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# A community lifestyle programme to improve the well-being of pregnant women with a body mass index (BMI) of 30 kg/m^2 or more

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 09/03/2010 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 22/04/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/07/2016 | Pregnancy and Childbirth | |

**Plain English summary of protocol**
Not provided at time of registration

## 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 community lifestyle programme to improve the well-being of pregnant women with a body mass index (BMI) of 30 kg/m^2 or more: a feasibility study

### Study objectives
The primary outcome of this study is to examine the feasibility of a 10-week lifestyle programme for pregnant women with a BMI of 30 kg/m^2 or more. Secondly, information will be provided regarding the influence of attendance at an antenatal 10-week lifestyle programme on women's physical, emotional and psychological wellbeing and weight gain.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. South Manchester NHS Research Ethics Committee (REC), 10/08/2009, ref: 09/H1003/80
2. The University of Manchester Ethics Committee, 14/09/2009, ref: 09142

### Study design
Feasibility study using mixed-methods of data collection

### Primary study design
Interventional

### Secondary study design
Non randomised study

### Study setting(s)
Community

### Study type(s)
Quality of life

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

### Health condition(s) or problem(s) studied
Weight gain during pregnancy

### Interventions
Women will be recruited to the study as soon after their booking appointment as possible (after 12 weeks gestation). They will be invited to attend a 10-week community lifestyle programme before 30 weeks gestation. The programme will be provided as a supplement to standard antenatal care. The programme is multi-faceted (addresses physical activity, healthy eating and emotional well-being), aimed at equipping participants with the skills and knowledge needed to

adopt healthy behaviours. The programme runs for one and a half hour a week for 10 weeks. The women are given questionnaires to complete at baseline, the start of the 10-week programme, the end of the 10-week programme and at 4 - 6 weeks post-partum. They are invited to a follow-up focus group at 4 - 6 weeks post-partum. The women are also asked to complete a daily diary from recruitment to the follow-up focus group.

### Intervention Type
Behavioural

### Primary outcome measure
1. Weight gain during pregnancy, weighed at booking and at the end of the pregnancy
2. Pregnancy outcome data (e.g., birth weight and mode of delivery), measured at end of the pregnancy

### Secondary outcome measures
1. Psychological outcomes including self-efficacy, well-being and goal attainment: measured at four timepoints in questionnaire (baseline, start of the 10-week programme, end of the 10-week programme and 4 - 6 week postpartum follow-up)
2. Women's experience of pregnancy and health care services: measured at four timepoints in questionnaire (baseline, start of the 10-week programme, end of the 10-week programme and 4 - 6 week postpartum follow-up) and daily diary from recruitment to 1 - 6 weeks postpartum
3. Amount of physical activity: measured at four timepoints in questionnaire (baseline, start of the 10-week programme, end of the 10-week programme and 4 - 6 week postpartum follow-up) and daily diary from recruitment to 1 - 6 weeks postpartum
4. Food intake: measured at four timepoints in questionnaire (baseline, start of the 10-week programme, end of the 10-week programme and 4 - 6 week postpartum follow-up) and daily diary from recruitment to 1 - 6 weeks postpartum
5. The suitability and acceptability of the intervention components: measured post-programme in the end of programme questionnaire and post-partum follow-up questionnaire and focus group

### Overall study start date
01/09/2009

### Completion date
01/08/2012

## Eligibility

### Key inclusion criteria
1. Female aged 18 years or over
2. Pregnant
3. Booking BMI of 30 kg/m^2 or more
4. Patient at Royal Bolton or Royal Oldham Hospital

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
400

### Key exclusion criteria
1. Booking BMI of less than 30 kg/m^2
2. Aged under 18 years
3. Intend to move in the next three months
4. Take weight control medication
5. Have been advised by a Health care professional to not take part in physical activity during their pregnancy
6. Have any cautions for starting exercise (using the Revised Physical Activity Readiness Questionnaire [PARQ]) and the Royal College of Obstetricians and Gynaecologists [RCOG])

### Date of first enrolment
01/09/2009

### Date of final enrolment
01/08/2012

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Manchester**
Manchester
United Kingdom
M13 9PL

## Sponsor information

### Organisation
University of Manchester (UK)

### Sponsor details

Oxford Road
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**Sponsor type**
University/education

**Website**
http://www.manchester.ac.uk/

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Government

**Funder Name**
Department of Health (UK) - Innovation, Excellence and Service Fund

**Funder Name**
Department for Children, Schools and Families (DCSF) (UK) - Children, Young People and Families Fund

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 27/05/2010 | | Yes | No |
| Results article | results | 01/02/2015 | | Yes | No |