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SmartMoms Canada: An evaluation of a pregnancy-specific mobile health application to manage weight gain during pregnancy

Submission date
16/12/2019

Recruitment status
Suspended

Registration date
20/12/2019

Overall study status
Completed

Last Edited
28/12/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Women are entering pregnancy with a greater body weight than any other time in history. Weight-related issues pose important challenges to health professionals, to the health care system, and most importantly to the short and long-term health of mother and child. More than 60% of mothers-to-be exceed gestational weight gain (GWG) guidelines, thereby increasing the risk of both delivering a large-for-gestational-age (LGA) baby and perpetuating the intergenerational cycle of obesity.

This study aims to assess the effectiveness of the SmartMoms Canada mobile health (mHealth) application in helping women adhere to GWG guidelines and improve pregnancy-related complications.

Who can participate?
Healthy pregnant women aged 18 – 40 years, carrying a single fetus.

What does the study involve?
Participating women will be provided with the SmartMoms Canada app to be installed on their mobile device. The SmartMoms Canada app also provides important information through features like 'SmartTips'. These tips will be delivered weekly during the majority of the second trimester, and then bi-weekly during the third trimester. SmartTips include topics such as physical activity, nutritional suggestions (e.g., sample meal plan, vitamin supplementation), sleep recommendations, and psychosocial considerations (e.g. mindfulness, motivation, and peer support). In addition to the SmartTips, the app features an exercise database that includes stretching, warm-up and an extensive list of recommended, safe exercises for women during pregnancy. Also, a list of local physical activity resource centres/facilities (i.e., walking parks) will be displayed by the app to facilitate exercising in the participant's area.

What are the possible benefits and risks of participating?
Participants will have the opportunity to increase their engagement with pre-natal care and ultimately improve maternal-fetal outcomes, which translates in a direct benefit to those

attending to the program. They will also be able to learn more about key health behaviours during pregnancy related to monitoring gestational weight gain, physical activity, eating habits, sleep pattern and stress management. They will receive a Fitbit and the Body+ scale to keep.
The results of this study will help other pregnant women and health care providers in the future with information regarding the app's effectiveness. As the data will be gathered from different sites and language profiles within multiple provinces across Canada, it will be possible to have a more comprehensive view of app's utility. The SmartMoms program will provide insights into what is the most efficient method of providing primary healthcare information to pregnant women nation-wide. Should the app prove effective during these research trials, consideration will be taken to fully release the SmartMoms Canada app to the Canadian public. The app will add pregnancy-health related knowledge to women, leading to an increase in pregnancy-related outcomes and behaviours, and ultimately a reduction in complications for both mom and baby. Providing a mobile health (mHealth) app that can share knowledge for the gestational period with women across Canada without requiring scheduled appointments, can reduce the present economic burden and lead to overall improvement in health.
There is no major risk associated with participating in this study. However, one of the cornerstone features of the application is the Withings/Fitbit/SmartMoms interaction aiming to control gestational weight gain through healthy lifestyle choices (e.g., physical activity, nutrition, sleep) during pregnancy. Although unlikely, there is a risk of falling or muscle soreness for anyone (not just pregnant women) engaging in physical activity. Physical activity performed at higher intensities may cause some negative physical effects (e.g., muscle soreness, muscular or joint stiffness, and/or cramps) or discomfort (e.g., tiredness and/or nausea), especially in those new to exercise routines. This may represent a minor risk to participation.
To minimize this issue, the app was predominantly created using research evidence as support /background to make the app content as safe as possible. That means the physical activities suggested in the app are those recommended specifically for pregnant women following national and international guidelines. Moreover, we strongly advise that any choice to partake in vigorous physical activity throughout pregnancy be done in consultation with one's health care provider to minimize risk and maximize an individual's results according to their needs and preferences.
The app has also been developed to facilitate weight management and thus to track body weight throughout pregnancy. Continuous monitoring may beneficial for weight management, assisting women in staying within the recommended gestational weight gain range based on IOM guidelines. However, it may cause psychological or emotional discomfort, such as anxiety, stress or loss of confidence if reaching the adequate weight gain becomes an issue. To mitigate any of these inconveniences, the SmartMoms Canada app provides participants with information to assist with stress-management and mental health support. As mentioned, it is crucial that participants are also in continuous contact with their prenatal health care provider to communicate any issues related to the app so it can be managed appropriately.
If the Edinburgh Perinatal/Postnatal Depression Scale scores in a range indicative of probable depression or suicide risk, the participant will be immediately referred to a primary care provider and/or specialist.

Where is the study run from?
University of Ottawa (Canada)

When is the study starting and how long is it expected to run for?
January 2019 to November 2020

Who is funding the study?
1. Public Health Agency of Canada
2. Canadian Obesity Network (Obesity Canada)

3. Pennington Biomedical Research Center
4. The Society of Obstretricians and Gynaecologists of Canada
5. Maternal Infant, Child and Youth Research Network of Canada
6. Canadian Society for Exercise Physiology
7. Royal College of Physicians and Surgeons of Canada

Who is the main contact?
1. Dr Kristi Adamo (scientific contact), kadamo@uottawa.ca
2. Kevin Semeniuk (public contact), ksemeniu@uottawa.ca

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
200597-160299

Study information

Scientific Title
SmartMoms Canada: An evaluation of a pregnancy-specific mobile health application to manage gestational weight gain

Study objectives
1. Women provided with the SmartMoms Canada app will be less likely to exceed their GWG recommendations as compared to their standard care comparators (i.e., historical control group) and will experience fewer pregnancy-related complications.
2. Engaging with the SmartMoms Canada app will be feasible, given the ubiquity of smartphone technology and the pervasiveness of wireless networks in North America. We believe the use of Wi-Fi enabled features will support and encourage participants to monitor progress by providing them with easy-to-understand, personalized information about their behaviours and how they match recommendations for health.
3. By using the app and its Wi-Fi enabled devices to measure/track body weight, daily physical activity, sleep, and nutrition, the SmartMoms Canada app will positively impact the adoption of healthful behaviours during pregnancy, and will improve HRQoL and reduce potential symptoms of depression.
4. The SmartMoms Canada app used during pregnancy will positively impact the postpartum period as women will feel motivated to maintain their healthy behaviour and choices during this period as well.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 18/11/2019, University of Ottawa, Office of Research Ethics and Integrity (550 Cumberland Street, Room 154, Ottawa, Ontario, K1N 6N5, Canada; +1 613-562-5387; ethics@uOttawa.ca), ref: H-09-19-4795
2. Approval pending, University of Manitoba (770 Bannatyne Avenue, P126 Pathology Building Winnipeg, Manitoba R3E 0W3 Canada; +1 204 789-3255; bannatynereb@umanitoba.ca)
3. Approval pending, Université de Sherbrooke (2500, boul. de l'Université, Sherbrooke, Quebec J1K 2R1 Canada; +1 819 821-8000; ethique.ess@usherbrooke.ca)
4. Approval pending, Hôpital Montfort (745-A Montreal Road, suite 102-2, Ottawa, Ontario K1K

0T1 Canada; +1 613-746-4621, ext. 2221; email not provided)
5. Approval pending, Dalhousie University (P.O Box 15000, Halifax, Nova Scotia B3H 4R2 Canada; +1 902-494-3423; ethics@dal.ca)

Study design
Multi-centre non-randomized interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Maternal and child health during pregnancy

Interventions
This is a multi-centre, non-randomized intervention study, in which we will collect and compare gestational weight gain (GWG) and infant anthropometrics between those engaged in the SmartMoms Canada mHealth intervention program vs. a matched historical control. Besides, we will compare clinical and behavioural outcomes between women who had higher adherence to the app vs. those with lower adherence in the prenatal and postpartum periods.

Intervention Group:
Participating women will be provided with the SmartMoms Canada app to be installed on their mobile device and the associated Wi-Fi enabled accessories during their first assessment. These accessories monitor body weight (Withings® Body+ Wi-Fi scale), daily physical activity, nutrition intake, and sleep patterns (Fitbit® Charge 2 activity tracker), and provide the participant with immediate feedback and information related to their daily activities and development. Both the Fitbit and Body+ have required applications that will need to be installed on the participant's electronic device. It should be noted that participants without a Wi-Fi enabled electronic device will receive one allowing them to participate in the study.
Participant weight and height will be obtained by each site using their standard stadiometer and scale, respectively. Gestational weight collected at minimum once per week by the app will be tracked in personalized graphs and used to provide an associated caloric equivalent calculation based upon a validated mathematical model. This allows participants to determine whether or not they need to reduce, maintain or increase daily caloric consumption in order to stay within the Institute of Medicine (IOM) recommended GWG guidelines. The system architecture for the SmartMoms project, detailing the direct and indirect equipment used, is available in the supporting REB documentation.
The SmartMoms Canada app also provides important information through features like

‘SmartTips’. These tips will be delivered weekly during the majority of the second trimester, and then bi-weekly during the third trimester. SmartTips include topics such as physical activity, nutritional suggestions (e.g., sample meal plan, vitamin supplementation), sleep recommendations, and psychosocial considerations (e.g. mindfulness, motivation, and peer support). In addition to the SmartTips, the app features an exercise database that includes stretching, warm-up and an extensive list of recommended, safe exercises for women during pregnancy. Also, a list of local physical activity resource centres/facilities (i.e., walking parks) will be displayed by the app to facilitate exercising in the participant’s area. Finally, with each new week of gestation, a ‘Dashboard’ greets the participants with the current stage of their baby's development with the representation of a fruit/vegetable of comparable size and a brief and simple description of the baby’s stage.

Historical Control Group:
We will collect GWG and clinical outcomes for our comparison group (control) from various partner organizations within the region/province for each site.
1. Better Outcomes Registry Network (BORN) Ontario (www.bornontario.ca). The BORN Information System (BIS) enables the collection of, and access to, data on every birth and young child in Ontario. This information is sourced from hospitals, labs, midwifery practice groups, and clinical programs
2. The CIRESSS platform (Centre Informatisé de Recherche Évaluative en Services et Soins de Santé, Centre Hospitalier Universitaire de Sherbrooke), which gathers data on labs, pregnancy visits and hospitalization for all patients seen in the Sherbrooke area
3. Manitoba’s IDEA (Impact Diet and Exercise Activity) study control group
4. Nova Scotia - Dalhousie University
Our control group will be matched for age, BMI, SES, gestational age, and offspring sex.

The ‘treatment’ duration can vary depending on the gestational age of the participants when engaging the study (eligible criteria ≤20 weeks of gestation) and their gestational age at delivery. However, it is expected that 'treatment' and follow-up duration will be approximately 6 months and 1 year, respectively. The total duration of the study participation is 1.5 years.

Intervention Type
Behavioural

Primary outcome measure
1. Gestational Weight Gain (GWG) calculated using body weight data collected by the ‘Body+’ scale connected to the study mobile application (SmartMoms Canada app) that each participant will receive. Participants will be required to measure their weight a minimum of once per week, but the SmartMoms app will collect weight records daily or as many times as the individual uses the scale.
2. Infant weight-for-length trajectory (self-reported) calculated as a numerical variable (weight-for-length z-score) from weights and lengths measured by the parent at four time points (at birth and 6 weeks, 6 months and 12 months postpartum) and collected using an online questionnaire
3. App adherence calculated from the rate of study completion (≥75%), results of the participant satisfaction questionnaire (>2) at the third trimester of gestation, and app software metrics (e.g. number of logins, app use or ‘counts’ on specific pages (i.e., nutrition, exercise, frequency of use per trimester) over the complete period of gestation

Secondary outcome measures

1. Demographic information collected using the Sociodemographic Online Questionnaire at baseline
2. Pregnancy-related complications assessed using an online questionnaire at 6 weeks postpartum
3. Physical activity assessed using the Godin Leisure-Time Exercise Questionnaire as a categorical variable ("active", "moderately active", "insufficiently active/sedentary") and numerical variable (score of the questionnaire) during the six (6) prenatal and postpartum assessments (trimesters 1, 2, and 3, and 6 weeks, 6 months and 12 months postpartum)
4. Physical activity assessed using steps recorded on the Fitbit fitness tracker, which is connected to the SmartMoms Canada app, throughout the trial period continuously as long as the participant wears their Fitbit. For study analysis, this variable will be analyzed during the six (6) prenatal and postpartum assessments
5. Hours of sleep recorded on the Fitbit fitness tracker, which is connected to the SmartMoms Canada app, throughout the trial period continuously as long as the participant wears their Fitbit. For study analysis, this variable will be analyzed during the six (6) prenatal and postpartum assessments.
6. Nutritional assessment using data collected by Fitbit app (participant-recorded nutritional information). For study analysis, this variable will be analyzed during the six (6) prenatal and postpartum assessments
7. Health-related quality of life assessed using the Medical Outcomes Study Short-form 36 Health Survey online questionnaire during the six (6) prenatal and postpartum assessments
8. Pre/postnatal depression assessed using the Edinburgh Postnatal Depression Scale (EDPS) online questionnaire and measured as categorical variables (depression not likely, depression possible, fairly high possibility of depression, probable depression) and numerical variable (score of the scale) during the six (6) prenatal and postpartum assessments
9. Sleep quality assessed using the Pittsburgh Sleep Quality Index (PSQI) online questionnaire and measured as categorical variables (poor sleep quality, good sleep quality) and numerical variables (score of the questionnaire) during the six (6) prenatal and postpartum assessments
10. Breastfeeding intentions and practices, and solid food introduction assessed using the infant feeding questionnaire during the 6-week postpartum assessment only
11. Breastfeeding practices and solid food introduction assessed using the quick breastfeeding question during the 6- and 12-month postpartum assessments

Overall study start date
18/11/2019

Completion date
17/05/2022

Eligibility

Key inclusion criteria
1. Medically cleared pregnant women (i.e. based on health care provider (HCP) assessment)
2. Less than 20 weeks pregnant (gestation)
3. Carrying a singleton fetus
4. Age 18-40 years old
5. Pre-gravid BMI between 18.5-39.9 kg/m²
6. Having Wi-Fi access

Participant type(s)

Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Consuming alcohol, tobacco or other drugs
2. Pre-pregnancy insulin-treated diabetes
3. Untreated thyroid disease
4. Hypertension requiring medication
5. Other medical conditions that may impact maternal or fetal weight
6. Serious fetal congenital anomalies
7. Contraindications to exercise during pregnancy (based on Mottola et al., 2018)
8. Planning to have the child adopted (as our team would be unable to measure infant outcomes)
9. Women who score > 13 on the Edinburgh Postnatal Depression Scale during the first assessment or who indicate that they are at risk of harming themselves (these women will be referred to a psychologist)
10. Unable to communicate in English or French

Date of first enrolment
06/01/2020

Date of final enrolment
17/11/2020

Locations

Countries of recruitment
Canada

Study participating centre
University of Ottawa
200 Lees Avenue
Ottawa
Canada
K1S 5S9

Study participating centre
Dalhousie University
1465 Brenton Street
Suite 402
Halifax
Canada
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Study participating centre
University of Manitoba
820 Sherbrook Street
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Study participating centre
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713 Montreal Rd
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Study participating centre
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3001, 12e avenue Nord
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Organisation
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Sponsor type
University/education

Website
http://www.uottawa.ca/en

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Government

Funder Name
Public Health Agency of Canada

Alternative Name(s)
Agence de la Santé Publique du Canada, L'Agence de la santé publique du Canada, PHAC, ASPC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Canadian Obesity Network (Obesity Canada)

Funder Name
Pennington Biomedical Research Foundation

Alternative Name(s)
PBRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
The Society of Obstetricians and Gynaecologists of Canada

Funder Name
Maternal Infant, Child and Youth Research Network of Canada

Funder Name
Canadian Society for Exercise Physiology

Funder Name
Royal College of Physicians and Surgeons of Canada

Alternative Name(s)
Collège royal des médecins et chirurgiens du Canada, Royal College, The Royal College of Physicians and Surgeons of Canada, RCPSC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
Results will be disseminated via research articles published in peer-reviewed journals in the field and oral/poster presentations in national and international conferences.

Intention to publish date
17/05/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the study will be discussed with the funder and collaborators of this research project, and will be made available at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/12/2022	28/12/2022	Yes	No