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Hypnotherapy for adherence to nutritional and physical activity recommendations during pregnancy in obese pregnant women: feasibility of an intervention

Submission date
18/02/2011

Recruitment status
No longer recruiting

Registration date
28/04/2011

Overall study status
Completed

Last Edited
28/04/2011

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

N/A

Study information

Scientific Title
Hypnotherapy for adherence to nutritional and physical activity recommendations during pregnancy in obese pregnant women: feasibility of an intervention, a randomised controlled trial

Study objectives
Obesity exposes mother and foetus to higher risks of perinatal complications. Institute of Medicine (IOM) recently suggested that obese women gain between 5 and 9 kg during pregnancy. Almost 30% of pregnant women are overweight and 60% of them had a gestational weight gain (GWG) that did not meet IOMs recommendations. Weight gain during pregnancy over the recommended values exposes the mother and her infant to higher risks for perinatal adverse outcomes independently of the body mass index (BMI), such as diabetes or large for gestational age infants. Lifestyle interventions might improve nutritional habits and the practice of physical activity during pregnancy. Psychological interventions have to be targeted to elicit effective responses to intervention programs. Cerebral structures act as a network to influence feeding behaviour and appetite control. A hypnotherapy intervention was thus developed to enhance motivation and adherence to healthy lifestyle habits (i.e. healthy nutrition and physical activity) during pregnancy in obese pregnant women.

Hypnotherapy is a promising tool for inducing changes in attitudes and perceptions in the management of eating disorders. By increasing self-esteem, self-efficacy and resilience, it may assist pregnant obese women with integrating healthy behaviours in a meaningful way in order to achieve successful perinatal outcomes. We hypothesised that a standardised hypnotherapy intervention for obese women during pregnancy will enhance motivation and adherence to nutritional and physical recommendations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Clinical Research, University Hospital Centre of Quebec ((Comite d'ethique de la recherche clinique du Centre Hospitalier Universitaire de Quebec) approved on 22nd April 2009, reference number:129.05.07(5-09-03-04)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Gestational obesity

Interventions
If the woman is randomised in the hypnosis group, she will receive four sessions of hypnotherapy (weeks 16, 18, 20 and 24). She is also given the option to attend two additional hypnotherapy sessions at weeks 27 and 32. Each session is delivered individually, lasting between 30 to 40 min in duration and is provided by one experienced hypnotherapist who reliably mastered all key elements of the intervention after training and observation. The intervention protocol is standardised in a manual for all six sessions. A written script is read to the participants.

If the woman is randomised in the control group, she does not receive any hypnotherapy session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Physical activity level as assessed by the Pregnancy Physical Activity Questionnaire (PPAQ) in the previous month (baseline, 25-26 weeks of gestation, and 35-36 weeks of gestation)
2. Total energy intake as assessed by a food frequency questionnaire in the previous month (baseline, 25-26 weeks of gestation, and 35-36 weeks of gestation)

Secondary outcome measures
1. Gestational weight gain
2. Birth weight
3. Adherence to the programme
4. Satisfaction with the programme

Overall study start date
24/07/2009

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Pregnant women, aged more than or equal to 18 years, with an intra-uterine pregnancy of < 15 weeks of gestation
2. Single foetus

3. Body mass index > 29 kg.m-2
4. Signature of consent form for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Women with an antenatal diagnosis of chronic hypertension, diabetes or renal insufficiency
2. Women taking antidepressants
3. Women who received a verbal notification from their physicians about a medical or obstetrical contraindication for exercise

Date of first enrolment
24/07/2009

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Canada

Study participating centre
2705 boul. Laurier
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Sponsor information

Organisation
University Hospital Centre of Quebec (CHUQ) (Canada)

Sponsor details
Centre Hospitalier de l'Université Laval (CHUQ)
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Sponsor type
University/education

ROR
https://ror.org/006a7pj43

Funder(s)

Funder type
University/education

Funder Name
Foundation of Stars (Fondation des Etoiles) (Canada)

Funder Name
Hospital Centre of Laval University (CHUL) (Centre Hospitalier de l'Universite Laval)(CHUL) (Canada)

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