



Published in final edited form as:

J Nerv Ment Dis. 2013 May ; 201(5): 414–420. doi:10.1097/NMD.0b013e31828e0fd6.

Treating late-life GAD in primary care: An effectiveness pilot study

Jessica S. Calleo, Ph.D.^{1,2,3}, Amber L. Bush, Ph.D.^{1,2,3}, Jeffrey A. Cully, Ph.D.^{1,2,3,5}, Nancy L. Wilson, M.S., M.S.W.^{1,2}, Cynthia Kraus-Schuman, Ph.D.^{2,3}, Howard M. Rhoades, Ph.D.⁶, Diane M. Novy, Ph.D.⁷, Nicholas Masozera, M.D.^{2,3}, Susan Williams, M.D.², Matthew Horsfield, M.D.², Mark E. Kunik, M.D., M.P.H.^{1,2,3,5}, and Melinda A. Stanley, Ph.D.^{1,2,3,5}

¹Houston VA Health Service Research and Development Service Houston Center of Excellence, Houston, TX

²Baylor College of Medicine, Houston, TX

³Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX

⁴Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine, Houston, TX

⁵Veterans Affairs South Central Mental Illness, Research, Education, and Clinical Center (MIRECC), TX

⁶The University of Texas Health Science Center at Houston, Houston, TX

⁷The University of Texas M. D. Anderson Cancer Center, Houston, TX

Abstract

Objective—To increase sustainability of Cognitive Behavior Therapy (CBT) in primary care for late-life anxiety, we incorporated non-expert counselors, options for telephone meetings, and integration with primary care clinicians.

Method—This open trial examines the feasibility, satisfaction and clinical outcomes of CBT delivered by experienced and non-experienced counselors for older adults with generalized anxiety disorder (GAD). Clinical outcomes assessed worry (Penn State Worry Questionnaire), GAD (Generalized Anxiety Disorder Severity Scale), and anxiety (Beck Anxiety Inventory and Structured Interview Guide for Hamilton Anxiety Scale).

Results—Following 3 months of treatment, Cohen's *d* effect sizes for worry and anxiety ranged from .48 to .78. Patients treated by experienced and non-experienced counselors had similar reductions in worry and anxiety, although treatment outcomes were more improved on the Beck Anxiety Inventory for experienced therapists.

Conclusion—Preliminary results suggest adapted CBT can effectively reduce worry. The piloted modifications can provide acceptable and feasible evidence-based care.

Keywords

cognitive behavioral therapy; generalized anxiety disorder; primary care; older adults; mental health

*Address correspondence to: Jessica S. Calleo, Ph.D., Houston Center for Quality of Care & Utilization Studies, 2002 Holcombe Blvd. (VAMC 152), Houston, Texas 77030, Office: (713) 794-8521, Fax: (713) 748-7359 jcalleo@bcm.tmc.edu.

Disclosure

The authors report no financial conflicts of interest.

Introduction

Generalized anxiety disorder (GAD) is one of the most common anxiety disorders among older adults in primary care, with prevalence from 3.1% to 11.2% (Tolin et al., 2005; Wittchen et al., 2002). The impact of persistent anxiety on older adults is substantial. Anxiety decreases quality of life (Stanley et al., 2003; Wetherell et al., 2004) and is associated with increased physical disability (Porensky et al., 2009), coexistent depression (Lenze et al., 2000), memory problems (Mantella et al., 2007), and mortality (Szekely et al., 2007).

Primary care treatment of anxiety typically involves medication. Benzodiazepines and antidepressants are effective treatments for late-life GAD (Pinquart and Deberstein, 2007); but benzodiazepines have serious risks, and many older adults prefer nonmedication options due to concerns about adverse effects and fears of becoming dependent on medication (Gum et al., 2006; Wetherell et al., 2004).

Cognitive behavior therapy (CBT) is an effective alternative treatment for GAD in older patients (Thorp et al., 2009); although response rates tend to be lower than for younger adults. Two pilot studies (Stanley et al., 2003; Wetherell et al., 2009) and 1 larger clinical trial (Stanley et al., 2009) have demonstrated positive effects of CBT for late-life GAD in primary care, but many design and treatment-delivery elements do not represent real-world care (e.g., 1-hour sessions; expert providers; inadequate communication between mental health providers and PCPs). Further study is needed to test models that increase generalizability and translational value in medical settings.

To ease implementation and sustainability of CBT in primary care, traditional mental health recruitment and administrative efforts need to be modified in primary care. Electronic medical records (EMR) have been used successfully to increase collaboration between primary care and mental health providers (Rollman et al., 2007). A similar system may be beneficial for older adults where overlap between mental and physical health symptoms is common (Wolitsky-Taylor et al., 2010). In addition, older adults may benefit from attention to patient preferences in content and delivery of treatment. In modular interventions, patients are active in tailoring their own treatment plans to meet their mental health needs. All patients receive core (required) skills and then choose from a variety of elective (optional) skills typically selected based on patients' symptoms and preferences. Modular anxiety interventions have been successfully studied in primary care to reduce anxiety and improve quality of life compared to usual care (Roy-Byrne et al., 2010). A modular version of CBT in primary care for younger adults led to positive outcomes for anxiety and improved quality of life compared to usual care (Roy-Byrne et al., 2010). Another modular intervention study also suggested positive outcomes for GAD in older-adult primary care patients although sample size was small, and outcomes were not different from those with enhanced community care (Wetherell et al., 2009).

Mental health professionals are expensive and rarely integrated into primary care practices (Moak, 2011). A growing literature finds that expert and nonexpert providers produce comparable results in treating anxiety and depression (den Boer et al., 2005; Montgomery et al., 2010). Psychotherapy delivered in primary care by nonexperts holds promise as an economical and feasible option to the de facto practice of patients receiving only medications for anxiety.

To increase effectiveness of CBT in primary care for late-life GAD, we developed a model of referral and treatment that uses the EMR and adapted prior modular CBT interventions

(Stanley et al., 2009; Wetherell et al., 2009) to incorporate patient preferences in content (choice of anxiety-reduction skills) and delivery (in-person versus telephone). This pilot study builds on the success of collaborative care models from younger adults with anxiety (Sullivan et al., 2007; Rollman et al., 2005) and older adults with depression (Areán et al., 2008,- IMPACT trial). However, given the smaller effect sizes for CBT demonstrated in previous clinical trials for late life anxiety trials, it cannot be assumed that the same models of care will generalize positively to late life anxiety. The adapted CBT intervention was delivered by expert and nonexpert mental health counselors. An open trial examined delivery and communication procedures, as well as feasibility of, satisfaction with, and clinical outcomes of the adapted treatment. The training, acceptability, and outcomes of nonexperienced mental health counselors relative to experienced providers were examined.

Method

This research was approved by the Houston VA Research and Development Committee and the Baylor College of Medicine (BCM) Institutional Review Board.

Participants

Participants age 60 and over were recruited through primary care clinics at BCM and the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC). Primary care providers (PCPs) and research staff worked together to identify patients seen the previous month with identified problems or medication for anxiety, depression, or sleep disturbances noted in the EMR. Referred patients received letters from their PCP and the study PI (MS) inviting them to participate (n = 106). Brochures and posters were placed in waiting and exam rooms.

During an initial visit, patients reviewed informed consent, provided demographic data, and completed the 2 anxiety screening questions from the Primary Care Evaluation of Mental Disorders (Spitzer et al., 1994). Patients answering positively on at least one anxiety screening question completed the Mini Mental State Examination (Folstein et al., 1975) and a diagnostic interview (Structured Diagnostic Interview for the *Diagnostic and Statistical Manual, Fourth Edition* (First et al., 1997) or the Mini International Neuropsychiatric Interview (Sheehan et al., 1998)¹ conducted by advanced doctoral trainees in psychology and social work. Patients with a principal or co-principal diagnosis of GAD were included. Patients with MMSE < 24, active suicidal intent, active substance use, psychosis, or bipolar disorder were excluded. Of 47 who agreed to participate, 1 was dropped because of loss of contact, 4 were included as clinical training cases, and 20 were excluded because of no anxiety (n = 1), no principal GAD ([n = 14]; no diagnosis [n = 4], principal depressive diagnosis [n = 8], principal panic disorder [n = 1] and principal PTSD [n = 1]), cognitive impairment (n = 4) or participation in another research study (n = 1); of the 22 patients included, 3 dropped before assignment to a clinician or completion of baseline assessment, leaving 19 patients to begin treatment.

Intervention

Over 3 months patients received up to 10 skills-based sessions lasting 30 – 40 minutes (except a 45- to 60-minute first session). Sessions 1 and 2 were in-person, and subsequent sessions were in-person or by telephone, according to patient preference. Patients were provided workbook pages with an outline of materials presented and practice exercises at each meeting. If meeting by telephone, clinicians mailed workbook pages and guided patients to follow along with the workbook during the skill presentation and practice. Two to

¹The MINI was administered mid-way through the study as an abbreviated diagnostic tool.

3 days after each session, clinicians contacted patients to review skills and answer questions. All patients received three core skills: (1) anxiety education, awareness training, and motivational interviewing; (2) deep breathing; and (3) coping self-statements. Patients selected elective skills (sessions 4 – 9): behavioral activation; exposure; sleep management; problem solving; progressive muscle relaxation; thought stopping and cognitive restructuring. Providers recommended modules based on an algorithm matching baseline scores on the Penn State Worry Questionnaire (PSWQ), Beck Depression Inventory-II, Beck Anxiety Inventory (BAI), Generalized Anxiety Disorder Severity Scale (GADSS), Pittsburgh Sleep Quality Index (Buysse et al., 1989) and Social Problem Solving Inventory – Revised Short form (D’Zurilla et al., 2002) with module content. Final decisions about elective modules were based on patient preference. See Table 1 for description of module algorithm and skill sessions. We recommended an average of 2.4 (SD = 1.0) modules per patient, and patients completed the recommended module 66% of the time. Modules were declined if we recommended more than they had time to complete (24% of the recommendations) and if they preferred to select another module (10% of recommendations). The 10th CBT session focused on review of all skills. After the initial 3-months of treatment, patients were called weekly for 4 weeks and then biweekly for 8 weeks to review skills and provide support for continued practice.

Providers

CBT was provided by anxiety counselor specialists (ACSs) or counselors with no previous mental health training or experience. ACSs were 4 clinicians with formal training and experience in CBT, late-life mental health, and/or anxiety disorders: 1 postdoctoral social work fellow, 2 predoctoral psychology interns, and 1 clinical psychology master’s-level clinician. Counselors included a recent bachelor’s-level graduate, a college senior, and a college junior. ACSs and counselors read informational materials, reviewed audiotapes, and obtained weekly supervision. ACSs were supervised by the last author (MS); counselors were supervised by an ACS, with oversight by the last author. Before seeing any patients, counselors received a 90-minute didactic presentation and role-played with experts on all modules (4.5 hours). Following this training, counselors observed an ACS providing treatment for 1 patient and next provided treatment with an ACS in the room. Finally, counselors provided treatment and sessions were audiotaped so that an ACS could listen to 1 full set of sessions. All sessions by all providers were audiotaped, and 20% were rated by the last author to assess therapist competence and adherence. Competence and adherence were measured on a scale of 0 (None) to 8 (Excellent/Optimal) for overall adherence and competence. The components (e.g., providing education, weekly skills review, teaching calming statements) of the sessions were also rated for competence and adherence to help guide the overall competence and adherence score. If therapist adherence or competence fell below a 4 (adequate) for 2 consecutive ratings, the supervisor would listen to all sessions and provide additional guidance/training as needed until ratings were at or above 4 for adherence and competence for at least 2 consecutive sessions. Mean ratings of competence and adherence for ACSs and counselors were high and equivalent (competence = 6.4, SD = .65, range 5 – 8 and 6.0, SD = .51, range 5 – 7 respectively [$t = 1.6, p = .19$]; adherence: 6.6, SD = .67, range 5 – 8 and 6.2, SD = .48, range 6 – 7 respectively [$t = 1.73, p = .09$]).

Outcome Measures

Feasibility—The overall feasibility of the treatment was assessed by examining a summary of content and delivery chosen by patients, attrition rates, comparison of provider/EMR and self-referral procedures, and treatment credibility-expectancy. Treatment credibility and expectancy were assessed with the Expectancy Rating Scale (ERS; Borkovec and Nau, 1972). It includes 4 items rated from 0 (not at all) to 10 (extremely) that assess how logical this type of treatment seems, how confident the patient is that this treatment will eliminate

worry; how confident the patient would be in recommending this treatment to others, and how much improvement the patient expects to result from the treatment. The first 3 items assess credibility, and the fourth assesses expectations.

Satisfaction—An Exit Interview was developed to assess patients' satisfaction with treatment. Patients were asked to rate on 4-point scales how useful the program was in helping them manage anxiety (1 = not at all helpful and 4 = very helpful), how confident they were that they would continue to use the skills (1 = not at all confident and 4 = very confident), how well their therapist understood their anxiety (1 = not at all understand and 4 = understood a great deal), and how helpful they found written materials (1 = not at all helpful and 4 = very helpful). Ratings of helpfulness were also obtained for each skill. Higher scores indicated more positive views of the program, therapist, and written materials.

Worry/Anxiety Outcomes—Worry severity was assessed with the PSWQ (Meyer et al., 1990) and the GADSS (Shear et al., 2006). The 16-item PSWQ has adequate psychometric properties in older patients (Stanley et al., 2001; Webb et al., 2008). The GADSS is a 6-item, clinician-rated scale for assessing GAD symptom severity, with adequate internal consistency, interrater agreement, convergent validity, and mixed discriminant validity (Weiss et al., 2009). The BAI (Beck and Steer, 1990) and the Structured Interview Guide for the Hamilton Anxiety Scale (SIGH-A) (Shear et al., 2001) were used to measure anxiety severity. The BAI is a 21-item, self-report measure with strong psychometric properties among older patients (Kabacoff et al., 1997). The SIGH-A is a 14-item, clinician-rated scale designed to increase reliability of the Hamilton Anxiety Rating Scale (Shear et al., 2001). Among older primary care patients, interrater agreement was adequate (Skopp et al., 2006).

Procedure

Included patients completed all self-report and clinician-rated outcome measures at baseline, 3 and 6 months, with the exception of the ERS, completed after session 1, and the Exit Interview, completed after 6 months. An independent evaluator (IE), who had no other contact with the study, conducted assessments by telephone. The ERS and exit interviews were administered by a research assistant. The assessment supervisors (DN and JAC) held regular calibration meetings with the IEs to discuss a single assessment recording, review ratings, and ensure consistent administration. All IE assessments were audio-recorded, and a random 10% of the clinician-rated measures were rated by one of the assessment supervisors. Interrater agreements between IE and assessment supervisor on the GADSS and SIGH-A with these procedures are good (Skopp et al., 2006; Weiss et al., 2009).

Following baseline assessments, patients were assigned to CBT with a counselor or an ACS, based on provider availability. Ten patients were assigned to ACSs and 9 patients to counselors. For included patients, ongoing communication with the PCP occurred via the EMR. Session notes were sent to the PCP for review, indicating the skills the patients were learning and pertinent health information. For excluded patients, diagnosis and referrals were provided to the PCP and the patient.

Data Analysis

Treatment characteristics, attrition, and satisfaction were examined using descriptive statistics and nonparametric tests (Fisher's Exact Test and the Wilcoxon-Mann-Whitney Test). Treatment effects were examined by comparing baseline to 3-month outcomes and 3- to 6-month outcomes using the Wilcoxon Signed Rank Sum Test. ACS and counselor subsamples were compared by examining effect sizes in conjunction with 95% confidence intervals (CIs) of effect sizes. Group differences were interpreted as meaningful when the effect for 1 subsample fell outside the CI of the effect for the other subsample.

Results

Sample Characteristics

Patients who started treatment ($n = 19$) had a mean age of 66.4 ($SD = 6.4$) and a mean education of 15.8 years ($SD = 2.8$); 52.6% were women. Most ($n = 11$; 57.8%) were non-Hispanic Caucasian, with 6 (31.6%) African Americans, and 2 (10.5%) Hispanics. Eight (42.1%) had a comorbid diagnosis of depression, and 7 (36.8%) had an anxiety diagnosis in addition to GAD. The majority ($n = 12$; 63.2%) were on psychotropic medication, including 6 (31.6%) on anti-anxiety medications, 5 (26.3%) on antidepressants, 2 (10.5%) on anti-psychotics and 2 (10.5%) on anti-hypnotic medications. Of those who completed the study ($n = 12$), 9 (75%) reported at least one change in medication between baseline and 3 months. Four patients (33.3%) added a new medication or increased dosage of a medication ($n = 1$ anti-anxiety, $n = 2$ anti-depressant, $n = 1$ anti-hypnotic), 4 stopped a medication or decreased dosage ($n = 2$ anti-anxiety, $n = 2$ anti-depressant), and 2 (16.7%) switched anti-depressant medications.

Feasibility

Participants received an average of 7.7 ($SD = 1.85$) skill sessions, out of a maximum of 10. Most patients ($n = 11$, 64.7%) elected to have a least 1 session over the telephone and only 1 patient was unable to hold telephone sessions due to hearing loss. Of those who had telephone sessions, the average number of telephone sessions was 3.1 ($SD = 1.30$). In-person sessions were longer than telephone sessions ($M = 41.58$ minutes, [$SD = 10.84$] and $M = 31.94$ minutes, [$SD = 10.56$]; $Z = -4.55$, $p < .0001$). For elective sessions, most patients selected progressive muscle relaxation ($n = 13$, 72.2%), behavioral activation ($n = 10$, 55.6%) or cognitive restructuring ($n = 10$, 55.6%); whereas half chose thought stopping ($n = 9$) and sleep management ($n = 9$), and a minority ($n = 6$, 33.3%) selected problem solving. Because materials were developed specifically for older adults (e.g., with larger font), no additional modifications were needed to address sensory deficits.

Of the 19 participants who began treatment, 53% were provider/EMR referrals; and 47% were self-referrals. Patients generally perceived the treatment to be highly credible after completing the first session ($M = 7.29$, $SD = 1.76$) and expected the treatment to be successful ($M = 6.79$, $SD = 2.12$). Attrition from baseline to 3-months was 21.1% ($n = 4$) and overall attrition from baseline to 6 months was 36.8% ($n = 7$) including the 4 who dropped during the initial 3 months and 3 who completed the intervention but missed or declined the final assessments. Overall attrition was not related to site ($n = 5$ BCM; $n = 2$ MEDVAMC; Fisher's exact test, $p = .64$), coexistent diagnosis of depression ($n = 3$ depression diagnosis; $n = 4$ no depression diagnosis; Fisher's exact test, $p = 1.00$), treatment provider ($n = 4$ ACS or $n = 3$ counselors, Fisher's exact test, $p = .76$) or baseline outcomes (Z s between $-.93$ and 1.19 , all p s $> .23$).

Satisfaction

The Exit Interview was completed by 75% of those who completed treatment ($n = 9$). Patients felt that the treatment helped them manage their anxiety ($M = 3.61$, $SD = .49$), that they would continue to use skills taught to cope with anxiety in the future ($M = 3.56$, $SD = .53$), that their therapist understood their anxiety problems ($M = 3.78$, $SD = .44$), and that written materials were helpful ($M = 3.44$, $SD = .53$). Patients found breathing ($M = 3.67$, $SD = 1.00$) and cognitive restructuring ($M = 3.5$, $SD = .84$) to be the most helpful skills.

Worry/Anxiety Outcomes

PSWQ and GADSS scores declined significantly from baseline to 3 months for treatment completers (Table 1; Cohen's $d = .61$, $.78$). Effect sizes for changes on other anxiety

measures were not statistically significant (Cohen's $d = .48$ to $.49$). No further changes occurred from 3 to 6 months on the same measures [$d = .02$ to $.17$], suggesting that effects were maintained.

Secondary Analyses: Anxiety Treatment Provider

Patients treated by ACSs and counselors did not differ in ratings of treatment expectancy and credibility (credibility: $M = 7.39$ for ACSs and $M = 7.21$ for counselors, $p = .70$ and expectancies: $M = 6.33$ for ACSs and $M = 7.13$ for counselors, $p = .41$) or satisfaction (all p s $> .39$). They showed similar reductions in scores on the PSWQ, SIGH-A, and GADSS from baseline to 3 months. Decreases in the BAI over this interval were larger for those treated by an ACS relative to those treated by a counselor, for whom scores slightly increased. Patients treated by ACSs and counselors showed similar change in PSWQ, SIGH-A, and BAI scores from 3 to 6 months. The GADSS increased from 3 to 6 months only for those treated by counselors ($d = .39$, 95% CIs $= -.09, .86$).

Discussion

The treatment, a modified CBT intervention, holds promise to reduce worry in late-life GAD and increase sustainability in primary care. The effect sizes for symptom improvements from baseline to 3 months were similar to those of a larger primary care treatment study for late-life GAD (Stanley et al., 2009), and participants maintained gains at 6 months. Attrition at 6-months was high but within the range reported for late-life anxiety studies (Wetherell et al., 2005). Thus, the overall modular CBT model incorporating shorter sessions, patient preferences in delivery (telephone or in-person) and content (modules), and utilization of nonexpert counselors could be a viable option of treatment delivery in primary care for older adults.

The pilot study enabled patients to select skills to be learned and mode of delivery. Telephone sessions provide access to care for patients with financial, health, and geographic limitations. Telephone delivery of care management has been used with positive outcomes in younger primary care patients with anxiety disorders (Rollman et al., 2005) but this study is one of the first to incorporate telephone contacts into treatment for late-life GAD. A preliminary study by Brenes et al. (2010) has also demonstrated potential benefits of telephone-based treatment for older adults with anxiety. Although patients liked the ability to conduct phone sessions, most sessions actually were conducted in-person. Additional feedback from patients in future studies about positive and negative experiences of in-person versus telephone sessions would be helpful in developing and enhancing interventions for late life anxiety. Although it is not known how many participants would have declined or dropped out of treatment if telephone sessions were not an option, availability of this option seems particularly important for personalized care of older adults. In-person meetings were of longer duration, perhaps due to increased social aspects of the meetings, fewer outside distractions, more in-depth discussions, and more in-session practice. Although briefer, telephone meetings may be particularly helpful in settings where participants are chronically ill, financially constrained, and/or residing in more rural settings.

The pilot study provided treatment within the primary care clinic, used the EMR to identify potential patients, collaborated with PCPs to inform patients of the study, and provided notes to the PCP. As in prior studies with younger adults, (Brenes et al., 2010) the EMR allows anxiety treatment to be integrated into routine care and increase awareness of anxiety among providers. Collaborative care studies for anxiety management in younger adults have used EMR prompts to facilitate physician referrals and found that EMR recruitment increased physician referrals for minority patients (Rollman, 2008). Although the current sample size

was too small to test this kind of effect, the use of the EMR to facilitate referrals of older adults with anxiety may allow for more ethnic and racial heterogeneity.

Counselors with no previous mental health or patient experience were trained to deliver CBT that overall reduced worry and was satisfactory to patients. Previous studies have successfully utilized nurses or masters levels clinicians to provide mental health care in primary care (Sullivan et al, 2007). However, counselors in this pilot project were all bachelors level or less with no previous experience in patient care or mental health care and thus, may be a more cost-effective addition to a primary care clinic. Characteristics of treatment provided by clinicians were equivalent, as were patient estimates of credibility and expectancy, patient-reported satisfaction, and rates of attrition. Future studies could also measure other aspects of therapy, such as therapeutic alliance, therapeutic style or homework adherence, which are also important aspects of CBT. The ability to train counselors with no previous mental health or patient care experience to provide effective CBT is instrumental in increasing the translational value of CBT in primary care, but additional studies need to compare outcomes for experienced and non-experienced mental health providers. Sample sizes here were very small, and outcomes were inconsistent.

Limitations of this study include the lack of a control condition, small sample size, and higher attrition rate for the complete 6 months of treatment. Although the study had blind independent evaluators for treatment outcomes and guidelines to evaluate treatment integrity, the treatment integrity rater was not blind to study conditions. In addition, ACSs in this study included ranges of experienced mental health clinicians. Subsequent larger studies would benefit from defining experienced clinicians as those with more advanced degrees and/or more experienced mental health providers among larger samples and with adequate controls. As is common in older adults with GAD, many patients had co-occurring depression and were on psychiatric medication. Due to the small sample size, this pilot focused on outcomes for anxiety; but future studies will need to assess depression and health outcomes and examine predictors of outcome (medication use, homework adherence, etc.). Future studies would benefit from including a greater number of older-old adults to facilitate generalizability across ages and developmental stages of older adults. A larger study with a control group is also essential to demonstrate the value of the intervention above and beyond the care typically received in primary care. Although most patients who completed treatment either decreased or maintained their psychiatric medication dose, without a control group we cannot know how many patients would have decreased worry by other management strategies. A control group would also provide more information on attrition in these diverse primary care clinics. The rate of attrition was not due to patient symptoms or clinician experience but in current study it is not known if due to specific study or patient characteristics.

Despite limitations, this study demonstrates the potential feasibility and acceptability of a CBT-based treatment model that enhances translational value in culturally diverse primary care clinics over previously tested models for older adults with GAD. Increased accommodation of patient preferences is important for providing patient-centered care. The relevance of training nonmental health or patient care experts to provide CBT was recognized in the President's New Freedom Commission on Mental Health Services (The President's New Freedom Commission on Mental Health, 2003) that recommended increasing available practitioners providing evidence-based geriatric mental health care. Although the need for evidence-based and sustainable late life anxiety treatments is recognized, research on effective psychosocial models of treatment and delivery need to be examined further in larger controlled trials with diverse populations of older adults (Schuermans and van Balkmon, 2010). The positive results from this preliminary study support future larger studies with this modified CBT treatment for older adults.

Acknowledgments

This research was supported by a grant from the Veterans Affairs South Central Mental illness Research Education and Clinical Center (MIRECC), the National Institute of Mental Health (NIMH) (R01-MH53932) to Dr Stanley and by the Houston VA Health Services Research and Development Center of Excellence (Houston Center for Quality of Care & Utilization Studies [HFP90-020]). The views expressed do not necessarily reflect those of the Department of Veterans Affairs/Baylor College of Medicine.

References

- Beck, AT.; Steer, RA. Beck Anxiety Inventory manual. San Antonio, TX: Psychological Corporation; 1990.
- Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther.* 1972; 3:257–260.
- Brenes GA, McCall WV, Williamson JD, Stanley MA. Feasibility and acceptability of bibliotherapy and telephone sessions for the treatment of late life anxiety disorders. *Clin Gerontol.* 2010; 33:62–68. [PubMed: 20661315]
- Buyssee DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Res.* 1989; 28:193–213. [PubMed: 2748771]
- den Boer PC, Wiersma D, Russo S, Van den Bosch RJ. Paraprofessionals for anxiety and depressive disorders. *Cochrane.Database Syst Rev.* 2005 CD00468.
- D'Zurilla, TJ.; Nezu, AM.; Maydeu-Olivares, A. Social Problem-Solving Inventory- Revised: technical manual. North Tonawanda, NY: Multi-Health Systems; 2002.
- First, MB.; Spitzer, RL.; Miriam, G.; Williams, JBW. Structured Clinical Interview for DSM-IV Axis I Disorders, research version, patient edition with psychotic. New York: Biometrics Research: New York State Psychiatric Institute; 1997.
- Folstein MF, Folstein SE, McHugh PR. “Minimentalstate”: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res.* 1975; 12:189–198. [PubMed: 1202204]
- Gum AM, Areán PA, Hunkeler E, Tang L, Katon W, Hitchcock P, Steffens CD, Dickens J, Unützer J. Depression treatment preferences in older primary care patients. *The Gerontologist.* 2006; 46:14–22. [PubMed: 16452280]
- Kabacoff RI, Segal DL, Hersen M, Van Hasselt VA. Psychometric properties and diagnostic utility of the Beck Anxiety Inventory and State-Trait Anxiety Inventory with older adult psychiatric outpatients. *J Anxiety Disord.* 1997; 11:33–47. [PubMed: 9131880]
- Lenze EJ, Mulsant BH, Shear MK, Schulberg HC, Dew MA, Begley AE, Pollock BG, Reynolds CF III. Comorbid anxiety disorders in depressed elderly patients. *Am J Psychiatry.* 2000; 157:722–728. [PubMed: 10784464]
- Lynch TR, Morse JQ, Mendelson T, Robins CJ. Dialectical behavior therapy for depressed older adults: A randomized pilot study. *Am J Geriatr Psychiatry.* 2003; 11:33–45. [PubMed: 12527538]
- Mantella RC, Butters MA, Dew MA, Mulsant BH, Begley AE, Tracey B, Shear MK, Reynolds CF III, Lenze EJ. Cognitive impairment in late-life generalized anxiety disorder. *Am J Geriatr Psychiatry.* 2007; 15:673–679. [PubMed: 17426260]
- Meyer TJ, Miller ML, Metzger RI, Borkovec TD. Development and validation of the Penn State Worry Questionnaire. *Behav Res Ther.* 1990; 28:487–495. [PubMed: 2076086]
- Moak GS. Treatment of late life mental disorders in primary care: We can do a better job. *J Aging Social Policy.* 2011; 23:274–285.
- Montgomery EC, Kunik ME, Wilson N, Stanley MA, Weiss B. Can paraprofessionals deliver cognitive-behavioral therapy to treat anxiety and depressive symptoms? *Bulletin of the Menninger Clinic.* 2010; 74:45–62. [PubMed: 20235623]
- Pinquart M, Duberstein PR. Treatment of anxiety disorders in older adults: a meta-analytic comparison of behavioral and pharmacological interventions. *Am J Geriatr Psychiatry.* 2007; 15:639–651. [PubMed: 17670995]
- Porensky EK, Dew MA, Karp JF, Skidmore E, Rollman BL, Shear MK, Lenze EJ. The burden of late-life generalized anxiety disorder: Effects on disability, health-related quality of life, and healthcare utilization. *Am J Geriatr Psychiatry.* 2009; 17:473–482. [PubMed: 19472438]

- Rollman BL, Fischer GS, Zhu F, Belnap BH. Comparison of electronic physician prompts versus waitroom case-finding on clinical trial enrollment. *J Gen Intern Med.* 2008; 23:447–450. [PubMed: 18373143]
- Rollman BL, Hanusa BH, Gilbert T, Lowe JH, Kapoor WN, Schulberg HC. The electronic medical record. A randomized trial of its impact on primary care physicians' initial management of major depression. *Arch Intern Med.* 2001; 161:189–197. [PubMed: 11176732]
- Roy-Bryne P, Craske MG, Sullivan G, Rose RD, Edlund MJ, Lang AJ, Bystritsky A, Welch SS, Chavira DA, Golinelli D, Campbell-Sills L, Sherbourne CD, Stein MB. Delivery of evidence-based treatment for multiple anxiety disorders I primary care: a randomized controlled trial. *JAMA.* 2010; 303:1921–1928.
- Shear K, Belnap BH, Mazumdar S, Houck P, Rollman BL. Generalized Anxiety Disorder Severity Scale (GADSS): a preliminary validation study. *Depress Anxiety.* 2006; 23:77–82. [PubMed: 16411185]
- Shear MK, Vander Bilt J, Rucci P, Endicott J, Lydiard B, Otto MW, Pollack MH, Chandler L, Williams J, Ali A, Frank DM. Reliability and validity of a structured interview guide for the Hamilton Anxiety Rating Scale (SIGH-A). *Depress Anxiety.* 2001; 13:166–178. [PubMed: 11413563]
- Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic interview for DSM-IV and ICD-10. *J Clin Psychiatry.* 1998; 59(Suppl 20): 22–33. [PubMed: 9881538]
- Skopp NA, Novy D, Kunik M, Daza P, Adams JH, senior A, Stanley M. Investigation of cognitive behavior therapy. *Am J Geriatr Psychiatry.* 2006; 14:292. [PubMed: 16505134]
- Spitzer RL, Williams JB, Kroenke K, Linzer M, de Grey FV 3rd, Hahn SR, Brody D, Johnson JG. Utility of a new procedure for diagnosing mental disorders in primary care: the PRIME-MD 1000 study. *JAMA.* 1994; 272:1749–1756. [PubMed: 7966923]
- Stanley MA, Beck JG, Novy DM, Averill PM, Swann AC, Diefenbach GJ, Hopko DR. Cognitive-behavioral treatment of late-life generalized anxiety disorder. *J Consult Clin Psychol.* 2003; 71:309–319. [PubMed: 12699025]
- Stanley MA, Novy DM, Bourland SL, Beck JG, Averill PM. Assessing older adults with generalized anxiety: a replication and extension. *Behav Res Ther.* 2001; 39:221–235. [PubMed: 11153975]
- Stanley MA, Wilson NL, Novy DM, Rhoades HM, Wagener PD, Greisinger AJ, Cully JA, Kunik ME. Cognitive behavior therapy for generalized anxiety disorder among older adults in primary care: A randomized clinical trial. *JAMA.* 2009; 301:1460–1467. [PubMed: 19351943]
- Székely A, Balog P, Benkő E, Breuer T, Székely J, Kertai MD, Horkay F, Kopp MS, Thayer JF. Anxiety predicts mortality and morbidity after coronary artery and valve surgery – a 4 year follow-up study. *Psychosom Med.* 2007; 69:625–631. [PubMed: 17724254]
- The President's New Freedom Commission on Mental Health. Achieving the promise: Transforming mental health care in America. Final Report. Rockville, MD: US Department of Health and Human Services; 2003. DHHS Pub. No. SMA-03-3832
- Thorp SR, Ayers CR, Nuevo R, Stoddard JA, Sorrell JT, Wetherell JF. Meta-analysis comparing different behavioral treatment for late life anxiety. *Am J Geriatr Psychiatry.* 2009; 17:105–115. [PubMed: 19155744]
- Tolin DF, Robison JT, Gaztambide S, Blank K. Anxiety disorders in older Puerto Rican primary care patients. *Am J Geriatr Psychiatry.* 2005; 13:150–156. [PubMed: 15703324]
- Webb SA, Diefenbach G, Wagener P, Novy DM, Kunik ME, Rhoades HM, Stanley MA. Comparison of self-report measures for identifying late life generalized anxiety in primary care. *J Geriatr Psychiatry Neurol.* 2008; 21:221–223.
- Weiss BJ, Calleo J, Rhoades H, Novy DM, Kunik ME, Lenze EJ, Stanley MA. The utility of the Generalized Anxiety Disorder Severity Scale (GADSS) with older adults in primary care. *Depress Anxiety.* 2009; 26:E10–E15. [PubMed: 18839400]
- Wetherell JL, Ayers CR, Sorrell JT, Thorp SR, Nuevo R, Belding W, Gray E, Stanley MA, Areán PA, Donohue M, Unnützer J, Ramsdell J, Xu R, Patterson TL. Modular psychotherapy for anxiety in older primary care patients. *Am J Geriatr Psychiatry.* 2009; 17:483–492. [PubMed: 19461257]

- Wetherell JL, Kaplan RM, Kallenberg G. Mental health treatment preferences of older and younger primary care patients. *Int J Psychiatry Med*. 2004; 34:219–233. [PubMed: 15666957]
- Wetherell JL, Lenze EJ, Stanley MA. Evidence-based treatment of geriatric anxiety disorders. *Psychiatr Clin North Am*. 2005; 28:871–896. ix. [PubMed: 16325733]
- Wittchen HU, Kessler RC, Beesdo K, Krause P, Höfler M, Hoyer J. Generalized anxiety and depression in primary care: Prevalence, recognition, and management. *J Clin Psychiatry*. 2002; 63(Suppl 8):24–34. [PubMed: 12044105]
- Wolitsky-Taylor KB, Catriotta N, Lenze EJ, Stanley MA, Craske MG. Anxiety disorders in older adults: A comprehensive review. *Depress Anxiety*. 2010; 27:190–211. [PubMed: 20099273]
- Sullivan G, Craske MG, Sherbourne C, Edlund MJ, Rose RD, Golinelli D, Chavira DA, Bystritsky A, Stein MB, Roy-Byrne PP. Design of the coordinated anxiety learning and management (CALM) study: innovations in collaborative care for anxiety disorders. *General Hospital Psychiatry*. 2007; 29:379–387. [PubMed: 17888803]
- Areán P, Hegel M, Vannoy S, Fan MY, Unutzer J. Effectiveness of problem-solving therapy for older, primary care patients with depression: results from the IMPACT project. *Gerontologist*. 2008; 48:311–323. [PubMed: 18591356]
- Schuurmans J, van Balkom A. Late life anxiety disorders: A Review. *Curr Psychiatry Rep*. 2011; 13:267–273. [PubMed: 21538031]
- Rollman BL, Belnap BH, Mazumdar S, Houck PR, Gardner W, Reynolds CF 3rd, Schulberg HC, Shear MK. A randomized trial to improve the quality of treatment for panic and generalized anxiety disorders in primary care. *Arch Gen Psychiatry*. 2005; 62:1332–1341. [PubMed: 16330721]

Table 1
DEVELOPING YOUR PEACEFUL LIVING PROGRAM

These meetings will cover a selection of topics depending upon your most important problems and current goals. Everyone will learn three basic skills (or tools) and three additional skills. Each additional skill will take 1 or 2 sessions to learn. Based on the assessments you have completed we recommend _____, _____, and _____. However, we find it most helpful for you to choose topics that you think can help achieve your goals and experience more Peaceful Living.

| My Peaceful Living Program | Session Topic | OVERVIEW | Module Algorithm Recommendations |
|-----------------------------------|---|--|--|
| ✓ | Anxiety Education and Becoming Aware of Anxiety | Learn about anxiety and become aware of your own physical signs, feelings, thoughts, and actions. | Everyone |
| ✓ | Learn How to Relax I | Reduce anxiety with slow, deep breathing. | Everyone |
| ✓ | Changing Your Thoughts to Manage Anxiety I | Manage your anxiety by using calming and reinforcing self-statements. | Everyone |
| | Changing Your Behavior for Depression | Break the downward spiral of depression by getting involved in activities you may avoid because of sad mood. | Hamilton Rating Scale for Depression score of 18 (Lynch et al., 2003) |
| | Changing Your Behavior for Anxiety | Stop engaging in repetitive behaviors and get involved in activities you may avoid because of anxiety. | A score of 3 or above on questions 5 or 6 of the Generalized Anxiety Disorder Severity Scale |
| | Getting to Sleep | Learn about things you can do to manage difficulties in sleep. | Pittsburg Sleep Quality Index > 5 (Buyssee, 1989) |
| | Problem Solving | Solve problems through effective steps. | Social Problem-Solving Inventory – Revised: Short form 85 (D’Zurilla et al, 2002) |
| | Learn How to Relax II | Pinpoint and release muscle tension using Progressive Muscle Relaxation. | Structured Interview Guide for Hamilton Anxiety Scale 17 (Weiss et al, 2009) |
| | Changing Your Thoughts to Manage Anxiety II | Stop dwelling on anxiety-related thoughts and images and challenge negative thoughts by replacing them with more realistic alternative thoughts. | Penn State Worry Questionnaire 62 (Stanley et al. 2001) |
| ✓ | Maintaining a Peaceful Life | Review your progress and develop a plan to continue Peaceful Living. | Everyone |

Table 2
Means and Standard Deviations of Primary Outcome Variables at Each Assessment for Treatment Completers, Followed by Results of Wilcoxon Signed Rank Sum Tests

| | Baseline | | 3 mo. | | 6 mo. | | BL to 3 mo. | | 3 mo. to 6 mo. | |
|---------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|--------------------|--------------------|--------------------|--------------------|
| | <i>M</i> (<i>SD</i>) | <i>M</i> (<i>SD</i>) | <i>M</i> (<i>SD</i>) | <i>M</i> (<i>SD</i>) | <i>M</i> (<i>SD</i>) | <i>M</i> (<i>SD</i>) | <i>Mean Change</i> | <i>d</i> (95% CIs) | <i>Mean Change</i> | <i>d</i> (95% CIs) |
| Total (<i>N</i> = 12) | 53.17 (7.94) | 48.00 (10.22) | 49.67 (13.90) | 45.83 (13.23) | 45.83 (13.23) | 45.83 (13.23) | -5.16** | .61 (-.24, .97) | 1.67 | .15 (-.16, .46) |
| PSWQ | | | | | | | | | | |
| ACS (<i>n</i> = 6) | 52.67 (8.82) | 48.17 (10.76) | 45.83 (13.23) | 45.83 (13.23) | 45.83 (13.23) | 45.83 (13.23) | -4.50 | .43 (-.09, .95) | -2.34 | .18 (-.18, .54) |
| Counselor (<i>n</i> = 6) | 53.67 (7.76) | 47.83 (10.68) | 53.50 (14.67) | 53.50 (14.67) | 53.50 (14.67) | 53.50 (14.67) | -5.83* | .63 (-.19, 1.08) | 5.67 | .45 (-.02, .92) |
| Total | 14.75 (3.77) | 11.58 (4.52) | 12.42 (4.96) | 12.42 (4.96) | 12.42 (4.96) | 12.42 (4.96) | -3.17* | .78 (-.10, 1.47) | .84 | .17 (-.14, .49) |
| GADSS | | | | | | | | | | |
| ACS | 14.33 (3.98) | 12.17 (5.56) | 12.17 (4.92) | 12.17 (4.92) | 12.17 (4.92) | 12.17 (4.92) | -2.17 | .46 (-.09, 1.01) | .00 | .00 (-.31, .31) |
| Counselor | 15.17 (3.87) | 11.00 (3.63) | 12.67 (5.47) | 12.67 (5.47) | 12.67 (5.47) | 12.67 (5.47) | -4.17 | .91 (-.41, 2.22) | 1.67 | .39 (-.09, .86) |
| Total | 18.83 (7.41) | 15.00 (11.50) | 13.50 (8.95) | 13.50 (8.95) | 13.50 (8.95) | 13.50 (8.95) | -3.83 | .48 (-.19, 1.15) | -1.5 | .12 (-.24, .48) |
| BAI | | | | | | | | | | |
| ACS | 19.33 (8.73) | 10.50 (7.71) | 10.83 (8.52) | 10.83 (8.52) | 10.83 (8.52) | 10.83 (8.52) | -8.83 | .85 (-.27, 1.98) | .33 | .04 (-.78, .85) |
| Counselor | 18.33 (6.62) | 19.50 (13.52) | 16.17 (9.30) | 16.17 (9.30) | 16.17 (9.30) | 16.17 (9.30) | 1.16 | -.15 (-.83, .53) | -3.33 | .21 (-.05, .47) |
| Total | 26.33 (8.12) | 22.08 (9.41) | 22.33 (14.16) | 22.33 (14.16) | 22.33 (14.16) | 22.33 (14.16) | -4.25 | .49 (.03, .94) | .25 | .02 (-.47, .52) |
| SIGH-A | | | | | | | | | | |
| ACS | 24.33 (6.68) | 19.83 (8.73) | 21.50 (14.72) | 21.50 (14.72) | 21.50 (14.72) | 21.50 (14.72) | -4.50 | .57 (-.02, 1.15) | 1.67 | .16 (-.67, .99) |
| Counselor | 28.33 (9.52) | 24.33 (10.33) | 23.17 (14.92) | 23.17 (14.92) | 23.17 (14.92) | 23.17 (14.92) | -4.00 | .35 (-.34, 1.05) | -1.16 | .10 (-.66, .47) |

Note:

** $p < .01$,

* $p < .05$