# Preventing excessive weight gain in pregnant women

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
22/03/2012		☐ Protocol		
Registration date 22/03/2012	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

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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 B15 2TT

# 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