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Preventing excessive weight gain in pregnant women

Submission date	Recruitment status	[X] Prospectively registered
22/03/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/03/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2017	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
11931

Study information

Scientific Title
Preventing excessive weight gain in healthy and overweight pregnant women

Study objectives
Gaining too much weight during pregnancy can have many negative effects, including gestational diabetes and complications when the baby is delivered. Many pregnant women gain more weight than they should during pregnancy. Studies have shown that many women reduce their physical activity and consume a more liberal diet during and after pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 12/WM/0059

Study design
Randomised interventional prevention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Reproductive Health & Childbirth

Interventions
1. Dietry
2. Education or Self-Management

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of the intervention to community midwife.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2012

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Low risk pregnant women receiving community midwife led/shared care
2. Aged at least 18
3. Within healthy or over weight BMI ranges (1830 kg/m2) at the 5/6 week gestation appoinment and scan/booking visit (12 - 14 weeks gestation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
UK Sample Size: 90

Key exclusion criteria
1. Obese women (BMI =30 (kg/m2) - as the focus is primary prevention and because obese women are deemed high risk and typically receive consultant led care.
2. Other women deemed high risk by the CMW at the booking appointment will not be invited to take part (e.g. more than one foetus, history of complications, preexisting chronic illness etc).
3. If a woman is deemed high risk at any time after the booking visit, the CMW will determine whether it is appropriate for her to continue in the study, but where possible we will try to retain them.

Date of first enrolment
01/06/2012

Date of final enrolment
01/10/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Birmingham
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
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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	16/09/2015		Yes	No