A Study on the Use of Real -Time Continuous Glucose Monitoring (RT-CGM) in Gestational Diabetes

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Informed consent

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UNIVERSITY OF WASHINGTON CONSENT FORM

A Study on the Use of Real -Time Continuous Glucose Monitoring (RT-CGM) in Gestational Diabetes

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24-hour emergency telephone number: Call the hospital operator at 206-598-6190 and ask for the diabetes care doctor on call.

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Your decision whether or not to participate will not affect service or medical care you receive from your provider. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

Why am I being invited to take part in this study?

We are inviting you to take part in a research study because you are pregnant and have gestational diabetes. This study gives you a chance to wear a medical device that monitors your blood sugars (glucose). This device is called a continuous glucose monitor (CGM). The CGM device is currently FDA-approved for diabetes, and it is sometimes used in pregnancy. However, the CGM is not specifically FDA-approved for use during pregnancy. One goal of this study is to see if using a CGM may improve blood sugar control in patients with gestational diabetes during their pregnancy.

How long is the study and what will I have to do?

Study participation is 14-22 weeks in length. If you enroll, you will be randomly placed into one of two groups: (1) the intervention group or (2) the control group.

Intervention Group: If you are in the intervention group, you will wear a real-time continuous glucose monitoring device (RT-CGM) throughout the study and your pregnancy. The RT-CGM will show you your glucose levels at all times on your phone or a display device.

Control Group: If you are in the control group, you will not wear a RT-CGM. Instead, you will wear a "blinded" CGM device. A blinded CGM is a device that monitors your glucose levels but does not show you the blood sugar results. You will use a blood glucose meter to check your glucose using finger sticks as recommended by your obstetrics (OB) provider.

Why might I want to be in this study?

You might want to be in this study if you want to contribute to research that may help improve gestational diabetes care. You may also want to learn about gestational diabetes and continuous glucose monitoring. If you are assigned to the intervention group, you may find using the CGM to see your blood sugars more convenient than doing fingersticks. Fingersticks are the current method in gestational diabetes care.

Why might I not want to be in this study?

You may not want to wear the CGM device for an extended period of time. You may want to wear a RT-CGM device for certain rather than be randomly assigned to the control group. You may not find study visits to be convenient with your schedule. You may be uncomfortable with some study procedures like body measurements or blood draws.

If you have any questions or concerns about the study, you can contact the study team by calling 206-616-6360 or emailing gdmcgmstudy@uw.edu.

PURPOSE OF THE STUDY

The goal of this study is to see:

- If using a RT-CGM improves blood sugar control in patients with gestational diabetes.
- If using a RT-CGM improves the health of mothers and babies in pregnancies affected by gestational diabetes.
- How gestational diabetes patients feel about wearing a RT-CGM.
- If using a RT-CGM lowers the need of gestational diabetes patients to start oral diabetes medication or insulin.

STUDY PROCEDURES

Overview:

Participation lasts for 14 - 22 weeks and entails five or six visits, depending on what stage of pregnancy you are in when you enroll. Each study visit is at least 2 weeks apart for most participants. Some visits will be done remotely. In-person study visits can take place after your regularly scheduled visits at your obstetrics clinic for your convenience, though they are not required to. If a visit is done remotely and body measurements are needed for the visit, the study will get the data for these measurements from your medical record. You will be monitored for any side effects throughout the study.

First, you will attend a screening visit to see if you are eligible to join the study. If you are eligible, you will be placed randomly into either the control group or the intervention group. You will have a 50% (1 out of 2) chance of being placed into either group. Neither you nor the study doctor will be able to choose the group which you are assigned to. In total, we expect that 100 people will participate in this study, with 50 participants assigned to each group. You will get standard gestational diabetes education and a glucose meter no matter which group you are in.

If you are randomized to the control group, then decided to withdraw from the study, , we will send you an email asking you to fill out a survey about the reasons of why you withdrew from the study.. The survey will be sent to your email through a link from Redcap. The survey will be voluntary to complete and it won't take more than 10 minutes to complete.

Continuous Glucose Monitoring Device (CGM):
Continuous glucose monitoring is a way to measure your blood glucose in real-time throughout the day. The CGM device has a slim sensor that is inserted under the skin of your abdomen by a skin prick. The sensor may be worn on a different site of the body, such as the back of the arm or buttocks. This sensor stays inserted and measures your blood sugar. A small transmitter sits on top of the skin using medical tape. The transmitter sends glucose results wirelessly to a smart phone or a display device.

Study Visits:
Below is a table showing what we will ask you to do at each study visit. You will also find brief descriptions of the blood draw and body measurement process.

Early Diagnosed Participants: If you have an early diagnosis of gestational diabetes, you may have one additional visit at 26-30 weeks of gestational age. This visit will be called "Visit 1^{B}". Procedures at Visit 1^{B} will be the same as Visit 1^{A}.

Participants Enrolled after 28 weeks: If you enroll in the study after 28 weeks of gestational age, you may attend Visit 2 earlier than study week 6. This is to ensure that you attend Visit 2 when you are at 30-34 weeks gestational age.

Visit Schedule:

Visit Type	Screening	1_{A}	2	3	4
Study Week	0	2	6/14	10/18	14/22
Study Activities for Each Visit					
Read & Sign Consent Form (Inperson or remote)	X				

Medical History (In-person or remote)	X				
Medication & Supplement Review (Inperson or remote)	X	X	X	X	X
Vital Signs (In-person or remote)	X	X	X	X	X
Body Measurements (In-person or remote)	X	X	X	X	X
A1C Test (Non-fasting blood draw/fingerstick)	X			X	
Fructosamine (Non-fasting blood draw)	X			X	
CBC Test (Non-fasting blood draw)	X				
Maternal Ultrasound Review	X	X	X	X	X
GDM Education Session	X				
Complete Questionnaires (Remote)	X	X		X	
Dispense/Return Glucose Logs	X	X	X	X	X
Dispense Glucose Meter	X				
CONTROL: Dispense and Place CGM (use for 10-day intervals)	X		X	X	
INTERVENTION: Dispense and Place CGM (use throughout study)	X	X	X	X	X
Check or Download CGM		X	X	X	X
Check or Download Glucose Meter		X	X	X	X

Blood draw information:

For visits where multiple blood tests are done, all the blood samples will be obtained in one draw/poke. You will not need to fast for these blood draws. If a visit that requires a blood draw is done remotely, we will ask you to visit your OB clinic at some point to

complete the required blood draw for that visit. Study blood draws can be done after a regularly scheduled OB clinic appointment for your convenience.

Before each visit requiring a blood draw, we will check your medical record to see if you have had a Hemoglobin A1C (A1C) and complete blood count (CBC) test in the last two weeks. An A1C test measures your average blood glucose levels over the last three months. A CBC test examines cells in the blood. If a recent A1C and/or CBC test is not available in your medical record, we will record the missing measurement at the study visit. We will measure A1C by either pricking your finger or by drawing about 1 teaspoon of blood from your vein. CBC will be measured by drawing 1 teaspoon of blood. At each blood draw, we will also draw an additional 1 teaspoon of blood to measure fructosamine, which is an estimate of blood glucose control.

Body measurement information:

We may ask you to record your body measurements at home if a study visit is done remotely and if recent body measurements cannot be retrieved from your medical record. These measurements may include height, weight, pulse, and blood pressure. Study staff will teach you how to obtain these measurements if you are asked to do this. You will use home-equipment given to you by your OB clinic to measure your blood pressure and pulse. If you are not provided with this equipment, the study will not obtain blood pressure and pulse measurements for that remote visit.

Screening Visit:

Screening visit activities can take place over two sessions. The first screening visit session will be a televisit with staff through phone or video call (Zoom). This televisit will last about 45 minutes. During this televisit, staff will go over the consent form with you. You will have the opportunity to ask questions and sign the consent form. You will also complete questionnaires remotely through REDCap. These questionnaires will ask you about your medical history, current medications you are taking, pregnancy history, physical activity, nutrition, and overall wellness.

The second screening visit session will last 1.5 – 2 hours. If we find that you are ineligible for the study, we will withdraw you from the study at that time. If you have not already signed the consent form before this session, you will have the opportunity to ask questions and sign the consent form at this time. We will record your vital signs and body measurements. Vital signs that are measured include two blood pressure and pulse readings. Body measurements include height and weight. If this session is remote and these measurements are not available in your medical record, we may ask you to obtain these measurements at home. We will also give you a blood glucose meter at this visit.

At the second screening visit session, you will be randomly placed into either the intervention group or the control group. The group you are assigned to will determine how you use the CGM device:

Screening Visit – Control Group: If you are put in the control group, we will give you a "blinded" CGM (meaning you will not see the measurements it is taking). Study staff will insert the blinded CGM for you. If you choose to do the second screening session remotely, then we will mail you the device and you will self-insert it during a televisit with study staff after you receive device. After insertion of the CGM, you will wear this device for the first of three 10-day periods in the study. We will teach you how to test your blood sugar by pricking your finger with the blood glucose meter. You will be told to follow instructions given by your pregnancy provider for using the blood glucose meter. You will remove the sensor from the blinded CGM after 10 days, or study staff can remove it at your next visit (14 days after the screening visit). We will ask you to continue your normal diet and activities when wearing the CGM.

Screening Visit – Intervention Group: If you are put in the intervention group, we will give you a RT-CGM. You will wear the RT-CGM throughout the study. We will teach you how to self-insert, change, and use the RT-CGM. If you choose to do the second screening session remotely, then we will mail you the device and you will self-insert it during a short televisit with study staff after you receive the device. You will continue monitoring your activity and diet and checking your blood glucose as instructed by your pregnancy provider. Below are additional points that study staff will go over with you at this visit:

Blood Sugar Education: We will give you additional education about blood sugars at this visit. This includes information about how to look at blood sugar trends and how different foods may affect them.

Displaying Blood Sugars: If you choose to use your phone to view your blood sugars, we will help you install 2 applications at this visit. One is the CLARITY app, which will display your blood sugars in real time. The other app is required for data sharing. You will use a display device to view your sugars if you cannot use a phone or don't want to.

Self-insertion of RT-CGM: You will need to change the device every 10 days. To help with this, we will give you a link to an online educational video that shows you how to self-insert the RT-CGM. This video will remind you how to change the sensor when you are at home at the end of the 10-day period. You can always call the study team if you need help or have questions.

Blood Sugar Alerts: The RT-CGM will alert you if your glucose is less than 55 or more than 140. If you end up requiring insulin during the study, we will turn on another alarm to alert you when your glucose is less than 65. The RT-CGM will also alert you if: (1) your glucose will be lower than 55 in less than 20 minutes, (2) your glucose rises or falls at a fast rate, and (3) if there is a signal loss between the RT-CGM and display device for more than 20 minutes. We will give you a guide of how to troubleshoot these alerts. You can always call the study team if you have questions.

Blood Glucose Log Sheets: We will give you glucose log sheets. These sheets will have you record your RT-CGM glucose values when fasting and 1 hour after each meal.

Visits 1[A] - 4:

Visits 1[A] - 4 will last between 30 minutes and 1 hour.

Prior to these visits, we may ask you to complete questionnaires remotely through REDCap. You can always call study staff if you have questions.

At Visits 1[A] - 4, vital signs and measurements will be recorded by study staff or retrieved from the medical record. If a visit is remote and recent body measurements aren't available in your medical record, we may ask you to record these measurements at home. Medications and ultrasounds will be reviewed at these visits. We will download data from your CGM, collect completed glucose log sheets (intervention group), and answer any questions you have. We will assist with placement of CGM and checking of blood glucose meter.

If you are in the control group, you will wear the blinded CGM for 2 additional 10-day periods during the study. These additional 10-day periods start at Visit 2 and Visit 3. You may return the CGM device at your regularly scheduled appointment with your obstetrician. If for any reason the CGM fails to record at least 3 days of glucose data, you may be asked to repeat this measurement at an additional unscheduled visit.

If you are in the intervention group, you will wear the RT-CGM for the duration of the study, changing the sensor every 10 days.

Depending on when you enroll in the study, Visit 4 will take place sometime between 38-42 weeks of gestational age. You will only complete visit 4 if your pregnancy reaches 38-42 weeks. If you deliver before reaching 38-42 weeks, then you will not have to complete this visit.

Delivery:
We will review your medical records after you deliver your baby to record details about the health of you and your baby. The study team may contact you for follow up after you have completed the study if you agree to this.

RISKS, STRESS, OR DISCOMFORT

You can call the 24-hour emergency number provided at the top of this consent form if you have any emergency you feel may be related to the study.

Fingerstick and venous blood draw: You may have temporary discomfort during blood tests. This may include possible bruising or redness of the skin, lightheadedness, dizziness, fainting or infection on rare occasion. We will give you an emergency number of who to contact if any problems arise.

Continuous Glucose Monitoring Device: You may have temporary discomfort when the CGM is inserted. This may include bruising, redness of the skin, rare allergy to medical tape, bleeding or

infection at the insertion site. If bleeding occurs, it is usually minor and temporary, and can be resolved by applying pressure at the site. You may experience dislike of having a medical device on your body for 10 days. When the CGM sensor is inserted, there is a risk that the insertion wire may break off under the skin and need to be removed. There is the risk that the CGM may fall out during use. If this happens, contact the study team at the number provided, and we will help you re-insert the device remotely.

There is the risk of RT-CGM reading being inaccurate if you take larger than prescribed doses of acetaminophen (Tylenol products). To prevent this, you will be told not to take more than a maximum dose of 1 gram (1,000 mg) of acetaminophen every 6 hours.

There might be times where the RT-CGM is not accurate. If you feel like you are having a low blood sugar but your RT-CGM is not showing one, you will be told to test your blood sugar by fingerstick.

There may be confusion about when to test your blood sugar. This confusion may cause anxiety. You will be told to always follow your provider's instructions. The study team will work with your OB provider for blood sugar testing and treatment.

Body measurements: You may experience discomfort or embarrassment during weight and height measurements**.**

Surveys and questionnaires: You may have some emotional discomfort when answering questions that are personal in nature. You can leave questions blank if you are uncomfortable answering them.

Confidentiality: Although unlikely, there is a risk of a possible breach in confidentiality. This includes some sensitive questions about medical history like alcohol, drug history and questions about previous pregnancies. Every effort is made to prevent this from happening. Also, every effort is made to perform research activities in a private and respectful manner by research staff with appropriate training and education. All research activities will take place in a private room.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Instead of being in this research study, your choices may include receiving routine pregnancy care and standard of care for gestational diabetes.

BENEFITS OF THE STUDY

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits from the RT-CGM intervention activities may include improved glucose levels and thus potential for better pregnancy outcomes for you and your baby. If you are in the control group, you will likely receive no direct benefit from the measurements beyond receiving notification of your results after the study, if desired. However, you do receive some teaching about blood sugar goals, which may help you improve your glucose during pregnancy.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from Dexcom, the manufacturer of the continuous glucose monitoring device.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. Your identity will not be shared in any reports or publications resulting from this study. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Some of the questionnaires ask if you have thought of hurting yourself. If you report that you have had those feelings, we will call you to talk about it and give you resources. We may also contact the head researcher for this study if we think you might hurt yourself. We may also call 911.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. Your participation in this study will be noted in your UW medical record.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you are in the intervention group and you want to use your phone to see your glucose levels, we will make an anonymous CLARITY account for you.

USE OF INFORMATION AND SPECIMENS

Returning your results to you:

You will see your real-time blood sugars if you are in the intervention group. Study staff will discuss how to use, read, and understand the CGM device. Study staff will also discuss how to understand what different glucose numbers mean. This information will be given to you when your CGM is inserted.

You also will see the glucose results from your blood glucose meter if you are in either group. You will be provided with information about how to treat low blood sugars and what to take, such as honey or orange juice.

If the study performs an A1C test for research purposes, these results will be entered into your medical record. A1C is often ordered by your OB provider so they may discuss your A1C test results with you as part of your clinical care. CBC test results will also be entered into your medical record if a CBC test is performed for research purposes. Your fructosamine results will not be returned to you, because this is not a validated test in pregnancy.

The CGM data will be available to your provider. Feel free to talk with your OB about your participation in this study.

If you are in the control group, we will give the blood sugar results from the blinded CGM to you after the study has been completed if you wish to receive them.

Using Your Data in Future Research:
Research samples and data that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may be used for future research studies or given to other researchers not involved with this study without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher Dr Nicole Ehrhardt at 206-520-8620. You may take this document home to read or to discuss with your family members or your doctor before deciding to take part in this research study.

You will receive a $50 gift card after completing Visit 0 and another $50 gift card after completing Visit 3. Visit 3 compensation will be given to you upon return of the blinded device or RT-CGM download at 34-36 weeks. If a lack of RT-CGM data requires unscheduled visits, you will be compensated an additional $25 per visit up to a maximum of $50 if 2 unscheduled visits are required.

If you are in the intervention group, you will receive the RT-CGM device for free for use in the study. If you are in the control group, the study will give you the blinded CGM device to use for free during the study. If you are in either group, the study will give you a glucose meter and test strips for free if they are not covered by your insurance. If your insurance is paying for a traditional glucose meter and testing strips, then you will use those during the study. If you decide to withdraw from the study later, you will be able to keep the glucose meter and testing strips given by the study. Study staff will also notify your provider that you have withdrawn.

If you sign this form electronically, a copy of the consent form will be emailed to you at an email address that you provide. It will be a “PDF” document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn’t already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, you can tell a member of the study staff.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Nicole Ehrhardt (clinic number: 206-520-8620. If you cannot reach her, call the hospital operator at 206-598-6190 and ask for the diabetes care doctor on call. They will treat you or refer you for treatment at a UW Medicine facility.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

If you are interested in being contacted about future research, you may indicate so by checking the box below.

□ I am interested in being contacted about participating in future research.

Copies to: Researcher
Subject
Subject's Medical Record (if applicable)