Pandemic Acceptance and Commitment Therapy (Pan-ACT): Feasibility and Acceptability of Telehealth Delivery with Older Veterans

NCT05433662

February 27, 2024

Participant Name: _____ Date: _____

Title of Study: Pandemic Acceptance and Commitment Therapy (Pan-ACT): Feasibility and Acceptability of Telehealth Delivery for Older Veterans

Principal Investigator: [redacted]s MD VA Facility: [redacted]

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is funded by Veterans Affairs Rehabilitation & Research Development (VA RR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Acceptance and Commitment Therapy (ACT) is a behavioral intervention that uses talk therapy and has been shown to improve a wide a range of problems, such as depression, anxiety, and poor self-management of health. ACT incorporates mindfulness, acceptance, and values to help patients create a more meaningful life. The purpose of this study is to pilot a 10-session telehealth ACT group with Veterans ages 50 and older who are experiencing pandemic-related emotional and physical distress. The first goal of the study is to determine if the study procedures and intervention are feasible and acceptable to participants. The second goal of the study is to explore the potential benefits of the intervention, such as improvements in pandemic-related stress and social isolation. Results of this study will inform the development of a larger randomized controlled trial to evaluate the intervention's effectiveness. Your participation in this research will last about 17 weeks. The intervention will take 10 weeks to complete and will be delivered one time per week. Each session will last 90 minutes. You will also complete questionnaires at four time points, which will take about an hour, and one 30-minute interview to give feedback on the intervention.

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

Although you may or may not personally be helped by taking part in this study, your participation may lead to knowledge that will help others. The main benefit of the proposed research is the potential to improve outcomes for older Veterans who are experiencing pandemic-related emotional and physical distress. There is also potential to decrease risk of suicide and well as decrease mortality and morbidity associated with untreated pandemic-related stress. Participation in the research study may also increase knowledge of available services and resources to this population at the TVAMC

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

You may choose not to volunteer or this study for a variety of reasons. Some of these reasons may be related to the risks involved (see a detailed list below). This is a treatment/intervention study. Choosing to participate (or not) **will not** impact your care at [redacted]. If you would like to learn about treatment options that use Acceptance and Commitment Therapy (ACT) or similar therapeutic approaches, the study team can refer you to a mental health provider for treatment if available at [redacted].

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.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] at the [redacted] VA Medical Center ([redacted]). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted]

DETAILED INFORMATION ABOUT THE STUDY

This research study is expected to take approximately two years; however, your participation will only take about 17 weeks, which will include assessments and the 10-week intervention.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

This study uses telehealth and an online survey format to administer questionnaires. If you decide to take part in this study, you will be asked if you have equipment for videoconferencing, internet access, and an email address. If you do not have access to these things, the research team will provide equipment that you may use for this study, which will need to be returned when you complete the study or if you end early. The research team will also assist you with creating an email account if you do not have one.

You will complete online questionnaires approximately 2 weeks before the first intervention session, at the intervention midpoint (around week 5), within one week after completing the 10-week intervention, and one-month after treatment is completed. You will receive the link for the questionnaires via email. If you do not complete the assessment within two days, you will receive a reminder telephone call and email with the link. If you do not complete the assessment within two days after the reminder, the Clinical Research Coordinator (CRC) will contact you by telephone again to inquire about possible barriers (e.g., technical issues), provide technical assistance as needed, and mail a hard copy and stamped envelope to the you to complete within one week, if needed. You must attend at least 1 session to participate in the

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assessments. You will also be asked to complete a 30-minute interview after completing the intervention to give feedback about the study procedures and treatment.

The intervention will be conducted in a virtual group room via Microsoft WebEx or other VA-approved telehealth platform. WebEx is approved for telehealth use and video recording at the [redacted]. Intervention sessions will be recorded and monitored by one member of the research team to ensure that the therapist provides the intervention as intended. Sessions will be recorded using the WebEx recording function, and a VA-approved audio recorder will be used as a backup in all sessions in case there is a technical issue with WebEx. WebEx also allows the "host" (i.e., therapist) to send a cell phone text with a link to the virtual group room to you, which could be useful if for any reason you are unable to locate the link in your email. If you are having technical issues with your video device, you will be able to call in to the WebEx virtual group room from a phone.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you take part in this study, it is important to know that the Pan-ACT is a closed group (i.e., all participants will start and end the group at the same time). Each 10-session telehealth Pan-ACT group will consist of 4 to 5 Veterans. This group size was chosen to maximize the amount of group time you will have to talk. Each session will be 90 minutes and will include a brief mindfulness exercise, ACT work review (i.e., home practice), at least one therapy exercise, group discussion, and home practice assignment for the next week. These in-session activities are intended to help you learn new ways to effectively handle difficult urges, memories, thoughts, and physical sensations, such as pain. The exercises will also help you clarify your values and take steps to creating a more fulfilling life.

We adapted the intervention content to target pandemic-related stressors and emphasize coping related to COVID-19 and the pandemic. In the first session, we will explore participants' experiences with stress, worry, depression, and grief during the pandemic. The session will conclude with discussing ways in which the pandemic has caused you to re-evaluate your values and identifying changes you would like to make to lead a more value-driven, purposeful life. Remaining sessions will teach you how to skillfully respond to distressing pandemic-related thoughts and feelings while moving towards value-based actions instead of remaining stuck in the struggle to get rid of or surrender to unhelpful thoughts and emotions.

Demographic data will be gathered from your online medical chart once you consent to participate, and several demographic questions will be included in the first online survey you complete. The following information will be collected: (a) socio-demographic information, including age, gender, race, ethnicity, level of education, household income, source of income,

marital status, living situation, and occupational status, (b) current mental health diagnoses, (c) current medical conditions, (d) previous psychotherapy treatment, and (e) impact of COVID-19.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Physical risks: Potential physical risks may include physical discomfort or fatigue caused by the length of the intervention group session. However, based on our experience, participants can generally tolerate a 90-minute session without difficulty. To minimize potential physical discomfort, you will be offered a short three- to five-minute break at the intervention group midpoint (45 minutes).

Psychological risks: Potential psychological risks may include mild discomfort with speaking in a group format, participating in ACT exercises, mental fatigue, boredom, or frustration with virtual technology. You may feel that the interview process and completion of the assessment/ interview are an invasion of privacy. While answering questions regarding suicide risk, you may experience brief anxiety, discomfort or embarrassment, or distressing memories may be triggered. Study procedures are not anticipated to exceed frustrations or distress encountered in your daily experiences. To minimize potential psychological discomfort, you will be encouraged to use whichever technology (telephone or video) you prefer. You will be informed that they do not have to answer any questions that make you feel uncomfortable. You will also be reminded that participation in the study and intervention group is voluntary and that you can discontinue participation at any time.

Social and legal risks: An unlikely legal or social risk associated with participating with this study may be invasion of privacy or breach of confidentiality in the remote chance that there is a loss of data containing Identifiable Personal Health Information (PHI) or Personal Identifying Information (PII). These are research risks, not therapeutic risks. The [redacted] has strict and detailed standard operating procedures regarding the use and storage of data containing PHI/PII and measures to guard against a breach of confidentiality. The investigators and other research staff are aware of these policies and will adhere to the policies and regulations. Confidentiality safeguards will be strictly maintained throughout the study. Screening and consent will be held in a private and secure area in a research office or via Microsoft WebEx, or another VA-approved virtual platform, that is secure and private. When/if you complete the consent process via telephone, you will mail the completed consent and HIPAA forms by United States Postal Service (USPS). Research records will not be released to you or a third party. All study documents will be stored in a locked office, or a computer located in a secure area, with limited password access. Your name will not be identified in the data analysis, publications, or presentations of the research results.

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Economic risks: Regarding economic risks, you may have to miss work and lose income or spend money on childcare or care of a dependent adult to participate in screening, consent process, and intervention group. You may have to use minutes from cellular data to participate in the 90-minute intervention group. These are research risks, not therapeutic risks. Every effort will be made to avoid economic risks. The Principal Investigator (PI) or Clinical Research Coordinator (CRC) will schedule the appointment for screening and the informed consent process at a time that is most preferable and convenient for you during normal business hours. Additionally, because the intervention group is conducted virtually, costs associated with transportation, childcare, or care of a dependent adult are reduced or eliminated. You may call from any phone, including a landline, that is most convenient or economically appropriate for you.

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 research consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include improvements in emotional and physical distress. There is also potential to decrease risk of suicide and well as decrease mortality and morbidity associated with untreated pandemic-related stress. While research on telehealth delivery of ACT for older adults is limited, preliminary results indicate it is feasible and as effective as ACT delivered in person.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

This is a treatment/intervention study. Choosing to participate (or not) will not impact your care at [redacted] If you would like to learn about treatment options that use mindfulness or similar therapeutic approaches, the study team can refer you to a mental health provider for treatment that may be available at [redacted].

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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If results of this study are reported in medical journals, at meetings, or grant applications for future research, you will not be identified by name, by recognizable photograph, by audio or video recording, or by any other means without your specific consent. Your medical records will be maintained according to this medical center's confidentiality requirements. Study team members will treat your identity with professional standards of confidentiality. Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

Efforts to maintain your privacy will be a top priority. Safeguards to protect your privacy will include conducting all appointments in a private and secure area. Whenever possible, the research team will encourage you to be in a different room (or otherwise private space) while participating in the virtual visits.

Considerations of privacy during virtual visits contact may be outside the research team's control, in that it will be difficult to know the level of privacy on the other end of the device/phone (for example, in the participant's home). Each member of the research team will discuss privacy considerations at the beginning of the appointment and will be available to answer any questions or problem-solve privacy issues in the home. The researcher will also ask you about privacy issues that may arise during the appointment(s) and will encourage you to move to a private location in the home if possible.

Privacy will also be protected within the VA research space. All study documents will be kept in a locked office or on a computer located in a secure area that is password protected. Electronic information including any recordings of the focus groups will also be kept on secure servers with limited access.

However, there are times when we might have to show your records to other people. For example, the Research Compliance Officer (RCO), federal oversight agencies, and the VA Institutional Review Board (IRB) may inspect your records.

The investigator's research records for this study will be maintained according to the disposition instructions by the National Achieves and Records Administrations and are published in VHA' s Records Control Schedule (RCS) 10-1, in accordance with the VHA' s Records Control Schedule 10-1 (RCS) policies for the Office of Research and Development; section 7.6. For a study such as this one (i.e. not FDA-regulated), the PI may destroy research records 6 years after the end of the fiscal year after completion of the research project, but the investigator may

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

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

If the study procedures have any implication on your care, the study team is required to put any details about your participation that are relevant to your care providers in the your medical record. We will include information about your study participation in your medical record.

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

You 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.

PAYMENT FOR PARTICIPATION IN THE RESEARCH

You will receive a total of $150 in compensation for your participation in this study ($15 for screening, $35 for baseline assessment, $10 for midpoint assessment, $35 for posttreatment assessment, $20 for interview after completing Pan-ACT group intervention, and $35 for one-month follow-up). The study team will work with you to receive the payments via direct deposits. To receive direct deposits into your personal bank account, you must complete the VA Vendor form to provide your personal banking information. You must also sign a voucher receipt, both of which will be provided to you. VA Payroll will have access to your PHI for the purpose of direct deposit.

Please indicate your preference by **checking one of the options below** (you may pick only one):

_____ I would like a **direct deposit** of $150 (amounts and intervals indicated above) and have included my banking information.

_____ I **do not want $150** for participating in this study.

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

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If you are injured because of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick because of taking part in this study, or if you have questions, concerns or complaints about your rights as a study participant, you may contact the Research Compliance Officer, at ([redacted] or the Institutional Review Board (IRB) Administrator who will have the IRB member subject representative contact you. The IRB Administrator can be reached at ([redacted] If the IRB Administrator cannot be reached, contact the IRB Clerical Assistant at [redacted] and your call will be directed to an IRB member.

If you have questions regarding this study or the procedures, if you have unexpected reactions, or if you are injured and become ill because of participation in this study, please call [redacted] at [redacted] or [redacted] (toll free). You may also call the Tuscaloosa VA operator at ([redacted] or [redacted] toll free) and have the operator call [redacted] on her VA phone.

If you are unable to reach [redacted] and need immediate medical assistance for a research-related injury, please call the [redacted] VAMC hospital operator at [redacted] or [redacted] and ask for the Triage Nurse to obtain advice.

You may also call [redacted] and request to be connected to other members of the study team or for answers to pertinent questions about the research.

If for any reason, you experience suicidality, please call 911 or the Suicide Prevention Hotline at [redacted] or the [redacted] Suicide Prevention Coordinator at [redacted]

DO I HAVE TO TAKE PART IN THE STUDY?

No. Your participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

You may discontinue taking part at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received.

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Participant Name: _____ Date: _____

Title of Study: Pandemic Acceptance and Commitment Therapy (Pan-ACT): Feasibility and Acceptability of Telehealth Delivery for Older Veterans

Principal Investigator: [redacted] VA Facility: [redacted]

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

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 IRB via the Health Systems Specialist/Research Committee Manager (RCM) at [redacted]. The IRB/RCM are responsible for overseeing the safety of human participants in this study. You may call if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You and your physician will be informed if any important discoveries are made during this study which may affect you. Specifically, information obtained in this study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Research staff member 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. You will receive a copy of this consent after you sign it.

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

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