

**Randomized Controlled Trial of Spanish Brief Group Neuroscience-Informed Cognitive-
Behavior Therapy for Anxiety**

Study Protocol and Data Analysis Plan

Date: May 15, 2025

Study Protocol and Data Analysis Plan

Purpose of Study

The purpose of this study will be to evaluate whether a nCBT neuroeducational group can reduce anxiety in a scalable brief format suited to Spanish-speaking communities with limited access to counseling. No study has tested a culturally adapted, Spanish-language version of the nCBT Waves Model. This study additionally will evaluate the effectiveness of a Spanish-language nCBT neuroeducational group intervention in enhancing body awareness and self-compassion. The study also will examine whether treatment credibility, outcomes expectancy, and working alliance predicted change. The study will address three research questions: (1) To what extent does group neuroeducation on the nCBT Waves Model reduce anxiety compared to a waitlist condition? (2) To what extent does group neuroeducation on the nCBT Waves Model enhance body awareness and self-compassion compared to a waitlist condition? (3) To what extent is anxiety reduction predicted by enhancements in body awareness and self-compassion, alongside the working alliance and credibility/expectancy?

The study will test the following hypotheses: (1) Receiving group neuroeducation on the nCBT Waves Model will reduce anxiety to a greater degree than a waitlist condition; (2) Receiving group neuroeducation on the nCBT Waves Model will enhance body awareness and self-compassion to a greater degree than a waitlist condition; (3) A model consisting of body awareness, self-compassion, working alliance, and credibility and expectancy will predict anxiety reduction following nCBT group neuroeducation.

Design

To test the hypotheses, the research team will conduct a randomized controlled trial with wait-list control and use stratified randomization to assign participants to the intervention or

waitlist control condition. The study will be conducted in a naturalistic community setting, strengthening ecological validity and relevance. We obtained Institutional Review Board approval prior to study initiation.

Participants

The research team will confirm eligibility and collect baseline measures prior to stratified randomization. At pre-registration, interested community members complete a signed informed consent document, a demographics questionnaire, and anxiety screening measure (PROMIS Anxiety Short Form, Spanish Version or PROMIS-A-SF-S; Teresi et al., 2016). The study has four inclusion criteria: (a) age 18 years or older, (b) identification as Latino/a, (c) Spanish fluency, (c) ability to attend three group sessions.

Randomized Assignment

The research team will screen participants for eligibility at two community sites and enrolled them in the study over the course of a six month study period. The team will implement stratified randomization using gender, age, and baseline anxiety as variables to ensure consistency between groups. This approach strengthens internal validity and reduces the likelihood of baseline imbalances due to chance (Sidani & O'Rourke, 2022).

To support single-blinding, the research team will not disclose assigned condition at the time of inclusion and waitlist participants will not know their assignment. Because of the short study duration (28 days) and facilitation of multiple concurrent groups, community members were unlikely to know their assignment on the basis of conversations with other members. Waitlist participants will receive the group intervention only after the initial study period ends.

The nCBT Waves Model Psychoeducation Intervention

The intervention consists of three 90-minute neuroeducational group sessions that follow three sequential phases from the nCBT treatment manual (Beeson et al., 2017). Session 1 corresponds with the first phase, *Attending to Physiological Reactions*, and focuses on developing therapeutic rapport, assessing needs, and conceptualizing treatment. Session 2 corresponds with the second phase, *Build the Brain from the Bottom-Up*, and focuses on helping participants prevent and regulate, rather than reactively respond to, Wave1 physiological activation and dysregulation. Session 3 corresponds with the third phase, *Connect Bottom to the Top*, and introduces strategies for tolerating activation and reappraising Wave1 responses.

Intervention Fidelity

To support intervention fidelity, an original nCBT model co-author will provide a two-day, 12-hour virtual nCBT training to the counselor who delivered the intervention. The co-author will observe the counselor's demonstration with a simulated client to determine competency and readiness using an nCBT treatment fidelity measure (Field et al., 2019). The co-author will also review the group materials before the study began, and will meet with the counselor on a regular basis throughout the study to review implementation and monitor fidelity.

Cultural Adaptation and Piloting

To prepare study materials for participant use, the research team refined the intervention through several stages in alignment with Barrera et al. (2013). First, the team developed group outlines and handouts that aligned most closely with the nCBT Waves Model. Second, the team evaluated the comprehensibility and cultural relevance of all materials and translated them into Spanish. Third, the team assessed all eight dimensions of cultural fit per Bernal et al. (1995), such as language, metaphors, content, concepts, goals, methods, and context. Fourth, Spanish-speaking clinicians outside the study then reviewed the translated materials and handouts, and

the team revised them to incorporate feedback. Fifth, the team conducted a final check of cultural and linguistic fit by piloting the curriculum and handouts with community members.

The research team also piloted the instrument packet. Spanish-speaking doctoral counseling students reviewed materials and completed the instruments to provide feedback. The team adjusted materials post-piloting by reducing the number of items in the instrument packet. For example, the team selected a briefer body awareness instrument.

Power Analysis

The research team conducted a power analysis using G*Power 3.1.9.4 (Faul et al., 2007) to determine the minimum sample size required for a large effect size with 80% power at an alpha level of .05, for three tests: (a) repeated-measures ANCOVA, (b) Welch's independent samples *t*-test, and (c) multiple regression with four predictors. The team selected a large effect because psychotherapy studies with a waitlist condition often yield large between-group effects (Cuijpers et al., 2024). Minimum required sample sizes were 52 for ANCOVA, 42 for *t*-test, and 36 for multiple regression.

Procedure

The research team will recruit participants in partnership with two community-based agencies serving Spanish-speaking communities in the Mountain West region of the United States. The team will distribute recruitment information through flyers posted in high-traffic community locations. In addition, the team will ask agency staff to share flyers with established community members and partner organizations. The flyers will provide information about the group structure, study duration, participant incentives, and contact information. The team will hold orientation meetings at both sites to explain the study purpose, potential benefits, risks,

expectations, and eligibility criteria. Participants will receive contact information for the research team in the event of an emergency.

Instruments

Participants will complete Spanish-language instruments that measured anxiety, body awareness, self-compassion, working alliance, and intervention credibility and outcomes expectancy. They will complete the anxiety, body awareness, and self-compassion measures at the end of each session. They will complete the working alliance and intervention credibility/expectancy measures at the end of the third and final session.

PROMIS Anxiety Short Form 6a – Spanish (PROMIS-A-SF-S)

The PROMIS-A-SF-S (Patient-Reported Outcomes Measurement Information System, 2012; Teresi et al., 2016) measures anxiety symptoms over the past 7 days with higher scores indicating greater anxiety severity. Participants rate each item on a five-point Likert scale from 1 (never) and 5 (always). The PROMIS-A-SF has strong internal consistency (Cronbach's $\alpha = .97$).

Body Awareness Questionnaire – Spanish Version (BAQ-S)

The BAQ-S (Sánchez-Sánchez et al., 2025) measures sensitivity to normal, non-emotive bodily processes. Participants rate items on a seven-point Likert scale from 1 (not at all true of me) to 7 (very true of me). Higher scores indicate greater body awareness. The Spanish version has good internal consistency (Cronbach's $\alpha = .82$).

Self-Compassion Scale – Short Form, Spanish Version (SCS-SF-S)

The SCS-SF-S (García-Campayo et al., 2014) measures perceived self-compassion during difficult moments. Participants rate items on a five-point Likert scale from 1 (almost never) to 5 (almost always). Higher scores indicate greater self-compassion. The Spanish version has good internal consistency (Cronbach's $\alpha = .85$).

Spanish-Language Working Alliance Inventory-Short for Patients, Revised (WAI-S-P)

The WAI-S-P (Andrade-González & Fernandez-Liria, 2016) measures the therapeutic alliance from the participant's perspective. Participants rate items on a seven-point Likert scale from 1 (seldom/never) to 7 (always). The Spanish version has strong internal consistency (Cronbach's $\alpha = .93$).

Credibility and Expectancy Questionnaire

The CEQ (Deville & Borkovec, 2000) contains six items measuring treatment credibility and outcome expectancy. The study used the nCBT-adapted version of the CEQ from Field et al. (2016). Participants rate six items on a 10-point Likert scale from 1 (not at all) to 10 (very much). Participants rate two items as percentages from 0 to 100%. The percentage items are converted to a 1-10 scale to compute a total score for the instrument, consistent with Field et al. (2016). Because no formally validated Spanish version currently appears in the published literature, the research team translated the CEQ into Spanish. The English version has strong internal consistency (Cronbach's $\alpha = .90$; Devilly & Borkovec, 2000).

Data Analysis Plan

The research team will assign participants a unique identification number to preserve anonymity. The team will clean and prepare the database prior to conducting statistical analyses. The team will use imputation to determine scores of missing data points, following the multiple imputation (MICE) method that uses data from all other participants at the same interval to predict the missing value. A repeated-measures ANCOVA will compare endpoint PROMIS-A-SF-S anxiety scores between groups while controlling for baseline anxiety. A complementary Welch's independent-samples *t*-test will compare baseline-to-endpoint anxiety change scores (Δ PROMIS-A-SF-S) between groups. For body awareness and self-compassion outcomes, a

Welch's independent-samples *t*-test will compare between-group endpoint scores. The team will calculate calculated effect sizes using Hedges' *g* for *t*-tests and partial η^2 for ANCOVA. A multiple linear regression analysis will test whether changes in body awareness (Δ BAQ-S), self-compassion (Δ SCS-SF-S), working alliance (WAI-S-P), and credibility and expectancy (CEQ) predict anxiety change (Δ PROMIS-A-SF-S).

Assumption Checks

The research team will examine assumptions before conducting the ANCOVA, *t*-test, and regression. These include Shapiro-Wilk distribution of residuals, Levene's test for homogeneity of variance, Q-Q plots for deviation from normality, homogeneity-of-regression-slopes assumption, and correlations, variance inflation factor (VIF) values, tolerance statistics, and Durbin-Watson values.

RESEARCH CONSENT FORM

Study Title:

An Explanatory Sequential Mixed-Methods Evaluation of the nCBT Waves Model for Spanish-Speaking Therapy Clients

Principal Investigator: Angel Manjarrez, MA.

Study team: Thomas Field, Ph.D.

Sponsor: None

Version: 1.1

SUMMARY

We are inviting you to take part in a research study. You do not have to be in the study if you do not want to. You can also decide to be in the study now and change your mind later.

We are conducting a mixed-methods study evaluating a neuroscience-informed cognitive-behavior therapy (nCBT) intervention tailored for Spanish-speaking individuals in psychotherapy. If you participate, you'll be randomly assigned to either a three-session nCBT group at no cost or continue with your usual therapy while waiting, and we'll measure changes in interoceptive awareness, self-compassion, anxiety, and depression. Upon completing the study, you will receive a \$20 gift card; if selected for a smaller, one-time focus group, you can earn an additional \$10.

We plan to make the results of this study public, but we will not include your name or other identifying information.

We would like you to ask us questions if there is anything about the study that you do not understand. You can call us at 720-281-9709 or email me at manjaran@oregonstate.edu.

You can also contact the Human Research Protection Program with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 737-8008 or by email at IRB@oregonstate.edu.

There are more details about the study in the following pages.

STUDY DETAILS

1. WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

We are seeking approximately 73 Spanish-speaking adults who are currently receiving therapy services and are willing to participate in three group sessions designed to evaluate a new counseling intervention. As part of the study, participants will also be asked to complete six instruments three times (pre study, post study, and three weeks after the study) after the group sessions. These questionnaires, which should take no more

than 15 minutes total to fill out each time, will help us determine how effective the intervention is.

To participate in the study, you must verify that you are at least 18 years old, primarily speak Spanish, and are participating voluntarily

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you choose to take part in this study, we will ask you to complete several brief questionnaires that measure various aspects of your mental and emotional health, including anxiety, depression, interoceptive awareness, self-compassion, and perceptions of treatment which includes the credibility and expectancy for treatment and the therapeutic alliance. We will also collect some basic demographic information (e.g., age, preferred language, therapy history). Altogether, these questionnaires should take around 15 minutes each time they are administered.

3. WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

The most serious risks related to being in this study are the potential for confidential data breaches. If that did occur, the confidentiality of your research responses would be comprised. We anticipate that this risk is low because we will protect patient privacy through several safeguards. The research team will have no prior contact with participants in the study. Each instrument packet will have a unique alphanumeric identifier in place of any names or other identifying information. The principal investigator (Manjarrez) will collect completed instruments from the participants and enter instrument responses into an Excel spreadsheet organized by alphanumeric identifiers. All demographic information will be entered into a separate spreadsheet so that participant responses to the instrument cannot be traced to demographic information. The principal investigator (Manjarrez) will store hard copies of all forms and electronic Excel spreadsheet data on a password protected computer in their locked office at their private practice. Only members of the research team will have access to participant data (Field and Manjarrez). While the study collects demographic information about participants, this data will be analyzed only in aggregate to provide general descriptions of the participant sample.

The questionnaires contain questions about responses to their mental health. Such questions may be uncomfortable to participants. Participants may choose to stop participation in the survey at any time.

4. WHAT ARE THE BENEFITS OF THIS STUDY?

All participants who complete the group sessions will receive a \$20 gift card for their participation. The gift card will be distributed by office staff at your clinic after you return the completed instruments. If you take place in the small focus group, you will receive a \$10 gift card for participating.

5. WHAT OTHER OPTIONS DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Participants may choose to stop participating in the study at any time. Participants may also request for their responses to be removed after completing the questionnaires. Any participant

who has completed the questionnaire packet is still eligible to receive the gift card even if they choose to remove their responses.

6. WHAT SHOULD I DO IF I WANT TO STOP BEING IN THE STUDY?

Any participant who wishes to remove their responses after completing the questionnaire packet may contact the primary investigator of the research team, Angel Manjarrez, at manjaran@oregonstate.edu.

7. WHO WILL SEE THE INFORMATION I GIVE?

Participant instrument responses will only be accessed by members of the research team (Field, Manjarrez). No other researcher nor entity will have access to questionnaire information.

8. DOES ANY MEMBER OF THE STUDY TEAM HAVE A CONFLICTING INTEREST?

No member of the study team has a conflict of interest.

9. WILL I BE PAID FOR BEING IN THIS STUDY?

All participants who complete the group sessions will receive a \$100 gift card for their participation. The gift card will be distributed by office staff at your clinic after you return the completed instruments.

10. WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

No, there are no costs associated with participating.

11. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you verify that you are at least 18 years of age.

Participant Name: _____

Participant Signature: _____

Date Signed: _____

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