Official Title: Data-Assisted Approach for High Intensity Weight Loss for Diabetes Remission

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Wake Forest®
School of Medicine

Division of Public Health Sciences,
Department of Epidemiology and Prevention

# DATA-ASSISTED APPROACH FOR HIGH INTENSITY WEIGHT LOSS FOR DIABETES REMISSION

Informed Consent Form to Participate in Research
Jamy Ard, MD, Principal Investigator

## SUMMARY

You are invited to participate in a research study. The purpose of this research is to test the effectiveness of weight loss in inducing diabetes remission. You are invited to be in this study because you have type 2 diabetes. Your participation in this research will involve 2 screening visits, 5 study visits, and several intervention visits (depending on your treatment assignment) and last about 12 months.

Participation in this study will involve changes to your current dietary and exercise habits. All research studies involve some risks. A risk to this study that you should be aware of is potential symptomatic hypoglycemia as a result of fluctuations in your blood glucose levels. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include continuing your course of diabetes care and/or weight loss treatment plan. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Jamy D. Ard, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

Jamy D. Ard, MD
[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have type 2 diabetes. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare the effects (good and bad) of a new approach for improving the control of type 2 diabetes with the most commonly used approach to see which is better. The new approaches focus on helping people with diabetes lose weight and use a mobile phone app with or without continuous glucose monitoring to assist the participant in achieving treatment goals. The standard or most common approach is diabetes self-management education.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 90 people will take part in this study, all of which will participate at this research site.

## WHAT IS INVOLVED IN THE STUDY?

If you agree, you will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group.

At your first study visits, medical history will be collected. A physical exam, health screenings including an EKG, and blood work will be completed. Information about dietary intake and physical activity will also be collected.

The High Intensity Weight Loss Group will receive a low calorie meal replacement for 12 weeks followed by gradually increasing caloric prescriptions for weight loss. Participants will be seen once weekly in clinic for the first 4 weeks of treatment. Participants will receive a wirelessly connected digital body weight scale and mobile phone based application or app that will be used to help guide the weight loss treatment plan. Following the first month, participants will use the app to track and monitor progress and receive updates to their treatment plan. The study doctor and treatment team will also send participants information through the app. Additional treatment appointments will be determined based on your progress and advice from the treatment team.

The High Intensity Weight Loss Group plus Continuous Glucose Monitoring will receive a low calorie meal replacement for 12 weeks followed by gradually increasing caloric prescriptions for weight loss. Participants will be seen once weekly in clinic for the first 4 weeks of treatment. Participants will receive a wirelessly connected digital body weight scale and mobile phone

based application or app that will be used to help guide the weight loss treatment plan. Participants will also receive a continuous glucose monitor that will be used to track blood sugars on a near instant basis. The continuous glucose monitor is a small sensor that is placed on the back of the upper arm or abdomen with adhesive and a thin, flexible filament inserted just under the skin to measure glucose. Following the first month, participants will use the app to track and monitor progress and receive updates to their treatment plan. They will also use the continuous glucose monitor to track how well their blood sugar is controlled. The study doctor and treatment team will also send participants information through the app. Additional treatment appointments will be determined based on your progress and advice from the treatment team.

The Diabetes Self-Management Education Group will receive standard of care diabetes education accredited by the American Diabetes Association. Participants will attend an initial group class or individual appointment in the first month, followed by at least quarterly individual appointments through the next 11 months. Additional appointments may be recommended by the diabetes educator. Participants will be prescribed a weight reducing diet focusing on carb counting and healthy diet quality. Participants will also receive a physical activity prescription using a combination of resistance training and aerobic exercise.

If you take part in this study, you will have the following tests and procedures: weight, BMI, HbA1c, other labs, health screenings, and physical exams. These will be conducted at the Weight Management Center at the start of the study, and weeks 12, 24, 36, and 48-52 (end of study). Dietary intake, continuous glucose monitoring for all participants, and physical activity assessments will be conducted at the screening visit, and weeks 12, 24, and end of study. We will also collect information on healthcare utilization over the course of the study, including medication usage, health care provider visits, hospitalizations, procedures, and out-of-pocket expenses.

**Blood drawing**
You will have approximately 1 tablespoon of blood withdrawn from a vein up to 10 times throughout the course of the study. The total amount of blood withdrawn during the study will be approximately 10 tablespoons.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study. Test results will include your HbA1c and electrolytes.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

**Blood storage**
Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, he/she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

____YES you may contact me for future research studies
____NO I do not want to be contacted regarding future research studies.

## HOW LONG WILL I BE IN THE STUDY?
You will be in the study for about 12 months.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

## WHAT ARE THE RISKS OF THE STUDY?
Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

You might experience fluctuations in blood glucose levels as a result of restricting calories and modifying the types of foods you consume. This could lead to symptomatic hypoglycemia which is reversible with appropriate therapy.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

The risks to participants in this study are not largely different from what might be experienced in the course of diabetes care and weight loss treatment in the general community.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep

your information safe.

As part of this study, you will be asked questions about quality of life and depression. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Following blood draws, you may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

The continuous glucose monitor will be worn throughout the study for those in the High Intensity Weight Loss Group plus Continuous Glucose Monitoring group and by everyone else during study visits at baseline and weeks 12, 24, and end of study. Use of the continuous glucose monitor could be associated with some skin irritation from the adhesive or the filament that is under the skin. Some people will notice some discomfort with use of the monitor.

## Reproductive Risks and other Issues to Participating in Research

Pregnant and lactating women are excluded from participation in this study. If you are a sexually active woman of childbearing potential and have not been using a reliable method of birth control, two negative pregnancy tests performed 15 days apart are required to check for possible early pregnancy prior to starting treatment.

## Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: weight loss, improvements in control of your blood glucose values, lower overall risk of heart disease, heart attack, or stroke, and possibly diabetes remission.

## What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you can continue your course of diabetes care.

## What Are the Costs?

All study costs, including any study products and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

## Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published

in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

## WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $50 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid $10 for each complete study visit at weeks 12, 24, and 36 and $20 for completing study visit at week 52.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Savvy Sherpa, LLC. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Jamy D. Ard, MD at [redacted] or [redacted] (after hours).

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study include demographics and medical history**.**

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state

privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Jamy Ard that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Jamy D. Ard, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Jamy Ard at [redacted] or [redacted] (after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm