

Title: Amigas Latinas Motivando el Alma (ALMA): A Delayed Intervention Control Trial of a Program to Reduce Mental Health Disparities in Latina Immigrant Women

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Study Title: Amigas Latinas Motivando el Alma (ALMA): A Delayed Intervention Control Trial of a Program to Reduce Mental Health Disparities in Latina Immigrant Women

Objectives: ALMA is an 8-week program offered in a group format to teach women new coping strategies, enhance their existing social ties, and increase social support to prevent and reduce depression and anxiety symptoms. The aim of this research is to evaluate the efficacy of ALMA, a mental health promotion intervention, among Latina immigrant women.

Study Design: The proposed study aims to test the efficacy of the Amigas Latinas Motivando el Alma (ALMA) intervention in a delayed intervention control trial. Participants are recruited in four waves (N = 50) of approximately 25 participants at each site. In each wave, one community-based organization served as the intervention group, and the other organization served as the delayed intervention comparison group. Participants were not blinded to their study condition.

During the first two waves of the study, participants received the intervention in-person (N=106), while those recruited during the last two waves received the intervention online via Zoom (N =119).

Participants: Our goal based on sample size calculations was to recruit 200 Latina immigrant women to participate in the intervention trial at two site community-based organizations (Casa Latina and El Centro de la Raza). Participants were recruited through the community-based organizations by trained research staff (N = 226). This included current clients and other community contacts.

Inclusion Criteria: Self-identify as female, Latina, immigrant, over age 18, and speak Spanish.

Exclusion Criteria: We screened potential participants for high levels of depressive symptoms (as indicated by a score of 20 or higher on the PHQ-9). The PHQ-9 is a clinical screener for depressive symptoms and scores of 20 or above indicate severe symptoms. Participants with scores above 20 were referred to the licensed mental health counselor on the study team. In these cases, the counselor discussed participation in the program with the potential participants and referred them to additional services if needed. If participants were currently receiving treatment and/or had symptoms under control, they were included in the study. If women were not already receiving mental health treatment, they were referred to mental health providers offering low-cost services in Spanish.

Recruitment and Intervention Sites: ALMA trial participants were recruited through two community-based organizations serving Latino immigrants (Casa Latina and El Centro de la Raza). The ALMA sessions were also held at these community organizations. For Waves 3 and 4 of the study, we will offer the ALMA groups virtually using HIPPA compliant Zoom Pro. The Principal Investigator is Latina and has a history of collaborating with community organizations to conduct research in Latino communities. Staff from the community organizations served as advisors to the project and review study procedures in advance. Participants were recruited by Spanish speaking research team members (many of whom are also Latinas and immigrants themselves). ALMA sessions were delivered in Spanish by trained research team members.

Recruitment and Screening: Participants will be recruited and screened by trained Spanish speaking UW research team members at Casa Latina and El Centro de la Raza through personal contact, either in person, or by email or phone. Participants were asked to provide verbal consent before being screened. In addition to the recruitment materials outlined below,

the ALMA staff held pre-program information sessions on study aims and program content, as well as to recruit and screen potential participants. For Waves 3 and 4, recruitment was completed virtually by email or phone. Additional pre-program information sessions were held on HIPPA compliant Zoom Pro. For the qualitative interviews, recruitment will be completed virtually by phone.

Recruitment materials: Community organization staff made announcements about the study to their clients through personal contact, flyers, email lists and social media. Potential participants were provided contact information for UW research staff so that they could contact them directly if they are interested in the study. In addition, we provided times and dates that UW research staff will be available on site at community organizations to recruit and screen potential participants. For Waves 3 and 4, recruitment was be done over the phone using a recruitment script.

Payment to participants: Participants completed four surveys in order to evaluate the efficacy of the intervention. Participants received \$30 for completion of each survey, for a potential total of \$120 per participant. For Waves 3 and 4, participants received a \$30 VISA gift card for completion of each survey, for a potential total of \$120 per participant.

Non-monetary Compensation: Participants were provided ORCA cards for transportation to the ALMA sessions, childcare during the ALMA sessions if needed, and refreshments at the ALMA sessions.

Consent Process: Information was provided to women about the ALMA trial during the recruitment and screening process. We obtained consent from all women that plan to attend the ALMA group sessions and complete the surveys. Women will be verbally read the consent form and given an opportunity to ask questions. If any participant decides at that time that they do not want to participate they will be free to leave. Women that decide to participate will sign their consent forms.

For Waves 3 and 4, women will be verbally read the consent form and given an opportunity to ask questions. If any participant decides at that time that they do not want to participate they will be free to leave. Women that decide to participate will provide verbal consent. We will also mail or email enrolled participants an information sheet based on our phone script highlighting details on the research study and their rights as a participant.

Study Procedures: Once screened, participants in the intervention group were invited to participate in ALMA, an eight-week intervention to promote mental health, at either Casa Latina or El Centro de la Raza. Over the course of the eight ALMA sessions, participants were (1) engaged in activities to identify coping strategies they are currently using and are encouraged to continue to use them; (2) introduced to new coping strategies (e.g. mindfulness techniques, increased social ties and social support); and, (3) provided resources for seeking additional help if needed. Sessions were facilitated by bilingual UW research staff, who have extensive experience working with the intervention components and the population. Women in the delayed intervention control group receive the intervention after their 6 month follow-up survey.

Participants completed four surveys in order to evaluate the efficacy of the intervention: baseline, 3-month follow-up, 6-month follow-up, and 9-month follow-up. These surveys were administered in person by a bilingual data collector on a tablet in a private location onsite at one of our two community partner organizations. Baseline surveys took 60 minutes to complete on average,

and each additional follow-up survey took about 45 minutes. Interviewers contacted participants by phone or text message to schedule a time to complete each follow-up survey.

Between program sessions, participants received newsletters and cards by mail highlighting ALMA staff members and general wellness information. They also received reminder phone calls and texts of upcoming ALMA sessions.

During ALMA program sessions, both attendance and fidelity were tracked. Session facilitators recorded attendance at each program session, to calculate an overall attendance count for each participant. They will also complete a fidelity checklist to assess fidelity to curriculum implementation. The checklist will include a list of outlined activities and themes for each session, where they will report to what degree the content was addressed. The checklist will also include space to report barriers and aids to participation and levels of engagement in session activities.

For Waves 3 and 4, once screened, participants were invited to participate in ALMA, a 6-week online intervention using HIPAA compliant Zoom Pro, in collaboration with either Casa Latina or El Centro de la Raza (two of our partner community-sites). We modified our 8-week ALMA sessions to include activities that would be feasible to complete using HIPAA compliant Zoom Pro. Over the course of the six ALMA sessions, participants were (1) engaged in activities to identify coping strategies they are currently using and are encouraged to continue to use them; (2) introduced to new coping strategies (e.g. mindfulness techniques, increased social ties and social support); and, (3) provided resources for seeking additional help if needed. Sessions were facilitated by bilingual UW research staff, who have extensive experience working with the intervention components and the population. We also offered an ALMA Orientation Session prior to the 6-week online sessions to provide participants an overview of the ALMA sessions, provide guidance and technological support in how to use Zoom, and answer any questions participant might have before they participate in the ALMA group.

Measures: Participant surveys include the following constructs: depression (PHQ-9), anxiety (GAD), somatic symptoms of depression (PHQ-15), stress (PSS), discrimination, immigration-related stressors, mindful awareness (MAIA), coping strategies (self-compassion scale short form), social support, social ties, resilience, and trauma.

Translations: All study procedures were conducted in Spanish (participants' native language). Our study team has a long history of working with this population and creating study materials that are linguistically and culturally appropriate. All materials were translated by consensus involving at least two native Spanish speakers, and also reviewed by the PI who also speaks and reads Spanish. We had community advisors that work with Casa Latina and El Centro de la Raza clients review the materials before we begin recruitment.

Statistical Analysis Plan:

Descriptive Analyses: To assess possible bias, we conducted descriptive analyses on demographic and primary outcome variables at baseline by group assignment and delivery modality. We used t-tests for continuous variables, including depression and anxiety. We used chi-squared tests to detect associations between binary, ordinal, and nominal variables, as well

as group assignment or intervention modality. We used a p-value of $<.05$ to determine significance. All data were analyzed using STATA SE version 16.1.

Intervention analyses: To test the efficacy of the ALMA intervention to reduce anxiety and depressive symptoms among Latina immigrant women, we used a generalized estimating equation model with proposed estimation and an unstructured working correlation matrix. GEE is an population-averaged model which produces efficient estimates of the coefficients by accounting for within-subject correlation due to repeated measures. Because the GEE model creates working pairs to estimate correlation for the entire sample, we used an intent-to-treat (ITT) analysis approach. We specified an unstructured correlation model that provides robust standard errors and imposes no pattern on the correlation matrix because we have few timepoints. Time-varying variables were specified as baseline, post-intervention, follow-up. We report adjusted models because outcomes were very similar to unadjusted models. We adjusted for modality, age, education level, and language spoken. To test the efficacy of ALMA within each modality (in-person versus online), we stratified the sample by modality and estimated adjusted GEE models for depression and anxiety using the same options as the general sample. Adjusted models for stratified analyses include age, education level, and language spoken.