Impact of Veteran Voices & Visions Peer Support Groups on Social Integration for Veterans with SMI/Psychosis

NCT05562674

April 6, 2026

VAGLA Research Study Protocol

TITLE: **Pilot Randomized Control Trial of Veteran Voices & Visions (VVV) Peer Support Groups for Veterans with Unusual Experiences**

Principal Investigator:

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1. Introduction/Background

Veterans with Serious Mental Illness (SMI) struggle with social integration - participation in work, housing, and citizenship - due to symptoms, stigma, and psychosocial functioning deficits. This has a tremendous impact on mortality, comparable to that of smoking and greater than obesity and alcohol abuse. Despite considerable VA efforts to provide mental health care to Veterans with SMI, programs that promote social integration are lacking. Veterans with SMI are at especially high risk for poor social integration and suicidal ideation during the COVID-19 pandemic. There is an urgency to advance treatments targeting Veterans' social integration.

This project addresses this need with a support group-based psychosocial intervention for Veterans with SMI, called "Veteran Voices and Visions" (VVV). VVV targets Veterans with SMI who experience psychosis, a group particularly in need of support for social integration. Virtual VVV groups are co-facilitated by VA mental health clinicians (MHCs) and Veteran peer support specialists (PSs) via online video conference. VVV is an adaptation of a community-based support group model called the Hearing Voices (HV) approach that was developed over 30 years ago in the Netherlands. It has since spread to over twenty-five countries, representing hundreds of support groups worldwide. The approach facilitates group cohesion around and normalization of the common psychotic symptoms of SMI: hallucinations, delusions, and social isolation. Despite its global scope, this approach has neither been formally adapted nor rigorously studied in public health systems, including the VA.

2. Study Team and Study Sites

PI – Ippolytos Kalofonos MD PhD MPH
Co-I – Erica Hua Fletcher PhD
Co-I - Shirley Glynn PhD
Co-I - Sonya Gabrielian MD MPH
Project Coordinator – Mariam Nazinyan MPA
Research Assistant - Susanna Friedlander PhD
Research Assistant – Jade Durst BS
Research Assistant – Ryan Vane BS

3. Aims and Purpose

We have begun developing this support group intervention in a previous pilot study. While this initial effort was so successful, the support groups have continued past the research period, we did not have a formal manual, training guidelines, or fidelity measure which are needed to better study the approach, systematically assess outcomes, and scale it up. We have developed these materials in a community-engaged manner. This pilot will

test these tools and materials via a Pilot Trial for Veteran participants. ***The aim is to evaluate the feasibility and acceptability of our new materials using the VVV group approach in preparation for a larger randomized control trial.*** We will run the study using the full collection of outcome measures (such as reduced distress due to psychosis, self-efficacy, and social functioning) that we would anticipate including in a subsequent RCT.

4. Activities Overview

Veteran participants (n=24) will be recruited for 12 sessions of 3 VVV groups (8 Veterans per VVV group). Pre-intervention and post-intervention follow-up assessments will evaluate the feasibility and acceptability of our new materials as well as collect outcome measures. Assessments will be conducted virtually, via VA approved video-conferencing platform or telephone, depending on the participant's preference and ability. Assessments will be audio-recorded. The intervention sessions will also be conducted virtually via a VA approved video-conferencing platform. All group sessions will be video-recorded.

5. Study Design

5.1. Data collection methods

Participants will complete assessments at two time points: 1) pre-intervention baseline, 2) post-intervention after 12 weeks of sessions. They will also be asked to fill out a brief survey following each group session. All group sessions will be recorded.

5.2. Sample (cohort) description, development and rationale

Participants are Veterans experiencing psychosis and receiving care from GLA.

Our inclusion criteria include:

1. Veteran status and medically eligible for VA services
2. Subjective experience of psychosis including hallucinations and delusions
3. Ability to join a group remotely via videoconference or telephone, English comprehension, ability to provide consent.

Rationale: Subjects with the above characteristics are most likely to benefit from the intervention, as indicated from our prior research which contained the same inclusion criteria.

Exclusion criteria include:

1. Previous attendance in a VVV group
2. Psychosis experienced is due to substance use only and is not chronic or present in the absence of substance use.
3. Significant neurological or medical disorder
4. Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the participant or quality of the data.
5. Unwilling or unable to access groups remotely.

Rationale: Data collected from subjects with the above exclusion criteria would be skewed, due to additional factors which are outside the scope of this study. Previous research contained similar exclusion criteria.

Sample Size Considerations: The sample size of n=24 (3 groups with 8 members), yielding an expected cohort of 18 subjects with complete data, was designed (a) to ensure sufficiently fine-grained coverage of our target population by age, sex, and severity/type of psychosis presentation, and (b) to provide sufficient granularity for feasibility metrics (rates can be estimated in increments of 3.3-4.0%).

5.3. Participant interactions and interventions

Veterans receiving services through GLAVAHS will be recruited from several sources, including flyers, medical record review, direct recruitment, provider referrals, and social media. See Section 6.1 for details.

The research team will then send out a recruitment letter and study information sheet via mail or email (depending on the Veteran's preference). Veterans will then complete an initial telephone screening, which may lead to an informed consent process. Once a subject has been determined eligible for the study, the research team will add them to a waitlist to start a group. Once a group has been filled, the research team will introduce the subject to the group facilitators and provide them information about joining weekly group sessions. They will schedule the first assessment, to be completed before the group begins. The research team will also provide training and support to any Veterans needing assistance with using the REDCap digital survey following each group session, and troubleshoot any likely questions related to securing a confidential setting.

6. Recruitment and Consent

6.1. Recruitment Methods

Veterans receiving services through GLAVAHS will be recruited from several sources: 1) flyers at outpatient mental health clinics, affiliated VA GLA Community-Based Outpatient Clinics (CBOCs) ; 2) medical record review via the VA VINCI administrative database; 3) direct mail to eligible Veterans via the MIRECC Treatment and Clinical Neuroscience Repository (Marder #0042); 4) approaching Veterans in-person from HUD-VASH, outpatient mental health clinics, the Domiciliary, affiliated CBOCs, and CPRS; 5) provider referrals; and 6) social media ads posted on-line on Craigslist, the VA Facebook page, and VA Twitter.

Participants must meet the inclusion and exclusion criteria detailed above, however, there are no exclusions based on gender, race, national origin, religion, creed, education, or socioeconomic status. We are using so many different recruitment methods to try to capture as broad and inclusive a group of participants as possible.

Our recruitment approaches are outlined below:

1. Review of Medical Records to determine eligibility of potential subjects: All potential subjects We will access the VA VINCI administrative database to help identify Veterans their medical record reviewed to determine eligibility. This includes identifying Veterans with psychosis spectrum diagnoses at GLA: schizophrenia, schizoaffective disorder, bipolar disorder with psychotic features, depression with psychotic features, schizophreniform disorder, unspecified schizophrenia spectrum, and unspecified psychotic disorder. We will request the following kinds of data from the CDW database: real SSNs, attending a GLA mental health appointment within the past 12 months. We may review CPRS to assess diagnostic and medical history and past and current medications, as well as current contact information (mailing address, telephone, email) for the Veteran. For those identified through the MIRECC repository or referred by providers, records will be reviewed prior to sending the mailed recruitment materials or calling the Veteran. All others will have the MR review completed after the interested Veteran contacts the study team.

   A HIPAA Waiver will cover this MR review. HIPAA Authorization will be obtained through the combined ICF/HIPAA form.

2. Flyers will be posted in acceptable locations at VA clinics, including affiliated VA GLA CBOCs, to recruit patients. We will also post at these locations with the research team's contact information for interested Veterans/potential research subjects. The flyers I will contain the research team's contact information for interested Veterans/potential research subjects. The research team will ask for permission from appropriate authorities prior to posting the flyers.

3. MIRECC Treatment and Clinical Neuroscience Repository (Marder #0042): We will access this repository to help identify Veterans with psychosis spectrum diagnoses at GLA. This repository contains Veterans who have participated in past studies and have agreed to be on a list for consideration for future studies. The Veterans on the Marder repository list who are deemed eligible will be mailed/emailed a recruitment letter and study information sheet (depending on their preference). In the letter to the Veterans on the Marder repository list, it will state that the Veteran can contact the recruitment office if they are interested in participating in the study. They will also be informed they can call the recruitment office to opt out of participating in the study and to request no further contact by study staff. Within two weeks of receiving the letter, the research team will call any Veteran who does not opt out to schedule a virtual appointment. The letter will inform the Veteran that if the recruiters don't hear from them, they will give them a call in 2 weeks to follow up. Our staff will not contact any Veteran more than 3 times total (1 letter and 2 phone calls).

4. Direct recruitment: Veterans will be directly recruited from HUD-VASH and outpatient mental health clinics within VAGLAHS, the Domiciliary, CPRS, affiliated VA GLA CBOCs. A research team member will hand out recruitment letters and flyers with an opt-in phone number for Veterans to call and answer questions about the study. Interested Veterans will call the study and if amenable, will answer screening questions before being consented. We have well-established connections to several VA clinics as well as HUD-VASH staff. These relationships have been built on a demonstrated respect of their policies. We only recruit at locations where the staff members have been fully informed about the type of research we perform, the associated risks and benefits, and have approved our recruiter's presence. Veterans who speak with a study team member and request that the Q&A be emailed, will provide their email address. The Q&A will be received as an attachment or embedded in the email text.

5. We have created a "Dear Provider" letter about the study that will be emailed to providers from clinicians at the relevant VA clinics from which we will recruit (HUD-VASH employees and outpatient mental health clinics within VAGLAHS, affiliated VA GLA CBOCs to solicit referrals of potentially appropriate subjects. We will also present the study at clinic huddles. Providers who identify initially eligible and interested Veterans (i.e., those who consent to be contacted by the research team) will reach out to the study team and securely pass on the name and contact information of the interested Veteran to our research team via encrypted email or phone. The study will confirm full eligibility through medical record review before calling the Veteran.

6. Social Media: We will post IRB-approved ads on Craigslist, the VA GLA Facebook, and Twitter websites. Social Media: As with the flyer, the posts will have the contact information for the study team and interested Veterans will call the study line. The social media advertisement is uploaded in the IRB package.

7. Phone calls: Veterans who are referred by their provider, those who leave a message with the study team requesting a call back, and those who on the Marder repository list who receive a recruitment letter and who do not opt out of further contact will be phoned at the number on file (or the preferred

number, if given). Up to 3 attempts will be made to contact the Veteran. The team will use a screening script to determine eligibility for those whose records have not yet been reviewed.

6.2. Informed Consent Procedures

For Veterans who express interest from any of the recruitment strategies listed above, a phone appointment will be made to assess eligibility and request agreement to participate. The study information sheet will be mailed or emailed to them (depending on their preference) so that they receive written information about the study.

For all study activities, Veterans will be asked to be in a quiet, private location. At the screening appointment, a brief eligibility script will take place over the phone. The script only elicit yes or no answers. Only the eligibility criteria number will be documented. It will include questions about their mental health history and whether they experience psychosis, including whether their experience of psychosis was substance-induced. Veterans will just respond with a "yes" or "no," and the recruiter will either proceed with next steps or will explain that they do not qualify for the study. If they are not eligible, their participation will end at this time.

If the subject is eligible and continues to be interested in the study, the research team will provide additional details about the study. Subjects will be encouraged to ask questions about the study, so that the research team can address any concerns they may have. The research team will be very careful to emphasize the voluntary nature of participation, and that whatever decision the person makes will have no bearing on their medical care or relationship with the VA GLA. They will also inform the Veteran that final eligibility will be determined by the team and will schedule a call back to inform them of whether they can participate and to obtain consent.

To further determine the subject's eligibility, the research team will review the subject's medical records (if not done prior to the call). If the subject continues to appear appropriate for the study, final determination of study eligibility will be established at the weekly research team case review. If they are not eligible, their participation will end at this time.

Capacity to sign consent will be assessed before the Veteran is consented. All subjects in this study will have the capacity to give informed consent. If there are concerns regarding comprehension of information specific to the study (i.e. purpose, procedures, risks, protections), during the informed consent process, the researcher will assess for capacity using the form "Evaluation of Capacity to Sign Consent." The researcher will ask the subject a series of questions about the study, such as what they are to do if they no longer want to participate, or what they would do if they experience distress during the study. Subjects who do not have the capacity to give informed consent (those who cannot successfully understand the consent form and respond to the questions in the Evaluation of Capacity to Sign Consent) will not be included. We will not include subjects who are under conservatorship. Subjects will be informed that participation in research is voluntary and refusal to participate will not jeopardize their care at their institution. Subjects who do not want to be video-recorded in group sessions will not be included in this study. There are no waivers or modifications of treatment for research purposes.

Consent will be obtained using virtual signature software (Docusign). Eligible participants will receive the Docusign consent forms via email prior to their interview to read and review their rights. During their scheduled interview date, research associates will go over the consent form and review it with the participant. After reviewing the document, researchers will ask the participants if they have questions or concerns. After answering their questions, research team members will then ask the participants to go ahead and sign the documents emailed earlier via Docusign and return the forms. After the form is signed and participant is officially consented, they are eligible to participate in all study actives. If a participant is having technical

difficulties signing the document, the research associate will guide them on how to complete the process. As all research activities are completed virtually, no paper consent form will be available, only Docusign.

Eligible Veterans will then be assigned to a VVV group. Once recruitment for this group reaches 8 Veterans, the group will be scheduled to begin. The subject will then be scheduled to participate in the next part of the study procedures. At that time, they will also receive the contact information for support group facilitators and will be given a brief tutorial on using VA approved video conference software and the weekly digital survey, as needed.

6.3. Waivers

All data collection for this study is done virtually. We are requesting a waiver of HIPAA for screening and initial recruitment purposes to access data from the MIRECC Treatment and Clinical Neuroscience Repository (Marder #0042), the VA VINCI database, and CPRS. Pre-recruitment screening and recruitment could not occur without this waiver because it would not be possible to identify an adequate number of eligible study subjects without the PHI listed below. The following PHI from the MIRECC Treatment and Clinical Neuroscience Repository (Marder 0042) may be accessed to assist with initial eligibility determination for subjects enrolling in this project: Name, probable psychiatric diagnoses; Vet or non-Vet; alcohol / substance use disorder (if any); current medications (if any); head trauma (if any), loss of consciousness (if any), and neurological conditions (if any), other medical conditions (if any). We will request the following kinds of data from the VINCI database: real SSNs, mental health stop codes containing relevant mental health diagnoses as well as attending a GLA appointment within the past 12 months. We may review CPRS to confirm psychiatric diagnostic and medical history and past and current medications, as well as current contact information (mailing address, email, phone number) for the Veteran.

6.4. Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Veteran status and medically eligible for VA services
2. Subjective experience of psychosis including hallucinations and/or delusions
3. Ability to join a group remotely via videoconference or telephone
4. English comprehension
5. Ability to provide signed consent.
6. Willingness to be video-recorded during group sessions.

Exclusion Criteria:

1. Previous attendance of a VVV group
2. Significant neurological or medical disorder
3. Psychosis experienced is due to substance use only and is not chronic or present in the absence of substance use
4. Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the participant or quality of the data
5. Unwilling or unable to access groups remotely
6. Unwilling to be video-recoded during group sessions.

7. Participant Protections

7.1. Privacy and Confidentiality

The privacy and confidentiality of subjects will be maintained at all times during the study. For assessments and documentation of consent which are done remotely, Veterans will be asked to be in a quiet, private location. Study data will be linked to a specific subject by a code rather than a direct identifier. While data may contain some protected health information, only someone possessing the code can link the data to a particular participant. Participants are assigned a unique subject number at the time of their enrollment in the study.

Given the observational nature of recorded experimental group sessions, it is critical for the research team to be able to track each subject's progression through the group, including their interactions with Veterans and facilitators. For these reason, individually identifiable information – including video images, voice, and participants first names – will not be separated from the data and will be retained on video recordings, audio transcripts, and fieldnotes through the close of data collection and analysis. This is common practice in anthropological/ethnographic research methods that involve intensive social interactions among participants, and the research team is highly skilled in working with this form of data.

For all subjects there will be only one electronic document linking the subject number codes with identifiers (i.e. name), stored at the VA on a secure server, encrypted and password protected. Only the PI, Co-Investigators, recruiters and project coordinators will have access to data with identifiers.

Electronic data with identifiers will be password protected, encrypted and stored on the secure VA network, and no data with identifiers collected at the VA will leave the VA protected environment. All video /audio recordings will be saved on the secure VA research network and will not be shared beyond the research team. Assessment data will be entered directly into REDCap, behind the VA firewall, and will contain no identifiers—only the study ID. Datasets downloaded from REDCap will be stored on the research server. No hard copies of data with PHI will be collected or produced. VA approved software for audio recording will be used for individual interviews, and VA approved software for video recording group sessions will be used. This data will be stored behind VA encrypted firewall designated to IRB approved VA research staff.

7.2. Risks and Benefits

Involvement in the Pilot Study involves some risks. Participants have the option to decline participating with no repercussions. Risks are comparable to participation in usual clinical care at the VA and in circumstances of daily living. These risks include fatigue, increased distress and frustration from topics discussed, and loss of privacy/confidentiality. See detailed definitions of each risk below.

Risk of Fatigue: There is a risk that Veterans will find the assessment interviews or group sessions to be tiring.

Risk of Distress and Frustration: There is a risk that the assessment interviews or group sessions may stir up challenging emotions that cause Veterans distress and frustration.

Risk of Loss of Privacy / Confidentiality: There is a risk that the private information Veterans share may be compromised and negatively impact their reputation among friends or family, VA staff or leadership, or otherwise lead to adverse financial or emotional consequences.

Study participants may gain improved understanding into their experiences through engaging in support groups and assessment batteries. Veterans in the active intervention condition will have a dedicated

opportunity to explore their experiences and understand themselves better, which may reduce their distress due to psychosis and improve social integration. Participants in the HM group will learn about healthy lifestyle choices which could improve their overall wellbeing. The intervention has the potential to benefit Veterans throughout GLA and beyond if it proves to effectively reduce distress related to symptoms of psychosis and reduce self-stigma and foster community integration. If the research is successful, the VA will have another tool to improve the lives of Veterans experiencing psychosis.

7.3. Risk mitigation measures

Participation is voluntary. If subjects become uncomfortable during any part of a study, they may decline to participate in any task or withdraw from the study entirely. The PI and co-investigators will be available to all subjects, family members, and clinicians for any concerns that arise regarding the study. Although this protocol does not contain procedures that would be expected to increase suicidal ideation or suicide risk, it is not uncommon for Veterans with SMI to have periods of suicidal ideation. Some of the measurement procedures may identify such suicidal ideation. If a Veteran study participant is in distress, an emergency protocol will be followed. In addition, the PI is a psychiatrist and, if deemed appropriate, will call the individual separately to check in with them and to assess the need for further intervention, such as having the Veteran call the VA Crisis Line, to present to the emergency room, or calling 911 to have emergency personnel come to the Veteran.

What follows is a list of potential risks that may occur due to participation and corresponding mitigation measures.

Risk of Fatigue: Subjects will be encouraged to take breaks as necessary during group sessions or assessments to alleviate fatigue. We will monitor nonverbal signs of fatigue and inquire about how the subject is feeling during the assessment at regular intervals to minimize any strain they may be experiencing. Any time the subject experiences undue strain or fatigue, the procedures will be halted and another time of evaluation can be scheduled. Any time the subject shows agitation or frustration, the assessment will be stopped, and a clinician will be available to talk to him/her. If any group participants need additional support during a group session, one of the 2 group facilitators can call them individually to check in with them.

Risk of Distress and Frustration: Subjects will be encouraged to take breaks as necessary during assessments and/or group sessions. We will monitor nonverbal signs of distress and inquire about how the subject is feeling during the assessment at regular intervals to minimize any strain they may be experiencing. Subjects are informed they may decline to answer any questions or to stop the interviews at any time. Any time the subject experiences undue distress, the procedures will be halted, and another time of evaluation can be scheduled. Any time a subject shows agitation or frustration, the assessment will be stopped, and a clinician will be available to talk to him/her and make a referral, if needed. If any group participants need additional support during a group session, one of the 2 group facilitators can call them individually to check in with them. If appropriate, the study emergency protocol will be administered for Veterans experience extreme distress or who indicate suicidal ideation (see Emergency Protocol document)

Risk of Loss of Privacy / Confidentiality: Participation in the study presents a risk of loss of privacy and confidentiality, particularly with respect to potentially embarrassing or harmful personal health information. This includes detailed and sensitive information regarding alcohol and drug use, and psychiatric symptoms. Potential release of such information could have serious ramifications for employment and insurability. To protect against this, all data are electronic and are password-protected and stored on the secure VA network. Confidentiality during Internet communication

procedures/video calls cannot be guaranteed. However, we will take every precaution to safeguard subjects' information.

Electronic data are password-protected and stored on the secure VA network. All electronic data will be stored on VA server or the VA-approved Research Electronic Data Capture (REDCap) system, a secure, HIPAA compliant, encrypted storage system with password protection for managing research. All research staff at VA GLA must complete a training and credentialing process with the before beginning to work in the lab. This process includes privacy education and training which must be renewed annually.

8. Data Sources and variables

8.1. Secondary Sources

Secondary sources will only include CPRS, CDW and the MIRECC Treatment and Clinical Neuroscience Repository to establish eligibility. This data is covered by a HIPAA Waiver. See 6.3 for variables.

8.2. Primary sources

Veterans will participate in a VVV group, which meet for 12 consecutive weeks for one hour. All participants will be asked to complete brief surveys at the end of each group via an emailed REDCap survey, to assess the acceptability of the group.

Veterans in the VVV group will participate in 2 assessments: pre-intervention and post-intervention.. At pre-intervention, there will be a baseline psychosocial history assessment (10 minutes) as well as a pre-intervention qualitative interview (45 minutes). The following surveys will be administered at both of the assessments: BPRS, PSYRATS-AH, PDI, MACS, BAVQ, GSE, ISMI, QPR, IMR, ULS-20, RFS, SUQ, and Rovai (65 minutes). The CSQ-8 will be administered at the post-intervention assessment only (5 minutes). Follow-up qualitative interviews (45 minutes each) will be administered at post-intervention.

In addition brief surveys will be administered following each intervention session. The chart below lists all data collection events.

Pre-intervention Assessment
-Psychosocial history assessment -Qualitative interview -Assessments (BPRS, PSYRATS-AH, PDI, MACS, BAVQ, GSE, ISMI, QPR, IMR, ULS-20, RFS, SUQ, and Rovai)
Video-recorded sessions for 12 weeks
Weekly Surveys (12 total)
-Intervention group survey
Post-intervention Assessment
-Qualitative interview -Assessments (BPRS, PSYRATS-AH, PDI, MACS, BAVQ, GSE, ISMI, QPR, IMR, ULS-20, RFS, SUQ, and Rovai) -CSQ-8

9. Data Analysis

Since this study is designed to assess whether the proposed intervention can be successfully implemented in the target population, most of the analyses will yield descriptive data. We conservatively estimate 25% attrition based on our previous pilot and other VA treatment studies. We therefore expect analyzable data for 18/24 participants enrolled.

Feasibility will be assessed based on recruitment, retention, and attendance. Specifically, we target (a) a retention rate (% of subjects who complete the post-intervention assessments) of at least 80% and (b) attendance at 80% or higher of sessions by a minimum of 85% of participants.

Acceptability will be assessed using the brief evaluations after each session and the CSQ-8 at 12 weeks. A total of 24 or higher (corresponding to a Likert-scale score of at least 3 out of 4 on each item) in the CSQ-8 will be considered reflective of acceptability. We target 75% of participants attaining this threshold.

Our primary outcome variables will be distress due to psychosis (PSYRATS-AH, PDI, MACS, BAVQ), self-efficacy (GSE), and social functioning (USL-20 and RFS) as these factors are highly associated with our ultimate target of downstream social integration and will serve as the outcome measures in a subsequent efficacy trial. The proposed study window is too short to directly evaluate social integration itself. We will also evaluate secondary outcome variables, such as self-stigma (ISMI), recovery (QPR, IMR) and service utilization (SUQ), which could mediate primary outcome variables.

Qualitative interviews will be audio recorded and professionally transcribed. Templated summaries of qualitative interviews will be made immediately following data collection, as a part of rapid ethnographic analysis methods. Rapid templated summaries and transcripts from semi-structured interviews will be analyzed thematically using qualitative data analysis software following a grounded theory approach that relies on thematic analysis. This approach identifies, analyzes, and interprets patterns of meaning (or "themes") within qualitative data. Themes from Veteran participants may include experiences and conceptions of psychosis, coping strategies, lessons learned from groups, and suggestions for feedback and improvement. Observational notes from all sessions will also be analyzed to identify content of group sessions, such as perspectives of psychosis or coping strategies, or process, such as instances of connection between facilitators and participants and amongst participants, validation, support, or conflict. Codes used in interview templated summaries, interview transcripts, and session notes will be developed into a codebook, which will then be applied across all qualitative data components. We will compare the qualitative data from both groups to see if participants in the two groups experiences similar kinds of changes.

10. Data Security Plan

10.1. Transmission and transportation of data

The ID number that is assigned to enrolled subjects will be used in place of identifiers for all data collected. Audio files from qualitative interviews will not include any individually identifiable information other than the voice and perhaps first names. Transcripts will be redacted of all identifying information. Approved staff from the Veterans Health Administration Salt Lake City (VHASLC) will transcribe the audio files. The VHASLC has a Centralized Transcription Services Program (CTSP) available to VA sites and monitored by their own IRB. The audio recordings to be transcribed by VHASLC staff will be labeled by the subject's unique alphanumeric code and saved behind the VA firewall in the study's secure shared project folder on the research server.

While intervention sessions and many assessment interviews will be conducted online, data will be collected through interviews. We will use a VA approved video conferencing platform for VVV groups and for interview assessments. Participants will be able to call in via telephone if they do not have devices with screens.

Assessment data will be entered directly into REDCap, behind the VA firewall, and will contain not contain any identifiers—only the study code. Datasets downloaded from REDCap will be stored on the research server. Recordings of group sessions will be stored on the secure VA research server.

10.2. Sharing and transfer of data

The VHASLC transcription staff will be given access to a sub-folder within the study's secure project folder. Approved study staff will place a copy of the audio files in this folder for an approved VHASLC transcriptionist to access for the purposes of transcription. The VHASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses.

Qualitative interviews, especially the pre-intervention interview, entail Veterans sharing their personal history and understanding of their experiences. They often share meaningful experiences and information. In our previous pilot study, a Veteran participant requested a copy of his qualitative interview. We would like to request permission to share typed transcripts of qualitative interviews with the subjects of those interviews if they are requested. The interviews will not reveal any PHI beyond what the interviewees themselves share with us.

10.3. Storage of, access to and destruction of data

The VA MIRECC at the VAGLA maintains a secure research server on the VA internal network which will be utilized for this study. This server has space that project staff will use to store, analyze, and back up sensitive data. A series of identification (ID) numbers will be generated for enrolled subjects. Once a subject is recruited and consent is obtained, research staff will assign an identification number to the subject. VA research staff will maintain a link file for all subjects. For patient participants, the link includes ID number, subject name, and last 4 of social security number. The link file will be kept on the VA MIRECC research server, behind the VA firewall, separate from coded data. Only staff that are listed on IRB approved project staffing lists, are credentialed by Research, have completed all required data security training, and are approved by the VA MIRECC will be given access to the project folder on the server. Staff may only access this folder by using their VA login behind the VA firewall. All sensitive information will be retained at the VA.

All electronic assessment data will be stored on the VA-approved Research Electronic Data Capture (REDCap) system, a secure, HIPAA compliant, encrypted storage system with password protection for managing research. All lab staff at VA GLA must complete a training and credentialing process with the before beginning to work in the lab. This process includes privacy education and training which must be renewed annually.

All information linking subjects to their data will be destroyed according to the VA rules and regulations set forth in the RCS 10-1 guidelines. by the local IRB and United States National Archives and Records Administration (NARA) Guidelines. Before analysis of the data, all identifying information will be removed from the data. No information that could identify study subjects will be published or presented. Information gathered during the project will be used only for scientific, educational, or instructional purposes.

11. Timeline

Recruitment for the Pilot Study will start immediately after IRB approval is granted. Groups will be created on a rolling basis, with a new group created as soon as 8 Veterans are recruited. Data analysis will be conducted on an ongoing basis and will conclude at the end of the first quarter of FY25 or as soon as 3 groups have run to completion, as this will depend on recruitment rates. Manuscript preparation will begin in February 2025 and conclude in December 2025.

12. Resources

12.1. Funding

VA Rehabilitation Research & Development Small Projects in Rehabilitation award (SPiRE).

12.2. VA resources to be utilized

Laboratory:

Office and for this project are located at the VA Greater Los Angeles Healthcare System (GLA) Mental Health Research Building (Building 206). This building houses the VISN 22 Mental Illness Research, Education, and Clinical Center (MIRECC) and Toward Homelessness Recovery and Integration for Veterans (THRIVe). The MIRECC has conducted numerous successful research projects at this site. Office space is also available in Building 206 for the research team. Members of the research team have their main offices in the GLA Mental Health Research Building (Building 206).

VA Mental Illness Research, Education, and Clinical Center (MIRECC)

The VISN 22 MIRECC (SR Marder, Director) has a mission that focuses on improving functional outcomes of Veterans with psychotic mental illnesses. The MIRECC provides infrastructure to clinical research projects at the VA Medical Centers at Los Angeles, San Diego, and Long Beach. Dr. Gabrielian is a faculty member of the MIRECC and Co-Director of the MIRECC Health Services & Implementation Unit (HSIU). Dr. Kalofonos is a core investigator with the MIRECC HSIU.

THRIVe

THRIVe serves as an interdisciplinary center to study community integration in homeless Veterans. The mission of this THRIVe is to understand and improve community integration in homeless Veterans and it consists of: 1) translational and intervention research, 2) training of young investigators and clinicians, 3) and facilitation of new research projects by supporting staff for subject recruitment. Investigators in the THRIVe have expertise in a range of research areas, including: translational cognitive neuroscience, outcomes research for community functioning, clinical trial methodology, psychiatric health services, and advanced biostatistics. THRIVe has allocated office and testing space on the 1st floor of Building 206.

Computers:

Twelve desktop computers (eleven for the research staff and one for the PI).

Office:
Office space exists in the MIRECC Unit (Building 206) for project staff.

12.3. Qualifications of Study Team Members

Ippolytos A. Kalofonos, MD, PhD, MPH, PI is responsible for the overall design and execution of this project. He will oversee and coordinate administration of subject enrollment, data collection, and interpretation of results. Dr. Kalofonos will have responsibility for cohesion across the different aspects of this project, and along with the co-investigators, for the presentation and publication of results. He will meet with co-investigators Drs. Gabrielian and Glynn and project support staff at weekly research team meetings to discuss implementation, monitor progress, and aid in ongoing problem solving and quality assurance reviews of the data. He will also supervise and advise support group facilitators and train and manage project staff. Dr. Kalofonos is the assistant director of the Psychosis Clinic at WLAVA where he prescribes medication, practices CBT for psychosis (CBTp), supervises trainees. He is trained in diverse therapeutic modalities for psychosis including advanced CBTp and Hearing Voices facilitation. He is a core investigator of the Desert Pacific VA Mental Illness Research, Education and Clinical Center (MIRECC) Health Services Unit (HSU), an investigator of the VA/UCLA Center of Excellence for Veteran Resilience and Recovery, and an affiliate investigator of the Center for the Study of Healthcare Innovation, Implementation and Policy (CSHIIP). He is an Assistant Professor in the Center for Social Medicine and the Humanities in the Department of Psychiatry and Biobehavioral Health at the David Geffen School of Medicine at UCLA. He is also a medical anthropologist with expertise in qualitative methods and is affiliated with the UCLA Department of Anthropology and the UCLA International Institute.

Sonya Gabrielian, MD, MPH, Co-I is a psychiatrist at VA Greater Los Angeles (GLA) Healthcare System; a health services researcher at the VA Los Angeles Health Services Research & Development (HSR&D) Center for the Study of Healthcare Innovation, Implementation and Policy (CSHIIP), the Desert Pacific VA Mental Illness Research, Education and Clinical Center (MIRECC), and the National Center of Homelessness among Veterans (NCHAV); and an Assistant Clinical Professor at the University of California, Los Angeles (UCLA). She is the Health Services Unit Director of the Desert Pacific MIRECC and the VA Research Director of the VA/UCLA Center of Excellence for Veteran Resilience and Recovery. She is a VA HSR&D Career Development Awardee (CDA, 2017-2022) focused on implementation approaches to improve community functioning for homeless-experienced Veterans with serious mental illness, substance use disorders, and other vulnerable populations. Dr. Gabrielian has extensive experience in health services research and implementation science approaches to improve community functioning for Veterans with SMI/psychosis. Dr. Gabrielian will advise Dr. Kalofonos and his team on data analysis and publication of study findings. Dr. Gabrielian has worked with Dr. Kalofonos for six years on several research projects including the initial pilot of the Veterans Voices and Visions groups and a mixed-methods evaluation of a VA intervention for unhoused Veterans.

Shirley Glynn, PhD, Co-I is a clinical research psychologist at the VA Greater Los Angeles Healthcare System Los Angeles and a research psychologist at the Semel Institute of Neuroscience and Human Behavior. She is an expert in psychosocial interventions for SMI/psychosis and in stakeholder engagement, as well as the ongoing training and supervision of mental health clinicians. Dr. Glynn has been directly involved in the design of the project and will continue to advise Dr. Kalofonos on ongoing problem solving related to program development on a monthly basis. Dr. Glynn has worked with Dr. Kalofonos for 8 years.

Erica Fletcher, PhD, Co-I will support the overall design and execution of this project. She will coordinate administration subject enrollment, participate in all aspects of data collection, and support the interpretation of results. She will contribute to weekly research team meetings to discuss implementation, monitor progress, and aid in ongoing problem solving and quality assurance reviews of the data. She has worked with Dr. Kalofonos for

3 years as a research assistant on the initial phases of this study and is familiar with the research protocol, including the data collection and data analysis plan. She will support subject recruitment and enrollment, conduct qualitative interviews and other assessments, and contribute to study coordination, data analysis, and manuscript development.

Mariam Nazinyan, **MPA** will serve as project coordinator. She is a Research Associate at UCLA Semel Neuropsychiatric Institute and Mental Illness Research, Education and Clinical Center at the Greater Los Angeles Veterans Affairs (VA). At UCLA, she has worked on research studies that focus on juvenile justice, child welfare, mental health and commercial sexual exploitation of youth in Los Angeles County. At the VA, Mariam coordinates and hosts stakeholder advisory boards, including a Veteran Engagement Group, to support research and innovation to address Veterans with complex needs including mental, substance use and physical health disorders, as well as homelessness and community integration needs. She will support recruitment and enrollment efforts, data collection, and data storage and management. She will also participate in weekly research team meetings and oversee all administrative issues.

Susanna Friedlander, PhD will serve as a research assistant and fidelity assessor. In this role, she will participate in weekly research meetings and support the implementation of a robust training structure, via feedback in booster sessions and Community of Practice meetings. She is a skilled clinical psychologist and has served as a VVV co-facilitator with Dr. Kalofonos since 2018. She has extensive experience in recovery-oriented community psychology, including work with peer support specialists. Dr. Friedlander has been an advisor on this project for 5 years and has been integral to its growth and development.

Jade Hawk, BS will serve as a research assistant, primarily as a recruiter. She will assist all recruitment duties, including those involving the use of the MIRECC Repository (Marder 0042), CPRS, and VINCI. She will also screen subjects via recruitment calls to determine eligibility.

Ryan Vane, BS will serve as a research assistant. Mr. Vane will work as a clinical interviewer and is certified by within-lab training to perform several diagnostic, symptom assessment, functional capacity and other clinical interviews. He is well trained to administer these assessments as a part of his work with PIs at the MIRECC THRIVe Center.

13. Relevant publications

1. Fletcher EH, Kalofonos I. Adaptation of a Hearing Voices Group Facilitation Training for VA Stakeholders. *Community Ment Health J*. 2022 Nov; 58(8):1592-1604.

2. Kalofonos I, Zito M, Fletcher E, Calderon R, Nazinyan M, Kern R. A Pilot Trial Examining the Effects of Veteran Voices and Visions, an Adaptation of Hearing Voices Groups for a Large Public Health System in the United States. International Journal of Social Psychiatry. 2023: 1-10.