

Pregnant women Community-based Activity and Nutrition programme (CAN)

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| Submission date 10/12/2009 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 05/02/2010 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 13/04/2017 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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SE 1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RJ109/N215

Study information

Scientific Title

Piloting and evaluating a community-based programme for obese pregnant women: a single-centre randomised controlled trial

Acronym

CAN

Study objectives

A combined community-based intervention with dietary and physical advice combined with behavioural support will alter dietary and exercise behaviour in obese pregnant women which will result in improved glucose homeostasis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service King's College Hospital Research Ethics Committee, 19/09/2009, ref: 09/H0808/49

Study design

Randomised controlled single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Maternal obesity

Interventions

The programme will commence at 16-20 weeks and last for approximately 20 weeks. The total duration of follow-up will be up to 6 months post-delivery.

The components are as follows:

At the group sessions healthy eating topics will include:

1. Low glycaemic index food which is patient and culturally focused
2. Fruits and vegetables
3. Reduced saturated fat intake
4. Food label reading

5. Portion sizes
6. More often rather than three big meals a day
7. Reduced sugar intake (especially sugar-rich beverages)
8. Supermarket tour
9. Basic cooking skills and recipe try-outs

Physical activity:

A menu of exercise choices, based on the participant's wishes and local availability will be offered. A participant will be able to choose, for example, weekly exercise sessions (land-based low impact exercise such as cycling and dancing and water-based exercise such as swimming and aqua-aerobics) which are provided in Lambeth by such organizations as Aqua_Natal and Sport England. Group exercise sessions will be fun, structured and non-competitive. For those that prefer exercising alone, walking is one of the menu options as the means to achieving agreed personal goals.

Postnatal women will be referred onto existing and well-established resources in the Children's Centres including breastfeeding cafés, mother and baby exercise classes and baby massage courses.

Behavioural change:

This psychology-based component will help women to change lifestyle through both one-to-one and group-based motivational sessions using a solution and problem-solving approach.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Glucose tolerance test at 28 weeks gestation

Secondary outcome measures

1. Total daily physical activity at 28 and 36 weeks measured by accelerometry and by self-reported duration of strenuous, moderate and mild physical activity and sedentary daily hours at 28 and 36 weeks
2. Diet at 28 and 36 weeks as assessed by structured questionnaire and 4-day diary at recruitment, 28 and 36 weeks
3. Attitudes towards diet and physical activity in pregnancy (the ADAPT questionnaire) will assess knowledge, perceived benefits and barriers, self-efficacy, motivation, social norms and attitudes
4. Other outcomes include: gestational diabetes, pre-eclampsia and severe pre-eclampsia, caesarean section (elective, emergency) and reasons for section, induction of labour, blood loss at delivery (ml), birth weight, prematurity, death (stillbirths and neonatal deaths up to 28 days), gestational age at delivery, placental weight, inpatient nights (antenatal and total), breastfeeding initiation rates and smoking cessation rates
5. 36-item short form health survey (SF-36) health status measure for assessment of costs per quality assured life years (QALYs), depression/anxiety score by Hospital Anxiety and Depression Scale, questionnaire and medical record data for evaluation of costs of intervention and healthcare costs
6. We shall also obtain the follow information at 6 months of age in the child:

- 6.1. Breastfeeding history questionnaire
- 6.2. Age at weaning
- 6.3. Weight gain at 28 weeks, 36 weeks and 6 months post-delivery

Overall study start date

01/02/2010

Completion date

31/01/2012

Eligibility

Key inclusion criteria

- 1. Pregnant women with a singleton pregnancy (14-16 weeks' gestation; 16 - 45 years)
- 2. Attending participating centre
- 3. Booking body mass index (BMI) greater than 30 kg/m²
- 4. No previous history of diabetes*
- 5. Currently not receiving anti-hypertensive medication
- 6. Fraser competence has been sought for those less than 18 years

*Women in whom Gestational Diabetes Mellitus (GDM) is diagnosed in the course of routine clinical care will remain in the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

200 obese pregnant women

Key exclusion criteria

- 1. Inability and unwilling to provide informed consent
- 2. Multiple pregnancy
- 3. Women currently receiving treatment for diabetes (including dietary control) or hypertension
- 4. Chronic underlying renal disease, lupus, antiphospholipid syndrome (APS)
- 5. Confirmed abnormal foetal karyotype

Date of first enrolment

01/02/2010

Date of final enrolment

31/01/2012

Locations

Countries of recruitment

United Kingdom

Study participating centre

Women's Health

London

United Kingdom

SE 1 7EH

Sponsor information

Organisation

Guy's and St Thomas' Charity (UK)

Sponsor details

First Floor, Counting House

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

Sponsor type

Charity

Website

<http://www.gsttcharity.org.uk/>

ROR

<https://ror.org/02p7svq74>

Funder(s)

Funder type

Charity

Funder Name

Guy's and St Thomas' Charity (UK) (ref: G081008)

Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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