Whole Health Pathway Study STUDY INFORMATION SHEET FOR VETERANS (April 2020)

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO SAN FRANCISCO VA HEALTH CARE SYSTEM

Evaluating the Implementation of a Novel Whole Health Pathway: A Model for Engaging Veterans in VA & Community Wellness Programs Using Telehealth & Web-Based Technology

This is a research study designed to evaluate and improve the new Whole Health Pathway program at the San Francisco VA. We want to learn about how the program affects veterans' health, quality of life, use of health and wellness services, and satisfaction with care.

You are being invited to take part in this study because you are a veteran at the San Francisco VA who participated in the new Whole Health Pathway program.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with family or friends if you would like to. If you have questions or would like more information, you can ask the research team. Please contact: Natalie Purcell, PhD, MPA, <u>Natalie.Purcell@va.gov</u>, 415-221-4810, x22381 Karen Seal, MD, PhD, <u>Karen.Seal@va.gov</u>, 415-221-4810, x24852

Why is this study being done?

This study is being done to learn about the impact of the new Whole Health Pathway program at San Francisco VA. We want to know about veterans' experiences with program, including whether and how the program affects their health, quality of life, use of health and wellness services, and satisfaction with care.

Who pays for this study?

The study is paid for by the VA Health Services Research Division (VA HSRD).

How many people will take part in this study?

Up to 450 veteran patients will participate in a study of health and wellness outcomes associated with the Whole Health Pathway. About 30 VA stakeholders will be interviewed for our implementation evaluation of facilitators, barriers, and best practices.

What will happen if I take part in this research study?

This study includes the option to participate in telephone surveys, a telephone interview, and the of tracking specific health outcomes in your medical record. You can choose to participate in some, but not all, of these. Each is described below:

Telephone Survey:

You will be asked to participate in three, 30-minute telephone surveys over about 6 months. The first survey will happen when you agree to participate. The next survey will happen about 3 months later. The final survey will happen about 3 months after that.

During the survey, a member of the research team will ask you about your general health and wellbeing, about your ability to meet your basic needs, about the health and wellness services you have used, and about your experience with the Whole Health program. We'll also ask you how the coronavirus pandemic may have impacted these, if at all. The surveys include questions that ask about private or personal information. For instance, you will be asked about your mood and your personal health goals, and this could include goals to address issues such as depression, or goals to reduce drinking or substance use. You will not have to answer these questions if you choose not to.

Telephone Interview:

You will also have the option to participate in a 30-minute qualitative telephone interview that asks open-ended questions about your experience with the Whole Health program, including how the program has affected you and how you think we can improve it. The telephone interview will be audio-recorded with your permission.

Health Outcomes Tracking:

We will track specific health outcomes recorded in your electronic medical record. The information that we will track includes the following:

- Number of and type of healthcare visits and wellness visits
- Body Mass Index (BMI) and/or Weight
- Blood Pressure
- A1C, fasting blood glucose, and lipid panel

We will track this information for up to a year prior to your first survey and up to 6 months after your last survey. We will directly capture the information using automated data extraction from the electronic health record. We will not need to go into your medical record to read notes or review any other information.

Study location:

All interviews will be conducted by study team members who are located in a private office at the San Francisco VA Medical Center (4150 Clement St., San Francisco, CA).

How long will I be in the study?

Most participants will be enrolled in the study for six months, but you may have up to a year to complete the surveys and interviews.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the researcher may stop you from taking part in this study at any time if he or she believes you are unable to participate safely or if the study is stopped.

What side effects or risks can I expect from being in the study?

You will be sharing health, well-being, mood, and other healthcare-related information that is usually kept private. Although the study team members will not share your private information with others, there is nonetheless some loss of privacy in sharing this information with the study team.

Not everyone may be comfortable responding to personal questions about their general health, well-being, mood, and care experiences/satisfaction. For some, choosing to respond anyway may cause minor discomfort or embarrassment.

The audio recording of qualitative interviews (optional) may also contribute to loss of privacy, which may cause minor discomfort.

Are there benefits to taking part in the study?

You may enjoy the experience of sharing your perspectives and feedback about your care experiences. You may feel listened to and be reassured that VA cares about and wants to improve your experiences.

You may enjoy engaging in the self-reflection required to answer survey and interview questions about yourself. Doing so may contribute to greater self-awareness or understanding, or help you to better see and appreciate any positive health or life changes you have experienced over the course of the study period.

You will be helping VA to evaluate and improve a new program, thus helping to inform further program development and to ensure that the services VA provides are better tailored to the needs of veterans, including yourself and other veterans like you.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. There will be no impact whatsoever on your healthcare or benefits at VA, and you can continue to participate in the Whole Health program.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

However, we cannot guarantee total privacy. Your personal information may be given out if required by law. Organizations that may look at and/or copy the research records for research, quality assurance, and data analysis include: the Veterans Health Administration and the University of California.

What are the costs of taking part in this study?

There are no specific costs associated with taking part in this study.

Will I be paid for taking part in this study?

You will be paid \$50 for each telephone survey or interview that you complete, for a total of up to \$200.

You may choose to receive your payments in cash or through Electronic Fund Transfer (EFT). If you choose EFT, you will need to provide the following information in order to process the payment: your name and address, your social security number, your bank's name and address, your bank account and routing transit numbers.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. You may call or write to:

Natalie Purcell, PhD, MPA, <u>Natalie.Purcell@va.gov</u>, 415-221-4810, x22381 Karen Seal, MD, PhD, <u>Karen.Seal@va.gov</u>, 415-221-4810, x24852

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. Researchers will complete a consent process with you over the telephone before you decide whether to participate. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.