Department of Veterans Affairs
VA New York Harbor Healthcare System

RESEARCH CONSENT FORM

Please type or print legibly: Last name, First name M.I.

Subject Name:

Study Title: The Peer Assisted Lifestyle (PAL) intervention protocol: A technology-assisted weight-loss intervention within Patient Aligned Care Teams at the VA

Principal Investigator: Melanie Jay, MD MS

Version Date: 07/29/2019

Participants full SSN:

INTRODUCTION

You are being asked to volunteer to participate in a VA-approved research study at **the VA New York Harbor Healthcare System** (VA NYHHS). It is important that you read and understand the information on this form and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide.

BACKGROUND AND PURPOSE

Purpose of the study: To pilot test a weight management intervention among Veterans in order to improve weight management counseling within VA primary care.

Expected enrollment: Up to 520 VA patients and 30 VA health providers/staff are expected to enroll. You are being asked to participate in this study because you have been identified as a patient who could gain a health benefit from personalized behavior change information in the area of diet and exercise to lose weight.

Study conducted by Principal Investigator: Melanie Jay, MD MS (VA New York Harbor Healthcare System, NYU Langone Medical Center) as part of a VA-funded grant to explore feasibility of a cluster randomized controlled trial at the VA New York Harbor Healthcare System.

DURATION OF THE RESEARCH

Expected research study length: 1 year (with potential monitoring of weight for an additional year)

Your individual participation requires 3 in-person study visits:

- Baseline study visit (~1-3 hours), Follow-up study visits at 6 and 12 months (1-2 hours)

Your individual participation may require additional participation in 10-12 brief (<30 minutes) phone conversations with a health coach over 1 year as part of the intervention study. To be eligible to participate, you need to have a cellular or traditional telephone.

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STUDY PROCEDURES

Baseline study visit: You will be asked to come to the Brooklyn VA for 1-3 hours and you will be randomly assigned to one of two intervention groups. You will complete a questionnaire with several questions to provide information about your dietary and exercise habits, your attitudes about your health, and your experiences with the healthcare system. Basic physical measurements (i.e. height, weight, waist circumference, blood pressure) will also be taken. You may also be asked to complete a routine blood draw at the Diagnostics Center to measure HbA1c and lipid levels. Depending on your group assignment, you may have the opportunity to use an online weight management and goal-setting tool to discuss these topics more in detail with a research team member and set behavior change goals and/or receive educational materials. Afterwards, you may be asked to complete an exit questionnaire.

Follow-up study visits: You will be asked to come back to the Brooklyn VA for 2 follow-up study visits at 6 and 12 months after the Baseline study visit. Each follow-up study visit (1-2 hours), you will be asked to complete follow-up questionnaires, basic physical measurements, and a routine blood draw at the Diagnostic Center.

Data Collection: Your interactions with research staff and health providers may be recorded for research purposes. In addition, research staff may share important information related to your care with your primary care provider. Additional data will be collected via paper/online questionnaires and study visits notes.

If you decide to take part in this study, you will also need to do the following to the best of your ability:

- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the investigator or research study staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- Tell the investigator or research staff about anything that may affect your participation in the study.

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POSSIBLE RISKS OR DISCOMFORTS

Any intervention has possible risks and discomforts and rare, unknown, or unforeseeable (unanticipated) risks also may occur. However, there are no more than minimal risks to your health or well-being from participation in this study.

For Participants with Diabetes Only: If you have diabetes, increasing physical activity and changing your diet can cause hypoglycemia (low sugar). While the risks of hypoglycemia happening as a result of this study are small, hypoglycemia can be life threatening. By agreeing to participate in this study, you accept this risk. You must be familiar with the symptoms of hypoglycemia and how to manage it. Symptoms of hypoglycemia include sweating, confusion, irritability, headaches, feeling shaky, and/or heart palpitations. Having sugar (glucose tablets or juice) immediately will improve the symptoms. If you experience an episode of hypoglycemia, you must notify your doctor and our study team. Also, if you are prescribed insulin during the study period, please let the study team know since this could increase the risks of hypoglycemia.

The researchers understand that exploration of these topics and a persons' individual struggle with their weight can be emotionally charged for many people, particularly considering the stigma placed on obesity in our society. The researchers have been trained in order to effectively facilitate conversations on this sensitive topic and will seek to minimize any emotional discomfort you may feel during the study. Additionally, any potential behavior changes related to diet or exercise will be assessed and approved by properly trained individuals including select research staff, the Primary Investigator, and health professionals. All research study procedures will be completed in a private setting.

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers about risks of usual care.

POTENTIAL BENEFITS

By participating in this intervention study, you will have the opportunity to receive weight management information. Talking about these topics with trained researchers could serve as support or motivation for the difficult task of diet and exercise behavior change. In addition, you may also be able to discuss weight management behaviors and use individualized techniques to improve diet and exercise and set health behavior change goals. This could help you with motivation and give you tangible methods for weight loss.

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ALTERNATIVE PROCEDURES

Your participation in this weight management intervention study is voluntary and completely optional. You may choose not to participate in this study. A decision to not participate in this study will not impact your normal medical care. You may discuss other weight management options with your doctor.

CONFIDENTIALITY

Taking part in this intervention study will involve collecting some private data about you via questionnaires, discussions, research notes, and a review of your medical record.

This data will be protected in the following ways:

- All written data will be kept in locked filing cabinets and electronic data (including survey responses, audio files, and responses to online tool) on secure VA servers and only accessible on VA password protected computers. Original audio files will be removed from recorders.
- Data will be accessed by research team members.
- For transcription of audio files, files will be sent as encrypted files through the secure server to the VA-contracted transcription company, Transcription Outsourcing, LLC. Transcripts will be de-identified by leaving all identifiable information out of the transcript and using only a unique coded identifier generated by the Principal Investigator. This unique identifier will not use any identifying information (i.e. it will not be generated using the subject's social security number, name, etc.) Recorded information will be transferred to Transcription Outsourcing via a HIPAA-compliant web portal using a VA computer. The transcripts will then be stored and analyzed on a VA secure server.
- The online weight management and goal-setting tool uses a web-interface to ask health questions and collect the data in order to deliver tailored advice. This website will be hosted on an NYU server. Data Use Agreements have been setup with both parties and the VA to protect ownership and use of collected coded data. Data will be regularly migrated from NYU's server to the VA server via encrypted USB drive.
- Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study.
- Except when required by law, study information shared with persons and organizations outside of the VA will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

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- When your study information will be disclosed outside of the VA as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. The VA will not disclose the code key, except as required by law.
- Your data will be combined with data from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you. We will not share your records or identify you unless we have to by law.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:* There will be no costs to you for any of the treatment or testing done as part of this research. However, medical care and services provided by the VA that are not part of this study (e.g. normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services. There will be no cost to you to be involved in this study other than transportation costs you may incur in getting to the Brooklyn VA.

Payment Offered for Participation:
For time and inconvenience to complete study-related questionnaires, you will be given:
- $60 cash voucher at the end of the Baseline study visit
- $45 cash voucher at the end of the 6 month study visit
- $50 cash voucher at the end of the 12 month study visit

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

We do not expect there will be a risk of injury, but all forms of medical (or mental health) discussion – whether routine or experimental – involves some risk. In addition, there may be risks associated with this study that we do not know about.

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:
- DURING THE DAY or AFTER HOURS
  - Dr. Melanie Jay at 212-263-4169 or 212-686-7500 x5097
  - Laura Wong, Research Coordinator at 212-686-7500 x5098 or 718-836-6600 x1304

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

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VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study: If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

If you do decide to withdraw your consent: please contact Dr. Melanie Jay and let her know that you are withdrawing from the study. Written requests to withdraw must be sent to her mailing address at VA New York Harbor Healthcare System, 423 East 23rd Street, 15 North, New York, NY 10010. Remember that withdrawing your authorization only affects the uses and sharing of information after your written request has been received, and you may not withdraw your authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research. The Principal Investigator or another research team member will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The Principal Investigator may decide to withdraw you from the study for certain reasons, including:

- ☐ worsening health or other conditions that might make it harmful for you to continue participating
- ☐ failure to keep appointments or follow directions as instructed
- ☐ termination or cancellation of the study by the VA

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PERSONS TO CONTACT

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the Principal Investigator Dr. Melanie Jay at 212-263-4169 or 212-686-7500 x5097.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA NYHHS IRB Office at 212-686-7500 Ext. 4455. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Research Administrative Officer if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input. At the NY campus call 212-686-7500 x 7474. At the BK campus call 718-836-6600 x 3838. Or you may contact the Research Compliance Officer at 212-686-7500 x 7443.

SIGNIFICANT NEW FINDINGS

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.
If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

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I authorize the principal investigator and her co-investigators to contact me about future research on **Primary Care Weight Management in Veterans** provided that this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.
If I agree, then someone from Dr. Jay's research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project.

☐ I agree to be contacted by the Principal Investigator or Co-Investigators for
☐ I **do not** want to be contacted by the Principal Investigator or Co-Investigator

_____

Signature of participant or legal representative Date

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research study has been explained to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.

SIGNATURE	PRINTED NAME	DATE SIGNED
Subject:		
Person Obtaining Consent:		

FOR IRB USE ONLY:

IRB Approval Date: 11/04/19 MIRB ID: **1607**

VA Form **10-1086**
As modified on 02/05/15

VA NYHHS IRB-APPROVED INFORMED CONSENT DOCUMENT