Safety and Feasibility Testing of AIDANET in Children Age 6-13 Years [AIDANET Pediatrics]

NCT07020936

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AS MODIFIED
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Parents' or Guardians' Permission for Your Child to Be in a Research Study

TITLE: Safety and Feasibility Testing of AIDANET in Children Age 6-13 Years

PROTOCOL NO.: None
WCG IRB Protocol #20252182
302210

SPONSOR: University of Virginia

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STUDY-RELATED PHONE NUMBER(S): 434-924-9971 / 434-924-0000, pager 3818 (24 hours)

Participant's Name_____ **Medical Record #** _____

In this consent form, "you" refers to the subject. If you are a parent or guardian, please remember that "you" refers to the study subject.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

How long will I be in this research?
We expect that your taking part in this research will last about 5 weeks.

Why is this research being done?
The purpose of this research is to test the safety of an investigative algorithm called Automated Insulin Delivery Adaptive NETwork, or AIDANET.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, the general procedures include: a screening process, physical exam, lab work, questionnaires, surveys, data collection (for 2 weeks prior to beginning study), a hotel session for training of device and observation (3 days and 2 nights), the at home study phase (2 weeks), and an end of study visit.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include risks of hyper or hypoglycemia, a loss of privacy or other unknown risks of this investigational device.

Will being in this research benefit me?
There may be no direct benefits for you to participate in this study. However, you would be helping researchers learn more about type 1 diabetes.

What other choices do I have besides taking part in this research?
Instead of being in this research, your choices may include not participating in this research study and continuing your personal care for management of your diabetes developed by your physician.

What else should I know about this research?
There is a possibility that identifiers might be removed from your private information or biospecimens and then used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH INFORMATION

In this form "you" means the person (your child) who is being asked to be in this study. As the parent or guardian, you are being asked to give permission for your child to be in this study. Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by Tandem Diabetes Care, Inc. (San Diego, CA). Supplies needed for this study will be purchased with this funding.

Note: You will need to provide your own insulin.

Key Information About This Research Study

What is the purpose of this study?

This is a research study about the UVA investigational Automated Insulin Delivery System known as Adaptive NETwork (AIDANET). This system consists of an insulin pump, continuous glucose monitor, and an automated insulin dosing algorithm (complex mathematical formula) which is installed on a smart-phone based control system. This system delivers insulin automatically trying to keep blood sugars in target range more often. It is referred to as a “fully closed loop” (FCL) system because the system will deliver all insulin for you, including background insulin (or basal insulin) and insulin for meals, without you needing to count carbohydrates or program bolus doses. We will test the system on you for 3 days and 2 nights (about 40 hours) in a hotel or rental house setting with study staff, including nurses, with you 24 hours each day to make sure the system is performing safely. Then, after the supervised study, you will continue to use the AIDANET system at home for another 14 days and 13 nights for diabetes management. While you are at home, the study staff will monitor your blood sugar levels remotely to help make sure the system is performing safely. Up to 52 participants will be enrolled in this research study.

You will be put into a study group by chance (like a coin toss/like drawing straws). You have a one out of four chance of being placed in each group. You cannot choose your study group.

If you are randomized to UC-Pre (Usual Care Control Period before use of experimental study system), you will be asked to collect two weeks of Usual Care data at home before the hotel session. UC-Post, (Usual Care Control Period after use of experimental study system) you will be asked to collect two weeks of Usual Care data at home after the hotel session and after the 14 FCL days at home session. You will use your personal equipment. If you are randomized to Normal-Glycemic Goal, you will be asked to have normal system adjustments for reaching blood glucose goals during the hotel session and for 14 FCL days at home. If you are randomized to Tight-Glycemic Goals, you will be asked to use a more aggressive adjustments to achieve glucose goals during the hotel session and for 14 FCL days at home. If you have questions about these adjustments, please ask the doctor and/or staff for more information.

What is the purpose of this study?

The purpose of this study is to test the safety of an algorithm called Automated Insulin Delivery Adaptive NETwork, or AIDANET. The AIDANET algorithm is an investigational device which means that it is not approved by the U.S. Food and Drug Administration (FDA). A variation of this algorithm has previously been tested in approximately 46 people. It has not yet been proven to be tolerated or helpful. The algorithm has been tested in a computer using insulin settings that have been collected from thousands of people with type 1 diabetes. This is called computer simulation. The algorithm is the only device that is being studied in this trial.

Why would you want to take part in this study?

You might like to take part in this study because this study may improve your understanding of your diabetes or may improve your ability to manage your diabetes. The information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?

You might not want to take part in this study because of the following reasons:

- This study uses an algorithm called ‘AIDANET’ which is investigational and not approved by the FDA.
- Your participation in the study will last about 5 weeks.
- You will need to share up to 6 months of your data from your insulin pump, CGM, activity tracker, and glucometer.
- You will need to stay at a local hotel with other study participants for about 40 hours. The study team will determine the hotel session dates when the hotel has availability. You will be asked if you can participate during those dates. If you are unable to participate during that time, you will not be able to participate in the study.

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What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- Wear a study issued or your personal Dexcom G6 CGM during the study. If personal CGM is the G7 model, you will be provided with a study G6 CGM to wear when using the study equipment. You will be provided with these supplies at no cost.
- Use lispro/aspart in the insulin pump during the study.
- Wear a study issued activity tracker (e.g., Fitbit) during the study. You will be provided with these supplies at no cost.
- Use a study glucometer to test your blood glucose values, if necessary. You will be provided with these supplies at no cost.
- Be instructed not to adjust your insulin parameters without first speaking with the study physician.
- Need to share your personal CGM data, insulin data, and activity tracker data with the study team.
- Need to participate in one hotel session lasting 3 days/2 nights (about 40 hours). Your hotel accommodation will be provided for you at no cost.

You will be provided with meals during the hotel session at no cost.

- Be allowed to eat snacks with carbohydrates per your usual routine at home. The study team will provide some snacks, but you are welcome to bring special snacks that you eat regularly at home.
- You will be asked to complete questionnaires to tell the study team about your expectations with the study equipment and then your experience with the study equipment. Completing these questionnaires will take about 30 minutes.
- Need to identify a person who lives with you or lives nearby (within 30 minutes) with the ability to locate you, is knowledgeable about emergency procedures for hypoglycemia and is willing to be in contact with study team if needed.
- If participant capable of becoming pregnant, must agree to use a form of contraception to prevent pregnancy while a participant in the study (e.g. hormonal contraception, abstinence from heterosexual intercourse).

What is the difference between being in this study and getting usual care?

If you take part in this study, the following things will be done differently than if you do not take part in this study.

You will need to participate in both remote (e.g., video chat, phone call, text message and/or email) and in-person study visits. You will have to give permission later in this consent form to be contacted via email or text message as it is optional.

You will need to have access to internet and willingness to upload data during the study.

You will use study equipment (e.g., smart phone based control system, study insulin pump, study CGM) during the study.

You will have regular check-in visits with the study team to see how you are feeling.

What other treatments may I receive if I decide to not take part in this study?

The following alternative treatments are available to you if you decide not take part in this study:

- You may continue your personal care for management of your diabetes developed by your physician.

How many people will take part in this study?

Up to 52 people will sign a consent form. The study will be performed at University of Virginia (UVA), the Barbara Davis Diabetes Research Center (BDC), and University of California, San Francisco (UCSF).

When a person or an organization has a financial or other interest large enough to seem as if it could affect their judgment, it is called a conflict of interest. Members of the UVA study team have a conflict of interest with this study. As owner of the intellectual property rights in AIDANET algorithm, the University of Virginia and some members of this research team may profit in the future if this study has good results. Please feel free to ask any further questions you might have about this matter.

How long will this study take?

Your participation in this study will require 8 study visits over about 5 weeks. There is a pre-screening visit which may occur up to 60 days before the actual study and it will involve reviewing the eligibility criteria to make sure you can qualify for the study as well as reviewing this consent form so that if you have any questions about the study, the procedures that will take place during the study or any other questions, the study doctor and team can answer your questions.

The screening visit (visit 1) will take about 60 minutes and may be completed by video, phone call, and/or in-person clinic visit. The Usual Care At Home data collection (Visit 3) for UC-Pre will be about 2 weeks. Visit 4 is a check-in visit with the study team and will take about 15-30 minutes each to complete and may also be completed by email or text messaging as well as video chat, phone call, and/or in-person clinic visit. The hotel sessions (Visit 5) will last about 40 hours.

Visit 7 will be two weeks of at home use of the study equipment for UC-Pre and UC-Post. UC-Pre will complete the study at the end of these two weeks. UC-Post will begin their two weeks of Usual Care data collection. A Post-Study Check-In Visit (Visit 8) will take about 15-30 minutes. This visit may be completed in person, telephone, video chat, email, and/or text messaging.

What will happen if you are in the study?

Prescreening Visit : Up to 60 days before the Screening visit.

Visit 1: Screening Visit

(Day 1) This visit may be completed in person, by telephone, or video chat and will last about an hour.

If you agree to participate, you will sign this consent form before any study-related procedures take place. Before you can start, you will have participated in the pre-screening visit. There will also be a screening period. You will have tests and procedures during the screening visit to make sure you are eligible, and it is safe for you to participate. These include the following:

- Demographics (date of birth, gender, race, and ethnicity).
- Contact information (name, phone number, e-mail address, mailing address).
- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature). A physical history from your endocrinologist or another physician dated within the last 12 months may be substituted.
- Blood may be taken from your finger to obtain a POC hemoglobin A1c test. This is the same test that you have done at your endocrinologist's office every 3 months to measure your blood glucose level over the last 3 months. A hemoglobin A1c value that was obtained within the last 30 days prior to the screening visit may be used for this test.
- If needed based on your medical history, the study physician may request a thyroid function or kidney/electrolyte blood test for laboratory testing. Changes in these lab results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin). Lab results within 3 months of your screening appointment may be used.
- If you are capable of becoming pregnant, a urine pregnancy test will be performed and must be negative for you to participate in the study. A blood test may be collected if other lab tests are necessary.

*All procedures completed in this study are for research purposes only.

Note: Potential eligibility may be assessed during a routine care physical examination. Any labs required may be obtained at a local laboratory (e.g. LabCorp, Quest) that is convenient to you.

If the study team determines that you are eligible to participate in the study, you will be asked to complete a Demographic Data Survey (date of birth, gender, race, ethnicity, where you live, your education level, etc.). You will be asked to complete the INSPIRE Questionnaire and Technology Acceptance Survey which is about living with diabetes and the use of technology in managing diabetes. These questions will take about 15 minutes to complete. You will complete this survey electronically with the use of your personal tablet or phone on a secure study website.

Visit 2: Randomization

Once you have been determined eligible to participate in the study, you will be randomly assigned (like the flip of a coin) to 1 of 4 study intervention groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your doctor can choose which treatment you are assigned.

- UC-Pre will complete a 2-week Usual Care period before use of the AIDANET system.
- UC-Post will complete a 2-week Usual Care period after use of the AIDANET system and the 14 FCL days at home session.
- Normal-Glycemic Goals will use the normal system adjustments to achieve blood glucose goals during the hotel admission and for 14 FCL days at home.
- Tight-Target will use more aggressive adjustments to achieve blood glucose goals during the hotel admission and for 14 FCL days at home.

Visit 3: Usual Care Data Collection Phase

(Day 3-16) Data collection will occur at home and will last about 2 weeks.

This data collection phase is to gather information on your normal insulin doses and amount of carbohydrates that you typically use each day. It is important to wear your CGM continuously during this phase of the study. This data will be stored in a cloud account.

During the Usual Care Data Collection Phase, you will be asked to use your personal insulin pump and personal CGM during this time. It is important to wear your CGM continuously during this phase of the study. You may use your insulin pump either in manual or automated mode, but this mode must permit downloading of the data by the study team. You will be provided with an activity tracker (e.g., Fitbit) to wear during the study during the Usual Care Period and the FCL Period. Researchers will use this data to analyze activity and exercise undergone during the study. You will be provided with a study glucometer to use to record any blood glucose values taken during the entire study.

You are asked to follow your normal routine involving diet, exercise, and insulin administration during this Usual Care phase.

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Visit 4: Pre-Hotel Session Check-In Visit

(About Day 15) This visit will be completed by phone, email, text, or video call and will take about 15-30 minutes.

You will be contacted by the study team approximately 1-3 days before the hotel session to:

- Ask you about any changes to your medical history and medication.
- Verify that a new CGM sensor was placed approximately 24-72 hours prior to the hotel session for proper warm-up.
- Remind you that the CGM reading should be less than 200 mg/dL at the start of the study at the hotel. The study physician may call you to see if you are experiencing low or high blood glucose levels prior to the hotel session.
- Remind you to bring your insulin and other medications that you will need during the study.
- You will be reminded to bring quiet activities to enjoy during the hotel session.
- Should any concerns regarding your health or unforeseen issues arise, the hotel session may be canceled at the discretion of the study physician.

Visit 5: Hotel Session

(Day 17-19) This visit will be completed in-person and will last 3 days/2 nights (about 40 hours).

After arrival at the hotel, you will be trained on the AIDANET system (smart phone based control system with the algorithm, study insulin pump, study Dexcom G6 CGM) and then start using it to manage your diabetes. You will eat 3 meals each day of your choice. There will be up to 6 participants during the hotel session at the same time.

Participants will be supervised at all times by research staff. There will be research staff present in the hotel overnight to perform overnight glucose testing as needed.

The hotel sessions will be the same for each group regardless of which group you are randomly assigned.

You will be allowed to use your CGM equipment if you are currently using a Dexcom G6 CGM, and you agree to share the CGM data with the study team.

Hotel Session Arrival:

- You will come to a hotel with your parent or guardian. They will stay with you during this admission.
- The hotel admission will last about 40 hours, which will include checking in and discharge activities. Testing of the system will last about 36 hours.
- The study team will confirm that you brought your insulin and regular medications to the hotel session.
- You will have vital signs (e.g., blood pressure, pulse, heart rate) completed.
- Your CGM reading and ketone values will be recorded. The study physician may recommend treatment if your CGM is not reading between 80-250 mg/dL.
- Your home insulin pump will be discontinued, and the study insulin pump will be initiated. The study team will ensure the proper function of the CGM, insulin pump, and activity tracker.
- The study team will provide snacks with carbohydrates if you need treatment for hypoglycemia (low blood sugar). The study team will need to record the carbohydrate information for any snack that you eat during the hotel study.

Hotel Session:

- Any adjustments to your current insulin parameters during the hotel session will be done with the assistance of the study physician.
- You will eat three meals per day during the hotel session. You will use your usual insulin: carbohydrate ratio at the dinner meal on one of the two nights. You will not bolus (give yourself insulin) for any other meals. The study team will record the time of these meals so they can evaluate the performance of the AIDANET algorithm.
- The CGM value must be at least 80 mg/dL to begin any physical activity. You are also free to engage in additional low-intensity activity during the hotel session. You must be accompanied by staff if you want to leave the hotel.
- Any CGM reading below 70 mg/dL or any potential low blood glucose symptoms will be confirmed with a fingerstick blood glucose using the study glucometer.
- At least two study team members (e.g., technician, nurse, physician, nurse practitioner, or physician assistant) will be present during the day and overnight hours of the hotel session. A study smart phone number will be provided to you so you can contact the study team.

Hotel Discharge:

- Your CGM value will need to be stable and between 80-250 mg/dL. Your ketone levels need to be stable (less than or equal to 0.6 mmol/L.). The study physician will talk with you about any treatment that you may need before you are discharged.
- You will be asked to monitor your ketone levels for up to 24-48 hours after discharge from the hotel session if ketones were elevated within 12 hours prior to discharge. Urine ketone strips may be provided to you, if needed.

Visit 6: FCL Equipment Training

As you use the FCL system during the hotel session, the study team will be training you on the use of this equipment (e.g., study smart phone, study insulin pump, and study CGM) so you are able to use this same equipment during the At Home FCL phase of the study. You will learn how to stop the system. You will also receive glycemic treatment guidelines on how to manage low blood glucose and high blood glucose events. You will be instructed on charging the insulin pump, the study smart phone, menu navigation, how to give yourself insulin, and infusion site changes.

Visit 7: At Home FCL Phase

(Day 20-33) Data collection will occur at home and will last about 2 weeks.

The study team will answer any remaining questions that you may have about using the AIDANET system at home. You will continue using the system to manage your diabetes for the next 14 days and 13 nights. You will be instructed to follow your normal routine involving diet, activity, and your diabetes management during the At Home FCL phase.

While at home you will eat at least three meals per day of your choice. It will not be necessary to record your mealtimes.

- You are asked to enter your usual insulin-to-carbohydrate ratio for all meals one full day (from waking to bedtime).
- You will be asked to announce when you begin to eat on one full day (from waking to bedtime).

You should continue with your usual activities and exercise. Study staff will be monitoring your blood glucose levels remotely, using the Dexcom app. Study staff will contact you if glucose is less than 55 mg/dL at any time, less than 70 mg/dL for 20 minutes, greater than 300 mg/dL for 60 minutes, and no sensor data for more than 60 minutes to ensure safety and help guide you in treating high and low blood glucose levels.

At the completion of the At Home FCL data collection period, you will return to using your personal equipment (e.g., insulin pump and CGM) and using your usual insulin parameters. A

qualified clinical study team member (e.g., MD, NP, PA, CDE) will be available to discuss the transition back to your usual care if you have questions.

You will be provided with a pre-paid shipment label to promptly return all study equipment (e.g., study smart phone, insulin pump, glucometer, and remaining CGM supplies). The glucometer can be returned to you after the study team has downloaded the data.

You will be asked to complete the INSPIRE Questionnaire and Technology Acceptance Survey at the conclusion of the At Home FCL phase. These questions will take about 15 minutes to complete.

Data collection for UC-Pre will be completed at the conclusion of the At Home FCL phase.

UC-Post will begin their two-weeks of Usual Care data collection. Data collection for UC-Post will be completed at the conclusion of the Usual Care phase.

Visit 8: End of Study Visit

(Day 33) Clinic, Telephone, or Video (approximately 15-30 minutes).

At the completion of the At Home Period, you will return to using your personal equipment (e.g., insulin pump and CGM) and using your usual insulin parameters. A qualified clinical study team member (e.g., MD, NP, PA, CDE) will be available to discuss the transition back to your usual care if you have questions.

You will be provided with a pre-paid shipment label to promptly return all study equipment (e.g., study phone, insulin pump, glucometer, and remaining CGM supplies). The glucometer can be returned to you after the study team has downloaded the data.

Visit 9: Post-Study Check-In Visit

(About Day 34) This visit will be completed by phone, email, text, or video call and will take about 15 minutes.

The study team will contact you about 24-48 hours after completing the post-hotel data collection period to:

- Ask you about any changes to your medical history and medication.
- Review any hypoglycemic events that are less than 70 mg/dL that you may have experienced.
- Review any hyperglycemic events that are more than 300 mg/dL that you may have experienced.
- Ask if you have any questions regarding the study. You can talk with the study physician or physician's assistant if you have questions related to adjusting back to your usual insulin parameters.

A member of the study data team may contact you if there are questions related to your data collection or equipment.

End of Study Participation:

After the Post-Study Check-In Visit 9, your participation in the study is complete. You will be referred to your primary care provider/or specialist for standard-of-care treatment.

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STUDY SCHEDULE

Contact type is clinic visit (CV), Remote (R), Phone (Ph) which includes text messages and emails.

	Screening	Randomization	Usual Care Data Collection	Pre-Hotel Check In	Hotel Session with FCL	FCL Equipment Training	2-week At Home FCL	End of Study	Post Study Check-In
Location	CV/R/Ph	CV/R/ Ph	Home x 2 week	R/Ph	House/ Hotel	House/ Hotel	Home x 2 week	CV/R/ Ph	Home
Visit	1	2	3	4	5	6	7	8	9
Timeframe	1	2	3-16	15	17-19	17-19	20-33	33	34
Informed Consent	X								
Eligibility Assessment	X								
Medical History	X								
HbA1c	X								
Pregnancy Test (if applicable)	X								
Blood Testing: BMP, Liver Functioning, Hematocrit, TSH (if requested by MD)	X								
Physical Exam (H&P within 6 months permitted as substitute)	X								
Vital Signs (including height/weight) (self-reported values permitted)	X				X				
Demographic Data Survey (if eligibility is met)	X								
Randomization		X							

Study Equipment Training						X			
CGM & Activity Tracker Use			X	X	X	X	X		
Fully Closed Loop (FCL) Use (e.g., AIDANET, study smart phone, study insulin pump, study CGM)					X	X	X		
Questionnaires	X						X		
Concomitant Medication Review	X				X				
Review diabetes management and AEs			X	X	X	X	X	X	X

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What are your parent/legal guardian's responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must attend each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- You should report any issues with the study equipment.
- Answer all of the study-related questions completely.

Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

Blood Testing

We will take (or "draw") up to 1 teaspoon of blood for screening. The blood we take will be tested to measure your hemoglobin A1c, a blood test used to monitor how well you're managing your diabetes. The total amount of blood we will take is less than 1 teaspoon of blood if tested at a laboratory and a droplet of blood if tested in the clinic.

If the study physician asks for additional labs (for example: hematocrit, pregnancy, and thyroid stimulating hormone) at your screening appointment, we will take less than 1 teaspoon of blood. The study physician may request these blood tests as these results may help show changes in your insulin resistance (when cells in your muscles, fat, and liver don't respond well to insulin).

When these tests are done any leftover sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

If you want to know about the results before the study is done:

During the study, your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

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What are the risks of being in this study?

Loss of Privacy:

A risk of allowing us to collect information about you is a potential loss of privacy. The study team will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot guarantee it will be completely safe.

- The study team will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach of confidentiality. All identifiable information about you will be replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- We encourage you to discuss the risks with your study doctor or any other health care professional who may understand our process.
- The hotel session will have other study participants also in attendance.
- The study team is not able to restrict other participants from sharing photographs that include you (e.g., social media) which could lead to a loss of confidentiality.

Risks and side effects related to the algorithm include:

Even though the study algorithm has been tested in a computer simulation or in another clinical study, there is still a risk that parts of the system may malfunction. As a result, you could receive less or more insulin than you need and be at risk for hyper- or hypoglycemia. The following are common cases of system malfunction:

- CGM sensor reads higher or lower than your actual blood glucose level.
- CGM sensor stops working or cannot communicate with the system.

Risks associated with staying at the hotel for research purposes:

Likely

- Loss of privacy
- Disruption of daily routine similar to staying at a bed and breakfast

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Risks and side effects related to treating type 1 diabetes (with or without using study equipment):

Likely

- Risks of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death. One of the ways this could happen is if the system delivers too much insulin when a meal was not eaten but the system detected what looked like a meal based on the CGM increasing.
- Risk of prolonged high blood sugar leading to Diabetic Ketoacidosis (DKA), hospitalization, and coma. DKA can lead to renal failure (kidney failure), cardiac arrhythmia (irregular heartbeat), myocardial infarction (heart attack), rhabdomyolysis (muscle breakdown), and even death.

Risks related to using a Continuous Glucose Monitoring Sensor:

Likely

- Failure or lack of sensitivity of the CGM sensor that requires replacement and or insertion of new sensor.
- Discomfort from insertion of sensor into the skin.

Less Likely

- Bruising less than ½ inch.
- Bleeding less than ¼ teaspoon.
- Inserting the sensor may cause infection, bleeding, or pain, and wearing the adhesive patch can irritate your skin.
- CGM sensor reads higher or lower than your actual glucose level.
- CGM sensor stops working or cannot communicate with the system.
- Skin irritation or allergic reactions to the sensor adhesives.
- Uncomfortable with study team members seeing your CGM values.

Rare but serious

- Using an unsecured Wi-Fi could expose the system to viruses and hacking.
- Breakage of the CGM sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.
- Bloodborne pathogen, such as Hepatitis B, if the shared CGM transmitter is not cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Risks associated with performing a urine pregnancy tests (women who can become pregnant):

Less Likely

- False positive or false negative results.

Risk of Sharing the Insulin Pump, Continuous Glucose Monitor, Glucometer, and Ketone Meter:

Insulin pump, continuous glucose monitor, glucometer, and ketone meter are 'single-patient use devices'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. All devices will be cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per approved cleaning procedure.

The CGM sensor will not be shared, and it will be discarded after use.

The glucometer will be returned to you once the data has been downloaded by the study team.

Risk of Activity:

There is a risk of musculoskeletal symptoms or injury from participating in physical activity. There are cardiovascular or cerebrovascular risks (including but not limited to dizziness, lightheadedness, syncope, arrhythmia [abnormal heart rhythm], or ischemia [inadequate blood supply to an organ]) associated with participating in physical activity.

Cybersecurity Risks:

Similar to other computer systems, medical devices may experience security breaches that may impact your safety. Manufacturers of these devices attempt to address these risks, but you should be aware that these risks do exist.

Connected Medical Devices, such as insulin pumps, CGMs, activity trackers, deliver care to you while collecting healthcare data through a wireless connection. Someone with advanced technical skills could potentially expose your personal health information or could potentially impact the safety of the device, such as changing your insulin pump settings which may cause hypoglycemia or hyperglycemia. We do what we can to decrease the chance of that happening, but it cannot be guaranteed.

Risks associated with having your blood drawn:
Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. State law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you. Ask the study doctor if you have questions about this.

Other Unexpected Risks:
You may have side effects that we do not expect or know to watch for now. Contact the study doctor or team if you have any symptoms or problems while on the study.

Blood Donation:
If you participate in this study, it may affect your ability to donate blood. If you have any questions, call the organization where you donate blood and talk to one of their nurses.

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Risks from Completing Questionnaires:
The questionnaires provided to you in this study may or may not cause any physical or emotional risks. These documents are de-identified, meaning your name is not associated with your answers. Rather, you will use only your assigned study subject number when answering the questions.

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Risks for women:
Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant or become pregnant during the study. If you have questions about birth control, please ask the study doctor or team. If you are pregnant now or get pregnant during the study, please tell us right away.

Could you be helped by being in this study?

People also may have good things happen to them because they are in research studies. These are called benefits. There may be no direct benefits for you to participate in this study. However, you may be helping researchers learn more about type 1 diabetes.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- managing your illness as recommended by your endocrinologist.

Will you be paid for being in this study?

You will be paid $500.00 for finishing this study. You will be compensated $100 for travel to the hotel session. You should get your payment about 6 weeks after your participation in the study is complete. The compensation payment may be reported to the IRS as income.

- All data collection phases: $250.00
- Hotel Session: $250.00
- Travel Compensation: $100

Payment for study visits completed will be provided after all study equipment has been returned to the study team, and study downloads have been completed. The study glucometer can be returned to you after the data is downloaded from the glucometer or the glucometer's app.

If you do not finish the study, you will be paid for the study visits that you have completed.

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If the study leader says you cannot continue, you will be paid the full amount for the study.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Hemoglobin A1c test
- Pregnancy test (if applicable)
- Study smart phone
- Insulin pump and infusion sets
- CGM supplies
- Glucometer and test strips
- Any additional laboratory tests the study physician requested from you to participate in this study
- Hotel and the meals provided during the hotel session

You will be responsible for the cost of your insulin that is used during the study. As previously noted, the use of the Dexcom Apps on a personal phone may result in data and text charges.

You and/or your insurance company will be billed for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may be billed for other drugs or treatments that are given to help you control any side effects. You will be billed for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The study doctor and study sponsor will determine whether your condition was caused by the CTP Mobi System, which is the insulin pump and software supporting the pump. Tandem will reimburse UVA the cost of treating your injury or illness only if it was caused by the CTP

Mobi System. No other medical expenses will be reimbursed by UVA or Tandem. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, gender, social security number, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

What happens if you leave the study early?

You can change your mind about being in the study any time. There are no penalties or loss of benefits to which you are otherwise entitled. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the site.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) You do not follow your doctor's instructions
e) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we ask that you notify the research team so any scheduled admissions may be cancelled. The study smart phone, study insulin pump, remaining study CGM and other supplies remain property of the study team and will need to be returned. The study glucometer may be returned to you once the study team has downloaded the data.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The study researchers are asking for your permission to gather, use, and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care.

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The institutions involved in this study include:

- University of Virginia Center for Diabetes Technology (UVA CDT)
- University of Colorado Denver | Anschutz Medical Campus | Barbara Davis Center for Diabetes (BDC)
- University of California, San Francisco (UCSF)

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, and date of birth.
- Social Security number ONLY IF you are being paid to be in this study.
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results.
- People or groups that oversee the study to make sure it is done correctly.
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research.
- Tandem Diabetes Care, Inc., and the people or groups it hires to help perform or review this research.
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study.
- Tax reporting offices (if you are paid for being in the study).
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites who are conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.
- Local Health Agencies--State/Provincial law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency.
- Members of the University of Virginia Center for Diabetes Technology (UVA CDT), the Barbara Davis Diabetes Research Center (BDC), and University of California, San Francisco (UCSF) and other non-medical staff may be present during the study to both observe and support the hotel session.

- People from Tandem Diabetes Care, Inc. may be present during your study hotel visit.
- Other participants may witness the study team attending to your needs (i.e. when your blood glucose level is low or high).
- Other participants will likely take photos of this event. Your face may be in these photos. Other participants may post these photos on social media without your permission. This may result in a loss of confidentiality and may help you decide if you would like to participate in the study or not.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the UVA, BDC, and UCSF. Every effort will be made to send this information without including your name, address, or phone number. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

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 if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please contact the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

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Please contact the Principal Investigator listed at the beginning of this document if you have questions, concerns or complaints or to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern or complaint about the study

What if you have a concern about this study?

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the site's Compliance Hotline phone number at 1-800-235-8700.

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Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that our institutions follow. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, our institutions cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect the phone number and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

You do not have to agree to use email or text message to be in this study.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone number and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Would you like to be contacted about future studies?
The researchers in this study would like to know if you wish to be contacted regarding participation in additional studies that may be appropriate for you. By agreeing to be contacted, you will allow a qualified member of the study team to contact you in the future to ask if you want to participate in additional studies. You have no obligation to participate in any study.

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Declining will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are otherwise entitled. Your clinic records will indicate that you do not want to be asked about future research by or through anyone but your treating physician.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the study team organizing the study. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of UVA without your permission.

You do not have to agree to be contacted about future research to be in THIS study.
PLEASE INDICATE YOUR CHOICE BELOW if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.
____ No, I do not want to be contacted about future research studies.

Signatures

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the child sign the assent form, unless the investigator determines that the child is NOT capable of signing.

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What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information, and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Parental/ Guardian Permission

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of child participant's parent, or individual authorized under state or local law to consent to the child participant's general medical care	Date
Printed name of participant (not required if participant personally provided consent)	Date

Person Obtaining Parental/Guardian Permission

By signing below, you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE)	PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME)	DATE

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Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.
Health Care Provider Name:
Health Care Provider Address:

Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study, or I do not have a health care provider.

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Leaving the Study Early

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by the study team via phone/email/text/video:

- Assessment of medical history or medications changes
- Assessment of glucose values <70 mg/dL and >300 mg/dL
- Assessment of urine ketone values measuring moderate or large range
- Assessment of adverse events, adverse device effects, drug issues, and device issues
- Discuss risk of severe hypoglycemia and/or severe hyperglycemia during the transition back to the subject's usual home basal insulin; participants will be advised that the study physician will be available for consultation during this transition period
- Return of study equipment

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

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Parental/ Guardian Permission

_____	_____
Signature of child participant's parent, or individual authorized under state or local law to consent to the child participant's general medical care	Date
_____	_____
Printed name of participant	Date

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE