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Effectiveness of regular weighing and feedback by community midwives in preventing excessive gestational weight gain

Submission date	Recruitment status	[X] Prospectively registered
29/10/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/10/2020	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Sue Clifford

Contact details
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
S.Clifford@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17504

Study information

Scientific Title
Effectiveness of regular weighing and feedback by community midwives in preventing excessive gestational weight gain: a randomised controlled trial (POPS 2)

Acronym
POPS2

Study objectives
During pregnancy many women gain too much weight because they do less physical activity and eat more food. This can lead to complications for the mother during pregnancy and it can also negatively affect the health of the baby. Weight gained during pregnancy which is not lost afterwards could lead to women becoming obese or starting subsequent pregnancies in an unhealthy weight state. There is a need therefore to evaluate interventions to prevent women gaining excessive weight during pregnancy. The ideal health professionals to help women do this are community midwives since they see women regularly throughout pregnancy and their role is to promote good outcomes for mother and baby. 490 women who are having a pregnancy without complications being cared for by community midwives will be eligible. Women will be randomised to receive usual care from their midwife or usual care plus the intervention. The intervention is led by community midwives who will regularly weigh pregnant women at routine antenatal visits, plot their weight on a weight gain chart, set parameters for healthy weight gain for each subsequent appointment, provide feedback on weight gain progress and encourage women to weigh themselves each week. Brief messages about the importance of eating healthily and physical activity during pregnancy Regular weighing of pregnant women by community midwives is not currently recommended in the UK. However our feasibility study has shown this type of intervention to be promising in preventing excessive weight gain during pregnancy and it does not cause women to become anxious. Weight will be measured at 10-14 weeks and 38 weeks of pregnancy to determine if they have gained excess weight. We also plan to interview up to 30 women and 30 community midwives about their experiences of participating in the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/1134; First MREC approval date 02/10/2014

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care, Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics), Reproductive health and childbirth; Disease: Reproductive Health & Childbirth, All Diseases

Interventions
Women will be randomised to receive usual care from their midwife or usual care plus the intervention.

Intervention:
1. Self-monitoring -The intervention will actively engage women in self monitoring by recording their weekly weight on a record chart.
2. Weighing - Community midwives will weigh women at each antenatal appointment and plot their weight on an IOM weight gain chart, appropriate to their BMI, set a maximum weight gain limit for each subsequent appointment, and give brief feedback on their progress emphasising the importance of healthy weight gain.
Follow Up Length: 7 month(s)

Intervention Type
Behavioural

Primary outcome measure
Proportion who exceed IOM guidelines for pregnancy weight gain. Timepoint(s): 38 weeks of pregnancy

Secondary outcome measures
1. Difference in change in weight from baseline to 38 weeks of pregnancy between groups. Timepoint(s): 38 weeks of pregnancy
2. Difference in change in weight gain per week of pregnancy between groups.Timepoint(s): 38 weeks of pregnancy.
3. Differences in changes in psychological health, QoL, physical activity and diet quality. Timepoint(s): 38 weeks of pregnancy
4. Maternal and neonatal complications. Timepoint(s): After birth of baby

Overall study start date
01/11/2014

Completion date
30/08/2015

Eligibility

Key inclusion criteria

1. Aged at least 18 years
2. Between 10+0 and 14+6 weeks of pregnancy.
3. Low risk singleton pregnancy.
4. BMI =18.5 kg/m2 receiving community midwife led care

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 490; UK Sample Size: 490; Description: SS incorporates 20% loss to follow up.

Total final enrolment
656

Key exclusion criteria
1. Obese women receiving consultant led care.
2. Unable to understand English or provide informed consent.
3. Women who are attending a weight management programme (i.e. Slimming World) whilst pregnant.
4. Current severe mental illness, known history of eating disorders or dependent on illicit drugs or alcohol.

Date of first enrolment
01/11/2014

Date of final enrolment
30/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR CLAHRC-Oxford; NIHR CLAHRC-West Midlands; NIHR School for Primary Care Research

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	05/02/2016		Yes	No
Results article	results	17/09/2019	15/10/2020	Yes	No
HRA research summary			28/06/2023	No	No