Official Title: Look AHEAD: Action for Health in Diabetes
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APPENDIX D.2c

MODEL Informed Consent Document Addendum

Look AHEAD Continuation Study – (Action for Health in Diabetes)

Look AHEAD-C

July 27, 2015June 6, 2014

Introduction

You are invited to be in a research study called Look AHEAD Continuation. This study is only for people who took part in the main Look AHEAD 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 and because you have been in the main Look AHEAD Clinical Trial. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Please 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 study is to continue to follow you and to help us understand the *long-term* effects of weight change on overall health. During the main part of Look AHEAD Clinical Trial, participants were assigned by chance to be in either the Intensive Lifestyle Intervention group or the Diabetes Support and Education group. We are no longer providing these separate programs; however, we want to know whether the many years of participation in these programs has long-term effects on your health.

There are many aspects to overall health. These include heart attacks and strokes, complications of diabetes, and psychological health. We focused on those aspects of health in the early phases of Look AHEAD and will continue to do so in the Look AHEAD Continuation. In addition, we now want to look at some other areas of health. These include your physical function (your strength and ability to walk a set distance) and your cognitive function (your memory and thinking skills). In the Look AHEAD continuation, we will also continue to follow the changes in your weight, your level of physical activity, your use of medications, and a variety of other health problems, including fractures, cancers, and hospitalizations. Continuing to follow you over time will allow us to determine whether there are long-term benefits or risks of weight loss on each of these different aspects of health.

How Many People Will Take Part in the Study?

We expect about 4,000 current Look AHEAD participants at nineteen clinical sites across the United States to continue in this study. The study will involve approximately (*insert number*) participants at this research site.

What Is Involved in the Study?

If you take part in this study you will be asked to sign this consent form and answer some questions about your understanding of what we will be doing in the study. If you have trouble understanding the consent form, you may choose to have a friend or family member help you understand the form and help you decide whether to participate, or we may ask you to have a friend or family member help you with the consent process. If you decide to participate in the Look AHEAD Continuation, you will be invited to one educational session and one social event. You will be contacted by phone every six months to ask questions about your health. You will be contacted by mail to fill out questionnaires for the clinic visit. You will be asked to come into the clinic for one clinic visit. The tests and procedures are described below:

Educational Session

You will be invited to one educational class during the continuation. The group class will be offered 3 – 5 times at different times (day/evening). The class will include a presentation

related to nutrition, a discussion/activity related to physical activity and an update on the study and research from the trial.

Social Event

You will be invited to attend one social activity during the continuation, and you may be invited to bring your spouse or a friend. The activities may include a lunch or dinner and some type of social activity. The purpose of this event is to thank you for your participation in Look AHEAD and to provide an opportunity for visiting with participants and research staff.

Questionnaires

You will be mailed a package of questionnaires for your visit and asked to return them by mail or bring them to your clinic visit. These questionnaires are similar to those asked in the past and include questions on thoughts and feelings, diabetes and diabetic complications, physical activity, behaviors, eating habits and medical events. It will probably take you about 30 minutes to fill out these questionnaires.

Telephone Calls

You will be contacted by study staff on the phone every six months to answer questions about your general health, medical conditions, the quality of your life, and any hospitalizations and outpatient visits you have had. If you have had a hospitalization or other event (such as a heart attack), the study staff will ask your permission to obtain medical records. Each call will probably take about 10 - 45 minutes depending on how many health problems you report.

Clinic Visit

You will come into the clinic for a visit lasting approximately three hours. This clinic visit will normally be completed as one visit; however, there may circumstances where it would be divided into two visits. You will need to fast before this visit, which means you should have nothing to eat or drink after midnight the night before. After completing some of the initial measures, you will be able to have something to eat and drink. The following tests will be done:

Physical Measures

We will measure your height and weight and take your blood pressure. You will have a brief foot exam (where a tuning fork is placed on your foot and the staff record the vibrations) and neuropathy test where the staff will place an instrument similar to fishing line against several areas of the foot and ask you to tell them when you feel it). You may have an electrocardiogram, which is a recording of the electrical activity of the heart, also called an ECG or EKG. We will ask you to provide a urine sample and approximately 5 teaspoons of blood will be withdrawn from a vein. 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.

Cognitive Function Measures

Staff will ask you some questions about your memory and thinking skills, concentration, and your ability to do certain physical tasks such as drawing lines or circles. Your memory tests may be recorded on audiotape (voices only) and sent to the Coordinating Center at Wake Forest. This is being done as a quality control measure to make sure the Look AHEAD staff is administering the test in a standardized way. These recordings will not identify you in any way and they will be destroyed immediately after use. You may request the recording be stopped at any time during the course of the research study. You should also understand that you will not be able to inspect, review, or approve the audiotapes before they are used in this study.

Physical Function Measures

Staff will ask you to perform some physical performance tasks that include: standing up from a seated position in a chair 5 times in a row, standing in 4 different positions to assess your balance, walking 400 meters with staff (about 5 minutes or like walking around the block), and gripping a device with your hands.

Interviewer Administered Questionnaires

Staff will ask you some questions on your thoughts and feeling, your overall health, hypoglycemia, physical activity and medical events.

How Long Will I Be in the Study?

You will be in the study through January 31,2016. You may refuse to continue to participate at any time. Regardless of your choice, you will not be penalized and you will not lose any benefits. The care you get from your doctor will not change. If you decide to stop participating in the study, we encourage you to discuss this decision with the investigators or study staff.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests.

Risks of Blood Draw

While rare, the risks of drawing blood for the study include the possibilities of brief pain, becoming faint during the blood draw, or developing a bruise or bump following the blood draw, and there is a slight risk of infection at the site where blood was drawn.

Blood Pressure Assessment

You may experience temporary discomfort during blood pressure recordings due to the pressure of the blood pressure cuff on your arm.

Risks of Physical Function Tests

Risks and side effects associated with the physical performance-based testing (the walking test, balance tests, rising from a chair) includes the risk of losing your balance and falling. In rare instances persons doing the walking test will experience leg or chest pain, heart palpitations, shortness of breath or light headedness. In very rare situations exercise can result in heart attack or sudden death. We will minimize this risk by: (1) safely escorting you to chairs located along the walking course should you become unsteady; (2) walking with you at a close distance; and, (3) being at your side should you need assistance. There is a risk that you may experience muscle soreness or discomfort as a result of the physical performance testing procedures.

Risks of Cognitive Function Tests

There are no risks associated with the memory-testing portion of the study. If you are uncomfortable with a question or task you may decline to answer or stop the task.

Other Risks

Taking part in this research study may involve providing information that you consider confidential or private. In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Are There Benefits to Taking Part in the Study?

There may be no direct benefit to you from this study. You will receive regular medical tests relating to diabetes and its complications. You will be notified of any concerns from your study results so you may discuss them with your doctor or if you provide permission, we can share the information with your doctor. This information about your health problems may be of benefit to you. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

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. By taking part in this research study, your personal health

information, as well as other information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health history, how you respond to study activities or procedures, laboratory and other test results, medical images, audiotapes and information from study visits, phone calls, surveys, and physical examinations. In all cases, only those study personnel and federal sponsors who have a need to see the information will be given access to the information. In addition, when the data are analyzed and published, there will be no information included that would identify individual participants.

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. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

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 law.

In addition, we are asking that you agree to have your Protected Health information shared with and electronically transferred to the Coordinating Center at Wake Forest University Health Sciences to ensure the success of the study. The reasons for transferring your personal identifiers to the Coordinating Center are:

1) The information would be used at the Coordinating Center in the event of natural or other major disaster affecting a clinical site (for example, if a clinic were destroyed by a hurricane or tornado, the Coordinating Center would be able to provide contact information for you to the clinics so that they could reach you).
2) This information would be used to allow direct contact with you, by telephone or mail, for the following purposes: to invite you to take part in another study that is connected to Look AHEAD; to conduct the study outcomes interview; to conduct other types of interviews, e.g., to inquire about current health status or body weight or to update contact information on designated friends and family member
3) The information would be used to allow searches of national databases such as the Centers for Medicare and Medicaid Services (CMS) and the National Death Index (NDI) for the purpose of determining your health, assessing medical and hospitalization visits and vital status. These would require that the Coordinating Center have access to names, addresses, birth dates, social security number, and/or Medicare number.

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 the Coordinating Center at Wake Forest University Health Sciences; and representatives from government agencies such as the National Institutes of Health, 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.

When you sign this consent and authorization form, you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Principal Investigator Name
Address
City, State, ZIP

If you withdraw your consent, you will not be able to be in this study. If you withdraw your consent, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable.

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. This authorization does not expire. 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.

What Are the Costs?

There are no costs to you for taking part in this study. All study costs 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 You Be Paid for Participating?

You will be paid a total of $200 for completing the clinic visit and phone calls during the Look AHEAD Continuation.

Who is Sponsoring this Study?

This study is being sponsored by the several agencies in the National Institutes of Health, including the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Heart, Lung and Blood Institute (NHLBI), and the Center for Disease Control and Prevention (CDC). These agencies are part of the U.S. Federal Government. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or in what is being studied.

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. The investigators also have the right to stop your participation in the study at any time.

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, *Name* at *telephone number (also include after-hours number)*.

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 *[insert phone number here]*.

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.

I agree to participate in the Look AHEAD Continuation. [ ] Yes [ ] No

If you have agreed to participate in the Look AHEAD Continuation, we ask that you to consider agreeing to the following. If you do not agree to these, you will still be able to participate in the Look AHEAD Continuation.

I agree to have you send important medical findings from my study tests/exams to my personal physician. [ ] Yes [ ] No

I agree to the audio recording of my cognitive tests. [ ] Yes [ ] No

I agree to provide the names of family members or close friends and have staff at my clinical site contact these individuals to provide information on my behalf if my health problems make it difficult for me to provide this information. [ ] Yes [ ] No

I agree to allow the staff at the clinical site to contact me before 12/31/2020 for reasons such as: to see if I would like to join another study connected with Look AHEAD, to inquire about current health status or body weight or to update contact information on designated friends and family member. [ ] Yes [ ] No

I agree to provide my name, phone, street and email addresses, and name of a friend or relative, so that the Look AHEAD Coordinating Center at Wake Forest University Health Sciences may contact me or my designated friends and family any time before 12/31/2020 for reasons such as: to see if I would like to join another study connected with Look AHEAD, to inquire about current health status or body weight or to update contact information on designated friends and family member. [ ] Yes [ ] No

I agree to provide my social security number and Medicare number so that the Look AHEAD Coordinating Center at Wake Forest University Health Sciences may search national databases for information about my health and vital status any time before 12/31/2020.

[ ] Yes [ ] No

I agree to allow other groups approved by the Look AHEAD investigators to use my contact information to get in touch with me for reasons such as: to see if I would like to join another study connected with Look AHEAD, to inquire about current health status or body weight or to update contact information on designated friends and family member and to search national databases for health information about me before 12/31/2020.

[ ] Yes [ ] No

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____

am pm

Person Obtaining Consent: _____ Date: _____ Time:

_____ am pm

The following should be included if you are recruiting subjects who cannot provide informed consent (for example due to diminished mental capacity):

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject.

Legal Representative Signature: _____ Date: _____ Time: _____ am pm

Documentation that a copy of this Informed Consent was given to the research participant is a Federal requirement. Prior to making a copy of the signed and dated Informed Consent please check all appropriate boxes as applicable to indicate copy provided to:

☐ **Study Volunteer** ☐ **Medical Record** ☐ **Researcher** ☐ **Other (Specify)**