

# **Supporting Women with Postnatal Weight MAnagement**



## **SWAN Feasibility Trial PROTOCOL**

**A two arm feasibility RCT of lifestyle information and Slimming World groups to promote weight management and positive lifestyle behaviour in postnatal women from an ethnically diverse inner city population**

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## Study Synopsis

Title	A two arm feasibility RCT of lifestyle information and Slimming World groups to promote weight management and positive lifestyle behaviour in postnatal women from an ethnically diverse inner city population
Protocol Short Title/Acronym	Postnatal weight management feasibility study/The SWAN Study
Protocol Version number and Date	Version 7 13/08/2017
Is the study a Pilot/Feasibility?	Feasibility
Study Duration	36 months
Methodology	Randomised controlled trial
Sponsor name	King's College London
Chief Investigator	Professor Debra Bick
REC number	16/LO/1422
Medical condition or disease under investigation	Postnatal weight management
Purpose of clinical trial	To assess feasibility of conducting a definitive RCT
Primary objective	To assess feasibility of conducting a definitive RCT to determine effectiveness and cost effectiveness of lifestyle information and access to Slimming World (SW) groups for 12 weeks to achieve and maintain longer-term healthy postnatal weight management and positive lifestyle behaviour in women at risk of poor weight management in an ethnically diverse inner city population.
Secondary objective (s)	<ul style="list-style-type: none"> <li>• Uptake of recruitment/time to recruitment and retention</li> <li>• Assess acceptability of trial procedures and intervention</li> <li>• Estimate impact of lifestyle information and postnatal access to SW groups on maternal weight change from first antenatal visit to 12 months postnatally</li> <li>• Explore influence of lifestyle information and postnatal access to SW groups on secondary outcomes at 6 and 12 months, including weight management, diet, physical activity, breastfeeding, smoking cessation, alcohol intake, physical and mental health, infant health, sleep patterns, body image, self-esteem and patient health-related quality of life</li> </ul>
Number of Subjects/Patients	190
Trial Design	A randomised two arm feasibility trial informed by a mixed methods approach to capture quantitative and qualitative data
Endpoints	Difference between arms in weight 12 months postnatally, expressed as % weight change or weight loss from booking weight.

Main Inclusion Criteria	Women who have a BMI of $\geq 25$ at pregnancy antenatal booking or have a normal BMI at booking but have excessive gestational weight gain at 36 weeks gestation.
Statistical Methodology and Analysis	Quantitative data. Estimated differences and 95% Confidence Intervals will be calculated for specified primary and secondary analyses (significance at 5%). Sensitivity analyses will assess robustness of conclusions to missing outcome data and departures from randomized treatment. Process data will be analysed using descriptive statistics. Qualitative data will be analysed using Framework analysis.

## **Glossary of Terms and Abbreviations**

AE	Adverse Event
AR	Adverse Reaction
ASR	Annual Safety Report
BMI	Body Mass Index
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trial Number
Main REC	Main Research Ethics Committee
NHS R&D	National Health Service Research & Development
PI	Principle Investigator
QA	Quality Assurance
QC	Quality Control
Participant	An individual who takes part in a clinical trial
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee



## **1. Introduction**

### **1.1 *Need for postnatal weight management support***

On discharge from maternity care at around 6 to 8 weeks postnatally, two thirds of women weigh more than their pre-pregnancy weight [1]. Women who start their next pregnancy overweight or obese have a higher risk of adverse outcomes for themselves and/or for their infants. Failure to manage postnatal weight is linked to poor health behaviours including smoking, dietary choices, lack of regular exercise and failure to breastfeed [2,3,4]. In the UK around half of all pregnant women are overweight or obese, with concerns increasing about women who develop excessive gestational weight gain (GWG) as defined using Institute of Medicine criteria from the USA [5]: > 18 kg if pre-pregnancy BMI < 18.5 kg/m<sup>2</sup>, > 16kg if BMI 18.5 to 24.99 kg/m<sup>2</sup>, > 11.5 kg if BMI 25 to 29.99 kg/m<sup>2</sup>, > 9kg if BMI ≥ 30 kg/m<sup>2</sup>. There are currently no equivalent guidelines for the UK population.

Failure to lose weight within 6 months of giving birth is an important predictor of future weight gain and obesity [6,7]. This is a major public health issue, as postpartum weight retention contributes to long-term obesity, hypertension, diabetes and degenerative joint disease [8]. Evidence from the UK shows that a significantly greater proportion of women from areas of high deprivation have weight management problems [9] and a large cohort study in the USA found that excessive pregnancy weight gain and failure to lose weight postnatally was highly prevalent among young, low income ethnic minority women [10]. Impacts of poor weight management are not confined to the woman. Their infants are at risk of higher BMI and blood pressure in childhood and young adulthood [4]. The complexity of supporting and treating overweight or obese individuals remains a challenge [11]. There is a clear need for an effective and cost effective postnatal weight management intervention in UK settings, but a lack of evidence to support what this should include [12], with provision, intervention and recruitment approaches targeted at postnatal women unclear [6]. There is evidence in general population studies that commercial organisations may be of more benefit than NHS providers to support individuals to manage their weight [13].

### **1.2 *Effects on short and longer term maternal and infant morbidity***

Recent trials of diet and weight management interventions during pregnancy, some of which included postnatal outcomes, have measured impact on risk of gestational diabetes, having a large for gestational age infant and caesarean birth [14,15,16,17] but there is limited evidence of effectiveness [18]. In the UK, public health guidance for weight management before, during and after pregnancy recommends that dieting and weight loss during pregnancy should be avoided due to concerns about impact on neonatal outcomes [19], although a recent Australian study found no evidence of harm [20]. UPBEAT, a UK based multi-centre trial of a behavioural intervention based on changing diet to foods with a lower glycaemic index and increasing physical activity aimed to reduce the risk of gestational diabetes and birth of large for gestational age infants [21]. Women who had a BMI ≥ 30 kg/m<sup>2</sup> were recruited between 15 and 19 weeks gestation, and followed up to 6 months postnatally to assess if the intervention led to sustained dietary and physical activity change. 1555 women with a mean

BMI of 36.3 kg/m<sup>2</sup> (SD 4.8) were recruited: 772 were randomly assigned to standard antenatal care and 783 to the behavioural intervention. No difference was found in GDM or incidence of large for gestational age babies. Gestational diabetes was reported in 172 (26%) women in the standard care group compared with 160 (25%) in the intervention group (risk ratio 0.96, 95% CI 0.79–1.16; p=0.68). Sixty-one (8%) of 751 babies in the standard care group were large for gestational age compared with 71 (9%) of 761 in the intervention group (1.15, 0.83–1.59; p=0.40).

The UK based Healthy Eating and Lifestyle in Pregnancy (HELP) cluster RCT aimed to assess if a theory based intervention during pregnancy for obese pregnant women could reduce women's BMI at 12 months postnatally by equipping women with knowledge and skills to make healthier choices for themselves and their unborn infants [17]. The women allocated to the intervention were offered a weekly 1.5hr weight management group which combined expertise from Slimming World with clinical advice and supervision from NHS midwives until 6 weeks postnatally. Secondary outcomes include weight gain in pregnancy, impact on diet, level of physical activity, mental health, social support and breastfeeding and cost effectiveness. Trial results are awaited.

Findings from studies which have evaluated postnatal weight management interventions are equivocal. A Cochrane systematic review of diet and/or exercise for weight reduction in women after childbirth [22] in which 12 trials contributed data on 910 women to outcome analysis, found that women who exercised did not lose significantly more weight than women in usual care groups (two trials, n=53, mean difference -0.10kg, 95% CI -1.90 to 1.71), but women who took part in a diet (one trial, n=45, mean difference -1.70kg, 95% CI -2.08 to -.132) or a diet plus exercise programme (seven trials, n=573, mean difference -1.93kg, 95% CI -2.96 to -0.89) lost significantly more weight than women in usual care groups. Trials were included of women who were obese, overweight or gained excessive weight in pregnancy, with study recruitment taking place from three weeks to 24 months postpartum and interventions duration ranging from 10 to 24 weeks postnatally. Interventions were often delivered as a 'package' for example walking for a set time each day, social support and healthy cooking sessions. Only one trial was from the UK. Despite considerable heterogeneity due to differences in the type or length/period of the intervention and differences in the participants' characteristics, the authors suggested that diet and exercise together rather than diet alone could help women to lose weight after giving birth because the former could improve their cardiovascular fitness level and preserve fat-free mass.

van der Pligt and colleagues completed a systematic review on interventions to reduce postpartum weight retention across all BMI categories [5]. Studies were selected for inclusion if postpartum weight was a primary outcome, and diet and/or exercise and/or weight monitoring were intervention components. Women were recruited from 4 weeks to 12 months postpartum. Interventions were administered from 11 days to nine months postpartum and included counselling, individualised physical activity plans, healthy eating groups, clinic visits. Of 11 studies selected for inclusion, 10 were RCTs, none from the UK. Seven reported a decrease in postpartum weight retention, six of which included diet and physical activity delivered by different health professionals. No study considered cost effectiveness and there was wide heterogeneity in approaches to how interventions were administered. Nevertheless, findings suggested that postnatal weight loss was achievable,

although the best setting, approach to delivery, intervention duration and recruitment approach were unclear. Of note is that intervention retention rates in the majority of studies were high (>80%).

Evidence that weight management within a postpartum lifestyle intervention could impact on other health behaviours, including smoking cessation was considered in a systematic review by Hoedjes et al 2011 [23]. Of 17 studies included eight assessed effects on weight loss, and nine on smoking cessation and relapse prevention. Of the weight loss studies, five reported significant effects of combined diet and exercise. Two of the four studies which assessed smoking relapse prevention found no evidence of effect. Four studies included interventions for both smoking prevention and prevention of relapse. One found increased abstinence (5.9% versus 2.7%) and reduced smoking relapse (45% versus 55%) at six months follow-up in the intervention group compared to control, but effects were not sustained at 12 months. Compared to the control group, one study reported significant effects on smoking cessation and smoking relapse prevention at six months and one study found a small benefit on smoking cessation at six months, but not smoking relapse. One study found no evidence of differences between groups at three months follow-up. Although the authors recommended that existing postpartum lifestyle interventions could achieve weight loss, smoking cessation or prevent smoking relapse, caution is needed. There was wide variability in study methods, details of who completed study selection and data extraction were not provided, and study quality was not assessed.

## **2. Trial Objectives, Design and Statistics**

### **2.1 *Primary and secondary objectives***

The primary objective of the trial is to assess the feasibility of conducting a definitive RCT to determine effectiveness and cost effectiveness of lifestyle information and access to Slimming World (SW) groups for 12 weeks in relation to achieving and maintaining long-term postnatal weight management and positive lifestyle behaviour in women at risk of poor weight management in an ethnically diverse inner city population. Objectives reflect clarifying uncertainty in relation to various aspects of the study in order to inform progression to a definitive RCT. Objectives are measurable and time-bound to support project monitoring in line with our 2 year project plan, namely to:

- assess recruitment/time to recruitment and retention (completed by month 21)
- assess acceptability of trial procedures and intervention (completed by month 20)
- estimate impact of lifestyle information and postnatal access to SW groups on maternal weight change from first antenatal visit to 12 months postnatally (completed by month 22)
- explore influence of lifestyle information and postnatal access to SW groups on secondary outcomes at 6 and 12 months, including weight management, diet, physical activity, breastfeeding, smoking cessation, alcohol intake, physical and mental health, infant health, sleep patterns, body image, self-esteem and patient health-related quality of life (completed by month 21)

- assess resource impacts across different agencies likely to be of relevance and identify data appropriate for economic evaluation in a definitive RCT (completed by month 21)
- decide if criteria to inform progression to a definitive RCT have been met, following discussions with Core Project Team, SW, Expert PPI group, Trial Steering Committee (TSC), NIHR PHR programme team and other key stakeholders.

## **2.2 Primary and secondary endpoints**

Our feasibility outcomes reflects MRC guidelines for complex interventions [31] with some important exceptions due to the nature of this study and intervention proposed. The purpose is not to evaluate the intervention itself as SW groups are a “standardised” intervention, with robust mechanisms to ensure intervention fidelity. Due to this robust in-built quality assurance and evidence base for the intervention this process evaluation is not designed to answer some standard questions seen in complex evaluations regarding generalizability of the intervention to other contexts/settings, assurance that implementation/delivery of the intervention has been consistent across study sites, or to determine mechanisms of impact. This study reflects a pragmatic trial approach – evaluating the impact of the intervention in the hands of many, where women can choose which group to attend, and can switch groups if they like, exactly as they could if they were a ‘standard’ self-referred member of SW.

### **2.2.1. Primary endpoint**

The primary assessment likely to be used in a future definitive trial is difference between study groups in weight 12 months postnatally, expressed as % weight change or weight loss from booking weight. Mean % change across all women gives greater power, and fewer women will need to be recruited. We will undertake pre-planned sub-group analysis of the primary assessment in women of different booking BMI categories. The primary endpoint for a future trial will be selected on grounds of power.

### **2.2.2. Secondary endpoint**

Rates of 5% and 10% weight reduction and changes in relation to aspects of healthy lifestyle and health behaviours, including diet and nutrition, breastfeeding, physical activity, smoking cessation and alcohol intake, self-esteem and body image. Measures selected are those most appropriate to meet research objectives for a feasibility trial, and some have been validated in relevant populations, including women of reproductive age and women who have given birth.

Measures will be included in follow up questionnaires women will be asked to complete at 6 and 12 months postnatally. Those marked\*\* will also be included in the baseline questionnaire. Questionnaires will be ‘tailored’ for the intervention or standard care arm, to enable questions on uptake of support for weight management to be included at 6 and 12 months which will inform trial process outcomes.

- Dietary intake: The Dietary Instrument for Nutritional Education (DINE)\*\* [32]
- Physical activity: The International Physical Activity Short-Form\*\* [33]
- Mental health: Edinburgh Postnatal Depression Scale [34]

- Breastfeeding intent\*\*, uptake, and duration, questions developed for study
- Sleep patterns: questions developed for the study
- Smoking: smoking status/cigarette dependence\*\* [35]
- Alcohol consumption: Alcohol Use Disorders Identification Test\*\* [36]
- Self-esteem: Rosenberg Self-Esteem Scale\*\* [37]
- Infant health: questions developed for study
- Impact on body image [38]
- Resource utilisation and costs outcome measures: the EQ-5D-5L\*\* and the Adult Service Use Schedule\*\* [39]

### **2.2.3. Process outcomes**

The process evaluation will focus on three key aspects:

- The acceptability of study processes and procedures
- The acceptability of the intervention and how the intervention is experienced by postnatal women (those who complete at least 10/12 groups and those who do not; those who complete each group attended for the full session and those who leave after being weighed; those who continue to attend Slimming World groups and those who do not)
- The likely variation in groups attended by women in relation to date/time of day, and whether women stay with one consultant/Group or try different groups.

### **2.3. Health economics**

The health economic component will explore if it will be feasible to use a future definitive trial as a vehicle for estimating the broad cost consequences of community based weight management groups and quality-adjusted life years (QALYs) gained through women's participation compared to cost and QALY outcomes expected under standard care. If feasible, a "cost-utility" analysis will enable the incremental cost-effectiveness of the intervention to be evaluated against existing NICE cost per QALY thresholds used to assess value for money. QALY gains over the period of the trial will be assessed directly using the EQ-5D-5L administered to women participating in the feasibility study.

## **3. Trial Design and Flowchart**

A randomised two arm feasibility trial with an integral mixed methods process evaluation

### **3.1. Planned interventions**

Standard care (described below as per control group), plus information on positive lifestyle behaviours from late pregnancy and access to a 12 week commercial weight management group commencing any time from 8 weeks up to 16 weeks postnatal.

Positive lifestyle information: As postnatal health planning should start in pregnancy [26] an evidence-based positive lifestyle leaflet reflecting current NICE public health guidance for women on breastfeeding, diet, importance of smoking cessation/prevention of relapse, reducing alcohol, and managing sleep [11,24,26] will be offered following recruitment and allocation to the intervention at 36 weeks gestation. The leaflet will be developed with our Expert Patient Group and written to comply with Plain English Society guidance, using pictures and tick/cross messages to enable women of all reading abilities to understand content and will reflect local cultural needs. Local women we consulted highlighted this information is not routinely offered to women, despite recommendations that it should be [26].

Weight management intervention: The content of SW group programmes is evidence based, with evidence of effectiveness in general population groups [13]. Content is underpinned by behaviour change models, unlike interventions in many previous postnatal studies and groups are homogeneous with respect to content and delivery [7,22]. Behaviour change techniques are supported by social cognitive theory, with a focus on motivation and self-efficacy for weight management and reducing relapse from the programme. Key techniques include goal setting, self-monitoring, recruiting social support, and positive reinforcement [27,28]. Consultants receive standardised training overseen by SW dietitians and nutritionists which includes motivation to support positive lifestyle changes to manage weight, nutrition, food facts, and role of exercise and activity in health and weight management. Consultants repeat training every 2 years to remain up to date with latest evidence and attend a local programme of safeguarding training approved by the NHS. Groups follow a standard format, starting with a weigh in, new member chat and discussion of group member's experiences of weight management to help change habits, share healthy swaps and discussions of what to eat. Sessions can include basic cooking skills, taking cost, cultural preferences and time constraints into account. A food optimising system encourages adherence to healthy eating and physical activity encouragement includes facilitation of behaviour change, redefining what 'activity' can include. SW will record initial and ongoing adherence to the group programme and weekly weight. Members attend for 12 groups which run over 14 consecutive weeks to allow 2 'holiday' weeks within the 12 group offer.

Commencement: The Research Midwife will contact women at 8 weeks postnatal to provide them with a dedicated SW telephone number to call SW member services up to 16 weeks postnatal. A SW consultant will provide the woman with information on the local groups she can join, times and venue etc (standard practice). Following this first call, if the woman is not yet ready to join (ie she is unwell), she will be asked to call SW member services again when she feels ready. We will assess adherence to allocation protocols, loss to follow-up and women's views of sustainability. To capture data on whether women attend for each complete Slimming World group session or leave after being initially weighed at the start of the session, we will ask women to complete a 'log' of the time they spent at each session attended as part of the SWAN intervention offer. Each woman will be sent a copy of the log and asked to complete and return in a pre-paid postage envelope to the research office. It will be possible to track women who continue to access SW beyond study requirements, and those who move between different groups. Follow up will capture data on women who continue attending SW groups or achieve their goal and stop attending to compare outcomes of interest with the control group.

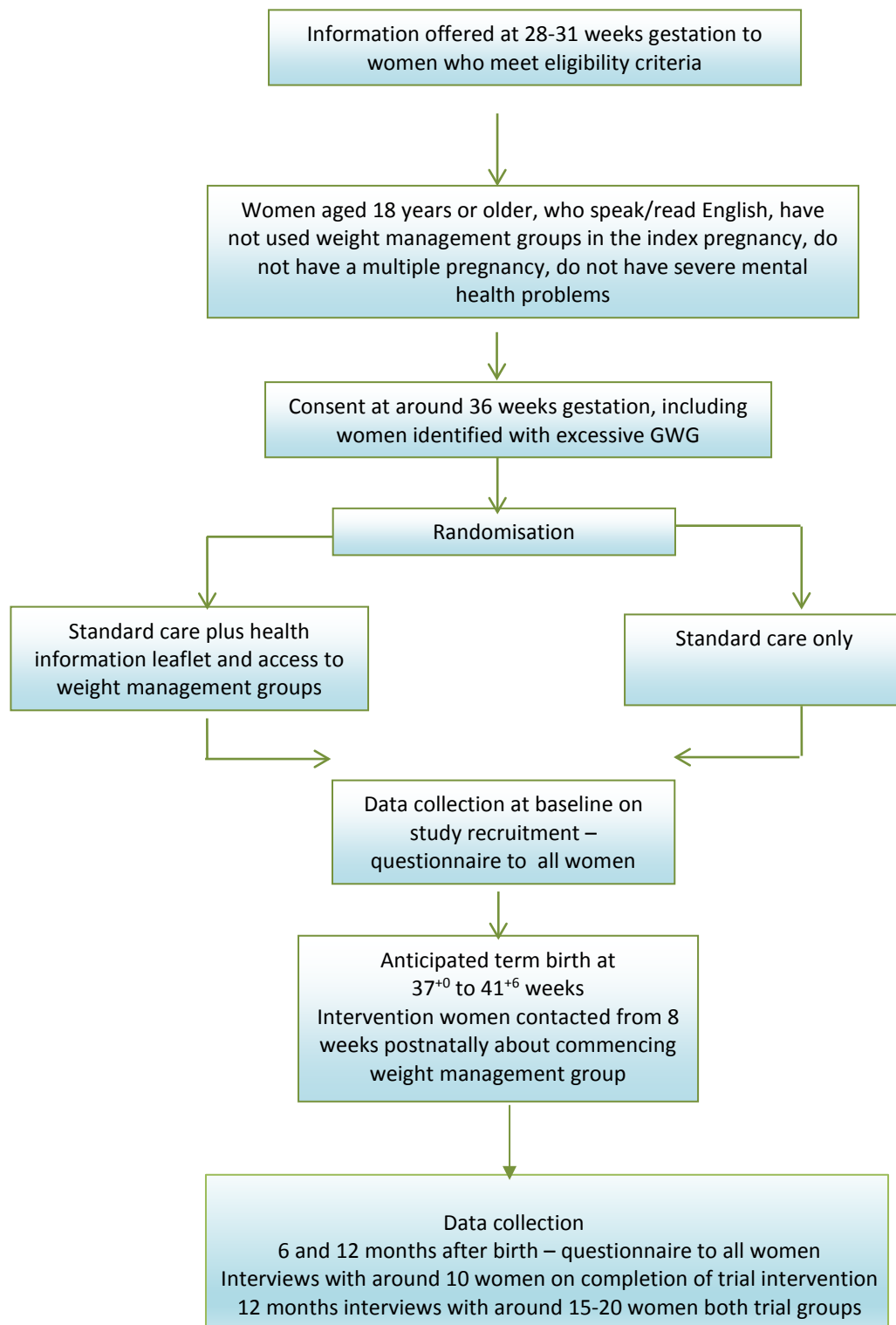
Intervention fidelity: Slimming World have robust quality assurance procedures which will ensure standardisation of weight management groups. This includes a weekly call between group Consultants and their local team managers to discuss the group that week and any concerns; and a Consultant Development Programme, whereby team developers visit and assess Consultants and their groups on a regular basis. Consultants also receive monthly mailouts containing local news for their locality and nationally (also containing training materials) and attend quarterly meetings with all colleagues from their district.

Women can choose which SW group they attend and when they commence groups to fit with their postnatal recovery, lifestyle and family demands. Women can take their babies with them. SW groups are run by Consultants from the local area, who are aware of cultural preferences, time and budget constraints local women face, and can advise on basic cooking skills and local shops selling healthy foods within women's budgets. The Food Optimising system used in SW groups includes pictorial use of recipes for women who may not have a high level of understanding of written English. As our postnatal population is likely to be more geographically mobile [29], women who move from one area to another can transfer their SW group membership to another local group anywhere in the UK. Women from both groups will be asked to attend an appointment with the Research Midwife at the study site at 6 and 12 months to be weighed, or can request a home visit from the Research Midwife if this is more convenient. Travel costs and costs of a £10 Love2Shop voucher to thank women for their time to complete study questionnaires will be offered.

### **3.2. Standard care**

Women allocated to standard care will receive standard NHS maternity care to 8 weeks postnatal prior to discharge from maternity care. This could include, for example, routine midwifery and health visitor contacts for infant feeding assessment, monitoring of recovery from the birth, commencement of the infant immunisation programme, routine assessment as part of Healthy Child programme, parenting interventions and other contacts with the family as determined by need. Women will usually be offered a routine contact with their GP at around 6-8 weeks postnatally. We will ask all recruited women at their 6 and 12 month follow up about their experiences of using weight management groups or other sources of support for weight management, healthy lifestyle and activity.

#### 4. Trial flow diagram





## 5. Trial statistics

### 5.1. *Primary analysis*

Quantitative and qualitative process data will be analysed separately before examining relationships between the two types of data, with synthesis of data completed in line with O’Cathain [40]. Quantitative data analysis will be led by PS. Data will be entered onto the MedSciNet web based data entry system. Retention and adherence will be considered from recruitment rate, consent rate, withdrawal and loss to follow-up (with reason), departures from randomized treatment and prevalence of SAEs reported by treatment group and overall. Estimated differences and 95% Confidence Intervals will be calculated for specified primary and secondary analyses (significance at 5%). Sensitivity analyses will assess robustness of conclusions to missing outcome data and departures from randomized treatment. Analyses of potential efficacy will be based on the ITT sample, utilising follow-up data from all randomised women. Differences between arms will be compared at 6 and 12 months post-birth adjusting for important prognostic factors (parity, maternal age, ethnicity, BMI at booking, and (as appropriate) baseline measurement). Data to inform our process outcomes will be evaluated using descriptive analysis. Numbers (with percentages) will be presented for binary and categorical variables and means (standard deviations), or medians (with lower and upper quartiles) or geometric means for continuous variables will be presented).

Qualitative data analysis will be led by CT supported by the NCT research assistant. Qualitative interview data will be analysed prior to knowing the results from the quantitative “outcomes” analysis to avoid bias in interpretation of findings [31]. Interviews will be recorded with women’s permission and transcribed and analysed using the Framework method for thematic analysis [41]. The key topics and issues emerging from interviews will be identified through familiarisation with the interview transcripts by at least two researchers (CT, NCT research assistant) who will initially work independently and then come together to discuss and agree the final coding framework with SMc. A series of thematic charts will be developed according to the coding framework, and data from each transcript summarized under each theme, enabling examination of similarities and differences of views within and between transcripts, and use of a constant comparative approach. Quantitative and qualitative data on acceptability of the intervention and other aspects of feasibility will be integrated using mixed methods matrices [40]. Similar/disparate findings will be shared and discussed with CPT and TSC.

### 5.2. *Economic evaluation*

All analyses will be conducted on the basis of intention-to-treat. As the data for costs are likely to be skewed, we shall use non-parametric bootstrap estimation to derive 95% confidence intervals for mean cost-differences between the trial groups. Non-parametric bootstrap methods will also be used to calculate 95% confidence intervals for incremental cost-effectiveness ratios. In the absence of stochastic data for all variables, a series of multi-way sensitivity analyses will be undertaken, to explore the implications of uncertainty on the base-case incremental cost-effectiveness ratios. In addition, cost-effectiveness acceptability curves will be constructed using the net-benefits approach.

## **6. Sample Size, Selection and Withdrawal of Subjects**

The proposed sample size is a total of 190 women. This will allow a 30% loss to follow up to ensure that we achieve our **required** sample size of 130 women. This study is designed firstly to establish the rates at which women could be recruited and retained in a future definitive RCT and estimate critical parameters with necessary precision to inform sample size requirements. In particular, we require estimates of the standard deviation, and design effect for the primary endpoint, allowing for clustering by intervention group. 130 women will allow estimates of the required sample size for any given clinically important difference to within 30% of the true value. Based on published data [13,42] the mean (SD) percentage weight change following a SW programme of 12 weekly groups is -5.5%, (3.3). Assuming these numbers are typical, 65 women in each group (130 in all) would be required to detect a difference of 2% between active and control groups with 90% power. Of around 6,600 women who give birth at the reference maternity unit over 12 months in 2013, 40% were overweight, 15% of whom were obese. Data on women with excessive GWG are not routinely collated. Potentially 55 women booking each week would meet obese/overweight inclusion criteria. Recruiting 7 - 8 women each week over a 8 month (32 week) period would be sufficient to achieve the desired sample size to meet the aims of this feasibility study.

### **6.1. Identifying and consenting participants**

- A) Women overweight (BMI 25–29.9 kg/m<sup>2</sup>) or obese (BMI ≥30 kg/m<sup>2</sup>) as identified at their first antenatal contact and B) Women with a normal BMI at pregnancy booking who have excessive gestational weight gain at 36 weeks [5].

### **6.2. Inclusion criteria**

Women eligible will include those aged 18 and over, who speak and read English, are expecting a single baby and have not accessed weight management groups in the index pregnancy.

### **6.3. Exclusion criteria**

- <18 years old
- Insufficient understanding of spoken and written English
- Current diagnosis of major psychiatric disorder documented. This is a vulnerable group of women who may be unable to participate because of their illness
- Fetus has known abnormality. To prevent additional stress to the woman and family
- Involvement in another postnatal study to reduce 'burden' of research participation
- Identified medical complications (for example cardiac disease, type 1 diabetes).
- Identified eating disorders. Women may be in receipt of ongoing clinical support and treatment to promote healthy diet and eating
- Previous surgery for weight management. Women may be in receipt of ongoing clinical support to promote healthy diet and eating

#### **6.4. Criteria for premature withdrawal**

Participants can withdraw at any point without giving a reason. Permission will be sought to access routinely collected clinical pregnancy outcome data.

### **7. Study procedures**

#### **7.1. Informed consent procedures**

There will be two approaches to informing women about the study. The first approach will be for women who have a BMI of 25 and over who will be identified from their booking details on the maternity administration system. At approximately 26 weeks of pregnancy, all identified women in this group will receive a study letter which briefly explains the aims of the study and advises women that a Research Midwife will be in contact within the next couple of weeks to explain the study further. The letter will also explain how the woman can contact the team if she does not want to receive any further information. Two weeks after sending the letter, the Research Midwife will make contact by calling women who have not asked to be removed from the contact list and explain the study in more detail.

It was considered important that all women who may be eligible are offered the opportunity to participate in the study, with initial consideration that clinical staff at the study site would raise awareness of the study with women. However, it is apparent that the current demands of the clinical workload will preclude midwives from discussing the study with all eligible women. Furthermore, evidence from methodological studies which have considered the benefits of an 'opt-out' approach have confirmed that this supported uptake of recruitment when compared to an 'opt in' approach [43,44], especially in studies considered to have a low risk for participants.

The second approach will be to women who have a normal BMI at pregnancy commencement, but gain excess weight gain during pregnancy as assessed at around 36 weeks gestation against IoM criteria [5]. These women will be offered the opportunity to self-refer to the Research Midwives, through posters placed at the study site and referrals from midwives and obstetricians who will be asked to raise women's awareness of the study from around 28 weeks gestation, and can give out study postcards inviting women to contact the research midwives, who will arrange to meet with women interested in the study. Women approached this way who are interesting in taking part will be asked to contact the Research Midwives to arrange to be weighed at around 36 weeks (or their next nearest antenatal appointment). If women in this group do not respond to advertising of the study via postcards and posters after 3 months of recruitment, we will also send similar opt-out letters over the final two months of the planned recruitment period to explore if this approach is feasible to recruit women with excessive GWG. Letters in this instance will be sent to all women when they are around 32-34 weeks gestation.

All women identified using these approaches will be offered a Patient Information Sheet (PIS) by the Research Midwives or midwives in antenatal clinics prior to seeking consent at around 36 weeks gestation. Women who are interested in participating will be met by the Research

Midwives at the study site (which could be the main obstetric unit or a community clinic where women are attending their antenatal appointment) to obtain consent to participate and complete the baseline questionnaire. Women who had gained excessive gestational weight could be recruited at their antenatal weight appointment if this takes place around 36 weeks gestation and they are happy to do complete the consent form at this contact. All women who are eligible who are recruited and provide their written consent to participate will be randomised to one of two groups, namely

- standard care\* plus lifestyle information and postnatal access to SW weight management groups
- standard care only

An existing SW/Royal College of Midwives leaflet will help to support discussions about recruitment with the women, with evidence that additional weight measurement in pregnancy has high uptake and no increase in anxiety [30]. All women who consent will be randomised and allocated to either the intervention or control group and asked to complete a baseline questionnaire. A screening form will be completed by a Research Midwife to record number of women approached, eligibility and when women declined to take part (when first approached or at consent) and reasons for declining, if women are willing to provide.

A separate study patient information leaflet will be mailed to recruited women purposively selected from both trial groups and invited to participate in a telephone or face to face interview with the research team when they have completed the study at 12 months postnatally. Similarly, women allocated to the intervention group who are purposively selected for interview about their experiences on completion of the intervention will be sent a separate study information leaflet to seek their consent to participate in this stage of the study process evaluation (see 7.4 for further details).

## **7.2. Randomisation procedures**

Randomisation and allocation will be carried out by KCL's Clinical Trials Unit web-based system ([www.ctu.co.uk](http://www.ctu.co.uk)). Women will be recruited at 36 weeks gestation at the antenatal clinic by the Research Midwife. Those who consent to participate will be registered on the InferMed MACRO web-based data entry system by the Research Midwife prior to randomisation to allocate each a unique study number 'PIN'. The Research Midwife will access the system and using the PIN, initials and date of birth, request randomisation. Email confirmations will be automatically generated. Unit of randomisation will be individual participant, allocated in a ratio of 1:1 to intervention and control. Use of a web-based system will protect against allocation bias, as it will not be possible for the woman or Research Midwife to be aware of the randomisation sequence or codes. Selection bias will be minimised by ensuring all women eligible and recruited have equal opportunity of being allocated to each of the study arms and follow up completed, with information on women randomised and allocated but who opt out presented but clearly indicated as such. We will monitor recruitment, follow up rates and compare characteristics of women at baseline to check for any unexpected differences that may indicate bias. Use of intention to treat (ITT) analysis will limit attrition and analytical bias. It will not be possible to 'blind' the Research

Midwife or the women to allocation but those responsible for analysis will be blinded to allocation.

### **7.3. Unblinding**

This is not a blinded study and therefore there are no unblinding procedures required.

### **7.4. Follow-up procedures**

Compliance issues are an important consideration and the reason for proposing a feasibility study. Loss to follow up among postnatal women has been reported to range from 30% to 40%, including women in inner city areas [29,45]. Experience of the applicants in large complex interventions in similar populations has shown that planned initiatives, for example contact with a Research Midwife, flexible follow up appointments (including the option to have a home visit), expenses to cover travel to appointments, vouchers for returning questionnaires and sending of reminders, can reduce loss to follow up. Follow up appointments can be offered at weekends and week days, with the option to complete questionnaires at these appointments if women have not returned already.

Data will be collected using semi-structured qualitative interviews with up to 10 intervention women to explore the acceptability of the trial intervention, targeting some when they have completed their Slimming World group offer (completion of 10-12 groups) and some women who did not complete the weight management group offer.

Semi-structured qualitative interviews will also be held with a purposive sample of intervention **and** control women (n=15-20) on study completion at 12 months postnatally to assess acceptability of study procedures (including intervention). Interviews will explore study processes and experiences of participating, including reasons for taking part/dropping out, recruitment and randomisation (expectations/understanding of the study and its aims), views on outcome measures, attendance for weighing appointments as part of study follow up and lifestyle behaviours.

Control group women will in particular be asked about the impact, if any, of participating on their levels of physical activity or any dietary changes. Telephone or face to face interviews at the 12 month weighing appointment, if more convenient for women, will be offered. Sampling for interviews will be based on maximum diversity in relation to age, parity, ethnicity, socio-economic status, and reflect the range of weight loss/gain of the sample. Intervention group women will additionally be sampled to reflect diversity in group characteristics including group 'quality', and include women who did and did not complete all 12 sessions. SW also routinely collect data (via a questionnaire) from all members at week 10 of the 12 week programme (those still engaged with the programme and those who have left). Anonymised feedback from women attending the groups involved in this study will be made available to the team to further enhance understanding regarding any group variation.

## 7.5. End of Study Definition

The end of the study declaration will be submitted to the relevant authorities after the woman completes follow up at 12 months postnatally. The end of the study will be reported to the REC and Regulatory Authority within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants and ensure that the appropriate follow up is arranged for all involved. A summary report of the study will be provided to the REC and Regulatory Authority within 1 year of the end of the study.

## 8. Assessment of safety

Although no serious adverse events are anticipated, it is possible that these may occur and a system for reporting these promptly is required. All SAEs occurring during the trial observed by the investigator or reported by the participant, whether or not attributed to the trial, will be reported on the data collection form. SAEs considered to be related to the trial by the investigator will be followed up until resolution or the event is considered stable. All related SAEs that result in a participant's withdrawal from the trial or are present at the end of the trial, will be followed up until a satisfactory resolution occurs. The Chief Investigator (CI) shall submit, once a year throughout the clinical trial, or on request, a safety report to the Research Ethics Committee that includes all SAEs.

### 8.1. Assessment of seriousness

The CI make an assessment of seriousness according to the criteria:

A serious adverse event is any adverse event that (at any dose):

- Results in death
- Is life threatening
- Requires hospitalization or prolongation of hospital stay
- Results in persistent or significant disability or incapacity

### 8.2. Assessment of causality

The CI will make an assessment as to whether the SAE is likely to be related to treatment according to the following definitions:

- 1) As there is no CTIMP in this study, all SAEs will be judged as having a reasonable suspected causal relationship ( eg possibly, probably, definitely) to the study intervention, and adverse reactions/serious adverse reactions (AR/SAR) will not apply.
- 2) **Unrelated:** where an event is not considered to be related to the intervention.
- 3) **Possibly:** although a relationship to the intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant treatment or temporal relationship make other explanations possible.
- 4) **Probably:** the temporal relationship and absence of a more likely explanation suggest the event could be related to the intervention.

- 5) Definitely:** the known effects of the study intervention or its consequence, suggest that the intervention should be considered and investigated.

### 8.3. Assessment of severity

The investigator will make an assessment of severity for each SAE and record this according to one of the following categories:

**Mild:** an event that is easily tolerated by the participant, causing minimal discomfort and not interfering with every day activities.

**Moderate:** an event that is sufficiently discomforting interfere with normal every day activities.

**Severe:** an event that prevents normal every day activities.

*Note: the term 'severe', used to describe the intensity, should not be confused with 'serious' which is a regulatory definition based on participant/event outcome or action criteria. For example, a headache may be severe but not serious, while a minor stroke is serious but not severe.*

### 8.4. Ethics reporting

Reports of related and unexpected SAEs will be submitted to the main REC within 15 days of the CI becoming aware of the event, using the NRES template. The form will be completed in typescript and signed by the CI.

For some women talking about their weight may trigger emotional issues, however SW in partnership with the Royal College of Midwives have materials to support midwives to raise issues of weight management with women and our recruitment processes will reflect 'best practice' in line with these and other guidance, including NICE [11]. Midwives are trained to identify emotional problems and refer women to sources of additional support if indicated. If women report positively to item 10 of the EPDS ('in the past week, the thought of harming myself has occurred to me') or generate a high score (>13) indicating a high likelihood of symptoms of depression, a Research Midwife will contact the women to ask if they would like help or for their health visitor and/or GP to be contacted. The 6 and 12 month questionnaire and study patient information leaflets make it clear that in some circumstances, the Research Midwives may contact the women who report adverse health issues. Access to the intervention will not require revision of any routine contacts women may be receiving from health or social care professionals; the woman can select which local SW group she attends, costs of which will be waived.

## 9. Trial Steering Committee

The trial will be supervised by an independent Trial Steering Committee (TSC). The specific tasks of the TSC are:

- (i) to approve the trial protocol;
- (ii) to approve necessary changes in the protocol based on considerations of feasibility and practicability;
- (iii) to resolve problems brought to it by the co-ordinating centre;

- (iv) to approve trial reports and papers for publication.

An independent data monitoring committee (DMC) is not required to oversee the safety of subjects in the trial. This is not a CTIMP, therefore the TSC will take overall responsibility for the conduct of the trial.

## **10. Ethics approvals**

The Investigators will ensure that this trial is conducted in full compliance with the current revision of the Declaration of Helsinki (last amended October 2008) and with relevant regulations and with the MRC GCP guidelines which are based on ICH Guidelines for GCP (CPMP/ICH/135/95) July 1996. The trial can only start after approval from a Research Ethics Committee and the local Research and Development departments at the participating site.



## **11. Data Handling**

### **11.1. Confidentiality**

Patient anonymity will be protected and maintained and identities of all participants will be protected from any unauthorised parties. All data from women's maternity records, baseline, 6 and 12 month follow up questionnaires, interview data and data which Slimming World have agreed to share on women's attendance and weight management progress will be anonymised, kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, The Research Governance Framework for Health and Social Care and Research Ethics Committee Approval. Each women will be allocated a unique study reference number. All records will be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor, its designee, Regularity Authorities, or the REC. No patient identifiable data will be used in any publications or presentations relating to this study.

The Investigator and the study site staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

### **11.2. Case Report Forms**

The Research Midwives will be responsible for completion of CRFs throughout the life cycle of the study. Data collated on CRFs will include the following:

- Inclusion and exclusion criteria
- Women's baseline and demographic data
- Data as per protocol requirement
- Loss to follow up, including failure to attend follow up appointments to be weighed
- Women who withdraw from the study
- SAEs

### **11.3. Record retention and Archiving**

Research records will be retained according to NHS Guidelines for the retention of documentation involving pregnant women. All medical records will be retained for at least 25 years after publication of the final study report. All research records will be retained for 5 years in line with the Research Governance Framework.

### **11.4. Compliance**

The CI will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (1996 [46]) and in accordance with all applicable regulatory

requirements including but not limited to the Research Governance Framework, Trust and Research Office policies and procedures and any subsequent amendments.

Compliance with the protocol will be ensured by a number of procedures:

#### ***11.4.1. Site set-up and training***

The Research Midwives will be based at the study site to implement and oversee adherence to the protocol and to deal with any specific site issues. Study site midwives involved with the trial will be fully appraised of issues such as consent, compliance with the protocol, and data collection processes by the study research midwife and the obstetric and midwifery clinicians who are on the CPT.

#### ***11.4.2. Data collection, processing and monitoring***

All trial data will be:

- Collected using specific study data collection forms.
- Processed and monitored centrally for consistency, viability and quality by the CPT
- Screened for out-of-range data, with cross-checks for conflicting data within and between data collection forms using computerised logic checking screens
- Referred back to the centre for clarification in the event of missing items or uncertainty
- Processed using a double data-entry system by an independent data clerk

#### ***11.4.3. Central statistical monitoring***

All data will be monitored by the trial statistician based at KCL for consistency, viability and quality using a bespoke data management system developed for the study by MedSciNet. Central statistical monitoring is used to monitor patterns of recruitment at sites, characteristics of women, time of recruitment, etc. Central statistical monitoring can be utilised 'for cause' purposes if necessary.

The MedSciNet programmer will run trial-specific programs to extract certain fields from the database (as requested by the Chief Investigator, or Trial Statistician) and to cross-check certain information. These fields may include measures of eligibility criteria, management after trial entry and compliance but not by allocation.

The MedSciNet programmer and Chief Investigator will review the results generated for logic and for any patterns or problems. Outlier data will be investigated. The Chief Investigator and Trial Statistician will decide if any action needs to be taken.

## **11.5. Clinical governance issues**

### **11.5.1. Inspection of Records**

Investigators and institutions involved in the study will permit trial related monitoring, audits, REC review and regulatory inspection(s). In the event of an audit the investigator agrees to allow the Sponsor, representatives of the Sponsor or regulatory authorities direct access to all study records and source documentation.

### **11.5.2. On-site monitoring**

- A random sample of cases will be monitored at source (Source Document Verification).
- The documents to be verified will be randomly selected using computerised trial number generation. Any major discrepancies found at the site visit would trigger a more extensive audit of trial data.

### **11.5.3. Local Co-ordination**

The participating study site will identify a site specific Principal Investigator who will nominate a local co-ordinator for that site (this may be him/herself) whose responsibilities will be to:

- be familiar with the Trial
- liaise with the Trial Co-ordinating Centre at the KCL Clinical Trials Unit
- ensure that all staff involved in the care of eligible women are informed about the Trial and have received requisite training
- ensure that mechanisms for recruitment of eligible women, including the ready availability of parent information, are in place; monitor their effectiveness and discuss the reasons for non-recruitment with relevant staff
- notify the Trial Co-ordinating Centre of any serious adverse events
- make data available for verification, audit and inspection processes as necessary
- ensure that the confidentiality of all information about Trial participants is respected by all persons

The sponsor of the trial is KCL. The trial will be run on a day-to-day basis by the Core Project Team. This group reports to the Trial Steering Committee which is responsible to the trial sponsor (KCL).

## **11.6. Non-Compliance**

Non-compliance with the study protocol will be captured from recruitment rates, CRFs, meetings and updates with all research staff and discussion with the CPT. The study sponsor will maintain a log of non-compliances to ascertain any trends developing which need to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with, the timeframe decided being dependent on the severity. If actions are not dealt with accordingly, the R & D office will agree an appropriate action, including an on-site audit.

## **12. Finance and Publication policy**

This study has been funded by a grant from the NIHR Public Health Research Programme, with a grant value of £432,275.00.

The Chief Investigator will co-ordinate dissemination of data from this trial. All publications using data from this trial to undertake original analyses will be submitted to the TSC for review before release.

To safeguard the scientific integrity of the trial, data from this trial will not be presented in public before the main results are published without the prior consent of the TSC. Acknowledgement will include all local co-ordinators and collaborators, the Trial Co-ordinating Centre and trial staff.

Authorship at the head of the primary results paper will take the form “The Postnatal Weight Management Feasibility Trial Group”. This avoids giving undue prominence to any individual. All contributors to the trial will be listed at the end of the report, with their contribution to the trial identified.

Those responsible for other publications reporting specific aspects of the trial may wish to utilise a different authorship model, such as “[name], [name] and [name] on behalf of the Postnatal Weight Management Feasibility Trial Group”. Decisions about authorship of additional papers will be discussed and agreed by the trial investigators and the TSC.

The women participating in the trial will be sent a summary of the final results of the trial, which will contain a reference to the full paper.

## **Appendix 1: Trial Steering Committee**

Professor Rona McCandlish (Chair)

Professor Hora Soltani, Sheffield Hallam University

Dr Richard Hooper, Queen Mary University London

Dr Nicola Heslehurst, Newcastle University

Ms Samantha Hainsworth, lay member

**Appendix 2 – Information with regards to Safety Reporting in Non-CTIMP Research**

	Who	When	How	To Whom
<b>SAE</b>	Chief Investigator	-Report to Sponsor within 24 hours of learning of the event  -Report to the MREC within 15 days of learning of the event	SAE Report form for Non-CTIMPs, available from NRES website.	Sponsor and MREC
<b>Urgent Safety Measures</b>	Chief Investigator	Contact the Sponsor and MREC Immediately  Within 3 days	By phone  Substantial amendment form giving notice in writing setting out the reasons for the urgent safety measures and the plan for future action.	Main REC and Sponsor  Main REC with a copy also sent to the sponsor. The MREC will acknowledge this within 30 days of receipt.
<b><u>Progress Reports</u></b>	Chief Investigator	Annually ( starting 12 months after the date of favourable opinion)	Annual Progress Report Form (non-CTIMPs) available from the NRES website	Main REC
<b><u>Declaration of the conclusion or early termination of the study</u></b>	Chief Investigator	Within 90 days (conclusion)  Within 15 days (early termination)  <i>The end of study should be defined in the protocol</i>	End of Study Declaration form available from the NRES website	Main REC with a copy to be sent to the sponsor
<b><u>Summary of final Report</u></b>	Chief Investigator	Within one year of conclusion of the Research	No Standard Format However, the following Information should be included:- Where the study has met its objectives, the main findings and arrangements for publication or dissemination including feedback to participants	Main REC with a copy to be sent to the sponsor

### **Appendix 3. History of amendments to protocol**

Substantial amendment 1: Ethics approval notice received 18/04/2017

- Revision to wording of postcard for recruiting women who had normal BMIs at pregnancy commencement, but gained excessive gestational weight
- Provision of a log book for women who attended Slimming World groups to complete after each group meeting to provide information on whether they stayed for the whole group session, or left after being weighed
- Revised questions about attendance at weight management groups in the 6 and 12 month questionnaires (control and intervention)

Substantial amendment 2: Ethics approval notice received 04/01/2018

- It was originally planned to collate data to consider likely variation in characteristics of Slimming World groups attended by women in relation to: characteristics of the groups: date/time of day; size of group; characteristics of group members: proportion of target members (members who reached their target weight); and demographics of group members (age, gender, postcode). Further discussions with Slimming World highlighted that these data are not routinely collected by Slimming World and they would not support data collection specifically for the feasibility trial.

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