Title: Calmer Life: Treating Worry Among Older Adults in Underserved, Low-income, Minority Communities

NCT#: NCT02391363

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October 16, 2018

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H-35754 - CALMER LIFE: TREATING WORRY AMONG OLDER ADULTS IN UNDERSERVED, LOW-INCOME, MINORITY COMMUNITIES

APPROVAL VALID FROM 10/16/2018 TO 10/15/2019

Dear Dr. KUNIK

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was reviewed and approved by Expedited procedures on 10/16/2018 by Board 4.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

Gabriel Habib

Association for the Accreditation of Human Research Protection Programs, Inc. — Full AAHRPP Accreditation

GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-35754**
Status: Approved
Initial Submit Date: 9/29/2014
Approval Period: 10/16/2018 - 10/15/2019

Section Aa: Title & PI

A1. Main Title

CALMER LIFE: TREATING WORRY AMONG OLDER ADULTS IN UNDERSERVED, LOW-INCOME, MINORITY COMMUNITIES

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Michael E. DeBakey Veterans Affairs Medical Center

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Worry and anxiety occur frequently among older adults (12%-15%) (Kessler et al., 2005; Byers et al., 2010). Even though these rates suggest higher prevalence of anxiety than depression, late-life anxiety has received significantly less attention. Clinically significant worry and associated disorders [generalized anxiety disorder (GAD) and anxiety otherwise specified (ADNOS)] are particularly common (Wolitzky-Taylor et al., 2010).

Most older adults with anxiety are unrecognized and undertreated (Calleo et al., 2009), thus increasing the potential for disability associated with both anxiety alone and co-occurring depression. Risk for inadequate recognition and care is particularly high for ethnic-minority elders in low-income, underserved communities (Brenes et al., 2008; Joo et al., 2010). Older adults, particularly minorities, prefer psychosocial treatments over medication for emotional difficulties (Givens et al., 2007). Cognitive behavioral treatment (CBT) produces positive outcomes for late-life worry/GAD in academic and primary care settings (Stanley et al., 2009; Wetherell et al., 2007), but minorities are significantly under-represented in clinical trials (Office of the Surgeon General, 2009: Woodall et al., 2010), and standard CBT poorly addresses the needs of low-income minority older adults in underserved communities. In these settings, culturally tailored, person-centered interventions developed and tested in the context of solid community-clinical partnerships are needed to overcome barriers such as stigma, mistrust, racism, and misconceptions about symptoms and treatment. Integration with the faith-based community and incorporation of religious/spiritual (R/S) coping may be

particularly important in communities with high prevalence of African Americans (Blank et al., 2002; Lefler, 2009), where community life often centers on faith-based organizations and where individuals seek treatment/support from religious-spiritual leaders. More attention needs to be given to service delivery of anxiety treatments for underserved older adults.

Calmer Life (CL) is a culturally tailored, participant-centered research study that offers a skills-based intervention for late-life anxiety and includes other elements of care to meet the needs of underserved, minority older adults, including the option to integrate religion/spirituality, flexible delivery modes, and modular treatment format. This research study will not recruit participants from the VA. One of the study aims is to examine the feasibility and acceptability of a novel intervention in low-income and underserved communities. The VA does not have the infrastructure to reach the targeted population. Furthermore, through community recruitment, we will be able to reach Veterans, living in these low-income, underserved communities, who may or may not come to the VA for medical care. Finally, the prevalence of anxiety and depression is high among Veterans, and information gathered from this study will benefit older Veterans with anxiety and mood problems.

We are not enrolling participants at MEDVAMC in this study because it is focused on identifying people outside of a medical clinic or hospital settings who live in underserved, low-income communities. In addition, we have an ongoing trial of CBT for anxiety that did enroll veterans with VA Prime Care providers (H-23798) and completed a trial of CBT for anxiety and depression for home-based primary care patients at MEDVAMC (H-30655).

Section D: Purpose and Objectives

The overall goals of the proposed research study are to: (1) examine quantitative outcomes in a well-conducted randomized clinical trial (RCT) of CL, relative to Enhanced Community Care (ECC), an information and referral intervention that represents care in a real-world community-service environment, and (2) evaluate implementation feasibility, which includes training community providers; examining program reach, engagement, acceptability, and barriers-facilitators; and preparing practical tools for replicating the program.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?
Mentally ill

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Recruitment will be conducted via community outreach activities and referrals from social service and faith-based organizations. During community outreach events, information about the study will be provided in the form of verbal presentations or written summaries in brochures, community organization newsletters, or bulletins. Potential participants will provide their contact information if they want to be contacted by the study staff or they will contact the study staff directly. Study staff will review the informed consent form with potential participants in person and answer questions. We will not include participants with cognitive impairment, current suicidal intent, psychosis, mania or substance abuse within the past month. Further, we will train our research staff in the most responsible conduct of research including proper informed consent, confidentiality protection, and the avoidance of any coercion. To maintain confidentiality, every participant in the study will receive a unique ID number.

A separate VA release form will be used to communicate with the patient's health care provider(s) and any referring community agency provider if at any time the participant needs immediate treatment (eg, for suicidal intent, psychotic symptoms).

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:
z.z) ARCHIVED DO NOT USE - Other: Non-pharmacologic RCT

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

Participants will be recruited in collaboration with partner settings in underserved neighborhoods with high prevalence of low-income minorities. Included participants will be randomly assigned to CL or ECC. In both conditions, ongoing community or medical care will continue and resource counseling will be provided to address unmet basic needs. CL and ECC will be provided over 6 months by nontraditional providers (eg, community health providers, case managers) already working in partner organizations who will be supervised by licensed mental health providers (Stanley, Wilson, Shrestha). Assessments will occur at baseline, 6 months and 9 months.

CL is a modular, participant-centered intervention that is skills based (anchored in standard CBT for late-life GAD) but with additional elements to enhance person-centeredness and implementation potential for low-income minorities in underserved communities. CL allows participants to choose session content (skills to be learned, whether to include Religion/Spirituality [R/S]), delivery method (home, community, telephone), and number of sessions. CL also includes resource counseling and facilitation of increased communication about anxiety/worry with primary care providers. During the first 3 months of CL, participants can choose up to 12 sessions, and we recommend a minimum of 6. We recommend that the first 1-2 sessions be conducted in-person, although participants may choose to have all sessions by telephone. Sessions last 30 to 45 minutes. Home practice is assigned for each session, and brief telephone contact (10-15 min) is available between sessions for skills/practice review. Resource counseling is initiated in session 1 and followed up as needed in subsequent sessions. In session 2, participants discuss how to communicate with health care providers about

anxiety/worry. Core modules occur during the first 3 sessions (education-awareness, motivational interviewing, deep breathing, self-statements). If participants desire to incorporate R/S, an R/S assessment occurs during session 2 to help the provider understand the participant's beliefs and practices. For subsequent sessions, participants select from elective modules with recommendations from the provider: progressive deep-muscle relaxation; cognitive restructuring; problem-solving; behavioral activation; and anxiety exposure. A sleep-management handout is available. R/S can be integrated into any module (e.g., R/S images or words in breathing and self-statements, increased R/S activities, emphasis on gratitude in thoughts/behaviors) or omitted entirely. Two separate workbooks are available. The last CL session is a review. During the second 3 months of CL, participants receive 3-4 follow-up calls to facilitate practice and continued use of skills, as well as evaluate ongoing functional and resource needs.

ECC is anchored in standard information and referral procedures and reflects a viable, real-world alternative to CL that will allow a critical comparison to inform implementation and policy. ECC includes information and referral for both mental health care and basic unmet needs along with brief telephone follow-up to discuss resources accessed and to evaluate any worsening of symptoms. ECC is provided over 6 months. Participants receive brief biweekly check-in calls for the first 6 weeks and then 1 brief check-in call 1 month later to inquire about access of community resources. During the second 3 months, ECC participants receive no more than one monthly phone call unless provider and supervisor determine that symptom severity warrants more frequent contact. At each call, providers will assess participants' ability to connect with identified resources, worsening of anxiety and depressive symptoms and need for crisis intervention. Participants will call project staff if symptoms worsen.

Outcome measures will be administered for participants in CL and ECC at baseline, 6 months, and 9 months as described in F.2.

Inclusion Criteria:

Inclusion criteria include 1) Age 50+; 2) significant worry as shown by a score of 50 or greater on the Penn State Worry Questionnaire (PSWQ); 3) must be English speaking; 4) must have a health care provider and provide written authorization to research team to communicate with this individual and any referring community agency provider; 5) must have access to a telephone, and 6) live, work, worship attend community functions, and/or receive health care in target geographic areas.

Exclusion Criteria:

Potential participants will be excluded only for conditions that threaten their and other's safety or those that preclude participation in the study. The exclusion criteria include 1) severe depression as indicated by a score of 20 or greater on the PHQ-9, 2) active suicidal intent, 3) psychosis, 4) bipolar disorder, 5) substance abuse within the last month, and 6) cognitive impairment indicated by 3 or fewer score on a six-item screener administered during initial assessment.

F2. Procedure

Recruitment will be conducted via community outreach activities and referrals from partner social service and faith-based organizations. During community outreach events, information about the study will be provided in the form of verbal educational presentations or written project descriptions in brochures, community organization and church newsletters, or bulletins (Attached in Section S - Please see Calmer_Life_Flyer.pptx and Calmer Life Bulletin.docx). Potential participants will provide contact information to be called by the study staff or they will contact study staff directly. In order for potential participants to express interest and provide their contact information confidentially at public events, staff will distribute handouts that will include the two approved telephone anxiety screening questions (GAD-2) to allow participants to decide if the Calmer Life study would be appropriate for them (see Section S, "Calmer_Life_Interest Form.docx"). Any responses to these screening questions will not be used as study data, but will rather serve as informational tools to assist potential participants in deciding if the Calmer Life study may be appropriate for them. These potential participants will be asked two anxiety screening questions (GAD-2) on the phone as an initial screener, but participant responses will not be used as data. Responses will be used only to determine who will be invited to an in-person consent appointment.

All individuals who express interest in participation and respond affirmatively to one of the two screening questions will be scheduled for an in-person visit in a community setting or the participant's home, based on participant preference, to review the consent form, conduct a more formal screening, and obtain demographic information. Participants who provide written consent will complete a demographic information form, two anxiety screening measures (GAD-2), a six-item cognitive screener, the PSWQ and the PHQ-9. This will take

10 minutes. Participants who screen positive (respond affirmatively to at least one of two GAD-2 items), score four or more on the six-item cognitive screener, score 50 or more on the PSWQ and score less than 20 on the PHQ-9 will complete the Structured Clinical Interview for DSM-5 (SCID) in person or over the phone. All SCID interviews will be audiotaped and a random 10% will be rated by another project staff or investigator to assess interrater reliability. If a participant needs immediate treatment (e.g., suicidal intent, active psychotic symptoms), he/she will be referred for immediate psychiatric assistance following standard community-based emergency protocols, and the health care provider and any referring community provider will be contacted.

Excluded participants will receive a list of community resources. Participants who meet all inclusion criteria will complete a baseline telephone assessment. During baseline, the following measures will be administered via telephone: A separate VA release form will be used to communicate with the patient's health care provider (s) and any referring community agency provider if at any time the participant needs immediate treatment (ie, for suicidal intent, psychotic symptoms). Penn State Worry Questionnaire (PSWQ), Geriatric Anxiety Inventory (GAI-SF), Generalized Anxiety Disorder 7 (GAD-7), Patient Health Questionnaire (PHQ-9), Geriatric Depression Scale (GDS), Late-life Functional Disability Index (LL-FDI), Health-related Quality of Life (SF-12), Insomnia Severity Index (ISI), Service Use Questionnaire, and Utilization of Medications, PTSD Checklist for DSM-5 (PCL-5) and the Brief RCOPE. Upon completion of baseline assessment, participants will be assigned randomly to CL or ECC and will follow 6 months of procedures as described in Section F1. Assessments at 6 and 9 months will repeat the baseline measures, except for the Brief RCOPE, with the addition of the Client Satisfaction Questionnaire (CSQ). Participants who complete the CL intervention and are classified as low or high performers (maximum of 30 total) will be selected to complete qualitiative interviews following completion of all outcome assessments. All assessments, qualitative interviews and intervention sessions will be recorded using the Olympus DS-5000id or DS-7000. Co-investigators will serve as supervisors to review integrity of randomly selected diagnostic and outcome assessments. Recordings from the CL and ECC sessions will be randomly selected for treatment integrity review by MEDVAMC psychologists on the research team who have expertise in the identification and treatment of late-life anxiety.

Telephone screening and appointment scheduling will be done at the MEDVAMC; however, MEDVAMC patients will not be recruited. Screening and diagnostic interviews will occur via telephone from VA leased space (IQUEST). Telephone-based study intervention sessions also will be conducted from IQUEST. All research activities at community settings also will be carried out by WOC or VA paid staff and investigators. BCM resources to be utilized include Office of Sponosored Programs and Department of Psychiatry grant administration, salaries paid via BCM to WOC employees and investigators with shared VA-BCM salary reimbursement (Stanley, Kunik, Amspoker), and BCM e-mail for communication with community providers and across investigators/staff who need to communicate at times when VA email access is unavailable.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?
Local: 300 Worldwide: 300

Please indicate why you chose the sample size proposed:

Effectiveness Aims. In our most recent primary care trial,89 we found moderate effect sizes for both primary (g = .40 - .50) and secondary (g = .40 - .57) measures. These effects are within the range of effect sizes reported for other trials of CBT and pharmacotherapy for late-life anxiety. Estimated sample sizes will be adjusted for study attrition, defined by failure to complete 6- and 9-month assessments. This team's prior studies have suggested study attrition ranging from 19% to 25%. Study attrition in our pilot community work is even lower (12%; H-30928.), potentially due to flexibility with regard to delivery options that minimize access barriers. Thus, we expect roughly 15% study attrition, but data analytic methods will employ multiple imputation procedures to use data from all participants. Study attrition will be minimized with provision of clear information about the project at the time of outreach and recruitment, the use of telephone-based assessments and person-centered treatment materials and procedures, and reminder calls. Reasons for withdrawal will be recorded. If differential study attrition occurs across groups, measures different by attrition status will be included as covariates in effectiveness outcome analyses. A 2-tailed type 1 error rate of 0.05 was used to calculate sample size. With 64 participants per group (total = 128), we will have 80% power to detect moderate group differences (d = .50) in primary and secondary outcomes. Given potential attrition of 15%, we will randomize 150 subjects (75/group). Exclusion rates in prior studies have been 50% or greater

(H-23798, H-30928), which means we will need to enroll at least 300 participants in order to include and randomize 150. Implementation Aims. A purposive sampling strategy will be used for the qualitative interviews targeting CL participants defined as high and low performers. In qualitative research, sampling is completed when categories are saturated (ie, when the targeted group no longer provides new information). No more than 15 interviews are expected from each CL subset (high- and low-performing participants; maximum 30 participant interviews).

Exploratory Aims. Assuming a medium effect size for models that include treatment group and an individual moderator, exploratory aims addressing interactions between treatment group and a moderator predicting 6-month outcomes will have 80% power to capture a change in R-square as small as .03.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Analytic procedures were guided by PCORI Methodology Standards and best practices for clinical-trials research. Attempts will be made to minimize missing data with telephone-based assessments and person-centered treatment procedures that limit study attrition. We will use the SPSS 17.0 Missing Values Analysis function to determine type of missing data. If Little's166 MCAR test is not significant, missing data will be viewed as missing completely at random. If Little's MCAR test is significant, separate variance t-tests will be used to determine whether missing data are missing at random or missing not at random (MNAR). If the missingness mechanism is MNAR, the dmiss (ie, the standardized respondent-nonrespondent mean difference for a variable) and f2miss (ie, the standardized respondent-nonrespondent difference in the relationship between 2 variables) systematic nonresponse parameters will be estimated to determine the extent to which (and the direction in which) a parameter estimate is biased by the response rate. Low response rates will more greatly compromise external validity when dmiss and f2miss are large. Results may be interpreted cautiously in the context of the magnitude and nature of bias present. Additionally, missing data will be addressed using multiple imputation procedures PROC MI and MINANALYZE in SAS Version 9.3.167 Prior to analyses to address specific aims, the distributional nature of all variables will be assessed, and nonparametric tests (eg, Fisher's Exact Test; Mann-Whitney test), data transformations (eg, log linear), or other alternate methods (eg, weighted least-squares regressions, dichotomizing variables) will be conducted where appropriate. We will initiate data analyses by comparing baseline demographic and clinical variables (including medication use) between CL and ECC with chi-square and independent samples t-tests. Variables with p values < 0.25 will be included as control variables or propensity scores in subsequent models. We will then compare baseline demographic and clinical variables between study completers and noncompleters, using chi-square and independent samples t-tests.

Specific Aim 1. Examine the comparative effectiveness of CL and ECC in older adults with clinically significant worry on primary outcomes (worry, GAD-related symptoms). Primary outcome analyses at 6 months will be intention-to-treat (ITT) and will use the multiple imputation procedures PROC MI and MINANALYZE in SAS Version 9.3 to estimate missing observations. Another set of analyses will be for completers and will include only observed data. We will first employ Analysis of Covariance (ANCOVA) to examine treatment differences in worry and anxiety at 6 months (post intervention). We will conduct separate models for worry and anxiety. All models will include treatment group (ie, CL versus ECC) as a predictor and respective baseline scores and any demographic or clinical variables that differed between treatment groups at baseline as covariates. Treatment effect sizes will be calculated. We will calculate intraclass correlation coefficients (ICC) for both primary outcomes to determine the degree of clustering within referral source (social service or faith-based setting). If a substantial proportion of variability in either outcome is accounted for by referral source (ie, ICC greater than 0.10), multilevel models will be employed using SAS PROC MIXED to minimize the bias of error terms that may occur from dependency due to nesting effects. These models will include the intercept as a random effect and treatment group, respective baseline scores, and variables that differed between treatment groups at baseline as fixed effects.

Specific Aim 2. Examine the comparative effectiveness of CL and ECC on secondary outcomes (anxiety, depression, sleep, functional status, quality of life, service use). Analyses will be conducted as in Aim 1, first using ITT and multiple imputation to estimate missing data. Another set of analyses will be conducted for study completers. We will use ANCOVA to examine treatment differences at 6 months in secondary outcomes (anxiety, depression, sleep, functional status, quality of life, service use), using separate models for each measure. Effect sizes will be calculated. As in Aim 1, these models will include the intercept as a random effect and treatment group, baseline scores, and variables that differed between treatment groups at baseline

as fixed effects.

Specific Aim 3. Examine the maintenance of outcomes in CL and ECC. Analyses for all primary and secondary outcomes will be repeated to examine treatment differences in outcomes at 9 months. All procedures will be as previously described.

Analysis of Implementation Potential. Differences in satisfaction between CL and ECC at 6 and 9 months will be examined with either an independent samples t-test or ANCOVA (if covariates are warranted). Descriptive data that address reach, participant initiation and engagement, and treatment fidelity will be reviewed by the CLC. CLC input will be used to modify the model of care if needed and to develop implementation strategies. Participant representativeness (vs. excluded participants and partner caseloads) will be examined with chi-square tests (ordinal variables) and independent sample t-tests (interval variables).

Qualitative data will be analyzed with framework analysis, whereby themes generating from both a priori issues and data are identified. Digital recordings of each qualitative interview will be transcribed verbatim into text. Transcripts will be imported into Atlas.ti to facilitate storing, management, and visualization. First, we will check transcripts for accuracy. Then, all data will be analyzed, and contact summary sheets completed after each interview, to establish a thematic framework. Raters will compare coding across transcripts and discuss/reconcile dissimilar coding. From the categories, themes within and across groups will be identified. Data analysis will identify recurring and important themes regarding acceptability, facilitators, and barriers. Descriptive statistics will characterize demographic data.

Heterogeneity of Treatment Effects (HTE). According to PCORI Methodology Standards, exploratory analyses will examine HTE to address for whom and under what conditions CL may be optimally useful. Although sample size may not be adequate to confirm sources of HTE, these exploratory analyses will allow us to describe patterns that can be examined in subsequent larger studies. HTE variables of interest include potential moderators and mediators of treatment effects. Potential moderators include demographics, baseline symptoms (PSWQ, PHQ-8), presence-absence of DSM diagnoses (anxiety disorders, depression), and baseline medication use. Moderation will be tested by including each separate moderator and the interaction term between treatment condition and the moderator in the ANCOVA models described previously. A significant interaction between treatment group and moderator will indicate that differences in treatment effects depend on the moderator. Simple slopes analyses will be conducted to follow-up significant interactions. Potential mediators include change in self-reported use of medication. Medications will be characterized as in our prior trials as antianxiety (benzodiazepine, buspirone, or other), antidepressant (SSRI, SNRI, tricyclic antidepressant, other), antipsychotic, or for medical problems. Medication-use frequencies in each category will be calculated and distributions inspected to decide if variables should be treated as binary (ie, presence/absence) or continuous (ie, number of each medication). As in our prior trials, change in each class of medications from baseline to 6 months will be quantified as (a) adding a new medication, (b) increasing the dosage/frequency of a medication, (c) discontinuing a medication, or (d) decreasing the dosage/frequency of use. Changes in medication use will be examined as potential mediators of the relationship between treatment group and 6-month outcomes to address person-centered questions related to the combined use of medication and CL/ECC.

Statistical analyses will occur at IQuEST.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

There is a risk of the potential loss of privacy. The following steps will be taken to minimize this risk. Information obtained about participants will be kept strictly confidential. Each participant in the study will receive a unique ID number to maintain anonymity. Documents with PHI information and participant data will be stored separately. Consent forms will be filed in a locked cabinet, separate from all coded study data. When study results are published, they will be anonymous and participants' identity will be disguised.

The assessment and treatment procedures may cause some mild increase in worry or related symptoms. Any such increases, however, are expected to be temporary. If at any time, participants experience any unease,

the study staff will make all attempts to address those concerns. Also, participants will have the opportunity to end treatment at any time during the study. Overall, we do not foresee any of these risks to be serious.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?
No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?
No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?
No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Benefits of study participation include a psychological evaluation at no cost, the results of which will be the basis for a treatment recommendation either within or outside the study. Benefits of treatment may include decreases in the frequency and/or severity of worry and associated symptoms (anxiety, depression, sleep problems) and improved overall functioning. All participants will receive significant education about the nature and possible treatment options for anxiety and community referrals to address basic unmet needs. If significant information, either positive or negative, is discovered about the treatment during the study, participants will be so informed.

Describe potential benefit(s) to society of the planned work.

CL may be an optimal intervention for underserved, minority older adults given its options to include religion/spirituality (an important value for many older adults, particularly minorities), individual tailoring with regard to content and delivery, the frequent need for connection to community resources, and potential benefits of increased communication with the PCP about mental health needs. Minorities are significantly under-represented in clinical trials, and standard CBT poorly addresses the needs of low-income minority older adults living in underserved communities. Therefore, a culturally sensitive, modular treatment like CL may increase access to and acceptability of psychosocial interventions to underserved population.

Four community-based providers will be trained to offer the treatment. These providers will receive training without any cost and will be an added asset to the partner organizations with which they work and in the target community at large.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

The assessment and treatment procedures may cause a temporary, mild increase in worry or related symptoms, but participants receiving CL may exhibit significant improvement in managing anxiety, and those who are not eligible to receive treatment will be provided with other referrals in the community. Therefore, we anticipate the benefits to outweigh potential risks.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?
No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI

PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Adults age 50 and over who live, work, worship, attend community functions, and/or receive health care in the identified geographic regions will be eligible. Recruitment will be conducted via community outreach activities and referrals from social service and faith-based organizations. Research or IRB approval is not required at these community sites. During community outreach events, information about the study will be provided in the form of verbal presentations or written descriptions in brochures, community organization newsletters, or bulletins. An anxiety awareness bingo game has been developed for the project to be used at these outreach events. See Section S, Attachments, "Bingo Information cards.docx" and "CL Bingo Boards.pptx". Potential participants will provide their contact information to be contacted by the study staff or they will contact the study staff directly. In order to allow interested potential participants to express their interest and provide their contact information in a confidential manner when study staff are presenting study material to groups at community centers, churches, and other public places/events, we are requesting approval of a form that provides the study screening questions to allow people to decide if the study may be appropriate for them and space to provide their contact so that study staff may reach them to schedule a confidential one-on-one meeting to review the informed consent form (see Section S: "Calmer_Life_Interest Form.docx"). This information would be used for recruitment purposes only, and answers to screening questions would not be used as study data. These potential participants will complete the GAD-2 as an initial screener on the phone, but these data will not be used for research purposes, only to determine eligibility for offering a consent appointment. All individuals who express interest in participation and respond affirmatively to one of the two GAD-2 items will be scheduled for an in-person visit in a community setting or the participant's home (based on participant preference and location) to obtain informed consent, conduct screening, and obtain demographic information with a project coordinator, research assistant, intern or postdoctoral associate. Screening will occur with the GAD-2, the Penn State Worry Questionnaire (PSWQ), and a 6-item cognitive screener. Participants who screen positive (a score of 4 or more on the 6-item cognitive screener, at least one affirmative endorsement on GAD-2, and a score of 50 or more on the PSWQ-A) will complete the the Structured Clinical Interview for DSM-5 (SCID). If a participant needs immediate treatment (e.g., suicidal intent, active psychotic symptoms), he/she will be referred for immediate psychiatric assistance following standard community-based emergency protocols, and the PCP and any referring social service agency providers will be contacted. No individual will be asked to participate in any research activity that they are unwilling to do. They will be informed that they are free to choose not to participate and can withdraw from participating at any time during the study.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
Yes

Specific information concerning drug abuse:
Yes

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Other:
No

At what institution will the physical research data be kept?
All physical PHI data will be stored at IQUEST, the MEDVAMC Center of Innovation in the John P. McGovern Campus, 2450 Holcombe Blvd, Suite 01Y, in room 221, which is a locked data storage room, or room 210, which is the project coordinator's locked office. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

How will such physical research data be secured?

All physical PHI data will be stored securely in locked cabinets and access will be monitored at all times by the project coordinator.

At what institution will the electronic research data be kept?

All electronic data, including audio files will be stored at MEDVAMC secure server on the M drive in the following folder: M\Research\Stanley_M_Calmer Life RCT_H-30928. Research records, including identifiers will be destroyed 6 years after cutoff (at the end of the fiscal year) after completion of the research project, but may be retained longer if required by other federal regulations or sponsor archive requirement.

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):

No

Such electronic research data will be secured via Other:

Yes, (describe below):
Electronic PHI data, including audio files, will be stored on the MEDVAMC secure server on the M drive in the following folder: M\Research\Stanley_M_PCORI_H-35754 in password protected files, and access to the project folder on the shared M drive will be restricted to research team members. Audio recordings are made for this study per previous ISO guidance and approval, using the Olympus DS-5000iD and DS-7000, which use biometric fingerprint and password encryption. All audio files are transferred to and are stored in the following folder at MEDVAMC: M\Research\Stanley_M_PCORI_H-35754. Recorders are stored in locked cabinets in a locked office at Nabisco.

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

Yes, identify the classes of the persons:
People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

No PHI will be transmitted outside of the VA. No PHI will be transmitted to sponsors or collaborators.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

The purpose of collecting information covered under 38 U.S.C. 7332 is to conduct scientific research and no personnel involved in this study will identify, directly or indirectly, any individual patient or subject in any report of such research.

We will collect protected health information (PHI) requested from participants including, name, date of birth, home address, contact phone number, and ages of people that my be over 89. No social security numbers will be requested from the participants. The audio recordings will not contain sensitive information and will be labeled with participant numbers.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

All evaluation and treatment procedures will be offered at no cost to the subjects other than travel to study sites. Participants will be reimbursed $25.00 via gift card for each telephone assessment and qualitiative interview completed.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid

upon completion, etc) of the payment.

Dollar Amount:
25

Distribution Plan:
All participants will receive a $25.00 gift card for each telephone assessment completed at baseline, 6 and 9 months. Participants who complete the CL intervention may be selected to complete an additional qualitiative interview for which they will also receive a $25.00 gift card. CL participants may receive a total of $100 in gift cards and and ECC participants may receive a total of $75.00 in gift cards.

Gift cards will be mailed to participants by the study coordinator.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)
No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug that is not approved by the FDA?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Other: Flyer and printed ad to be used in community locations

Exact language of Advertisement:

Please see updated flyer and printed ad, included in Section S ("Calmer Life Flyer update 11.20.14.ppt" and "Media Outreach Blurb 11.20.14.docx"). . These materials will be used in community locations.