**ABSTRACT** 

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SPANISH SPEAKING LATINOS

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Major depressive disorder (MDD) is highly prevalent among U.S. Spanishspeaking Latinos. Although MDD is very treatable, the lack of empirically-supported treatments precludes this population's access to quality mental health care. Following the promising results of a small open-label pilot study in which we tested the efficacy of Behavioral Activation Treatment for Depression (BATD) in a sample Latinos with Spanish-speaking preference, we conducted a randomized control trial (RCT; N = 46) that compared BATD (N = 23) to supportive counseling (N = 23) across various domains, including depression, BATD proposed mechanisms (activity level and environmental reward), and non-specific psychotherapy factors. Results indicated that relative to SC, BATD led to greater decreases in depressive symptoms over time (p =0.04) and greater MDD remission at the end of treatment and at the one-month followup (p = 0.01). Activity level (p = 0.01) and environmental reward (p = 0.05) showed greater increases over time among participants who received BATD compared to SC. Further, proposed BATD mechanisms of change did not correspond over time with depressive symptomatology. Treatment adherence, therapeutic alliance, and treatment

satisfaction did not differ between the groups (ps > 0.17). The one-month follow-up suggested sustained clinical gains across therapies. The current study adds to a limited treatment research literature and suggests that BATD, a time-limited and straightforward intervention, is efficacious in reducing depression and increasing activity level and environmental reward in this important, yet underserved population of the U.S. The current study sets the stage for a larger RCT to examine BATD against an empirically-supported treatment, with additional moderators of treatment and mechanisms of change.

# EVALUATING THE EFFICACY OF BEHAVIORAL ACTIVATION AMONG SPANISH SPEAKING LATINOS

By

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BDI-II.

### Chapter 1: Introduction

#### 1.1 Major Depressive Disorder

Major Depressive Disorder (MDD) is a highly prevalent affective disturbance across race and ethnicity (Kessler, Chiu, Demler, Walters, 2005). MDD is characterized by episodes of depressed mood and/or loss of interest in activities for at least two weeks or more (DSM IV TR, 2000). The core MDD symptoms consist of any combination of five criteria, including shifts in eating behaviors, weight or sleep, difficulty concentrating, decreased energy and changes in body movement activity, feelings of worthlessness or guilt, and recurrent suicidal ideation (DSM IV TR, 2000: 356). Suicide attempts or completions are the most severe consequence of a depressive episode (DSM IV TR, 2000). MDD has been estimated to be the primary cause of disability worldwide (Murray & Lopez, 1997), impairing physical, social, and economic life areas (Ciechanowski, Katon & Russo, 2000; Lustman, Clouse & Freedland, 1998).

#### 1.2 Rates of Depression among Latinos

Although depression is a highly treatable condition, disparities in mental health treatment have been implicated in preventing low-income, ethnic, and immigrant populations from accessing effective interventions (Blanco et al, 2007; Brown, Ahmed, Gray, & Milburn, 1995). Specifically, Latinos represent 16.6% of the US population, are the fastest growing minority group, (US Census Bureau, 2010), yet are less likely to utilize mental health services (Hu, Snowden, Jerrell & Nguyen, 1991; Wells, Klap, Koike, & Sherbourne, 2001). A report by Blanco and colleagues (2007) concluded that between 1993 and 2002, mental health-related visits decreased from 12.2% to 11.7%

among Latinos while it increased from 13.1% to 15.7% among non-Latinos. One plausible interpretation of these findings could be that during this decade the occurrence of MDD among Latinos was lower than for other groups, but such an explanation is contradicted by research suggesting that mental health morbidity is equivalent for Latinos. In fact, in the United States, the lifetime prevalence of MDD has been reported between 6-17% for the general population and between 3-18% among Latinos residing in the United States (Mendelson, Rehkopf & Kubzansky, 2008; Kessler et al., 2003; Vega et al., 1998). With the exception of a small number of studies suggesting that Latinos in the United States are twice as likely to experience depression relative to non-Hispanic White Americans (e.g., Alegria, Canino, Stinson & Grant, 2006; Oquendo et al., 2001), the majority of the literature indicates that there are no significant differences in the prevalence of the disorder between these groups (Dunlop et al., 2003; Kessler et al., 1994; Kessler et al., 2003).

However, when examining the occurrence of MDD within specific Latino subgroups, higher prevalence of the disorder has been observed in Latinas relative to White and African American women (Bromberger, Harlow, Avis, Kravitz, & Cordal, 2004; Shatell, Smith, Colwell & Villalba 2008) and in the last two decades, significant increases in the prevalence of suicide attempts among adult Latino males have been reported (Baca-Garcia et al., 2010). In a sample of 6,321 White non-Hispanics, English-speaking Latinos, and Spanish-speaking Latinos, Folsom et al. (2007) found the highest prevalence of MDD in the latter group. In earlier research, Muñoz and colleagues (1993) also found rates of current major depression to be as high as 25% in Spanish-speaking primary care patients, which is higher relative to the general population (Kessler et al.,

2003). Altogether, these findings highlight the pressing need for depression treatment delivery in this group.

#### 1.3 Depression Treatment Disparities among Latinos

As mentioned previously, treatment-related disparities often prevent proper care for minority groups (e.g., Department of Health & Human Services [DHHS], 2001). Psychosocial treatments for depression have been found to benefit Latinos; nevertheless, Latinos exhibit lower utilization of mental health services in comparison to other ethnic minorities and non-Hispanic Whites (Wells, Klap, Koike & Sherbourne, 2001), specially for Latinos who report a Spanish language preference (Keyes et al., 2012). Consistent with these disparities, a study of the quality of care for depression and anxiety disorders indicated that only 24% of Latinos received appropriate mental health care, compared to 34% of non-Hispanic White Americans (Young, Klap, Sherbourne & Wells, 2001). In the 1990s, it was reported that fewer than 1 in 5 Latinos born in the United States who suffered from mental health disorders sought help from general practitioners, decreasing to 1 in 11 who contact specialized mental health services (DHHS, 2001). These data are more indicative of poor utilization of services when specifically examining Latino immigrants, in which less than 1 in 10 individuals sought these services from general health practitioners and 1 in 20 from mental health professionals (Hough et al., 1987; Vega et al., 1999).

These striking statistics are further exacerbated by reports indicating that not only is there less access to mental health services for this group and that services are often delayed when available (Wells, Klap, Koike & Sherbourne, 2001), but that when service is actually delivered, it is substandard; Latinos who seek help for depression in

primary care settings are less likely to receive evidence-based depression care than non-Hispanic White patients (Young, Klap, Sherbourne & Wells, 2001). Subsequent research has indicated that Hispanics are more likely than non-Hispanic White clients to have persistent and recurring psychiatric disorders, suggesting inadequate treatment practices for this group (Breslau, Kendler, Su, et al., 2005). Common reasons postulated for these treatment inequalities are language barriers, the inability to afford the cost of services, and lack of culturally-congruent treatment services (DHHS, 2001).

1.4 Spanish Language Preferences as a Deterrent to Receiving Depression Treatment

In a population survey that examined the prevalence of psychiatric disorders in 3,012 respondents of Mexican origin, 33% of U.S. born adults indicated a language preference towards Spanish, rising to 64% and 75% for immigrant males and females, respectively (Vega et al., 1998). Another population survey showed that U.S. Latinos who preferred speaking in Spanish utilized mental health services at much lower rates than those who preferred speaking in English, controlling for controlling for ethnic subgroup, disorder severity, time spent in the US, and economic and practical barriers (Keyes et al., 2012). More recently, Aponte-Rivera and colleagues (2014) showed that Spanish-speaking Latinos had greater depression severity and reported a greater number of suicide attempts relative to English-speaking Latinos.

The importance of language is highlighted by reports suggesting that as many as 30% of Latinos report difficulty in communicating with health care providers in English (Vega, 2007). Moreover, as a result of English literacy requirement exclusions, Latinos have historically been highly underrepresented in both clinical and research samples (Miranda et al., 1996; Wells et al., 2001), leading to a paucity of mental health treatment

research within this population (Delgado et al., 2006; Schraufnagel, Wagner, Miranda & Roy-Byrne, 2006). Thus, it is not surprising that findings suggest higher rates of depression among Spanish-speaking Latinos relative to other ethnic groups given research indicating that language barriers promote Latinos' social isolation and limited access to health care, resulting in distress, low perceived self-efficacy, and higher depression prevalence (Ding & Hargraves, 2009; Woodward, Dwinell & Arons, 1992). Addressing language barriers is crucial given findings indicating that when disparities in both language and culture are reduced, Latinos' utilization of mental health services is similar to that of the general population (Alegria, Mulvaney-Day, Woo, et al., 2007; Cabassa et al., 2006).

Given the indication that a language barrier may be contributing to treatment disparities for an important subset of Latinos, research has examined the importance of providing therapy in the clients' native or preferred language. A meta-analysis suggested that interventions conducted in clients' native language (if other than English) were twice as effective as interventions conducted in English (Griner & Smith, 2006). This finding is consistent with research suggesting the psychological counseling should be conducted in clients' preferred or native language, which enhances their engagement in the therapeutic process and decreases the likelihood of being distracted by non-therapy related concerns, such as difficulty with pronunciation (Dwight-Johnson, Lagomasino, Aisenberg & Hay, 2004). Clearly, delivering efficacious treatment in clients' preferred language should be an important consideration for addressing the low retention rates in this group.

In addition to language preferences, well-established stigma fears associated with a depression diagnosis and its treatment are believed to play a fundamental role in the underutilization of mental health resources. Common fears include being negatively perceived by mental health professionals or believing that personal problems should not be disclosed to others outside the home (Alvidrez & Azocar, 1999; Edge & Rogers, 2005; Eisenman et al., 2008; Van Hook, 1999). In Latinas, stigma towards mental illness has also been identified as stemming from the fear of being perceived as "loca" or crazy (Collins et al., 2008; Pincay & Guarnaccia, 2007). Immigrant Latinas' reports of stigma towards mental health services are higher relative to non-Hispanic White American women (Nadeem et al., 2007). This is concerning given that in immigrant Latinas, stigma is predictive of decreased interest in receiving psychological services (Rastogi, Massey-Hastings & Wieling, 2012) and of treatment noncompliance, even after controlling for socioeconomic variables (Nadeem et al., 2007). Increased stigma has also been associated with less likelihood of disclosing depression to either family or friends (Vega, Rodriguez & Ang, 2010). Therefore, treatments that conceive depression as originating from external factors (i.e., individual's environmental context) in contrast to internal factors such as cognitions, or genetics have been proposed as more appropriate for this population (Kanter, Santiago-Rivera, Rusch, Busch, & West, 2010; Santiago-Rivera, Kanter, Benson, DeRose, Illes & Reyes, 2008).

#### 1.6 General Attitudes towards Depression Treatment

With the goal of reducing depression treatment disparities among Latinos, it is critical to first examine their general attitudes toward different types of mental health treatment. In general, Latinos' attitudes towards the use of medication for the treatment of depression have been predominantly negative. Findings by Cabassa and colleagues (2007) indicated that almost 50% of patients in their sample believed that using antidepressants would result in addiction and reported apprehension and ambivalence toward their use. Similarly, Cooper et al. (2003) showed that Latinos preferred antidepressant medication significantly less than non-Hispanic Whites. A comprehensive literature review regarding the use of antidepressants noted that depressed Latinos were more likely to be noncompliant than depressed non-Latino White Americans (Lanouette, Folsom, Sciolla & Jeste, 2009). Further, a study comparing adherence to medication treatment among a sample of Latino patients showed that those who described their English proficiency to be less than "good" or "excellent" were more likely to discontinue the use of antidepressants in comparison to their more proficient counterparts, even after controlling for relevant demographic and clinical variables (Hodgkin, Volpe-Vartanian & Alegría, 2007), which underscores the need for additional treatment options for this group.

Organista (2000) suggested that a possible reason for the overall resistance toward taking medication was that using pharmacotherapy would go against the much-valued belief of being able to "poner de su parte" (put effort or do their part) in this group (Interian et al., 2010; Pincay & Guarnaccia, 2007). Medication therefore, is thought of as interfering with the process of individual contribution to one's recovery. Given the current state of evidence and in order to promote treatment adherence and

prevent both treatment dropout and stigma related concerns, it may be more beneficial to focus on the use of effective psychosocial treatments with Latinos.

In fact, Latinos tend to endorse positive attitudes towards the psychosocial treatment for depression. Karasz and Watkins (2006) found that Latinos receiving treatment in primary health facilities expressed hope regarding the effectiveness of depression treatments available to them, including physician consultation, medication, but most of all, psychotherapy. Patients believed that physicians could most assist them through supportive talk, including advice, guidance, and comfort. Moreover, a sample of low-income, depressed Latinos perceived their depression as having a social or environmental origin (e.g., as caused as an emotional reaction to life stressors) or as a psychological problem (e.g., low self-image, low self-esteem). According to these beliefs, the study sample reported that depressed individuals would be more likely to benefit from psychotherapy and not antidepressant medication (Karasz, Sacajiu & Garcia, 2003).

In general, speaking intimately in a supportive setting was most commonly considered by Latino patients to be helpful for depression (Karasz, Sacajiu & Garcia, 2003). Research by Cooper et al. (2003) showed consistent results and further suggested that Latinos were more likely than non-Hispanic White individuals to regard counseling as acceptable. In another study, after being presented with a vignette of an individual experiencing depression, 75% of a Latino sample agreed that counseling would help restore this individual's functioning to a normal level (Cabassa, Lester & Zayas, 2007). Additionally, it has been reported that in comparison with non-Hispanic White

American women, immigrant Latinas are more likely to want treatment (Nadeem et al., 2007).

1.7 Attrition from Depression Treatments as another Source of Treatment Disparities among Latinos

The experience of barriers associated with the underutilization of mental health services mentioned previously may also lead to other complications that can hinder the process of informing effective depression treatment practices for Latinos. Although Latino patients have endorsed more positive attitudes toward psychotherapy overall, high treatment attrition rates remain problematic. Though scant, when treatment research has been conducted with Latino participants, attrition rates reported have been higher than those established for White non-Hispanic participants (Organista, Muñoz & Gonzales, 1994). In their CBT depression study, Organista and colleagues (1994) reported dropout rates of 58%. The authors speculated that such high attrition rates could be in part due to half of the sample having serious medical conditions. In other studies however, similar dropout rates have been evidenced. Miranda et al. (2003) reported only 32% of low-income minority women (approximately half of whom were Hispanic) attended 6 or more sessions of an 8-session CBT intervention. This pattern has also been observed in individual counseling settings, in which it has been estimated that 50% of Latino clients who seek these services do not return after the first session (La Roche, 2002; Sue, Zane & Young, 1994.; Walitzer, Dermen, & Connors, 1999). In general, attrition rates of Latinos from research studies are disproportionally large in comparison to reports ranging from 0% to 43% in the overall population across different psychosocial therapies (Cuijpers, van Straten, Andersson, & van Oppen, 2008).

Several studies have proposed different strategies to address the high dropout rates evidenced in these populations. In earlier research, Sue, Fujino, Hu, Takeuchi & Zane (1991), found that for clients whose primary language was not English, ethnic and language match was a predictor of length and outcome of treatment. In a more recent study, a trial comparing Motivational Enhancement Therapy (MET) and Counseling as Usual for Spanish-speaking substance users, 66% of participants (n = 405) completed the 3-session protocol. Reasons proposed by the investigators for the unusually high retention rates for this population included the delivery of services in Spanish, and the client-centered, collaborative-style of MET (a derivative of Motivational Interviewing) (Carroll et al., 2009). However, the low attrition rates could also have been attributed to the few treatment sessions required in this study. Further, in a pilot study (N = 15) that delivered a 12-session Spanish version of CBT for major depression to primary care Hispanic patients, only 4 participants dropped out, which the authors believed to be favorable in comparison to higher attrition rates reported in the literature. The researchers recommended understanding clients' unique cultural characteristics and hypothesized that retention and treatment success was a result of utilizing fluent, culturally-relevant Spanish and their various efforts in promoting treatment attendance, such as contacting clients at their scheduled appointment time if they had not arrived (Interian, Allen, Gara & Escobar, 2008). In general, addressing low retention in this group has shown to be crucial as revealed by reports that participants who remained in treatment significantly reduced their depressive symptoms (Miranda et al., 2003).

1.8 Depression Treatment Research Outcomes for Spanish-Speaking Latinos

Depression treatment studies that have included Spanish-speaking Hispanic samples are noticeably scarce, but a small literature suggests that CBT specifically is an efficacious treatment intervention for this group. In 1995, Muñoz and colleagues were the first to develop and evaluate a CBT depression manual for use in Spanish-speaking Latinos, further editing it in 2000 to incorporate sessions that placed an emphasis on interpersonal relationships (Muñoz et al., 1995). In their first trial, 45 impoverished Puerto Rican participants with low levels of education were randomized to either CBT delivered in group format, to treatment as usual, or to a medication group. Findings indicated that group CBT showed superior results in relation to the other treatments (Reyes, Vera, Bernal & Huertas, 2002 as cited in Bernal & Reyes, 2008).

Miranda and colleagues (2003) have also found evidence that CBT was effective in reducing depressive symptoms in a sample that consisted of mostly low-income, young, Latinas. In their study, they compared the effectiveness of traditional cognitive-behavioral group therapy and the same therapy with a supplemental case management for impoverished Latina medical outpatients. The Spanish- and English-speaking patients in this sample responded equally well to cognitive-behavioral therapy alone (Miranda et al., 2003). In another study, Lara, Navarro, Rubí, & Mondragón (2003) recruited participants in Mexico to evaluate the effectiveness of a 6-week psychoeducational group approach and a one-time individual orientation that also included psychoeducational material. The researchers saw an overall reduction in depressive, anxiety, and somatic symptoms in both conditions. Further, in a sample of 5 Latinas, Gelman et al. (2005) saw a significant reduction in depression scores after a 12-session CBT intervention. Finally, in a sample of low-income African American (*n* =

117), White American (n = 16), and Spanish and English-speaking Latina women (n = 134) with mild to moderate depressive symptoms, Miranda et al. (2003) found that treatment gains of 6-month pharmacotherapy and 8-week CBT (but not for the control group that consisted of providing community referrals) were sustained as indicated by a 1-year follow-up. More than 50% of participants who completed at least 6 weeks of CBT did not endorse criteria for depression at the year follow-up. Despite the encouraging results, authors have discussed disparities in mean reductions of depressive symptomatology in Latinos relative to those evidenced in non-Latino White samples, which have been hypothesized to occur as a result of early termination of therapy (Interian, Allen., Gara & Escobar, 2008). In fact, research has suggested that Latinos who remain in treatment evidence significant reductions in depressive symptoms (Miranda et al., 2003).

Recommendations to Increase the Likelihood of Retention and Positive Outcomes

The lower reductions in depressive symptomatology and its close association with high attrition rates reported in this group relative to the overall population indicate the need to consider Latinos' preference toward mental health services prior to the implementation of psychosocial treatments for depression. Miranda (1976) and Gelman (2004) advocated for short-duration treatments that provide direct problem-focused guidance given the various life circumstances that require immediate attention in this group. A second consideration is to utilize treatments that are in accordance with the view of "poner de su parte" which was introduced in a previous section. Among this population it is considered favorable to put effort into one's recovery by being an active participant of the therapeutic process (Organista, 2000). A third consideration is the role

of stigma toward mental health treatment, which has been frequently recognized as an important deterrent toward seeking services among Latinos (e.g., Vega, Rodriguez & Ang, 2010) and cause of attrition (Sirey et al., 2001). Evidently, treatments that reduce stigma should be selected. For example, interventions that explain depression as a result of individuals' internal processes contribute to this stigma and to the fear of being perceived as "crazy" (Collins et al., 2008; Pincay & Guarnaccia, 2007) among Latinos. A final consideration in selecting treatments to address the mental health needs of this group is that Latinos comprise various subgroups-each reflecting a complex combination of individual cultural patterns and values. As a result, a treatment approach that allows for individual tailoring, that is, one which utilizes idiographic treatments aimed towards accommodating personal values on a case-by-case basis without global, culturallyspecific modifications, may be best suited to address the depression care needs of this population. The use of such treatments could potentially address key issues pertaining to generalizability when individuals do not share characteristics identical to the clients for whom the intervention was validated. As a result of Latinos' high within-group heterogeneity, this is a particularly important strength of interventions allowing individual tailoring.

may be especially well-received by Latinos as such approaches often exemplify the valued-belief of being able to do their part in one's recovery ("poner de su parte"; Organista, 2000).

Support for a focused behavioral treatment was first provided by Comas-Diaz (1981) who evaluated the efficacy of group-format behavioral therapy, group-format cognitive therapy, and a waitlist control was assessed in a small sample of Latinas (N =26). Study results showed a 64% and 51% mean reduction of depressive symptoms for those assigned to cognitive therapy and behavioral therapy, respectively. Both of these treatments demonstrated superior results relative to the waitlist control group, and comparable results to each other in reducing depressive symptomatology. Nonetheless, treatment gains did not persist at a 5-week post-treatment follow-up assessment for those randomized to cognitive therapy, but maintained for participants in the behavioral therapy condition. The author posited that participants sustained improvement in the behavioral treatment condition as a result of scheduling rewarding activities. Moreover, Comas-Diaz (1981) indicated that through scheduling rewarding activities, participants were able to perceive control over everyday situations in contrast to the lack of control that minorities often experience when confronting marginalizing experiences, including poverty and racism. In fact, behavioral treatments may be especially well-received by Latinos as such approaches often exemplify the valued belief of being able to do their part in one's recovery ("poner de su parte"). In particular, a behavioral treatment that has received wide empirical support in the general population, and more recently, demonstrated promise in depressed Spanish-speaking Latinos is Behavioral Activation.

#### 1.10 What is Behavioral Activation?

The theoretical framework of Behavioral Activation (BA) is based on the principles of learning theories, for which positive and negative reinforcement play a significant role. BA conceptualizes depression as originating from a lack of positive reinforcement for healthy, nondepressive behaviors (Ferster, 1973; Lewinsohn, 1974; Skinner, 1953), while being maintained by sources of positive reinforcement towards unhealthy, depressive behavior (e.g., receiving sympathy from others) as well as through negative reinforcement, such as avoiding unpleasant situations or responsibilities (Lewinsohn, 1974).

According to the BA model, by decreasing engagement in pleasant activities, depressed individuals create an environment deplete of positive reinforcement possibilities (MacPhillamy & Lewinsohn, 1974). Lewinsohn and Graf's research (1973) suggested a negative association between depressed mood and frequency of pleasant activities. More recently, research has also suggested that decreased environmental reward is significantly associated with depression (Carvalho, Trent, Hopko 2011). Therefore, through BA, clients learn to schedule positive healthy activities and monitor their respective mood. It is expected that there will be a proportional increase between the frequency of pleasant activities in which the individual engages and positive interactions with their environment, resulting in elevated mood and subsequently, in improvements in cognitions (Hopko, Lejuez, Ruggiero & Eifert, 2003).

In a randomized controlled trial conducted by Jacobson and colleagues (1996) three components of CBT were evaluated to determine the contribution of each in treating depression. The components were: 1) the behavioral activation part of CBT

(BA), 2) BA in addition to skills training, which are thought of as assisting in modifying dysfunctional automatic thoughts (AT), and 3) the full cognitive behavioral treatment, which included the two previous components in addition to addressing core beliefs and the schema associated with depression. The authors concluded that contrary to previous hypothesized outcomes, no one treatment was more effective than the others. In addition, when examining the purported mechanism of change for the full cognitive behavioral treatment (i.e., change in negative attributions), the authors reported that all groups showed equal improvement in negative attributions as those who received the intervention component specifically aimed at modifying cognitive structures. In addition, for those assigned to receive BA, fewer negative cognitive attributions early during treatment predicted more improvements in depression relative to those with more negative cognitive attributions. A 6-month and 2-year follow-up of this seminal study indicated sustained progress of the interventions (Jacobson et al., 1996; Gortner et al., 1998). This seminal study provided evidence for a parsimonious version of CBT and against the necessity to directly address dysfunctional thinking with additional cognitive components.

In a subsequent randomized trial consisting of 241 depressed adults, participants were randomly assigned to one of four treatment conditions: BA, CBT, antidepressant medication or a medication placebo (Dimidjian et al., 2006). BA and the antidepressant medication were most effective for moderately to severely depressed patients but as effective as the other interventions for mildly depressed patients. However, those randomized to BA sustained progress and remained in treatment longer than those randomized to antidepressant medication.

Currently, two major BA approaches are widely used. One of these approaches was proposed by Jacobson, Martell and Dimidjian (2001). The other major approach was developed by Lejuez and colleagues (2001; 2011) and is referred to as the Brief Behavioral Activation Treatment for Depression or BATD, for short. In contrast to the intervention developed by Jacobson and colleagues (2001), BATD offers a more behavior-based treatment; the treatment model does not employ practices that are associated with other psychosocial treatment approaches, including cognitive rehearsal (e.g., Jacobson et al., 1996), skill building, such as assertiveness and communication skills (e.g., Jacobson et al., 1996), mindfulness (e.g., Dimidjian et al., 2006; Coffman, Martell, Dimidjian, Gallop & Hollon, 2007), or exposure to situations that the client would usually avoid. In addition, BATD consists of 10 sessions, more than half the number traditionally required by the BA approach utilized by Jacobson et al. (2001). BATD has been described as being more efficient, less costly and more straightforward than the other BA approach (Barraca Mairal, 2009; Hopko, Lejuez, LePage, Hopko & McNeil, 2003). Therefore, the specific BA approach has been described as highly practical (Barraca- Mairal, 2009) and suggests the particular utility of BATD in Latinos with Spanish-language preference. In addition, BATD has been identified as a treatment suitable for the incorporation of clients' ideographic needs which is optimal given the high within-group heterogeneity of US Latinos, which was outlined in a previous section (for a more extensive review of the differences between the two BA techniques, please see Barraca Mairal, 2009 and Hopko et al., 2003).

Further supporting the use of BATD its efficacy has been established with a variety of samples, including patients in a community mental health center (Lejuez,

Hopko, LePage, Hopko, & McNeil, 2001), patients in an inpatient psychiatric facility (Hopko, Lejuez, LePage, Hopko, & McNeil, 2003), as a supplemental intervention for patients with coexistent Axis II disorders, (Hopko, Sanchez, Hopko, Dvir, & Lejuez, 2003), and cancer patients (Hopko, Bell, Armento, Hunt & Lejuez, 2005).

To date, 4 meta-analyses have revealed the effectiveness of BA approaches broadly including BATD specifically in treating depression. Cuijpers, van Straten, Warmerdam (2007) found that pleasant activity scheduling was superior to other psychological treatments and equal to the full CBT at end of treatment and follow-ups, reporting an effect size of 0.87. A later meta-analyses conducted by Ekers, Richards, and Gilbody (2008) included 17 studies and concluded that BA was superior to controls, brief psychotherapy, supportive therapy, and equal to CBT. These results were confirmed by a more recent meta-analysis that compiled 34 studies and explored whether more complex versions of BA accounted for more variance in comparison to more parsimonious versions of the approach (Mazzucchelli, Kane & Rees, 2009). In this recent meta-analysis, BA also showed superiority to control conditions in addition to suggesting that the variants of BA did not differ significantly from each other (*p* = .23).

#### 1.11 Use of Behavioral Activation in Spanish-Speaking Latinos

Following the work of Comas-Diaz (1981) two decades earlier, Kanter et al. (2010) developed a culturally-modified version of BA in Spanish from the original approach proposed by Jacobson et al. (2001). The researchers conducted an initial evaluation of the culturally adapted version of BA in an open-label trial pilot study with 10 Latinas. In this version of BA, in addition to scheduling pleasant activities, clinicians

utilize cognitive rehearsal, skill building, mindfulness, exposure to activities for which avoidance is displayed, and role-playing. As part of their modified treatment, Kanter's team indicated simplifying the treatment rationale and paying close attention to values commonly attributed to Latinos that would affect the course of treatment. Among these values was the centrality of family in individuals' lives ("familismo"), the establishment of differential matriarch and patriarch roles ("machismo" and "marianismo"), and sympathy in daily interactions ("simpatía"). During the treatment for example, therapists requested that clients integrate their family members into the treatment by having them attend the sessions with them (Kanter et al., 2010). The evaluation indicated a significant decrease in depression severity on the Beck Depression Inventory-II at post-treatment which represented a large effect size (d = 1.67). Additionally, there was a significant reduction in depressive symptoms for the intent-to-treat sample that also indicated a large effect (d = 1.07). Although the authors posited that BA's effectiveness was possibly a result of the cultural modifications, a lack of a comparison group prevented empirical support to this statement. Despite the promising results, retention in this study was low: only 3 clients completed the 12-session treatment. The authors noted that the rate of session attendance was high in comparison to other psychosocial depression interventions delivered at the same mental health facility. The authors attributed the relative success of retention rates to the treatment's simplicity and straightforward rationale, which compared to CBT have been regarded as easier to explain and to implement into clients' daily lives (Hollon, 2000). Among other study limitations of this trial were the inclusion of only female participants, no examination of the BA proposed mechanisms of change, a lack of follow-up data, and no systematic evaluation for

guiding the cultural modifications they performed to the original BA manual (Kanter et al., 2010). Recent work by Kanter and colleagues (in press) supports the efficacy of this culturally-modified BA. The authors conduced a RCT between BA (n = 21) and an unstructured treatment as usual (TAU) condition (n = 22) among monolingual Latinos. The authors reported that people in the BA condition completed more sessions than those in the TAU condition. Further, there was a significant session by treatment by time interaction (p = 0.05) such that participants who completed more sessions of BA showed greater improvements in depression. Limitations of the study include the lack of examination of proposed BA mechanisms, the unstructured and unspecified nature of the TAU condition, and the examination of mean score values as opposed to individual change over time.

1.12 Rationale for Using (BATD) as a Treatment among Spanish-Speaking Latinos

Although Kanter and colleagues (2010; in press) provided promising evidence for BA, there are several reasons to consider BATD in the treatment of depression among Latinos with Spanish language preference. The first reason is that BATD's idiographic nature may allow the incorporation of individuals' unique personal values. The process of value identification and subsequent activity selection is entirely client-directed and focused; with the help of the therapist, the client identifies important life areas (e.g., relationships), values within those life areas (e.g., be an involved parent), and activities in which the client can engage that are congruent with those values (e.g., attend the child's extracurricular activities). Therefore, the therapist does not make any assumptions as to the individual's values. This may be an especially important feature of BATD to implement within Latinos in the US, given the high degree of within-group

heterogeneity characterizing this group. Latinos represent over 20 countries, each embedded within different sociocultural contexts and histories. As such, BATD strikes an appropriate balance in maintaining cultural sensitivity by tailoring treatment to diverse cultural groups while providing for attention to individual differences.

An additional reason for considering BATD as a potentially beneficial depression treatment within this group is that it has shown great potential in reducing the likelihood of drop-outs in underserved minority samples facing similar problematic retention rates, treatment seeking challenges, and treatment utilization disparities as US Latinos (e.g., Fortuna, Alegria & Gao, 2010; Alegria et al., 2002; Kanter et al., in press), while also decreasing depressive symptomatology (Daughters et al., 2008; Magidson et al., 2011). BATD is also able to accommodate the needs of low-literacy clients through modified treatment materials (Lejuez et al., 2011) that address the needs of a variety of clients belonging to diverse educational backgrounds.

Collectively these characteristics suggest BATD may be a culturally-relevant treatment in that it is 1) accessible, 2) congruent with the client's cultural values, thereby acknowledging individual differences among subgroups, and 3) inclusive of the client as an active participant of his or her intervention development (see criteria by Muñoz & Mendelson, 2005 as cited by Comas-Diaz, 2006; Rogler, Malgady, Costantino & Blumenthal, 1987). Based on these reasons Collado and colleagues (2013) evaluated the BATD in an open-label trial with 10 Latinos who lacked English language proficiency and self-reported a Spanish-language preference.

1.13 Preliminary Outcomes of the Open-Label Trial of BATD with Spanishspeaking Latinos

The open-label trial conducted by Collado and colleagues provided initial evidence suggesting the promise of BATD in treating depression in this group. Hierarchical Linear Model analyses revealed that over the course of the treatment, depressive symptomatology decreased ( $\beta = -1.64$ , SE = 0.21, p < .001) and the proposed BATD mechanisms, activity engagement ( $\beta = 1.91$ , SE = .0.79, p = .04) and environmental reinforcement ( $\beta = 0.45$ , SE = .16, p = .02) increased. Effect sizes for these clinically-relevant variables pre- and post-treatment ranged from medium to large (d's = 0.50-1.45). Further, increases in activation corresponded concurrently with decreases in depression ( $\beta = -0.14$ , SE = 0.04, p = .01), such that while activation increased, depression decreased simultaneously. On the other hand, environmental reinforcement predicted decreases in depressive symptomatology ( $\beta$ = -0.26, SE= 0.11, p =.04), such that when environmental reinforcement increased, depressive symptomatology decreased in the subsequent session. In addition, paired t-tests revealed sustained clinical gains in depression and activation (p > .05), and an increase in environmental reinforcement at the one-month follow-up (t = -2.63, df = 7, p = .03). Of note was that treatment adherence and attendance were high in this small sample; eight participants completed all treatment sessions, and the remaining two participants completed 4 sessions. Those who completed treatment did so between 10 weeks and 13 weeks. Mean percentage rate of homework completion was 86.54 %, exceeding rates observed in the literature (e.g., Floyd et al., 2004). Further, in-depth interview results also conducted at the one-month follow-up suggested high levels of treatment acceptability and did not suggest the need for specific changes to BATD's content, cultural or otherwise.

1.14 Extensions to the Preliminary Study of BATD with Spanish-speaking Latinos

Although the preliminary findings of BATD delivered to a small sample of Latinos with Spanish-speaking preference were positive, the study had several limitations, primarily consisting of a small sample size, lack of a contact-time matched control, and the utilization of elevated depressive symptoms rather than MDD as inclusion criteria. In fact, in their publication, Collado and colleagues specifically called for the inclusion of all of these components in future work. First, a control group would enable further investigation as to whether the observed beneficial effects of BATD on depressive symptomatology and proposed treatment mechanisms could not be better explained by increased individualized attention that clients received or other nonspecific therapy-related factors. With a larger sample size as a study extension, sufficient power to detect significant changes as a result of participants undergoing treatment would be made possible. Finally, the inclusion of an MDD diagnosis for study eligibility would allow for determining the efficacy of the intervention in treatment of clinical depression. This is an important extension given that BA has been found to be most effective for moderately to severely depressed patients but as effective as the other interventions for mildly depressed patients (Dimidjian et al. 2006). Therefore, an extension of Collado and colleagues' preliminary study would continue to establish the efficacy of the BATD intervention programmatically (e.g., Carroll & Nuro, 2002) in treating depression in Latinos whose preferred language is Spanish.

Thus, the current study involved a randomized controlled trial (RCT) with 46 depressed Latinos in the community who report a preference of Spanish language randomized to BATD (n = 23) or to Supportive Counseling (SC) (n = 23). To our

knowledge, this constitutes the first effort toward conducting a RCT comparing a behavioral intervention to SC with a sample consisting solely of Latinos in the US who report Spanish language preference. This is a sample that has been historically underrepresented in both clinical and research samples (Miranda et al., 1996; Wells et al., 2001).

The study consisted of three main aims. The first aim was to compare the BATD Spanish translation and a SC condition on participants' levels of depression. The second aim compared group differences on the proposed mediators of BATD, including activation and contact with environmental reinforcement. The third aim examined SC and BATD group differences on key conceptually-relevant variables associated with treatment completion and outcomes in Latinos, such as treatment satisfaction (e.g., McCabe et al., 2009), therapeutic alliance (e.g., Añez, 2005), and perceived stigma (e.g., Sirey et al., 2001). These variables have shown to affect treatment outcomes and retention in this population. In addition, dropout rates were compared between conditions in the context of the third aim.

For the first aim, we expected that participants randomized to BATD would evidence greater reductions in depressive symptoms and a higher percentage remission of MDD relative to participants randomized to the SC condition throughout treatment course at a one-month follow-up. In the second aim, we hypothesized that participants assigned to the BATD condition would evidence greater increases in activation and contact with environmental reinforcement relative to those assigned to the SC condition over the course of treatment and at the one-month follow-up. We also expected increases

in activation and contact with environmental reinforcement to correspond with decreases in depression.

Finally, as part of Aim 3, we expected that relative to participants assigned to the SC condition, participants randomized to BATD would evidence higher treatment satisfaction over treatment course. This outcome is hypothesized given the heavy emphasis of BATD on putting effort into one's recovery from depression ("poner de su parte"), a treatment expectation highly valued in this population (e.g., Cabassa et al. 2007; Organista 2000). Further, we hypothesized greater therapeutic alliance in the BATD condition given the collaborative approach expected to emerge between the client and the therapist in this treatment condition (Lejuez, Hopko, Levine, Golkhar & Collins, 2006). We also hypothesized that as a result of BATD's conceptualization of depression as originating from the lack of environmental reinforcement, perceived stigma levels would decrease relative to the SC condition over the course of treatment. Finally, we expected that treatment retention would be greater in the BATD condition than in the SC condition based on previous findings suggesting this trend (e.g., Daughters et al., 2008; Magidson et al., 2011).

## Chapter 2: Method

#### 2.1. Overall Design

Forty-six depressed Latinos from the community who reported a preference toward Spanish language were randomized to receive individual BATD (n = 23) or an individual contact time-matched SC condition (n = 23). This design allowed the examination of treatment group differences in depression, activity level and contact with environmental reward, treatment adherence, treatment satisfaction, perceived stigma toward receiving depression treatment, and therapeutic alliance between conditions which comprised our first, second and third aim.

#### 2.2. Recruitment

Participants (*N* = 46) were primarily recruited from the District of Columbia Metro area, including Montgomery and Prince George's counties in Maryland. The current Latino population in the DC Metro Area was estimated to be 700,000, in 2010, an increase of 62% from the previous decade (Fraga et al., 2010; U.S. Census Bureau, 1990; U.S. Census Bureau, 2000). Recruitment followed a similar pattern as the open label trial that served as basis for the proposed study. Specifically, participants were recruited through various community organizations that served predominantly low-income Spanish-speaking Latinos, flyers, and radio stations for the Spanish-speaking community of the DC Metro area. Flyers were posted in grocery stores, bus stops, public libraries, and community centers. Authorization was sought prior to the distribution of recruitment materials to be in accordance with all local and national laws, as well as with the guidelines of the University of Maryland Institutional Review Board (IRB).

#### 2.3. Procedures

Initial eligibility was determined via a telephone screener, which included questions from the Mood Disorders, Substance Use and Dependence, and Psychotic Disorders modules of the Structured Clinical Interview for DSM-IV-TR (SCID-IV; First, Spitzer, Gibbon & Williams, 2002). Inclusion criteria consisted of the following:

1) be a minimum of 18 years of age, 2) be of Latino descent, 3) self-report Spanish-language preference, 4) meet current MDD criteria, 5) have completed the 4<sup>th</sup> grade or higher either in their country of origin or in the US, 6) not have current substance abuse or dependence, 7) have no Bipolar or Psychotic Disorders, and 9) not be currently receiving psychotherapy, and 10) if currently taking antidepressants, demonstrate pharmacological stability as indicated by 3 or more consecutive months of use.

Excluded individuals were referred to mental health resources within the community.

After a participant was deemed eligible over the telephone, he or she was provided with a brief description of the study and participation. Participants were then scheduled for an appointment at the University of Maryland's Center for Addiction, Personality, and Emotion Research (CAPER) to complete the baseline assessment and to attend the first BATD session. Participants were informed over the telephone that final eligibility would be determined at the baseline session.

When participants attended the first session to complete the assessments, a research assistant (RA) fluent in Spanish greeted them at CAPER. At the beginning of the appointment, the RA reviewed study procedures, answered any questions regarding the study, and obtained verbal informed consent. Ms. Collado was available to answer questions about the treatment, if needed. Along with the verbal informed consent which

was approved by the IRB, participants were informed about the certificate of confidentiality obtained with the purpose of protecting any identifiable information they provide during the treatment from forced disclosure. Of particular concern was protecting participants' immigration status, whose disclosure could potentially result in adverse legal consequences. After providing verbal informed consent, a member of the staff trained in administering the *SCID-IV*, administered the Mood Disorders, Substance Use and Dependence, Psychotic Disorders, and Anxiety Disorder modules of the Interview to confirm eligibility for the study and characterize the sample's psychopathology appropriately. *SCID-IV* interviews were audiotaped and uploaded to a password protected database so that the diagnostic reliability of 20% of all SCID-IV interviews could be assessed. The recording was erased within a week, after the reliability check was conducted.

Participants did not receive monetary compensation for attending therapy.

However, they earned \$15 for completing questionnaires at the baseline assessment (conducted immediately prior to session 1), at the end-of-treatment assessment (conducted immediately prior to session 10), and at the follow-up assessment (conducted one month after session 10). Participants earned \$10 for the remaining scheduled assessment points, with an additional \$5 for transportation at each time point.

Participants were only paid for the assessment points that they completed.

In the case that participants were not eligible for the study during the baseline assessment, they were paid for this meeting. These participants were provided with mental health referrals in the community. Those who did qualify for the study were asked to complete Spanish-language questionnaires in a private room, with the option of

completing the questionnaires by themselves or being read the questions by the research staff. The completion of the assessments during the first and last meetings took up to 70 minutes, and up to 30 minutes for the remaining meetings. After their completion, participants were compensated.

A staff member not involved in the study conducted the randomization using a computerized random number generator and informed the participant's therapist of the assigned therapy condition in person. We used a randomized block design for gender. Each research assistant that conducted assessments was blind to participants' assigned treatment condition. Blinding was facilitated by the fact that participants completed identical assessment measures regardless of their assigned condition throughout the course of the study. This removed any need for research assistants to be informed about participants' randomization outcome. Therapy commenced thereafter, and therapy sessions lasted approximately 60 minutes.

## 2.4. Overview of the BATD

The current trial utilized the most current version of the Spanish BATD manual (Lejuez et al., 2011; Maero et al., unpublished). As outlined in the manual, the first session of BATD focused on providing depression psychoeducation, reviewing the treatment's rationale, discussing the importance of monitoring daily activities, describing session attendance policies and stressing the importance of attending every session weekly, and explaining the relationship between treatment adherence and the likelihood of treatment success. Starting in the first session and continuing until the end of treatment, the homework assignment focused on participants monitoring their daily

activities until the subsequent session and reporting a numerical rating of both enjoyment and importance for each activity completed.

The second BATD session consisted of briefly reviewing the content of the previous session, discussing activities completed as well as the ratings of enjoyment and importance, making use of the completed daily monitoring record forms, and assessing any difficulties associated with homework completion. The remainder of the second session was devoted to a thorough discussion of life areas (e.g., relationships) and corresponding values (e.g., be a caring husband) important for participants, with the purpose of selecting activities consistent with these values in future sessions (e.g., taking spouse on monthly dates)

During the third session, participants worked on selecting at least fifteen activities they considered rewarding (taking into consideration both expected enjoyment and importance) that are consistent with life areas they deemed important and their expressed personal values. These could constitute activities already a part of the participants' schedule or new activities. Participants proceeded to rank the activities in terms of difficulty such that they completed easier activities toward the beginning of treatment and progressed towards more challenging activities. From the fourth through the tenth sessions, participants worked toward accomplishing three to five activities on their list that reflected their values.

Specific to session 5, participants were introduced to "contracts", which provided the opportunity to request assistance from friends and family in order to accomplish selected activities because the activity is challenging for participants or because company may potentially increase the "enjoyment" and "importance" of the activity. Of

note is that discussing contracts with individuals from a supportive network did not require that participants disclose they are seeking depression treatment or sign any document; rather, participants could simply ask these individuals to join them in completing the specific activity.

No new material was introduced beyond this point. Sessions 6 through 10 consisted of continued engagement on meaningful activities and daily monitoring, as well as of discussions of an individualized post-treatment plan within a behavioral activation framework of scheduling activities corresponding to participants' values and drafting "contracts" with people in their support network. Throughout treatment, depressogenic and non-depressogenic patterns were identified with the assistance of the monitoring forms and ratings of enjoyment and importance.

## 2.5 Overview of SC

To control for the non-specific elements of therapist contact, half of the clients received SC. The SC manual was modeled after Novalis, Rojcewicz and Peele (1993). SC did not follow a clearly defined theoretical model and was best described as offering the client support. The discussion for each session was patient-driven, and the manual included training in therapy using SC techniques including reflections, empathic listening, encouragement, help in feelings and experiences exploration and expression, without advice-giving, solution-offering or skills-acquisition. The manual was organized in a way that reviewed the basis for supportive psychotherapy, the meaning of establishing a supportive relationship, steps for beginning the therapy session, session management, crisis management, and ethical factors in supportive psychotherapy.

Therapists were trained in these procedures, in using non-directive techniques and in

avoiding BATD techniques. These topics were covered in different chapters within the manual. Features such as the use of a therapist manual (with discussion topics) and journal writing homework forms were incorporated into SC. Further, each session ended with one of three relaxation exercises: progressive muscle relaxation, visual imagery, and breathing retraining. Amount of homework assigned was matched with BATD. Clients were asked to write one entry each day about any feelings that they were experiencing.

## 2.6. Therapists and Research Staff

A CAPER research assistant, two volunteer research assistants, and Ms. Collado, all of whom have native Spanish fluency and training in administering the *SCID-IV*, administered the semi-structured interview and conducted weekly assessments. In every case, *SCID-IV* interviewers were different from the therapist assigned to the client. All RAs were supervised by Ms. Collado. Therapists for the proposed project consisted of five post-baccalaureate research assistants, a master's level graduate student, and two graduate students from CAPER, including Ms. Collado. All therapists had fluency in Spanish. Given the differing degrees of clinical training among the therapists, randomization across conditions took place to control for therapist effects. Under the supervision of Drs. Lejuez and MacPherson (Dissertation Proposal Co-Chairs), Ms. Collado was responsible for therapist training. Weekly clinical supervision was provided by Ms. Collado and Ms. Long, both advanced graduate students who have received extensive training in implementing BA and supportive therapies. Spanish manuals for both conditions were used at all times to ensure standardization of treatment.

## 2.7. Therapist adherence, fidelity, and competence

Treatment integrity, fidelity, and competence were a priority. Therapists received extensive training and supervision. All therapy sessions except for five (due to logistical errors) were audiotaped. Therapy tapes were rated by an independent rater (e.g., a Spanish Speaking RA not working with the client from the pool of three study research assistants) to assess therapist adherence and competence with the treatment protocol, using separate rating checklists and scales developed by Ms. Collado for the SC and BATD conditions for 20% of audiorecorded sessions. Therapists also self-reported their adherence for each session across conditions. Ms. Collado listened to every session and provided feedback to each therapist in the weekly, two-hour supervision meeting.

Therapists self-reported that they were completely adherent to SC and BATD. Independent rating indicated that therapists were strongly adherent to the respective treatments to which they were assigned. Therapists demonstrated a 96.7% adherence to BATD therapy. Deviations were due to not having enough time within the 60-minute treatment to discuss specific components of BATD. Any missed components of BATD were discussed during the following session. Adherence tests for SC were also high (97.4%) with the exception of four sessions in which there was one deviation noted. In two of these sessions, participants raised the possibility of engaging in activities to overcome depression (a topic closely related to BATD) and the therapist continued this discussion. In the remaining two sessions in which a deviation occurred, the therapist made a reference to participant values (a main component of BATD). All of these treatment divergences were discussed with the respective therapists individually and were discussed during group supervision.

#### 2.8. Materials and Measures

In line with our study aims, questionnaires were selected to assess five principal domains. The first domain focused on participants' characteristics including their demographic information, English language proficiency, current antidepressant use, immigration status, acculturative stress, income, and depression treatment history. These variables were treated as covariates in the case that they were related to our main treatment outcomes (depression, activation, and/or contact with environmental reinforcement). To measure the second domain, we utilized a self-report assessment and a semi-structured clinical interview to identify individuals' depressive symptomatology and MDD diagnosis, respectively for the study duration. The third domain of interest consisted of measuring the extent of clients' activation and their receipt of positive reinforcement from the environment. To assess the fourth domain we examined treatment attendance. The fifth domain of assessment consisted of measuring clients' attitudes toward treatment. Within this domain we explored clients' perceived therapeutic alliance, treatment satisfaction, and stigma associated with depression treatment.

Table 1 offers a summary of the questionnaires that were used, the domain that was assessed, and the time-point at which these were administered.

## Domain 1- Participant Characteristics

General Information: A standard demographics questionnaire used at CAPER and also used in the preliminary trial was modified to include items regarding participants' education, income, years of residence in the United States, depression

treatment history, level of English language proficiency, immigration status, and reason(s) for immigrating (if applicable).

Multidimensional Acculturative Stress Inventory (MASI; Rodriguez et al., 2002): Originally created to measure acculturative stress from living in the United States for individuals of Mexican origin, the scale is comprised of four subscales including English Competency Pressures (7 items), Pressure to Acculturate (7 items), Pressure Against Acculturation (4 items), and Spanish Competency Pressures (7 items). Given the non-applicability of the last subscale for the current sample, we only used the first three subscales. Higher scores indicate greater stress. The Spanish version of the questionnaire has achieved Cronbach alpha values ranging from .74 to .91. Cronbach's alpha for the MASI in the current study was .73.

Medication use: To determine study eligibility and the potential effect of pharmacotherapy or other medications on the results of the treatment, we collected information on participants' medication use, including the names and length of use. Participants were excluded from the study if they were taking medication but did not demonstrate psychotropic stability as indicated by three or more months of consistent use. Two people in the study were taking medication for the treatment of depression over the course of treatment and follow-up.

## Domain 2- Depressive Symptomatology

For diagnostic inclusion as well as to identify depressive mood variations through the study trial, we utilized the *Beck Depression Inventory-II (BDI-II*; Beck, Steer & Brown, 1996). The inventory consists of 21 items that assess severity of depressive symptomatology. *BDI* cumulative scores range between 0 and 63; scores

ranging between 14 and 19 are indicative of mild depression, scores between 20 and 28 are indicative of moderate depression, and scores of 29 or above are indicative of severe depression. The Spanish version of the *BDI-II* was developed by Sanz, Perdigón & Vázquez (2003) and was evaluated with a sample of 470 Spanish community adults. Internal consistency for the *BDI-II* in the current study ranged from .86 to .91 across all sessions and the one-month follow-up.

Additionally, to establish an MDD diagnosis and evaluate remission rates, we administered the *Structured Clinical Interview for DSM-IV* (*SCID-IV*, non-patient version; First, Spitzer, Gibbon, & Williams, 1995). For the current study, specific modules of the *SCID-IV* were used to assess for: 1) primary affective disorders, including major depression and manic episodes, 2) substance use disorders, including abuse and dependence, 3) primary anxiety disorders, including panic disorder, generalized anxiety disorder, and posttraumatic stress disorder, and 4) and psychotic symptoms.

Domain 3- Behavioral Activation and Reinforcement/Punishment Derived from the Environment

We utilized two different measures of activation in our study given purported differences between the constructs they are intended to assess: *The Behavioral Activation for Depression Scale (BADS;* Kanter, Mulick, Busch, Berlin, & Martell, 2007) and the *Reward Probability Index (RPI*; Caravalho et al., 2011).

The *Behavioral Activation for Depression Scale (BADS;* Kanter, Mulick, Busch, Berlin, & Martell, 2007) consists of 25 items and was designed to measure the extent to which individuals become more activated and less avoidant through the course of the

BA intervention. Among the questionnaire subscales are Activation,

Avoidance/Rumination, Work/School Impairment, and Social Impairment. Given that examining participants' activation levels through treatment course is highly relevant to our study hypotheses, we will examine increases in the total *BADS* scale as well as in the *BADS Activation* subscale specifically. The *Activation* subscale contains items related to the engagement in focused, goal-directed activities as well as to the completion of scheduled activities (Kanter et al., 2006) which allows examining activation changes while isolating impairment elicited by avoidance or rumination (also measured within the *BADS*). Items comprising this subscale include "I am content with the amount and types of things I did" and "I engaged in a wide and diverse array of activities." The internal consistency of the Spanish version of the complete *BADS* scale has been reported at .80 and at .81 for the *BADS Activation* subscale when administered to a sample comprised of students at a Spanish university (Barraca, Pérez-Álvarez, & Bleda, 2011). BADS' internal consistency ranged from .86 to .91 across all sessions and the one-month follow-up.

The *Reward Probability Index (RPI*; Carvalho. et al., in press) is a 20 item scale that was developed to assess availability of reinforcement in the environment. The total *RPI* consists of two subscales: 1) the Reward Probability Index, which includes items measuring the likelihood to which individuals are able to obtain reinforcement through instrumental behaviors, and 2) the Environmental Suppressors Index, consisting of items that describe the availability of aversive and unpleasant experiences in respondents' environment (Caravalho et al., 2011). Total *RPI* score is calculated by adding scores of the items measuring Reward Probability Index with reversed scores of the items

measuring Environmental Suppressors. Internal consistency of the total *RPI scale* was  $\alpha$  = .90 and the test-retest reliability r=.69 in the original validation study. Because there is no psychometric evaluation of a Spanish translation of the *RPI*, the team that translated the original BATD treatment into Spanish also translated this assessment tool. Ms. Collado was responsible for back-translating the items into English (please see Fouad & Bracken, 1986 for more information about this procedure). Discrepancies between the back-translation and the original version of the questionnaire were discussed among the parties and addressed. In the original validation study (Carvalho et al., 2011), psychometric properties of each subscale suggested a strong internal consistency ( $\alpha$  = .82 - .90) as well as strong test–retest reliability (r = .83- r = .86) (Carvalho et al., 2011). In the current study, the Cronbach's alpha for the Spanish translation of the total *RPI* scale ranged between .77 and .81. Further, Cronbach's alpha for the *Reward Probability Index* ranged between .76 and .95 and between .75 and .88 for the *Environmental Suppressors Index* across sessions.

Our rationale for administering both the *BADS* and the *RPI* was based on the purported differences between the constructs they assess. Manos, Kanter and Busch (2010) indicated that the *BADS* measures frequency of activation, escape, and avoidance, whereas the *RPI* measures the probability of obtaining reinforcement through access to environmental rewards. Further, throughout the course of the preliminary study we conducted, we observed differing magnitudes between the correlations among our activation measures, which may support the argument that these questionnaires are tapping into different constructs; correlations ranged from .09 and .75 for the *RPI* and *BADS*, across our treatment sessions.

#### Domain 4- Treatment Adherence

Attendance: Session attendance was logged for every client. In addition, homework completion was verified and noted at each session.

#### Domain 5- Attitudes toward Treatment

To measure stigma-related concerns associated with depression treatment, participants completed the *Stigma Checklist Questionnaire* (Vega, Rodriguez & Ang, 2009), which was specifically designed for use with low income Spanish speaking or bilingual primary care Latino patients. The questionnaire consists of 7 items designed to identify participants' perceptions of others who have depression and take medication, as well as their fear of relatives learning that they are dealing with depression. The reliability of the scale has been reported at a Cronbach's alpha of 0.69. The internal reliability of the SCQ in the current study ranged from .23 to .57. Because of these low reliabilities, we decided not to use the questionnaire in further analyses as had been previously planned.

The Therapeutic Alliance with Clinician Questionnaire (TAC; Neale & Rosenheck, 1995) assesses the strength of the therapeutic relationship using a 9-item Likert scale format. The Spanish version of the questionnaire (Bedregal, Paris, Jr., Añez, Shahar & Davidson, 2006) was evaluated with a sample predominantly comprised of depressed individuals and achieved high internal consistency ( $\alpha$  = .96) and an item component correlation of 0.70. The authors concluded that the measure has both clinical and research utility. In the current study, alpha coefficients ranged from .94 to .97 across all sessions in which the TAC was administered.

To elicit feedback about both treatments, we administered an in-house developed questionnaire every other session. Participants rated the treatments on a 1 to 6 Likert-type scale

across 9 items including "to what extent do you believe that this treatment has improved your depression/low mood?", and "how valuable do you think this treatment would be for individuals who experience depressed/low mood?" The questionnaire contained one last item in which the participant was asked to rate the extent to which the treatment helped from 1 ("no help") to 4 meaning ("helped substantially"). This treatment satisfaction scale ranged from 10 to 58, with higher scores representing higher treatment satisfaction. Internal consistency ranged between .91 and .96 across all of the sessions in which the CDS was administered.

## 2.9. Design Considerations

We made a number of choices that led to the current study design with the overarching goal of balancing internal validity and generalizability. First, we chose SC as a comparison group, following the recommendations of Chambless and Ollendick (2001), who outlined the benefits of a programmatic approach to treatment development research involving progressive stages for the evaluation of novel treatments. Although we considered the use of a waitlist control group, we believed that in a sample afflicted with MDD, the use of this comparison group would not be ethical. Second, research has shown that Latino clients attribute depression to a lack of support (Cabassa, Lester & Zayas, 2007). As such, SC would provide an initial source of support to clients randomized to this condition.

An additional design consideration surrounding the use of SC as a control treatment condition was that the use of the therapy could potentially limit our ability to detect significant differences. However, we believed that this concern was mitigated because activation and contact with positive environmental reward are targeted in BATD but not in SC. Thus, even if no statistically significant between-group effects

would be detected, the study could yield important information regarding within-group changes in activation and environmental reinforcement and their relation to depression. Despite the small sample of our pilot study (Collado-Rodriguez et al., 2013), we observed significant increases in activation and environmental reinforcement which corresponded to depression. Further, a within-subject analytic approach like HLM (see Data Analysis Plan) coupled with the frequency of assessment administration would increase our power to look at concurrent changes between BA proposed mechanisms and depression outcomes. Even in the case that statistically significant depression differences between groups were not detected, the data would provide important information regarding beneficial treatments for this underserved and underrepresented group. We also conducted a power analyses that suggested we had sufficient power to detect significant differences across conditions (see Sample Size Considerations). Similarly, we examined other outcomes (e.g., stigma, treatment satisfaction, therapeutic alliance), highly relevant to our sample of interest, which could provide important knowledge about the effect of BATD and SC on these treatment correlates. Although we considered examining these variables as potential mediators of the relationship between each treatment and decreases in depression, there was currently insufficient research in this area to support these analyses. Therefore, as a first step, we planned on examining differences on these key variables across the treatment conditions. Results from these analyses may lay the groundwork for an important future direction in a larger randomized controlled trial.

Given that our decision to include SC as a treatment condition still generated ethical and safety concerns, we implemented an extensive safety protocol with which

research assistants and therapists were trained at length (see *Protection of Participants* below). In addition, participants were given the choice of receiving the other treatment to which they were not assigned after their participation in the study concluded.

Fourth, we chose to exclude patients with co-occurring bipolar I, psychotic, and present substance dependence disorders, as these conditions would require alternative treatment approaches. For substance use disorders, we required that participants had no DSM-IV substance dependence diagnosis in the past six months. Participants with other Axis I comorbidity were not excluded to preserve a higher degree of generalizability.

Fifth, we considered delivering the treatment in a group format which would increase cost-effectiveness of the treatment. However, we ultimately chose an individual format for two reasons. First, application of this work to community settings is crucial for generalizability and individual therapy is preferable for this reason given it is more commonly utilized in these settings. Second, our pilot data indicated that frequently changing work schedules would be particularly evident among our study population and therefore the relative flexibility of scheduling for individual sessions as compared to group sessions was seen as a considerable strength of the former for treatment attendance and retention through follow-up.

Sixth, we strongly considered the assessment schedule for this study for our primary outcome variables. Although the frequency of questionnaires may appear burdensome, in line with a number of BATD-based studies ongoing in CAPER, we routinely administer this battery of measures in concert with treatment sessions. Thus, we strongly believe that at this stage, systematically assessing these highly relevant variables of interest would be able to provide a better understanding of how these factors

affect the course of both treatments. Consistent with preceding research examining treatment correlates among our sample of interest (e.g., Kanter et al., 2010; Muňoz & Mendelson, 2005), we considered that limiting the administration of these questionnaires to three times through the course was appropriate.

## 2.10. Protection of Participants

Given that the decision to include a SC condition as a depression treatment generated concerns, we incorporated a Data Safety Monitoring Board (DSMB) specifically to monitor and ensure participants' safety through the course of treatment. Members of the DSMB included five independent researchers who all had extensive experience in treatment research with Behavioral Activation Treatment for Depression (BATD) and depression treatment research in general. These individuals were involved in the project as DSMB members in order to guarantee objectivity regarding participants' safety, study conduct, and recommendations concerning the continuation or modification of the project's safety protocol. Any potential issues (during screening or during study participation) were discussed immediately over the telephone with the DSMB. However, no potential safety issues were detected at any stage of the study. Participants were closely monitored during the duration of the trial. Overall, the safety procedures were as follows:

At every appointment, participants completed the *BDI-II* which contains questions about suicidal ideation and intent. If the suicidality item would have been endorsed at any time (e.g., "I would like to kill myself" or "I would kill myself if I had the chance"), our primary goal was to ensure participants' safety. If a participant reported elevated suicidality, a risk assessment protocol would have been initiated.

Every research assistant involved in the study was trained in these procedures following an already-established protocol for depression treatment development projects conducted at CAPER and Ms. Collado's previous work with depressed Spanish-speaking Latinos to ensure participants' safety.

First, a Spanish version of the MSSI (Modified Scale for Suicidal Ideation) which was translated in the center for the initial pilot study would have been administered to assess for severity of suicidal ideation. Prior to administering the MSSI the PI and client's therapist would have been notified. Immediately after conducting the MSSI, the RA would have informed the therapist of the results. The therapist would then engage in an honest discussion with the client about his or her likelihood of carrying out suicide. The therapist would also conduct a lethality risk assessment and draw a contract with the client that he or she would not make any attempts to carry out the plans. The outcome of the discussion as well as the therapist's impressions would involve the RA to document this information. If the client indicated that he/she was in imminent danger (in or out of session), the appropriate authorities would be notified. Ms. Collado, Drs. Lejuez, MacPherson (Dissertation Co-Chairs) and the members of the DSMB would then be informed of the outcome of the MSSI conducted by the RA and the impressions of the therapist. A conference call discussing relevant details would have then taken place with all of the DSMB members. DSMB members would have provided a future plan to ensure the client's safety.

For cases of suicidal ideation, a similar protocol was utilized. If suicidal ideation would be indicated, a lethality risk assessment would be put in place. At no point during the study, was the implementation of these procedures necessary. Please see participant

safety procedures along with lethality risk assessment and reasons for living contract in Appendix 1. Please see Figure 1 for a depiction of these procedures.

## 2.11. Sample Size Considerations

We based our sample size needs on effects observed in the literature, including other treatment studies, and by making informed decisions about the magnitude of effects of BATD in this population that would likely be of clinical significance. For the primary outcome that BATD would result in greater reductions in depressive symptoms (Aim 1), we calculated the sample size required based on a recent meta-analysis conducted that examined the effect size of BA relative to control conditions (Ekers, Richards & Gilbody, 2008) and on a treatment study that compared CBT to an active treatment condition (Interpersonal Psychotherapy) conducted by Rosselló, Bernal and Rivera-Medina (2008) in a Spanish-speaking Latino sample which yielded effect sizes of .43 and .74, respectively, indicating medium to large effect sizes. Conservatively, our proposed sample size of 23 in each cell is well within that suggested by a power analysis using these two reported effect sizes to allow for a power of .80 using an alpha of .05 (Cohen, 1988).Our sample size also follows Rounsaville and colleagues' (2001) recommendations of including 15-30 subjects per cell in Stage 1b trials.

#### 2.12. Data Analysis Plan

Hierarchical Linear Modeling (HLM; Raudenbush & Bryk, 2002) were used to examine within-subject change of depression (first aim) activation and reward derived from the environment (second aim) over the course of treatment. The nature of HLM analyses allowed us to control for baseline scores of each measure, include multiple

measurement points while accommodating missing data, examine individual change over time in outcomes, and include the average change and the individual variation around this average change. We specified all of our HLM Level-1 intercepts as random, given that we expected first session depressive symptomatology, activation, and availability of reinforcement in the environment to differ across our participants. We centered all variables of interest (except for time) around the grand mean of respective scores to avoid multicollinearity. Centering variables also allowed us to determine the impact of each individual's relative shift from their own mean weekly scores on these measures. Planned covariates in these analyses included recruitment method, English language proficiency level, assigned therapist, education, age, baseline levels of depressive symptoms as well as the main effect of treatment condition and the linear effect of time. Inclusion of the time by treatment condition interaction would indicate the extent to which treatment differences are more or less pronounced early versus later across treatment sessions. Categorical rates of remission of MDD (also evaluated within Aim 1) as indicated by the SCID-IV were examined across treatment conditions using the Cochran-Mantel-Haenszel test.

To examine the correspondence between increases in activation and environmental reinforcement with depression (examined within the second aim), we also used HLM to examine correspondence of these variables over time. We examined correspondence between depression with activation and environmental reinforcement only if these study variables of interest demonstrated change over time. These models included the aforementioned covariates in addition to including activation and environmental reinforcement as time-varying predictors of depression, the main effect of

treatment condition, the linear effect of time, a two-way interaction between treatment condition and the linear effect of time, a two-way interaction between the linear effect of time by activation or environmental reward, and a three way interaction of time by treatment condition by activation or environmental reward. Because of the difficulty in attributing causality between variables assessed at the same time point, we also conducted analyses predicting depression with environmental reward and activation assessed at the previous time point as time-varying covariates (please see Figure 1 depicting the concurrent and lagged analyses). In this model, for example, *RPI* score at session 5 was specified as predicting *BDI –II* at session 6. These lagged analyses indicate whether the predictors precede changes in depressive symptomatology consistent with the BATD framework that activation and environmental reward are expected to increase before depression decreases.

To examine more closely the effects of treatment on attendance (third aim), we conducted a Cox proportional hazards survival analysis predicting sessions to attrition. This allowed us to examine the extent to which BATD was able to increase the latency to treatment attrition.

To test our remaining hypotheses within the third aim, we conducted t-tests examining differences between BATD and SC in treatment satisfaction and therapeutic alliance at each session these correlates were examined.

## Chapter 3: Results

## 3.1. Participants

A total of 110 callers contacted CAPER expressing interest in our study. Out of those callers, 12 could not be re-contacted after they left a message on the study voicemail. At least five attempts were made by study staff to contact these potential participants, with messages left at each contact attempt. Out of the 98 remaining callers that were screened, 22 were excluded from participation based on our study criteria. In addition, 12 callers were not interested in the study after they were provided with information about the project. Of the remaining 64 potential participants, 16 did not show for the baseline appointment. Although several attempts were made to reschedule these callers through numerous telephone calls, these individuals did not show for subsequent appointments. Of the 48 individuals that attended the baseline appointment, two were deemed ineligible. The 46 participants remaining participants were enrolled in the study within eight months. Please see Figure 2 for a Consort Diagram for the study.

Participants enrolled in the study represented the following countries: El Salvador (n = 13), Guatemala (n = 7), Honduras (n = 6), Mexico (n = 6), Colombia (n = 4), Peru (n = 2), Chile (n = 2), Nicaragua (n = 1), Paraguay (n = 1), Dominican Republic (n = 1), Costa Rica (n = 1), Ecuador (n = 1) and the United States (n = 1).

Participants reported having lived in the United States for a mean of 4.07 years (SD = 2.69). Participants' ages ranged from 18 to 74 and their mean age was 35.91 years (SD = 13.80). The sample consisted of 39 females and seven males. The number of males recruited was proportionally lower in this current trial (15%) relative to the initial

pilot trial (30%) that we conducted (Collado et al., 2013) Thirty-seven percent of participants reported earning a yearly income of less than \$14,999; 41% indicated being employed full time, 24% reported being unemployed, and 11% reported being employed part-time. Participants' mean education was a 10.93 grade level (SD = 3.74). There was wide variability in the sample's English speaking and reading proficiency. The majority of participants indicated that they were able to understand "a little" spoken and written English. Twenty-two percent and 28% indicated that they were able to understand spoken English and written English, respectively. Approximately 13% of the sample self-reported that they were not able to understand spoken and written English. In terms of marital status, 28% of participants indicated they were married and 37% reported being single. Most (91%) indicated having immediate family in the U.S. Table 2 summarizes baseline demographic characteristics for the complete sample and across the SC and BATD condition.

#### 2.2. Clinical Characteristics at Treatment Onset

To assess for psychiatric disorders, we administered the *SCID-IV*. Participants demonstrated high levels of comorbidity. Other than meeting criteria for MDD, 43.5% of participants met criteria for Dysthymia, 24% for Panic Disorder, 28% for Posttraumatic Stress Disorder, and 65% for Generalized Anxiety Disorder. In terms of participants' depressive symptomatology, the sample's mean *BDI-II* score at the first assessment was 29.70 (SD = 10.36), indicating severe depression. Participants' total mean activation score as indexed by the *BADS*, was 54.13 (SD = 23.97) on a 0 to 150 scale. The mean score of the *BADS Activation* subscale was 20.28 (SD = 9.82) out of 42, with higher scores indicating more activation. The total mean reinforcement derived

from the environment assessed by the RPI was 47.56 (SD = 8.82) in a 0 to 80 scale, with higher RPI scores indexing higher access to environmental reward. The baseline mean score for Environmental Suppressors was 18.91 (SD = 4.97) with higher scores representing a higher likelihood of punishment derived from the environment and 28.64 (SD = 6.09) for Reward Probability, with higher scores indicating a higher likelihood of reward obtained from the environment. The maximum score for each Index is 40. Finally, participants obtained a mean score of 26.28 (SD = 17.25) on the MASI scale out of a possible score of 95 indicating low levels of acculturative stress overall.

Only two participants reported taking antidepressants at baseline for at least 1 year. These participants indicated that they continued their medication use throughout the course of the study and the one-month follow-up. In addition, 28% of participants indicated that they had received treatment for depression in the past. Please see Table 3 for a complete summary of participants' clinical characteristics as part of the complete sample and in each condition. Neither demographic nor clinical characteristics showed significant between-group differences (ps > 0.20). In addition, one-month follow-up numbers were not significantly different between BATD (n = 15) and SC (n = 11) (p = 0.24).

#### **Covariates**

We controlled for education in models containing depressive symptomatology as a result of their significant association over time (p = 0.01). Although there were nobetween group differences in demographic or clinical characteristics, we also controlled for therapist assigned to participants given the wide range in therapists' education and

training. The nature of HLM analyses also allowed us to control for baseline scores of each of the outcome variables when examining their change over time.

#### 2.3. Aim 1 - Results

<u>Depressive Symptomatology</u>: Depressive symptomatology as measured by the *BDI-II* decreased over time over the course of treatment ( $\beta$  = -2.16, SE = 0.21, p < 0.001). Further, the interaction between treatment condition and the linear effect of time was significant ( $\beta$  = -0.59, SE = 0.28, p = 0.037), indicating that participants assigned to BATD evidenced greater reductions in depressive symptoms over time relative to those assigned to SC. Please see Figure 4 for the depiction of these results.

MDD Remission: Categorical rates of remission of MDD were examined across treatment conditions using the Cochran-Mantel-Haenszel test. The results of this test indicated that at end-of-treatment participants showed a significant effect in favor of BATD ( $\chi 2$  (1) = 6.52, p = 0.01; 14 participants (93.3% of the 15 who completed treatment) in the BATD condition showed remission of MDD relative to 6 participants (50% of the 12 who completed treatment) in SC. Please see Figure 5 for a depiction of these results.

## 2.4. Aim 2- Results

For the second aim, we examined changes in the proposed mechanisms of BATD and hypothesized reductions in depressive symptomology, including activity level (using the total *BADS scale* and *BADS Activation* subscale) and environmental rewards and punishment (using the total *RPI* scale, the *RPI-reward probability* subscale, and the *RPI-environmental suppressors* subscale). We examined the interaction of time by condition

of each of these constructs. For our concurrent and lagged analyses, we examined three-way interactions between time, condition, and proposed mechanism of change only in cases in which lower-order interactions were significant. Therapist assignment was included as a covariate.

Activity Level: Activity level as measured by the total *BADS* scale showed a significant linear effect of time suggesting that this construct increased over the course of treatment ( $\beta$  = 3.88, SE = 0.61, p < 0.001). The interaction between treatment condition and the linear effect of time was not significant ( $\beta$  = 0.67, SE = 0.82, p = 0.41), indicating that there were no differential effects of treatment across time in activity level.

As mentioned previously, the *BADS* scale is comprised of an activation subscale that allows the examination of activation changes while isolating impairment elicited by avoidance or rumination (also measured within the *BADS*). Activity level measured by the *BADS Activation* subscale showed a significant linear effect of time suggesting that this construct increased over the course of treatment ( $\beta = 0.61$ , SE = 0.25, p = 0.02). Further, the interaction between treatment condition and the linear effect of time was also significant ( $\beta = 0.83$ , SE = 0.28, p = 0.01), showing that those who were randomized to the BATD condition reported greater activity level over time relative to those who were assigned to the SC condition. Please see Figure 6 for a depiction of this interaction.

Environmental Reward and Suppressors: To examine changes in environmental reward and punishment across treatment, we utilized the total *RPI* scale, which includes two different subscales: the *Reward Probability* subscale and the *Environmental* 

Suppressors (i.e., punishment) subscale. As part of this aim, we examined the total *RPI* scale, and each of its subscales independently. Reward probability as indexed by the total *RPI* scale showed a significant linear effect of time ( $\beta = 0.79$ , SE = 0.16, p < 0.001) suggesting that this construct increased over the course of treatment. The interaction between treatment condition and the linear effect of time was significant ( $\beta = 0.46$ , SE = 0.23, p = 0.05), demonstrating that participants randomized to BATD showed greater increases in the construct over time relative to participants who received the SC intervention. Please see Figure 7 for a depiction of this interaction.

There was also a significant linear increase over time for environmental reward as measured by *RPI*'s *Reward Probability* subscale ( $\beta = 0.47$ , SE = 0.08, p < 0.001). The interaction between treatment condition and the linear effect of time was not significant ( $\beta = 0.27$ , SE = 0.15, p = 0.08), showing that participants randomized to BATD showed similar increases in the construct over time in comparison to those who were randomized to SC.

Environmental punishment showed a linear effect of time ( $\beta = 0.32$ , SE = 0.100, p = 0.003) such that over the course of treatment, the construct decreased in the entire sample. The interaction between treatment condition and the linear effect of time was non-significant, indicating no differential effects of treatment across time ( $\beta = 0.12$ , SE = 0.16, p = 0.47). Please see Table 4 for a summary of changes over time in clinical variables of interest.

Also as part of Aim 2, we tested the correspondence of the proposed mechanisms of BATD and depression concurrently and prospectively in models 1 and 2, respectively. We outline the results below:

# <u>Model 1- Concurrence of Activity Level and Environmental Reward with Depression</u> over Time

Model 1 tested the extent to which these proposed mechanisms at one session corresponded simultaneously with depressive symptomatology at the same session over time (i.e., activity level at session 1 with depression at session 1, activity level at session 2 with depression at session 2, and so forth).

Concurrence of Activity Level and Depressive Symptomatology: Activity level as measured by the total BADS scale and depressive symptomatology, measured by the BDI-II did not correspond simultaneously over time (p=0.77), indicating that these constructs did not change together and at the same time. We also examined activity level as indexed by the BADS Activation subscale. These results did not show a relation between activation and depression over time (p=0.08). As such, three-way interactions between time, activity level, and condition were not performed given non-significance of the lower-order interactions.

Concurrence of Environmental Reward and Depressive Symptomatology: Environmental reward measured by the total RPI scale and depressive symptomatology did not correspond simultaneously over time (p = 0.67) indicating that environmental reward and depression did not change together. We also examined environmental reward and punishment as indexed by RPI's  $Reward\ Probability$  and Environmental Suppressors subscales, respectively. These results indicated no relationship between these two constructs and depression (ps > 0.21). Three-way interactions including time, condition and environmental reward or punishment were not performed given that the

lower-order interactions were not significant. Please see Table 5 for a summary of these results.

Model 2: Lagged Analyses between Activation and Environmental Reward with depression

Our second analytic model consisted of lagging activation and environmental reward and punishment to test whether these constructs corresponded to depressive symptomatology at a subsequent session; that is, whether activation and contact with environmental reinforcement preceded depressive symptoms over the course of treatment (i.e., reward probability at session 1 with depressive symptoms at session 2, reward probability at session 2, depressive symptoms at session 3, etc.)

Lagged Activation Level and Depressive Symptomatology: Lagged analyses indicated that activity level measured by the total BADS scale did not precede depressive symptomatology over time (p = 0.92). Similarly, the interaction of time by activity level measured by BADS- Activation subscale was not significant (p = 0.16) suggesting that activity level did not precede changes in depression symptomatology.

<u>Lagged Analyses – Environmental Reward and Depressive Symptomatology:</u> Lagged analyses indicated that higher total environmental reward did not precede decreases in depression in the study sample (p = 0.07). Results also indicated *RPI*'s *Reward Probability and Environmental Suppressors* did not precede changes in depression (ps > 0.26). Please see Table 6 for a summary of these results.

2.5. Aim 3 - Results

Treatment Adherence

Averaging across clients, a mean of 7.35 (SD = 3.65) sessions were completed over a mean of 9.02 weeks (SD = 4.58). Participants randomized to BATD completed a mean of 7.96 sessions (SD = 3.36) in an average of 9.65 weeks (SD = 4.68). Individuals assigned to the SC condition completed a mean of 6.74 sessions (SD = 3.86) in an average of 8.39 weeks (SD = 4.50). There were no significant differences between conditions in terms of sessions completed (p = 0.26) or weeks until treatment was completed (p = 0.36).

Three participants randomized to SC and two participants in BATD completed only one treatment session. Five participants randomized to SC and three participants in BATD completed between two to four sessions. Three participants randomized to SC as well as to BA completed between 5 and 8 sessions of treatment. Twelve participants assigned to SC and 15 participants assigned to BATD completed all 10 sessions of treatment. Independent samples t-test did not show SC or BATD differences in rates of treatment completion (p = 0.38). Please see Figure 2 for a breakdown of sessions completed for each session.

Cox proportional hazards survival analysis was also used to predict BATD and SC latency to treatment attrition. The model included baseline symptoms of depression (*BDI-II*) and therapist assignment as covariates. The model was not significant ( $\chi^2(11)$ ) = 14.65, p = 0.20, see Figure 9) suggesting that BATD and SC were equal in their effect on treatment completion after adjustment for the relevant covariates included in the model. Please see Figure 9, which depicts these results.

An additional measure of treatment adherence considered in the current study was homework completion. Among participants who completed more than one session

in either treatment (N= 40), homework completion for BATD participants was 75.18% and 63.35% for SC participants. Homework completion was not significantly different between the SC and the BATD (F (1, 37) = 1.63; p = 0.21) after statistically controlling for completed sessions. Altogether, treatment adherence was not significantly different between SC and BATD.

## Treatment Satisfaction

For Aim 3, we examined treatment satisfaction using HLM analyses. Results suggested that treatment satisfaction increased over time ( $\beta = 0.59$ , SE = 0.18, p = 0.002), but did not differ by condition (p = 0.17).

## Therapeutic Alliance

Also within Aim 3, we examined differences in therapeutic alliance over time and between conditions. HLM analyses suggested that therapeutic alliance increased over time ( $\beta = 1.02$ , SE = 0.19, p < 0.001) but was not different for participants assigned to BATD and SC (p = 0.91).

Maintenance of Clinical Gains over a One-Month Follow-up

We sought to examine whether improvements made during the course of treatment were sustained from the last treatment session to the one-month follow-up. Toward this end, we conducted paired t-tests and expected to find that clinical gains would be sustained, particularly for the BATD condition. A total of 15 people randomized to BATD and 11 people randomized to SC completed the one-month follow-up. Paired t-tests between end-of-treatment and the one-month follow-up clinical variables were not statistically significant (all ps > 0.06), indicating that clinical gains were sustained across all clinical variables of interest for both the BATD and SC

condition. There were also no significant changes in remission rates between both conditions from end of treatment to the follow-up period (p = 1.00), suggesting that MDD diagnosis or remission did not change in this time frame. Given that MDD rates remained consistent between conditions, a higher percentage of BATD participants evidenced remission relative to those in the SC ( $\chi 2$  (1) = 6.52, p = 0.01). Please see Table 7 for a summary of the one-month follow-up results.

# Chapter 4: Discussion

## 4.1 Summary of Main Findings

The current RCT (N = 46) evaluated the efficacy of BATD against a time-matched SC protocol among depressed Latinos with Spanish-speaking preference. Our study aims aligned with an effort to expand the mental health treatment literature for this much underserved US population. The current study builds on the results of a small open-label trial (Collado et al., 2014) that demonstrated significant clinical gains over the course of BATD for a similar target group in the following ways: 1) inclusion of a contact time and homework-matched control condition (SC), 2) examination of the effect of treatment on proposed BATD mechanisms of change (i.e., environmental reward and activity level), 3) an increase in sample size to examine between-treatment differences and to increase generalizability of results, and 4) inclusion of MDD as a criterion for eligibility. Specific outcomes of interest in the comparison of the two treatments groups were a) depressive symptomatology over time and MDD remission; b) environmental reward and activity level; and c) treatment satisfaction, therapeutic alliance, and treatment adherence.

## Aim 1: Between-Group Changes in Depression

As part of Aim 1, we had hypothesized that participants randomized to BATD would evidence greater reductions in depressive symptoms. Our results were consistent with this hypothesis. In our trial, participants who completed BATD reduced their BDI depression scores from a baseline average of 30 (indicating severe depression) to an

average of 10 at the last treatment session (signaling minimal depression). This symptom reduction compared favorably to what has been reported in other trials among depressed Latinos who completed empirically-supported treatments, such as CBT (e.g., Organista et al., 1994; Miranda et al., 2003; Reyes, Verna, Bernal & Huertas, 2002) and Interpersonal Therapy (Spinelli & Endiccot, 2003). Furthermore, the reduction of depression scores for participants in this 10-session BA treatment study fared favorably with those observed in other studies (e.g., Gawrysiak, Nicholas & Hopko, 2009; Dimidjian et al., 2006). Altogether, these results support the efficacy of BATD as a treatment for depression in depressed Spanish-speaking Latinos. Study outcomes also suggested that participants who were enrolled into BATD had a higher percentage remission of MDD relative to participants randomized to the SC condition throughout treatment course and at the one-month follow-up assessment. These findings were consistent with our Aim 1 hypothesis. The current RCT is among the few treatment research studies with U.S. Latinos that have included MDD as an eligibility criterion (e.g., Miranda et al., 2003; Reyes et al., 2002; Spinelli et al., 2003; Comas-Diaz, 1981) and the first that has assessed MDD at treatment conclusion and at follow-up.

As part of our study aims, we also examined the extent to which clinical gains were sustained through the one-month follow-up in both treatment conditions. Clinical gains were maintained for both SC and BATD participants. One important finding to note, is that clinical gains were observed during active treatment duration and were no different during the follow-up. This stresses the importance of striving for MDD remission prior to treatment conclusion.

Aim 2: Between-Group Changes in Clinical Constructs

For the second aim, we hypothesized that over the course of treatment, participants assigned to BATD would evidence greater increases in activity level and contact with environmental reward relative to those assigned to the SC condition.

Consistent with our predictions and with the results from the initial BATD open-label trial, results indicated that the *BADS Activity* level subscale and *RPI's* total *Environmental Reward* scale showed greater increases over time among BATD relative to SC participants. Altogether, more pronounced changes in the *BADS*-Activation subscale and the total *RPI* scale among BATD relative to SC participants suggests that the treatment was effective in increasing these constructs over time.

The finding that activity level measured by the *BADS Activation* subscale changed, but not the total *BADS* scale, may reflect that other domains measured by the total scale (i.e., Avoidance/Rumination, Work/School Impairment, and Social Impairment) are not as directly relevant for a treatment that is more focused on helping clients to add valued activities into their lives as opposed other aspects of activation such as rumination and life impairment which may be addressed equally well by SC and BATD.

As part of Aim 2, we also examined concurrent and prospective associations between depressive symptoms with activity and environmental reward. Our results did not support our hypotheses about the timing of these processes. Specifically, environmental reward and activation did not co-occur with or precede depressive symptoms. The lack of relation between these constructs has also been reported in two recent trials (Ryba, Lejuez & Hopko, 2014; Hershenberg, Paulson, Gros & Acierno, 2014). Both of these trials indicated that participants who received BATD increased the

activities that they completed over time, yet these changes were not systematically related to depressive symptomatology. This research combined with findings from the current study, suggest that the relationship between depression and activation may be more complex than previously hypothesized. In our trial, we conceive that one possible explanation for the lack of relation between activation and depressive symptomatology is that these variables may not shift together or do so from one week to the next in a consistent manner.

Aim 3: Between-Group Therapeutic Alliance, Adherence, and Satisfaction

Finally, for Aim 3, we expected that relative to participants assigned to the SC condition, participants randomized to BATD would report higher treatment satisfaction, greater therapeutic alliance, and greater treatment retention. Our analyses did not support our Aim 3 hypotheses.

Moreover, while future work should consider the impact of BATD on these important therapeutic variables, the current results can be interpreted to support that the changes that we observed in depression, activity level, and environmental reinforcement are due to the treatment content of BATD and not to non-treatment specific variables that have generally shown to strongly relate to clinical gains (e.g., Chatoor & Kurpnick, 2001). Retention for both conditions, participant completion of homework, number of sessions completed, and latency to attrition were not different between conditions. As such, concerns about investigator and therapist bias toward BATD are somewhat mitigated as a result of these findings.

## 4.2. Limitations/Future Directions

Following Carroll and Nuro's (2002) suggestions for a sequential model for psychotherapy manual development and following positive results of an open-label trial, the current study consisted of a RCT with 46 participants. A first limitation of the study, is its relatively small sample size which not only could have prevented the detection of potentially significant relationships between depressive symptomatology and activation and environmental reward in the current study, but could also limit the generalizability of our results. For example, the interaction between treatment condition and the linear effect of time was trending significance for RPI's Reward Probability subscale (p =0.08), as was our test of simultaneous correspondence between environmental reward measured by the total RPI scale and depressive symptomatology (p = 0.07). Therefore, it is important that future research recruit a larger sample size to confirm current results. A small sample size also raises the concern of limited generalizability to the greater Latino population given that Latinos in the United States are a very heterogeneous group. Another factor that could potentially limit the generalizability of our results are the high levels of comorbidity that characterized our sample (65% met criteria for Generalized Anxiety Disorder, 25% for Posttraumatic Stress Disorder, 24% for Panic Disorder, and 44% for Double Depression defined as co-occurring MDD and Dysthymia). This comorbidity may reflect the clinical severity of this sample as well as well as the need for treatments for U.S. Latinos with reported Spanish language preference. Further, it is uncertain whether the high comorbidity of our sample could have impacted the observed clinical improvements. Both participants enrolled in SC and BATD evidenced improvements in all clinical domains assessed in this treatment study.

A second important limitation inherent to efficacy trials, is the wide range of therapist expertise in this trial. Although randomization and therapist training and supervision in the principles of BATD and SC could assuage this concern, the significant difference in levels of clinical psychology training differed greatly, which could have decreased the efficacy of the treatments. However, the discrepancy in training could also be considered a strength of the trial. Most therapists (n = 5) had only received training in SC and BATD, which could have resulted in the high treatment adherence rates. In addition, therapists' novice status underscores that relative ease and feasibility by which BATD and SC may be provided. This is perceived as a great advantage given that the literature underscores the limited availability of trained Spanish-speaking therapy providers. Given the limited time and training needed to implement this treatment, it appears ideal for an underserved population in immediate need of depression care.

Third, the weekly administration of questionnaires may have been too proximal to capture perceived environmental rewards or activity engagement, which may be slower to occur than overt behavior change. With a larger sample size, future studies may consider utilizing a dual latent growth curve modeling approach to predict the slope of depressive symptoms over time with the slope of BATD treatment mechanisms (e.g., activity level or environmental reward). Future work is also warranted with the goal of identifying mechanisms of BATD that contribute to reduced depressive symptoms, including avoidance (e.g. Hershenberg, 2014); testing these hypotheses will require more complex analyses of mediation, which were unable to be conducted in the current study given the small sample size.

Fourth, the *RPI and BADS* (as well as each of these measures' subscales) have not been tested or validated in Latinos with Spanish-speaking preference. The translation of the *RPI* was conducted internally for use in this study. Therefore, it is questionable whether this measure lacking psychometric evaluation in our sample and language of interest accurately reflects the factors proposed by Carvalho and colleagues (2011). Similarly, the *BADS* Spanish translation has been evaluated in a sample of university Spanish students, a sample that may not only differ culturally from our current sample, but also in terms of participants' socio-economic level. Therefore, caution is suggested when interpreting these results. Psychometric tests of these measures are warranted in future studies in our sample of interest with a specific goal of examining these constructs as they relate to depression.

Fifth, the study used SC as the control condition. Future research may consider utilizing an empirically-supported treatment as a comparison group. Despite the lack of evidence base for the intervention, it was well-received by study participants as indicated by high treatment satisfaction scores and high adherence rates (relative to the clinical research literature among this population). Furthermore, given that the SC condition was consistent with "desahogo" which is the frequently reported expectation among Latinos that therapeutic improvement is caused by relief through venting or getting things off one's chest, we believe that this was an optimal comparison therapy for this stage of treatment evaluation.

Altogether, there exist numerous limitations and opportunities to expand upon and enhance this line of research to further establish the efficacy BATD in improving depression (along with levels of activation and contact with environmental

reinforcement) among US Latinos with Spanish language preference. Despite these limitations however, study findings continue to support the promise of BATD as an efficacious, acceptable treatment for this underserved, understudied group in high need of depression mental health services.

To our knowledge, this constitutes the first effort towards conducting an RCT comparing a behavioral intervention and a well-defined, manualized SC condition in a sample of depressed Spanish-speaking Latinos in the US with Spanish language preference. This group has been historically under-represented in both clinical and research samples, which has prevented drawing conclusions about the efficacy of psychotherapeutic treatments for depression for this population. Together, the increasing Latino population, the elevated MDD rates among Latinos with a Spanish-speaking language preference, high attrition rates, and suboptimal treatment gains reported in previous depression treatment studies, make the evaluation of BATD in this group a pressing need. Therefore, the present study contributes to a scarce yet much needed evidence base and it sets the stage for a larger RCT that is able to examine BATD against an empirically-supported treatment, examine additional moderators of treatment, and explore other mechanisms of change.

Table 1 Schedule of Questionnaire Administration

Assessment	Baseline/ Ses.1	Ses.2	Ses.3	Ses.4	Ses.5	Ses.6	Ses.7	Ses.8	Ses.9	Ses.10	Follow-up
Domain 1: Participant Characteristics											
Demographics	X										
Acculturative											
Stress	X										
Other Med /											
Treatment Use	X									X	X
		D	omain 2:	Depress	ive Symp	tomatolog	gy				
SCID-IV											X
Modules	X									X	
BDI-II	X	X	X	X	X	X	X	X	X	X	X
De	omain 3: Bel	navioral A	Activation	n and Rei	nforceme	ent Derive	d from th	e Environ	ment		
BADS	X	X	X	X	X	X	X	X	X	X	X
RPI	X	X	X	X	X	X	X	X	X	X	X
		Г	Omain 5:	Attitude	s Toward	l Treatmer	nt				
Stigma											
Checklist**		X			X			X		X	
TAC		X			X			X		X	X
Treatment											X
Satisfaction		X			X			X		X	

Note. SCID-IV; BDI-II= Beck Depression Inventory, 2<sup>nd</sup> Edition; BADS = Behavioral Activation Depression Scale; RPI= Reward Probability Index Scale; TAC = Therapeutic Alliance with Clinical Scale. \*Questionnaire was not included as part of our analyses as a result of administration error. \*\*Questionnaire was not included as part of our analyses as a result of low internal consistency.

Table 2
Comparisons of Baseline Demographic Characteristics Across Treatment Conditions

Demographic	Overa	ll Samp	le	BATD	<u>.</u>		SC		<u> </u>	
Characteristic	M	SD	%	M	SD	%	M	SD	%	p
Age	35.91	13.80		33.74	12.25		38.18	15.20		0.29
Gender (female)			85			83			87	0.68
Education (grade)	10.93	3.74		11.45	3.71		10.38	3.78		0.35
Years in the U.S.	4.07	2.69		11.41	8.10		12.77	9.29		0.61
Total Annual Income										0.44
<u>&lt;</u> \$14,999			37			45			47	
\$15,000- \$29,999			22			20			35	
\$30,000- \$44,999			17			25			18	
\$45,000- \$59, 999			4			10			0	
Employment Status										0.62
Employed half-time			11			50			36	
Employed full-time			41			9			14	
Marital Status										0.91
Single/never married			37			44			35	
Married			28			30			30	
Divorced			13			13			15	
Other			15			13			20	
Immigration Status										0.34
Permanent Resident			22			18			27	
Undocumented			41			36			50	
Citizen			17			23			13	
Other			16			23			10	
Immediate Family in the										
U.S. (yes)			91			86			91	0.60
Able to Understand										0.04
Spoken English						• •				0.34
Yes			22			30			13	
No			13			13			13	
A little			65			57			74	
Able to Understand Written English										0.43
Yes			28			35			22	U. <del>4</del> 3
No										
			20			13			26	
A little			_ 52 _			52			52	

Table 3

Comparisons of Baseline Clinical Characteristics Variables Across Treatment Conditions

Clinical Characteristic	Overall Sample		F	BATD			SC			
	M	SD	%	М	SD	%	М	SD	%	p
DSM-IV-TR Psychiatric										
Diagnosis										
Dysthymia			44			39			48	0.55
Panic Disorder			24			22			26	0.73
Posttraumatic Stress Disorder			28			35			22	0.33
Generalized Anxiety Disorder			65			74			57	0.22
Ever received treatment for depression (yes)			28			36			22	0.28
MASI score	26.28	17.25		26.59	18.40		26.00	16.56		0.91
BDI score	29.70	10.36		30.05	9.41		29.53	11.53		0.88
RPI score	47.56	8.82		48.22	7.52		46.86	10.14		0.61
Reward Probability Index subscale score	28.64	6.09		29.35	5.84		27.90	6.39		0.44
Environmental	10.01	4.05								
Suppressors subscale	18.91	4.97		10.07	1.60		10.00	E / 1		0.06
Score	5412	22.07		18.87	4.62		18.96	5.41		0.96
BADS score	54.13	23.97		49.52	17.99		58.74	28.42		0.20
BADS-Activation subscale score	20.28	9.82		19.17	7.62		21.39	11.70	CN 4 1	0.45

*Note.* BATD: Behavioral Activation Treatment for Depression; SC: Supportive Counseling; DSM-IV-TR: Diagnostic Statistical Manual, 4th Edition- Text Revised; MASI: Multidimensional Acculturative Stress Index; BDI: Beck Depression Inventory; RPI: Reward Probability Index; BADS: Behavioral Activation Depression Scale.

Table 4

HLM Primary Analyses- Changes over Time in Clinically-Significant Variables

Predicted Variable and Fixed Effects	В	SE	T	P
BDI				
Intercept	29.605	1.629	18.175	< 0.001
Time	2.162	0.210	- 10.307	< 0.001
Condition	-0.593	0.275	- 2.161	0.037
BADS				
Intercept	53.291	3.344	15.993	< 0.001
Time	3.881	0.610	6.364	< 0.001
Condition	0.667	0.821	0.825	0.414
BADS Activation Subscale				
Intercept	20.822	1.386	15.021	< 0.001
Time	0.612	0.247	2.479	0.017
Condition	0.825	0.280	2.940	0.005
RPI				
Intercept	47.020	1.130	41.619	< 0.001
Time	0.789	0.158	5.007	< 0.001
Condition	0.458	0.227	2.016	0.050
RPI- Reward Probability				
Intercept	28.597	0.750	38.122	< 0.001
Time	0.471	0.082	5.659	< 0.001
Condition	0.266	0.146	1.814	0.077
RPI- Environmental Suppressors				
Intercept	18.400	0.639	28.806	< 0.001
Time	0.322	0.101	3.197	0.003
Condition	0.118	0.160	0.736	0.465

*Note*. Random intercept and slope values presented for participants (N=46). Significant changes over time highlighted using bolded text. BDI = Beck Depression Inventory; BADS = Behavioral Activation for Depression Scale.

Table 5
Simultaneous Concurrence between Depressive Symptomatology and Proposed Moderators of Treatment

Intercept and Fixed Effects	В	SE	t	p-value
BADS				
Time	-1.152	0.903	-1.277	0.203
Condition	2.647	2.763	0.958	0.339
Time x Condition	-0.501	0.614	-0.816	0.415
Time x BADS	-0.003	0.011	-0.291	0.771
BADS- Activation				
Time	-3.298	1.050	-3.140	0.002
Condition	-0.259	2.562	-0.101	0.920
Time x Condition	0.660	0.663	0.996	0.320
Time x BADS Activation	0.064	0.037	1.732	0.084
RPI				
Time	-3.508	2.612	-1.343	0.181
Condition	-0.573	2.526	-0.227	0.821
Time x Condition	0.584	1.346	0.434	0.665
Time x RPI	0.023	0.051	0.448	0.665
RPI- Reward Probability Index				
Time	-4.369	2.082	-2.098	0.037
Condition	-0.434	2.595	-0.167	0.867
Time x Condition	1.096	1.181	0.938	0.354
Time x RPI Reward Probability Index	0.065	0.060	1.097	0.273
RPI- Environmental Suppressors				
Time	-3.479	1.776	-1.959	0.051
Condition	0.160	2.542	0.063	0.950
Time x Condition	0.454	0.970	0.468	0.640
Time x RPI Environmental Suppressors	0.105	0.083	1.262	0.208

*Note*. Random intercept and slope values presented for participants (*N*=46). Significant changes over time highlighted using bolded text. BDI = Beck Depression Inventory; BADS = Behavioral Activation for Depression Scale.

Table 6
Lagged Relationship between Depressive Symptomatology and Proposed Moderators of Treatment

Intercept and Fixed Effects	Coefficient	SE	t	p-value
BADS				
Time	-1.675	1.389	-1.206	0.229
Condition	1.700	3.635	0.468	0.641
Time x Condition	-0.431	0.788	-0.546	0.586
Time x BADS	0.002	0.015	0.097	0.923
BADS- Activation				
Time	-3.175	1.005	-3.159	0.002
Condition	0.959	3.622	0.265	0.791
Time x Condition	0.399	0.651	0.614	0.540
Time x BADS Activation	0.049	0.035	1.400	0.163
RPI				
Time	-5.046	3.887	-1.298	0.196
Condition	-1.037	3.439	-0.302	0.763
Time x Condition	0.940	1.827	0.514	0.607
Time x RPI	0.038	0.074	0.514	0.608
RPI- Reward Probability Index				
Time	-5.285	2.517	-2.100	0.037
Condition	-0.573	3.534	-0.162	0.871
Time x Condition	1.634	1.293	1.263	0.208
Time x RPI Reward Probability	-0.039	0.035	-1.136	0.257
Index	0.037	0.033	1.130	0.237
RPI- Environmental Suppressors				
Time	-3.632	2.518	-1.442	0.151
Condition	-0.725	3.527	-0.206	0.837
Time x Condition	0.224	1.180	0.190	0.850
Time x RPI Environmental Suppressors	0.085	0.109	0.782	0.435

*Note*. Random intercept and slope values presented for participants (N=46). Significant changes over time highlighted using bolded text. BDI = Beck Depression Inventory; BADS = Behavioral Activation for Depression Scale.

Table 7

Changes in Depressive Symptomatology, Activation, and Contact with Environmental Reinforcement between End-of-Treatment to the 1-Month Follow-up (n=22)

Clinical	End-of-Treatment	1-Month Follow-up	p	
Variables	Mean (SD)	Mean (SD)		
BATD (n = 14)				
BDI	10.08 (6.45)	9.58 (8.14)	0.74	
BADS	90.87 (19.34)	87.57 (18.23)	0.16	
BADS-Activation	30.15 (7.00)	30.31 (6.40)	0.48	
RPI	53.14 (7.29)	54.14 (8.11)	0.24	
RPI – Reward Probability	32.07 (5.73)	33.93 (7.13)	0.34	
RPI- Environmental Suppressors	21.39 (3.54)	21.77 (4.00)	0.28	
SC(n=8)				
BDI	14.15 (6.83)	13.50 (9.30)	0.76	
BADS	85.58 (21.03)	90.50 (26.39)	0.45	
BADS-Activation	27.13 (7.81)	24.13 (8.43)	0.88	
RPI	50.00 (6.35)	51.88 (6.33)	0.53	
RPI – Reward Probability	29.38 (4.96)	30.25 (4.77)	0.63	
RPI- Environmental Suppressors	20.63 (3.62)	21.63 (3.78)	0.67	

*Note*. Means and standard deviations presented for participants. BDI = Beck Depression Inventory; BADS = total Behavioral Activation for Depression Scale; RPI = Reward Probability Index.

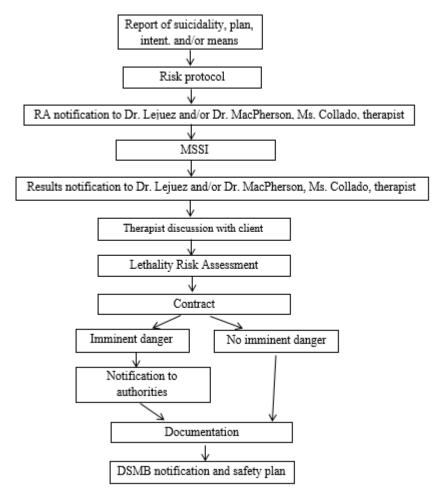


Figure 1. Protection of Participants Procedure Tree

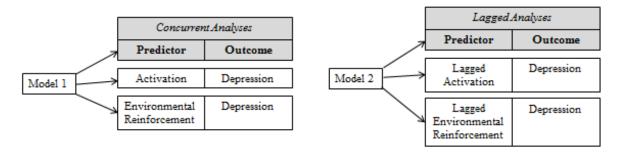


Figure 2. Representation of models that tested the correspondence between increases in activation and contact with environmental reinforcement, and decreases in depression. Model 1 tested the simultaneous correspondence between depression with activation and environmental reinforcement. Model 2 tested if increases in activation and contact with environmental reinforcement predicted depression.

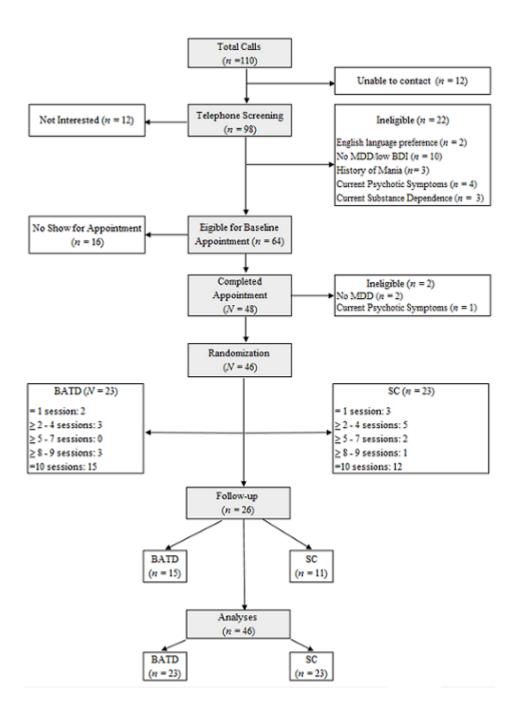


Figure 3. Consolidated Standards of Reporting Trials (CONSORT) flowchart of study participants, randomization, treatment, follow-ups, and inclusion analyses. BATD: Behavioral Activation Treatment for Depression; SC: Supportive Counseling; MDD: Major Depressive Disorder; BDI: Beck Depression Inventory.

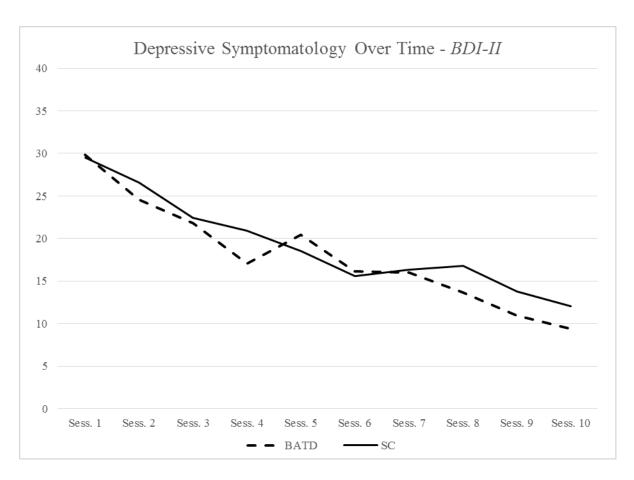


Figure 4. Depressive symptomatology over time between conditions measured by the BDI-II. BATD= Behavioral Activation Treatment for Depression; SC= Supportive Counseling

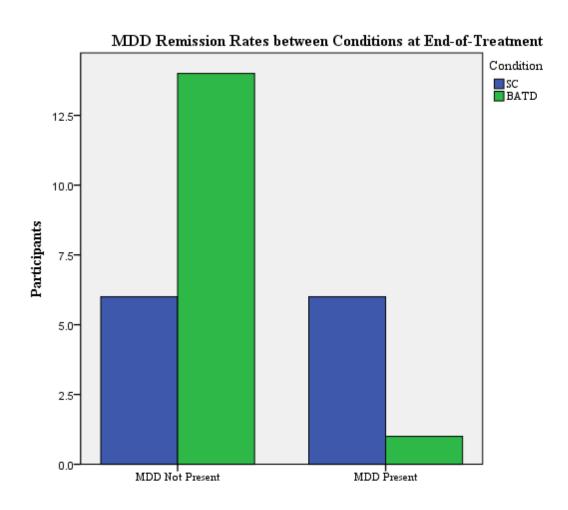


Figure 5. Remission of Major Depressive Disorder between treatment Conditions

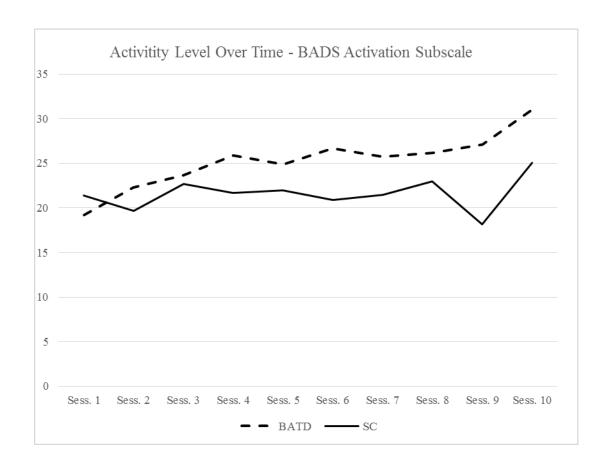


Figure 6. Activity level between conditions over time measured by the BADS Activation subscale. BATD= Behavioral Activation Treatment for Depression; SC= Supportive Counseling.

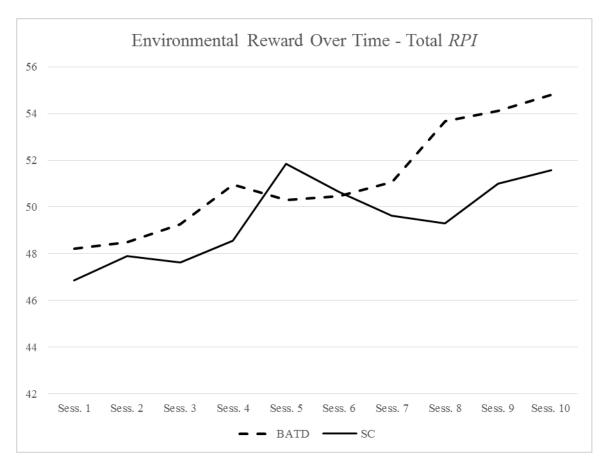


Figure 7. Environmental reward between conditions over time measured by the RPI total scale. BATD= Behavioral Activation Treatment for Depression; SC= Supportive Counseling.

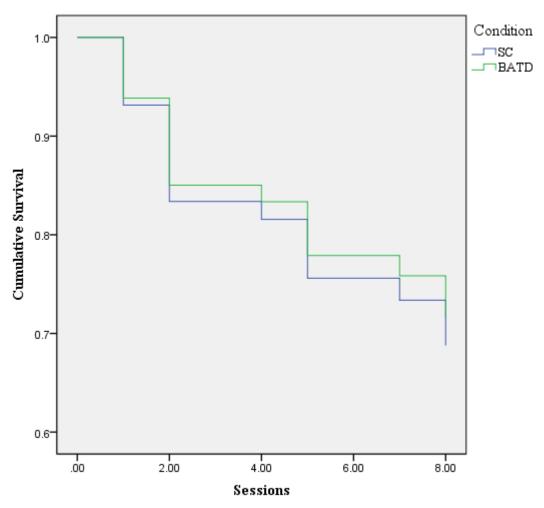


Figure 8. Time to Treatment Attrition.

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