Official Title: American Sign Language-Accessible Diabetes Education

NCT Number: NCT03980808

Informed Consent Form: September 15, 2020

IF YOU ARE LOCATED IN A EUROPEAN UNION (EU) COUNTRY, YOU ARE NOT PERMITTED TO PARTICIPATE IN THIS STUDY DUE TO THE GENERAL PROTECTION DATA REGULATION (GDPR).

Georgia Institute of Technology
Center for Advanced Communications Policy

Informed Consent for Research Study:

American Sign Language-Accessible Diabetes Education (ASL-ADE) Project

Investigators: Muslimah "Salimah" LaForce and M.S., Maureen A. Linden, M.S. BME

Protocol and Consent Title: Protocol number: H19229, Informed Consent for Research 06/07/19v3

Key Information:

What Am I Being Asked To Do?
You are being asked to be a volunteer in a research study. This section will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?
The purpose of this study is to is to test how well and ASL-accessible educational video is at increasing knowledge about diabetes. First, you will complete a questionnaire about what you currently know about diabetes and associated health behaviors, then you will view the video, then you'll complete the questionnaire again. That will take about 90 minutes. Then one month later you would take another questionnaire (in person or via videophone) about what you know about diabetes and associated health behaviors. That will take about 45 minutes.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?
The risks are no greater than those normally faced while traveling around a city, talking to friends, using a phone or the internet. The

primary risk is breach of confidentiality, but we avoid personal identification of research participants.

What Are the Reasons You Might Want to Volunteer For This Study?
By being in this study, you will have helped the research being done to improve diabetes educational outreach to the Deaf population. You may also personally benefit by learning about diabetes.

As compensation for your time, we are offering $40 for the first session and $20 for the 30-day follow-up. You will be given the funds even if you decide to leave the study early.

Do You Have to Take Part in the This Study?
It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

Purpose:

This study will assess a video about diabetes health information to see how to make it accessible to people whose first language is American Sign Language (ASL). The *ASL-ADE* project goal is to test how well the educational video is at increasing knowledge about diabetes. Your feedback will be used to create an ASL-adapted diabetes education program.

An estimated forty (40) participants are expected to be involved.

Inclusion/Exclusion Criteria:

To participate in the study, you must be 18 years of age or older, Deaf, and primarily communicate using ASL. **Or** be 18 years of age or older, Deaf, primarily communicate using ASL, and have diabetes.

You cannot participate if you are under 18 years of age or are unable to give consent. Also, if you are located in a European Union (EU) country, you are not permitted to participate in this study due to the General Protection Data Regulation (GDPR).

Procedures:
If you decide to be in this study, your part will involve no more than two sessions one month apart. You will be randomly (by chance, like flipping a coin) assigned to one of two groups, an *ASL-ADE* intervention group or a control group. In the initial session (via video conferencing or in-person if COVID-19 restrictions have been lifted), which will take about 90 minutes, you will complete a short questionnaire about diabetes and related health behaviors, watch a video, then take a short questionnaire about diabetes. At the second session (via videophone or video conferencing), which will take place in approximately one month, you will take a short questionnaire about diabetes and related health behaviors.

Your total time commitment will be up to 2 hours and 15 minutes:

- One 90-minute session over video or in-person during a single visit to Deaf Link, Inc., or Georgia tech, and
- One 45-minute follow-up questionnaire over videophone or video conferencing.

An ASL interpreter will always be present to interpret the questionnaires and voice your responses to the researchers. Remember, you may stop at any time.

Risks/Discomforts
The risks are no greater than those normally faced while traveling around a city, talking to friends, using a phone or the internet. The primary risk is breach of confidentiality, but we avoid personal identification of research participants.

Benefits
By being in this study, you will have helped the research being done to create accessible diabetes education tools for the Deaf population. You may also personally benefit by learning about diabetes.

Compensation to You

You will be compensated $40 for participation in session one of the research before you leave the premises. For session two, you will be compensated $20 for the 30-day follow-up questionnaire. If conducted over a videophone/video conference, a check will be mailed to an address that you provide.

You will be paid separately, in full, for each phase of the study regardless of if you terminate early.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing your Information:

Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Confidentiality

The following procedures will be followed to keep your personal information confidential in this study: The data that is collected about you will be kept private to the extent required by law. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files, and only study staff will be allowed to look at them, unless you give specific consent otherwise. Your name and any other fact that might point to you will not appear when results of this study are presented or published.

To make sure that this research is being carried out properly, the Georgia Institute of Technology IRB may review study records. The Office of Human Research Protections may also look at study records. The sponsor of this study, National Institutes of Health, has the right to review study records as well.

We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate

cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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.

Costs to You

Participation in this study will incur no costs to you other than that associated with transportation to the site, and your time.

Questions about the Study or Your Rights as a Research Subject

- If you have any questions about the study, you may contact Muslimah LaForce, principal investigator, at telephone (404) 894-8297.
- If you have any questions about your rights as a research subject, you may contact Ms. Melanie Clark, Georgia Institute of Technology at (404) 894-6942.

In Case of Injury/Harm

If you are injured because of being in this study, please contact Muslimah LaForce, principal investigator, at telephone (404) 894-8297. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

Questions about Your Rights as a Research Participant:

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.

- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

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Subject Name

Subject Signature **Date** **Time**

Signature of Person Obtaining Consent **Date**