Initial Testing of Whole Health STEPS (Structured Tiered Engagement with Peer Support)

NCT04390451

October 24, 2023

Informed Consent Documentation for *Initial Testing of Whole Health STEPS (Structured Tiered Engagement with Peer Support)*

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Principal Investigator*: Emily M. Johnson
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Brief Description of Informed Consent Requirements and Process:

This project was determined to be exempt research and does not require formal written documentation of informed consent. The consent process entailed:

1. A handout containing comprehensive consent and HIPAA information along with contacts for the study mailed to participants in initial recruitment materials.
2. A verbal scripted informed consent process to review the handout and all essential consent information, address participant questions, and ensure participant capacity to consent through an Impaired Decision-Making Capacity screening.

We have included the most recently approved consent documents for the final study phase as listed below, redacting personal information about study staff.

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Research Consent and HIPAA Informational Handout

Title of Study: Initial Testing of Whole Health Structured Tiered Engagement with Peer Support (STEPS)

Principal Investigator: Emily M. Johnson, PhD **VAMC:** Syracuse

We would like you to participate in a research study testing Whole Health STEPS (Structured Tiered Engagement with Peer Support). This study is part of a series of studies testing Whole Health STEPS, a new primary care service for Veterans with mental health symptoms. In Whole Health STEPS, you will work with a Peer Specialist on health and wellness. We will ask about your mental and physical health, wellness, and healthcare, and get feedback about Whole Health STEPS.

If you choose to participate, this is what you can expect:

- This study is about 4-5 months long. About 44 Veterans will participate.
- If you agree (or consent) to participate, you will complete an interview and questionnaires. Your answers determine whether you are eligible for the study. This part will last around 1 hour. You will either be asked to continue, or your participation will end. If you are eligible to continue, you will complete additional questionnaires. These will take about 1 additional hour. Both parts together last about 2 hours total.
- You will have regular check-ins with the peer about your health and wellness. You have a 50/50 chance of starting immediately or waiting for 2 months. This is random, using a process like a flip of a coin. The level of support you get will increase or decrease based on your progress and preferences. That means, if you need more support, you may have longer sessions or more sessions. If you are doing well, you may have shorter or fewer sessions. We will ask for your permission to audio record your sessions with the peer and a feedback interview to understand how peers do Whole Health STEPS.
- We will ask you to complete follow-up questionnaires and/or interviews halfway through the study and at the end. The exact length of the study depends on your sessions with the peer and when you finish the questionnaires. Appointments can be in person, over the phone, or online depending on your preferences, available technology, and current public health guidelines.

More Details about Time and Payment:

- You do not have to pay for peer sessions, but you will also not be paid for attending peer sessions. You will get paid for time you spend on other research activities as described in the table below:

Research Activity	Estimated Time	Payment
Initial Interview & Questionnaires Part 1	1 hour	$20
Initial Interview & Questionnaires Part 2	1 hour	$20
Mid Questionnaires	1 hour	$20
Final Questionnaires	1 hour	$20

Post Whole Health STEPS Questionnaires	½ hour	$10
Post Whole Health STEPS Interview	½ hour	$10

- The Post Whole Health STEPS questionnaires and interview will be added to either the mid or final assessment depending on whether you start with the peer right away or wait.
- You can earn about $100 total. Payments will be pro-rated. If you only complete half the questions, you will only be paid half the amount. There are two ways we can pay you. You can choose either an electronic transfer to your bank account or a debit card sent to you in the mail. If you choose the direct transfer, we will ask for your banking information for payment processing purposes.

You do not have to participate. Here are your other options:

- Participation is entirely voluntary. You can refuse to participate or withdraw at any time after enrolling.
- Participation does not affect your healthcare services or other rights. You may continue to receive your usual care. You can talk with your VA provider about your care. Your responsibility to pay for VA services, tests, and medications does not change.
- You may be taken out of the study if the investigator believes it is not in your best interest to continue. If you are taken out of the study or withdraw by choice, we will do our best to connect you with services and give you the opportunity to ask questions.

Information about your confidentiality, and privacy if you participate:

- Federal and state laws and the federal medical law, the HIPAA Privacy Rule, protect your privacy. We will get information from your VA medical records and the questionnaires/interviews described above. Information from your medical records includes your name, address, date of birth, medical and mental health diagnoses, and medical and mental health treatment. Information collected from your medical records may also include drug and alcohol use. Your social security number will be used to ensure we have the correct information. Clinically relevant results from the behavioral health screenings you complete for the research trial will be shared with you. These results may also be shared with VA providers to help coordinate your clinical care (e.g., place referrals that you request, coordinate with your primary care team, etc.). If you have any questions or concerns about who we may share information with, we encourage you to ask research staff and we will work with you to address your concerns.
- Data will be stored in locked filing cabinets and password-protected secure computer networks at the Syracuse VA. Only research staff has direct access to the data. All data will be retained according to VA policies. The research team may also share information with oversight committees. Oversight committees may include the Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability (GAO), and our funder (VA Office of Rehabilitation Research & Development).
- Your information could be used for future studies or by another investigator for future research studies without your formal consent. Should this happen, information that could identify you will be removed.

- If results are reported in medical journals or at meetings, you will not be identified by name, recognizable photograph, or other means without your specific consent. This trial is registered at Clinicaltrials.gov and results of the trial will be reported there. No patient identifiers will be provided to Clinicaltrials.gov.

There is minimal risk to participating in this study:

- You may feel uncomfortable (e.g., anxious, sad) when answering sensitive questions about yourself. Please discuss any discomfort or concerns with research staff. You may stop answering questions or talk to a clinician at any time.
- If you plan to harm yourself or others, we may need to share this information to ensure your safety and the safety of others. We may need to report abused or neglected children or elderly persons (including child pornography) to appropriate authorities. Also, any sexual assaults on VA property will be reported to VA police to ensure safety of other patients, visitors, and staff.
- We do not anticipate injury or illness associated with this project. However, as a Veteran, you are entitled to medical care and treatment for injuries suffered as a result of participating in a VA research program. You will not have to pay for this medical care and treatment. If you have an injury or illness related to this research project, please contact one of the individuals listed at the bottom of this page. ***If you have a medical or mental health emergency, call 911, or go to the Emergency Room.*** If you need to speak with a mental health provider during normal business hours, please call the Syracuse VA Mental Health Clinic at 315-425-3463. ***If you have a mental health crisis or it's outside of normal business hours, please call the Veterans Crisis Line at 988 and press 1 at the prompt.***

Potential benefits from this study:

- You may or may not benefit from this study. However, you will receive Whole Health STEPS a service designed to improve your health and wellness. We hope that the information learned from this study will help other Veterans in the future. By conducting research studies like this one, we can learn whether Whole Health STEPS and similar programs can improve VA services.

Contact Information:

- Call [RESEARCH ASSISTANT NAME] at ###-###-#### to get more details or participate. Call Dr. Emily Johnson, Principal Investigator, at ###-###,#### for concerns about this study.
- To talk with someone outside this project to discuss concerns, request information, or offer feedback, call the Chairperson of the Syracuse VAMC Institutional Review Board or the Human Research Protection Program Administrator, at ###-###-#### or the Syracuse VA Patient Advocate at ###-###-####.

Verbal Informed Consent

Now, I would like to provide more information about the study and make sure you understand your rights as a research participant. All this information is discussed more in-depth on the Research Consent and HIPAA Informational Handout. If you have your Research Consent and HIPAA Informational Handout, you can follow along with me. If you did not receive, or misplaced this handout, I can give you another copy for your reference.

- *As you know, you are being asked to take part in a study called "Initial Testing of Whole Health Structured Tiered Engagement with Peer Support, Whole Health STEPS." This study is part of a series of studies testing Whole Health STEPS, which is a new primary care service for Veterans with mental health symptoms*
- *If you agree (or consent) to participate, you will complete an interview and questionnaires about your mental health, physical health, wellness, and healthcare use. Your answers will determine whether you are eligible for the study. If you are eligible to continue, you will complete additional questionnaires.*
- *You will have regular check-ins with the peer about your health and wellness. You have a 50/50 chance of either working with the peer immediately or waiting for 2 months. The level of support you receive will increase or decrease based on your progress and preferences. That means, if you need more support, you may have longer or more frequent sessions. If you are doing well, you may have shorter or less frequent sessions. We will ask you to complete follow-up questionnaires and/or interviews halfway through the study and at the end. We will also ask you for permission to audio record the peer sessions and a feedback interview.*
- *The exact length of the study depends on your sessions with the peer and when you finish the questionnaires. Research appointments can be in person, over the telephone, or online depending on your preferences, available technology, and current public health guidelines.*
- *You can earn about $100 for participating if you complete all the required interviews and questionnaires. Please see the payment table on your handout for the exact breakdown of payments. There are two ways compensation can be given to you. You can choose either an electronic transfer into your bank account or a VA debit card. If you choose the direct deposit option, we will ask for your banking information for payment processing purposes.*
- *Your participation in the study is voluntary. You do not have to participate and can withdraw at any time without any effects on your healthcare services or other rights. You may continue to receive the care you have been receiving or talk with your provider about getting additional care.*
- *You may be taken out of the study if the investigator believes it is not in your best interest to continue. If you are taken out of the study or withdraw by choice, we will do our best to connect you with services and give you the opportunity to ask questions.*
- *We also want you to know that we will be collecting certain private health information from you and that there are rules to protect your private health information, such as the HIPAA Privacy Rule. The information we will be collecting from you is specified on the handout. You may take back our permission to access this information at any time. Study staff will share*

clinically relevant results with you including the results from behavioral health screenings that you complete for the research trial. We may also share these results with VA providers to help coordinate your clinical care (e.g., place referrals that you request, coordinate with your primary care team, etc.). If you have questions or concerns about who we share information with please review your handout with the research team.

- *Any information obtained about you in this study will be treated as confidential. Only research staff and the oversight committees listed on your handout will have access to the data. If results of this study are reported, you will not be identified.*
- *Your information could be used for future studies or by another investigator for future research studies without your formal consent. Should this happen, information that could identify you will be removed.*
- *You may or may not benefit from Whole Health STEPS but we hope this research will improve services at the VA for other Veterans. There is minimal risk to participating in these research activities. You may feel uncomfortable when answering sensitive questions about yourself. Please discuss any discomfort or concerns with research staff. You may stop answering the questions or talk to an on-call clinician at any time.*
- *If you have questions about this study, you can contact Dr. Emily Johnson at the number provided on the bottom of your handout. If you would like to speak with an individual who is unaffiliated with this specific research study, there is contact information for those individuals at the bottom of your handout as well.*

Once finished, ask: *Do you have any questions?* Answer any questions the Veteran has. Then, continue to the **IDMC.**

Impaired Decision-Making Capacity (IDMC) Screening

Say: *Now that we have reviewed the details of the study, I'm going to ask you a few questions to make sure you fully understand the research study. This is a standard procedure for research studies.*

Ask the following questions:

1. *What is this research project about?*
2. *What risks does it present to you?*
3. *What happens if you do not participate in this study?*
4. *What happens to you if you do decide to participate?*
5. *What is the benefit to you of participating?*

IF INCORRECT: Review points of consent that were not understood. If the participant appears unable to provide informed consent thank the participant for her time and discontinue the research study.

IF CORRECT: *Excellent, based on everything we discussed so far, do you consent (or agree) to participate in this research study?*

☐Yes→*Great!* Proceed to questions below.
☐No→*Thank you for your time.*

As we discussed, we do ask for separate consent to do audio recordings of your peer sessions. Are you willing for us to do audio recordings of your sessions with the peer and a feedback interview?

☐Yes→*Thank you.*
☐No→*Ok, we'll skip that part.*

Wonderful. **Proceed to Baseline Interview Questionnaire.**