

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

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<b>Registration date</b> 28/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/04/2011	<b>Condition category</b> Pregnancy and Childbirth	<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

### Contact name

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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<sup>-2</sup>
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

Quebec

Canada

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**Sponsor information****Organisation**

University Hospital Centre of Quebec (CHUQ) (Canada)

**Sponsor details**

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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'Université 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