

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

Submission date 29/10/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 29/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/10/2020	Condition category Pregnancy and Childbirth	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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
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England
United Kingdom
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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