WOOP VA: Mental Contrasting with Implementation Intentions to Promote Weight Management in Primary Care

NCT05014984

October 23, 2024

Participant Name: _____ Last4SSN: _____ Date: _____

Title of Study: WOOP VA: Mental Contrasting with Implementation Intentions to Promote Weight Management in Primary Care

Principal Investigator: [redacted] VA Facility: VA NYHHS Manhattan

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are testing a weight management intervention among Veterans to promote weight management in Primary Care.

By conducting this study, we hope to learn if this intervention is effective among Veterans. Your participation in this research will last about 12 months (one year).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you would like to lose weight and enroll in the VA's weight management program (MOVE!/TeleMOVE! or any local or national VA program that support weight management), volunteering to participate in this study may help you and the information we learn from this study can help Veterans like you in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you do not wish to lose weight and enroll in the VA's weight management program (MOVE!/TeleMOVE! or any local or national VA program that support weight management) or cannot travel to the Manhattan VA for four in-person visits this study may not be appropriate for you.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] at the VA NYHHS Manhattan. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted]

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

Weight management is a key concern among Veterans and often losing weight can improve your health. However, managing your weight can be difficult. We are testing an intervention that may help Veterans achieve their weight loss goals.

By conducting this research project, we hope to learn if this intervention is effective among Veterans

HOW LONG WILL I BE IN THE STUDY?

Up to 405 Veterans will be enrolled in this study.

This research study is expected to take approximately 4 years to complete. Your individual participation in the project will take about 12 months (one year), with 4 in person visits or remotely via telephone or video calls.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you choose to participate in this study, you will be asked to either come into the Manhattan VA or join remotely via telephone or video calls for an Enrollment Visit, a Baseline Visit, a 6 Month Visit and a 12 Month Visit. At 6 or 12 months, you may also be asked to participate in an interview to share your satisfaction with the intervention, barriers to adherence, and recommendations to improve the intervention.

Enrollment Visit (*approximately* 2 hours): You will be asked to come into the Manhattan VA or join remotely via video call where research staff will measure (if in person) or instruct you to measure (if remote) your height, weight, and waist circumference. We will also ask you to answer some surveys. We will also provide you with an accelerometer, a device that you wear on your wrist like a watch that measures your physical activity, which we will ask you to wear for 7-10 days and return to us at your next visit. We will also ask you to complete another survey at home.

Baseline Visit (*approximately* 1 hour): At your Baseline Visit you will return the accelerometer, be enrolled in the MOVE!/TeleMOVE! Program and research staff will provide you with weight management information. You will be randomly assigned, like the flip of a coin, to one of two groups Depending on your group assignment, you may be asked to meet with an educator to learn a visualization strategy. All groups may receive follow up phone calls at 3 days, 4 weeks and 2 months.

6 Month and 12 Month Visits (1 hour): At the 6 and 12 Month Visits we will measure (if in person) or instruct you to measure (if remote) your height, weight, and waist circumference. We will also ask you to answer some surveys.

6 or 12 month Interview (1 hour): We will conduct a qualitative interview (either in-person or via telephone).

Data Collection: Your interactions with research staff 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.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

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.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

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.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

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.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

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.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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.

<u>This data will be protected in the following ways:</u>

- 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 (for fidelity monitoring of MCII, Veteran interviews and Key Informant interviews) we will use the VA's Centralized Transcription Services Program. Files will be uploaded directly to a VA password-protected computer from the audio recorders immediately following the interview/visit. Research team members and the members of the VA Centralized Transcription Services Program will be the only ones with access these files, solely for the purpose of transcription. The transcripts will then be stored and analyzed on a VA secure server by approved research staff.
- 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.
- 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.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO) the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility o you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

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 Manhattan VA.

Payment Offered for Participation:
For time and inconvenience to complete study-related questionnaires, you will be given:

- $25 cash voucher for the Enrollment study visit
- $30 cash voucher for the Baseline study visit
- $40 cash voucher for the 6 month study visit
- $50 cash voucher for the 12 month study visit
- $30 cash voucher for the 6 or 12 month interview (if applicable)

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

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 unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

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 [redacted]

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.

DO I HAVE TO TAKE PART IN THE STUDY?
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 [redacted] 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, [redacted]. 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 MY 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

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

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 [redacted]

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.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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.

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 [redacted] 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.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information 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.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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