Official Title:	Personalized Dietary Management in Type 2 Diabetes
NCT Number:	NCT05046886
Study Number:	20-01088
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Research Subject
Informed Consent Form

Title of Study:	The **DIA**betes **TELE**medicine **MED**iterranean Diet Study (DIATELEMED) ss20-01088
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study. People who agree to take part in research studies are called “participants”, “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of the study is to compare 3 different dietary management approaches for achieving blood sugar control for people with early-stage type 2 diabetes. In this phase of the study, we are currently enrolling participants for two out of the three groups. Your participation will contribute to our scientific understanding of dietary management of type 2 diabetes and may help to improve health recommendations for people living with the disease.

3. How long will I be in the study? How many other people will be in the study?

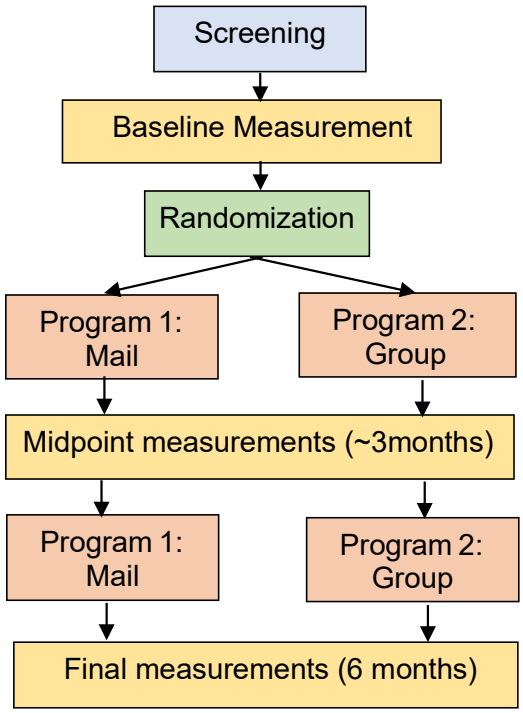
This study will last 8 months or less. Approximately 300 study subjects between the ages of 21 and 80 will be invited to join the study.

4. What will I be asked to do in the study?

We will screen you to determine if you are eligible for the study. **Screening** involves some questionnaires, blood testing at a Quest location near you, and an assessment of your ability and willingness to record your diet in a mobile phone application. If you appear to be eligible, you will be scheduled for a virtual baseline **Measurement** appointment. Measurements will involve surveys, dietary recalls, and use of remote technologies or sensors to measure blood sugar, physical activity, and weight. Following your baseline measurement appointment, you will be

Randomized (like the flip of a coin) to one of two 6-month dietary **Programs** (Program 1 or Program 2). Neither you nor the study investigators will know in advance which group you will be assigned to. You will have an equal chance (1 in 2) of being assigned to each group. Regardless of which group you are assigned to, you will receive state-of-the-art diabetes self-management education from a Diabetes Care & Education Specialist (DCES) as well as instruction in the American Diabetes Association-recommended Mediterranean-style diet. **Measurement** appointments (virtual) will be repeated at 3 months (midpoint) and 6 months (final) after and will include a return visit to your local Quest laboratory. The purpose of these measurement appointments is to collect data that will tell us how the three programs compare for management of early-stage type 2 diabetes. Other than the need for you to travel 3 times to a nearby Quest location for blood testing, all study activities (**Screening, Measurement, Randomization**, and the **Programs**) occur using WebEx[1] (a free videoconference program similar to Zoom and FaceTime) which you can join from any location. We will help you install WebEx onto your preferred device (mobile phone, laptop or home computer) and show you how to use it. Each of these steps is shown in Figure 1 below, followed by details concerning what occurs during **Screening**, **Measurement**, and the 2 **Programs**.

Figure 1: Flow Diagram



If you enroll, you will continue to receive routine care from your treating physician throughout the study. The proposed intervention does not replace medical care. Before engaging in this program, you may want to check with your physician to make sure that a Mediterranean-style diet is right for you. At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can still be used.

[1] WebEx™ is a communications application on the NYULMC Cisco Server, which is a highly secure, HIPAA compliant, fully virtualized, behind-the-firewall conferencing program. WebEx™ allows users to sign-in securely, and join meetings from mobile devices without requiring VPN access to the corporate network.

Study procedures

Screening – WebEx appointment (length = 1 hour)

- ✓ We will gather information to determine if you are eligible for the study.
- ✓ We will help you download an application called WebEx onto your mobile phone and train you how to use it to meet with study staff, provide signed informed consent, complete study measurements, and join our group videoconferences.
- ✓ We will obtain signed informed consent from you.
- ✓ We will schedule you for a blood testing appointment with a Quest lab location most convenient to you.

Screening – Quest appointment (length = 1 hour)

- ✓ We will schedule an appointment at your local Quest to get blood drawn by a certified phlebotomist (somebody who is trained to draw blood).This test will measure your HbA1c, which tells us about your average blood sugar levels over the last 2-3 months. You will not need to fast for this bloodwork.

Baseline measurement visit (length = 1 hr, 30 mins):

- ✓ Prior to your visit, we will ask you to complete a dietary recall in which we ask you to recall everything you ate in the past 24 hours.
- ✓ We will ask you to complete questionnaires that ask about your medical history, personal habits, and characteristics such as your race, ethnicity, and gender (sex). We will collect and review your questionnaires for completeness, and may call you if clarification is needed.
- ✓ We will help you download an application called MyNetDiary onto your mobile phone, and train you in how to use it to record your meals. (If you do not have a mobile phone, or you do not have the right type of mobile phone, you will be provided one at no charge).
- ✓ We will train you and observe you in self-insertion of two small FDA-approved blood sugar sensors on your upper arms called continuous glucose monitors. These sensors are painless, and insertion is painless for most people. The sensors estimate your blood sugar every 15 minutes for up to 2 weeks. We will send you the sensors and any supplies you need in the mail. The sensors will be adhered to your skin using Skin Tac adhesive wipes. We will ask you to remove the sensors after 12 days and mail them back to us using a postage-paid box that we send to you. If the sensors begin to come off before 12 days are up, please tell the researchers immediately and we will ask you to replace it with a new one, if necessary.
- ✓ If you do not own a bathroom scale, we will send you a basic body weight scale. You will be asked to weigh yourself at the beginning, middle, and end of the study.
- ✓ We will provide you with an activity monitor (Actigraph GT9X link[2]). This device is worn on your wrist and tracks your sleep and physical activity. You will be instructed to wear the activity monitor at all times over a 12-day period. You will return the activity monitor in the postage paid box.

Dietary Program activities

- ✓ Program 1: In the first month, you will attend 4 weekly one-hour WebEx group sessions on diabetes self-management including the Mediterranean-style diet. For the next 5 months you will receive bi-weekly emails or text messages (per your preference) containing links to brief videos pertaining to the Mediterranean-style diet.
- ✓ Program 2: In the first month, you will attend 4 weekly one-hour WebEx group sessions on diabetes self-management including the Mediterranean-style diet. For the next 5 months you will attend bi-weekly one-hour group counseling sessions pertaining to dietary management of type 2 diabetes. You will log your meals, in real-

[2] The Actigraph GT9X is FDA 510(k) cleared Class II medical device.

time, into the MyNetDiary app and receive feedback regarding calories, carbohydrates, fat and protein.

Measurements at 3 and 6 months – WebEx appointments (length = 1 hr each):

- ✓ We will call you to schedule your 3-month and 6-month measurement appointments.
- ✓ All supplies required for these measurements will be sent to you in advance of your appointment.
- ✓ We will ask you to go to your nearest Quest laboratory to obtain your HbA1c, as completed during the baseline measurement.
- ✓ Prior to your visit, we will ask you to complete a dietary recall in which we ask you to recall everything you ate in the past 24 hours.
- ✓ You will be asked to fill out a questionnaire, and to weigh yourself using the scale we provided at the beginning of the study.
- ✓ We will send you an activity monitor and ask you to wear it for the next 12 days and return it to us in the postage paid box.
- ✓ We will ask you to insert two glucose sensors, one on each arm. After 12 days we will ask you to return the sensors in the postage paid box. If your sensor falls off early, we may need you to insert another sensor.

5. What are the possible risks or discomforts?

- ✓ Risks of blood testing. Blood testing will be performed. Bruising, bleeding, pain, redness, and minor tenderness at the needle site sometimes accompany blood tests. Occasionally, but rarely, infection may occur. In very rare cases, nerve damage may occur as the result of a blood test. Fainting or feeling faint is a possible risk. Tell the Quest staff right away if you feel faint.
- ✓ Blood sugar sensor: Minor pain may be experienced on insertion of the sensors. Infection, irritation, inflammation, or bleeding at the sensor insertion site are possible. It is rare that subjects will require treatment other than over-the-counter treatment. A microscopic piece of the sensor membrane may occasionally remain underneath the skin after the sensor is removed. This dissolves on its own and poses no health or safety risk.
- ✓ The risk of hypoglycemia (low blood sugar): Changes in diet or physical activity may increase the risk of hypoglycemia. Symptoms of hypoglycemia include sweating, jitteriness, and not feeling well. Occasionally, there is the possibility of fainting or seizures (convulsions). Because participants in this study are not taking medications that cause low blood sugar, it is highly unlikely that you will experience hypoglycemia as a result of the study intervention.
- ✓ The risk to privacy and confidentiality: A variety of measures are used to reduce information security risk. First, all study staff will be trained in the New York University Langone Medical Center (NYULMC) Research Practice Fundamentals, which include training in how to maintain confidentiality. All study staff will be required to sign a confidentiality agreement. Identified and de-identified data will be maintained in separate files in locked file cabinets in a locked office. Access to these data will be restricted to the PI (Dr. Collin Popp), the medical co-PI (Dr. Michael Bergman), the project manager, and study staff responsible for gathering data and maintaining research files. The dietary self monitoring app (MyNetDiary) will be programmed by study staff with your age, gender, height, weight, dietary recommendations, a study ID number and a password. The dietary self-monitoring app is secured and data encrypted, and does not collect or transfer: a) your health information or personal identifiers; b) mobile phone numbers, serial numbers or any other information that can be used to identify you; c) GPS tracking or information on your location. Data will be entered into a centralized database maintained on a secure server called RedCap. Data in these files will be linked to you only through your ID number. All data collected will be used expressly for the purpose of the proposed study.

- ✓ Unforeseeable risks: While we will do everything we can to protect your safety and privacy, it is possible that the research may involve risks that are currently unforeseeable.
- ✓ Time: We estimate the total time for all measurement appointments to be roughly 10 hours, and we will do everything we can to minimize the time needed to perform the measurements. There is the possibility of some measurements running longer than normal. Program 1 participants will attend WebEx group sessions lasting 4 hours, and an additional 4 hours watching videos sent to them. Program 2 participants will attend WebEx group sessions lasting 14 hours.

6. What if new information becomes available?

During the course of this study we may find out more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

We cannot promise that participation in this study will result in better glucose control or prevent future complications of type 2 diabetes. Your participation in this study will provide information that may help others with type 2 diabetes in their efforts to manage this disease.

8. What other choices do I have if I do not participate?

You may choose to not participate in this research study. You may discuss alternatives with your physician. You may seek dietary counseling from other healthcare professionals.

9. Will I be paid for being in this study?

You will be paid $25.00 upon completion of each of the 4 screening and measurement visits as compensation for your time. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid only for the study visits that you complete. As reimbursement for cell phone data usage, you will also be paid $5.00 for each of the WebEx sessions that you attend, for a total of up to $170.00 by your final measurement visit.

10. Will I have to pay for anything?

There will be no charge to you for your participation in this study. Your health insurance will not be billed for any study activities, tests, or procedures. The National Institutes of Health is providing financial support to NYU School of Medicine to conduct this study. The cost of all procedures and tests will be covered by funds received from the sponsor. The sponsor will pay for all study supplies, including blood glucose sensors, activity monitors, and mobile phones (if you need one). During the study, you will be responsible for the cost of any medication that you continue taking while in the study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the Principal Investigator as soon as possible. The Principal Investigator's name and phone number are listed at the top of page 1 of this consent form. We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the NYU Grossman School of Medicine or NYULMC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the Principal Investigator, your physician, or the study sponsor without your consent because:

- ✓ The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- ✓ You have not followed study instructions.
- ✓ The study sponsor, the Principal Investigator or other body responsible for monitoring the safety of the study has decided to stop the study. If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will my information be protected?

NYULMC, which includes NYU Hospitals Center and NYU Grossman School of Medicine, is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

What information about me may be used or shared with others?
The following information may be used or shared in connection with this research:

- ✓ Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires and diaries.

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Medical Center policies and applicable law.

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- ✓ The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study
- ✓ The study sponsor: The National Institutes of Health (NIH)
- ✓ Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- ✓ Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- ✓ NYULMC Institutional Review Board that oversees the research
- ✓ Public Health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- ✓ Laboratories that perform research related study procedures

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the Principal Investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. Interest in future studies

If you are interested in being contacted about future studies, please check the box below:

☐ Checking this box indicates I agree to be contacted about future studies.

Subject Initials _____

15. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information will include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission. NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

Subject Initials _____

16. Laboratory results

We will contact your physician to let them know about laboratory results that are out of range. If you have a MyChart account, your lab results will also be available for your NYU-affiliated physician to view. If at any time you would like to change the physician on record, please contact study staff at: 646- 501-3470.

Physician name: _____

Physician phone number: _____

17. Consent to be contacted via cell phone text message (optional)

It may be necessary that our study staff contact you via text message in order to clarify your entries into the MyNetDiary app, or to send appointment reminders. Text messages will only be used for non-sensitive matters. In order to protect your privacy, no personal health information or otherwise identifying information will be exchanged.

☐ Checking this box indicates my consent to communication with the DiaTeleMed research team via text message. I understand that any communication via text message is not encrypted or secure during transmission and may be intercepted.

Subject Initials _____

18. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – like the one you are considering. The IRB protects the rights and welfare of the people taking part in the research studies. The IRB follows rules and guidelines from the Federal Government and reviews each research study using these guidelines. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Grossman School of Medicine's IRB is made up of:

- ✓ Doctors
- ✓ Nurses
- ✓ Non-scientists
- ✓ People from the Community

You may contact the IRB if you have any questions about your rights as a subject, if you think you are not treated fairly or if you have any questions about this research study. The NYU IRB Office number is (212) 263-4110.

19. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110. 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 website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions havebeen answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date