NYU Langone Health

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Research Subject Informed Consent Form

Title of Study:	BRInging the Diabetes Prevention Program to GEriatric Populations (BRIDGE) s21-01039
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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 “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 this research is to see if a year-long diabetes prevention program designed with the needs of older adults in mind can help older adults lose weight and lower their risk of developing Type 2 Diabetes. Research subjects will randomly be assigned to receive the program either in person or online using a computer or tablet computer. If you are assigned to receive the program online using a computer or tablet computer, we can give you a tablet computer to use for this study or you can use your own.

We are asking you to take part in this research study because you may be at risk for developing Type 2 Diabetes. Type 2 Diabetes is a long-lasting disease that affects how your body turns food into energy. We will compare your health at the beginning of the study to your health at the middle of the study (6 months) and the end of the study (1 year).

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

The study is one year long. You will be assigned to a group with 10-15 people who are also participating in the study. For the first 16 weeks of the study, you and your group will have weekly 60-minute meetings with a trained lifestyle coach. The lifestyle coach will teach you how to lead a healthy lifestyle and support your efforts to lower your risk of developing Type 2 diabetes. After 16 weeks, you and your group will meet once a month for 6 months. In total, 230 research subjects will participate in the study.

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

In this study, you will be asked to keep track of your daily physical activity and the foods that you eat. You will discuss these with your lifestyle coach and, if you feel comfortable, with the other members of your group. We will measure your weight every week. Every 6 months (for a total of 3 times), we will also do a more comprehensive evaluation of your health.

You do not have to participate in any study activities that make you uncomfortable. You can withdraw from the study at any time. If you withdraw, no more information will be collected from you. If you want to withdraw from the study, we will ask for your permission to use the data we collected from you.

Any identifiable information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

Below is a list of the study visits. It includes more detailed information about what you will do at each visit and how long each visit will take.

<u>Screening / Baseline Visit</u>

In this first visit, we will screen you to see if you are a good fit for this study. If you pass the screening and choose to participate in the study, this will be your baseline visit. If you do not pass the screening, we will tell you why.

At this visit, we will:

- Ask you questions about your health and activities
- Measure your height, weight, and waist circumference
- Do a blood test to measure your blood sugar
- Tell you what to expect for the first group meeting
- Give you handouts with information about this study
- Scan your index finger with a device called a Veggie Meter that uses a light to measure your fruit and vegetable intake.

This visit will take about 1 hour to complete.

Diabetes Prevention Program Group Meetings

If you join this study, you will be assigned to a group that works with a trained lifestyle coach to complete a Diabetes Prevention Program. Your group will either meet online or in-person, depending on the group that you are assigned to. This assignment is random and cannot be changed. In other words, if you are assigned to a group that meets online, you cannot switch to a group that meets in-person. Likewise, if you are assigned to a group that meets in-person, you cannot switch to a group that meets online.

For the group meetings, we will:

- Ask you to keep track of your daily physical activity and the foods that you eat. You will have the option of using a paper and pen log, a website, or a cell phone application your foods.
- Measure your weight every week using a digital scale and a cell phone application.
    - Online program: You will be given a special scale to use for the study. When you weigh yourself on this scale, the numbers will be sent to the research team using an app on your cell phone.
    - In-person program: A member of the research team will measure your weight using a scale that is located in a private room. We will also provide you with a special scale to use at home. When you weigh yourself on this scale, the numbers will be sent to the research team using an app on your cell phone.
- Give you educational videos and handouts

Each meeting will last about 1 hour. The groups will meet weekly for 16 weeks and then monthly for the next 6 months for a total of 22 meetings.

6-month and 12-month Follow-up Visits

At 6 months and 12 months after the time you start the study, we will ask you to repeat some of the things that you did during your baseline visit. This will allow us to see if there have been any changes to your health since you started the study. an app on your cellphone.
A week before these visits, we will ask you to keep a food diary for 4 days. A food diary is a record of everything that you eat over the course of a day. You can either write down your food diary on a piece of paper or use the HealthWatch 360 app. You will also be asked to wear an activity tracker for 7 days. An activity tracker is a small device that you wear on your arm like a watch. It records information about your heart rate, which shows us how physically active you are.

At the 6 and 12-month visits, we will:

- Review your 4-day food record
- Ask you questions about your health and activities
- Do a blood test to measure your blood sugar
- Measure your weight and waist circumference
- Scan your index finger with a device called a Veggie Meter that uses a light to measure your fruit and vegetable intake.

These visits will take about 1 hour to complete.

You will receive reminders from the study team before each educational session and before your baseline, 6-month and 12-month visit. You can let the study team know if you prefer to receive reminders via email, text message or phone call.

What are the possible risks or discomforts?

Risk of Study

As part of this study, you will be asked to make changes to your daily eating and exercise habits. The program that you will follow is based on another program that is approved by the Centers for Disease Control and Prevention (CDC) to safely lower a person's risk for developing Type 2 diabetes. You should ask your doctor if participating in this study is right for you. We will also check with your doctor to make sure that you can participate in this study safely.

You will be asked to do a blood test every 6 months (for a total of 3 times) during your participation in this study. The blood test will check the amount of nutrients that are in your body, and what your risk of developing Type 2 diabetes is. For each blood test, we will need up to 2.5 mL (less than one teaspoon) of blood from a vein in your arm. The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. The blood test will be done by a healthcare professional at NYU Langone, who can help you if you do not feel well after giving blood.

You will also be asked to answer questions about your health and issues related to your health throughout the study. Some of the questions may make you feel upset or uncomfortable. You do not have to answer any questions that you do not want to. If you think that you need to talk to a professional about your feelings, tell the study team member asking you questions or 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.

In any research study, there is a risk of loss of confidentiality. This means that your private information was accessed by someone who is not a member of the study team. We have put several measures in place in order to reduce the chance of this happening. If there is a loss of confidentiality, we will let you know immediately. We will also notify the NYU Grossman School of Medicine's Institutional Review Board (IRB), which is an organization that protects the safety of everybody participating in human research at NYU Langone.

5. What if new information becomes available?

During the course of this study we may find 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.

6. What are the possible benefits of the study?

You may benefit from being in this study. In other studies like ours, participants lost weight and felt better. They also learned how to make healthier choices. Your participation can help to improve the program. This program can help more people at risk for Type 2 Diabetes.

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

This study is not the only way to learn about how you can lead a healthier lifestyle. There are other ways to lower your risk for Type 2 Diabetes. You can talk to your personal doctor about which program is best for you.

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

To thank you for your time and participation, we will give you a ClinCard at the start of the study. A ClinCard is a reloadable MasterCard that we can use to compensate you as you complete study activities. We will add $50 to your ClinCard for each of the following visits that you complete: the screening / baseline visit, 6-month visit, and the 12-month visit. We may also ask you to complete interviews about your experience participating in the study at the 6-month and 12-month visits. In this case, you will receive an additional $50 on your ClinCard for each interview that you complete.

If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for the visits that you have completed.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment through your ClinCard, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise the study's principal investigator, whose contact information is provided on page 1 of this consent form.

9. Will I have to pay for anything?

You will not have to pay for anything to participate in this study. We will provide you with all materials and devices required for the study.

10. 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 School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

11. 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 your physician, the or 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 anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

12. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

As a patient at NYU Langone Health, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes) will be placed in your EMR maintained by NYU Langone Health. This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?
The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately. As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

The research-related information that will be available to you immediately are as follows:

- Results from blood tests
- Weight measurements

Access to research-related information within your EMR can be found through NYU Langone Health's patient portal, MyChart.

13. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the

privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: The National Institutes of Health (NIH) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others 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.

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.

What if I do not want to give permission to use and share my information for this study?

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

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 for this research study. 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.

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.

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

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

15. 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 Web site at any time.

This study will use mobile applications and wearable device to gather information for the researchers as part of this study. These mobile applications ares provided by Renpho and HealthWatch360 and the wearable device is provided by ActiGraph and there are terms of use that the vendor requires of all users. You will need to review the vendor's terms of use and privacy policy. The vendor may retain some of the data collected through the mobile application and wearable device, even after the study ends. If you do not want this data collection to continue by the vendor after the study ends, you will need to uninstall/discontinue use of the mobile application. Even after you have uninstalled the application, the vendor may still retain your data so make sure to read the privacy policy and end user agreement/terms of service. The research team can help explain how to do this.

We will ask you to share information with us about your health and how active you are by using a product or device made by a company or organization. Products or devices are things like fitness trackers, mobile apps that can be used on a smartphone or tablet, websites and web apps, or types of computer software.

These mobile apps are provided by Renpho and HealthWatch360. This application can collect information from your mobile phone that would identify your geographic location when data is collected. To help protect your privacy, the research team can help to deactivate the location services if you wish.

These mobile applications and wearable devices will use the data function on your phone, and, depending on much data you use for other things, you may have data charges.

If you do not already have the product or device, we may give one to you to use for the study. If we give you a product or device to use, you must agree to the company's rules before you can use it, just as if you bought the product or service for yourself. The researchers of the study do not control these rules. We will help you understand these rules in the "Terms of Service" or the "End User License Agreement" that come with the product or device. Please read these rules carefully. These rules may ask you to agree to certain things, like not to sue the company if something goes wrong with the product or device. These rules may also allow the company to get, keep, or give others a copy of your information that comes from the product or device. Although this study will protect the copy of your

information that you give us, we cannot protect or control what the company does with the copy that goes to them. If you do not agree to the company's rules, you do not have to take the product or device. You can say no and still be in other parts of the study. Terms of service for each app and device can be found at these links:
Renpho Scale:
https://renpho.com/de/pages/terms-of-use
Renpho App:
https://renpho.com/pages/terms-of-use-app
HealthWatch360 App: https://www.gbhealthwatch.com/Terms_Conditions.php
Actigraph activity tracker: https://actigraphcorp.com/terms-of-use/

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 have been 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

DC 05/08/2020

Last Updated: 5/7/2020