Vale+Tú Salud: Corner-Based Randomized Trial to Test a Latino Day Laborer Program Adapted to Prevent COVID-19

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Protocol Title:	Vale+Tú Salud: Corner-Based Randomized Trial to Test a Latino Day Laborer Program Adapted to Prevent COVID-19
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Population:	Latino day laborers, N= 600, males, ages 18 and older, ordinary health status living in the Houston metropolitan area location
Number of Sites:	Single site
Study Duration:	Five years
Subject Duration:	From baseline to post-test is one month approximately.

General Information

Our project, Vale+Tú Salud (Your Health is Worth More) is a five-year intervention study that extends our previous work addressing injury prevention among Latino Day Laborers (LDL). Our project's goal is to promote group problem solving and a commitment to implement COVID-19 mitigation strategies among LDL by using evidence-based participant recruitment, engagement, and intervention strategies that have been successfully tested among LDL in our previous study (Vale+Tú). We hope to address the following question: Can an adapted Latino Day Laborer program increase adherence to COVID-19 mitigation practices, including vaccination, which reduce the risk of COVID-19?

Background Information

Latinos across the US, particularly those born outside the US, are disproportionally affected by the COVID 19 pandemic. In Texas, although Latinos compose 40% of the State's population, they account for the majority of COVID 19 fatalities. Within the immigrant Latino community, LDL may be especially vulnerable. LDL are older, on average, than other Latinos and are less likely to have health insurance. LDL often experience periods of homelessness or live in substandard housing and share living quarters in crowded conditions. Many LDL are engaged in occupations such as construction and cannot work from home. LDL perceive their well-being (bien estar) in terms of their ability to provide for their families, but experiences of wage theft and other forms of abuse lead to feelings of isolation and despair (*desesperación*) as well as depression and anxiety. On the other hand, LDL possess resources which promote resiliency. These include social support networks composed of other LDL, family, friends, employers, church members, and sports teams.

Adherence to COVID 19 mitigation practices among LDL is often lacking. LDL do not always have access to restrooms or are given time by employers to engage in hand washing. Social distancing at locations where LDL gather to seek employment (corners) may be problematic as LDL want to socialize with their coworkers and approach potential employers in groups. Our recent observations of Houston corners found low levels of mask use and social distancing among LDL. In addition, less than 50% of Hispanics received the influenza vaccine during the 2018-2019 flu season in Texas.

How these structural and psychological factors effect COVID-19 mitigation practices and how they can be addressed in a brief intervention have not been studied locally.

Program content. Vale+ Tu Salud is designed as a small group, corner-based participatory learning and action intervention that is intended to be easily adopted by existing community-based organizations working with the LDL community for dissemination across geographic sites in the U.S. and corners where LDLs gather for work. Three core components comprise the intervention:

Group Problem Solving Component: This component incorporates popular education activities aimed at: developing social cohesion among LDLs; building awareness about COVID-19 risks and protective behaviors; and developing a plan of action to reduce their and their peers' risk for COVID-19 transmission. Action plans to be developed by the participants may include development of a personal and group commitment to keep each other safe via COVID-19 prevention practices; increasing PPE use (masks), handwashing, and observing social distancing practices (e.g., new ways for greeting other than handshaking) at worksites; and dissemination of information regarding social service resources to buffer the effects of COVID-19. As part of this component, LDL participants will be presented with pictures and narratives describing hypothetical hazardous COVID-19 workplace scenarios, and then problem solve together to develop risk reduction strategies, resulting in a plan of action to promote individual and LDL coworker protection from COVID-19.

Navigation Component: This component will consist of providing information and linking LDLs with social service providers that can help buffer some of the social and economic effects of the COVID-19 pandemic, which may include resources for increasing food security, access to healthcare, and other social service support. As cited above, we will also aim to link LDL participants with COVID-19 testing and vaccination sites.

"Multiplicador de salud"/Health Multiplier Component. The health multiplier component builds from the theoretical and practice-based method of mobilizing social networks and social support, defined as *encouraging social networks to provide informational, emotional, appraisal, and instrumental support* as cited in the Taxonomy of Behavior Change Methods. LDL participants will be invited to be key partners with Vale+ Tú Salud and to participate in our diffusion efforts by mobilizing their peers, co-workers, and families to take action to protect themselves and others from COVID-19. In doing so, participants will be provided with COVID-19 prevention flyers and social resource lists to distribute within their immediate social circles.

Study Design

Being mindful of the need to address the current pandemic emergency, we propose to implement our COVID prevention program using an adaptive, pragmatic approach for pandemic trials recently recommended by Branch-Elliman et al., (2020) that will allow us to deliver our intervention promptly. We will test the effectiveness of our program in three phases that progressively build on each other and target evolving prevention priorities-including those that are emerging (e.g. vaccination) and those that are more established (e.g. face mask use), using prevention strategies previously tested in our Vales+Tu injury risk reduction intervention and adapted for our current purposes.

Implementation of the trial will occur using a phased approach, including a rapid initial phase that will adapt our current resources so that we may start the intervention program faster. The three phases will proceed as follows:

- Rapid adaptation – AIM 1 & AIM 2 (Phase 1).

We will combine AIM 1 and AIM 2 (Phase 1) into a rapid adaptation phase by using existing Vales+Tu (injury risk reduction) manuals of study procedures describing enrollment, intervention, and evaluation procedures applicable to this new trial; this will save valuable time in getting the study up and running.

Using intervention mapping, the program content will be adapted from COVID data on mitigation practices (PPE, mask, and hand sanitizer use) and barriers collected in the current injury trial, and from a review of the literature identifying antecedent factors to implementing COVID-related mitigation practices among day laborers and other Latino immigrants. We will combine the process described above to expedite the implementation of the trial, to develop a baseline survey instrument to collect information about the determinants of COVID 19 mitigation practices among Latino Day Laborers.

The information collected during this rapid phase will serve as the foundation to answer our AIM 1 research question and as the initial phase 1 of our clinical trial (AIM 2) from which subsequent phases will be adapted.

- AIM 2 (Phase 2 & 3).

These phases will build on lessons learned in the rapid adaptation/Phase 1, including the structural equation modeling of psychosocial determinants (AIM1) that will improve our ability to more solidly target determinants of COVID prevention practices unique among our target population in the second iteration of the program. We will conduct two additional clinical trial phases, each consisting of 200 participants, to test our AIM 2 hypothesis. After each phase, analysis will be conducted, and the information will be used to improve upon the next phase.

Our study also includes a third aim (AIM 3) that is focused on disseminating the results from phases 1-3 and on capacity building.

Implementation phases 1-3 are part of the cluster randomized trial to determine our COVID program efficacy among Houston LDL . We will use an experimental and control group design with both conditions randomly assigned at the street-corner level, while the intervention will be delivered at the individual (LDL) level. The treatment arm will consist of a small group, corner-based participatory learning and action intervention. The standard of care arm will consist of COVID-19 informational and OSHA safety brochures. This will be a five-year study. An individual's participation would consist of a baseline and a one-month follow-up survey.

We will develop a survey tool to gather information related to workers' current personal and psychosocial characteristics, work conditions, attitudes and beliefs regarding COVID-19 and vaccination, and COVID-19 mitigation practices. The assessment will validate psychosocial and other measures used in our previous studies as well as newly developed items. This assessment will be used during our rapid implementation phase and allow us to make any necessary adjustments to our study measures before conducting phase 2 and phase 3 of our clinical trial.

Initially, our intention is to use the same baseline instrument for all three phases unless our formative work post phase 1 indicates a need to make substantial changes to our tool before conducting phases 2 and 3. If changes are made to the instrument after phase 1, we will re-submit our materials for CPHS approval.

Objectives

There are three specific aims of this study.

Rapid Adaptation phase includes AIM 1 and AIM 2 (PHASE 1)

> **AIM 1:** ***Determine the cultural, socioeconomic, inter/personal and work-related factors that influence COVID 19 mitigation practices including social distancing, hand-washing and PPE use.***

Due to increasing needs of our population and the disproportionate impact that COVID 19 is having on Latino Immigrant workers, we are doing a rapid adaptation phase to accomplish aim 1. The goal of the

rapid assessment include:

a. Conduct COVID 19 needs assessment survey with 200 LDL at randomly selected corners.
b. Establish the influence of multilevel determinants on mitigation practices using a structural equation model.

Research question: What multilevel determinants influence LDL adherence to COVID 19 mitigation practices?

AIM 2: Adapt, implement, and test Vale+Tú Salud in a cluster randomized trial to assess the extent to which LDL report increased adherence with COVID 19 mitigation practices 1 month post intervention.

a. Use Intervention Mapping to adapt current LDL program (NIH Stage I) for COVID 19 prevention.

b. Test Vale+Tú Salud efficacy in a CRT with 600 LDL (200 X Phase 1 (Rapid Adaptation) (200 x Phase 2) (200 x Phase 3) from 30 randomly selected corners.

Hypothesis: At post-test, LDL who participate in (a) a small group problem-solving activity will report greater adherence with COVID 19 mitigation practices compared to (b) LDL receiving COVID-related resources only.

Aim 3: AIM 3: Promote Vale+Tú Salud just-in-time results and increase its capacity to rapidly disseminate findings among groups that serve LDL and other Latino immigrants.

a. After CRT Phase 1, work closely with the CAB and LDL leaders to rapidly disseminate strategies that effectively increase COVID 19 mitigation using social media and other appropriate Latino media channels.

b. If CRT Phase 1 and 2 are successful, work with community-based organizations to disseminate best practices, and provide curriculum materials and technical assistance to maximize the adoption of practices that can assist multiple groups of vulnerable Latino workers in preventing COVID 19.

This application is being submitted in response to PAR-20-237 *Community Interventions to Address the Consequences of the COVID-19 Pandemic among Health Disparity and Vulnerable Populations*. In the short term, we expect our program to address the urgent need to prevent COVID 19 among LDL by testing its effectiveness in promoting mitigation practices and the COVID 19 vaccine, when it becomes available. Over the longer term, we expect that the lessons learned in this COVID 19 prevention program will transfer to other work and life domains where LDL may adopt similar practices to reduce other health risks.

Clinical Trial Description

Clinical Trial

Selection of the study population. The study population will be Latino Day Laborers present at randomly selected study corners.

Inclusion/exclusion criteria. A screener form will be used to assess eligibility. In order to be eligible, an LDL must be at least 18 years old; identify as Hispanic or Latino; be at the corner for the purpose of looking for work; and have been previously hired at a corner. LDL not meeting these requirements will be thanked for their time and informed they are not eligible to participate. LDL will also be asked if they have experienced symptoms of COVID-19 in the previous 48 hours (fever, cough, sore throat,

fatigue, etc.). Those reporting symptoms will be thanked for their time and informed they are not eligible to participate and will be given a brochure with COVID related resources.

Obtaining Informed Consent:

Participants will be asked to provide oral informed consent to take part in the survey. Potential participants will be told the purpose of the assessment, that they can refuse to answer any item and that they can pause the assessment to talk to potential employers or attend a job. The interviewer will explain that the study has been granted a Certificate of Confidentiality and that all responses will be protected. If the potential study participant does not provide informed consent, he will be thanked for his time but will not be able to take part in the survey.

Recruitment Strategy. The Outreach Coordinator and the LDL interviewers will visit the selected corners and approach LDL about participating in our study. After obtaining oral informed consent, the participant will be asked to complete the baseline survey, which should take no more than 45 minutes to complete. Corners will be randomly assigned to receive the intervention or the standard of care, with all LDL recruited at a given corner being assigned to the same study arm. We will select a mixture of corners based on the number of LDL previously observed: small (less than 15 LDL), medium (15-29 LDL), and large (30 or more LDL).

Study Procedures

Eligible LDL who wish to participate will be asked to provide verbal informed consent. After enrollment into the study, participants will complete a baseline survey. The survey will be administered electronically via an iPad and each participant will complete the survey in private, with assistance from study personnel. The baseline survey should take approximately 45 minutes to an hour to complete. The purpose of the assessment is to gather information related to workers' current personal and psychosocial characteristics, work conditions, attitudes and beliefs regarding COVID-19 and vaccination, and COVID-19 mitigation practices. The assessment will validate psychosocial and other measures used in our previous studies as well as newly developed items. The results of the assessment will help us identify priority needs for COVID-19 prevention and mitigation that will inform the intervention mapping process and implementation of phase 2 and 3 of the intervention program.

See table 1 below for additional information about the constructs to be included in our survey.

The intervention will consist of three core components:

Group Problem Solving Component: This component incorporates popular education activities aimed at: developing social cohesion among LDLs; building awareness about COVID-19 risks and protective behaviors; and developing a plan of action to reduce their and their peers' risk for COVID-19 transmission. Action plans may include development of a personal and group commitment to keep each other safe via COVID-19 prevention practices; increasing PPE (masks), handwashing, and social distancing practices (e.g., new ways for greeting other than handshaking) at worksites; and dissemination of social service resources to buffer the effects of COVID-19. As part of this component, LDL participants will be presented with pictures and narratives describing hypothetical hazardous COVID-19 workplace scenarios, and then problem solve together to develop risk reduction strategies, resulting in a plan of action to promote individual and LDL coworker protection from COVID-19.

Navigation Component*:* This component will consist of providing information and linking LDLs with social service providers that can help buffer some of the social and economic effects of the COVID-19 pandemic, which may include resources for increasing food security, access to healthcare, and other social service support. As cited above, we will also aim to link LDL participants with COVID-19 vaccination services contingent upon vaccination availability.

"Multiplicador de salud"/Health Multiplier Component. The health multiplier component builds from the theoretical and practice-based method of mobilizing social networks and social support, defined as *encouraging social networks to provide informational, emotional, appraisal, and instrumental support* as cited in the Taxonomy of Behavior Change Methods. LDL participants will be invited to be key partners with the Vale+Tú Salud by mobilizing their peers, co-workers, and families to take action to protect themselves and others from COVID-19. In doing so, participants will be helping our diffusion efforts and they will be provided with COVID-19 prevention flyers and social resource lists to distribute within their immediate social circles.

The specific elements of the intervention will be refined based on the results of the intervention mapping sessions described above to adapt our Vales+ Tu injury program. In addition, results from the rapid adaptation will be used to further improve our intervention.

The standard of care arm will receive COVID-19 prevention flyer and social resources list only.

One-month follow-up surveys with participants will be conducted following the baseline survey and intervention. The follow-up survey will be conducted by phone at a time convenient for the participant. We will consider using an automated phone survey system such as CallFire to conduct the follow-up.

The clinical trial will be conducted in three phases and will follow the schedule below:

- Rapid Adaptation Phase 1 (AIM 1 & AIM 2 (Phase 1)) will be conducted with 200 LDL.
- Phase 2 (AIM 2 (phase 2) will be conducted with 200 LDL.
- Phase 3 (AIM 2 (phase 3) will be conducted with 200 LDL.

After each phase, we will review the implementation of the trial and baseline survey results. Recruitment activities, the survey, and the intervention will be revised as necessary.

No invasive procedures will be employed, and no biological specimens will be collected.

Clinical Trial Compensation

Participants in the trial will receive a $50 gift card for completing the baseline survey and group activity and a second $75 gift card for completing the follow-up survey. At post test, arrangements will be made to mail the gift card to the participant or to deliver the card in person at an agreed upon location. Interviewers will be responsible for the distribution of the incentives. An incentives log will be kept to track the distribution process.

Table 1. Constructs and Measures for Vale+Tú Salud

Constructs	Scale	Previous Use	Original Source	# of Items	α
COVID-19 Psychosocial Factors	COVID-19 Knowledge	Adapted from Geldsetzer, 2020.		4	
	Perceived Severity	Adapted - John Hopkins University COVID-19 Community Response Survey		4	
	Perceived susceptibility	Adapted - John Hopkins University COVID-19 Community Response Survey		3	

	COVID Self-Efficacy and Outcome Expectations	Adapted - World Health Organization COVID-19 Survey Tool and Guidance, 2020.		5	
	COVID Exposure	Adapted – Boston University COVID-19 Symptoms & Social Distancing Web Survey		6	
	Health Status and Access to Care	Adapted – Boston University COVID-19 Symptoms & Social Distancing Web Survey & the Houston Education Research Consortium – Gulf Coast Coronavirus (COVID-19) Community Impact Survey		12	
	COVID-19 Impact	UTHealth Community Attitudes Toward COVID-19 and Mental Well-Being & Data Foundation COVID-19 Household Impact Survey		22	
	COVID-19 Work Impact	Adapted – Boston University COVID-19 Symptoms & Social Distancing Web Survey		11	
	Sources of Information	Adapted - Data Foundation COVID-19 Household Impact Survey		5	
	Trust in sources of information	Adapted - Data Foundation COVID-19 Household Impact Survey		1	
	Intention to adhere to Mitigation Practices	Developed by the research team		11	
	Barriers to Health Care Access	Developed by the research team		3	
	COVID-19 Vaccine attitudes	Adapted - World Health Organization COVID-19 Survey Tool and Guidance, 2020.		8	
	Social Isolation	Social Isolation	Diaz, Ayala, Bein et al., 2001.	7	.78
	Stress	Perceived Stress Scale	Adapted from Cohen, Kamarck, & Mermelstein, 1983.	6	.86
	Anxiety	6-item STAI-E (STAI-E6)	Perpiñá-Galvañ, et al, 2013.	6	.79
	Quality of Life	CDC			
	Substance use	Adapted - Alcohol Use Disorders Identification Test (AUDIT)	Used in Fernández-Esquer, Gallardo, & Diamond, 2018.	10	-
	Depression	Used in Corner survey	7-item CES-D Levine, 2013.	7	.83
	Resilience	Brief Resilience Scale	Smith, Dalen, Wiggins et al., 2008.	6	.84
	Optimism	Life Orientation Test – Revised (LOT-R)	Efuni, 1994.	9	.66
	Religiosity	Religiosity	Boyas, Valera & Ruiz, 2018.	3	-

	Coping Strategies	Brief COPE	Carver, 1997.	24	.50 +
	Perceived Social Support	Used in Rapid Needs Assessment	Barrera, Sander, & Ramsay, 1981.	10	.93
Practices	COVID Mitigation Practices	Adapted from Park, Russell, Fendrich et al., 2020.		8	-
Work conditions	Wage Theft	Used in Rapid Needs Assessment	Adapted from Zoeckler, Lax, Gonos, et al., 2014.	2	-
	Safety Climate	Used in Corner Survey	Fugas, Silva, & Mejia, 2012.	6	.85
	Risks at the jobsite	Used in Corner Survey	Fernández-Esquer, Fernández-Espada, Atkinson et al. 2015.	6	.77
	Work Conditions	Used in Corner Survey	Fernández-Esquer, Fernández-Espada, Atkinson et al., 2015.	14	.89
	Risks at the corner	Used in Corner Survey	From Focus Groups	9	.77
	Working Climate	Used in Corner Survey	Fernández-Esquer, Fernández-Espada, Atkinson et al. 2015.	11	.82
Socio-Economic Stressors	Everyday Discrimination	Used in Rapid Needs Assessment	Williams, et al., 1997; Kessler, Michelson, & Williams, 1999.	5	.84
	Discrimination justification	Used in Rapid Needs Assessment	Williams, et al., 1997; Kessler, Michelson, & Williams, 1999.	13	.90
	Immigration Stress	Disappointment about Life in US. Deportation-Related Worry Fear of Venturing Out as an Imm.	Fernández-Esquer, Gallardo, & Diamond, 2018.	5 3 7	.71 .71 .89
	Situational Stress	Used in SHILOS	Fernández-Esquer, Gallardo, & Diamond, 2018.	19	.80

HUMAN SUBJECTS

Overview

The School of Public Health is mindful of the need to balance two concerns during the current pandemic. One is to conduct robust and significant community-based research. The other is two respect the safety of research participants and staff. Towards addressing these concerns, the School has developed *Guidelines for Conduct of Community-based Research During the COVID-19 Pandemic*. This *Guide* includes best practices for preparing staff, participants, and study sites for research activities.

Summary of Investigator Actions Needed to Conduct Research with the COVID-19 Pandemic

1. Follow standard recommendations where applicable. This include UTHealth guidance; state-, county-, and city-level rules; Centers for Disease Control and Prevention (CDC) recommendations; OSHA recommendations; and any guidance specific to the community setting (e.g., Texas Education Agency (TEA) for schools).
2. Prepare for community-level research with COVID-19. Preparations include: staff preparation/training, assessment of staff risk, modification to protocols, obtaining personal protective equipment (PPE).
3. Assess risk level in the community and for study participants. Entry into the community and staff/research preparation will depend on the current level of community transmission, as well as the setting (e.g., school, childcare center, long-term care facility, prison, etc.).
4. Communicate frequently with research staff, community partners, and appropriate UTHealth departments (e.g., Committee for the Protection of Human Subjects, etc.).
5. Document the process.

Research staff will adhere to recommendations regarding the use of PPE and social distancing, both at the School and in the field. Staff will be trained in the proper use of equipment and other protective measures. We will maintain an adequate supply of equipment for use by staff and distribution to participants in the field. We will maintain use of PPE and social distancing in the field. We will assess risks in the field by consultation with LDL at potential recruitment sites and monitoring of relevant data sources. We will provide testing information and referrals to staff member and participants and will take appropriate step for individuals who may exhibit symptoms. We will maintain regular communication between research staff and our community partners. We will adjust protocols as necessary.

The *Guidelines* contain a set of Checklists for the recommended guidelines. Training in the use of these will be provided to research staff. The use of these and other relevant procedure will be included in a Manual of Procedures.

We have incorporated Covid mitigation procedures into our activities below.

Subject Characteristics.

As outlined in the body of the proposal, study participants will be Latino day laborers (LDL). Participants will be Latino immigrant men from Mexico and Central America (mostly from Honduras, El Salvador and Guatemala), recruited from street corners and other day labor sites located in neighborhoods predominantly populated by Latinos in the Houston metropolitan area. Program activities will be conducted by phone and in-person.

Sources of Materials

Once participant consent has been requested and obtained, primary assessment data will be collected through individual interviews. All the information will be stored in a password-protected computer and only the principal investigator (Dr. Fernandez-Esquer) and the project director will be granted access to

records that identify individual participants. Any tracking information written on paper will be destroyed after it has been entered in the computer.

Potential Risks

We anticipate that the most likely risks of participation in the interviews are the following: (1) embarrassment and anxiety, (2) lack of trust in the interviewers, (3) fear of loss of privacy, (4) missed opportunity to get a job, (5) conflict with coworkers, (6) conflict with police. We discuss the strategies we will adopt to minimize these risks below.

Experiencing embarrassment and anxiety during the interview: The discussion of the impact of COVID 19 related social and contextual stressors may be sensitive for some workers who prefer not to share this information with outsiders. Although most participants in our previous surveys spoke candidly about their experiences, we expect there will be a few LDL unwilling to share this information. Given the precarious nature of day laborers' living conditions (poverty, undocumented status, unstable jobs), they may feel anxious about sharing information of a sensitive nature during the interviewing process. We will instruct interviewers to address participants' concerns, to note their comments in the section indicated at the end of the interview, and to provide a list of health services and other community referrals (e.g. community organizations, churches, support groups) to assist LDL with COVID 19-related needs or other health concerns for which they may need support.

Lack of trust in the interviewing team: Strategies to reduce distrust and increase comfort with the interviewers will be discussed during interviewer training. Although day laborers at the corners selected for recruitment may already be familiar with the UT team through our previous injury prevention program activities, they might not be familiar with the LDL interviewers to be hired for this proposed study. To foster trust in both the face-to-face and in the phone administration of program activities, we will emphasize the anonymous nature of the activities and procedures to protect data collected for this study. To foster trust in the interviewers, for surveys conducted over the phone (Aim 1), we will train the interviewing staff to establish rapport before the start of the interview. If the survey is conducted on location, staff members familiar with the corners will introduce the interview team to the workers present, explain the purpose of the interviews and will stay present (observing social distance) during the interview process to be of further assistance if necessary. Interviewers will also provide workers with the names and telephone numbers of the principal investigators and will encourage workers to contact them by phone if they have any questions.

Loss of privacy: Interviewers will conduct phone-based activities form our office location, where we will be able to use cubicles designated for interviewing purposes. Each interviewer will be assigned to a separate cubicle to maintain social distance and privacy of the interview. Field-based activities will be conducted in a public location, most likely the corner itself. This means that there will be activity and other people present, while the day laborers are completing the interview or intervention and that there will be a need to enforce social distancing. We will create social distance by creating "rooms" with the use of orange cones and yellow tape that will allow the interviewing team to create a barrier between onlookers and the interview process, while at the same time maintaining auditory privacy in a public space. Each interviewer will also be trained to be aware of other people in the vicinity of the interview and respectfully request onlookers to move away from this location. We will position the interviewing "rooms" in an area that is at a distance from the busiest hiring location to avoid interfering with other workers' activities. LDL who participate in our program activities will be required to wear a face covering while interacting with program staff. If they do not have a face covering, we will provide them with a face mask. In addition, we will provide them with hand sanitizer at the beginning and at the end of their participation in our research activities. Project staff will also be required to use hand sanitizer frequently and to wear gloves. All COVID-19 protective equipment will be provided as part of our project.

Loss of a potential job: We are aware that day laborers are at the corner waiting for an opportunity to get a job. We will be mindful of their needs and will be ready to suspend interviews when necessary. During the informed consent process, participants will be told that they can leave the interview at any time. If they are waiting for a boss, and he arrives, they can stop the interview and complete it on a different date.

Balancing the need to suspend an interview with the need to minimize attrition will be monitored carefully, and the workers' needs will take priority. Interview times will vary throughout the day, so as not to have interviewers always present at the peak of the hiring activity. We will design an interview that will take no more than 45 minutes to administer, considering the time pressures at the corner. We will implement a detailed set of procedures to minimize the risk of missed job opportunities. Procedures will include being flexible in conducting and suspending program activities, allowing participants to leave for jobs and resume activities at a later time, and minimizing interfering with day laborer activities.

Conflict with coworkers not participating in the interviews: We expect that not all LDL looking for work at a selected corner will be interested in participating in our study. In our previous programs at the corners, we have found that participants not interested in being interviewed simply ignored the presence of our team and kept their attention on ongoing job hiring activities. Considering that the mere presence of our team at the corner may make some LDL uncomfortable, we will inform all LDL during recruitment that the program will emphasize documenting the experiences of LDL in dealing with COVID-19 while protecting conversations and respecting day laborers' ability to make their own choices. If workers at a location feel uncomfortable with our activities, we will opt for a different program location and will document instances of resistance to our study.

Despite the low incidence of conflict in our previous studies, the safety and well-being of day laborers is a constant concern that will be revisited during the current study. In the previous project we instituted strategies that we plan to implement again to protect the confidentiality and safety of study participants. Interviews at the corner will be conducted away from the area where job hiring activities are taking place. This distance may minimize employers' curiosity about program activities. However, if employers want to inquire about the presence of the project team at the corner and the ongoing activities, they will be informed about our study and provided with the contact information of the principal investigator if they would like more information. Typically, most potential employers stop at a day labor corner long enough to solicit workers and establish a basic working agreement. This engagement lasts no more than 3-5 minutes, and we expect that after they are informed about the purposes of our project, most employers will be satisfied and move on to focus on their own affairs.

Conflict with the police: Even when the presence of the Latino day laborers is public and at locations where there is heavy traffic, they are rarely the direct target of police intervention or immigration raids. Instances when a corner group is targeted by the police due to a neighborhood complaint, the group often relocates to a different nearby location before returning to the corner. As local businesses that cater to LDL are typically aware of their movements, we will contact them to identify the new corner location and continue our program activities.

An immigration arrest is an event likely to happen to Latino immigrants anywhere in Houston, even at day labor corners, without warning, and due to circumstances outside the control of our study. We believe that participation in our study will not bring undue attention from ICE or alter LDL arrest risk. We will request a Certificate of Confidentiality to reassure day laborers concerned about sharing personal information with our project. If a worker is arrested or could have been arrested in an immigration-related event, we will provide assistance by linking the study participants or their families to professionals and other community organizations who can provide legal and other types of assistance.

Adverse events

Should any unintended or adverse events occur, we will follow procedures for reporting adverse events which is required by the University of Texas Health Science Center Committee for the Protection of Human Subjects.

The research team will utilize the following response procedures for adverse events:

1. Research team members will immediately report any breaches of data security or confidentiality directly to all other research team members and to members of the CAB via email.

2. Research team members will immediately report any perceived distress related to program activities as well as the response of the team member to that distress such as providing a specific referral. These reports will be further discussed at team meetings and with the CAB to insure that our current procedures are minimizing the risk and are working as desired.

3. Research team members will immediately report any perceived loss of a work opportunity related to program activities as well as the response of the team member to that situation. These reports will be further discussed at team meetings and with the CAB to insure that our current procedures are minimizing the risk and working as desired.

4. For all events listed above, the PI (Drs. Fernandez-Esquer) will complete a Problem Report Form and submit the form to the Committee for the Protection of Human Subjects (CPHS) at UTSPH. The form is reviewed by an IRB Administrator/Coordinator.

5. Upon receipt of the Problem Report Form and appropriate level of review by staff, CPHS will make a determination about whether further action may be required. Available actions may include:

a. Modification to the protocol.

b. Notification to past participants by phone or letter.

c. Modification of the continuing review schedule.

d. Monitoring of the research.

e. Suspension or termination of the research according to IRB SOP on "Suspension or Termination of IRB Approved Research".

f. Referral to legal counsel, risk management or the institutional official.

g. Other appropriate action as determined by the IRB.

Adequacy of Protection Against Risks

Recruitment and Informed Consent.

All 3 phases of the study will involve the completion of a baseline survey, delivery of the interventions at the corner, and post-test survey conducted over the phone. Day laborers will be approached at the corners where they wait for work by the corner coordinator and other study recruitment staff and will be invited to participate in the study. We will describe procedures to protect the confidentiality of the collected information. If an individual agrees to take part in an interview, they will be directed to one of our interviewing "rooms." As described above, this will consist of a space delineated by orange cones and tape. The interviewer will request oral consent after reading a consent statement explaining the overall purpose of the study and of the interview and intervention, the right to refuse to answer any question, and the right to terminate the interview at any point without reprisals. The consent process will include a balanced discussion of the potential benefits and harms associated with participation in this study. We will specify in the consent form that any participant can withdraw from the interview, at any time without fear of experiencing harm, reprisals, or incurring ill will. This will be explained in the Informed Consent Form and discussed with each worker prior to his participation. The consent form will also explain that the benefits of participation include getting a better understanding of the their ability to adopt actions to mitigate the transmission of COVID-19. It will note that potential harms include anxiety, minor discomfort or concern due to the content of the survey, the potential for missing a job opportunity while participating in the survey, and breach of confidentiality. These factors will be clearly delineated in the consent form and discussed individually with each potential participant.

When recruiting at the corners, research personnel will wear masks, apply hand sanitizer, and maintain social distancing. LDL will be offered masks and sanitizer and will be required to wear masks for the duration of the baseline survey and intervention. Promotores leading the group session will observe safety practices. Personnel will observe practices and minimize physical interaction in the distribution of the safety cards in the intervention arms employing them.

Follow-up interviews conducted by phone. As with Aim 1, these will be conducted from separate cubicles at UT. Each interviewer will be assigned its own cubicle as to observe social distance. In addition, UT offices require that all personnel wear masks while in the building.

The navigation component will consist of providing information and linking LDL with social service providers that can help buffer some of the social and economic effects of the COVID-19 pandemic. We expect most interactions between navigators and LDL will not involve face-to-face contact.

Day laborers approached for this study will only be recruited at street corners and other day laborer hiring sites. Interaction with all study participants is expected to occur only in Spanish and at the day labor corners or by phone. We will request their name or nickname and names and contact information for those who may know how to reach the participant if necessary to conduct their follow-up survey and who we may contact with the participant's permission.

We will provide incentive payments that will be tracked by number and monitored by the project director and an administrative assistant who has fiscal responsibility for all disbursements at the Center for Health Promotion and Prevention Research, where this project will be housed. All procedures will be submitted for approval to the Committee for the Protection of Human Subjects at the University of Texas Health Science Center at Houston.

All consent instructions and procedures will be prepared in Spanish and English and will be available for review by the Committee for the Protection of Human Subjects, to whom all forms will be submitted for approval.

Protection against Risk

We will also protect the confidentiality of the interview location. All data records will be coded by unique ID numbers. Each post card will contain a unique bar code number to deter LDL from sharing their post cards with Non LDL family members and friends. In addition, postcards will include the corner ID of the corner where they were distributed to accurately track corner location information. This information will be stored in password protected computers. Research personnel retrieving tracking information from this computer file will be instructed to keep it in a locked cabinet while in use, and to destroy it immediately after it is no longer needed. Data will be coded using ID numbers; as the interviews are anonymous, and all data contained in the dataset will be absent of personal identifiers. All contact information will be securely stored, on password protected computers and/or locked file cabinets.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Potential direct benefits to study participants will include increased understanding of the safety measures they may need to take to protect themselves against COVID-19. Furthermore, participants will be provided a resource sheet with contact information for food banks, low cost health clinics, COVID-19 testing centers, the Fe y Justicia Worker Center and other resources which may help them obtain access to health care and other community resources. Information obtained from this study will be provided to the Community Advisory Board and to local community and employer organizations interested in the safety of day laborers including those involved in worker safety and health care professionals.

4. Importance of the Knowledge to be Gained

Latino Day Laborers are an especially vulnerable population within the population of Latino immigrants. The long-term effects of COVID-19 are yet to be determined. As such, the potential benefit of our study to society is great in that a clearer understanding of the factors related to the COVID-19 mitigation

practices of LDL and the resulting interventions may increase adherence to mitigation practices. This, in turn, can help minimize hospitalizations and other adverse health outcomes. Reducing day laborers' COVID-19 risk will also reduce public health, economic and social costs to themselves, their families and the larger society.

Inclusion of Women

It is very unlikely that we will interview women as part of this study, as there are very few women day laborers in the local area. However, if a woman is present at a corner, she will be enrolled if she consents to take part in the study. Given our experience conducting interviews with day laborers, we expect to interview fewer than five women throughout the study.

Inclusion of Minorities

Most day laborers contacted at the corner are likely to be foreign-born immigrants mostly of Hispanic/ Latino ancestry or descent. Recruitment data collected in our previous local studies indicate that members of other ethnic minority groups are rarely present at day labor corners and if present, they rarely participate in job hiring activities. Thus, these individuals do not meet the main inclusion criteria for this study: looking for work at the day labor corner.

Inclusion of Children

Children under the age of 18 will not be included in this study, and those between ages 18 and 21 will be included if they are seeking work as day laborers at one of the corners where we conduct recruitment. Our previous recruitment records indicate that the total number of minors under 18 likely to found at day labor corners is extremely small. Participation of minors in the study is less an issue of excluding them from scientific inclusion, but rather a rare event as evidenced by our previous study. Additionally, their participation would have to be evaluated separately, introducing additional heterogeneity to our study.

Data Safety and Monitoring Plan

Several procedures will be used to maintain the integrity of the data. All databases will be stored in a centralized location on an UTSPH server, which is backed up daily, with access limited to specific users at the discretion of the principal investigators. The PI will monitor security of the data throughout the study and will work with the project director and data manager to monitor data collection activities and the transfer of personal data collected during interviews to our password protected computer drive. The PI will audit selected subsets of data and work with Dr. Atkinson, the data manager, to set up appropriate safeguards of participant privacy. Privacy safeguards will include appropriate password protection and the physical security for all computer systems. There will be no personal names stored in data files.

Study data will be collected from human subjects using survey interviews. No invasive measures will be used to generate data. As data collection objectives will be finalized during the study, we expect that data will consist of socio-demographic characteristics, mitigation practices, and psychosocial variables that influence those practices. To protect confidentiality of the participants, code numbers will be used as identifiers for participants and corner locations.

The data manager will program the survey interview using Qualtrics to capture data electronically. He will conduct data quality checks on a weekly basis during the data collection period and will provide reports of detected errors in the data file such as out of range responses, skip pattern errors, duplicate identification numbers, and inconsistent responses. Data will be transferred for analysis to SPSS, and data monitoring reports will be generated to assess completion time and data quality, and for statistical analysis.

Survey data will be maintained on a secure server that is password protected and accessible only to study staff who are engaged in data analytic activities. The survey data will be collected by interviewers using tablets to be disinfected before and after each use. Data will be downloaded from the tablets on a regular basis by the data manager to a secure server. These tablets will be equipped with state of the art security,

and the data will be encrypted; the encryption is another level of security in case a tablet is lost. When not in use, tablets will be stored in a locked cabinet. If we need to transfer files, identifying information will be deleted, and the new file will be encrypted before transmission, in accordance with HIPPA and University policy. Survey data will not be associated with personal identifiers since each participant will be assigned a study number at the time of consent.

The Institutional Review Board (IRB) for the Committee for the Protection of Human Subjects at University of Texas Health Science Center at Houston will review and approve all aspects of the proposed study, including protecting the confidentiality of study participants and informing participants of the potential benefits and risks of taking part in the study. The IRB requires that the confidentiality of study participants be protected and that procedures be implemented to securely collect and process data. Principal investigators are required by the IRB to report any adverse events as a condition of conducting the research. The IRB also requires that principal investigators inform study participants of these requirements and provide them with the principal investigator's and the IRB's phone numbers. If members of the IRB have questions, investigators are required to provide written responses. The IRB must approve any proposed changes to study protocols prior to implementation.

Study investigators will be responsible for creating the survey instrument and the guidelines for its administration. The principal investigator will work closely with our community partner, Fe y Justicia Worker Center, to coordinate project activities. All personnel will be appropriately trained in all aspects of the study and will complete a Human Subjects certification available in Spanish. They will be introduced to the goals and significance of the study and to the procedures for recruitment, tracking, and retention of participants. They will also sign a confidentiality agreement. All interviewers will be fluent in Spanish. Study investigators will require field personnel to inform the project director if any adverse events are reported during survey administration.

F. VERTEBRATE ANIMALS

Not applicable

DATA SHARING PLAN

The proposed research will conduct surveys with Latino Day Laborers (LDL) in the Houston metropolitan area. Data from the survey will be used to assess a conceptual model describing the factors which influence LDLs' adherence to COVID-19 prevention measures. Data will also be used to evaluate the effects of interventions designing to improve adherence. It is anticipated that approximately 600 participants will be enrolled for all three phases of the study. The principal investigator of the study is Dr. Maria Fernandez-Esquer of the Center for Health Promotion at the University of Texas School of Public Health in Houston.

Following data collection, the research team will develop a policy to share data collected from this project with the scientific community. This policy will include a dissemination plan, a central repository for the data through which requests can be funneled, and a plan to evaluate requests for data use.

The dissemination plan will include publishing manuscripts and presenting results at academic conferences. Manuscripts and presentations will contain notices that the data are available for use by other researchers and a link to a web page housed at the University of Texas-Houston School of Public Health that can be accessed by those interested in the data. The web page will provide contact information (surface mail address, email address, phone number, and fax number) of a designated project representative. This representative will coordinate receipt of requests, as well as review of the proposal and notification of the proposal status for the applicant requesting data access.

De-identified files will be maintained for all data collected during the study period, and we will operate under the guidance of the University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects, to ensure that University Institutional Review Board requirements for confidentiality of subjects will be met.

Applicants will be required to submit a data application form along with a brief research proposal and biographical data. The applicant must agree to several restrictions before being allowed to use the data. These will include:

1) Use of the data for the sole purpose of the research described;

2) Prior notification of the investigators of any publications or presentations with the data;

3) Acknowledgement of the study investigators;

4) Agreement not to contact subjects;

5) Compliance with informed consent forms;

6) Compliance with IRB requirements at both the University of Texas and the requester's institution.

The new investigator will be required to provide 6-month reports on use of the data files. If, at any time, the requestor does not adhere to the requirements of this agreement, the agreement will be terminated, and the requestor will be required to abandon the proposed research project.

DISSEMINATION PLAN

We will ensure that the clinical trial proposed under the current award is registered and the results are submitted to ClinicalTrials.gov as outlined in the NIH Policy on the Dissemination of Clinical Trial Information (the Policy NOT-OD-16-149) and according to specific timelines stated in the Policy. Registration and results reporting in ClinicalTrials.gov will be completed within the following timeframes:

- Registration will occur no later than 21 days after enrollment of the first participant.
- Once a study record is established, required updates will be performed at least once every 12 months, or more frequently as required, confirming the completeness and accuracy of the study record.
- Summary results will be submitted by the standard results due date (no later than 12 months after the trial's primary completion date); however, results submission may be delayed for up to two additional years for trials results whose approval, or clearance is being sought. Any required results updates will be submitted within the time frames specified in the ClinicalTrials.gov regulations.

The informed consent documents of our clinical trial will include the FDA-required statement related to posting of clinical trial information at ClinicalTrials.gov: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

Our institution (The University of Texas Health Science Center at Houston) has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with the NIH Policy and HHS regulations. Processes are in place at our institution to ensure compliance include the following:

- At the time of IRB review, the PRS administrator reviews all studies that are reviewed by the full board to determine whether they are subject to the NIH Policy, the HHS regulations, and/or ICMJE recommendations.
- The PRS administrator notifies the investigator of the registration requirements, and the PRS administrator offers to assist with registration. The PRS administrator follows up with the investigator until the study is registered.
- The PRS administrator reminds the investigator to update their study records at least annually.
- The PRS administrator contacts the investigator at least 6 months in advance of the results reporting due date to remind the investigator of the reporting obligation, and offers to assist the investigator with results reporting. The PRS administrator follows up with the investigator until results are reported in ClinicalTrials.gov.
- Non-compliance will be reported to the investigator's Department Chair. If the issue is still not resolved, then it will be reported to the institution's Executive Vice President and Chief Academic Officer or designee.
- The PRS administrator provides resources and training on ClinicalTrials.gov reporting requirements to investigators and study teams.
- The PRS administrator assists investigators and study teams with access to and questions about the PRS system.
- The PRS administrator facilitates communication between investigators and PRS staff.

Statistics

Corner selection and randomization

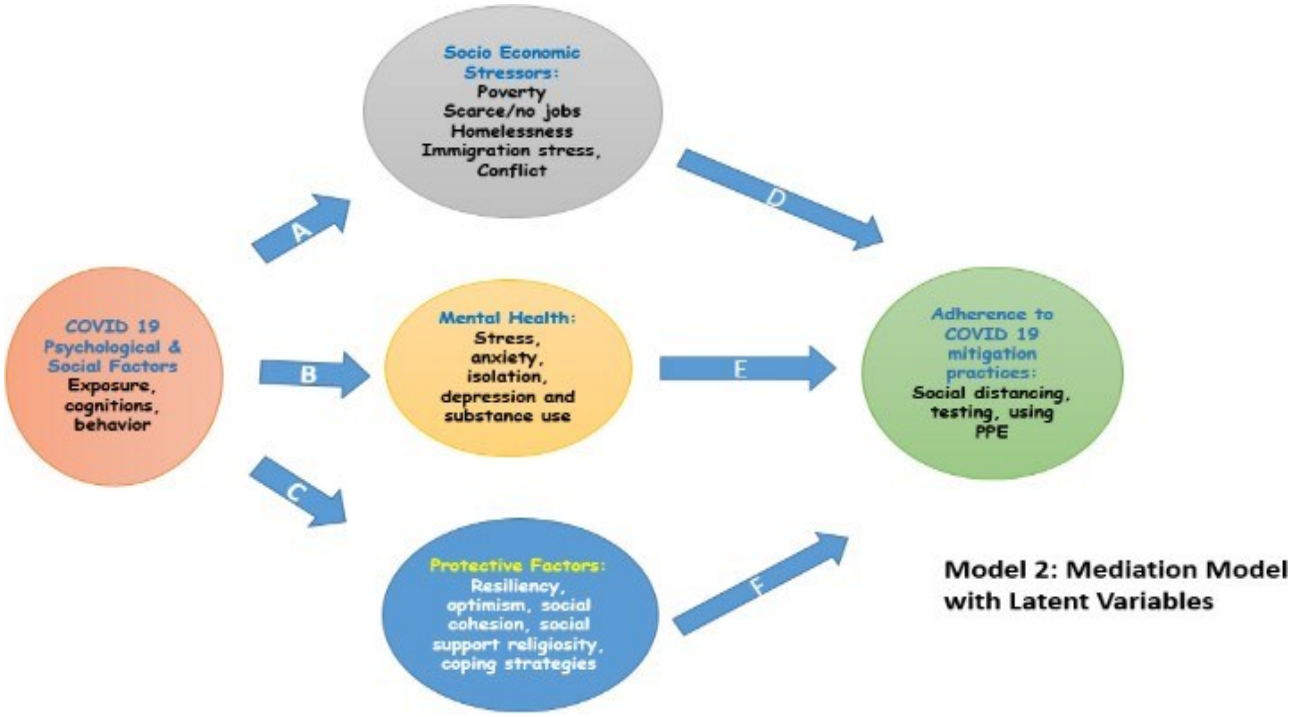
A "corner" is a) a labor hiring public location such as a street corner, bus stop, gas station or home improvement stores within the designated geographic area, b) an independent hiring site (independence as defined by at least 3 blocks of physical distance from the nearest corner), and c) a hub for day laborers observed seeking employment at that location. Locally, corners range in size from quite small (5 to 10 men) to very large (> 75 men), with the majority supporting 12 to 30 LDL looking for work on a given day. Our recent rapid needs assessment in October-November 2019 mapped corners in the Houston area (mainly bounded by the Sam Houston Tollway), covering about 350 square miles. The Corner Outreach Coordinator from Fe y Justicia will survey the corner sites to confirm their stability and identify new corners prior to the start of the trial. To reach our enrollment goal of a total of 200 LDL each in phases 1 and 2 of the trial, we will randomly sample 20 corners from the total number identified and select an average of 10 LDL at each corner to enroll in the study. To account for unmeasured cluster-level factors that may differ by corner size, we will randomize corners within three strata of corner size (small medium and large), thus treating corner size as a blocking factor. Within strata, corners will be randomly assigned to intervention or control conditions. Since this is a cluster-randomized design, all individuals recruited from a given corner will receive the same condition.

Aim 1

COVID survey. Prior to formal data analysis, we will look for evidence of variability, patterns of missing data, and check for data accuracy and adherence to the assumptions of planned statistical procedures (basic data cleaning). We will look at frequency distributions or calculate means and standard deviations for responses to all questions on the questionnaire as well as any computed scales. We will evaluate differences in proportions or means by salient sample characteristics using appropriate statistics, and we will look at salient zero order correlations among items/scales. The primary statistical analyses for AIM 1 will be descriptive (frequencies, correlations, means) in order to understand how participants vary by time in the US, age, corner type, and other critical demographic factors. Appropriate psychometric analyses (e.g. EFA, CFA) will be conducted to determine the reliability and validity of all multi-item scales needed for Aim 1 and for subsequent analyses of more complex predictive relationships, both cross-sectional and longitudinal, needed to answer the questions of Aim 2. For the initial descriptive and correlational analyses, a significance level of 0.05 will be used. As we will conduct multiple tests, we will realize the limitations of any test of significance and will interpret results accordingly. We will also conduct preliminary analyses to identify predictors of mitigation behaviors. Since this survey is only conducted at one time point, the results of any predictive analyses should be interpreted with caution, however they will inform subsequent analyses when we do have longitudinal data. We have strategically included measures of how LDL cope with illness, poverty, immigration, and loneliness, which are known to be significant stressors that have been intensified by the pandemic. We will use regression analysis to identify significant predictors of individual mitigation behaviors (PPE, hand washing, and social distancing) as well as the COVID Mitigation Practices Summative Index described at the end of the Measures section.

Proposed Structural Models. We will use Structural Equation Modeling (SEM) to test several competing models looking at the influence of COVID 19 on the mitigation, health, and practices of Latino day laborers. These analyses will differ from the ones discussed above in that we will use Exploratory and confirmatory factor analyses to develop latent variables consistent with some of the key constructs of interest. We will then use these latent variables to test structural models suggested by the Pathways to Health Model or other empirical work. The advantage of this approach is that it will allow us to explicitly account for measurement error, provide a way to look at both direct and indirect effects among the constructs, and test hypothesized mediated and moderated effects between predictors and mitigation behaviors. Initially we will model a latent variable regression that parallels the regression modeling conducted with manifest variables. Model 1 shown below reflects this type of model. All predictors are seen as correlated with one

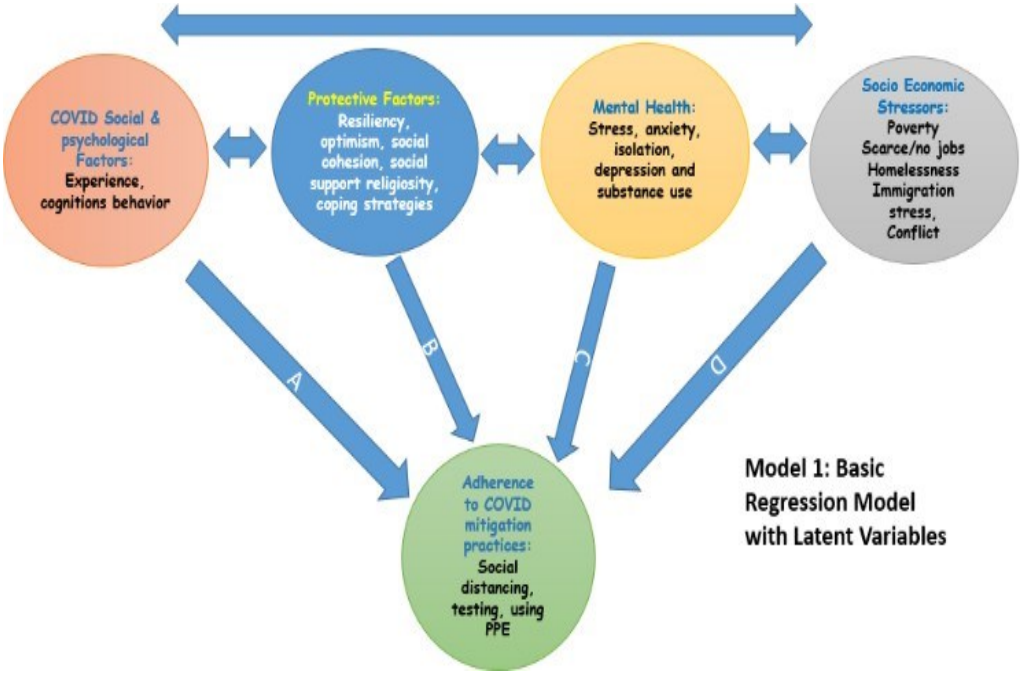
another and each is predictive of the outcome. Model 2 shows how a more complex relationship among the latent variables can be developed and tested. Here COVID-19 is seen as an upstream variable having a direct effect on Socioeconomic Stressors, Mental Health, and Protective Factors. Those 3 variables are then predictive of Mitigation Practices. This model implies that the COVID-19 factor does not have a direct effect on mitigation practices but influences them through its relationship with the 3 mediators pictured. We will develop models similar to these examples based on the focus group conversations (see preliminary studies), our proposed conceptual framework, and empirical work with similar constructs. Models that meet established criteria for fit will guide the adaptation of the program to be tested in a controlled trial in Aim 2. Data collected in Aim 2 will be used to cross-validate models developed, and tested in Aim 1.



Power and Precision. External validity and a careful description of the population is of utmost importance for the analyses in Aim 1. We estimated the sample size consistent with the objective of Aim 1, which is to provide descriptive data needed to inform the development of the intervention in Aim 2. As such, sample size is optimized to provide precise point estimates of variables of interest. Assuming a 95% confidence interval, an estimated true prevalence of between 0 and 30% for the factors of interest (or, equivalently, between 70 and 100%), and a desired precision of +/- 5% (that is, the width of the confidence interval), we require a sample size for Aim 1 of 290 individuals. For the structural modeling analyses and other difference testing we will be concerned more with *internal validity*. For the structural equation modeling it is important to have enough power to reject models that are inconsistent with the data. One-way power to reject a model can be estimated is to select a value for the RMSEA (one of our primary measures of fit) beyond which we would conclude that the model is inconsistent with the data (e.g. .10); we also need to choose a value below which we can conclude that the data fits adequately (e.g. .05). We can then use procedures outlined by Browne and Sugawara (1996) to the sample size required to obtain adequate power to reject hypothesized models. Loehlin (2004) provides tabled power values for several combinations of df (degrees of freedom) and sample size. Using this table and calculating hypothetical df for our Model 2 assuming a minimum of 2 indicators per latent variable and the cut-offs for RMSEA noted above we can expect power of > 90 to reject the model with our planned sample size of 300. Since the structural equation modeling, requires a larger sample size than the descriptive aspect, this N will control

sample selection for Aim 1. Given a sample size of 300, we will also have 85% power to detect a group difference in PPE usage of 0.6 points or higher (a difference consistent with our pilot data), giving us sufficient power to conduct inferential analyses in Aim 1 as well.

Aim 2



Sample size. To determine sample size for Aim 2, we made the following assumptions: A cluster-randomized design (with corners as the clusters), two assessment points (one pre-test and one post-test), 20 corners randomized to two conditions (intervention and control), an intraclass correlation coefficient (ICC) of 0.025, an across time correlation in the outcome of 0.60, a minimum detectable difference in the previously described COVID-19 Mitigation Practices Index outcome a minimum detectable difference expressed as a standardized effect size of 0.5, desired power of at least 0.80, and nominal alpha of 0.05. Based on these assumptions, we require an average of 10 workers per corner, and 10 corners per condition (20 total corners), for a total of 200 individuals per phase of Aim 2.

Data analysis. To estimate the treatment effect for Aim 2, we propose to use cluster-robust standard error regression models. Since our design includes two time points (a pre-test and post-test) and 20 clusters total, more complex longitudinal models, such as multilevel models for repeated measures and generalized estimating equations, would not be appropriate. In this approach, the post-test value of the dependent variable is modeled as a function of both intervention group membership (intervention v control) and the baseline value of the dependent variable. To correct for clustering of individual workers within corners (the clusters), the standard errors are inflated using the sandwich estimator. While not explicitly part of our aims, it is possible to incorporate exploratory moderators into this model, whereby proposed moderator variables are interacted with intervention status. This will help us understand the conditions under which the intervention does or does not achieve an effect. Examples of possible moderators include demographic variables, anxiety, alcohol use, country of origin, etc.

Missing data. To counteract the possibility that we will have missing data due to loss to follow up, we will implement a multiple imputation strategy. Dr. Durand has extensive practical experience in developing statistically valid multiple imputation models in the context of randomized controlled trials.

Ethics

IRB approval will be sought from CPHS.

Study personnel will explain the nature of the study and the benefits and risks of participating. LDL will be assured that they can pause the interview if they are offered a job and resume the interview later. Consent will be sought after this process, and eligible LDL wishing to participate will signify their consent by selecting the appropriate button presented on the iPad used to present the consent form.

Quality control and assurance

All data collection procedures and instruments will be pilot tested and revised as necessary. Computerized surveys will be programed to minimize out of range, inconsistent, or missing date.

The data manager will regularly audit data for problematic entries and provide feedback to the Principal Investigator and data collectors.

We do not have plans to employ third party monitoring.

Publication Plan

Manuscripts will be prepared for submission to relevant peer reviewed journals. Anticipated manuscripts will address participants' characteristics at baseline and the significance of changes in workplace injury and psychosocial items from baseline to follow-up within and between intervention groups.

We do not anticipate retuning results to participants.