



A Randomized Hybrid Efficacy and Effectiveness Trial of Behavioral Activation for Latinos With Depression

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Depression presents a significant public health burden for Latinos, the largest and fastest-growing minority group in the United States. The current study performed a randomized controlled trial of Behavioral Activation (BA) for Latinos (BAL, $n = 21$), with relatively minor modifications, compared to treatment as usual (TAU, $n = 22$) in a community mental health clinic setting with a sample of depressed, Spanish-speaking Latinos. TAU was a strong comparison condition, taking place at the same clinic, under the same guidelines and clinic protocols, with similar levels of ongoing consultation, and using the same pool of therapists as BAL. Results indicated that BAL performed well with respect to treatment engagement and retention. Regarding acute treatment outcomes, an interaction emerged between number of sessions attended and condition. Specifically, only BAL clients who were engaged in treatment and attended more sessions

demonstrated significant reductions in depression and improvements in quality of life and mental health functioning. Results are discussed in terms of the balance of efficacy and effectiveness issues addressed in this trial.

Keywords: behavioral activation; Latinos; psychotherapy; depression

LATINOS ARE THE LARGEST MINORITY GROUP in the United States, comprising over 50 million individuals in 2010 (Passel, Cohn, & Lopez, 2011), with projections that the population will double in size by 2050 (Passel & Cohn, 2008). Depression, identified by the World Health Organization (2008) as one of the most burdensome diseases in the world, presents a significant public health problem for Latinos in the United States (U.S.), with U.S. Latinos reporting comparable rates of major depression diagnoses and possibly higher levels of depressive symptoms compared to non-Latino Whites (Mendelson, Rehkopf, & Kubzansky, 2008).

Many contextual factors are important to the etiology of depression among U.S. Latinos (Cabassa, Lester, & Zayas, 2007; Martinez-Pincay & Guarnaccia, 2007). Research has related the onset

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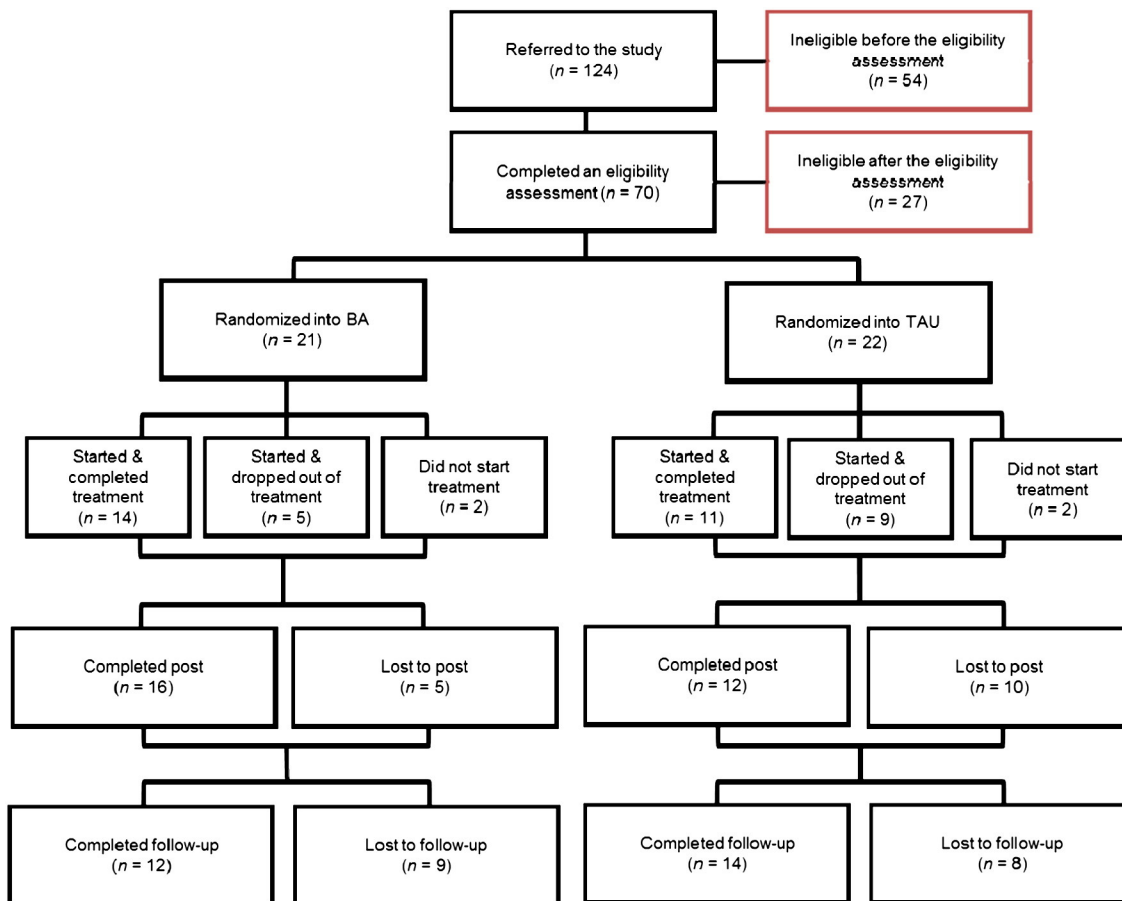


FIGURE 1 Flow of Study Participants.

of depression among U.S. Latinos, for example, to stressful immigration experiences (Grzywacz et al., 2010), the process of acculturation and adapting to a new environment (Organista, Organista, & Kurasaki, 2003), separation from children and family (Miranda, Siddique, Der-Martirosian, & Belin, 2005), and overrepresentation in low socio-economic status brackets (Bruce, Takeuchi, & Leaf, 1991; Vega et al., 1998). Other contextual factors, including experiences of racism and discrimination, stressful interactions with agencies, and language barriers, also are seen as important (Santiago-Rivera, Arredondo, & Gallardo-Cooper, 2002). In line with these factors, U.S. Latinos tend to conceptualize depression as having contextual origins, rather than in other terms (e.g., biological or cognitive; Martinez-Pincay & Guarnaccia, 2007).

A primary obstacle to the psychotherapeutic treatment of depression in U.S. Latinos has been engaging and retaining Latinos in treatment (Fortuna, Alegria, & Gao, 2010). Variants of cognitive-behavior therapy (CBT) have been developed (Muñoz & Mendelson, 2005; Muñoz & Miranda, 1986) and evaluated (Voss Horrell, 2008) to

address this issue. In these trials, improvements in retention rates have been observed, often after the introduction of supplemental, resource-intensive interventions such as additional case management, psychoeducation for those unfamiliar with depression, provision of child care services and transportation, and cultural competency training for therapists (Miranda, Azocar, Organista, Dwyer, & Areane, 2003; Miranda, Cheng, et al., 2003; Miranda, Duan, et al., 2003). Depression treatment outcomes have also improved in these studies, which typically involve complex, multifaceted CBT interventions sometimes as part of larger, collaborative care models (Wells et al., 2004).

More research is needed to produce culturally sensitive, resource-efficient interventions that are disseminable to community settings in order to improve treatment engagement, retention, and outcomes for U.S. Latinos with depression. Kanter, Santiago-Rivera, and colleagues (Kanter, Dieguez Hurtado, Rusch, Busch, & Santiago-Rivera, 2008; Kanter, Santiago-Rivera, Rusch, Busch, & West, 2010; Santiago-Rivera et al., 2008) proposed that Behavioral Activation (BA; Kanter, Busch, & Rusch,

2009; Martell, Addis & Jacobson, 2001) may represent a promising treatment option in this regard. BA, identified as an empirically supported treatment for depression (Mazzucchelli, Kane, & Rees, 2009), primarily involves identifying and scheduling personally meaningful activities to reduce depression for clients by addressing avoidance and other obstacles to activation (Kanter, Manos, et al., 2010).

BA may be a good fit for Latinos for several reasons. First, the rationale for BA treatment focuses directly on contextual factors such as those described above and thus may be seen as relevant and acceptable to Latinos, who tend to prefer present-focused, active treatment strategies (Santiago-Rivera et al., 2008). Second, because BA treatment targets are collaboratively determined based on the client's identified values and life goals, BA may be easily adapted to be consistent with Latino cultural values without compromising its mechanism of action (Kanter et al., 2009; Santiago-Rivera et al., 2008). Third, because of BA's parsimonious and relatively straightforward set of treatment techniques, many authors have suggested that BA holds promise as easy to train and disseminate, especially to clinicians working with populations that have barriers to access to quality mental health care, such as recent immigrants who are not familiar with Eurocentric models of treatment (Kanter, Puspitasari, Santos, & Nagy, 2012). Thus, it was hypothesized that BA, with relatively minor adaptations, would be feasible, appropriate, and effective when administered in Latino community mental health clinic settings. Results of an open trial of BA for Latinos (BAL) at such a clinic provided preliminary support for the feasibility and effectiveness of BAL in terms of treatment adherence, retention, and outcomes (Kanter, Santiago-Rivera, et al., 2010).

The current study extended the open trial of BAL (Kanter, Santiago-Rivera et al., 2010) to a randomized controlled trial of BAL compared to treatment as usual (TAU) at a bilingual (Spanish-English) community medical/mental health clinic. Several features of this trial, which combined elements of efficacy and effectiveness research consistent with the treatment development model of Weisz (2004), are noteworthy. First, the study took place at a comprehensive community medical/mental health center targeting the medically underserved located centrally in a Latino enclave of a large midwestern urban center. Many possible obstacles to treatment utilization and engagement by Latinos (Alegría et al., 2002) are successfully addressed by this center as part of their TAU, including access to behavioral health specialists (all therapists were master's or Ph.D. level), the presence of multilingual therapists, easy access

(located on a major arterial in the center of the Latino community), financial affordability (acceptance of Medicaid and uninsured/undocumented), and cultural competence (the center has earned a strong reputation in the community as culturally competent). Thus, the community clinic setting for this trial was a model for adherence to many of the recommendations for addressing Latino health disparities as the U.S. adapts to the increasing Latino population (McGuire & Miranda, 2008). A demonstrated improvement in treatment retention or outcomes over TAU at such a clinic would be meaningful.

A related noteworthy feature of this study is the nature of the TAU comparison condition. In the past, concerns about the use of TAU comparison conditions in randomized trials have been raised, because in some trials TAU has consisted of nothing more than referral to unspecified and untracked outside providers, selected in advance to function as TAU therapists, while the therapists in the experimental treatment arm were hand-selected, were required to pass significant training criteria, and received significant amounts of supervision and monitoring over the course of the study, among other differences (Wampold et al., 2011). Such research design decisions confound the treatment-TAU comparison and bias results against TAU. The current study, in contrast, employed a strong, ecologically valid TAU condition, with procedures in place to ensure equivalence between BAL and TAU on variables such as treatment setting, treatment affordability, treatment availability, availability of consultation, and institutional reputation. This was done to ensure that the research results would be informative with respect to improving real-world community clinic functioning. Likewise, the training of BAL therapists was kept to levels that would be potentially implementable in community clinic settings, and a 12-session protocol was chosen in line with feasibility of implementation in this setting.

The two primary hypotheses were that BAL would improve retention rates and treatment outcomes compared to TAU at the end of acute treatment. Secondary outcome measures included health functioning and quality of life. An additional aim of this study was to explore outcomes over a 9-month follow-up period. However, an unexpected outcome of this study was a large amount and differential pattern of attrition to follow-up that co-varied with depression change over the course of therapy, rendering the follow-up outcomes unreliable and possibly misleading. These observed patterns of attrition are presented and discussed in lieu of follow-up outcomes.

Methods

PARTICIPANTS

The study protocol was approved by the Institutional Review Boards of the University of Wisconsin–Milwaukee and the Sixteenth Street Community Health Center (SSCHC). Written informed consent was obtained from all clients before initiating study participation.

Participants were low-income, monolingual Spanish-speaking Latinos who were referred for psychological services at the behavioral health clinic of the SSCHC over a 9-month period. The SSCHC is a large community health center that provides comprehensive medical, dental, and mental health care and is the only community-based agency in the area with a full-service bilingual (English-Spanish) mental health clinic. At the time of the study, the center served a client population that was 80% Latino, the majority of which were monolingual Spanish speakers. At the time of the study, the behavioral health clinic was staffed by five psychiatrists, four licensed psychologists, six master's-level clinicians, a psychiatric nurse, and a graduate intern, for a total of 17 providers.

Inclusion criteria included self-identifying as Latino, age between 18 and 65, a score of 16 or higher on the first 17 items of the 25-item modified Hamilton Rating Scale for Depression (HRSD; Miller, Bishop, Norman, & Maddever, 1985) and meeting criteria for major depressive disorder according to the *Diagnostic and Statistical Manual of Mental Disorders* (4th ed., text rev. [DSM-IV-TR]; American Psychiatric Association, 2000) assessed via the Mini International Neuropsychiatric Interview version 5.0.0 (MINI; Sheehan et al., 1998). Exclusion criteria included any problem requiring immediate inpatient hospitalization, organic brain syndrome or an intellectual or developmental disability according to medical records, probable alcohol abuse, a lifetime diagnosis of psychosis or bipolar disorder as indicated by the MINI, a current diagnosis of panic disorder as indicated by the MINI, or being on an antidepressant medication at the time of eligibility assessment.

Figure 1 presents the flow of study participants. A total of 124 individuals were referred to the study. Of these, 54 were found to be ineligible before completing or otherwise did not complete the comprehensive eligibility assessment (age, $n = 1$; medication, $n = 6$; illicit drug use, $n = 1$; did not show for scheduled assessment, $n = 33$; no longer interested, $n = 13$). Of the 70 participants who completed an eligibility assessment, 43 were randomized to condition: 21 participants were assigned to BAL and 22 were assigned to TAU. The 27

participants who were ineligible after the assessment were as likely to be female ($n = 13$) as male ($n = 14$) and were excluded due to subthreshold depression severity ($n = 14$), diagnosis of panic disorder ($n = 5$), diagnosis of bipolar disorder ($n = 1$), suspected substance abuse ($n = 6$), or a history of psychotic episodes ($n = 1$).

PROCEDURE

Clients were referred primarily by medical doctors and other providers (e.g., social workers) working within the clinics of the SSCHC. Referrals were made directly to the study assessor, either by phone or in person, who was located on-site at the behavioral health clinic. The study assessor explained the study to potential clients and performed a brief eligibility screen (age, self-reported ethnicity, primary presenting problem, and current use of antidepressant medication). Depending on the results of the initial screening, participants were scheduled for an on-site clinical evaluation during which written informed consent was obtained and eligibility was determined. Following eligibility confirmation, the assessor conducted the pretreatment evaluation before randomization to condition. Participants then were randomly assigned by the project coordinator to one of two acute treatment conditions, BAL or TAU, using a computerized adaptive biased-coin randomization procedure that uses the urn design (Wei & Lachin, 1988) balancing on gender, marital status, and depression severity, in that order. Participants were assigned to therapists within condition based on clinician availability.

During the study, a research assistant contacted all participants regularly (approximately once per month) to maintain good communication and to update contact information records as necessary. In addition, therapists assisted in reminding clients that they would be contacted for important assessments at the end of treatment and at follow-up. In cases in which a study assessor had been unable to reach a client, therapists contacted clients to help schedule assessment appointments. This was handled by the project coordinator in order to keep the assessor blind to condition.

THERAPISTS

Eight existing mental health practitioners of the behavioral health clinic at the SSCHC were recruited to participate in the trial. Of these, half were randomly assigned to function as BAL therapists and the other half as TAU therapists. All normal procedures of the clinic were followed by both sets of therapists. The first and second authors provided the BAL group with a 16-hour BAL training before the start of the trial and, subsequent to that, attempts

were made to provide equivalent experiences for BAL and TAU therapists over the course of the trial. Both BAL and TAU therapists met with each other for weekly 1-hour consultation sessions to review study cases. The first and second authors participated in the BAL therapists' weekly meeting. Study therapists did not participate in any joint consultation meetings throughout the duration of the trial in an attempt to protect against leakage of BAL into the clinic and contamination of the TAU condition. Both BAL and TAU therapists followed equivalent standard clinic procedures with respect to the scheduling of sessions and phone follow-ups with clients in the case of missed sessions (BAL therapists engaged in additional in-session strategies to encourage session attendance, discussed below).

BAL therapists were all female and varied with regard to degree earned, licensure, age, and years of experience working with Latinos. They included one therapist with a master's degree in social work with a clinical practice license (36 years old, 9 years of experience working with Latinos), one therapist with a master's degree in social work in the process of obtaining licensure (29 years old, 4 years of experience), one therapist with a master's degree in marriage and family therapy with a clinical practice license (62 years old, 38 years of experience), and one therapist with a master's degree in counseling psychology with a clinical practice license (39 years old, 13 years of experience). Three of the four TAU therapists were female. TAU was provided by one therapist with a doctoral degree in clinical psychology with a clinical practice license (49 years old, 5 years of experience working with Latinos), one therapist with a doctoral degree in counseling psychology with a clinical practice license (48 years old, 18 years of experience), one therapist with a master's degree in social work with a clinical practice license (65 years old, 15 years of experience), and one therapist with a master's degree in social work working toward obtaining licensure (31 years old, 5 years of experience).

TREATMENTS

The BA model (Kanter et al., 2009; Martell et al., 2001) suggests that depression is the result of decreased environmental reinforcement which leads to decreased activation behaviors and associated depressed mood (Manos, Kanter, & Busch, 2010). The model also suggests that depression leads to an increase in avoidance behaviors that may be responsible for maintaining the depressive cycle. BA works to break this cycle by prompting and increasing activation behaviors in which the client reengages in his or her life and receives positive reinforcement as a result. BA therapists explain to

clients that an effective way of overcoming depression is to disengage from avoidance and passivity and instead take action to solve problems and increase pleasure and meaning in life. Each week, the BA therapist works collaboratively with the client to identify core problems, target them by identifying and scheduling specific activation assignments, track progress with homework assignments from session to session, and address obstacles to activation and modify activities as necessary. The ultimate goal is to help the client successfully complete activation assignments from week to week.

The specific BAL protocol evolved through several years of development. The goal of treatment development was to retain the core treatment mechanism and techniques of the original BA model (Martell et al., 2001) while simplifying the procedures to maximize training efficiency and flexibility with respect to idiosyncratic assessments of cultural values (Kanter et al., 2008; Santiago-Rivera et al., 2008). Caution was taken not to produce a cultural adaptation of the approach that deviated significantly from the original approach. Some experiences during treatment development, however, suggested necessary alterations at the level of technique, such as a simplified treatment rationale, less reliance on written homework assignments, removal of specific acronyms that were emphasized in the original model because they did not translate well, and increased emphasis on family and community resources. Procedures for using BA strategies to activate clients to come to treatment sessions and overcome obstacles to session attendance were also added to the BAL protocol. Therapists were specifically encouraged to follow these procedures to maximize treatment retention.

TAU therapists were asked to provide their typical treatment for depression to the best of their abilities, and providers implemented a diverse set of techniques based on their theoretical orientations and training (discussed below).

Treatment for participants in both conditions consisted of up to 12 sessions, generally scheduled weekly for 50 minutes. Time allowed to complete treatment was extended to accommodate challenges with scheduling commonly observed in the population. All clients were required to be medication-free at the time of the eligibility assessment, but medication usage was not restricted during the study. Clinic records were reviewed to determine medication usage throughout the study.

MEASURES

Diagnostic Measures

The MINI version 5.0.0 (Sheehan et al., 1998) is a brief structured diagnostic instrument for evaluation

Table 1
Baseline Characteristics of Participants

	BAL (<i>n</i> = 21)	TAU (<i>n</i> = 22)	Full Sample (<i>N</i> = 43)
Female: <i>n</i> (%)	16 (76.2)	18 (81.8)	34 (79.1)
Age: <i>M</i> (<i>SD</i>)	38.7 (11.7)	37.5 (10.1)	38.1 (10.8)
Unemployed: <i>n</i> (%)	11 (52.4)	12 (54.5)	23 (53.5)
Income*: <i>n</i> (%)			
≤\$10,000	9 (42.9)	11 (50.0)	20 (46.5)
\$10,000-20,000	6 (28.6)	5 (22.7)	11 (25.6)
>\$20,001-\$30,000	3 (14.3)	5 (22.7)	8 (18.6)
Married or common law: <i>n</i> (%)	11 (52.4)	12 (54.5)	23 (53.5)
Not born or raised in the U.S.: <i>n</i> (%)	18 (85.7)	16 (72.7)	34 (79.1)
Country of Origin**: <i>n</i> (%)			
Mexico	14 (66.7)	15 (68.2)	29 (67.4)
Puerto Rico	6 (28.6)	3 (13.6)	9 (20.9)
Other	1 (4.8)	3 (13.6)	4 (9.3)
Pre-treatment BDI-II: <i>M</i> (<i>SD</i>)	34.4 (9.2)	29.4 (10.1)	31.8 (9.9)
Low severity (BDI-II 14–28): <i>n</i> (%)	6 (28.6)	11 (50)	17 (39.5)
High severity (BDI-II 29–63): <i>n</i> (%)	15 (71.4)	11 (50)	26 (60.5)
Post-traumatic Stress Disorder: <i>n</i> (%)	7 (33.3)	7 (31.8)	14 (32.6)
Any other comorbidity: <i>n</i> (%)	7 (33.3)	8 (36.4)	15 (34.9)

Note. Results of independent samples *t*-tests for continuous variables and chi-square tests of independence for categorical variables demonstrated no difference between the treatment groups. *Missing for four people (3 from BAL). **Missing for 1 person (TAU). BDI = Beck Depression Inventory; HRSD = Hamilton Rating Scale for Depression.

of depression and other Axis I disorders in medical and psychiatric patients. MINI depression diagnoses demonstrated sensitivity = .96 and specificity = .88 compared to the Structured Clinical Interview for DSM, good interrater reliability ($\kappa = 1.0$) and good test-retest reliability ($\kappa = .87$; Sheehan et al.). Bobes (1998) found sensitivity and specificity for major depression to be 94.1 and 62.2, respectively, for the Spanish version of the MINI compared to a gold-standard psychiatrist.

Depression Severity Measures

Depression severity was assessed using the first 17 items of the Spanish version of the 25-item modified HRSD (Miller et al., 1985), as recommended by Bobes et al. (2003) and consistent with Dimidjian et al. (2006). The Spanish version of the HRSD has accumulated evidence for good internal consistency (.72); interrater reliability (.99); content, concurrent, and discriminant validity; and good fit with the English-language factor structure (Ramos-Brieva & Cordero-Villafáfila, 1988; Ramos-Brieva, Cordero Villafáfila, & Yañez Sáez, 1994). The internal consistency (α) of this scale in the current study was .63.

The Beck Depression Inventory–II (BDI-II; Beck, Steer, & Brown, 1996), a 21-item self-report inventory, is one of the most widely used measures of depression severity. It has been translated and validated with bilingual clinical and college student samples (Novy, Stanley, Averill, & Daza, 2001; and Wiebe & Penley, 2005, respectively). The Spanish

version has demonstrated good internal consistency (.91–.95), no significant language effect (Wiebe & Penley), and a high correlation between responses obtained using an English and Spanish language version (Novy et al., 2001). The BDI-II was administered at preintervention, postintervention, and before each session. The internal consistency (α) of this scale in the current study was .95.

Secondary Measures

The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q; Endicott, Nee, Harrison, & Blumenthal, 1993) is a 16-item measure designed to assess satisfaction and enjoyment in various domains of functioning, including physical health, work, and social relationships. The Q-LES-Q has been used with samples from Spain (e.g., Barraza & Moreira, 2012; Iglesias-García & Prieto, 2012) and other Spanish translations have been used in multinational psychopharmacological trials. There is little published data, however, on the reliability and validity of the measure in Spanish, specifically with samples from Latin America. The internal consistency (α) of this scale in the current study was .73.

The 12-item Short Form Health Survey (SF-12; Ware, Kosinski, & Keller, 1996) was used to assess health functioning and is comprised of the Physical Component Summary (PCS) and the Mental Component Summary (MCS) subscales. Results of an evaluation with a Colombian sample demonstrated internal consistency of greater than 0.7

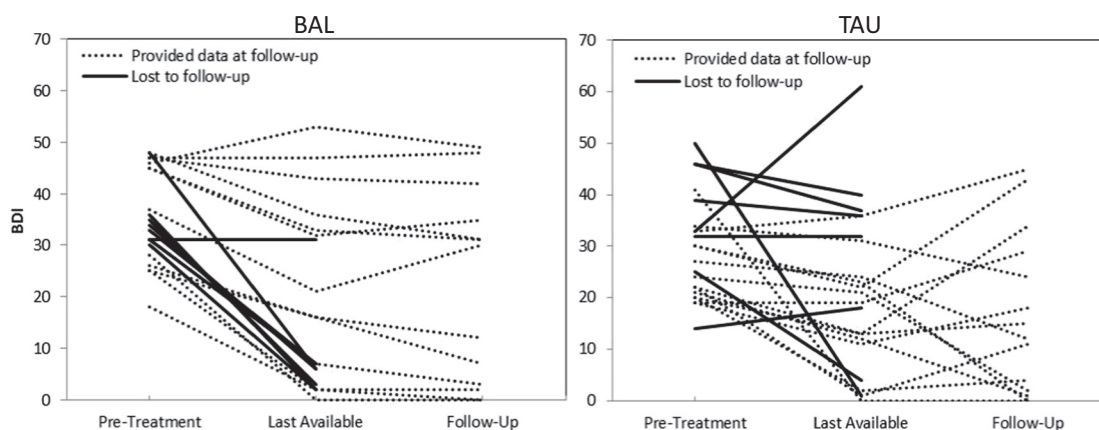


FIGURE 2 BDI-II Scores for BAL and TAU Participants Who Provided Data at Follow-up and Who Were Lost to Follow-up.

(Ramirez-Velez, Agredo-Zuniga, & Jerez-Valderrama, 2010). The internal consistency (α) of the PCS and MCS subscales in the current study were .92 and .82, respectively.

TREATMENT INTEGRITY

Two measures of treatment integrity were developed for this study. First, an objective BAL adherence scale was developed and a randomly selected subset of study sessions was coded using this measure. Second, to capture what occurred in TAU and to supplement the objective adherence ratings, a therapist-report session checklist was developed and completed after every session by the therapists.

Adherence Coding

The 15-item BAL Adherence Scale (BALAS) was developed by the research team based on previous unpublished work by Dimidjian and colleagues for adherence coding in the Dimidjian et al. (2006) BA study. Items included “discusses client avoidance,” “schedules activities,” “re-establishes routines,” and “attends to premature termination.” After a therapy session tape was observed by the coder, each BALAS item was coded on a scale from 1 to 7 with 1 = “not at all,” 3 = “some,” 5 = “considerably,” and 7 = “extensively” to indicate the degree to which the therapist engaged in the behavior indicated by the item. A randomly selected subset of “early” (Sessions 1–4), “middle” (Sessions 5–8), and “late” (Sessions 9–12) BAL and TAU sessions was coded using the BALAS, resulting in 22 BAL sessions (12 early, 6 middle, and 6 late) and 24 TAU sessions (13 early, 4 middle, and 5 late) coded. The internal consistency (α) of the BALAS in the current study was .92.

BALAS coding was conducted by an independent, blind graduate-student coder, trained by the first author, who achieved five consecutive reliability scores, using intra-class correlation coefficients (ICC), of greater than .70 on an item-by-item basis

with the first author before beginning coding. During the study, an advanced graduate student criterion coder, who had participated in the BAL training sessions and helped develop the BALAS, rated eight of the independent coder’s tapes for reliability. The ICC between the criterion and the independent coder across these eight tapes was .85.

Session Checklist

To develop the Global Session Checklist (GSC), first all study therapists were interviewed to determine their usual interventions for depression, and these interventions became checklist items (e.g., social support/interpersonal interventions, encouraged client emotional experiencing, discussed transference issues, explored the importance of childhood events, hypnosis). Second, BAL-specific interventions were added (e.g., scheduled new activities, focused on avoidance, assigned homework) by the research team. Third, general culturally competent therapist behaviors were added (e.g., discussed or included family, attended to client’s cultural values, focused on spiritual/religious themes) by the research team. Therapists checked yes/no for whether they employed each item after each therapy session. Items were coded “yes” = 1 and “no” = 0. From these 22 items, a 5-item BAL-specific techniques subscale was created a-priori, including problem solving negative life events, focusing on avoidance, scheduling new activities, assigning homework, and reviewing homework. In the current study, the internal consistency (α) of this subscale was .75, and it correlated highly and significantly with obtained BALAS scores, $r = .82, p < .001$.

ASSESSOR TRAINING

The study assessor functioned independent of all study procedures other than screening and assessment and was blind to the treatment condition of the participants. The assessor was a bilingual, Latina,

Table 2
Frequency (%) of Occurrence of Global Session Checklist Items by Condition

	BAL	TAU	<i>p</i> -value
Items with BAL > TAU			
Motivational strategies	46 (30.5)	2 (02.0)	<.001
Scheduled new activities	130 (86.1)	19 (18.6)	<.001
Problem solved life events	92 (60.9)	38 (37.3)	<.001
Focused on avoidance	93 (61.6)	4 (03.9)	<.001
Attended to client's cultural values	101 (66.9)	47 (46.1)	.001
Assigned homework	132 (87.4)	28 (27.5)	<.001
Reviewed homework	115 (76.2)	13 (12.7)	<.001
Items with TAU > BAL			
Encouraged emotional experiencing	55 (36.4)	61 (59.8)	<.001
Explored childhood events	14 (09.3)	30 (29.4)	<.001
Cognitive restructuring	34 (22.5)	55 (53.9)	<.001
Focused on spirituality/religion	25 (16.6)	35 (34.3)	.001
Items with TAU and BAL not different			
Encouraging social support	98 (64.9)	76 (74.5)	.069
Providing empathy and validation	142 (94.0)	100 (98.0)	.208
Assessment	55 (36.4)	33 (32.4)	.591
Relaxation	17 (11.3)	5 (04.9)	.110
Discussing or including family	108 (71.5)	81 (79.4)	.185
Case management	12 (07.9)	14 (13.7)	.146
Solution-focused work	24 (15.9)	22 (21.6)	.319
Focusing on skills	7 (04.6)	11 (10.8)	.081
Discussion of transference issues	0 (00.0)	1 (00.7)	1.00
Hypnosis	0 (00.0)	0 (00.0)	—
Guided imagery	2 (01.3)	1 (01.0)	1.00
Experiential/gestalt techniques	3 (02.0)	1 (01.0)	.650
EMDR	0 (00.0)	2 (02.0)	.162

Note. *P*-value is Fisher's Exact Test (two-sided).

master's-level clinician in training to receive her Ph.D. with several years of clinical experience with Latinos. The assessor was trained in the MINI and HRSD by the first author using role-play assessments and fictitious case studies, and achieved reliability with the first author's ratings at .70 or above on both the MINI and HRSD on three practice cases before beginning study assessments.

STATISTICAL ANALYSES

Analyses of baseline comparisons, adherence, session attendance/dropout, and response/remission/reliable change were conducted for continuous variables using either analysis of variance (ANOVA) or independent samples *t*-tests. Fisher's exact test was used for categorical variables.

Regarding our primary outcome analyses at the end of acute treatment, an *a priori* power analysis assuming two time points, $\alpha = .05$, a one-tailed test, and a maximum attrition rate of 20% suggested 26 participants per group to achieve .80 power in order to find a medium-sized effect at posttreatment on our primary outcome variable, the HRSD. The achieved sample was slightly underpowered for this analysis given higher than expected dropout. For analyses of

primary outcome variables (HRSD and BDI-II) and secondary outcomes (Q-LES-Q, PCS, and MCS), a series of generalized mixed model analyses of variance were implemented in SAS through the GLIMMIX procedure, with full information maximum likelihood estimation for missing values, based on the macro by Littell, Milliken, Stroup, and Wolfinger (1996). Because the number of sessions attended differed between treatment conditions, this variable was included in the mixed model analyses. These analyses were conducted using the full intent-to-treat sample (all 43 participants, including the 4 who never attended a first session).

Inclusion of sessions attended in the models resulted in the analysis of three-way interactions between time (preintervention, postintervention), condition (BAL, TAU), and number of sessions attended across the different outcome variables. To do this, the sessions-attended variable was trifurcated into 0 – 4 sessions (BAL = 7 clients, TAU = 14 clients), 5 – 8 sessions (BAL = 3 clients, TAU = 4 clients), and 9 – 12 sessions (BAL = 11 clients, TAU = 4 clients). Simple within-subjects effects (the effect of time for BAL and TAU at each level of the sessions-attended variable) and between-subjects

Table 3
Means and Standard Deviations of Primary Outcome Variables by Condition

	Pre-Treatment		Post-Treatment		Effect Size (Cohen's <i>d</i>)
	BAL	TAU	BAL	TAU	
	M (SD)	M (SD)	M (SD)	M (SD)	
HRSD	21.05 (3.75)	20.82 (5.21)	11.00 (9.14)	12.83 (9.70)	.28
0 – 4 sessions	22.71 (4.03)	21.92 (5.03)	18.00 (9.63)	10.14 (9.70)	-.58
5 – 8 sessions	23.00 (5.57)	17.50 (3.51)	14.00 (9.54)	19.00 (4.24)	1.05
9 – 12 sessions	19.45 (2.50)	20.25 (6.85)	06.89 (7.24)	15.00 (12.49)	1.01
BDI-II	34.38 (9.19)	29.41 (10.05)	17.00 (16.73)	18.17 (15.27)	.16
0 – 4 sessions	39.71 (9.12)	31.00 (10.58)	29.60 (14.01)	17.29 (16.81)	-.49
5 – 8 sessions	31.00 (6.00)	26.50 (4.80)	14.67 (7.09)	22.50 (2.12)	1.48
9 – 12 sessions	31.90 (9.04)	26.75 (12.89)	11.40 (17.48)	17.33 (20.26)	1.05
Q-LES-Q	33.95 (5.37)	34.33 (7.09)	44.59 (12.46)	39.67 (15.41)	.58
0 – 4 sessions	33.43 (4.72)	35.14 (8.12)	38.25 (10.59)	42.29 (18.17)	-.31
5 – 8 sessions	31.33 (5.51)	32.67 (1.53)	41.33 (8.08)	32.50 (0.71)	1.44
9 – 12 sessions	35.10 (5.93)	32.75 (6.18)	48.10 (13.74)	38.33 (15.37)	.84
PCS	39.90 (8.94)	44.05 (10.26)	45.41 (12.63)	41.60 (9.24)	.44
0 – 4 sessions	38.00 (11.47)	44.57 (12.49)	37.75 (11.06)	42.80 (9.26)	-.27
5 – 8 sessions	33.00 (4.24)	42.00 (3.46)	46.00 (13.23)	38.00 (7.07)	1.09
9 – 12 sessions	42.36 (7.24)	44.25 (6.50)	48.30 (12.99)	42.00 (13.08)	.37
MCS	20.10 (5.99)	24.09 (10.65)	34.24 (14.12)	37.30 (16.96)	.05
0 – 4 sessions	20.57 (7.85)	21.29 (8.64)	27.25 (15.17)	45.60 (17.62)	-1.21
5 – 8 sessions	21.00 (4.24)	33.25 (11.67)	26.33 (7.57)	26.50 (2.12)	1.20
9 – 12 sessions	19.64 (5.37)	24.75 (13.60)	39.40 (13.88)	30.67 (17.79)	1.04

Note. HRSD = Hamilton Rating Scale for Depression; BDI-II = Beck Depression Inventory-II; Q-LES-Q = Quality of Life Enjoyment and Satisfaction Questionnaire; PCS = Physical Component Summary of 12-item Short Form Health Survey; MCS = Mental Component Summary of 12-item Short Form Health Survey. Effect size = Cohen's *d* comparing BAL change on variable from pre-post to TAU change on variable from pre-post.

effects (the effect of condition at each time point and at each level of the sessions-attended variable) were analyzed using paired *t*-tests and independent samples *t*-tests, respectively, for all outcome variables. We adjusted for 12 multiple comparisons for each outcome variable resulting in *p*-values of .004 or below.

Results

BASELINE CHARACTERISTICS AND ASSESSMENT RETENTION

Table 1 presents demographic and clinical characteristics of the sample at baseline. Significant differences between the treatment groups on randomization or other demographic and clinical characteristics were not observed.

Significant attrition to research assessment at posttreatment was observed. Of the 43 clients in the original sample, 15 (34.9%) clients did not provide posttreatment data, including 5 (23.8%) BAL clients and 10 (45.5%) TAU clients. This led to concerns about outcome analyses at posttreatment possibly being biased by differential attrition. To explore this, post-hoc analyses examined several key variables, specifically pretreatment BDI-II and HRSD scores, number of sessions attended, and final session BDI-II

before dropout, for possible differences by condition between those who provided data for the posttreatment assessment and those who did not. To be conservative, these analyses were not corrected for multiple comparisons. Findings suggested that there were no interactions between condition and postintervention assessment attrition on pretreatment HRSD scores, but trends were observed for both BAL and TAU clients with respect to pretreatment BDI-II scores. Specifically, BAL clients who did not provide posttreatment data tended to have higher pretreatment BDI-II scores ($M = 40.80$, $SD = 9.94$) compared to BAL clients who did provide posttreatment data ($M = 32.38$, $SD = 8.26$), $F(1, 19) = 3.62$, $p = .07$, while TAU clients who did not provide posttreatment data tended to have lower pretreatment BDI-II scores ($M = 25.30$, $SD = 7.01$) compared to TAU clients who did provide posttreatment data ($M = 32.83$, $SD = 11.16$), $F(1, 20) = 3.42$, $p = .08$. However, this possible difference disappeared over the course of therapy, before the clients were lost, as per last session BDI-II scores, which reversed the pattern observed at pretreatment and were not significantly different. Therefore, evidence for a biased impact of differential attrition on primary outcomes at posttreatment was not found.

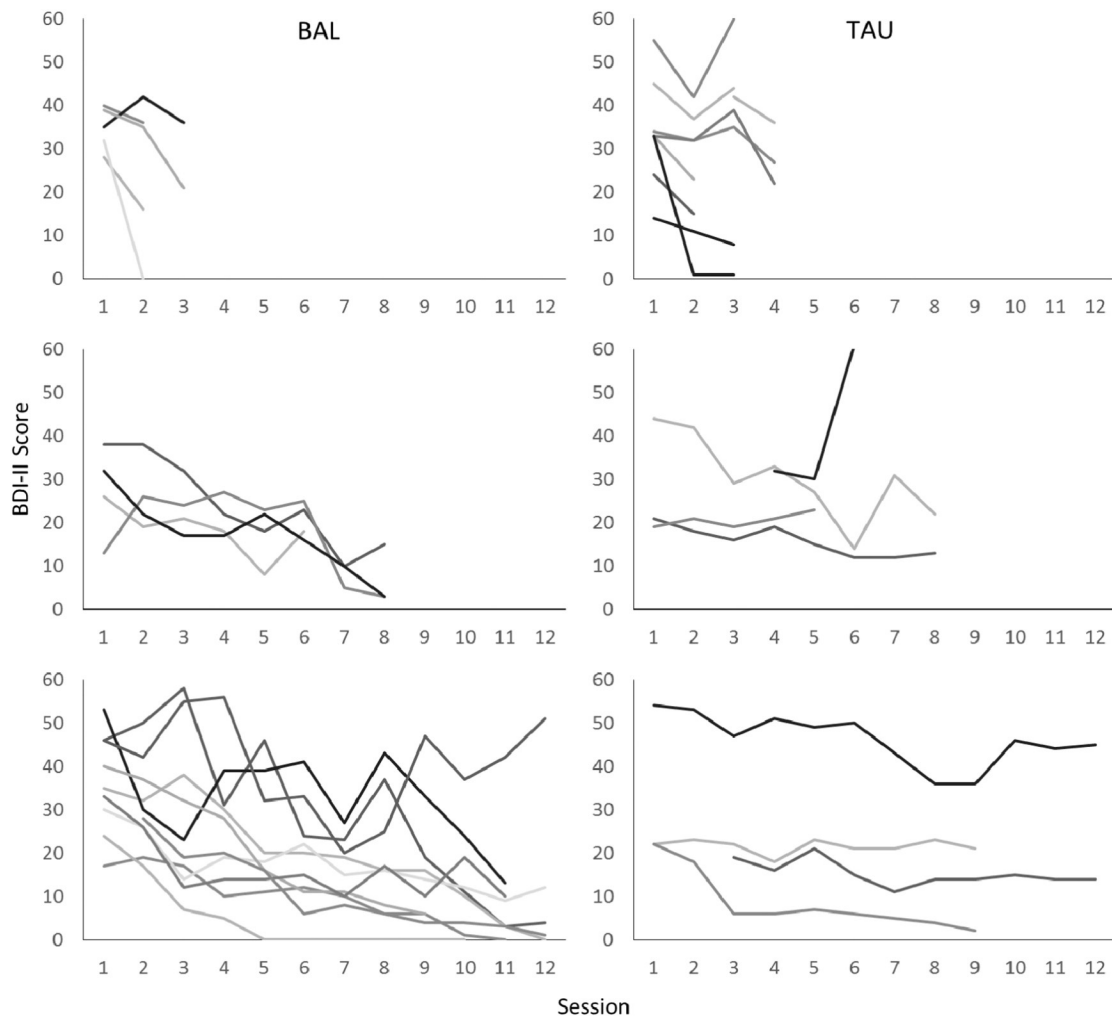


FIGURE 3 Session-by-Session BDI-II scores for Individual BAL and TAU Clients Split by Sessions Attended (top panel = 1–4 sessions, middle panel = 5–8 sessions, bottom panel = 9–12 sessions).

At follow-up, significant attrition to research assessment also was observed, with 18 (41.9%) clients who did not provide follow-up data, including 10 (47.6%) BAL clients and 8 (36.4%) TAU clients. Post-hoc analyses suggested that pretreatment BDI-II scores and BDI-II scores over the course of therapy predicted a differential pattern of attrition to the follow-up assessment between BAL and TAU clients. Regarding pretreatment BDI-II scores, TAU clients lost to follow-up had significantly higher pretreatment BDI-II scores ($M = 35.63$, $SD = 12.15$) compared to TAU clients who provided data at follow-up ($M = 25.86$, $SD = 6.80$), $F(1, 20) = 5.94$, $p = .03$. Furthermore, the BAL clients who were lost at follow-up had significantly lower last available BDI-II scores before they were lost ($M = 6.00$, $SD = 6.63$) compared to BAL clients who provided data at follow-up ($M = 20.56$, $SD = 17.19$), $F(1, 17) = 6.18$, $p = .02$, while the TAU clients who were lost at follow-up had significantly higher last

available BDI-II scores ($M = 38.43$, $SD = 20.09$) compared to TAU clients who provided data at follow-up ($M = 17.85$, $SD = 9.62$), $F(1, 18) = 9.81$, $p = .006$. These findings are depicted in Figure 2. In other words, it appeared to be the case that most of the clients who were doing relatively well in BAL (according to their last available BDI-II scores) were lost to the follow-up assessment, while clients who were doing relatively poorly in TAU were lost to follow-up, and this pattern represented a reversal from other findings at posttreatment. Thus, because of significant concerns about the biasing effects of these patterns of differential attrition on follow-up data, follow-up results were not presented.

TREATMENT INTEGRITY

Results from the BALAS indicated that BAL therapists were significantly more adherent to BAL ($M = 3.15$, $SD = .62$) than were TAU therapists ($M = 1.35$, $SD = .18$), $t(44) = 13.06$, $p < .001$, $d = 1.76$, with

the low TAU value suggesting that very little BAL occurred in the TAU sessions. Therapist post-session reports using the GSC converged on this result, suggesting that BAL therapists engaged in significantly more BAL-specific work ($M = .74$, $SD = .23$) than did TAU therapists ($M = .20$, $SD = .19$), $t(251) = -19.67$, $p < .001$, $d = 1.59$.

To characterize what occurred in BAL and TAU in more detail, a series of exploratory analyses were performed on each item of the GSC, using Fisher's Exact Test to evaluate possible differences between conditions in the frequencies of specific items. Results are reported in Table 2. Although some BAL techniques did occur in TAU, results indicated that they were implemented in a piece-meal, uncoordinated fashion, rather than as an integrated set of techniques as in BAL. According to therapist self-report, all five of the "BAL-specific" techniques identified on the GSC occurred in 29.8% of BAL sessions, and four of five occurred in another 33.8% of BAL sessions, while no TAU session evidenced four or more BAL-specific techniques. In contrast, more TAU sessions evidenced no BAL-specific techniques (36.3% of sessions) or one BAL-specific technique (35.3% of sessions), while no BAL-specific techniques or only one BAL-specific technique were rare in BAL sessions (0.7% and 4.0% of sessions, respectively).

Medication Usage

A total of five clients (three BAL, two TAU) were prescribed and initiated antidepressant medications over the course of the study (two paroxetine, one bupropion, one fluoxetine, one sertraline). Three of these clients (one BAL, two TAU) were also prescribed a benzodiazepine. The significant three-way interactions reported below did not change when those with medication usage were removed from the analysis.

TREATMENT RETENTION

Treatment dropout status was determined using all clients who attended a first session (two clients assigned to BAL and two clients assigned to TAU did not attend the first session). Treatment completion was determined using this same subsample and was defined as attending at least 10 sessions as per the open trial of BAL (Kanter, Santiago-Rivera, et al., 2010). BAL clients attended significantly more sessions over the course of therapy ($M = 8.21$, $SD = 3.95$) compared to TAU clients ($M = 4.95$, $SD = 3.41$), $t(37) = 2.76$, $p = .009$, and significantly more BAL clients (9 of 19, 47.4%) were classified as treatment completers compared to TAU clients (2 of 20, 10.0%), Fisher's Exact Test, $p = .014$. The proportion of clients who dropped out of treatment

was not significantly different, $p = .320$, although the pattern of results was consistent with the above findings. Specifically, of the 19 BAL clients who started therapy, 5 dropped out over the course of treatment (26.3%), compared to 9 of 20 TAU clients (45%). Because of these significant differences in dosages of therapy received by BAL and TAU clients, the number of sessions attended was included as a factor in outcome analyses.

TREATMENT OUTCOMES

Means and standard deviations for all outcome comparisons are presented in Table 3, along with effect sizes (Cohen's d) comparing pre-post change scores between conditions for each dependent variable at each level of the trifurcated sessions-attended variable. For the HRSD, a significant main effect for Time, $F(1, 38) = 10.61$, $p = .002$, a trend with respect to the Treatment \times Time interaction, $F(1, 38) = 3.23$, $p = .08$, and a significant Session \times Treatment \times Time interaction were found, $F(2, 37.2) = 3.35$, $p = .046$. Follow-up tests revealed a significant decrease in HRSD scores for BAL clients who attended 9–12 sessions, $t(8) = 5.97$, $p < .001$, $d = 1.99$. No other post-hoc tests were significant. However, because of small sample sizes for post-hoc between-condition comparisons, the pattern of effect sizes was also explored. For clients who only attended 0–4 sessions, the effect size favored TAU, but for clients who attended 5–8 and 9–12 sessions, effect sizes favored BAL, with large effects.

For the BDI-II, a significant main effect for Time was observed, $F(1, 37.6) = 6.15$, $p = .02$, suggesting that both treatments improved on the BDI-II over the course of therapy. A significant Session \times Treatment \times Time interaction was not found for the BDI-II. However, the pattern of effect sizes for the three-way interaction mirrored that of the HRSD. To explore this pattern in more detail, session-by-session BDI-II scores for each client at each level of the sessions-attended categorical variable were plotted in Figure 3, showing the pattern of depression change over therapy before treatment completion or dropout for BAL and TAU clients. The last available BDI-II, shown in Figure 3, correlated significantly with both posttreatment BDI-II scores ($r = .73$, $p < .001$) and posttreatment HRSD scores ($r = .56$, $p = .002$). The pattern observed in these plots is consistent with the posttreatment effect sizes, in which BAL clients show a more consistent pattern of improvement with more sessions attended. TAU clients, in comparison, did not yield an easily interpretable pattern of BDI-II change over the course of therapy, and interpretation of TAU is additionally complicated by higher therapy dropout rates.

For the MCS, a significant main effect for Time, $F(1, 33.5) = 11.05, p = .002$, a significant Treatment \times Time interaction, $F(1, 33.5) = 7.67, p = .009$, and a significant Session \times Treatment \times Time interaction were found, $F(2, 31.2) = 6.03, p = .006$. As with the HRSD, follow-up tests revealed a significant change in MCS scores for BAL clients who attended 9 – 12 sessions, $t(9) = 4.02, p = .003, d = 1.27$. No other post-hoc tests were significant.

For the Q-LES-Q and PCS, a significant three-way interaction was not observed. The only significant finding was a significant improvement in Q-LES-Q scores for BAL clients who attended 9 – 12 sessions, $t(8) = 4.27, p = .003, d = 1.42$. For the Q-LES-Q and PCS, the pattern of effect sizes with respect to the three-way interactions was similar to that observed with the HRSD and BDI-II: For clients who only attended 0 – 4 sessions, effect sizes favored TAU, but for clients who attended 5 – 8 and 9 – 12 sessions, effect sizes favored BAL, with mostly large effects.

RESPONSE, REMISSION, AND RELIABLE CHANGE

Differences in proportions of clients who met response, remission, and reliable change criteria were examined for the sample that provided HRSD data at post-test and the intent-to-treat sample, assuming nonresponse/remission for those who did not provide data. “Response” was calculated as more than a 50% reduction in a client’s HRSD score and “remission” as an HRSD score of 7 or less (Frank et al., 1991). Rates of response and remission were calculated separately but response and remission results were identical in that any participant who was a responder was also a remitter and vice versa. For the intent-to-treat sample, a trend emerged favoring BAL, with 9 of 21 clients (42.9%) achieving response/remission criteria, compared to 4 of 22 TAU clients (18.2%), Fisher’s Exact Test, $p = .08$. This test was not significant when only those who provided post-treatment data were compared (BAL = 9 of 16 clients, 56.2%; TAU = 4 of 12 clients, 33.3%).

Reliable change index scores were calculated for each participant on the HRSD as per Jacobson and Truax (1991) with test-retest reliability estimated to be .87 as per Trajković et al. (2011). Ten (10) of 16 BAL clients (62.5%) achieved reliable change, compared to five (5) of 12 TAU clients (41.7%). This difference was not significant.

Discussion

This project sought to evaluate Behavioral Activation for Latinos with depression by partnering with a bilingual (English-Spanish) community medical/mental health clinic and conducting a randomized controlled trial of BAL against an ecologically valid

TAU comparison condition within the clinic setting. TAU was a stronger comparison condition than most previous TAU conditions as it took place at the same clinic, under the same guidelines and clinic protocols, with similar levels of ongoing consultation, and using the same pool of therapists as BAL. The first finding to emerge from this study was that BAL performed well with respect to treatment engagement and retention, as it did in a previous open trial (Kanter, Santiago-Rivera, et al., 2010). Specifically, BAL clients attended more sessions and were more likely to complete therapy compared to TAU clients. Treatment retention is a major issue with community clinics in general, as Latinos have higher rates of premature termination (Kouyoumdjian, Zamboanga, & Hansen, 2003). Problems with premature termination exist even after structural barriers are removed, suggesting that qualities of the therapy itself may require improvement to fully address this issue (Snowden & Yamada, 2005). Therefore, the replicated finding that BAL improves treatment retention compared to TAU in a clinic that has addressed many other structural barriers is noteworthy.

The mechanism through which BAL improved treatment retention in the current study is unknown. Although both BAL and TAU therapists followed the same clinic protocols between sessions with respect to calling clients who missed sessions or to remind clients to attend sessions, BAL therapists likely worked harder in session to encourage session attendance. This is because the BAL protocol specifically encouraged therapists to spend time in session discussing the importance of session attendance with their clients, and scheduling session attendance as a behavioral activity like other activation assignments. The presence of the BA experts in the consultation meetings may also have inspired the therapists to work harder at this, as this issue was frequently discussed in consultation. It also may be the case the clients found the BAL rationale to be more credible and acceptable than those offered in TAU; however, no measures of treatment credibility or expectations were employed in this study.

The interaction between number of sessions attended, outcomes and condition was explored because of the differential session attendance and treatment completion exhibited by the two conditions. BAL treatment completers were the only subgroup to demonstrate significant improvements (for the HRSD, MCS, and Q-LES-Q) in the analyses of this interaction. Given different amounts of sessions attended, session-by-session BDI-II data were explored to observe how clients were responding to treatment before they dropped out of treatment. For BAL clients, a clear pattern emerged in which BAL clients who

were engaged in treatment and attended more sessions had better outcomes, with all but one of the BAL treatment completers demonstrating a good response to treatment according to the last-session BDI-II data.

In TAU, the patterns were not significant and less clear. Observation of the session-by-session data suggested that a subset of clients appeared to be “rapid responders” (Ilardi & Craighead, 1994) who got better very quickly and then dropped out of treatment. While speculative, this pattern is consistent with perceptions of client improvement by therapists at the clinic: Clients start treatment significantly depressed, rapidly receive some compassionate and relevant counseling, feel better quickly, and drop out. Otherwise, patterns of session attendance and improvement in TAU were difficult to characterize meaningfully, with considerable variability demonstrated in both session attendance and outcomes. No significant findings emerged within the TAU data in our post-hoc analyses (although sample sizes were small).

The specific acute-treatment outcome comparison between BAL and TAU was difficult to interpret, specifically because of the differential pattern of session attendance and the observed three-way interaction, which was not hypothesized and the study was not fully powered to investigate. It is possible, for example, that had TAU a better mechanism for engaging the non-rapid-responders in treatment, those clients would have benefited from a stronger dose of TAU. However, the current data do suggest that BAL may have advantages over TAU, as it was currently implemented, with respect to engaging clients in treatment and—for those clients successfully engaged—BAL produced significant improvements in depression, quality of life, and mental health functioning. BAL also may have brought more clients to response/remission status compared to TAU by the end of treatment.

A significant unexpected complication to this research study was attrition of participants to the posttreatment assessment and a pattern of *differential* attrition to the follow-up assessment which prevented interpretable analyses of follow-up outcomes. Specifically, analyses suggested that the BAL condition appeared to have lost to follow-up many clients who were doing well before they were lost, while the TAU condition appeared to have lost to follow-up many clients who were doing poorly before they were lost. We do not yet have a good explanation for this differential pattern of attrition, and there is no precedent in the literature for such a finding—in which clients who are doing well are more likely to be lost to follow-up compared to clients who are doing poorly. It may be random error unrelated to the treatment conditions. It is

possible, however, that with this sample, BAL was successful at activating clients, and this activation specifically led clients to find employment, relocate their addresses, or perhaps move away or back to their countries of origin. This is speculative.

The lack of follow-up data is an important limitation of the current study. It is a priority in depression treatment research to demonstrate not just acute improvements but an ability to prevent relapse and maintain gains over time (Hollon, Stewart, & Strunk, 2006), so any enthusiasm for BAL must be tempered until data on longer term effectiveness are acquired. Although BA in other contexts has performed well over time (Mazzucchelli et al., 2009), the current conclusion is that BAL’s performance with respect to follow-up is unknown and it may be the case that the circumstances of depression with low-income U.S. Latinos predict differential patterns of long-term outcomes. Future research, with more resources for ensuring successful follow-up retention with a relatively transient population such as low-income Latinos, is necessary.

The current study had several additional significant limitations. In general, because several methodological decisions were made to emphasize effectiveness and relevance of findings to community clinics, the limitations concern some resulting sacrifices with respect to internal validity (Wells, 1999). These limitations necessarily result in an inability to rule out some alternative explanations for our results. First, while a strength of the study was that the TAU controlled for many important confounds that are typically uncontrolled in TAU comparisons (e.g., treatment setting, treatment affordability, treatment availability, availability of consultation, and institutional reputation), it was still an unstructured TAU so it is difficult to characterize exactly to what BAL has been compared in this study.

Likewise, although therapists were randomly selected to receive either the BAL training or function as TAU, the small sample of therapists employed overall still limits our confidence with respect to claiming that the BAL therapists were fully equivalent with TAU before training and did not permit modeling of therapist effects. An alternative methodology that would have ensured that BAL and TAU therapists were fully equivalent before training would have been to employ a within-therapists design in which the same therapists provided both treatment conditions. Without this, we cannot state unequivocally that our results are not due to preexisting differences between therapists.

Second, training in BAL was kept to levels that were seen as reasonable for a community clinic, and no attempt to ascertain competence in specific BAL techniques was made before therapists began

treating study clients. This was done to prioritize making the results relevant to administrators of clinics faced with decisions about how and in what to train their therapists. However, this decision may have weakened our ability to fully implement our independent variable—Behavioral Activation—with full fidelity. It is possible that additional training in BAL, additional sessions, or identification and removal of therapists struggling to administer BAL with competence could have improved BAL outcomes. Furthermore, although the adherence measurement in the current study did suggest clear differences in primary techniques employed between BAL and TAU therapists, the limited number of sessions rated by the independent coder and the nonstandardization of TAU raises the possibility that unmeasured BAL techniques were employed at higher doses in TAU, and unmeasured violations of the BAL protocol occurred in BAL. Although unlikely (as therapists and administrators most likely would have heard about this due to the small community), it is also possible that clients obtained supplemental treatment outside the clinic during the study period and this supplemental treatment may have differentially influenced outcomes. Additionally, as stated above, treatment credibility and expectancies were not measured as part of this study and it is possible that differences in these variables between conditions influenced outcomes in favor of BAL as a more credible treatment approach. Finally, the internal consistency of the HRSD in the current sample (.63) raises a concern about the reliability and validity of our outcome measure, but the consistency of findings across measures tempers this concern somewhat.

Although this study employed several features of effectiveness research (Wells, 1999), it was underpowered to fully explore effectiveness outcomes and unable to fully utilize more appropriate statistical methods for the design given the small sample size and high dropout rates, so it is best seen as a pilot of a randomized BAL effectiveness trial. The findings are encouraging with respect to BAL being a viable tool for community clinics working with low-income Latino populations and merit a larger investigation.

Important additional future directions for this line of research include explorations of BAL's mechanism of action, possible moderators of treatment outcome, and the ease of dissemination of BAL. Regarding mechanisms and moderators, a key priority of this research was to keep modifications of BA to a minimum to ensure that BA's hypothesized treatment mechanism—specifically the scheduling of activities for clients to contact positive environmental reinforcement—remained intact. Adherence analyses, both objective and therapist-self-report, suggested

that BAL therapists successfully adhered to the treatment protocol and did not engage in anti-BA techniques. No analyses, however, of the relation between adherence, client change in levels of activation, and outcome have been conducted. It should be stated that no sophisticated mediator research in support of BA's mechanism has been published to date, so this is an important area for BA researchers, generally (Manos, Kanter, & Busch, 2010).

Exploration of moderators of treatment outcome is particularly important because of the nature of the current research that involved taking an empirically supported intervention and applying it in a context that is culturally distinct from the contexts in which the intervention gained empirical support. Specifically, because the TAU conducted in this study was a culturally sensitive approach (all of the therapists were bilingual, aware of Latino cultural values, and were working in a bilingual clinic in the Latino community), it is important to evaluate the degree to which cultural variables may have moderated outcomes in BAL versus TAU, and to explore the degree to which BAL may be beneficial across a very heterogeneous U.S. Latino population. In other words, we need to determine whether BAL is most beneficial and needs tailoring for population subsets.

Finally, research on the ease of dissemination of BAL is important given the priority for research to be relevant to community stakeholders and to have a pragmatic, positive impact on relevant community clinics. An initial promise of BA, in fact, was its ease of training and dissemination compared to other forms of cognitive-behavioral therapy (Kanter et al., 2012). The development of training approaches that are consistent with this promise, as well as research on the effectiveness of training and the impact of training approaches on client outcomes, is necessary.

Conflict of Interest Statement

The authors declare that there are no conflicts of interest.

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