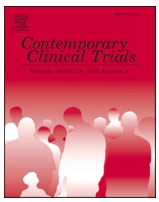
Contemporary Clinical Trials 161 (2026) 108200

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



iMprovIng the meNtal hEalth of home healTh AiDeS: A study protocol for the MINDSET study

Madeline R. Sterling [a,*], Michelle Shum [a], Ronica Peramsetty [a], Joselyne Aucapina [a], Faith Wiggins [b], Carmen Colon [b], Joanna Bryan Ringel [a], Ariel C. Avgar [c], Nicola Dell [d], Bibi N. Habib [b], Samprit Banerjee [a], Emma Tsui [e], Susan J. Andreae [f], Elissa Kozlov [g], Courtney Landis [a], Ian René Solano-Kamaiko [d], Monika M. Safford [a]

[a] Weill Cornell Medicine, New York, NY, USA
[b] 1199SEIU Training and Employment Funds, New York, NY, USA
[c] ILR School, Cornell University, Ithaca, NY, USA
[d] Cornell Tech, Cornell University, New York, NY, USA
[e] School of Public Health, CUNY, New York, NY, USA
[f] University of Wisconsin, Madison, WI, USA
[g] School of Public Health, Rutgers University, Piscataway, NJ, USA

ARTICLE INFO

Keywords:
Home health
Home health aides
Mental health
Long term care
Clinical trial design

ABSTRACT

Home health aides and attendants (HHAs) are a fast-growing healthcare workforce who are integral to the rising movement that allows older adults to age in place. However, HHAs themselves are a vulnerable group of caregivers. Mostly middle-aged women of color paid dismally low wages, HHAs' work is physically taxing, emotionally challenging, and socially isolating. Consequently, HHAs have high levels of depressive symptoms and stress. Prior studies suggest that HHAs want to address this, but do not know how and cannot access or afford traditional mental health services. Here we describe the protocol for a pilot randomized control trial (RCT) that aims to improve the mental health of HHAs through peer coaching (PC), an established and effective behavioral health intervention which has never been applied to HHAs or their workplace, the home environment. In collaboration with a labor and management fund of the largest healthcare union in the US (1199SEIU), we will conduct a single-site parallel arm pilot RCT with 100 HHAs to evaluate the feasibility, acceptability, and effectiveness of an adapted *Living Healthy Program for HHAs* delivered by PCs (intervention arm) vs. a general health promotion program (attention control arm). Primary effectiveness outcome will be a reduction in depressive symptoms; secondary effectiveness outcomes will be a reduction in stress and loneliness. This study offers a novel and potentially scalable way to improve the health of HHAs, an often overlooked, undervalued, but increasingly vital workforce that is needed to care for our rapidly aging population.

1. Introduction

Nearly 75 % of older adults, including those with multiple chronic conditions, prefer to stay in their homes and communities for as long as they can and avoid nursing homes, a concept referred to as "aging in place." [1,2] To do so, they require help at home from family caregivers and home health aides and attendants (HHAs) [3,4]. HHAs are trained and certified health professionals who provide assistance with activities of daily living (e.g., bathing, dressing) and instrumental activities of daily living (e.g. preparing meals, cleaning, shopping), along with emotional support and medically-oriented care [5,6]. Unlike other health professionals, HHAs are with patients on a daily or near-daily basis, which gives them a unique vantage point from which to observe, support, and advise patients.

Despite their contributions to patient care, HHAs themselves are a vulnerable workforce susceptible to poor mental health [7,8]. This is in part due to their marginalized positioning in the healthcare industry and historically poor labor protections as a workforce [9,10]. Additionally, HHAs – who are mostly women and people of color – are paid dismally low wages and 26 % lack health insurance, which limits access to health

* Corresponding author.
E-mail address: mrs9012@med.cornell.edu (M.R. Sterling).

https://doi.org/10.1016/j.cct.2025.108200
Received 21 March 2025; Received in revised form 7 December 2025; Accepted 19 December 2025
Available online 21 December 2025

care [8]. Unfortunately, the COVID-19 pandemic had additional adverse consequences on their mental health [11]. During COVID-19, HHAs often provided care without the necessary personal protective equipment and other basic supports that institutionally-based workers had (i.e. hospitals or nursing homes) [12]. Notably, two-thirds of HHAs were struggling to manage their mental health post-pandemic and 70 % sought support to cope with stress, anxiety, and their mood [13]. Left untreated, HHAs' poor mental health threatens their own well-being but also their ability to provide high-quality patient care.

In a qualitative study, HHAs voiced a strong desire for education and peer support (i.e. fellow HHAs who could relate to their stressors) to improve their mental health [14]. Peer coaching (PC), defined as "*support from a person who has experiential knowledge of a specific behavior or stressor and similar characteristics as the [intended] population*," [15] has successfully improved the health of adults in the population at large with chronic conditions [16,17]. Among HHAs, a recent randomized controlled trial (RCT) demonstrated that a-PC delivered health program improved HHAs' overall safety and well-being on the job [18]. Other PC-led programs among HHAs have focused on hypertension and mobility [19,20]. However, it has never been used for mental health. Discussions with HHAs and community partners revealed interest in adapting an existing PC-delivered behavioral health program to HHAs.

To address this gap, the goal of this pilot RCT is to examine the feasibility, acceptability, and effectiveness of an adapted PC-delivered behavioral health intervention (*Living Healthy for HHAs*) that incorporates cognitive behavior training techniques (CBT) among agency-employed HHA at risk for poor mental health. This paper describes the research protocol for this pilot RCT.

2. Methods

2.1. Study objectives and hypotheses

The overall goal of the study is to improve the mental health of HHAs, an essential sector of the healthcare industry, comprised predominantly of middle-aged women of color with high levels of depression, stress, and social isolation. The long-term goal is to improve the health of both HHAs and their patients, which we will formally evaluate in a future study.

The two main objectives of this pilot RCT are to test the: 1) feasibility and acceptability of the adapted *Living Healthy* intervention among at-risk HHAs and 2) effectiveness of the intervention on HHAs' mental health, compared to HHAs who receive the control condition. We hypothesize that: (H1): the intervention will be feasible ($>$ than 70 % of HHAs enrolled will complete the study) and acceptable ($>$ 80 % of HHAs enrolled will find it acceptable); (H2): HHAs who receive the intervention will experience fewer depressive symptoms and (H3) stress at follow-up compared to those receiving the attention control condition.

2.2. Study setting

The study involves a collaboration between an academic medical center, Weill Cornell Medicine, and a labor management benefit fund of the 1199 Service Employees International Union (SEIU) United Healthcare Workers East, the 1199SEIU Training and Employment Fund (TEF). The 1199SEIU is the largest health care union in the US, representing more than 400,000 workers in hospitals, nursing homes, clinics, and home care agencies. The 1199SEIU TEF provides education and training benefits to 75,000 HHAs employed by 55 Medicare and Medicaid-funded certified and licensed home care services agencies in New York, NY. To meet their annual training requirements, HHAs use an mHealth application called CareConnect, an eLearning mobile platform that provides educational courses for HHA certification and keeps track of their service hours to maintain NYS compliance [21–23].

Notably, 1199SEIU TEF has experience with PC programs, including a successful program to help HHAs manage their diabetes [19]. HHAs who worked with PCs had reductions in glycemic control and were enthusiastic about the program. Our own team's feasibility pilot with 1199SEIU TEF during COVID-19 utilized PCs to enhance professionalism and support and was successful [24,25].

2.3. Study design

This is a single-site parallel arm pilot RCT, that plans to enroll 100 participants (HHAs) and randomize them (1:1) into the intervention arm or attention control arm. Participants will be in the trial for up to 6 months (Fig. 1). Participants in the intervention arm receive the PC-delivered program, *Living Healthy for HHAs*, which includes CBT techniques and regular telephone or Zoom calls with their PC. The study team works to ensure HHAs are paired with PCs at a different agency and matched based on their language concordance. Participants in the attention control arm receive a health education program, *Getting Healthy for HHAs*, with regular check-in telephone or Zoom calls from a designated study team member (Fig. 1). Data will be collected from participants at day 0 and at completion (roughly at) 6 months (Table 2). Recruitment will begin in the Winter of 2025.

2.4. Study sponsorship and institutional review board approval

This study is supported by the Doris Duke Charitable Foundation (Grant # 2022053). The content is solely the responsibility of the authors and does not necessarily represent the official views of the foundation. This trial is registered (ClinicalTrials.gov: NCT06071221) and approved by the Institutional Review Board of BRANY (# 23–12–744-380) and Weill Cornell Medicine (IRB #23–10026585) [14].

2.5. Recruitment and training of peer coaches for the trial

Prior to the pilot RCT, 12 1199SEIU TEF members were recruited to become PCs for the intervention arm. To be eligible, they had to have been previously employed as an HHA, received prior training on PC from 1199SEIU TEF, be available to undergo training with our study team on the *Living Healthy Program for HHAs*, speak English or Spanish, and certify as a PC. The PC certification process is described elsewhere [26,27].

Those who were successfully certified were then provided an overview of this study including their responsibilities. If eligible, interested, and PC-certified, they were asked to participate in this study and provided electronic consent. PCs who participate in the trial will receive compensation.

2.6. Eligibility criteria of study participants (HHAs)

To be eligible, HHAs must be currently employed for a licensed or certified home care agency affiliated with 1199SEIU TEF, be $\geq$18 years old, speak English or Spanish, have $\geq$ mild or greater depressive symptoms (Personal Health Questionnaire 8-item [PHQ8] scale $\geq$5 points) or other risk factors for poor mental health and well-being as assessed by the following domains and their corresponding validated scales: stress (Cohen's Perceived Stress 4-item scale [PSS4] $\geq$ 5) or loneliness ($\geq$ 6 on the 3-item UCLA Loneliness scale). A version of these inclusion criteria were previously used in our prior qualitative study, which informed this trial, of HHAs and mental health [14]. While we initially intended to recruit only participants with $\geq$ mild or greater depressive symptoms and one or more other risk factors, feedback from our community partner indicated that to reach our target sample (of 100 HHAs), a relaxed criteria (as stated above) would be advisable. This way, participants with high stress levels, who might not, for example rule in on depressive symptoms, would qualify. Since COVID-19, our partners indicated that depressive symptoms, stress, and loneliness have been highly prevalent (not just depressive symptoms alone).

Using a standardized recruitment script, 1199SEIU TEF staff

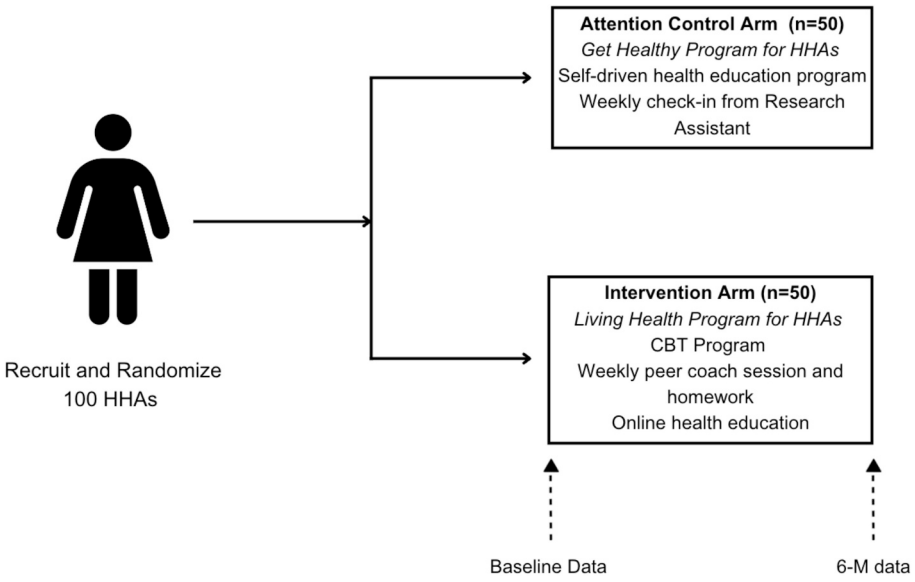


Fig. 1. Schematic of Pilot RCT with HHAs.

members (coordinators) will perform telephone outreach to affiliated HHAs who are a) in contact with 1199SEIU TEF and b) employed by home care agencies that utilize the mHealth app. For those who are not interested, the 1199SEIU TEF staff will document their reason(s) for declining. If interested in participating, Weill Cornell Medicine research assistants (RAs) will then send an electronic screening survey to HHAs to assess eligibility. Participants who are eligible and interested will be scheduled for an in-person onboarding session. Participants will provide written (electronic) informed consent, complete a baseline survey, and will be randomized using a block randomization design (blocks of 4 and 6 using the R package 'blockrand'). Both arms will be oriented to study materials. After onboarding, participants will receive a $100 gift card. PCs and HHA participants will be matched by language (English or Spanish).

2.7. The intervention arm: living healthy for HHAs

Participants randomized to the intervention arm will receive the *Living Healthy for HHAs* program, an 8-session health promotion program with CBT delivered by trained PCs by telephone and/or Zoom over 3–4 months [27,28]. Informed by Social Cognitive Theory [29], PCs work with participants to adopt positive health behaviors through personalized goal setting, motivational interviewing, and peer modeling. (Fig. 2). Each content-based session incorporates principles of CBT, teaching participants to recognize and modify negative thinking and modifying outcome expectations through self-monitoring, reflection, and practice. Participants receive an activity book, health-monitoring calendar, and educational content. Prior to a session with their PC, participants are asked to view the educational materials. During the one-hour weekly session, PCs guide participants through the structured program which includes reviewing homework, setting behavioral goals, and problem-solving barriers. In between weekly sessions, participants monitor their mood and practice cognitive restructuring. The program concludes with two lessons that prepare learners to maintain and extend these activities after the study. This program was previously tested across 4 cluster RCTs and were found to improve depressive symptoms and pain among low-income Black women [28,30].

Informed by HHAs' feedback and educational needs, the program content and lesson topics were adapted to the workforce, and hereafter we refer to the program as *Living Healthy for HHAs*. Curriculum content areas are shown in Table 1. Educational content for each lesson is placed on their existing e-learning system via the mHealth app, CareConnect, a caregiver workflow optimization platform which 1199SEIU TEF and many agencies use to provide education/training, onboarding, and shift-matching services, as well as HR compliance and secure communications for field caregivers [20]. Participants will also be offered access to educational content using the Patient Activated Learning System (PALS) a web-based, theory-driven, question-based platform with evidence-based referenced answers that covers basic facts about health, diseases, and their treatments [31]. It is designed for diverse populations with low health literacy. Answers are in the form of short text phrases and engaging videos. Participants who may have limited access to the mHealth app or internet will be provided with printed program materials as needed.

2.8. Attention control arm: getting healthy for HHAs

Participants randomized to the attention control arm will receive the *Getting Healthy* program, an 8-session general health program consisting of a similar sessions as *Living Healthy* (8) but with different topics: Asthma and COPD, hypertension, nicotine exposure, cancer screening, diabetes, cholesterol, Dementia and Alzheimer's disease, and heart failure. Similar to the intervention, the *Getting Healthy* program will be divided into lessons that get uploaded on their existing mHealth app e-learning system, CareConnect [23]. The program is expected to take 3–4 months to complete with weekly sessions lasting 15–30 min. Unlike *Living Healthy*, no principles of CBT are included. Participants will receive an equal number of sessions of similar length delivered by a trained RA. These sessions are developed to mimic the social support and attention being received by the intervention group.

2.9. Study timeline

Each HHA participant will be involved for up to 6 months. Each PC participant will be involved for at least 12 months. There will be two data collection points for each HHA participant, baseline (0 months) and 6 months, or before should they finish the program early. There will be two data collection points for each PC participant, baseline and 12 months.

2.10. Data collection and data sources

We will collect data using a multi-modal approach (Tables 2, 3, 4).

Fig. 2. Examples of content delivered during *Living Healthy* Program for Home Health Aides and Attendants (HHAs).
Clockwise from top left 1) Behavioral goal setting using SMART goals; 2) The three steps to living healthy, designed to teach HHAs how to recognize and modify negative thinking; 3) Example content from Lesson 2 on the impact of stress on health; and 4) Strategies for stress management.

Table 1
Curriculum content: living healthy for home health aides and attendants (HHAs) (Intervention Arm).

Lesson	Topic
1	Stress and Unhealthy Thinking
2	Stress and Your Mood
3	Physical Activity
4	Healthy Eating and Your Mood
5	Sleep and Your Mood
6	Combating Loneliness: Friends and Family
7	Navigating Relationships with Clients
8	Practicing and Planning for the Future

This will include baseline and follow-up surveys of endpoints and covariates, observation notes, usage data (i.e., CareConnect platform) a website, and interviews. Surveys will be administered through Research Electronic Data Capture (REDCap) software; a secure data management system [32,33].

A baseline survey for HHAs (T = 0) includes socio-demographics, general health status, mental health and well-being outcomes, self-efficacy and coping, lifestyle and health behavior data, and employment data (Table 2).

PC participants will complete a baseline survey (T = 0) that includes socio-demographics, peer coach skills and motivation, and employment data (Table 3).

Table 2
Summary of data and data collection timeline for study participants (HHAs).

Domain	Validated Scale or Measure	Description	Data Source
Mental Health Outcomes			
Depressive Symptoms	Personal Health Questionnaire 8-item Scale (PHQ-8) [34]	An 8-item validated scale that measures current depressive symptoms.	Baseline & 6 M Assessments
Stress	Cohen's Perceived Stress Scale [35]	A 4-item validated scale that measures the degree to which situations in one's life are perceived as stressful	Baseline & 6 M Assessments
Loneliness	UCLA Loneliness Scale [43]	A 3-item validated scale that measures perceived loneliness	Baseline & 6 M Assessments
Social and Behavioral Health			
Physical and Mental Health	Short Form 12 Health Survey (SF-12) [44]	A 12-item validated scale that assesses physical and mental health	Baseline Assessment
Pain Intensity	PROMIS [45]	A 1-item scale that assesses pain intensity	Baseline & 6 M Assessments
Social Support	Social Support Scale [46]	A validated 4-item measure of perceived adequacy of social support from people in one's life and on the job	Baseline & 6 M Assessments
Self-Efficacy	Generalized Self-Efficacy Scale [47]	A validated 10-item scale measuring confidence in handling situations related to health, job, personal life	Baseline & 6 M Assessments
Health Behaviors			
Health Behaviors and Mood	Novel Questions about Daily Behaviors	13-item questions assessing health behaviors to manage mood	Baseline & 6 M Assessments
Diet	Dietary intake questionnaire	4 questions to assess types of food eaten in the last 7 days	Baseline & 6 M Assessments
Exercise	REGARDS Study [48]	1 question regarding physical activity engagement per week	Baseline & 6 M Assessments
Sleep	Behavioral Risk Factor Surveillance System (2010) [49]	1 question regarding hours of sleep per day	Baseline & 6 M Assessments
Employment Outcomes			
Job Satisfaction	Work Domain Satisfaction Scale [50]	5-item validated scale to assess satisfaction with current job	Baseline & 6 M Assessments
Turnover Intention	Turnover Intentions Scale [51]	2-item scale that assesses turnover intention	Baseline & 6 M Assessments
Acceptability Assessment			
Acceptability	Acceptability of Intervention Measure (AIM)	4-item instrument measuring the acceptability of an intervention	6 M Assessment
Feasibility Assessment			
Feasibility	Feasibility of Intervention Measure (FIM)	4-item instrument measuring the feasibility of an intervention	6 M Assessment
Fidelity Outcome			
Fidelity	Certification Guidelines Competency Checklist	Measuring the degree to which a specific intervention is implemented as intended	6 M Assessment

Table 3
Summary of data and data collection timeline for peer coach (PC) participants.

Domain	Validated Scale or Measure	Description	Data Source
Program Outcomes			
Peer Coach Motivation	Novel questions about motivation to be a peer coach	A 4-item scale that measures experience as a peer coach and motivations for participating	Baseline
Peer Coach Skills	Novel questions about skills as a peer coach	A 10-item validated scale that measures the degree to which Peer Coaches have the skills to be a good peer coach	Baseline & 12 M
Peer Coach Feedback	Novel questions about overall experience	A 3-item scale assessing Peer Coaches experience in the program	12 M
Employment Outcomes			
Job Satisfaction	Work Domain Satisfaction Scale [50]	5-item validated scale to assess satisfaction with current job	Baseline & 12 M Assessments
Turnover Intention	Turnover Intentions Scale [51]	2-item scale that assesses turnover intention	Baseline & 12 M Assessments
Acceptability Assessment			
Acceptability	Acceptability of Intervention Measure (AIM)	4-item instrument measuring the acceptability of an intervention	12 M Assessment
Feasibility Assessment			
Feasibility	Feasibility of Intervention Measure (FIM)	4-item instrument measuring the feasibility of an intervention	12 M Assessment

Throughout the study period, access to and completion of the *Living Healthy* and *Getting Healthy* lessons will be monitored by the research team via CareConnect and a study website dashboard.

At study end, HHAs and PCs will be interviewed about their experiences in the study. The HHA topic guide will broadly focus on how the intervention influenced health and overall attitude towards their work. The PC topic guide will focus on challenges and facilitators as a PC.

All HHA participants receive a $100 gift card for each completed data collection.

2.11. Study outcomes

The three main outcomes are feasibility, acceptability, and effectiveness for both attention control and intervention arms.

2.12. Feasibility

To assess feasibility, the RE-AIM implementation framework will be

Table 4
Evaluation of study design, outcomes, and implementation with the RE-AIM framework.

Dimensions	Definition	Context of Study	Data source
Reach	The absolute number, proportion, and representativeness of individuals willing to participate in the study	- Eligibility Criteria - Eligible target population - Number of HHAs approached - Number of HHAs eligible but did not participate - Barriers to recruitment	- Research protocol - Screening form - Records (data recruitment) from study staff - Demographic survey and interview question
Effectiveness	The impact of an intervention on outcomes	Primary and secondary outcomes Staff - Roles - Credentials - Experience, including motivating factors and barriers Peer Coaches	- Surveys - Interviews
Adoption	The absolute number, proportion, and representativeness of participants who participate in the study	- Roles - Credentials - Experience, including motivating factors and barriers HHAs - Number approached - Number who completed onboarding, training, trial - Extent to which the intervention was adopted	- Research records - Attendance records - Interviews
Implementation	The study and interventions' fidelity to the protocol, including consistency of delivery as intended, time, and interventions' adaptations	- Feasibility - Acceptability - Fidelity to study by staff and peer coaches - Adaptations to the intervention - Use of intervention materials - Study teams' delivery of the intervention - Challenges/ barriers to delivery/ implementation - Successes	- Research record - Observations by study team - Surveys - Interviews - Data from eLearning - CareConnect - Interviews with study staff - Interviews with participants - Interviews with union staff
Maintenance	The extent to which the intervention becomes part of the routine organizational practices and policies	- To be assessed in future large-scale study	

used, which stands for: Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance (Table 4). Reach will be assessed by tracking the number of participants approached and enrolled, and reasons why they declined; effectiveness through baseline and follow-up assessments; adoption by the number who completed educational sessions (both arms), PC sessions (intervention arms), and completed the trial (both arms). With respect to implementation, data will be collected on fidelity to the study protocol (defined as the extent to which the intervention was delivered as planned), intervention adaptations, completion rate of intervention components, and staff required to deliver the intervention, among others. Maintenance will be assessed in a future study.

2.13. Fidelity

Program fidelity will be monitored by reviewing completed program materials (i.e. usage and completion of each lesson in CareConnect). Additionally, a fidelity checklist will be established for both arms to record the quality and consistency of participants and study staff activities. The checklist will ensure that PCs and RAs all have appropriate training and orientation to their roles (recruiting, and onboarding, coaching, and providing support during the trial). The checklist will also place emphasis on maintaining a consistent recruitment process and ensuring that participants receive the intervention as intended; intermittent PC calls will be recorded and scored by the research team.

PCs will individually meet with a program staff member weekly throughout the implementation period. The primary purpose of this meeting will be to provide support and encouragement to the PCs and to identify implementation issues quickly so they could be addressed in a timely manner.

2.14. Acceptability

Acceptability will be assessed through qualitative interviews with HHAs, PCs, and staff. Semi-structured interviews will be conducted by RAs. Participants from both arms will be interviewed about their experiences with the program(s); those in the intervention arm will be asked about their experience with their PC and their use of CBT techniques. PCs will be asked about their experiences delivering the intervention and their overall experience in the trial. Staff will be asked about their experiences providing support to the attention control arm participants.

2.15. Effectiveness

Effectiveness will be assessed with a primary outcome, depressive symptoms, using the Personal Health Questionnaire depression scale (PHQ-8) [34] (Table 4). The PHQ-8 is a self-reported measure of depressive symptoms composed of 8 Likert type items with a response scale ranging from 0 (Not at all) to 3 (Nearly every day), that refer to the presence of that symptom during the previous 2 weeks. The PHQ-8 final score is obtained by adding the score for each of the items, ranging from 0 to 24 (higher scores corresponding to higher levels of depression). A score of $\geq$5 is considered positive for mild depressive symptoms.

We will also assess two secondary outcomes: stress and loneliness. Stress will be assessed using the Cohen's Perceived Stress 4-item scale (PSS-4), a validated four item version of the PSS, which assesses perceived stress experienced over the prior month [35]. Questions inquired about the degree to which the respondent felt (1) unable to control important things in their life, (2) confident in their ability to handle personal problems, (3) that things were going their way, and (4) that difficulties were piling up in life. Each category is scored using a 5-point scale (0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, 4 = very often). Final composite scores ranged from 0 to 16, where a higher score indicated a higher level of perceived stress [36]. A score of $\geq$5 was considered positive for moderate or greater stress symptoms. Loneliness will be assessed using the 3-item UCLA Loneliness scale [34].

This scale reflects feelings of isolation, lack of companionship, and being left out. Response options (on a 3-point Likert scale) were "hardly ever or never" (1), "some of the time" (2), and "often" (3). Scores are summed to provide a total loneliness score (3–9), with higher scores indicating greater loneliness. A score of $\geq$6 will be considered positive for loneliness.

2.16. Exploratory outcomes

These include employment-related outcomes (job satisfaction and turnover intention) and mediators (self-efficacy and social support).

2.17. Additional data

Covariates including: socio-demographic data (age, gender, race/ethnicity, primary language spoken, foreign born status, zip code), employment characteristics (current agency, years worked as an HHA), behaviors (coping, physical activity, diet, sleep) and quality of life.

2.18. Statistical methodology

2.18.1. Analytical plan for quantitative data

Data from REDCap will be exported to STATA for analysis. Descriptive statistics will be performed to characterize the sample. Differences in participant characteristics by study arm will be examined using tests of association (chi-squared, *t*-tests for normally distributed data and Mann-Whitney *U* test for non-normally distributed data). We will also compare the characteristics of participants who consented and enrolled to those who declined to participate. Usage data from CareConnect, the mHealth app, as well as data from fidelity checklists, will also be analyzed by study arm.

To determine the effect of the intervention on the primary outcomes, we will use mixed effects models to compare change depressive symptoms between and within study arms. Mixed-effects included a fixed effects categorical variable for time point (baseline/follow-up), an indicator for study arm (control/intervention), a study arm by timepoint interaction and subject-specific random intercept. We will also investigate including a random slope in the model and choose the final model which has the lowest Akaike Information Criterion (AIC). The treatment effect will be estimated from this mixed model using contrasts that test the difference in improvement of outcomes from baseline to follow-up between the two treatment arms.

Primary analyses will be conducted using intention-to-treat, when appropriate. We will examine participant characteristics across trial arms and adjust for covariates that are imbalanced ($p < 0.10$). We will also categorize the primary outcome and assess difference in proportion without depressive symptoms (PHQ-8 score 0–4) at follow-up between control and intervention arm. Differences will be assessed with a chi-square test and logistic regression. We will conduct the same analyses for the secondary outcomes of stress and loneliness. We will explore the indirect effect of mediators. Additionally, we will conduct a per-protocol analysis as a sensitivity analysis by limiting participants in the randomized arm to those who adhered to the peer coaching intervention. To account for the fact that a few different PCs will guide HHAs through the intervention arm, we will consider a nested random intercept (i.e., participants nested within PCs and multiple assessments with a patient). To generate this random intercept, we will group the control participants into one cluster as they do not have a PC, (but rather an RA that checks in with them) and cluster intervention participants to each PC. Models with nested vs. subject-level random intercepts will be compared by Bayesian Information Criteria (BIC).

We will use three approaches for incomplete data, (i.e. complete cases) [37], multiple imputation, or methods that account for the non-random missing mechanism, e.g., pattern-mixture models [38–40] and selections models [41] depending on the characteristics of missing data.

2.19. Analytical plan for qualitative data

Semi-structured interviews will be audio-recorded and professionally translated and transcribed. Data will be stored and organized in Dedoose qualitative software. Using the PRISM/RE-AIM Framework, we will perform a thematic analysis [42]. Two investigators trained in qualitative research methods will independently code the first three transcripts using a set of a priori codes (from the framework) and inductively add new codes as concepts emerge. A third investigator and the lead investigator (M.R.S.) will review the coded transcripts and reconcile discrepancies with the team, consolidating the codes into a codebook. The codebook will be reapplied to these and subsequent transcripts. The codebook will be iteratively refined until all transcripts are coded. Common codes will be compared using dimensions and properties and collapsed into categories (sub-themes), which will then be further refined into broader themes.

2.20. Sample size determination and power

Sample size was estimated for the effectiveness hypothesis. With a sample size of 50 per treatment arm (total $n = 100$), we will have 80 % power to detect a difference of 3.4-point change in PHQ-8 score (minimum detectable difference) between the control and treatment group. Accounting for the updated, relaxed inclusion criteria while keeping other assumptions the same, we will be able to detect a 3.85-point change in PHQ-8 in the sub-sample recruited with the relaxed inclusion criteria. In addition, power calculations were assumed to have an ICC = 0 at the group level given that no estimates are available. While not powered for effectiveness at the group level, from exploratory analyses (we assumed ICC = 0), we will determine the ICC for sample size calculations for the future definitive trial to follow.

3. Results

The results of this study will be disseminated to a scientific and lay audience. The study team will maintain the clinicaltrials.gov (Identifier # NCT06071221) registration and reporting record in accordance with the Weill Cornell Medicine and clinicaltrials.gov reporting guidelines. All data will be de-identified to maintain participant confidentiality and published in aggregate form.

3.1. Assessment of adverse events and harms

The intervention being assessed is a low-risk, behavioral health intervention. PC for well-being, albeit not mental health, has been used at our community partner site before. Based on this, we do not anticipate any harm or adverse events. However, participants, 1199SEIU TEF staff (of which a licensed social worker is a part of the study team) RAs, as well as PCs, will be encouraged to report adverse events, including depressive symptoms, on an ongoing basis to the study team, including the Research Program Manager and PI. Additionally, our study team will monitor PCs' weekly notes and intervene if clinically appropriate (i.e., if a participant is symptomatic, linking them to appropriate mental health services).

4. Discussion

4.1. Overview of the study

This pilot RCT aims to improve the mental health and well-being of HHAs through PC, a well-established and effective behavioral health intervention which has never been applied to HHAs' mental health needs. We will conduct a 2-arm pilot RCT among 100 HHAs to evaluate the feasibility, acceptability, and effectiveness of the intervention on HHAs. The primary effectiveness outcomes are a reduction in depressive symptoms and stress. This study builds the foundation for a dramatic

transformation in the health of HHAs, an often overlooked, undervalued, but increasingly vital workforce that is needed to care for our rapidly aging population. The study features a partnership between an academic medical center and a labor management fund of the largest healthcare union in the US. The RE-AIM framework will guide the intervention implementation and evaluation, and we will use a multimethod approach to data collection and analysis. The data collected from this pRCT will inform the design and delivery of a fully powered definitive trial, if deemed appropriate.

4.2. Strengths and limitations

Strengths include a pRCT conducted in partnership with the largest healthcare union in the US, and an evidence-based behavioral health intervention focused on the HHA workforce. This study uses a mixed methods design, including the collection and analysis of both quantitative and qualitative data from participants receiving the intervention and PCs delivering it. This is rare in-home care-related research and a unique opportunity to understand the experiences and impact of the trial on all involved. Finally, the intervention we are testing has been adapted in partnership with HHAs and other key organizational partners in home care to meet the needs of the workforce, which offers an opportunity for future scalability.

Limitations, however, exist. First, due to HHAs employment structure, there may be challenges in recruitment and onboarding. We will carefully monitor and document modifications throughout the implementation and evaluation process. Second, while participants are randomly assigned to a study arm, they are not blinded to their assignment, nor are the RAs conducting the onboarding process with them. To reduce the risk of contamination and bias, other study staff will be blinded. Third, because intervention sessions are delivered by PCs while attention control sessions are delivered by research staff, there is some potential for attention or expectancy bias, which may influence participant responses. Also, both study arms were matched in frequency (weekly) and program duration (3–4 months), however session length and homework were not equivalent between both arms due to the CBT-based intervention design. These differences can introduce variation in treatment dose and affect outcomes. We will conduct a sensitivity analysis to determine whether session length and homework completion influenced the outcomes meaningfully.

4.3. Innovation and impact

This is the first study to address the mental health challenges of HHAs, a workforce that provides the backbone of home health care to older adults and those with chronic conditions, but one that is at risk for poor mental health. This proposal is innovative as it will adapt and test a PC-delivered CBT program for HHAs, a workforce and workplace (the home) that has rarely been the focus of health-related behavior change interventions. It is likely that addressing the mental health of HHAs will result in an engaged, productive, and healthier workforce capable of caring for a rapidly aging population. The study will also generate empirical data on whether such an intervention can promote workforce retention, an increasingly challenging issue in long-term care. The trial to follow this foundational work will include patient outcomes.

Credit authorship contribution statement

Madeline R. Sterling: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Michelle Shum:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Investigation, Data curation. **Ronica Peramsetty:** Writing – review & editing, Writing – original draft, Resources, Project administration, Investigation, Data curation. **Joselyne Aucapina:** Writing – review & editing, Writing – original draft, Resources, Project administration, Investigation, Data curation. **Faith Wiggins:** Resources, Conceptualization. **Carmen Colon:** Resources. **Joanna Bryan Ringel:** Writing – review & editing, Software, Formal analysis, Data curation. **Ariel C. Avgar:** Writing – review & editing, Funding acquisition, Conceptualization. **Nicola Dell:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Conceptualization. **Bibi N. Habib:** Resources. **Samprit Banerjee:** Writing – review & editing, Software, Formal analysis, Data curation. **Emma Tsui:** Writing – review & editing. **Susan J. Andreae:** Writing – review & editing, Methodology. **Elissa Kozlov:** Writing – review & editing. **Courtney Landis:** Writing – review & editing, Resources. **Ian René Solano-Kamaiko:** Writing – review & editing, Resources. **Monika M. Safford:** Funding acquisition, Writing – review & editing, Methodology, Conceptualization.

Funding

This study is being funded by the Doris Duke Charitable Foundation and a Clinical Scientist Development Award (Grant # 2022053). Additional support is being provided by the Initiative on Home Care Work, within the Center for Applied Work at Cornell University in the School of ILR. The content is solely the responsibility of the authors and does not necessarily represent the official views of the foundation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

N/A - it is a protocol paper

References

[1] An Aging Nation. https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html.
[2] 2018 Home and Community Preferences: A National Survey of Adults. https://www.aarp.org/research/topics/community/info-2018/2018-home-community-preference.html.
[3] M.R. Sterling, A.L. Shaw, Sharing the care-a patient and her caregivers, JAMA Intern. Med. 179 (12) (2019) 1617–1618, https://doi.org/10.1001/jamainternmed.2019.4231.
[4] C.H. Van Houtven, R.T. Konetzka, E. Taggert, N.B. Coe, Informal and formal home Care for older adults with disabilities increased, 2004-16, Health Aff. (Millwood). 39 (8) (2020) 1297–1301, https://doi.org/10.1377/hlthaff.2019.01800.
[5] M.R. Sterling, J.B. Ringel, J. Cho, C.A. Riffin, A.C. Avgar, Utilization, contributions, and perceptions of paid home care workers among households in New York state, Innov. Aging 6 (2) (2022) igac001, https://doi.org/10.1093/geroni/igac001.
[6] J.M. Reckrey, E.K. Tsui, R.S. Morrison, et al., Beyond functional support: the range of health-related tasks performed in the home by paid caregivers in New York, Health Aff. (Millwood). 38 (6) (2019) 927–933, https://doi.org/10.1377/hlthaff.2019.00004.
[7] J. Cho, B. Toffey, A.F. Silva, et al., To care for them, we need to take care of ourselves: a qualitative study on the health of home health aides, Health Serv. Res. 58 (3) (2023) 697–704, https://doi.org/10.1111/1475-6773.14147.
[8] M.R. Sterling, J. Li, J. Cho, J.B. Ringel, S.R. Silver, Prevalence and predictors of home health care workers' general, physical, and mental health: findings from the 2014–2018 behavioral risk factor surveillance system, Am. J. Public Health 111 (12) (2021) 2239–2250, https://doi.org/10.2105/AJPH.2021.306512.
[9] A. Bercovitz, A. Moss, M. Sengupta, E.Y. Park-Lee, A. Jones, L.D. Harris-Kojetin, An overview of home health aides: United States, 2007, Natl. Health Stat. Report 34 (2011) 1–31. https://www.ncbi.nlm.nih.gov/pubmed/21688727.
[10] L.I. Iezzoni, N. Gallopyn, K. Scales, Historical mismatch between home-based care policies and Laws governing home care workers, Health Aff. (Millwood). 38 (6) (2019) 973–980, https://doi.org/10.1377/hlthaff.2018.05494.
[11] M.R. Sterling, E. Tseng, A. Poon, et al., Experiences of home health care workers in new York City during the coronavirus disease 2019 pandemic: a qualitative analysis, JAMA Intern. Med. 180 (11) (2020) 1453–1459, https://doi.org/10.1001/jamainternmed.2020.3930.
[12] E. Franzosa, T. Wyte-Lake, E.K. Tsui, J.M. Reckrey, M.R. Sterling, Essential but excluded: building disaster preparedness capacity for home health care workers

and home care agencies, J. Am. Med. Dir. Assoc. 23 (12) (2022) 1990–1996, https://doi.org/10.1016/j.jamda.2022.09.012.
[13] S. Pinto, C. Ma, F. Wiggins, S. Ecker, M. Obodai, M. Sterling, Forgotten front line: understanding the needs of unionized home health aides in downstate New York during the COVID-19 pandemic, New Solut. 31 (4) (2022) 460–468, https://doi.org/10.1177/10482911211058839.
[14] M. Yanez Hernandez, E.F.-C. Kuo, Y. Henriquez Taveras, et al., Mental health and well-being among home health aides, JAMA Netw. Open 7 (6) (2024), https://doi.org/10.1001/jamanetworkopen.2024.15234 e2415234-e2415234.
[15] C.L. Dennis, Peer support within a health care context: a concept analysis, Int. J. Nurs. Stud. 40 (3) (2003) 321–332 (In eng), https://doi.org/10.1016/s0020-7489(02)00092-5.
[16] E.B. Fisher, R.I. Boothroyd, E.A. Elstad, et al., Peer support of complex health behaviors in prevention and disease management with special reference to diabetes: systematic reviews, Clin. Diabetes Endocrinol. 3 (2017) 4, https://doi.org/10.1186/s40842-017-0042-3.
[17] M.P. Gallant, The influence of social support on chronic illness self-management: a review and directions for research, Health Educ. Behav. 30 (2) (2003) 170–195, https://doi.org/10.1177/1090198102251030.
[18] R. Olson, S.V. Thompson, D.L. Elliot, et al., Safety and health support for home care workers: the COMPASS randomized controlled trial, Am. J. Public Health 106 (10) (2016) 1823–1832, https://doi.org/10.2105/AJPH.2016.303327.
[19] How Peer Mentors are Helping 1199SEIU Members Manage Their Diabetes. https://www.crainsnewyork.com/article/20171107/PULSE/171109916/how-peer-mentors-are-helping-1199seiu-members-manage-their-diabetes.
[20] P.H. Feldman, M.V. McDonald, N. Onorato, J. Stein, O. Williams, Feasibility of deploying peer coaches to mentor frontline home health aides and promote mobility among individuals recovering from a stroke: pilot test of a randomized controlled trial, Pilot Feasibil. Stud 8 (1) (2022) 22, https://doi.org/10.1186/s40814-022-00979-4.
[21] 1199SEIU Traning and Employment Fund. https://www.1199seiubenefits.org/training/.
[22] 1199SEIU United Healthcare Workers East: Quality Cares and Good Jobs for All. https://www.1199seiu.org/.
[23] Care Connect L, CareConnect for Caregivers (Version 1.1.25). App Store. https://apps.apple.com/us/app/careconnect-for-caregivers/id1364337839.
[24] A. Poon, V. Hussain, J. Loughman, A.C. Avgar, M. Sterling, N. Dell, Computer-mediated peer support needs of home care workers: emotional labor & the politics of professionalism, Proc ACM Hum-Comput Interact 5 (CSCW2) (2021), https://doi.org/10.1145/3476077. Article 336.
[25] A. Poon, M. Luebke, J. Loughman, et al., Computer-mediated sharing circles for intersectional peer support with home care workers, Proceed. ACM Human-Comp. Interact. 7 (2023) 1–35, https://doi.org/10.1145/3579472.
[26] A. Cherrington, M.Y. Martin, M. Hayes, et al., Intervention mapping as a guide for the development of a diabetes peer support intervention in rural Alabama, Prev. Chronic Dis. 9 (2012) E36 (In eng), https://doi.org/10.5888/pcd9.110053.
[27] S.J. Andreae, L.J. Andreae, A.L. Cherrington, et al., Development of a community health worker-delivered cognitive behavioral training intervention for individuals with diabetes and chronic pain, Fam. Comm. Health 41 (3) (2018) 178–184 (In eng), https://doi.org/10.1097/fch.0000000000000197.
[28] S.J. Andreae, L.J. Andreae, J.S. Richman, A.L. Cherrington, M.M. Safford, Peer-delivered cognitive behavioral training to improve functioning in patients with diabetes: a cluster-randomized trial, Ann. Fam. Med. 18 (1) (2020) 15–23, https://doi.org/10.1370/afm.2469.
[29] A. Bandura, Health promotion from the perspective of social cognitive theory, Psychol. Health 13 (4) (1998) 623–649, https://doi.org/10.1080/08870449808407422.
[30] S.J. Andreae, L.J. Andreae, J.S. Richman, A.L. Cherrington, M.M. Safford, Peer-delivered cognitive behavioral therapy-based intervention reduced depression and stress in community dwelling adults with diabetes and chronic pain: a cluster randomized trial, Ann. Behav. Med. 55 (10) (2021) 970–980, https://doi.org/10.1093/abm/kaab034.
[31] Patient Activated Learning System (PALS). https://palsforhealth.com/.
[32] P.A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J.G. Conde, Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support, J. Biomed. Inform. 42 (2) (2009) 377–381, https://doi.org/10.1016/j.jbi.2008.08.010.
[33] P.A. Harris, R. Taylor, B.L. Minor, et al., The REDCap consortium: building an international community of software platform partners, J. Biomed. Inform. 95 (2019) 103208, https://doi.org/10.1016/j.jbi.2019.103208.
[34] K. Kroenke, T.W. Strine, R.L. Spitzer, J.B.W. Williams, J.T. Berry, A.H. Mokdad, The PHQ-8 as a measure of current depression in the general population, J. Affect. Disord. 114 (1) (2009) 163–173, https://doi.org/10.1016/j.jad.2008.06.026.
[35] S. Cohen, T. Kamarck, R. Mermelstein, A global measure of perceived stress, J. Health Soc. Behav. 24 (4) (1983) 385–396, https://doi.org/10.2307/2136404.
[36] W.T. O'Neal, W. Qureshi, S.E. Judd, et al., Perceived stress and atrial fibrillation: the REasons for geographic and racial differences in stroke study, Ann. Behav. Med. 49 (6) (2015) 802–808 (In eng), https://doi.org/10.1007/s12160-015-9715-2.
[37] A.C. Leon, C.H. Mallinckrodt, C. Chuang-Stein, D.G. Archibald, G.E. Archer, K. Chartier, Attrition in randomized controlled clinical trials: methodological issues in psychopharmacology, Biol. Psychiatry 59 (11) (2006) 1001–1005, https://doi.org/10.1016/j.biopsych.2005.10.020.
[38] D. Hedeker, R.J. Mermelstein, Application of random-effects regression models in relapse research, Addiction 91 (Suppl) (1996) S211–S229 (In eng).
[39] J.A.L. Roderick, Pattern-mixture models for multivariate incomplete data, J. Am. Stat. Assoc. 88 (421) (1993) 125–134, https://doi.org/10.2307/2290705.
[40] R.J.A. Little, Modeling the drop-out mechanism in repeated-measures studies, J. Am. Stat. Assoc. 90 (431) (1995) 1112–1121, https://doi.org/10.1080/01621459.1995.10476615.
[41] J. Heckman, The Common Structure of Statistical Models of Truncation, Sample Selection and Limited Dependent Variables and a Simple Estimator for Such Models, NBER Book Chapters, 2012, p. 5.
[42] R.E. Glasgow, T.M. Vogt, S.M. Boles, Evaluating the public health impact of health promotion interventions: the RE-AIM framework, Am. J. Public Health 89 (9) (1999) 1322–1327, https://doi.org/10.2105/ajph.89.9.1322.
[43] M.E. Hughes, L.J. Waite, L.C. Hawkley, J.T. Cacioppo, A short scale for measuring loneliness in large surveys:results from two population-based studies, Res. Aging 26 (6) (2004) 655–672, https://doi.org/10.1177/0164027504268574.
[44] D. Turner-Bowker, S.J. Hogue, Short form 12 health survey (SF-12), in: A. C. Michalos (Ed.), Encyclopedia of Quality of Life and Well-Being Research, Springer Netherlands, Dordrecht, 2014, pp. 5954–5957.
[45] Cella D, Riley W, Stone A, et al. The patient-reported outcomes measurement information system (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J. Clin. Epidemiol. 2010;63(11): 1179–94. (In eng). DOI: https://doi.org/10.1016/j.jclinepi.2010.04.011.
[46] M.C.W. Peeters, B.P. Buunk, W.B. Schaufeli, Social interactions, stressful events and negative affect at work: a micro-analytic approach, Eur. J. Soc. Psychol. 25 (4) (1995) 391–401, https://doi.org/10.1002/ejsp.2420250404.
[47] R. Schwarzer, M. Jerusalem, J. Weinman, S. Wright, M. Johnston, Generalized Self-Efficacy Scale. Measures in Health Psychology: A User's Portfolio Causal and Control Beliefs Windsor, 1995.
[48] V.J. Howard, M. Cushman, L. Pulley, et al., The reasons for geographic and racial differences in stroke study: objectives and design, Neuroepidemiology 25 (3) (2005) 135–143, https://doi.org/10.1159/000086678.
[49] Centers for Disease Control and Prevention (CDC) Behavioral Risk Factor Surveillance System Survey Data. U.S. Department of Health and Human Services n.d.
[50] N. Bérubé, M. Donia, M. Gagné, N. Houlfort, E. Lvina, Validation evidence for the work domain satisfaction scale in two languages, Inter. J. Psychol. Stud. 8 (2024) 26–39, https://doi.org/10.5539/ijps.v8n3p26.
[51] J. Schaubroeck, J.L. Cotton, K.R. Jennings, Antecedents and consequences of role stress: a covariance structure analysis, J. Organ. Behav. 10 (1) (1989) 35–58, https://doi.org/10.1002/job.4030100104.