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Supporting women with postnatal weight management

Submission date	Recruitment status
01/02/2016	No longer recruiting
Registration date	**Overall study status**
19/05/2016	Completed
Last Edited	**Condition category**
14/06/2023	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Many women are overweight or obese when they become pregnant, or gain more weight in their pregnancy than they need to. These women are more likely to suffer problems such as diabetes or high blood pressure, to need medical intervention during birth (such as a cesarean section) and are less likely to breastfeed. They are also more likely to have ongoing weight problems, increasing the risk of poor outcomes (such as miscarrying) in future pregnancies and of long term health conditions such a heart disease. Babies born to women who are overweight or obese are more likely to have heavier birth weight, birth defects, to be stillborn or to become obese themselves later in life. Women who live in disadvantaged communities are more likely to have weight management problems. Developing good quality postnatal advice about diet and lifestyle is an important way of supporting women and their families in these communities. However, it still is unclear how or when to engage women and how best to support them with weight management. This study is going to look at whether attending Slimming World groups, supported by good quality information on healthy lifestyles, could support women in a deprived inner city population to better manage their postnatal weight and to take up more positive health behaviours, such as breastfeeding, increasing physical activity and stopping smoking. The aim of this study is to find out whether running a large-scale study is feasible, by conducting a smaller scale study.

Who can participate?
Overweight or obese women who are 36 weeks pregnant with a single baby.

What does the study involve?
Participants are randomly allocated to one of two groups, either the ‘weight management plus usual care’ group or the ‘usual care only’ group. Women allocated to the weight management group are offered advice on healthy lifestyles and are invited to start attending local weight management groups at any time from 8 weeks to 16 weeks after having their baby. They are invited to attend weekly groups over a total of 12 weeks, and can decide which group they wish to attend (for example based on its location in relation to their home) and the time of day it is held (for example an afternoon group or an early evening group). During this period, they also continue to receive any routine contacts with healthcare professionals for themselves and their baby. Women allocated to the ‘usual care only’ group continue to have any routine contacts with

healthcare professionals for themselves and their baby only. At the first appointment with the Research Midwife, women are asked to complete a questionnaire on their current health. Six and twelve months after having their baby, women in both groups are asked to complete a questionnaire about their health and their baby's health. Women are also weighed at these times. They may also be asked if they would be interested in taking part in a short interview with one of the researchers to discuss their experiences of weight management after having a baby.

What are the possible benefits and risks of participating?
There are no guaranteed benefits of participating, although taking part may help women to lose weight and thus improve their health. The women who attend the weight groups during the study have the opportunity to continue to attend at a reduced fee should they wish to carry on. The women in the control group are offered the opportunity to join a Slimming World group on completing the study for a reduced fee. There are no notable risks of participating.

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2015 to November 2017

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

Who is the main contact?
Prof. Debra Bick
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A two arm feasibility trial 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

Acronym
The SWAN Feasibiity Trial

Study objectives
The aim of this study is to:
1. Assess recruitment, time to complete recruitment, retention rates and estimate effect sizes for a range of hypothesised outcomes to inform progression to a definitive RCT and appropriate trial design
2. Test acceptability of study procedures to women, including randomisation procedures
3. Estimate contamination between study arms
4. Consider women's experiences of the intervention and its acceptability
5. Conduct a preliminary economic evaluation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee: London Camberwell St Giles, 11/10/2016, REC ref: 16/LO/1422

Study design
Two arm single-centre feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet

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

Health condition(s) or problem(s) studied
Obesity during pregnancy

Interventions
Participants are randomised to one of two groups in a 1:1 ratio using KCL's Clinical Trials Unit (CTU) web-based system (www.ctu.co.uk).

Control group: 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.

Intervention group: Women receive standard care, plus information on positive lifestyle behaviours from late pregnancy and access to a 12 week commercial weight management group (provided by Slimming World) commencing any time from 8 weeks up to 16 weeks postnatally.
1. Positive lifestyle information: As postnatal health planning should commence in pregnancy, 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 will be offered following recruitment and allocation to the intervention at 36 weeks gestation.
2. Weight management intervention: The Research Midwife will contact women at 8 weeks postnatally to provide them with a dedicated Slimming World telephone number to call member services about commencing a local weight management group. The content of SW weight management group programmes is evidence based, with some evidence of effectiveness of attendance at commercial weight management groups in general population studies. The content is underpinned by behaviour change models, and groups are homogeneous with respect to content and delivery. Behaviour change techniques are supported by social cognitive theory, with a focus on motivation and self-efficacy for weight management and reducing relapse. Key techniques include goal setting, self-monitoring, recruiting social support, and positive reinforcement. Weight management groups are led by consultants who receive standardised training overseen by Slimming World dieticians 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 two 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. Slimming World 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 two 'holiday' weeks within the 12 group offer.

Women from both groups will be asked to attend an appointment with the Research Midwife (which could take place at the study site or the woman's home, according to the woman's preference) at 6 and 12 months postnatally to be weighed. Women will be able to complete follow up questionnaires at these appointments if they would prefer to do so, or can complete and return by post. Travel costs and costs of a £10 Love2Shop voucher to thank women for their time to complete study questionnaires will be offered.

Intervention Type
Behavioural

Primary outcome measure
Weight is measured at baseline (first antenatal appointment) and 12 months postnatally.

Secondary outcome measures
1. Dietary intake is measured using The Dietary Instrument for Nutritional Education (DINE) at baseline (36 weeks gestation), and 6 and 12 months postnatally
2. Physical activity is measured using The International Physical Activity Short-Form' at baseline (36 weeks gestation), and 6 and 12 months postnatally
3. Mental health is measured using Edinburgh Postnatal Depression Scale 6 and 12 months postnatally
4. Breastfeeding intent, uptake, and duration is measured using questions developed specifically for the study at baseline (36 weeks gestation), and 6 and 12 months postnatally
5. Sleep patterns are measured using using questions developed for the study 6 and 12 months postnatally
6. Smoking status/cigarette dependence is measured at baseline (36 weeks gestation), and 6 and 12 months postnatally
7. Alcohol consumption is measured using Alcohol Use Disorders Identification Test at baseline (36 weeks gestation), and 6 and 12 months postnatally
8. Self-esteem is measured Rosenberg Self-Esteem Scale 6 and 12 months postnatally
9. Infant health is measured questions specifically developed for the study 6 and 12 months postnatally
10. Impact on body image is measured 6 and 12 months postnatally
11. Resource utilisation and costs outcome measures are measured using the EQ-5D-5L and the Adult Service Use Schedule at baseline (36 weeks gestation), and 6 and 12 months postnatally

Overall study start date
01/12/2015

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Women overweight (BMI 25–29.9 kg/m²) or obese (BMI ≥30 kg/m²) as identified as their first antenatal contact
2. Women with excessive GWG when weighed at 36 weeks gestation, as defined using IoM criteria at risk of postnatal weight retention
3. Aged 18 and over

4. Speak and read English
5. Are expecting a single baby
6. Have not accessed weight management groups in the index pregnancy

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
190

Total final enrolment
193

Key exclusion criteria
1. <18 years old
2. Insufficient understanding of spoken and written English
3. Current diagnosis of major psychiatric disorder documented
4. Fetus has known abnormality
5. Involvement in another postnatal study
6. Identified medical complications (for example cardiac disease, type 1 diabetes)
7. Identified eating disorders=
8. Previous surgery for weight management
9. Multiple pregnancy

Date of first enrolment
15/11/2016

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Road

London
United Kingdom
SE1 7EH

Sponsor information

Organisation
King's College London

Sponsor details
Research Management Office
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SE1 4UL.

Sponsor type
University/education

Website
www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication of study protocol and results papers
2. Planned submission of abstracts for conference presentations including presentation at the Royal College of Midwives conference in 2017 and the British Maternal and Fetal Medicine Society conference in 2018

2019 results in University of Surrey report http://epubs.surrey.ac.uk/852449/

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/10/2019	04/11/2019	Yes	No
Results article	results	05/12/2019	10/08/2020	Yes	No
Results article		01/08/2020	14/06/2023	Yes	No
Results article		21/07/2020	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No