Improving Vocational Outcomes of Veterans with Psychiatric Disorders: Career Counseling & Development

NCT04698967

November 17, 2023

Participant Name: _____ Date:_____

Title of Study: Improving Vocational Outcomes of Veterans with Psychiatric Disorders: Career Counseling & Development

Principal Investigator: [PI Name] VA Facility: Bedford VAMC

Sponsor of Study: Department of Veterans Affairs

We are asking you to choose whether or not to volunteer for a research study. This consent form will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary. A total of 50 participants will take part in this study.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is the final part of a three-part study to improve vocational services for veterans. We are comparing two vocational treatment options: 1) Transitional Work Experience and 2) Transitional Work Experience plus career counseling. This study is funded by the Department of Veterans Affairs. By doing this study, we hope to better help veterans reach their employment goals.

2. WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

If you decide to participate in this study, you will be randomly assigned to one of the two treatments. This process is like flipping a coin.

Your participation in this research will last six months. During the first 12 weeks, you will meet with the Transitional Work Experience staff as required by the program. You will complete surveys about work, career, and employment in addition to your mental health, at week 1, week 6 and week 12 during your time in this study. These surveys may be completed in person or online and take about 35 minutes to complete. Around week 12 you will also complete an interview with a research staff member about your experience of the vocational services you had received. You may meet with the researcher in person or virtually through VA-approved video-conferencing software like VA Video Connect.

Some people will also participate in up to 12 sessions of career counseling, once per week, for approximately one hour with a research clinician. These counseling sessions will be focused on topics related to career, employment, and job development. These sessions may occur in person or virtually through VA-approved video-conferencing software.

Three months after the 12 weeks of treatment have concluded, you will be asked to complete a follow-up survey that will take about 35 minutes to complete. You may participate in person or virtually.

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

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Receiving career counseling in this study may improve your career development.

You will contribute to the development of a new career counseling and development counseling program that will be used to help veterans reach their employment goals.

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

You may experience discomfort in answering personal questions in study assessment visits. You may find some questions surrounding employment and/or unemployment to be emotionally upsetting.

There is possibility of breach of confidentiality if participant data, either in electronic or hard copy form, or audio recorded interviews, were to be accessed by an unauthorized person.

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. You may also discontinue participation at any time.

5. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [PI Name] of the VA Bedford Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is: [PI Phone Number].

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in a research study to develop a new career counseling program aimed at helping veterans reach their employment goals. You have been invited because you are currently participating in Transitional Work Experience (TWE) services at the Bedford VA. By doing this research, we hope to improve vocational services at the VA.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your individual participation in the project will take about 6 months.

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WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

Treatment Phase. You will be randomly assigned (like a flip of a coin) to one of two treatment groups (Treatment A or Treatment B). The reason you will be randomly assigned to a treatment, rather than you choosing a treatment, is so that researchers can determine which treatment works best. We expect that 50 people will be randomized in this study. You will complete some surveys about work, career, and employment in addition to your mental health during week 1 and week 6. These surveys may be completed in person or online and take about 35 minutes to complete.

Treatment Group A: (25 participants)
If you are assigned to Group A, you will receive Transitional Work Experience (TWE) as typically offered to veterans at the Bedford VA.

Treatment Group B: (25 participants)
If you are assigned to Group B, you will take part in Transitional Work Experience (TWE) as typically offered at the Bedford VA, in addition to individual career counseling. You will receive up to 12 weekly individual counseling sessions of this treatment. You may participate in these sessions either in person or online through VA-approved video conferencing software (such as VA Video Connect). Participants are encouraged to explore their careers and work toward short and long-range career goals. The treatment sessions will take around one hour of your time. We will ask to record your treatment sessions so that the study investigators can monitor and ensure the quality of these sessions. We will review these tapes to monitor how therapists are delivering treatment and to make sure they are delivering treatment according to each treatment's procedures. These audiotapes will be kept confidential and will be listened to only by study personnel. They will not be released outside the VA except to send to a VA-approved transcription company.

Final Assessments. At the end of about 12 weeks, you will be asked to complete the same surveys you filled out during week 1 and week 6, and you will be asked to participate in a 30-minute interview with a researcher. During the interview, a researcher will ask about your experience in treatment. You may choose to complete the surveys and interview either in person or online. Audio recording is a required part of the study. You may request for the recording to be stopped at any time and it will be stopped.

Follow-up survey. A research follow-up survey will be scheduled for 3 months after the end of treatment for all participants. The survey may be completed in person or online. You will fill out a series of questionnaires about employment and mental health, which will take about 35 minutes of your time. We will call you to remind you about your appointments, including treatment and follow-up sessions.

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WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

You may experience discomfort in answering personal questions in study assessment visits. You may find some questions may be emotionally upsetting surrounding employment and/or unemployment. If you are uncomfortable with any part of the interview, you may skip the question or take a break. You will have the opportunity to take breaks to minimize fatigue and discomfort. Please let the research staff know if you become too uncomfortable. You can also contact the researchers if your symptoms bother you after you go home.

Your clinician will monitor your safety at each counseling session and if needed can refer you to appropriate mental heath resources to address any emotional concerns including programming at Bedford VAMC or other local organizations in their community. If the research staff is concerned about your safety during the study, a study clinician may evaluate you and refer you for further evaluation and/or treatment. If a clinician determines that you are a danger to yourself or others, you may be held in a hospital against your will. These actions are to insure your safety and the safety of others.

At any point during the study, we will discharge you if we are concerned that staying in the study may cause you physical or psychological harm. If the research team discharges you from the study, we will contact your regular clinician to coordinate and provide you with the most appropriate care to address these issues. If you do not have a regular clinician, we will discuss possible sources of medical care and encourage you to seek treatment.

When completing surveys, some people may become uncomfortable at being asked questions about employment and mental health if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

If you have any unusual or uncomfortable feelings during the study, contact the research staff. You can reach study staff by calling a member of the research team during normal business hours. You can also come in to the Mental Health Clinic (Hours: Monday-Friday, 8:00 am-4:00 pm; Building 78, 2nd Floor; [Mental Health Clinic Phone Number). You may also come in to the Bedford VAMC Urgent Care Center during their main hours (Monday-Friday, 8:00 am-4:00 pm; Building 78, 1st Floor; [Urgent Care Phone Number]) or after hours. You may also call the doctor on call after hours ([Doctor on call Phone Number]). If you become suicidal, hospitalization is possible.

Since we are concerned about your health and safety, there are some situations when we will contact your primary care physician or other clinical professional that is providing care for you, such as to inform him/her that:

- You need to be taken to Urgent Care for medical reasons
- You report suicidal thoughts or homicidal thoughts
- You are hospitalized

- You experience serious side effects that are a concern to you and/or the study team
- You experience an adverse event or reaction that occurs in the course of the study where the PCP has not already been informed
- You may be potentially harmed by continued participation in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with their employment goals.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data. All research information will be kept in locked files or behind the VA firewall at all times. Only authorized persons will have access to the information gathered in this study unless required by law. Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) may have access to the records. If results of this study are reported in journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. All data will be kept in accordance with VA regulations. Audio recordings will be used to accurately remember what you said, and will not be released outside the VA except to send to a VA approved transcription company.

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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.

We will include information about your study participation in your medical record. A medical record will be created if you do not already have one. Notes from your visits will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

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

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENTS TO YOU

You will receive a $40 gift card immediately after completing your week 1 survey. You will receive this gift card even if you choose to withdraw from the study during or after your first appointment. You will receive this gift card even if you are withdrawn from the study during or after your first appointment by the investigator. You may choose to receive this gift card in person or by mail.

You will receive a $40 gift card immediately after completing your week 6 survey. You will receive this gift card even if you choose to withdraw from the study after completing this survey. You may choose to receive this gift card in person or by mail.

You will receive an $80 gift card immediately after completing both your week 12 survey and final 30 minute exit interview with a researcher. You may choose to receive this gift card in person or by mail. You will not receive the $80 gift card if you choose to withdraw from this study before the final interview. You will not receive the $80 gift card if you are withdrawn from the study by the investigator before the final interview.

You will receive an $40 gift card immediately after completing your three month follow-up survey. You may choose to receive this gift card in person or by mail. You will not receive the $40 gift card if you choose to withdraw from this study before the three month follow-up survey. You will not receive the $40 gift card if you are withdrawn from the study by the investigator before the three month follow-up survey.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time without penalty or loss of benefits to which you are entitled.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Data already collected prior to the participant's withdrawal, that the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Investigators may end your participation in this study if they feel it is in your best interest, and/or if you are not complying by program rules. If you choose to participate in other vocational services through the Vocational Evaluation Center (VEC) or Supported Employment (SE) throughout the course of the study, you may be withdrawn. The reason for your discontinuation will be explained to you.

If you stop participating in the study for one of these reasons, you will have the option of obtaining mental health treatment in the Mental Health Clinic, through your other health care providers, or will be referred to local mental health treatment providers. If you withdraw at any point during the study, we will still use the data that has already been collected. However, you may choose to withdraw your study data if you indicate this to research staff. If you decide to withdraw from the counseling treatment, you may also continue to fill out questionnaires at each assessment point until the end of the study, and you will be compensated for your time and travel for your participation. If you decide to withdraw from both counseling treatment and decide not to fill out questionnaires, you will not be compensated and will be discontinued from the study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

The study team will inform you of any important information about your participation that may affect you or your willingness to be in this study.

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

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call [PI Name] at [PI Phone Number] during the day, and after hours call [Local Facility Phone Number] and have the doctor on call paged.

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures.

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

If you have any questions about the research, you may contact [Principal Investigator Name] at [PI Phone Number].

If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, [Local IRB Coordinator] at [Local IRB Phone Number], and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

[PI Name] or study staff has explained the research study 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. You also confirm that you have read this consent, or it has been read to you. A copy of the consent will be given to you.

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