

A pilot trial of health coaching to improve
functioning and reduce suicide risk among
reintegrating Veterans

NCT05199467

February 3, 2023

Subject Name: _____ Date: _____

Title of Study: A pilot trial of health coaching to improve well-being among reintegrating Veterans

IRB Number: [REDACTED]

Principal Investigator (Researcher): [REDACTED]

ICF Version Date: 5/26/22**WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?**

About the research, call [REDACTED] [REDACTED]

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call [REDACTED] (the study clinician/co-investigator) at [REDACTED]

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at [REDACTED] or the VAPORHCS Privacy Officer at [REDACTED]

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**WHAT AM I BEING ASKED TO DO?**

We are asking you to take part in a research study that is being funded by the Department of Veterans Affairs. We conduct research studies to try to answer questions about how to prevent, diagnose, or treat diseases.

You are being asked to participate because you are a Veteran of the U.S. military or National Guard/Reservists who has separated from service to civilian life within the past three months.

TAKING PART IN THIS STUDY IS YOUR CHOICE

You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form and the authorization. However, to participate in this study, you must sign this consent form and the authorization.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

WHY IS THIS STUDY BEING DONE?

This study is being done to answer the following question: What do newly separated Veterans think about health coaching and is it potentially helpful? We are doing this study because we want to find out if Veterans like health coaching and whether it is worth further study.

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ICF Version Date: 5/26/22**WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?**

You may choose to take part in a different research study, if one is available.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?

If you decide to participate in this study, you will be randomly assigned to one of two study groups. If you are assigned to the health coaching group you will receive health coaching and printed materials that describe VA benefits. Your participation in the study will consist of up to 12 coaching sessions over 16 weeks (four months). Coaching visits will last 30-60 minutes. You will be asked to complete four online questionnaires throughout the study that ask questions about your thoughts, feelings, and behaviors.

If you are assigned to the VA benefits information group, you will receive printed materials describing VA benefits. You will be asked to complete four online questionnaires throughout the study that ask questions about your thoughts, feelings, and behaviors.

A detailed description of all study procedures that will be done as part of this study is located below in the "What will happen during this study?" section.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

RISKS

We want to make sure you know about a few key risks right now however we provide more below information in the "What are the risks and possible discomforts from participation?" section.

The risk to participants is minimal. There is a risk you could become uncomfortable or upset by questionnaires or questions that the health coach asks you. Some of these questions may seem very personal or embarrassing. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor. You may refuse to answer any questions at any time.

If you are receiving VA healthcare, this study involves collecting administrative information from your medical record in which risks could include breach of confidentiality via inadvertent disclosure of personal health information. The research team will make every effort to protect your information. However, a loss of privacy could occur.

BENEFITS

You may or may not personally benefit from being in this study. However, by serving as a participant, you may help us learn how future Veterans may benefit from health coaching.

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Yes, you can decide to stop taking part in the study at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?

Yes. During this research project, new information may become available from the research that may affect whether or not you want to remain in the study. If this new information becomes available, you will be notified. You may decide if you still wish to stay in this study.

In rare instances, the study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The purpose of this study is to learn more about what Veterans think about health coaching and potential benefits of coaching.

DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

No.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 100 people will participate in this national research study housed at the VA Portland Health Care System.

WHAT WILL HAPPEN DURING THIS STUDY?

The study procedures will be done for research purposes and will not be completed if you decide not to take part in the study. If you choose to take part in this study, here is what you can expect to happen:

1. You will be randomly assigned to one of two groups. Your assignment to one of the groups will be decided by chance, like tossing a coin. You have a 50-50 chance of getting into either group in this study.
2. If you are assigned to the health coaching group, you will be assigned to a health coach and engage in up to 12, 30-60-minute, virtually-delivered (telephone or video) health coaching sessions over the course of 4 months; sessions will be scheduled approximately weekly, with flexibility to accommodate your schedule. During sessions, your health coach will ask you questions about your life and health, and help you set and

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work towards goals of your choosing. Coaching sessions will be audio recorded so that we can evaluate coaching quality. You will also receive printed materials describing VA benefits.

3. If you are assigned to the VA benefits information group, you will receive printed materials describing VA benefits.
4. All participants will complete an online questionnaire at four different time points throughout the study. Questionnaires will consist of questions about yourself, your life, and your health. Each questionnaire will take approximately 20-30 minutes to complete. A link will be sent by email for each questionnaire and data will be stored using Oregon Health and Science University's REDCap database (an online survey program). Paper versions will be available for participants who prefer this option.

In addition to the above activities, we will invite up to 30 Veterans in the health coaching group to participate in a 40–60 minute, semi-structured interview. Participants will be randomly selected to be invited to participate in the interview. We will ask about their experience receiving coaching, perceived benefits (including goal progress and perceived impact on their health), and any negative experiences that may have occurred during the coaching sessions. We will also ask for their thoughts on the feasibility and appeal of different modes of delivery (telephone, video); and how to best reach Veterans after service separation.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

The risk to participants is minimal. Information that identifies you will be used in this study and shared with research staff. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft.

There is a risk you could become uncomfortable or upset by questionnaires or questions that the health coach asks you. Some of these questions may seem very personal or embarrassing. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor. You may refuse to answer any questions at any time.

If you should ever express thoughts of wishing to harm yourself or considering suicide, we may call the National Suicide Prevention Hotline and/or the Veterans Crisis Line and transfer you to that call.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: First Name, Last Name, Address (Street, City, State, ZIP), Phone Number, social security number,

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date of birth, dates of healthcare visits, service separation date, and email address. These identifiers may be used in this study to obtain information about you from VA records and to contact you for study activities. We may also collect your bank account information if you choose payment by electronic funds transfer.

In the future, identifiers may be removed, and de-identified information about you used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

Your data will be shared with other researchers as part of this study (a statistician for data analysis). A one-time use code number will be assigned to your data. Only personnel for this study will be authorized to link the code number to you. Other researchers who may receive your data will be given only the code number and will not be given any other information to link the code back to you.

Your name and email will be shared with DocuSign to allow for electronic documentation of your consent to participate in this study and authorize our access to your personal health information if you choose to complete this process electronically.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the data, unless you provide written permission or unless otherwise required by law.

By signing this informed consent, you give permission for the transfer of a copy of your data (your name, contact information, dates of study activities, and information from study visits and questionnaires) to REDCap at Oregon Health & Science University (OHSU). The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU). OHSU and [REDACTED] will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared outside the VA may no longer be protected under federal law.

Research records may be reviewed and/or copied by the sponsor.

The audio recordings will be produced during health coaching sessions for the purpose of understanding how to improve the coaching program. These recordings will not be disclosed outside the VA. The audio recordings will contain your voice and any identifiable information you choose to give during the interview. By signing this consent form, you authorize the use of these recordings for research purposes. All research-related audio recordings will be held in accordance with the VA records control schedule.

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Mandatory reporting of suspected child, elder, or vulnerable adult abuse. Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

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

Possibility of Disclosure and Notice of Privacy Practices.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you or you may find it at

https://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=1090.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?

We will not contact you with results of this study after this study is completed. It is not expected that results will directly affect you or your health.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

Participants. A VA participant will not be required to pay for care and services received as a participant in a VA research project.

None of the participants will pay for any of the following because they are only for research study purposes:

- The 12 health coaching sessions,
- four questionnaires, and
- potential one-time interview.

Participants will pay for their usual healthcare, if applicable.

WILL I BE PAID FOR PARTICIPATING?

You will be paid in increasing amounts for each questionnaire that you complete (\$20, \$25, \$30, and \$40 respectively). Participants invited for a qualitative interview will receive \$30 for the completion of the interview. We will initiate the payment process at the end of each completed questionnaire or invited interview. If you drop out of the study before completing all the of the questionnaires, you will be paid for the questionnaires that you completed. If you complete all of the scheduled questionnaires, you will have received a total of \$115 (or \$145 if invited for one-time interview).

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For payment, we use a third-party vendor called ClinCard, which is like a debit card for research. Any time you complete something for the study we will manually load payment onto your card.

Your name, date of birth, and address will be shared with Greenphire for compensation.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY?

No.

WHAT WILL HAPPEN IF I AM HURT?

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 your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.

The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA General Counsel at [REDACTED]. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

To withdraw, you must write to [REDACTED] at [REDACTED] [REDACTED] or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study.

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Signature

_____ has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call [REDACTED] at [REDACTED], [REDACTED], and [REDACTED] at [REDACTED]. If any medical problems occur in connection with this study, the VA will provide emergency care.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information as described in this form. In the future, if I decide that I no longer wish to participate in this research study, I agree that my information, which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

Printed Name of Subject

Signature of Subject

Date

Time

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Time

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