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FINAL RESEARCH REPORT

Comparing Two Ways to Help Latinx Patients With Depression Who Are Age 50 or Older

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ABSTRACT

Background: Late-life depression is a common disorder, frequently causing devastating personal outcomes, and it is a major health hazard that imposes a significant burden on individuals, caregivers, and society. Compared with younger adults, older adults are less likely to experience remission, have twice the rate of completed suicides in the United States, have different symptom presentation profiles, and are less likely to receive guideline-concordant depression care. Older racial and ethnic minorities experience disparities in treatment outcomes and care. Although their depressive episodes are more persistent with fewer remissions over time, and they experience more functional impairments and disease burden, they are more likely to receive substandard depression care.

Older Latinos represent the fastest growing segment of the older adult US population, will represent approximately 15 million people by 2050, and will constitute the largest racial/ethnic minority group older than age 65 by 2028. Considerable evidence indicates that older Latinos have higher rates of recurring depression episodes and related disabilities, longer duration of periods of depression, and are less likely to receive treatment or guideline-concordant care than other ethnic groups.

Objectives: The primary aim of Programa Esperanza (Project Hope) was to test the comparative effectiveness of an 8-session psychosocial intervention, problem-solving treatment (PST), that teaches rational problem-solving skills and behavior activation, vs enhanced usual care (EUC), an intensive psychoeducational session for depression. The comparative effectiveness trial was directed primarily toward Spanish-speaking Latino patients 50 years of age or older with depression and multiple medical conditions. The project also ascertained the feasibility and acceptability of training nontraditional interventionists (ie, non–graduate-level practitioners) to deliver the psychosocial treatment.

Methods: We used a randomized trial-mixed methods design with a qualitative component among 259 patient enrollees from the AltaMed Program of All-Inclusive Care for the Elderly (PACE) to test the 2 bilingual comparator interventions delivered by trained bilingual non–graduate-level interventionists. PST consisted of 8 manualized sessions and 3 boosters (ie, sessions were presented in a step-by-step format to ensure uniformity across interventionists) based on rational problem-solving strategies and behavioral activation. EUC consisted of 1 depression psychoeducation session with detailed handouts along with routine PACE services. The primary trial outcome was severity of depression as measured on a continuous scale by the Patient Health Questionnaire (PHQ)-9, frequently used in published studies assessing adult and geriatric depression. All trial outcomes (primary outcome of depression and secondary outcomes of anxiety, mental health quality of life, and functional well-being) were measured at baseline and at 3, 6, and 12 months. Mixed-effects regression models for longitudinal data as well as end point analyses were used for quantitative data analyses. Content analysis of project meetings and phenomenological qualitative analyses were used to analyze 43 interviews with participants, interventionists, and AltaMed managers.

Results: In total, 1522 participants were screened, and 259 enrolled and completed baseline assessments. Study attrition was low (94.6% completed the study to 12-month follow-up), and treatment adherence was high: Among PST participants, 81.5% received the planned 8 face-to-face sessions, and 62.5% received all face-to-face and booster sessions. For participants randomly assigned to EUC, 100% received the single psychoeducational session. In general, PST delivered by non–clinically trained interventionists was no more effective than EUC. On the primary trial PHQ-9 outcome, both PST and EUC groups showed significant changes over the 12-month follow-up (both within-group *P* trends < .0001). Effect sizes (mean 12-month change divided by standard deviation) were 0.81 in PST participants and 0.88 in EUC participants. No differences were found between the 2 groups with regard to other mental health, physical functioning, or psychosocial outcomes over time. PST participants had significantly more primary care visits at the 6-month (median, 26 vs 21 visits; *P* = .003) and 12-month (median, 44 vs 35 visits; *P* = .017) follow-ups, yet in contrast had significantly lower use of emergency department (ED) visits in the first 6 months following study enrollment (17.0% vs 26.7% with at least 1 ED visit; *P* = .008). Moreover, skilled nursing facility admissions during the first 6 months (0% vs 4.8%; *P* = .01) and 12 months (2.2% vs 6.4%; *P* = .12) following enrollment were lower in the PST group. Programa Esperanza provided access to depression screening and treatment to levels that had not been seen before at the PACE sites. Overall, participants and providers reported high satisfaction with the treatments and identified areas for future sustainability. Iterative processes of engagement, consultation, and integration of stakeholder feedback occurred across a continuum of activities to enhance stakeholder engagement and principles of evidence-based science.

Conclusions: Depression and related mental health outcomes improved to a similar degree in both PST and EUC groups. Future research is needed to ascertain if improvements are due specifically to the treatments, spontaneous improvement, or nonspecific effects of the care received in the treatment setting for older adults with comorbid depression and multiple medical conditions whose English is limited.

Limitations: Results are likely generalizable to the target study population, that is, older Latinos who are at least mildly to moderately depressed, cognitively intact, and receiving outpatient managed health care for high physical and behavioral health needs. The primary study limitations relate to the challenges associated with trial implementation in a pragmatic setting. Limitations include possible contamination effects of the study interventions, staff and interventionist turnover or reassignments to different clinical sites, and the administrative decision to alter the employment profile of the workforce of staff holding a bachelor's degree in social work. Although PST adherence was high, some participants were difficult to schedule and required more time to complete the PST intervention. By nature of the interventions and treatment setting, participants could not be blinded to their randomized group assignment. Lack of a true no-treatment comparator group precludes us from concluding that the change in depression outcome from baseline to 12 months is due entirely to the interventions. Nonetheless, the significant results for the health care use data signals change in other important areas that might not have been detected by the PHQ-9.

BACKGROUND

Late-Life Depression Among People With Medical Comorbidity

Late-life depression is defined as unipolar depressive syndromes in older adults, typically around the sixth decade of life or older: major depression, dysthymic disorder, adjustment disorder with depressive features, and clinically significant depressive symptoms or minor depression.[1] Affecting upward of 20%, or 6 million older people in the United States,[2,3] depression is the most prevalent mental disorder among older adults across all racial and ethnic groups[4-10] and a leading cause of disease burden and disability.[11-13] The World Health Organization ranks depression second only to cardiovascular disease in burden (ie, impact on disability-adjusted life-years).[14] Part of this burden is attributable to the fact that depression typically co-occurs with medical conditions and cognitive impairment, leading to significant disability, increased risk of suicide, and increased all-cause mortality.[1,12,15-19] For particular disorders like major depression, prevalence is between 1% and 4% in the general population[1] and up to 24% in nursing homes. Minor depression has a prevalence of 4% to 13%; dysthymic disorder occurs in about 2% of the older adult population. For people in nursing homes, or who are nursing home eligible, the rates of minor depression or clinically significant symptoms of depression range up to 50% due to higher prevalence of multiple chronic medical illnesses in this population.[20]

Although depression is devastating at any age and can affect members of all racial and ethnic groups, several notable differences exist: Compared with younger age groups, older adults (1) are less likely to experience remission; (2) have twice the rate of completed suicides in the United States[1,17,18,21]; (3) have different symptom presentation profiles (loss of pleasurable activities, psychomotor changes, cognitive and somatic complaints, weight loss, and medial temporal lobe abnormalities)[22,23]; and (4) are less likely to receive depression care. Older racial and ethnic minorities experience disparities in treatment outcomes such that their depressive episodes are more persistent with fewer remissions over time, causing significantly more functional impairments and disease burden, yet they do not typically receive adequate guideline-concordant depression care.[24-27]

The Critical Evidence Gap Facing Older Latinos

Older Latinos, Depression, and Treatment Disparities

Older Latinos represent the fastest growing segment of the older adult population in the Unites States, which will increase from 8% in 2014 to 22% in 2060. This population will represent approximately 21.5 million people by 2060,[28] and will constitute the largest racial/ethnic minority group older than 65 years by 2030.[29] Although depression rates are among the highest for immigrant Latinos aged 60 or older in the United States,[6] minimal depression research has been conducted with this culturally distinct population.[30]

Older Latinos have up to double the rates of clinically significant depression compared with both whites and African Americans.[31-34] Prevalence rates for major depression are higher (about 28%) in low-income primary care practices composed primarily of minority patients in urban settings.[35-40] Although prevalence studies of psychiatric disorders of younger Latinos indicate more favorable mental health outcomes for immigrant vs US-born Latinos for selected disorders,[41] older immigrant and low-acculturated Latinos, especially women, tend to be at higher risk for depression. Elevated depression rates in older Latinos are associated with female sex, older age, low income, low social support, high stress, chronic financial strain, functional decline, low acculturation, and limited English fluency.[42-47]

The association among chronic medical conditions, physical disability, and higher depression prevalence and risk is well established.[1,48-50] Although health-related advancements have been made, especially in the area of life expectancy,[51] health disparities among older Latinos persist.[25] For example, compared with non-Hispanic whites, older Mexican Americans, who comprise more than 50% of US older Latinos, have a high incidence of diabetes, obesity, cognitive decline,[52,53] and low access to primary care services;[54] they are more functionally impaired,[55] have low rates of physical activity and report more disabilities,[56] and report a higher number of risk factors for impaired cognitive functioning.[51,57] Older persons and Latinos are overrepresented among the group of dual eligibles[58-60] (ie, persons with disabilities who participate in both Medicare and Medicaid). About 60% of dual-eligible individuals are age 65

and older, and Latinos (as well as African Americans) are 6 times more likely than whites to be dual eligible due to long-standing poverty and low access to employer-covered health and retirement benefits. Improving the quality and coordination of psychiatric care for vulnerable populations is a crucial component of addressing health care disparities.[61]

Psychosocial interventions addressing the clinical complexity and the interplay of depressive symptoms with chronic health conditions are critical for older adults. Less than 50% of older adults taking antidepressants achieve remission of late-life major depression.[62] Nevertheless, treatment-related differences in remission rates are not clinically significant between older and younger depressed patients,[63-65] underscoring older adults' favorable response to depression treatment. Despite evidence that depression is treatable in older adults, comorbid illnesses often co-occur with late-life depression. Comorbidity can negatively influence the diagnosis and initiation of depression treatment[66,67] as well as treatment response.[65,68] Unfortunately, depression undertreatment or nonadherence to treatment are found among geriatric patients as well as among racial and ethnic minorities due to well-documented patient, provider, and organizational barriers to care.[33,64,69-71]

Improving the quality and coordination of care is a crucial component of addressing health care disparities among vulnerable populations.[59,72] Although strong evidence supports the efficacy of geriatric depression treatments, generalization to older US racial and ethnic minorities, particularly with respect to persons with limited English and low literacy, remains unclear. Considerable evidence shows that older Latinos have higher rates of recurring depression episodes and related disabilities as well as longer duration of periods of depression, and they are less likely to receive treatment or guideline-concordant depression care. A systematic review[73] of 1068 studies found that (1) only 5 depression treatment studies reported outcomes pertaining to older minorities; (2) no research included geriatric Latino patients in prospective studies examining depression over longer follow-up periods; and (3) very few studies attended to sociocultural modifications to enhance person-centered care and treatment outcomes.

Significant barriers to older Latinos lead to limited access to mental health services. System-level barriers—such as insufficient (or inaccessible) mental health resources, lack of bilingual/bicultural providers, long wait times, inadequate outreach, lack of transportation, lack of information on services, service fragmentation, lack of health insurance, and low level of Medicare and Medicaid reimbursement—are often the most important barriers to mental health service use.[74-79] Thus, older Latinos often wait until their condition worsens before seeking care or following up with their treatment regimens, which may lead to more chronic disease trajectories. This is unfortunate given the emerging work indicating that younger low-income Latinos can respond favorably to depression treatment,[80,81] and, according to 1 case of collaborative care, older English-speaking Latinos may experience better treatment effects than whites.[79]

Lack of a Competent Geriatric Mental Health Workforce

A significant gap is the lack of a competent workforce to provide mental health treatment to older adults in general, and older adults with comorbid medical conditions whose English is limited, in particular. Commissioned by the US Congress, a 2012 Institute of Medicine report addressed the shortage of a mental health workforce needed to care for older Americans, particularly older minorities.[21] These were the significant findings: (1) The increasing proportion of older racial and ethnic minorities will demand a workforce prepared to work with diverse populations; (2) older Latinos have the highest rates of psychiatric comorbidity (namely depression and posttraumatic stress disorder) compared with whites, African Americans, and Asian/Pacific Islanders; and (3) the lack of a culturally and linguistically competent mental health workforce for underrepresented racial and ethnic groups borders on a crisis.

A major emergent strategy is the deployment of trained non–graduate-level interventionists to provide screening, identification, and brief psychosocial interventions for persons with mental health needs.[82] Given the limited numbers of trained bilingual/bicultural mental health providers, task-shifting involves engagement of human resources or personnel, generally with no professional-level training in the care of mental health disorders.[83] There is growing evidence of the effectiveness of task-shifting in the management of some chronic

health conditions, including mental disorders such as depression.[84-90] Aside from potential cost-saving benefits, task-shifting allows these providers, who are representative of community norms and help-seeking behaviors, to effectively recruit, engage, and intervene with patients in a manner that is community-informed and person-centered. Although the integration of task-shifting opportunities has been studied in low- to middle-income countries, the evidence for the effectiveness of task-shifting in the US geriatric mental health workforce is unknown. The integration of community health workers in US health care systems exists in term of health care issues such as diabetes, HIV/AIDS, and domestic violence, among others, but the evidence for workforce development in geriatric mental health is lacking.[21] To strengthen the evidence, research must address the barriers to and facilitators of task-shifting to non–graduate-level providers in relatively under-resourced communities where facilitating recruitment and engagement in mental health care studies has been a challenge.

Social workers are major providers of mental health services in the United States,[91] accounting for 7 of 10 mental health providers,[92] and are well positioned to provide depression care services in primary care settings. Unlike clinical social workers who have a master's degree level of education and clinical licensure (MSWs), bachelor's-level social workers (BSWs) are trained in case management and resource-brokering strategies and are typically recruited from their surrounding communities; however, they have limited behavioral health training for working with persons with complex comorbid medical and psychiatric conditions.[21] Social workers make key contributions to evidence-based depression treatment programs such as the Program to Encourage Active, Rewarding Lives (PEARLS) and Healthy IDEAS.[73] It is anticipated that with proper supervision, BSWs would be able to integrate competencies commensurate with the targeted interventions: adding to knowledge about depression medications, offering structured counseling skills, and increasing frequency of communication between social workers and prescribing physicians.[93]

Drawing from the emerging research on the role of community workers (nongraduate level) or Promotoras(es) de Salud in health education,[94] disease prevention,[95,96] and depression detection and management,[97] we must examine the feasibility and acceptability of nonclinical

BSWs in providing short-term counseling to vulnerable populations, especially where access to specialty behavioral health providers is limited. The benefits of this service extender/task-shifting approach include potential cost savings[98,99] and building on unique and existing alliances between social workers, patients, and caregivers.

In sum, gaps in evidence exist in terms of (1) the relative effectiveness of treatment options for late-life depression in low-income, primarily Spanish-speaking older Latinos with chronic medical conditions; and (2) potential barriers to and facilitators of task-shifting social worker roles to depression care.

Summary of Study Goals and Specific Aims

Becoming depressed late in life is a common health problem with serious consequences for many adults, caregivers, and society as a whole. Older Latinos have high rates of depression, tend to stay depressed longer than other ethnic groups, and are less likely to get the best depression care. This study compares 2 models of depression treatment provided primarily by BSWs to Spanish-speaking patients in a patient-centered medical home (PCMH) outpatient setting: AltaMed's Program of All-Inclusive Care for the Elderly (PACE).[100]

Objectives

The study aim was to test the comparative effectiveness of Programa Esperanza (Project Hope)—a short-term culturally modified psychosocial intervention for Spanish-speaking Latino patients 50 years of age or older with depression and multiple medical conditions—vs enhanced usual care (EUC) in a PCMH care setting. A brief psychosocial intervention called problem-solving treatment (PST) teaches people about their mental health problems, offers them problem-solving skills, and suggests actions they can take to feel better. EUC includes an intensive 1-hour psychoeducational session with detailed bilingual handouts about depression and depression treatment for older adults, as well as routine services.

The results of this study may help older Latinos, their families, and their health care providers make decisions about treatment for depression in the face of chronic medical conditions. Organizations may use the results to organize service delivery in different ways such

as providing behavioral health care though non–clinically trained interventionists who speak their language and are culturally aware of the unique needs of the target population.

The long-term goal is to widely disseminate the results and actionable steps needed to increase the adoption and sustainability of evidence-based behavioral health practices for geriatric populations with low incomes and limited English.

Research Questions

The quantitative study addressed these research questions.

Primary quantitative research question. Among recruited low-income, primarily Spanish-speaking Latinos at least 50 years of age with high medical comorbidity, will Programa Esperanza improve depression-related outcomes (primary outcome, Patient Health Questionnaire [PHQ-9]; secondary outcome, Symptom Checklist Depression Scale [SCL-20]) compared with EUC over the course of 1 year?

Secondary quantitative research questions. In this population, will Programa Esperanza improve secondary trial outcomes of anxiety, problem-solving skills and behavior activation, physical functioning, and quality of life, compared with EUC over the course of 1 year? Will Programa Esperanza be more or less effective for some patient subgroups compared with others?

The qualitative study addressed these research questions.

Primary qualitative research question. Will qualitative reports from the patient population and provider stakeholders provide key insights related to treatment effectiveness, acceptance, and satisfaction, as well as adoption of the intervention within the PCMH setting?

Secondary qualitative research question. Among patients, interventionists, and organizational providers, what factors may increase acceptability and effectiveness of delivering depression care by non–clinically trained interventionists to this population?

The randomized trial recruited 259 participant enrollees from the AltaMed PACE, a PCMH model for nursing home–certifiable participants with at least 3 limitations in activities of daily living and multiple medical conditions. Manualized sessions based on problem-solving, behavior activation, and psychoeducation were facilitated by trained non–graduate-level interventionists. Manualized psychosocial interventions rely on a step-by-step format with prescribed goals and activities to be conducted during each session to ensure uniformity across interventionists and to address the core mechanisms of action that account for the intended psychosocial change.[101] Trial outcomes were measured at baseline and at 3, 6, and 12 months. We used mixed-effect regression models and performed constant-comparative analyses for quantitative and qualitative data, respectively.

The proposed study addresses critical gaps in the current knowledge that can improve health care and outcomes important to patients and their providers. Ascertaining subgroups with heightened vulnerability for depression can increase understanding of the factors underlying disparities in access—and response—to quality depression treatments. Personalizing the care of geriatric depression, including environmental and cultural factors, has emerged as a unifying concept in geriatric psychiatry.[102] Predictors of response to depression treatment range from clinical (limitations in physical and emotional functioning) to psychosocial factors (low income, low access to culturally congruent services, poor self-efficacy, and stigma). Because older Latinos have heightened exposure to predictors of poor outcomes, it is important to target predictors considered modifiable, such as self-care strategies and behaviors, problem-solving, self-efficacy, and referrals, to the primary care physician for follow-up evaluations.

PARTICIPATION BY PATIENTS AND OTHER STAKEHOLDERS

Overview of Stakeholder Involvement

The Programa Esperanza team embraced the patient-centered outcomes research (PCOR) approach from the pre-award phase through the dissemination activities of the study. The overarching principle that guides Programa Esperanza is that patients affected by depression, and those who provide care, are the best guides to understanding depression, depression treatment, stakeholder satisfaction, and best stakeholder engagement approaches. This type of approach ensures high-quality and relevant evidence to inform health care decisions for persons directly affected by depression or their care providers. Thus, the research team included people representing the population of interest and naturally occurring groups of patient and provider representatives who acted as advisors. Stakeholder input encompassed the types of study outcomes to select, selection of interventionists, location of treatment, how to set up and monitor study processes, what type of materials to develop, how to engage stakeholders, when and how to troubleshoot challenges, and what type of dissemination activities to pursue, to name a few. The study team remained actively engaged with the stakeholders on an ongoing basis to ascertain progress and strategies to keep focused on stakeholders and their contributions.

Types and Number of Stakeholders Involved

Decisions About Stakeholder Balance, Study Design, Processes, and Outcomes

Several types of stakeholders were engaged: patients who were current users of PACE services, a patient representative who served on the scientific research team, a PACE research coordinator, PACE interventionists, and PACE supervisors and managers. Except for family members, this represented the entire spectrum of stakeholders involved in the study. The initial research team actually delayed submitting the PCORI award application until the next funding cycle to shore up the stakeholder elements of the application. It was important to include the voices of those directly impacted by the situation/problem/dilemma to be addressed. Thus, the team focused primarily on the patient's voice by facilitating multiple focus groups and in-depth

interviews, all while gathering information on their preferences for depression care. The scientific team identified patient representatives and providers by visiting a total of 6 patient advisory councils representing the then-existing PACE sites during that year. In total, the team met with upward of 170 individuals to formulate preliminary ideas about what type of research questions to answer, the study design, and developing the PCOR plan to integrate stakeholders into future research activities. An important consideration of who would serve on the research team emerged such that a patient representative was requested to serve on the team. This person remained on the team throughout the study period.

During the pre-award period, patient participants provided the name of the study, Programa Esperanza (Project Hope), and offered insights into the parameters of an intervention they would support: a brief nonpharmacologic intervention involving individual (not group) sessions. They stated they were "tired of taking so many medications" and "feared the addictive properties of any psychoactive medications." Although the patients preferred individual counseling, the organizational representatives would have preferred group-mediated settings to save time and limit costs. Patients preferred sharing their psychological problems with those who were closest to them in the PACE milieu, mainly their assigned case managers (social workers). They already felt close to them, trusted them, and saw them weekly.

All of the stakeholders (patients, case managers, organizational providers) informed the study design by unilaterally rejecting a cluster randomized trial, with randomization at the level of a clinical site. They did not want anyone to be excluded from potentially receiving the PST intervention (patient side) or providing it (case manager side). Organizational providers wanted to be able to show that PST was a value-added service to their existing menu of programs for patients.

All stakeholders were keen on examining depression outcomes and keeping track of changes in mental health through repeated measures ("see if this works"), but patients were also interested in the impact that the interventions would have on physical health and daily functioning. Thus, these elements were added to the study outcome measures.

All stakeholders asked that intervention materials be streamlined due to limited literacy and numeracy issues and that the materials be straightforward, in Spanish and English, to increase inclusion of limited-English speakers. They also asked that the sessions be scheduled at the PACE sites and not in their homes because of privacy issues. Lastly, they wanted to begin the program right away; thus, it became necessary for the scientific team to state a very clear disclaimer at the beginning of any interview or interaction with the stakeholders because they assumed the program was already funded.

The research team entered the ecosystem of the PACE sites to anticipate how patients and providers worked, engaged, and interacted at the different sites: how they provided care, their workloads, processes of work, how decisions were made, and the dynamics across stakeholder interactions. It was important to understand how patient and organizational stakeholders were accustomed to receiving care or working at their respective sites. The decision was made early on to continue the spirit of diverse representation of stakeholders to include patients and providers, as well as interventionists, supervisors, research coordinator, managers, and senior leadership. The balance was maintained throughout the study period. By the end of the study period, the Programa Esperanza stakeholder pool included 50 patients, 45 AltaMed providers, and 1 scientific team member (patient representative).

These stakeholders were recruited in diverse ways depending on the stakeholder type. Patients were approached through the naturally occurring patient advisory council composed of PACE participants and facilitated by AltaMed personnel, and via personal solicitations through patients' assigned case managers or supervisors. All AltaMed providers were asked to serve as stakeholders: Interventionists participated as stakeholders given their key role in screening and administering the interventions (EUC and PST). They were given permission by their supervisors to serve in this role; other AltaMed providers and leadership participated on an ongoing basis. Screeners and supervisors were given permission by AltaMed to serve as stakeholders, and senior leadership served on an ongoing basis. The AltaMed research coordinator was assigned to serve as a stakeholder given her liaison role between AltaMed and

the scientific research team, and she was the most involved in monitoring study compliance at the research sites.

Methods, Modes, and Intensity of Engagement

Programa Esperanza used an array of methods and modes of stakeholder interactions, and levels of intensity. Here is a synopsis.

- **Advisory councils:** Composed of patients and provider facilitators; group; on site; bilingual; formal presentations using slides and paper handouts; doubled up the frequency per council members' request from 2 to 4 meetings per year. These continued throughout the study period.
- **Training, booster, and case reviews with interventionists:** Group and individual meetings; in person, via telephone and emails, formal presentations using slides and paper handouts. These occurred during the first 18 months of the study and continued throughout the study period.
- **Progress update meetings with supervisors and managers:** Quarterly, in person; on site; formal presentations using slides and handouts. These continued throughout the study period.
- **Quality control and troubleshooting meetings to address challenges:** ongoing; on site; in person; via email and telephone with interventionists and AltaMed research coordinator.

Perceived or Measured Impact of Engagement

Relevance of the Research Question

As stated earlier, the patients and providers selected the research questions.

Study Design, Processes, and Outcomes

As stated previously, the patients and providers selected the study design, repeated measures, and outcomes.

Study Rigor and Quality

To ensure study rigor and quality, we had to first explain these concepts and what occurs when rigor and quality are compromised. We accomplished this by holding meetings with all stakeholders during the early stages of the study. We provided examples about the need to ensure rigor and quality: complying with screening, consent, and recruitment goals; ensuring gender representation; following screening protocols to avoid bias; developing strategies to mitigate missed PST sessions and outcome interviews; maintaining privacy; safeguarding patient health information and protections of human participants; modifying workload and work processes; enhancing interventionist response to case reviews; and ensuring documentation was timely, complete, and relevant.

Participant Recruitment

The trial screened 1522 PACE participants, enrolled 259 older Latinos with complex high-need medical and psychiatric conditions, and completed randomization assignment to either the EUC or PST group for 259 patients who completed the baseline assessment. The entire effort depended on a complex web of resources, persistent monitoring, and engagement across diverse stakeholders, university scientific personnel, and organizational resources, to name a few. The study met the recruitment goals for both the randomized trial and the qualitative component.

Transparency of the Research Process

As noted earlier, there was 100% transparency of the research process through frequent methods and modes of interaction across a variety of stakeholders that entailed a feedback loop of getting to know one another, discussion, decision-making, reporting back, problem-solving, feedback, and change.

Adoption of Research Evidence Into Practice

Making the business case for the adoption and sustainability of the Programa Esperanza program in PACE settings is a natural next step. Depression care strategies exemplified in

Programa Esperanza are the type that AltaMed would like to adopt, either totally or partially, and they were discussed with AltaMed leadership in a series of meetings. These were the key strategies identified:

- Bilingual and bicultural procedures, practices, and materials provided in English and Spanish.
- Screening and identification of PACE non–cognitively impaired participants with moderate to severe depression using existing PACE depression screening tools (PHQ-9 and Brief Interview for Mental Status [BIMS]).
- Proposing depression care menu (identification, referral, follow-up, and quality improvement) to PACE participants who meet depression criteria.
- Delivery of evidence-based person-centered short-term intervention (PST) to PACE participants who meet criteria.
- Data entry of all screening and PST sessions entered into NextGen electronic health record system.
- Stakeholder engagement of PACE participants and their providers in ongoing quality improvement strategies.
- Staffing, training, certification, and supervision of depression care staff including task-shifting of BSW and health educator roles.
- Follow-up and evaluation of the depression care program and quality improvement.
- Alignment of Programa Esperanza with AltaMed's vision, mission, strategic statement, and quality-of-care goals.
- There is an excellent track record of collaboration between the University of Southern California (USC) research team and AltaMed Senior Care programs.
- Organizational champions from leadership and direct-line staff levels are committed to the project and its sustainability.
- A total of 9 BSWs, 4 health educators, and 4 MSWs were trained on evidence-based depression screening and the delivery of both the intervention (PST) and comparator (EUC).

- PACE participants report high satisfaction with PST and research outcome interviews.
- Preliminary secondary mental health outcomes indicate increased well-being.
- Adherence to PST sessions is high—actually higher than adherence to antidepressant care as cited in the literature.
- Collaborative efforts led to attainment of participant recruitment goals from June 2015 through December 2016.
- BSW and health educator productivity during screening phase increased significantly from year 1 to year 2 of the study.
- The study met all reporting requirements per PCORI funding.
- Budget covered AltaMed project activities through sub-award/contract.
- Potential exists for application of Programa Esperanza to other PACE populations (eg, other racial and ethnic groups, other workforce sectors, other psychiatric conditions).
- Need to address what worked and what did not.
- A goal is to apply for a PCORI Dissemination and Implementation project that may include other community stakeholders.

METHODS

Study Overview

The primary aim was to test the comparative effectiveness of Programa Esperanza (Project Hope)—a short-term culturally modified psychosocial intervention for Spanish-speaking Latino patients 50 years of age or older with depression and multiple medical conditions—with EUC. The randomized clinical trial design aimed to randomly assign 250 patients from the AltaMed PACE. Trial outcomes were measured at baseline, and at 3, 6, and 12 months.

Study Design

Programa Esperanza was a comparative effectiveness trial (ie, a randomized open-label unblinded trial) comparing EUC with a culturally modified PST intervention provided by non–clinically trained BSW interventionists.

Study Setting

The sample was composed of participants from 1 of 8 AltaMed PACE sites in Los Angeles County. The Programa Esperanza trial was approved by the USC institutional review board. A trial data and safety monitoring board met semiannually to review study progress and safety. All participants provided written informed consent. The trial is registered at ClinicalTrials.gov (NCT02459860).

Participants

Trial inclusion criteria were being Latino/Hispanic or of Latino/Hispanic descent; speaking English or Spanish; being age 50 or older; receiving services from any AltaMed PACE site; and having a PHQ-9 score of 8 or higher. Potential participants were excluded from random assignment if they met any of the following criteria: had current alcohol problems; had a disorder with active mania or psychotic symptoms; had cognitive impairment precluding ability to provide informed consent or participate in interventions (>2 incorrect on BIMS); had an active medical condition with life expectancy less than 6 months; or anticipated absence or disenrollment from the AltaMed PACE. Potential participants were screened from the pool of

PACE enrollees and identified by AltaMed staff based on routine PHQ-9 screening conducted face to face. Those who scored positive for depression (>8 on the PHQ-9) and met all other study inclusion criteria were invited to participate in the study.

Interested participants completed an informed consent following routine screening of PACE enrollees by AltaMed staff or study research personnel. Upon documented written consent, trial personnel conducted a face-to-face structured baseline interview and reviewed any questions the participants (and their caregivers) might have regarding informed consent and the study.

Following signing of informed consent, confirmation of trial eligibility, and completion of the baseline interview, study participants were randomly assigned in a 1:1 allocation to PST or EUC. Randomization was stratified by the interventionist to ensure balanced allocation of PST and EUC for each interventionist. Randomization was additionally blocked, with a block size of 2; the block size was not revealed to study investigators or staff. Participants and interventionists were not blinded to study allocation. Upon completion of all baseline assessments, the interviewer completed a web-based randomization (entering the trial interventionist and the participant study ID). An automated email confirming the randomly assigned intervention group was sent to the trial coordinator, data manager, and interventionist. The interviewer provided the participant with the appropriate packet of intervention materials and further instructions. The PST and EUC approaches were delivered and the data collected at each participant's AltaMed PACE site; data collection could also occur at participants' homes. All trial participants received a $30 gift card to a local store for their participation in each of the baseline, 3-month, 6-month, and 12-month outcome interviews.

Intervention and Comparator

Problem-Solving Treatment

PST sessions are intended to increase rational problem-solving and behavioral activation to mitigate maladaptive coping in the face of stressors. Patients are empowered to solve their here-and-now problems in a structured, easy-to-follow manner that ultimately increases self-

efficacy and motivation, thus decreasing the association of stress and problems on mood such as depression. A step-by-step process of rational problem-solving is discussed, put into action, and evaluated during each session. All sessions involve identifying the scheduling of pleasant activities for the following week. The self-management elements of PST are likely to be effective among persons who face illness/disability-related and environmental stress that require ongoing effective coping.

After the last PST session, each participant was asked to complete 3 monthly booster sessions (about 15-20 minutes each) as a brief "check-in" to assess whether the patient was continuing to apply the PST problem-solving model or framework. The PST protocol is intended to be highly structured, time limited, and manual driven; sessions include PST handouts and homework as well as social and behavioral activation strategies (ie, scheduling pleasant activities).[103] More information is available at https://aims.uw.edu/collaborative-care/behavioral-interventions/problem-solving-treatment-pst.

PST has a rich history of evidence supporting its effectiveness in depression care dating back to the 1980s. In randomized studies, PST reduced depressive symptoms among cancer patients and their caregivers,[104,105] older adults,[106] primary care patients with major depression,[107-112] and people with minor depression in community-based services.[98] More recent studies provide further evidence of the effectiveness of PST in older chronically ill patients, including a meta-analysis of problem-solving therapies for depression.[113-116]

The PST protocol is highly structured (ie, prescriptive in terms of phases or steps to take to learn problem-solving), time limited, and manual driven; sessions include PST handouts and homework as well as social and behavioral activation strategies.[105,106,113,116-126] Weekly individual face-to-face PST sessions over a span of 8 weeks were conducted at all PACE sites (8 sessions total; each lasting 45 minutes to 1 hour). After the last weekly PST session, 3 monthly booster sessions were held (about 15-30 minutes each).

The first session consisted of a review of the patient's depressive symptoms, depression psychoeducation, introduction of the rationale and relevance of PST for depression, and

development of an action plan and pleasant activities as homework for the following week's session. Sessions 2 through 8 reviewed the prior week's action plan, provided an outcome rating for the completion of the plan, and developed a subsequent action plan based on the patient's identification of a problem to address.

We undertook a preliminary review of the initial problem-solving session, specifically the problems identified in the patients' action plans. The following problems were the most frequently endorsed: health and functional impairments, family/relationship conflicts, financial issues, death of a close other, and chronic pain.

Enhanced Usual Care

During the full psychoeducational session, all EUC patients received a similar psychoeducational program for depression as their PST patient counterparts. EUC participants received a full 1-hour psychoeducational session with detailed bilingual materials on depression, depression treatment for older adults, and a contact person for services. The session involved face-to-face interaction and discussions with the interventionist regarding depression symptoms, treatment options, and where to go to for help. Similar to PST, the psychoeducational materials and discussions were based on information developed in the previous pilot study, Programa Mano Amiga,[127,128] where materials were developed in Spanish and English, and modest cultural adaptations were added from the stakeholder feedback described earlier. The delivery of PST was documented in 62 patients older than age 60 with multiple chronic care conditions in a similar treatment setting with significant changes in depression outcomes at the 4-month follow-up period.

The interventionist and patient engaged in a discussion regarding the same topics listed previously. The main differences between PST and EUC were (1) number of sessions (8 PST vs 1 EUC session); (2) EUC did not include information regarding PST, problem-solving strategies, and so on; and (3) no action plans were developed with EUC. If needed, both PST and EUC participants received referrals to specialty mental health providers (eg, psychiatrist, licensed

clinical social worker, licensed marriage and family therapist) from their interventionist for depression treatment.

Both PST and EUC participants continued to receive the full complement of PACE services (medical care, on-site day care, rehabilitation services, personal assistance, and social activities) including referrals to specialty mental health services, if needed. Interventionists tracked and documented participant attendance for all PST (regular/booster) sessions and the EUC psychoeducational session at the time of delivery in the computerized patient health record.

Interventionist Training and Fidelity of Treatment Delivery

A total of 13 interventionists (12 women, 1 man; all between 25 and 35 years of age) were recruited and trained to deliver the trial interventions. Nine interventionists were initially selected from the pool of BSWs; later, 4 MSW health educators were selected. All were employed by AltaMed PACE programs and fluent in both English and Spanish. Interventionists did not conduct baseline or outcome assessments. All were trained in study screening, recruitment, and informed consent protocols.

PACE social work and health educators were trained over a period of 6 months totaling about 50 hours of initial training, subsequent booster trainings, and case reviews by the study's principal investigator, who is a nationally certified PST trainer. Each interventionist received supervision across at least 3 case reviews to establish PST trained-to-competence status using an adherence rating scale for 8 domains rated from low (1) to high (3). Adherence ratings and feedback were provided in these domains: (1) depression psychoeducation; (2) defining the problem and setting a goal; (3) generating potential solutions and deciding on a solution; (4) implementation; (5) evaluating the outcome; and (6) global rating. Trained-to-competence status was achieved with a score of 3.0. Only 3 interventionists needed more than 3 case reviews to attain trained-to-competence status. Initial and booster trainings included didactic lectures, observation, practice and modeling sessions, and self-study. Interventionists received

additional training by AltaMed study personnel regarding online data entry/coding, managing IT system entries, and submission of study records to USC study personnel.

Study Outcomes

Primary and Secondary Outcomes

The primary trial outcome was a continuous measure of depression, measured by the PHQ-9 total score. Previous evidence supports the PHQ-9 as a reliable and valid measure to assess late-life depression in adults without neurocognitive disorders and its relative utility compared with other geriatric depression rating scales.[129-131] Although our specified primary outcome was targeted at this population of older depressed Latino adults, we included a number of secondary trial outcomes that we hypothesized could be directly improved with the PST intervention or could be improved secondary to reduced depression. Given this, we specified secondary quantitative research questions evaluating the effects of PST compared with EUC on anxiety, quality of life, problem-solving skills and behavior activation, and physical functioning.

Secondary trial outcomes therefore included (1) PHQ-9 defined categories of depression improvement (clinically significant depression response, partial depression response, depression remission); (2) depression symptoms, measured by the SCL-20; (3) generalized anxiety, measured by the 7-item Generalized Anxiety Disorder scale (GAD-7); (4) dysthymia; (5) problem-solving abilities, measured by the Social Problem-Solving Inventory (SPSI); (6) physical function, measured by hand grip strength, walking speed, and a composite measure of frailty; and (7) health-related quality of life, measured by the 12-item Short Form Survey (SF-12; both Mental Health and Physical Health subscales).

Adverse Events

There were no expected adverse events specific to the PST intervention. However, given the population of older depressed adults, the primary safety assessment was suicide risk. At each outcome assessment (baseline, 3 months, 6 months, and 12 months), research interviewers completed a structured suicide risk assessment protocol. A positive response to

suicide risk was reported as a serious adverse event and immediately reported to AltaMed staff and the trial principal investigator.

Time Frame for the Study

Weekly face-to-face PST sessions were delivered over 8 weeks, followed by 3 monthly booster sessions. Trial outcomes were measured at baseline (prerandomization) and at postrandomization periods at 3 months (to assess short-term intervention effect), 6 months (to assess longer-term intervention effect), and 12 months (to assess longer-term postintervention effect).

Data Collection and Sources

Participants were contacted either via telephone or at the PACE sites to schedule trial outcome assessments. All assessments were conducted in person, and data were recorded by trained interviewers using electronic data capturing management programs. Very few were conducted in participants' homes. Reasons for withdrawal from the trial were obtained directly from the participant or family members; reasons for loss to follow-up were obtained from family members or AltaMed staff. Linkage of trial data to the electronic health record used the AltaMed participant identifier, with checks on the accuracy of the identifier linkage to the trial study identifier. PST sessions were documented by the interventionists in the participants' electronic health records. All trial outcomes employed validated scales and tests used in geriatric research and were suitable for older English and Spanish speakers.[130,132-135]

Analytical and Statistical Approaches

Sample Size

Preliminary data from a previous pilot trial (Programa Mano Amiga) were used to compare PST with EUC among 100 participants (62 PST, 38 EUC). The pilot trial showed a 4-month treatment effect size (mean group difference divided by standard deviation [SD]) on the Hamilton Depression Rating Scale of 0.51. For a 2-sided α level of .05 and 90% power, 82 participants per group were required to detect this effect size of 0.51. Because Programa Esperanza was designed to evaluate the PST intervention in an older, more medically ill patient

population and to accommodate possible dropout, a total of 125 participants per group (250 total participants) were planned for recruitment. A dropout rate of 10% allowed detection of treatment effect sizes of 0.37 and higher (smaller than the 0.51 found in the pilot).

Analysis Plan

Demographic and other baseline characteristics as well as baseline levels of trial outcomes were reported by randomly assigned treatment groups using descriptive statistics (mean, median, and frequencies). Group comparisons on trial outcomes were conducted using an intention-to-treat approach; comparisons of trial outcomes for treatment efficacy included all randomly assigned participants, regardless of their adherence/participation to their assigned trial intervention.

Trial outcomes were compared between randomly assigned treatment groups using hierarchical generalized linear mixed-effects models. The unit of analysis was participant, nested within interventionist. Random effects were specified for subject and interventionist. Dependent variables were the trial outcome with repeated measurements at 3, 6, and 12 months postrandomization. Continuous outcomes (eg, PHQ-9 level) used an identity link function; dichotomous trial outcomes (eg, dysthymia) used a logit link function. The baseline PHQ-9 value was included as a model covariate for all outcomes. Assessment times (at 3, 6, and 12 months) were modeled as indicator variables; interactions of randomized treatment by assessment time tested for treatment group differences in trial outcomes (mid-intervention at 3 months, end of intervention at 6 months, postintervention sustainment of treatment effect at 12 months).

Because each of these treatment group comparisons addressed a separate research hypothesis (timing of intervention effect, sustaining of treatment effect), all tests were conducted at a 2-sided α of .05. A *P* value of .05 was considered statistically significant for the primary PHQ-9 trial outcome; *P* values for secondary trial outcomes should be interpreted with caution due to multiple hypothesis testing. Participants with complete vs incomplete trial outcome data were compared on demographic and other baseline characteristics, including

baseline levels of the trial outcomes. Because of the high rate of trial completion (251 of 259 completing the 6-month and 245 of 259 completing the 12-month follow-up and outcome assessments), analyses were restricted to completed outcomes, and missing outcome data were not imputed.

Heterogeneity of treatment effects. All subgroup analyses were performed as exploratory, or hypothesis-generating analyses. The main treatment-modifying effects evaluation, specified a priori in the trial protocol, included age (<65, ≥65 years); baseline depression severity (PHQ-9 <15, mild to moderate depression vs ≥15, moderately severe and severe depression); sex; and education (≤6th grade, >6th grade). Possible modification of treatment efficacy by these variables was tested with inclusion of an interaction term in the mixed-effects models (eg, age group × treatment group × time). Using appropriate contrasts, we presented parameter estimates and standard errors (SEs) for the treatment group differences for each subgroup. Because the trial sample size was not statistically powered to detect treatment interactions, and we did not have clear hypotheses on the direction of such treatment modification, all subgroup analyses presented are hypothesis generating.

Sensitivity analyses. The following additional sensitivity analyses were conducted, using the mixed-effects model approach detailed previously: (1) An adherence-based analysis limited data to participants who were adherent to their assigned intervention, and an adherent PST subject attended all weekly PST sessions; and (2) baseline variables were included that differed between groups as model covariates.

Changes to the Original Study Protocol

In the first year, 4 AltaMed health educators were added to the pool of PST interventionists. This protocol change was enacted for several reasons: (1) to increase the size of the pool of interventionists earlier in the face of an anticipated challenge in staff (interventionist) turnover; (2) recent Centers for Medicare and Medicaid Services (CMS) regulations prohibiting the hiring of BSWs for psychosocial assessments or treatment of PACE participants led AltaMed to decide not to hire any new BSWs in the future for psychosocial

assessments; and (3) the AltaMed research site was interested in identifying a larger workforce to administer behavioral health care to their PACE consumers. The health educators received the same training, follow-up training, and case review and monitoring as the social work interventionists.

We modified the timing and methods of the qualitative component. First, we modified scheduling of interviews so the interviews could be conducted with randomly selected participants after they had already completed their 12-month outcome interview, not before. This was done to avoid contaminating results before trial treatment completion and 12-month outcomes. Second, we modified the method of conducting focus groups to conducting individual in-depth interviews only. The quarterly stakeholder meetings served a similar function as focus group interviews, and employees might have been reticent to participate in group interviews with their staff peers, and possibly, their supervisors.

RESULTS

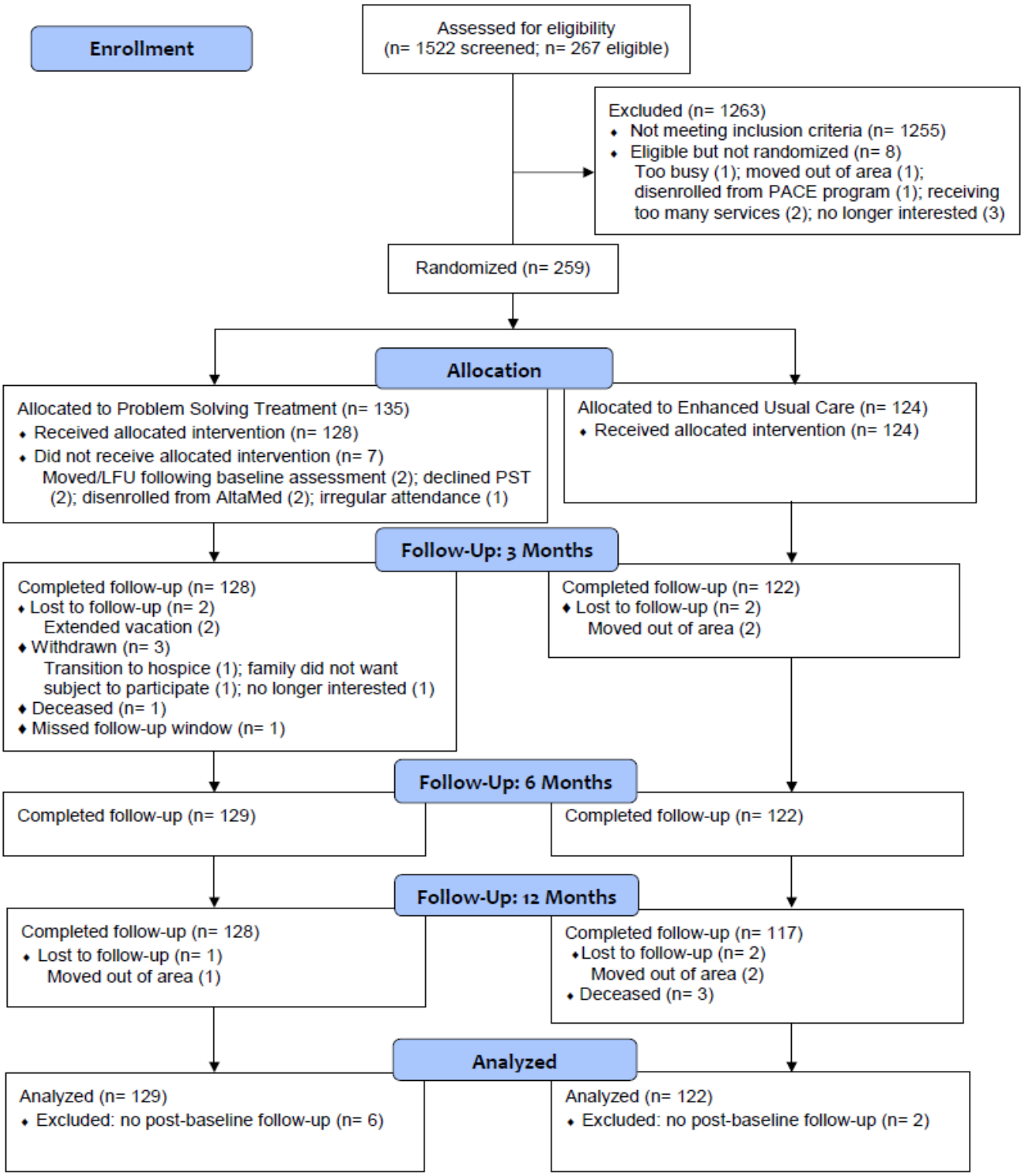
Results of the Comparative Effectiveness Trial

Trial Flow

Screening and randomization occurred between June 2015 (first screening and first randomization) and February 2017 (final randomization); participant follow-up was completed in January 2018. A total of 1522 potential participants were screened for inclusion (Figure 1); 259 were eligible, consented, and randomly assigned (17.5% of screened). Of 1255 individuals who did not pass the screening, the primary reason for ineligibility was PHQ-9 score lower than 8 (n = 960 [63.1% of screened participants]). The second major exclusion was cognitive screen failure (by BIMS; n = 188 [12.3%]). A total of 259 of the resulting 267 eligible participants (97% of eligible) were randomly assigned to PST (n = 135) or EUC (n = 124).

A total of 8 participants (6 PST, 2 EUC [3.1% of randomly assigned]) did not reach the first follow-up assessment at 3 months. Reasons for loss of 6 PST participants were loss to follow-up (extended vacation, n = 2), withdrew from study (n = 3), and deceased (n = 1). The 2 EUC participants had moved out of the area. The remaining 251 participants (129 PST, 122 EUC) provided follow-up to at least 6 months (1 of these in the PST group missed the 3-month follow-up). A total of 245 participants (128 PST, 117 EUC [94.6% of randomly assigned]) completed the 12-month follow-up. Six participants completing the 6-month follow-up did not complete the 12-month follow-up, including 1 PST participant (moved out of area) and 5 EUC participants (2 moved out of area; 3 died).

Figure 1. Programa Esperanza CONSORT diagram



Abbreviations: LFU, lost to follow-up; PACE, Program of All-Inclusive Care for the Elderly; PST, problem-solving treatment.

Baseline Characteristics

Programa Esperanza sample characteristics are presented in Table 1 (demographics) and Table 2 (trial outcomes) by randomly assigned group. The groups showed excellent comparability on all characteristics. With an average age of 70.2 years (SD, 8.87 years), the sample was primarily female (78.4%), born outside of the United States (93.4%), and preferred speaking Spanish (92.3%). One-third were married or in a partner relationship, and approximately one-half were widowed, divorced, or separated (50.6%). The great majority of the sample (88.8%) had not graduated high school, with 17% reporting no formal education. The 242 foreign-born participants had on average lived in the United States for 35.0 years (SD, 14.2 years); most were born in Mexico (66.1%), El Salvador (17.8%), or Guatemala (7.4%). On average participants reported 3.2 stressful life events (SD, 1.9) (of a total 16 specific events queried) over the previous 12 months.

The average PHQ-9 level of 13.0 (SD, 4.3) at baseline indicated an average moderate level of depression. By PHQ-9, level of depression was mild in 25.9% of participants, moderate in 42.9%, moderately severe in 22.8%, and severe in 8.5%. The average GAD-7 anxiety score was in the range of moderate anxiety; most (57.5%) participants reported moderate to severe anxiety. Approximately one-third (34.7%) of the sample were dysthymic; the average SF-12 Mental Health subscale score was 35.8 (SD, 10.6). In terms of physical function, most (63.7%) were rated as pre-frail and 20.1% were rated as frail, using a frailty algorithm that combined unintended weight loss, exhaustion, lowest 20% of grip strength, lowest 20% of walking speed, and lowest 20% of physical activity. The average SF-12 Physical Health subscale score was 30.7 (SD, 6.3).

Table 1. Programa Esperanza Baseline Characteristics (N = 259)

	EUC, n = 124	PST, n = 135
	n (%)	n (%)
Age, y		
Mean (SD)	70.7 (9.0)	69.8 (8.6)
55-64	36 (29.0)	51 (37.8)
65-74	49 (39.5)	42 (31.1)
75-84	31 (25.0)	36 (26.7)
≥85	8 (6.4)	6 (4.4)
Sex		
Male	24 (19.3)	32 (23.7)
Female	100 (80.7)	103 (76.3)
Marital status		
Married/Living with partner	41 (33.1)	45 (33.3)
Divorced	14 (11.3)	11 (8.1)
Separated	10 (8.1)	21 (15.6)
Widowed	40 (32.3)	35 (25.9)
Single/Never married	19 (15.3)	23 (17.0)
Education		
None or no formal education	24 (19.4)	20 (14.8)
Grade 1-6	71 (57.3)	82 (60.7)
Grade 7-11	17 (13.7)	16 (11.8)
High school diploma or GED	4 (3.2)	9 (6.7)
Beyond high school	8 (6.4)	8 (5.9)
Preferred language		
English	5 (4.0)	11 (8.1)
Spanish	117 (94.3)	122 (90.4)
Bilingual	2 (1.6)	2 (1.5)
Country of birth		

	EUC, n = 124	PST, n = 135
	n (%)	n (%)
United States	6 (4.8)	11 (8.2)
Mexico	83 (66.9)	77 (57.0)
El Salvador	18 (14.5)	25 (18.5)
Guatemala	11 (8.9)	7 (5.2)
Nicaragua	2 (1.6)	5 (3.7)
Honduras	2 (1.6)	3 (2.2)
Ecuador	1 (0.8)	2 (1.5)
Colombia	0 (0)	2 (1.5)
Cuba	0 (0)	2 (1.5)
Argentina	0 (0)	1 (0.7)
Peru	1 (0.8)	0 (0)
Years in United States[a]		
1-10	9 (7.6)	6 (4.8)
11-19	13 (11.0)	9 (7.3)
20-29	20 (17.0)	16 (12.9)
30-39	31 (26.3)	45 (36.3)
40-49	30 (25.4)	37 (29.8)
≥50	15 (12.7)	11 (8.9)
No. of stressful life events in past 12 mo (possible range, 0-16), mean (SD)	3.4 (2.0)	3.1 (1.7)

Abbreviations: EUC, enhanced usual care; PST, problem-solving treatment.
[a]Years in United States reported among 242 foreign-born participants.

Table 2. Programa Esperanza Psychological and Physical Characteristics at Baseline (N = 259)

	EUC, n = 124	PST, n = 135
	Mean (SD) or n (%)	Mean (SD) or n (%)
Psychological outcomes		
PHQ-9 depression	13.1 (4.3)	12.9 (4.3)
PHQ-9 depression categories		
Mild, 8-9	28 (22.6)	39 (29.9)
Moderate, 10-14	56 (45.2)	55 (40.7)
Moderately severe, 15-19	30 (24.2)	29 (21.5)
Severe, 20-27	10 (8.1)	12 (8.9)
SCL-20 depression symptoms	1.5 (0.7)	1.5 (0.8)
GAD-7 anxiety	10.8 (5.8)	10.5 (5.3)
GAD-7 anxiety categories		
Minimal, 0-4	18 (14.5)	18 (13.3)
Mild, 5-9	34 (27.4)	40 (29.6)
Moderate, 10-14	35 (28.2)	49 (36.3)
Severe, 15-21	37 (29.8)	28 (20.7)
Dysthymia	39 (31.4)	51 (37.8)
SF-12 Mental Health	36.5 (10.9)	35.2 (10.4)
Physical outcomes		
Frailty		
Not frail	22 (17.7)	20 (14.8)
Pre-frail	81 (65.3)	84 (62.2)
Frail	21 (16.9)	31 (23.0)
Grip strength, kg	16.4 (12.4)	14.6 (8.3)
Walking speed, s	6.2 (2.5)	6.3 (2.9)
SF-12 Physical Health	30.3 (6.0)	31.0 (6.6)

Abbreviations: EUC, enhanced usual care; GAD-7, General Anxiety Disorder scale; PHQ-9, Patient Health Questionnaire; PST, problem-solving treatment; SCL-20, Symptom Checklist Depression Scale; SF-12, 12-item Short Form Survey.

Receipt of PST and EUC Interventions

Most of the 135 participants randomly assigned to PST received the full intervention of 8 face-to-face and 3 booster sessions (n = 88 [62.5%]) (Table 3). The large majority (n = 110 [81.5%]) received the planned 8 face-to-face sessions. Seven participants (5.2% of PST) did not receive any PST interventions; reasons for not receiving PST were participants moved (n = 2), declined PST (n = 2), disenrolled from AltaMed (n = 2), and had irregular PACE attendance (n = 1). Seventeen (12.6%) participants received 4 or fewer PST sessions. All EUC participants (100%) participated in and received 1 full-hour psychoeducational session at enrollment (described later).

Table 3. Receipt of PST Interventions (n = 135)

	n	%
No. of sessions and boosters		
8 sessions + 3 boosters	88	65.2
8 sessions + 2 boosters	7	5.2
8 sessions + 1 booster	11	8.1
8 sessions + 0 boosters	4	3.0
Partial completions of sessions		
7 sessions	0	0
6 sessions	3	2.2
5 sessions + 1 booster	1	0.7
5 sessions	4	3.0
4 sessions	3	2.2
3 sessions	0	0
2 sessions	2	1.5
1 session	5	3.7
0 sessions	7	5.2

PST Effects on Primary and Secondary Trial Outcomes

Intervention group comparisons on trial outcomes assessed at 3, 6, and 12 months are presented in Tables 4 through 7. Mixed-effects regression models compared the outcomes at follow-up among the 251 participants who had at least 1 follow-up assessment (128 PST and 122 EUC at 3 months; 129 PST and 122 EUC at 6 months; 128 PST and 117 EUC at 12 months). Tables show the model-estimated mean (SE of the mean) outcomes by randomized group at each follow-up, with an estimate (and 95% CI) and *P* value on the mean group difference at each assessment time. A treatment × time interaction tests whether the group differences significantly differ over the follow-up period. Also presented is a statistical test for within-group changes in the outcome over the 12-month follow-up. Results for dichotomous outcomes are presented as percentages and relative differences.

Primary outcome, PHQ-9. Both PST and EUC groups showed statistically significant declines in PHQ-9 over the trial (both $P < .0001$), with no significant differences between groups at any follow-up time (Table 4). Effect sizes for the 12-month within-group change in PHQ-9 (mean change from baseline to 12 months, divided by baseline SD) were large, 0.81 for PST and 0.88 for EUC. In contrast, the 6-month treatment effect size (PST vs EUC, at the end of the protocol-specified PST intervention period) was 0.09. At 12 months, approximately one-third of participants in each group showed improvement, measured as a reduction in PHQ-9 of at least 50% from baseline (model estimated, 37.4%; SE, 5.4%) in PST, 32.4% [SE, 5.2%] in EUC); the group difference was not statistically significant (PST minus EUC = 5.0% [95% CI, −9.8% to 19.8%]) (Table 5). Groups also showed no differences in rates of remission (Table 5), defined as achievement of a PHQ-9 score below 5; at 12 months, model-estimated remission rate was 20.8% (SE, 4.6%) in PST participants and 18.3% (SE, 4.4%) in EUC participants (group difference, 2.5% [95% CI, −10.1% to 15.1%]).

Secondary psychological health outcomes. Similar to the primary PHQ-9 results, the PST and EUC groups showed no statistically significant differences in mean levels of secondary psychological outcomes (including SCL-20, GAD-7, SF-12 Mental Health, and dysthymia) over the trial follow-up (Tables 4 and 5). Statistically significant within-group

declines in continuous outcomes of depression symptoms (SCL-20; within-group 12-month effect size of 0.45 in PST, 0.32 in EUC); anxiety (GAD-7; within-group 12-month effect size of 0.40 in PST, 0.24 in EUC); and SF-12 Mental Health (within-group 12-month effect size of 0.33 in PST, 0.25 in EUC) were seen in both PST and EUC groups (all $P < .015$). In contrast, the dichotomous outcome of dysthymia showed no significant within-group changes over the 12-month follow-up (Table 5).

Table 4. Programa Esperanza Psychological Health: Continuous Outcomes Analyzed in Linear Mixed-Effects Models (n = 251)[a]

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	LSM (SE)	LSM (SE)	Difference Mean (95% CI)	*P*	
PHQ-9					.87
Baseline	13.1 (0.5)	13.0 (0.5)	−0.1 (−1.3 to 1.1)	.89	
3 mo	10.5 (0.5)	10.3 (0.5)	−0.2 (−1.4 to 1.1)	.80	
6 mo	9.8 (0.5)	9.4 (0.5)	−0.4 (−1.6 to 0.8)	.49	
12 mo	9.3 (0.5)	9.5 (0.5)	0.2 (−1.1 to 1.4)	.78	
P trend	< .0001	< .0001		.70	
GAD-7					.65
Baseline	10.7 (0.5)	10.8 (0.5)	0.05 (−1.2 to 1.3)	.94	
3 mo	9.1 (0.5)	9.0 (0.5)	−0.1 (−1.4 to 1.2)	.87	
6 mo	9.2 (0.5)	9.2 (0.5)	0.0 (−1.3 to 1.3)	.99	
12 mo	9.4 (0.5)	8.6 (0.5)	−0.8 (−2.1 to 0.5)	.25	
P trend	.04	.0002		.27	
SCL-20					.50
Baseline	1.45 (0.07)	1.52 (0.06)	0.07 (−0.08 to 0.23)	.36	
3 mo	1.33 (0.07)	1.31 (0.06)	−0.02 (−0.17 to 0.14)	.83	
6 mo	1.25 (0.07)	1.22 (0.06)	−0.02 (−0.18 to 0.13)	.78	
12 mo	1.19 (0.07)	1.16 (0.06)	−0.03 (−0.19 to 0.13)	.71	
P trend	< .0001	< .0001		.25	
SF-12 Mental Health subscale					.057

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	LSM (SE)	LSM (SE)	Difference Mean (95% CI)	*P*	
Baseline	36.6 (1.0)	35.0 (0.9)	−1.6 (−4.1 to 0.9)	.22	
3 mo	37.9 (1.0)	39.6 (0.9)	1.7 (−0.8 to 4.2)	.18	
6 mo	37.6 (1.0)	38.6 (0.9)	1.1 (−1.4 to 3.6)	.41	
12 mo	39.2 (1.0)	38.5 (0.9)	−0.6 (−3.2 to 1.9)	.62	
P trend	.015	.008		.92	

Abbreviations: EUC, enhanced usual care; GAD-7, General Anxiety Disorder scale; LSM, least squares mean; PHQ-9, Patient Health Questionnaire; PST, problem-solving treatment; SCL-20, Symptom Checklist Depression Scale; SF-12, 12-item Short Form Survey.

[a]Linear mixed-effects model, specifying random effects for interventionist and interventionist nested within subject, fixed effects for treatment, assessment time (as indicator variables), site, the interaction of treatment × time, and adjustment for baseline PHQ-9. Analysis includes 997 observations among 251 participants with at least 1 postbaseline assessment.

Table 5. Programa Esperanza Psychological Health: Dichotomous Outcomes Analyzed in Logistic Mixed-Effects Models (n = 251)[a]

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	Model-fitted, % (SE)	Model-fitted, % (SE)	Difference (95% CI)	*P*	
Dysthymia					.84
Baseline	28.4 (5.0)	36.0 (5.3)	7.6 (−6.7 to 21.9)	.28	
3 mo	26.6 (4.9)	26.5 (4.7)	−0.1 (−13.4 to 13.2)	.99	
6 mo	22.1 (4.4)	23.0 (4.4)	0.9 (−11.4 to 13.1)	.88	
12 mo	26.1 (4.9)	29.1 (4.9)	2.9 (−10.7 to 16.6)	.66	
P trend	.66	.36		.75	
Improvement: ≥50% PHQ-9 score reduction from baseline					.88
3 mo	24.8 (4.6)	33.3 (5.2)	8.5 (−5.2 to 22.1)	.22	
6 mo	25.7 (4.7)	34.0 (5.2)	8.3 (−5.5 to 22.1)	.24	
12 mo	32.4 (5.2)	37.4 (5.4)	5.0 (−9.8 to 19.8)	.51	
P trend	.19	.51		.62	
Improvement: ≥50% SCL-20 score reduction from baseline					.55
3 mo	10.8 (3.0)	13.4 (3.2)	2.6 (−6.0 to 11.2)	.55	
6 mo	14.0 (3.4)	17.1 (3.7)	3.1 (−6.8 to 12.9)	.54	
12 mo	21.5 (4.3)	18.0 (3.8)	−3.5 (−14.7 to 7.8)	.54	
P trend	.02	.36		.30	
Remission: PHQ-9 <5					.83
3 mo	11.0 (3.2)	16.3 (4.0)	5.3 (−4.7 to 15.3)	.27	
6 mo	15.7 (4.0)	21.1 (4.7)	5.5 (−6.5 to 17.5)	.34	
12 mo	18.3 (4.4)	20.8 (4.6)	2.5 (−10.1 to 15.1)	.68	
P trend	.13	.45		.54	
Remission: SCL-20 <0.5					.37
3 mo	7.2 (2.5)	7.9 (2.6)	0.7 (−6.4 to 7.8)	.83	
6 mo	6.5 (2.4)	11.9 (3.4)	5.3 (−2.8 to 13.5)	.16	
12 mo	12.1 (3.6)	10.6 (3.2)	−1.5 (−10.9 to 7.9)	.73	
P trend	.12	.54		.45	

Abbreviations: EUC, enhanced usual care; PHQ-9, Patient Health Questionnaire; PST, problem-solving treatment; SCL-20, Symptom Checklist Depression Scale.

[a]Logistic mixed-effects model, specifying random effects for interventionist and interventionist nested within subject, fixed effects for treatment, assessment time (as indicator variables), site, the interaction of treatment × time, and adjustment for baseline PHQ-9. Analysis includes 997 (dysthymia) and 746 (improvement and remission outcomes) observations among 251 participants with at least 1 postbaseline assessment.

Secondary social problem-solving outcomes. No statistically significant treatment × time interactions were noted for any of the social problem-solving scales (Table 6). Statistically significant within-group changes in scales were noted in both PST and EUC groups for Avoidance Style (decrease over time), Impulsive/Careless Style (significant decreasing trend in EUC group only), and Negative Problem Orientation (decrease over time). Neither group showed significant changes in Rational Problem-Solving or Positive Problem Orientation. Although the PST group showed significantly higher scores than the EUC group on both Rational Problem-Solving and Positive Problem Orientation at baseline, adjustment for these baseline scores did not alter the findings.

Table 6. Programa Esperanza Social Problem-Solving Inventory Analyzed in Linear Mixed-Effects Models (n = 251)[a]

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	LSM (SE)	LSM (SE)	Difference Mean (95% CI)	*P*	
Avoidance Style					.24
Baseline	6.3 (0.4)	7.6 (0.4)	1.2 (0.2 to 2.2)	.018	
3 mo	6.9 (0.4)	7.2 (0.4)	0.3 (−0.7 to 1.3)	.54	
6 mo	6.6 (0.4)	6.9 (0.4)	0.3 (−0.7 to 1.3)	.54	
12 mo	5.6 (0.4)	6.5 (0.4)	0.9 (−0.1 to 2.0)	.07	
P trend	0.015	0.005		.85	
Impulsivity/Carelessness Style					.37
Baseline	7.0 (0.4)	7.4 (0.5)	0.4 (−0.6 to 1.4)	.43	
3 mo	6.8 (0.4)	7.6 (0.4)	0.8 (−0.2 to 1.8)	.10	
6 mo	6.6 (0.4)	7.1 (0.4)	0.5 (−0.5 to 1.5)	.32	
12 mo	5.8 (0.4)	7.0 (0.4)	1.3 (0.3 to 2.2)	.012	
P trend	0.001	0.19		.15	
Negative Problem Orientation					.73
Baseline	8.3 (0.4)	8.7 (0.4)	0.4 (−0.6 to 1.3)	.46	
3 mo	7.7 (0.4)	7.9 (0.4)	0.2 (−0.7 to 1.2)	.63	

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	LSM (SE)	LSM (SE)	Difference Mean (95% CI)	*P*	
6 mo	7.6 (0.4)	8.0 (0.4)	0.4 (−0.5 to 1.4)	.37	
12 mo	6.7 (0.4)	7.5 (0.4)	0.8 (−0.2 to 1.8)	.11	
P trend	<0.0001	0.002		.31	
Rational Problem- Solving					.42
Baseline	7.6 (0.5)	9.1 (0.4)	1.5 (0.5 to 2.5)	.003	
3 mo	7.9 (0.5)	8.9 (0.4)	1.0 (0.05 to 2.0)	.04	
6 mo	8.1 (0.5)	8.9 (0.4)	0.8 (−0.2 to 1.8)	.12	
12 mo	8.1 (0.5)	8.6 (0.4)	0.5 (−0.4 to 1.5)	.28	
P trend	0.23	0.30		.11	
Positive Problem Orientation					.79
Baseline	7.3 (0.4)	8.3 (0.4)	1.0 (0.1 to 2.0)	.04	
3 mo	8.3 (0.4)	9.1 (0.4)	0.8 (−0.1 to 1.7)	.10	
6 mo	8.2 (0.4)	8.8 (0.4)	0.6 (−0.4 to 1.5)	.22	
12 mo	7.9 (0.4)	8.4 (0.4)	0.5 (−0.5 to 1.4)	.32	
P trend	0.26	0.81		.33	

Abbreviations: EUC, enhanced usual care; LSM, least squares mean; PST, problem-solving treatment.
[a]Linear mixed-effects model, specifying random effects for interventionist and interventionist nested within subject, fixed effects for treatment, assessment time (as indicator variables), site, the interaction of treatment × time, and adjustment for baseline Patient Health Questionnaire-9. Analysis includes 997 observations among 251 participants with at least 1 postbaseline assessment.

Secondary physical function outcomes. Measures of physical function of grip strength, walking speed, SF-12 Physical Health, and frailty showed no significant differences between treatment groups (Table 7). Except for a marginally significant decline in grip strength in the EUC group (*P* = .04), measures of physical function also showed no significant within-group changes over the 12-month period.

Table 7. Programa Esperanza Physical Function Outcomes Analyzed in Linear Mixed-Effects Models (n = 251)[a]

	EUC n = 122	PST n = 129	Group comparison PST minus EUC		*P*, Time × treatment interaction
	LSM (SE)	LSM (SE)	Difference Mean (95% CI)	*P*	
Grip strength, kg					.33
Baseline	17.0 (1.1)	14.8 (1.1)	−2.3 (−4.7 to 0.1)	.06	
3 mo	16.6 (1.1)	16.2 (1.1)	−0.4 (−2.8 to 2.0)	.73	
6 mo	16.6 (1.1)	16.1 (1.1)	−0.6 (−3.0 to 1.9)	.64	
12 mo	15.3 (1.1)	14.8 (1.1)	−0.5 (−2.9 to 2.0)	.71	
P trend	.04	.77		.21	
Walking speed, s					.34
Baseline	6.2 (0.2)	6.2 (0.2)	−0.03 (−0.7 to 0.7)	.94	
3 mo	6.3 (0.3)	5.8 (0.2)	−0.6 (−1.3 to 0.1)	.11	
6 mo	6.0 (0.3)	5.9 (0.2)	−0.2 (−0.9 to 0.5)	.65	
12 mo	6.3 (0.3)	5.8 (0.2)	−0.4 (−1.1 to 0.3)	.23	
P trend	.84	.18		.43	
SF-12 Physical Health subscale					.94
Baseline	30.3 (0.6)	30.9 (0.6)	0.6 (−1.1 to 2.2)	.49	
3 mo	30.4 (0.6)	31.0 (0.6)	0.6 (−1.1 to 2.2)	.50	
6 mo	30.8 (0.6)	31.2 (0.6)	0.2 (−1.4 to 1.9)	.79	
12 mo	31.1 (0.6)	31.4 (0.6)	0.2 (−1.5 to 1.9)	.80	
P trend	.12	.40		.59	
	%	%	Odds ratio PST vs EUC (95% CI)	*P*	Time × treatment interaction, *P*
Frailty					
Baseline					.46
Not frail	18.0	14.7	1.48 (0.74 to 2.92)	.26	
Pre-frail	64.8	63.6			
Frail	17.2	21.7			

	%	%	Odds ratio PST vs EUC (95% CI)	*P*	Time × treatment interaction, *P*
3 mo					
Not frail	13.1	20.3	0.85 (0.43 to 1.68)	.63	
Pre-frail	73.0	62.5			
Frail	13.9	17.2			
6 mo					
Not frail	13.9	17.1	0.85 (0.43 to 1.68)	.63	
Pre-frail	68.0	65.9			
Frail	18.0	17.0			
12 mo					
Not frail	21.4	19.5	0.99 (0.50 to 1.97)	.98	
Pre-frail	60.7	64.1			
Frail	17.9	16.4			
***P* trend**	.80	.18		.45	

Abbreviations: EUC, enhanced usual care; LSM, least squares mean; PST, problem-solving treatment; SF-12, 12-item Short Form Survey.

[a]Continuous outcomes used linear mixed-effects model, specifying random effects for interventionist and interventionist nested within subject, fixed effects for treatment, assessment time (as indicator variables), site, the interaction of treatment × time, and adjustment for baseline Patient Health Questionnaire-9. Frailty variable used ordinal logistic mixed-effects model with same fixed and random effects. For SF-12 Physical Health and frailty, analysis includes 997 observations among 251 participants; for grip strength, 861 observations among 222 participants; and for walking speed, 811 observations among 210 participants.

Adverse Events

Five deaths occurred among the 259 randomly assigned participants (1 death occurred after withdrawal from the study, due to transfer to hospice care). Deaths occurred in 2 PST participants (cervical cancer and sudden cardiac death) and 3 EUC participants (respiratory failure, sudden cardiac death, and cause unknown) (exact *P* value = .67). None of the deaths was associated with the study protocol.

Based on participant responses to flagged items on the PHQ-9 and SCL-20, 176 suicide risk assessments were completed: 58 participants at baseline (EUC n = 31 [25.0%]; PST n = 27 [20.0%]; exact *P* = .37); 47 participants at 3 months (EUC n = 30 [24.6%]; PST n = 17 [13.3%];

exact *P* = .02); 41 participants at 6 months (EUC n = 22 [18.0%]; PST n = 19 [14.7%]; exact *P* = .50), and 30 participants at 12 months (EUC n = 18 [15.4%]; PST n = 12 [9.4%]; exact *P* = .17). Among those assessed for suicide risk, 11.9%, or 21 participants, expressed positive responses and were referred to AltaMed staff for immediate follow-up: 6 (4 EUC; 2 PST; exact *P* = .68) at baseline; 5 (4 EUC, 1 PST; exact *P* = .64) at 3 months; 6 (5 EUC; 1 PST; exact *P* = .19) at 6 months; and 4 (3 EUC; 1 PST; exact *P* = .63) at 12 months. No attempted suicides occurred during the trial period.

Electronic Health Records: Healthcare Use and Clinical Measures

Abstracted CMS data were received from AltaMed for services received and clinical measures obtained in the 12-month period before randomization, and in the 0- to 6-month and 0- to 12-month periods following randomization. Although the number of primary care visits did not differ between PST and EUC groups in the 12 months before randomization, PST participants had significantly more primary care visits than EUC participants in the 6 months (*P* = .003) and 12 months (*P* = .017) following randomization (Table 8). In contrast, the number of emergency department (ED) visits was reduced in PST compared with EUC: 17% of PST and 29.8% of EUC participants had at least 1 ED visit in the first 6 months (*P* = .008), and 28.1% of PST and 38.7% of EUC participants had at least 1 ED visit in the 12 months following randomization (*P* = .06). Admission to a skilled nursing facility was also reduced in PST compared with EUC (0% PST and 4.8% EUC at 6 months, *P* = .01; 2.2% in PST and 6.4% in EUC at 12 months, *P* = .12). Hospitalizations and home care visits did not differ between groups. No psychiatric hospitalizations occurred.

PST and EUC participants did not differ significantly on body mass index (BMI), blood pressure, cholesterol levels, or hemoglobin A_{1c} (HbA_{1c}). In both groups, average BMI was in the obese range (>30 kg/m^2), average systolic blood pressures were well above 120 mm Hg, and average HbA_{1c} was in the range of diabetes not at treatment goal (>7%; Table 9).

Table 8. AltaMed CMS Abstracted Data: Service Use by Study Period

Service		EUC n = 124	PST n = 135	*P* value[a]
Primary care visits		**Median (25th-75th percentile)**	**Median (25th-75th percentile)**	
12 mo before Programa Esperanza		16.5 (2-33.5)	16 (2-34)	.89
0-6 mo		21 (14.5-29)	26 (18-35)	.003
0-12 mo		35 (26-52.5)	44 (31-61)	.017
Other specialty visits				
12 mo before Programa Esperanza		13 (7.5-21)	14 (8-22)	.92
0-6 mo		7 (4-11.5)	7 (4-10)	.93
0-12 mo		13.5 (8-20.5)	12 (8-19)	.56
Service	**Number**	**EUC n = 124**	**PST n = 135**	***P* value**
		n (%)	**n (%)**	
ED visits				
12 mo before Programa Esperanza	0	91 (73.4)	93 (69.9)	.81
	1	19 (15.3)	24 (17.8)	
	2	10 (8.1)	10 (7.4)	
	3	3 (2.4)	4 (3.0)	
	4	1 (0.8)	3 (2.2)	
	5	0 (0)	0 (0)	
	6	0 (0)	1 (0.7)	
0-6 mo	0	87 (70.2)	112 (83.0)	.008
	1	28 (22.6)	11 (8.1)	
	2	7 (5.6)	8 (5.9)	
	3	2 (1.6)	2 (0.8)	
	4	0 (0)	2 (1.5)	
0-12 mo	0	76 (61.3)	97 (71.9)	.06
	1	34 (27.4)	18 (13.3)	
	2	9 (7.3)	10 (7.4)	

Service		EUC n = 124	PST n = 135	*P* value[a]
	3	4 (3.2)	6 (4.4)	
	4	1 (0.8)	2 (1.5)	
	5	0 (0)	2 (1.5)	
Home care				
12 mo before Programa Esperanza	0	121 (97.6)	134 (99.3)	.42
	1	2 (1.6)	1 (0.7)	
	2	1 (0.8)	0 (0)	
0-6 mo	0	122 (98)	135 (100)	.23
	1	2 (1.6)	0 (0)	
0-12 mo	0	122 (98.4)	135 (100)	.23
	1	2 (1.6)	0 (0)	
Hospitalizations				
12 mo before Programa Esperanza	0	113 (83.7)	108 (87.1)	.79
	1	12 (8.9)	9 (7.3)	
	2	8 (5.9)	5 (4.0)	
	3	1 (0.7)	2 (1.6)	
	4	1 (0.7)	0 (0)	
0-6 mo	0	123 (91.1)	111 (89.5)	.51
	1	8 (5.9)	11 (8.9)	
	2	4 (3.0)	2 (1.6)	
0-12 mo	0	112 (83.0)	101 (81.4)	.89
	1	16 (11.8)	18 (14.5)	
	2	6 (4.4)	4 (3.2)	
	3	1 (0.7)	1 (0.8)	

Abbreviations: CMS, Centers for Medicare and Medicaid Services; ED, emergency department; EUC, enhanced usual care; PST, problem-solving treatment.

[a]*P* values by exact test.

Table 9. AltaMed CMS Abstracted Data: Clinical Variables[a]

Service	PST n = 135	EUC n = 124	*P* value[b]
	Median (25th-75th percentile)	Median (25th-75th percentile)	
BMI, kg/m^2			
12 mo before Programa Esperanza	32.3 (28.3-36.2)	32.2 (28.3-38.6)	0.64
6 mo	30.7 (27.6-36.7)	33.0 (28.3-38.9)	0.09
12 mo	30.7 (27.6-35.9)	32.2 (28.0-39.1)	0.19
Diastolic BP, mm Hg			
12 mo before Programa Esperanza	74 (68-80)	71.5 (66-80)	0.10
6 mo	72 (68-78)	70 (62-78)	0.11
12 mo	72 (68-80)	73 (65-80)	0.70
Systolic BP, mm Hg			
12 mo before Programa Esperanza	132 (122-141)	130 (120-140.5)	0.43
6 mo	130 (120-140)	131 (120-141)	0.75
12 mo	130 (120-142)	132.5 (120-144.5)	0.56
HbA_{1c}, %			
12 mo before Programa Esperanza	7.2 (6.2-8.4)	7.3 (6.1-8.9)	0.84
6 mo	7.4 (6.1-8.7)	7.45 (6.1-9.3)	0.64
12 mo	7.4 (6.1-8.7)	7.1 (6.1-8.8)	0.78
HDL cholesterol, mg/dL			
12 mo before Programa Esperanza	46 (38-57)	49 (41-60)	0.22
6 mo	48 (41-56)	48.5 (41-59.5)	0.70
12 mo	48 (41-59)	48 (41-56)	0.78
LDL cholesterol, mg/dL			
12 mo before Programa Esperanza	87 (64-104)	92 (70-109)	0.33
6 mo	95 (75-118)	91.5 (68-119)	0.70
12 mo	89 (67-119)	86.5 (65-112)	0.50

Abbreviations: BMI, body mass index; BP, blood pressure; EUC, enhanced usual care; HbA_{1c}, hemoglobin A_{1c}; HDL, high-density lipoprotein; LDL, low-density lipoprotein; PST, problem-solving treatment.

[a]Data are most recent values (ie, at baseline, 6, and 12 months).

[b]*P* values by Wilcoxon rank sum test.

Analyses and Results of the Qualitative Component

Overview

The study's secondary aim was to explore stakeholders' perspectives on the perceived effectiveness and satisfaction with PST, and potential sustainability factors. Qualitative methods address the complexities of clinical services research in naturalistic settings and can lead to a detailed understanding of how the intervention functioned in PACE settings as well as how barriers to disparities in care are addressed. Qualitative evaluations of clinical trials lend themselves to more robust assessments of factors that facilitate or hinder feasibility and acceptability of interventions, thus closing the gap between effectiveness research and translational science.[136-138]

Methods

Toward that end, we conducted 43 in-depth face-to-face interviews with study participants, interventionists, supervisors, and managers from AltaMed.

Study design/Qualitative approach. The qualitative component of the study followed a phenomenological approach that focused on the exploration of study participants' experiences and perceptions about depression treatment.

Sampling strategy. Postintervention semistructured in-depth patient interviews were conducted with randomly selected study participants and AltaMed providers after they completed their 12-month outcome interview. Participants were selected randomly, and recruitment of new interviewees was stopped when a saturation of themes emerged.

Data collection methods. Data were collected vis-à-vis 43 qualitative interviews conducted by telephone with 21 patient participants (16 women/5 men: 18 Spanish and 3 English speakers) and 22 AltaMed providers (21 women/1 man: all English speakers). The interviews lasted about 60 minutes, followed a semistructured interview guide, and were audiotaped and transcribed in the language conducted. Spanish-language interviews were

translated to English. All interviewees received a $30 gift card to a local store for their participation.

We conducted an open-ended component to assess more in-depth explorations of depression and the treatment experience, and longer-term issues that may emerge with PST or EUC. The method of collecting data was based on a guide/questioning route designed to collect in-depth information on the participant's own perceptions and reactions to treatment. Dropouts as well as completers were included. Providers (ie, interventionists, AltaMed managers, and executive leadership) comprised the nonpatient qualitative sample.

Qualitative interviews were developed a priori and included questions and follow-up probes on facilitators of and barriers to effective depression treatment. Similar questions were developed for both sets of patient and provider interviews. Interview questions were guided by the extant clinical services literature on psychosocial depression treatment and information that emerged during our initial stakeholder meetings. These interview guides are available upon request.

Data analysis. Data analysis was completed using an iterative process of data collection and analysis, in which new information from interviews informed the questioning route and probes of preceding interviews. All transcripts were manually coded and reviewed multiple times by at least 2 analysts. Data were analyzed using a thematic approach, and content was coded to reflect experiences and perceptions of the treatment and sustainability factors. Analyses were based on the constant comparison approach to determine whether a particular topic was similar to or different from a topic raised earlier and where discussion of a particular topic began and ended.[139] Codes were assigned to transcript segments reflecting meanings formulated from significant statements, phrases, and words. Codes and subcodes were discussed, matched, and integrated into 1 codebook through multiple consensus meetings and reviews of transcripts and audiotapes. During the axial stage, connections and relationships between the codes were identified. Thus, codes related to interviewees' perceptions and meanings of depression treatment and sustainability are reported next.

Synthesis, Interpretation, and Empirical Data

Themes emerged during the interviews and reviews of transcriptions and audiotapes. The results are presented by type of participant: patients and providers. Table 10 lists the themes and subcodes rather than listing them in the summary here.

Patient participants.

Patient participants, overall, expressed high satisfaction with their experience in Programa Esperanza. They discussed how they perceive depression and the significance of "relationship" in ensuring quality depression care.

Participant theme 1: Depression.

The "depression" code allowed participants to provide feedback on their experience of depression and how they recognize the symptoms of depression in themselves and others, and reflections on treatment. Captured within this theme are ideas about the causes of depression (ie, biological, psychological, and social/interpersonal factors) as well as comorbidities (eg, injuries, cardiac problems).

> **Patient:** *Like you're sad, you feel hopeless, you can't concentrate; you feel down and out . . . you have no hope . . . I'm sure there are more, I just can't think of them right now. . . . Yeah . . . you get the anxiety; you get the panic attacks; you're bad with your hygiene; you're not really motivated. I don't know . . . but there is a whole bunch!*

> **Patient:** *The depression, well, I speak for my experience, right, that one gets very decayed. You do not want to do anything. No, you don't have the will. You don't have the will to do anything, then, and it is very sad, without the will . . . and all that happens to you when you think negative things. That is what, what has happened to me. Just thinking things. Well, that are not, they are not good things. Well, some friends I've . . .I do not want to get up or I do not want to cook. Nothing, nothing.*

Provider: *Depression is feeling sad about certain things for extensive periods of time whether* [it] *is within you or yourself, or about something else that is causing you to feel that way.*

Acceptable treatments for depression included help-seeking behaviors such as talking to confidants or staff, using coping skills, taking medications, taking walks, and reading for pleasure. Family was discussed as both a trigger for depression and a potential mode of treatment that can provide a support system and people to confide in.

Participant theme 2: Relationship. Relationships were central to the treatment of depression, encompassing provider characteristics, how the provider related to the participant and others during sessions, and the importance of language and culture for effective communication. Acceptability and perceived effectiveness of the study interventions were seen as direct benefits stemming from the patient-interventionist relationship. For instance, specific interventionist skill or attributes were identified that either helped or hindered in their treatment process (eg, ability to remain calm and affable during sessions).

Patient: *Well like I said, she's very . . . you know she has a good heart—she's not like some people who, like, just come in and do their job. She does her job because she does listen to you; and she explains things to you—that way you don't leave the session not knowing what's going on.*

Patient: *They are good because you know, you know, you vent. It takes away that load that one carries or, or at least with Lupita* [she is a] *very, very good person and she says "no," she says, "Do not worry." There are solutions for everything. She says, "Here we are going to help her." And she gives very good advice.*

Provider: *Yes, I think so. I've heard a lot of great, great feedback from the patients here at our center. They really enjoyed it, and they verbalized that they benefited from the program. They really formed good relationships with their . . .*

interventionist. They really trusted them, and they had nothing but good things to say about their interventionists and also their experience.

AltaMed providers.

Overall, AltaMed providers indicated that participation in the program was beneficial to PACE participants, and they expressed interest in continuing the program with specific ideas regarding sustainability factors.

Provider theme 1. Organization.

The first provider theme to emerge was the concept of the "organization," its specific structure and functions, and how it affects program delivery and subsequently patient outcomes and satisfaction. The qualitative findings identified not only the structure and function of the overall AltaMed organization, but also the elements and structure of PACE, specifically. For example, providers were interested in "dedicated interventionist time" to work on the program, and the need for "supervisors' support" to help attain program goals. Hiring additional bilingual/bicultural staff was highlighted as well as integrating facilitators to sustainability and mitigating barriers. Stakeholder engagement was seen as a key source of information on the satisfaction and value-added as a service on their menu of planned activities.

> **Interventionist:** *I mostly had assigned days* [to provide sessions] *for the sites so, on Tuesday I was at* [site 1]*, Wednesday, I was at* [site 2]*, and Thursday, I was at* [site 3]*. So my schedule had to shift a little so my health education classes—I would try to do it; I would try to give them the same day as I would the screening and the intervention.*

Provider theme 2. Challenges.

Challenges to the implementation, success, and provision of screenings or interventions were identified by all providers (ie, screeners, interventionists, and managers). Providers, at times, talked about challenges to the implementation of the interventions such as time constraints, paperwork requirements, and competing responsibilities and priorities. These included competing programs that required attention from staff providing care or the time burden of screenings or paperwork associated with the study. Patients also presented with different priorities that were often punctuated by

crises stemming from their very low incomes and disruptions in family living arrangements. Although the agency made significant attempts to apportion space as needed for sessions and follow-up interviews, space limitations continued to pose problems.

> **Provider:** *Well, the assessment process was the same, except when I did identify somebody who would be a good candidate for the program, it would take me longer to, not to finish the assessment, but with the screening process. So I would say maybe it would take me about 30 minutes to an hour longer to do the screening, finish the screening, and then put together all of the paperwork.*

> **Provider:** [A] *lot of times I had problems with space. I had problems with specific rooms with computers. So that prevented me from seeing, screening more patients as I would like.*

> **Provider:** *I wanted to see more of on how to deal with . . . I guess training on how to deal with a difficult situation because some of the patients that I had, were undergoing depression—not only depression, but they were in a very hostile environment at home.*

Provider theme 3. Benefits/Positives.

Providers frequently discussed benefits of the study intervention, not only for the clients, but for themselves as well. Whenever a provider mentioned positive aspects of Programa Esperanza, elements mentioned included specific benefits to the organization, the development of positive relationships, ability to engage in self-reflection, and positive changes in attitude.

> **Provider:** *I think I saw, I saw them differently . . .the way they dealt with depression differently. Because even though I wasn't an interventionist I did, being involved in the program, did encourage me to look into problem-solving therapy. So I did my own research about that because I did want to know what they . . . were doing, and so I didn't provide the therapy myself because I'm not certified to, but I learned about the therapy, the problem-solving, and while I was*

doing my own assessments I kind of was thinking in my head, "Well, she has positive problem-solving orientation," or negative problem-solving orientation, and so that, I gained that knowledge from it.

Provider: *I have actually benefited from the intervention; about a year ago I actually started to become depressed because my mother had passed away. So I actually benefited more about opening up—because I myself was actually seeing a psychologist at the same time. So, it was funny because even before. . . I did not know that I was depressed until I saw my primary doctor and he started asking me the same questions, questions that I would ask my patients when I would screen them for depression and I would think "That's funny" because I would ask my patients these questions, but I would not understand that I was actually depressed myself.*

Provider: *Most definitely, seeing the changes in the participants . . . I did see some changes that participants as patients; there was a decrease in the depression. So obviously, seeing the benefit of that would also be very good.*

Provider: [A] *lot of them were really surprised because of them being . . . that they were depressed. So, for them it was more like, "No . . . this doesn't happen to me. It can't . . . I am not depressed." So, I did notice that a lot of patients did have problems accepting it. And so we kind of were talking about whoa . . . because of the symptoms that you are telling me you are either sleeping more, eating more, or you are isolating yourself more, or you are having these kind of thoughts; you know these are kind of indications that you are depressed. Then, once we were talking about—you know, what could possibly be causing them to be depressed; and that's when they started to realize that, "Whoa, yes you are right. I am depressed!"*

Table 10. Synopsis of Qualitative Analysis: Codes

No.	Theme	Patient participants		
1.0	Depression	1.1 Causes	1.1.1-1.1.4	Biological, psychological, social/interpersonal, comorbidities
		1.2 Recognition and symptoms	1.2.1-1.2.5	Emotional, cognitive, physical, motivational, behavioral
		1.3 Treatments for depression	1.2.1-1.2.4	Health-seeking behaviors (providers, others); medications; nonpharmaceutical treatments
2.0	Relationship	2.1 Provider characteristics	2.1.1-2.1.3	Language, culture, other skills/attributes
		2.2 Increased acceptability, effectiveness	2.2.1-2.2.2	How relationship attributes lead to higher acceptance and perceived effectiveness
No.		**AltaMed providers**		
1.0	Organization	1.1 Overall AltaMed	1.1.1-1.1.2	Structure, functions
		1.2 PACE program (specifically)	1.2.1-1.2.2	Program, structure
		1.3 Stakeholders	1.3.1-1.3.2	Stakeholder meetings, feedback
		1.4 PACE sites	1.4.1-1.4.3	PACE sites/locations, demographics, policies
		1.5 Staff roles	1.5.1-1.5.8	Screeners, interventionists, managers, administrator, supervisor, social worker health educator, promoters
2.0	Challenges	2.1 Time constraints	2.1.1-2.1.4	Competing programs, time burden, paperwork, different priorities in care delivery
		2.2 Limited space	2.2.1-2.2.2	Space constraints, privacy
		2.3 Management, supervisory concerns	2.3.1-2.3.2	Management concerns, supervisory expectations vs staff and participant needs/preferences
		2.4 Staff motivation	2.4.1-2.4.3	Staff motivation in providing care, engaging with the study, staff buy-in

No.	Theme	AltaMed providers		
		2.5 Patient's life challenges	2.5.1-2.5.2	Low income/social status, difficult living situations
		2.6 Participant attrition	2.6.1-2.6.3	Participant disenrollment, reasons, disruptions
		2.7 Staff turnover	2.7.1-2.6.3	Staff turnover, reasons, "turnover" disruptions
3.0	Benefits/ Positives	3.1 Benefit to patient	3.1.1	Observed or perceived benefit to patient/participant from participating in PST or other study-related activities
		3.2 Benefit to provider	3.2.1	Observed or perceived benefit to provider from participating in PST or other study-related activities
		3.3 Benefit to organization	3.3.1	Observed or perceived benefit to provider from participating in PST or other study-related activities
		3.4 Relationships	3.4.1	Increase in rapport, understanding

Abbreviations: PACE, Program of All-Inclusive Care for the Elderly; PST, problem-solving treatment.

DISCUSSION

Programa Esperanza examined the comparative effectiveness of a brief psychosocial depression intervention (PST) vs EUC among 259 Spanish-speaking Latino patients 55 years of age or older with depression and multiple medical conditions. Findings indicate that depression and related mental health outcomes improved to a similar degree in both the PST and EUC groups in which treatment was delivered by non–clinically trained interventionists; therefore, our primary hypothesis that PST would be superior to EUC was not supported. Most changes with regard to mental health or physical functioning were within groups, whereas between-group differences were not significant. The improvements could have been due to a variety of factors including regression to the mean, spontaneous improvement, nonspecific effects of the treatment setting, or the specific treatments (PST or EUC).

It is unknown why our reasonably sized preliminary study (N = 100) showed a between-group effect size of 0.51 that was not detected in the current study. A possible explanation could be limited availability of clinically oriented supervision for the interventionists over the entire study period. Although PST was not superior to EUC, our findings signaled large improvements in both groups because the magnitude of within-group changes for depression was large (effect sizes >0.80). Overall, participants had high treatment adherence rates and low study attrition. Health services use differed in some respects between the groups (eg, primary care, ED visits, skilled nursing care admissions), yet these findings should be interpreted with caution because PACE populations have high functional limitations and are not reflective of low comorbidity/primary care populations.

Qualitative results underscored participant and provider satisfaction with Programa Esperanza, and suggestions addressing challenges to implementation and sustainability. Additional qualitative analysis is needed to examine potential similarities or contrasts in how depression and depression treatment is perceived by both patient participants and providers.

Context for Study Results

This is the first large randomized comparative effectiveness study to treat late-life depression among Latinos—and among Spanish-speaking Latinos, in particular—with high rates of psychiatric and medical comorbidity; it is also among the few US studies that test the implementation of an evidence-based intervention delivered by non–clinically trained interventionists. The sample was characterized as predominantly female, around 70 years of age on average, and consisted primarily of immigrants residing in the United States for more than 20 years. One-third were married or partnered; 30% were widowed. On average, they had faced more than 3 significant stressful life events in the past year.

High psychiatric comorbidity existed in the sample: All participants were depressed at baseline given the study's inclusion criteria, and about 3 of 4 reported PHQ-9 scores above 10, indicating possible major depression. Moreover, about 1 of 3 suffered from dysthymia, and 58% endorsed symptoms of anxiety consistent with generalized anxiety disorder. SCL-20 scores indicated impaired mental and physical health functioning. Upward of 84% of the sample were characterized as physically frail or pre-frail with high rates of diabetes and metabolic syndrome (ie, obesity, hyperlipidemia, and hypertension) that have been associated with depression in Latinos.

The study had high feasibility and acceptability as indicated by a high study retention rate: 94.6% of randomly assigned participants completed the 12-month follow-up. Likewise, more than 8 of 10 received the planned 8 PST face-to-face sessions, and all EUC participants received the 1-session psychoeducational intervention and referrals to specialty mental health providers for depression treatment. No previous depression intervention studies in the United States have documented comparable retention and adherence rates as reported here with a population with low levels of education and whose English is limited.

Findings from the comparative effectiveness trial indicate that both the PST and EUC groups experienced statistically significant declines in the primary PHQ-9 depression outcome, although the differences between the 2 treatment groups were not significant. Previous randomized psychosocial depression treatment studies showed similar declines with older

populations that included older English-speaking Latinos.[118,131,140] There are no previous depression psychosocial trials that include specific subgroup analyses for older Spanish-speaking Latinos in the analytic sample.

Secondary mental health outcomes also indicated significant declines for depression as measured by the SCL-20 and significant declines in GAD-7 anxiety scores. Improvements in SCL-20 depression outcomes echo those of previous studies that included older English-speaking Latinos,[131,140] middle-aged Latinos in collaborative depression care programs,[132] and low-acculturated older Latinos in an exercise program.[141,142]

Likewise, SF-12 Mental Health improvements were significant for both groups over the trial period. Overall, improvements in secondary mental health outcomes as measured by the SF-12 echo previous work with middle-aged Latinos with diabetes[132] in a collaborative care trial in which the differences between intervention groups were statistically significant.[132]

These declines in mental health symptoms signal the viability and positive outcomes with regard to the delivery of brief bilingual psychosocial interventions by non–clinically trained providers internal to the organizational setting. Nevertheless, we must use caution when drawing the conclusion that implies the intervention changed depression outcomes, given that we did not include a true no-treatment group available to us in this treatment setting. Extending mental health screening and treatment to historically underserved populations with high mental health disparities and extending the behavioral health workforce responds to national initiatives on the geriatric mental health and substance use workforce.[21] Including community health workers, lay workers, peers, and other types of service extenders in the behavioral health workforce in screening depression care has had promising results in the United States and abroad, although some studies did not adopt randomized trial designs.[87,130,143-147]

No differences were found with respect to differences between PST and EUC in terms of the primary and secondary mental health outcomes. Previous psychosocial depression trials based on older African Americans and middle-aged Latinos parallel these findings, such that no

treatment group × time differences were found between experimental, comparator psychosocial depression intervention, or EUC, respectively.[117,130]

Several explanations may exist for the no between-group finding in Programa Esperanza. First, there might have been opportunities during the trial period for diffusion or imitation of Programa Esperanza information and treatment strategies to occur. This diffusion or transmission of information could have occurred on 2 levels: PACE participants are in close contact with their social peers at the treatment sites when they attend the day program for several hours each week. Furthermore, interventionists and MSW care managers provided Programa Esperanza intervention strategies to patients on their respective PACE caseloads that included EUC participants. As such, these factors could have led to cross-contamination between PST and EUC.

Second, decisions from our multiple stakeholder meetings before and during the initiation of the trial precluded us from integrating a true no-treatment comparator group in our research design. Ethical and pragmatic reasons regarding the perception of "withholding treatment" were very palpable issues that emerged during our stakeholder meetings. Qualitative findings indicated a high satisfaction level with PST across interventionists, supervisors, and managers, and thus there might have been an inducement to engage in PST-like activities (problem-solving, behavior activation) with PACE participants in general.

Third, although there was an intensive period of training and case reviews at the front end of the study, determination of fidelity to the intervention might not have been accounted for sufficiently. For example, the primary social work director was reassigned to another department, and no replacement was available in later phases of the study to provide monitoring of the fidelity to the model.

Fourth, significant changes in social workers' site assignments (ie, change in job responsibilities due to new CMS ruling, reassignments to different PACE sites, and interventionist attrition) might have played a role in the overall delivery of the PST intervention. Thus, workforce factors related to the uptake of the intervention, possible contamination

effects, and routine reassignments or workforce attrition are important considerations in the implementation and sustainability of psychosocial interventions in real-world settings.

Fifth, other study effects could have been at work such as regression to the mean, the Hawthorne effect, or other study-specific processes. For example, because the primary inclusion criterion was a PHQ-9 score of at least 8, regression to the mean could also have contributed to the improvements in PHQ-9 and correlated trial outcomes in both the PST and EUC groups. In addition to the possibility of beneficial effects of both PST and EUC treatments, other nonspecific and unmeasured effects of the intensive primary care PACE program or overall study effects could have contributed to the within-group improvements in trial outcomes. Without collection of more detailed process data, we are not able to disentangle these possible study-specific explanations.

It is important to note the differences that emerged with regard to health care use. PST participants used significantly more primary care visits in the 6- and 12-month follow-ups, yet in contrast they had significantly lower use of ED visits and skilled nursing facility admissions during the 6 months after study enrollment compared with EUC participants. Programa Esperanza provided access to depression screening and treatment to levels that had not been seen before at the PACE sites. An explanation for the decreased ED and skilled nursing care use might have been prompted by the longer duration of interactions with the interventionists and the nature of the PST sessions. The content of the sessions often included attempts to access and negotiate primary care interactions to address unresolved medical issues such as emerging symptoms needing immediate attention, chronic and intensive pain, medication management, and scheduling appointments with providers. Although the primary care visits were higher in the PST group, this could have served to reduce the use of more intensive services such as ED and skilled nursing visits. Future work should establish the association between psychosocial treatment and changes in types and degree of health care use that could affect overall medical expenditures.

Our qualitative results also highlight high satisfaction among both participants and AltaMed interventionists in terms of psychotherapeutic benefits to the participants and career

advancement benefits to interventionists. Supervisors and managers perceived benefits such as participating in something innovative, observing the affective improvements across participants, and creating a renewed sense of purpose among interventionists.

The study interventionists were identified from the existing health care system PACE sites and went through intensive training and case reviews. Relying on existing BSWs (and later health educators) who have ongoing interactions with participants was identified early on by stakeholders as a key element of the intervention delivery. Social closeness and racial/ethnic similarity were crucial attributes in stakeholders' identification of existing staff as interventionists. Task-shifting was a major consideration for both social workers and health educators as their new Programa Esperanza activities were added to their existing employment responsibilities.

Previous work addressing implementation factors identified individual and provider barriers to implementing evidence-based practices in real-world settings, such as patient and family beliefs, provider beliefs and practices, stigma, cultural competency, environmental barriers, and a trained workforce.[24,30,148-157] Qualitative results indicated a preference by both interventionists and supervisors to identify strategies that alleviate the burden of taking on new responsibilities at the same time as managing an existing caseload of study participants.

In terms of the sociocultural context in which the trial was conducted, several themes emerged. Depression screening and the 2 approaches (PST and EUC) were offered in the participants' language of preference, and bilingual materials were written in straightforward language to accommodate low literacy. The nature of PST is that it is person-centered and relies on the individual participant to provide information on their own presenting problems and solutions in a nonstigmatizing, easy-to-follow manner. The fact that interventionists acted in dual roles as case managers and depression interventionists was also considered a benefit due to the already established trust and knowledge of the participant's presenting problems.

Generalizability of the Findings

Given the high rate of participation (259 of 267 eligible [97%]) and low rate of attrition (251 of 259 [97%] providing 6-month trial follow-up and 245 of 259 [95%] providing 12-month follow-up), these comparative effectiveness trial results are likely generalizable to the target study population (ie, older Latinos who are at least mildly to moderately depressed, cognitively intact, and receiving outpatient managed health care for their complex physical and behavioral health conditions). Results may be less generalizable to older non-Latino populations or to populations that do not have stable access to such a medical setting. Another characteristic of the sample that must be considered when evaluating generalizability includes the fact that the sample was predominantly Spanish speaking and foreign born (although living in the United States for many years) and had relatively low levels of education.

Implementation of Study Results

Aside from the previous discussion about adoption of research evidence into practice, several challenges were identified by AltaMed's provider stakeholders:

- CMS stipulated that only MSWs can perform PACE psychosocial assessments in the future.
- Identifying eligible participants, screening participants, and documenting outcomes was time intensive.
- To boost recruitment, the number of health education classes was reduced.
- Interventionists report that some participants lost interest in later sessions.
- Interventionists report the need for designated time to devote to program activities per caseload.

Subpopulation Considerations

Four subpopulations were considered of a priori interest to evaluate for possible differential effects of the PST intervention: (1) age (<65, ≥65 years); (2) baseline levels of depression; (3) sex; (4) and education (≤6th grade, >6th grade). Analysis of primary and

secondary trial outcomes did not identify any group within these subpopulations that benefited more from PST compared with EUC.

Study Limitations

The primary study limitations relate to the challenges associated with trial implementation in a pragmatic setting. Aside from the limitations discussed earlier, other limitations include the following: Staffing issues included interventionist turnover, reassignments to different clinical sites, and the administrative decision to alter the employment profile of the BSW workforce and expand the role of health educators, necessitating the addition of health educators to the PST interventionist team. Although PST adherence was very good, with 65% of participants completing all face-to-face and booster PST sessions and 81% receiving all face-to-face PST sessions, some participants were difficult to schedule and required more time to complete the PST intervention. By nature of the interventions, participants could not be blinded to their randomized group assignment. Unblinding was dealt with in part by using structured instruments and electronic health records for assessment of trial outcomes; interventionists were not involved in outcome assessment. At the time that this report was written, data regarding use of specialty mental health care, for both groups, were not yet available. Thus, inferences regarding the degree of other mental health care received and how this might have affected our primary outcomes are not viable.

Future Research

The Programa Esperanza trial database is a rich longitudinal database with follow-up on psychological, quality of life, physical function, and other variables among older depressed Latino adults. Post hoc trial analyses will evaluate factors related to improvements or declines on key outcomes, longitudinal relationships among these outcomes, and possible moderating or mediating effects including psychopharmacology treatment rates. Exploratory subgroup analyses, such as latent class analyses, will identify subgroups of participants and characteristics related to beneficial changes on trial outcomes. Future trials in this population may consider modification of the duration of the intervention (longer vs shorter), a longer follow-up period to

ascertain duration of effects, and the inclusion of family caregivers in the intervention model.[25,157]

Future work should consider methodological limitations in pragmatic trials in real-world settings where integrating no-treatment control groups in the research design may not be available, feasible, or ethical. Lastly, more work should be dedicated to studying whether single or minimal psychoeducational sessions provided by interventionists trained intensively in manualized care could be effective in decreasing depression in older people with high medical comorbidity.

CONCLUSIONS

Depression and related mental health outcomes improved to a similar degree in both PST and EUC groups; therefore, our primary hypothesis that PST would be superior to EUC was not supported. The EUC intensive psychoeducational depression program had similar effects on depression and related mental health and physical outcomes as the PST intervention. Most changes with regard to mental health or physical functioning were within groups, whereas between-group differences were not significant. Future research should address potential factors such as regression to the mean, spontaneous improvement, nonspecific effects of the treatment setting, possible heterogeneity of the PST and EUC groups, feasibility of integrating no-treatment control groups, and Hawthorne effects.

Although no significant differences were observed in our primary outcomes, the significant lower use of ED visits and skilled nursing facility admissions by PST participants compared with EUC participants should signal implications for future work. Attention to workforce factors related to the acceptability and uptake of the intervention, possible contamination effects, and routine reassignments or workforce attrition is needed in the future implementation and sustainability of psychosocial interventions in real-world settings. The study is an example of strong stakeholder engagement and robust recruitment and retention outcomes with respect to older adults with comorbid depression and multiple medical conditions whose English is limited.

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