about regular self-weighing (intervention group) using the Daily Self-weighing Perceptions questionnaire
- Eating habits (conscious energy restraint, emotional eating and uncontrolled eating) using the Three-Factor Eating Questionnaire
- Body image using the Body Image State Scale
- Physical activity using the PPAQ

10.2. Case Report Form (CRF) Completion

Data reported on each form will be consistent with the source data and any discrepancies will be explained. All missing and ambiguous data will be queried.

CRFs completed at the baseline and follow-up home visit will be completed by a member of the PIMMS-WL research team. Some CRFs, including the immunisation data, will be completed by the PI (or delegate) at the GP practice. All staff completing CRFs for the PIMMS-WL trial will be trained to adhere to the BCTU guideline on CRF completion:

- Entries on the CRF will be made in ballpoint pen, using blue or black ink;
- Errors will be crossed out with a single stroke, the correction will be inserted and the change initialled and dated. If it is not clear why a change has been made, an explanation should be written next to the change. Correction fluid should not be used;
- Data reported on each CRF should be consistent with the source data or the discrepancies explained;
- Reasons for missing data should be documented on the CRF;
- Where information is not known or refused, this will be clearly indicated on the form;
- Where data is missing without explanation, or unclearly entered onto the CRF, a data query will be raised by the BCTU team and returned to the research team or site, as appropriate for completion using Data Clarification Forms (DCF) and following the Data Clarification Process.

If CRFs have been completed by the PIMMS-WL research team, it remains the responsibility of the CI to ensure that the CRF has been completed correctly and that the data are accurate. This will be evidenced by the signature of the CI or an authorised member of the PIMMS-WL research team (as delegated on the PIMMS-WL site delegation log) on the CRF. If CRFs have been completed by the Principal Investigator (or delegate) at the GP practice, it remains the responsibility of the PI to ensure that the CRF has been completed correctly and that the data are accurate. This will be evidenced by the signature of the PI or an authorised member of the PIMMS-WL research team (as delegated on the PIMMS-WL site delegation log) on the CRF.

The completed originals will be submitted to the PIMMS-WL Trial Office at the BCTU.

CRF templates may be amended by the PIMMS-WL Trial Office, as appropriate, throughout the duration of the trial. While this will not constitute a protocol amendment, new versions of the CRFs must be implemented immediately on receipt.

10.3. Participant Completed Questionnaires

The trial questionnaires will be administered and completed by the participant at baseline and at follow-up. Ideally, the questionnaire should be completed by the participant alone (without assistance from friends, family or the research team). Any assistance or proxy completion will be recorded and flagged on the CRF. On completion, the questionnaires will be checked on site by a member of the PIMMS-WL research team for missing data. The participant will be given the opportunity to complete any missing data. If for any reason, the participant is unable to complete the questionnaires during the baseline or follow-up visit, they should be given a Freepost envelope and asked to return it by post. When possible, the questionnaires will be sent to participants by post prior to their follow-up visit. Any questionnaires returned by post will be checked for missing data. Where possible, participants will be contacted by letter or telephone and given the opportunity to complete any questions they have missed out, within one week of the questionnaire being returned by the patient.

10.4. Data Management

Processes will be employed to facilitate the accuracy of the data included in the final report. These processes will be detailed in the PIMMS-WL trial-specific data management plan. Coding and

validation will be agreed between the trial manager, statistician and programmer and the trial database will be signed off once the implementation of these has been assured.

The PIMMS-WL Trial Office will check incoming CRFs for compliance with the protocol, data consistency, missing data and timing. For CRFs completed by the PI (or delegate) at the GP practice, sites will be asked for missing data or clarification of inconsistencies or discrepancies. Participant questionnaires, and patient-specific data from the baseline and follow-up CRFs, will be reviewed on receipt at the PIMMS-WL Trial Office and inconsistent and/or missing data will be queried with the participant. To ensure that participants do not feel harassed, a single letter will be sent to participants outlining the discrepancy and/or missing data and requesting this information. Occasionally participants may be telephoned to request or clarify missing or ambiguous data queries (where participants have consented to be telephoned), again the trial team will not speak to the participants on more than one occasion regarding a missing /ambiguous set of data.

All data will be entered onto the PIMMS-WL trial database by suitably trained BCTU staff as soon as feasible once it has arrived in the PIMMS-WL trial office. ICFs, completed CRFs and questionnaires will be stored in lockable filing cabinets in a secure, swipe access part of the University of Birmingham. Password protected electronic databases, on secure UoB servers, for trial data will have limited access to BCTU members of staff working on the trial. Investigators and delegates will have access to the web-based system. The database will have ranges applied to data items where suitable.

Data collected through the POWeR website will be electronically securely transferred from the University of Southampton to the PIMMS-WL Trial Office at the University of Birmingham throughout the trial. This will be an upload through the PIMMS-WL trial database.

10.5. Data Security

The security of the system is governed by the policies of the University of Birmingham. The University's Data Protection Policy and the Conditions of Use of Computing and Network Facilities set out the security arrangements under which sensitive data should be processed and stored. All studies at the University of Birmingham have to be registered with the Data Protection Officer and data held in accordance with the Data Protection Act. The University will designate a Data Protection Officer upon registration of the trial. The Trial Centre has arrangements in place for the secure storage and processing of the trial data which comply with the University of Birmingham policies.

The system incorporates the following security countermeasures:

- Physical security measures: restricted access to the building, supervised on-site repairs and storages of backup tapes/disks are stored in a fire-proof safe.
- Logical measures for access control and privilege management: including restricted accessibility, access controlled servers, separate storage of non-identifiable data etc.
- Network security measures: including site firewalls, antivirus software, separate secure network protected hosting etc.
- System Management: the system shall be developed by the BCTU Programming Team and will be implemented and maintained by the BCTU Programming Team.
- System Design: the system shall comprise a database and a data entry application with firewalls, restricted access, encryption and role-based security controls.
- Operational Processes: the data will be processed and stored in the Trial Centre (University of Birmingham).
- Data processing: Statisticians will only have access to anonymised data.
- System Audit: The system shall benefit from the following internal/external audit arrangements:
    - Internal audit of the system

- An annual IT risk assessment

- Data Protection Registration: The University of Birmingham has Data Protection Registration to cover the purposes of analysis and for the classes of data requested. The University's Data Protection Registration number is Z6195856.

10.6. Archiving

It is the responsibility of the PI to ensure all essential trial documentation and source documents (e.g. signed ICFs, qualitative study documents, ISFs, participants' medical notes, etc.) at their site are securely retained for at least 25 years.

11. QUALITY CONTROL AND QUALITY ASSURANCE

11.1. Site Set-up and Initiation

The CI is required to sign a University of Birmingham CI agreement to document the expectations of both parties. The CI agreement document must be completed prior to participation. The CI is required to sign a Clinical Trials Task Delegation Log which documents the agreements between the CI and BCTU. In addition, all local PIs will be asked to sign the necessary agreements including a Site Signature and Delegation Log between the PI and the Clinical Trials Unit (CTU) and supply a current CV and GCP certificate to BCTU. All members of the site research team are required to sign the Site Signature and Delegation Log, which details which tasks have been delegated to them by the PI.

Prior to commencing recruitment, each recruiting site will undergo a process of initiation, following the standard BCTU Operating Procedure (BCTU QCD14), either a meeting or a teleconference, at which key members of the site research team are required to attend, covering aspects of the trial design, protocol procedures, AE reporting, collection and reporting of data and record keeping. Site initiation is documented on the Checklist for Site Initiation, the Site Management SOP and the Green Light Procedure for authorisation to start the trial (minus the CTA check and Shipment of the IMP). Sites will be provided with an ISF containing essential documentation, instructions, and other documentation required for the conduct of the trial. The BCTU trials team must be informed immediately of any change in the site research team.

11.2. Monitoring

Monitoring will be carried out as required following a risk assessment and as documented in the monitoring plan. This will consist of central monitoring carried out by the PIMMS-WL trial team.

Given the low-risk nature of this trial, central monitoring will be routine and additional on-site monitoring may be triggered.

11.3. On-site Monitoring

Any monitoring activities will be reported to the trials team and any issues noted will be followed up to resolution. On-site monitoring visits may be triggered, for example by low or lack of GP response for immunisation data, low SAE reporting rates or an excessive number of participant withdrawals or deviations. If a monitoring visit is required the trials team will contact the site to arrange a date for the proposed visit and will provide the site with written confirmation. Investigators will allow the PIMMS-WL trial staff access to source documents as requested. The monitoring will be conducted by PIMMS-WL trial team.

11.4. Central Monitoring

Trials staff will be in regular contact with the site research team to check on progress and address any queries that they may have. Trials staff will check that immunisation data is compliant with the protocol, data consistency, missing data and timing. Sites will be sent DCFs requesting missing data or clarification of inconsistencies or discrepancies in the above data.

Copies of signed ICFs and other documentation will be sent to the PIMMS_WL Trial Office for in-house review for all participants providing explicit consent. This will be detailed in the monitoring plan.

11.5. Audit and Inspection

The PI will permit representatives of the Sponsor to perform trial-related monitoring, audits, ethical review and regulatory inspection(s) at their site, providing direct access to source data/documents. The investigator will comply with these visits and any required follow-up. Sites are also requested to notify BCTU of any relevant inspections.

11.6. Notification of Serious Breaches

In the unlikely event that a serious breach occurs, BCTU procedures and SOPs for serious breach reporting will be followed. The Sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with that trial or the protocol relating to that trial. Sites are therefore requested to notify the PIMMS-WL Trials Office of any suspected trial-related serious breach of GCP and/or the trial protocol. Where the Trials Office is investigating whether or not a serious breach has occurred, sites are also requested to cooperate with the Trials Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action

Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment. Any major problems identified during monitoring may be reported to the Trial Management Group (TMG), TSC, and the REC. This includes reporting serious breaches of GCP and/or the trial protocol to the REC. A copy is sent to the University of Birmingham Clinical Research Compliance Team at the time of reporting to the REC.

12. END OF TRIAL DEFINITION

The end of the trial will be one month after the last data capture at the 3-month follow-up home visit. The BCTU trial team will notify the main REC and RGT that the trial has ended and a summary of the clinical trial report will be provided within 12 months of the end of the trial.

13. STATISTICAL CONSIDERATIONS

13.1. Sample Size

This is a feasibility trial, therefore, a formal sample size calculation has not been conducted. The trial is not designed or powered to detect a statistically significant difference in efficacy between the two treatment groups. A recruitment target of 80 women from 10-12 GP practices recruited over 8 months has been set.

13.2. Analysis of Outcome Measures

A separate Statistical Analysis Plan will be produced and will provide a more comprehensive description of the planned statistical analyses. A brief outline of these analyses is given below in relation to the proposed STOP-GO criteria for this feasibility trial.

The primary comparison groups will be composed of those in the weight management intervention group versus those in the comparator (control) group. In the first instance, all analyses will be based on the intention to treat principle, i.e. all clusters and participants will be analysed in the group to which the GP practice was randomised, irrespective of compliance or other protocol deviation. The data analysis for this feasibility trial will be descriptive and mainly focus on confidence interval estimation, with no hypothesis testing performed.

13.2.1. Primary Outcome Measure

The primary outcome from this trial is 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 (described here) and qualitative data (see section 8.6), and will include assessment of the following:

- whether the trial is appealing to women (via assessment of the recruitment rate to ensure a full phase III trial is feasible);
- whether the intervention is acceptable;
- whether the intervention has any adverse impact on infant immunisation rates;
- the number of women who complete the trial and complete the trial questionnaires.

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.

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 the 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 will be the authoritative source, and if this is not available then data from the POWeR programme will be used as the measure of intervention adherence.

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 will be 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.

Recruitment, adherence and immunisation rates will be summarised as proportions with 95% confidence intervals.

13.2.2. Secondary Outcome Measures

Not applicable.

13.2.3. Subgroup Analyses

No subgroup analyses are planned for this feasibility trial.

13.2.4. Missing Data

Every attempt will be made to collect full data on all trial participants; it is thus anticipated that missing data will be minimal. The assessment of missing data is an outcome measure of this feasibility trial.

13.3. Planned Interim Analysis

No interim analyses are planned for this feasibility trial. During the trial, the TSC will monitor the immunisation uptake rates at the GP practices randomised to the intervention group (see sections 8.2.8 and 13.2.1).

13.4. Planned Final Analyses

The primary analysis for the trial will occur once all participants have completed the 3-month follow-up assessment and corresponding outcome data has been entered into the trial database and validated as being ready for analysis. This analysis will include data items up to and including the 3-month follow-up assessment.

13.5. Decision to Progress to the Phase III Trial

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 will, 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.

Green light

- Recruitment rate ≥40% of eligible women, ≥50% of the intervention group weighs themselves weekly ≥60% of the time and ≥60% of participants have registered with the online POWeR programme. If all three criteria are met we will proceed to an application for the full trial with the protocol unchanged (unless there is a clear message from the interviews that would improve the protocol).

Amber light

- Recruitment rate of 25-39% of eligible women, 40-49% of the intervention group weighs themselves weekly 40-59% of the time and 40-59% of the intervention group registered with the online POWeR programme. If one or more of our amber-light criteria are met, we will plan to adapt the protocol in light of the results of the feedback from the interviews and our experience to improve whichever criteria are not at the "green-light" level before proceeding to the application for the full trial. In discussion with the TSC we will assess whether adaption of the protocol will require further assessment before progressing.

Red light

- Recruitment rate of <25% of eligible women, <40% of the intervention group weighs themselves weekly 40-59% of the time and <40% of the intervention group have registered with the online POWeR programme. If one or more of these criteria are met, we would consider the current protocol not feasible and not progress to an application for a full RCT. Additional red-light criteria would be concerns from the TSC that immunisation rates have been adversely affected.

14. TRIAL ORGANISATIONAL STRUCTURE

14.1. Sponsor

The University of Birmingham is the Sponsor for the PIMMS-WL trial.

14.2. Coordinating Centre

The day-to-day management of the trial will be coordinated by the BCTU at the University of Birmingham. BCTU is fully registered as a UKCRC trials unit.

14.3. Principal Investigator at Each Site

Each GP practice should nominate one person to act as the Local Principal Investigator. This should be a GP. The local PI shall bear responsibility for the conduct of research at their centre. The responsibilities of the local PI will be to ensure that all medical and nursing staff involved in the care of patients are well informed about the trial and trained in trial procedures. The local PI should liaise with the trial coordinator on logistic and administrative matters connected with the trial. Updates and newsletters would be sent to the local PI, and they would be invited to training and progress meetings.

14.4. Trial Management Group

The TMG includes those individuals responsible for the day-to-day management of the trial, including the co-chief investigators, trial statistician, trial manager and data manager. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

The TMG will meet regularly (usually monthly, with additional meetings as required) to ensure successful implementation of the trial. They will monitor participant recruitment; any departure from the expected recruitment rate will be dealt with according to the specific issues discovered.

14.5. Trial Steering Committee

The role of the TSC is to provide the overall supervision of the trial. The TSC will include members who are independent of the investigators, their employing organisations, funders and sponsors. The TSC will meet once at the beginning of the grant, once at the end of the trial and 6-monthly throughout the trial to assess progress and will be chaired by Professor Michael Ussher. The TSC will monitor trial progress and conduct and advise on scientific credibility. An explicit purpose of the TSC is to monitor the immunisation uptake rates at the GP practices (see section 8.2.8).

14.6. Data Monitoring and Ethics Committee

As this is a feasibility trial, we do not propose to hold a DMEC. The TSC will provide oversight of the trial.

14.7. Finance

The PIMMS-WL trial is funded by NIHR HTA Programme. The PIMMS-WL trial is an NIHR portfolio trial.

15. ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, 1964, amended by the 48th WMA General Assembly, Somerset West, Republic of South Africa, 1996 (website: *http://www.wma.net/en/30publications/10policies/b3/index.html*).

The trial will be conducted in accordance with the Research Governance Framework for Health and Social Care, the applicable UK Statutory Instruments, (which include the Data Protection Act 1998) and the principles of GCP. The protocol will be submitted to and approved by the main REC prior to circulation.

Before any participants are enrolled in the trial, the PI at each site will obtain local R&D approval/assurance. Sites will not be permitted to enrol participants until written confirmation of R&D approval/assurance is received by the BCTU trials team.

It is the responsibility of the PI to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual clinicians' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.

16. CONFIDENTIALITY AND DATA PROTECTION

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 1998 and its subsequent amendments.

Participants will always be identified using their unique trial identification number on the CRFs and correspondence between the Trial Office and the participating site. The participant's name, address and date of birth will be collected once at the time of trial entry and held at the University of Birmingham. Participants will give their explicit consent for the movement of their consent form, giving permission for BCTU to be sent a copy. This will be used to perform in-house monitoring of the consent process.

At the end of the trial, once the trial results had been sent to participants, all information collected will be anonymised with personally identifiable information removed and securely archived at the University of Birmingham or in an approved facility for a minimum of 25 years.

The investigator must maintain documents not for submission to BCTU (e.g. Participant Recruitment and Identification Logs) in strict confidence. In the case of specific issues and/or queries from the regulatory authorities, it will be necessary to have access to the complete trial records, provided that participant confidentiality is protected.

BCTU will maintain the confidentiality of all participant's data and will not disclose information by which participants may be identified to any third party. Representatives of the PIMMS-WL trial team, regulatory authorities and Sponsor may be required to have access to participant's notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times.

17. FINANCIAL AND OTHER COMPETING INTERESTS

At the time of writing the protocol, not all sites and personnel have been identified. Information on financial and other competing interests will be collected and documented in the Trial Master File.

18. INSURANCE AND INDEMNITY

The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at site, and other clinical care of the patient, responsibility for the care of the patients remains with the NHS organisation responsible for the Clinical Site and is therefore indemnified through the NHS Litigation Authority.

The University of Birmingham is independent of any pharmaceutical company, and as such, it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation.

19. AMENDMENTS

Any changes to the protocol must be reviewed and agreed by the TMG. All changes must be agreed by the CI prior to submission to REC and HRA. Submission of amendments and communication to the relevant stakeholders (including the funder, REC, R&D) will be coordinated by the BCTU at the University of Birmingham.

20. PUBLICATION POLICY

20.1. Access to the Final Trial Data Set

Following completion of the trial, the full anonymised data set shall remain the property of the University of Birmingham. Site investigators will not have access to the full data set and must not use, disseminate or publish any trial data without the prior written consent of the TMG.

20.2. Publication

Results of this trial will be submitted for publication in a peer-reviewed journal. The manuscript will be prepared by the CI, with support from appropriate members of the research team, and authorship will be determined by mutual agreement.

Any secondary publications and presentations prepared by investigators must be reviewed and approved by the TMG. Manuscripts must be submitted to the TMG in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Authors must acknowledge that the trial was performed with the support of the Sponsor (University of Birmingham). Intellectual property rights will be addressed in the Clinical Trial Site Agreement between Sponsor and the site.

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TRIAL SCHEMA

Every two weeks Birmingham Women's Hospital (BWH) completes searches to identify women who have given birth in the last four weeks who are registered at GP practices participating in PIMMS-WL.

BWH sends invitation letter and patient information leaflet (PIS)

Women who have given birth and who are registered at GP practices participating in PIMMS-WL and have not yet attended the 2-month immunisation appointment are given an invitation letter and PIS directly from the GP or other health care professional at the GP practice

Interested women contact research team for initial screening and those eligible are booked a home visit for the baseline assessment. Women will not be entered into PIMMS-WL trial until at least four weeks post-delivery

Baseline home visit (about 6-7 weeks postnatal and prior to first immunisation visit). Written informed consent obtained. Height, weight and % body fat assessed and eligibility confirmed. Baseline questionnaires completed.

Inclusion Criteria:

- Aged 18 years or more
- Women who are at least four weeks postnatal and who have not yet attended the first child immunisation appointment
- Planning to have their child immunised within the national immunisation programme
- BMI 25kg/m^2 or more at the time of recruitment at the baseline home visit
- Patient able and willing to provide written informed consent

Exclusion Criteria:

- Mothers whose babies have died or have been removed from their care at birth
- Women who indicate they are already actively involved in a weight loss programme or weight management trial to lose weight
- Unwilling to give consent to notify their GP
- 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

Receive intervention according to treatment group GP practice (cluster) was randomised to deliver

Allocated to intervention

- Attends 2, 3, 4 month immunisation appointments
- Receive healthy lifestyles leaflet
- Encouraged to self-weigh weekly
- Weight checked by nurse and recorded on record card in child red book at start of each child immunisation visit
- Signposted to POWeR online weight loss programme

Follow up home visit of trial outcomes
3 months from recruitment (when baby 4-5 months old)

Semi-structured interviews with women and practice nurses who delivered the intervention

Allocated to comparator
Receive healthy lifestyle leaflet

Follow up home visit of trial outcomes
3 months from recruitment (when baby 4-5 months old)