INFORMED CONSENT FORM

Official title: Feasibility and effectiveness of real-time, remote continuous glucose monitoring in adolescents with poorly controlled type 1 diabetes

NCT number: NCT04540536

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Title of Study: Feasibility and effectiveness of real-time, remote continuous glucose monitoring in adolescents with poorly controlled type 1 diabetes

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center
Children's Medical Center of Dallas and any of its affiliated entities

Key Information about this Study

The purpose of this research study is to determine if real time feedback of glucose (blood sugar) values improves diabetes care in poorly controlled adolescents with Type 1 diabetes. Study participants will wear the Dexcom Continuous Glucose Monitor (CGM) and share the data with the diabetes team. The medical research team will monitor the glucose data in real time and send a text message to each participant if they note high or low glucose or if the CGM is out-of-signal. The team will send a weekly text message to communicate insulin dose changes. Study participants can use the CGM for routine diabetes care including insulin dosing. They can communicate with the medical team using a secure group text messaging platform. After 3 months of the study, the participants will continue to wear the CGM for self-management of diabetes for another 3 months. However, they will not receive real-time text messages and feedback from the research team.

The participants will need a minimum of 3 in-person visits during the study period. The researchers will review the medical history, perform a physical examination, hemoglobin A1c measurement and complete quality-of-life and behavioral surveys. Visits will occur every 3 months for the duration of the study. The study is expected to last for six and a half months. The participants and their guardians will receive training on CGM placement.

Continuous glucose devices are FDA approved to monitor glucose levels in type 1 diabetes. Listed side effects include skin problems like itching, pain, redness, and infection at the insertion site

You may not receive benefit from taking part in this study. Your taking part in this study may help scientists, doctors, and people with type 1 diabetes understand more about the treatment of your disease. By taking part in this study, your health will be monitored closely at study visits.

Information about this form

Enrolling Children or Incompetent Adults
If you are providing consent for someone else, for example your child, your next-of-kin or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney, please note that in the sections that follow, the word "you" refers to the person you are providing consent for.

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT

Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Abha Choudhary, MD, Division of Pediatric Endocrinology.

Funding
This is an investigator initiated study. Dexcom, Inc, a for-profit company, is funding this study by providing the Dexcom G6 Continuous Glucose Monitors. Children's Foundation, a non-profit organization that promotes scientific research, is funding this study. This organization is providing money to UT Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

You are asked to participate in this research study for real-time remote continuous glucose monitoring (CGM) for Type 1 diabetes. The purpose of this research study is to determine if real time feedback of glucose values improves diabetes control in teenagers with Type 1 diabetes in poor control.

CGM is routinely used in diabetes management, and the data are routinely shared remotely with the medical team. However, providing real time feedback has not been studied.

The researchers hope to learn if the involvement of medical research personnel who remotely monitor glucose levels with real time feedback improves diabetes care.

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.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you have poorly controlled type 1 diabetes. Based on your hemoglobin A1c and history of prior hospitalizations for diabetic ketoacidosis (DKA), we estimate that you have a 40% chance of being hospitalized in the next 12 months if nothing changes
How many people are expected to take part in this study?
This study will enroll approximately 25 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend 3-4 visits with the research staff. It will be necessary for you to return to the clinic every 3 months. The study visits may be held in conjunction with routine diabetes care visits.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. Many of the procedures are described

below as "**standard of care**" and would be done even if you do not take part in this research study. You will be told which ones are for "**research only**".

Screening Procedures

- The medical history, physical examination, and hemoglobin A1c done during your routine diabetes clinic visit will be used to determine eligibility.
- If you are capable of becoming pregnant, a pregnancy test will also be done before you enrolling in the study. If your parents or guardian ask, we will tell them the results of your pregnancy test or that you are using birth control.

The research procedures will add approximately 1 hour to the length of a routine care visit.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.

Study Procedures - as a participant, you will undergo the following procedures:

You will wear a Dexcom G6 CGM for the duration of the study. At the beginning of the study, the research staff will insert a "blinded" CGM that you will be required to wear for 10 days. During this time, you will not be able to see your glucose readings. At the end of 10 days, and for the next 3 months, you will wear a "non-blinded" CGM that you will use to check your glucose levels and manage your diabetes for the duration of the study. You will be asked to check a finger stick blood glucose if your CGM shows glucose less than 70 mg/dl or greater than 250 mg/dl. You will share the glucose data with the medical personnel for 3 months. The researchers will monitor your glucose levels between 8 AM and 8 PM every day. They will send you and your legal guardians a secure text message if your glucoses are very high, very low or your CGM is not sharing data. You should respond to text messages promptly. At the end of 3 months, you will be provided with CGM to wear and use but you will not share your glucose data with the researchers. You will not be able to use the secure text messaging platform. You will be able to use the standard ways of communication with the clinic through telephone and the electronic patient portal (MyChart) throughout the study period.

<u>Procedures and Evaluations during the Research</u>:

Visit 1 Clinic (Up to 1 hour; up to 1 month before Visit 2, may be combined with Visit 2):

- Informed consent
- Collection of information necessary to determine if you are eligible to participate in the study including the type of diabetes, the duration of your diabetes, your medical history, your last hemoglobin A1c, and history of hospital admissions and emergency room visits in the last year.

Visit 2 Clinic (Up to 2 hours)

- Information including date of birth, gender, race, ethnicity, medical and surgical histories, current medications, and your school schedule
- Your insulin doses, adverse events and other medications will be reviewed
- Height, weight, vital signs (pulse, blood pressure) and a complete physical examination will be obtained.
- Finger stick blood sample to test hemoglobin A1c (HbA1c)
- A urine pregnancy test will be performed if you are a female capable of becoming pregnant.
- You will be given 4 questionnaires:
    - A quality of life survey
    - A depression screening survey
    - A questionnaire that will ask you about your comfort in managing your diabetes
    - A questionnaire to assess how you and your parents collaborate to take care of your diabetes.
- Researchers will insert a blinded continuous glucose monitor in the office (you will not be able to see your

glucose levels from this monitor, but researchers will be able to look at your readings.
- Researchers will install the required software and notifications on your personal cell phone and your guardian's cell phone that will allow sharing your real-time glucose data with the researchers.
- Researchers will send you a text message through Tiger Connect, a secure messaging platform. You will not need to download any software to be able to use this platform.

Between Visit 2 and Visit 2B or 2T
- You will wear a blinded Dexcom G6 continuous glucose monitor

Visit 2B (Clinic Follow-up) or 2T (Telephone Follow-up)
- Telephone call or clinic visit scheduled 10-14 days after placement of the blinded continuous glucose monitor
- Researchers will download and review your blinded continuous glucose monitor.
- You may not be able to continue in the study if you have not worn the blinded continuous glucose monitor for at least 60% of the time.
- You will be asked to remove the blinded continuous glucose monitor and insert a non-blinded CGM at home. You will share the glucose values with the clinic for real-time glucose monitoring. If you are able to insert and start the continuous glucose monitor and start sharing at home, you will not need to come to the clinic.

Between Visit 2B or 2T and Visit 3 (a period of 11-12 weeks +/- 5 days)
- You will wear a continuous glucose monitor and replace it regularly per manufacturer's instructions.
- You will share your data continuously with the clinic staff through the available "Share" function on the Dexcom App in your cellphone.
- Researchers will monitor your glucose levels every day between 8:00 AM and 8:00 PM.
- You will be provided a letter for school to indicate that you are participating in a research study and are allowed to carry your cell phone and respond to texts from us. We will work with you to make sure that only medically urgent communications happen during school hours.
- Researchers will communicate with you and your legal guardian through secure text messaging as follows:
    - Alert you if your blood glucose is more than 300 mg/dL for more than 2 hours, for blood sugars below 70 mg/dL that has double arrows down for more than 10 minutes, and if there is signal loss from your continuous glucose monitor for more than 4 hours.
    - Coordinating a time to review your glucose trends every 7 days (+/- 3 days) to evaluate if you need to change your insulin doses.
    - Reminders about upcoming visit appointments
    - Texts to encourage you to take good care of your diabetes.
    - Coaching texts in response to any questions you or your parents might have about your diabetes care or managing abnormal blood glucoses or ketones.
- We will store and use all text messages in a secured file. We will use this information to calculate the time used by our staff, the time it takes you and your guardian to read and respond to a text.

Visit 3 (Up to 1 hour; 11-12 weeks after Visit 2T +/- 5 days)
- We prefer this visit to be in person at the clinic but in extenuating circumstances, this visit can be performed via telemedicine visit.
- Insulin doses, adverse events and other medications will be reviewed
- Height, weight, vital signs and physical examination will be performed.
- Finger stick blood sample to test HbA1c
- You will be given 4 questionnaires:
    - A quality of life survey
    - A depression screening survey
    - A questionnaire that will ask you about your comfort in managing your diabetes
    - A questionnaire to assess how you and your parents collaborate to take care of your diabetes.
- The share function with the clinic will be turned off.

- Tiger Connect secure texts will be disconnected.

Between Visit 3 and 4 (a period of 11-12 weeks +/- 5 days).

- You will wear a continuous glucose monitor and use it to help you manage your diabetes.
- You may share the data in real-time with your parents or guardians, but you will not share it with the researchers.
- You will still be able to communicate with our clinic through the electronic participant portal and by calling the urgent line.

Visit 4 (Up to 1 hour; 11-12 weeks after Visit 2T +/- 5 days)

- We prefer this visit to be in person at the clinic but in extenuating circumstances, this visit can be performed via telemedicine visit.
- Insulin doses, adverse events and other medications will be reviewed
- Height, weight, vital signs and physical examination will be performed.
- Finger stick blood sample to test HbA1c
- You will be given 4 questionnaires:
    - A quality of life survey
    - A depression screening survey
    - A questionnaire that will ask you about your comfort in managing your diabetes
    - A questionnaire to assess how you and your parents collaborate to take care of your diabetes.
- This is the final study visit. You will not receive any further continuous glucose monitors from the researchers after this visit. You can discuss with your doctor the options to continue on continuous glucose monitors if you choose to do so.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. Any clinically relevant results of the research will be communicated to you. Clinically relevant means that the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable and it can be confirmed. In that case, we will attempt to notify you using the contact information you have provided.

If you do not want to be notified of any of these incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

Risks – "What are the risks of participation in the research?"

Risks from the specific research procedures (drug(s), interventions, or procedures)

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Psychological – Questionnaires, Surveys, and Monitoring

Some patients and families may find the repeated behavioral and psychological evaluations uncomfortable. In addition, some teenagers might feel annoyed when they know that a clinical professional is watching their glucoses very closely.

Loss of Confidentiality
Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of using a Continuous Glucose Monitor
Continuous glucose devices are FDA approved to monitor glucose levels in type 1 diabetes. Listed side effects include skin problems like itching, pain, redness, and infection at the insertion site.. Sometimes, readings from the continuous glucose monitor might be inaccurate and you might need to test your blood glucose by fingerstick.

Risks of Blood Drawing
You will have a fingerstick to collect your hemoglobin A1c as part of standard medical care for your type 1 diabetes. We will use your hemoglobin A1c results to study the outcomes of our research.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes questionnaires. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is that you will be able to use a continuous glucose monitor to manage your diabetes and will get the benefit of a medical personnel monitoring your glucose readings in real-time. In addition, you will have the support of your research team and can easily communicate with the them about any aspects of your diabetes care. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other people with similar conditions in the future.

Payments – Will there be any payments for participation?

You will receive $10 for every follow-up study visit attended (Visit 2B/2T, Visit 3, and Visit 4). You will receive a maximum of $30 for attending all study visits. If you withdraw from the study prior to completion will still receive $10

for each study visit prior to the completion of the study.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of follow-up study visits. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as the costs associated with a clinic visit and measuring a hemoglobin A1c. You will be responsible to obtain a cell phone to use to read the continuous glucose monitor data. Your phone needs to be connected to the Internet for the duration of the study to allow you to share data with the researchers in real-time. The sponsor will provide the continuous glucose monitors free of charge during this study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

How will my information and/or tissue samples be used?
With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research

study. In carrying out this research, the health information we will see and use about you will include:

- Your medical history and previous blood work.
- Information from the medical records related to your medical history and all treatments prior to the study
- Information that is created or collected during your participation in the study including information about your blood glucose levels.
- Secure text messages you send us during the study period and the time it takes you to read researchers' messages and to respond to them.
- Other information about you that we collected in the study such as during interviews or from the study questionnaires
- Results of Hemoglobin A1c while on treatment.
- Demographic information like your age, gender, marital status, and race/ethnicity

We will get this information by asking you and looking in your chart at Children's Health.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, University of Texas Southwestern Medical Center. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the company, Dexcom Inc, that makes the study drug/device and that will fund the study.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at: Children's Medical Center of Dallas.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of Children's Medical Center of Dallas for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to Dr. Abha Choudhary, 5323 Harry Hines Blvd, Dallas, TX 75390-9063. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Pooja Choudhari, MD can be reached at (214) 456-5959.

If primary is not available, contact
Abha Choudhary, MD can be reached at (214) 648-3501
The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

			AM PM
Printed Name of Participant	Signature of Participant	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

Surrogate Signature Section

			AM PM
Printed Name of Participant	Signature of Participant Giving Assent (*If incapable of signing, person obtaining consent should initial here*)	Date	Time
			AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent ☐Parent/☐Guardian/☐Legally Authorized Representative	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

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Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:
By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM