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The Maternal Obesity Management (MOM) Trial: lifestyle intervention during pregnancy to minimize downstream obesity in mother and child - a Pilot Study

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12/08/2009

Registration date
28/08/2009

Last Edited
06/01/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] 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

Protocol serial number
OTG88590

Study information

Scientific Title
Lifestyle intervention during pregnancy to minimize downstream obesity in mother and child: a single centre randomised controlled pilot trial with a two-arm, parallel-group design

Acronym
The MOM Trial Pilot Study

Study objectives
Primary Research Questions:
To determine the effects of a structured prenatal physical activity and nutrition intervention provided to overweight/obese pregnant women during their 2nd and 3rd trimester on gestational weight gain and infant birth weight.

We hypothesise that women in the intervention group will experience less gestational weight gain and give birth to fewer macrosomic offspring than those in the control group.

Secondary Research Questions:
What are the effects of a structured prenatal physical activity and nutrition program provided to overweight/obese pregnant women during their 2nd and 3rd trimester on:
1. Meeting Institute of Medicine (IOM) weight gain guidelines
2. Post-partum weight retention and body composition (dual energy x-ray absorptiometry [DEXA], body mass index [BMI], hip and waist circumference)
3. Pregnancy related complications (gestational diabetes, pre-eclampsia, instrumental delivery, caesarean section, Neonatal Intensive Care Unit [NICU] admission, foetal distress, low APGAR scores)
4. Maternal biomarkers (glucose, insulin, HbA1c, insulin-like growth factor binding protein 1 [IGFBP-1], adiponectin, cortisol, leptin, C-reactive protein [CRP])
5. Psychosocial functioning (stress, social support, depression, attitudes)
6. Maternal physical activity and dietary habits
7. Longitudinal infant/child body composition (BMI and sum of skin folds-measured at 3 months, 6 months, 1 year and 2 year)

We hypothesise that those randomised to the intervention group will have a higher physical activity level, have better dietary habits as measured by caloric consumption and specific macronutrient breakdown, have fewer pregnancy related complications, fewer biomarkers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Children's Hospital of Eastern Ontario Research Ethics Board approved on the 28th May 2009 (ref: 09/03E)
2. Ottawa Hospital Research Ethics Board approved on the 13th July 2009 (ref: 2009014-01H)
3. University of Ottawa Research Ethics Board approved on the 6th August 2009 (ref: H07-09-06)

Primary study design
Interventional

Study design
Randomised single centre two-arm parallel group controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Maternal obesity and offspring health

Interventions
Standard Care Control Group:
Those women randomised to standard care will receive the normal prenatal care as recommended by their health care practitioner and Health Canada's "A Sensible Guide to a Healthy Pregnancy" booklet.

Intervention Group:
These women will receive a Healthy Gestation Workbook that will provide background regarding the dangers of maternal obesity and excessive gestational weight gain, outline the weight gain guidelines, provide helpful suggestions, recipe ideas and contain 'tear-out' food record and physical activity log forms. They will also participate in a nutrition and physical activity component:

Nutrition component:
In addition, this group will receive nutritional guidance and counselling designed by our inter-disciplinary team of professionals including physiologists, nutritionists, physicians, endocrinologists, perinatal specialists, psychologists and a knowledge translation expert. We have attempted to combine the very personalised, and successful individual counselling approach employed previously, with a more economical group approach that includes sessions lead by health professionals as well as a regular mail-out campaign.

Programs to prevent progression of obesity generally offer nutritional counselling that recommends monitoring current eating habits and that addresses the importance of negative eating behaviours (limiting portion sizes and consumption of high energy dense foods) while introducing appropriate food choices. Selection of healthy, well-balanced foods with low energy density, not energy restriction, will be encouraged in our study population. Our strategy will include nutritional assessment, counselling sessions with a registered dietitian, and nutrition education classes.

All intervention subjects and their partner, if applicable, will have a baseline session with a dietitian immediately after recruitment (beginning of 2nd trimester). The dietitian will discuss weight and diet history, fast food consumption, current eating habits and will emphasise the nutritional guidelines and healthy weight gain trajectories (goals) as recommended by Health Canada's nutritional guidelines for pregnancy and postpartum and Canada's Food Guide for Healthy Eating. Each subject will also be taught how to keep a 3-day food record. These 7-day records will be collected, reviewed by the dietitian, and analysed at baseline, and every 4 weeks thereafter, with the ESHA Food Processor SQL dietary analyses software, using the 2007 Canadian Nutrient File.

The study nutrition staff will use the participant's measured daily caloric need (resting energy expenditure) determined by indirect calorimetry, in combination with food records to plan a dietary strategy in order to ensure diet adequacy. Dietary goals will be established by the women in collaboration with the dietitian (e.g. have breakfast each morning, switch to water or milk instead of soft drinks, have fresh fruit and/or vegetables with every meal etc.). Since dietary guidelines do not currently exist for overweight or obese pregnant women and Canada's

prenatal guidelines are currently under review, we will support the recommendation of Artal et al., reinforced by the work of Butte et al. indicating that, in normal weight and overweight women, a small caloric increase is needed during the 2nd and 3rd trimester of pregnancy equivalent to about 300 kcal/d over non-pregnant values. In keeping with the evidence indicating that raising the protein content of the diet from 15% up to 20% - 30%, at the expense of carbohydrates, increases the satiating effect of the diet and interacts with exercise to improve lean mass retention, our specific advice regarding macronutrient distribution will be as follows: 20% of energy derived from protein, 50% from carbohydrates, emphasising fruit and vegetable intake as well as whole grain and high fibre, and 30% from fat and eating plan deemed easy to maintain and that ensures the fetus will not be deprived of nutrition. Frequent visits and reminders foster good compliance rates which are a predictor of success in weight management, thus group-nutrition education classes will be scheduled each month over the course of participation. These group education classes, specifically geared towards healthy dietary behaviours during pregnancy, will be offered in the form of 3 modules (transition between 1st and 2nd trimester, transition between 2nd and 3rd trimester and mid 3rd trimester) that will take place following one of the weekly exercise sessions and be delivered by Master's level staff or doctoral candidates in nutrition. In addition, participants will also receive a post-card mail-out every 4 weeks reviewing their nutritional needs at that stage of pregnancy (7 in total) and reinforcing their goals. A final personalised session with the dietitian will take place at the beginning of the 3rd trimester.

Physical Activity component:
Energy expenditure is an important weight management strategy for all populations and thus women randomised to the intervention arm will be expected to attend 2, 45 - 60 minute (including warm-up and cool-down) supervised exercise classes each week during their 2nd and 3rd trimester of pregnancy. Safe and specifically designed exercise classes for pregnant women will be offered that incorporate the evidence-based SOGC/CSEP Canadian National Guidelines for Exercise during pregnancy and post-partum. These classes, lead by CSEP-certified exercise physiologists (CEP) with a specialization in maternal health will be offered through the Ottawa University - Lees Ave campus. Classes will incorporate both aerobic and resistance exercises, that minimize the risk of loss of balance and fetal trauma, as recommended by the clinical practice guidelines. The American College of Obstetricians and Gynecologists guidelines suggest that women exercise at or below 70% of their maximal heart rate (HR). Since pregnancy is associated with an 10 to 15 bpm increase in resting HR and blunted HR response to maximal exercise, our participants will be instructed on how to monitor HR and be encouraged to stay within age-specific, modified target zones. These range from 125 to 155 bpm. In addition, women will be encouraged to perform 30 minutes of aerobic activity (i.e. walking), independently, at least 3 other days/wk thereby meeting the physical activity guidelines of 30 min or more of moderate intensity physical activity on most, if not all, days of the week.

All nutrition and exercises classes will be offered in the evenings.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Gestational weight gain will be calculated by subtracting weight at the first prenatal visit in the first trimester from weight at her last prenatal visit before delivery. This will be logged as an

absolute value. We will also record the average weekly weight gain to account for the variable length of the observation period (i.e., gestational age at recruitment and delivery).
2. Infant birth weight (grams) will be obtained from obstetrical records and recorded as a continuous variable in grams and further categorised as:
2.1. Small for gestational age (less than 10th percentile)
2.2. Normal for gestational age
2.3. Large for gestational age otherwise known as macrosomia (birth weight greater than 90th percentile), based on weeks gestation

Key secondary outcome(s)

1. GWG will be further categorised as gaining less than recommended, the recommended amount, or more than recommended according to the IOM gestational weight gain guidelines. For obese women, the upper limit of the recommended range will be set at 11.5 kg. Weight will also be measured at the end of each trimester over the course of the intervention to monitor the pattern of weight gain.
2. Data on other complications during pregnancy or delivery will be obtained as recorded at prenatal visits and from obstetrical records during delivery:
2.1. Gestational Diabetes (Yes or No) will be defined as an abnormal glucose tolerance test (2-hour 75 g glucose tolerance test [GTT] after fasting with sampling at 0 hours, 1 hour and 2 hours) following initial screening collected through prenatal obstetrical records
2.2. Pre-eclampsia (Yes or No) will be defined as: systolic blood pressure greater than 140 mm Hg or diastolic greater than 90 mm Hg on at least two readings and/or the presence of HEELP syndrome (haemolysis, elevated liver enzymes, and lowered platelets)
2.3. Instrumental delivery collected through obstetrical records (vacuum, forceps etc.)
2.4. C-section collected through obstetrical records (yes or no, scheduled or emergent)
2.5. NICU admission collected through obstetrical records
2.6. Foetal distress collected through obstetrical records
2.7. Low APGAR (less than or equal to 3 at 5 minutes) scores collected through obstetrical records
3. Biomarkers: As it is exceptionally difficult, and in most cases not possible to actually measure the intrauterine environment in humans we will take blood samples, at study intake and at the end of each trimester, to measure biomarkers as surrogates of intrauterine environment. Foetal growth is largely determined by nutrient transfer across the placenta, which is dependent on maternal nutrient levels and placenta transport capacity. Hormones such as insulin, leptin, and insulin-like growth factor-1 (IGF-1) have been shown to stimulate nutrient transport. Earlier than expected changes in hormones associated with maternal metabolism or dietary intake in OW/OB pregnant women may have marked effects on foetal growth trajectory. We will measure markers related to glucose homeostasis, fat mass, nutrient transport, inflammation and stress since preliminary research has identified the role of these variables in pregnancy and outcomes related to obesity:
3.1. Glycosylated hemoglobin (HbA1c) reflects the mean concentration of blood glucose over the previous 2 - 3 months
3.2. Insulin resistance is estimated using the homeostatic model assessment (HOMA) formula, which calculates insulin resistance based on the fasting plasma glucose and insulin. The HOMA model is a structured model of the glucose-insulin feedback system in the homoestatic (overnight-fasted) state.
3.3. Insulin-like growth factor binding protein-1, which binds and modulates the activities of IGF-1 and IGF-2, is thought to upregulated placental nutrient transport. Serum levels are associated with birthweight and pre-eclampsia.
3.4. Cortisol is a hormone involved in glucose metabolism and appetite regulation but is also involved in the stress response

3.5. Leptin circulates at levels proportional to fat mass and provides input to the brain regarding energy storage so it can regulate appetite and metabolism and has been linked to placental nutrient transport
3.6. Adiponectin is produced by the adipocyte, is inversely related to fat mass, has anti-inflammatory properties and influences the body's response to insulin
3.7. C-reactive protein (CRP) is a marker of inflammation and elevated levels are common in diabetes and obesity. CRP level is a very strong independent CVD risk factor in women and if elevated during pregnancy is a predictor of increased atherogenesis in offspring. Research indicates that endurance training reduces CRP.
4. Physical activity level will be measured both directly and indirectly. Accelerometers will be used to collect objective, reliable and accurate measures of physical activity. The 7 Day Physical Activity Recall (7 Day-PAR), a valid self report measure of physical activity and sedentary behaviour in women will also be used to assess PA. This tool will be used to specify what type of activity participants are doing when they are active and how they are spending their time in sedentary behaviour in their natural environment.
5. Dietary habits: Resting energy expenditure (REE) will be measured in the HALO lab using indirect calorimetry (Ultima PF/PFX a metabolic system), to predict an individual's daily energy requirements. The determination of daily caloric need is fundamental in nutritional assessment and necessary for helping individuals attain and maintain a healthy body weight. Total calories consumed, calories from snacks and meals, and macronutrient composition (percent of calories from fats, carbohydrates and protein), will be assessed using 7-day food records at study intake and at the end of each trimester.
6. Psychosocial functioning: Although many psychosocial factors may play a role in gestational weight gain, the literature points to four being especially important: stress, social support, depression, and attitudes towards pregnancy. We will measure these variables at study intake and at the end of each trimester.
6.1. Pregnancy experience scale (PES): this 41-item scale measures pregnancy-specific daily hassles and provides the most balanced assessment of stress during pregnancy
6.2. Maternal Social Support Index (MSSI): this scale consists of 24 questions relating to patient's perceptions of daily task-sharing among household members, satisfaction with relationships, availability of emergency help, and degree of community involvement. Total scores range from 0 (low social support) to 19 (high social support).
6.3. The Edinburgh Postnatal Depression Scale (EPDS) is an effective 10 item screening tool used to identify patients at risk for 'perinatal' depression. Respondents are asked how they have been feeling the past 7 days. Items are assessed by scales ranging from "not at all or never" to "most of the time".
6.4. Pregnancy and Weight Gain Attitude Scale is comprised of 18 items, 15 about weight-related attitudes and 3 about behaviours during pregnancy. Responses for each statement range from "strongly disagree" to "strongly agree". Low scores represent a negative attitude toward weight gain in pregnancy, and high scores represent a positive attitude.
7. Post-partum: Maternal variables will measured at 3, 6, and 12 months post-delivery
7.1. Weight retention, calculated as measured weight at follow-up minus pregravid weight, will be measured during a home visit at 3 and 6 months and in the HALO lab at 1 year
7.2. Body composition: body fat, and lean body mass will be measured at the HALO lab at 1 year via DEXA. DEXA is rapidly becoming the clinical method of choice for direct calculation of total fat, lean and bone tissue because of its low radiation dose, speed, ease of application, and superior reproducibility over other non-invasive methods that estimate tissue characteristics. Precautions will be taken to ensure that women are not pregnant prior to undergoing the DEXA.
7.3. Dietary habits (see above)
7.4. Physical activity level (see above)
7.5. Infant feeding practices will be determined by asking the mothers about how long (in weeks) they had fully breastfed their child for, defined as breast milk only without any

supplemental solid foods or liquids other than water. If the mother is still fully breastfeeding, this question is repeated at each subsequent visit (e.g, 6, 12 months) until complementary feeding is initiated.
8. Post-partum: offspring variables will be measured at 3, 6, and 12 and 24 months after birth:
8.1. Offspring height: Infants will be measured crown-heel in the recumbent position to the nearest 1 mm. Weight: infant weight will be measured using an electronic baby scale to the nearest 1 g (less than 3 kg), 2 g (3 - 6 kg), or 5 g (greater than 6 kg). Child growth trajectories and obesity over the 1st year will be calculated using the gender and age- specific (nearest 6 months of age as recommended) BMI cut off points recommended for use in international comparisons of prevalence of overweight and obesity.
8.2. Offspring body composition will be estimated from the sum of skin folds assessed in duplicate at 4 sites on the right side of the body at the biceps, triceps, subscapular, suprailiac to the nearest 0.1 mm with infant skin fold calipers
8.3. Physical activity (self-generated and spontaneous movement) will be measured by placing an activity monitor (Actiwatch®, Respironics/Mini Mitter), that records a digitally integrated measure of gross motor activity via accelerometry, on the right ankle using an ankle band and another Actiwatch® will be placed just above the iliac crest on the infants' right side using hypoallergenic medical tape to hold it in place along with a no alcohol liquid barrier to further decrease chance of irritation. The 24-h activity data will be analyzed to determine the separation of moderate-to-vigorous activity and sedentary-to-light activity, the classification of sleep and wake state for each data point, and the transition points from day to night and night to day.

Completion date
01/09/2011

Eligibility

Key inclusion criteria
Current inclusion criteria as of 03/08/2012:
1. Normal weight, overweight or obese pregnant women (pre-pregnancy BMI greater than 18.5 kg/m2)
2. Aged 18 years or older
3. Known to be carrying a singleton foetus
4. Plans to deliver locally and keep the infant
5. Given medical clearance by their health care provider, based on their PARmed-X for Pregnancy questionnaire

Previous inclusion criteria until 03/08/2012
1. Overweight or obese pregnant primparous (i.e., first-time mothers) women (pre-pregnancy BMI greater than 25 kg/m^2)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
Female

Key exclusion criteria
1. Smokers
2. Have medical conditions that might impact body weight (untreated thyroid disease, insulin treated diabetes, hypertension requiring medication)
3. Have known contraindications to exercise as outlined in the joint Society of Obstetricians and Gynaecologists of Canada (SOGC)/ Canadian Society for Exercise Physiology (CSEP) clinical practice guidelines
4. Present absolute contraindications such as:
4.1. Ruptured membranes
4.2. Preterm labour
4.3. Hypertensive disorders of pregnancy
4.4. Incompetent cervix
4.5. Restricted foetal growth
4.6. Placental previa after 28th week
4.7. Persistent 2nd or 3rd trimester bleeding
4.8. Any serious cardiovascular, respiratory or systemic disorder
5. Presenting the following relative contraindications:
5.1. Second trimester abortion or greater than two abortions
5.2. Moderate/significant cardiovascular or respiratory disorders
5.3. Anaemia (Hb less than 100 g/L)
5.4. Malnutrition/eating disorder
5.5. Twin pregnancy after 28th week
5.6. Any other significant medical condition

Warning signs to terminate exercise while pregnant include vaginal bleeding, significant dyspnoea prior to exertion, dizziness, headache, chest pain, muscle weakness, calf pain or swelling (rule out thrombophlebitis), preterm labour, and amniotic fluid leakage.

Date of first enrolment
01/09/2009

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
Canada

Study participating centre
Children's Hospital of Eastern Ontario
Ottawa, ON
Canada
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Sponsor information

Organisation
Childrens Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

ROR
https://ror.org/05nsbhw27

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (Canada) - Strategic Initiative Obesity and Related Diseases (ref: OTG88590)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2013		Yes	No