STUDY PROTOCOL

OFFICIAL TITLE

Relations of Glucose Variability With Cognitive Function and AD Risk Markers Among Older Adults at Risk for Diabetes

CLINICALTRIALS.GOV IDENTIFIER (NCT NUMBER)

NCT04201600

DATE OF DOCUMENT

January 20, 2022

PROCEDURES

If you qualify, there are two visits in total for this study. The following describes the tests and procedures included in each of these visits (at VAMHCS and/or UMSOM).

Visit 1 (3 hours)

This study visit will take place in the GRECC on the 4th floor of the Baltimore VA Medical Center or the GCRC on the 10th floor, D wing of the University of Maryland Medical Center. Visit 1 includes:

Consent (Approximately 30 minutes): During the visit for the consent process, we will review all the details of the research program in a private setting. You will be given enough time to have your questions answered, concerns addressed or clarified, and time will be provided for you to consider whether or not you wish to participate. A copy of this typed and signed consent form will be given to you.

Blood Draw (Approximately 10 minutes): Initially, we will assess point of contact glucose via a finger stick glucometer. Then, you will have blood drawn to make sure you are eligible for this study. Prior to this blood draw you will be asked to fast (not eat or drink anything except for water and your usual medications) for 12 hours. Approximately 15 cubic centimeters, which is equal to 3 teaspoons of blood, will be drawn to measure blood-based levels of blood sugar, cell counts, cholesterol, and markers of inflammation in the body. We will be storing some of this blood for future research. These samples will be stored indefinitely (as long as possible) in GRECC lab freezers at the Baltimore VA Medical Center. The tubes containing your blood samples will be coded so that your name cannot be readily identified. However, your identity can be determined by matching the code on the sample with your name in the study file.

After your blood is drawn, you will be given a light meal. If new medical abnormalities are detected during this visit, we will tell you and with your permission, results will be forwarded to your primary doctor.

Notification about whether you qualify for the remainder of the study (Visit 2), will come soon after we process Visit 1 screening results.

CGMS placement (Approximately 20 minutes): We will fit you with the Dexcom G6-Blinded Professional CGMS on your abdomen, which will automatically monitor your glucose (blood sugar) levels over the next ten days. More specifically, the CGMS includes an applicator with an attached wire sensor, and a separate small transmitter device. The applicator allows the short wire sensor to be placed just under your skin of your abdomen, a process that is only temporarily uncomfortable. The small transmitter device sits just on top of your skin and held in place with an adhesive patch. Every five minutes, this transmitter sends your blood sugar levels to a receiver, which is like a small phone that you will keep in your pocket. We will go over the use of the device and you

will be able to ask any questions you might have. We will also provide you with instructions on how to use and take care of your CGMS device while you are wearing it at home. We will also give you an accelerometer to wear until you return for your second visit to the GCRC or GRECC. The accelerometer will keep track of your activity levels throughout the day.

Medical History and Physical Examination (Approximately 30 minutes): After you provide your written consent, at this first visit, a medical history and physical examination will be performed. We will measure your height and weight. In addition, you will complete some brief questionnaires that assess your memory, thinking, and concentration. If you receive your health care at the VA, we will also access your medical file to obtain additional information about your medical history and medications.

Neurocognitive Assessment (Approximately 1 ½ hours): You will also complete a standard testing battery to assess various domains of cognitive function, such as your ability to pay attention, concentrate, learn, remember new information, and perform speeded thinking tasks. This assessment will take approximately 1 ½ hours.

10-Day Period between Visit 1 and Visit 2:

You will wear the CGMS and accelerometer over a ten-day period while you go about your daily activities at home. We will contact you by phone 1-2 times over this 10-day period to check on how the device is functioning, and help you solve any issues you might be having to ensure that the device is functioning well, and is comfortable to use. In the uncommon event that the CGMS device becomes detached accidentally or there are other technical issues, we will provide you with a phone number to call, and collaborators of this study, Dr. Ilias Spanakis and Lakshmi G. Singh, and the study coordinators will work to resolve any issues.

Visit 2 (2 to 2 ½ hours):

The following tests and activities will be performed during Visit 2:

Oral Glucose Tolerance Test (OGTT; Approximately 2 hours): Before the CGMS device is removed, we will assess your glucose tolerance with a standard test. Prior to this test you will be asked to fast (not eat or drink anything except for water and your usual medications) for 12 hours. At the beginning of this test, a needle will be inserted into a vein in your arm, which will allow us to draw small samples of blood during the test. Then, we will ask you to consume a drink containing 75 grams of glucose. Blood samples of 5 cubic centimeters (approximately 1 teaspoon) will be obtained 10 minutes and 5 minutes before you have had the glucose drink, and also 0, 30, 60, 90, 120, and 150 minutes after you have had the glucose drink. Approximately 40 cubic centimeters, which is equal to 8 teaspoons of blood, will be drawn during this procedure. An additional 20 cubic centimeters of blood, equal to 4 teaspoons, will be drawn to measure markers of Alzheimer's Disease.

Questionnaires (Approximately 1 hour): We will ask you to complete assessments that inquire about demographic information, your use of the health care system, your health habits and behaviors, and your mood and quality of life. Completing these questionnaires can take approximately 1 hour, and may be completed while you are undergoing the Oral Glucose Tolerance Test.

CGMS Device Removal (Approximately 15 minutes): Towards the end of this visit, we will remove the CGM device from your abdomen. We will also ask you for your thoughts about participating in the study and wearing the CGMS device.

You will not be enrolled in this study unless you agree and are willing to follow study procedures. You may be asked to repeat one or more of the tests if there is an error in its measurement, if a sample is too small for measurement, or if there was an unexpected problem with data collection.