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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 10/12/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 05/02/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 13/04/2017 | Nutritional, Metabolic, Endocrine | [ ] 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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## Additional identifiers

**Protocol serial number**
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

## Study type(s)
Quality of life

## 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(s)
Glucose tolerance test at 28 weeks gestation

### Key secondary outcome(s)
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

### 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/m^2

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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### 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)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration