**Study Title** Power-Up: An Effectiveness Trial of the Diabetes Prevention Program

**NCT Number** NCT04104243

**IRB Protocol ID** 2019-10343

**Informed Consent Approval Date** 8/24/2022

# ORAL CONSENT SCRIPT

The Diabetes Prevention Program consists of sessions that discuss topics such as staying active, eating healthy and reducing stress. The program has been shown to prevent or delay the onset of Type 2 diabetes by helping participants to lose weight and increase physical activity. The purpose of this study is to see if a diabetes prevention program created for men will increase participation and decrease the risk for diabetes compared to a standard diabetes prevention program not designed specifically for men. We are asking you to join this study because your doctor identified you as someone eligible to participate based on your age, weight, and risk for developing diabetes. Your blood sugar levels were higher than normal the last time you had blood work completed. There is no cost for participating in this study. If you agree to participate, you will be randomly assigned to participate in either the men's-only diabetes prevention program (Power-Up) workshop or the standard diabetes prevention program workshop. The first part of the program will consist of at least 16 core sessions. After these sessions, you will attend about 8 maintenance sessions for the final part of the program. The entire program is about 22 – 28 sessions over the course of 12 months. Sessions will take place online. If you decide to join, we will send you a link or phone number which you will use to log into the session using a smartphone, computer, or tablet. You will need internet connection in order to join the sessions. During the course of the program, you will be asked to complete 3 different surveys. You can be compensated up to $120 for completing all activities related to this research study, and you will also receive a weight scale and workshop book.

As a part of the study, you will also receive a digital wireless scale that will send weight information to you and the research study team. You will be asked to record a weight measurement at the first session, the 16-week session, and the 12-month session. For each weight measurement you will receive $25, for a total of $75 for all 3 measurements. You will also be asked to complete a survey at three different times during the program: before the first session of the program, about half way through the program, and after completing the program. You will receive $15 for each completed survey, for a total of $45. This makes a total of $120. The incentives will be paid on a prepaid debit card mailed to you. If you choose to withdraw from the study before all weight measurements and surveys are completed, you will be paid only for the activities you completed.

Some, but not all, participants will be selected to complete a longer interview to better understand their experience in the program. Additional compensation will be given for those selected to complete this portion of the study.

What are the potential benefits for participating in the study?

You may or may not receive a personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include weight loss and the reduction in the risk of diabetes. Others may benefit from your participation because we may be able to learn more about how to effectively involve men in diabetes prevention programs in the future.

**What are the risks of participating in the study?**

You may feel uncomfortable answering some of the questions. If so, you do not have to answer all the questions and you may skip questions or stop at any point in time.

We will do our best to keep your information safe by using secure research files. However, a potential risk is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to do everything possible to protect your privacy.

**The researchers and study staff follow federal and state laws to protect your privacy.** This part of the consent form describes what information about you may be used and shared in the research study. If you do not provide your verbal consent, you may not participate in this research study.

The health information that we may use or disclose for this research study includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, and medical record numbers.

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests for your information are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, 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.

The only people who can see your research records are:

- Researchers and the research team, who work with the researchers
- Organizations and institutions involved in this research, Montefiore Health System, the Albert Einstein College of Medicine, and the New York City Department of Health and Mental Hygiene (NYC-DOHMH), as well as those that funded the research, the National Institutes of Health (NIH)
- Groups that review research such as the Einstein Institutional Review Board, the Office for Human Research Protections.

All of these groups have been asked to keep your information confidential. However, these groups may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be

protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Your study information will be kept as long as they are useful for this study. In addition, medical information collected during the research, such as test results or weights, may be entered into your electronic medical record and will be available to doctors and other staff who provide care to you. The purpose of this entry is to provide research information that has the potential to impact your medical care.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your doctor.

A description of this clinical trial study will be available on the ClinicalTrials.org website, 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.

If you decide to take part in the study, you are free to stop participating at any time for any reason. This will not affect your care and you will continue to be treated at your facility.

If you change your mind and do not want your information used for the study anymore, you can call the person in charge of this study. His name is Dr. Earle Chambers and he can be reached at 718-430-2599. Or, you can call Einstein Institutional Review Board at 718-430-2253. They will let you know how to write to the person in charge of this study to let him know you want to stop participating. Just remember, the researchers may continue to use and share the information they have already collected. Information from this study may be used in future research studies by our study team.

Do you have any questions? You may ask me now, or contact Dr. Chambers about your questions or problems with this study.

Do you voluntarily agree to participate?

If no,

Thank you for taking the time to talk. If you have any questions or would like to receive resources/materials about diabetes prevention, please reach out to your primary care provider.

Thank you.

If yes,

Thank you for taking the time to learn more about the research study, and answer these questions. I will share your information with the research team. Someone from the research team will call you within a week to ask you additional questions and assign you to a Diabetes Prevention Program. Is this number the best number to reach you on? Is there an additional

number you can share, like a partner, or family member, where you can be reached in the event we are unable to reach you on this line?

If you have any further questions, please do not hesitate to contact the study team at 718-430-2599. We are available from Monday to Friday, 9am to 5pm.
Thank you for taking the time to speak to me.

## CONSENT TO PARTICIPATE

| Printed name of the person conducting the consent process | Signature | Date |
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