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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

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/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

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