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Combined Medication and CBT for Generalized Anxiety Disorder with African American Participants: Reliability and Validity of Assessments and Preliminary Outcomes

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Abstract

Using data from a study of combined cognitive behavioral therapy (CBT) and venlafaxine XR in the treatment of generalized anxiety disorder (GAD), the current article examines the reliability and convergent validity of scales, and preliminary outcomes, for African American compared to European American patients. Internal consistency and short-term stability coefficients for African Americans (*n*=42) were adequate and similar or higher compared to those found for European Americans (*n*=164) for standard scales used in GAD treatment research. Correlations among outcome measures among African Americans were in general not significantly different for African Americans compared to European Americans. A subset of patients with DSM-IV–diagnosed GAD (*n* = 24 African Americans; *n* = 52 European Americans) were randomly selected to be offered the option of adding 12 sessions of CBT to venlafaxine XR treatment. Of those offered CBT, 33.3% (*n* = 8) of the African Americans, and 32.6% (*n* = 17) of the European Americans accepted and attended at least one CBT treatment session. The outcomes for African Americans receiving combined treatment were not significantly different from European Americans receiving combined treatment on primary or secondary efficacy measures.

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Keywords

Generalized Anxiety Disorder; Cognitive-Behavioral Therapy; venlafaxine; combined treatment; African American

Despite the large number of studies conducted on cognitive behavioral therapy (CBT) and its application to the treatment of a considerable number of disorders, data on the use of CBT with African Americans is sparse. Several reviews exist that examine the issue of limited literature on the effectiveness of CBT with African Americans, and they largely converge on the conclusion that CBT is beneficial in the treatment of depression (Miranda, Azocar, Organista, Dwyer, & Areane, 2003; Miranda et al., 2006; Voss Horrell, 2008), anxiety disorders (Voss Horrell, 2008; Carter, Mitchell, & Sbrocco, 2012; Miranda et al., 2005; Benish, Quintana, & Wampold, 2011; van Loon, van Schaik, Dekker, & Beekman, 2013), and perhaps substance use disorders (Voss Horrell, 2008) with African Americans.

However, there are relatively few studies on CBT for African Americans with anxiety disorders. Carter et al.'s (2012) recent review of this topic found 14 studies that examined the outcomes of African Americans in the treatment of anxiety disorders, with most of the studies examining a CBT treatment. In the treatment of panic disorder, there was some indication of relatively worse outcomes from African Americans compared to European Americans. However, in the treatment of both post-traumatic stress disorder and obsessive compulsive disorder, studies suggested that CBT was equally beneficial for African Americans and European Americans. No studies have specifically examined the outcomes of CBT for African Americans with generalized anxiety disorder (GAD) in adults.

The lack of studies examining treatment outcomes for African Americans with GAD is surprising given the prevalence and functional impact of this disorder. The lifetime prevalence for DSM-IV diagnosed GAD is 5.7% and the projected lifetime prevalence at age 75 is 8.3% (Kessler et al., 2005). This renders the need to treat GAD of special importance as it is one of the most costly (Newman, 2000; Hoffman, Dukes, & Wittchen, 2008) and disabling psychiatric disorders (Grant et al., 2005). There is some evidence that the prevalence of GAD is lower in African Americans, with several studies reporting a lifetime prevalence in the range of 3.0 to 5.1 (Wilson & Cottone, 2013; Asnaani, Richey, Dimaite, Hinton, & Hofmann, 2010; Breslau et al., 2006; Himle, Baser, Taylor, Campbell, & Jackson, 2009). This lower prevalence is somewhat surprising given that a disproportionate percentage of African Americans live below the poverty line (in comparison to European Americans) (U.S. Census Bureau, 2008), and thus experience more social and economic stressors that might contribute to the development or severity of GAD. In addition, African Americans experience other factors that may be associated with the onset of GAD, such as race-based discrimination (Soto, Dawnson-Andoh, & BeLue, 2011; Rucker, West, & Roemer, 2010). Regardless of the causes of GAD, some researchers assert that the discrepant results of prevalence may have more to do with measurement error, stemming from a decreased likelihood of reporting an anxiety disorder among African Americans due to factors such as stigma and mistrust of the medical establishment (Hunter & Schmidt, 2010).

Measurement issues have also arisen with respect to the factor structure of certain assessments commonly used in GAD research, such as the Penn State Worry Questionnaire (PSWQ). Some studies have found that, despite having high internal consistency with African American participants, the PSWQ has a different factor structure for African Americans compared to European Americans (Carter et al., 2005) and Hambrick et al. (2010) determined that 7 of the 11 items functioned differently in African Americans. However these studies were conducted with non-clinical undergraduate samples and Hambrick et al. (2010) explain that these differences were observed at the low end of the latent construct and thus necessitate further examination in a clinical sample, an impetus for examining reliability and validity in the current study.

In general, CBT is a well-established treatment for GAD (DeRubeis & Crits-Christoph, 1998). A review of 13 treatment outcome studies determined that CBT outcomes were better compared to waitlist and alternative GAD treatments (Borkovec & Ruscio, 2001). However, the percent of African Americans present in these CBT for GAD studies has generally been quite low (e.g. 2 out of 55 participants in Borkovec & Costello, 1993; 3 out of 12 participants in Stanley et al., 2003; 1 out of 83 participants in Newman et al., 2011; 2 out of 69 participants in Borkovec, Newman, Pincus, & Lytle, 2002), and this has likely hampered any examination of outcome as a function of race or ethnicity. Furthermore, the reliability and validity of many commonly used scales in GAD research has not been examined specifically for clinical samples of African Americans. Studies using non-clinical samples have suggested that the content of worries between African American and European American populations may differ (Scott, Eng, & Heimberg, 2002), raising questions about the adequacy of standard anxiety-related scales for African Americans.

Though there is a dearth of research on GAD treatment outcome in African American adults, there are studies which examine the treatment of anxiety disorders, including GAD, in African American children and adolescents (e.g. Ginsburg & Drake, 2002). Huey Jr. and Polo (2008) reviewed some of these studies and found no apparent difference in outcome for African American youth with anxiety disorders.

The purpose of the current study was to report reliabilities and convergent validity of outcome measures used in GAD studies in an African American sample, and to conduct a preliminary examination of the outcomes of CBT, in combination with medication, for African Americans in comparison to European Americans with GAD. Evaluating CBT in the context of medication has high clinical relevance in the treatment of GAD. More recent studies of anxiety disorders in general report high estimates of medication use, ranging from 63.8% (Wu, Wang, Katz, & Farley, 2013) to 90.9% (Olfson & Marcus, 2010). For GAD in particular, one study found that 61.9% of the 756 patients with GAD had used a psychotropic in the past 6 months (Stein et al., 2011). To accomplish these aims, the current study used data from an existing trial of venlafaxine, and combined venlafaxine and CBT, for GAD (Crits-Christoph et al., 2011; Rickels et al., 2010).

Method

Study Design

Data for examining reliability and validity of scales was drawn from a large-scale medication study (Rickels et al., 2010). The medication study consisted of three treatment phases over 18-months, the first of which was a 6-month open-label venlafaxine flexible-dose treatment phase (75 mg–225mg/day). Both the second and third phases were 6-month randomized, double-blind, placebo-controlled relapse phases. The current report only includes data from the first phase. The majority of the patients (n = 239) who were enrolled in the medication trial were recruited at one of four suburban primary care practices, and were seen by research psychiatrists placed at these sites. A psychopharmacology clinic in a university setting was also involved and an additional group of patients (n = 95) was enrolled there. For more details regarding the parent trial see Rickels et al. (2010).

The combined CBT plus medication for GAD study was an add-on project to an ongoing medication study. The combined treatment study began once the parent medication study was already in effect. The option of adding 12 weeks of CBT in addition to venlafaxine XR was presented to randomly selected patients who were enrolled in the medication study. Generally, these patients were invited to consider this option at the first study visit after beginning medication (week 2). A 2:1 (CBT: medication) randomization scheme was used. Study visits occurred at baseline and were scheduled on a biweekly basis for 8 weeks and monthly after those first 8 weeks, during the 6-month open-label medication phase.

The parent medication trial was conducted from 2005 to 2009 with the approval and oversight of the local Institutional Review Board (IRB). The combined treatment CBT addition was conducted from October, 2006 to March, 2008, and also received IRB oversight and approval. For participation in the medication trial patients provided written informed consent. Separate written informed consent was obtained for patients who participated in the CBT addition study.

Participants

Recruitment of patients occurred via community outreach presentations, media advertising, mailings, and referrals from health care professionals, including the primary care physicians at the study's primary care sites. The eligibility requirements were that patients needed to be adults (over 18 years of age), meet the criteria for GAD according to the Structured Clinical Interview for DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1996), and receive a score higher than 4 on the Clinical Global severity scale (CGI: Guy, 1976) and a score higher than 20 on the Hamilton Anxiety Rating Scale (HAM-A; Hamilton, 1959). The effects of comorbid disorders were eliminated by excluding patients who had a score higher than 18 on the Hamilton Depression Scale (HAM-D; Hamilton, 1960), met criteria for any other current DSM-IV anxiety diagnoses, or had an episode of major depressive disorder in the past six months. Within the 14 days prior to beginning the study patients could not have regular use of any of the following drugs: buspirone, neuroleptics, anticonvulsants, and antidepressants.

The study psychotherapists (2 women; 3 men; all European Americans) were all doctoral-level licensed psychologists who were on average 10 years post-doctoral. They all had experience working as research protocol therapists and with applying CBT to the treatment of anxiety disorders. An experienced CBT trainer/supervisor used a CBT for GAD treatment manual to train therapists. The training procedures involved a workshop and didactic instruction, which were followed by supervision on a minimum of one training case. The supervisor met with the therapists weekly for individual supervision sessions and rated training case tapes using rating scales developed to evaluate the integrity of CBT (Borkovec et al., 2002). These ratings showed no indication of therapists including interpretive reflections or any other therapeutic method that had clear roots in psychodynamic, experiential, or interpersonal therapies.

Procedures

After a screening, a psychiatric interview was scheduled if the patient met the initial inclusion criteria. The psychiatric interview consisted of a full psychiatric and medical evaluation in order to ensure that all study criteria were fulfilled. Amongst the baseline assessments were the SCID, an assessment of illness and demographic variables, and a physical examination. A psychiatrist who administered the venlafaxine XR in a flexible dose of 75–225 mg/day also performed all post-baseline assessments.

All participants who were offered the opportunity to add CBT, and chose to accept this offer, received CBT sessions once a week for 12 weeks, free of charge. The CBT for GAD treatment manual that guided treatment in the current study was the same as that which was implemented in the Borkovec and Costello (1993) and Borkovec et al., (2002) studies. This intervention package included the following techniques: applied relaxation/self-control desensitization (SCD) involving presentation of the multiple coping response CBT model and rationale; training in self-monitoring of somatic, environmental, affective, imaginal, and thought (especially worry) cues that trigger anxiety spirals with an emphasis on increasingly early cue detection; formal slowed diaphragmatic breathing and progressive relaxation; external and especially internal cue hierarchy development; training in differential and cue-controlled relaxation applied relaxation training; development of coping self-statements to use in response to cues; and use of self-statements and applied relaxation during formal SCD imagery for practicing coping responses.

The treatment manual also included the following cognitive therapy (Beck & Emery, 1985) techniques: presentation of the role of cognition in anxiety; training in self-monitoring of automatic thought occurrence and early worry; identification of cognitive beliefs, interpretations, assumptions, and core beliefs underlying the threatening nature of events or cues; logical analysis; examination of evidence; logical error labeling; decatastrophization; generation of alternative thoughts and beliefs; early application of these alternatives to aspects of daily life; the formulation of behavioral experiments to acquire evidence for new beliefs; and utilization of cognitive perspective alterations learned in cognitive therapy during SCD rehearsals.

To assess adherence to the CBT model, the current study employed the CBT for GAD adherence checklist that was used in CBT for GAD trials discussed above (Borkovec &

Costello, 1993; Borkovec et al., 2002). The CBT supervisor completed this checklist after having listened to audiotapes of treatment sessions. The total number of sessions rated was 127, amounting to an average of 4.9 sessions rated for each of the 26 patients that had at least one CBT session. Across patients receiving CBT, an average of 70% of sessions were selected for rating adherence by the CBT supervisor. Among all the sessions that were checked for protocol adherence, 62 (48.8%) were from sessions 1–4, 36 (28.4%) were from sessions 5–8, and 29 (22.8%) were from sessions 9–12. On the whole, no sessions contained any interventions that were not allowed as part of the CBT treatment model. The average session contained 7.7 (SD = 2.6) of the 15 CBT techniques listed in the adherence checklist. Because CBT techniques are introduced in a logical sequence and in ways not to overwhelm the client, the use of 7.7 techniques per session (out of a total list of 15 used over the full course of treatment), with no non-allowed techniques, was viewed by the clinical supervisor as very good adherence.

Assessments

Demographic data were collected with a self-report background questionnaire. The questionnaire asked ethnicity (Hispanic/Latino vs. not) and race (white, Black or African American, American Indian, Asian, Native Hawaiian or Pacific Islander, or Other/ Unknown).

The primary efficacy measure was the HAM-A which was used to measure anxiety symptoms. In addition, the HAM-A was used to assess clinical response, which was defined as a 50% or greater reduction from baseline to last value with the 24-week open-label medication phase (Ballenger, 1999). To assess severity of depressive symptoms the 17-item format of the HAM-D was employed. To evaluate the severity of illness and global improvement the Clinical Global Impressions Severity and Improvement scales (CGI-S, CGI-I; Guy; 1976) were used, respectively. Research psychiatrists who were highly trained and experienced in their use conducted the SCID, HAM-A, HAM-D, CGI-S, CGI-I ratings. Evaluators were not told which patients received the CBT intervention and were instructed not to inquire about it.

The patient-report measures used included the Penn State Worry Questionnaire (PSWQ: Meyer, Miller, Metzger, & Borkovec, 1990), the quality of life subscale of the General Health Questionnaire (GHQ/12-QL; Bech, 1993), the Hospital Anxiety and Depression (HAD) scale (Zigmond & Snaith, 1983), and The Medical Outcomes Study Short Form Health Survey-12 (SF-12; Ware Jr., Kosinski, & Keller, 1996). The GHQ/12-QL scale contains 11 disability and quality of life items that are selected from the GHQ and summed for a total score. The HAD provided information allowing for the assessment of patients' report of anxiety and depression symptoms. The SF-12 is a 12-item self-report questionnaire that assesses symptoms, functioning, and health-related quality of life. It generates a Mental Component Score (MCS) and a Physical Component Score (PCS) and uses a subset of items from the longer Medical Outcomes Study Short Form Health Survey-36 (SF-36) that was designed for use in general practice. The HAM-A, CGI-S, CGI-I, and HAD were administered at each medication study visit; the SF-12 mental and physical components

were assessed at baseline, and the HAM-D and GHQ/12-WL were assessed at intake and 24 weeks.

Clinically significant change was examined using the PSWQ. An estimated (based on linear mixed effects model) endpoint score of less than 50.9 on the PSWQ was used to define clinically significant change (Jacobson, Follette, & Revenstorf, 1984). To compute this endpoint score (50.9), the authors plugged the following into Jacobson et al.'s (1984) formula "c" for clinically significant change: normative data on the PSWQ mean and standard deviation provided by Gillis, Haaga, and Ford (1995), and the baseline PSWQ mean and standard deviation from the current sample. The Jacobson et al. formula provides a cutoff that indicates whether or not a patient's level of functioning has a statistically greater likelihood of being the functional rather than the dysfunctional population.

Statistical Analysis

For examining reliability of scales, data were drawn from the middle of Phase I of the medication study. This was because the range on scales was restricted at both baseline (because of an entry criterion that ensured no patients with low to mild anxiety symptoms) and endpoint (because most patients had relatively low anxiety by endpoint). For calculation of internal consistency (Cronbach's alpha) of scales, week 12 data were used. Multi-item scales administered at week 12, for which no existing data on reliability for African Americans within a clinical GAD sample could be found, included the following: HAM-A, HAM-D, HAD-Anxiety, HAD-Depression, and PWSQ. The SF-12 has previously been found to be reliable and valid in a sample of low-income African Americans (Larson, Schlundt, Patel, Hargreaves, & Beard, 2008) and therefore was not examined here. For calculation of short-term stability, scales (HAM-A, HAD-Anxiety, HAD-Depression, CGI-I, CGI-S) that were assessed at week 6 were correlated (Pearson correlations) with the same scales administered at week 8 (this time interval showed little mean change between assessments). Separate internal consistency and short-term stability coefficients were calculated for African Americans and European Americans.

Convergent validity was examined by calculating correlations among all outcome measures separately for African Americans and European Americans using the week 12 assessment. A standard z-test for the significance of the difference independent correlations was used to evaluate whether each correlation was different for African Americans compared to European Americans. In addition, an overall test (chi-square) of the homogeneity of the covariance matrix among all outcome measures was conducted (Morrison, 1976).

For the examination of preliminary outcomes, the primary sample consisted of African American and European American patients randomized to CBT who attended a minimum of one CBT session. To examine baseline differences between African Americans and European Americans, chi-square was used for categorical variables and *t*-tests were used for continuous variables.

To compare African Americans and European Americans on the efficacy variables, the data were analyzed with mixed effects models that tested for differential slopes over time (baseline through week 24) for these two groups using only available scores—no imputation

for missing data. For the implementation of these models SAS Procedure Proc MIXED (Littell, Milliken, Stroup, & Wolfinger, 1996) was used. For the HAM-A, a shifted log-transformation of time of assessment implemented to account for a pattern of improvement characterized by a relatively rapid improvement early in treatment which subsequently leveled off. For measures assessed only at baseline and week 24, analyses of covariance were used, with the baseline score as the covariate. Chi-square was used to compare response rates across treatment groups. Clarke, O'Campo, and Wheaton (2006) determined that sample sizes of 5 or more avoid biased estimations of fixed effects and their accompanying standard errors within multilevel models. Therefore, a sample of 8 African Americans was considered sufficient to examine group differences. However, these statistical analyses were conducted on an exploratory basis given the limited statistical power due to the relatively small sample sizes.

Results

Patient Disposition and Baseline Characteristics

There were 334 patients enrolled in the parent medication trial. From these, 41 African American patients, and 161 European Americans, were available who had week 12 scores for examining internal consistency reliability and concurrent validity. There were 42 African Americans and 164 European Americans who had scores available at week 6 and week 8 for examining short-term stability of scales.

Of the 334 patients enrolled in the medication trial, during the time period in which the CBT study was recruiting, 77 patients were randomly assigned to be offered CBT (i.e. to have the option to receive or not receive CBT). Among the 77 offered CBT, there were 45 patients who expressed interest in hearing more information about the study, 29 (37% of those offered) of whom decided to participate and signed a consent form. Of these 29 individuals, 26 attended at least one CBT session (33% of the patients who were initially offered CBT), and 12 of these 26 (46%) attended 10 or more CBT sessions. Participants' race was determined via self-report. All three of the individuals who did not attend at least one CBT session were European American. Of the 26 that attended at least one CBT session, 17 were European American, 8 were African American, and one was Asian, such that 32.6% (17/52) of the European Americans and 33.3% of the African Americans (8/24) offered CBT accepted and attended at least one treatment session. One participant self-identified as African American and Hispanic, and was included in the analyses as an African American. The Asian patient was excluded from the current analyses, leaving a final sample of 25 patients for examining preliminary outcomes.

The 41 African Americans with data available at week 12 had an average (*SD*) age of 53.2 (15.9) years; 39.0% were employed (full time), 78.1% were women, and 29.3% were married/living with partner. The 161 European Americans had an average age of 48.0 (15.7) years; 56.5% were employed (full time), 59.6% were women, and 53.4% were married/living with partner.

In the sample of 25 individuals who received CBT and venlafaxine XR, the 8 African Americans had an average (SD) age of 43.6 (11.4) years; 50% were employed (full time),

100% were women, 60% had earned a college degree or higher, and 25% were married/living with partner. The 18 European Americans had an average age of 47.9 (17.1) years; 47.1% were employed (full time), 52.9% were women, 70.5% had received a college degree or higher, and 23.5% were married/living with partner. Tests for differences between the African Americans and European Americans in these demographic variables revealed the following: gender, Fisher's exact test p =.02; age, .64(23), p = .53; marital status, Fisher's exact test p = 1.0; employment, Fisher's exact test p = 1.0; education, χ^2 [3] = 3.81, p = .28.

The African American group and the European American group did not differ significantly on any of the baseline efficacy measures in either the reliability/validity sample or outcome sample. Between-group effect sizes (Cohen's *d*, using a pooled *SD*) were: HAM-A total score = −.42; HAD anxiety = −.35; HAD depression = −.46; HAM-D total score = .08; PSWQ = −.10 GHQ/12Q = −.20; SF-12 physical = .45; SF-12 mental = .43. Although not statistically significant, the effect sizes revealed that African Americans had more anxiety symptoms on average, but less depressive symptoms, and showed greater impairment on the SF-12 mental component, compared to European Americans.

Reliability of Scales within African Americans and European Americans

Internal consistency reliabilities (Cronbach's alpha) within the African American sample were all adequate to high (.80 to .93) for the HAM-A, HAM-D, HAD-Anxiety, HAD, Depression, and PSWQ (Table 1). All of the alpha coefficients for the African American sample were higher than the comparable coefficients for the European American sample, with the exception of the PSWQ (.86 vs. 90). Similarly, Pearson correlations indexing short-term stability (week 6 vs. week 8) were adequate (.77 to .83) within the African American sample and higher than those found in the European American sample (Table 1).

Concurrent Validity of Outcome Measures for African Americans and European Americans

Intercorrelations among all 10 outcome measures at week 12, calculated separately for African Americans and European Americans, are presented in Table 2. Overall, the covariance matrix for the outcome variables for African Americans was not significantly different from that for European Americans (χ^2 [55] = 58.4, p = .35). Of the 45 correlations, 5 were significantly different between African Americans and European Americans. In all cases, the correlations in the African American group were higher than in the European American group.

Preliminary Efficacy of Combined Treatment for African Americans and European Americans

There were also no significant differences between European Americans and African Americans on any of the primary or secondary efficacy measures (F (*df*), p-values: HAM-A: 1.51 (1, 199), .22; HAM-D: .99 (1, 63), .32; HAD-Anxiety: 2.50 (1, 196), .12; HAD-Depression: .92 (1, 196), .34; GHQ-12: .43 (1, 63), .51; SF-12 physical: .00 (1, 62), .98; SF-12 mental: .99 (1, 62), .33; PSWQ: .17 (1, 64), .69; CGI-improvement: 1.32 (1, 196), .25; CGI-Severity: .82 (1, 196), .37. As was evident in the full sample (Crits-Christoph et al., 2011), both European American and African American patients showed considerable improvement over time (Table 3). Between-group effect sizes (Cohen's *d*, calculated from

the *F* value obtained from the mixed effects models) were: HAM-A total score = .17; HAD anxiety = .23; HAD depression = .14; HAM-D total score = .25; CGI-severity = .13; CGI-improvement = .16; PSWQ = .10 GHQ/12Q = .17; SF-12 physical = .01; SF-12 mental = .25 (positive effect sizes indicate African Americans had relatively faster improvement than European Americans). Of European American patients, 58.8% (10/17) met criteria for HAM-A clinical response by week 24 (or endpoint) compared to 75% (6/8) of African American patients (Fisher exact test, $p = .66$). Clinically significant change on the PSWQ was seen in 47.1% (8/17) of European American patients and 75% (6/8) of African American patients (Fisher exact test, $p = .23$).

Because of the confound with gender between the African American and European American groups, we conducted additional analyses to see if outcomes for European Americans differed by gender. Mixed effect analyses revealed no significant differences on any of the outcome measures for men vs. women among the European Americans.

Discussion

Reliability of commonly used scales in GAD treatment studies was found to be adequate to good within an African American sample with GAD. Internal consistency and short-term stability reliabilities were generally as high or higher in the African American sample as in the European American sample. Similarly, correlations among outcome measures for African Americans were generally as large, or larger, than that found for European Americans, suggesting adequate convergent validity. For the scales examined, these data represent, to our knowledge, the initial examination of reliability and convergent validity within a clinical GAD sample.

This study failed to detect any significant differences between African American and European American patients in the efficacy of CBT for Generalized Anxiety Disorder in the context of concurrent treatment with venlafaxine XR. This finding was supported across a wide range of outcome measures and assessments of clinical response and clinically significant change. Although this was a preliminary study with very limited statistical power for detecting differences, it is noteworthy that, descriptively, African Americans had faster rates of change than did European Americans. Thus, our study fails to support the suggestion that the session content of standard CBT for GAD, at least in the context of medication treatment, should be modified when used with African American individuals. Although African Americans who received CBT typically had good outcomes, the current data does not rule out modifications to the service delivery system that might be needed to make CBT more accessible to African Americans.

Existing studies of CBT for post-traumatic stress disorder and obsessive compulsive disorder, like the results for GAD found here, have also failed to find that outcomes differ between African Americans and European Americans (Carter et al., 2012; Miranda et al., 2005). It may be that cultural/ethnic modifications of CBT are especially important for certain disorders (e.g., panic disorder), but not other disorders. Whether outcome differences for some anxiety disorders, but not others, is a function of the disorder or the nature of the CBT techniques used in different disorders, should be explored in future research.

One limitation to interpreting these findings is that inter-rater reliability was not assessed for the rater assessed measures (e.g. SCID, Hamilton). However, the assessors were research psychiatrists with substantial experience conducting these assessments. Another limitation to examining the outcomes of treatments for GAD among African Americans and European Americans is that the measurement of GAD symptoms may be influenced by cultural/racial factors. Studies have indicated that there may be a difference in the presentation of GAD, namely the content of worries, between African American and European American populations (Carter et al., 2005; Scott, Eng, & Heimberg, 2002). Specifically, Scott, Eng, and Heimberg (2002) found that African Americans reported the most frequent worry about financial issues. This could result from the fact that African Americans are exposed to more social and economic stressors than European Americans, and perhaps this means that they experience a different type of anxiety. Additionally, African Americans experience more somatic symptoms and are less vocal regarding their cognitive and emotional symptoms—such as chronic worry—than European Americans (Hunter & Schmidt, 2010). As a result of these differences in how GAD manifests, the psychometric properties of the instruments used to measure GAD can be somewhat skewed, such that they do not always tap into the same constructs in African Americans as they do in European Americans (Carter et al., 2005). The good internal consistency, short-term stability, and convergent validity within our African American clinical sample provide some evidence that the scales are adequately reliable and valid, but cultural issues might affect other aspects of these scales (i.e., factor structure) not examined here. However, the previous psychometric studies were conducted with non-clinical samples and thus necessitate further research before any firm conclusions can be drawn (Hunter & Schmidt, 2010). Moreover, the lack of outcome differences between African American and European Americans in the current sample was also apparent on other types of outcome measures beyond GAD symptoms. Thus, our overall lack of differences cannot be attributed to cultural factors in the reporting of GAD symptoms.

Despite being the largest sample of African Americans in a study of CBT for GAD, the current study was also limited by its sample size. Additionally, the designation of African American race was made by self-report which did not include an option for any other subgroup of Blacks, such as Caribbean Black. Previous research has found differences in health outcomes for mixed-race individuals based on which parent is African American, as well as differences stemming from country of origin, (i.e., differences between Jamaican Blacks and Kenyan Blacks) (Williams & Jackson, 2000). It is unknown whether these complexities of measuring race (mixed race; country of origin) would impact GAD treatment responsiveness; further research will be needed to investigate this.

The current study was also limited by its exclusion of participants with some comorbid diagnoses, because GAD often presents with additional psychiatric diagnoses (Grant et al., 2005). Consequently this exclusion criterion limits the generalizability of these findings to patients with comorbid diagnoses. In addition, none of the African Americans who received CBT were men. Thus, the generalizability of the current results to African American men is unknown. Furthermore, although not significantly different, effect sizes revealed some moderate baseline differences on some efficacy measures between the African American

and European American samples; covariance analyses may not fully adjusted for such differences.

Another limitation in the current study is that it examined combined CBT and medication (venlafaxine XR) as opposed to CBT alone. Although combined treatment is highly relevant to real-world clinical practice, and thus gives the study external generalizability – in fact research suggests that GAD is treated more commonly in primary care settings than in the mental health sector (Wittchen & Hoyer, 2001; Roy-Byrne & Wagner, 2004; Hoffman, Dukes, & Wittchen, 2008) and a majority of patients are treated with medication (Stein et al., 2011; Olfson & Marcus, 2010; Wu et al., 2013) – the use of combined treatment potentially makes it more difficult to detect differences between the efficacy of CBT alone in African Americans compared to European Americans. This is because strong efficacy results for venlafaxine XR alone in the treatment of GAD were evident in the parent medication trial (Rickels et al., 2010). At the same time, the lack of differences between African Americans and European Americans with regard to drop-out from treatment suggests that African Americans perceived the treatment to be as efficacious as did the European Americans.

Similarly, the question of medication has been raised with respect to differing preferences regarding medication and psychotherapy as a function of race. Studies examining this issue with depression and panic disorder have found that African Americans suffering from these disorders prefer psychotherapy to medication (Cooper et al., 2003; Hazlett-Stevens et al., 2002), though no studies have looked at preferences in the context of GAD . This could limit generalizability of our findings such that they only generalize to African Americans who would take medication, as well as only those who would participate in a research study.

In consideration of the above limitations, future research that includes a larger sample size and CBT alone (without medication) will be useful to further understand the generalizability of the current efficacy results.

Conclusions

The data presented here indicate that some standard scales used in GAD treatment research have adequate reliabilities (internal consistency; short-term stability) and convergent validity for use with African Americans. Our findings suggest the possibility that African Americans who seek and receive medication treatment can be effectively treated with concurrent standard CBT for GAD. However, adaptations of CBT may still be needed specifically to make CBT more accessible and acceptable to African American clients who would not enroll in a medication treatment study. Further studies need to be conducted to determine the content of any modifications and the specific populations for whom they are necessary.

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Research Highlights

- We analyze data from a study of medication plus CBT for GAD.
- We compare African Americans to European Americans on efficacy measures.
- Reliability and validity of scales were adequate in the African American sample.
- No significant differences in outcome were found between the two groups.
- In fact, descriptively, African Americans had better outcomes.

Table 1

Internal Consistency and Short-Term Stability of Scales

	Internal Consistency		Short-Term Stability	
Scale	**African Americans**	**European Americans**	**African Americans**	**European Americans**
HAM-A	.93	.83	.83	.71
HAM-D	.80	.74	-	-
HAD-Anxiety	.92	.88	.77	.77
HAD-Depression	.91	.88	.80	.82
PSWQ	.86	.90	-	-
CGI-I	-	-	.76	.62
CGI-S	-	-	.81	.67

Note. Sample sizes are 42 African Americans and 164 European Americans (slight reduction with some measures due to missing data). Internal consistency coefficients are Cronbach's alpha using week 12 scores. Short-term stability coefficients are Pearson correlations between week 6 and week 8 scores. HAM-A = Hamilton Anxiety Rating Scale. HAD-Anxiety = Hospital Anxiety and Depression Scale - Anxiety. HAD-Depression = Hospital Anxiety and Depression Scale - Depression. HAM-D-17 = 17-item Hamilton Rating Scale for Depression total score. CGI-I = Clinical Global Impressions Improvement scale. CGI-S = Clinical Global Impressions Severity scale. PSWQ = Penn State Worry Questionnaire.

Table 2

Correlations Among Outcome Measures at Week 12 for African Americans and European Americans

Measure	HAM-A	HAD-Anx.	HAD-Dep.	HAM-D	CGI-S	CGI-I	GHQ/12QL	PSWQ	SF-12 Physical	SF-12 Mental
HAM-A										
HAD Anx.	.69, .67									
HAD Dep.	.62, .51	**.83, .59**								
HAM-D	.87, .83	.73, .66	.69, .51							
CGI-S	**.95, .88**	.66, .60	.54, .47	.85, .78						
CGI-I	**.93, .78**	.59, .59	.50, .41	.75, .72	**.93, .82**					
GHQ/12QL	.62, .57	.64, .49	.73, .70	.71, .54	.58, .52	.60, .46				
PSWQ	.45, .41	.58, .50	.57, .30	.50, .47	.40, .38	.38, .36	.56, .30			
SF-12 – Physical	−.32, −.11	−.30, −.09	−.48, −.33	−.31, −.18	−.29, −.14	−.36, −.06	−.40, −.29	−.23, −.12		
SF-12 – Mental	−.66, −.64	−.64, −.63	−.69, −.67	−.65, −.63	−.60, −.62	−.70, −.60	−.73, −.72	**−.72, −.41**	.27, .09	

Note. Correlation for African Americans (n=41) is given followed by correlation for European Americans (n=161). HAM-A = Hamilton Anxiety Rating Scale total score. HAD Anx. = Hospital Anxiety and Depression Scale - Anxiety. HAD Dep. = Hospital Anxiety and Depression Scale – Depression. HAM-D = Hamilton Rating Scale for Depression 17-item total score. CGI-S = Clinical Global Impressions Severity scale. CGI-I = Clinical Global Impressions Improvement scale. GHQ/12QL = General Health Questionnaire Quality of Life scale. PSWQ = Penn State Worry Questionnaire. SF-12 Physical = SF-12 Physical Component scale. SF-12 Mental = SF-12 Mental Component scale. Bolded text indicates a p value < .05, using test for difference between two independent correlations.

Table 3

Mean Scores (and Standard Deviations) for Primary and Secondary Efficacy Measures by Minority Status

Measure	Assessment Visit								
	Baseline *M (SD, n)*	**Week 2** *M (SD, n)*	**Week 4** *M (SD, n)*	**Week 6** *M (SD, n)*	**Week 8** *M (SD, n)*	**Week 12** *M (SD, n)*	**Week 16** *M (SD, n)*	**Week 20** *M (SD, n)*	**Week 24** *M (SD, n)*
HAM-A Total									
European Americans	25.7 (2.5,17)	19.9 (4.5,17)	17.4 (4.6,17)	13.7 (5.3,17)	13.4 (6.4,17)	10.5 (5.5,16)	8.1 (5.0, 12)	7.3 (6.2, 12)	7.5 (6.0, 11)
African Americans	26.8 (2.2,8)	23.1 (5.9,8)	17.3 (8.0,8)	14.0 (8.9,8)	12.5 (9.7,8)	12.4 (9.8,8)	9.1 (9.5,7)	4.2 (3.2,6)	4.7 (3.5,6)
HAD Anxiety									
European Americans	13.1 (2.9,17)	10.4 (4.3,17)	10.1 (3.7,17)	8.9 (4.1,17)	8.1 (3.5,16)	6.6 (3.2,16)	6.7 (4.4,12)	6.3 (4.5,12)	6.4 (2.3,10)
African Americans	14.4 (4.5,8)	14.6 (5.0,8)	12.8 (5.9,8)	10.8 (5.6,8)	11.6 (5.9,8)	8.0 (6.0,8)	8.0 (6.6,7)	5.8 (5.1,6)	5.8(5.1,5)
HAD Depression									
European Americans	10.4 (6.0,17)	8.1 (5.7,17)	7.4 (4.7,17)	6.4 (4.8,17)	6.6 (4.9,16)	5.7 (4.2,16)	5.8 (4.0,12)	5.2 (4.5,12)	5.9 (3.7,10)
African Americans	7.8 (4.8,8)	9.0 (4.2,8)	8.0 (5.8,8)	6.5 (5.8,8)	8.0 (6.5,8)	5.5 (5.8,8)	5.6 (6.6,7)	2.7 (3.4,6)	2.2 (3.3,5)
HAM-D-17 Total									
European Americans	13.1 (2.3,17)					7.2 (3.5,16)			6.1 (4.0,11)
African Americans	12.9 (2.0,8)					6.7 (4.5,6)			3.2 (3.6,6)
CGI-Severity									
European Americans	4.7 (0.6,17)	3.9 (0.6,17)	3.6 (0.6,16)	3.1 (0.9,17)	3.1 (1.1,17)	2.4 (0.8,16)	2.1 (1.0,12)	1.8 (1.1,11)	1.9 (1.0,11)
African Americans	4.9 (0.4,8)	4.4 (0.7,8)	3.5 (1.2,8)	2.9 (1.4,8)	2.8 (1.6,8)	2.6 (1.6,8)	2.2 (1.5,6)	1.3 (0.5,6)	1.7 (1.2,6)
CGI-Improvement									
European Americans	2.4 (2.0,17)	3.2 (0.7,17)	2.6 (0.7,16)	2.5 (0.7,17)	2.4 (1.2,17)	1.7 (0.8,16)	1.5 (0.7,12)	1.5 (0.8,11)	1.4 (0.7,11)
African Americans	3.5 (1.4,8)	3.4 (0.7,8)	2.8, (1.2,8)	2.3 (1.3,8)	2.3 (1.3,8)	2.1 (1.2,8)	1.8 (1.2,6)	1.2 (0.4,6)	1.3 (0.5,6)
GHQ/12QL									
European Americans	33.9 (7.8,17)					25.8 (7.0,16)			24.5 (6.9,10)
African Americans	35.3 (5.5,8)					23.8 (8.1,8)			22.5 (6.7,6)
PSWQ									
European Americans	61.1 (10.1,17)					49.1 (10.9,16)			47.4 (9.8,11)
African Americans	62.0 (8.5,8)					48.8 (14.5,8)			44.7 (14.0,6)
SF-12 – Physical Component									
European Americans	47.7 (12.7,16)					49.5 (11.5,16)			47.2 (13.3,11)
African Americans	41.5 (15.2,8)					38.6 (12.9,7)			42.3 (12.0,6)

Measure	Assessment Visit								
	Baseline *M (SD, n)*	**Week 2** *M (SD, n)*	**Week 4** *M (SD, n)*	**Week 6** *M (SD, n)*	**Week 8** *M (SD, n)*	**Week 12** *M (SD, n)*	**Week 16** *M (SD, n)*	**Week 20** *M (SD, n)*	**Week 24** *M (SD, n)*
SF-12 – Mental Component									
European Americans	30.6 (10.4,16)					41.7 (9.3,16)			41.9 (11.5,11)
African Americans	26.5 (6.6,8)					40.8 (14.0,7)			46.8 (12.2,6)

Note. HAM-A = Hamilton Anxiety Rating Scale. HAD Anxiety = Hospital Anxiety Depression Anxiety Scale. HAD Depression = Hospital Anxiety Depression – Depression Scale. HAM-D-17 = 17 item Hamilton Rating Scale for Depression total score. CGI = Clinical Global Impression. PSWQ = Penn State Worry Questionnaire. GHQ/12QL = General Health Questionnaire Quality of Life scale.