# 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 [ ] Statistical analysis plan Registration date Overall study status 22/04/2010 Completed [X] Results [ ] Individual participant data Last Edited Condition category Pregnancy and Childbirth 28/07/2016

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

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# Additional identifiers

Protocol serial number

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<sup>2</sup> 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<sup>2</sup> 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

## Study type(s)

Quality of life

## 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(s)

- 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

## Key secondary outcome(s))

- 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

## 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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

#### Sex

Female

## Key exclusion criteria

- 1. Booking BMI of less than 30 kg/m<sup>2</sup>
- 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**United Kingdom

England

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

# Sponsor information

## Organisation

University of Manchester (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**

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?
Results article	results	01/02/2015	Yes	No
Protocol article	protocol	27/05/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes