



HHS Public Access

Author manuscript

J Behav Cogn Ther. Author manuscript; available in PMC 2022 July 08.

Published in final edited form as:

J Behav Cogn Ther. 2021 June ; 31(2): 91–103. doi:10.1016/j.jbct.2020.11.007.

Randomized pilot trial of cognitive-behavioral therapy and acceptance-based behavioral therapy in the treatment of Spanish-speaking Latino primary care patients with generalized anxiety disorder

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Abstract

The evidence base supporting the usefulness of traditional cognitive-behavioral therapy (CBT) and newer acceptance-based CBT treatments for generalized anxiety disorder (GAD) has grown over the past decades. GAD is prevalent among several Latino subgroups, particularly Puerto Ricans. However, there remains uncertainty regarding the appropriateness of these interventions for Spanish-speaking Latinos since they have been routinely excluded in both efficacy and effectiveness studies. As an initial step to bridge this gap, this pilot study examined the potential efficacy of two CBT interventions for GAD, traditional CBT and acceptance-based behavioral therapy (ABBT), in a sample of Spanish-speaking Latinos. Ninety primary care patients with GAD were randomly assigned to receive CBT ($n=30$), ABBT ($n=30$), or treatment as usual (TAU) ($n=30$). Excessive worry, the core feature of GAD, was assessed with the Penn State Worry Questionnaire (PSWQ), which is considered the gold standard measure of GAD-related worry. At follow-up, PSWQ scores for participants in the CBT and ABBT groups were statistically lower than those of the TAU group and statistically comparable to each other. CBT and ABBT reduced worry level to a greater degree than usual care by follow-up. Our findings provide preliminary, yet crucial data, which support the potential of both interventions targeting GAD symptoms among Spanish-speaking Latino primary care patients.

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Disclosure of interest

The authors declare that they have no competing interest.

Ethical approval

The study protocol was approved by the University of Puerto Rico, Medical Sciences Campus Institutional Review Board.

Keywords

Latinos; Generalized anxiety disorder; Cognitive-behavioral therapy; Acceptance-based behavioral therapy; Primary care

Introduction

Generalized anxiety disorder (GAD) is prevalent among Latinos (Alegría et al., 2008a,b; Asnaani, Richey, Dimaite, Hinton, & Hofmann, 2010). Data from the most recent epidemiological survey of mental disorders collected from representative samples of Latino adults in the United States revealed that 4.2% of Latinos experienced GAD in their lifetime (Meng, Alegria, Chan, & Liu, 2004). However, when the data were disaggregated differences emerged among Latino subgroups. The GAD lifetime prevalence rate was 6.0% for Puerto Ricans, 5.8% for Cubans, 4.1% for Mexicans, and 3.5% for other Latinos. Similarly, high rates of GAD have also been reported for Puerto Rico residents. Data drawn from a household probability sample survey of 3062 adults showed that the prevalence rate for past-year GAD was 5.2% (Canino et al., 2016).

The core feature of GAD is out-of-control, excessive worry regarding ordinary daily situations (American Psychiatric Association, 2013). People with GAD show an increased hypervigilance to danger, continually perceiving threats that exist just in the mind and in the imaginary future (Borkovec, Newman, & Castonguay, 2003; Goodwin, Yiend, & Hirsch, 2017). According to Borkovec et al. (Borkovec et al., 2003; Borkovec, Alcaine, & Behar, 2004), worry functions as a type of cognitive avoidance mechanism used to identify ways of preventing anticipated disasters and to cope with the emotional reactivity generated by the perceived threat. The high level of anxiety and uncontrollable worry limits the ability to conduct daily activities, leading to significant impairment (Alonso et al., 2004; Kessler et al., 2009; Stein et al., 2005), poor quality of life (Barrera & Norton, 2009; Mendlowicz & Stein, 2000), low work productivity (Revicki et al., 2012), and increased health care utilization (Bereza, Machado, & Einarson, 2009; Hoffman, Dukes, & Wittchen, 2008; Revicki et al., 2012).

GAD is the most common anxiety disorder seen in primary care, but it is often unrecognized as many patients usually present with somatic symptoms that are often attributed to physical disorders (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007; Wittchen et al., 2002). GAD frequently coexists with other psychological and medical health problems, such as depressive disorders and multiple cardiovascular, gastrointestinal, respiratory, and endocrine conditions (Culpepper, 2009; Kessler, Keller, & Wittchen, 2001). When GAD is comorbid with another condition, patient outcomes are poorer compared to those with GAD alone (Bélanger, Ladouceur, & Morin, 2005; Davidson, Feltner, & Dugar, 2010). Furthermore, GAD patients with comorbidities are among the highest utilizers of medical services (Deacon, Lickel, & Abramowitz, 2008). Liu, Tian, Liu, Nigatu, and Wang (2019) examined the impact of GAD on the course of cardiovascular disease, they found that while GAD contributes to increase the risk of cardiovascular disease (CVD), a reduction of GAD symptoms is associated with reduced risk of new-onset CVD. These findings highlight

the need for improved recognition and treatment of GAD patients within the primary care population.

Cognitive-behavioral therapy (CBT) enjoys high clinical approval and empirical support for the treatment of GAD (Borkovec et al., 2004; Butler, Chapman, Forman, & Beck, 2006). Traditional CBT models for GAD address behavioral avoidance and worry as maladaptive coping strategies used by the individual in the attempt to problem-solve and reduce undesirable thoughts and emotions (Borkovec, 1994; Borkovec et al., 2004). Intervention components include cognitive therapy to deal with worry and cognitive biases, applied relaxation to address tension, self-monitoring, imaginal exposure to catastrophic images, and exposure to stressful situations to practice learned coping responses (Borkovec, Newman, Pincus, & Lytle, 2002; Borkovec & Ruscio, 2001; Borkovec et al., 2003). Findings from meta-analyses and systematic reviews show that traditional CBT significantly reduces GAD symptoms and is more effective than no treatment or alternative treatments (Borkovec & Ruscio, 2001; Cuijpers et al., 2014; Gould, Safren, Washington, & Otto, 2004). Furthermore, the benefits of CBT are comparable to those reported for pharmacological interventions and tend to be sustained over 6- and 12-month follow-up (Borkovec et al., 2002; Covin, Ouint, Seeds, & Dozois, 2008; Cuijpers et al., 2014; Heuzenroeder et al., 2004; Mitte, 2005). However, even though traditional CBT has been extensively studied and is considered by many as a first treatment option for GAD, the proportion of individuals that attain clinically significant change following treatment is lower than rates usual for other anxiety disorders (Bolognesi, Baldwin, & Ruini, 2014; Borkovec et al., 2002; Newman, Llera, Erickson, Przeworski, & Castonguay, 2013).

CBT evidence-based treatments have expanded over the past years to improve therapeutic approaches that facilitate distancing from pathological worries and anxious thoughts. Findings from studies focused on further advancing CBT for GAD provide promising evidence for approaches that integrate mindfulness and acceptance-based strategies to cognitive-behavioral therapies, particularly acceptance-based behavioral therapy (ABBT) (Orsillo & Roemer, 2011; Roemer & Orsillo, 2009) for GAD. ABBT is characterized by a focus on altering how individuals react to their internal experiences (thoughts, emotions, sensations, and memories) instead of changing the content or frequency of the experiences themselves (O'Connor, Munnely, Whelan, & McHugh, 2018; Roemer, Williston, Eustis, & Orsillo, 2013). The basic premise underlying the therapy is that anxious responses can be kept from intensifying by responding with awareness, openness, and acceptance rather than efforts to control or avoid unwanted feelings (Orsillo & Roemer, 2005). Processes central to treatment, such as experiential acceptance, values clarification, and attention to the present moment, are targeted with a variety of clinical methods, including psychoeducation, self-monitoring, mindfulness practices, and behavior change strategies (Hayes-Skelton, Roemer, & Orsillo, 2013; Roemer & Orsillo, 2009). Research findings show that ABBT has been associated with considerable improvements in anxiety and depression symptoms (Hayes-Skelton et al., 2013; Roemer, Orsillo, & Salters-Pedneault, 2008; Treanor, Erisman, Salters-Pedneault, Roemer, & Orsillo, 2011). In an initial crossover study, in which randomized participants received ABBT immediately or were placed on a waiting list to receive it later, ABBT significantly reduced GAD symptoms to non-clinical levels at follow-up, with benefits sustained over further 9 months (Roemer et al., 2008). More recently, investigators

examined the effectiveness of ABBT in comparison to an established CBT treatment (Hayes-Skelton et al., 2013) showing that both treatments led to significant change across treatment and follow-up.

Over the past decades, increased emphasis has been placed on the inclusion of minorities in clinical research (US Department of Health & Human Services, 2001a). However, despite the National Institutes of Health requirement of sufficient inclusion of racial minority groups in their funded clinical trials, systematic reviews of mental health clinical trials show consistently low representation of Latinos (Benuto, Bennett, & Casas, 2020; Mendoza, Williams, Chapman, & Powers, 2012; Williams, Powers, Yun, & Foa, 2010). Although the evidence base supporting the usefulness of both traditional and acceptance-based cognitive-behavioral therapies for GAD has grown over the past decades, there remains uncertainty regarding the appropriateness of these interventions for Spanish-speaking Latinos since they have been routinely excluded in treatment outcome studies (Lau, Chang, & Okazaki, 2010). We bridge this gap by assessing whether Spanish-speaking Latinos with GAD benefit from traditional or acceptance-based cognitive behavioral treatments. Specifically, this randomized pilot study compared two interventions, CBT and ABBT, versus treatment-as-usual to examine the potential efficacy of each intervention for the treatment of GAD in a sample of low-income, Latino, primary care patients. We focused on Latino patients disadvantaged by income because low socioeconomic status has been associated with adverse effects on mental health and limited access to mental health specialty care (Allen, Bafour, Bell, & Marmot, 2014; Anakwenze & Zuberi, 2013). The primary care setting is especially important for mental health care delivery in patients disadvantaged by income, education and minority status (Department of Health and Human Services, 2011; McGuire & Miranda, 2008).

Methods

Participants and procedures

Ninety primary care patients were recruited to the study. The mean age of the randomized sample was 41 years, with range from 18 to 64 years. Most were women (86.7%) and were married or cohabitating (45.6%). Forty-one percent were employed and almost 30% had not completed high school (Table 1). Eligible participants were adults attending participating primary care clinics for general medical treatment. Criteria for inclusion included: ages 18 to 64, scores of at least 5.7 on the Generalized Anxiety Disorder Questionnaire (GAD-Q-IV) (Newman et al., 2002) and 56 on the Penn State Worry Questionnaire (PSWQ) (Meyer, Miller, Metzger, & Borkovec, 1990), fluent Spanish speaker, willingness to be randomized to treatment condition, and the intention to use the clinic as their main source of medical care in the following six-month period. Patients were excluded if they had a health problem or other situation that interfered with participation (severe medical illness, suicidal ideation, significant cognitive problems), had a history of schizophrenia or psychotic disorder, used drugs during the past six months, scored positive on the Alcohol Use Disorders Identification Test (AUDIT-C) (Bradley et al., 1998), or were receiving mental health treatment.

A nonconsecutive convenience sample was drawn among patients presenting for physical health care at 10 primary care clinics, serving primarily low-income patients in urban areas of San Juan, Puerto Rico. Fig. 1 depicts the CONSORT flow diagram, which summarizes the recruitment and allocation of participants. Patients were individually approached by a research assistant while waiting for their medical appointment. In total, 5714 patients were screened for eligibility, over 80% of those approached agreed to participate. Screening interviews were conducted in private offices to ensure confidentiality. Three hundred and seven potential participants who appeared to be eligible for participation were invited for further assessment: 21 declined participation, 101 did not present for the assessment, and 185 completed the baseline assessment. A total of 130 patients with significant GAD symptoms were eligible for randomization, of these 40 were lost to further contact leaving a sample of 90 patients that were randomized: 30 to treatment as usual (TAU), 30 to ABBT, and 30 to CBT. Trained research staff with background in psychology was responsible for enrolling eligible participants using a number sequence developed by a computer random number generator. To obtain random assignment information for each participant, enrollment staff contacted the central office to receive information corresponding to the assigned treatment condition. Additional assessments were conducted in the primary care clinics where each participant was recruited. Assessments were arranged outside of treatment session and were conducted by assessors blind to randomization. Participants could stop therapy and continue with study assessments. In addition to baseline the following percentages completed week-20 and week-28 assessments: week-20, 90% TAU patients, 73.3% ABBT patients, and 73.3% CBT patients, and week-28, 96.7% TAU patients, 70% ABBT patients, and 86.7% CBT patients. Of the 60 patients randomized to ABBT and CBT, 12 (20%) did not initiate treatment. Among treatment initiators, treatment was completed (15 sessions or more) by 63.6% in the ABBT group and 42.3% in the CBT group. The average number of sessions attended was 12.8 for ABBT and 9 for CBT.

Treatment conditions

Cognitive-Behavioral Therapy—CBT for GAD consisted of 15 individual sessions of 1.5 hours. Sessions were delivered weekly, except for a separation of two weeks before the final session. The intervention followed a manualized CBT intervention for GAD developed by Borkovec et al. (2003). The manual was translated to Spanish and culturally adapted to include language, idioms, and examples relevant to Latino culture (Bernal, Jiménez-Chafey, & Domenech Rodríguez, 2009). Special emphasis was placed on the attainment of conceptual and cultural equivalence, while maintaining fidelity to the active core elements in the English CBT manual. The intervention is based on four main components: self-monitoring, applied relaxation training, cognitive therapy, and the rehearsal of learned coping responses (Borkovec & Sharpless, 2004; Borkovec et al., 2003). Central to CBT treatment is teaching participants to identify early anxiety cues that trigger their responses and interpretations of threat. Self-monitoring activities focus on helping them take notice of their interior and exterior experiences, with the goal of increasing recognition of their perceptions of threat and worrisome thoughts about the imagined future. Participants were encouraged to use applied relaxation techniques learned during treatment to cope with anxiety and worry. Targeted muscle relaxation exercises aimed to increase participants' ability to rapidly produce relaxation to interrupt emerging

anxiety and worry spirals. Meanwhile, cognitive therapy strategies allowed generating more accurate interpretations and perspectives of threat and worrisome reactions. The accuracy of cognitions was examined through the evaluation of their logic, probability, and past evidence, using strategies such as, decatastrophizing, worry outcome diary, and the Socratic method. The practice and implementation of newly learned relaxation and cognitive coping responses was emphasized throughout treatment to facilitate replacing habitual perspectives of worrisome activity with more adaptive ones.

Acceptance-based Behavioral Therapy—ABBT for GAD was delivered in 16 weekly sessions, the first four lasting 90 minutes and the rest 60 minutes. The ABBT implemented in this trial was based on a culturally adapted, Spanish version of the manualized intervention for GAD developed by Roemer and Orsillo (2009). While maintaining fidelity to the core elements of the English ABBT manual, the Spanish version includes language, idioms, and examples relevant to Latino culture (Bernal et al., 2009). ABBT includes behavioral elements derived from traditional CBT, while cognitive strategies that focus on correcting dysfunctional thoughts and emotions were replaced with strategies that promote psychological processes based on acceptance and mindfulness. ABBT clinical strategies, including psychoeducation, self-monitoring, and mindfulness practices, intend to demonstrate that the avoidance or suppression of unwanted internal states is not always helpful and could even contribute to worsen anxiety (Roemer & Orsillo, 2009; Roemer et al., 2013). Instead of focusing on controlling internal experiences ABBT familiarized participants with an acceptance-based behavioral model of anxiety, and facilitated the application of skills that fostered expanded awareness of the present moment and willingness to experience unwanted internal experiences. The focus was on increasing engagement in personally meaningful actions by facilitating behaviors that were consistent with participants' personal values rather than motivated by worry, anxiety, and avoidance of thoughts, sensations, and feelings viewed as threatening and dangerous.

Treatment as usual

Patients randomly assigned to receive TAU were informed of their condition and the mental health resources available in keeping with their insurance coverage. Physicians were informed via a standardized form included in the medical record that the patient had been assigned to TAU. Patients were encouraged to discuss GAD treatment options with their provider. The standard of care in the participating primary care clinics was that patients were referred to the mental health system of care for specialized mental health treatment. The specialized sector of care provided pharmacological or psychological treatment. The amount of time spent in treatment and the strategies used could vary among providers. This was a pragmatic intervention that aimed to explore the outcome of a typical referral.

Therapists

Two female licensed psychologists, with three and five years of clinical experience, were the main therapists in this trial. To reduce the confounding of therapist effects they delivered CBT and ABBT. They received ABBT training from Drs. Roemer and Orsillo and CBT training from Dr. Borkovec. All sessions were recorded, and a random sample was reviewed. For fifty percent of ABBT and CBT participants, one session was randomly chosen from

sessions 1–5, one from 6–11, and one from 12–16, when available. A total of 71 (ABBT = 36; CBT = 35) sessions were rated for adherence to the respective protocols by doctoral students in clinical psychology. For each session an adherence checklist listed the required components which were considered as proxy measures for therapy essential elements. Around 95% of the required components were covered for both ABBT (94.47%) and CBT (95.20%).

Outcome measures

Penn State Worry Questionnaire (PSWQ)—The PSWQ (Meyer et al., 1990) is a 16-item self-report assessment designed to measure worry. The items measure the occurrence, intrusiveness, intensity, and other characteristics of an individual's experience with worry. Each item is rated on a 5-point Likert scale ranging from 1 (not at all typical of me) to 5 (very typical of me). Possible scores range from 16–80, with a recommended cut-off score of 45 or higher to identify high worrying individuals (Behar, Alcaine, Zuellig, & Borkovec, 2003). The PSWQ has shown excellent reliability and validity (Brown, Antony, & Barlow, 1992; Fresco, Heimberg, Mennin, & Turk, 2002). The Spanish version of the PSWQ has demonstrated appropriate test-retest reliability, high internal consistency, and good convergent and discriminant validity (Nuevo-Benítez, Montorio-Cerrato, & Ruiz-Díaz, 2002; Rodríguez-Biglieri, 2011). In the current study, the PSWQ demonstrated good internal consistency at pre-treatment ($\alpha = .80$). It was administered at baseline and week-28 assessments.

Patient Health Questionnaire (PHQ-9)—The PHQ-9 (Spitzer, Kroenke, & Williams, 1999) is a 9-item, self-report scale that assesses the presence of the nine DSM-IV diagnostic criteria for major depression. Each item asks patients to indicate the frequency with which they experienced the depressive symptom, scored on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). Possible scores range from 0 to 27, with higher scores indicating increased levels of depression symptoms. The PHQ-9 has demonstrated good psychometric properties and has been shown to have excellent discriminatory power to identify patients with depression (Williams et al., 2005). Psychometric studies sustain the validity of the Spanish version of the PHQ-9 (Diez-Quevedo, Rangil, Sanchez-Planell, Kroenke, & Spitzer, 2001; Baader et al., 2012). Internal consistency in the current study was excellent at pre-treatment ($\alpha = .90$). Participants completed the PHQ-9 at baseline and week-28.

Depression and Anxiety Stress Scale (DASS-21)—The DASS-21 (Lovibond & Lovibond, 1995) is a 21-item, self-report questionnaire that measures distress in three different subscales: depression, anxiety, and stress. Each subscale consists of 7 items rated on a 4-point Likert scale ranging from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). Scores on the DASS-21 are multiplied by two to calculate the final score. Higher scores indicate greater levels of symptoms. The depression subscale assesses hopelessness, low self-esteem, and lack of involvement. The anxiety subscale assesses autonomic arousal, skeletal muscle symptoms, situational anxiety, and subjective experience of anxious arousal. The stress subscale assesses tension, agitation, over reaction, and impatience. The DASS-21 demonstrates high internal consistency and

concurrent validity indicating that it distinguishes well between features of depression, anxiety, and stress (Antony, Cox, Enns, Bieling, & Swinson, 1998). The psychometric properties and factor structure of the Spanish version of the DASS-21 were comparable to those of the English version (Daza, Novy, Stanley, & Averill, 2002). In the current study, the subscales demonstrated good internal consistency at baseline with Cronbach's alpha coefficients of 0.84 for the depression subscale, 0.83 for the anxiety subscale, and 0.86 for the stress subscale. The DASS-21 was administered at baseline, week-20, and week-28.

Statistical analysis

Descriptive statistics, including frequencies, means, and standard deviations, were estimated to examine sample demographic and clinical characteristics. Distributions for the intervention and control groups were examined for baseline equivalency by using t tests for continuous data and chi square tests for categorical data. To test the effect of two treatments for GAD (CBT and ABBT) versus treatment-as-usual we compared changes from baseline to posttreatment on an intention-to-treat basis. Treatment effects for each dependent measure were estimated primarily through the group-by-time interactions, followed by pairwise comparisons for the three groups. Different covariance structures were examined to determine the best one for our data. A compound symmetry covariance matrix was specified to account for the within-patient correlation among repeated assessments. The model adjusted by outcome baseline values when appropriate. Calculations were conducted using PROC MIXED and GLIMMIX procedures in SAS software, version 9.4 (SAS Institute Inc., 2013). In accordance with Jacobson and Traux (1991), clinically significant change was examined by calculating a reliable change index for the PSWQ. For each treatment group, the standard deviation of the baseline measurement and a reliability coefficient of 0.93, as informed by Meyer et al. (1990), was used to identify the proportion of participants in each group who met the criteria for reliable change on the PSWQ.

Results

Primary outcomes: worry, anxiety, and stress symptoms

PSWQ—Mean scores on the PSWQ scale for both ABBT and CBT groups show that the level of worry improved from the high range at baseline to the moderate range at follow-up, whereas mean scores for usual care participants remained at a high level (Table 2). Mixed-effects regression models evidence statistically significant main effects for the interaction between time and treatment ($F = 3.09, p < .051$). As shown in Table 3, pairwise comparisons indicate that in comparison to TAU both ABBT ($t = -2.69, p = .008$) and CBT participants ($t = -3.27, p = .001$) demonstrated significantly greater reductions in worry. When comparing outcomes between participants in the ABBT group versus those in the CBT group, no significant differences were observed at follow-up ($t = 0.59, p = .557$). Based on criteria for clinically significant change, 57% of the ABBT group, 60% of the CBT group, and 43% of the TAU group were classified as having achieved a reliable decrease in PSWQ scores. In addition, a significant increase in PSWQ scores at follow-up was identified for 20% of the TAU group.

DASS-21 anxiety subscale—As Table 2 shows, baseline mean DASS-21 anxiety subscale scores were significantly different among the three treatment groups (ABBT: 22.60, 95% CI: 19.05 to 26.15; CBT: 26.67, 95% CI: 22.22 to 31.11; TAU: 18.33, 95% CI: 14.51 to 22.16). Mean scores for both ABBT and CBT participants improved from extremely severe anxiety at baseline to moderate anxiety at follow-up (ABBT: 11.81, 95% CI: 6.98 to 16.64; CBT: 14.15, 95% CI: 9.16 to 19.14). Meanwhile, the mean scores for TAU participants shifted from the severe anxiety range at baseline to moderate anxiety at follow-up (TAU: 13.59, 95% CI: 9.75 to 17.42). Intent to treat analysis yielded a significant result for the time-by-group interaction ($F = 3.29, p < .01$) (Table 2). Pairwise comparisons show that at follow-up the CBT group was associated with significantly greater improvement in anxiety symptoms than the TAU group ($t = -2.55, p = .011$) (Table 3). In comparison to the TAU group, the ABBT group showed a marginally significant improvement ($t = -1.86, p = .065$). No significant differences in anxiety symptoms were found when comparing ABBT and CBT participants at follow-up ($t = 0.60, p = .551$).

DASS-21 stress subscale—Findings for the DASS-21 stress subscale showed significant differences in baseline mean scores among the three treatment groups (ABBT: 30, 95% CI: 26.49 to 33.51; CBT: 29.73, 95% CI: 26.01 to 33.46; TAU: 22.87, 95% CI: 19.37 to 26.37). Levels of stress improved for both ABBT and CBT participants from severe level at baseline to mild at follow-up (ABBT: 14.95, 95% CI: 9.79 to 20.12; CBT: 18, 95% CI: 12.47 to 23.53) (Table 2). Whereas mean scores improved for usual care participants from moderate at baseline to mild at follow-up (17.72, 95% CI: 13.31 to 22.14). Findings showed a significant interaction effect between time and treatment ($F = 4.30, p < .01$). At follow-up, in comparison to the TAU group participants in the ABBT group demonstrated a significantly greater improvement ($t = -2.61, p = .010$). Outcomes did not differ significantly when comparing CBT versus TAU participants ($t = -1.36, p = .175$) and ABBT versus CBT participants ($t = -1.32, p = .189$) (Table 3).

Secondary outcomes: depression symptoms

PHQ-9—Mean PHQ-9 scores differed significantly at baseline among the three treatment groups (ABBT: 14.50, 95% CI: 12.43 to 16.57; CBT: 16.07, 95% CI: 14.33 to 17.81; TAU: 12.10, 95% CI: 10.16 to 14.04) (Table 2). Baseline depression severity mean scores were at the moderately severe level for the ABBT and CBT groups and at the moderate level for the TAU group. Depression severity level shifted to mild for the ABBT group (6.89, 95% CI: 4.01 to 9.78) and moderate for the CBT group (9.88, 95% CI: 7.14 to 12.62), while severity level remained moderate for the TAU group. The interaction effect for time and treatment was significant ($F = 5.34, p < .007$). Table 3 shows that in comparison to TAU both ABBT ($t = -2.96, p = .004$) and CBT ($t = -3.74, p = .001$) were associated with significantly greater reductions in depression severity at follow-up. Outcomes for the ABBT group versus the CBT group were not significantly different at follow-up ($t = 0.84, p = .404$).

DASS-21 depression subscale—Baseline mean DASS-21 depression subscale scores showed significant differences among the three groups (ABBT: 21.80, 95% CI: 18.59 to 25.01; CBT: 24.00, 95% CI: 19.69 to 28.31; TAU: 17.20, 95% CI: 14.08 to 20.32). Mean scores improved from severe depression for both ABBT and CBT participants at baseline,

to a normal range for those in ABBT and mild depression for those in CBT at follow-up (ABBT: 9.24, 95% CI: 4.70 to 13.78; CBT: 13.15, 95% CI: 8.55 to 17.76). Scores for TAU participants improved from the moderate level at baseline to mild depression at follow-up (TAU: 12.76, 95% CI: 9.10 to 16.42). Mixed-effects regression estimates yielded a significant result for the time-by-group interaction ($F = 3.63, p < .008$) (Table 2). At follow-up, ABBT participants showed a significantly greater reduction in depression symptoms in comparison to those in TAU ($t = -2.38, p = .019$), whereas CBT participants demonstrated a marginally significant reduction ($t = -1.96, p = .052$) in comparison to those in TAU (Table 3). When comparing outcomes between those in ABBT versus those in the CBT ($t = -0.48, p = .636$), no significant differences emerged.

Discussion

Although GAD has been found to be prevalent among several Latino subgroups, particularly Puerto Ricans, appropriate evidence-based treatments for this population are missing (Alegría et al., 2007; Alegría, Alvarez, Ishikawa, DiMarzio, & McPeck, 2016). The randomized pilot study reported here was designed to examine the potential efficacy of two interventions for GAD, traditional CBT and ABBT, in a sample of Spanish-speaking Latino primary care patients. Excessive worry, the core feature of GAD, was assessed with the PSWQ, which is considered the gold standard measure of GAD-related worry. At follow-up, PSWQ scores for participants in the CBT and ABBT groups were statistically lower than those of the TAU group and statistically comparable to each other. Our results demonstrate that CBT and ABBT resulted in clinically significant improvements. This improvement was evidenced in a sample within a high range baseline worry level. This study also evaluated changes in other primary and secondary outcomes. Overall, symptoms of general anxiety and depression improved over time for most of the outcome measures for clients receiving either CBT or ABBT. No significant benefit of one treatment over the other was evidenced for either general anxiety or depression symptoms. Overall, our findings suggest that both traditional CBT and ABBT are promising interventions for the treatment of Spanish-speaking Latinos with GAD. These results are in line with previous studies that support the efficacy of traditional and newer CBT approaches for GAD in predominantly non-Hispanic White populations (Borkovec et al., 2004; Butler et al., 2006; Hunot, Churchill, Teixeira, & Silva de Lima, 2007; Orsillo & Roemer, 2011; Otte, 2011; Roemer & Orsillo, 2009).

Several limitations in the interpretation of our data need to be considered. This study is subject to the potential biases associated with a pilot study. First, the small sample size and low retention rates limited generalizability and statistical power. Although subjects were recruited from multiple sites, these were mainly in low-income urban areas, limiting information for participants from other socioeconomic groups. Dropout rates before initiating treatment and during treatment were high. These findings are consistent with multiple studies that document poor initiation and retention in mental health treatment for low-income and ethnic minority populations (Arnold et al., 2007; Bados, Balaguer, & Saldaña, 2007; Blanco et al., 2007; Kozhimannil, Trinacty, Busch, Huskamp, & Adams, 2011; Santiago, Kaltman, & Miranda, 2013). Future studies with larger sample sizes are needed to further evaluate any treatment effects, as well as systemic, cultural, and individual

barriers that may impact access and retention in mental health care. A second limitation was that study recruiters did not systematically select patients for screening in primary care reception rooms; this may subject the data to some selection bias. A third limitation was the use of a brief follow-up period. Studies using a longer follow-up period of six-months or twelve-months are needed to evaluate whether study findings can be maintained over time. Despite these limitations, findings from this trial can be viewed as early data that support the potential efficacy of traditional CBT and ABBT for Spanish-speaking Latinos with GAD.

To our knowledge, this is the first randomized trial to investigate the use of both traditional and newer CBT approaches for the treatment of GAD in Spanish-speaking primary care patients. Our findings are particularly important because they provide evidence in favor of the potential benefits of traditional CBT and ABBT for low-income, Spanish speaking Latinos in primary care settings. Substantial evidence sustains that Latinos' mental health care needs are largely unfulfilled. In comparison with non-Hispanic Whites, studies have demonstrated that Latinos rely more on primary care providers for mental health care and are less likely to receive guideline congruent treatment for mental health problems (Alegría et al., 2002a,b, 2016; Chapa, 2004; Hogan, 2003; Lagomasino et al., 2005; Cabassa, Zayas, & Hansen, 2006; Institute of Medicine, 2003; US Department of Health and Human Services, 2001b).

A major goal of the Healthy People national initiative is to improve mental health by ensuring access to appropriate, quality mental health services (Office of Disease Prevention and Health Promotion, 2020). Monitoring activities led by the Agency for Healthcare Research and Quality (Mompe et al., 2015) to examine progress in health care for Latinos revealed that mental health care was worsening. For many measures of mental health care Latinos received worse quality of care than non-Hispanic Whites, showing no narrowing of disparities overtime. Alegría et al. (2016) sustain that a major factor that has contributed to the persistence of mental health care disparities is the mistaken assumption that evidence-based treatments are easily available for diverse populations. They highlight that the scant availability of linguistic and culturally competent services is a key barrier to mental health care access for minority populations. According to a 2015 report by the Migration Policy Institute about 25.1 million persons in the United States were identified as limited English proficient (LEP), defined as speaking English less than very well (Zong & Batalova, 2015). Spanish speakers comprised approximately 64% (16.2 million) of the US total LEP population. Both LEP Latinos and English proficient Latinos are more likely to be under-educated and poor in comparison to non-Hispanic Whites (Brach & Chevarley, 2008). Studies which have examined mental health treatment engagement, report lower initiation and retention rates for the poor, racial/ethnic minorities, and those who are LEP (Aguilera, Garza, & Muñoz, 2010; Alegría et al., 2008a,b; Arnow et al., 2007; Blanco et al., 2007; Caplan & Whittemore, 2013; Chavira et al., 2014; Miranda and Cooper, 2004; Santiago et al., 2013; Vega et al., 2007). To address disparities in mental health treatment engagement for this population, researchers underscore the need to take into consideration the role of personal, family, and society stigma as it affects the willingness to seek care, language barriers, self-reliant attitudes, economic considerations (i.e. work demands, transportation, child care, insurance), and the limited availability of suitable empirically supported treatments (Alegría et al., 2002a,b; Alegría et al., 2008a,b; Benuto, Gonzalez,

Reinosa-Segovia, & Duckworth, 2019; Caplan & Whittemore, 2013; Cardemil et al., 2010; Nadeem et al., 2007; Pincay & Guarnaccia, 2007; Vega, Rodriguez, & Ang, 2010).

With the large population of Spanish-speaking US citizens in Puerto Rico and LEP Spanish speakers in the US, effective treatments for Spanish-speaking Latinos with GAD are needed if high quality mental health care is to be achieved. As a first step to address this challenge, this randomized trial pilot tested two CBT based interventions for GAD, traditional CBT and ABBT. Our findings provide preliminary, yet crucial data, which support the potential of the ABBT and CBT Spanish translated and culturally adapted manualized interventions for targeting GAD symptoms among low-income, Spanish-speaking Latinos. Both interventions for GAD yielded positive outcomes. However, similar to other studies among poor and ethnic minority populations, treatment initiation and retention rates among our participants were low (Aguilera et al., 2010; Blanco et al., 2007; Caplan & Whittemore, 2013; Santiago et al., 2013). These findings highlight the need to address the multiple individual, logistic, and systemic barriers to mental health care engagement faced by low-income Latinos. Thus, it is important that future research further explore treatment effects, as well as engagement strategies relevant for improving the quality and effectiveness of GAD treatment for low-income, Spanish-speaking Latinos.

Conclusion

This pilot RCT is the first to explore the potential benefits of two CBT based interventions for the treatment of Spanish-speaking Latino primary care patients with GAD. Study findings provide a preliminary evidence base that supports the promise of traditional CBT and newer ABBT to improve GAD outcomes. Future research should expand upon these findings to increase understanding of the best approaches to provide treatment to low-income Spanish-speaking Latinos with GAD.

Acknowledgements

We would like to thank Drs. Tom Borkovec, Lizabeth Roemer, and Susan Orsillo who provided training to therapists. Thanks also to all primary care patients that participated in our study.

Funding

This research was supported by the National Institute of Mental Health (NIMH; MH90599).

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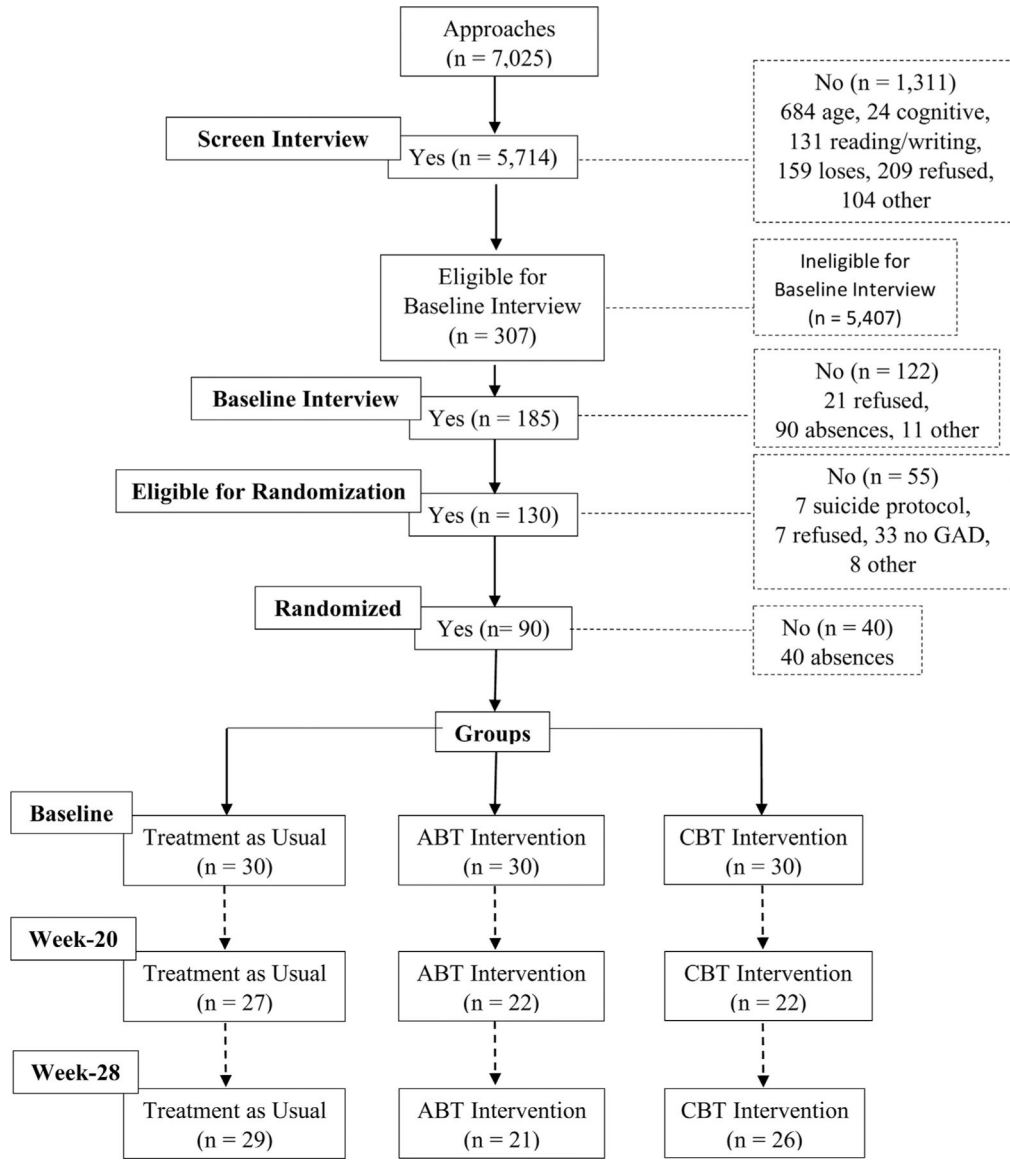


Fig. 1.
CONSORT flow diagram.

Table 1

Baseline demographic characteristics across groups.

Characteristic	Total (n = 90)		ABBT (n = 30)		CBT (n = 30)		TAU (n = 30)		F/X ²	p
	n	%	n	%	n	%	n	%		
Female	78	86.7	26	86.7	25	83.3	27	90.0	0.14	0.71
Age, m (SD)	40.77 (11.2)	39.7 (10.8)	42.4 (10.9)	40.2 (12.1)	0.46	0.63				
Married or cohabitating	41	45.6	16	53.3	14	46.7	11	36.7	1.70	0.43
High school or more	64	71.1	24	80.0	23	76.7	17	56.7	4.65	0.10
Employed	37	41.1	12	40.0	15	50.0	10	33.3	1.74	0.42

SD: standard deviation.

Table 2

Intent-to-treat analyses of primary and secondary measures

Outcome	ABBT			CBT			TAU			Group × Time			
	n	Mean	95% CI	n	Mean	95% CI	n	Mean	95% CI				
PSWQ													
Baseline	30	66.73	64.24 to 69.23	29	67.76	65.01 to 70.51	30	66.67	64.46 to 68.88	0.05	< .001	3.09	0.051
Follow-up	21	45.95	38.21 to 53.69	26	48.27	41.67 to 54.87	29	59.93	54.06 to 65.80				
DAS-ANX													
Baseline	30	22.60	19.05 to 26.15	30	26.67	22.22 to 31.11	30	18.33	14.51 to 22.16	0.14	< .001	3.29	0.013
Week 20	22	11.64	7.64 to 15.64	22	13.27	8.08 to 18.47	27	12.67	8.67 to 16.66				
Follow-up	21	11.81	6.98 to 16.64	26	14.15	9.16 to 19.14	29	13.59	9.75 to 17.42				
DASSTR													
Baseline	30	30.00	26.49 to 33.51	30	29.73	26.01 to 33.46	30	22.87	19.37 to 26.37	0.07	< .001	4.30	0.003
Week 20	22	15.73	11.02 to 20.43	21	14.29	8.51 to 20.06	27	19.19	15.13 to 23.24				
Follow-up	21	14.95	9.79 to 20.12	26	18.00	12.47 to 23.53	29	17.72	13.31 to 22.14				
PHQ-9													
Baseline	30	14.50	12.43 to 16.57	30	16.07	14.33 to 17.81	30	12.10	10.16 to 14.04	0.08	< .001	5.34	0.007
Follow-up	19	6.89	4.01 to 9.78	25	9.88	7.14 to 12.62	26	11.08	8.72 to 13.43				
DASDEP													
Baseline	30	21.80	18.59 to 25.01	29	24.00	19.69 to 28.31	30	17.20	14.08 to 20.32	0.09	< .001	3.63	0.008
Week 20	22	9.82	5.79 to 13.85	22	10.64	6.25 to 15.03	27	12.81	8.82 to 16.81				
Follow-up	21	9.24	4.70 to 13.78	26	13.15	8.55 to 17.76	29	12.76	9.10 to 16.42				

PSWQ: Penn State Worry Questionnaire; DAS-ANX: DASS-21 Anxiety Subscale; DASSTR: DASS-21 Stress Subscale; PHQ-9: Patient Health Questionnaire; DASDEP: DASS-21 Depression Subscale.

Table 3

Pairwise comparisons for pre- and follow-up outcome measures scores.

Measure	Treatment	<i>t</i> value; <i>p</i>
PSWQ	TAU vs. ABBT	-2.69; 0.008
	TAU vs. CBT	-3.27; 0.001
	ABBT vs. CBT	0.59; 0.557
DASANX	TAU vs. ABBT	-1.86; 0.065
	TAU vs. CBT	-2.55; 0.011
	ABBT vs. CBT	0.60; 0.551
DASSTR	TAU vs. ABBT	-2.61; 0.010
	TAU vs. CBT	-1.36; 0.175
	ABBT vs. CBT	-1.32; 0.189
PHQ-9	TAU vs. ABBT	-2.96; 0.004
	TAU vs. CBT	-3.74; 0.001
	ABBT vs. CBT	0.84; 0.404
DASDEP	TAU vs. ABBT	-2.38; 0.019
	TAU vs. CBT	-1.96; 0.052
	ABBT vs. CBT	-0.48; 0.636

PSWQ: Penn State Worry Questionnaire; DASANX: DASS-21 Anxiety Subscale; DASSTR: DASS-21 Stress Subscale; PHQ-9: Patient Health Questionnaire; DASDEP: DASS-21 Depression Subscale.