TITLE:

Assessing the Feasibility of Continuous Glucose Monitoring in Reimagine Primary Care Clinics

SUMMARY:

A parallel randomized, multi-site prospective trial was conducted at four Intermountain Healthcare Clinics using a new CGM device (Dexcom G6) compared to a standard of care finger stick glucometer (FSG) (Contour Next One). All participants received usual care in Primary Care clinics for six consecutive months while using these devices. Data were collected via electronic medical records, device outputs, exit surveys, and insurance company (SelectHealth) claims in accordance with Institutional Review Board approval.

AUTHORS:

Isaacson B, Kaufusi S, Sorensen J, Joy E, Jones C, Ingram V, Mark N, Phillips M, Briesacher M

PROTOCOL ID #: 1050955

IRB #: 1050955

DOCUMENT DATE: November 08, 2018

Intermountain Healthcare, Salt Lake City, Utah, United States

May 21, 2020

Consent Form

Title: Assessing the Feasibility of Continuous Glucose Monitoring in Reimagine Primary Care Clinics

Location: Intermountain Healthcare's Reimagine Primary Care Clinics (Cottonwood Family Practice, Cottonwood Senior, Avenues Internal Medicine, and Holladay Internal Medicine)

Principal Investigator: Liz Joy, MD, MPH

Co-Investigator: Brad Isaacson, PhD, MBA, MSF

Sponsor: Intermountain Healthcare

When: 13 Months (November 1, 2018 – December 31, 2019)

Background: Intermountain is conducting a pilot on continuous glucose monitoring (CGM) to understand if this study can help with diabetes management. Successful demonstration of CGM may allow patients to manage their condition, which may avoid the highs and lows of glucose monitoring and make patients feel better. This may reduce healthcare utilization and cost for the patients and the healthcare system on a whole.

We are asking you to join because you have been identified as a patient in one of our Reimagine Primary Care clinics who may benefit from enhanced diabetic management. You are being asked to track your glucose levels and share feedback and your clinical experience to improve our clinical workflows. Your contribution will involve downloading mobile applications, entering/tracking your data, engaging with your physicians, and participating in an exit survey. As part of this study, you will be randomly put into one of two groups. The people in one of these groups will receive care as usual which involves checking sugars with a finger stick and a familiar glucometer. The people in the other group will check sugars with an FDA-approved device that monitors sugars continuously and does not involve finger sticks. Approximately 125 people will take part in this study at Intermountain Healthcare. The length of participation in

the study will include patient recruitment, three months of device usage, and six months of follow up.

Please read this form and ask any questions you may have before you decide whether to be in this research study.

Study Procedures

You will be recruited from the waiting room in the Reimagine Primary Care clinics because you have been identified as a patient with diabetes who currently participates in glucose monitoring or you will be offered this during your current appointment. If you wish to participate, you agree to be placed into one of two groups and follow the directions for that group. Your placement will be done randomly, and you have a 50% chance of being in either study group. Group #1 will use the Dexcom G6 continuous monitor or "Dexcom CGM". Group #2 will use standard of care which means that you will check your sugars with a ContourNext One glucometer as many times as is determined appropriate by you and your doctor. If you are randomized into Group #1, your coordinator will instruct you on how to properly install the device. You will then be required to wear the patch for the duration of the study (6 months). The patch will need to be changed every ten days and your coordinator will also instruct you on how to do this and will provide you with enough patches to last the duration of the study. The Dexcom CGM and ContourNext One devices are equipped with Bluetooth and data will be automatically uploaded and sent to Intermountain Healthcare personnel through online portals. This will require downloading applications on your phone (apps) (e.g. Dexcom G6, Dexcom Clarity, ContourNext One) to view and transmit your data. A pamphlet with pictures about the devices will be provided at your appointment (Appendix A). During your study participation two blood draws will be required to compare HbA1c levels at study start up at study closing. The first blood draw will be performed on day of consent and the last blood draw will be performed upon study completion (6 month follow up ± 2 weeks). Cost of the first blood draw will be fully covered by the study and the second blood draw will be covered by your insurance. If your insurance will cover a 3-month blood draw or if your Reimagine Provider believes one should be conducted to measure your HbA1c, the study will also collect those samples for data comparison.

Risks

Patient safety is our number one goal, however with any research trial there may be risks involved. The primary risks of this study are to your privacy. All glucose-related data will be secured in approved Intermountain apps (REDCap, Contour Next and/or Dexcom Clarity). Data from Intermountain Healthcare's Enterprise Data Warehouse (EDW), which stores your standard health record information (medications, laboratory services used, clinical encounters, demographic information, etc.) will be combined to make a dashboard without your personal information (Tableau or similar) to understand the device use on care delivery. We may perform predictive analytics with a research partner of ours (Savvysherpa) to help future patients, however, your identifiable information will not be shared with that entity.

You may also experience pain with obtaining a blood sample for the finger stick glucose readings, however it is just like you are already doing without any expectation for additional pain or bleeding. If you are in the Dexcom CGM group there is potential for pain on application of the patch every ten days, but the pain is about the same as a finger stick glucose. Unforeseeable risks may occur, outside of what is noted above, and the study team will report these findings to you if there is a health concern.

Benefits

You may benefit from this study if you are able to manage your glucose levels more carefully. This can improve your health/wellbeing and reduce doctor visits which are costly. Further, information that we learn from this study may help us to better treat patients in the future.

Voluntary Participation

You do not have to be in the study. Your decision to take part in this study is completely voluntary. You may discontinue participation at any time. You can change your mind later and ask us to stop collecting your information. You can give this notice to your study team or mail it to:

Liz Joy, MD, MPH
Intermountain Healthcare
36 S. State Street
Salt Lake City, UT 84111

If this happens, we will not collect new information about you and you will not be able to continue in the study. However, we will continue to use the information we have already collected.

You may be voluntary terminated from this study if you fail to use the glucose devices and report data back on a daily basis. You will be notified by the study personnel if this occurs. Further, if new study findings are discovered that may influence your decision to participate in this study (e.g. additional risks), then they will be communicated to you.

Costs and Compensation

You will not be charged for any of the study costs nor will your insurance. You will not be paid for being in this study, but you will receive the appropriate glucose meter and replacements sensors/strips for participation during the study period. These devices/strips/sensors will be paid for by Intermountain Healthcare however if you are randomized into The Contour Next One group, we will ask you to please mail the device back upon study completion. A prepaid card will be given to you to cover the mailing expense at the time of consenting.

Alternative (Non-Research) Treatments

In this study, we will be using devices that are commercially available. The ContourNext One glucometer is the current standard of care and is the most accurate of its kind available while the Dexcom G6 CGM is a novel FDA-approved device that will continue to measure your glucose every 5 minutes throughout each day. These devices are commonly used by patients to understand and control their blood glucose. Other devices do exist, but the only other alternative for diabetic management is diet, exercise and blood draws for HBA1c levels. Aside from these options, you may choose to not participate in this study.

Will the researchers be paid for running this study?

This study is paid for by Intermountain Healthcare. The researchers do not receive extra payment for conducting this study.

In research a conflict of interest (COI) can happen when someone has more than one interest in the study. For example, a physician doing research could also own stock in a company that is paying for his or her research or the development of a new drug or product used in a study. In this study, the researchers have indicated that they do not have any conflicts of interest.

Research Injury:

If you become injured while taking part in this study, Intermountain Healthcare can provide medical treatment. We will bill you or your insurance company in the usual way. Because this is a research study, some insurance plans may not pay for your treatment. If you believe you have been injured as a result of being in this study, please call the Principal Investigator right away. You may also contact the Intermountain Institutional Review Board (IRB) at 1-800-321-2107 or IRB@imail.org.

Person to Contact:

If you have questions, concerns, or complaints about this study, you can contact Dr. Liz Joy at liz.joy@imail.org or 801-442-3721.

If you have questions regarding your rights as a research subject or if problems arise which you do not feel you can discuss with the study team, please contact **Intermountain's IRB at 1-800-321-2107 or IRB@imail.org.**

How will my information be used and protected?

If you decide to take part in this study, Intermountain Healthcare will use your glucose data to understand how these management techniques impact patient outcomes, cost and utilization of services. This information will be stored up to 5 years, along with the survey data we collect. However, any data shared with our research partner (Savvysherpa) will always be anonymized to protect your confidentiality.

Consent

I have read and I understand this consent document. I have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose information about me for this study, as you have explained in this document.

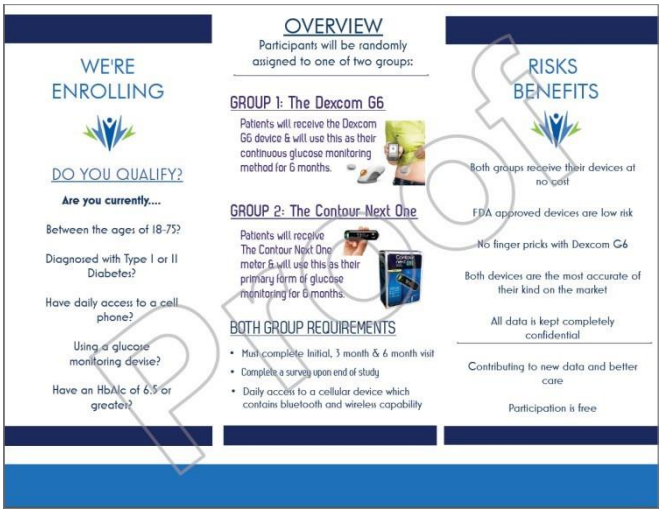
Participant's Name (Print)

Participant's Signature Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent Date

Appendix A: Pamphlet with Device and Study Information



CGM Pilot Phone Script

Hi [patient name],

My name is [site coordinator's name]. I am working with your doctor, [physician's name], at [their Reimagine Clinic] and Intermountain Healthcare. Thank you for taking my call. How are you today?

I'm calling because [physician's name] informed me that you may benefit from a study that we are currently enrolling for; do you have a moment to talk?

IF	**THEN**
Yes	Proceed with Script
No	Ask to schedule a call back.
Call back Declined	"We can meet with you in the clinic prior to your appointment to walk through it." Meet patient in clinic and attempt to recruit/consent.

As a brief overview,

Intermountain is conducting this pilot study to understand the impact of continuous glucose monitoring versus the standard of care, or finger-prick method, of glucose monitoring. Successful demonstration of this study may allow patients to better manage their condition.

We are asking you to participate because your doctor has identified you as someone who may benefit from enhanced diabetic management. If you qualify, you will receive 6 months of glucose monitoring supplies at no cost to you. Your contribution would involve downloading mobile applications, entering/tracking your data, engaging with your physicians, completing an exit survey, and providing two blood draws.

Is this something that would interest you?

IF	**THEN**
Yes	Proceed with script.
No	Thank patient for their time, provide contact info for if they have any further questions

Qualifying factors for this study include:

- Being between the ages of 18 and 80.
- Current diagnosis of Type 1 or Type 2 Diabetes. Most recent HbA1c level of 6.5 or higher. Monitoring glucose levels on a daily basis Have daily access to a smart phone.

Do you have any questions or concerns with the study criteria?

IF	**THEN**
Yes	Answer questions appropriately
No	Continue with script
Do not qualify per exclusion above	Thank patient for their time, provide contact info if patient has further questions

As part of this study, you will be randomly assigned to one of two groups. Group 1 will check sugars with an FDA-approved device that monitors blood sugar continuously and does not involve finger sticks. Group 2 will receive care as usual which means checking blood sugar with a familiar FDA approved finger stick glucometer. Either device would be supplied to you at no cost for the duration of your participation, which will last six months.

Do you have any questions about this study?

Is this something you'd be willing to participate in?

IF	**THEN**
Yes	Continue with script
No	Thank patient for their time, provide contact info if patient has further questions

Thank you! I would like to schedule a time when we can meet at [site name] to review eligibility and sign a consent form for participation. The consent form will further explain what we have discussed over the phone and provide details as to how your information will be protected.

When are you available to meet? (obtain date and time)

Thank you for taking the time to speak with me.

Here is my phone number so that you may call or text me with any questions. [phone #]

Intermountain® Healthcare

{Todays Date}

{Study Designee}
Intermountain Healthcare
36 S. State Street
Salt Lake City, UT 84111

{Recipients Name}
{Recipients Street Address}
{Recipients City/State/Zip code}

Dear {Recipients Name},

You have been identified as a patient who is currently enrolled in Intermountain Healthcare's continuous glucose monitoring pilot study.

This letter is to inform you that a maximum of 3 telephone calls and/or emails have been attempted for your participation in study #1050955, *Assessing the Feasibility of Continuous Glucose Monitoring in Reimagine Primary Care Clinics*. We are requesting a verbal or written response in an effort to reestablish contact between you and your Study Coordinator. If contact is reestablished, interest in continued participation will be verbally confirmed and documented, and you will return to active study participation as appropriate.

With failure to re-establish contact, and failure to find new contact information, you will be considered lost to follow up and removed from this study.

Sincerely,

{Study Designee}