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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

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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