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MAMÁ EMPODERADA: PILOT TRIAL OF A NOVEL PARENTING AND MENTAL HEALTH PREVENTION INTERVENTION FOR MIGRANT MOTHERS WITH YOUNG CHILDREN

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ABSTRACT

Introduction: Migrant women in transit face high risk of developing mental health problems such as depression and anxiety, driven by gendered social-structural factors including violence, social isolation, migration uncertainty, limited access to services, and gender inequities. Although migrant women who endure such conditions have high need for mental health prevention, few evidence-based interventions are tailored to this population. Moreover, while women and children's mental health are interconnected, few mental health interventions address parenting needs. The aim of this study is to pilot-test a novel parenting and mental health prevention intervention for migrant mothers with young children (MMC) in Tijuana, Mexico, including a) assessing acceptability**,** b) estimating effect sizes on symptoms of depression, anxiety, and parenting stress, c) identify which theory-based mechanisms of action predict changes in outcomes, and d) identify factors associated with differential intervention response.

Methods and analysis: 'Mamá Empoderada' [Mom Power] is a theory-based, trauma-informed group intervention to promote mental health and responsive parenting among mothers with young children (0-5 years). This is an evidence-based intervention that has been previously evaluated in the U.S. and has been recently adapted for Spanish-speaking mothers. We have recently adapted this intervention for MMC in Mexico and will conduct a pilot randomized controlled trial (RCT) of the intervention with MMC (N=100; $N_{treatment}$=50; $N_{control}$=50). The intervention group (IG) will receive 10 group and 3 individual sessions addressing attachment-based parenting skills, linkage to resources (e.g., food, shelter), social support, and self-care and resilience over a 5-week period. The control group will receive standard of care programming and will be offered participation in the intervention following completion of the study by the IG (i.e., after 6 months). Both groups will complete baseline and exit surveys, as well as follow-up surveys at 2-, 4- and 6- months post-intervention. Statistical analyses will compare primary (i.e., symptoms of depression and anxiety; parenting stress) and intermediate outcomes (e.g., resilience, service utilization) by exposure to intervention condition using descriptive, bivariate, and multivariable logistic regression.

Ethics and dissemination: This study is approved by the San Diego State University and El Colegio de la Frontera Norte Institutional Research Boards. Findings will inform a larger trial to evaluate intervention efficacy. In collaboration with our community partners, results will be disseminated via peer-reviewed publications, presentations, and plain-language reports, infographics, and presentations to community, clinical, and policy audiences. If efficacious, this intervention is highly promising as a novel, low-cost, and feasible model that could be implemented in border settings in Mexico, the U.S. and elsewhere. Amid rising population displacement and prolonged and traumatic migration journeys, this study addresses an urgent need for scalable and tailored mental health prevention for MMC in border contexts.

Keywords: mental health prevention; migration; parenting intervention; women's health

Strengths and Limitations:

- This study will pilot-test a newly adapted evidence-based parenting and mental health prevention intervention among migrant mothers with young children.
- Findings are anticipated to identify a critical, timely, and highly promising mental health prevention intervention model that if efficacious, would serve as a novel, low-cost, and feasible model for border settings in Mexico, the U.S. and elsewhere.
- This intervention holds high promise for sustainability, as it is a community-based program that could be feasibly implemented by trained staff in resource-limited settings.
- As a pilot study with a small sample size, statistical power to detect rare outcomes or potential mediating or moderating effects is limited; rather, our primary goal is to generate effect size data to inform a subsequent efficacy trial.
- As in other prospective studies with marginalized and mobile populations, there is high potential for loss to follow up, which we have accounted for in our retention protocols.

INTRODUCTION

Global migration continues to rise at record-high rates, with the number of women traveling with children continuing to rise at the Mexico-U.S. border - the busiest land border crossing globally. The border city of Tijuana, Mexico is facing unprecedented challenges resulting from rising displacement due to violence, political conflict, lack of economic opportunity, and climate change, exacerbated by migration policies that have forced many migrants to wait in Mexico for long periods under unsafe conditions. Globally and at the Mexico-U.S. border, migrant women in transit face high risk of developing mental health problems such as depression and anxiety,[1–7]driven by gendered social-structural vulnerabilities including violence, social isolation, migration uncertainty, and limited access to services (e.g., food, housing).[2,4,8–10] Although migrants in transit who endure such conditions have high need for mental health prevention, most evidence-based approaches focus on mental health and trauma-related needs during the resettlement phase,[11,12] and few are tailored to the gendered needs of migrant women in transit.[11,13] Moreover, while women and children's mental health are closely interconnected, few mental health interventions in this context address parenting needs,[14–16] and mental health prevention interventions that can be delivered with migrant mothers with young children who are in transit are greatly needed.[12]

To address the need for feasible and tailored parenting and mental health prevention interventions for migrant mothers**,** this study will pilot-test ***'Mamá Empoderada' -*** an evidence-based, trauma-informed group intervention to promote mental health and responsive parenting outcomes among mothers with young children (0-5 years). The original *'Mom Power'* intervention was developed for marginalized mothers in the U.S., has demonstrated efficacy on reducing parenting stress and symptoms of depression, anxiety, and PTSD among trauma-exposed mothers in the U.S.,[17,18] and has been implemented across 9 U.S. states. The present study represents the first adaptation and pilot of the '*Mom Power'* intervention with migrant mothers. The intervention includes 10 group and 3 individual sessions addressing attachment-based parenting skills, linkage to resources (e.g., food, shelter), social support, and self-care and resilience delivered over a 5-week period. This program was recently translated from English into Spanish (***'Mamá Empoderada')***. With consultation from the developers of the original intervention, we have further adapted the program for migrant Latin American mothers through focus groups, consultations with our project's Community Advisory Board, and pre-testing of the intervention between Fall 2023-Summer 2024. This formative work has identified very high community support and enthusiasm for the proposed intervention, notably its focus on creating a safe space to address parenting and migration stressors and build social support and parenting skills with other migrant mothers and families.

While much past research has emphasized individual-level behavioral or cultural explanations for migrant health inequities,[19–21] this intervention addresses gendered parenting stressors and related social-structural vulnerabilities including social isolation and limited access to resources through a trauma-informed approach. Mom Power is theoretically underpinned by the ***Protective Factors Framework***[22] and ***Trauma Theory.***[23–25] The Protective Factors Framework postulates that parental resilience, social connections, knowledge of parenting and child development, and concrete support in times of need represent key protective factors that help families navigate adverse circumstances. Trauma Theory recognizes that exposure to traumatic experiences has a powerful impact on stress responses, health behaviors and outcomes, and identifies ***trauma-informed practice*** as a means of promoting survivors' wellbeing. Core practices include creating a safe, non-judgmental space that normalizes clients' experiences

using a non-victimizing approach; acknowledging the impact of trauma on challenges and coping strategies; situating challenges as shaped by social-structural factors; and empowering clients to manage their circumstances by expanding resources and support options.[23,24]

The aim of this study is to pilot-test a novel mental health prevention intervention for migrant mothers with young children in Tijuana, Mexico, including a) assessing acceptability**,** b) estimating effect sizes on symptoms of depression, anxiety, and parenting stress, c) exploring which theory-based mechanisms of action predict changes in symptoms of depression, anxiety, and parenting stress, and d) identify factors associated with differential intervention response.

METHODS AND ANALYSIS

Study Design

This pilot randomized controlled trial is being conducted in close partnership with Al Otro Lado (AOL) - a binational non-governmental organization that works with migrants in Tijuana, Baja California and San Diego, California. The trial will be conducted between October 2024 and August 2026. We will enroll 100 participants ($N_{treatment}$=50; $N_{control}$=50). The study will be conducted in Tijuana, a city of 1.9 million located adjacent to San Diego. Tijuana is the busiest land border crossing in the world and a hotspot for in-transit migrants planning to cross into the U.S., including asylum seekers and internally displaced persons. Services for migrants are mainly provided by a network of non-governmental organizations who operate shelters, food kitchens, clinical, mental health, and other services.

Following randomization, those allocated to the intervention group will participate in trauma-informed group and individual sessions addressing parenting, active linkage to resources (e.g., food, shelter), social support, and self-care and stress coping skills to nurture resilience. Those assigned to the control condition will receive standard of care programming and will have the opportunity to participate in the intervention following completion of all study visits (i.e., after 7 months). Both groups will complete baseline and exit surveys, as well as follow-up surveys at 2-, 4-, and 6- months post-intervention, with both groups receiving the same honoraria at the same intervals for their participation in the surveys. Sessions for the intervention will take place at the AOL Tijuana community office. Participants will be invited to bring their children <age 6 to their study visits, who will attend high-quality onsite childcare. All participants will receive active referrals to relevant supports and services.

Description of Intervention and Control Conditions

The ***intervention condition*** to be tested is a culturally adapted version of the multi-component *'Mom Power'* intervention, an integrated mental health and parenting program with intensive and active connection to resources (e.g., food, safe shelter, childcare) and activities designed to strengthen social support among and between migrant mothers with young children. *'Mamá Empoderada'* will be delivered at the AOL Tijuana community office across 10 group sessions (6-10 women/group) and 3 individual sessions held at the beginning, midpoint, and end of the intervention. The intervention draws on a version of the manualized intervention with content collaboratively tailored by the study team and intervention developers based on parent and provider feedback on parenting education and skills, connection to resources, strengthening social support, and resilience and self-care through a trauma-informed approach. Following delivery of the intervention content and activities, each group intervention session ends with the group and facilitators sharing a nutritious and culturally appropriate meal. Due to high mobility of the study population and the unpredictable nature of migration timing, delivery of the

intervention was adapted from weekly to bi-weekly (over 5 weeks) sessions. Participants are offered transportation support to encourage attendance at all in-person sessions.

Participants randomized to the ***control condition*** will receive standard of care services available through AOL and other community partners (e.g., 'know your rights' workshops, legal aid, perinatal support programs, humanitarian supports). Referrals and connections to these services will be provided through three one-on-one check-in sessions with control group participants (via phone or in-person) that will be held at the same intervals as the intervention group (beginning, midpoint, and end of the 5-week intervention period). For ethical reasons, control group participants will be offered the opportunity to participate in the full intervention condition following the completion of the intervention and all study-related assessments (post-6 month survey completion).

Eligibility Criteria

Eligible participants will: 1) Self-identify as a mother to at least one accompanying child <age 6; 2) Have migrated to Tijuana from a Latin American country other than Mexico, or born in Mexico and internally displaced; 3) Be available to participate in the full duration of '*Mamá Empoderada*'; 4) Be able to speak Spanish; 5) Be aged ≥18 years old; 6) Be able to provide informed consent; 7) Screen below clinical cut-offs for major depression and anxiety disorder.

Recruitment and Screening

We will recruit participants via posters, flyers, and direct referral by community partners. Potential participants will be invited to contact the study coordinator for additional information. Interested participants will be informed of the study's aims and procedures and will be screened for eligibility via a brief (10-minute) screener that includes brief depression (PHQ-9)[26] and anxiety (GAD-7)[27] scales, the number and age of accompanying children, place of origin, languages spoken, and migration plans. All screened individuals who are deemed ineligible will be connected to standard of care services at AOL, as well as referrals to relevant local mental health, maternal and child health services. Eligible participants will be connected with the study coordinator for more information about study procedures, risks and benefits, and potential participants will be guided through the informed consent process prior to enrolment.

Randomization and Enrollment

After enrollment, participants will be randomized at a 1:1 ratio to the intervention or control arm on a rolling basis. The data manager will create a pre-programmed randomization schedule. When a participant is enrolled, the study coordinator will use the list to assign them to the intervention or control condition. Once enough participants are randomized to each condition to form a group, the first session for the group will be scheduled and participants will be notified of their dates.

Measures

Guided by our conceptual framework (Figure 1), baseline, exit, and follow-up survey questions were selected and adapted from theory-based, empirically validated measures (Table 1). Enrollment, baseline and exit questionnaires will be conducted at the AOL Tijuana office or on community outreach. Follow-up and baseline questionnaires are similar; fixed demographic and lifetime questions are asked at baseline only, and the follow-up recall period will be the last

two months. The exit questionnaire will have additional questions for the intervention condition participants regarding the acceptability, feasibility, ethicality, and sustainability of the intervention.[28] Baseline and exit questionnaires will be administered by trained study staff via RedCap following enrolment and the final session for each group, respectively. Follow-up surveys at 2-, 4-, and 6-month post intervention will be completed either in-person or via phone. A detailed connection to services tracking sheet[29] will be used to document active referrals to services for each participant. We will provide modest honoraria to compensate participants for their time for completion of each study assessment: $10 USD for baseline (BL) survey; US$18 for exit survey; US$20 for the 2-month follow-up survey; $25 for the 4- and 6-month follow-up survey, consistent with other local research and based on input from our local partners and Mexican investigators on appropriate compensation. Compensation will not be provided for attendance at intervention sessions, as this was advised by local community partners and investigators as critical for long-term feasibility and sustainability of intervention uptake locally.

Counseling and Referrals. Given the sensitive nature of the topics addressed in this study, all study staff have received training in trauma-informed approaches and in the recognition and first response (psychological first aid) for emotional distress. We have prepared detailed resource lists containing pre-vetted mental health providers available in the city or remotely, which will be provided to all participants. Participants exhibiting distress during implementation will be immediately connected to a study coordinator (a trained counselor) and connected to known local mental health providers.

Participant Retention and Follow-up. To support follow-up and retention over the 5-week intervention and at 2-, 4- and 6-month follow up periods, we will use the following cohort retention strategies: 1) Maintaining and updating contact information (e.g., cell phone, WhatsApp, address, services visited, trusted contacts) at each visit; 2) Providing increasing incentives at follow-up survey visits; 3) Follow-up surveys will be offered by phone or in person to increase accessibility and account for potential out-migration; 4) Visit reminders provided via phone/text reminders, community outreach, and ongoing communication with participants; 5) Community-based project staff with extensive experience in developing rapport and maintaining connections with local migrant women will lead recruitment, follow-up, and facilitate sessions, as they are deeply familiar with the needs and realities of our target population; 6) Working closely with local partner NGOs that maintain regular contact with the study population.

Training and Fidelity Monitoring. All data collection and intervention sessions are led by a team of local coordinators and facilitators/interviewers, which includes clinically trained staff (licensed psychologists or social workers) alongside community-based staff members with substantial expertise working with migrant women and families locally. All coordinators and facilitators/interviewers have participated in intensive training (20+ hours) on the delivery of the manualized intervention and control content, which includes didactic presentations, role modeling of intervention components, and role-playing exercises, as well as ongoing reflective consultation. Staff also receive extensive training in research ethics, trauma-informed practices, questionnaire administration, and participant referrals and support. All staff will receive ongoing training and check-ins on a weekly basis to troubleshoot issues and support consistent intervention and control content delivery. Intervention sessions will be monitored for fidelity. We will review the first 4 intervention sessions and a random sample (10%) of sessions

thereafter using these quality control procedures: (1) scoring sessions for content adherence, (2) monitoring sessions for content consistency, and (3) re-training, where needed, to strengthen fidelity.

Power: Consistent with the goals of a pilot study, this study is not powered to detect significant differences in outcomes by study arm, but rather designed to obtain estimates of effect sizes for a subsequent efficacy trial. The proposed sample size (N=100) is consistent with methodological literature suggesting this to be sufficient for a pilot study.[30] Based on effect sizes from the original *'Mom Power'* intervention, we expect to have >85% power to detect a significant change in prevalence of depressive symptoms.

Statistical Analyses. Statistical analyses will compare primary (symptoms of depression and anxiety; parenting stress) and intermediate outcomes (e.g., resilience, service utilization) of participants by exposure to intervention condition. Bivariate and multivariable models will consider potential confounders that differ between comparison groups and are *a priori* known/suspected to be related to outcomes based on our conceptual framework (Fig 1) and prior literature. Models will also consider product terms (one at a time) between exposures of interest and these covariates. Although this is a pilot study, our analytic plan will follow CONSORT guidelines for RCTs.[31] We will assess descriptive statistics on intervention *acceptability* using data from the intervention condition participants' exit surveys. To assess whether the intervention predicts changes in primary outcomes, we will conduct intent-to-treat analyses of differences in primary (symptoms of depression and anxiety; parental stress) and secondary outcomes between intervention and control groups at exit, 2-, 4- and 6-months, using GLMMs for categorical outcomes and linear mixed models to model continuous outcomes. We will use unadjusted and multivariable logistic regression with GLMMs to explore which theory-based mechanisms of action predict changes in depression and anxiety symptoms and parenting stress and explore factors associated with differential intervention response (e.g., longer migration duration, trauma). Although the study is not powered to formally detect mediating or moderating effects, descriptive analyses of possible differential intervention response based on comparisons by demographics, migration stressors (e.g., duration, legal status), and trauma will provide an important basis for effect sizes and hypotheses for a subsequent efficacy trial.

Patient and public involvement

Meaningful community engagement is critical for addressing power imbalances inherent in research with marginalized communities, as well as to ensure the relevance and appropriateness of the research. All aspects of this study will involve community engagement[32] and support capacity-building with our local NGO partners. Intervention adaptation, recruitment, interpretation, and translation of findings are being conducted in close collaboration with ***Al Otro Lado*** ([AOL), a large binational NGO providing support to >10,000 migrants in the U.S. and Tijuana annually; as well as the study's Community Advisory Board (CAB), which is comprised of stakeholders, community leaders, and service providers from nine local NGOs.

We have worked closely with our community partners, CAB, and local MMC and health and community stakeholders to develop and adapt the '*Mamá Empoderada'* intervention and study design. From Fall 2023 - Spring 2024, we gathered local community feedback on the intervention content, delivery, and evaluation design from a series of focus groups with migrant mothers and NGO stakeholders, and established our CAB. The insights generated from these

activities were used to carefully adapt and refine the intervention content, delivery, and questionnaire measures. Working closely with AOL and the CAB, we will continue to meet with the CAB quarterly throughout the duration of the trial to review progress, seek guidance and support for addressing potential barriers and facilitators to recruitment and retention, troubleshoot unanticipated challenges, interpret interim and final results, and collaborate on dissemination efforts. Finally, the entire intervention protocol was pre-tested with a diverse sample of MMC (n=14) prior to launching the pilot trial, which informed final adaptations (e.g., addressing barriers to participation and retention, increasing cultural appropriateness and participant appeal, refining survey measures) prior to initiation.

ETHICS AND DISSEMINATION

This study has been registered at ClinicalTrials.Gov (ID: *NCT06468046*) and has been approved by the San Diego State University (SDSU) (Protocol #: *HS-2023-0135)* and El Colegio de la Frontera Norte (COLEF) (Protocol #: *105_261023*) Research Ethics Boards and complies with ethical guidelines set out by the Declaration of Helsinki. All participants will provide informed consent prior to enrolment. Potential participants will be informed about the nature of the study and its possible risks and benefits during the informed consent process, which will include a detailed explanation of aims, procedures, risks, benefits, and the voluntary nature of the study based on principles of co-learning. The consent form is available in Spanish and will be reviewed with the participant in a private location with a member of the study team prior to enrollment. The participant will be informed that they can refuse to answer any question and may leave the study at any time.

For the purposes of this study, participant data will be de-identified and securely stored in RedCap. To monitor recruitment and retention, the data manager will generate weekly reports of each from RedCap and will export RedCap datasets on a weekly basis to monitor data quality. All surveys will be programmed and administered electronically in RedCap. Overall data safety and monitoring and oversight responsibilities for the study are held by the PIs and the IRB. Scientific oversight will be led by the PIs and the research team in collaboration with a Scientific Monitoring Committee (SMC) at SDSU and COLEF. SMC members are interdisciplinary researchers experienced with behavioral interventions with marginalized populations including migrants and other marginalized populations at the Mexico-U.S. border who are deeply familiar with the local study context and population. All SMC members are external to the proposed project. The SMC will meet a minimum of annually. Monitoring of potential adverse events will be a standing item on the research team's weekly meeting. All adverse events will be documented, as will any resulting responses implemented by the study team.

In accordance with requirements from the National Institute of Mental Health (NIMH), we will create a unique pseudo-Global Unique Identifier (pseudo-GUID) to securely share data with the NIMH Data Archive repository.

In collaboration with our community partners, results will be disseminated via peer-reviewed publications, presentations, and plain-language reports to community, clinical, and policy audiences. If efficacious, this intervention is highly promising as a novel, low-cost, and feasible model that could be implemented in border settings in Mexico, the U.S. and elsewhere. Amid rising population displacement and prolonged and traumatic migration journeys, this study addresses an urgent need for scalable and tailored mental health prevention for migrant women and families in border contexts.

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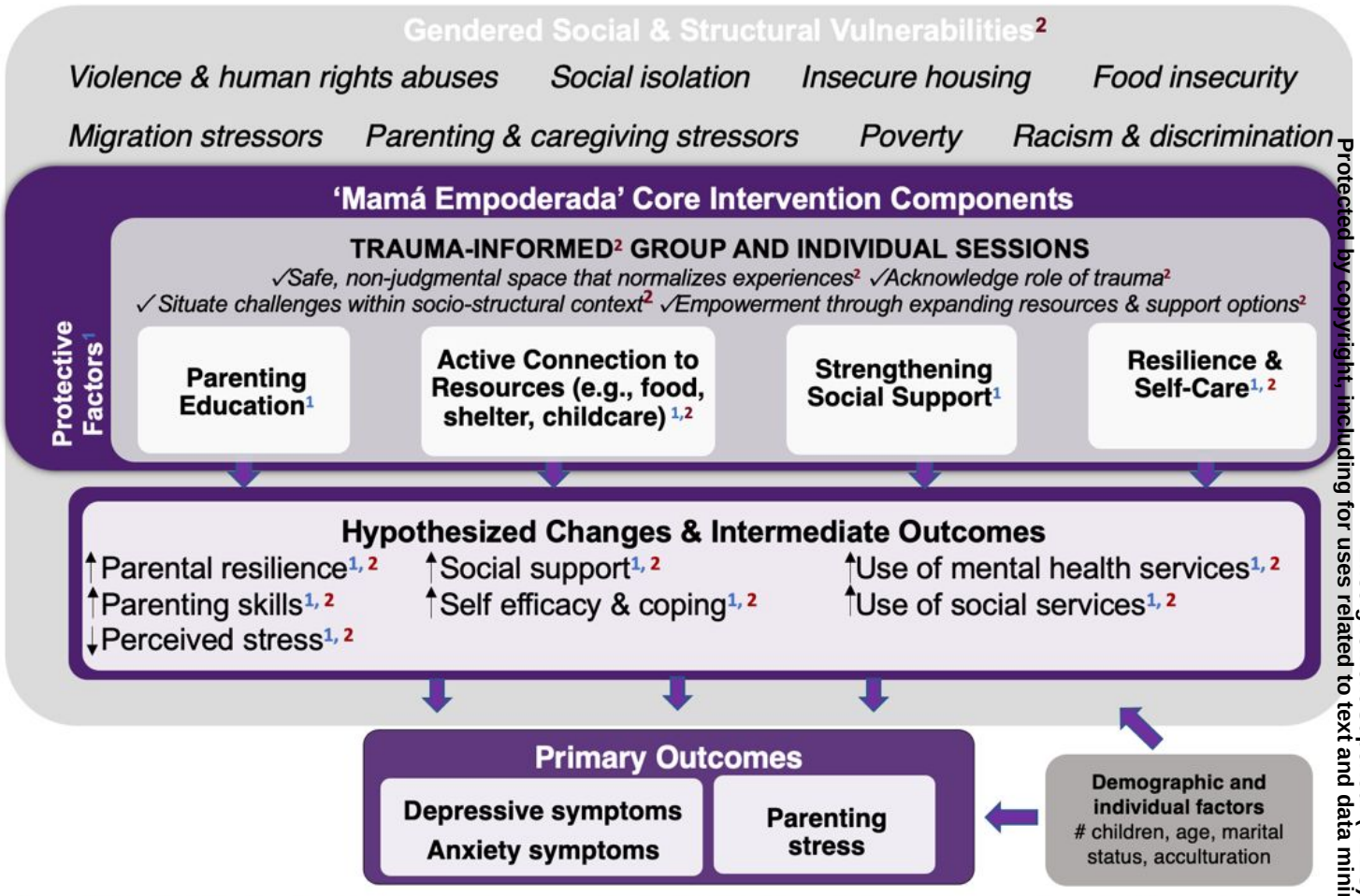
TABLES AND FIGURES

Figure 1: Theory-Based 'Mamá Empoderada' Intervention Components, Proposed Mechanisms, and Outcomes



[1]Components and mechanisms informed by the Protective Factors Framework; [2]Components and mechanisms informed by Trauma Theory
NOTE: Intervention components will be adapted based on Aim 1 findings

Table 1: Study Measures	
Primary Outcomes	
Anxiety symptoms	General Anxiety Disorder Scale (7-item) (GAD-7)[27]
Depression symptoms	Patient Health Questionnaire (PHQ-9)[33]
Parenting Stress	Parental Stress Scale[34]
Intermediate/Secondary Outcomes	
Resilience & coping	Brief Resilience Scale[35], DSM-5 Level 1 Cross-Cutting Measure[33]
Parenting skills	Parenting Sense of Competence Scale[36]
Service utilization	Use of HIV/STI services, use of other health services, barriers to services
Social support	Multidimensional Scale of Perceived Social Support[37], DSM-5 Level 1 Cross-Cutting Measure[33]
Substance use	Global Adult Tobacco Survey[38], Alcohol Use Disorders Identification Test (AUDIT-C) (3-item)[39], DSM-5 Level 1 Cross-Cutting Measure[33], use of other substances
Health and healthcare Access	Self-rated health[40], experiences of care-seeking and treatment, recent healthcare needs and treatment
Disability	WHODAS 2.0[41] (cognition, mobility, self-care, social interactions, life activities, community participation)
Mental health	DSM-5 Level 1 Cross-Cutting Measure[33], Post-Traumatic Stress Checklist (PC-PTSD-5)[44]
Individual and demographic factors	
Demographics	Age, race, sex at birth, gender, sexual orientation, marital and partner status, household size, education level
Reproductive history	Methods of contraception; HIV/STI risk behaviors; pregnancies and live births; access to prenatal and perinatal care; pregnancy intention; Pregnant Persons Experience of Mistreatment by Providers Index[42]; Reproductive Autonomy Scale[43]
Gendered social and structural vulnerabilities	
Violence	Sexual Relationship Power Scale[45]; frequency, types, and perpetrators of violence, WHO Intimate Partner Violence Scale[46]
Economic factors	Household income, employment status
Housing & household	Living situation in Tijuana, housing insecurity, presence of children
Migration experiences	Country of origin, duration in Tijuana, duration of transit, migration trajectory, immigration status, detention/deportation
Racism and discrimination	Everyday Discrimination Scale[47], Border Community & Immigration Stress Scale[48]
Food insecurity	Reduced Coping Strategies Index[49]
Process indicators	
Acceptability of intervention	Perceived intervention effectiveness, coherence, and acceptability[28]

Authors' contributions: SG drafted and critically revised the protocol and led all aspects of the study. KR contributed to co-drafting sections of the protocol. All other authors (CH, CMT, GR, KR) critically reviewed and edited the protocol. All authors reviewed and approved the final version prior to publication.

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Competing interests statement: We have no competing interests to declare.

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Mamá Empoderada: Protocol for a Pilot Trial of a Novel Parenting and Mental Health Prevention Intervention for Migrant Mothers with Young Children at the Mexico-U.S. Border

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Mamá Empoderada: Study Protocol for a Pilot Trial of a Novel Parenting and Mental Health Prevention Intervention for Migrant Mothers with Young Children at the Mexico-U.S. Border

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ABSTRACT

Introduction: Migrant women in transit face high risk of developing mental health problems such as depression and anxiety, driven by gendered social-structural factors including violence, social isolation, migration uncertainty, limited access to services, and gender inequities. Although migrant women who endure such conditions have high need for mental health prevention, few evidence-based interventions are tailored to this population. Moreover, while women and children's mental health are interconnected, few mental health interventions address parenting needs. The aim of this study is to pilot-test a novel parenting and mental health prevention intervention for migrant mothers with young children (MMC) in Tijuana, Mexico, including a) assessing acceptability**,** b) estimating effect sizes on symptoms of depression, anxiety, and parenting stress, c) identifying which theory-based mechanisms of action predict changes in outcomes, and d) identifying factors associated with differential intervention response.

Methods and analysis: 'Mamá Empoderada' [Mom Power] is a theory-based, trauma-informed group intervention to promote mental health and responsive parenting among mothers with young children (0-5 years). This is an evidence-based intervention that has been previously evaluated in the U.S. and has been recently adapted for Spanish-speaking mothers. We have recently adapted this intervention for MMC in Mexico and will conduct a pilot randomized controlled trial (RCT) of the intervention with MMC (N=100; $N_{treatment}$=50; $N_{control}$=50). The intervention group (IG) will receive 10 group and 3 individual sessions addressing attachment-based parenting skills, linkage to resources (e.g., food, shelter), social support, and self-care and resilience over a 5-week period. The control group will receive standard of care programming and will be offered participation in the intervention following completion of the study by the IG (i.e., after 6 months). Both groups will complete baseline and exit surveys, as well as follow-up surveys at 2-, 4- and 6- months post-intervention. Statistical analyses will compare primary (i.e., symptoms of depression and anxiety; parenting stress) and intermediate outcomes (e.g., resilience, service utilization) by exposure to intervention condition using descriptive, bivariate, and multivariable logistic regression.

Ethics and dissemination: This study is approved by the San Diego State University and El Colegio de la Frontera Norte Institutional Research Boards. Findings will inform a larger trial to evaluate intervention efficacy. In collaboration with our community partners, results will be disseminated via peer-reviewed publications, presentations, and plain-language reports, infographics, and presentations to community, clinical, and policy audiences. If efficacious, this intervention is highly promising as a novel, low-cost, and feasible model that could be implemented in border settings in Mexico, the U.S. and elsewhere. Amid rising population displacement and prolonged and traumatic migration journeys, this study addresses an urgent need for scalable and tailored mental health prevention for MMC in border contexts.

Keywords: mental health prevention; migration; parenting intervention; women's health

Trial Registration: *NCT06468046*

Strengths and Limitations:

- This study will pilot-test a newly adapted evidence-based parenting and mental health prevention intervention among migrant mothers with young children.
- This study is evaluating a culturally adapted and timely mental health prevention intervention model for Latin American migrant mothers in border settings.
- This intervention holds high promise for sustainability, as it is a community-based program that could be feasibly implemented by trained staff in resource-limited settings.
- As a pilot study with a small sample size, statistical power to detect rare outcomes or potential mediating or moderating effects is limited; rather, our primary goal is to generate effect size data to inform a subsequent efficacy trial.
- As in other prospective studies with marginalized and mobile populations, there is high potential for loss to follow up, which we have accounted for in our retention protocols.

INTRODUCTION

Global migration continues to rise at record-high rates, with the number of women traveling with children continuing to rise at the Mexico-U.S. border - the busiest land border crossing globally. The border city of Tijuana, Mexico is facing unprecedented challenges resulting from rising displacement due to violence, political conflict, lack of economic opportunity, and climate change, exacerbated by migration policies that have forced many migrants to wait in Mexico for long periods under unsafe conditions. Globally and at the Mexico-U.S. border, migrant women in transit face high risk of developing mental health problems such as depression and anxiety,[1–7]driven by gendered social-structural vulnerabilities including violence, social isolation, migration uncertainty, and limited access to services (e.g., food, housing).[2,4,8–10] Although migrants in transit who endure such conditions have high need for mental health prevention, most evidence-based approaches focus on mental health and trauma-related needs during the resettlement phase,[11,12] and few are tailored to the gendered needs of migrant women in transit.[11,13] Moreover, while women and children's mental health are closely interconnected, few mental health interventions in this context address parenting needs,[14–16] and mental health prevention interventions that can be delivered with migrant mothers with young children who are in transit are greatly needed.[12]

To address the need for feasible and tailored parenting and mental health prevention interventions for migrant mothers**,** this study will pilot-test ***'Mamá Empoderada' -*** an evidence-based, trauma-informed group intervention to promote mental health and responsive parenting outcomes among mothers with young children (0-5 years). The original *'Mom Power'* intervention was developed for marginalized mothers in the U.S., has demonstrated efficacy on reducing parenting stress and symptoms of depression, anxiety, and PTSD among trauma-exposed mothers in the U.S.,[17,18] and has been implemented across 9 U.S. states. The present study represents the first adaptation and pilot of the '*Mom Power'* intervention with migrant mothers. The intervention includes 10 group and 3 individual sessions addressing attachment-based parenting skills, linkage to resources (e.g., food, shelter), social support, and self-care and resilience delivered over a 5-week period. This program was recently translated from English into Spanish (***'Mamá Empoderada')***. With consultation from the developers of the original intervention, we have further adapted the program for migrant Latin American mothers through focus groups, consultations with our project's Community Advisory Board, and pre-testing of the intervention between Fall 2023-Summer 2024. This formative work has identified very high community support and enthusiasm for the proposed intervention, notably its focus on creating a safe space to address parenting and migration stressors and build social support and parenting skills with other migrant mothers and families.

While much past research has emphasized individual-level behavioral or cultural explanations for migrant health inequities,[19–21] this intervention addresses gendered parenting stressors and related social-structural vulnerabilities including social isolation and limited access to resources through a trauma-informed approach. Mom Power is theoretically underpinned by the ***Protective Factors Framework***[22] and ***Trauma Theory.***[23–25] The Protective Factors Framework postulates that parental resilience, social connections, knowledge of parenting and child development, and concrete support in times of need represent key protective factors that help families navigate adverse circumstances. Trauma Theory recognizes that exposure to traumatic experiences has a powerful impact on stress responses, health behaviors and outcomes, and identifies ***trauma-***

informed practice as a means of promoting survivors' wellbeing. Core practices include creating a safe, non-judgmental space that normalizes clients' experiences using a non-victimizing approach; acknowledging the impact of trauma on challenges and coping strategies; situating challenges as shaped by social-structural factors; and empowering clients to manage their circumstances by expanding resources and support options.[23,24]

The aim of this study is to pilot-test a novel mental health prevention intervention for migrant mothers with young children in Tijuana, Mexico, including a) assessing acceptability**,** b) estimating effect sizes on symptoms of depression, anxiety, and parenting stress, c) exploring which theory-based mechanisms of action predict changes in symptoms of depression, anxiety, and parenting stress, and d) identifying factors associated with differential intervention response.

METHODS AND ANALYSIS

Study Design

This pilot randomized controlled trial is being conducted in close partnership with Al Otro Lado (AOL) - a binational non-governmental organization that works with migrants in Tijuana, Baja California and San Diego, California. The trial will be conducted between October 2024 and August 2026. We will enroll 100 participants ($N_{treatment}$=50; $N_{control}$=50). The study will be conducted in Tijuana, a city of 1.9 million located adjacent to San Diego. Tijuana is the busiest land border crossing in the world and a hotspot for in-transit migrants planning to cross into the U.S., including asylum seekers and internally displaced persons. Services for migrants are mainly provided by a network of non-governmental organizations who operate shelters, food kitchens, clinical, mental health, and other services.

Following randomization, those allocated to the intervention group will participate in trauma-informed group and individual sessions addressing responsive parenting, active linkage to resources (e.g., food, shelter), social support, and self-care and stress coping skills to nurture resilience. Those assigned to the control condition will receive standard of care programming and will have the opportunity to participate in the intervention following completion of all study visits (i.e., after 7 months). Both groups will complete baseline and exit surveys, as well as follow-up surveys at 2-, 4-, and 6- months post-intervention, with both groups receiving the same honoraria at the same intervals for their participation in the surveys. Sessions for the intervention will take place at the AOL Tijuana community office. Participants will be invited to bring their children <age 6 to their study visits, who will attend high-quality onsite childcare. All participants will receive active referrals to relevant health and humanitarian services.

Description of Intervention and Control Conditions

The ***intervention condition*** to be tested is a culturally adapted version of the multi-component *'Mom Power'* intervention, an integrated mental health and parenting program with intensive and active connection to resources (e.g., food, safe shelter, childcare) and activities designed to strengthen social support among and between migrant mothers with young children. *'Mamá Empoderada'* will be delivered at the AOL Tijuana community office across 10 group sessions (6-10 women/group) and 3 individual sessions held at the beginning, midpoint, and end of the intervention. The intervention draws on a version of the manualized intervention with content collaboratively tailored by the study team and intervention developers based on parent and provider feedback on parenting education and skills, connection to resources, strengthening

social support, and resilience and self-care through a trauma-informed approach. Following delivery of the intervention content and activities, each group intervention session ends with the group and facilitators sharing a nutritious and culturally appropriate meal. Due to high mobility of the study population and the unpredictable nature of migration timing, delivery of the intervention was adapted from weekly to bi-weekly (over 5 weeks) sessions. Participants are offered transportation support to encourage attendance at all in-person sessions.

Participants randomized to the ***control condition*** will receive standard of care services available through AOL and other community partners (e.g., 'know your rights' workshops, legal aid, perinatal support programs, humanitarian supports). Referrals and connections to these services will be provided through one group and three one-on-one sessions with control group participants (via phone or in-person) that will be held at the same intervals as the intervention group (beginning, midpoint, and end of the 5-week intervention period). For ethical reasons, control group participants will be offered the opportunity to participate in the full intervention condition following the completion of the intervention and all study-related assessments (post-6 month survey completion).

Eligibility Criteria

Eligible participants will: 1) Self-identify as a mother to at least one accompanying child <age 6; 2) Have migrated to Tijuana from a Latin American country other than Mexico, or born in Mexico and internally displaced; 3) Be available to participate in the full duration of '*Mamá Empoderada*'; 4) Be able to speak Spanish; 5) Be aged ≥18 years old; 6) Be able to provide informed consent; 7) Screen below clinical cut-offs for major depression and anxiety disorder.

Recruitment and Screening

We will recruit participants via posters, outreach, and direct referral by community partners. Potential participants will be invited to contact the study coordinator for additional information. Interested participants will be informed of the study's aims and procedures and will be screened for eligibility via a brief (10-minute) screener that includes brief depression (PHQ-9)[26] and anxiety (GAD-7)[27] scales, the number and age of accompanying children, place of origin, languages spoken, and migration plans. All screened individuals who are deemed ineligible will be connected to standard of care services at AOL, as well as referrals to relevant local mental health, maternal and child health services. Eligible participants will be connected with the study coordinator for more information about study procedures, risks and benefits. Potential participants will be guided through the informed consent process prior to enrolment, which will cover the study's purpose, design, and potential risks and benefits (see Supplementary Material).

Randomization, Blinding, and Enrollment

After enrollment, participants will be randomized at a 1:1 ratio to the intervention or control arm on a rolling basis , using a pre-programmed block randomization schedule. When a participant is enrolled, the study coordinator will use the list to assign them to the intervention or control condition. Once enough participants are randomized to each condition to form a group, the first session for the group will be scheduled and participants will be notified of their dates. Using a single-blind approach, data analysts will be blinded to the intervention assignment.

Measures

Guided by our conceptual framework (Figure 1), baseline, exit, and follow-up survey questions were selected and adapted for the local population and cultural context from theory-based, empirically validated measures (Table 1). Enrollment, baseline and exit questionnaires will be conducted at the AOL Tijuana office or on community outreach. Follow-up and baseline questionnaires are similar; fixed demographic and lifetime questions are asked at baseline only, and the follow-up recall period will be the last two months. The exit questionnaire will have additional questions for the intervention condition participants regarding the acceptability, feasibility, ethicality, and sustainability of the intervention.[28] Baseline and exit questionnaires will be administered and entered by trained study staff via RedCap following enrolment and the final session for each group, respectively. Follow-up surveys at 2-, 4-, and 6-month post intervention will be completed either in-person or via phone. We will provide modest honoraria to compensate participants for their time for completion of each study assessment: $10 USD for baseline (BL) survey; US$18 for exit survey; US$20 for the 2-month follow-up survey; $25 for the 4- and 6-month follow-up survey, consistent with other local research and based on input from our local partners and Mexican investigators on appropriate compensation. Compensation will not be provided for attendance at intervention sessions, as this was advised by local community partners and investigators as critical for long-term feasibility and sustainability of intervention uptake locally.

Counseling and Referrals. Given the sensitive nature of the topics addressed in this study, all study staff have received training in trauma-informed approaches and in the recognition and first response (psychological first aid) for emotional distress. We have prepared detailed resource lists containing pre-vetted mental health providers available in the city or remotely, which will be provided to all participants. Participants exhibiting distress during implementation will be immediately connected to a study coordinator (a trained counselor) and connected to known local mental health providers.

Participant Retention and Follow-up. To support follow-up and retention over the 5-week intervention and at 2-, 4- and 6-month follow up periods, we will use the following cohort retention strategies: 1) Maintaining and updating contact information (e.g., cell phone, WhatsApp, address, services visited, trusted contacts) at each visit; 2) Providing increasing incentives at follow-up survey visits; 3) Follow-up surveys will be offered by phone or in person to increase accessibility and account for potential out-migration; 4) Visit reminders provided via phone/text reminders, community outreach, and ongoing communication with participants; 5) Community-based project staff with extensive experience in developing rapport and maintaining connections with local migrant women will lead recruitment, follow-up, and facilitate sessions, as they are deeply familiar with the needs and realities of our target population; 6) Working closely with local partner NGOs that maintain regular contact with the study population.

Training and Fidelity Monitoring. All data collection and intervention sessions are led by a team of local coordinators and facilitators/interviewers, which includes clinically trained staff (licensed psychologists or social workers) alongside community-based staff members with substantial expertise working with migrant women and families locally. All coordinators and facilitators/interviewers have participated in intensive training (20+ hours) on the delivery of the manualized intervention and control content, which includes didactic presentations, role modeling of intervention components, and role-playing exercises, as well as ongoing reflective

consultation. Staff also receive extensive training in research ethics, trauma-informed practices, questionnaire administration, and participant referrals and support. All staff will receive ongoing training and check-ins on a weekly basis to troubleshoot issues and support consistent intervention and control content delivery. Intervention sessions will be monitored for fidelity via use of a standardized scoresheet evaluating each session for content adherence and consistency; re-training will occur, where needed, to strengthen fidelity.

Power. Consistent with the goals of a pilot study, this study is not powered to detect significant differences in outcomes by study arm, but rather designed to obtain estimates of effect sizes for a subsequent efficacy trial. The planned sample size (N=100) is consistent with methodological literature suggesting this to be sufficient for a pilot study.[30] Based on effect sizes from the original *'Mom Power'* intervention, we expect to have >85% power to detect a significant change in prevalence of depressive symptoms.

Statistical Analyses. Statistical analyses will compare primary (symptoms of depression and anxiety; parenting stress) and intermediate outcomes (e.g., resilience, service utilization) of participants by exposure to intervention condition. Bivariate and multivariable models will consider potential confounders that differ between comparison groups and are *a priori* known/suspected to be related to outcomes based on our conceptual framework (Fig 1) and prior literature. Models will also consider product terms (one at a time) between exposures of interest and these covariates. Although this is a pilot study, our analytic plan will follow CONSORT guidelines for RCTs.[31] We will assess descriptive statistics on intervention *acceptability* using data from the intervention condition participants' exit surveys. To assess whether the intervention predicts changes in primary outcomes, we will conduct intent-to-treat analyses of differences in primary (symptoms of depression and anxiety; parental stress) and secondary outcomes between intervention and control groups at exit, 2-, 4- and 6-months, using GLMMs for categorical outcomes and linear mixed models to model continuous outcomes. We will use unadjusted and multivariable logistic regression with GLMMs to explore which theory-based mechanisms of action predict changes in depression and anxiety symptoms and parenting stress and explore factors associated with differential intervention response (e.g., longer migration duration, trauma). Although the study is not powered to formally detect mediating or moderating effects, descriptive analyses of possible differential intervention response based on comparisons by demographics, migration stressors (e.g., duration, legal status), and trauma will provide an important basis for effect sizes and hypotheses for a subsequent efficacy trial.

Patient and public involvement

Meaningful community engagement is critical for addressing power imbalances inherent in research with marginalized communities, as well as to ensure the relevance and appropriateness of the research. All aspects of this study will involve community engagement[32] and support capacity-building with our local NGO partners. Intervention adaptation, recruitment, interpretation, and translation of findings are being conducted in close collaboration with ***Al Otro Lado*** ([AOL), a large binational NGO providing support to >10,000 migrants in the U.S. and Tijuana annually; as well as the study's Community Advisory Board (CAB), which is comprised of stakeholders, community leaders, and service providers from nine local NGOs.

We have worked closely with our community partners, CAB, and local migrant mothers and health and community stakeholders to develop and adapt the '*Mamá Empoderada'* intervention and study design. From Fall 2023 - Spring 2024, we gathered local community feedback on the intervention content, delivery, and evaluation design from a series of focus groups with migrant mothers and NGO stakeholders, and established our CAB. The insights generated from these activities were used to carefully adapt and refine the intervention content, delivery, and questionnaire measures. Working closely with AOL and the CAB, we will continue to meet with the CAB quarterly throughout the duration of the trial to review progress, seek guidance and support for addressing potential barriers and facilitators to recruitment and retention, troubleshoot unanticipated challenges, interpret interim and final results, and collaborate on dissemination efforts. Finally, the entire intervention protocol was pre-tested with a diverse sample of migrant mothers with young children (n=14) prior to launching the pilot trial, which informed final adaptations (e.g., addressing barriers to participation and retention, increasing cultural appropriateness and participant appeal, refining survey measures) prior to initiation.

ETHICS AND DISSEMINATION

This study has been registered at ClinicalTrials.Gov (ID: *NCT06468046*) and has been approved by the San Diego State University (SDSU) (Protocol #: *HS-2023-0135)* and El Colegio de la Frontera Norte (COLEF) (Protocol #: *105_261023*) Research Ethics Boards and complies with ethical guidelines set out by the Declaration of Helsinki. All participants will provide informed consent prior to enrolment. Potential participants will be informed about the nature of the study and its possible risks and benefits during the informed consent process, which will include a detailed explanation of aims, procedures, risks, benefits, and the voluntary nature of the study based on principles of co-learning. The consent form is available in Spanish and will be reviewed with the participant in a private location with a member of the study team prior to enrollment. The participant will be informed that they can refuse to answer any question and may leave the study at any time.

For the purposes of this study, participant data will be de-identified and securely stored in RedCap. To monitor recruitment and retention, the data manager will generate reports of each from RedCap and will export RedCap datasets on a weekly basis to monitor data quality. All surveys will be programmed and administered electronically in RedCap. Overall data safety and monitoring and oversight responsibilities for the study are held by the PIs and the IRB. Scientific oversight will be led by the PIs and the research team in collaboration with a Scientific Monitoring Committee (SMC) at SDSU and COLEF. SMC members are interdisciplinary researchers experienced with behavioral interventions with marginalized populations including migrants and other marginalized populations at the Mexico-U.S. border who are deeply familiar with the local study context and population. All SMC members are external to the study, and are independent from the funding agency. The SMC will meet a minimum of annually to provide scientific oversight and guidance, including reviewing and providing guidance on the protocol, progress, interim results, unanticipated challenges, and other factors that could arise or affect scientific progress. Monitoring of potential adverse events will be a standing item on the research team's weekly meeting. All adverse events will be documented, as will any resulting responses implemented by the study team.

In accordance with requirements from the National Institute of Mental Health (NIMH), we will share protocols, instruments, data dictionaries, and data with the NIMH Data Archive (NDA) repository. De-identified data will be uploaded via creation of a unique pseudo-Global Unique Identifier (pseudo-GUID) to securely share data for consenting participants. Quantitative data from this pilot trial will be preserved to enable sharing of data, with the exception of migration experiences given the highly criminalized and marginalized nature of the population and the risks of disclosing such data.

In collaboration with our community partners, results will be disseminated via peer-reviewed publications, presentations, and plain-language reports to community, clinical, and policy audiences. If efficacious, this intervention is highly promising as a novel, low-cost, and feasible model that could be implemented in border settings in Mexico, the U.S. and elsewhere. Amid rising population displacement and prolonged and traumatic migration journeys, this study addresses an urgent need for scalable and tailored mental health prevention for migrant women and families in border contexts.

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Table 1: Study Measures	
Primary Outcomes	
Anxiety symptoms	General Anxiety Disorder Scale (7-item) (GAD-7)[27]
Depression symptoms	Patient Health Questionnaire (PHQ-9)[33]
Parenting Stress	Parental Stress Scale[34]
Intermediate/Secondary Outcomes	
Resilience & coping	Brief Resilience Scale[35], DSM-5 Level 1 Cross-Cutting Measure[33]
Parenting skills	Parenting Sense of Competence Scale[36]
Service utilization	Use of HIV/STI services, use of other health services, barriers to services
Social support	Multidimensional Scale of Perceived Social Support[37], DSM-5 Level 1 Cross-Cutting Measure[33]
Substance use	Global Adult Tobacco Survey[38], Alcohol Use Disorders Identification Test (AUDIT-C) (3-item)[39], DSM-5 Level 1 Cross-Cutting Measure[33], use of other substances
Health and healthcare Access	Self-rated health[40], experiences of care-seeking and treatment, recent healthcare needs and treatment
Disability	WHODAS 2.0[41] (cognition, mobility, self-care, social interactions, life activities, community participation)
Mental health	DSM-5 Level 1 Cross-Cutting Measure[33], Post-Traumatic Stress Checklist (PC-PTSD-5)[44]
Individual and demographic factors	
Demographics	Age, race, sex at birth, gender, sexual orientation, marital and partner status, household size, education level
Reproductive history	Methods of contraception; HIV/STI risk behaviors; pregnancies and live births; access to prenatal and perinatal care; pregnancy intention; Pregnant Persons Experience of Mistreatment by Providers Index[42]; Reproductive Autonomy Scale[43]
Gendered social and structural vulnerabilities	
Violence	Sexual Relationship Power Scale[45]; frequency, types, and perpetrators of violence, WHO Intimate Partner Violence Scale,[46] Exposure to Community Violence
Economic factors	Household income, employment status
Housing & household	Living situation in Tijuana, housing insecurity, presence of children
Migration experiences	Country of origin, duration in Tijuana, duration of transit, migration trajectory, immigration status, detention/deportation
Racism and discrimination	Everyday Discrimination Scale[47], Border Community & Immigration Stress Scale[48]
Food insecurity	Reduced Coping Strategies Index[49]
Process indicators	
Acceptability of intervention	Perceived intervention effectiveness, coherence, and acceptability[28]

Authors' contributions: SG drafted and critically revised the protocol. The study was co-designed by multi-PIs SG and IB. KR contributed to co-drafting sections of the protocol. All authors (CH, CMT, EP, GR, MA, KR, KR, IG, SG) critically reviewed, edited, and approved the protocol prior to publication. SG serves as guarantor of the data.

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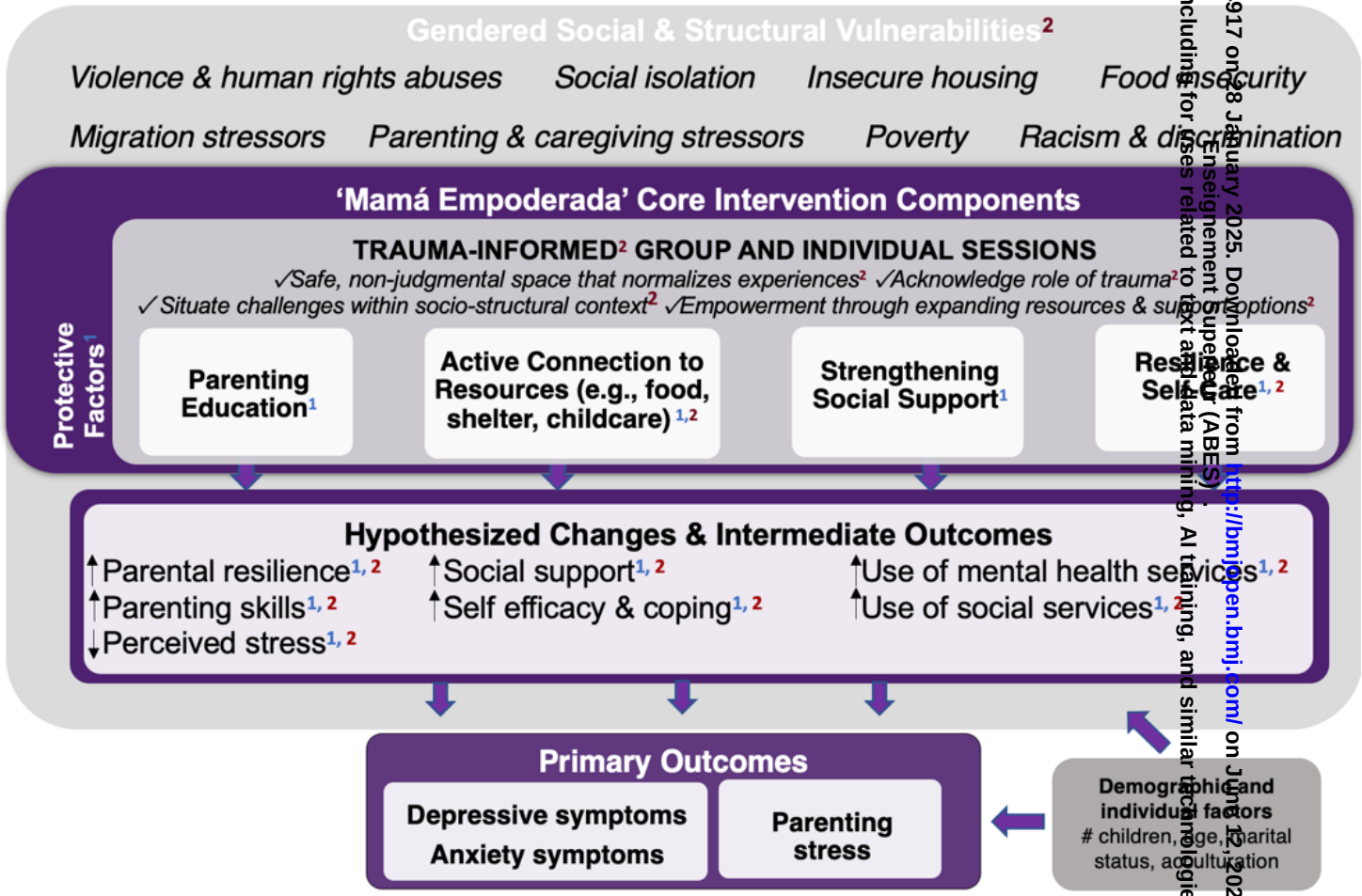
Figure legend

[1]Components and mechanisms informed by the *Protective Factors Framework*

[2]Components and mechanisms informed by *Trauma Theory*

Figure 1: Theory-Based 'Mamá Empoderada' Intervention Components, Proposed Mechanisms, and Outcomes



[1]Components and mechanisms informed by the Protective Factors Framework; [2]Components and mechanisms informed by Trauma Theory

MAMÁ EMPODERADA INFORMED CONSENT: PILOT STUDY

INTRODUCTION----------

Researchers at San Diego State University, El Colegio de la Frontera Norte and our community partners are adapting a program (called "Mamá Empoderada") to improve mental health and parenting practices for migrant mothers with young children. We would like to understand how the adapted program works and the impact that it has on migrant mothers' mental health and parenting.

VOLUNTARY PARTICIPATION----------

Participating in this study is ***completely voluntary.*** Even if you agree to participate now, you can change your mind at any time, without giving a reason. If you decide to end your participation, all research data you share with us will be destroyed. You may decline participation in this research study and this will not negatively affect your relationship with Al Otro Lado or any other agency (e.g., SDSU, COLEF). Whether or not you participate will not impact any services or supports you may receive or be able to access.

RESEARCH DESIGN----------

This study aims to pilot-test the Mamá Empoderada program and evaluate its impacts on parenting and mental health for migrant mothers with young children. This is a randomized trial. This means that participants will be randomly selected for either the intervention group or the control group. Participation in both groups will involve participation over a 5-week period, as well as at 2, 4, and 6 month follow-up visits by phone. All participants will complete four questionnaires over the study duration that address parenting, mental health, migration, sexual and reproductive health, and perceptions of the intervention.

- **Intervention group** participants will participate in group and individual sessions addressing parenting, self-care, emotions, self-regulation, and referrals.
- **Control group** participants will be referred to existing services available to migrant mothers at Al Otro Lado and other local health and migration agencies.

You are being invited because you migrated to Tijuana, you are a mother to a least one child 5 or younger who is with you in Tijuana, you are available to participate in the full duration of the study, you are at least 18 years old, and you speak Spanish. Signing this consent form means that you agree to be enrolled in this study and in the questionnaires. If you are not selected for the intervention group, you will have the chance to participate in the intervention after the study is complete (not part of the research study).

POTENTIAL RISKS ----------

The main risk to you participating in this study is that you may share personal experiences or details that may cause discomfort or distress, including your experiences with migration, violence, and discrimination. If you are feeling this way during study participation, we are happy to connect you with counseling and provide referrals to local services. If you need emergency psychological support, you can contact the Hospital de Salud Mental de Tijuana (664-607-9090), Línea de la Vida (800-911-200), or SAPTEL (55-5259-8121). We are also happy to directly refer you to these services in Tijuana.

There is also the possibility that the information you share will not remain entirely confidential. We will ask all participating in the group-based sessions to keep confidential the information shared during the sessions. To protect confidentiality, you do not have to answer any question, share any information, or participate in any activities that you do not want to and you do not need to share your real name or those of others as part of your participation.

POTENTIAL BENEFITS ----------

Potential benefits from this study include the satisfaction of sharing your experiences to help us understand the needs of migrant mothers with children. Potential benefits include improved mental health, parenting skills, increased resilience, social support, and increased connections to resources (e.g., food, housing).

COMPENSATION ----------

You will receive compensation for each questionnaire: $10 USD for the first, $18 USD for the second (at 5-weeks), $20 USD at 2-months, $25 USD at 4-months; and $25 USD at 6-months.

WHAT IF I AM INJURED DURING MY PARTICIPATION? ----------

If any injury arises as a direct result of your participation in this study, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization because of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. Neither San Diego State University nor San Diego State University Research Foundation will pay for any care, lost wages, or provide other financial compensation. However, if you feel you have a claim that you wish to file against the State of California or the San Diego State University Research Foundation, please contact the Human Research Protection Program at (619) 594-6622 to obtain the appropriate claim forms.

PRIVACY ----------

Baseline and exit questionnaires will be completed in person, and 2, 4 and 6 month questionnaires will be completed via phone, WhatsApp, or Zoom. If you are selected to participate in the intervention, group-based sessions will be recorded for quality purposes; these will not be used for research purposes and will not be shared outside the research team. All research data will be de-identified and any information collected that could identify you will be removed prior to publication of findings. We will collect minimal contact information from you at the beginning of the study so that you can be contacted throughout the study period; this information will be stored separately from your study data. According to Mexican law, in the case of a child being harmed, we are required to report this situation. The researchers are **NOT** required to tell police about other criminal activity. For example, we will **NOT** report anything related to immigration, substance use, or other criminalized activities to police or other authorities.

DATA SHARING----------

De-identified data from this study will be shared with the National Institute of Mental Health Data Archive (NDA), which is a database of deidentified study data from many research studies. All personal information about participants (such as name) is removed and replaced with a code number as part of this process. We will assign each participant a random study code for this purpose (a pseudo-GUID). The study researchers will make every attempt to protect your identity and will not be collecting information such as your full name. Every researcher who requests to use this deidentified data must promise to keep the data safe, although there is a small risk that your study data could be accidentally shared with an unauthorized person. You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this study even if you decide that you do not want your data shared. If you decide any time after today that you do not want your data to be shared, please let us know and we will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind.

- ☐ I consent to having my deidentified data shared
- ☐ I do not want to have my de-identified data shared

INFORMATION STORAGE----------

Participant data will be used to create a unique code to identify your data. Once this has been created, all research data will be de-identified (identifying information will be removed) before analysis. All electronic information will be password-protected. All consent forms, questionnaire data, and notes will be kept in a locked cabinet at our research office. Study research data will be kept for 5 years after the last research results are shared, and then destroyed. De-identified data that shared to the NDA will be stored in their secure online environment in perpetuity.

STUDY RESULTS----------

The results of this study will be used to advocate for interventions to improve mental health and parenting among migrant mothers and their families. They may also be used for future research analyses and publications. Broad results of this project may be shared through reports, research papers, conferences, meetings with community organizations and policy-makers, and potentially other places. If you would like a copy of the results once this study is complete, we would be happy to share them with you via e-mail.

YOUR RIGHTS AND WHO YOU CAN CONTACT ----------

If you have any questions about this broad consent form, in the United States please contact Dr. Shira Goldenberg, at *(619) 594-3761 or sgoldenberg@sdsu.edu;* in Mexico, you may contact Dr. Ietza Bojorquez, at +52 (664) 631-6300, ext. 1212 or ietzabch@colef.mx. If you want to report or have questions regarding an injury that you believe you have suffered as a result of giving broad consent, please contact the San Diego State University, Human Research Protection Program (SDSU HRPP) at 619-594-6622 or irb@mail.sdsu.edu or El Colegio de la Frontera Norte (COLEF) Subcomité de Bioética at Dra.Hilda García, Coordinadora del Comité de Ética en Investigación, +52 (631) 3143710, hgarciaperez@colef.mx
Please ask the study team to explain anything in this form that you do not understand. Please take time to think about this consent form and/or discuss it with someone you trust before agreeing to participate.

FUTURE CONTACT----------

We would like to request permission to contact you for potential follow-up sessions, such as future studies that focus on the health and wellbeing of migrant women. We would be honored to work with you again if you are interested. If you are interested, please provide your contact information below:

Phone:_____ Email: _____

Participant Name Date

Participant's or Legally Authorized Representative Signature Date

Signature of Person Obtaining Consent Date