Feasibility of Remote Data Collection With a Point of Care Device to Measure HbA1c

Protocol

May 16, 2025

NCT05725746

Primary Aim

- What is the acceptability and feasibility of virtual instruction for home data collection using an A1c point of care device?

Design and Methods

- Observational Study
- Parents enrolled in a home visiting program (at least 18 years of age; English or Spanish speaking) were contacted by the research team. Those that consented were sent AIc point of care device. Research staff completed a virtual meeting with participants to use the A1c device. Participants completed a short survey that included questions regarding their satisfaction with using the device.

Statistical Analysis Plan

Descriptive statistics were only applied to assess feasibility and accessibility.

Background and Significance

Diabetes and cardiometabolic disease are increasing in people of childbearing age at alarming proportions. There is a critical need to develop and test effective strategies to mitigate these diseases. However, barriers to in-person data collection limit opportunities for participation in research that tests lifestyle interventions, particularly for parents due to barriers such as time and transportation. With the recent widespread use of virtual technology (e.g., live videoconferencing) there is an opportunity to conduct research assessments virtually, potentially mitigating time and transportation constraints to participation.

References

Plüddemann A, Thompson M, Price CP, Wolstenholme J, Heneghan C. Point-of-care testing for the analysis of lipid panels: primary care diagnostic technology update. Br J Gen Pract. 2012 Mar;62(596):e224-6. doi: 10.3399/bjgp12X630241. PMID: 22429442; PMCID: PMC3289831.

Sohn AJ, Hickner JM, Alem F. Use of Point-of-Care Tests (POCTs) by US Primary Care Physicians. J Am Board Fam Med. 2016 May-Jun;29(3):371-6. doi: 10.3122/jabfm.2016.03.150249. PMID: 27170794.

Lilly CM, Ensom E, Teebagy S, DiMezza D, Dunlap D, Hafer N, Buchholz B, McManus D. Patient Preferences for Point-of-Care Testing: Survey Validation and Results. Point Care. 2020 Dec;19(4):112-115. doi: 10.1097/poc.0000000000000214. PMID: 34707464; PMCID: PMC8547737.

FOR IRB USE ONLY
IRB ID #: 202212059
APPROVAL DATE: 12/14/23
RELEASED DATE: 12/14/23
EXPIRATION DATE: N/A

CONSENT INFORMATION SHEET

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis.

You are being asked to participate in this research study because you are participating in the Parents as Teachers program. The purpose of this study is to evaluate data collection procedures for a project called ENRICH.

If you agree, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to meet with someone virtually to obtain your AIC (a measure of your average glucose level over the past three months) through device placed on your upper arm for 5 minutes to collect a blood sample. The equipment you need will be mailed to you. The research team will obtain the measurement via video call. If you are unable to do a video call, the research team will instruct you over the phone.

You will also need to complete a phone survey that takes about 5 minutes. The survey will ask questions about your overall opinion of the data collection process, as well as demographic information and health related to diabetes and heart disease.

If you agree to text messaging later in this consent document, you will receive a maximum of 2 text messages unless you want to use text to schedule and/or reschedule data collection visits in which you may receive a few more text messages.

The National Institutes of Health is funding this research study.

Video Recording

One aspect of this study involves making video recordings of you. The video recordings will be used to help us improve on the data collection process. Only members of the research team will be able to review the audio recordings and they will be destroyed once the study is complete.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your recording.

I give you permission to make video recordings of me during this study.

_____ Yes _____ No (Record response)

The data we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

FOR IRB USE ONLY
IRB ID #: 202212059
APPROVAL DATE: 12/14/23
RELEASED DATE: 12/14/23
EXPIRATION DATE: N/A

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and the general public. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Approximately 15 people will take part in this study at Washington University.

The main risks to you if you participate are discomfort when obtaining your AIC. There is a slight risk of infection, bruising and bleeding at the site. You are free to skip any questions that you prefer not to answer. You may choose to stop participating and withdraw from the study at any time.

You will not not benefit from participating in this study. However, we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study.

You will be paid for being in this research study. You will be given a $30 gift card after you complete the data collection visit. You will be asked to provide your social security number (SSN) in order for us to pay you.

We will keep the information you provide confidential by labeling your data with a unique ID that can be linked to you. The research team will enter your data online using a unique ID. The record that links these IDs to your information will be encrypted and stored on a secure server. Data will be stored in an encrypted format on a secure server. Any hard copy information will be kept in a locked cabinet in a locked office.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

Federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records

FOR IRB USE ONLY
IRB ID #: 202212059
APPROVAL DATE: 12/14/23
RELEASED DATE: 12/14/23
EXPIRATION DATE: N/A

pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

We would like to contact you by text message for the purposes listed below. Some of these messages may contain information that identifies you.

- If needed we may ask you to send us a picture from your data collection visits. Also, if needed, we may text to schedule the data collection visit.

Only the research team will have access to your texting communications. We will only communicate by text to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document. Message and Data rates may apply.

You should be aware that there are risks associated with allowing us to text you for the purposes of this study.

- Text messaging is not a secure communication method.
- There is always a risk that the text message could be intercepted or sent to the wrong telephone number. To avoid sending messages to the wrong number, the first text we send you will be a test message to ensure we have the correct telephone number.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send you text messages as described above?

_____ Yes _____ No (Record response)

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time.

FOR IRB USE ONLY
IRB ID #: 202212059
APPROVAL DATE: 12/14/23
RELEASED DATE: 12/14/23
EXPIRATION DATE: N/A

Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, you can stop taking the survey or not obtain the measurement. You will not be penalized or lose any benefits for which you otherwise qualify. You can continue to participate in PAT.

If you do not wish to participate in this study, you may tell the study team or parent educator that you are not interested.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Cindy Schwarz, 314-935-3063**.** If you feel you have been harmed from being in the study, please contact: Dr. Rachel Tabak, 314-935-0153. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.