STUDY TITLE:	Addressing the Social-Structural Determinants of Mental Health through Adaptation of a Transdisciplinary Ecological Intervention Model for Mexican Immigrants
VERSION DATE:	12/11/2018
PRINCIPAL INVESTIGATOR:	Jessica Goodkind
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BACKGROUND/SCIENTIFIC RATIONALE

Social and structural inequities contribute significantly to increasing health disparities globally,[1] with the increasing numbers of migrants throughout the world bearing a disproportionate burden.[2] The immigrant share of the U.S. population has risen steadily over the past four decades, comprising 13.5% of the total population in 2015,[3] with Mexican-born immigrants accounting for 27% of all immigrants.[4] The social, legal, and economic context of the migration process, including increasing uncertainty, discrimination, stigma, lack of access to resources, and fear of deportation and family separation based on immigration policies and public perception of immigrants as a threat all have a critical impact on adverse mental health outcomes among Mexican immigrants in the U.S.[5-10] In addition, Mexican immigrants have low utilization rates for mental healthcare,[11,12] in part because of barriers that include lack of health insurance, ineligibility for governmental health programs, discrimination, lack of interpretation services and culturally appropriate care, and an anti-immigrant political and economic climate.[13-15] Although evidence points to the need to address socio-structural determinants, many mental health interventions offered to Mexican immigrants have focused on individual-level predictors of mental health.[16,17] Also, Mexican immigrants' health outcomes are often viewed within the Latino health paradox,[18,19] and therefore are frequently overlooked in mental health research and development of appropriate interventions[20], despite mounting evidence of mental health disparities and disproportionate exposure to trauma.[21-24] Thus, multilevel, transdisciplinary intervention approaches that address social-structural determinants of mental health, are culturally appropriate, build upon Mexican immigrants' strengths, are cost-effective and scalable, and occur in non-stigmatized settings are needed.

In prior NIH-funded research, the PI and community partners developed and tested a 6-month community-based advocacy, learning, and social support intervention, which pairs paraprofessional university students with refugee adults to engage in mutual learning and social change efforts. The intervention was found to decrease participants' psychological distress, improve their quality of life, access to resources, social support, and English proficiency, and improve communities' responsiveness to refugees; and also proved to be highly acceptable, cost effective, and sustainable.[25-27] The goal of this research is to advance the science of community-level mental health interventions that aim to reduce social inequities and health disparities. The proposed study will adapt and integrate a successfully implemented multilevel, ecological intervention that addresses social-structural determinants of mental health into existing efforts at three community partner organizations that focus on mental health, education, legal, and civil rights issues for Latinx immigrants in New Mexico. Using a mixed methods longitudinal design, the processes and outcomes of the collaborative, community-based intervention efforts, including the impact of the quality of the community-based participatory research (CBPR) partnerships on individual, organizational, and community-level outcomes, will be illuminated.

OBJECTIVES/AIMS

The objective of this study is to: a) adapt the intervention for Latinx immigrants (*Immigrant Wellbeing Project; IWP*); b) integrate *IWP* into existing efforts at four community partner organizations; and c) elucidate new understandings of partnership and intervention processes that lead to sustainable multilevel changes and the reduction of mental health disparities and related social inequities.

Aim 1. Conduct an in-depth study of the mental health needs, stressors, current political/economic/social context, and local solutions as experienced by 24 Latinx recent and non-recent immigrants and their families residing in Bernalillo County New Mexico and contextualized by staff at four community partner organizations.

Aim 2. Building on the data from Aim 1, use a CBPR approach to adapt the intervention model (*IWP*) and integrate it within existing service delivery and social change efforts at four community partner organizations.

Aim 3. Using a mixed methods longitudinal design, investigate the feasibility and acceptability of the adapted community-based mental health intervention and test the quality of the CBPR partnership and impact of the intervention on mental health problems and protective factors among 90 Latinx immigrants and on organizational and government changes in policies and practices impacting

immigrant mental health.

3.1 The *IWP* and collaborative adaptation/integration process will be feasible and acceptable and will serve as a model for implementing and studying multilevel, community-based intervention efforts.

3.2 *IWP* participants' psychological distress will decrease significantly over time.

3.3 *IWP* participants' protective factors (access to resources, English proficiency, environmental mastery, social support) will increase significantly over time.

3.4 Lower levels of psychological distress will be mediated by the protective factors.

3.5 Qualitative data will document changes in organizational and governmental policies and practices and the context of implementation at each site, explore other impacts, and inform interpretation of quantitative data.

3.6 Quality of CBPR partnership at each site will be related to policy/practice changes and health outcomes.

STUDY DESIGN

I. *Target Population and Inclusion/Exclusion Criteria*

All Latinx immigrant adults (ages 18 and older) residing in Bernalillo County, NM will be eligible to participate. We will include Latinx immigrants with a wide range of time in the U.S. in order to explore the utility of the *IWP* across recent and non-recent immigrants. This is particularly important given research findings related to the Latino health paradox. Exclusion criteria will be severe cognitive functioning problems, imminent suicide risk, or mental illness that is so severe as to impede participation in a group and that warrants immediate individual treatment. Participants may or may not speak English. The focus of this study is on Latinx immigrants, so it is important to include non-English speaking participants. In addition, the Latinx immigrant participants in the study may or may not have legal documentation for being in the United States. However, we will not ask participants about their legal status, and will take the extra precautions to protect participants' rights and welfare. Organizational staff who participate in interviews will not necessarily be Latinx immigrants, but will be adult staff employed at our three community partner organizations.

II. *Participant Enrollment*

24 Latinx immigrant adult participants will be enrolled in Aim 1.
90 Latinx immigrant adult participants will be enrolled in Aim 3 to participate in the intervention and 4 interviews each.
6 organizational staff will be enrolled in Aim 3 to complete 2 qualitative interviews each.

III. *Recruitment and Screening Procedures*

Recruitment will occur in coordination with the four community partner organizations (Centro Sávila, Encuentro, New Mexico Dream Team, and New Mexico Immigrant Law Center) and will be conducted by the Research Coordinator and RA Mr. Chavez. Organizations will identify potential participants among those whom they are serving. We do not anticipate using flyers or recruitment materials, but if our partner organizations think that a flyer would be helpful, we will create it with feedback from our partner organizations and submit it to the IRB for approval prior to conducting recruitment. The Research Coordinator and/or Mr. Chavez will meet in-person with potential participants who are referred by community partner organizations. The study staff member will ensure that the potential participant is a resident of Bernalillo County and an immigrant from Mexico. If the potential participant does not meet these eligibility requirements, he/she will not be enrolled in the study. No data will be collected from potential participants who do not meet eligibility requirements. No data will be collected from potential participants who do not meet eligibility requirements. Exclusion will be based on review of interview data by the PI and Mr. Bill Wagner, therapist and director of Centro Sávila. Excluded adults (except those with cognitive functioning issues already being addressed or those already in treatment) will be referred immediately for individual treatment. Data collected from any excluded adults will be destroyed.

IV. *Informed Consent Process*

Latinx immigrant participants will read a consent form that explains the nature and purpose of the interview and/or intervention, ensures confidentiality, describes the participant compensation, and makes clear that participation is completely voluntary and may be terminated at any time. Participants will be made aware that they are free not to answer any question and/or to stop at any time without negative consequence. Each potential participant will be provided the consent form in Spanish or English (whichever they prefer) in advance of the interview. The consent form will also be read aloud to each potential participant, since some participants may not be literate. The consent form will be explained in detail, emphasizing the individual's right to choose not to participate. It will be clearly stated that the individual will not be penalized in any way for choosing not to participate, and refusal to participate will in no way affect the individual's access to services at the community organization which is coordinating recruitment or any services to which he or she is otherwise entitled. Next, each potential participant will be asked if they have any questions regarding the study. Each potential participant will be given adequate time to consider whether they want to participate in the study. The participants will then verbally indicate their consent (which will be documented by signature of study team member but will not require the participant's signature in order to protect confidentiality) and will be given a copy of the consent form to keep before the interview begins. A **waiver of consent documentation (no signature)** is being requested because a signed consent form would be the only record linking the participant and the study, and breach of confidentiality would be the principal risk, due to the potential situation in which some participants may not have legal status in the United States.

Organizational staff participants will be read and asked to sign a consent form that explains the nature and purpose of the interview, ensures confidentiality, describes the participant compensation, and makes clear that participation is completely voluntary and may be terminated at any time. Participants will be made aware that they are free not to answer any question and/or to stop at any time without negative consequence. Each potential staff participant will be provided the consent form in advance of the interview. Each potential staff participant will be asked if they have any questions regarding the study. Each potential staff participant will be given adequate time to consider whether they want to participate in the study.

HIPAA Authorization: N/A

Non-English Speaking Participants: We expect that all participants in the study will complete informed consent and interviews in Spanish (their native language). The consent process will be conducted in Spanish by a Spanish-speaking member of the research team (either the Research Coordinator or RA Mr. Chavez). The consent form and all interview guides will be translated by two study team members (Mr. Chavez and co-I Dr. Handal) and back-translated by two study team members (Research Coordinator and co-I Dr. Hess), and differences will be reconciled through in-person discussion of any discrepancies. The Spanish language consent form and interview guides will be submitted to the IRB for approval prior to study enrollment.

Cognitively Impaired Adults/ Use of a Legally Authorized Representative (LAR): N/A

V. *Data Collection Procedures*

Aim 1: The Research Coordinator and Mr. Chavez will conduct the 24 ethnographic interviews in Spanish. The interviews will be 1-1½ hours in length. If participants agree, the interviews will be digitally recorded. Interviews will occur in locations convenient for participants (e.g., home or community partner organization). The draft interview guide is included in this submission. Please note that the interview guide will be finalized in collaboration with our community partners and the study Community Advisory Council (CAC) during Months 1-3 of the study, and we will submit the finalized interview guide for IRB approval as an amendment. Topics covered in the interview guide will include pre- and post- migration experiences, current stressors, racism/prejudice, mental health services participants find helpful or not helpful, and use of existing services. We will also conduct in-depth

interviews with staff from each community organization to understand the structural stressors faced by immigrants (e.g. barriers regarding documentation, access to medical care).

Aim 3: Aim 3 involves an intervention and 4 individual interviews with each participant. The Immigrant Well-being Project (IWP) Intervention Model is a 6-month intervention with two main components: 1) Learning Circles. Learning Circles (LCs) occur once per week for six months (total of 24 LCs). Each meeting is two hours and includes immigrants and undergraduate paraprofessionals. LCs have two parts: cultural exchange and one-on-one learning. Cultural exchange occurs for the first hour and is facilitated together by one undergrad and one immigrant who choose the topic. To enable all participants to share in the discussion, interpreters are present. Cultural exchange provides a forum for immigrants and undergrads to learn from each other, share ideas, develop plans for collective action, and realize the important contributions they are capable of making. The second component of the LCs is one-on-one learning. For the last hour, immigrants and undergrads work in pairs. During one-on-one time, immigrants direct their own learning (e.g. English, job applications). 2) Advocacy. Advocacy begins after the first two weeks of LCs. For the remaining 5½ months of *IWP*, undergrads spend an additional 4-6 hours each week (outside of the LCs) with their immigrant partner(s) to engage in advocacy together around any issues the immigrant(s) would like to address. They follow a 4-phase process (assessment, implementation, monitoring, and secondary implementation) for each unmet need or goal. Undergrads also work to transfer advocacy skills to their partner, through shared engagement in advocacy, modeling, and role plays. The *IWP* employs a holistic approach that integrates advocacy and learning to address multiple needs of immigrants (i.e., English proficiency, access to resources, understanding of their environment, social support, valued social roles). However, rather than emphasizing only what immigrants need to learn to survive in the U.S., the *IWP* focuses on
mutual learning, through which immigrants both learn from and teach people born in the U.S.

Quantitative interview procedure. Each participant will complete 4 quantitative interviews: pre, mid (~3 months after pre), post (~6 months after pre), and follow-up (14 months after pre). The 1-1½ hour

Table 2. Quantitative Measures

Variable	Measure	Detail	Psychometrics
Trauma Exposure/PTSD Symptoms	Trauma Exposure Scale PTSD Symptom Checklist[99]	- Measures multiple potentially traumatic events - Has been used with immigrants	- 27-item dichotomous exposure scale, includes immigration-related traumas - 17-item Likert scale; reliable & valid
Depression Symptoms	Hopkins Symptoms Checklist-25[100,101]	- Has been used with immigrants to measure depression symptoms	- 25-item Likert scale; reliable & valid
Culturally-Specific Distress	Hispanic Women's Social Stressor Scale[102]	- Measures stress and distress related to 6 domains of life for Mexican immigrant women	- 40-item Likert scale; reliable & valid; includes subscales on immigration-related stressors and racism-related stressors
Access to Resources	Satisfaction with Resources Scale[78] Difficulty Obtaining Resources Scale[103]	- Assesses satisfaction with resources in 12 domains - Assesses perceived difficulty in accessing resources	- 12-item Likert scale; used with immigrants - 12-item Likert scale; used with immigrants
English Proficiency	Basic English Skills Test (BEST)[104]	- Measures communication, fluency & comprehension	- Cronbach's alpha = .91; widely used with immigrants
Environmental Mastery	Environmental Mastery subscale of Psychological Well-being Scale[105]	- Measures capacity to manage effectively one's life and surrounding community	- 20-item Likert scale; adequate reliability; used with immigrants
Mental Health Service Use and Help-Seeking	Composite International Diagnostic Interview (selected questions)[106]	- Measures counseling and medications received from a helping professional for "problems with emotions or nerves" doctor	- Reliable, valid & used with immigrants - Questions will be added about traditional healing practices, and support from family, friends or religious or spiritual leaders
Social Support	Multi-Sector Social Support Inventory[107] "Important Matters" network generator[108]	- Measures social support in family, ethnic group, & community - Ego-based social network measure	- 33-item Likert scale (11-items per sector); used with immigrants - # of individuals respondent discussed important matters & relationship with each

interviews will be conducted by trained bilingual/bicultural interviewers who are not a part of the intervention and will occur at participants' homes or a community location convenient to participants. When interviews are conducted at participants' homes, interviewers will have the option to go in pairs, if they feel more comfortable. Interviews will be conducted via computer-assisted personal interview

(CAPI), in which interviewers ask questions to the participants and enter the information directly into a laptop. The quantitative interview questions are included as an attachment to this proposal. Most measures have been used with Spanish-speaking immigrants. When necessary, we will translate measures using a team approach, following the TRAPD (Translation, Review, Adjudication, Pretesting, and Documentation) process.[93,94]

Qualitative interview procedure. The qualitative interviews will coincide with quantitative CAPIs and will occur after completion of the CAPI. With participants' consent, the interviews will be digitally-recorded. The qualitative pre-interview will focus on participants' backgrounds, migration and post-migration experiences and current resource and learning needs. The mid, post, and follow-up interviews will explore experiences in and satisfaction with the *IWP* and changes over time in individual, family and community life. In addition, immigrants and their undergrad partners will participate together in a qualitative interview at the end of the *IWP* to explore their experiences (e.g., what partners learned from and taught each other, best and most difficult things about working together, how the project met or did not meet their expectations). The partner interviews serve a different purpose from the other qualitative interviews – to enable pairs to have mutual dialogue about their experiences (30 pairs x 3 waves = 90 interviews).

Organizational staff interview procedure. To further document and analyze the adaptation and integration processes, understand the role of community context, and document changes in organizational and local/state governmental policies and practices, qualitative interviews will be conducted pre- and post-implementation of *IWP* with leaders/staff of the community organizations (2 individuals x 3 organizations x 2 time points = 12 interviews). The interview guide will be developed in conjunction with the CAC. With participants' consent, the interviews will be digitally-recorded. Interviews will be semi-structured, with open-ended questions that establish pre-existing conditions and contexts including leadership, organizational and community capacity, and facilitators and barriers to adaptation, integration, and implementation of *IWP*. Post-interviews will explore change at multiple levels applying a socioecological approach, among individual participants, within the organization and community, and in particular with respect to sustainable systems change.

VI. *Study Timelines*

The study is funded for almost 5 years (9/23/18-6/30/23). Aim 1 data collection will occur during Year 1 (January-March 2018). Aim 3 intervention and data collection will be implemented in three waves (months 15-20, 27-32, 39-44). Each wave will occur at a different community partner organization and will be adapted and integrated into existing activities and services in different ways, with the goal of creating sustainable, community-level changes by building upon community mobilization/organizing/social change efforts and social networks that are essential components of achieving sustainable, community-level changes. Data collection will end by October 2022.

VII. *Study Location(s)*

The intervention will be adapted with and integrated into the ongoing efforts of four community partner organizations: Centro Sávila, Encuentro, New Mexico Dream Team, and the New Mexico Immigrant Law Center. Centro Sávila (http://www.centrosavila.org/) is a community-based mental health organization that employs a comprehensive approach to mental health to address individual and social determinants. They are deeply engaged with Latinx immigrant communities, offering affordable mental health services to individuals and families in Bernalillo County that include outpatient mental health services, case management, and free health insurance enrollment assistance. Encuentro (http://www.encuentronm.org/) is a community-based organization that focuses on educational and economic opportunities for Latinx immigrant families. Their mission is to transform New Mexico into a thriving community for all of its residents by engaging Latino immigrant families in educational opportunities that build skills for economic and social justice. The vision of the New Mexico Immigrant Law Center (http://nmilc.org/) is to help create a vibrant New Mexico where all people – regardless of immigration status – can achieve their full potential and are treated with dignity and respect. They provide access to affordable legal services related to immigration, and they

collaborate with community partners to impact health and safety, family stability, economic security, education and civic engagement. The research involves close collaboration with all four organizations. Thus, the proposed research is informed and guided by the current mental health, social, educational, and economic needs of Latinx immigrants as understood by Latinx immigrants themselves and the multiple community organizations and service providers with whom they interact. In addition, through coordination with the three community organizations described, channels for participant recruitment have been established and coordination with other available services for Latinx immigrants in New Mexico is ensured. Research interviews will occur at these three sites and at participants' homes (whichever they prefer).

VIII. *Participant Compensation*

Aim 1: The 24 ethnographic interview participants will receive $25 cash for their time. These interviews are expected to take between 1 and 1½ hours. Compensation of $25 is reasonable for this amount of time, but not so great as to be potentially coercive.

Aim 3: The 90 intervention participants will be paid for their time for completing the four interviews ($25, $25, $30, and $35 cash for time points 1, 2, 3, and 4, respectively). These interviews are expected to take between 1-2 hours. Compensation of $25-$35 is reasonable for this amount of time, but not so great as to be potentially coercive. Increasing interview payments over time has been shown to improve retention in longitudinal studies.[97,98] The 6 organizational staff participants will receive $25 cash for their time for completing each of the two interviews.

IX. *Study Resources*

Our research study team and the overall NM TREE Center team and consultant pool have extensive experience conducting studies with Latinx populations of mixed immigration status and with utilizing protocols that we have found effective for minimizing risks while working with these populations. These include: 1) not asking about immigration status; 2) ensuring we have a Certificate of Confidentiality from NIH; 3) orally reading informed consent forms to participants in their preferred language; and 4) minimizing collection of identifiable and private data as much as possible.

The facilities and other resources available to the PI and the research team include the necessary support, equipment and materials to undertake and complete the proposed research project successfully. The PI Dr. Goodkind and co-I Dr. Huyser's offices and labs are located in the UNM Department of Sociology and UNM Center for Health Policy. Dr. Handal has her office in the College of Population Health (COPH) on the UNM HSC campus. Dr. Hess has her office and research space in the UNM Health Sciences Center Department of Pediatrics Division of Prevention and Population Sciences (DPPS). The Department of Sociology, Center for Health Policy, DPPS, and COPH all have shared equipment for staff to use such as copiers, printers, Skype for Windows telecommunication software and equipment, fax machines, scanners, audio-visual equipment, and speaker phones. Computer resources, including desktop PCs and printers, are available for most of the proposed staff on this project – some funding is included in the proposal for desktop and laptop computers. Software for routine project tasks, such as word processing, email, and internet access is available, as well as most data management and statistical software. In addition to shared equipment, there are administrative support staff and computer technical support to assist investigators in their daily work. Physical space for project material storage and meetings are also available in the PI's lab space and in the Center for Health Policy. The intellectual environment is rich with other extramurally-funded investigators who are doing work that is complementary to what is proposed here. A strength of the proposed research is that it brings together UNM faculty and staff and community organization staff and community members who represent multiple disciplines, academic homes, perspectives, and experiences to engage in truly transdisciplinary research.

EXPECTED RISKS/BENEFITS

I. *Potential Risks*

- Psychological risks may be more than minimal because participants in ethnographic interview and

intervention studies will be asked questions about their current mental health, past trauma, and current stressors. These questions could potentially be upsetting. Participants can skip any questions they do not want to answer and can end their participation at any time. The interviewers will be trained to provide empathy and community partner Dr. Wagner (PhD; licensed clinical therapist) will be available to provide assistance, if necessary. In the event that a participant expresses suicidal and/or homicidal thoughts or intentions, we have an established protocol that requires the interviewer or advocate to remain with the participant and immediately call Dr. Wagner. Dr. Wagner will assess the situation and determine whether the participant needs to be taken to University of New Mexico Psychiatric Emergency Services. If that is necessary, Dr. Wagner and/or the interviewer or advocate will accompany the participant. If emergency care is not required, Dr. Wager will arrange an outpatient appointment with an appropriate mental health professional. Interviewers and advocates receive training and a two-page handout on mental health emergency contact information and procedures that include instructions for handling suicidality, emotional distress, expression of danger to others, and child abuse.

- Participation in this research study will involve a loss of privacy as participants are being asked to share personal information. However, every effort will be made to maintain confidentiality and privacy of all participants' responses. Another confidentiality concern involves the size of the Latinx immigrant community. In small communities, this is an important consideration. We will ask participants to keep personal information that is shared in the Learning Circles confidential. One of the explicit goals of the intervention is to develop trust and strengthen relationships among families and group members.

If participants are distressed during an interview or the intervention, they will have the opportunity to speak with Mr. Wagner, the licensed clinical therapist on the study, or he can refer them to other available mental health services through UNM or Centro Sávila. In the event that a participant expresses suicidal and/or homicidal thoughts or intentions, we have an established protocol that requires the interviewer or advocate to remain with the participant and immediately call Mr. Wagner. Mr. Wagner will assess the situation and determine whether the participant needs to be taken to University of New Mexico Psychiatric Emergency Services. If that is necessary, Mr. Wagner and/or the interviewer or advocate will accompany the participant. If emergency care is not required, Mr. Wagner will coordinate an outpatient appointment with an appropriate mental health professional. Interviewers and advocates receive training and a two-page handout on mental health emergency contact information and procedures that include instructions for handling suicidality, emotional distress, expression of danger to others, and child abuse. Because the intervention will be open to all interested immigrants, participants who participate will not be identified as having particular mental health problems.

It is possible that study participants may be hesitant to participate in our study because of their immigration legal status or fear that we may disclose their identity to government/federal agencies. Our team along with the NM TREE leadership and consultant pool has substantial experience in recruiting and consenting Latinx populations of mixed immigration status, including undocumented immigrants. Therefore, have ensured that we have a Certificate of Confidentiality from NIH. As it states on the NIH website "Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants." We will explain this Certificate of Confidentiality and its protections and possible limitations to participants as part of our informed consent process to assure confidentiality and privacy of their data.

II. *Benefits*

The risks of this project are reasonable when compared to the expected benefits to the participants and others. The potential benefits of this study are great. Immigrant adults will have the opportunity to learn, work together to address community issues, increase their social support, and improve their access to community resources. Based on the previous studies of the intervention model, it is expected that the intervention will reduce distress and increase protective factors among participants. Latinx immigrants in New Mexico and throughout the United States continue to struggle and experience high rates of psychological distress. Thus, this intervention has significant potential for improving the lives of these groups. Furthermore, if the intervention and the adaptation process demonstrate feasibility, acceptability, appropriateness, and effectiveness, the intervention and adaptation process can be disseminated throughout the United States to improve the lives of other immigrants and marginalized populations.

The knowledge that will be acquired from this study will further our understanding of community-based mental health interventions for marginalized populations that address social-structural determinants of mental health and will contribute to our ability to reduce the high rates and disproportionate burden of mental illness experienced by socioeconomically disadvantaged Latinx immigrants in the United States. As stated previously, this knowledge has important implications for Latinx immigrants, as well as all other immigrants and refugees who resettle in the United States. In addition, the knowledge generated from this study is important in furthering the fields of research of immigrant mental health and health disparities. It is particularly important to design, implement, and evaluate innovative, multilevel mental health interventions for immigrants that address the social and structural determinants of health because limited research exists in this area. There are also specific benefits to communities and broader society in terms of the data that are collected, because the data can further our understanding of the experiences of Latinx immigrant adults and can demonstrate that universities in partnership with communities can provide evidence-based interventions. Thus, the potential benefits to participants and other immigrants and the knowledge gained outweigh the slightly more than minimal risks to study participants.

III. *Privacy of Participants*

All consent procedures and interviews will be conducted in private settings with only the interviewer and participant present (unless the participant would like to include other people during the consent process). We will ensure that these private rooms have doors that can be closed to further protect participants' privacy. Participants can choose to complete the interviews in the setting they feel most comfortable (e.g., their home, the community organization, or other community setting). To further protect participants' privacy, the quantitative components of the interviews are completed using computer-assisted personal interview (CAPI), in which interviewers ask questions to the participants and enter the information directly into a laptop. As with the PI's previous *Refugee Well-being Study*, the participants will have the option of entering their responses to the mental health sections of the interview themselves, which enhances participants' privacy even further. Learning Circles will be held in private rooms with doors at the community organizations or community centers. Learning Circle participants will be asked not to share any information from the group outside of the Learning Circles.

IV. *Unanticipated Problems/Adverse Events*

Data and safety monitoring will be overseen by the PI, Drs. Handal, Hess, and Huyser, Mr. Wagner, and the Data Safety Monitoring Board of the NM TREE Center. Learning Circle facilitators and interviewers will be required to report any adverse events to the PI, who will discuss them with Mr. Wagner, document them in writing, and report them to the NM TREE Center DSMB and UNM IRB immediately. The PI, the co-Is, and Mr. Wagner will meet monthly to review the research protocol, data on recruitment and retention, quality control, adherence, and adverse events and safety, as well as data management systems and study results. They will monitor the well-being of participants as reported in the periodic interviews and through any concerns raised by interviewers during weekly research team meetings. Monitoring of participants' well-being by intervention staff (research

coordinator and RAs) will occur on an on-going basis as well, and they will also be asked to share any issues or concerns at weekly research team meetings. Unanticipated problems will be reported to the IRB within 7 days.

V. *Participant Complaints*

Participants will have multiple channels for communicating potential complaints and/or requesting additional information. In addition to the phone number for the PI and the UNM IRB, which will be provided on the consent form, participants will be able to discuss complaints and/or submit them anonymously in writing to the interviewers and intervention facilitators. Furthermore, participants can also discuss any concerns with staff at the community partner organization through which they are participating. These staff will have a form for documenting concerns/complaints and submitting them confidentially to the PI.

STUDY DATA

I. *Data Management Procedures and Confidentiality*

All qualitative interviews will be digitally recorded (if participant agrees) and transcribed verbatim. The digital recordings will be kept on a password-protected UNM Shared Drive (which the PI already has in her lab). The only people with access to file on the Shared Drive with the digital recordings will be the PI, Dr. Hess, and RA Ms. Locklear. The digital recordings will be destroyed (by deleting the files) once the study is completed. The transcripts will be electronic only and will not include any identifying information. If participants use any names during the qualitative interviews, these will be changed to pseudonyms in the transcripts.

The quantitative data will be collected via Computer-Assisted Personal Interviewing (CAPI), which means it will be entered directly into password-protected laptops. Thus, there will be no paper records of quantitative data. The CAPI data will include ID numbers only and will be transferred from the laptops to the Secure Shared Drive as soon as it is collected.

The only individually identifiable private information that will be collected from participants is name, address, and phone number for tracking purposes. The PI, co-investigators, research assistants, and interviewers will have access to participants' names, addresses, and phone numbers. However, this information will be kept separate from all interview and intervention data collected. Each participant will be assigned a unique numerical identifier (five-digit ID number) and this code will be placed on the interview forms, digital recordings, and transcripts. The master list linking participants to ID numbers will be kept separate from the data set in a locked file cabinet in the PI's lab and on the PI's password protected computer. This master list will be destroyed prior to study closure.

All information will be kept confidential to the extent allowable by law. No names or identifying information will be included on interviews, digital recordings, or transcripts. We will not inquire about immigration status at any point during the study. No identifying information will be included in any reports or presentations resulting from this study. Furthermore, only general themes appearing across participants will be reported. Intervention participants will also be asked to keep all information shared in the Learning Circles confidential.

As stated on the NIH website (https://humansubjects.nih.gov/coc/NIH-funded), "Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC (Certificate of Confidentiality).

II. *Data Analysis/Statistical Considerations*

Quantitative data analysis. All raw data will be examined to verify quality and identify potential outliers and distributional issues. Psychometric properties of existing scales will be verified, and psychometric analyses will be conducted on modified measures. To reduce Type I errors, data reduction (e.g., second-order confirmatory factor analysis) will be used, where feasible, to guide the combination of individual scales and variables into meaningful constructs. Significant findings on composite constructs will be followed up with parallel analyses on component variables. Additional

analyses will identify characteristics of individuals who drop out or receive lower dosage. Covariates of attrition will be used to estimate complier average causal effects.[109] Although missing data will be minimized through use of incentives, culturally sensitive assessment, and proactive retention strategies, it is a potential problem in longitudinal research. Pattern mixture modeling[110] will be used to determine whether missing data affect study conclusions or are "ignorable" (i.e., conditionally missing at random). Missing data determined to be ignorable will be estimated using expectation maximization and multiple imputation procedures appropriate for longitudinal data.[111] Sensitivity analysis will be used to examine the possible impact on study conclusions involving any missing data found to be non-ignorable.[112]

Hypothesis 3.2 *Participants in IWP will show lower psychological distress over time and* ***Hypothesis 3.3*** *IWP participants' protective factors (access to resources, English proficiency, environmental mastery, social support) will increase significantly over time.* Growth curve modeling will be implemented using hierarchical linear modeling (HLM).[113] Analyses will proceed sequentially beginning with baseline 'intercept-only' models, then testing fully parameterized model (see Goodkind, et al., 2012[102] for detailed description of analytic method). If this iterative process identifies that the best fitting model includes significant random effects corresponding to the significant fixed effects (i.e., that there is significant variability in intercepts and/or slopes), we will attempt to model it using level-2 predictors. Level-2 predictors to be tested as potential moderators will include sex, age, length of time in the U.S., and intervention hours, which will allow us to identify relevant individual difference variables (e.g., age) that may predict response to the intervention and to test whether intervention dosage predicts differential change (a finding that would strengthen the inference of treatment effects). Calculating effect sizes for multilevel models is complex; because our focus will be the effect of the intervention over time, we will examine the percentage of variance explained (PVE) by the addition of time to each model[114] by comparing the PVE of the best fit Level 1 model to the Level 1 intercept-only model.

Hypothesis 3.4 *Lower levels of psychological distress will be mediated by increased access to resources, English proficiency, environmental mastery, and social support.* The mechanisms of intervention effectiveness will be examined through structural equation modeling (SEM), which will allow modeling of mediation pathways linking intervention components to primary outcomes via effects on protective factors. Multigroup SEM[115] will provide tests of mediation effects. Latent change and latent trajectory modeling[116] will be used to assess longitudinal mediation effects, including the effects of change from baseline to mid- and post-intervention on protective factors (e.g., access to resources, English proficiency, social support, environmental mastery) on subsequent change in primary outcomes (e.g., PTSD, depression, and culturally-specific distress symptoms over time) and parallel- or lagged-process links between change trajectories on protective factors and primary outcomes over time.[117] Mplus software[118] will be used for these analyses, due to its flexible estimation capabilities and ability to test specific mediation effects.[119]

Qualitative data analyses. Qualitative data will contribute to addressing questions related to Aims 1, 2 and 3. For Aim 1, we will examine the participants' perspective on how sociopolitical and policy contexts impact their psychological distress, as well as their experience and perspective on the development of protective factors and relationship of these to well-being. Aim 2 will be explored qualitatively, through conducting in-depth process evaluation case studies of local context and how these impact the adaptation and implementation at each site, facilitators and barriers, and evaluation of change resulting from the intervention. Aim 3 will be evaluated with a convergent mixed methods design; the qualitative component will serve a complementary and explanatory role in conjunction with the quantitative component to explore participant experiences in the intervention as well as change. We will employ a constructivist grounded theory approach,[131] which is a well-known way to explicate processes, in this case change related to the intervention. Theory is "grounded" in the data themselves. Constructivist grounded theory therefore uses a combined inductive and deductive approach, coupled with the recognition that study participants and researchers 'co-construct' data, thus making it a good fit for community-based participatory research designs. As such, analyses are based on data derived directly from research questions and on open-ended questions that aim to allow participant perpsective and meaning to be fully developed as part of the research process.[131] A

key aspect of this approach is its iterative nature, thus analysis will be ongoing and inform the questions asked in subsequent interviews. Interviews will be professionally transcribed, then checked for accuracy, and imported into NVivo 11, a qualitative data analysis software program. Dr. Hess will lead an analysis team that includes Ms. Locklear, and members of each community organization. Coding of each interview will be done by two team members. The first level of analysis will involve two steps: 1) coding the content of each interview according to question so that each question can be examined across the data, and 2) text-based coding, where the coding team read the text and mark recurrent themes or statements. Thus, the initial research questions, as well as themes that emerge from the data, will be assigned codes (e.g., during analysis of data in previous studies, changing gender roles was repeatedly identified as important by interviewees, but was not originally a topic of analysis). As themes emerge, coders will meet to define and standardize them, to agree on a structural framework to elucidate the relationship of themes to each other, and to determine how they should be applied to the data. All interviews will then be coded using the coding framework. This constitutes the second level of analysis in which text is coded into thematic categories. The third level involves focused coding of prominent thematic clusters, analyzing the content of these themes for patterns and meaning.[131] At each step, the team will meet with the CAC to engage in member checking of the analytical categories and in collaborative analysis.

Integration of mixed methods data. In a mixed methods study, the integration of quantitative and qualitative data is paramount.[132] This study can be characterized as a convergent mixed methods design. The qualitative component in Aim 1 is formative. In Aim 2, qualitative data collected in Aim 1 will inform the adaptation, and additional qualitative data will be collected on the adaptation process, as well as on organizational readiness, capacity and how local and community context informed the adaptation and implementation of the intervention model. In Aim 3, the quantitative compenent is primary with an embedded qualitative component, the function of which is to provide convergence, complementarity and expansion on quantitative data for individual participants.[133] Convergence occurs when qualitative and quantitative methods are used to answer the same research questions (e.g., how outcomes change over time). Quantitative and qualitative data will be integrated in two primary ways.[134] First, the data will be *connected* wherein quantitative data (e.g., demographics; distress) will be incorporated into our qualitative data set to inform qualitative data collection from participants. Second, data will be *merged* to explore individual change quantitatively and qualitatively. An additional qualitative component for Aim 2 will analyze the process of adaptation and implementation of the intervention and Aim 3 will analyze multilevel outcomes related to changes in organizational, local, and state policies and practices. The PI and Co-Is will have monthly meetings throughout data collection and analysis to ensure that processes are well-integrated and findings are informing the complementary approaches.

III. *Participant Withdrawal*

Participants are free to withdraw at any point from the study. If a participant indicates their desire to withdraw from the study, we will not collect any further interview data from the participant. Any data collected previously from a participant who withdraws from the study will be destroyed [removed from the SPSS (quantitative) and NVivo (qualitative) databases and not included in analyses].

PRIOR APPROVALS/REVIEWED AT OTHER IRBS

N/A

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