# MOVE!+UP: Testing a Tailored Weight Management Program for Veterans With PTSD

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# *MOVE!+*UP - A Study to Test Weight Management for Veterans with PTSD

**Researchers**
**Principal Investigator: Katherine Hoerster, PhD, MPH**

**Study Contact Number**
REDACTED

**Research Staff:**
REDACTED

## Researchers' Statement

We are inviting you to participate in a research study. The purpose of this Information Statement is to give you information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we are asking you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study.

## PURPOSE OF THE STUDY

The purpose of this study is to learn whether *MOVE!*+UP, a program designed to improve weight loss for Veterans with posttraumatic stress disorder (PTSD), is effective. The focus of *MOVE!*+UP is to help Veterans who have current PTSD be more successful in losing weight and decrease their PTSD symptoms. To be eligible to join this study, the following must be true:

- You have been diagnosed with having PTSD symptoms;
- You are classified as overweight or with obesity;
- You are a VA Puget Sound Health Care patient;
- You are currently receiving care for PTSD;
- You have access to a telephone; and

You are willing to be audio-recorded during *MOVE!*+UP (and some *MOVE!*) group sessions. Veterans who enroll in this study will be randomly assigned to participate in *MOVE!*+UP or *MOVE!* for 16 weeks. We expect to enroll approximately 170 Veterans from VA Puget Sound Health Care System ("VA Puget Sound"). Participating in the study will take about 1 year. Assessment visits will be held when participants first enroll in the study and again in 6 months. A questionnaire will also be sent via mail or email to all participants at 16 weeks and a final PTSD symptom and weight check will be done 1 year after enrollment to assess progress.

This study is being conducted by the VA Health Services Research and Development through a grant from VA Research and Development.

## STUDY PROCEDURES

You will need to participate in weekly virtual group sessions by participating via VA Video Connect (VVC) or another approved video conferencing service or by using a backup phone conferencing system if needed. We will make every attempt to have study participation be comfortable and convenient.

You will be randomized (similar to flipping a coin) to participate in one of groups below, which include the following:

| Group Session | What it involves |
|---|---|
| ***MOVE!***<br>**16** 60-minute sessions | • Learn about and be encouraged to practice healthy eating, physical activity, and behavior change.<br>• Monitor weight and behaviors (like physical activity and eating).<br>• Sessions may be audio-recorded so that we can assess whether the program is being delivered as intended. |
| | |
| ***MOVE!*+UP**<br>**16** 2-hour sessions | • Learn about and be encouraged to practice healthy eating, physical activity, and behavior change. Monitor weight and behaviors (like physical activity and eating).<br>• Learn basic skills to manage PTSD symptoms and achieve weight loss.<br>• Walk in your community for about 30 minutes or 1-2 miles, depending on pace.<br>• Sessions will be audio-recorded so that we can assess whether the program is being delivered as intended.<br>• Two dietitian visits held by video or phone: one visit near the start of the program and one around the middle of the program. |

Study participation will also involve the following commitments for **both** groups:

| Study procedure | When / How Often | Duration (approx.) |
|---|---|---|
| Virtual assessment visits over phone or video conferencing with staff and self-administered mailed questionnaire assessments | At enrollment and 6 months | 30-45 minutes each |
| questionnaire assessment | At 16 weeks | 30 minutes |
| Weight and PTSD symptom check over phone or video conferencing | At enrollment, 6 months, and 12 months | 30 minutes each |
| Wear Activity Tracker | At enrollment and 6 months | 1 week |
| Complete Activity Tracker Wear and Sleep Log | At enrollment and 6 months | 35 minutes per day for 1 week |
| Complete Diet/Activity Log | At enrollment and 6 months | 35 minutes per day for 1 week |

For all participants, during the enrollment visit, we will need to ask you some demographic questions, which will include the following:

- Race and ethnicity
- Marital status
- Education
- Income
- Employment

At enrollment, 6 months, and 12 months, we will have you measure your weight using a scale provided by the study. In order to measure your physical activity, we will ask you to wear an accelerometer. An accelerometer is a small device, about the size of a pager, which is worn on your belt or wrist. You will need to wear this device for 1-week periods on two occasions (immediately after this visit and in 6 months). We will provide you with postage-paid packets in order for you to mail the accelerometer back to us after these occasions. We will ask you to keep a diary recording any time you take the device off, as well as your daily sleep schedule, for that week.

Today and in 6 months, we will have you fill out a questionnaire that pertains to:

- Your mental health symptoms
- Your diet and eating behaviors
- Your activity and exercise
- Your social support
- Your sleep
- Your engagement in weight-loss services

We also will ask you complete a PTSD symptom questionnaire in 12 months.

The study procedures may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. The following risks are what we currently know:

**Questionnaires.** Some questions may be personal or sensitive in nature, such as, “Over the last two weeks, have you felt down, depressed, or hopeless?” Or, “In the past month, how much were you bothered by repeated, disturbing, and unwanted memories of the stressful experience?” You may refuse to answer any question or item in any questionnaire, as appropriate to the study.

**Activity Tracker.** You may find it inconvenient or uncomfortable when wearing an accelerometer. We will work with you to make wearing the accelerometer comfortable and convenient.

**Voice recording.** The *MOVE!*+UP (and some *MOVE!*) group sessions will be audio-recorded. Please note that your voice is technically identifiable according to patient privacy rules, so we will do everything possible to protect your voice identity.

**Confidentiality.** There is a possible risk of loss of privacy. We will make every effort to stress the importance of confidentiality to the group members. We cannot guarantee, however, that comments will not be made

outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting your privacy.
We will protect all identifying health care information with great care. We have extensive measures in place to keep a breach of confidentiality from happening and expect these measures to protect your personal information.

**Pregnancy (for female participants).** If you become pregnant during the study, we will require that you speak with your primary care provider or gynecologist to confirm that it is okay for you to continue participating in the study.

All study procedures will be conducted completely remotely via VVC (or another approved video conferencing service) or telephone.

## POTENTIAL RISKS AND DISCOMFORTS

It is possible that your participation in this study will not provide you with any direct benefits. While studies of similar treatments have benefited patients by improving their health and mental well-being, no one can know in advance if it will be helpful in your particular case. Discomforts resulting from this study may include anxiety from the questionnaire or frustration about not losing enough weight.

The results of this study may provide important information regarding ways that health and mental health can be improved for Veterans with PTSD classified as overweight or with obesity.

## POSSIBLE BENEFITS

This study is voluntary and for research purposes only. You may still participate in the standard *MOVE!* program without being enrolled in this study.

## OTHER INFORMATION

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

If you decide to withdraw from the study, data already collected will continue to be part of the analyses, and we will still pull information from your VA medical record to find additional information about you, including how many other VA visits you attend, certain medications you take, and diagnoses you may have so that we are best able to test how well the interventions support Veterans with PTSD. However, we will not ask you to participate in any further study activities. The study Principal Investigator has the right to terminate your participation in this study if she feels that it is not in your best interest to continue in the study. This termination will not require your consent.

If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

When the study concludes and the main findings are published, we will share a summary of findings with you by mail.

## COMPENSATION

If you choose to participate in this study, we will compensate you up to $120 for your time and effort. You may expect to receive this compensation approximately up to 16 weeks after you have completed all study activities. To receive compensation, we will collect your social security number so as to comply with Internal Revenue Service (IRS) guidelines. You may receive an IRS Form 1099.

Participant payments will be made via Direct Deposit. If you do not have Direct Deposit established but would like to do so, it will require that your banking information be on file with VA. Our study staff can help you get that set up. As with all study activities, we will keep this information confidential and will only share it with those involved with setting up direct deposit payment. If you do not wish to set up Direct Deposit with the VA, we may be able to provide payment in the form of gift cards in the future (subject to approval). You may also opt not to receive study payment.

| Study Procedure | Possible Compensation |
|---|---|
| Assessment completion: | |
| • At enrollment | $20 |
| • At 6 months | $20 |
| • At 12 months | $20 |
| • 16 Week Survey | $20 |
| | |
| In receipt of mailed Activity Tracker: | |
| • At enrollment | $20 |
| • At 6 months | $20 |
| | |
| **TOTAL POSSIBLE AMOUNT** | **$120** |

## CONFIDENTIALITY

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- VA Health Science Research & Development (HSR&D)

- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The VA Puget Sound Fiscal Department and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The information collected from you for this study will remain confidential, used for research purposes only, and will not be sold. Information about you will be combined with information from other people taking part in this study. We will write about the combined data we gather in this study. Any presentations or papers about this study will not identify you. A description of this clinical trial will be available on 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 and you can search this website at any time.

If you agree to participate in our study, we will assign information about you with a study code number. Your name or social security number will not appear on any of the information that we collect from you. Only your study code number will be used. We will keep the master list that links your name to your code number separate from the study data in a secure password-protected computer file.

**Voice Recording**
The audio-recordings of the *MOVE!*+UP group sessions (and some *MOVE!* sessions) will be listened to by a member of the research staff to evaluate *MOVE!*+UP facilitators' adherence to the expected content and format. These session recordings may be transcribed (written down word for word). Recordings that have not yet been uploaded into the password-protected VA network folder will be stored in a locked file cabinet in an office which will be locked when unoccupied. Current VA regulations require us to keep recordings indefinitely. Recordings and transcriptions will be stored in a secure place and separately from your identifying information or other study data.

**Medical Record**
We will look at your VA medical record to find additional information about you, including how many other VA visits you attend, certain medications you take, and diagnoses you may have. In addition, we will put basic information about you, such as your weight and clinical information related to your weight and to your PTSD from this study, into your medical record. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be retained in accordance with the VA records retention policy.

Once this study is completed, we will not use your data (or the study code linking it to you) for any additional research. We will keep your data and code in a secure database in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed).

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing.

Neither you nor your family will gain financially from discoveries made in the future using the information you provide.

We will complete every safety measure possible to protect your well-being. If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment.

## QUESTIONS OR CONCERNS RELATED TO THE STUDY

If you have any questions about the study, you may contact the VA Institutional Review Board (IRB) Office at 206-277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research.

## RESEARCH SUBJECT'S RIGHTS

If you have any questions about the study purpose, procedures, risks, discomforts, possible benefit, choices available to you, or your rights as a research subject, please discuss them with one of the researchers listed above prior to agreeing to participate in this research activity.

*We very much appreciate your consideration*
*in participating in this study. Thank you!*

**Study Oral Script for Patient Consent**

# *MOVE!+*UP: A Study to Test Weight Management for Veterans with PTSD

***[INTRODUCTION]***

Thanks again for your interest Mr./Ms. /Mrs. _____, what I would like to do is describe the study in detail and go through the consent process so that you can decide if you'd like to participate. Please feel free to interrupt me at any time and ask questions as we go.

*If yes, continue*

*If no, schedule call back if needed*

**[*BACKGROUND AND PURPOSE*]**

Before you decide to take part in this study, 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. As you consider participating, you should keep in mind that taking part in this study is completely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

The purpose of this study is to learn whether *MOVE!*+UP, a program designed to improve weight loss for Veterans with posttraumatic stress disorder (PTSD), is effective. The focus of *MOVE!*+UP is to help Veterans who have current PTSD be more successful in losing weight and decreasing their PTSD symptoms.

To be eligible to join this study, the following must be true:

- You have been diagnosed with having PTSD symptoms;
- You are classified as overweight or with obesity;
- You are a VA Puget Sound Health Care patient;
- You are currently receiving care for PTSD;
- You have access to a telephone; and
- You are willing to be audio-recorded during *MOVE!*+UP (and some *MOVE!*) group sessions.

This study is being conducted by the VA Health Services Research and Development through a grant from VA Research and Development. This research study is expected to take approximately 4 years. We expect to enroll approximately 170 Veterans from VA Puget Sound Health Care System ("VA Puget Sound"). Your actual participation time will be about 1 year.

***[STUDY PROCEDURES]***

If you consent to be in the study will need to participate in weekly virtual group sessions by participating via VA Video Connect (or another approved video conferencing service) or by using a backup phone conferencing system if needed. We will make every attempt to have study participation be comfortable and convenient.

You will be randomized (similar to flipping a coin) to participate in one of two groups:

| Group Session | What it involves |
|---|---|
| ***MOVE!***<br>**16** 60-minute sessions | • Learn about and be encouraged to practice healthy eating, physical activity, and behavior change.<br>• Monitor weight and behaviors (like physical activity and eating).<br>• Sessions may be audio-recorded so that we can assess whether the program is being delivered as intended. |
| | |
| ***MOVE!*+UP**<br>**16** 2-hour sessions | • Learn about and be encouraged to practice healthy eating, physical activity, and behavior change. Monitor weight and behaviors (like physical activity and eating).<br>• Learn basic skills to manage PTSD symptoms and achieve weight loss.<br>• Walk in your community for 30 minutes or 1-2 miles, depending on pace.<br>• Sessions will be audio-recorded so that we can assess whether the program is being delivered as intended.<br>• Two dietitian visits held by video or phone: one visit near the start of the program and one visit near 16 weeks. |

Study participation will also involve the following commitments for **all participants**:

| Study procedure | When / How Often | Duration (approx.) |
|---|---|---|
| Virtual assessment visits over phone or video conferencing with staff and self-administered mailed questionnaire assessments | At enrollment and 6 months | 30-45 minutes each |
| Questionnaire assessment | At 16 weeks | 30 minutes |
| Weight and PTSD symptom check over phone or video conferencing | At enrollment, 6 months, and 12 months | 30 minutes each |
| Wear Activity Tracker | At enrollment and 6 months | 1 week |
| Complete Activity Tracker Wear and Sleep Log | At enrollment and 6 months | 35 minutes per day for 1 week |
| Complete Diet/Activity Log | At enrollment and 6 months | 35 minutes per day for 1 week |

For all participants, during the enrollment visit, we will need to ask you some demographic questions, which will include questions related to Race and ethnicity, Marital status, Education, Income, and Employment.

At enrollment, 6 months, and 12 months, we will have you measure your weight using a scale provided by the study. We will measure your physical activity levels at enrollment and 6 months using an accelerometer. An accelerometer is a small device, about the size of a pager, which is worn on your belt or wrist. You will need to wear this device for 1 week. You will need to return the accelerometer

in the pre-paid postage envelope we provide you. We will ask you to keep a diary recording any time you take the device off, as well as your daily sleep schedule, for that week. We will also ask you to complete questionnaires pertaining to your mental health, diet, eating behaviors, activity, exercise, social support, sleep, and your engagement in weight-loss services at enrollment and 6 months.

The procedures I described are all being done for research purposes. While you are in the study, your healthcare provider will continue to provide your usual care. Your study participation does not restrict the treatment choices available to you.

***[POSSIBLE RISKS OR DISCOMFORTS]***

There is always a chance that any procedure may harm you. The procedures in this study are no different. The study procedures may involve risks that are currently unknown and we may need to contact you if we learn of a new study risk, even if you have completed the study. The following risks are what we currently know:

**Questionnaires.** Some questions may be personal or sensitive in nature, such as, "Over the last two weeks, have you felt down, depressed, or hopeless?" Or, "In the past month, how much were you bothered by repeated, disturbing, and unwanted memories of the stressful experience?" You may refuse to answer any question or item in any questionnaire, as appropriate to the study.

**Activity Tracker.** You may find it inconvenient or uncomfortable when wearing an accelerometer. We will work with you to make wearing the accelerometer comfortable and convenient.

**Voice recording.** The *MOVE!*+UP (and some *MOVE!*) group sessions will be audio-recorded. Please note that your voice is identifiable according to patient privacy rules, so we will do everything possible to protect your voice identity.

**Confidentiality.** There is a possible risk of loss of privacy. We will make every effort to stress the importance of confidentiality to the group members. We cannot guarantee, however, that comments will not be made outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting your privacy.

We will protect all identifying health care information with great care. We have extensive measures in place to keep a breach of confidentiality from happening and expect these measures to protect your personal information.

**Pregnancy (for female participants).** If you become pregnant during the study, we will require that you speak with your primary care provider or gynecologist to confirm that it is okay for you to continue participating in the study.

***[POTENTIAL BENEFITS]***

We can't promise that you will get any benefit from taking part in this research study. While studies of similar treatments have benefited patients by improving their health and mental well-being, no one can know in advance if it will be helpful in your particular case.

The results of this study may provide important information regarding ways that health and mental health can be improved for Veterans with PTSD who are classified as overweight or with obesity.

***[ALTERNATIVES TO PARTICIPATION]***
You may choose not to participate. The study is voluntary and is for research purposes only. If you choose not to participate in our study, you may still participate in the standard *MOVE!* program without being enrolled in this study.

***[PARTICIPATION IS VOLUNTARY]***
You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

If you decide to withdraw from the study, data already collected will continue to be part of the analyses, and we will still pull information from your VA medical record to find additional information about you, including how many other VA visits you attend, certain medications you take, and diagnoses you may have so that we are best able to test how well the interventions support Veterans with PTSD. However, we will not ask you to participate in any further study activities. The study Principal Investigator has the right to terminate your participation in this study if she feels that it is not in your best interest to continue in the study. This termination will not require your consent.

If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

When the study concludes and the main findings are published, we will share a summary of findings with you by mail.

***[COST TO PARTICIPANTS]***
You will not be charged for participating in this study. If you pay co-payments for medical care and services, you will still have to pay these co-payments as long as they are not related to this research study.

We will compensate you as follows:

| Study Procedure | Possible Compensation |
|---|---|
| Assessment completion: | |
| • At enrollment | $20 |
| • At 6 months | $20 |
| • At 12 months | $20 |
| | |
| Questionnaire/Survey: | |
| • At 16 weeks | $20 |

| | |
|---|---|
| In receipt of mailed Activity Tracker: | |
| • At enrollment | $20 |
| • At 6 months | $20 |
| | |
| **TOTAL POSSIBLE AMOUNT** | **$120** |

We estimate the payments may take up to 16 weeks to receive after completing each assessment and returning your Activity Tracker, although sometimes it takes longer for the checks to be issued. Checks will be mailed directly from the Department of the Treasury.

Participant payments will also be made via Direct Deposit. If you do not have Direct Deposit established but would like to do so, it will require that your banking information be on file with VA. Our study staff can help you get that set up. As with all study activities, we will keep this information confidential and will only share it with those involved with setting up direct deposit payment. If you do not wish to set up Direct Deposit with the VA, we may be able to provide payment in the form of gift cards in the future (subject to approval). You may also opt not to receive study payment.

***[CONFIDENTIALITY]***
Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

There are times when we might have to show your records to other people. For example:

- Research team members
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The VA Puget Sound Fiscal Department will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The information collected from you for this study will remain confidential, used for research purposes only, and will not be sold. Information about you will be combined with information from other people taking part in this study. We will write about the combined data we gather in this study. Any presentations or papers about this study will not identify you. A description of this clinical trial will be available on 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 and you can search this website at any time.

If you agree to participate in our study, we will assign you a study code number. Your name or social security number will not appear on any of the information that we collect from you. We will keep the master list that links your name to your code number separate from the study data in a secure password-protected computer file.

**Voice Recording**

The audio-recordings of the *MOVE!*+UP group sessions (and some *MOVE!* sessions) will be listened to by a member of the research staff to evaluate *MOVE!*+UP facilitators' adherence to the expected content and format. These session recordings may be transcribed (written down word for word). Recordings that have not yet been uploaded into the password-protected VA network folder will be stored in a locked file cabinet in an office which will be locked when unoccupied. Current VA regulations require us to keep recordings indefinitely. Recordings and transcriptions will be stored in a secure place and separately from your identifying information or other study data.

**Medical Record**

We will look at your VA medical record to find additional information about you, including how many other VA visits you attend, medications you may be taking, and diagnoses you may have. We may put basic information about you, such as your weight and clinical information related to your weight and to your PTSD from this study, into your medical record. Only authorized users of the national VA medical records system will have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be retained in accordance with the VA records retention policy.

Once this study is completed, we will not use your data (including any recordings and transcriptions, if applicable) or the study code linking it to you for any additional research. We will keep your data in a secure database in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). Some data will be shared, communicated, or stored during or after this research study.

Information learned from this research may be used commercially for the development of weight-management programs or for the diagnosis or treatment of overweight Veterans with PTSD. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

***[MEDICAL TREATMENT AND COMPENSATION]***

We will complete every safety measure possible to protect your well-being. If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment.

***[PERSONS TO CONTACT ABOUT THIS STUDY]***

You should have received an information sheet in your mailed packet, however if it has been lost, we can send another one. If you have questions pertaining to the study, you may contact the study PI, Dr. Hoerster at REDACTED. After business hours (nights and weekends), please call (206) 762-1010

and ask the operator to page the on-call VA psychiatrist. You may also call the Veterans Crisis Hotline 24 hours a day at 1-800-273-8255.

Please contact the study researcher(s) if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at 206-277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

***[AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY]***

At this time, I want to make sure that you fully understand the purpose of this study and what is involved if you choose to participate. Remember that your participation is completely voluntary. If you decide to participate, you may withdraw at any time without penalty. The benefits may not directly affect you, however this information may help create programs for future Veterans who have weight management problems.

Do you consent to be in the study? Yes ☐ No ☐

- *If the potential patient says no, the interviewer will thank the potential participant for their time before completing the visit. Ask the Veteran if they would like the number for MOVE! and a list of Mental Health resources.*

*Interviewer's signature below signifies they have covered all information in the script, answered all of the participant's questions, and the participant has consented to participate in the study.*

_____

*Subject Name (First Middle Last)*

_____ Click or tap to enter a date.

*Study Staff Signature (PIV certificate preferred)* *Date*