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Calmer Life: A Hybrid Effectiveness-implementation Trial for Late-life Anxiety Conducted in Low-income, Mental Health-Underserved Communities

Srijana Shrestha, PhD,

University of St. Thomas and Baylor College of Medicine, Houston, TX

Nancy Wilson, MSW,

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VAMC, and Baylor College of Medicine, Houston, TX

Mark E. Kunik, MD, MPH,

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center, South Central Mental Illness Research, Education and Clinical Center (a virtual center), and Baylor College of Medicine, Houston, TX

Paula Wagener,

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VAMC, and Baylor College of Medicine, Houston, TX

Amber B. Amspoker, PhD,

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VAMC, and Baylor College of Medicine, Houston, TX

Terri Barrera, PhD,

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey VAMC, and Baylor College of Medicine, Houston, TX

Jessica Freshour, PhD,

Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX

Cynthia Kraus-Schuman, PhD,

Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston, TX

Jane Bavineau,

Sheltering Arms Senior Services, Houston, TX

Maria Turner, and

Catholic Charities, Houston, TX

Melinda A. Stanley, PhD

Please send correspondence to: Srijana Shrestha, PhD, University of St. Thomas, 3800 Montrose Blvd., Houston, TX 77006 (shrests@stthom.edu).

The authors declare no conflicts of interest.

Houston VA HSR&D Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center, South Central Mental Illness Research, Education and Clinical Center (a virtual center), and Baylor College of Medicine, Houston, TX

Abstract

Objective—Anxiety is common among older adults and is associated with multiple negative outcomes. Late-life anxiety is usually unrecognized by providers and undertreated, although evidence supports the effectiveness of psychosocial treatment. Access to mental health care is especially poor among African American seniors. New treatment models are needed to expand the reach of mental health care to minority elders.

Methods—Our article outlines a study designed to test the effectiveness and implementation potential of Calmer Life, a community-based, person-centered, flexible and culturally tailored intervention for late-life anxiety and worry, offered in low-income, mental health-underserved and predominantly African American communities. Calmer Life is skills-based, but also includes resource counseling and an option to integrate religion/spirituality. The study population included individuals 50 years of age and older who were experiencing high levels of worry. The program was developed in the context of a community-academic partnership with organizations that provides services for seniors in underserved communities, and it trains nontraditional community providers to deliver the intervention.

Results—Study progress to date, challenges, and lessons learned are discussed. Data collection is ongoing, and study findings will be available in late 2017.

Conclusions—Calmer Life will offer valuable information to help expand the reach of anxiety treatment among minority seniors living in underserved neighborhoods.

Keywords

comparative effectiveness research; underserved areas; cognitive-behavioral therapy; cultural tailoring; African American; health; minority; mental health

Anxiety disorders are common among older adults,^{1–3} but they are often unrecognized and untreated.^{4,5} Older African Americans are at particularly high risk for inadequate receipt and benefit of care.^{6,7} Racial disparities in mental health care are compounded by biases in diagnostic criteria that have an impact on the reporting and identification of anxiety among minorities.^{8,9} Unmet mental health needs among African Americans are a major public health challenge.¹⁰

To address these and other mental health care needs, the National Institute of Mental Health¹¹ and the Institute of Medicine¹² outlined directions for mental health care research, including the need to conduct research in real-world settings within medical care or social service delivery systems; collaborate with key stakeholders in these systems; and develop innovative delivery approaches, including training of nontraditional mental healthcare providers. In addition, moving from disorders based on the *Diagnostic and Statistical Manual of Mental Disorders (DSM)* toward clinically significant symptoms across diagnostic categories may improve identification and clinical outcomes for underserved

groups, including, African Americans.¹³ These approaches are consistent with person-centered, practical research that enhances more rapid translation of research findings into improved healthcare practice.¹⁴

Clinically significant worry, a core component of generalized anxiety disorder (GAD), is a common anxiety symptom among older adults,¹⁵ and it is associated with significant negative health outcomes, including increased cognitive difficulties,¹⁶ medical symptoms,¹⁵ depression,¹⁷ and sleep impairment.¹⁸ Cognitive-behavioral therapy (CBT) is effective for treating worry/anxiety in older adults;^{19–21} but most studies have been involved older adults with GAD in racially homogeneous samples with high levels of education and income, whereas available data do not address the potential utility of CBT for worry/anxiety in a racially diverse sample.

Individual-, environmental- and institutional-level barriers hinder participation of minority individuals in research.²² Community-academic partnerships offer a model that could expand late-life anxiety research by addressing barriers, helping develop culturally appropriate programs, and identifying delivery options suitable for real-world settings. Such partnerships have been successful in late-life depression treatment outcome studies,^{23–26} but they have not yet been tested in late-life anxiety research. Treatment models that include attention to religion and spirituality may be particularly culturally relevant for African Americans, who tend to use religious coping to deal with mental health symptoms^{27,28} and seek out religious leaders for support.^{29,30}

We created a community-academic partnership with social service and faith-based organizations serving older adults in underserved, low-income, mostly minority communities³¹ to inform development and administration of a culturally sensitive intervention for minority older adults with worry/anxiety. This partnership is overseen by the Emma Cooper Community Leadership Council (EC-CLC), which includes key leaders of partner organizations, other community leaders, consumers, counselors, and academic partner leaders. Leaders from two community partners also served as project co-investigators. The study incorporated input from these stakeholders on all aspects of the study. To facilitate ongoing input, the EC-CLC met at least semi-annually, and smaller task force groups were formed and individual conversations scheduled to address particular issues as needed. The community co-investigators attended monthly research meetings. Working in these multiple formats, stakeholders helped to develop culturally appropriate outreach and recruitment strategies, refine intervention materials (provider manual, participant workbook) to include culturally appropriate language, identify and facilitate partnerships with community sites where interventions are delivered, and address community needs. The research team also consulted seniors in the target areas on their experiences of worry and how to best introduce and implement a mental health program in their communities. Informed by these partnerships and input, we created Calmer Life (CL), a person-centered intervention for late-life worry/anxiety anchored in CBT with novel components, including the opportunity to incorporate religion/spirituality,³² person-centered delivery tailoring (sessions at home, in a community setting, or by telephone), attention to basic unmet needs that may contribute to worry/anxiety, enhancement of communication

with primary care providers about worry/anxiety, and use of nontraditional providers to deliver care.

In a recent pilot randomized trial involving 40 mostly low-income, African American women, CL demonstrated effectiveness in reducing the severity of GAD and associated symptoms relative to Enhanced Community Care (ECC), a comparison intervention anchored in standard community-based information and referral.³³ However, sample sizes in that study were small with power only to detect large effects, no follow-up data were collected. In addition, the participants were mostly women, and the care providers included advanced trainees with significant expertise in mental health care. A larger trial was needed to examine the effectiveness of CL offered by nontraditional providers in community settings and allow initial examination of its implementation potential.

In this article, we describe an ongoing, larger hybrid effectiveness-implementation trial that was designed to examine outcomes following CL and ECC among older adults with clinically significant worry recruited from underserved, low-income, mostly minority communities. The study design is grounded in our community-academic partnership and was influenced by Institute of Medicine recommendations for expanding access to and engagement with mental health care¹² and patient-centered and practical research methods.¹⁴ This study will provide guidance for all practitioners on ways to overcome barriers to access to mental health care in underserved communities and yield lessons on strategies for personalized and culturally appropriate tailoring of treatment to allow attention to the psychosocial needs and spiritual values of older adults. The study is experimentally rigorous to determine treatment effectiveness and provide a strong scientific base for stakeholder acceptance, while concurrently allowing investigation of implementation potential that will facilitate future adoptability of CL.

Our primary goal in this study is to examine the relative effectiveness of CL and ECC in older adults with clinically significant worry by evaluating worry severity and GAD-related symptoms (primary outcomes) at posttreatment (6 months). A secondary goal is to evaluate the relative impact of CL and ECC on anxiety, depression, sleep, functional status, health-related quality of life, and service use (secondary outcomes) at posttreatment (6 months). A third goal is to examine the maintenance of effects of CL and ECC at 9 months. We hypothesize that participants receiving CL will report improved symptoms at 6 and 9 months compared with participants receiving ECC. Implementation potential will be examined using the RE-AIM framework (which focuses on the 5 dimensions of reach, efficacy, adoption, implementation, and maintenance).³⁴ Thus in our study we focused attention on reach, participant initiation and engagement, treatment fidelity, and acceptability, barriers, and facilitators of CL.

Methods

Study Design

This randomized, controlled, comparative-effectiveness trial is testing the effectiveness of CL relative to ECC in 150 participants with clinically significant worry (Figure 1). The final sample size was calculated based on a 2-tailed type 1 error rate of 0.05, 80% power to detect

moderate group differences ($d = 0.50$) in primary and secondary outcomes, and 15% attrition rate comparable to the pilot phase that preceded the current trial. Treatment occurs over 6 months, with assessments at baseline, 6 months, and 9 months.

Recruitment, Eligibility, and Randomization

Individuals 50 years and over living, working, receiving services, or worshiping in specified underserved neighborhoods are eligible. Recruitment occurs in collaboration with the EC-CLC and community partner organizations (social service agencies, churches, community centers, senior housing) via both self-referrals and referrals from community providers. Self-referral relies on culturally appropriate flyers, brochures, and informational talks in community settings by research staff and consumers. Consumers who previously participated in pilot phases of CL development take part in community presentations by providing personal testimony supporting the program. Provider referral occurs in settings where social service providers are available.

Interested participants complete a telephone screening involving a 2-item screener for generalized anxiety disorder (GAD-2)³⁵ and are then scheduled for an in-person visit to review consent, collect demographic information, and conduct a more thorough screening to assess the severity of their worry, depression, and cognitive impairment. Inclusion criteria are: 1) age ≥ 50 years, 2) score on Penn State Worry Questionnaire–Abbreviated ≥ 23,³⁶ ability to speak English, and 4) availability of a healthcare provider. Potential participants who do not have access to a healthcare provider are assisted in linking with a provider in their community. Exclusion criteria are: 1) severe depression (Patient Health Questionnaire-8 ≥ 20³⁷); 2) active suicidal intent; 3) substance abuse in the past month or substance dependence; 4) active psychosis or mania; and 5) cognitive impairment, defined as 3 or more items missed on a 6-item cognitive screener derived from the Mini-mental State Examination.³⁸ A modified version of the Structured Clinical Interview for DSM-IV (SCID)³⁹ that evaluates *DSM-5* criteria is administered to characterize participants with regard to anxiety and depression diagnoses and evaluate exclusion criteria. (The SCID-5 was unavailable at project initiation.) Excluded individuals who report needing immediate care are referred to local mental health resources.

CL Intervention

CL combines 1) person-centered, flexible skills training to reduce worry with 2) resource counseling to address unmet basic needs and 3) facilitation of communication with health care providers about urgent (medical, psychiatric) care needs and communication about worry/anxiety (Table 1). Skills training includes core (education-awareness, motivational interviewing, deep breathing, calming statements) and elective skills (progressive deep-muscle relaxation, thought stopping, cognitive restructuring, problem-solving, behavioral activation, anxiety exposure, and a sleep management handout). Participants have the option to include religion/spirituality (R/S) in all, some, or none of the core and elective skills (e.g., R/S images or words in breathing and self-statements, increased R/S activities in behavioral activation). They also have the option to receive skills training at home, in a community setting, or by telephone, although counselors recommend that the first 1 or 2 sessions be conducted in person to facilitate trust and rapport building. CL is offered over 6 months;

skills training occurs during the first 3 months, and participants receive brief phone calls to help review and practice the skills during the remaining 3 months.

Counselors recommend at least 6 skills training sessions,³² although participant preference determines the number of sessions. Home practice is assigned for each session. Brief telephone contact (10-15 min) is available, based on participant preference between sessions for skills/practice review. The last CL session is a review of skills learned and planning for the future.

Resource counseling is offered when basic unmet needs are identified either at the baseline assessment or during the initial CL session. To meet these needs, participants receive a list of potential resources, with detailed information and coaching about how to pursue these options. No information about mental health resources is provided. To facilitate communication with healthcare providers, participants create a written description of their symptoms and the CL intervention to use as a guide for communication at their health care visit.

Enhanced Community Care (ECC)

ECC was developed in collaboration with the EC-CLC to reflect the provision of standard information and referrals that address both basic unmet needs and mental health needs. ECC also offers emotional support and allows the opportunity to monitor worsening of symptoms. ECC contacts are brief (approximately 15 minutes; first session can last up to 30 minutes) and by telephone, with calls occurring every other week for the first 3 calls, then once a month thereafter for a total of 6 months. Participant preference and level of basic unmet needs are considered in how many ECC phone calls are made.

Before the initial contact, participants are mailed a community resource list of local mental health and social service resources that includes annotated descriptions of community organizations, types of services provided, location, contact information, fee structure and insurance accepted. During the initial call, resources are suggested with attention to identified basic and mental health needs, participant geography, and preference for counseling and/or medication, and insurance/financial status. Follow-up calls include a discussion of resources contacted (feedback, helpfulness), problem-solving to address inability to contact resources, identification of additional resources as needed, inquiry about worsening of anxiety or depressive symptoms, and need for crisis intervention.

Counselors

Counselors are community-based providers (community health workers or case managers) without training in mental health treatment. Counselors are identified by community partners from their workers who serve the social service needs of seniors. Our recent work has supported the validity of training nonexpert providers to deliver effective care for late-life anxiety.^{19,40} The same counselors deliver care in both CL and ECC to reduce provider effects that might be nested within the treatment condition.

Training in both intervention conditions includes didactic training, review of audio tapes, role plays, and expert review of audiotapes of the initial sessions. Ongoing weekly

supervision facilitates continued treatment integrity. Training and supervision are provided by the first and senior authors (Shrestha: ECC; Stanley: CL), with input as needed by other co-authors (Wilson, Kunik). In both CL and ECC, treatment integrity is monitored by 2 raters with significant expertise in late-life worry (Barrera, Kraus-Schuman).

Measures

The primary effectiveness outcomes are participant-reported worry and GAD symptom severity. Secondary effectiveness outcomes involve assessment of anxiety, depression, sleep difficulties, functional status, health-related quality of life and service use. Additional measures assess implementation potential (satisfaction, reach, participant initiation and engagement, treatment fidelity, and acceptability-barriers-facilitators). The assessment tools are outlined in Table 2.

Data Collection

Data collection occurs at baseline, 6 months, and 9 months via telephone. Assessments last 30-40 minutes and are conducted by independent evaluators (IEs) uninformed about study conditions (CL or ECC). Qualitative interviews with a subgroup of CL participants who have completed the 9-month assessments are conducted at 6-month intervals. Counselors also complete 3 qualitative interviews over the course of the study. All key community leaders will be interviewed after all CL procedures have been completed, although they contribute ongoing feedback through the EC-CLC.

Analytic Plan

We will first individually compare baseline demographic and clinical variables between 1) CL and ECC and 2) study completers and study noncompleters. Variables that differ significantly between the two groups will be included as control variables in primary and secondary outcomes models. Primary and secondary outcome analyses at 6 and 9 months will be conducted in intention-to-treat and completer groups. Differences in satisfaction between CL and ECC at 6 and 9 months will also be examined. Descriptive data addressing reach, participant initiation, and engagement and treatment fidelity will be reviewed by the EC-CLC. Qualitative data will be analyzed to generate themes both from a priori issues and after identification of data. Data analysis will identify recurring and important themes regarding acceptability, facilitators, and barriers.

Study Progress

As of July 2016, we have enrolled 122 participants, with an average age of 65.9 years ($SD = 9.1$ y). The majority of the participants have been women ($n = 101$, 82.8%) and African American ($n = 92$, 75.4%). Participants have an average of 13.4 years of education ($SD = 3.1$ y), and 73.0% ($n = 89$) make less than \$20,000 annually.

Study Challenges and Lessons Learned

The program has faced challenges related to recruitment, barriers to participation, and lower than projected completion of phone assessments. In tackling each of these challenges, we

learned lessons that benefitted the program and might provide insight to clinical and research programs that target older adults in underserved communities. Recruitment and enrollment of participants are major challenges facing researchers and providers of mental health care who work with older adults.⁴⁹ Study sign-up is often hampered by the stigma associated with mental illness. Because all of the recruitment events in our study occurred in group settings, we worked to decrease the stigma of acknowledging in public that potential participants might be struggling with mental illness by identifying a strategy to increase privacy. All attendees at a recruitment event were provided a form on which they could write their name to be included in a drawing for a door prize. Those interested in learning more about the study were asked to add their phone number, thus allowing an anonymous way for potential participants to share their interest in the study while maintaining confidentiality.

In addition, to improve recruitment, we increased the involvement of consumers in outreach events. We invited participants who completed the program to join the EC-CLC and to be spokespeople for the program. One of our first consumer members referred a large number of friends and acquaintances to the program. Her advocacy for the program prompted the development of a promotional video about the program and the induction of past consumers into the leadership council. All consumers, who live, work, or worship in the target communities, provide testimonials at outreach events that increase the appeal of the mental health services offered. Overall, the consumers help reduce the stigma associated with mental illness by speaking about their own personal struggles, explaining the confidentiality agreement that was honored by the program, and highlighting the option to integrate their religious/spiritual beliefs. Consumer involvement has undoubtedly increased the perception of the trustworthiness of the program among potential participants who might otherwise be skeptical of the researchers.

Another recruitment challenge the team faced was recruiting male participants. Men tend to have a more difficult time reaching out for mental health services,^{50,51} and recruiting men for research and mental health care is difficult.⁵² With guidance from the EC-CLC, the team implemented multiple steps to reach men, one of which involved hiring an African American male Veteran to assist at outreach events, reaching out to Veterans' groups in the community, explicitly stating during recruitment that the program may be beneficial to both men and women, and encouraging private discussion about the study among male audience members. Although enrollment of women still outnumbered men, the rate of inclusion of men has improved.

Finally, the research team is continually seeking new locations to reach new constituents. In this effort, the EC-CLC members, counselors, and consumers provide significant input with considerable success. Rather than waiting for the community organizations to invite the team to events, members searched the internet and community bulletin boards for potential outreach opportunities. Informal conversations with attendees at community fairs also yielded new locations to reach people in need.

Once participants were recruited, lack of resources among some study participants posed a barrier, as they did not have enough phone minutes to complete study assessments and intervention procedures that were conducted over the phone. One of the counselors, who is a

case manager at a partnering organization, recommended a community resource that offered no-cost phone access to individuals with a low income. In addition, community partner organizations offered private rooms in their locations where participants could have confidential access to phones.

At various points of the study, no-show rates for in-person screening and telephone assessment appointments were high. Other researchers have discussed scheduling problems as a hindrance to study participation.⁵³ The team implemented several strategies to reduce the no-show rate, including the use of blue envelopes for mailing study materials to distinguish study correspondence from other mail, increased warm hand-offs between screening and diagnostic appointments, a “kind-but-firm” approach to scheduling, and reminder calls from study counselors for the 6- and 9-month assessments that highlighted the significance of these assessments for evaluating our ability to improve mental health services in their communities. In addition, the counselors were enlisted to call participants who were hard to reach; because they had been more likely to have developed a trusted relationship with the participants while delivering the study interventions. These strategies have improved no-show rates.

The program also faced other logistical challenges. Recruitment started during the holiday season (Thanksgiving and Christmas), at a time when organizations serving older adults already had a busy schedule and academic staff were also taking holiday leave, both of which slowed down outreach efforts. The target areas also experienced multiple instances of flooding that necessitated cancellation of scheduled appointments and a subsequent slow-down in outreach events, as partner sites were reallocating their resources to address the immediate needs of the flooding victims. Thus, the timing of the start of the program and natural disasters added to recruitment challenges. Finally, since the program targeted low-income communities, some participants who signed up for the program had immediate basic needs that were severe enough to impede their participation in the program. These situations were categorized as similar to those of participants who may need immediate crisis intervention, and the participants were referred to appropriate community organizations and asked to circle back to the research team once their immediate needs were fulfilled.

Discussion

In this randomized, controlled, comparative-effectiveness trial, we are testing the effectiveness of CL vs. ECC in reducing worry among older adults in predominantly low-income, mental health-underserved and minority neighborhoods and examining the implementation potential of CL. Several elements of the CL model align with areas identified by experts in late-life mental health for improving services: CL uses a community-based model to reach underserved African American communities, allows cultural tailoring to enhance traditional psychosocial treatment, and offers patient-centered care in community settings.^{54,55} CL will offer lessons to practitioners on ways to address access barriers and enhance traditional care that are easily adopted. Furthermore, CL identifies and trains nontraditional mental health providers from the community, offers an integrative approach to address worry and immediate basic needs, and facilitates communication with healthcare providers. Lessons learned from the trial will offer valuable information on selecting and

training community-based providers to deliver psychosocial interventions. CL might be a good fit in team-based care recommended to improve mental health care services for seniors, in which psychosocial interventions are embedded within medical care settings.⁵⁴ It is likely that integrative approaches, such as CL, can be delivered by trained nontraditional providers under the supervision of expert consultants, such as licensed psychiatrists, psychologists, and social workers. Obtaining input from the many stakeholders involved in CL will contribute information on implementation issues related to selection and supervision of community providers. The CL trial will also yield valuable information about how symptoms are expressed in older adults from culturally diverse backgrounds, information that can be used to further adapt and improve treatment for these communities.⁵⁵ CL is poised to provide much-needed empirical data related to the effectiveness of late-life anxiety treatment for African American seniors in mental health-underserved areas.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
CONSORT Flow Diagram for Calmer Life.

*All excluded individuals with immediate needs were offered referrals.