COVER PAGE

Study number: NCT05404711

Study Title: Feasibility and Acceptability of Home Use of Continuous Glucose Monitors for Type 2 Diabetes Risk Evaluation in Youth

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Informed Consent

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UPMC | CHILDREN'S HOSPITAL OF PITTSBURGH

Informed Consent to Participate in a Research Study,

HIPAA Authorization Form

Study Title: **Feasibility and Acceptability of Home Use of Continuous Glucose Monitors for Type 2 Diabetes Risk Evaluation in Youth**

Short Title: **CGM for T2D Risk Evaluation**

Version Date: 9/07/2023

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You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Your physician may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

KEY INFORMATION

You are being asked to take part in this research study because you are between the ages of 8-18 years old and have prediabetes or are at risk of developing prediabetes or type 2 diabetes.

The purpose of this research study is to determine whether continuous glucose monitors (CGM) are a safe, effective, and acceptable way to evaluate type 2 diabetes risk in youth as compared to the standard 2-hour oral glucose tolerance test (OGTT).

Study visits will be in person and at home. You will be asked to come to UPMC Children's Hospital of Pittsburgh (CHP) for one study visit. If you enroll, you will take part in the study for 10 days. You will be asked to:

- Fast overnight for a minimum of 10 hours before the in-person study visit
- Complete a 2-hour oral glucose tolerance test (OGTT) test at the study visit
- Complete questionnaires
- Complete a 2-hour glucose challenge at home
- Complete a 2-hour mixed food challenge at home
- Wear a Dexcom G6 continuous glucose monitor for 10 days
- Wear a physical activity tracker (ActiGraph) on your wrist for 10 days
- Complete surveys sent via text message to your phone
- Complete an interview

The main risks from this study are from wearing a continuous glucose monitor, which may cause a mild rash where it is placed on the skin, as well as potential nausea after the OGTT and at-home glucose challenge.

You may benefit directly from being in this study by learning more about your risk of developing type 2 diabetes.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor.

Please see below for additional details about the study.

What is the standard procedure for diagnosing type 2 diabetes?

An oral glucose tolerance test (OGTT) is one of the standard tests used to diagnose type 2 diabetes. This involves drinking a sugary drink and testing the blood sugar levels with blood draws at 0 minutes, 30 minutes, 60 minutes, 90 minutes and 120 minutes after drinking the glucose drink. This test is typically done at a hospital or doctor's office.

Continuous glucose monitors are used routinely for management of diabetes in children and adults but are not usually used for diagnosis of, or screening for, diabetes.

What is involved in this study?

We are testing whether continuous glucose monitors can be a safe, effective, and acceptable alternative to standard OGTT for evaluating diabetes risk in children. This study will involve wearing a CGM, wearing a physical activity tracker, responding to surveys, and completing at-home glucose and mixed food challenge while wearing the CGM. You will also be asked to complete an interview by phone or videoconference after wearing the CGM.

What are the study procedures?

Tests that are a part of your routine medical care will continue to be performed. The study involves the following research tests and procedures:

Research Visit Procedures:
You will not be able to eat or drink anything except plain unflavored water after 11:00 PM the night before the on-site study visits. You may eat after the blood draw is completed.

Questionnaires: During the study visits, a member of the study team will guide you through filling out questionnaires related to your medical history, family history, and social history such as school and work details. You may either read and answer the questionnaires yourself, or a staff person can read each questionnaire out loud to you, and you will let that person know your answers.

Review of Medical Records: With your permission, we will collect information from your medical record for the study. The purpose is to be sure that we collect all important and accurate information about your medical history including, any illness or medication use. We will enter the blood test results from this study in your medical record.

Physical Examination: We will measure your weight, height, blood pressure, heart and breathing rate at the visits. The study doctor will also check how you are progressing in puberty by examining breast development (in girls/women) or testicular size (in boys/men). You may refuse the exam you if you are uncomfortable.

Pregnancy Test: If you are pregnant, you will not be allowed to participate in this study. You will be asked to take a urine pregnancy test before starting this study. The results will be shared with you and not with your parent(s). We strongly encourage you to share the results with your parents. If you are found to be pregnant, you will not be able to continue participation in the study.

Oral glucose tolerance test (OGTT): We perform this test to assess your body's response to sugar. You will be given a cup of flavored sugar water to drink over 5 minutes. Blood samples will then be drawn from an IV catheter 5 times at 30-minute intervals. The test will last for 2 hours. The total volume of blood that will be withdrawn will be approximately a little more than 1 tablespoon [18ml]. The blood obtained from this test will be analyzed for blood sugar, insulin and C-peptide (hormones that regulate blood sugar levels) and hemoglobin A1c, a marker of average blood sugar.

Continuous glucose monitor (CGM) wear: A Dexcom G6 Pro CGM will be placed on your abdomen by trained study staff while you are completing the OGTT at the study visit. This monitor will test your blood sugar levels under your skin every 5 minutes. You will wear this for 10 days, then remove it by simply peeling it off. You will return the CGM to the research team by mailing it back in a prepaid, addressed envelope.

Activity tracker (ActiGraph) wear: You will be given an ActiGraph GT9X Link physical activity and sleep tracker to wear on your wrist for 10 days. You will return it to the research team by mailing it back in a prepaid, addressed envelope with the CGM.

Home Procedures:

The study visit will be Day 1. From Day 1 through Day 10, you may eat and participate in all activities that you normally do, except for when you do the at-home glucose and mixed food challenges described below, during which you should rest for 2 hours.

Home glucose challenge: This will be similar to the OGTT done in the research center. You will drink the same glucose solution after fasting for at least 10 hours, then rest for 2 hours. You will use a text message-based survey to let the research team know when you drank the glucose. The CGM will measure your blood sugar during this test.

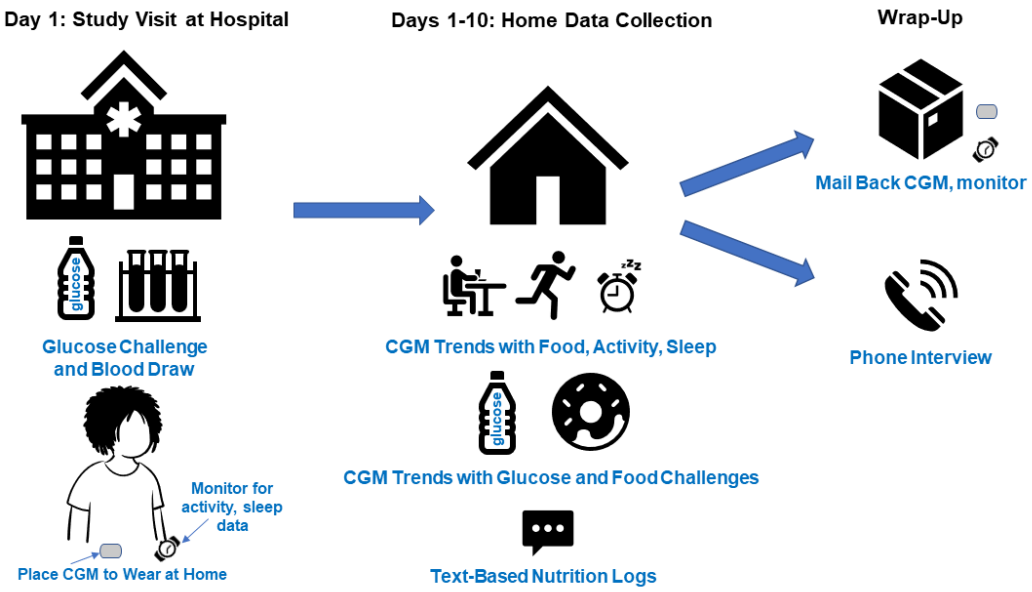
Home mixed food challenge: This will be similar to the home glucose challenge, but instead of a glucose drink, you will choose a snack or meal that has at least 50 grams of carbohydrate, as well as fat and protein in it. This test will also be done after fasting for at least 10 hours, followed by 2 hours of rest. You will use a text message-based survey to let the research team know when you completed this mixed food challenge. The CGM will measure your blood sugar during this test.

Text message-based surveys: You will be sent surveys 3 times daily via text message, asking about food and drink intake, physical activity, and time in bed (start/stop times).

Interview: We will call you by phone or set up a videoconference call with you to obtain feedback on your experience. At the discretion of the research team, we may ask your parent or legal guardian to join you in the interview and will ask them the same questions about your experience. This will be audio-recorded. We will also ask you to fill out a questionnaire about your eating habits and any episodes of binging.

Visit Schedule:

The diagram below shows a description of the study procedures, which will take place over 10 days:



What will be done with my data and specimens during this study?

During the study, we will collect blood samples from you. By agreeing to participate in the study, you agree to give these samples to Children's Hospital of Pittsburgh for research purposes.

Will I receive any results from the tests done as part of this study?

Results that could be important for your clinical care will be shared with you, as described above. We will not share other results with you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risks associated with overnight fast:

An 8 hour fast may cause you to have an upset stomach, a headache, or feel light-headed in the morning before the visit. These symptoms are uncomfortable but not serious.

Risks associated with physical exam and blood pressure measurement:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care. When blood pressure is taken during the physical exams, the blood pressure cuff may cause discomfort or bruising to the upper arm.

The exam of your pubertal status may make you uncomfortable. You may stop the exam at any time. To minimize this possibility, the exam is done in private by a health professional skilled in determining pubertal status. In addition, you will be asked in advance if you prefer to have your parent/guardian present when the puberty exam is done.

Risks associated with wearing an Actigraph GTX9X Physical Activity and Sleep Tracker:
You may experience discomfort related to wearing the Actigraph. It is uncommon but sometimes the band can irritate your skin.
Risks of Interview and questionnaires:
There are no physical risks, but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.
Risk of Breach of Privacy and Confidentiality:
As with any study involving collection of data, there is a possibility that someone could see your private information who does not have permission. This is called a breach of confidentiality. Every precaution will be taken to secure your personal information to ensure confidentiality. When you sign this consent form, you will be assigned a study identification number. This number will be used on data collection forms, blood samples, and in the database instead of names and other private information. A separate list will be maintained that links each participant's name to the study identification number for future reference and communication. Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

You should also know that text messages are not encrypted or secure when they are sent, and they could be captured by someone who is not authorized. However, your responses will be collected by a secure survey link to minimize this risk.

Risks of Oral glucose tolerance test (OGTT) and at-home glucose challenge: The risks associated with the OGTT are the same as those for having blood drawn as described above. The OGTT is safe and is used clinically in children and adults of all ages. Glucose is a normal nutrient found in many different foods. About one out in ten people have mild nausea or an upset stomach with the glucose (sugar) drink that is given during the OGTT. This can be minimized by drinking the sugar drink slowly over 5 minutes. Rarely, some people experience a mild low blood sugar reaction (symptoms like nervousness or sweating) at the end of the test. You will be offered a snack to guard against this from occurring.

Risks of the At-home mixed meal challenge: You are at no greater risk than usual when you consume foods of choice at home.

Risk of Wearing Dexcom G6 Pro device for 10 days: The primary risks with Dexcom G6 Pro wear include skin irritation due to adhesive; bleeding, pain or infection at insertion site; and remote chance of sensor wire breakage. To minimize risk of irritation or poor adhesion, you should refrain from using insect repellent, sunscreen, perfume, or lotion on your abdominal skin. To minimize risk of insertion complications, only trained study staff will place CGM on you. Staff will clean and dry hands, then put on gloves before insertion. The insertion site will be cleaned with alcohol wipes, and device inserted after the skin is dry. The device will be placed away from waistbands, scarring, tattoos, irritation, or bones (such as hip bone). To minimize risk of sensor wire breakage

upon removal, you will be instructed on safe removal technique via a Dexcom-created video as well as explanation by study staff. Sterile broken or detached sensor wires pose minimal medical risk. You will be encouraged to call the study team with any concerns as soon as possible and you may remove the device at any time if needed. If there is concern that the sensor wire has broken off under the skin, you will be advised to not remove it, but to contact the study team. You may also contact Dexcom's 24/7 Technical Support at 1-844-607-8398. You may require professional medical help if sensor wire is retained in skin, particularly if they have symptoms of infection or inflammation at the insertion site. You should not undergo magnetic resonance imaging (MRI), computed tomography (CT), or diathermy while wearing CGM due to reading inaccuracies that may result from magnetic fields or heat.

Are there any benefits to taking part in this study?

There is a potential for the study to benefit you by informing you of health abnormalities such as type 2 diabetes.

The knowledge gained from this research may help doctors better understand how to use continuous glucose monitors to evaluate the risk and/or diagnose type 2 diabetes in youth. The results of this study may change how we care for children and adolescents who are at risk for developing prediabetes or type 2 diabetes.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to follow the study doctor's instructions, keep all study appointments, and participate in the study as directed.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at Children's Hospital of Pittsburgh. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you out of the study if:

- The study is stopped.
- You cannot meet all the requirements of the study.
- New information suggests taking part in the study may not be in your best interests.

What choices do you have other than this study?

There are options for you other than this study, including not participating in this study. You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Protected Health Information (PHI) and confidentiality?

As part of this research, we will collect information from your medical record at CHP, including prior tests, physical exams, medication use and past medical history. We will enter information from the study into your CHP medical record, include physical exams or tests done in the clinical lab. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at Children's Hospital of Pittsburgh and the University of Pittsburgh Office of Research Protections
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services Office for Human Research Protections.
- Individuals monitoring the safety of this study;

By law, CHP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers may continue to analyze data for many years and it is not possible to know when they will be completely done.

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- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. You must inform the study team in writing. Please send your request to

Dr. Mary Ellen Vajravelu
Children's Hospital of Pittsburgh
Division of Pediatric Endocrinology, Diabetes, and Metabolism
One Children's Hospital Drive
4401 Penn Avenue Pittsburgh, PA 15224

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

- Participants will be paid $20 for travel or parking for the study visit
- Participants will be compensated $100 for the study visit
- Participants will also be paid $20 for wearing the Actigraph for 8 out of the 10 study days
- Participants will receive an additional $15 for participating in a phone/videoconference interview.

You will be paid on a reloadable debit card. Your name, address, and social security number will be released to the Accounting Office. All compensation is taxable income to the participant. If you receive $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

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What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, email the study doctor, Dr. Mary Ellen Vajravelu at MaryEllen.Vajravelu@pitt.edu. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at the University of Pittsburgh has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

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.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of CHP including federal repositories. This could include for profit companies. We will not ask for your consent before using or

sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

None is planned for the current study, but your samples may undergo genetic analysis in the future. This could include whole genome sequencing ("WGS"). WGS is identifying your unique genetic code from your biological parents.
There are risks to collecting genetic information. Genetics can tell us many things. It can confirm who your parents are by blood tests and if you are more likely to get certain diseases. This is confidential information. Whenever this information is stored, there is always a small chance someone can view it that is not supposed to. This is called a breach of confidentiality and is against the law. In some cases, it could be used to make it harder for you to get or keep a job, or insurance. Genetic information about diseases that some people have negative opinions about could be used in ways that could cause you or your family distress.
We protect you from this by taking your name or anything else that could identify you from the test results. The computer that holds the information has extra security with passwords. We limit how many people on the study team can know the password.
In addition, a federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers. GINA does not protect you against discrimination from genetic diagnoses that were already known.

Consent to Inform Your Doctors of Your Study Participation (OPTIONAL)

Please indicate whether you would like us to inform your non-CHP doctor(s) of your participation in this study. Please note that this only applies to non-CHP doctors, as research results will be included in your medical record at CHP.

_____ (initials) I request that my non-CHP doctor(s) **not** be informed of my participation in this study.

_____ (initials) I request that my non-CHP doctor(s) be informed of my participation in this study.

VOLUNTARY CONSENT

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your/your child's participation. You are also authorizing the use of your/your child's medical record information as discussed above. If you don't agree to the collection, use and sharing of medical record information, you cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

_____
Name of Subject

_____ _____
Signature of Subject (18 years or older) Date

_____ _____
Name of Authorized Representative (if different than subject)

Relation to subject:
[ ] Self [ ] Parent [ ] Legal Guardian

_____ _____
Signature of Authorized Representative Date

Child Assent to Take Part in this Research Study

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject Date

INVESTIGATOR CERTIFICATION:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date

CONSENT FOR CONTINUED RESEARCH PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative since I was unable to provide direct consent at the time that this initial consent was requested. I have now turned age 18 and I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during the course of this study. Future questions, concerns or complaints will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. I agree to participate in this research study and provide my authorization for the use of my medical records.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

Participant's Signature_____ Date_____