McMaster University Health Sciences

Hamilton Health Sciences

PARTICIPANT INFORMATION SHEET

Title of Study: A culturally-tailored personalizeD nutrition intErvention in South ASIan women at risk of Gestational Diabetes Mellitus: a randomized trial (DESI-GDM)

Investigator: Dr. Russell de Souza RD, ScD, Associate Professor, Health Research Methods, Evidence, and Impact, McMaster; and Associate Scientist, Population Health Research Institute)

Funding Source: CIHR

You are being invited to participate in a research study because you are of South Asian Origin and are currently pregnant.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form provides detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss your participation with your family and friends.

WHY IS THIS RESEARCH BEING DONE?

Some women without diabetes develop high blood sugar levels during pregnancy. This condition, called “gestational diabetes”, is a health risk to the mother during pregnancy, and to her baby at birth. It also increases both her and her baby’s risk of developing diabetes or heart disease in the future. People from the Indian subcontinent, called South Asians, are among the largest nonwhite ethnic groups in Canada, and they develop gestational diabetes twice as often as White women. Diet changes during pregnancy may improve her blood sugar levels. It is hard to make diet changes during pregnancy, but many women do because it is good for her and her baby's health. We think that seeing a nutrition coach during pregnancy can help a woman improve her diet, but we are not sure if this will result in important changes in blood sugar levels.

WHAT IS THE PURPOSE OF THIS STUDY?

The purposes of this study are to:

1) Test whether a personalized nutrition plan designed for South Asian women, and delivered by a health coach, can improve blood sugar levels during pregnancy.

2) Test whether a personalized nutrition plan designed for South Asian women, and delivered by a health coach, can, can prevent gestational diabetes.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

If you agree to participate in this study, we will ask you to do the following things:

1) Review and sign this Informed Consent Form.
2) Meet with study personnel from the DESI-GDM team at a mutually convenient location and time for you and the study team.
3) Agree to receive a text message each week to encourage increased walking, and make an effort to follow the suggestions we provide on how to do this.
4) Allow the study team to collect your physical measurements.
5) Provide your medical history, pregnancy history, lifestyle and demographic information, an Ayurvedic assessment, COVID-19 and vaccine questionnaires, and INTERHEART FFQ (at baseline and OGTT visits) by completing a questionnaire (online or in-person)
6) On two occasions, allow us to test your blood sugar using a “finger prick”, and provide a fasting blood sample (about 1 tablespoon) and a specimen jar (10 ml) of fasting urine.
7) Complete an “oral glucose tolerance test” to diagnose gestational diabetes at the end of the coaching intervention. The oral glucose tolerance test (OGTT) measures your body's ability to use a type of sugar, called glucose, which is the body's main source of energy.
8) We may as collect additional blood samples at timed intervals during your OGTT for future analysis and related research studies.
9) Provide, via a phone call, your baby’s birth measurements.
10) Agree to complete an electronic survey at the end of study participation

If you are randomly selected to be a part of the intervention group, we will also ask you to do the following things (in addition to the list above):

1) Meet with a Health Coach to develop diet goals and a plan to achieve them.
    a. If you are not the primary cook in your household, we may also ask them to come to this meeting.
2) Install up to 2 applications on your mobile device to enable tracking of food, physical activity, and coaching.
3) Agree to wear a FitBit for 16 weeks, and share these data with the research team.
4) Agree to receive up to 5 weekly SMS message, to encourage you in achieving your diet goals.
5) Agree to track your food using “BiteSnap” for 16 weeks
6) Meet with your Health Coach over phone or video call every other week, to discuss how you are doing with your diet goals.
7) Agree to your meetings with Health Coach being captured using audio recording device.
8) Agree to complete a visit reflection questionnaire after each bi-weekly contact with Health Coach

If Ontario’s COVID-19 pandemic responses prevent in-person study visits, this study will use the Zoom platform, which is an externally hosted cloud-based service. A link to their privacy policy is available here https://zoom.us/privacy. While the Hamilton Integrated Research Ethics Board has approved using the platform to collect data for this study, there is a small risk of a privacy breach for data collected on external servers.

If you are concerned about this, we would be happy to make alternative arrangements for you to participate, perhaps via telephone. Please talk to the researcher if you have any concerns. The researchers will not make any recordings of the baseline visit. Participants must agree to not make any unauthorized recordings of the baseline visits using the Zoom platform.

At the initial and OGTT visits, we will also ask you to provide the following biological samples:

1) A fasting blood sample (about 1 tablespoon)
2) A fasting urine sample (10 ml)

WHAT IS THE 75-g Oral Glucose Tolerance Test (OGTT)?

On the day of testing, the following steps will be done:

- A blood sample will be collected when you arrive. This is your fasting blood glucose value. It provides a baseline for comparing other glucose values.
- You will be asked to drink a sweet liquid containing a measured amount of glucose. It is best to drink the liquid quickly. For the glucose tolerance test, you will drink 75 grams of glucose.
- Blood samples will be collected at timed intervals of 1, 2, and sometimes 3 hours after you drink the glucose. Blood samples may also be taken as soon as 30 minutes to more than 3 hours after you drink the glucose.
- We will collect additional blood samples at these timed intervals for future analysis and related research studies. These additional blood samples are optional and you may opt out of providing them.

WHAT WILL HAPPEN WITH MY SAMPLES?

The results of your 75-g OGTT will be shared with your care provider ordering the test (i.e. family physician or OB/Gyn),

All samples will be used for the purpose of this study and other related research studies. Samples will be stored under appropriate conditions at the Hamilton Health Sciences research lab, labeled and analyzed in a manner that will not allow direct identification of you, and may be shared with colleagues at other laboratories for measurements relevant to the study.

We would like to collect fasting blood (about 1 tablespoon) and 1 container of fasting urine (10 ml), which we will store for future related research studies, at each visit. We will collect additional blood samples (about 1 tablespoon) at multiple times during the OGTT for future analysis and related research studies.

The stored samples will be used for research and such use may result in inventions or discoveries that create new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researchers/sponsor. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the samples.

You ***may refuse*** to provide these storage blood and urine samples, and still participate in this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is an extremely remote possibility of loss of confidentiality of participants' questionnaire responses, physical measurements, or results of analyses of their biospecimens. Data security features at the time of collection, data entry and for long-term storage will be used to maximize confidentiality.

This study may require you to use third party devices (FitBit) and apps (BiteSnap). The information

you provide to these third parties are subject to their own privacy agreements, and they may store their data in the United States. As a result, any data you provide may be subject to American data privacy laws, which are less rigorous than Canadian laws. To minimise the personal information you provide to each company, we have set up an account with each device for you, so that the only information anyone outside our team can collect from this technology is the anonymous data the devices are collecting (i.e. the food you eat, how many steps you are taking). We ask that you do not update the account information with your own personal information, for your own privacy safety.

In order to contact you via broadcasted text messages, we will use a platform designed by a third-party, called MemoText. Please read their terms of service carefully before signing up, and discuss with the research staff any questions you have before doing so. We will provide MemoText with your cellular phone number. Upon agreeing to participate in this research study, you are agreeing to receive text messages and phone calls, for study purposes, from the MemoText platform. Message and data rates may apply You may be subject to standard messaging and data fees from your carrier according to your mobile messaging plan. Please refer to your plan details for more information. Your carrier and McMaster university are not liable for delayed or undelivered text messages.

If you already have a FitBit, you may choose to sync your account with our digital health platform or use a study account/device. We will not sync any data beyond that generated during the 16-week study period, beginning at the initial visit, and ending at the OGTT visit.

Blood collection may cause bruising, pain or, rarely, fainting. In order to minimize the risk, blood collection will only be performed by certified phlebotomists or qualified health professionals. There are no known risks associated with the collection of urine samples.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

We anticipate approximately 190 South Asian women will participate in this study.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?

You will learn about your blood sugar readings, food intake, and exercise patterns through the app. You will have a chance to share your opinions of the process with the team, which we will use to help develop strategies to help South Asian women to stay healthy during pregnancy and contribute to improving how we deliver advice to South Asian mothers.

If you are randomly selected to be a part of the intervention group, you will also receive a personally-tailored culturally relevant diet plan, designed to reduce your personal risk of diabetes during pregnancy. You will have access to a health coach who will meet with you over phone or video every other week to discuss your specific dietary goals in more detail.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

It is important for you to know that you can choose not to take part in the study. Choosing not to participate in this study will in no way affect your access to the healthcare system.

WHAT INFORMATION WILL BE KEPT PRIVATE?

(1) We will not share your data with anyone except with your consent or as required by law.

(2) The information you provide during baseline and follow-up data collection will be linked to you only by a randomly assigned identification number, which cannot be used to identify you personally. All tapes/recordings will be labelled with the identification number only and will not be directly traceable to you.

(3) A list linking the number with your name will be kept in a secure place, separate from your study file. The data, with identifying information removed will be securely stored in a locked office in the research office, on a secure server. The data for this research study will be retained for 25 years.

(4) For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of the Hamilton Integrated Research Ethics Board (HiREB) may consult your research data. However, your confidentiality will be maintained if this occurs. By signing this consent form, you authorize such access.

(5) Personal health information including your health card number will be shared with the Institute for Clinical Evaluative Sciences and linked to Ontario health records to analyze and evaluate your and your child's usage of health care services (such as hospitalizations) in Ontario.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.

CAN PARTICIPATION IN THE STUDY END EARLY?

Yes, you may withdraw at any time. In this case, study personnel will review options with you to help you make an informed decision about what is best for you. You may refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this study if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

If you agree to take part, we will reimburse you for your parking costs if you come to in-person visits

WILL THERE BE ANY COSTS?

Your participation in this research project will not involve any additional costs to you.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

If you are injured as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.

Signing this consent form does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?

If you have any questions about the research now or later, please contact the research office of Dr. Russell de Souza at 905-525-9140 ext. 22109 or 905-630-5473.

If you have any questions regarding your rights as a research participant, you may contact the Office of the Chair of the Hamilton Integrated Research Ethics Board (HiREB) at 905-521-2100, ext. 42013.

CONSENT STATEMENT

I have read the preceding information thoroughly. I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I will receive a signed copy of this form.

I agree that my family physician may be contacted by the study team for any required information and for the purpose of completing data collection or to obtain my updated contact information in the event that I would have not updated the study on any change and they are unable to contact me.

- ☐ I agree to wear a FitBit for 16 weeks if required Initials: _____
- ☐ I agree to track my food using "BiteSnap" for 16 weeks if required Initials: _____
- ☐ I agree to provide my feedback in a short survey if required Initials: _____
- ☐ I agree to provide a urine sample at the initial visit Initials: _____
- ☐ I agree to provide a blood sample at the initial visit Initials: _____
- ☐ I agree to provide a urine sample at the OGTT visit Initials: _____
- ☐ I agree to provide a blood sample at the OGTT visit Initials: _____
- ☐ I agree to provide physical measures at the initial visit Initials: _____
- ☐ I agree to provide physical measures at the OGTT visit Initials: _____
- ☐ I agree to receive weekly SMS messages about walking (and potentially about diet) for 16 weeks Initials: _____
- ☐ I agree to provide my infant's weight and length after birth Initials: _____
- ☐ I agree to provide the study team information about any delivery complications Initials: _____
- ☐ I agree to provide my health card number to be shared with the Institute for Clinical Evaluative Sciences and to linked to Ontario health records of myself and my child Initials: _____
- ☐ I agree that my family physician may be contacted for any required information and for the purpose of completing data collection Initials: _____

I agree to the storage of fasting blood and urine samples to be used for the measurements of new tests that may arise and be deemed relevant for this project.

☐ No ☐Yes Initials:_____

I agree to the collection and storage of additional OGTT blood samples to be used for the measurements of new tests that may arise and be deemed relevant for this project.

☐ No ☐Yes Initials:_____

_____
Name of Participant

_____ _____
Signature of Participant (or Legally Authorized Representative) Date

Consent form administered and explained in person by:

_____
Name and title

_____ _____
Signature Date

Verbal Consent

Person Obtaining Verbal Consent:
I have discussed this study in detail with the participant and they have provided verbal consent to participate. I believe the participant understands what is involved in this study.

_____
Name and title

_____ _____
Signature Date