PROTOCOL TITLE:

TERTULIAS: Addressing Social Isolation to Reduce Depression Among Female Mexican Immigrants

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1.0 Objectives

The purpose of this project is to test TERTULIAS (Spanish for "conversational gatherings"), an innovative peer support group model for reducing social isolation and depression among female Mexican immigrants (FMIs).

TERTULIAS is a peer support group model with bi-directional knowledge exchange with a trained facilitator and culturally appropriate food sharing and storytelling.

Goal: We will conduct a randomized controlled trial with 240 female FMIs. Intervention participants will attend a weekly peer group session over 12 months. Control group participants will receive a bimonthly check-in call. All will be surveyed using validated instruments and give hair samples gathered at baseline and 12 months. A subset will be interviewed, and group sessions will be documented. We will triangulate data gathered using different methods with a QUAL➔QUAN simultaneous data collection and analysis approach to integrate, converge, and elaborate findings in a way that would not be feasible using only one method. Our prior work and demonstrated capacity to work with a hard-to-reach population will make this project a success.

Aim 1. To measure whether a culturally situated peer group intervention will reduce depression and stress associated with the experience of immigration.

***Question*:** Does an intervention design that reproduces culturally important interactions, activities, and constructs that are lost through immigration result in decreased participant depression and stress?

***Hypothesis*:** Incorporating peer-to-peer social interaction, food sharing, and storytelling into the design of a peer support group intervention will leverage positive aspects of participant culture and create an experiential context that will (a) decrease participant depression scores by at least 6.5 points more on the Center for Epidemiologic Studies Depression Scale (CES-D) as compared to controls (effect size Cohen's $d = 0.43$), and (b) lower stress scores in participants more than in controls with $d \geq 0.5$ as measured by the Perceived Stress Scale (PSS). We will also assess stress using a cutting-edge biological assessment of hair cortisol as a biomarker for chronic stress.

Aim 2. To test whether an intervention using a "women's funds of knowledge" approach results in improved resilience, knowledge and empowerment.

***Question*:** Does an intervention design that encourages participants to share knowledge they developed through life experience and that values this knowledge as a form of expertise nurture protective factors (resilience and knowledge/empowerment) to help FMIs adapt to the immigration context and disrupt the mechanisms that produce health disparities?

***Hypothesis*:** Incorporating, valuing and validating women's knowledge and experience in the design of a peer support group intervention will improve participant capacity to adapt to the immigrant context and provide participants with empowering knowledge to deal with new situations. Intervention participants will have higher scores at 12 months and have a larger increase over time as compared to controls ($d = 0.5$) on the Connor-Davidson Resilience Scale-25 (CD-RISC 25). We will assess knowledge and empowerment at 12 months and expect to find high scores with the Trauma-Informed Practice (TIP) Scale (which is designed for post-use).

Aim 3. To investigate whether a culturally situated peer group intervention using a women's funds of knowledge approach can give participants' a sense and experience of social and physical connection ("emplacement") that is lost in the process of immigration.

Question: Can the proposed peer support group intervention recreate social and physical connections lost through immigration and strengthen participant social networks?

Hypothesis: The peer group will create a culturally appropriate context for establishing interpersonal connections between group members and will give participants a sense of belonging within a social and contextual milieu. At study end, (a) intervention participants will have a marked increase in social support scores v.s. the control group using the Medical Outcomes Study Social Support Survey (MOS SSS) ($d \geq 0.5$), and (b) stronger, more dense social connections as described by a social network analysis.

Project Outcomes. This intervention with FMIs will test an innovative intervention to reduce social isolation as a mechanism for reducing depression by leveraging positive cultural dynamics and women's funds of knowledge to nurture social connectedness, knowledge, and resiliency factors in the lives of participants in a transformative way. **Generalizability**. This trial of TERTULIAS will create a replicable, scalable model for culturally appropriate health promotion with FMIs that has implications for health promotion work with other women from recent and first generation immigrant populations.

2.0 Background

Social Isolation: A Critical, Complex Health Problem.

Social Isolation is a critical health risk factor affecting millions of people in the U.S. and, disturbingly, has been shown to have an even larger social impact.[1,2] While most people would not think of social isolation as a "health" issue *per se*, as a chronic stressor, it is a well-established health risk factor[3] associated with the experience of depression, loneliness, and other mental health problems,[4–8] increased risk for the development of chronic disease,[9–12] and even mortality.[13–18]

Under-Assessed & Under-Addressed: No Clinic-Based Solution.

Despite evidence that social isolation is both a major health risk factor and that it is increasing, it continues to be under-assessed and under-addressed.[19] There is a lack of consensus on how to screen for risk of social isolation,[20] and few studies have attempted to document prevalence beyond narrow populations (such as older adults[21] or individuals with a chronic health condition[22,23]). Most reviews of social isolation as a health risk suggest that actual prevalence in the U.S. is much higher than has been documented.[24] Because social isolation is caused by a complex concatenation of individual, family, social, and structural factors, any solution must go beyond individual treatment. Therefore, it is difficult to design an intervention that is functionally viable or economically sustainable in a clinic setting. The need, then, is determining what type of intervention can be developed given that few successful or sustainable examples have been documented.[17]

Social Isolation, Depression, & Health Disparities Among Immigrants.

Cacioppo & colleagues describe how a lack of social relationships can become "toxic,"[25] with severe, negative, cascading impacts on individual health and family wellbeing.[17,19] However, the challenge of dealing with "toxic" social isolation is disproportionately greater for immigrants and contributes to mental and physical health disparities.[26–28] Immigrants leave behind meaningful social, emotional, and cultural connections in their home country. In the new setting, it is often difficult to create social relationships, feel socially, emotionally, and culturally connected to other people, or have knowledge regarding access to essential resources. Language barriers, social stigma, discrimination, and poverty[29]—the structural circumstances[24] of immigrants' lives—exacerbate this dynamic. Increasingly, the migration experience itself is understood as a risk factor for clinically significant mental health problems.[30] For Mexican immigrants, despite a protective effect of immigration on health discussed as the "Latino paradox"[31] in which many first generation immigrants demonstrate better health than their U.S.-born counterparts, further

cross-border research[32] that controls for demographic variables has revealed that Mexican immigrants have twice the risk (odds ratio of 1.8) for first onset of any depressive disorder than those in Mexico who do not immigrate. As such, recognizing social isolation and related depression as health disparities requires that we consider both the complex, multifactorial nature of how social isolation operates in the lives of immigrants through multiple "social determinant" pathways, as well as the multilevel impact on individuals, families, and the immigrant community. Merrill Singer[33] conceptualized how multiple streams of influence can come together to form a "syndemic" in which the synergistic interaction of social, environmental, economic, and political factors produce disease—often disproportionately affecting a particular group. The syndemic framework was explored in a recent special edition of The Lancet[34,35] as a comprehensive approach for addressing health disparities. A syndemic framework is useful for thinking about how social isolation creates toxic health problems in immigrant communities and highlights the need for holistic solutions.

The Specter of Social Isolation and Depression for Women Immigrants.

Women immigrants, in particular, are at high risk for social isolation.[26,27,36–41] For many first generation female Mexican immigrants (FMIs) from low-income households (per NIH definition in the RFP, first gen = born in Mexico), the elements that have been identified as key protective factors[42–44] (culture and family) are eviscerated by social isolation. For FMIs, social isolation from the loss of extended family networks is often experienced as a form of cultural bereavement[26] that is emotionally traumatic,[27,45] leading to disproportionately high rates of depression. As a group, Latinas (Hispanic women) have higher rates of depression (14%) compared with non-Hispanic white women (7%).[44] Yet troublingly, Latinas are less likely to receive mental health treatment (56% vs 72%).[46] However, research has shown that for FMIs, while many recent immigrants report less depressive symptomology the closer they are to arrival in the U.S., the longer a FMI lives here, her risk for depression increases.[44] Moreover, the rate of depressive disorders among FMIs is twice that for male Mexican immigrants.[41,47] While it is challenging to find statistical data to describe an immigrant subgroup such as FMIs, a number of studies that disaggregate data or that have focused specifically on FMIs reveal alarming insights. A study with Latinas in South Florida, 95% of whom were immigrants including many FMIs, found that 38% of participants screened positive for depressive symptoms.[48] In a study of a nursing intervention with FMIs and their children, 36% of participants reported depression at or above cut-off for referral—higher than the national average of 10% for all Americans.[49] And in a study of Mexican immigrant patients at a health center in San Antonio, FMIs were three times more likely (32%) than non-Hispanic white women (10%) to present with depression.[50] Building on Singer's[33,35] conceptualization of syndemic health, Mendenhall[51] developed a groundbreaking model of "syndemic suffering" that opens our eyes to the fundamental synergistic nature of disease and social determinants in the lives of FMIs as she demonstrates interconnections between social isolation, depression, and diabetes risk within an experiential framework of pervasive violence (physical, emotional, and structural). As such, health disparities related to social isolation are not merely concerns of individual immigrant women, but instead, reflect even deeper complex social and cultural dynamics that affect the health of entire families. In Albuquerque, New Mexico (NM), social isolation among FMIs has been identified as a compelling health concern by health providers, organizations, and members of the community. In a study we conducted with a FMI social isolation support group,[52] participants shared stories related to their own experiences of social isolation and the dangers and challenges associated with immigrating. We documented reports of depression, stress, loneliness, chronic disease, rape, domestic violence, and poverty. We found that it is common for women to have a great deal of fear when seeking social assistance or interacting with people they do not know or who do not speak Spanish,[53] and often they do not have a way to make friends or build relationships.[52]

Our Preliminary Research On Women's Social Networks.

In two of our prior community-engaged, NIH-funded research projects, we revealed the key nature of group interaction in the lives of Latina women, including FMIs. One of our projects[36,37] focused on women's social networks and food insecurity in a historic Latino community, and our intervention involved project events ("fiestas") where women learned to lead meetings and interacted with each other in a way that resulted in increased participant ability to adapt to new circumstances (resilience), increased recognition of personal assets (empowerment) and more social connectivity. Social interaction helped participants to see their own reality reflected in the lives of other women. Information presented and discussed at project events improved critical understanding of the things that influence people's lives and increased women's desire to become involved in the community. In our other study,[52] we worked with the FMI social isolation support group discussed above. For immigrant women, the realities of the immigration experience mean that the process of building relationships and creating or finding a social network of support is often extremely challenging.[54] We found that 100% of the FMI participants reported that their experience in the support group had been helpful or even transformational in their lives in relation to forming social relationships and friendships, and increasing their sense of social connectedness by making them feel as if they are not alone. Listening to others, and sharing experiences, feelings, ideas, and information helped them understand their own problems and the problems of others with a new lens. Participants reported:

> "*I don't have anyone here. No sister, or sisters-in-law, not anyone. But since I have been coming here [to the group], the others listen to me and I feel good. It is important to get everything that is inside us to come out—that's how we feel good. We need people to listen to us. Here we come to learn and I have learned many things about what has happened to each one. So I have listened to the others and then I compare my own situation with theirs and I see that mine is not as bad as some of the others. So if they can move on and move ahead, then I can do it also. This is what listening is about. I feel supported by the group by the way they listen to me."*[52]

> *"I have adored getting to know these women. … I am so glad to be with this group. It has been very healthy for me to get to know them. I think I will stay in the group until my blood stops running! I plan to stay because it is such a good experience. For me, this group is very important. There is no other place for people to listen to the problems I have. You know, sometimes you feel ashamed or shy, you don't want people to know what is really happening in your life. But then you hear the braver ones talk about what they did and the others give advice on how to resolve the problem and it helps you. This is important because if the same thing happens to a few of us, you hear different situations but you say this is what is happening to me and this is what I have to do. Here with the group, I found two different ideas about how to deal with a problem I was having ... I had been trying to deal with this problem since I was small and wow, I found the solution. The women here helped me figure it out. This group, for me, has so much value."*[52]

Participation in the group also reduced depression and relieved stress and anxiety. For example:

> *"When you come here, you start to see changes in yourself…in your character and in your personality. It is because you are getting out of the house. You come here, you de-stress a bit. Then when you go back home and you continue with your kids,*

you are a bit more relaxed. You see things in a different manner. This is an outlet for a release of tension. I think this is really a good thing."[52]

"There are people who God sends to our life and for me it is this group. Sometimes coming here is like wiping the slate clean and starting new. You are able to let go of what has been going on and when you leave you are like new. You have a new outlook on things. … It gives you energy and desire to do things….Or maybe you have been feeling depressed and you haven't been wanting to eat and you come here and then you feel like trying the food. Coming here you just get motivated in a lot of ways."[52]

And, participants reported that participation in the group was empowering to them as women. They said:

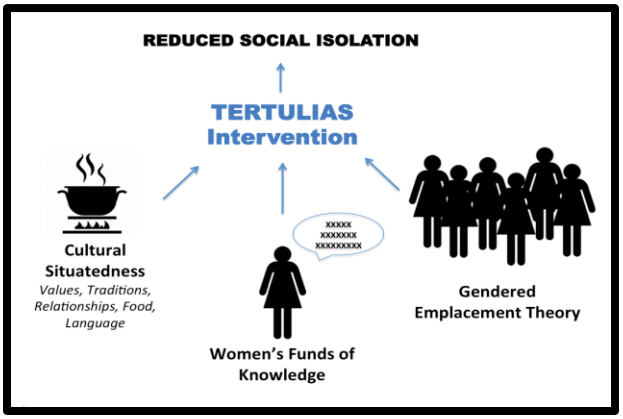
"I feel as if in my life I have lacked a sense of myself as a woman and haven't had a voice. But here I learned. It was through this group that I learned about myself and about how to be with my kids. It has been so helpful to me. And I feel really good about it."[52]

"I think the group has been important in keeping me healthy. The discussions we have help me feel good about my body, about myself… And here in the group, I learned that we don't have to try to be perfect. Not everyone is happy with what they have been given, but you have to feel good about yourself. The group helps lift us up and feel good about ourselves—to give us self-esteem and to try so that everyone in the group feels good."[52]

For FMIs then, social interaction plays a critical role in assisting them to rebuild their lives, redefine or reclaim their identity(s), and maintain health through shared knowledge and access to resources.[55–57] The group experience in our project was key in creating a mechanism for positive social engagement.

INNOVATIONS

The Proposed TERTULIAS Intervention Research is Innovative in Three Notable Ways. The proposed project challenges and seeks to shift current research and practice: Innovation #1.) We utilize a novel integrated theoretical framework that accounts for the interplay of multiple factors that together become a mechanism producing health disparities in the lives of FMIs; Innovation #2.) We implement an intervention using an innovative design that incorporates cultural dimensions of women's lives and creates a context for co-learning; and, Innovation #3.) We use a cutting-edge biological measure for research on chronic stress.



#1) INNOVATIVE THEORETICAL ARTICECTURE. To account for the syndemic complexity associated with understanding the interconnectedness of the domains of inquiry for this study, our hypothesis and research design are based on a fusion of three conceptual frameworks:

■) **Cultural and contextual situatedness.** Trickett's conceptualization of cultural and contextual situatedness[58–60] proposes integrating components of an intervention "into the local expression of culture as reflected in the multiple levels of the ecological context."[60] Rather than

merely "tailoring" an intervention to target a specific context or population (*e.g.,* by offering curriculum materials in Spanish or using images of individuals who "look" Latino), Trickett emphasizes the need for an intervention to be "*situated*" to fit *synergistically* within broader community dynamics (*culture and context*). An intervention should find a cultural and contextual "fit," but it should also be strategically designed to leverage dimensions of culture and context to enhance intended outcomes. Thus, culture becomes a vehicle for promoting positive outcomes.

■) **Funds of knowledge**. Moll, Gonzalez, & colleagues' notion of funds of knowledge[61–63] from the literature on learning and culture has implications for health intervention programming for FMIs. They postulate that women have "historically accumulated and culturally developed bodies of knowledge and skills."[61] We propose that women bring these funds to their participation in health interventions and that the success of a health intervention is mediated by the extent to which program design positively leverages cultural values and accommodates the socio-economic circumstances of a population in a way that incorporates and values participants' knowledge and experience (*funds of knowledge*), and creates synergy with the specific social dynamics that define participants' everyday lives (*situated in participants' culture and context*). This synergy creates a learning environment that promotes transformative personal and social change, and nurtures empowering individual psychosocial dynamics that increase resilience and improve health outcomes.

■) **Gendered emplacement theory.** Gendered emplacement theory[64–67] informs our use of a structured dialogue peer support group as the foundational design of the intervention. A large body of literature has explored the significant ways place is connected to health and wellness[68] through multi-level environmental influences in which an individual is embedded—many of which are defined as the social determinants of health. However, social science researchers have identified that the ways that a person experiences and perceives a connection to a place is also key. This sense of "*emplacement*," both spatial and social, plays an important role in personal wellbeing. Social connectedness is an essential component of this dynamic. Feminist scholars have expanded this concept through investigation of the gendered dimensions of "emplacement" in which women are *displaced* from historically male dominant spaces and therefore compelled to create alternative, protected spaces for feeling connected and engaged.[64–67] For obvious reasons, immigrants experience this sense of *displacement* in an inherently heightened way, which for women immigrants is doubly disorienting.

#2) INNOVATIVE INTERVENTION DESIGN: Structured Dialogue.

We will test the integration of our 3 theoretical frameworks in **TERTULIAS**, **an innovative peer support group intervention**. Peer support groups have been shown to be efficacious for a variety of contexts, populations, and health conditions.[69–73] For women immigrants, culturally based interaction with peers in protected spaces that promote personal empowerment is important for rebuilding lives, redefining or reclaiming identity(s), and knitting a strong social fabric to make women and their families healthy and resilient.[36,37,54,74,75] Yet just bringing women together would not likely result in systematic change to improve health outcomes and reduce health disparities. As per our theoretical architecture, cultural and contextual dimensions of women's lives need to be considered (*situated*), women's own knowledge and experience (*funds of knowledge*) must be valued and validated, and women need to develop a feeling of personal connection with others and have a way to conceptually understand their lives within a larger social context (*emplacement*). In our preliminary research, we worked with women from the Latino community, including FMIs, to develop a novel "structured dialogue" approach for engaging small groups of participants in a way that integrates these three theoretical frameworks.[36,37,52] **The structured dialogue approach upon which the TERTULIAS intervention is based involves 3 fundamental components:**

■) **Peer-to-Peer Interaction**. In both of our previous projects, participants shared stories, experiences, and ideas with each other. Through the group design of the intervention, participants expanded their social networks by making friends, helping each other, and learning about resources available in the community. From each other, they learned about, explored, discussed, and analyzed issues that they found to be of interest, they listened to ways that others in the group (women like themselves) confronted challenges and resolved problems, they developed their skills and knowledge for dealing with the situations that they experience, and they increased their capacity to deal with adversity with resilience.

■) **Bi-Directional Expert Facilitation**. In our prior research, a trained facilitator led bi-directional "structured dialogue" that allowed discussion to occur in an organic, open-ended manner**.** The facilitator built on themes emerging in the peer-to-peer discussion by presenting powerful life stories and analyses from other studies of women's health, and themes that emerged from the interviews with individual participants. The group considered stories and themes that were presented and discussed them in relation to their own lives and experience—weaving together their own experiences with those of other women, both inside and outside the group. Through this process, they developed an understanding of the broader forces that influence and structure their choices and practices on an everyday basis. We found that this approach engaged women in a way that decreased depression and other negative emotional states, improved their capacity to deal with socioeconomic conditions and relationships with intimate partners, and gave them a new way of thinking about their own lives and for understanding their community.[36,37,52] Women described these changes as personally empowering and transformative.

■) **Food-Sharing and Storytelling.** Food-sharing and storytelling are central components of the innovative structured dialogue group intervention that we have developed. ***Food-sharing*** is a well-established core cultural value for Latinos and particularly for Mexican Americans, especially at gatherings. But food (in its guises as kitchenspace,[76] food sourcing and food access expertise,[77] food preparation, cooking, and meal serving) is also important as a symbol and domain of women's identity.[36,36] In our projects, funds allowed for some provision of food, but of their own accord, the women in each of the groups developed a potluck-style process to bring food to share with others. Although it may seem insignificant, food-sharing created a culturally situated context for women to feel engaged and connected, and the food itself integrated something from women's funds of knowledge into the group. Given that many of the participants in our projects experience food insecurity in their homes, the fact that they were interested in and enthusiastic about bringing food to the meetings must be understood as a reflection of the significance the group held in their lives. And, both projects used ***storytelling***, an evidence-based strategy from research on empowerment among women that has been found to be particularly effective among women of color.[78–80] In our projects, the participants shared stories of their experiences, or the facilitator presented stories from other women. For women in our studies, the act of storytelling was evocative. They shared experiences, expressed feelings, and saw the connection between their own stories and stories of others. Women found participation in this process to be empowering, giving them information and tools to understand the root causes of disparities they recognize in their own lives. The group-centered learning was generative through the development of social connections, and the identification of both individual actions and group strategies to improve health. Structured dialogue helped women participants create their own narratives in a way that was healing and personally transformative (*empowering*). The peer-to-peer nature of the proposed structured dialogue group intervention will help participants "locate" and "ground" (*emplace*) themselves within a supportive social network. The critical social "literacy" that accrues from the structured dialogue design of our model will help women further "locate" and "ground" themselves in relation to shared stories and experiences—stories and experiences from others in the group and those presented by the facilitator—that tether participants' lives to policy and structural relations of power through transformative learning, building resilience, and becoming empowered.

#3) INNOVATIVE RESEARCH METHODOLOGY: Hair Cortisol Bio-Measure of Chronic Stress. Health disparities research has matured through the application of the social determinants of health framework. However, the need to move beyond merely understanding social determinants to action-oriented intervention research is increasingly recognized. Identifying biomarkers to support this work is imperative. Therefore, as part of this project, we will gather hair samples to test for cortisol, a biomarker of stress. We know that stressful experience influences physical and psychological health,[81] and we now understand that stress can accumulate or become toxic, ultimately influencing the biology of the human body, including the hormones, cortisol and adrenalin, and the immune system. Such chronic toxic stress is an emerging construct in health research.[82–84] However, measuring stress biochemically in the context of research is challenging. Many studies (the proposed study included) use psychosocial instruments that rely on self-report or recall. While often revealing valuable information, data from these instruments can be limited by respondent subjectivity or reporting bias.[85] Hence there is a critical need to develop an objective biomarker that can be used for unbaised measurement of chronic stress,, such as altered hormone levels that the experience of stress provokes. In the context of this study, advances in studying hair cortisol, an emerging validated biomarker for chronic stress,[86–90] offer exciting opportunities**.** Cortisol levels are altered in people with chronic stress. Cortisol has traditionally been measured in blood, saliva, or urine by a variety of clinical testing approaches.[91] Because of the diurnal variation in cortisol levels, these measures are unreliable. Furthermore, measures of bodily fluids offer only a snapshot of cortisol levels at any particular moment that can have valuable clinical uses, but fails to reveal the bigger picture of chornicity Unlike bodily fluids, hair provide a long-term read-out of cortisol levels over time. Typically hair grows by 1 cm per month. Therefore, cortisol extracted from 3 cm of hair detects the average cortisol levels in that person over the preceding 3 months. This innovative, non-invasive bio-measure of long-term or chronic stress is emerging with applications to a range of questions, including stress and diabetes, stress and poverty, and stress and child maltreatment**.** In recent literature, measurement of cortisol levels in hair has proven useful to determine the long-term effects of stress[86,92–99], including in relation to depression.[100–102] Previously, there has been no good assay to determine this effect. Now, with the ability to measure average cortisol over a span of time, more complex relationships will be identified and analyzed.[103,104] This line of inquiry is a major advance in revealing the often subtle ways that dysregulation of cortisol levels is implicated in the risk of disease and negative health outcomes.[100] We recently received NIH (NCATS) funding to analyze correlations between hair cortisol, depression, and A1c for 100 Latino participants (many of them Mexican immigrants) sampled at 2 time points. Specimen collection concludes in February 2019. This experience with cortisol testing and analysis provides us a solid foundation to pursue this innovative approach to measuring chronic stress in the study proposed here.

3.0 Inclusion and Exclusion Criteria

Population. This project focuses on FMIs for 4 reasons: ***1.)*** FMIs experience disparities in the prevalence of depression and in lack of access to treatment compared with Mexican immigrant men and non-Hispanic white women.[44,105] ***2.)*** Social isolation and depression among FMIs has been identified in our community work and research as compelling health concerns by health providers, organizations, and members of the Latino community. ***3.)*** The PI's previous research has expanded our understanding of the negative impact that social isolation has on the lives of Latinas (FMIs and nonimmigrants) and their families, and the ways that supportive groups and expanded social networks can positively transform health and social outcomes.[36,37,52] ***4.)*** It is our experience that women tend to be more likely to be interested in community-engaged activities

and they are uniquely positioned within the household to provide connection to other family members and influence health dynamics among extended family networks.

Inclusion Criteria. All participants will be female immigrants over the age of 18 (maximum age 90) who were born in Mexico, report household income below 250% of the Federal Poverty Level (FPL), and speak Spanish fluently (because group sessions will be conducted in Spanish). We will not recruit children, individuals unable to provide consent, or individuals that are incarcerated or pregnant women. Pregnant women will be excluded because pregnancy will influence cortisol levels, one of the measures being used in this study.

4.0 Study-Wide Number of Subjects

Sample Size. We will recruit **252 participants (N=252)**. **We will randomize participants into one of two arms.** We will enroll 60 participants each year during Y1 and Y2 (30 Arm 1 and 30 Arm 2). During Y3 and Y4, we will increase enrollment to 66 each year (33 Arm 1 and 33 Arm 2) to ensure we account for attrition to be able to power the study. Sample size accommodates attrition**.**

■) Arm 1 (n=126): Control participants will be recruited in four 12-month cohorts to coincide with the intervention cohorts. At the end of their 12-month participation in the control group, they will be offered the option of participating in the Y2, Y3, or Y4 intervention cohort or if they prefer, to join the ongoing group at the Hopkins Center outside of the research.

■) Arm 2 (n=126): Intervention participants will be recruited in four 12-month cohorts. Each cohort will be divided into three groups. With 3 groups in each cohort, over the four cohort cycles, we will have a total of 12 groups.

5.0 Study-Wide Recruitment Methods

Recruitment.
We will recruit a total of 260 FMI participants. Our two research partner agencies (Centro Sávila with its affiliate, The Hopkins Center and One Hope Centro de Vida) that both have a large Mexican immigrant clientele will recruit at their sites, but we will also reach out to other agencies where we have contacts. Potential participants will be contacted in-person, by email, by phone, by text, or by Zoom. For all in-person recruitment, we will follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces.

We will document successful recruitment strategies**.** We will track methods used to identify potential participants at each site, # approached for interest, # who are interested/not interested, # who are screened for eligibility, and # of eligible participants who agree/decline to enter the study. We will use Consort standards[106,107] to track recruitment and attrition. We will document contextual factors or aspects of the intervention that influence participation and retention**.** We will track reasons for interest/no interest and reasons eligible participants decline to participate, and we will ask potential participants to indicate the importance of different aspects of the project in their decision (*e.g.,* time, location, group design, food sharing, babysitting, etc.). We will track attendance at meetings and attrition, and document reasons if participants leave the study.

Deciding to Participate
In our current HPRO-approved, PCORI-funded research study with Latinos from low-income households, we have recruited 452 participants. Of those, 183 are FMIs. The level of education for this subset of PCORI participants is: 47% have less than an 8th grade education and another 18% have some high school but no diploma. Because we will be recruiting from the same immigrant population for this study, we anticipate that potential participants for this study will

have a similarly low level of education. In addition, we know that this population may also be wary of the idea of participating in a research study. This means that we need to ensure that the consent process provides potential participants with sufficient information to allow them to provide informed consent but that it does not become so burdensome and complicated that it will be counterproductive to the study by discouraging individuals from electing to participate—which would significantly affect our ability to recruit from a participant population that is already known to be challenging to recruit.

Participation in this study would normally present no greater than minimal risk, however because of COVID-19, risk is elevated. As a result, we have instituted safety measures to protect staff and participants. Potential participants will be contacted in-person, by phone, by email, by text or by Zoom. For recruitment, data collection and intervention-related meetings, we will use Zoom meetings when possible and follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces.

In addition, because the study is complex, the consent form is extremely long (9 pages in Spanish). Moreover, randomization is a complicated concept and will need to be explained in a way that potential participants can be sure to understand what it means and why we do it. Consenting for this study will be conducted in Spanish by FMI members of the research team who have extensive experience consenting individuals from this population through our current PCORI-funded project that has enrolled and consented 452 low-income Latino diabetes patients and social supports, including many Mexican immigrants. Given our experience, we anticipate that individual informational/consent sessions will take an hour or more to go over everything in a way that will ensure that the participant understands what it will mean to be randomized and the nature of their participation in order to decide whether or not to participate. The length of this process would create great burden on our project staff and on participants and challenge the feasibility of the study.

To address these issues, we obtained approval for an alteration of the consent process that includes a meeting, a PowerPoint presentation, and a randomization video (see attached script in English—the video itself is in Spanish and will be submitted when complete). Because of COVID-19 social distancing restrictions, in Year 1, we will hold this meeting by Zoom in 6 groups of 10 participants each. In subsequent years, we will determine the appropriate safety context for whether or not we meet in-person or not. We have designed a culturally appropriate group information meeting that includes detailed information about why we are doing the study and what participation will be like for individuals in both the control group and the intervention group. The presentation will include all required information that is in the consent form.

The informational meeting will be held by Zoom or at a convenient location in the community and will follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces. The meetings will be conducted in Spanish by FMI members of the research team. The informational meeting will have the following:

- A PowerPoint presentation describing (in Spanish) (English version attached) the scientific and social contribution that this study will make and why we are doing it. This will be submitted for HRRC approval when it becomes available and before recruitment starts.
- A detailed explanation about the research and what participation entails. The presenter will clearly explain the research, the risks to participants, and the procedures for safeguarding their privacy. Participants will be informed that they will be assigned

randomly to a group, that they can refuse to answer any questions and stop the survey, interview, or participation in a focus group at any time. The investigators have training and will understand the importance of these issues and their responsibility for maintaining high ethical standards and they will have current human subjects research training certification.

- An explanation of what randomization means and why we do it. To this end, NIH funded us to produce a brief video with FMI presenters describing (in Spanish) (English script attached) how the randomization works, and why randomization is important, to help participants understand why we have structured the project to have two arms. After viewing the video, participants interested in participating will continue the informed consent process (in English or Spanish, depending on participant preference).

Randomization

After the presentation is over, those who decide not to participate in the larger research study will then be free to leave the meeting (whether by Zoom or in-person). Those who decide to participate will be asked to approach a table or if by Zoom, will be told they will be contacted to sign the consent form and research team members at the consent table or who do the contact will do a brief review of the consent form. If an in-person meeting is not feasible because of COVID-19 restrictions, oral consent will be obtained prior to conducting the baseline data collection survey.

There will be an option for conducting an informational session individually either in-person or by Zoom with women who cannot attend the informational meeting or those who choose to do the consent process in private, but we will encourage potential participants to attend the meeting because we believe that for this population, the meeting process will be more engaging and a superior context for learning about the research than going over the lengthy consent form individually, and because it will also alleviate feasibility concerns.

Consented participants will randomized to the intervention group or control group. Each woman will draw a number from a bowl. The numbers will have been randomized to one of the groups prior to the meeting. Randomization will be done using a block randomization design to allocate 50% of participants to the control group and 50% to the intervention. Randomization will be done using a block randomization design to allocate 50% of participants to the control group and 50% to the intervention. Random block sizes of 2, 4, and 5 will be implemented to ensure balance between arms. Intervention group participants will be offered three group meeting options to accommodate participants' schedules related to day/time and location considerations, but the three options will all be conducted using the same structure and format.

1) COVID-related change: Because of COVID-19 restrictions, we previously obtained approval to hold weekly peer support group meetings for the intervention arm by Zoom. In doing so, we have identified a need to make two modifications. Participants in the intervention arm will be notified of these changes, but control participants would not be notified.

a.) Now that the meetings are being held by Zoom, the participants are generally participating from their homes. To ensure sufficient privacy for the meetings that will ensure privacy for all participants, we are adding that we will supply participants with inexpensive ear bud-style earphones.

b.) The intervention arm participants are joining a weekly 2-hour Zoom meeting. We have identified that many participants do not have sufficient internet connection or data use plans to allow this to continue and that it is an expense to them. We are adding in a payment of $30/month per intervention arm participant to help cover the cost of allowing them to have sufficient bandwidth/plans to be able to participate. This is fundable because we had money for babysitting that we are not using because we are holding the meetings remotely. This is not an incentive, it is covering the costs they are incurring and making participation feasible.

6.0 Multi-Site Research

N/A

7.0 Study Timelines

Each participant will be in the study for 12 months. .

This is a 5-year project. If funded, the project would tentatively start in late summer or fall of 2019.

We expect to end the intervention in month 6 of Y5.
We will complete analysis by month 12 of Y5.

8.0 Study Endpoints

The research endpoint for each participant is after the 12-month data collection appointment.

The study research endpoint will be in month 6 of Y5 when the last cohort of participants completes 12-month follow-up data collection appointments.

There are no safety endpoints identified for this study.

9.0 Procedures Involved*

QUANTITATIVE DATA COLLECTION:

■) **Surveys**. We will administer a multi-dimensional pre/post survey to all participants at baseline prior to the first group session and at 12-months. The survey will combine demographic questions with questions from validated instruments to measure domains of interest (Depression[109,110], Stress[111], Resilience and Adaptability[112], and Social Support[113,114]) plus questions to document the participant's social network to measure social connectedness[113,114] to inform the social network analysis (see Table and attachments). **At baseline**, all participants will also be asked demographic questions. **At baseline and 12 months**, all participants will be asked the pre/post survey questions. **At 12 months**, Arm 1 (*control*) participants will be asked to answer questions about interest in participating in an intervention group, and Arm 2 (*intervention*) participants will also be asked a series of questions designed to evaluate their participation in and perspective on the TERTULIAS intervention, including the Trauma-Informed Practice Scale to measure Empowerment and Knowledge[115,116]. **At each time point,** data collection appointments will be in-person because of the need to gather hair samples and will follow COVID-19 guidelines as appropriate related to screening questions, temperature screening, face masks, social distancing as much as possible, and use of sanitizing products. The survey will be administered

orally in Spanish or English (depending on the preference of the participant) by trained FMI data collectors using IPads and entering data into REDCap, the secure data capture system operated by the UNM CTSC. Participants will receive a $50 merchandise card. We have developed a protocol and have professional team members to assist any participant (control or intervention) identified as needing immediate medical or counseling services**.**

Impact on Construct or Domain	**Measure or Instrument** *All instruments have validated Spanish versions available
Decrease **Depression**	Center for Epidemiologic Studies Depression Scale (CES-D), 20 items, total score range from 0 to 100. (α= .85-.90)
Decrease **Stress**	Perceived Stress Scale (PSS-14), 14 items, total score range from 0 to 56 (α=0.84-0.86)
	Lab analysis of hair cortisol
Increase **Resilience** & Adaptability	Connor-Davidson Resilience Scale (CD-RISC), 25 items, total score range 0 to 100 (α= .81)
Increase **Social Support**	Medical Outcomes Study Social Support Survey (MOS SSS), 19 items, total scaled score ranges from 0 to 100. (α= .97)
Increase **Social Connectedness**	Social Network Analysis Questions
Increase **Knowledge & Empowerment**	Trauma-Informed Practice (TIP) Scale (α= .85-.98)

We will alter the data collection process for our Social Network Analysis (SNA) beginning with data collection for baseline Y3 and 12-month follow-up for Y2 that will occur in summer 2022, and then we will continue using the new process for the remainder of the project. The reason for this alteration is that the SNA questions were very repetitive and extremely tedious for both the data collectors and the participants. When Dr. Thomas joined the team (replacing previous SNA analyst, Molly Bleecker), he brought enhanced SNA expertise. He made the suggestion that we could improve data collection and enhance the scientific quality of our data by moving to Network Canvas software, an NIH-funded SNA App. Dr. Thomas will program the Network Canvas software to ask the specific Tertulias questions.

> *Network Canvas (https://networkcanvas.com/about.html)*
> *Funded by NIH # R01 DA042711 (or 5R01DA042711-02?)*
> *"netCanvas: Development, Hardening, and Dissemination of a Software Suite for the Collection of Complex Network and Contextual Data in HIV and Drug Research"*
> *PI Michelle Birkett, Northwestern University*
> *other PI Gregory Phillips II*
> *https://reporter.nih.gov/project-details/9306043*

The Network Canvas software suite is an Open-Sourced package of applications developed by researchers at Northwestern University and Oxford University with NIH funding, for the purpose of collecting survey data on the personal social networks of subjects in the field with one-on-one help from interviewers. Per NIH requirements, the Network Canvas software technology is appropriate for use in research studies and was designed for ease of use. The Network Canvas interface is interactive and uses graphic images that the participant can name, click, drag, and drop rather than merely answering a series of repetitive questions. The software significantly eases the cognitive burden of this process on both subjects and interviewers, compared to earlier social network survey techniques, which reduces the time the survey takes and improves the quality of the data collected. The software also eases the management of the data collection process across multiple interviewers in multiple locations. Network Canvas consists of three component applications: Architect, for designing surveys, Interviewer, for conducting the survey in the field, and the optional Server component, for transmitting data securely from the devices in the field to a computer managed by the project team (at UNM in this case).

For the new process, instead of merely asking a series of questions and putting the answers into REDCap, the SNA question portion of the data collection will be gathered by the Data Collectors on the same tablet device (*i.e.,* an iPad) that they use for the REDCap log-in and survey data collection. The IPads will run the Network Canvas Interviewer application. The data is stored locally on the device (which is kept in the Data Collector's possession) until it is either manually copied from the device by the Tertulias team, or transmitted to the Network Canvas Server at UNM, which is administered by the Tertulias team. Transmission of data from the tablet devices to the Network Canvas Server uses end-to-end encryption, employing a symmetric Advanced Encryption Standard (AES) algorithm to encyrpt the data pre-transmission, and then using a Transport Layer Security (TLS) for the transmission. Any third-party interception of the transmission between the iPad and the Network Canvas Server would only yield heavily encrypted data. Data from the Network Canvas apps for this project will never be transmitted to any other server or entity except for the server at UNM.

Network Canvas data from the iPads will be transmitted to the Network Canvas Server in one of two ways: 1) by connecting the iPad to the UNM network via a Virtual Private Network (VPN), and then connecting to the campus-located computer running the Network Canvas Server and uploading the data, or 2) by physically bringing the iPads to campus to connect to the server on the secure UNM local area network (LAN), or 3) by transferring the data directly from the iPad to a Tertulias team laptop by a physical cable.

The Network Canvas technology will allow us to add a series of questions to measure additional characteristics of the people in the respondents' networks (their "alters"), to estimate how and whether the Tertulias interventions change the diversity and composition of their networks. These include age, gender, ethnicity, education and occupation. We will also add questions to measure additional information about the participants' relationships with each alter (the people they know). These include frequency of interaction, when and how they first met the person (if not family).

To measure alters' gender, the interface will show the respondents a visualization of the people they have identified in the survey, and prompt them to "select the people you know who are Males".

The interface will then show them an assortment of circles labeled with different ethnic/racial categories, and ask the respondents "Please place each person in the circle that best matches their ethic or race". These will include "Hispanic/Latino", "Anglo", "Black", "Asian", "Native American", and "Other/Multiracial" (which initiates a text prompt).

To measure education, the interface will show them a scale ranging from "No Formal Education" to "High School or Equivalent" to "College Degree" and "Advanced Post-College Degree". It will prompt the respondents to "Please place each person on the scale to match their level of education".

To collect data on age and occupation, the survey will show the respondent a list of questions for each alter (one alter at a time), asking them to type in their age and occupation in text boxes.

To measure frequency of interaction, the interface will show the respondents a scale of frequency (e.g. "Daily" "Every few days" "Once a week" "Once a month" "Less than once a month") and ask them to drag and drop each alter into a place on the scale ("How often do you talk to each of these people you know?").

To measure how they first met each alter who isn't a blood-relationship, the survey will show them a list of ways people first meet each other, and ask them to choose all that apply (separately for each alter, one at a time). Options will include "Through Friends" "Through Family" "At a party" "At Work" "In my Neighborhood" etc.

To measure how long have they known each alter, the interface will ask participants to select their (the participant's) age when they first met the alter.

The Network Canvas software allows us to measure the closeness that people feel to others in a more nuanced way that the previous survey. The original survey instrument simply asked if the respondent felt close to the other person, yes or no. The new Network Canvas version of the survey will ask respondents to place each of the people they tell us about in a 2-dimensional space, by dragging their icons with their finger or stylus. This screen has three concentric circles in the background representing differing levels of closeness, with the central circle representing feeling most close to the person, and the larger circles representing more peripheral feelings of closeness, and outside of the circles entirely representing feeling not close. The interviewers will explain this interface to the subjects, though we expect this exercise to be quite visually intuitive to most respondents. The resulting data file includes the coordinates of each icon placement, allowing for detailed metrics of closeness.

Respondents are currently asked about their relationships to various other people in their lives, but they are not asked about the relationships between those people. For instance, in the current survey instrument the respondents tell the Tertulias team about the people they know who they do fun activities with, but we do not measure whether those people participate in entertainment activities with each other, or even know each other at all. We will add a question asking the participants to indicate which of the people in their life that they have told us about know which other people in their life, using the same measures of "knowing" that we use for subject-alter relationships. The new Network Canvas software makes this relatively simple for us to implement, and a quick task for the subjects to complete.

■) **Additional Survey Questions**. At the end of Y2, we conducted a preliminary analysis of the data. Qualitative data were extremely powerful regarding participant self-report about the importance of the intervention and the deep significance it has had on them as individuals and in their lives. These findings are clear in the data from meeting notes, interviews, evaluation discussions, and Ripple Effects Mapping sessions, and are supported by perceptions of team members who facilitate the peer support groups. However, when we analyzed the pre/post survey data using quantitative methods, there was little or no difference between the arms. It didn't seem possible that being in such an intensive intervention with reports from the participants of such deep impact could be the same as receiving nothing. So the results were not only surprising to us, they don't make sense. After much discussion with team members, our Advisory Board, individuals from the population of study, and experts in research methods, and reviewing the literature, we hypothesize that the discrepancy and lack of alignment between our qualitative and quantitative data may reflect the following: 1.) There may be some impact from the pandemic which was universally affecting participants from both arms of the study, 2.) Although the survey is conducted by 2 female Mexican immigrant data collectors, the participants do not know the data collectors—they are strangers—and this makes disclosing truthful answers to questions about mental and behavioral health (the focus of this study) challenging. There is much published data regarding the fact that in Mexican culture, people tend not to want to disclose information about mental and behavioral health (the focus of this study), and that this is particularly true for Mexican women. 3.) There is a lot of shame associated with mental and behavioral health issues in Mexican culture. 4.) Many people from the population of study do not really understand what

depression and social isolation are, and therefore when asked questions about these issues, they do not associate them with their own lives and experience. 5.) There may be a "response-shift bias" occurring in our data collection process. Tugwell & Knottnerus (2014) define this as "a change in the meaning of one's self-evaluation of a target construct as a result of 1) a change in the respondent's internal standards of measurement (ie, scale recalibration); 2) a change in the respondent's values (ie, the importance of component domains constituting the target construct; ie, reprioritization), or 3) a redefinition of the target construct (ie, reconceptualization)." In this study, that would mean that at baseline, participants in both arms are answering the questions from the perspective that they don't know the data collectors, that there is shame in admitting mental and behavior health problems, and that they don't see these things as relevant to their lives. So, everyone at baseline kind of answers the same – "I'm fine"—which may or may not reflect how they really feel. At follow-up, the control participants have not had any experience to shift the way they answer the questions, so they still just answer "I'm fine." For the intervention arm participants, they have had a transformative experience in the group and they are now much more trusting of the data collectors and they have a much deeper understanding of what depression and social isolation are and they have a lot of experience disclosing and talking about these types of mental health issues. So at follow-up, they answer the questions and they say "I'm fine," but it now means something completely different that is not captured by the quantitative survey instrument. So, while the two arms score similarly on the survey instrument, the responses no longer align between pre and post, and they do not align with the qualitative data.

Retrospective pre-test design

We want to validate the qualitative data analysis because it seems to align with the experience people report and that we observed, while the preliminary results of the survey data analysis do not align with what we have observed or what people report. To deal with this mis-alignment, we consulted with a methodologist who suggested we use a "retrospective pre-test design" and administer some new questions. With this method, we will use the qualitative results as the constructs for the new questions. Each question will get asked at the 12-month follow-up in 2 ways using this format on a scale of 1-5:

1. Before you started Tertulias, how would you rate **your knowledge of resources in the community**? 2. When you finished Tertulias, how would you rate **your knowledge of resources in the community**?
3. Before you started Tertulias, how would you rate **your confidence using technology such as Zoom**? 4. When you finished Tertulias, how would you rate **your confidence using technology such as Zoom**?
5. Before you started Tertulias, how **lonely or socially isolated did you feel?** 6. When you finished Tertulias, how **lonely or socially isolated did you feel?**?
7. Before you started Tertulias, how **much of a sense of belonging did you feel**? 8. When you finished Tertulias, how **much of a sense of belonging did you feel**?

The literature suggests that this format of question asked at follow-up tends to elicit more truthful responses from participants. We will compare these responses with answers to the validated instrument questions and to the qualitative data.

We will add these questions to the 12-month follow-up survey and administer them to all of the Y3 and Y4 participants as part of the 12-month data collection. We will be gathering follow-up data from Y3 participants in July/August of this year and from Y4 participants in July/August 2024.

For Y1 and Y2 participants who have already completed the intervention and completed follow-up data collection, we will reach out to them by phone, text, Zoom, or email and ask them if they would be willing to answer a few more questions. We will use the attached recruitment script. If they are willing, one of the team members will set up the meeting, administer the new questions orally, and record the responses in REDCap using a tablet or laptop. The additional data collection for Y1 and Y2 participants should only take 15-20 minutes. Participants will receive a $25 merchandise card for answering the additional questions. Because for Y3 and Y4 participants, the questions will be incorporated into the follow-up data collection, we will not offer additional incentive.

We are requesting approval to obtain oral consent for Y1 and Y2 participants to answer these additional questions. They have already signed the consent form for the project. We will document the fact that they consented in REDCap.

Lit Review

We conducted literature reviews Mexican immigrant women and reporting mental and behavioral health issues, Response-Shift Bias, and Retrospective Pre-Test Design.

Mental Health Disclosure and Culture

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■) **Hair Samples**. We will gather hair samples from all participants at baseline and 12 months to measure average levels of circulating cortisol as a biological marker for chronic stress**.** As indicated above, our team has experience gathering hair samples with this population. The data collectors will use scissors to obtain a pencil-width (at least 3 cm long) of hair from the crown of the participant's head. Hair will be stored in pre-prepared foil packets placed inside plastic bags to maintain the orientation of the head-end of the hair sample. Participants will receive a $50 merchandise card. In our pilot and ongoing studies, we have had 78% of Latino subjects agree to have their hair tested (or are able to—some participants are bald or have extremely short hair and are unable). We have established collection procedures and our research assistants have been trained and >90% of samples yield measurable amounts of cortisol. Each assay is performed in duplicate. Inconsistent measurements between duplicates are discarded or

re-tested. We control for hair dye, although hair products are not known to affect cortisol measurements.

QUALITATIVE DATA COLLECTION:

What's App. We will enroll women from each Tertulias group into separate What's App chat groups. Participants will be informed of the potential risks to privacy that exist when participating in an online chat group—both within the group as all members of the group see the posts, and external from threats to internet security. In Y1, we will reconsent the participants orally mid-year and document oral consent in REDCap. In subsequent years Y2-Y4, this information will already be included in the consent form from the beginning of when participants enroll in the study. Given that we are still operating remotely under COVID-19 safety restrictions, we will use our existing HRPO approval for the mid-year oral consent right now in Y1. Because we conduct baseline data collection appointments in-person, subsequent consent will most likely be conducted in-person, except in cases where that is not permissible for COVID-19 safety concerns.

The What's App chat groups serve two purposes:

- The first purpose is logistical/practical, given the COVID-19 restrictions and the new, sudden need for electronic solutions. Women in the group are primarily attending the Zoom meetings using their phones. Few of them have access to a computer and few of them have an email address—and of those with an email address, few check it with any regularity. What's App is a platform that is widely used by Mexican immigrants and their families both in the US and in Mexico. The vast majority of participants already use What's App, they are familiar with how it functions, and they have the app on their phone. We will use the What's App chat to communicate things about trouble shooting access to zoom or reminders for the meetings.

- The second purpose is social, created by the new need for an electronic solution in the context of COVID-19 restrictions. Because we had to transition to a Zoom-based meeting for the intervention, the opportunity for social interaction/making friends/sharing information that would normally happen before or after the meetings or during the food sharing that would have been a feature of the meetings is lost. This interaction is key to the success of the intervention. Therefore, it is important for us to try to find a way for the participants to be able to communicate and interact outside of the very restrictive type of interaction that occurs through Zoom. What's App is the perfect solution. It is used extensively in the Mexican immigrant population. It is free and people are able to maintain an everyday connection with friends and family in Mexico or here in Albuquerque. Almost all of our participants already have the What's App app on their phone. So when we create a What's App chat group, they will already be familiar with how it functions.

We will review the chat streams as qualitative data.

- Analytic purpose
    - We will analyze the What's App chat streams because interaction between the participants in the context of the weekly Zoom meetings is very structured. With the What's App chat group, they have an opportunity to interact in an unstructured way. The use of the chat so far in the project has been constant for all three groups. The participants are extremely engaged, giving each other tips, sending each other information about resources, praising each other, offering support, comforting each other, etc. Therefore the What's App chat groups have become an unanticipated rich source of research data that can help us understand

more about the impact of the social support between participants that is happening as a result of and in the context of the intervention. Given that this is a project focusing on social isolation, the chat group narratives are important data.

- Also important is the manner from a research perspective is the actual language and content of the chat communication (e.g., use of emojis, pictures, emphatic text fonts, etc.) because this will help us to understand something about the content of the social interaction between participants and how it unfolds during the intervention. We have seen that participation in the chat groups has made the group participants more comfortable with each other in a way that would not have been likely to occur if they only had the opportunity to talk with each other or interact with each other in the structured Zoom meetings. This will also shed light on unanticipated dimensions of the remote social context required by COVID-19.
- In our meeting notes, we have documented that participants have mentioned the interaction in the What's App chat groups and specifically how important the chat groups, the Tertulias groups, and the women in them have already become in their lives, and that they derive strength and support from participating together in both the chat and the weekly group meetings. Therefore, this is an important domain for us to understand more fully. It will allow us to understand how the chat group contributes to the success of the intervention in the context of COVID 19 restrictions which prohibit in-person meeings.

- Benefit to participants
  - It became clear immediately after the groups started that the What's App chat groups were important to the participants. All of the participants joined the study because they really WANT and were desperate for social support from other women. Of 64 women who attended project interest meetings for recruiting participants, 56 joined the study and we only had to recruit 4 participants individually. This is an amazing statistic given that the intervention is intensive (weekly for 2 hours by Zoom) and that the population of study is considered extremely hard to reach and retain. So we knew from the outset that the intervention was one that was of interest to women in the community.
  - This is a community-engaged study and we are working with community partner agencies and members of the community to implement the research. We have not specified a particular way that we will communicate the results of this study back to the participants, but we will be working with our partners as the data analysis for this study is completed in order to determine the best method for informing participants and other members of the community about the study results. We believe that they will be very interested to learn what happens since they are contributing to the research. Our meeting notes documented that participants are very committed to contributing and want their participation to be meaningful.

In Y1, we will re-consent the participants in order to obtain their permission to use the What's App chat groups in the context of this project. We will do in July 2021 prior to the end of the Y1 groups on July 28. We will not begin analyzing the What's App data until re-consenting has been completed. Because of continuing COVID-19 restrictions on meetings all of the project activities except baseline and 12-month data collection (which require obtaining hair samples) are being conducted remotely. We already obtained permission from HRPO to consent individuals orally if necessary because of COVID restrictions, so in this instance, a team member will contact each participant individually by phone or by Zoom. The participants already understand what participating in the What's App groups entails so the team member will explain the risks involved

using an approved script and obtain their consent orally regarding continuing to participate in the What's App group. We will document oral consent in REDCap.

In Y2-Y4, we will use the revised consent form (see attached revised consent 3-5-21) to inform participants about the What's App when they join the study.

■) **Participant Observation and Meeting Logs.** We will conduct participant observation of TERTULIAS group sessions. PI Page-Reeves, an experienced anthropologist, will attend TERTULIAS group meetings on a rotating basis and keep an observational log on a laptop computer. Facilitators will maintain weekly group meeting logs to document group dynamics of interest. Observation notes and logs will serve as an objective measure of dimensions of women's participation and aspects of the group dynamic of interest in this study.

■) **Policy Log**. We will document multilevel impacts**.** In our previous work, we documented that TERTULIAS has multilevel impact on individual women, on women's family relationships and families, and on the group. In addition, we recognize that some of the factors influencing women's lives in relation to social isolation may be larger structural, systems, or policy issues that are outside the control of individual women, their families, or the group that could be addressed or targeted for change in a future project. Facilitators and the participant observer will keep a policy component as part of their logs to document these types of issues identified from group discussions.

■) **Interviews**. We will conduct interviews with a subset of participants (n = 24). For in-person interviews, we will follow COVID-19 safety guidance for at the time of the activity, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces. In keeping with standards for systematic theoretical sampling in qualitative research,[126–129] interviewees will be identified by the facilitators as individuals likely to have something to contribute to our understanding of the group dynamic. Interviews will be conducted by the PI in Spanish or English, depending on the preference of the participant, and will last approximately one to two hours. We will use an ethnographically inspired approach to allow participants to drive the flow of the interview. Questions will be posed in a semi-structured format with some open-ended questions. The interviewer will use interviewee responses to formulate prompts and follow-up questions. When appropriate in the context of the interview and depending on the content of the interviewee's narrative, concepts from preceding interviews and group session will be incorporated into prompts and follow-up questions to engage the interviewee in a discussion of ideas or issues emerging within the context of the research. Interviews will be audio-recorded and transcribed/ translated. Interviewees will receive a $50 merchandise card.

■) **Group Discussion**. In the later part of each year, we will ask participants to contribute a 1-2- page creative work (e.g., story, poem, drawing, photo, etc) that says something about themselves or about their experience in the group, and we will make copies of all the contributions and create 3-ring binders to give to each of them. We will audio record their explanation what the art work represents when they present the work to the group. Audio recordings will be transcribed and translated. We will use the final group session at the end of 12 months of each of the 12 groups to ask participants to discuss the intervention (n=12), its impact on their lives, and the domains of interest related to health outcomes. Depending on the social distancing requirement, we will hold the meeting by Zoom or in-person. We will follow COVID-19 safety guidance at the time regarding in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate. The session will be facilitated by PI Page-Reeves, together with Co-Is/Lead Group Facilitators J.Perez and Regino, and will be audio-recorded, transcribed, and translated. Participants will receive a $50 merchandise card.

There is a new method for facilitating a group meeting called Ripple Effects Mapping (REM). We will add this technique into a couple of the group meetings near the end of the study. Participants will be informed about the process that will be used. REM is an innovative participatory evaluation technique that provides a way to document the "radiant" impacts of a program in a way that captures the dynamics of context. REM reveals interconnections between program elements, activities and impacts in a way that helps to understand what actually happened. REM uses software to create visual "maps" that can tell the story of change and impacts. REM captures and documents complex processes – the "ripples" that happen in the program or in the community. REM elicits stakeholders to give input on how something (like an intervention) has had an impact--to capture impacts that generally aren't easily quantifiable--like X thing helped all of us feel more involved and because we felt we are more involved, we have made new friendships, and because we have new friendships, we are less depressed--etc. And during the Tertulias meeting a "scribe" from the team will take notes into this new software that allows you create visual "maps" of how the data are connected--kind of like a tree. Then we will display the results back to the group and get them to see what they are saying the impacts or "ripples" are and get commentary on that. Invisible changes such as building social connections (which are the precursors of change), changes in policy, shifts in narrative, and cultural transformation can be documented and mapped visually. I was able to bring in a trainer to train folks here at UNM in this method. We will use this facilitation technique into two meetings of each of the Tertulias group meetings at the very end of each cohort year. We will audiorecord each REM session and take notes from the recording and then destroy the recording.

10.0 Data and Specimen Banking

Data generated through this study will be administered in accordance with both University and NIH policies. Data will be accessible only to the study staff to ensure confidentiality.

In the consent form, we ask for the participant to allow us to keep their contact information in the form of a "contact list" for follow-up in future studies by the PI only.

After lab analysis of hair samples, remaining hair will be destroyed.
After transcription, audio recordings of interviews, REM sessions, and presentations of artwork will be destroyed. Each participant will indicate on the consent form whether or not they want their name associated with the art work or the explanation of the work that they contribute

After data analysis is completed, study materials will be kept in the PI's locked office and destroyed after five years.

After final analysis of data is concluded, de-identified, quantitative data from the survey and hair cortisol testing will be available to interested researchers only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify or attempt to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying the data after analyses are completed.

Qualitative data will contain large amounts of personal identifiers. Deidentification will not be feasible. Therefore, qualitative data will not be available to share.

The products/resources that are a result of this study will be disseminated via publications, presentations at national conferences, presentations and reports to study stakeholders.

11.0 Data and Specimen Management

Data & Safety Monitoring Plan

Participants will be asked to provide the following data:

- Name
- Contact information
- Signed consent forms or oral consent
- Baseline and 12-month survey responses related to the following domains:
    - Demographic information
    - Depression
    - Stress
    - Resilience
    - Empowerment
    - Social support
    - Social connectedness (social networks—informational and personal)
    - Evaluation the experience of participating in the intervention
- Baseline and 12-month hair samples that will be analyzed for hair cortisol
- A subset of participants will be interviewed and interviews will be audio-recorded and transcribed.
- Observational notes and group meeting logs will be kept by study team members
- A piece of creative work (a story, poem, drawing, recipe, etc.) will be gathered and copied and all participants will receive a notebook with creative works from all the participants in their cohort year.
- We will create an audio recording of the explanation of what the project means/represents for each participant when they present the work at a group session. Audio-recordings will be transcribed and translated.
- We will conduct REM sessions that will be audio-recorded and then notes will be taken from the recordings.
- The final group session of the year of participation will be a research meeting and the group discussion will be audio-recorded and transcribed.

Overall Framework for Data and Safety Monitoring Commensurate with Risk

Participation in this study would normally present no greater than minimal risk, however because of COVID-19, risk is elevated. As a result, we have instituted safety measures to protect staff and participants. Potential participants will be contacted in-person, by email, by phone, by text or by Zoom. For all recruitment, data collection and intervention-related meetings, we will use Zoom meetings when possible and follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

We will assign a study ID to all participants and no participant identifiers will be associated with the data or stored together with the data. The link will be kept separately. All data will be labeled with the study. Survey data and hair cortisol results will be stored in REDCap. Contact information will be stored in REDCap in a separate project that will only be accessible to project staff who need to have access, but it will not be associated with the data. Qualitative data (interview and group session transcripts, observational notes and meeting logs will be stored on password protected computers and hardcopy documents will be stored in a locked drawer. The

consent forms will be stored in a binder in a separate locked drawer in the office of the PI. A list of the names of individuals who have been consented orally will be stored together with the signed consent forms.

We will alter the data collection process for our Social Network Analysis (SNA) beginning with data collection for baseline Y3 and 12-month follow-up for Y2 that will occur in summer 2022, and then we will continue using the new process for the remainder of the project. The reason for this alteration is that the SNA questions were very repetitive and extremely tedious for both the data collectors and the participants. When Dr. Thomas joined the team (replacing previous SNA analyst, Molly Bleecker), he brought enhanced SNA expertise. He made the suggestion that we could improve data collection and enhance the scientific quality of our data by moving to Network Canvas software, an NIH-funded SNA App. Dr. Thomas will program the Network Canvas software to ask the specific Tertulias questions.

> *Network Canvas (https://networkcanvas.com/about.html)*
> *Funded by NIH # R01 DA042711 (or 5R01DA042711-02?)*
> *"netCanvas: Development, Hardening, and Dissemination of a Software Suite for the Collection of Complex Network and Contextual Data in HIV and Drug Research"*
> *PI Michelle Birkett, Northwestern University*
> *other PI Gregory Phillips II*
> *https://reporter.nih.gov/project-details/9306043*

The Network Canvas software suite is an Open-Sourced package of applications developed by researchers at Northwestern University and Oxford University with NIH funding, for the purpose of collecting survey data on the personal social networks of subjects in the field with one-on-one help from interviewers. Per NIH requirements, the Network Canvas software technology is appropriate for use in research studies and was designed for ease of use. The Network Canvas interface is interactive and uses graphic images that the participant can name, click, drag, and drop rather than merely answering a series of repetitive questions. The software significantly eases the cognitive burden of this process on both subjects and interviewers, compared to earlier social network survey techniques, which reduces the time the survey takes and improves the quality of the data collected. The software also eases the management of the data collection process across multiple interviewers in multiple locations. Network Canvas consists of three component applications: Architect, for designing surveys, Interviewer, for conducting the survey in the field, and the optional Server component, for transmitting data securely from the devices in the field to a computer managed by the project team (at UNM in this case).

For the new process, instead of merely asking a series of questions and putting the answers into REDCap, the SNA question portion of the data collection will be gathered by the Data Collectors on the same tablet device (*i.e.,* an iPad) that they use for the REDCap log-in and survey data collection. The IPads will run the Network Canvas Interviewer application. The data is stored locally on the device (which is kept in the Data Collector's possession) until it is either manually copied from the device by the Tertulias team, or transmitted to the Network Canvas Server at UNM, which is administered by the Tertulias team. Transmission of data from the tablet devices to the Network Canvas Server uses end-to-end encryption, employing a symmetric Advanced Encryption Standard (AES) algorithm to encyrpt the data pre-transmission, and then using a Transport Layer Security (TLS) for the transmission. Any third-party interception of the transmission between the iPad and the Network Canvas Server would only yield heavily encrypted data. Data from the Network Canvas apps for this project will never be transmitted to any other server or entity except for the server at UNM.

Network Canvas data from the iPads will be transmitted to the Network Canvas Server in one of two ways: 1) by connecting the iPad to the UNM network via a Virtual Private Network (VPN), and then connecting to the campus-located computer running the Network Canvas Server and uploading the data, or 2) by physically bringing the iPads to campus to connect to the server on the secure UNM local area network (LAN), or 3) by transferring the data directly from the iPad to a Tertulias team laptop by a physical cable.

Responsible Party for Monitoring
The PI will be the ultimate individual responsible for monitoring risk, but facilitators and data collectors who interface with participants will have training and protocols in place in the event that they encounter a data or safety issue.

Procedures for reporting Adverse Events/Unanticipated
Adverse events or unanticipated issues related data or safety will be reported to the UNM Human Research Protections Office (HRPO).

Confidentiality
The primary risk is loss of privacy/confidentiality from participants sharing their personal data with the study team. Participants in both arms have the normal risk of loss of privacy/confidentiality that comes with participation in a research study associated with signing a consent form and providing personal information on surveys, through biological samples, and in interviews. We make all efforts to protect participant data. All project staff are trained and certified in HIPAA and CITI. We keep consent forms or lists of individuals consented orally in a locked cabinet in the office of the PI. We have protocols for dealing with hair sample data and we keep tight control over access and conduct quality control checks. Once we turn samples over to the UNM Clinical and Translational Science (CTSC) Lab, there is another protocol for logging delivery/receipt. We use the CTSC's REDCap secure data capture for survey data entry and storage, and all of our staff who deal with data through REDCap will have the required UNM account access passwords. IPads used by the Data Collectors to collect survey data are UNM password-protected. We conduct quality checks to ensure that our REDCap database is properly structured and functioning. We have a UNM-approved FTP site for safe electronic transfer of audio recording to our professional transcriptionists/translators and receipt of transcripts. Only the PI has access to this site. Qualitative data is stored on the UNM password-protected computer of the PI. We do recognize that immigrant populations often have heightened sense of the need for personal privacy/confidentiality. Therefore the Certificate of Confidentiality that we will obtain from NIH will be a part of our privacy protocol.

STATISTICAL ANALYSIS OF SURVEY RESPONSES

All statistical analyses for the project will be led by Co-I biostatistician Murray-Krezan. Descriptive statistics (e.g., means, standard deviations, medians, frequencies, and percentages) will be calculated to summarize characteristics of the study arms and to identify any variables that may differ between them thus implying need for inclusion in modeling. In general, should any outcome measures have substantial departure from normality, remedial measures such as appropriate transformations or robust methods will be used for analyses. For the primary and secondary outcome measures of each Aim described below, unadjusted mean changes over time will be calculated and compared between the study arms. Linear mixed models will be fitted to the measures with the primary independent variable of interest Study Arm**. Covariates will**

include age, marital status, number of children, other family or close friend living in same location as participant, speaks English, employed, health status, and number of group sessions attended. Least squares mean estimates and their 95% confidence intervals (CIs) for the changes over time and for the difference between arms will be calculated for the primary and secondary outcome measures. The extent of missing data will be examined, and the patterns of missing data will be assessed for randomness. This will be accomplished in part by comparing participant characteristics of those who complete the 12-month survey and related instruments to those who do not, using the non-missing data from all participants. In addition to these checks for patterns of missingness, we will evaluate whether multiple imputation methods might be appropriate. We will analyze the data using both case deletion and multiple imputation approaches and compare the results from the two methods. Should the two approaches differ markedly, we will conclude that the data missingness did not occur completely at random and will perform additional sensitivity analyses prior to reporting the results that are the least sensitive to the observed pattern of missing data. Analyses will be performed in SAS 9.4 and R 3.5 or higher.

Aim 1. To measure whether a culturally situated peer group intervention will reduce depression and stress associated with the experience of immigration**.** *Primary Hypothesis*: Intervention participants will decrease their depression scores by at least 8 points, as measured by the CES-D, from baseline to 12 months with at least a 6.5-point greater decrease than control participants (between arms effect size Cohen's $d = 0.43$ with SD=15), as shown to be feasible in prior work.[117,118] Power and Sample Size: With 100 participants completing in each arm, the minimum hypothesized changes in these measures will be detected with >80% power, assuming type I error = 0.017 for three primary outcome measures (one in each Aim). *Secondary Hypothesis*: Perceived stress (PSS-14) will decrease more over this time period in the intervention arm versus in the control arm (Cohen's $d = 0.50$).[118,119] As a tertiary outcome measure, changes of hair cortisol levels over time will be compared between arms using similar methods. The correlation between hair cortisol levels and the other outcome measures will be assessed.

■) **Lab Analysis of Hair Cortisol.** Lab analysis of hair cortisol will be led by Co-I Bearer. Hair will be pulverized in a Retsch Mixer Mill Type MM 400 100-240V 50/60HZ and extracted in methanol overnight, dried and re-suspended in buffer. Cortisol concentration will be measured by a Salimetrics immunoassay. Cortisol levels will be compared to the established averages and determined to be within normal limits or not. Summary measures (means or medians and corresponding 95% CIs, as appropriate) will be computed for hair cortisol measures at each time point and the mean changes and 95% CIs over time in each arm will be compared between arms. Correlational analysis will be performed to understand how hair cortisol levels, as a marker for stress, is related to our primary and secondary outcome measures. Following lab analysis, any remaining hair samples will be destroyed.

Aim 2. To test whether an intervention using a "women's funds of knowledge" approach results in improved resilience, knowledge and empowerment**.** ***Primary Hypothesis***: Intervention participants will have higher scores at study completion and have a larger increase over time as compared to controls on the Connor-Davidson Resilience Scale-25 (CD-RISC 25). Based on previous literature, we expect to find a moderate effect size ($d = 0.5$) of the change scores between arms, favoring the intervention arm. **Power and Sample Size:** Based on standard deviations of CD-RISC scores reported in the literature for changes over time reported when comparing two arms (SD = 1.0-9.2)[119–121], with 100 participants per arm completing both time points, we can detect a Cohen's d effect size ≥ 0.33 with 80% power and type I error = 0.017. The range of effect sizes for differences between arms previously reported range from 0.32 to 7.4.[119–121] *Secondary Descriptive Measure*: To assess knowledge and empowerment in the intervention arm only, we will calculate summary statistics for the six subscales of the Trauma-Informed Practice (TIP) Scale administered post intervention at 12 months, and an overall total score. Means and 95% CIs for the total and subscales will be reported.

Aim 3. To investigate whether a culturally situated peer group intervention using a women's funds of knowledge approach can give participants' a sense and experience of social and physical connection ("emplacement") that is lost in the process of immigration. ***Primary Hypothesis:*** **T**he experimental participants will have a marked increase in social support scores than the control group using the MOS SSS (expect $d \geq 0.5$). A limited number of previous studies[122–124] assessed changes over time between arms and reported that interventions have variable effects on social isolation, with effect sizes ranging from small ($d = 0.2$) to very large ($d = 1.5$). **Power and Sample Size:** Given our previous work where we qualitatively observed extremely positive changes in perceived social isolation[52], our sample size (100 participants per arm) will provide >86% power to detect differences between arms in change scores from baseline to 12 months on the MOS SSS with effect sizes as small as $d = 0.5$ (type I error = 0.017). *Secondary Measure*: Social connectedness will be measured using **Social network analysis (SNA).** Led by Co-I Reuben Thomas, our SNA will involve three types of analyses: *1.)* Using answers to questions modeled after the General Social Survey[113], an individual social network will be constructed for each participant. Baseline and post-survey individual networks will be compared and changes in network density and characteristics (e.g., family, friends, locality, distance) will be assessed. *2.)* The level of inclusion of *other* study participants in individual social networks pre- and post-intervention will be assessed. Combining the individual networks of participants in each intervention group will constitute what is referred to as a "complete network."[114] Complete networks can be analyzed using network-level measures--centrality, betweenness, and degree--to identify internal social dynamics of the intervention groups. *3.)* Using questions about local resources (e.g., the health insurance exchange, health navigation programs, local subsidized food coop programs, public food and benefit programs such as SNAP or WIC, free legal assistance programs, low-cost ESL and GED programs, domestic violence programs, local food charities, local clothing charities, transportation and utilities assistance programs, etc.), we will assess changes in each study participant's awareness of, knowledge about, and likelihood of accessing resources.

ANALYSIS OF QUALITATIVE DATA

■) **Qualitative Data Analysis** will be led by PI Page-Reeves using accepted qualitative analysis techniques to analyze observational, group, and policy logs, participant observer notes, transcripts from interviews and the final group session, and the stories, poetry, and art created by the participants as part of the group process**.** We will review these data using a rigorous, disciplined approach to create an empirical analysis according to Hammersley's[130] criteria for qualitative research based on plausibility, credibility, and relevance. We will follow Gläser and Laudel's[131] framework for theory-driven qualitative content analysis. We will review the transcripts and identified conceptual categories and patterns related to the domains of inquiry, extract data, and develop conceptual summaries. Following review and summary, we will code extracted data internally for systematic subthemes and their domains. We will use "constant comparison"[132] to explore interconnections between theme/sub-theme categories and make connections with concepts we identify in the literature by developing a holistic interpretation of the data. Input for the interpretation will also be provided by the Advisory Board. Based on this analysis we will further refine conceptual categories and patterns, and we will develop conceptual summaries of issues of interest. Using this refined analysis, we will conduct a secondary review of the literature to identify further ideas, concepts, and approaches to help us understand what we were seeing in the data, and we will identify ways that data from this study and our emerging analysis could address gaps in the literature and/or contribute to theory in relation to immigrant health disparities.

■) **Policy Analysis**. Policy analysis will be led by Co-I Wagner. We will document issues that we uncover that may have policy implications from the observational and meeting logs and

from interviews using the *Center for Disease Control's (CDCs) Policy Analytic Framework*[133] to inform our future implementation of this model of peer support in the context of a larger multi-level intervention. We will identify problems faced by participants, appropriate policy solutions/options, and outline strategies for policy change

ANALYTIC INTEGRATION & TRIANGULATION.

Through triangulation, we will integrate quantitative and qualitative data[134,135] with a QUAL➔QUAN simultaneous data collection and analysis approach.[136] PI Page-Reeves is experienced in using this approach. To enhance the quality and credibility of results from different methods/data sources,[137] determine areas where more complex understanding of issues may be needed, and provide a strong basis for conclusions, we will undertake side-by-side comparisons of data derived from ***1.)*** Different qualitative methods/data sources (e.g., observational, group, and policy logs, participant observer notes, transcripts from interviews and the final group session, and the stories, poetry, and art created by the participants as part of the group process), ***2.)*** Survey responses, ***3.)*** Hair cortisol testing, and ***4.)*** Social network analysis. We will create a series of user-friendly matrices intended to identify and illustrate issues of convergence, complementarity, and expansion. For example, do results from one method/data source corroborate, complement, and validate results from another method/data source, or yield a more holistic understanding of the issues under investigation. Matrices outlining different methods/ data sources will make it possible to determine the degree to which results are consistent or provide the same answer to the same research questions, i.e., does interview data concur with survey data on the degree to which participants experience a change in depression? The matrices may also reveal areas of divergence, prompting us to delve into the reasons for discrepancies. These comparisons can yield insight into points of expansion.

Dissemination

As part of the dissemination of the results of this project, we will create an art exhibit using the stories, poetry, and art created by the participants as part of the group process to show others how impactful the Tertulias project has been. We will include text of participant explanations of their work. Participants will can decide whether they want their name associated with their project, or whether they would like to have it be anonymous. They will indicate this decision on the consent form. All participants will be invited to come and see all the work.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety/Wellbeing

Risk #1: Because this research does focus on mental and behavioral health issues there is a risk that we could identify a participant who needs support or assistance beyond the regular components of participation in the study. All of our facilitators are trained in Mental Health First Aid, two of our team members are licensed mental health professionals—any of whom can be available if we identify a woman who needs individual additional mental health support related to participation in this study.

Risk #2: We recognize that it is essential that we do not just go into the community and create something and then leave the participants in a lurch when the research is done. Our work in with participants in this community-engaged study creates a responsibility on our part. Therefore, we

have created an infrastructure to ensure that the participants have the possibility of continued social support. Centro Sávila has a continuous supply of interns (social work and counseling students) who spend at least 1 year working with clients about mental and behavioral health issues. When TERTULIAS groups end, we will invite participants to continue meeting with facilitation by a pair of Centro Sávila interns. This infrastructure creates a feasible way to create continuity and sustainability.

Risk #3: There is now a risk of COVID-19 contagion associated with any in-person meeting. Therefore, participants will be at elevated risk during data collections appointments (cannot be done by Zoom or by phone because we have to gather hair samples) and group meetings—if we are able to start holding them in-person at a later point after the start of the group. We believe that the risk is offset by the potential for benefit for the participant related to both social isolation and depression. We have people in the community telling us how much they need this intervention now, more than ever. To reduce risk, we will follow COVID-19 safety guidance at the time of the activity regarding in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

13.0 Withdrawal of Subjects

We do not anticipate that any participants will need to be removed from the study without their consent. However, given that this is a group project, if a participant becomes disruptive in group sessions or has a conflict with another participant outside of the group settings that is manifesting during group sessions, we will tell the participant that they can no longer participate in the study. If any individual wishes to withdraw, they can do so at any time by notifying one of the facilitators who they interact with. If an individual is withdrawing for personal reasons or because they no longer wish to participate, they can either have the data they have provided continue to be used in the study and or they can inform us that they wish to have their data removed by letter to the PI as indicated in the consent form. If the latter, we will exclude their data from the analysis. The research team will not be required to destroy or retrieve any information that has already been used or shared before the date that the request for withdrawal is received.

14.0 Risks to Subjects

This project does not pose more than minimal risk to participants.

Before gaining informed consent of individuals, investigators will clearly explain the research, the risks to participants, and the procedures for safeguarding their privacy. Participants will be informed that they can refuse to answer any questions and stop the survey, interview, or participation in a focus group at any time. The investigators will have training and will understand the importance of these issues and their responsibility for maintaining high ethical standards and they will have current human subjects research training certification.

Confidentiality

Risk #1: The primary risk in this study is loss of privacy/confidentiality. Participants in both arms have the normal risk of loss of privacy/confidentiality that comes with participation in a research study associated with signing a consent form and providing personal information on surveys, through biological samples, and in interviews. We make every effort to protect

participant data. All project staff are trained and certified in HIPAA and CITI. We keep consent forms and a list of the names of those who have provided oral consent in a locked cabinet in the office of the PI. We have protocols for dealing with hair sample data and we keep tight control over access and conduct quality control checks. Once we turn samples over to the UNM Clinical and Translational Science (CTSC) Lab, there is another protocol for logging delivery/receipt. We use the CTSC's REDCap secure data capture for survey data entry and storage, and all of our staff who deal with data through REDCap will have the required UNM account access passwords. IPads used by the Data Collectors to collect survey data are UNM password-protected. We conduct quality checks to ensure that our REDCap database is properly structured and functioning. We have a UNM-approved FTP site for safe electronic transfer of audio files to our professional transcriptionists/translators and receipt of transcripts. Only the PI has access to this site. Qualitative data is stored on the UNM password-protected computer of the PI. We do recognize that immigrant populations often have heightened sense of the need for personal privacy/confidentiality. Therefore the Certificate of Confidentiality that we will obtain from NIH will be a part of our privacy protocol.

Risk #2: In addition to the normal individual risk of participating in a study and having participants share their data with research team members, in this study, intervention arm participants will attend group meetings where individuals will share personal stories and information. This creates another level of risk. Although we cannot assure that participants will not share information from group sessions with outsiders, we have found that group participants appreciate having a group discussion about privacy in the first group session so that everyone is clear about the risk, and if all participants are in agreement, they sign a letter of commitment to keep the personal information of others private and not to share it with outsiders. Signing the letter of commitment helps participants to realize and remember the need for privacy.

Now that the meetings are being held by Zoom, the participants are generally participating from their homes. To ensure sufficient privacy for the meetings that will ensure privacy for all participants, we are adding that we will supply participants with inexpensive ear bud-style earphones.

Safety/Wellbeing

Risk #1: Because this research focuses on mental and behavioral health issues, there is a risk that we could identify a participant who needs support or assistance beyond the regular components of participation in the study. All of our facilitators are trained in Mental Health First Aid, two of our team members are licensed mental health professionals—any of whom can be available if we identify a woman who needs individual additional mental health support related to participation in this study.

Risk #2: We recognize that it is essential that we do not just go into the community and create something and then leave the participants in a lurch when the research is done. Our work in with participants in this community-engaged study creates a responsibility on our part. Therefore, we have created an infrastructure to ensure that the participants have the possibility of continued social support. Centro Sávila has a continuous supply of interns (social work and counseling students) who spend at least 1 year working with clients about mental and behavioral health issues. When TERTULIAS groups end, we will invite participants to continue meeting with facilitation by a pair of Centro Sávila interns. This infrastructure creates a feasible way to create continuity and sustainability.

Risk #3: There is now a risk of COVID-19 contagion associated with any in-person meeting. Therefore, participants will be at elevated risk during data collections appointments (cannot be

done by Zoom or by phone because we have to gather hair samples) and group meetings—if we are able to start holding them in-person at a later point after the start of the group. We believe that the risk is offset by the potential for benefit for the participant related to both social isolation and depression. We have people in the community telling us how much they need this intervention now, more than ever. To reduce risk, we will follow COVID-19 safety guidance at the time of the activity regarding in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

Risk #4: In Y3 of the study, in the context of one of the groups, two participants in the same group recently disclosed that they are living in a situation that could be characterized as domestic violence. In neither case has there been any physical violence. In both cases, the abuse from the male spouse/partner is emotional/psychological, jealously, and controlling behaviors related to how the woman spends her time and who she sees or talks with. In one of the cases, the male sometimes takes her phone away from her and keeps it for weeks.

Immediately following the meeting where this was disclosed, members of our team who are trained in mental health first aid and experienced with domestic violence support contacted the participants individually. This was done in a way so that the participants were not put in danger. The conversations took place when the participants felt safe and when their male partners were not be aware of or disturbed by the contact. We also scheduled a meeting with our Data and Safety Management Board to discuss our response to this situation.

There are many issues to consider in relation to this situation. These women trusted in the group to open up and disclose this very private and traumatic information. At the same time, we realize that there are challenges to the safety of the participants if the spouse feels threatened by their participation in the group or to the safety of the group since the meetings occur remotely by Zoom from the participants' homes. We discussed these issues with our DSMB. The DSMB emphasized the need to consider safety first, both of the participants and for the group. The team feels very strongly that if we were to remove these participants from the group because they disclosed domestic violence, this would be experienced as punitive and the result would actually be that they would be left completely isolated and without support. This feels like it would be unethical.

In order to address the situation, we have taken a number of steps:

- Our team is keeping regular individual communication with both of the participants.
- One participant lives in Las Lunas, NM and she is already connected to a domestic violence organization there. However, she said that she does not feel that she is really receiving any meaningful support from that organization. At her request, we connected her with Enlace Comunitario.
- The other participant lives in Albuquerque. At her request, we connected her with Enlace Comunitario.

- Unfortunately, Enlace Comunitario currently has a long waitlist and while both participants are now on the waitlist, neither participant has been able to receive individualized services.
- Therefore, our team is working with each of these participants to create an "emergency plan" that would be followed if the participant feels threatened and communicates this to us, or if the participant fails to show up at meetings or to respond to texts and calls. If these things were to happen, the participants agree that we should contact the police. We have advised both participants to create an "emergency kit" containing a couple of changes of clothes for themselves and children, important documents, some money (if possible), and telephone numbers of important contacts, and to store this kit with a trusted friend outside of the home.
- We have made it clear to them that they can reach out to our team if they need assistance, resources, or a referral.
- We provide all participants with earbuds to provide as much privacy as possible since they are joining the meeting from their homes. However, we have provided these two participants with higher quality earbuds that provide heightened privacy. We are in the process of providing the rest of the participants with the same kind of earbuds.
- Each of the groups created a "safe word" that the participant can use if they feel that they are not free to talk. We have done this for every group from the beginning of the project, recognizing that participants might have children or other people around. This will prevent the people around them to know what the conversation is about. The groups have chosen safe words like chocolate that when uttered out of context, we would know that they are listening but cannot contribute to the conversation. For these two participants we are also in the process of agreeing upon a "safety signal" that the participant could use if they are on camera but cannot use the safety word and/or are in danger.
- To protect the privacy and safety of the entire group of participants, we have stopped having participants' full names displayed on the Zoom screen. Instead, we now label the zoom screen with first names and last name initial only.

15.0 Potential Benefits to Subjects

Based on our previous research and experience, we anticipate that this project will have a positive impact in the lives of participants. As indicated in the Aims, we hypothesize improvements in social isolation, social connectedness, resource knowledge, depression, stress, and empowerment. It is our experience that rather than producing anxiety, it is more likely that participants may find it interesting, rewarding, or empowering to participate in the research or to discuss the issues involved. Intervention participants will participate in a peer support group which we have hypothesized will have beneficial impact on their health and social experience. Furthermore, this research will contribute to the science of addressing health disparities for FMIs, which may be important to participants interested in an altruistic contribution.

16.0 Vulnerable Populations

We will not recruit children, individuals unable to provide consent, individuals that are incarcerated, or pregnant women.

We will obtain a Certificate of Confidentiality to further protect participant privacy.

17.0 Community-Based Participatory Research

This is a community-engaged study. We are partnering with Centro Sávila the Hopkins Center for Children and Families, and One Hope Centro de Vida. The proposed study is based on previous HRPO-approved/CTSC-funded/community-engaged research conducted by the PI with collaborators at the Hopkins Center.

The PI has extensive experience conducting research using community-engaged principles and has developed a reputation for this work both locally and nationally.

Collaborators at all three sites were involved in conceptualizing and writing the proposed project. The research team includes members from all three sites as co-investigators and the project budget is equitable in distribution of resources and salaries. Any member of the team who contributes to the work will have the potential to work on and be a co-author on presentations and publications that emerge from this research.

The Data Collectors for this project will be women who participated in the pilot study who are part of the original peer group co-created by Hopkins Center counselors and women in the group. Other team members are also members of the community of study (see table below in section 20), and ½ of the team are immigrants from Mexico or have parents who were immigrants.

All of the patient-facing members of the team are fluent in Spanish, and the majority of them have Spanish as their fist language.

Community partners and members of the population of study will be involved in all aspects of the research (conceptualization, design, recruitment, implementation, data collection, data analysis, and dissemination).

18.0 Sharing of Results with Subjects

Dissemination Strategies

■) Dissemination in New Mexico.

1.) We will present findings from this study to our research advisory board consisting of 12 FMIs who participate in the original TERTULIAS group at the Hopkins Center and who helped develop the model. We will not present results directly to the participants.

2.) We will present findings from this study at the New Mexico Public Health Association (NMPHA) which is held annually in either Albuquerque or Las Cruces.

We have budgeted for us to be able to present our work as a panel involving multiple members of the team, including community partners and members of the Advisory Board. We believe that this work will be of great interest to the professional community in New Mexico as the issues of social isolation and depression among FMIs are recognized as key health disparities. Our ability to demonstrate a scientific and measurable quantitative impact will be received as extremely exciting.

3.) Members of our team from UNM, Centro Sávila and One Hope Centro de Vida will be available to advise organizations interested in pursuing this model.

■) Local Continuity and Sustainability.

We recognize that it is essential that we do not just go into the community and create something and then leave the participants in a lurch when the research is done. Therefore, we have created an infrastructure to ensure that the participants have the possibility of continued social support. Centro Sávila has a continuous supply of interns (social work and counseling students) who spend at least 1 year working with clients about mental and behavioral health issues. When TERTULIAS groups end, we will invite participants to continue meeting with facilitation by a pair of Centro Sávila interns. This infrastructure creates a feasible way to create continuity and sustainability. One Hope will seek funding to be able to support the facilitators for groups held at their site.

■) Dissemination Nationally.

1.) We will present findings from this study at national professional conferences such as the American Public Health Association, the American Anthropological Association, the Health Disparities Conference, the Addressing Health Disparities Conference, the Southwest Anthropological Association Conference, or other relevant venues.

2.) We will publish findings from this study in peer-reviewed journals. The PI has a prolific publication record and the capacity to lead the team to produce multiple manuscripts from this work.

■) Future Research.

1.) We will apply for R01 funds to scale-up[150–153] our approach to investigate the cascading impacts of the intervention at multiple levels: on the health of children and families, on the community at large, on how participation in TERTULIAS affects participants' adaptation to the new context, if participation increases social/economic success for participants and their families, and if policy change could improve outcomes.

2.) We will develop future research to use our model for work with women from other immigrant groups.

3.) We will explore the possibility of adapting the design of this model to be appropriate to work with men.

19.0 Setting

Facilities

Recruitment and data collection will take place at locations in the community, primarily at Centro Sávila, the Hopkins Center for Children and Families, and One Hope Centro de Vida Health Center.

Centro Sávila is a behavioral health services nonprofit in the South Valley that serves a primarily low-income Latino population.

The Hopkins Center, which is run by Centro Sávila, is a behavioral health counseling center in the La Mesa Presbyterian Church in Albuquerque's International District.

One Hope is a community clinic operated by East Central Ministries, a faith-based organization in Albuquerque's International District.

All three sites work with a large number of Mexican immigrant clients and are currently participating or previously have participated in HRPO-approved research with UNM investigators, including with the PI on this project.

Advisory Board
We will present findings from this study to our research Advisory Board consisting of 12 FMIs who participate in the original TERTULIAS group at the Hopkins Center and who helped develop the model, and who previously participated in the CTSC-funded pilot study conducted by the PI and partners at the Hopkins Center. The Advisory Board will meet quarterly and provide input for troubleshooting recruitment or data collection challenges that are related to participant lifestyle or culture, and for interpreting results of qualitative analyses and final results. Advisory Board members will not have access to any raw participant data.

20.0 Resources Available

The research team reflects a collaborative partnership between researchers at UNM with the Hopkins Center for Children and Families (and its parent, Centro Sávila), and One Hope Centro de Vida Health Center. This team provides a powerful, complementary blend of clinical expertise, behavioral health science research experience, community-connectedness, academic knowledge, and community acumen that will create the synergy necessary to make this project successful. The investigators have substantial experience working with the immigrant community on health disparities, demonstrated ability to conduct research in Spanish, and the team includes 6 FMIs and 1 male Mexican immigrant team member. The PI and other team members bring expertise from anthropology that is not commonly employed in health research, and the PI has expertise in gender theory and research with women and is experienced with conducting research with the Mexican immigrant community using a community-engaged approach.

Research Team.

Research Team Member	Team Position	Title & Project Role	1st Gen Mexican Immigrant	Institution
Janet Page-Reeves, PhD **Associate Professor** Department of Family & Community Medicine & Office for Community Health	**PI**	Principle Investigator		**UNM**
Elaine Bearer, MD-PhD, FAAAS Professor Department of Pathology	Co-I	Hair Cortisol Research Lead		UNM
Molly Bleecker, MA Senior Research Scientist 1 Office for Community Health	Co-I	Social Network Analyst		UNM
Cristina Murray-Krezan, Research Assistant Professor	Co-I	Biostatistician		UNM

Department of Internal Medicine Ph.D. Candidate				
Daniel Perez Research Assistant Office for Community Health	Co-I	Research Manager		UNM
Lidia Regino, BA/BUS Health Extension Rural Officer Office for Community Health	Co-I	Lead Facilitator #2		UNM + One Hope Centro de Vida
Felisha Rojan-Minjares, MD Assistant Professor Department of Family & Community Medicine	Co-I	Project Physician	**2nd Gen Mexican Immigrant**	UNM
Bill Wagner, PhD, MSW, LCSW Executive Director & Founder Centro Sávila	Co-I	Policy Analyst & Licensed Mental Health Professional		Centro Sávila
Jackie Perez, MSW, LCSW Director, The Hopkins Center	Co-I	Lead Facilitator #1 & Licensed Mental Health Professional		Hopkins Center for Children & Families (A Project of Centro Sávila)
Maria Tellez, Lic. Research Coordinator One Hope Centro de Vida	Co-I	Co-Facilitator #1		One Hope

All members of the research team will receive training in research on human subjects. Each will take the online Human Subjects Research Training Modules from the Collaborative Institutional Training Initiative (CITI) to fulfill the requirement for NIH human subjects training. They will also take a HIPAA compliance training, obtain HIPAA certification to conduct the proposed research, and complete the UNM Conflict of Interest training and certification.

We will ensure that all team members are properly trained in the specific procedures outlined in our protocol. For Data Collectors, they will be trained on the specifics of Data Collection and protecting participant privacy, and will have REDCap passwords when appropriate.

All facilitators are trained in Mental Health First Aid and two of our team members are licensed counsellors—any of whom can be available if we identify a woman who needs individual mental health support related to participation in this study.

Study Timeline

<table>
<tr><th>Study Year</th><th>Month</th><th colspan="2">Activity</th></tr>
<tr><td rowspan="12">Year 1</td><td>1.</td><td colspan="2" rowspan="3">Hire Data Collectors, Train Staff (CITI, COI, HIPAA), Create Protocols
Create contract with local filmmaker for randomization video (a filmmaker has been identified)
Produce randomization video
conclude team certifications.</td></tr>
<tr><td>2.</td></tr>
<tr><td>3.</td></tr>
<tr><td>4.</td><td rowspan="3"></td><td rowspan="3">Recruit for COHORT #1
Consent, Randomize & Baseline</td></tr>
<tr><td>5.</td></tr>
<tr><td>6.</td></tr>
<tr><td>7.</td><td rowspan="11">COHORT #1
GROUPS</td><td rowspan="6">Conduct Interviews</td></tr>
<tr><td>8.</td></tr>
<tr><td>9.</td></tr>
<tr><td>10.</td></tr>
<tr><td>11.</td></tr>
<tr><td>12.</td></tr>
<tr><td rowspan="6">Year 2</td><td>1.</td></tr>
<tr><td>2.</td></tr>
<tr><td>3.</td></tr>
<tr><td>4.</td><td rowspan="3">Recruit for COHORT #2
Consent, Randomize & Baseline</td></tr>
<tr><td>5.</td></tr>
<tr><td>6.</td></tr>
</table>

	7.	COHORT #2 GROUPS	COHORT #1 Post Survey
	8.		
	9.		Conduct Interviews Analyze QUAL data from COHORT #1
	10.		
	11.		
	12.		
Year 3	1.		
	2.		
	3.		
	4.		Recruit for COHORT #3 Consent, Randomize & Baseline
	5.		
	6.		
	7.	COHORT #3 GROUPS	COHORT #2 Post Survey
	8.		
	9.		Conduct Interviews Analyze QUAL data from COHORT #2
	10.		
	11.		
	12.		
Year 4	1.		
	2.		
	3.		
	4.		Recruit for COHORT #4 Consent, Randomize &
	5.		
	6.		
	7.	COHORT #4 GROUPS	COHORT #3 Post Survey
	8.		
	9.		Conduct Interviews Analyze QUAL data from COHORT #3
	10.		
	11.		
	12.		
Year 5	1.		
	2.		
	3.		
	4.		
	5.		
	6.		
	7.	Analyze QUAL data from COHORT #4	COHORT #4 Post Survey Analyze Meeting Transcripts, Observation Notes, Logs & Participant shared notebooks from COHORT #3
	8.		Analyze QUANT data
	9.		
	10.	Create matrices QUAL & QUAN data	
	11.	Triangulate	
	12.	Final Analysis	

Facilities

Recruitment and data collection will take place at locations in the community, primarily at Centro Sávila, the Hopkins Center for Children and Families, and One Hope Centro de Vida Health Center.

Centro Sávila is a behavioral health services nonprofit in the South Valley that serves a primarily low-income Latino population. The PI works with them on a Kellogg-funded program grant.

The Hopkins Center, which is run by Centro Sávila, is a behavioral health counseling center in the La Mesa Presbyterian Church in Albuquerque's International District. The PI has worked with

them on a variety of projects for many years, including collaboration on an HRPO-approved/CTSC-funded pilot study that provided data for this project.

One Hope is a community clinic operated by East Central Ministries, a faith-based organization in Albuquerque's International District. The PI has collaborated with them on a variety of projects over many years, including 2 HRPO-approved research projects—one a CTSC-funded pilot and a large PCORI-funded study (current).

All three sites work with a large number of Mexican immigrant clients and are currently participating or previously have participated in HRPO-approved research with UNM investigators, including with the PI on this project.

Hopkins Center for Children and Families (The Hopkins Center)
The Hopkins Center for Children and Families (The Hopkins Center), a research partner for this project, is a behavioral health counseling program that primarily serves Mexican immigrant families located at La Mesa Presbyterian Church in Albuquerque's International District. The Hopkins Center is the continuation of the St. Joseph's Center for Children and Families (SJCCF), formerly of the Samaritan Counseling Center. The counseling program was founded in 2004 in response to a community needs assessment conducted with residents of the International District. Dr. Paul Hopkins, then the Executive Director of Samaritan, was instrumental in starting and shaping the mission of the program. In 2017, Centro Sávila (described below) took over operations at SJCCF and renamed the program The Hopkins Center. The Hopkins Center program focuses on providing quality, affordable bilingual counseling services and support for the Spanish-speaking and immigrant community in the International District. Current program director, Co-I Jackie Perez and the staff team includes licensed clinical social workers, licensed counselors, a Pathways Navigator from UNM who provides essential case management and systems navigation, and master's level interns from local social work programs. In 2009, in response to a high incidence of female patients presenting with the combined concerns of social isolation and depression, Co-I Perez implemented a social isolation support group that meets weekly. Preliminary research for the proposed project was conducted by the PI in collaboration with Perez and women from the group.

Centro Sávila
As indicated above, Centro Sávila is the parent organization for the Hopkins Center and will partner with us on this project. Centro Sávila Director, Co-I Bill Wagner will lead the policy component of the proposed project. Begun in 2012, Centro Sávila is the only Behavioral & Mental Health Clinic in Albuquerque's South Valley that serves the Spanish-speaking community. Because "place matters", their innovative support services – like Community Health Systems Navigation, *Promotoras*, Community Gardening, and Medicaid/Health Exchange Enrollment – are integrated with evidence-based individual, group, and family treatment and prevention services to meet clients "where they are." Their comprehensive model of care works to decrease health disparities in Bernalillo County by providing: outpatient mental health services, case management, Free Health Insurance Enrollment Assistance for Medicaid and the NM Health Insurance Exchange, school-based restorative justice programs, food security support, drug and alcohol counseling and recovery support, and supervision, training and research opportunities for students and health professionals. Centro Sávila, is a 501 (c) (3) non-profit organization governed by a volunteer board of seven Directors. Their treatment approach is based on the key principles of public health prevention, collective impact, community building, and collaboration. Their current staff of 18 professionals, five graduate level social work student interns, and a network of volunteers provide culturally competent care that enhances the natural resiliency of our clients. In 2017, they provided services to over 2,000 families within their

clinical, outreach & enrollment, case management, and food security programs. Their mission is to improve the behavioral health of our community through prevention and by ensuring access to linguistically and culturally appropriate, quality behavioral health services in Bernalillo and surrounding areas. Their services are offered in English and Spanish and are accessible to community members regardless of their ability to pay. In addition, they have a successful pipeline program in coordination with Highlands School of Social Work to increase the number of culturally and linguistically appropriate trained social workers through internships. Centro Sávila provides regular trainings from veteran community health workers to staff and clients about systemic barriers to accessing services that meet clients most basic needs in a manner that is strengths based, client-centered and trauma informed. In addition, The relationship of trust that Centro Sávila has created in the Mexican immigrant community will be important in allowing us to recruit from a hard-to-reach population for the proposed research project.

One Hope Centro de Vida Health Center /East Central Ministries
One Hope Centro de Vida Health Center, a research partner on this project, is a community clinic run by East Central Ministries (ECM), a non-profit, grassroots, faith-based, and social justice-oriented organization in Albuquerque's International District. ECM is the parent 501c3 organization for One Hope. Co-I Regino was a the long-time clinic Director at One Hope, Co-I Tellez is based at One Hope, and One Hope will be the site for implementation of two TERTULIAS groups each year during this project. Co-I's Regino and Tellez and One Hope have been collaborating with PI Page-Reeves for many years developing diabetes research with the Mexican immigrant community and they currently collaborate on a large PCORI-funded research project (about diabetes) under the direction of the PI. This expertise and experience provides an important foundation for the proposed project and will contribute greatly to our success.

ECM operates programs and initiatives to assist community members (primarily Latino immigrants) with access to health care through One Hope and a variety of on-site social services, including a food pantry with nonperishable goods and fresh produce, an urban farm initiative with a community garden, a housing cooperative, after school tutoring, patient navigation, and diabetes self-management and prevention services. In the summer of 2005, ECM partnered with over 50 residents of the La Mesa and Trumbull neighborhoods in Southeast Albuquerque to hold a Community Health Fair. The event was a huge success with more than 250 neighborhood participants. From that pivotal event a long-term collaborative effort formed—One Hope began that year as a partnership with the community to create a community-run clinic. One Hope has grown from a small one-room clinic to a health center with three exams rooms, two dental stations, follow-up interviews, and case management. One Hope operates three days a week to serve approximately 50 patients a week. The clinic is run by Community Health Workers, staffed entirely by volunteer providers, and does not accept health insurance. One Hope uses a multi-dimensional Chronic Care Model (CCM) for care provision. The mission of One Hope is to improve the total health of their community by partnering to leverage resources to provide affordable healthcare, follow-up, holistic health support, education, and spiritual guidance in a friendly and welcoming environment. The relationship of trust that One Hope and ECM have created in the Mexican immigrant community will be important in allowing us to recruit from a hard-to-reach population for the proposed research project.

21.0 Recruitment Methods

Recruitment.
We will recruit a total of 252 FMI participants. Our two research partner agencies (Centro Sávila with its affiliate, The Hopkins Center and One Hope Centro de Vida) that both have a large

Mexican immigrant clientele will recruit at their sites, but we will also reach out to other agencies where we have contacts. Potential participants will be contacted in-person, by email, by phone, by text, or by Zoom. For all in-person recruitment, we will follow COVID-19 safety guidance, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

We will document successful recruitment strategies**.** We will track methods used to identify potential participants at each site, # approached for interest, # who are interested/not interested, # who are screened for eligibility, and # of eligible participants who agree/decline to enter the study. We will use Consort standards[106,107] to track recruitment and attrition. We will document contextual factors or aspects of the intervention that influence participation and retention**.** We will track reasons for interest/no interest and reasons eligible participants decline to participate, and we will ask potential participants to indicate the importance of different aspects of the project in their decision (*e.g.,* time, location, group design, food sharing, babysitting, etc.). We will track attendance at meetings and attrition, and document reasons if participants leave the study.

For Y1 and Y2 participants who have already completed the intervention and completed follow-up data collection, we will reach out to them by phone, text, Zoom, or email and ask them if they would be willing to answer a few more questions. We will use the attached recruitment script. If they are willing, one of the team members will set up the meeting, administer the new questions orally, and record the responses in REDCap using a tablet or laptop. The additional data collection for Y1 and Y2 participants should only take 15-20 minutes. Participants will receive a $25 merchandise card for answering the additional questions. Because for Y3 and Y4 participants, the questions will be incorporated into the follow-up data collection, we will not offer additional incentive.

Deciding to Participate

In our current HPRO-approved, PCORI-funded research study with Latinos from low-income households, we have recruited 452 participants. Of those, 183 are FMIs. The level of education for this subset of PCORI participants is: 47% have less than an 8th grade education and another 18% have some high school but no diploma. Because we will be recruiting from the same immigrant population for this study, we anticipate that potential participants for this study will have a similarly low level of education. In addition, we know that this population may also be wary of the idea of participating in a research study. This means that we need to ensure that the consent process provides potential participants with sufficient information to allow them to provide informed consent but that it does not become so burdensome and complicated that it will be counterproductive to the study by discouraging individuals from electing to participate—which would significantly affect our ability to recruit from a participant population that is already known to be challenging to recruit.

Participation in this study would normally present no greater than minimal risk, however because of COVID-19, risk is elevated. As a result, we have instituted safety measures to protect staff and participants. Potential participants will be contacted in-person, by email, by phone, by text or by Zoom. For all recruitment, data collection and intervention-related meetings, we will use Zoom meetings when possible, and we will follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

However, because the study is complex, the consent form is extremely long (9 pages in Spanish). Moreover, randomization is a complicated concept and will need to be explained in a way that

potential participants can be sure to understand what it means and why we do it. Consenting for this study will be conducted in Spanish by FMI members of the research team who have extensive experience consenting individuals from this population through our current PCORI-funded project that has enrolled and consented 452 low-income Latino diabetes patients and social supports, including many Mexican immigrants. Given our experience, we anticipate that individual informational/consent sessions will take an hour or more to go over everything in a way that will ensure that the participant understands what it will mean to be randomized and the nature of their participation in order to decide whether or not to participate. The length of this process would create great burden on our project staff and on participants and challenge the feasibility of the study.

To address these issues, we are obtained an alteration of the consent process that includes a meeting, a PowerPoint presentation, and a randomization video (see attached script in English—the video itself is in Spanish and will be submitted when complete). Because of COVID-19 social distancing restrictions, in Year 1, we will hold this meeting by Zoom in 6 groups of 10 participants each. In subsequent years, we will determine the appropriate safety context for whether or not we meet in-person or not. We have designed a culturally appropriate group information meeting that includes detailed information about why we are doing the study and what participation will be like for individuals in both the control group and the intervention group. The presentation will include all required information that is in the consent form.

The informational meeting will be held by Zoom or if later it is deemed acceptable, at a convenient location in the community. Any in-person meeting will follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate. The meetings will be conducted in Spanish by FMI members of the research team. The informational meeting will have the following:

The informational meeting will have the following:

- A PowerPoint presentation describing (in Spanish) the scientific and social contribution that this study will make and why we are doing it. This will be submitted for HRRC approval when it becomes available and before recruitment starts.
- A detailed explanation about the research and what participation entails. The presenter will clearly explain the research, the risks to participants, and the procedures for safeguarding their privacy. Participants will be informed that they will be assigned randomly to a group, that they can refuse to answer any questions and stop the survey, interview, or participation in a focus group at any time. The investigators have training and will understand the importance of these issues and their responsibility for maintaining high ethical standards and they will have current human subjects research training certification.
- An explanation of what randomization means and why we do it. To this end, NIH funded us to produce a brief video with FMI presenters describing (in Spanish) how randomization works, and why randomization is important to help participants understand why we have structured the project to have two arms. After viewing the video, participants interested in participating will continue the informed consent process (in English or Spanish, depending on participant preference).

Randomization

After the presentation is over, those who decide not to participate in the larger research study will then be free to leave the meeting. Those who decide to participate will be asked to approach a

table or be told that they will be contacted to sign the consent form and research team members at the consent table or who do the contacting will do a brief review of the consent form. For those who are not able to participate in an in-person baseline data collection appointment because of COVID-19 restrictions, we will obtain oral consent.

There will be an option for conducting an informational session individually (in-person or by Zoom) with women who cannot attend the informational meeting or those who choose to do the consent process in private, but we will encourage potential participants to attend the meeting because we believe that for this population, the meeting process (whether in-person or by Zoom) will be more engaging and a superior context for learning about the research than going over the lengthy consent form individually, and because it will also alleviate feasibility concerns.

Consented participants will randomized to the intervention group or control group. Each woman will draw a number from a bowl. The numbers will have been randomized to one of the groups prior to the meeting. Randomization will be done using a block randomization design to allocate 50% of participants to the control group and 50% to the intervention. Random block sizes of 2, 4, and 5 will be implemented to ensure balance between arms. Intervention group participants will be offered three group meeting options to accommodate participants' schedules related to day/time and location considerations, but the three options will all be conducted using the same structure and format.

■) **Arm 1: Control**. Using a modified Attention Control Placebo (ACP) design[108] to reduce attrition over the control participation year, control arm participants will receive a bimonthly phone call from our project coordinator to check in with them and to let them know that the study is continuing. They will be given priority for entering the intervention cohort the following year as a delayed intervention if they are interested.

■) **Arm 2: Intervention.** We will conduct TERTULIAS structured dialogue groups using the model we developed and tested through our preliminary research. Each group will have 10 women and will meet weekly for two hours over a 12-month period. Group meetings will be conducted by Zoom or in-person at the community partner facilities. If in-person, they will follow COVID-19 safety guidance as appropriate for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces. Meetings will be conducted in Spanish, led by a team of two FMI facilitators. Co-Is J.Perez & Regino, experts in community-engagement with extensive experience with this population, will be the lead facilitators. All of our facilitators are trained in Mental Health First Aid, two of our team members are licensed mental health professionals—any of whom can be available if we identify a woman who needs individual additional mental health support related to participation in this study. Facilitation will use our structured dialogue approach.

Participants in both groups will not be compensated *per se.* But we recognize the time commitment they make to provide us with data and we provide an incentive to thank them for taking the time to contribute to the research. All women who attend the meeting will receive a $50 merchandise card to remunerate them for their time regardless of whether they decide to participate or not. For those who decide to participate, after they have been randomized at the meeting, each woman will receive a T-shirt with the project name and Logo. There is no requirement that they wear the T-shirt but we anticipate that it will help them feel connected to and stay involved with the research.

Those who join the study will later receive a $50 merchandise card for each research component ($50 for baseline survey, $50 for baseline hair sample, $50 for 12-month survey, $50 for 12-month hair sample, $50 for the final group meeting discussion and $50 for a subset who are

invited to have an interview), but not for participating in the support group. All participants who receive a merchandise card will be asked to sign a receipt that is required by UNM. The receipt will be used solely for project accounting purposes and will not otherwise be associated with the research data. Babysitting will be provided during group sessions and a meal will be shared. For the additional survey questions, Y1 and Y2 participants will be asked to do the survey as an additional data collection appointment. They will receive a $25 merchandise card. For Y3 and Y4 participants, the questions will be added into the 12-month follow-up survey and no additional incentive will be provided.

22.0 Number of Subjects

Sample Size. We will recruit **252 participants (N=252)**. **We will randomize participants into one of two arms.** We will enroll 60 participants each year during Y1 and Y2 (30 Arm 1 and 30 Arm 2). During Y3 and Y4, we will increase enrollment to 66 each year (33 Arm 1 and 33 Arm 2) to ensure we account for attrition to be able to power the study. Sample size accommodates attrition**.**

■) Arm 1 (n=136): Control participants will be recruited in four 12-month cohorts to coincide with the intervention cohorts.

■) Arm 2 (n=136): Intervention participants will be recruited in four 12-month cohorts. Each cohort will be divided into three groups. With 3 groups in each cohort, over the four cohort cycles, we will have a total of 12 groups.

23.0 Provisions to Protect the Privacy Interests of Subjects

Privacy & Confidentiality

Guidelines for the protection of participant privacy and confidentiality will be followed in all cases. All members of the research team will maintain current Human Subjects training. They will understand the importance of privacy issues and their responsibility to maintain the highest research ethical standards in all respects. As indicated above, we are requesting permission to make alterations to the consent process using a meeting, a PowerPoint presentation and a video. We believe that this will lead to superior understanding by the participants regarding the nature of participation and the concept of randomization. It will also make the study more feasible. However, women who choose will be able to have the information presented individually in a private setting. Also, we are requesting permission to obtain oral consent from those who are unable to attend an in-person baseline data collection appointment because of COVID-19 restrictions. When we are attempting to schedule the appointment, it may not be feasible to have the data collectors meet with the participant in-person where the consent form would be signed prior to answering baseline survey questions or obtaining the baseline hair sample if the participant answers affirmatively to COVID-19 screening questions (e.g., positive COVID-19 test, contact with a COVID-19 person, recent out-of-state travel, fever or other symptoms of illness). We are attempting to conduct in-person data collection appointments because we need a baseline hair sample in addition to the survey questions. However, if the participant is unable to meet in-person, we do not wish to exclude the participant since the intervention is being conducted by Zoom and there is no further risk of contagion apart from the baseline data collection appointment. Therefore, we will obtain oral consent by phone or Zoom and document the participant's name, the date of consent and the team member who conducted the consent. All of the consenting participants will have attended a 2-hr Zoom meeting where we describe the

study and the contents of the consent form in detail and show the randomization video. Following oral consent, we will provide the participant with a printed copy of the consent form by mail. We will conduct the baseline survey by phone or Zoom and we will attempt to schedule the hair sample collection at a later date, if feasible. If not feasible, the lack of hair sample for that participant will be recorded as missing data.

Now that the meetings are being held by Zoom, the participants are generally participating from their homes. To ensure sufficient privacy for the meetings that will ensure privacy for all participants, we are adding that we will supply participants with inexpensive ear bud-style earphones.

Surveys, gathering of hair samples, and interviews will be conducted at a location to provide privacy. The final group session will not be private as it will be a group discussion resembling a focus group.

At the beginning of each 12-month group cohort, the facilitator will instruct participants regarding privacy measures for the group context. The group participants will discuss the concept of privacy and if there is consensus, they will sign a letter committing not to discuss the content of the sessions with outsiders. All participants will be asked to sign a receipt for a merchandise card incentive which will be used for project accounting purposes only and will not be linked with or associated with research data.

Consents and participant contact information sheets will be assigned a study ID. The ID and the contact sheet will be the only link between the participant and the data. We need to be able to maintain a link between the participant and the data to be able to notify participants of meeting logistics, to schedule follow-up appointments at 12 months, to schedule interviews, and to be able to make bi-monthly check-in calls with control participants. Consent Forms, the list of participants who provided oral consent, and contact information will be stored in separate locked cabinets in the office of the PI and with access only by the investigators. All other research data will be de-identified. The only link between the participant and the data or contact information will be through the study ID. Contact information will be destroyed 5 years following the end of the study. Consent Forms and the list of those who provided oral consent will be kept for 3 years following the end of the project, at which time they will be destroyed. Participant information will be considered confidential and will not be shared. De-identified quantitative project data will be shared only per our Data Sharing Protocol. Qualitative data cannot be de-identified and therefore will not be shared. De-identified project data will be kept for at least 5 years.

Data Management
Consents and contact information will be assigned a study ID. The ID will be the only links between the participant and the data. These will be stored in separate locked cabinets in the office of the PI and with access only by the investigators. Contact information will be destroyed 5 years following the end of the study. Consent Forms and the list of those who provided oral consent will be kept for 3 years following the end of the project, at which time they will be destroyed. Participant information will be considered confidential and will not be shared. De-identified quantitative project data will be shared only per our Data Sharing Protocol. Qualitative data cannot be de-identified and therefore will not be shared. De-identified project data will be kept for at least 5 years.

Participant demographics, hair sample testing results, and survey data will be entered into REDCap. Data from REDCap will be exported to STATA and stored on a secure, managed network share maintained by our university's Health Sciences Library and Informatics Center's IT services. Data from observational notes and meeting logs will be stored on the password-protected computer of the PI. Data from interviews and group meetings will be captured on an

audio-recording device and transcribed. If in Spanish, transcripts will be translated into English for analysis. Following transcription/translation, audio-recordings will be destroyed. Transcripts of interviews and focus groups will be identified by the project ID. Electronic transcript files will be stored on secure UNM computers, accessible only to the researchers via their password-protected machines. Hard copy data will be stored in binders in the locked offices of the PI.

24.0 Compensation for Research-Related Injury

This study does not involve more than minimal risk and we do not believe there is a likelihood of research-related injury.

25.0 Economic Burden to Subjects

We do not anticipate that participation in this study will impose significant economic burden to participants. Travel to/from data collection appointments and group sessions will be necessary, but we do not believe this will be outside of the ordinary for daily life. During group sessions, childcare will be provided on-site and the group will share a meal. For data collection appointments that occur outside of the group meetings, data collectors can meet participants at a location of convenience to them which may reduce any potential economic burden. In addition, we will provide participants with a $50 merchandise card at each data collection appointment to thank them for their participation in the research and we believe that this will defray any costs incurred in participation.

Now that the meetings are being held by Zoom, the participants are generally participating from their homes. To ensure sufficient privacy for the meetings that will ensure privacy for all participants, we are adding that we will supply participants with inexpensive ear bud-style earphones. In addition,

In addition, the intervention arm participants are joining a weekly 2-hour Zoom meeting. We have identified that many participants do not have sufficient internet connection or data use plans to allow this to continue and that it is an expense to them. Since we do not want participation to be an economic burden, we are adding in a payment of $30/month per intervention arm participant to help cover the cost of allowing them to have sufficient bandwidth/plans to be able to participate. This is fundable because we had money for babysitting that we are not using because we are holding the meetings remotely. This is not an incentive, it is covering the costs they are incurring and making participation feasible.

26.0 Consent Process

Following recruitment and screening for eligibility, for participants indicating interest, a member of the research team will schedule a meeting to go over the details of the study. Whenever feasible, we will obtain written consent from all participants prior to collecting any data. We are requesting a waiver of written consent for gathering the data required to determine eligibility and contact information.

This information is necessary up front for us to recruit because as described above, we will be conducting a group informational meeting describing the research and the consent form, and because this is a randomized study, we need to show them the randomization video as described above and below to determine if they really do want to participate. We will destroy the contact information from participants who later decline to participate at the time of written consent.

In our current HPRO-approved, PCORI-funded research study with Latinos from low-income households, we have recruited 452 participants. Of those, 183 are FMIs. The level of education for this subset of PCORI participants is: 47% have less than an 8th grade education and another 18% have some high school but no diploma. Because we will be recruiting from the same immigrant population for this study, we anticipate that potential participants for this study will have a similarly low level of education. In addition, we know that this population may also be wary of the idea of participating in a research study. This means that we need to ensure that the consent process provides potential participants with sufficient information to allow them to provide informed consent but that it does not become so burdensome and complicated that it will be counterproductive to the study by discouraging individuals from electing to participate—which would significantly affect our ability to recruit from a participant population that is already known to be challenging to recruit.

Participation in this study would normally present no greater than minimal risk, however because of COVID-19, risk is elevated. As a result, we have instituted safety measures to protect staff and participants. Potential participants will be contacted in-person, by email, by phone, by text or by Zoom. For all recruitment, data collection and intervention-related meetings, we will use Zoom meetings when possible and follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate.

To address these issues, we are obtained approval for an alteration of the consent process that includes a meeting, a PowerPoint presentation, and a randomization video. Because of COVID-19 social distancing restrictions, in Year 1, we will hold this meeting by Zoom in 6 groups of 10 participants each. In subsequent years, we will determine the appropriate safety context for whether we meet in-person or not. We have designed a culturally appropriate group information meeting that includes detailed information about why we are doing the study and what participation will be like for individuals in both the control group and the intervention group. The presentation will include all required information that is in the consent form.

The informational meeting will be held by Zoom or at a convenient location in the community. If it is an in-person meeting, we will follow COVID-19 safety guidance for in-person meetings, using screening questions, thermometers, facial coverings, social distancing (6-ft when possible), and sanitization of hands and surfaces as appropriate. The meetings will be conducted in Spanish by FMI members of the research team. The informational meeting will have the following:

- A PowerPoint presentation describing (in Spanish) (English version attached) the scientific and social contribution that this study will make and why we are doing it. This will be submitted for HRRC approval when it becomes available and before recruitment starts.
- A detailed explanation about the research and what participation entails. The presenter will clearly explain the research, the risks to participants, and the procedures for safeguarding their privacy. Participants will be informed that they will be assigned randomly to a group, that they can refuse to answer any questions and stop the survey, interview, or participation in a focus group at any time. The investigators have training and will understand the importance of these issues and their responsibility for maintaining high ethical standards and they will have current human subjects research training certification.
- An explanation of what randomization means and why we do it. To this end, NIH funded us to produce a brief video with FMI presenters describing (in Spanish) (English script attached) how the randomization works, and why randomization is important, to help

participants understand why we have structured the project to have two arms. After viewing the video, participants interested in participating will continue the informed consent process (in English or Spanish, depending on participant preference).

After the presentation is over, those who decide not to participate will then be free to leave the meeting. If the meeting is in-person, those who decide to participate will be asked to approach a table to sign the consent form and research team members at the consent table will do a brief review of the consent. There will not be a waiting period for consent as there is no safety or scientific purpose to a delay. If the meeting is by Zoom, the participant will be told that a member of the team will contact them to obtain consent.

The research team members at the tables or those who obtain consent later will be Spanish-speaking and will ensure that participants understand that their participation is voluntary and that they can choose not to participate or to withdraw their participation at any point in the study. The consent form contains contact information for the PI and for the UNM HRPO in case the participant has a question or concern. Both the participant and the research team member will sign the consent form. The participant will be given a copy of the consent to keep for their files.

Also, we are requesting permission to obtain oral consent from those who are unable to attend an in-person baseline data collection appointment because of COVID-19 restrictions. When we are attempting to schedule the appointment, it may not be feasible to have the data collectors meet with the participant in-person where the consent form would be signed prior to answering baseline survey questions or obtaining the baseline hair sample if the participant answers affirmatively to COVID-19 screening questions (e.g., positive COVID-19 test, contact with a COVID-19 person, recent out-of-state travel, fever or other symptoms of illness). We are attempting to conduct in-person data collection appointments because we need a baseline hair sample in addition to the survey questions. However, if the participant is unable to meet in-person, we do not wish to exclude the participant since the intervention is being conducted by Zoom and there is no further risk of contagion apart from the baseline data collection appointment. Therefore, we will obtain oral consent by phone or Zoom and document the participant's name, the date of consent and the team member who conducted the consent. All of the consenting participants will have attended a 2-hr Zoom meeting where we describe the study and the contents of the consent form in detail and show the randomization video. Following oral consent, we will provide the participant with a printed copy of the consent form by mail. We will conduct the baseline survey by phone or Zoom and we will attempt to schedule the hair sample collection at a later date, if feasible. If not feasible, the lack of hair sample for that participant will be recorded as missing data.

In addition, participants will be asked to fill out a contact information sheet. The contact information will be gathered on a separate sheet that will be kept separately from the demographic data. The contact information will be used to schedule follow-up appointments, for meeting invitations, and for control arm check-in calls.

The consent form requests permission to be allowed to contact the participant if we have a future project that we think might be of interest to them. We will keep their contact information for 5 years after the study ends and after that it will be destroyed.

There will be an option an individual informational session with women who cannot attend the informational meeting or those who choose to do the consent process in private, but we will encourage potential participants to attend the meeting because we believe that for this population, the meeting process will be more culturally appropriate, more engaging and a superior context for

learning about the research than going over the lengthy consent form individually, and because it will also alleviate feasibility concerns.

At interviews and 12-month data collection, we will remind the participant about the study and the consent they signed and answer questions if they have any.

In Y1, we will reconsent the participants with a new consent form and an approved script that reflects the addition of the What's App chat groups in July 2021 prior to the end of the Y1 groups on July 28. We will not begin analyzing the What's App data until re-consenting has been completed. In subsequent years Y2-Y4, this information will already exist in the consent form. Given that we are still operating remotely under COVID-19 safety restrictions, we will use our existing HRPO approval for oral consent in Y1. Because we conduct baseline data collection appointments in-person, subsequent consent will most likely be conducted in-person, except in cases where that is not permissible for COVID-19 safety concerns. The consent form will have an option for the participant to select whether they would like to be part of the What's App chat group—an opt in/opt out. **With those who opt out, they will not be included in the chat group and we will communicate with them directly regarding any logistical information about the meetings.**

In January 2023, we submitted an amendment to the consent form. On the consent form, the interview with a subset of participants was listed under the bullets describing group 2 (the intervention). We have already interviewed 11 intervention participants from Y1 and have decided that we would also like to conduct interviews with some of the control participants to help us contextualize the survey responses from both groups. We are amending the consent form by moving the interview to the bulleted list that describes activities that are or are potentially conducted with participants from both arms. When we call the control participants and invite them to do an interview, we will indicate that we we added in these interviews with control participants because we want to understand their experience in the study and so we will be asking them to re-sign the amended consent form at the time of the interview to reflect the fact that they understand and agree to this change.

In addition, we changed the wording in the Spanish version of the consent to re-word the places where participants opt in or out of the WhatsApp chat group and having their name associated with the creative project. We were instructed by the data collectors who invite the participants to sign the consent that this wording was confusing to participants and always had to have more explanation. We believe that the re-wording will clarify that for when we consent Cohort #4 in summer 2023 (the last cohort).

For the additional survey questions to validate the interim qualitative analysis results: For Y1 and Y2 participants who have already completed the intervention and completed follow-up data collection, we will reach out to them by phone, text, Zoom, or email and ask them if they would be willing to answer a few more questions. We will use the attached recruitment script. If they are willing, one of the team members will set up the meeting, administer the new questions orally, and record the responses in REDCap using a tablet or laptop. The additional data collection for Y1 and Y2 participants should only take 15-20 minutes. Participants will receive a $25 merchandise card for answering the additional questions. Because for Y3 and Y4 participants, the questions will be incorporated into the follow-up data collection, we will not offer additional incentive.

We are requesting approval to obtain oral consent for Y1 and Y2 participants to answer these additional questions. They have already signed the consent form for the project. We will document the fact that they consented in REDCap.

Non-English Speaking Subjects
Because this is a study with FMIs, we anticipate that they will have Spanish as their first language and that many may not speak English well or at all. Fluency in Spanish is a criteria for inclusion in the study, as group sessions will be conducted in Spanish.

All of our project materials, including consent and the recruitment video will be available in English and Spanish. We anticipate that the vast majority of participants will prefer Spanish language materials, but in case they prefer English, both will be available.

All of the data collectors and facilitators who interface with participants in this project have Spanish as their fist language. The PI, who will conduct interviews, is fluent in Spanish.

27.0 Data Transfer/Sharing

Complete this section if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☒ Yes

☐ No. **The remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing: outgoing
C. Provide the name of the entity that data will be transferred/shared with: University of Pittsburgh
D. Provide the contact name, email and phone number with whom data is being transferred/shared with: Cristina Murray-Krezan, PhD, cmmk@pitt.edu, 412-864-3023
E. Who is responsible for transmission of the data? Janet Page-Reeves, PhD
F. Who is responsible for receiving the data? Cristina Murray-Krezan, PhD
G. Describe how the data will be transferred/shared. Please note data cannot be transferred/shared without assistance from UNM HSC IT. **Requesting HSC Central IT Transfer is detailed on the Sponsored Projects website:** Dr. Murray-Krezan will have access to REDCap. Data will be downloaded from REDCap and stored on an access-limited, password-protected University of Pittsburgh secured server behind the institution's firewall.
H. For data being transferred/shared with outside locations or entities, describe the following:

- Where is data storage and how will it be maintained in a secure manner (i.e. encryption, password protection, use of Qualtrics or REDCap, etc)?

Data downloaded from REDCap will be stored on an access-limited, password-protected University of Pittsburgh secured server behind the institution's firewall.

- What is method in which data will be collected and stored (i.e. electronic, hard copy, etc)? Data will be collected by UNM research personnel and entered directly into UNM's REDCap system.
- How long will the data be stored? The data will be stored on the University of Pittsburgh server for up to 5 years following completion of the study.
- Who will have access to data? Only Cristina Murray-Krezan, PhD will have access to the data at the University of Pittsburgh.

I. Please list all specific data elements, variables, etc. to be sent out and/or received. Indicate if the data contains identifiers and health information. Please note that identifiers that MUST be removed to make health information de-identified are as follows: Names, All geographic subdivision smaller than a State, All elements of year (except year), Telephone, Fax numbers, E-mail addresses, Social Security, Medical record number, Health plan beneficiary, Account numbers, Certificate/license numbers, Vehicle identifiers and serial numbers, Device identifiers and serial numbers, Web URLs, IP address numbers, Biometric identifiers, full face photographic images, and Any other unique identifying number, characteristic or code.) Demographic characteristics including DOB, health status (pregnant, whether using medications, sleep quality), questions about experiences with social isolation, discrimination, COVID questions (ever tested, diagnosed, employment/healthcare/lifestyle disruption/changes due to COVID), Center for Epidemiologic Studies Depression Scale (CES-D), Perceived Stress Scale (PSS-14), Connor Davidson Resilience Scale (CD-RISC), Medical Outcomes Study Social Support Survey, Trauma-Informed Practice Scale (TIP), intervention evaluation questions.

J. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information? Yes
   a. ***Or*** is HIPAA authorization altered or waived? No

K. What is the classification of the data (de-identified, limited data set, protected health information, other). Limited data set

L. Does the request to transfer/share data include clinical data that belongs to the UNM Health Systems? No

M. Does the data to be transferred/shared include information about patients seen at external health system or at a third party medical provider? No

N. Is the external entity a "covered entity"? yes

O. Is the data that is going to be transferred/shared owned or partially owned by another party or have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)? no

P. Is the data publically available? If yes, please provide details: no

Q. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health? Yes-depression only

28.0 Specimen Transfer/Sharing

Complete this section if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

- *Where is specimen storage and how will it be maintained in a secure manner?*
- *What is method in which specimens will be collected and stored?*
- *How long will the specimens be stored?*
- *Who will have access to the specimens?*

29.0 Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☐ ☑ The information supplied in this form and attachments are complete and correct.

☐ ☑ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☐ ☑ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of de-identified data**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.