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# Culturally-Adapted Cognitive Behavioral Therapy for Bilingual Latinx with Depressive Symptoms

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# CULTURALLY-ADAPTED COGNITIVE BEHAVIORAL THERAPY FOR BILINGUAL LATINX WITH DEPRESSIVE SYMPTOMS

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## ABSTRACT

The prevalence of depression is particularly high in the Latinx population, and this population is associated with lower rates of depression diagnosis and treatment. One intervention that has shown to be effective in treating mild to moderate depression is cognitive behavioral therapy. Though the effects of culturally adapted therapy, language being the most common adaptation, have been studied, the difference in outcomes for bilingual, bicultural speakers has not been examined. In this randomized control trial, we will compare the effectiveness of Spanish language cognitive behavioral therapy to that of English language therapy in bilingual, foreign-born, Latinx patients with depressive symptoms. We expect patients will have a statistically significant difference from baseline in their depressive symptoms at six months with S-CBT. This work may help improve access to effective care for depressive symptoms in this population and may suggest broader use of "native-language therapy" to improve outcomes.

# CHAPTER ONE: INTRODUCTION

## 1.1 BACKGROUND

Only 5.8% (53,526) of active physicians in 2018 identified as Latinx[1], while 56.2% (516,304) identified as White, in the US. Meanwhile, the Latinx population in America has reached almost 61 million as of 2019[8]. This makes the Latinx population the largest ethnic minority in the United States. 47.9% of Latinx adults were born in another country in 2015[4], and though 62% of Latinx adults in the United States speak English or are bilingual, an overwhelming 38% mainly use Spanish in daily communications[5]. 43.7% of 2011 American Community Survey Spanish-speaking respondents 5 years or older spoke English less than "very well"[9]. Consequently, many Latinx, Spanish-speaking patients are not provided with adequate care in the appropriate language.

Some studies suggest that socioeconomic disadvantage and lower acculturation levels may be associated with lower English proficiency among Latinx patients, however, there is conflicting data on whether language proficiency or preference is associated with physical and mental health disparities[6]. Socioeconomic status can limit access to necessary health care resources, access to education, and is related to level of acculturation. Acculturation, or the cultural modification of an individual by adapting to or borrowing traits from another culture, plays an important role in health care. The prevalence of English-speaking providers, access to culturally sensitive care, and stigmas against health care in particular cultures can all affect a patient's outcomes and are all affected by their level of acculturation. By limiting some of these barriers, a clearer relationship between treatment in Spanish and health outcomes may be extrapolated.

Major depressive disorder is one of the most prevalent psychiatric disorders and represents an enormous burden on the affected population. Depression can be a consequence of social, psychological, and biological factors and can result in stress, functional disruptions at school or work, physical somatizations of the disorder, and possible suicide. People with depression are more likely to have cardiac disease, diabetes, asthma, obesity, and to be current smokers. In the U.S., the prevalence of depressive disorders is 5.9%, or almost 18 million people[9] and 8.2% of persons aged 20 and over with depression are of Latinx descent[7].

In addition to the high prevalence amongst the Latinx population, several studies have illustrated disparities in diagnosing and treating depression in Latinx clients across all ages, environments, and levels of acculturation. Other studies have shown that Latinx patients are more likely than non-Latinx white clients to receive substandard care, have poorer outcomes from antidepressant treatment, and may prefer psychotherapy over pharmacotherapy[6]. As with many other ethnic minority groups, talking about emotions or acknowledging mental health issues is often stigmatized. A lack of understanding, in these communities, about mental health issues enhances this stigmatization. All of these issues are potentially exacerbated when the provider does not speak the same language as the patient and does not understand the cultural norms and background that contribute to patient decisions.

Psychotherapy, such as cognitive behavioral therapy or interpersonal therapy, is the mainstay of treatment for those patients with mild to moderate depression and has lower rates of relapse than SSRIs and other anti-depressants and a decreased side effect burden. In spite of the effectiveness of these treatments, it has been shown that Latinx

clients underutilize these resources. Anecdotally, Latinx patients cope with mental health issues by talking to friends, family, and religious figures, but struggle to broach these topics with health care providers[2]. Though it is known that with thorough treatment, depressive symptoms can be managed, clinical trials focusing on bilingual, Latinx patients and their mental health outcomes with Spanish-only psychotherapy are rare.

A literature review has shown that lower rates of diagnosis of depression and poorer outcomes among adult Latinx Americans could be related to language disparities, differences in health literacy, variances in cultural idioms used to indicate or describe distress, and variances in somatic presentations amongst Latinx patients[6]. Additionally, though there are increasing efforts to improve cultural training, offer translators, and train providers to speak Spanish, monolingual Latinx still have lower medication adherence rates, substantial impediments to medication adherence, and lower rates of previous visits for mental health care[3].

The main question this study hopes to answer is: Do Latinx, bilingual patients with depressive symptoms living in the United States have improved mental health outcomes in response to Spanish-only cognitive behavioral therapy than the same population receiving treatment in English? To our knowledge, this question has not been systemically addressed, but considering the known health disparities for Latinx, the under-diagnosis of depression in this population, and lack of effective treatment, it is an important topic to study. Of note, throughout this paper, there will be references to Latinx, Latino/a, or Hispanic populations. For the current study, we chose to use Latinx as the most appropriate and current term to refer to this population. However, many of the studies referenced use Hispanic or Latino to refer to this group.

## 1.2 STATEMENT OF THE PROBLEM

Depression is under-diagnosed and undertreated in the Latinx group and research shows that this group prefers psychotherapy to medication therapy. Limited non-pharmacological studies have been conducted and psychotherapy in the bilingual patient's native tongue has not been explored.

## 1.3 GOALS AND OBJECTIVES

This study's overall goal is to improve global functioning and decrease depressive symptoms in Latinx patients with depressive symptoms by providing them with cognitive behavioral therapy in Spanish. The aim of the study is to determine whether psychotherapy in Spanish provides better mental health outcomes than psychotherapy in English for bilingual, foreign-born, Latinx patients. Another aim is to determine whether patients subjectively enjoy/feel more comfortable during their clinic visits with Spanish or English therapy.

## 1.4 HYPOTHESIS

When Spanish-language psychotherapy, as compared to English language psychotherapy, is provided to bilingual, foreign-born, Latinx patients aged 25-50 with depressive symptoms, they will have a statistically significant difference in mean change in baseline in their depressive symptoms at six months based on Beck's Depression Inventory II.

## 1.5 DEFINITIONS

**Psychotherapy:** the treatment of mental disorder by psychological rather than pharmacological means.

**Beck's Depression Inventory II:** a short, self-report questionnaire created to measure the severity of depression symptomatology.

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# CHAPTER TWO: LITERATURE REVIEW

## 2.1 INTRODUCTION

A comprehensive literature search of relevant materials for the proposed study was conducted between June 2020 and April 2021 using PubMed, Cochrane, Scopus, Ovid, and MEDLINE with the assistance of librarians at the Yale School of Medicine. This review discusses the current literature on cognitive behavioral therapy delivered in different languages, the importance of language in emotional expression, and the significance of culturally-adapted care. The following keywords were searched in the aforementioned databases in a variety of combinations: *depression, therapy, psychotherapy, cognitive behavioral therapy, immigrants, Hispanic Americans, Latinos/Latinx, multilingualism, Beck Depression Inventory (BDI), Spanish, English, bilingual, bicultural, depressive symptoms, native language/tongue and mother-tongue.* A limitation was placed on year of publication to including years 1990 and on. The search was limited to English language sources and included systematic reviews, meta-analyses, cohort studies, randomized clinical trials, and case-control studies. Sources cited by selected articles were reviewed to find additional sources. This literature review explores the existing evidence while illustrating the limitations of existing data and justifying the need for this proposed study.

## 2.2 CURRENT TREATMENT

Depression is a disorder that negatively affects how one feels, thinks, and acts. Major depressive disorder is defined as a depressed mood or anhedonia and 5 or more of the following symptoms for at least 2 weeks: insomnia/hypersomnia, anhedonia, guilt or

feeling worthless, decreased energy, reduced cognition or difficulty concentrating, changes in appetite or weight, psychomotor agitations or retardations, and suicidal ideation. Milder forms of depression can exist with fewer of these symptoms.

There are many forms of treatment for depression or depressive symptoms and it is difficult to say whether there is a standard of care that fits all patients. However, with shared decision making, the first line treatments most frequently offered are psychotherapy or second-generation antidepressants. Many studies show that a combination of these methods has the greatest efficacy over either technique alone. The types of psychotherapy include: behavioral therapy, cognitive therapy, cognitive-behavioral therapy (CBT), interpersonal psychotherapy (IPT), mindfulness-based cognitive therapy (MBCT), psychodynamic therapy, and supportive therapy. Combined treatment of cognitive-behavioral therapy or interpersonal psychotherapy plus a second-generation antidepressant is the recommended treatment for optimal results[33]. Additionally, interpersonal therapy and cognitive behavioral therapy have been shown to be as effective as medication-treatment for mild to moderate depression, while having a lower relapse rate and side effect burden. While both methods of care are critical to treating depression and depressive symptoms, this study focuses only on psychotherapy, and more specifically, cognitive behavioral therapy.

### *2.2.1 Cognitive Behavioral Treatment*

The goal of cognitive behavioral therapy is to emphasize what is currently going on in a patient's life and not what led up to their difficulties, and help them develop coping skills and address erroneous thoughts. In standard of care cognitive behavioral

therapy in English, a trained clinician challenges negative patterns of thought that a patient has about themselves and their surroundings in order to alter unwanted behavioral patterns or mood disorders. This is accomplished via several strategies: learning to recognize distortions in thinking and reevaluating them in reality, gaining an understanding of others' behaviors and motivations, using problem-solving to cope with situations, using role play to prepare for problematic interactions, and learning to calm one's mind and body[33]. Again, based on shared-decision making, the clinician and patient will decide which, if not all, of these methods is most effective for the patient.

The first landmark study by Rush et al.,[52] CBT was demonstrated to be more effective than tricyclic antidepressant therapy in patients with clinical depression. A follow-up study showed that relapse rates were lower among patients who received CBT (39%) over those receiving antidepressant medication (65%), although this did not meet criteria for statistical significance. Though the Rush study is now believed to be sufficiently flawed to negate its findings, many qualitative and quantitative reviews have found that CBT effective treats depression, is at least comparable to medication treatment, and may have lower rates of relapse when compared to medication[41].

In the Latinx population, psychotherapy is preferred over pharmacotherapy. There is limited engagement with antidepressant pharmacotherapy amongst Latinx, even after addressing many existing structural barriers, due to the incongruence of medication therapy and Latinx culture. The Latinx population has been found to: report lower preference for antidepressants[25], more concern about medication addiction and harmfulness[10], greater stigmatization of pharmacotherapy for psychological issues[30], illness constructs that are inconsistent with antidepressant treatment[9], more reliance on

faith-based services to cope with depression[10], lower likelihood of communicating complaints to clinicians about medication treatment[58], and more unmet expectations of clinician relationship with them during treatment[18].

## 2.3 REVIEW OF EMPIRICAL STUDIES

### *2.3.1 CBT with Latinx*

Providing that Latinos are at increased risk for psychiatric disorders and underutilization of services, it is all the more important that culturally and linguistically appropriate services are generated. Though Latinos share a language, the group is a heterogenous one with influences from an array of cultures, socioeconomic backgrounds, race, and more. Irrespective of these differences, the literature mentions social constructs that are believed to be integral in the lives of Latinos, including: familismo (family orientation), personalism (personal relationships over institutional), respeto (mutual and reciprocal respect), confianza (trust and intimacy), dichos (idioms or popular sayings), fatalismo (fatalism), controlarse (self-containment), aguantarse (to withstand stressful situations), and sobreponerse (self-suppression)[6]. These values are important in developing the therapeutic alliance between patient and provider.

There is a plethora of treatment options for depression in the Latinx population. Amongst these options are motivational interviewing, cognitive behavioral therapy, group therapy, group exploratory/supportive, medication, community referral, interpersonal therapy, problem solving therapy, behavioral activation, and more.

The most commonly studied therapy is cognitive behavioral therapy, which has been shown to be as effective as medication treatment. A systematic review of depression

psychotherapies among Latinos found that cognitive behavioral therapy fairs better compared to treatment as usual, i.e. referrals upon request, care provided by a primary care provider, or an intervention selected at the therapist's discretion[14]. In this review, 7 out of 8 randomized clinical trials, showed that CBT provided better depression outcomes when compared to usual care or minimal treatment. Additionally, this review illustrated that Latinos tend to seek out mental health care from primary care rather than mental health providers. The implementation of culturally and linguistically appropriate care at every level of care is necessary in order to address the needs of this population.

A randomized clinical trial assigned impoverished minority women with current major depression to guideline-based care for depression—either paroxetine/bupropion or cognitive behavioral therapy for 8 weeks—or referral to community care[43]. The group consisted of black women born in the United States, Latinas born in Latin America, and white women born in the United States. Women were given access to transportation for care visits, child care funds to enable women to participate, participating providers, 1 was black and 3 were Spanish-speaking, with all having extensive experience in treating low-income and minority patients. 50.2% of patients were of Latin origin. More patients engaged and remained compliant with pharmacotherapy over psychotherapy, and only 17% of patients referred to community care attended even one session. Based on the Hamilton Depression Rating scale, women receiving the medication intervention and the psychotherapy intervention had a greater mean change in depressive symptoms than community referral patients experienced. The CBT intervention resulted in improved social functioning (P = .02) and women that were assigned to pharmacotherapy were twice as likely (odds ratio, 2.04; 95% confidence interval, 0.98-4.27; P=.057) to achieve a

Hamilton Depression Rating Scale score of 7 or less by month 6 as were those referred to community care[43]. Though this study illustrates that, for low-income populations, pharmacotherapy may be more effective than psychotherapy due to faster onset of action and shorter intervention onset time, it also shows that guideline-concordant care for major depression is effective in this diverse and impoverished population if they are given support to overcome barriers to care. Limitations of this study include: self-reported measures, clinician bias in assessing PTSD, 50% of women that screened positively for depression did not follow up for diagnostic interviews, women receiving follow-up calls said they were helpful which could have attenuated intervention results compared to the community referral service, and finally, the enhancements provided to allow women access to treatment cannot be separated from the treatment and the resulting outcomes. Recognizing the barriers to care elucidates some of the other disparities besides language that may confound the results of this study. There is a need for further investigation into the different facets that affect therapeutic outcomes in minority populations.

In another randomized clinical trial, CBT group therapy alone was compared to the same therapy supplemented width clinical case management[42]. This study showed that Spanish-speaking patients who received supplemental case management with their CBT treatment showed greater reductions in depressive symptoms and improved retention than those undergoing CBT alone. Spanish-speaking patients also received culturally-adapted care, including bilingual and bicultural providers, providing all materials in Spanish, training staff to include *respeto* (respect) and *simpatia* (sympathy), values important to Latinx patients, and allow for warmer interactions than are typical for

English-speaking patients. Case management involved assessing patients' self-reports of problems in housing, employment, recreation, and relationships with the patient to set goals for change[42]. For Spanish-speaking patients, the mean change in depressive symptoms with just CBT, based on BDI, was 26.2% ±10.2, while with supplemental case management, it was 30.8% ±10.8 ($p=0.03$ for Spanish-speaking and $p=0.05$ for English-speaking). The additional case management was less effective for those whose first language was English. The study lists the following limitations: the effect of supplemental case management and its dependence on culture was not predicted, case management activities differed between groups because Latinos received more home visits, the case study intervention influenced patient participation and introduced bias, and small sample size with borderline statistically significant results. Despite these limitations, this shows that language is an important moderator of health and treatment outcomes. Because only Spanish-speaking patients received culturally and linguistically modified care, the is no matched control population and it is, therefore, difficult to extrapolate whether the additional case management or the modifications led to the greater mean change in depressive symptoms. Nevertheless, this study illustrates that CBT, with or without case management, is effective for the Spanish-speaking, Latinx population when modified appropriately.

Another study compared group cognitive behavioral therapy, behavioral therapy (BT), and waitlist control among Spanish-speaking only, Puerto Rican women with self-reported depression with a Puerto Rican, Spanish-speaking therapist. The depression in this population was found to stem from three main themes—powerlessness, inferiority, and helplessness that have been socialized into their cultural background[16]. Using the

Beck Depression Inventory and the Hamilton Rating Scale for depression, there was a 64% mean reduction in depressive symptoms for CBT and a 51% mean reduction for behavioral therapy. For the BDI, $F(l, 20) = 30.32$ and $p < .001$ and for the HRSD, $F(1, 20) = 23.37$, $p < .001$, showing significant differences between control and therapy groups. At the 5-week follow-up, treatment gains for CBT were reduced, while behavioral therapy continued to allow for improvement. The author postulated that this could be due to the inclusion of scheduled rewarded activities with BT. The study lists the following limitations: brevity of follow-up and narrow diversity in sample population. This study is limited by the incorporation of group psychotherapy along with the CBT and BT. Because group psychotherapy is a format that is more consistent with Puerto Rican cultural values and the concept of extended family prevalent in this community, it is difficult to ascertain specifically what created the improvement in depressive symptoms. This study was also limited by brevity of follow up and a narrow range of population (middle-aged, unemployed, Puerto Rican women with low educational level)[16].

A pilot study in Australia studied delivery of culturally-adapted CBT by bilingual health professionals to carers (caretakers) of patients with dementia, of Chinese or Latinx descent, in their respective native tongues[37]. A CBT was formulated for people of culturally and linguistically diverse backgrounds (CALD) within Australia, focused on educating patients about managing their family members with dementia and handling their own stress. Participants were excluded if they did not speak Cantonese, Mandarin, or Spanish at a sufficiently fluent level to be able to fully participate in the study. A significant decrease in depression, anxiety, and stress was seen in both groups based on the Depression Anxiety and Stress Scale (DASS). Specifically, half of all participants

displayed a statistically significant change during intervention—31.8% recovered from their depression, 13.6% were recovering, and 13.6% were improved. With regards to the Spanish-speaking group, significant improvement was observed in the DASS overall ($t_{11}$ =3.74, p< .01) and significant decreases in depression ($t_{11}$=2.60, P < .05). Because this study was focused on carers and their stress reduction, rather than the language in which the therapy was delivered, the qualitative report showed that the majority of participants found the content relevant, helpful in reducing their stress levels, taught them coping skills, and increased their level of empathy. Though the generalizability of this study is limited by the niche population of carers and the limited sample size, it further illustrates how the increasing rates of worldwide migration must have an equivalent response of increasing availability of bilingual, bicultural providers who can deliver effective support programs for CALD communities living in other countries.

A similar study provided a CBT-based small group intervention program to carers for relatives with Alzheimer's disease or other dementia[23]. The study population consisted of non-Hispanic White women and Latinx women. Within each ethnic group, the women were randomly assigned to the CBT or to a minimal telephone-based control condition. Interviews and interventions were conducted by bilingual providers in either English or Spanish with culturally-specific modifications for the Latinx population. Both groups received approximately 16-week protocol driven treatments. The limitations of this paper include: female only caregivers, one ethnic group creating lack of a diverse sample population, and only one post-assessment time was measured leading to unknown sustained effects of results. Though no direct ethnic or racial comparisons were made in this study, both non-Hispanic White and Latinx caregivers showed significant decreases

in depressive symptoms and burden, along with improvement in coping mechanisms, social support, and self-care and were more effective than telephone-based care (CESD ($t(177) = 12.61$, $p = .000$), PSS ($t(177) = 11.46$, $p = .000$), and the RMBPC-CB ($t(177) = 10.25$, $p = .000$). No significant difference was found between groups. Thus, while there was no significant difference between the non-Hispanic group and the Latinx group, this is equally valuable. The few reported efforts to culturally sensitize this treatment show that structed interventions can help Hispanic/Latino caregivers if appropriate modifications are made to account for language and other cultural influences. Though this population is very specific, the information may easily be extrapolated to a larger Latinx audience.

*2.3.2 Language Adaptation*

A significant portion of Latinos living in the United States are disadvantaged and experience many psychosocial and medical problems including, acculturative stress, use of illicit substances and alcohol, HIV infection, high rates of unemployment, poor housing, limited educational attainment, and diminished nutrition. These issues can exacerbate or instigate substance use or psychiatric disorders. Latinos, moreover, tend to underutilize mental health services due to stigma against mental health services, cultural and linguistic barriers, lack of bilingual/bicultural providers, cost of services, and lack of validated treatments for this specific population[6].

In addition to relevant social constructs and barriers, language is an integral part of one's identity and one's ability to interact with the world around them. According to the Whorfian hypothesis, the language a person speaks structures perception, thought,

and is a part of a group identity[34]. While the connection between language and perception has been contested, the idea that language serves as a body of social norms and values is essential.

For bilingual speakers, this idea of perception controlled by language is complicated by the existence of two bodies of norms and values within each language and at which point in their lives they learned each language. It has been suggested that bilingual speakers acquire their languages either as a compound or coordinate language system. A compound system is the experience of two languages within one context, i.e. a child learning two languages since birth. A coordinate system is the person who learns one language during the early period in their life and the second language at some point later on in their life. This can affect how a person expresses themselves and create associations between a specific language and certain memories, values, and ideals. Furthermore, a second language is usually learned in a more neutral environment than the first[27]. Most bilingual Latino immigrants would fall into the latter category of coordinate systems, having learned Spanish in their country of origin, and learning English later on in their lives.

In the therapeutic setting, it has been observed that bilingual patients tend to be more emotionally withdrawn in their second language as opposed to their mother tongue and more affect is expressed in the mother tongue. Additionally, studies using the Thematic Apperception Test (TAT), which measures an individual's personality, values, or attitudes, in two different languages, have found that patients appear to have different personalities or have significantly different responses between languages[27].

In a study considering Spanish-English and English-Spanish coordinate individuals by Guttefreund (1990), Spanish-English and English-Spanish coordinate individuals were subjected to a Depression Adjective Checklist (DACL), which contains 34 adjectives that describes a person's mood and has been found to be a reliable measure of depression as a mood state, and the State-Trait Anxiety Inventory (STAI), which is valid as a measure of anxiety as a mood state and long-standing trait. Additionally, the subjects were subject to the Marlow-Crowne Social Desirability Scale (MC-SDS), which measures the extent to which an individual is responding so as to appear socially acceptable. The findings of this paper suggest that it is not mother tongue, but rather the qualities of a specific language that have an impact on emotional expression since both types of coordinate individuals expressed more affect in Spanish irrespective of mother tongue. Though this study shows that it is Spanish that allows greater emotional expression regardless of mother-tongue, the findings nevertheless have important implications for the Latino group who was better able to express their emotions in the native language. The Latino population may benefit from the Spanish-language therapeutic alliance, allowing patients to express themselves more comfortably and create distance in the discussion using the second language when needed.

One of the most common disparities for the Latinx population is access to care in the appropriate language. Language not only changes the way memories are encoded and allows communication, but is also part of an identity. Conventional attempts to adapt care have included using interpreters or translations of interventions not proven successful in Latinx communities, which do not use cultural constructs specific to the Latinx community and the Spanish language. A meta-analytic literature review found that

mental health treatments were more effective when they are culturally modified for a specific group based on cultural context and values[26]. When disparities in language and culture are reduced for the Latinx population, the utilization of mental health services is similar to that of the national population[3,4,10]. Controlling for these factors and adjusting therapy to be culturally relevant is a necessity to provide competent care for what is becoming a majority of the American populace.

### *2.3.3 Spanish Translation of Existing Treatments*

A study tested the improvement of depressive symptomatology with direct Spanish-language translation of behavioral activation treatment for depression (BATD), with no other cultural modifications in a population of Latinx with limited English proficiency (LEP)[13]. Patients were also assessed for activity engagement and environmental reward. The Beck depression inventory II was administered to determine diagnostic inclusion and weekly to identify variations in depressive symptomatology. Results showed a decrease in depressive symptoms ($p<0.001$) and an increase in activation ($p=0.04$) and environmental reward ($p=0.02$) over the course of the BATD. Follow-up interviews revealed a sustained clinical improvement in depression and activation. Though this study is limited by a small sample size and the use of an untested translation of a BATD manual, a large effect size ($d = 1.45$) was found for changes in depressive symptoms. In-depth interviews with patients showed that a direct Spanish translation of the BATD manual was culturally-sensitive and comprehensible. Because there is no control group and this is a population of limited English proficiency, one cannot state that the behavioral activation was more effective because of the language it

was delivered in. The limited sample size means that there may be inadequate power to detect significance, lack of generalizability, and inflated effect size estimations. This study also used RPI and BADS instruments, which have not been validated in this population and may include questions that include questions which may be normative experiences to this immigrant population, i.e. “I have few financial resources, which limits what I can do” or “People have been mean or aggressive toward me.” This means that seeing a change in scores for these scales is unlikely. However, no other cultural modifications were made besides adapting language of therapy to Spanish, meaning that improved symptomatology due to availability of Spanish language BATD cannot be ruled out. This study characterizes the need for a study clarifying the role of language in therapy.

Study investigators conducted a secondary data analysis of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D), which compared clinical characteristics and outcomes after treatment with citalopram for Latinx outpatients whose language preference was either English or Spanish[31]. Patients received citalopram for 14 weeks, with dosage adjustments made based on regular clinical assessments. The resulting data found that Spanish speakers were older, more likely to be women, less educated, of lower income status, had more medical burden, were more likely than English speakers to be seen in a primary care clinic over a psychiatric clinic, that Spanish-speaking Latinx patients may have a less robust response to antidepressants, and that mental disorder rates were found to be higher among Latinx proficient in English than Spanish. Before adjustment for baseline differences, Spanish-speaking patients had lower rates of remission, slower times to remission, and lower response rates compared

with English speakers. After adjustment, these differences were no longer significant (hazard ratio: 1.028 Hispanic vs. white; p=0.42). It is, therefore, more likely that the preadjustment results are due to sociodemographic, socioeconomic, or acculturative differences. Addressing only language disparity and not creating a culturally sensitive medication inducement process did not improve outcomes for Spanish-speakers to the same extent as for English-speakers. Though this study used language as a proxy for acculturative status, it is unknown whether this is an accurate measure, however, it may still have some utility based on the significant differences found between language groups. This study illustrates the complexity of treatment options for Latinx patients with depression. Though, as aforementioned, Latinx participants tend to prefer psychotherapy over pharmacotherapy, language concordance with pharmacotherapy may not be enough to significantly improve health outcomes for depression. This suggests that one must address cultural needs as well as linguistic and level of cultural sensitivity may vary with level of acculturation, thus, highlighting the need for further investigation into the effect of language and cultural sensitivity on the effectiveness of cognitive behavioral therapy.

Vida Alegre, a CBT program in Spanish, was initiated to serve the Latino population in their mother tongue. A study applying Vida Alegre showed how useful using a patient's mother tongue could be to decrease depressive symptomatology in immigrants Latinx mothers[48]. The pretest/posttest design examined a small, nonrandomized sample using a modified, Spanish version of the empirically supported manual: Group Therapy Manual for Cognitive-Behavioral Treatment of Depression. This program also educated bilingual graduate students to become proficient mental health providers for Latinx patients. The results, based on a center for epidemiological studies—

depression (CES-D) score, showed a significant decrease in depression scores after participating in the intervention. At pretest, the average CES-D score was 25 (range: 9-44) and the average posttest score was 12 (range: 0-26). Additionally, a large effect size of r = 0.67 was found despite a small sample size. Participants described that the intervention was helpful to regulate mood and family relationships. Limitations included, a high dropout rate that led to a small sample size, a lack of comparison group because it is a feasibility study, and lack of generalizability to communities without bilingual services. Despite these limitations, this study demonstrates, again, that services which are culturally and linguistically accessible create improved health care outcomes for Latinx patients.

*2.3.4 Language Concordance versus Interpreter Use*

Researchers headed a study focusing on the effects of language concordance and interpreter use on the therapeutic alliance in Spanish-speaking integrated behavioral health care patients[60]. Use of interpreters is a possibility to increase access and overcome the linguistic barrier for many patients, however, there are concerns about whether this impedes the therapeutic alliance. In this study, patients completed a brief therapeutic alliance scale at their behavioral health appointments and 10 Spanish-speaking patients, 10 behavioral health consultants, and 10 trained interpreters completed qualitative interviews. While quantitative results showed no significant effect on therapeutic alliance of interpreter compared to a bilingual provider ($F(1, 456) = 1.81$, $p = .179$), qualitative results showed that 80% of patients preferred a bilingual interpreter, but felt interpreters were a good alternative to not receiving services at all. Among the listed reasons for

preference of a bilingual provider included, enhanced privacy, increased trust and understanding, enhanced communication, and session length. One patient stated that, even though she was fluent in English, speaking in Spanish with her behavioral health consultant was like being “en casa” [at home] and that she could express herself more freely. Many patients mimicked this sentiment, feeling that they could connect more easily with bilingual providers. This study is limited in that trained interpreters were used, while in reality, most patients will receive care from ad hoc (untrained) bilingual providers or interpreters. Additionally, for the qualitative portion, patients were not chosen who were representative of the original sample, possibly limiting the therapeutic alliance themes that may have emerged. This study, again, shows that language interpretation is not enough for ideal outcomes. Patient preference for Latinx, bilingual providers shows that the language concordance is possibly a desire for cultural concordance as well.

### *2.3.5 Significance of Bilingualism in Therapy*

Though the use of native language with patients is mentioned in the therapists’ ethics rules, it does not allude to its therapeutic significance—meaning that the ethical rules of the American Psychological Association (2017) only request sensitivity to a patient’s cultural background, but there is no reference to the treatment of cultural-linguistic minorities[59]. Additionally, there is no reference for treatment of bilingual patients. As previously discussed, memory encoding may occur in different languages and, therefore, only accessible in respective languages, but patient bilingualism can also

affect the therapeutic relationship by impacting attitude of patient and provider towards each other and patient experience based on respective languages[38,56].

Several studies have found that allowing a client to use both of their languages may foster a stronger relationship, exposes client feelings toward the therapist, and allows for more efficacious therapy[50,51]. Moreover, allowing language switching permits patients to express themselves in whichever language most appropriately addresses their emotions. A qualitative study examining whether language switching bolsters alliance showed that bilingual therapists switched languages or use a specific word, phrase, or idiom in Spanish to increase trust. Furthermore, therapists could use a shift in language to assist Latinx patients in expressing specific thoughts, that they had trouble with in English, in Spanish[54].

Although the current study will focus on cognitive behavioral therapy in Spanish or English singularly, it is important to consider the possibility of a potentially more efficacious treatment modality that incorporates both English and Spanish. Moreover, acculturative status may affect how much preference there is towards one language and how important Latinx values are to a person during therapy.

### *2.3.6 Acculturation*

Cultural identity includes both ethnic and national identity and centers on an individual's sense of belonging to one or more cultural groups[45]. As a facet of acculturation, cultural identity involves a person's self-perception, but one may also have multiple independent cultural identities without renouncing one for the other[28,35,46]. Language, according to the ethnolinguistic identity theory (ELIT), represents a

fundamental property of one's cultural and social identity [24]. Several studies show that higher proficiency and usage in a person's ethnic, or native, language is associated with stronger national identity[40,47]. It is also often used as a proxy for acculturation. Though this measure is not validated, it is most commonly used because it is easiest to measure and involves assessing differential capacities to read, speak, and think, as well as levels of use based on preferences or opportunity for use. It is important to measure acculturation, which has limited research assessing its effect on mental health outcomes.

## 2.4 POTENTIAL CONFOUNDING VARIABLES

With all clinical trials, there are many possible confounding variables that can inadvertently affect the results of the study. This effect can be minimized with randomization and strict constraints on the study population, but still, some variables cannot be realistically controlled for. The most common source for potential confounding is sociodemographic status. Lack of engagement in treatment may not be solely dependent on the efficacy of cognitive behavioral therapy in each respective language, but on factors such as unemployment, inflexible work schedules, uninsured status, minimal education leading to difficulty grasping concepts, lack of child care, lack of familial support, and more [1].

Immigration status along with country of emigration can be another confounding factor. While immigration can be an arduous and depression-inducing ordeal, not all immigrants will have the same experience. For example, people from Puerto Rico are born as citizens of the United States, meaning that their immigration experience will be very different from that of an undocumented person from Mexico crossing the border into

the United States or that of a person from the Dominican Republic entering the country after waiting a decade for a green card[2].

Acculturation can also be a confounder. If language is a proxy for acculturation, several studies have found that monolingual Spanish status or limited English proficiency, or less acculturated Latinx patients, are more likely to be non-adherent. It has also been found that patients who saw a Spanish-speaking non-Latino therapist were less likely to adhere to treatment, and more likely to adhere with a Latino therapist; thus, this suggests that ethnic concordance, not just language concordance can improve adherence and patient outcomes[20,21,32].

Mental health stigma is common in the Latinx population and is a possible confounder of outcomes. This stigmatization includes a fear of being negatively perceived by others and believing that personal problems should not be disclosed[5,53]. Mental health stigma is also related to higher levels of attrition and nonadherence, and it can continuously affect patients throughout treatment[15]. There is not a significant amount of research on how stigma affects mental health treatment or on how to combat its effects. Therefore, since it has not been controlled for in this study, it could negatively affect outcomes.

Somatization— in which psychological concerns are converted into physical symptoms—is common amongst Latinx individuals[29]. Our proposed study includes no measure of somaticized symptoms; these symptoms, in combination with self-reported measures, could potentially create falsely high or low readings of depression symptomatology.

## 2.5 REVIEW OF RELEVANT METHODOLOGY

This section of the literature review focuses on methodology relevant to the proposed study. The following will provide a review of proposed methods described in Chapter 3.

### *2.5.1 Study Design and Setting*

The proposed study will be a prospective randomized clinical trial comparing the outcomes of bilingual Latinx patients receiving culturally-sensitive cognitive behavioral therapy in English or Spanish (S-CBT). A systematic review of efficacy of depression treatments for immigrant patients showed that the generalizability of findings reported in many of the studies were limited in sample size, reported high attrition rates, and the range of ethnic populations was narrow[8]. Single group designs, mostly feasibility studies or pre/posttest studies, threaten the internal validity of these studies by overestimating the effectiveness of intervention. We will be performing a randomized clinical trial in order to establish a causal relationship between the given intervention and primary outcome of decreased depressive symptoms. Randomization will also lessen selection bias and confounding within the sample population. The study will utilize a multi-center randomized clinical trial design, thereby validating the generalizability of the results.

### *2.5.2 Selection Criteria*

Of the studies found in the literature review, most used referrals from a primary care provider or a psychiatrist to recruit patients[1,16,22,29,42]. Others were recruited through community centers serving a particular ethnic populations and local ethnic media and

flyers[12,13,23,37]. For the projected study, we will be following most closely the schema of referral from an office. Because the Latino Behavioral Health System (LBHS) is a collaborative endeavor of local agencies providing behavioral health services to the Latinx population of the greater New Haven and surrounding areas, a wider range of patients will be eligible for our study.

*2.5.3 Intervention*

The intervention of the proposed study is to use language as  and perceive any differences between the efficaciousness of cognitive behavioral therapy delivered in English or Spanish. A study by Collado et al. (2014), delivered behavioral activation therapy in Spanish, with no other cultural modifications, to a sample of 10 Latinos with limited English proficiency and depressive symptomatology. This study had no comparison group, but showed positive results from delivering the therapy in Spanish. Piedra et al. (2012) used a pretest/posttest design to examine whether exposure to Vida Alegre, a culturally-modified group cognitive behavioral therapy, would improve depressive symptoms. In this study, there was again, no comparison group and no randomization. Other authors created similar therapeutic studies looking at how the success of cognitive behavioral therapy (or other therapeutic methods) would be affected by delivery of the therapy in Spanish, or other native tongue[1,12,16,22,23,29,37,44]. These studies used monolingual patients or patients with limited English proficiency. Each study used Spanish, or native language, as part of the intervention, but did not directly look at the role language has on therapeutic outcomes. These studies, moreover, had no active control group, choosing either to do a feasibility study with a pre/posttest study or

to have a treatment as usual (i.e. no treatment, waitlist, community referral, etc.) group as the comparison arm.

The proposed study is looking at bilingual patients receiving the same therapy in English or Spanish. To our knowledge, there are no similar studies using language as the independent variable in proficiently bilingual patients. Therefore, the study design will be based on the aforementioned studies, but will be a randomized clinical trial, with language as the primary intervention and matched baseline characteristics of the study groups.

*2.5.4 Primary and Secondary Outcome Measures*

For the primary outcome of mean change in depressive symptoms, the Beck Depression Inventory II (BDI-II) will be used to assess symptomatic changes. The BDI-II is a reliable and well-validated assessment of depression severity in English and Spanish with a high 1 week test-retest stability of 0.93 and a coefficient alpha of 0.92-0.94, showing high internal consistency[55]. There will be several secondary measures. To examine acculturation, the bidimensional acculturation scale is a 24-item list that enables the assessment of biculturality by evaluating language use, language proficiency, and media preferences[39]. The World Health Organization Disability Assessment Schedule 2.0 will be used to measure global functioning by assessing disability across several domains. Finally, a qualitative measure of patient satisfaction, that is correlated with the aforementioned culturally relevant values, will be assessed once a month via a 17-question survey illustrated in the appendix.

*2.5.5 Sample Size*

Many of the reviewed trials have reported sample sizes as a limitation for effective statistical analysis[8,49], reflecting poor internal validity and insufficient power for the study. In order to appropriately power the study, we have reviewed several other studies looking at cognitive behavioral therapy delivered in English or another native language to calculate a relative effect size for the determination of an acceptable sample size.

Additionally, while Latinx are more likely to find counseling acceptable than Whites [17], they are also more likely to drop out of psychotherapy more frequently than non-Latino Whites. Other studies have found that attrition rates for Latinos can range widely, some seeing dropout rates of up to 58%[1,29,42,44]. In order to preemptively reduce bias caused by attrition limiting sample size, we will incorporate a larger than usual presumed dropout rate into our calculation for sample size.

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# CHAPTER THREE: METHODS

## 3.1 STUDY DESIGN

We propose a multi-center, randomized clinical trial analyzing the effect of Spanish versus English cognitive behavioral therapy for depressive symptoms in bilingual, foreign-born, Latinx patients aged 25-50. Study investigators at thirteen collaborating agencies, included in the Connecticut Latino Behavioral Health System (LBHS), will enroll patients who score at least a 5 on the Patient Health Questionnaire, and when further evaluated, score at least a 14 based on Beck's Depression Inventory II, fit study inclusion criteria, and agree to participate in the study. Participants and study investigators will not be blinded to the treatment allocation due to the nature of the study.

## 3.2 STUDY POPULATION, SAMPLING, AND RECRUITMENT

The study population of interest is patients, over 25 years old and under 50 years old, who have a score on Beck's Depression Inventory II of at least 14, indicating mild clinical depression. They must be bilingual, foreign-born, Latinx patients. The study sample will be selected using convenience sampling by adding a Patient Health Questionnaire (PHQ-9) to intake paperwork of all patients at the thirteen branches of the LBHS. The locations of LBHS include: APT Foundation, Birmingham Group Health Services, Bridges… A Community Support System, Chemical Abuse Services Agency/Multicultural Ambulatory Addiction Services, Connecticut Mental Health Center (Latinx Clinic), Crossroads, Fair Haven Community Health Center, Fellowship Place, Harbor Health Services, Hill Health Center, Hispanos Unidos, Yale Behavioral Health (Workers Achieving Gainful Employment), and Yale-New Haven Psychiatric Hospital.

Patients who score at least a 5 on the PHQ-9, will be referred to investigators who will obtain informed consent and collect relevant history to ensure the patients fits inclusion criteria. There will be 4 study investigators who will be bilingual, Latinx master level clinicians with greater than 1 year of experience working with cognitive behavioral therapy and with Latinx populations. They will complete a one-day course on culturally concordant care for Latinx patients and on the protocol for this randomized clinical trial.

A study investigator will meet with each participant to review the study, potential risks and benefits, and to obtain consent. The consent form will in plain language, in Spanish and English, and will inform the study participant about: study guidelines, procedures, study length, eligibility, and medical implications of the study. It will inform patients that participation is voluntary throughout the study.

Language proficiency will be measured by the Duolingo English test. Though this scoring system is not validated, the more commonly used and validated Test of English as a Foreign Language (TOEFL), International English Language Testing System (IELTS), Cambridge Certificate of Advanced English (CAE), and Cambridge Certificate of Proficiency in English (CPE), are markedly more expensive, much longer (3-4 hours long), and require an appointment at specific times to take the exam. Therefore, with the Duolingo English test, we will set up several dates for participants to take the exam in a computer lab. The exam is only an hour long and the expense will be covered by the study. The minimum score required, out of the 160 possible points, will be 120, which the Duolingo website states describes a participant who: can understand a variety of demanding written and spoken language, can grasp implicit, figurative, pragmatic, and

idiomatic language, and can use language flexibly and effectively for most social, academic, and professional purposes.

Upon patient agreement and obtainment of informed consent, eligible patients will be randomized to Spanish or English cognitive behavioral therapy. Randomization will be done using the number generator "random.org," with the range of possible number outputs being preset to minimum – 1 and maximum – 2. Each patient encounter that generates a 1, the patient will receive CBT in English; each that generates a 2 will receive CBT in Spanish. Investigators will allocate patients to an intervention at the point of referral. Designation of intervention status will be recorded on a study sheet.

Patient education on the process of cognitive behavioral therapy will be the responsibility of study investigators. Participants will receive gift cards of a nominal amount for a supermarket in the area in which they live at the intake meeting and at the final session of therapy.

*Exclusion and inclusion Criteria:*

Patients will be eligible for inclusion if they are greater than 25 years old and less than 50 years old; are bilingual in Spanish and English confirmed by a language proficiency exam; presenting to one of the LBHS facilities; have a screening PHQ-9 score indicative of at least mild depression (score >5); provide written informed consent; minimum of 6$^{th}$ grade reading level; and agree to follow-up after the cognitive behavioral therapy sessions for the following three months. Patients must not: have a concurrent substance abuse or dependence; meeting diagnostic criteria for a current psychotic disorder; and meet criteria for bipolar disorder. If they are currently taking

antidepressants, they must demonstrate stability as indicated by three or more months of consecutive use. Participants who do not meet these criteria will be referred back to the LBHS for mental health services from another provider.

Requested patient information includes: MRN, age, race, sex, current medications, medical records, patient income, immigration status and reason for migration, highest level of education reached, and language preference. Patients who do not meet these criteria will be excluded from the study.

### 3.3 SUBJECT PROTECTION AND CONFIDENTIALITY

Prior to recruitment, the protocol of the proposed study will be submitted to the Institution Review Board (IRB) for approval to be conducted at Yale organizations. All organizations will require approval from their own institutional review boards. We will require written, informed consent from all eligible participants. Per the Yale IRB, the consent will detail the purpose of research, proposed study procedures, expected duration, scientific benefit, and personal benefits of participation. It will explain the risks of participation of the study and disclose alternative methods of management for depressive symptoms and will include an explanation of confidentiality and privacy practices. Investigator contact information and a sample study timeline with patient responsibilities will be included. A sample consent form is provided in Appendix B. Participants will be given a signed copy of this consent for their records and will be given a handout of their rights under HIPAA. Study subjects can withdraw from the study at any point without explanation.

The study will comply with the standards and requirements set forth by all committees. All study investigators will have evidence of institutional training in the Health Insurance and Portability and Accountability Act of 1996 (HIPAA) Privacy Training and complete the National Institutes of Health (NIH) Protecting Human Research Participant Training via the NIH training website. Study protocols will be done in accordance with HIPAA regulations and data will be deidentified and replaced with a computer generated, randomly allocated identification number. Patient information will only be accessed on secure institutional servers. Electronic devices containing patient data will be password protected.

During enrollment for the study, participants will be told to immediately notify study investigators or reach out for urgent medical attention if they experience worsening of their depressive symptoms, new or worsening suicidal ideation, or any new symptoms related to their depression.

### 3.4 STUDY VARIABLES AND MEASURES

In this randomized clinical trial, the experimental intervention will be cognitive behavioral therapy in Spanish for patients with depressive symptoms. The control is cognitive behavioral therapy in English.

The primary dependent variable of the proposed study is a change in baseline in depressive symptoms after six months, as rated by outcome assessors (psychiatrists) who have worked with the patient during cognitive behavioral therapy, based on the Beck's Depression Inventory II in Spanish or English. This measure will be performed after every 2 weeks of CBT. This measures characteristic attitudes and symptoms of

depression based on 21 items. This is a continuous outcome measure. The psychiatrists involved in the study will be bilingual and culturally-concordant, meaning they will be Latinx as well.

The secondary dependent variable measured will be global functioning of the participants, using the World Health Organization Disability Assessment Schedule 2.0. This self-administered questionnaire asks about difficulties due to any health conditions and assesses disability across six domains, including understanding and communicating, getting around, self-care, getting along with people, life activities, and societal participation. This measure will be administered once every three months.

Acculturation will be measured with the Bidimensional Acculturation Scale to correlate acculturative status with pre- and post-intervention outcomes. Language proficiency will be assessed with the Duolingo English test. These measures will be assessed at the onset of the study.

## 3.5 METHODOLOGIC CONSIDERATIONS

*Allocation of Treatment:*

Each patient will be randomly allocated to the intervention of Spanish-language cognitive behavioral therapy, or to the control group of English-language cognitive behavioral therapy. We will utilize a random-number generator and a 1:1 allocation to each group. This allows for equal allocation of participants to respective interventions and supports appropriate statistical analysis.

Due to the nature of the intervention and that the language allocation would be revealed upon initiation of therapy, blinding clinicians and patients is not possible.

Patient data will be collected by research assistants and de-identified before being entered into a database. Collected data will be analyzed by individuals blinded to group assignment. These factors will assist in avoiding interpretative bias.

*Methods of Culturally-Adapted Cognitive Behavioral Therapy:*

In order to reduce variability in quality of therapy between practitioners, all practitioners delivering therapy will be evaluated by study investigators to ensure they all provide the appropriate and consistent level of care.

All providers will deliver therapy following Beck's manualized guidelines for cognitive behavioral therapy in the general population. However, all treatment will be culturally modified. Providers will receive a one-day training in the application of Latinx cultural values in cognitive behavioral therapy based on "Engaging Latinos Through the Integration of Cultural Values and Motivational Interviewing Principles," which discusses topics including, *personalismo* (emphasis on personal relationships), *respeto* (respect), and *confianza* (trust)[7]. Any written materials will be provided in Spanish and English. Similar to "Effectiveness of iCBT for Chinese Australians with depression; provided in Chinese and English," we will modify phrases, concepts, and descriptions to be consistent with Latinx cultural values and terminology[37]. Providers at the LBHS have all been trained in these principles and are able to deliver these concepts in English or Spanish. Therefore, this one day training will serve to ensure minimal provider discrepancies.

*Confounding Factors*

There are many confounding factors, especially while studying a psychosocial issue. Through recruitment and study design, we will attempt to control for confounders of the intervention. Randomization of participants and controlling during recruitment for several factors, enumerated in the inclusion and exclusion criteria, in addition to performing ANOVA analyses for within and between group differences based on confounders will help minimize the effects of any confounding variables.

Overall, acculturation level, English-language competency, types of jobs available for immigrants, and low level of literacy are just some of the issues that are associated with increased depressive symptoms[2]. Additionally, lack of Spanish-speaking providers is correlated with decreased utilization of mental health services, lesser sense of privacy and trust, and decreased accuracy of communication[15].

### 3.6 DATA COLLECTION

Study investigators will collect baseline self-reported Beck's Depression Inventory II scores and conduct World Health Organization Disability Assessment Schedule 2.0 surveys and then continue to collect these data points on a monthly basis. After the 6 months of cognitive behavioral therapy, participants will come into the clinic once a month for the following three months to conduct score measures post-intervention. The Bidimensional Acculturation Scale will be used to measure level of acculturation in patients, with separate scores ranging 1-5 for "Latino" and "non-Latino," allowing for the assessment of biculturality, defined as a score >2.5 on each subscale[39].

### 3.7 SAMPLE SIZE CALCULATION

Due to the novelty of this study, comparable studies comparing English versus Spanish cognitive behavioral therapy with a primary outcome of Beck's Depression Inventory were uncommon. Thus, our sample size calculation is based on a relative effects size based on the averages of prior studies studying English and Spanish cognitive behavioral therapy, respectively. The first set of studies used cognitive behavioral therapy in English as the control in patients with depressive symptoms[11,19,36,57]. The second set of studies used cognitive behavioral therapy in Spanish, or native language, as the intervention[12,16,22,29]. From these data sets, a baseline for the control arm, English-language therapy, of 12.07 +/- 4.15 points of improvement on the BDI can be expected and a mean between-group difference of 5.84 points is the determined effect of Spanish language CBT. This represents an effect size of 1.3688 or 48.38%. Due to the heterogeneity of these studies, we will aim to detect a between-group difference of 3.621 or 30% relative effect of Spanish CBT. This study will assume an 80% power, with beta = 0.2, and 2-sided t-test with alpha = 0.05. This data provides a required sample size of 30, with 15 participants per treatment arm. We will adjust for an expected 40% dropout rate and ensure an even number of participants for randomization, which will require 42 participants in total, and 21 participants per treatment arm. See appendix for calculations for sample size and effect size.

### 3.8 ANALYSIS

Analysis of baseline characteristics, primary, and secondary outcomes will be done using statistical tests prior to using computer analysis. Categorical and dichotomous variables will be analyzed by 2-tailed Chi square test for proportional differences.

Continuous variables will be recorded as means (+/- Standard Deviation) and analyzed by t test. The primary outcome will be analyzed via a 2-tailed independent t test for means +/- SD of normally distributed, continuous variables. Between group data will be analyzed using a dependent t test for means +/- SD.

### 3.9 TIMELINE AND RESOURCES

The study period, including recruitment and protocol completion, will be 2 years. Admission to the protocol will be rolling and the study will begin accepting patients on May 1st, 2021 and will stop recruitment on August 1st, 2022 given that the maximum duration of study participation is 9 months from the start of therapy to the end of follow up. 2 principle investigators and 4 participating providers are required for the study. Providers will screen eligible subjects. 4 research assistants will record outcome data for all participants. The study will be focused at the Latinx clinic and overseen by the primary and co-primary investigators.

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# CHAPTER 4: CONCLUSION

## 4.1 STRENGTHS

There are several strengths and weaknesses to the proposed study. Because this is a randomized clinical trial, if conducted properly, this will allow us to determine a causal relationship. Conducting research at several different clinical sites allows the study to have a wider breadth of patient diversity in race, sex, culture, duration of symptoms, previous treatments, and more. Convenience sampling will ensure that there is a large study population from which to sample patients. With relatively few restrictions, the population is a wide enough selection that it is a representative sample. These strengths increase the generalizability of study findings.

The study investigators will be 4 bilingual, Latinx master level clinicians with greater than 1 year of experience working with CBT and Latinx populations. They will also undergo a one-day course on culturally concordant care for Latinx patients and on the protocol for study. These elements ensure uniformity of care, however, there still may be practitioner variability. The outcome of each patient's therapy will not be blinded to the intervention or outcomes due to the nature of the intervention, i.e. patients and providers will know if there is progress over the successive sessions. An online program will be used to determine randomization of a patient's treatment allocation, thus, preventing bias by study investigators for treatment allocation. With the additional qualitative data to accompany the quantitative data, there is more detailed information to explain complex findings and there are multiple methods of data collection on sensitive subjects.

## 4.2 LIMITATIONS

A limitation of this study is in that though manualized therapy is used, the adaptations used are not part of manualized therapy. Though providers at these facilities have been trained in these adaptations, the lack of an empirical standardization and direct measures of these adaptations may introduce bias due to differences in treatment and possible effect of adaptations on outcomes. A possible future study could compare bilingual therapists that are trained or untrained in culturally adapted cognitive behavioral therapy and compare outcomes in depressive symptomatology. Another limitation is the lack of a therapist-scored clinical measure. Though the BDI will be administered by a clinician in this study, it is a self-report measure. The inclusion of self-report measures introduces bias to the outcomes. Though there are few available measures for depressive symptomatology that are not self-report, future studies could include measures such as the thematic apperception test (TAT), which asks clients to write a story about a drawing or figure, or an adapted version of the Minnesota Multiphasic Personality Inventory (MMPI), which is a psychological test that assesses personality traits and psychopathology, but is not currently validated in the Latinx population. The niche population of bilingual, Latinx clients limits the generalizability of this study to other groups, but can be used as a reference point for future studies. Another limitation is that the population sample does not exclude participants based on socioeconomic status. Income and job stability can introduce other, uncontrollable variables causing depressive symptoms. Additionally, limiting participants by socioeconomic status would severely limit the sample and create an unrepresentative population sample. By covering costs of the intervention, we hope to limit, as much as possible, the effects of socioeconomic

status on health outcomes. Finally, although certain values may be similar across Latinx groups, it is important to acknowledge that not all populations in the Latinx amalgamation are exactly the same. With each subculture, there are differences in immigration stories, socioeconomic issues, specific cultural values, and more. Though clinicians will be bicultural (American and Latinx), it is not reasonably feasible to match participant subculture to clinician subculture.

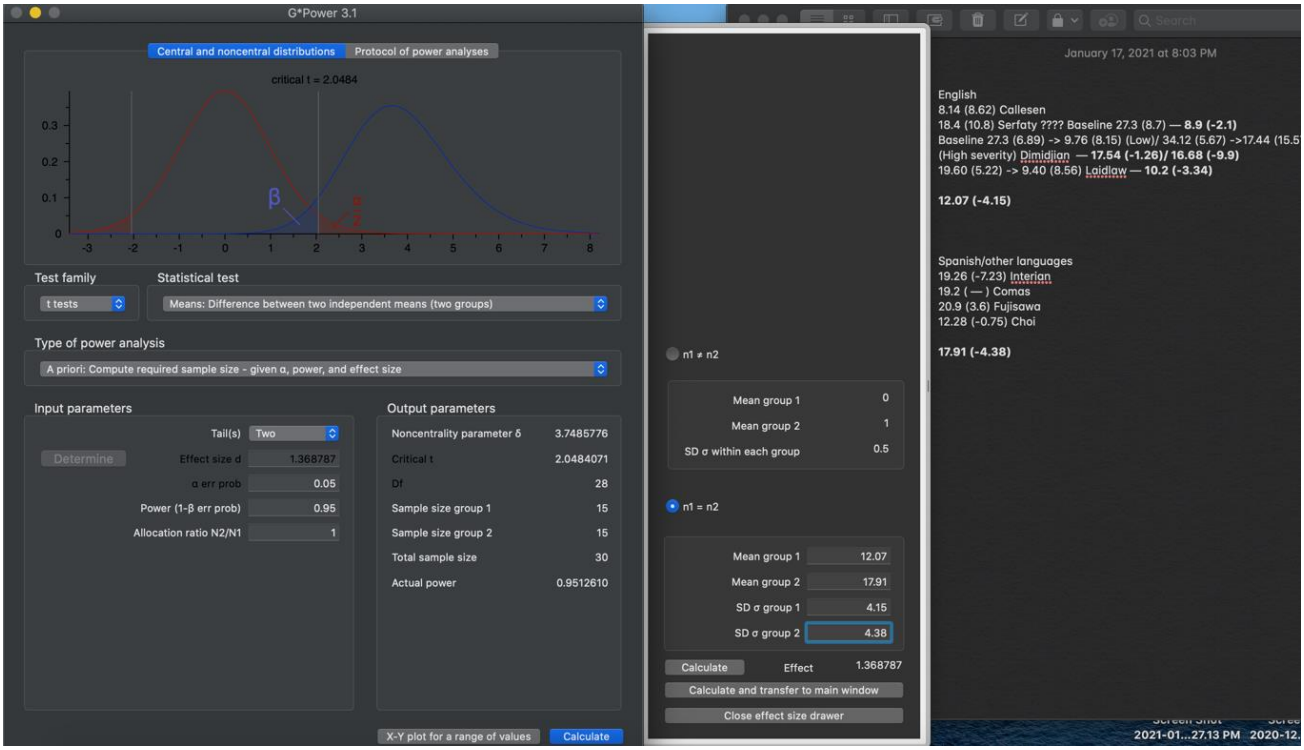
### 4.3 CLINICAL SIGNIFICANCE

Our proposed study has significant implications for the bilingual, Latinx population. Because the role of language of has not been studied directly as an intervention for depressive symptoms, this study could yield one of the following results: one, a causal link between native language cognitive behavioral therapy and improved depressive symptoms, or two, there is no significant difference in outcomes, which demonstrates, as previous data has, that an array of variables, including acculturative status, socioeconomic status, stigma, or other social and environmental factors are associated with poorer outcomes of mental health incomes.

With this knowledge, the most important initial step is to increase the number of bilingual and/or bicultural providers available to all clients of Latinx descent, while also educating existing providers on the necessity of providing culturally-appropriate care. The role of mental health clinicians, and all providers, is to recognize and appropriately treat their patients with depression or depressive symptoms. If Spanish-language cognitive behavioral therapy in bilingual, Latinx patients proves to be more effective than standard, English therapy, optimizations can be set in place to improve mental health

outcomes for this population. As we already know, more Spanish-speaking, bicultural providers are needed for the Spanish-only speaking Latinx population, however, with this added population, continued work is necessary to address all of the barriers for Latinx patients to achieving improved health outcomes.

## APPENDIX A: Sample Size Calculation




| | |
|---|---|
| Alpha | 0.05 |
| Number of Tails | 2 |
| Power | 0.95 |
| Intervention Mean | 17.91 (SD: -4.38) |
| Control Mean | 12.07 (SD: -4.15 |
| Estimated Attrition Rate | 40.0% |
| Sample Size per arm | 21 |

**APPENDIX B: Compound Consent Form and Privacy Rule Authorization Form**

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE

**Study Title:** Culturally-Adapted Cognitive Behavioral Therapy for Bilingual Latinx with Depressive Symptoms

**Care:** A Randomized Controlled Trial

**Study arms:** Cognitive Behavioral Therapy in English or Cognitive Behavioral Therapy in Spanish

**Principal Investigators:** Leanne Gonzalez, PA-SII and Luis Añez, Psy.D

**Invitation to Participate and Description of Project**
You are invited to participate in a research study designed to look at the comparison of mental health outcomes in adult patients with depressive symptoms who are receiving cognitive behavioral therapy in English or Spanish. You have been asked to participate because you are experiencing depressive symptoms and fit the qualifying descriptors.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible waiting time to treatment.

Description of Procedures
If you agree to participate in this study, you will be asked questions relative to your demographics by our study coordinator. These questions will include age, race, sex, ethnicity, current medications, medical records, patient income, immigration status and reason for migration, highest level of education reached, and language preference. The study coordinator will review your medical records to learn more information about other conditions you may have.

This information will help us understand your quality of life and the barriers to care you may have. The PHQ-9 is a screening tool used for depression. It will be administered to all patients receiving either intervention. It will be administered at one of the Latino Behavioral Health System clinics. The Beck Depression Inventory II is a validated tool in the Latinx population. This will be used as a measurement tool throughout the study for tracking depressive symptoms after every 2 weeks of cognitive behavioral therapy sessions. The World Health Organization Disability Assessment Schedule 2.0 will be

assessed every 3 months to assess global functioning. The Duolingo Language test will be performed once at the start of the study to assess English proficiency. The Bidimensional Acculturation Scale will be administered once at the start of the study to assess acculturative status and biculturality.

An example of the questions we will ask you are:

DIRECTIONS:
Choose one option for each questionnaire item.

1
0 I do not feel sad.
1 I feel sad.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2
0 I am not particularly discouraged about the future.
1 I feel discouraged about the future.
2 I feel I have nothing to look forward to.
3 I feel that the future is hopeless and that things cannot improve.

| In the past 30 days, how much difficulty did you have in: | | | | | | |
|---|---|---|---|---|---|---|
| **Understanding and communicating** | | | | | | |
| D1.1 | Concentrating on doing something for ten minutes? | None | Mild | Moderate | Severe | Extreme or cannot do |
| D1.2 | Remembering to do important things? | None | Mild | Moderate | Severe | Extreme or cannot do |
| D1.3 | Analysing and finding solutions to problems in day-to-day life? | None | Mild | Moderate | Severe | Extreme or cannot do |

| **(Bubble only one response to the following questions)** | **almost never** | **sometimes** | **often** | **almost always** |
|---|---|---|---|---|
| 1. How often do you speak English? | ○ | ○ | ○ | ○ |
| 2. How often do you speak in English with your friends? | ○ | ○ | ○ | ○ |
| 3. How often do you think in English? | ○ | ○ | ○ | ○ |
| 4. How often do you speak Spanish? | ○ | ○ | ○ | ○ |
| 5. How often do you speak in Spanish with your friends? | ○ | ○ | ○ | ○ |
| 6. How often do you think in Spanish? | ○ | ○ | ○ | ○ |

If you qualify for this study, you will be randomized to either the intervention group or a control group. The intervention group is assigned to meet with a bilingual, bicultural

master level clinician once per week for six months for cognitive behavioral therapy in Spanish. The control group will receive the same treatment, but in English. Randomization will be done through a computer based system in which you have an equal chance of being assigned to the intervention or control group. Once you are assigned to a group, you will be assigned a unique study code that designates your place in the study. This code will be used to identify you throughout the study. Once you have been randomized to one of the two groups, you will be contacted by study personnel to inform you of your group assignment.

Baseline testing includes:
PHQ-9
Beck Depression Inventory II
World Health Organization Disability Assessment Schedule 2.0
Bidimensional Acculturation Scale
Duolingo Language Test

If you are randomized to either the intervention or control group, baseline testing will be performed within two weeks of randomization at your first appointment with your master level clinician. You should attend one meeting per week for six months with your clinician.

During the 6-month intervention period and 3-month follow-up period you will have the following measurements taken:

| Measurement Tool | Baseline | Month 3 | Month 6 | Month 9 |
|---|---|---|---|---|
| PHQ-9 | X | | | |
| Beck Depression Inventory II | X | X | X | X |
| World Health Organization Disability Assessment Schedule 2.0 | X | X | X | X |
| Bidimensional Acculturation Scale | X | | | |
| Duolingo Language Test | X | | | |

If you agree to participate in this study, you will be asked to:

Consent to being randomly assigned to either Spanish or English cognitive behavioral therapy.

If assigned, you will be required to set up appointments with a master level clinician with the help from study personnel. You will be required to answer questionnaires about your depressive symptoms and global functioning as mentioned above.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You will be told of any significant new findings that are develop during the course of your participation in this study that may affect your willingness to continue to participate.

Risks and Inconveniences

Cognitive behavioral therapy has been thoroughly explored in many other populations with many other chronic conditions, including anxiety, depression, eating disorders, and other mental health disorders. There are no physical risks associated with this study. However, some questions may make you feel uncomfortable and there is the possible risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

The measurement tools that we use to assess depressive symptoms, global functioning, English fluency, and acculturation take approximately 1.5-2 hours to complete but ask questions directly related to your health and home life. Some questions may be difficult to answer, but you should fill out as much information as you are comfortable providing.

Benefits

Participation in this study allows you to randomly be assigned to cognitive behavioral therapy in English or in Spanish, which could lead to improved mental health outcomes and health related quality of life. You will have access to all data collected during this trial which you can give to your primary medical doctor or personal psychiatrist/psychologist.

Economic Considerations

There are no costs directly associated with this study. All interventions provided to you are provided at no cost. If you drop out of the study, you may be responsible for additional medical care and associated costs if referred by our team, however all additional care is optional and all financial information will be thoroughly discussed before referrals are made.

Treatment Alternatives

If you decide not to participate in this study, you will be referred back to the Latino Behavioral Health System to partake in a treatment suitable to your needs.

Confidentiality

All identifiable information collected during the study trial will remain confidential and will only be disclosed with your written permission or as required by the U.S. or State law. Information that is legally required by the government includes abuse of an elderly or cognitively impaired person.

Your data will be de-identified and given a unique study code. All research related materials will be stored at each study center in locked cabinets in locked rooms. All electronic data will be stored on a secure server and protected by passwords only known by the study investigator and research assistants. As research is conducted and presented in meetings or published in academic journals, all of your information will be de-identified.

Information obtained during this trial will be entered into your Electronic Medical Record (EMR). Once data is entered into your EMR, other providers who access your medical record will be able to obtain these entries. Other people who have access to your EMR such as your disability provider or insurances companies may also see this information. This level of accessibility to your EMR is the standard of practice under your current treatment. This will not change because of enrollment in the study.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

As this study is part of Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee may review procedural details of the study at any given time in the two years. These committees review, approve, and monitor research conducted on human subjects. Each member of the committee is instructed to keep all information seen during auditing completely confidential.

Voluntary Participation and Withdrawal

You are able to decide if you do not wish to participate in this study. If you decide to participate in this study, you are able to withdrawal at any time during the study duration without penalty. Refusing to participate or withdrawing from the study will not result in loss of benefits to which you are otherwise entitled such as standard of care treatment.

If you wish to withdrawal from the study, please contact a study coordinator at your earliest convenience and state why you are no longer wish to participate in the study at this time. This will end your time in the trial and you will continue with treatment as usual. Not participating in this trial or withdrawing from this trial will not affect your entitlement to standard of care treatment.

During the study, researchers may choose to withdraw you from the study if necessary. Reasons for withdrawal include but are not limited to: inadequate treatment of co-morbid conditions which compromise your health, noncompliance with treatment, or other medical factors that would acutely affect your health-related quality of life. You are not losing your constitutional rights by signing this form.

Questions

This form is comprehensive for the entire 2-years of this study on depressive symptoms. We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you decide.

*Authorization*

I have read (or someone has read to me) this form and have decided to participate in the research study described above. The general purposes, the particulars of my involvement, and the possible hazards and inconveniences of participation have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject: _____

Signature:_____ Date:_____

Relationship:_____ Date:_____

_____ Date:_____
Signature of Principal Investigator

or

_____ Date:_____
Signature of Person Obtaining Consent

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Luis Añez, PsyD at (203) 815-3915 or co-principle investigator, Leanne Gonzalez, PA-SII.

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

**APPENDIX C:** Qualitative Questionnaire

| | Not at all true | Somewhat true | Moderately true | Very true | Completely true | N/A |
|---|---|---|---|---|---|---|
| My clinician is warm, supportive, and listened. | | | | | | |
| My clinician is trustworthy. | | | | | | |
| My clinician is respectful. | | | | | | |
| My clinician listened to me. | | | | | | |
| My clinician understood what I was feeling. | | | | | | |
| I am able to express myself during sessions. | | | | | | |
| I spoke about the issues bothering me. | | | | | | |
| I learned new methods of coping with my problems. | | | | | | |
| I believe these sessions are helpful. | | | | | | |
| I am satisfied with these sessions. | | | | | | |
| I did not feel comfortable during my sessions. | | | | | | |
| Sometimes, I disagreed with my clinician. | | | | | | |
| Answering some of the questions was difficult for me. | | | | | | |
| My answers, sometimes, did not represent how I really felt. | | | | | | |
| I did not want to upset my therapist by criticizing them. | | | | | | |
| What did you like the least about the session? | | | | | | |

**APPENDIX D:** Beck Depression Inventory II

Roche

V 0477

**Beck Depression Inventory**

CRTN: _____ CRF number: _____ Page 14 patient Inits: _____

**Baseline**

The BDI-II contains 21 questions, each answer being scored on a scale value of 0 to 3. The cutoffs used differ from the original: 0–13: minimal depression; 14–19: mild depression; 20–28: moderate depression; and 29–63: severe depression. Higher total scores indicate more severe depressive symptoms.

**Instructions:** This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today.** Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

**1. Sadness**

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

**2. Pessimism**

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

**3. Past Failure**

0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

**4. Loss of Pleasure**

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

**5. Guilty Feelings**

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

**6. Punishment Feelings**

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

**7. Self-Dislike**

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

**8. Self-Criticalness**

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

**9. Suicidal Thoughts or Wishes**

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

**10. Crying**

0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

Subtotal Page 1

Continued on Back

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**11. Agitation**

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

**12. Loss of Interest**

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

**13. Indecisiveness**

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

**14. Worthlessness**

0 I do not feel I am worthless.
1 I don't consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

**15. Loss of Energy**

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

**16. Changes in Sleeping Pattern**

0 I have not experienced any change in my sleeping pattern.
1a I sleep somewhat more than usual.
1b I sleep somewhat less than usual.
2a I sleep a lot more than usual.
2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1–2 hours early and can't get back to sleep.

**17. Irritability**

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

**18. Changes in Appetite**

0 I have not experienced any change in my appetite.
1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.
2a My appetite is much less than before.
2b My appetite is much greater than usual.
3a I have no appetite at all.
3b I crave food all the time.

**19. Concentration Difficulty**

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

**20. Tiredness or Fatigue**

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

**21. Loss of Interest in Sex**

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

3 4 5 6 7 8 9 10 11 12 A B C D E

Subtotal Page 2

Subtotal Page 1

Total Score

**APPENDIX E:** PHQ-9

## PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

ID #: _____ DATE: _____

Over the last *2 weeks,* how often have you been bothered by any of the following problems?
*(use "✓" to indicate your answer)*

| | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| **1.** Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| **2.** Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |
| **3.** Trouble falling or staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| **4.** Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| **5.** Poor appetite or overeating | 0 | 1 | 2 | 3 |
| **6.** Feeling bad about yourself—or that you are a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| **7.** Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| **8.** Moving or speaking so slowly that other people could have noticed. Or the opposite — being so figety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| **9.** Thoughts that you would be better off dead, or of hurting yourself | 0 | 1 | 2 | 3 |
| add columns | | + | + | |

*(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card).* TOTAL:

**10.** If you checked off *any problems,* how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all _____
- Somewhat difficult _____
- Very difficult _____
- Extremely difficult _____



A2663B 10-04-2005

**APPENDIX F:** Bidimensional Acculturation Scale

eProst ID: 20110512 Approval Date: 10/3/2012
Version:
Approved

Interview Date: ____/____/_____ Relationship Code: _____

**(BAS) Bidimensional Acculturation Scale (Marin and Gamba, 1996)**

***INTERVIEWER READ OUT LOUD:*** I will now ask you about your language preferences

| (Bubble only one response to the following questions) | almost never | sometimes | often | almost always |
|---|---|---|---|---|
| 1. How often do you speak English? | O | O | O | O |
| 2. How often do you speak in English with your friends? | O | O | O | O |
| 3. How often do you think in English? | O | O | O | O |
| 4. How often do you speak Spanish? | O | O | O | O |
| 5. How often do you speak in Spanish with your friends? | O | O | O | O |
| 6. How often do you think in Spanish? | O | O | O | O |
| | **very poorly** | **poorly** | **well** | **very well** |
| 7. How well do you speak English? | O | O | O | O |
| 8. How well do you read in English? | O | O | O | O |
| 9. How well do you understand television programs in English? | O | O | O | O |
| 10. How well do you understand radio programs in English? | O | O | O | O |
| 11. How well do you write in English? | O | O | O | O |
| 12. How well do you understand music in English? | O | O | O | O |
| 13. How well do you speak Spanish? | O | O | O | O |
| 14. How well do you read in Spanish? | O | O | O | O |
| 15. How well do you understand television programs in Spanish? | O | O | O | O |
| 16. How well do you understand radio programs in Spanish? | O | O | O | O |
| 17. How well do you write in Spanish? | O | O | O | O |
| 18. How well do you understand music in Spanish? | O | O | O | O |
| | **almost never** | **sometimes** | **often** | **almost always** |
| 19. How often do you watch television programs in English? | O | O | O | O |
| 20. How often do you listen to radio programs in English? | O | O | O | O |
| 21. How often do you listen to music in English | O | O | O | O |
| 22. How often do you watch television programs in Spanish? | O | O | O | O |
| 23. How often do you listen to radio programs in Spanish? | O | O | O | O |
| 24. How often do you listen to music in Spanish? | O | O | O | O |

**APPENDIX G:** World Health Organization Disability Assessment Schedule 2.0

**WHODAS 2.0**
WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

| 12 |
|---|
| Interview |

## Section 2 Demographic and background information

This interview has been developed by the World Health Organization (WHO) to better understand the difficulties people may have due to their health conditions. The information that you provide in this interview is confidential and will be used only for research. The interview will take 5–10 minutes to complete.

***For respondents from the general population (not the clinical population) say:***

Even if you are healthy and have no difficulties, I need to ask all of the questions so that the survey is complete.

I will start with some background questions.

| | | | |
|---|---|---|---|
| A1 | ***Record sex as observed*** | Female | 1 |
| | | Male | 2 |
| A2 | How old are you now? | _____ years | |
| A3 | How many years in all did you spend studying in school, college or university? | _____ years | |
| A4 | What is your current marital status?<br>***(Select the single best option)*** | Never married | 1 |
| | | Currently married | 2 |
| | | Separated | 3 |
| | | Divorced | 4 |
| | | Widowed | 5 |
| | | Cohabiting | 6 |
| A5 | Which describes your main work status best?<br>***(Select the single best option)*** | Paid work | 1 |
| | | Self-employed, such as own your business or farming | 2 |
| | | Non-paid work, such as volunteer or charity | 3 |
| | | Student | 4 |
| | | Keeping house/ homemaker | 5 |
| | | Retired | 6 |
| | | Unemployed (health reasons) | 7 |
| | | Unemployed (other reasons) | 8 |
| | | Other (specify)_____ _____ | 9 |

***Please continue to next page...***

## Section 4 Core questions

***Show flashcard #2***

| In the past 30 days, how much difficulty did you have in: | | None | Mild | Moderate | Severe | Extreme or cannot do |
|---|---|---|---|---|---|---|
| S1 | Standing for long periods such as 30 minutes? | 1 | 2 | 3 | 4 | 5 |
| S2 | Taking care of your household responsibilities? | 1 | 2 | 3 | 4 | 5 |
| S3 | Learning a new task, for example, learning how to get to a new place? | 1 | 2 | 3 | 4 | 5 |
| S4 | How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can? | 1 | 2 | 3 | 4 | 5 |
| S5 | How much have you been emotionally affected by your health problems? | 1 | 2 | 3 | 4 | 5 |

| In the past 30 days, how much difficulty did you have in: | | None | Mild | Moderate | Severe | Extreme or cannot do |
|---|---|---|---|---|---|---|
| S6 | Concentrating on doing something for ten minutes? | 1 | 2 | 3 | 4 | 5 |
| S7 | Walking a long distance such as a kilometre [or equivalent]? | 1 | 2 | 3 | 4 | 5 |
| S8 | Washing your whole body? | 1 | 2 | 3 | 4 | 5 |
| S9 | Getting dressed? | 1 | 2 | 3 | 4 | 5 |
| S10 | Dealing with people you do not know? | 1 | 2 | 3 | 4 | 5 |
| S11 | Maintaining a friendship? | 1 | 2 | 3 | 4 | 5 |
| S12 | Your day-to-day work/school? | 1 | 2 | 3 | 4 | 5 |

| | | |
|---|---|---|
| H1 | Overall, in the past 30 days, how many days were these difficulties present? | ***Record number of days ____*** |
| H2 | In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition? | ***Record number of days ____*** |
| H3 | In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition? | ***Record number of days ____*** |

This concludes our interview. Thank you for participating.

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