

Hello Everyone,

Quantitative Research Design

This research study will use a randomized controlled trial (RCT) design to evaluate the effectiveness of integrated culturally-tailored behavioral health services (CBT) compared to standard care in reducing depression symptoms among immigrant and refugee populations. This approach will involve comparing outcomes between two parallel groups: one receiving a culturally-tailored cognitive-behavioral therapy (CBT) intervention for Latino adults with depression, and the control group (receiving standard care/non-tailored CBT or usual clinical services). Randomization will ensure a degree of control over confounding variables and will allow inference of an outcome based on an intervention.

While the study population as per the PICOT question is all immigrant and refugee groups, the pilot phase of this study will focus specifically on Latino immigrants. Several factors justify this narrower, targeted focus. First, there is an availability of validated evaluation tools for the Latinx population. For instance, the Spanish version of the PHQ-9, which is widely used is screening for depression, has been validated for Latino populations.^{1,2,3,11} Secondly, Latinx populations can be easily accessed through existing partnerships with community health centers and advocacy organizations. Third, existing research findings indicate Latino immigrants experience disproportionately high rates of untreated depression.^{4,5} This has been attributed to structural barriers like language, stigma, and limited access to mental health services. Finally, by using this study as a pilot RCT, recruitment, data collection and analysis will be manageable; while guaranteeing feasibility of findings that can be extended to other immigrant and refugee populations, albeit with limitations. For a comprehensive evaluation, future phases can expand and evaluate other immigrant and refugee groups.

Population and Sampling Strategy

Target Population: Foreign-born Latinx adults, aged 18–65, diagnosed with moderate to severe depression (PHQ – 9 score ≥ 10),¹¹ and currently receiving health care services through primary care or a mental health clinic.

- Inclusion Criteria: Self-identify as Latinx or Latino/a, foreign-born (immigrant status), fluent in English or Spanish, willing and able to participate in a 12-month study period, not currently receiving psychiatric treatment (e.g., no active medication or psychotherapy for depression).
- Exclusion Criteria: Diagnosis of severe mental illness (such as schizophrenia, schizoaffective disorder, or active psychosis), bipolar disorder, active substance use disorder (within the past 6 months), suicidal ideation with imminent risk or requiring emergency intervention, concurrent participation in another clinical trial or psychotherapy study.

Power Analysis and Sample Size

To determine the minimum sample size, a power analysis was conducted using G*Power 3.1. The minimum sample size needed to detect a medium effect size between these two independent groups using a t-test (two-tailed) was based on the following parameters:

- Effect size (Cohen's d) = 0.50 (medium), based on existing evidence demonstrating moderate clinical improvements in similar interventions.^{6,7,8}
- Alpha (α) = 0.05
- Power ($1-\beta$) = 0.80

- Statistical test: Two-tailed independent samples t-test

Based on these parameters, the minimum required sample size is 64 participants per group, for a total of 128 participants. To account for an anticipated attrition rate of 20%, which is commonly observed in longitudinal psychotherapy trials,^{9,10} the total participant recruitment target will be 160 participants or 80 per group.

Participant Recruitment

Participants will be recruited from community health centers, Latino-serving primary care practices, and local community organizations and churches. The study will use recruitment material and techniques in both English and Spanish such as flyers, provider referrals, and social media campaigns. To obtain informed consent prior to commencement of the study, bilingual research staff will provide culturally appropriate informed consent forms.

Data Collection and Instruments

Data will be collected using the Patient Health Questionnaire-9 (PHQ-9) score. It will be available in both English and Spanish. Both English¹⁵ and Spanish¹⁶ versions have been validated for use among Latinx populations.^{1,2,3} The PHQ-9 score is a validated, quantitative tool that is brief, easy to administer, and widely used in both clinical and research settings.¹¹ It is therefore suitable in the assessment of the severity of depression symptoms. It includes 9 items, with each scored from 0 to 3, for a total possible score of 0 to 27. Higher scores indicate more severe depressive symptoms and v/v. PHQ-9 scores are continuous, making them suitable for parametric testing.

The primary outcome will be the change in PHQ-9 score from baseline to 12 months. Additional measurements at 3, 6, and 9 months will help observe trends over time. This measure will allow for collection of precise, standardized, and statistically analyzable data for comparison of depression symptoms between the intervention vs control groups.

- Independent Variable: This will be the type of intervention (Group 1: Culturally tailored mental health intervention; Group 2: Standard mental health intervention). This variable is categorical (nominal).
- Dependent Variable: Change in depression severity (PHQ-9 scores). This variable is continuous.

Statistical Analysis

- Descriptive statistics for baseline demographics and PHQ-9 scores
- Independent samples t-tests to compare mean PHQ-9 scores between groups at each time point

Effect size will also be reported using Cohen's d.

Ethical Considerations

Prior to recruitment, IRB approval will be obtained. The study will also adhere to HIPAA standards. In addition, participants will provide written informed consent. All materials such as consent forms and PHQ-9 surveys will be available in both English and Spanish. Confidentiality will be maintained through de-identification of data and secure storage. Participants will be informed of their right to withdraw at any time without consequence. Any participant with severe symptoms will be referred to a health clinic for

immediate patient care. Finally, all participants, including those in the control group, will have access to appropriate mental health referrals and care throughout the study.

Justification for Study Design

A randomized controlled trial (RCT) design allows for high internal validity and is particularly appropriate given the goal of determining whether culturally tailored CBT reduces depression severity more effectively than standard care.^{12,13,14} Using PHQ-9 ensures consistency with prior studies and facilitates comparison.

References

1. Martinez A, Teklu SM, Tahir P, Garcia ME. Validity of the Spanish-language Patient Health Questionnaires 2 and 9: a systematic review and meta-analysis. *JAMA Netw Open*. 2023;6(10):e2336529. doi:10.1001/jamanetworkopen.2023.36529
2. Urtasun M, Daray FM, Teti GL, et al. Validation and calibration of the Patient Health Questionnaire (PHQ-9) in Argentina. *BMC Psychiatry*. 2019;19:291. doi:10.1186/s12888-019-2262-9
3. Familiar I, Ortiz-Panozo E, Hall B, et al. Factor structure of the Spanish version of the Patient Health Questionnaire-9 in Mexican women. *Int J Methods Psychiatr Res*. 2015;24(1):74-82. doi:10.1002/mpr.1461
4. Batalova J. Frequently Requested Statistics on Immigrants and Immigration in the United States. Migration Policy Institute. Published March 12, 2025. Accessed July 19, 2025. <https://www.migrationpolicy.org/article/frequently-requested-statistics-immigrants-and-immigration-united-states>
5. Escobedo LE, Cervantes L, Havranek E. Barriers in healthcare for Latinx patients with limited English proficiency—a narrative review. *J Gen Intern Med*. 2023;38:1264-1271. doi:10.1007/s11606-022-07995-3
6. Camacho Á, González P, Castañeda SF, et al. Improvement in Depressive Symptoms Among Hispanic/Latinos Receiving a Culturally Tailored IMPACT and Problem-Solving Intervention in a Community Health Center. *Community Ment Health J*. 2015;51(4):385-392. doi:10.1007/s10597-014-9750-7
7. Benish SG, Quintana S, Wampold BE. Culturally adapted psychotherapy and the legitimacy of myth: a direct-comparison meta-analysis. *J Couns Psychol*. 2011;58(3):279-289. doi:10.1037/a0023626
8. Kroenke K, Spitzer RL, Williams JB, Löwe B. The Patient Health Questionnaire Somatic, Anxiety, and Depressive Symptom Scales: a systematic review. *Gen Hosp Psychiatry*. 2010;32(4):345–359. doi:10.1016/j.genhosppsych.2010.03.006
9. Swift JK, Greenberg RP. Premature discontinuation in adult psychotherapy: a meta-analysis. *J Consult Clin Psychol*. 2012;80(4):547-559. doi:10.1037/a0028226
10. Vancampfort D, Sánchez CPR, Hallgren M, et al. Dropout from exercise randomized controlled trials among people with anxiety and stress-related disorders: a meta-analysis and meta-regression. *J Affect Disord*. 2021;282:996-1004. doi:10.1016/j.jad.2021.01.003
11. Kroenke K, Spitzer RL, Williams JB, Löwe B. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. *Gen Hosp Psychiatry*. 2010;32(4):345-359. doi:10.1016/j.genhosppsych.2010.03.006
12. Purgato M, Gross AL, Betancourt T, et al. Focused psychosocial interventions for children in low-resource humanitarian settings: a systematic review and individual

- participant data meta-analysis. *Lancet Glob Health*. 2018;6(4):e390-e400.
doi:10.1016/S2214-109X(18)30046-9
13. Patel N, Williams ACdeC, Kellezi B. Reviewing outcomes of psychological interventions with torture survivors: conceptual, methodological and ethical issues. *Torture*. 2016;26(1):2-16. doi:10.7146/torture.v26i1.108060
 14. Bass JK, Annan J, Murray SM, et al. Controlled trial of psychotherapy for Congolese survivors of sexual violence. *N Engl J Med*. 2013;368(23):2182-2191.
doi:10.1056/NEJMoa1211853
 15. Spitzer RL, Williams JBW, Kroenke K, et al. *Patient Health Questionnaire (PHQ)*. Pfizer Inc. Accessed July 27, 2025.
<https://www.drugsandalcohol.ie/26814/1/Patient%20Health%20Questionnaire.pdf>
 16. Spitzer RL, Williams JBW, Kroenke K, et al. *Cuestionario sobre la salud del paciente-9 (PHQ-9)*. Pfizer Inc. Accessed July 27, 2025.
<https://www.ochealthinfo.com/sites/hca/files/import/data/files/82600.pdf>

Appendix A: PHQ-9 English Questionnaire

The Patient Health Questionnaire (PHQ-9)

Patient Name _____ Date of Visit _____

Over the past 2 weeks, how often have you been bothered by any of the following problems?

	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 asleep, 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're 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 fidgety 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 in some way	0	1	2	3

Column Totals _____ + _____ + _____

Add Totals Together _____

10. If you checked off any problems, how difficult have those 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

Appendix B: PHQ-9 Spanish Questionnaire

CUESTIONARIO SOBRE LA SALUD DEL PACIENTE-9 (PHQ-9)

Durante las últimas 2 semanas, ¿qué tan seguido le han afectado cualquiera de los siguientes problemas?
(Marque con una "✓" para indicar su respuesta)

	Para nada	Varios días	Más de la mitad de los días	Casi todos los días
1. Poco interés o placer en hacer las cosas	0	1	2	3
2. Se ha sentido decaído(a), deprimido(a), o sin esperanzas	0	1	2	3
3. Dificultad para dormir o permanecer dormido(a), o ha dormido demasiado	0	1	2	3
4. Se ha sentido cansado(a) o con poca energía	0	1	2	3
5. Con poco apetito o ha comido en exceso	0	1	2	3
6. Se ha sentido mal con usted mismo(a) – o que es un fracaso o que ha quedado mal con usted mismo(a) o con su familia	0	1	2	3
7. Ha tenido dificultad para concentrarse en cosas tales como leer el periódico o ver televisión	0	1	2	3
8. ¿Se ha estado moviendo o hablando tan lento que otras personas podrían notarlo?, o por el contrario – ha estado tan inquieto(a) o agitado(a), que se ha estado moviendo mucho más de lo normal	0	1	2	3
9. Ha pensado que estaría mejor muerto(a) o se le ha ocurrido lastimarse de alguna manera	0	1	2	3

FOR OFFICE CODING 0 + + +
=Total Score:

Si usted marcó cualquiera de estos problemas, ¿qué tan difícil fue hacer su trabajo, las tareas del hogar o llevarse bien con otras personas debido a tales problemas?

Para nada difícil <input type="checkbox"/>	Un poco difícil <input type="checkbox"/>	Muy difícil <input type="checkbox"/>	Extremadamente difícil <input type="checkbox"/>
--	--	--	---