INFORMED CONSENT FOR CLINICAL RESEARCH STUDY
Texas A&M University

Title: Towards understanding the relationship between meals and blood biomarkers

Principal Investigator: Sherecce Fields, Associate Professor

Study site: Texas A&M University, 675 John Kimbrough Blvd

You are being invited to take part in a research study being conducted by Texas A&M University. Please take your time and read this entire form. Ask questions before deciding if you want to take part in this research project.

1.) KEY INFORMATION:

a. The purpose of this study is to establish the reasonableness of using food-based photo diaries and continuous glucose monitors (CGM) to engage in counterfactual thinking strategies. These strategies may improve food choices among participants diagnosed with type 2 diabetes (intervention group).
b. You will be placed in one of the two study groups: intervention (receiving counterfactual thinking strategies) or control (no intervention) group.
c. Risks or discomforts from this study include mild pain and skin irritation. This is due to placement of the CGM.
d. There is no guarantee this study will benefit you.
e. The alternative is not to participate in this study.
f. We will ask for your permission to obtain your protected health information (PHI) that will be used for this research only.

2.) WHAT SHOULD YOU KNOW ABOUT A RESEARCH STUDY?

a. Someone will explain this research study to you.
b. Whether or not you take part is up to you.
c. You can choose not to take part.
d. You can agree to take part and later change your mind.
e. Your decision will not be held against you.
f. You can ask all the questions you want before you decide.

3.) WHY IS THIS STUDY BEING DONE?

The purpose of this study is to establish the reasonableness of using photos of food consumed and CGM monitors to engage in counterfactual thinking strategies. These strategies may improve food choices among diabetic participants.

4.) WHY AM I BEING ASKED TO BE IN THIS STUDY?

You are being asked to be in this study because you are diagnosed with type 2 diabetes (T2D) and take glucose-lowering medication(s). You are also motivated to learn how to regulate your blood glucose through non-medical intervention such as changes to eating behavior.

5.) HOW MANY PEOPLE WILL BE ASKED TO BE IN THIS STUDY?

We will enroll up to 40 participants in the study, up to 20 subjects in the intervention group and up to 20 subjects in the control group.

6.) WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?

The alternative to being in the study is not to participate.

7.) WHAT WILL I BE ASKED TO DO IN THIS STUDY?

Your participation in this study will include 1 screening visit and 6 study days. All study procedures performed are for research purposes only. They are not considered medical treatment or standard medical care. All personnel have received training for performing the research procedures. They may not have a medical license. The procedures you will be asked to perform are described below.

The screening visit

a. This visit will last about 2 hours. You will need to arrive fasted. Before any study-related tests and procedures are performed, study personnel will discuss the study with you. They will discuss its risks, benefits, and compensation with you. If you agree to participate, you will need to sign this consent form.
b. During the screening visit, you will be asked questions about your health history. You will also be asked about your use of medication. These will be used to determine your eligibility for the study.
c. We will also measure your A1c level or fasting plasma glucose. This will be used to determine your baseline glucose levels. A blood draw and/or finger stick will be required to complete this test.
d. Furthermore, we will assess body weight, height, and vital signs.
e. If accepted into the study, you will be asked to provide a food diary of all the meals you eat. You will do this by sending us messages through WhatsApp. WhatsApp is an application on your smartphone. We will ask you to provide pictures of your meal. With this picture you will provide a brief text description. Generally speaking, food eaten within an hour of other food will be considered the same meal.

Study day 1:

On this study day a CGM monitor will be placed on your upper arm. You will undergo baseline interviews and questionnaires with the research personnel before you leave. You will return in 2 weeks after this visit. For these 2 weeks, you will wear the CGM and send pictures of every meal and any snacks that you eat.

Study day 2:

On this study day the CGM monitor data will be collected. Once the data is collected the CGM will be removed. A new CGM monitor will be placed. You will wear this new monitor for 1 week. During this week you will continue to send photos of all the food you eat.

Study day 3:
For this third visit, the CGM monitor data will be downloaded and removed. It will again be replaced with a new CGM monitor. At this session you will also be randomly assigned to behavioral intervention group.

- Counterfactual thinking - During this intervention, you will look at your CGM readings throughout the first two weeks and compare them to the food you ate at those specific times. You will then use a "might have been" approach based on which foods were considered healthy and unhealthy in relation to your blood glucose levels.
- Reflective writing - During this intervention, you will look at your CGM readings throughout the first two weeks and compare them to the food you ate at those specific times. You will then have the opportunity to reflect on the meals and how you feel about the changes in glucose levels based on the food choices you made.

After this visit you will go home and wear the CGM monitor for another 2 weeks. You will continue to take pictures of all the food you eat. This session will be video recorded.

Study day 4:
After returning from the 2 weeks, the CGM monitor will be permanently removed from your arm. You will also undergo post-treatment interviews and questionnaires with a researcher. You will be instructed to resume your normal life for 2 months. After the 2 months you will come back for the first of two follow-up visits.

Study day 5:
At this visit, your A1c or fasting plasma glucose will be measured. A blood draw and/or finger stick will be required to complete this test. You will also undergo delayed-post test interviews and questionnaires with a researcher. After 2 months you will come back for the final follow-up visit.

Study day 6:
At this last visit, your A1c or fasting plasma glucose will be measured. A blood draw and/or finger stick will be required to complete this test. You will also undergo delayed-post test interviews and questionnaires with a researcher.

All the above mentioned procedures are experimental. Results of testing are available upon your request.

8.) WILL PHOTOS, VIDEO OR AUDIO RECORDINGS BE MADE OF ME DURING THE STUDY?

The researchers will make an audio and video recording during the study so that the quality of the intervention (study day 3) can be monitored and your responses can be accurately coded. If you do not give permission for the photograph/audio/video recording to be obtained, you cannot participate in this study.

_____ I give my permission for audio & video recordings to be made of me during my participation in this research study.

9.) CAN THIS STUDY BE TERMINATED BEFORE MY COMPLETION?

You may be removed from the study by the nurse or investigator when, in their opinion, any of the following situations is applicable:

- Determination that a condition developed that would interfere with the research methods, and which was not applicable at screening (e.g., illness, drugs).
- Signs and symptoms not seen at baseline or that worsen in severity during/after intervention
- You are not willing or unable to comply with the guidelines and procedures explained to you and mentioned in this Informed Consent form.

Early termination of your participation in the study, as decided by the Principal Investigator, can occur without your consent. This will not have negative consequences for your medical care.

10.) ARE THERE ANY RISKS TO ME?

The things that you will be doing or undergoing have significantly more risk than you would come across in everyday life. The discomforts and risks include the following:

a. Blood draws: The total volume of blood drawn during the study will be up to approximately 4 mL at the screening visit and at study day 5. While the blood is withdrawn; you should experience no noticeable effects of the blood withdrawal. A risk associated with having blood drawn is a low concentration of red blood cells. This condition is called anemia. This might increase the need for blood transfusions. However, the occurrence of anemia with the described amount of blood withdrawal for study purposes is not likely. Furthermore, the risk of infection due to blood drawing exists. This risk will be small as well, because it will be done using strict procedures to prevent infections.
b. The research staff are trained and follow standard operating procedures for all clinical measurements including blood glucose. If your measurements are outside the normal range, we will immediately inform the principal investigator. They will assess your potential safety and ability to continue protocol. We will also provide you with the appropriate documentation showing any abnormal findings so that you may bring this to the attention of your doctor
c. FreeStyle Libre Pro: You may experience mild pain from the insertion of the device. You may also experience some mild skin irritation. This may include erythema, edema, rash, bleeding, itching, bruising, scaling skin, and induration around the insertion site and adhesive area. You should not participate in this study if you have any of the following medical procedures planned: Xylose absorption testing (oral sugar testing), CT, MRI, X-ray, Diathermy treatment (high-frequency electric current to stimulate heat generation within body tissues). The sensor should be removed if any of these measurements are required during your participation in the study.

Although the researchers have tried to avoid risks, you may feel that some questions/procedures that are asked of you will be stressful or upsetting. You do not have to answer anything or undergo any procedures you do not want to.

10.) ARE THERE ANY BENEFITS TO ME?

There are no direct benefits for participating in this study. With that being said, your participation may help researchers learn more about thinking strategies. These strategies may improve food choices amongst those with prediabetes.

11.) WILL THERE BE ANY COSTS TO ME?

Aside from your time, there are no costs for taking part in the study.

12.) WILL I HAVE TO PAY ANYTHING IF I GET HURT IN THIS STUDY?

Side effects (injury) can happen in any research study. These effects may not be your fault or the fault of the researcher involved. Known side effects have been described in the "Are there any risks to me?" section of this consent form. However, side effects that are not currently known may happen and require care.

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You will not give up any of your legal rights by signing this consent form.

If you believe you are injured because of the research, you should contact the Principal Investigator, Sherecce Fields, Associate Professor at (979) 845-3774 or Research Staff at 979-422-1789.

13.) WILL I BE PAID TO BE IN THIS STUDY?

The tests included in this study are free of charge to you. You will receive $10 for the screening visit. You will also receive $1 per meal photographed/sent and will get a bonus of $3 per day for three or more meals photographed (up to $6 per day). These pictures will consist of at least 2 main meals and snacks with general estimates of portion size. These pictures will be collected for the 35-day CGM period. You will receive $20 for each follow-up visit you complete (up to $40). This will amount to a total compensation of $260 for the complete study period. We will then request your payment to the Texas A&M University System. From this point, it will take around 4-6 weeks to receive your payment if delivery is through the mail. It will take around 2-4 weeks if receiving your payment through direct deposit. If the study is not completed, you will still receive compensation for the study visits completed.

14.) WILL INFORMATION FROM THIS STUDY BE KEPT PRIVATE?

The records of this study will be kept private. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only study staff will have access to the records.

Information about you will be stored in a locked file cabinet and computer files will be protected with a password. This consent form will be filed securely in an official area. Once your medical

record is released from the physician you identified, it is no longer considered protected health information and will be stored securely with our research records.

Information about you will be kept confidential to the extent permitted or required by law. People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) and entities such as the Texas A&M University Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly.

You have the right to access your PHI that may be created during this study as it relates to your treatment or payment. Your access to this information will become available only after the study analyses are complete.

15.) WHO MAY I CONTACT FOR MORE INFORMATION?

You can call the Principal Investigator or Study Coordinator to tell them about a concern or complaint about this research study

- Sherecce Fields, Associate Professor at 979-845-3774 or by sending an email to safields@tamu.edu
- Research Staff at 979-422-1789 or by sending an email to research@ctral.org

For questions about your rights as a research participant; or if you have questions, complaints, or concerns about the research and cannot reach the Principal Investigator/Study Coordinator or want to talk to someone other than these people, you may call the Texas A&M Human Subjects Protection Program office.

- Phone number: (979) 458-4067
- Email: irb@tamu.edu

16.) WHAT IF I CHANGE MY MIND ABOUT PARTICIPATING?

Your participation in this study is voluntary. You may withdraw from this study at any time. Your refusal to participate will involve no penalty or loss of benefits (e.g., medical care) to which you are otherwise entitled. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your participation in this research may be terminated by the investigator without your consent if you are unable or unwilling to comply with the guidelines and procedures explained to you or if the study is terminated prior to your completion.

Any new information discovered about the research will be provided to you. This information could affect your willingness to continue your participation. You may cancel your permission to use your Protected Health Information at any time by notifying the Principal Investigator in writing. If you cancel your permission you can no longer be in the research study. If you choose to cancel your permission, any information previously disclosed cannot be withdrawn and may continue to be used but no new health information identifying you will be used or shared

Authorization for Use and Disclosure of Protected Health Information (PHI) or Personally Identifiable Information (PII):

A. During the course of this study, Texas A&M University will be collecting and using your PHI or PII, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, the research team may share your PHI or PII with:

a. The IRB and officials of Texas A&M University
b. Study monitors and auditors who verify the accuracy of the information
c. Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI or PII. They may also view additional PHI or PII in study records during the monitoring process. Texas A&M University contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. Texas A&M University will keep your PHI or PII confidential when possible (according to state and federal law).

Once your information is disclosed to parties outside of Texas A&M University, federal privacy laws may no longer protect your PHI or PII.

D. The permission to use your PHI or PII will continue indefinitely unless you withdraw your authorization in writing. Contact the study team to withdraw this authorization [research contact info]. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

F. There will be no attempt to identify you as a person during the reporting of study results

STATEMENT OF CONSENT

I agree to be in this study and know that I am not giving up any legal rights by signing this form. The procedures, risks, and benefits have been explained to me, and my questions have been answered. I know that new information about this research study will be provided to me as it becomes available and that the researcher will tell me if I must be removed from the study. I hereby authorize the use and disclosure of my individually identifiable health information. I can ask more questions if I want. A copy of this entire consent form will be given to me.

_____ _____
Participant's Signature Date

_____
Printed Name

INVESTIGATOR'S AFFIDAVIT:

Either I have or my agent has carefully explained to the participant the nature of the above project. I hereby certify that to the best of my knowledge the person who signed this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

_____ _____
Signature of Presenter Date

_____
Printed Name