

A community lifestyle programme to improve the well-being of pregnant women with a body mass index (BMI) of 30 kg/m² or more

Submission date 09/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/04/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 28/07/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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/m² 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/m² 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/m² 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/m²
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

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