WHOLE HEALTH IN VA MENTAL HEALTH: A RANDOMIZED CONTROLLED TRIAL OF OMNIS SALUTIS

NCT05400252

IRB Approval Date: 10/29/2025

INFORMATION SHEET FOR WHOLE HEALTH IN VA MENTAL HEALTH: A RANDOMIZED CONTROLLED TRIAL OF OMNIS SALUTIS

You are being asked to participate in a research study conducted by Diana Whitham, PhD at the VA Maryland Health Care System, the Washington DC VA Medical Center, the Martinsburg VA Medical Center, and the VA Eastern Colorado Health Care System. We are conducting a study to understand the impact of a patient-centered educational intervention on Veterans' social and physical functioning and Veteran participation in VA health care. Patient centered care is providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

We are conducting a research study to understand the impact of a patient-centered educational intervention on Veterans' social and physical functioning and Veteran participation in VA health care.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, all study activities will be conducted remotely by phone or computer. All study activities are considered experimental, in other words they are being done solely for the purposes of research as opposed to part of your standard care. All study activities will be conducted by research study staff, not your usual care team. Study participants should be prepared to participate in all activities of the study. If you participate in this study you will take part in the following activities:

- You will meet remotely with a Research Assistant to discuss this Information Sheet and decide if you want to participate in the study. This will take approximately one hour.
- You will receive an online link to a series of questionaries you will be asked to complete. This is the first of 4 times you will be asked to complete these questionaries. In this document we will call this first set of questionnaires "Q1". If you do not wish to complete the questionaries by yourself online you can request that the Research Assistant help you complete them remotely. You will be free to skip any questions that you would prefer not to answer. This will take approximately one hour.
- You will be randomized by a Biostatistician to an experimental or control condition. This means that by chance, like the flip of a coin, you will be assigned to participate in a new patient-centered educational intervention or a standard patient education intervention. This will not take any of your time.
- You will be contacted by an Interventionist to schedule 3, 1-hour intervention sessions which must be completed within two months of Q1. The sessions will be scheduled at your convenience and you will remotely participate in the 3, 1-hour sessions. You may

have worksheets you will complete outside these meetings. This will take approximately 4.5 hours. The 3, 1-hour sessions will be videorecorded to ensure Interventionists are delivering the interventions correctly. Session recordings will not be shared outside the study team supervision structure.

- Approximately 3-months after Q1 you will receive an online link to a series of questionaries you will be asked to complete. If you do not wish to complete the questionaries by yourself online you can request that the Research Assistant help you complete them remotely. You will be free to skip any questions that you would prefer not to answer. This will take approximately one hour.
- Approximately 3-months after Q1 you may be asked to participate in an interview about your experience in the 3 intervention sessions. Only 30 participant will be interviewed. You may decide to not be interviewed and still participate in all other study appointments. If you agree, you will be interviewed remotely and you will receive an additional $50 payment. This will take approximately one hour.
- Approximately 6-months after Q1 you will receive an online link to a series of questionaries you will be asked to complete. If you do not wish to complete the questionaries by yourself online you can request that the Research Assistant help you complete them remotely. You will be free to skip any questions that you would prefer not to answer. This will take approximately one hour.
- Approximately 12-months after Q1 you will receive an online link to a series of questionaries you will be asked to complete. If you do not wish to complete the questionaries by yourself online you can request that the Research Assistant help you complete them remotely. You will be free to skip any questions that you would prefer not to answer. This will take approximately one hour.

Following completion of the study and statistical analysis of data, you will receive a report of the overall study results.

Participation in this research study is voluntary. Refusal to take part in the study will not involve a penalty or loss of benefits to which you are otherwise entitled.

You may stop taking part in the research study at any time without any penalty or loss of benefits. If you withdraw you will still receive the same standard of care that you would otherwise have received.

The investigator may continue to review the data already collected for the study prior to your withdrawal. However, the investigator cannot collect further information.

ARE THERE ANY RISKS OR DISCOMFORTS?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- When completing questionnaires, some participants may feel embarrassed when they have to answer questions that they may feel are personal. The likelihood of this is rare: In 100 people, 3 or fewer may experience these risks. Most people get used to the situation and relax after a few minutes. You will be free to skip any questions that you would prefer not to answer.
- When completing questionnaires, participant may feel bored or tired due to the length of time required to participate. The likelihood of this is rare: In 100 people, 3 or fewer may experience these risks. You will be able to take a break if you need to rest or the encounter can be continued on another day if you prefer.

- Some people may feel uncomfortable with being video recorded in their individual sessions with the study interventionists. The likelihood of this is rare: In 100 people, 3 or fewer may experience these risks. Most people get used to the situation and relax after a few minutes. You can ask the interventionist not to record if you do not feel comfortable.
- There is an unlikely risk of breach of confidentiality. Loss of confidentiality will be minimized by storing paper data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected or stored on restricted computer drives. Only designated research staff members have access to the password protected file that links participants' identities to their codes. Data will only be available to project staff as needed to complete their job duties. All project staff are thoroughly trained in issues relating to confidentiality. Statistical analyses will be based on group data; no individual data will be reported.
- There may be risks in this study which are not yet known.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

ARE THERE ANY BENEFITS?

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers understanding of patient-centered educational interventions.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential. In order to protect your private information, physical data will be stored in a secure location. Electronic data will be password-protected or stored on restricted computer drives behind the VA firewall. Only designated research staff members have access to the password protected file that links participants' identities to their codes. Data will only be available to project staff as needed to complete their job duties. All project staff will be thoroughly trained in issues relating to confidentiality. Statistical analyses will be based on group data; no individual data will be reported.

Research staff must follow legal requirements concerning reporting abuse of vulnerable populations such as children or elders. If you tell us about abuse of vulnerable populations, we must disclose this information to the appropriate individuals and/or authorities.

If the research staff hears or sees that you intend to harm yourself or someone else, we will need to tell your treatment provider or some other authority so that you can get help, even if that means telling them without your permission. In this situation, research staff would only disclose information that would prevent harm to you or other people that might be in danger.

All identifiable private information may be removed from the data collected to create a “de-identified data set”. After such de-identification, the data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

Following each of the 4 times you complete questionnaires you will be paid $50, for a possible total of $200. If you are asked and agree to participate in the additional interview you will be paid $50, for a possible total of $250.

You will be paid at the completion of each research appointment. You will receive a direct deposit if you already have this arranged with VA, or a check from the Department of the Treasury will be sent to you. If payments are made through the Austin Financial Services Center an Internal Revenue Service Form 1099 will be generated regardless of the amount paid to you. In this instance your social security number will be used to issue the IRS Form 1099.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with study procedures. Please immediately contact [XXX] at [XXX-XXX-XXX] or [XXX] at [XXX-XXX-XXXX].

If you have any other questions, comments or concerns about the research, please contact contact [XXX] at [XXX-XXX-XXX] or [XXX] at [XXX-XXX-XXXX].

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 Central Institutional Review Board (IRB) toll free at X-XXX-XXX-XXXX.