

STUDY PROTOCOL

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Pilot trial protocol: community intervention to improve depressive symptoms among Peruvian older adults

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Abstract

Background Non-pharmacological interventions have proven effective at alleviating depression and anxiety symptoms in older adults. Methodological refinement and testing of these interventions in new contexts are needed on a small scale before their effectiveness and implementation can be evaluated. The purpose of this pilot study is to assess the feasibility of a future large-scale trial comparing an adapted mental health multi-component evidence-based intervention (VIDACTIVA) versus standard care for older adults experiencing depression symptoms in urban, resource-limited settings in Lima, Peru. Furthermore, this study will explore the acceptability, feasibility, and fidelity of implementing the intervention.

Methods We will conduct an open-label, mixed methods pilot feasibility study with two parallel groups. A total of 64 older adults, stratified by sex, will be randomized at a 1:1 ratio to either the “intervention” or “control.” Participants will be followed for 22 weeks after enrollment. Those in the intervention group will receive eight VIDACTIVA sessions administered by community health workers (CHWs) over 14 weeks, with an additional eight weeks of follow-up. Participants in the control group will receive two psychoeducation sessions from a study fieldworker and will be directed to health care centers. Standard care does not involve CHWs. We will evaluate screening rates, recruitment strategies, retention rates, the acceptability of randomization, and assessments. Additionally, we will assess preliminary implementation outcomes—acceptability, feasibility, and fidelity—from the perspectives of CHWs (interventionists), older adults (main participants), older adults’ relatives, and healthcare professionals.

Discussion If the findings from this feasibility trial are favorable, a fully powered randomized controlled trial will be conducted to evaluate both the effectiveness and implementation of the intervention. This research will make a substantial contribution to the field of mental health in older adults, particularly by emphasizing a meticulous examination and documentation of the implementation process. By doing so, this study will offer valuable methodologies and metrics for adapting and assessing mental health interventions tailored to the unique needs of older adults in resource-constrained contexts and diverse cultural settings.

Trial registration The current trial registration number is NCT06065020, which was registered on 26th September 2023.

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Keywords Depression, Anxiety, Old age, Feasibility studies, Implementation, Adaptations, Community health workers, Loneliness

Background

Depression is highly prevalent among older adults [1] and affects approximately one in three older adults worldwide [2]. Depression often coexists with anxiety symptoms [3] and are linked to adverse outcomes such as falls, disability, cognitive impairment, dementia, suboptimal management of chronic conditions, and an increased risk of suicide [4–6]. Loneliness frequently accompanies depression [7] and is independently associated with negative health consequences, including mortality [8].

Despite the availability of effective non-pharmacological treatments such as behavioral activation and problem-solving therapy for late-life depression and anxiety symptoms [6, 9, 10], these therapies often remain out of reach for those in need. The scarcity of mental health professionals, including psychologists and psychiatrists, is a significant barrier, particularly in low- and middle-income countries (LMICs) [11, 12]. To address this challenge, the World Health Organization (WHO) promotes task-shifting and task-sharing interventions that integrate non-specialists into routine healthcare delivery [13]. Task-shifting involves redistributing tasks from highly trained professionals to individuals with less extensive training, including non-professionals to maximize resource efficiency. Task-sharing underscores the importance of collaborative care within a team of providers, with mental health specialists transitioning from direct service providers to trainers, supervisors, and consultants [14]. Task-sharing interventions that tap into community resources, such as community health workers (CHWs), not only expand the workforce but also reduce mental health stigma and can provide essential support to older adults [15, 16].

In Peru, despite its classification as an upper-middle-income country, a significant gap exists between the demand for and supply of mental health services, with historical limitations in centralized care in psychiatric hospitals. However, in the last 12 years, there has been an increase in political will highlighted by the approval of Law 29889, which guarantees rights and promotes comprehensive mental health reform. This included the creation of community mental health centers (CMHCs) to provide specialized mental health care to communities, strengthening primary care [17–19]. Typically, CMHCs are staffed with specialized mental health professionals, including psychiatrists and psychologists, while the primary care centers may occasionally have psychologists on their teams. CMHCs offer care for moderate and severe

cases while providing technical support to primary care centers [18].

Among Peruvian older adults with depression, more than 75% do not receive any form of treatment [20]. Psychiatrist-to-population ratio is 3 per 100,000 people, and the psychologist-to-population ratio is 10 per 100,000 [21]. Given these limited structural and human resources for mental health, there is an urgent need for innovative approaches to delivering mental health care to older adults.

We present a protocol for a pilot feasibility trial of a community-based mental health multi-component intervention designed to alleviate depressive symptoms among Peruvian older adults living in urban, resource-limited settings. This trial builds upon previous community-level studies that enhanced our understanding of older adults' perceptions of mental health and their specific needs in the Peruvian context [22, 23]. In alignment with the community-based approach endorsed by the Peruvian Ministry of Health and the WHO, we iteratively adapted components of the Program to Encourage Active Rewarding Lives (PEARLS), an evidence-based intervention for underserved older adults with depression developed in the USA [24, 25], to create the *Vidas Activas y Valiosas (VIDACTIVA)* program tailored to the Peruvian context. The primary components of VIDACTIVA include problem solving [10], behavioral activation [26], and psychoeducation provided by CHWs under the supervision of a clinical team.

The objective of this protocol is to evaluate the feasibility of conducting a larger-scale clinical trial while simultaneously assessing preliminary implementation and clinical outcomes. We will assess the acceptability and feasibility of the intervention from the various perspectives of those involved (CHWs, older adults, family members, and health professionals) and evaluate the fidelity of intervention delivery by CHWs within a resource-constrained urban setting.

Methods

Study setting

Our study will be conducted in Villa El Salvador (VES), an urban district situated to the south of Lima. VES is home to a population of 432,170 residents, among whom 7% are aged 60 years and older [27]. The majority of older adults in this area are Andean migrants who initially settled here during 1970s. As of 2022, the poverty rate among older adults in this district was high,

reaching 28%, with an estimated monthly income averaging less than 358.60 Nuevos Soles (approximately 95 US dollars) [28]. The life expectancy in VES is slightly below the national average, at 72.8 years, compared to the country's average of 76.9 years. Within the older adult population, 20% of respondents reported experiencing illiteracy, and half lacked access to a pension [29]. In VES, in 2023, there were three CMHCs and 16 primary health centers serving the community. Both primary health centers and CMHCs have CHWs, who are community members that volunteer to support various health activities. The size of CHW networks and their specific duties and responsibilities can vary significantly depending on the health center.

Study design and sample size

Our study adopts a mixed-method feasibility pilot trial, employing an open-label design with a type 2 implementation-effectiveness focus and featuring two parallel groups. We plan to randomize a total of 64 older adults (60 years and older) stratified by sex and dividing them equally into “control” and “intervention” groups. The decision to include 64 participants was influenced by the availability of pairs of trained CHWs, who will be responsible for delivering the intervention to a group of 32 participants each. The trial is scheduled to run for a duration of 22 weeks from the start of enrollment. For a visual representation of our study design, please refer to Fig. 1.

Study participants

Our study encompasses four distinct participant categories:

Older adults

This group will be the focus of our intervention, and they will be randomized into either the intervention or control

group. Older adults will have to meet the following inclusion criteria:

- Older adults ≥ 60 years old with the capacity to provide consent.
- Current residence in VES, Lima, Perú.
- Depressive symptoms, determined by a score equal to or greater than 6 on the Patient Health Questionnaire-9 (PHQ-9).

The exclusion criteria for will be:

- Previous self-reported diagnosis of bipolar disorder, dissociative disorder, psychosis, or dementia.
- Alcohol abuse, using the 4-item CAGE screening questionnaire. Individuals with a score equal or greater than 2 will be excluded [30].
- Cognitive impairment based on six-items screener [31]. The score ranges from 0 (worst) to 6 (best). If participants score less than 3, they would be excluded.

Relatives or family members

This category comprises family members or relatives of the older adult participants. Preliminary work has revealed that older adults do not live alone and that family members can play significant roles as both facilitators and/or barriers to the acceptance of mental health care [22, 23]. Their involvement will be on sharing their perspectives regarding any observed changes in the older adult receiving the intervention and identifying strategies for engaging relatives in potential future family-oriented interventions. To be eligible for participation in this category, individuals must meet the following inclusion criteria:

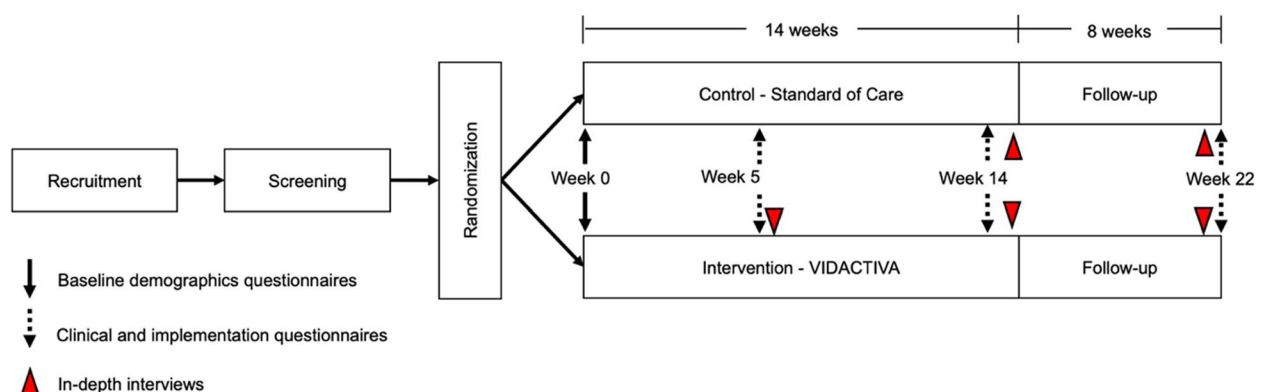


Fig. 1 Schematic of the protocol study design and assessments

- An adult aged 18 years or older with the capacity to provide informed consent.
- Reside in the same household as an older adult who is participating in the intervention group.
- Be referred by an older adult who is actively participating in the intervention group.

Health professionals

This category encompasses a diverse group of health professionals, such as nurses, technicians, social workers, psychologists, and psychiatrists, who are actively engaged in providing care or holding managerial roles within the healthcare system. Their pivotal role in this study involves offering valuable insights, perspectives, and opinions concerning the delivery of the intervention. To be eligible for participation in this category, individuals must meet the following inclusion criteria:

- Be currently employed at primary health care centers or community mental health centers or within the local Ministry of Health administration in the district of VES.
- A minimum of 6 months of work experience in the district of VES.

Community health workers

CHWs will play a crucial role in delivering the intervention. Fourteen CHWs will actively participate in this pilot trial. These CHWs have undergone comprehensive training totaling 27 h, carefully designed, and conducted by our clinical team. The training curriculum was centered on the nuances of mental health in older adults and on the specific components of the intervention. Additionally, these CHWs were actively engaged in the iterative adaptation phase preceding this pilot trial. We will obtain and register their experiences, opinions, and insights regarding the intervention delivery.

Recruitment

Recruitment and enrollment of older adults

To ensure effective recruitment and enrollment of older adults, our approach will be led by two fieldworkers. We will employ two primary strategies:

- Engagement with community organizations: Initially, we will collaborate with leaders of community organizations in which older adults actively participate, such as Soup Kitchens and Church gatherings. In this collaborative effort, we will provide essential information about our study to these organizations. Subsequently, we will organize group meet-

ings within these community settings to personally acquaint older adults with the study details. We will thoroughly explain the study and leave contact information for our study coordinator, making it convenient for interested individuals to enroll.

- Door-to-Door invitations: Recognizing that some older adults may not actively participate in community groups, we will take a more proactive approach. Our team will visit residences on the outskirts of the VES district, extending personal invitations to potential participants. We believe that reaching out to older adults who may not be part of community organizations will allow us to include those who are potentially most in need.

After providing written informed consent, individuals will undergo a screening process based on our eligibility criteria. For those who express interest but do not meet the eligibility requirements, we will provide valuable information about their nearest primary care center. This approach ensures that even those ineligible for our study receive guidance on accessing healthcare resources.

Recruitment of relatives of older adults

Relatives of older adults will be recruited directly through referrals from older adults participating in the trial. We will initiate contact through phone calls to obtain consent for conducting in-depth interviews.

Recruitment of health professionals

Health professionals, with whom we collaborated during the previous iterative pilot study of adapting the VIDAC-TIVA, will be invited for in-depth interviews about their perspectives on the intervention. We will reach out to them via phone calls.

Community health workers

CHWs who have previously worked with us in the iterative pilot will continue their involvement in this trial.

Randomization

Upon establishing the eligibility of older adults who consented to join the study, they will undergo randomization administered through an online platform (accessible at <https://www.sealedenvelope.com/>) by the research team. This computer-based randomization system will employ a 1:1 allocation scheme to assign individuals to either the intervention group or the usual care group. The allocation will be stratified based on sex and will utilize random permuted blocks of varying sizes.

Blinding

Fieldworkers in charge of periodic assessments will be blinded to the treatment allocation. Researchers and study participants will not be blinded to treatment allocation due to the nature of the intervention.

Study groups

Intervention arm

In the intervention arm, participants will receive the comprehensive VIDACTIVA intervention, which consists of eight in-person sessions led by two CHWs over a 14-week period. There will be an additional eight-week follow-up phase, during which participants will receive monthly phone calls (a total of two calls) to maintain contact and support (see Fig. 2).

Each pair of CHWs will work closely with one older adult participant throughout the intervention journey. To establish a strong foundation, a “meeting zero” will occur before the first session. During this introductory meeting, CHWs will have the opportunity to introduce

themselves, foster mutual understanding, and build trust with the participant.

The core VIDACTIVA intervention consists of eight sessions, each encompassing the following components:

- Problem-solving exercises.
- Planning of pleasant, social, and physical activities.
- Psychoeducation on depression and anxiety in older adults.

For a detailed breakdown of the content covered in each session, please refer to Table 1.

Throughout the trial, alongside their individual sessions with older adult participants, CHWs will actively engage in weekly group and individual supervision sessions led by a clinical psychologist. These supervision meetings will serve as platforms for discussing challenges and difficulties encountered during the intervention, providing constructive feedback, tracking the progress of each older adult, and offering space for CHWs to share

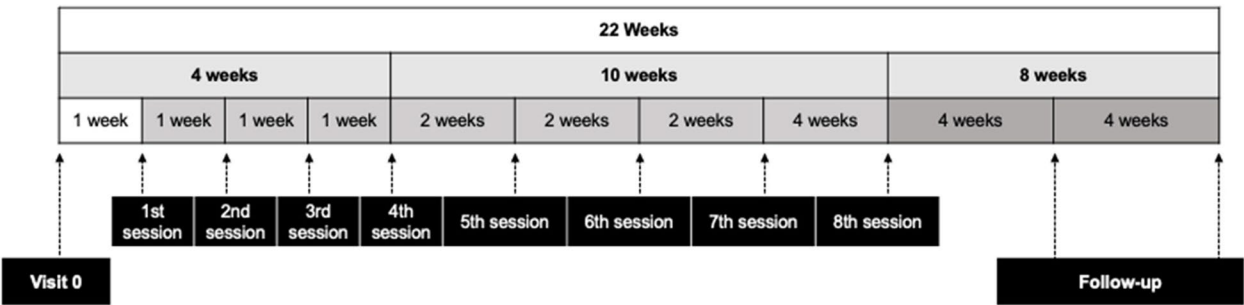


Fig. 2 Timeline of the intervention sessions for VIDACTIVA. Visit 0: This initial visit is an informal introduction by CHWs. Sessions 1–8: These structured sessions share the same format but progressively taper. The first 4 sessions occur weekly, session 5th to 7th occur every 2 weeks and session 8th is 4 weeks after 7th session. Follow-up: Two monthly phone calls also conducted by CHWs

Table 1 Components of the VIDACTIVA intervention administered by CHWs

Component	Description
Problem-solving exercises	These structured exercises aim to train older adults in problem-solving activities. During these exercises, older adults take the lead, with the CHW acting as a facilitator. The CHW's role is to guide rather than provide advice. The process involves selecting a problem, setting a goal, brainstorming potential solutions, choosing the best solution, and taking steps toward its achievement
Behavioral activation	This component involves planning and "scheduling" physical, social, and/or enjoyable activities that older adults select based on their interests and capabilities. Its aim is to reduce sedentary behavior and assist in organizing activities. Individuals with depression often withdraw from activities they once enjoyed, so scheduling meaningful activities in advance can help enhance mood and energy levels
*Education on depressive and anxiety symptoms	This component primarily aims to convey and emphasize three key points: • Symptoms such as sadness, lack of energy, and sleep problems may be indicative of depression • Depressive or anxiety symptoms can be connected to unresolved issues • Physical activity, or body activation, can play a role in reducing depressive symptoms Additionally, participants will receive essential information about available community resources for improving mental health, including services, community mental health centers, and senior citizens' clubs. This information aims to contribute to the reduction of stigma associated with mental health

Participants in the intervention group will receive the same components at each session. *Participants in the control group will receive 2 psychoeducation sessions and referral to primary care centers by a study fieldworker

their thoughts and emotions. Importantly, these meetings will also facilitate peer support and emphasize self-care among CHWs.

Control group

Participants will receive psychoeducation sessions addressing depression and anxiety at older age, which will be delivered through two separate visits (week 0 and week 10) by a trained study fieldworker.

During the initial visit at week 0, participants will receive comprehensive information about the community resources available to them. They will also receive guidance on how to access standard care services provided at their local health canter. If a participant is already receiving some form of mental health care, educational sessions will still be offered, enhancing their existing care. Importantly, any changes in mental health treatment status, whether initiation or cessation, will be meticulously recorded during the study assessments.

Measures and evaluation

Research evaluations will include baseline (week 0), middle (week 5), end of intervention (week 14), and at the end of follow-up (week 22); see Fig. 1. Quantitative data from questionnaires will be electronically collected by a trained fieldworker using REDCap electronic data capture tools and tablets.

Baseline demographics

After providing informed consent, baseline information will be obtained on age, sex, gender, literacy, civil status, working status, household composition, health insurance, and whether participants are caregivers. Additionally, we will ask about the medications used and the presence of chronic conditions, namely, hypertension, diabetes, chronic respiratory disease, osteoporosis, cataracts, glaucoma, chronic kidney disease, cancer, anxiety disorders, and mood disorders. Furthermore, we will obtain information about self-reported hearing status [32] and self-reported vision status [33]. Finally, we will measure quality of life with the EuroQoL-5D (EQ-5D-5L) [34], independence (Katz Index) [35], food insecurity

scale [36], physical frailty [37], and perceived social support (Medical Outcomes Study Social Support Survey—mMOS-SS) [38]. We will obtain information on whether the participant is receiving any type of mental health therapy (pharmacotherapy or psychotherapy).

Feasibility of carrying out a larger trial

We will collect feasibility data from the pilot trial, which will allow us to assess and plan a full-scale randomized controlled trial (RCT). A comprehensive overview of these feasibility domains, encompassing quantitative indicators, qualitative data, and predefined success criteria, can be found in Table 2. The qualitative data will be sourced from a variety of avenues, including field notes maintained by the study coordinator and interviews with participants. Special attention will be given to those who chose not to participate or who withdrew from the study. These interviews will allow us to elucidate the underlying reasons and barriers contributing to their decisions, thereby enhancing our understanding of the trial's feasibility and participant perspectives.

Our progression criteria are not solely based on quantitative success thresholds; instead, we will integrate qualitative data from semi-structured interviews with the quantitative criteria for each domain described in Table 2. For instance, if we do not reach the screening and recruitment targets, we will explore from the fieldworkers' perspectives how we can improve for a future phase. Reasons could include the number of fieldworkers, the way the study is presented, the recruitment strategies, or other factors. In the domain of retention, if a high proportion of participants drop out after being randomized to the control group, we will use the semi-structured interviews to understand their reasons. This feedback may lead us to reconsider the study design, or the type of control used for the future trial.

Implementation outcome measures

Implementation outcomes serve as a vital lens through which we can unravel the intricacies of the implementation process, allowing us to pinpoint and address intermediate factors that may impact the success of an

Table 2 Feasibility assessment for conducting a fully powered randomized controlled trial

Item	Quantitative assessments	Qualitative interviews	Target/criteria for success
Screening	# participants screened/month	Barriers and facilitators to screening and recruitment	80% older adults enrolled/4 months
Enrollment	# participants enrolled/month Average time to reach enrollment goal		
Retention	% older adults who remain in the study in both study groups	Reasons for dropout	80% trial retention at both groups at week-14 75% trial retention at both groups at week-22
Assessments	% of assessment administered as planned	Barriers and facilitators to delivering the intervention	75% evaluations complete

intervention within its specific context [39, 40]. These outcomes hold immense significance because they enable us to assess the effectiveness of delivery of VIDACTIVA, paving the way for future research and practice. Without successful implementation, clinical outcomes remain elusive.

To comprehensively evaluate the acceptability, feasibility, and fidelity of the intervention delivery, we will employ mixed methods approaches [37, 38]. A concise overview of the domains, methodologies, and schedule for data collection is provided in Table 3, which offers a clear roadmap for our assessment process.

Acceptability and feasibility

To evaluate the acceptability and feasibility of our intervention, we will employ an explanatory sequential mixed-methods approach. For older adults, we will start by collecting quantitative data through the Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM) Likert scales [41]. Subsequently, we will conduct in-depth interviews with a subset of 16–20 older adults, including those who were both less and more satisfied with the intervention. These interviews aim to delve into the participants' experiences with the program. During these interviews, we will explore feelings about the intervention, thoughts on the activities facilitated by the CHWs, aspects older adults' value and

find satisfying, as well as areas they believe could be improved.

We will use a convergent mixed-methods approach with CHWs, older adult relatives, and health professionals, combining quantitative scores from the Feasibility and Acceptability Likert scales with in-depth interviews, all within the same phase [42]. This comprehensive approach ensures a holistic interpretation of the data.

Interviews with CHWs will focus on various aspects, including challenges faced while providing the intervention to different older adults, time invested, compensation, self-care practices, and overall satisfaction. In addition to these interviews, we will collect valuable insights during weekly supervision sessions, where a designated note-taker will document CHWs' experiences and interactions with participants and their families, if applicable.

Interviews with family members will explore their perceptions of mental health care, their acceptance of the intervention, positive changes observed in the family member receiving the intervention, and various other related topics.

Interviews with health professionals will seek to understand their perspectives on the long-term feasibility of the intervention and explore potential avenues for support and collaboration, such as funding opportunities and referrals. This multifaceted approach ensures a

Table 3 Evaluation of implementation outcome domains: definition, method, data source, and timeline

Implementation domain	Definition	Method	Data source	Timeline
Acceptability	Extent to which an intervention aligns with an individual's preferences, needs, and expectations	In-depth interviews Acceptability Likert Scale	Older adults Relatives of older adults Health professionals	week-5, week-14, week-22 week-14 week-14
Feasibility	Practicality of implementation, considering available resources and circumstances	Fieldnotes In-depth interviews Feasibility Likert Scale	Supervision sessions Older adults Relatives of older adults Health professionals	weekly week-5, week-14, week-22 week-14 week-14
Fidelity	The degree to which an intervention is delivered as intended	Fieldnotes Indicators: % of older adults who receive 4 and 8 sessions % of older adults who schedule and do pleasant, social, and physical activities % of older adults who agree to have in-home sessions vs sessions outside % of sessions delivery according to schedule Average time of study visits	Supervision sessions Log Study coordinator	weekly Throughout the trial
		Fieldnotes Audio-recording of visits + Checklist	Supervision sessions CHWs-Older Adult interaction	Weekly Week-6 (Session 5)

thorough examination of the intervention's acceptability and feasibility from multiple perspectives.

Fidelity

We will evaluate the fidelity of the delivery of intervention using a convergent mixed methods approach that includes quantitative indicators and in-depth interviews. The details are displayed in Table 3.

We will analyze various indicators derived from the PEARLS fidelity instrument [43]. Additionally, we will audio record one session (middle session) to evaluate the interaction and relationships of CHWs with older adults, communication skills, and rapport. We will closely evaluate the execution of problem-solving exercises and the scheduling of activities. To facilitate this assessment, we are developing a concise checklist outlining the essential steps of problem-solving exercises.

This multifaceted approach to assessing fidelity will offer a nuanced perspective on the accuracy and integrity of intervention delivery by CHWs, providing rich data that will help guide how to adapt VIDAIVA intervention and implementation for future RCTs.

Clinical measures

The preliminary primary clinical outcome will be depressive symptoms. The secondary outcomes will include anxiety symptoms and loneliness.

Depressive symptoms

To assess the severity of depressive symptoms, we will use the self-report Patient Health Questionnaire-9 (PHQ-9). We will utilize the Spanish version validated for use in Peruvian population [44, 45]. The PHQ-9 is a 9-item questionnaire. Each item is rated on a 4-point scale. Scores within the range of 5 to 9 indicate mild symptoms, scores between 10 and 14 signify moderate symptoms, a range of 15 to 19 indicates moderately severe symptoms, and scores of > 20 suggest severe depression.

Anxiety symptoms

We will evaluate the severity of anxiety symptoms using the Generalized Anxiety Disorder-7 (GAD-7), a validated Spanish version [46]. The questionnaire has 7 items, each with a 4-point scale, with scores between 0 and 21 points. Scores are considered as follows: 0–4 (minimal), 5–9 (mild), 10–14 (moderate), and 15–21 (severe) symptoms [46]. The GAD-7 has demonstrated excellent psychometric properties [47].

Loneliness

Loneliness will be assessed using the Three-Item Loneliness Scale (TIL-3) in its Spanish version [48, 49]. Respondents will indicate how frequently they experience

feelings of lacking companionship; being excluded; and experiencing social isolation. Participants will provide responses on a 3-point Likert scale, ranging from 1 “hardly ever” to 3 “often.” Individual responses will be summed, with higher scores indicative of greater loneliness. The TIL-3 yields a score ranging from 3 to 9.

Data analysis

To visualize participant flow, we will employ a CONSORT diagram [50]. For a comprehensive overview, we will provide summary statistics, including means, standard deviations, medians, interquartile ranges, counts, or percentages, for all baseline characteristics, implementation outcomes, and clinical measures.

To provide a comprehensive view of the intervention's delivery process, we will adopt a mixed-methods approach [42, 51]. This approach will facilitate the creation of a detailed and holistic portrayal of the intervention's implementation. Our plan includes obtaining meta-inferences and creating joint displays for both the implementation and clinical outcomes.

Qualitative data will be organized using MAXQDA software (VERBI GmbH, Berlin, Version 18.2). Qualitative data from in-depth interviews will be analyzed by a multi-disciplinary team. We will examine the initial transcripts and generated preliminary coding categories through an inductive process using the constant comparative method [52]. Through this analytical process, we will identify patterns and commonalities, as well as particularities, that will enhance our understanding of the acceptability and feasibility of the intervention from the perspective of participants, their relatives, CHWs, and other health professionals involved in providing care to older people.

Clinical outcome measures will be summarized for each trial arm at specific time points. We will estimate effect sizes as between-group mean differences for each outcome using linear mixed models post-trial (week 14) and at the end of the follow-up period (week 22). We will present parameter estimates along with 95% confidence intervals. It is important to note that hypothesis testing will not be conducted because this is a pilot trial. All the statistical analyses will be performed using Stata v.17 software provided by StataCorp (College Station, TX).

Planned interim analysis and stopping rules

No interim analysis has been planned.

Multiple testing

Given that this feasibility study is exploratory and that there is no hypothesis testing, there will be no adjustment made to the analysis for multiple testing.

Ethics

The following protocol study has been approved by Universidad de San Martín de Porres (USMP) Institutional Ethical Review Board (reference #948–2023) and Asociación Benéfica PRISMA Ethical Committee (reference #CE0453.23): This trial is registered at ClinicalTrials.gov with the identifier NCT06065020. We will obtain written informed consent from the study participants.

Discussion

We present the justification and methods for the pilot feasibility trial “VIDACTIVA,” a multi-component CHW-led intervention for Peruvian older adults experiencing depressive and anxiety symptoms. The VIDACTIVA intervention has undergone iterative adaptation from the well-established “Program to Encourage Active, Rewarding Lives” (PEARLS), which has been successfully implemented in the USA over the past 15 years [24, 25, 53].

While PEARLS has indeed shown significant positive outcomes in addressing depressive symptoms and improving quality of life [54], it is essential to recognize the limitations in generalizing its results to low-resource settings and distinct cultural beyond the United States and in the adoption of CHW-led mental health interventions.

The primary objective of this pilot feasibility trial is to bridge these knowledge gaps and prepare for a more extensive and comprehensive trial. The insights gathered throughout this trial will be instrumental in refining our strategies for the main trial. Pilot feasibility testing becomes notably intricate when conducted with populations that have historically been underrepresented in clinical trials, such as older adults [55], and in low-resource settings characterized by significant organizational, cultural, and infrastructural challenges [42]. Explicit attention to culture is needed to obtain health equity [56]. The findings from this study have the potential to inform future adaptations, assessments, and implementations of interventions involving CHWs in urban resource-constrained settings, thereby expanding the mental health workforce to address pressing needs.

While the intervention primarily targets the alleviation of depressive and anxiety symptoms, we recognize that most older adults experience multiple chronic conditions, a phenomenon known as multimorbidity [57]. We anticipate that case discussions during supervision sessions can provide valuable insights into other potential components of a future or refined CHW-led intervention. Furthermore, a key element of the problem-solving component is that older adults themselves select the problems they wish to address and propose solutions. During these exercises, the identified problem may relate to other

chronic conditions that older adults are managing (e.g., improving diabetes control). This user-centered approach has the potential to indirectly impact the management of other health conditions, illustrating the broader positive effects of the intervention. This approach aligns with the efforts to integrate mental health with non-communicable diseases care, centering the experience of the people living with mental illness (PAHO) [16, 58].

Trial status

At the time of manuscript submission, recruitment for this study was ongoing. Recruitment started on 23rd October 2023, is not yet complete and is due to completion on 30th July 2024. This is protocol version 1.2. The trial sponsor is the Universidad de San Martín de Porres.

Abbreviations

CHW	Community health worker
CMHC	Community mental health center
RCT	Randomized controlled trial
LMICs	Low-middle income countries
USMP	Universidad de San Martín de Porres
PEARLS	Program to Encourage Active, Rewarding Lives
WHO	World Health Organization
PAHO	Pan-American Health Organization

Acknowledgements

We wish to extend our sincere gratitude to Mr. Tony and the Oscar Romero Parish Center for their invaluable contribution in generously providing a spacious training facility for our community health workers. Our appreciation also goes out to the University of San Martín de Porres, School of Medicine, and the Center for Aging Research (CIEN) in Lima, Peru, for their unwavering and fundamental support throughout this endeavor. Furthermore, we would like to express our deep thanks to AB PRISMA for their meaningful collaboration, which greatly enriched the development of this project.

Authors' contributions

JFP, SLP, LS, JGG, and OFF conceived the protocol. TCR, IC, DOO, VP, DL, RVR, and OFF are conducting the study trial. OFF secured the study funding. TCR, AZM, and OFF wrote the manuscript. All the authors contributed to the critical review of the manuscript. All the authors approved the final version of the manuscript.

Funding

The trial is part of an Oscar Flores-Flores Fellowship supported by the Fogarty International Center (FIC) and the National Institute of Mental Health (NIMH) of the National Institutes of Health (NIH), United States, under Award Number K43TW011586. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

The following protocol study has been approved by Universidad de San Martín de Porres (USMP) Institutional Ethical Review Board (FWA 00015320, reference #948–2023) and Asociación Benéfica PRISMA Ethical Committee (FWA00001219, reference #CE0453.23). Written informed consent will be obtained from all participants before enrollment into the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 17 December 2023 Accepted: 5 August 2024

Published online: 22 August 2024

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