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The Blossom Project: Moms2Move (M2M)

Submission date
04/12/2013

Recruitment status
No longer recruiting

Registration date
10/01/2014

Overall study status
Completed

Last Edited
21/08/2015

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Maternal obesity and excessive gestational weight gain (weight gain during pregnancy) cause a continuing 'vicious cycle' of obesity. These obese women or women who gain excess gestational weight have a higher risk of giving birth to large for gestational age infants, who then, years later, can become obese adults entering into their own pregnancies. Many observational studies have supported the role of physical activity (PA) in helping pregnant women to minimize, if not prevent, excessive gestational weight gain (GWG). Since maternal PA has potential to prevent excessive GWG and decrease the risk of delivering large-for-gestational-age (LGA) infants, identifying strategies to help pregnant women increase their PA participation during gestation becomes critical in light of the increasing obesity prevalence for both adults and children. We conducted an initial small study 'Moms to Move' (M2M). The objectives of this study were to promote moderate PA participation among previously non-exercising, overweight and obese pregnant women, and to evaluate the impact of increased moderate PA on GWG and birth outcomes.

Who can participate?
Pregnant women who are overweight or obese.

What does the study involve?
Participants were randomly allocated to the intervention or the control group. The intervention in this study was a walking program. Participants were informed about the current physical activity guidelines, 150 minutes of moderate PA spread through the week, and were given a treadmill for home use. The walking program began no earlier than week 12 and no later than week 15 of gestation and lasted until at least week 35. Depending on the length of each participant's pregnancy, all the intervention participants were able to complete at least 20 weeks of the walking program. All participants reported to the clinical research centre at each of the following time points: weeks 10 - 14, 17 - 19, 27 - 29 and 34 - 36 of gestation. At each gestational data collection time point, body measurements, physical activity measurements with an armband accelerometer and information on diet were collected for one week at a time. Following delivery all participants completed a questionnaire. The questionnaire included pregnancy risks and labor procedures (i.e., use of epidural, cesareansection delivery) as well as infant's birth outcomes. Data regarding the mothers and infants were collected one and six months after delivery. The control group did not receive any intervention materials. They were not told to change their behaviour in any way during the intervention. They were required to

participate in the same assessments/measurements at the same time points as the intervention group.

What are the possible benefits and risks of participating?
Participants may not receive any direct benefit from taking part in this study. We hoped that this research may benefit society by generating data that may contribute to future development of low- cost, effective interventions that can be easily implemented and used to lower the risk of gestational diabetes and obesity for pregnant women. Potential risks of the study were minimal. The study did not provide any foreseeable risks to participants. Blood samples may have been uncomfortable; blood was drawn by an experienced phlebotomist under strict aseptic conditions to minimize pain and infection risk. Participants may have experienced discomfort from fasting overnight for the blood draws. Immediately following the blood draw, participants were offered a snack containing approximately 250 calories. Some individuals experience skin irritation from wearing the armband. There might be risk associated with walking on a treadmill. Participants were provided instructions on how to get on and off treadmills and how to use the safety device.

Where is the study run from?
The study was conducted at the Nutrition and Wellness Research Centre at Iowa State University, Ames, IA, USA.

When is the study starting and how long is it expected to run for?
Recruitment for participants occurred from January 2011 to March 2012. All participants completed the study protocol by June 2013.

Who is funding the study?
The study was funded by Iowa State University (Nutrition and Wellness Research Centre and the College of Human Sciences) (USA).

Who is the main contact?
Lorraine Lanningham-Foster, PhD
lmlf@iastate.edu

Contact information

Type(s)
Scientific

Contact name
Dr Lorraine Lanningham-Foster

Contact details
220 MacKay Hall
Ames
United States of America
50011
+1 (0)515 294 4684
lmlf@iastate.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10-509

Study information

Scientific Title
Early prevention of childhood obesity: Impact of maternal physical activity on pregnancy and child outcomes

Acronym
M2M

Study objectives
The hypotheses were that previously non-exercising, overweight and obese women could increase moderate physical activity (PA) participation during pregnancy via a walking intervention, and those who increased their moderate PA participation would have more favorable pregnancy and birth outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional committees of Iowa State University (Institutional Review Board, ISU IRB Protocol 10-509).
The original ethics/IRB approval date was 07/12/2010. The protocol is still active for data analysis purposes and the most recent approval date was 06/12/2013.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Obesity

Interventions
The intervention in this study was an unsupervised walking program. Immediately after the baseline data collection, women in the intervention group attended a training session. At this session, the women were verbally given the 2008 U.S. Physical Activity (PA) Guidelines, which is to accumulate a minimum of 150 minutes per week of moderate PA during pregnancy. The women were advised to spread their walking throughout the week, such as 30 minutes of walking five days per week. The women were also given permission to walk in shorter bouts; however, they were advised to keep the bouts to at least 10 minutes. Walking could occur indoors, such as walking at the mall, or outdoors, such as walking at the park. To help participants in the intervention group achieve their walking goal, treadmills were provided to use in their homes for the duration of the study and were returned following the completion of the walking program.

The control group did not receive any intervention materials. They were not told to change their behaviour in any way during the intervention. They were required to participate in the same assessments/measurements at the same time points as the intervention group.

There has not been any follow-up for either of the study arms.

Intervention Type
Behavioural

Primary outcome measure
1. Physical activity
2. Weight
3. Pregnancy weight gain

Secondary outcome measures
1. Dietary intake
2. Self-efficacy
3. Infant outcomes (anthropometrics, developmental milestones)

The following measurements were made at baseline (approximately weeks 10-14 of pregnancy): height, weight, body composition (BIA), physical activity (pedometer and accelerometer), diet (3-day weighed diet record).

The following measurements were made at the second study visit (weeks 17-19 of pregnancy): weight, body composition (BIA), physical activity (pedometer and accelerometer), diet (3-day weighed diet record).

The following measurements were made at the third (weeks 27-29 of pregnancy) and fourth (weeks 34-36 of pregnancy) study visits: height, weight, body composition (BIA), physical activity (pedometer and accelerometer), diet (3-day weighed diet record), and self-efficacy (scales for barrier and task self-efficacy).

The following measurements were made at study visit 5 (1 month postpartum): birth weight reported, health outcomes of mother and child (survey), maternal weight, infant anthropometrics (weight, length, body composition using PEA POD), developmental milestones of child (mother report).

The following measurements were made at study visit 6 (6 months postpartum): maternal weight, infant anthropometrics (weight, length, body composition using PEA POD), developmental milestones of child (mother report), maternal self-efficacy (scales for barrier and task self-efficacy).

Overall study start date
15/01/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Participants who were enrolled met the following inclusion criteria:
1. Maternal age between 18-45 years old
2. Singleton pregnancy
3. Non-smoker
4. Self-reported overweight (Body Mass Index [BMI] > 25.0 kg/m2) or obese (BMI > 30.0 kg/m2) prior to pregnancy
5. No prior history of chronic diseases (including type 1 diabetes, cardiovascular disease, thyroid disorder or lung disorder), and no prior history of gestational diabetes.
6. In addition, only women who engaged in less than three times per week of Leisure Time Physical Activity (LTPA) for 30 minutes or more per session, 6-months preceding their enrollment into the study were recruited. Pre-pregnancy PA participation was self-reported (questions in the screening process) and LTPA was defined as activities performed each week beyond normal daily routines.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
40

Key exclusion criteria
Exclusion criteria will be necessary to limit confounding factors of the data which includes:
1. Multiple fetuses (this may not be known at the time of enrollment)
2. History of gestational diabetes
3. Chronic disease
4. Lung or thyroid disorders
5. History of exercising regularly (>3 times per week of moderate exercise for at least 6 months prior to conception)
6. Anyone with a pacemaker or electromagnetic device or using portable oxygen
7. Physical restrictions that would prevent the woman from walking for 30 minutes on most days
8. Inability to communicate due to language or mental status

Date of first enrolment
15/01/2011

Date of final enrolment
01/03/2012

Locations

Countries of recruitment
United States of America

Study participating centre
220 MacKay Hall
Ames
United States of America
50011

Sponsor information

Organisation
Iowa State University (USA)

Sponsor details
College of Human Sciences
E262 Lagomarcino Hall
ISU Campus
Ames
United States of America
50011
-
hswebmaster@iastate.edu

Sponsor type

University/education

ROR
https://ror.org/04rswrd78

Funder(s)

Funder type
University/education

Funder Name
Iowa State University (Nutrition and Wellness Research Center, College of Human Sciences) (USA)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014		Yes	No