

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

Funding Agency: Rehabilitation & Research Development (RR&D)

Principal Investigator/Study Chair: Lori L. Davis, MD

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ABSTRACT

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

Principal Investigator: Lori Davis, MD

Co-Investigators: M. Lindsey Jacobs, PhD, MSPH, ABPP; Teresa Granger, PhD;

1. **Objectives:** The purpose of this study is to pilot a 10-session telehealth Pandemic ACT group intervention (i.e., Pan-ACT Group) with Veterans ages 50 and older who are experiencing pandemic-related emotional and physical distress. Results will inform the development of a full-scale randomized controlled trial to evaluate the intervention's effectiveness in improving psychological, social, and physical well-being among older Veterans with pandemic-related emotional and physical distress.
2. **Research Design:** This study will use a single group quasi-experimental design to evaluate the feasibility and acceptability of the study procedures and intervention and explore preliminary effectiveness.
3. **Methodology:** Twenty-five (25) Veterans ages 50 and older experiencing pandemic-related emotional or physical distress will be enrolled. The 10-session closed group intervention will be delivered in a virtual group room via Microsoft WebEx or another VA-approved virtual platform. Sessions will be video- and audio-recorded for treatment fidelity monitoring. Each group cohort will consist of 4 to 5 Veterans, and sessions will be delivered weekly for 90 minutes. Feasibility and acceptability data will be collected throughout the study. Feasibility and acceptability of study procedures will be measured by referred-to-enrolled rate, telehealth access and capability, electronic data collection of outcome measures, and qualitative feedback on data collection procedures and measures. Feasibility and acceptability of the intervention will be measured by attendance; attrition; homework completion; participant ratings of the intervention's feasibility, acceptability, and fit; qualitative feedback; and treatment fidelity. Outcome data will be collected via Qualtrics at baseline, posttreatment, and one-month follow-up and will consist of measures of pandemic-related emotional and physical distress, psychological flexibility, depression, anxiety, social connectedness, perceived health, functional impairment, and meaningful engagement. A brief midpoint assessment at week 5 of the group will consist of measures of social connectedness and functional impairment. Participants will participate in a 30-minute posttreatment qualitative interview to provide feedback on the intervention and study procedures as well as input on perceived efficacy to implement intervention skills and specific emotional or behavioral changes participants have noticed in themselves as a result of the intervention.
4. **Significance:** Acceptance and Commitment Therapy (ACT) decreases emotional suffering, improves well-being, promotes and supports healthy behavior changes, and treats a wide range of diagnoses by increasing psychological flexibility through mindfulness, acceptance, and values-based behaviors. Higher psychological flexibility has been associated with pandemic-related coping and well-being. 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. This will be the first study to investigate the feasibility and acceptability of telehealth ACT in an older Veterans population.

List of Abbreviations

ACT	Acceptance and Commitment Therapy
ABPP	American Board of Professional Psychology
ACT-FM	Acceptance and Commitment Therapy Fidelity Measure
BVAHCS	Birmingham VA Health Care System
CBT	Cognitive behavioral therapy
CIH	Complementary integrated health
Co-I	Co-Investigator
CompACT	Comprehensive Assessment of Acceptance and Commitment Therapy
COVID-19	Coronavirus 2019
CRC	Clinical Research Coordinator
C-SSRS	Columbia-Suicide Severity Rating Scale
FY	Fiscal Year
HADS	Hospital Anxiety and Depression Scale
HIPAA	Health Insurance Portability and Accountability Act
HR	Human Resources
IIR	VA Merit
LET	Life Engagement Test
MBRS	Mindfulness-based stress reduction
MD	Doctor of Medicine
MSPH	Master of Science in Public Health
NIH	National Institutes of Health
Pan-ACT	Pandemic Acceptance and Commitment Therapy
PCL-5	Post-Traumatic Stress Disorder Checklist for Diagnostic and Statistical Manual - 5
PhD	Doctor of Philosophy
PI	Principal Investigator
PTSD	Post-Traumatic Stress Disorder
RCT	Randomized controlled trial
RR&D	Rehabilitation Research and Development
SPiRE	Small Projects in Rehabilitation Research
TICS-M	Modified Telephone Interview for Cognitive Status
TVAMC	Tuscaloosa Veterans Affairs Medical Center
US	United States
UA	University of Alabama
VA	Veterans Affairs
VHA	Veterans Health Administration

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

1.0 Study Personnel

- Provide name, contact information, facility/organization, and affiliations/employee status for the following:

Principal Investigators/Study Chair:

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○ Clinical Study Coordinator:

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○ Backup Coordinator:

- Allyshia Hinton, MPH
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- Indicate the number of potential participating sites (both VA and non-VA) and if there is any graduated start-up plan for the sites
 - One participating site: Tuscaloosa VA Medical Center (TVAMC)

2.0 Introduction

The COVID-19 pandemic has had a substantial impact on the lives of many older adults.¹⁻⁴ Not only do older adults comprise the majority of COVID-related deaths,⁵ but they are the most vulnerable to long-term health and psychological effects caused by the pandemic. According to a survey conducted by the Kaiser Family Foundation in 2020, almost 50% of adults ages 50 and older report that pandemic-related worry and stress has had a negative impact on their mental health.⁶ Pandemic-related restrictions are a major source of stress in adults ages 60 and older.⁴ The categorization of older adults as “high risk,” the measures taken to ensure social distancing for this age group, and the slow uptake of digital technology and social networking apps are likely causing a more isolating experience for older adults compared to other age groups.⁷ Older adults report feeling confined in their homes, being lonely and alone most of the time, and feeling as though they have lost their freedom.⁴ Although social distancing is necessary to mitigate risk of COVID-19, it has potential to lead to detrimental long-term effects in older adults, i.e. social isolation, loneliness, and low perceived control are predictors of poor quality of life and increased morbidity and mortality in late life.^{1, 8} Pandemic-

related restrictions have also led to limited life-space mobility⁹ as well as poorer physical and nutritional well-being.² Not only are poor health and loneliness associated with higher risk of poor outcomes if exposed to COVID-19, but they are also prominent risk factors for suicide in late life.⁶⁻¹⁶ Given that suicide rates are highest among older males,¹⁷ it is imperative to address these risk factors in older Veterans.

Telehealth-adapted psychological interventions that target a wide range of issues are needed to adequately address the pervasive impact of pandemic-related emotional and physical distress among older adults, and ACT is an ideal intervention to meet this need. ACT is transdiagnostic, meaning that the underlying therapeutic processes and therapy content are applicable to any presenting problem.¹⁸ Research spanning more than 20 years has consistently shown that it is an effective treatment for a variety of psychiatric and behavioral health problems in adults.¹⁹ The American Psychological Association recommends ACT for depression, anxiety disorders, chronic pain, obsessive-compulsive disorder, and psychosis.²⁰ In addition to treating emotional distress, ACT is effective at helping individuals implement and maintain positive behavioral health changes, such as healthy eating and physical exercise.²¹⁻²² More recent research has demonstrated the benefits of ACT in specific medical populations, including stroke²³ and cancer survivors.²⁴

Despite the expansive literature on the efficacy of ACT to treat adults with a wide range of psychiatric disorders and behavioral health problems,¹⁹ research on ACT with older adults is limited. The existing literature on ACT in this population is characterized by pilot studies, small sample sizes, and quasi-experimental design, and has focused only on its utility in treating depression, anxiety, and chronic pain.^{11-13, 15, 25} Wetherell et al. conducted a small, randomized pilot study comparing ACT to cognitive behavioral therapy (CBT) in older adults with generalized anxiety disorder.¹³ In both groups, significant improvements were evidenced in worry and depression, and gains were maintained after a six-month follow-up. Wetherell et al. also noted that participants in the ACT condition were less likely to withdraw from treatment compared to those who received CBT, indicating that ACT may be a more acceptable treatment for this demographic. Using a single group design, Karlin et al. demonstrated that older depressed Veterans participating in individually delivered ACT experienced a significant decrease in depressive symptoms.¹¹ Moreover, compared to their younger counterparts, older participants were more likely to engage in all sessions or terminate early due to remitted symptoms. Using the same quasi-experimental design, McCracken et al. investigated the benefits of a group-based ACT intervention for chronic pain in older patients at a residential pain treatment center.¹⁵ Participants showed significant improvements in depression and physical and psychosocial disability. Only one randomized controlled trial has been conducted with older adults. Alonso-Fernandez et al. investigated the effectiveness of an ACT group for chronic pain in comparison with a minimal support group in nursing home residents and found that it resulted in improvements in acceptance, compensation strategies, depression, pain anxiety, and pain interference with mood and walking.¹²

The evidence base for ACT in late life is small but promising, and most ACT research with older adults has used a group format.^{12, 15, 25} Group therapy has been effectively used to treat depression and anxiety among older adults.²⁶⁻²⁷ A group format has advantages over individual therapy that are particularly relevant to older adults, especially during the current pandemic. Group therapy offers a space to connect with peers in a meaningful and supportive way,²⁸ which can ameliorate social isolation and loneliness.²⁹ Receiving support and feedback from peers may normalize experiences of distress and facilitate acceptance.²⁸

While research on telehealth delivery of ACT for older adults is limited, preliminary results of pilot studies with a combination of young, middle age, and older adult samples indicate it may be as feasible and effective as in-person delivery.³⁰⁻³² A recent feasibility pilot study with patients ages 35 to 82 with advanced cancer demonstrated that telephone-delivery of ACT is feasible, acceptable, and has potential to significantly reduce psychological distress and improve functioning.³⁰ Another pilot investigated the feasibility and acceptability of a group-based ACT delivered via videoconference to individuals ages 29 to 83 living in rural communities: 95% liked the telehealth format, ~70% preferred telehealth over in-person, and ~85% reported feeling connected to other participants in the telehealth group.³² A randomized pilot study with Veterans ages 25 to 89 with chronic pain found that ACT delivered via videoconference was as effective at treating pain-related psychological distress and improving functional outcomes compared to in-person delivery.³¹ Although attrition was higher in the ACT videoconference condition in the overall sample, older adults were significantly more likely to complete the telehealth treatment compared to their younger counterparts. Still, no study has investigated feasibility, acceptability, or effectiveness of group-based telehealth ACT with older Veterans.

Conceptual Model

ACT aims to improve psychological flexibility by increasing openness to and acceptance of the present moment while taking meaningful action in the service of one's values, with the goal of life enrichment and sense of purpose.¹⁸ The underlying premise of ACT is that human suffering is a result of psychological *inflexibility*.¹⁸ Psychological *inflexibility* includes rigid avoidance of unpleasant experiences (e.g., avoiding exercise because it conjures distressing thoughts about one's weight or health status), fusion with unhelpful thoughts (e.g., belief that thoughts are true), lack of contact with the present moment (e.g., worrying about the past or dreading the future), fusion with a narrow self-narrative (e.g., believing one cannot change because they are "old"), and lack of clarity and contact with one's core values in life.¹⁸ Psychological *inflexibility* captures the unhelpful or unworkable ways in which individuals respond to emotional discomfort.

ACT is different from traditional CBT in that it does not attempt to change thoughts or directly eliminate pain. Rather, it teaches individuals to live purposeful lives despite having uncomfortable or unpleasant thoughts, emotions, urges, or sensations via six core therapeutic processes (see Table 1). ACT is a particularly relevant treatment for older adults with physical and psychosocial vulnerabilities, especially during the COVID-19 pandemic when many factors of life seem outside of one's control.^{1-4, 14}

Metaphors and experiential exercises are the primary ingredients of ACT.³³ They have a story-like quality that make abstract concepts more concrete and facilitate one's ability to relate to their internal experiences in a different way.³³ Moreover, they make therapy content more memorable and easier to recall in between therapy sessions and after completing treatment. The use of metaphors is congruent with older adults' approach to meaning making when experiencing emotional or physical pain.³⁴

Gaps in Knowledge

Though no research has been published on the use of ACT during the pandemic, several studies have demonstrated that higher psychological flexibility (i.e., the ACT conceptual model) among middle age adults is associated with better coping during the COVID-19 pandemic.

Specifically, psychological flexibility predicted lower levels of depression,^{15,35} anxiety,^{15,35} and insomnia,¹⁵ and was associated with greater family cohesion and lower family discord.³⁶ In contrast, psychological inflexibility was associated with increased health-related stress,³⁷ anxiety,³⁵ and depression,³⁵ lower energy,³⁷ and poorer perceived sleep quality.³⁷

The proposed study will be the first to pilot an ACT Group focused on coping with pandemic-related emotional and physical distress, as well as the first known study to investigate the feasibility and acceptability of telehealth-delivered ACT Group for older Veterans. The emotional and physical toll that this pandemic has caused for older adults is likely to continue for years to come.³⁸ The current literature does not yet capture what we, as clinicians, have observed in clinical settings. Additionally, the pandemic has highlighted and exacerbated two major public health concerns pertaining to older adults, namely social disconnectedness and ageism. Loneliness and isolation were concerningly prevalent among older adults prior to the pandemic, with estimates as high as almost 30% in the older Americans.³⁹ The constant media messages that older adults are the “most vulnerable,” and the paternalistic (albeit, useful) measures taken to protect them, have perpetuated and amplified ageist beliefs and attitudes. Ageism, especially once it is internalized, has a serious negative impact on older adults’ emotional and physical well-being.⁴⁰ As demonstrated in the case vignette, the ageist message that all older adults are vulnerable, with no regard of one’s health status, may be internalized and lead to self-identification as a “vulnerable person,” and can ultimately lead to further isolation and loneliness. For some individuals, the pandemic has led to a personal assessment of their values in life, a reflection on their life’s purpose, and a desire to take actionable steps to live a meaningful life. The findings from this feasibility pilot study and future RCT will not expire once the pandemic ends and the world has found a “new normal.” Rather, the telehealth Pan-ACT Group for older Veterans has potential to be an effective treatment for issues that affect the older population even during post-pandemic times.

3.0 Objectives

Research setting: The intervention will be conducted in a virtual group room via Microsoft WebEx. WebEx is approved for telehealth use and video recording at the TVAMC. VA Video Connect was considered; however, there are three features of WebEx that make it a preferred platform for this study. WebEx has recording capability, which will be used to record sessions for fidelity monitoring. An external, FIPS 140-2 encrypted audio recorder will be used as a backup in all sessions in case there is a technical issue with the WebEx recording function. WebEx also allows the “host” (i.e., group leader) to send a cell phone text with a link to the virtual group room to a participant, which could be useful if a participant is unable to locate the link in their email. Finally, if for some reason a participant is having technical issues with their video device, they will be able to call in to the WebEx virtual group room from a landline or cell phone.

Purpose or aims of the study including hypothesis (es) to be tested:

The purpose of this study is to pilot a 10-session telehealth Pandemic ACT group intervention (i.e., Pan-ACT Group) with Veterans ages 50 and older who are experiencing pandemic-related emotional and physical distress.

Specific Aim 1: Conduct a single-arm feasibility pilot trial of the telehealth Pan-ACT Group with older Veterans experiencing pandemic-related emotional distress.

Aim 1a: Feasibility will be measured by referred-to-enrolled rate, percent of participants who have a personally owned device with telehealth capability, length of time spent providing education on and troubleshooting technology, percent of participants who complete pre- and post-treatment measures electronically (hard copy measures will be mailed to those who are unable to complete them electronically), participants' rating on the Feasibility of Intervention Measure, and the interventionist's adherence to the protocol (i.e., protocol adherence) and ability to deliver treatment with an ACT-consistent approach via telehealth (i.e., competence).

Aim 1b: Acceptability will be evaluated by attendance, attrition, participants' completion of homework, participants' ratings on the Acceptability of Intervention Measure and the Intervention Appropriateness Measure, and qualitative feedback during brief individual semi-structured interviews focused on the participants' impressions of the telehealth intervention and assessment procedures.

Specific Aim 2: Explore preliminary responsiveness of outcome measures. Outcome measures will include pandemic-related emotional distress, psychological functioning, social connectedness, psychological flexibility, perceived health, and meaningful engagement. Within-subjects change will be analyzed to provide preliminary insight into potential treatment effects.

4.0 Resources and Personnel

- Include a list of personnel, their location, role in the study and their VA affiliation status
- No DUA, CRADA, nor contractors are required for this study

1. List the Investigators and study personnel managing the study.

Name and Degree	Project Role	Delegation of Duties Codes	Obtaining Informed Consent? (Yes/No)	Access PII or PHI? (Yes / No)	Handle Bio Specimens (Yes/ No)	CITI Training Expiration Date
Lori Davis, MD [TVAMC]	PI	A, B, D, E, G, H, K, L, M, N	Y	Y	N/A	03/20/26
M. Lindsey Jacobs, PhD, MSPH, ABPP [UA]	Co-I	A, D, F, K, L, M, N	Y	Y	N/A	09/01/25
Teresa Grenawalt, PhD [TVAMC]	Co-I	D, F, L, M	N	Y	N/A	09/21/24
Rebecca Allen [UA]	Consultant (Fidelity Monitor)	K, N	N	N	N/A	04-25-25
Kimberly Alexander, MEd [TVAMC]	Clinical Research Coordinator	A, B, D, E, G, H, K, L, M	Y	Y	N/A	01/22/24
Amber Collins, MS [TVAMC]	Backup Coordinator	A, B, D, E, G, H, K, L, M	Y	Y	N/A	04-06-25
Allyshia Hinton, MPH	Backup Coordinator	A, B, D, E, G, H, K, L, M	Y	Y	N/A	12-13-25

Note: Additional project members may be added by inserting more rows above.

Delegation of Duties Codes (additional details or rows may be added)	
A	Make eligibility or termination decisions; perform screening tasks
B	Obtain informed consent; document informed consent
C	Direct clinical care of participant (treatment decisions)
D	Data collection, data entry, data corrections
E	Evaluate adverse events; document adverse events
F	Prescribe or provide treatment or study intervention (if drugs, list on 10-9012)
G	Document protocol deviations and unanticipated problems
H	Maintain Study Files
I	Collect biospecimens (include on safety form)
J	Package and Ship Biospecimens (requires training documentation)
K	Administrative/regulatory/financial functions
L	Perform rating scales; collect self-reports; collect qualitative information
M	Document encounters in the medical records
N	Data analysis

5.0 Study Procedures

5.1 Study Design

- **Research Design:** This study will use a single group quasi-experimental design to evaluate the feasibility and acceptability of the study procedures and intervention and explore preliminary effectiveness.
- **Methodology:** Twenty-five (25) Veterans ages 50 and older experiencing pandemic-related emotional or physical distress will be enrolled. The 10-session closed group intervention will be delivered in a virtual group room via Microsoft WebEx or another VA-approved virtual platform. Sessions will be video- and audio-recorded for treatment fidelity monitoring. Each group cohort will consist of 4 to 5 Veterans, and sessions will be delivered weekly for 90 minutes. Feasibility and acceptability data will be collected throughout the study. Feasibility and acceptability of study procedures will be measured by referred-to-enrolled rate, telehealth access and capability, electronic data collection of outcome measures, and qualitative feedback on data collection procedures and measures. Feasibility and acceptability of the intervention will be measured by attendance; attrition; homework completion; participant ratings of the intervention's feasibility, acceptability, and fit; qualitative feedback; and treatment fidelity. Outcome data will be collected via Qualtrics at baseline, posttreatment, and one-month follow-up and will consist of pandemic-related emotional and physical distress, psychological flexibility, depression, anxiety, social connectedness, perceived health, functional impairment, and meaningful engagement. The participants must attend at least 1 session to participate in the assessments. A brief midpoint assessment at week 5 of the group will consist of measures of social connectedness and functional impairment. Participants will participate in a 30-minute posttreatment qualitative interview to provide feedback on the intervention and study procedures as well as input on perceived efficacy to implement intervention skills and specific emotional or behavioral changes participants have noticed in themselves because of the intervention.
- **Transcription of interviews:** The recorded interviews will be transcribed by the VA Centralized Transcription Service Program (CTSP) located in Salt Lake City, UT. The

interviews will be transcribed verbatim, with any identifying information removed prior to analysis.

- **Participant Fees:** As incentive for adherence, an offset of out-of-pocket expenses, time for completing the assessments, and expression of appreciation for participation, each participant will receive \$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, for a total of \$150 per participant. Payments will be in the form of direct deposit only.
- **Risks (physical, psychological, social, and economic) and steps taken to minimize these risks**
 - **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, participants will be encouraged to take breaks as needed.
 - **Psychological risks:** The most common risk for participants is that the intervention could trigger psychological distress. The second most serious risk relates to risk of disclosure of mental health and/or physical health in a group treatment, and the possible stigma associated with that. A third risk is the potential for a group participant to share with someone outside of the therapy group (i.e., not part of the intervention group or study) personally identifiable information that was disclosed by another participant/group member. The most likely risk is that participants may experience discomfort speaking about their struggles during the pandemic. In addition to potential risks stated above, participants may feel that the self-report questionnaires, qualitative interview, and video and audio recordings are an invasion of privacy. While answering questions regarding their psychological symptoms, perceived health, and pandemic stressors, participants may experience transient anxiety, sadness, discomfort, or embarrassment. Participants may experience mild discomfort with speaking in a group format, participating in ACT exercises, mental fatigue, boredom. Participants who are unfamiliar with technology and have difficulty using the loaned government-issued tablet or a personally owned device when logging in to a therapy session or completing the electronic questionnaires may experience frustration. Participants may also be wary of sharing personal information via virtual platforms. These are research risks, not therapeutic risks, that are mild and transient.

Study procedures are not anticipated to exceed frustrations or distress encountered in their daily experiences. The investigators and CRC will make every effort to minimize potential psychological risks by maintaining a pleasant and professional manner, encouraging dialogue regarding the research process, and allowing the participant to take rest breaks or discuss any reactions or feelings as they occur during and/or after visits (i.e., screening visit, technology education and technology troubleshooting visits, group intervention sessions, and post-intervention follow-up interview). To minimize discomfort and distress, all visits will be conducted by trained professionals with a clinical background or

experience. To minimize frustration with technology, the CRC will provide an orientation on the technology equipment and platforms to participants, and the CRC will be available throughout the study to assist with any technology-related difficulties. In addition, participants will be allowed to take breaks during the ACT group sessions. Participants will be able to complete baseline, midpoint, and post-intervention assessments at their own pace. To further protect against the risk of psychological distress, the following precautions will be taken. All participants will receive a hard copy document with phone numbers for the VA Suicide Prevention Hotline, the office number of the PI (Dr. Lori Davis), and contact information for the primary care team at TVAMC, which is staffed with licensed mental health providers who are available during business hours.

- **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 TVAMC 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 a participant completes the consent process via telephone, the participant will mail the completed consent and HIPAA forms by priority mail or FedEx/UPS with tracking. Research records will not be released to participants 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. Participants' names will not be identified in the data analysis, publications, or presentations of the research results.
- **Economic risks:** Regarding economic risks, the participant 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. These are research risks, not therapeutic risks. Every effort will be made to avoid economic risks. The PI or CRC will schedule the appointment for screening and the informed consent process at a time that is most preferable and convenient for the Veteran 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. Participants may call from any phone, including a landline, that is most convenient or economically appropriate for them.

The investigators are experienced licensed mental health professionals who are operating in a supportive medical center environment where medical and mental health specialists are conveniently located for immediate consultation if needed. While we do not anticipate any serious adverse events, participants will be given detailed information (verbal and written) regarding the steps to take in the event of a serious side effect or emergency. A physician or nurse will be available 24 hours and 7 days per week for the participant to contact or be

evaluated by in the event of a serious adverse event or emergency. Inpatient psychiatric or medical hospitalization is available at the TVAMC.

It is policy to identify Veterans' location when they are receiving care via telehealth. This is a necessary step to help get a Veteran immediate assistance in the event of a medical or mental health emergency. The CRC will document/confirm Veterans' emergency contact name and telephone number at the start of the screening visit. The CRC and PI will confirm and document participants' addresses/locations and presence of emergency contact at the start of each contact so that a study team member can get emergency help to a participant if the need arises. The investigative team members at TVAMC will conduct all telehealth appointments in a secure and private setting that has a computer with Microsoft Teams and WebEx and a telephone. If a Veteran reports or demonstrates imminent risk related to a medical, psychiatric, or substance use emergency during screening, assessment, or treatment, the CRC/PI will immediately contact the e911, which is a service that providers use to be routed to emergency dispatch services in the Veteran's area. The PI will notify the Veteran's VA primary care team and work with VA staff to ensure appropriate transfer and follow-up care.

The Columbia-Suicide Severity Rating Scale (C-SSRS) Screening Version will be used to structure suicide risk assessments. At screening, the trained CRC will inform all potential participants (regardless of C-SSRS responses) of the TVAMC plan for mental health crises. This plan includes knowing the signs of suicide risk, contacting the VA Suicide Prevention Hotline if experiencing distress, and going to the nearest hospital if experiencing suicidal thoughts. During the screening, if a potential participant reports "wishing to be dead" or having thought of suicide, as assessed by the C-SSRS, the CRC will immediately notify the PI (Davis), who will conduct a full suicide risk assessment at that moment. If Dr. Davis is unavailable for any reason, Dr. Jacobs or Dr. Grenawalt will conduct the assessment. Should the investigator deem the participant to be at heightened risk of suicide, the participant will be treated in the most clinically appropriate setting (outpatient or inpatient) and appropriate AE or SAE reports will be filed with the IRB. If immediate attention is required, local procedure protocol will be followed to ensure the Veteran receives immediate care. If the risk assessment is conducted at TVAMC in person and it is determined that immediate care is needed, the PI will walk the Veteran to the Minute Clinic or to Mental Health at TVAMC. For all virtual appointments, the study team member will document the Veteran's physical location at the outset of the appointment, in accordance with telehealth practices; this information is vital should emergency personnel involvement be indicated. If the risk assessment is conducted virtually, the PI will confirm the Veteran's location. If immediate care is needed, the PI will follow local VA protocol to assist Veteran with receiving immediate help.

The PI will also have referral information and important resources (e.g., the Veteran's crisis line, suicide prevention coordinator numbers) available. If the PI is not available to provide clinical coverage, another licensed provider on the research study team will be asked to provide coverage. The PI and members of the research team are licensed independent mental health providers with extensive training and experience in remote risk assessment and suicide prevention and have published articles on suicide assessment. Any observations or reports of acute distress that could compromise safety (e.g., risk of harm or neglect to self or others) will be handled in compliance with standard operating procedures and within VA ethical guidelines. Participants will be monitored closely for possible adverse events. At each intervention session, immediately following completion of baseline, posttreatment, and one-month follow-up measures, and during the post-intervention interview, the PI and/or CRC will monitor the participant and document adverse events accordingly.

5.2 Recruitment Methods

- Participants will be primarily recruited from primary care, home-based primary care, and outpatient mental health clinics. A HIPAA waiver for screening and recruitment is requested. Recruitment strategies will include outreach to clinical staff and program directors in these clinics in person and via email, IRB-approved flyers posted in these clinics, and introductory invitation letters and flyers to prospective participants. Thus, recruitment will occur in one of the following ways:
 - Through a clinical provider: Participants receiving services in TVAMC primary care, home-based primary care, and outpatient mental health will be informed about the study by a member of their clinical team. Clinical providers will alert a research member on the investigative team by encrypted email when a Veteran expresses interest in learning more about or participating in the study. A member from the study team will contact the Veteran to provide additional information about the study and determine eligibility.
 - Research outreach: Clinical providers may identify and refer potential participants to the TVAMC research team. No “cold calls” will be conducted. In these instances, a study team member will verify eligibility via chart review. If the potential participant is eligible, an introductory invitation letter will be mailed to the potential participant. As stated in the letter, if the research team does not hear back from the Veteran expressing their desire to “opt out”, a research team will contact the Veteran by telephone one week after sending the mailout to ask if they received the letter and if they are interested in participating in the study. The research team will also identify potentially eligible participants via chart review. Veterans age 50 and older who do not have an exclusionary diagnosis will be mailed an IRB-approved introductory letter. Procedures described above will be followed. A flyer with contact information may also be posted on approved social media sites.
 - Self-referral: Recruitment flyers will be distributed in clinical areas, and Veterans may initiate contact with the study team without a referral from a clinical provider.

5.3 Informed Consent Procedures

- Prospective participants will complete a telephone screening under an approved-HIPAA waiver for purposes of screening and recruitment. Veterans who are eligible will be invited to schedule another appointment to complete the informed consent procedures, which may take place by telephone, at the TVAMC, in-home, or at an agreed upon location in the community based on their preference. If the prospective participant chooses telephone, consent forms and a stamped envelope will be mailed to the individual prior to the appointment. At the appointment, the trained CRC will meet with the prospective participant and will provide detailed information regarding the study’s sponsor, purpose, procedures (including the audio and video recording of all intervention sessions and individual interview at one-week follow-up), potential risks and benefits, alternatives to participating in the study, payment, and other required elements in the IRB-approved written informed consent form. Potential participants will be given ample time to consider enrollment in the study and can involve family members, significant others, and/or their VA providers (e.g., therapist or psychiatrist) in their decision. Potential participants will be informed that refusal to participate in this research study will not penalize them or change their eligibility for VA services, treatment, or disability payments. A Veteran’s willingness or refusal to take part in this study will be noted in the source documentation. The original copy of the signed participant’s informed consent form will be filed in the source document, the participant will be given a copy. Participants will also sign a consent form to be audio and videotaped

during the intervention sessions and individual interview at follow-up, as well as a confidentiality agreement that asks that confidential information shared in the intervention group not be disclosed to others. Since the intervention will be delivered in English, we will not enroll participants who are unable to speak English.

Upon providing written informed consent, the Clinical Research Coordinator (CRC) will mail a Participant Treatment Manual to the participant. The CRC will ask the participant if they have a personally owned device with video capability, such as a smart phone, tablet, or computer with a webcam, as well as home internet access and an email address. Participants who do not have a personally owned device, and individuals who only own a computer but have no home internet, will be loaned a government-issued tablet with a built-in data plan to use during their participation in the study. Mobile devices will be encrypted, and the encryption is FIPS 140-2 validated. The CRC will provide a brief tutorial on how to use the device. Participants who do not have an email address will receive technical assistance from the CRC to create an email account. All participants will receive a brief tutorial on how to access and use Microsoft WebEx and Qualtrics, which will be used for intervention delivery and data collection.

5.4 Inclusion/Exclusion Criteria

- Inclusion criteria: (a) age 50 and older, (b) score of ≥ 9 on the COVID-19 Mental Health Impacts Scale, (c) English speaking, and (d) provides written informed consent (i.e., no surrogate consent allowed).
- Exclusion criteria: a) diagnosis of dementia, (b) score of ≤ 31 on the Modified Telephone Interview for Cognitive Status (TICS-M), (c) actively suicidal or homicidal (as measured by Columbia-Suicide Severity Rating Scale Screening Version and self-report), (d) actively psychotic (as measured by Psychosis Screening Interview), (e) unstable medical conditions (identified in the medical record {and via self-report, and conceptualized as a significant medical condition or acute illness requiring hospitalization within one month prior to the screening visit), (f) active substance use disorder,} and/or (f) currently participating in another cognitive behavioral therapy (CBT) (this includes traditional CBT, ACT, mindfulness based cognitive therapy, cognitive processing therapy, prolonged exposure therapy, and problem-solving therapy).

Although not a strict eligibility criterion, the PI will monitor the characteristics of the participants to ensure an adequate representation in terms of gender and race. The study will not enroll prisoners, minors, persons with a known terminal illness, or persons with a cognitive or mental disorder which may interfere with their decision-making capacity. All participants must be capable of providing their own consent (i.e., no surrogate consent is allowed). This study will not include non-Veterans. This study will include women and minorities (~8% women and ~48% minorities) and aim to represent the percentage reflected in VA medical care system. Most Veterans are male, and percentage of female Veterans is lower among the older population compared to younger age groups. Therefore, there will be a difference in gender that will impact the gender distribution during enrollment. No decision to exclude any person from this study will be based upon gender, sexual orientation, minority status, ethnicity, or socioeconomic background.

5.5 Study Evaluations

- **Screening:** Telephone screening will be conducted by the IRB-approved Clinical Research Coordinator (CRC) or PI (Davis). The CRC will receive extensive training on the screening measures and procedure prior to screening potential participants. The telephone screening will include: (a) a brief chart review to confirm that Veteran is 50 or older, does not have a diagnosis of dementia in the problem list, and does not have a terminal or unstable medical condition in the problem list; (b) screening of homicidal ideation {and current alcohol and substance use}; (c) confirmation that potential participant will not be in another cognitive behavioral psychotherapy group during study participation; and (d) completion of the screening measures presented in Table 1. If a participant reports active suicidal or homicidal ideation, a full risk assessment will be immediately conducted by the PI who is a licensed clinical psychologist.

Table 1. Screening measures

<i>COVID-19 and Mental Health Impacts (short version):</i> This 5-item measure is a shortened version of the 17-item questionnaire that was developed for the COVID-19 Community Response Survey protocol and available to the public on PhenX Toolkit. Psychometric data is not yet available for this measure. The five items ask about the frequency of COVID-related mental health symptoms in the past week and are rated on a 4-point Likert scale ranging from “not at all or less than 1 day” to “5-7 days.” Scores range from 5 to 20, with higher scores indicating greater psychological distress. Administration time is estimated at 1 to 2 minutes.
<i>Modified Telephone Interview for Cognitive Status (TICS-M):</i> The TICS-M is a brief, 5 to 10-minute, cognitive screening tool that was developed for use via telephone. Domains include orientation, attention, verbal learning and memory, praxis, and language. Scores range from 0 to 50, with scores ≤31 indicative of mild cognitive impairment.
<i>Columbia-Suicide Severity Rating Scale (C-SSRS) Screening Version:</i> The C-SSRS Screening Version is a 6-item measure the assesses suicidal thoughts, plan, intent, and past behaviors. Items are scored as Yes/No. If the respondent reports No for the second item, the screening is discontinued. C-SSRS has good convergent and divergent validity with other suicide measures and has high sensitivity and specificity compared to other common measures. Administration time is estimated at 1 to 5 minutes, depending on responses.
<i>Psychosis Screening Interview:</i> This six-item screening interview was adapted from supplemental material in <i>The Beginning Psychotherapist’s Companion</i> published by Oxford University Press. Response choices are Yes/No. Administration time is estimated at 1 to 2 minutes.

- **Data Collection:** Participants will complete study measures at baseline (approximately 1 to 2 weeks before intervention), midpoint (5 weeks), posttreatment, and one-month follow-up via Qualtrics. Qualtrics is a web-based survey software tool. Research investigators at TVAMC have Qualtrics licenses, which will be used for this study. At baseline, the survey will include a demographics questionnaire and will collect the following: a) socio-demographic information, including age, gender, race, ethnicity, level of education, household income, source of income, marital status, living situation, and occupational status and (b) impact of COVID-19, including questions about personal experiences with COVID-19 (e.g., assessing if participant has been exposed to or contracted COVID-19, if loved ones or friends have had COVID-19, the losses they have experienced due to COVID-19). Demographic data will be verified via chart review. The baseline Qualtrics survey will also include the 8 outcomes measures listed in Table 2. The

midpoint assessment is brief and will consist only of the Three-Item UCLA Loneliness Scale, De Jong Gierveld Loneliness Scale, and Sheehan Disability Scale. Posttreatment assessment will consist of all outcomes measures as well as the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure. One-month follow-up assessment will consist of outcome measures only.

Participants will receive the Qualtrics link via email. If they do not complete the assessment within two days, they will receive a reminder telephone call and email with the link. If they do not complete the assessment within two days after the reminder, the CRC will contact the participant 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 participant to complete within one week, if needed.

Table 2. Study measures		
Source	Items completed by participant	Measurement
<u>Study protocol feasibility and acceptability measures</u>		
1. Referred-to-enrolled rate		Frequency
2. Ownership of device with telehealth capability		Frequency
3. Internet access		Frequency
4. Participants requesting telehealth assistant to troubleshoot technology		Frequency
5. Completion of assessments in Qualtrics		Frequency
6. Adherence to study timeline		Frequency
<u>Intervention feasibility and acceptability measures</u>		
1. Attendance		Frequency
2. Attrition		Frequency
3. Completion of homework (self-report at each session)		Frequency
4. ACT Fidelity Measure (ACT-FM) ^a		4-point Likert scale
5. Interventionist adherence checklist		Yes/No
6. Feasibility of Intervention Measure	4 items	5-point Likert scale
7. Acceptability of Intervention Measure	4 items	5-point Likert scale
8. Intervention Appropriateness Measure	4 items	5-point Likert scale
<u>Outcome measures</u>		
1. COVID-19 Specific Emotional and Physical Distress ^b	13 items	5-point Likert scale
2. Hospital Anxiety and Depression Scale (HADS)	14 items	4-point Likert scale
3. Three-Item UCLA Loneliness Scale	3 items	3-point Likert scale
4. De Jong Gierveld Loneliness Scale	6 items	3-point Likert scale
5. Comprehensive Assessment of ACT (CompACT)	23 items	7-point Likert scale
6. Life Engagement Test (LET)	6 items	5-point Likert scale
7. Sheehan Disability Scale (SDS)	3 items	10-point Likert scale
8. General Health scale of the RAND SF-36	5 items	5-point Likert scale
Note. ^a ACT-FM has two subscales (ACT consistency and ACT inconsistency). Only the ACT consistency items will be used (13 items). This is an acceptable strategy, as noted in the measure instructions, and will provide insight into the feasibility of maintaining an ACT consistent approach via telehealth. ^b COVID-19 Specific Emotional and Physical Distress measure will be adapted for this study. Two items from the original survey are specific to cancer; <i>health</i> will be used in place of <i>cancer</i> for this study (i.e., “I fear how the COVID-19 will impact my <i>health</i> care,” and “I am concerned that my <i>health</i> puts me at greater risk for being infected or dying from COVID-19.”).		

Upon completing the intervention, participants will be contacted by the CRC to schedule a 30-minute individual interview. The interview will be completed approximately one week after completing the intervention for the purpose of gathering participants’ impressions of the telehealth intervention and assessment procedures. The interview will be conducted via WebEx and recorded and transcribed.

Table 3. Interview questions	
Target	Question

Satisfaction with intervention	1. On a scale of 1 to 5, with 1 being extremely dissatisfied and 5 being extremely satisfied, how would you rate your experience with the telehealth ACT group? 2. Describe what factors led you to rate your satisfaction at a [insert rating]?
Impression of intervention components	3. What content did you find most useful or valuable? 4. What changes would you recommend for the ACT group content? 5. How confident are you in using the intervention skills [scale of 0 to 10]? 6. Describe any changes you have noticed in yourself as a result of Pan-ACT.
Impression of telehealth format	7. Describe your experience with participating in the group virtually. 8. What changes would you recommend to the telehealth setup or delivery?
Impression of assessment procedures	9. Describe your experience with accessing and completing the electronic questionnaires. 10. What changes would you recommend?

The research team will track number of Veterans referred and contacted, number enrolled, number completing study, number enrolled who have telehealth capability for the duration of the trial, start and stop dates of cohorts, number of homework assignments completed, number of assessments completed, number of enrolled veterans who attend the Pan-ACT sessions, and ratings on the study measures.

Treatment fidelity will be evaluated using an interventionist protocol adherence checklist (to be developed by research team within first 90 days of the study start date) and the ACT-FM. At least 20% of recorded sessions will be selected for fidelity monitoring. Purposeful sampling stratified by session number will be used to ensure fidelity monitoring is completed across all 10 sessions of the intervention. Treatment fidelity in this study is conceptualized as a measure of feasibility and is consistent with other ACT feasibility studies.

- Intervention:** 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 cohort will consist of 4 to 5 Veterans. This group size was chosen to maximize the amount of group time each participant will have to talk. Each session will be 90 minutes and will include a brief mindfulness exercise, ACT work review (i.e., homework; included in sessions 2-10), at least one metaphor and experiential exercise relevant to the session theme, discussion, and identification of and commitment to ACT work for the week (i.e., homework). These in-session activities are intended to help participants: (a) cultivate present-moment awareness and acceptance of thoughts and emotions about the pandemic and themselves, (b) unhook from rigid and unhelpful thoughts and beliefs by fostering flexibility in relating to uncomfortable internal experiences, and (c) clarify values and commit to taking values-based action in their lives. We modified the intervention content to target pandemic-related stressors and emphasize coping related to COVID-19 and the pandemic. The first session will set the tone for the group by exploring (a) their experiences with stress, worry, depression, and grief during the pandemic, (b) attempts they have made to manage their symptoms of distress, and (c) the costs of those attempts. The session will conclude with discussing ways in which the pandemic has caused them to re-evaluate their values and identifying changes they would like to make to lead a more value-driven, purposeful life. Remaining sessions will teach participants 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 succumb to unhelpful thoughts and emotions.

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 TVAMC. VA Video Connect was considered; however, there are three features of WebEx that make it a preferred platform for this study. WebEx has recording capability, which will be used

to record sessions for fidelity monitoring. An external encrypted audio recorder will be used as a backup in all sessions in case there is a technical issue with the WebEx recording function. WebEx also allows the “host” (i.e., group leader) to send a cell phone text with a link to the virtual group room to a participant, which could be useful if a participant is unable to locate the link in their email. If a participant is having technical issues with their video device, they will be able to call in to the WebEx virtual group room from a phone.

5.6 Data Analysis

- Demographic variables and feasibility and acceptability measures will be analyzed using descriptive statistics. Linear regression using generalized estimating equations to account for clustering within groups will be used to estimate the potential impact of Pan-ACT on treatment outcomes and will be reported with 95% confidence intervals. Intraclass correlation coefficients will be estimated to help inform the design of subsequent larger studies. Qualitative data gathered from the post-treatment interviews will be analyzed inductively, using thematic analysis to guide the phases of coding.⁴¹ Thematic analysis phases are (1) familiarizing oneself with the data, (2) generating initial codes that define or represent the basic raw data, (3) searching for themes in the data and codes, (4) reviewing and refining themes, and (5) defining and naming themes. The transcripts will be analyzed by two members of the study team. Having two independent coders is important to promote trustworthiness of the research findings. After completing phases 1, 2, and 3 independently, the two coders conduct phases 4 and 5 together. Any coding disagreements will be discussed. If needed, a third member of the research team will be included to reach consensus. Results will be used to inform the design of an VA Merit (IIR) proposal and revise or adapt the Pan-ACT manual.

5.7 Withdrawal of Subjects

- Subjects will exit the study once one of the following conditions are met:
 - Completion of all study procedures
 - Serious or life-threatening adverse event. If a participant develops suicidal, homicidal, or psychotic symptoms or a significant exacerbation of psychological distress, the individual will be withdrawn from the study and treated by a mental health provider in the appropriate setting.
 - Withdrawal of consent by Veteran
- While every attempt will be made to retain participants in the study for the full period, participants may discontinue at any time due to personal preference, adverse event, inadequate response, dissatisfaction with the study procedures, or other reasons. In the event of an early exit from the intervention, the participant’s reason for early termination will be documented and a post-intervention assessment will be conducted.

5 Reporting

- The research team members are trained in recognizing medical and psychiatric emergencies. Participants will be monitored closely for possible adverse events. At each intervention session, immediately following completion of baseline, posttreatment, {and one-month follow-up measures,} and during the post-intervention interview, the PI and/or CRC will monitor the participant and document adverse events accordingly. In the unlikely event that a research team member encounters such an unanticipated adverse event or emergency during

screening, the informed consent process, or the intervention group, the research team member will either call 911/e911 (if immediate medical attention is needed) and/or call the PI. All serious adverse events (SAEs) related to the study procedures and unanticipated adverse events will be reported to the IRB. If a Veteran reports or demonstrates imminent risk related to a medical, psychiatric, or substance use emergency, the PI will notify the Veteran's VA primary care team and work with VA staff to ensure appropriate transfer and follow-up care.

The PI will audit database entries and informed consent forms for compliance with procedures for data safety and human subject protection. Training of the study staff will include steps to assure accuracy and integrity of the data. Study staff will be trained with regards to adverse events and unforeseen problems that could occur, and the required procedures for communicating about these events, including IRB report forms. The PI will promptly review all adverse events and unforeseen problems. These will be reviewed and reported per TVAMC IRB guidelines.

6 Privacy and Confidentiality

- The research team will make professional and concerted efforts to protect the confidentiality and privacy of the Veterans enrolled. These safeguards include conducting screening and the informed consent process in a private and secure area (private research office), conducting intervention groups via Microsoft WebEx (a VA-approved, secure virtual platform), and using priority certified mailing and/or FedEx/UPS for participants to mail signed documents with PII to the research study team. A HIPAA authorization will accompany the informed consent form to notify the participant in what capacity their identifiable PHI or PII will be used. Both documents provide a detailed outline of the provisions utilized to protect their confidentiality. All study documents will be kept in a locked office or on the secured VA Network Server within the VA firewall in a protected folder. All other materials will be stored in locked cabinets in locked rooms under the control of the research team. Access to research files will be restricted to only those with appropriate IRB approval and only on an as-needed basis. Access to the files will also be monitored by local VA's Office of Information and Technology (OI&T). No data will be transferred off the secure site server without approval from OI&T. Data for this study will be collected, handled, maintained and stored according to VA research program's standard practices and policies. PHI or PII will not be included in the data analyses, publications, and presentations of research results. Data for this study will be collected, handled, maintained and stored according to VA research program's standard practices and policies. This includes:
 - As defined by HIPAA, PHI is used only for purposes related to the activities of this study.
 - All electronic PHI data are stored on secure VA servers. If a non-government furnished equipment (GFE) laptop will be used, the non-GFE laptop must work on the data through the VA's VPN and not store information locally on the laptop.
 - Highly confidential protected health information (HCPHI: names, Social Security Number, address and phone numbers) collected by the study are defined in the informed consent or HIPAA.
 - When necessary, PHI and PII may be transported between secure VA servers. Use of laptops by the investigators that access research data are approved by the local Information Security Officer and all other oversight officials. These devices are encrypted, and password protected FIPS 140-2 certified compliant program. Physical data transfers are not anticipated for this study; however, should the need arise, a traceable mail system (e.g., UPS with chain of custody), must be used.
 - PHI/PII may only be sent via encrypted VA MS Outlook message utilizing a PIV-badge.

- Only VA-owned equipment or equipment configured to VA security standards is permitted to connect to the VA network and servers in accordance with VA Directive 6500.
 - VA information security training for all investigators and research staff will be required.
 - Access to the study data housed within the Microsoft InfoPath/SharePoint system is afforded the same level of security as all forms of VA protected and/or highly sensitive information. Access is heavily restricted to properly credentialed research staff. Before being granted access, these individuals must be compliant with VA security trainings (i.e., Research Data Security, HIPAA and VA Privacy Training, Cyber-Security and Good Clinical Practices).
- **Participant Identification and Case Report Forms:** Upon enrollment, each study participant will be assigned a unique study identification number (study ID). Personal identifiers (name, SSN, date of birth) will be collected on source documentation only and protected with strict confidentiality in a secure environment. The study ID will identify each individual case report form (CRF) so that data entered into the database will be de-identified. All personable identifying information (PHI) will be maintained in a separate secure location from the database. Additionally, information connecting the study ID with the participant is accessible only to study personnel.
 - **Database Creation:** The PI will design and maintain the Qualtrics survey and research excel database with the assistance of the CRC. The survey and database will be password protected and only available to approved study personnel. Data quality will be monitored for accuracy.
 - **Data Collection and Quality Assurance:** Screening and chart review data will be collected by the CRC at the point of entry and entered into the excel database. The CRC will also track several measures of feasibility throughout the study. The CRC will be provided a checklist of the data to track, and the PI will monitor the process to ensure all data is collected. Data will also be collected via Qualtrics (and mailed hard copy assessments, if needed) and monitored by the CRC for completion. The PI/Interventionist will track attendance, attrition, and homework completion, which will be entered into the excel database. Qualitative data will be collected via interviews. Errors will be corrected by the individual study personnel who collected the original data and if necessary, participants will be reassessed to fill in missing data. All data will be checked by the CRC and PI for consistency, conflict, and disparities within each CRF and across CRFs.
 - **Data Security:** All paper forms and audio recordings will be kept in a locked filing cabinet within a locked research designated office. The office is only accessible to approved research staff. The electronic database will be password protected and only accessible to approved study personnel. All data will be stored and maintained on a VA server that is backed up daily (\\S:\research\Investigator Files\Jacob's Studies\Active Protocols\Pan-ACT. All video files and the database will be stored and maintained in a secure folder (only approved study personnel will have access) on a secure VA server that is backed up daily. All IRB guidelines for conducting research involving humans will be followed.
 - **Termination of Data Access:** Removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team by removing the individual's access to the VA server file locations.

- **Retention of Records:** Research data is retained and archived within the VA. Paper documents are archived in accordance with VHA policies, which at this time is six years after the study closes, or longer if needed, in accordance with VHA's Records Control Schedule. Digital data is archived within VA according to data repository standard operating procedures. Records of this research study will be maintained in accordance with VHA's Records Control Schedule 10-1 (RCS) policies for the Office of Research and Development; section 7.6 - Research Investigator Files.
- **Planned Procedures for Misuse, Loss or Theft of VA Sensitive Information:** The investigators will comply with VHA policies on prompt reporting of loss, theft, or actual or suspected breaches involving sensitive information, along with any other privacy or security incident or complaint. The ISO will promptly determine whether an incident warrants further reporting and actions. At a minimum, the following should occur as soon as it is discovered that there has been a loss:
 - Report the loss or theft to the VA security/police officers immediately.
 - During travel or at another institution, notify the security/police officers at the institution such as hotel security, university security, etc. as well as the police in the jurisdiction where the event occurred.
 - Obtain the case number, name, and badge number of the investigating officer(s). If possible, obtain a copy of the case report.
 - Immediately call or email the following regarding the incident:
 - The persons' immediate supervisor
 - The local Information Security Officer
 - The Chief of Staff
 - The Medical Center Director
 - The Associate Chief of Staff for Research and Development
 - The local Privacy Officer must be notified by phone and email within 1 hour, providing a description of the event, when there is any unauthorized use, loss, or disclosure of individually identifiable patient information.
 - Any such event must also be reported to Dr. Davis and the IRB as an unexpected adverse event.

7 Communication Plan

- All required local site approvals will be obtained and the Director of the participating sites will be notified via the IRB (VAIRRS). Any changes to the protocol, informed consent, and HIPAA authorization will be made through IRBNet (VAIRRS) for both participating sites. Any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study will be reported according to local protocol. The study will require engagement of both sites.

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