VALES+Tú: Targeting Psychosocial Stressors to Reduce Latino Day Laborers Injury Disparities

NCT04800757

Version Date: 10/15/2021

Protocol Title:	VALES+Tú: Targeting Psychosocial Stressors to Reduce Latino Day Laborers Injury Disparities
Principal Investigator:	Maria Eugenia Fernandez-Esquer
Co-Investigators:	Louis Brown, Casey Durand, Craig Field, Andrew Springer
Study Coordinator:	TBA
Population:	Latino day laborers, N= 300, males, ages 18 and older, ordinary health status living in the Houston metropolitan area location
Number of Sites:	Single site
Study Duration:	Five years July 1st 2018 – June 30th, 2023
Subject Duration:	From baseline to post-test is one month approximately.

General Information

Our project, VALES+Tú (VALES Más Tú, You are worthy of more) is a 5 year injury prevention study that naturally extends our Phase I pilot project, "Prevention Program to Reduce Injury Disparities among Latino Day Laborers," an R34 grant funded by NIMHD under RFA-MD-12-006 (CBPR Initiative to Eliminate or Reduce Health Disparities).

Background Information

The construction boom in Houston has resulted in historically high rates of LDL injury, and the need to address their worsening conditions and risks grows ever more urgent. Texas, where a disproportionate number of construction workers are LDL, has the highest US injury fatality rate in the industry, and within Texas, Houston is the epicenter.16,8 Tragically, many fatal injuries at Texas construction sites were likely preventable, had the workers had the information, resources, and skills needed to protect themselves. However, there are no locally or nationally available workplace risk reduction programs with evidence of effectiveness in the language LDL understand (Spanish), from people they trust (peers), that are portable to the corners where they wait for work. The need for effective interventions has never been greater. In the aftermath of Hurricane Harvey, the exposure of LDL in the Houston area to hazardous and precarious work conditions was exacerbated by the urgency of the cleanup and disaster recovery work performed by LDL.

Program content. The content of the VALES+Tú emphasizes workers' ability to assess their own stressors and act on risk reduction priorities that fit their personal circumstances and the norms of their peers at the corner. The program includes the following intervention strategies: (a) an individual intervention approach based on the principles of Motivational Interviewing to encourage LDL to formulate a personal risk reduction plan, and (b) a group intervention approach that emphasizes a group's ability to use problem solving skills to formulate a risk reduction plan to reduce the workplace risks of its members. The program is also based on the workers ability to formulate a safety plan that

is informed by the awareness of their work environment, including an assessment of how work-related risks may affect them, safety procedures for mitigating risks, and the decision to practice safer behaviors. Awareness of these conditions is essential for adopting safety practices, and it is couched in the belief that one can enact necessary changes and that other people will support them.

The VALES+Tú program developed and tested in the Phase I pilot study, relies on two complementary strategies to reduce the risk for injury at work. The program content encourages evidence-based safety awareness and risk reduction priorities. The interpersonal delivery strategies selected by LDL members of our CAB and represent empowerment-based participatory strategies previously tested in this population. The purpose of these strategies is to (i) validate workers' experience of multiple stressors, (ii) their ability to act upon personally chosen hazardous exposures and (iii) encourage social cohesion among corner LDL peers to reinforce peer safety norms, reduce isolation, stress and its associated dangers at work. The content of this program is based on a key CBPR principle: the right and ability of individuals to act on their own behalf to gain control of problems and to use of their skills to resolve them.

Pilot test of the program. The content of the program developed in Phase I was tested in a pilot study in 2015. Prior to implementing the study, we assessed the prevalence of injury and exposure to hazardous working conditions in a corner survey with 329 LDL seeking work at 28 randomly selected corners. We tested the content of the program in three conditions: (1) Brief Motivational Intervention, (2) Group problem-solving and (3) a standard-of care control group which received OSHA 10 safety cards. Three day labor corners were selected and each was assigned to one of the three study conditions.

Latino day laborers administered a brief pre-intervention survey prior to delivering each intervention to LDL at the assigned corner. Pretest interviews were completed with a total of 75 participants who then proceeded to complete the intervention program. About two weeks post-intervention (17 days on average) 65 participants (88%) were re-contacted by phone or in person to complete the post-test. Results indicate that exposure to workplace hazards decreased significantly for all study participants from pretest to post-test (PRE 17.7, POST 15.7, N=63, t 4.26, $p<.001$). The subgroup analysis revealed that across groups, these decreases were significant only for the Brief Motivational Intervention (BMI) group. Reported risk reduction practices and reducing workplace dangers significantly increased for all participants (PRE 32.2, POST 34.0, N=61, t 2.00, $p<.05$), especially for the (BMI) group.

We also tested the influence of the intervention program on stressors. There were no significant reductions in immigration stress, situational stress or depression at post-test. However, there was a significant increase in perceived group cohesion in the group problem-solving condition only (PRE 9.68, POST 10.47, N=19, $p<.035$). These results suggest that both the Brief Motivational Intervention and the Group Problem Solving approaches offer promising strategies that have evidence of helping LDL reduce their risks for injury at work. In the proposed study, we will determine whether these two approaches significantly reduce hazardous exposures at work among LDL in a fully powered cluster randomized trial.

Objectives

There are two specific aims of this study.
AIM1: Determine the efficacy of VALES+Tú in reducing hazardous exposures at work

Hypotheses:

a. Latino day laborers participating in the Brief Motivational Intervention condition will report fewer hazardous exposures at work at post-test compared to the standard-of-care control group.

b. Latino day laborers participating in the Group Problem Solving condition will report fewer hazardous exposures at work at post-test compared to the standard-of-care control group.

AIM 2 Determine the mediating effect of psychosocial stressors on VALES+Tú primary outcomes

Research question:

a. How do situational and immigration stressors mediate the impact of the intervention program on hazardous exposures at work?

The short-term goal of VALES+Tú is to reduce LDL exposures to workplace hazards by involving them in a corner-based safety program that effectively addresses situational and immigration related stress. These psychosocial factors are seldom targeted in safety programs but evidence indicates that they increase hazardous exposures at work. Our *long-term goal* is to reduce the high rates of injury in the Latino day laborer population. If successful, we will prepare VALES+Tú for future dissemination among LDL who look for work at day labor corners in other areas of the United States with large Latino enclaves.

Activities to be conducted prior to the start of the clinical Trial

I. Rapid Needs Assessment

Prior to the implementation of the clinical trial, we will also conduct a Rapid Needs Assessment (RNA). The purpose of the RNA is to gather information related to workers' current personal characteristics, work conditions, and injury experiences. Due to the amount of time that has elapsed since the culmination of the pilot study, conducting this rapid need assessment is a critical step in ensuring our clinical trial reflects current trends and dynamics among day laborers. The RNA will be conducted with LDLs at randomly selected corners. The assessment will be administered electronically by trained interviewers using iPads. The assessment will validate psychosocial and other measures used in our previous studies as well as newly developed items. The assessment will allow us to make any necessary adjustments to our study measures before conducting the clinical trial.

RNA participant selection and Recruitment:

In order to participate in the RNA, a day laborer must be 18 years of age or older, self-identify as Hispanic or Latino, be present at the corner for the purpose of looking for work, and have been previously hired for work at a corner. We will conduct the RNA at corners identified in our previous study.

The LDL interviewers will visit the selected corners and approach LDL about participating in our study. After explaining the purpose of the study and verifying requirements, the interviewer will obtain oral informed consent and administer the Assessment.

Obtaining Informed Consent for the RNA:

Participants will be asked to provide oral informed consent to take part in the survey. Potential participants will be told the purpose of the RNA, 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.

RNA Compensation:

Participants will receive a one-time $25 Walmart gift card after completing the survey. Interviewers will be responsible for the distribution of the incentives. An incentives log will be kept to track the distribution process.

II. Corner Observation and Group Conversation

Prior to the implementation of the clinical trial, a corner observation and data collection activity will be conducted at local day labor corners. The purpose of this activity will be to update clinical trial procedures pertaining to participant recruitment and selection. The corner observation and data collection will be completed by a team of promotores (Latino outreach workers) to be coordinated jointly by UTSPH and the Fe y Justicia Workers Center. These promotores will be trained by the Principal Investigator and Fe y Justicia, both parties with prior experience in collecting data at local day labor corners.

The corner observation and data collection will consist of two parts: (1) observe and record information about corner characteristics and worker activities, and (2) a brief group conversation about current events relevant to day laborers to be held with workers present. This second activity does not require specific recruitment procedures as it is intended to get a general impression of events that may influence recruitment, selection and retention of workers during the trial and it may also inform interview procedures. Thus, this activity may involve one or multiple informants whose comments will be recorded anonymously.

III. <u>Latino Day Laborers Virtual COVID-19 Focus Group</u>

Rationale.

The purpose of this research activity will be to engage a group of Latino Day Laborers (LDL) in biweekly discussions about the impact of COVID-19 on (1) their daily life, (2) social relationships, (3) work practices and (4) personal wellbeing. Latino Day Laborers are a vulnerable population with limited access to health care and personal protective equipment. Given the current crisis, this activity is important to chronicle the impact of the pandemic on their lives, as we expect that it will impact them personally and collectively.

In addition, we need to document the way this unprecedented crisis has altered the dynamics at the corners and disrupted the lives of the Latino Day Laborers in order to anticipate the impact of the pandemic on the eventual implementation of our currently planned community randomized trial.

Participants and procedures.

LDLs will be asked to join six group meetings lasting two hours to be held over Zoom every two weeks. The group will consist of 6-8 LDL who are members of the Vales+Tu Community Advisory Board (CAB) and/or volunteers of the Fe y Justicia Workers Center, our community partner.

Prior to the start of the conversations, research staff members will set a time to teach each participant how to use Zoom and to help them get connected. At this time, participant consent will also be obtained. Potential participants will be told the purpose of the virtual focus groups, that they can refuse to answer any questions and that they can stop participating in the discussions at any time. 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 focus group.

The group conversations will be held in Spanish and facilitated by the principal Investigator (Dr. Fernandez-Esquer). General prompts related to the above-mentioned topics will be used to guide conversation. Examples provided in this document are meant to start the initial conversation and will be used again as appropriate. As researchers and participants become more accustomed to the topics being discussed, the prompts will be adjusted and probing will be used to solicit meaningful responses according to the participants' familiarity and concerns.

Audio recordings of the conversation will be transcribed through a professional transcription service. Project staff will collect and maintain both the audio and the transcribed conversation data. Data storage and qualitative analysis will utilize ATLAS.ti (8.1). The collected information will be confidential, and participants will only be identified by a number assigned to each group member prior to the start of the conversations. A research assistant will take detailed ethnographic field notes during these conversations to assess degree of participation and general content of the meeting in order to supplement the content of the group conversation during data analysis.

Participant Compensation

Each participant will receive a gift card from Walmart ($75) for attending each meeting for a total of $450 over the course of the six meetings. This stipend amount has been regularly provided to Latino Day Laborers that participate in our CAB meetings; this was part of an agreement that was voted by the Vales+Tu CAB membership in the previous pilot study (2013-2015). This incentive is justified as CAB members weigh the benefit of participating in research activities against time spent away from work. Given the significance of the information that will be gathered during this research activity and its implication for the implementation of the clinical trial, this also justifies this incentive.

Qualitative analysis.

Once the conversations are transcribed, the information will be entered and coded in Atlas TI. A codebook with key themes related to the four topics above will be developed and validated by a team of bilingual researchers and students who will later content analyze the conversations. Once all conversations have been transcribed, the original audio files will be destroyed to protect participants' confidentiality. Information will be stored in a password-protected electronic folder.

IV. Small Pilot Feasibility Study

The clinical trial is scheduled to employ research methods we have used in previous studies of LDL. These include approaching LDL at locations where they congregate to seek employment, explaining the purpose of the study, and assessing the eligibility of interested individuals. Methods also include the

administration of surveys using iPads, and the delivery of workplace injury risk reduction interventions in individual and group sessions.

However, we are mindful of the potential impact of the COVID-19 outbreak on implementing these methods. As a result of this recognition, prior to implementation of the clinical trial in the spring of 2021, we will conduct a small pilot study in October 2020 to assess the feasibility of implementing the clinical trial at the corners in light of the COVID-19 pandemic. Similarly, we have made some modifications to our intervention materials to include COVID-19 as an additional occupation hazard faced by LDL while looking for work. Our study outcomes and focus remain the same, an injury prevention program among LDL. Results from the pilot study will allow us to better implement and deliver the clinical trial interventions and meet our goal of reducing risks for workplace injuries.
We will conduct the pilot at two corners to be determined. To be eligible to participate in the study, a day laborer must be 18 years of age or older, self-identify as Hispanic or Latino, be present at the corner for the purpose of looking for work, and have been previously hired to work at a corner.
Ten LDL will be recruited from each corner following the Recruitment Strategy presented below in the Clinical Trial Description. Participants will be presented with an informed consent electronically on an iPad and will signal their consent by selecting the appropriate button. Using an iPad, interviewers will administer the baseline described under Study Procedures. The survey has been revised to include a section of participants' experiences with the coronavirus outbreak. Following administration of the baseline survey, participants at one corner will receive the Brief Motivational Interview intervention and participants at the other corner will receive the Group Problem Solving intervention described below.

Participants will be contacted one month later by phone and will be administered the follow-up survey. Participants will receive a $30 gift card for completion of the baseline survey. Participants will receive a $50 gift card for completion of the baseline survey and the individual/group activity. Participants will receive an additional $30 gift card for completion of the follow-up survey.

We will assess the feasibility of implementing safety measures to mitigate the risk of disease transmission. These will include the use of masks/face shields, gloves, and hand sanitizer by study personnel. We will also provide these materials to LDL. Social distancing will be observed. We will use tape and traffic cones to delineate "rooms" in which surveys and interventions will be delivered. Distancing and the use of masks and hand sanitizer will also be observed by study personnel while in their offices. We will follow departmental guidelines in the case any study personnel exhibits symptoms of infection.

Clinical Trial Description

Study Design

We will conduct a cluster randomized trial of the intervention to determine its efficacy as implemented among Houston LDL. We will use an experimental and control group design with three conditions randomly assigned at the street-corner level, and the intervention delivered at the individual (LDL) level. The treatment arm will include two conditions: (1) individual (Brief Motivational Intervention) and (2) group (Group Problem Solving) interventions. The standard of care control group will consist of (3) a distribution of OSHA 10 safety cards. This will be a five-year study. An individual's

participation would be approximately six months and would comprise a baseline and two-follow-up surveys.

Clinical Trial

Selection of the study population. The study population will be LDL present at study corners.

Inclusion/exclusion criteria. To be eligible to participate in the study, a day laborer must be 18 years of age or older, self-identify as Hispanic or Latino, be present at the corner for the purpose of looking for work, and have been previously hired to work at a corner.

Recruitment Strategy. The Outreach Coordinator and the LDL interviewers will visit the selected corners and approach LDL about participating in our study. After explaining the study and eligibility requirements, the interviewer will emphasize to the participant that the interview can stop at any time so that he can attend to job recruitment activities. S/he will also inform the laborer that arrangements can be made to complete the interview at a later time if he wishes to continue. After obtaining oral informed consent, the participant will be asked to complete the Pre-test survey, which should take no more than 45 minutes to complete.

A screener form will be used to assess participant's eligibility to take part in our study (including during pre-clinical trial activities such as the pilot study). 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.

Study Procedures

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 if desired. The baseline survey should take approximately 45 minutes to complete. The survey will collect sociodemographic information and information related to their recent work history and any injuries or "near misses" experienced. The survey will also include psychosocial measures related to general anxiety and depression as well as stressors related to specific situations and status as an immigrant, risk reduction practices, and self-efficacy. We will also ask about recent alcohol use.

Participants will be randomly assigned to one of three study conditions as described below.

OSHA 10 Safety Cards. Participants in this standard of care control group will receive four wallet size cards with information about risk reduction strategies to deal with the four hazards responsible for most workplace fatalities in Texas: falls, struck by, heat exposure and cuts. The laminated cards are adapted from OSHA's website publicly available materials in Spanish for workers with limited literacy.

Brief Motivational Intervention (BMI). This intervention is a person-centered, brief yet directive method for enhancing intrinsic motivation change by exploring and resolving ambivalence. Effective use of BMI necessitates the definition of a target behavior, in this case, formulating a plan to reduce injury-related risk behaviors. Sessions will be initiated by exploring working conditions and psychosocial factors (perceptions of injury risk, social norms and self-efficacy) that may influence risk for work related injuries. If the LDL is motivated to change the target behavior, a 'change plan' will be developed. Change plans involve identifying reasons for change, goals in making change, specific actions and timelines, and others who may help the person change. BMI has been shown through clinic-based randomized control trials to increase behavior changes. The goal of the BMI session is to get workers to focus on aspects of their shifting work experience that they feel is within their control in increasing their workplace safety. BMI sessions to be implemented during the VALES+Tú trial are expected to last 30-45 minutes and they will be conducted in one-on-one sessions by a Spanish-speaking facilitator trained to use an injury risk reduction dialogue consistent with standard BMI procedures. The final step in the BMI session will be the development of a personal safety plan to reduce work place risks and a discussion of the following topics: (a) how they will know if their plan is successful, (b) potential obstacles, and (c) what the worker can do if the plan does not work. Finally, each worker will be asked to write and sign a personal pledge ("Mi Promesa") to implement his own safety plan. Fidelity of BMI implementation will be based on two criteria: 1) adherence, or whether the LDL promotor carried out specified procedures as indicated in the manual of procedures, and; 2) competence, based on the skills of the promotor in implementing the intervention.

Group problem-solving dialogue. This intervention activity is based on participatory methodology and on our observation that small groups are the natural organization of Latino day laborers, who congregate in groups of 4-7 workers, as they stand waiting to be hired at the corner. Small group activities have been found to facilitate discussions around a problem that a group can tackle and solve together. They are also a commonly adopted strategy to diffuse safety knowledge and skills and to reinforce peer norms. The goal of the proposed group activity is to promote safety awareness, positive peer norms and safety planning, using popular education methods.

The group activity intervention will consist of a discussion between 3-4 LDL and a promotor (a peer LDL) trained as a group facilitator. The sessions are expected to last 30-45 minutes and are intended to provide an opportunity for the participants to work on a safety problem together, get to know each other, and enhance their mutual safety through mutual support. The ultimate goal of the activity will be to generate a safety plan that participants can implement at work.

Follow-up surveys will be conducted by phone one month after the baseline survey. Oral informed consent will be obtained prior to each follow-up survey. The follow-up surveys will reassess participants' work and injury experiences and experiences with the safety intervention they were provided – safety cards, change plan, or safety plan.

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

Clinical Trial Compensation:

Participants will receive a $50 gift card after completing the baseline survey, and a $75 gift card for completing the follow-up survey.

Forms
Additional forms will be used in the field to help track recruitment and other procedures in the field.

Interviewer forms:

- Recruitment & Selection Tracking Form #2. The purpose of this form is to keep track of: 1) the total number of LDLs approached at each corner for study participation, 2) the number of LDLs who agreed to participate in the study, 3) the number of LDLs who refused to participate in the study, 4) the reasons for non-participation, 5) the number of LDLs who are eligible to participate in the study, and 6) for those ineligible, the reason for exclusion.
- Recruitment Script #17. The purpose of this forms is to assess jornaleros' eligibility to participate in our study. Interested candidates who meet the inclusion criteria outlined in this form will then be asked to provide informed consent using our consent forms.
- Survey Completion Tracking form #3. The purpose of this form is to track all survey participants. This form allows interviewers to keep track of all individuals who have attempted or completed the survey, and provides a written record of date of consent, participant contact information for surveys that were not fully completed, and re-schedule dates.

Supervisor forms:

- Corner Sample Count Form # 13. The purpose of this form is to document the labor pool at each corner by documenting the number of jornaleros observed at each corner.
- Summary of Daily Participation. The purpose of this form is to track the number of the field data collectors who surveyed the corner, the start and end time for each field data collector's shift, and the total number of completed interviews for each field data collector, and the total number of interviews completed that day. This form allows field supervisors to keep track of the work of all field data collectors.

Data and Safety Monitoring

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 PIs 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. Privacy safeguards will include appropriate password protection and physical security for all computer systems. There will be no personal names to be 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, worker practices and psychosocial variables that influence those practices. To protect confidentiality of the participants, code numbers will be used as identifiers. The data manager will program the survey interview to capture data as it is being entered and 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 error, 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.

Pre-Post-Follow-up survey data from the Vales+Tú clinical trial 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 tablet computers. Data will be downloaded from the tablets on a regular bases by the data manager to the 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 double 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 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 will continue to monitor the study throughout and will conduct mandatory annual assessments. 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 this requirement 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 changes to study protocols before changes can be implemented.

Study investigators will be responsible for creating the survey instrument and the guidelines for its administration. The Project Director will be responsible for overseeing and coordinating field activities and supervision of interviewers and follow-up activities. The principal investigator and project director will work closely with the Worker Center to coordinate project activities. All field personnel (interviewers and promotores) 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 project and to the procedures for recruitment, tracking and retention, and follow-up of participants. They will also sign a confidentiality agreement. All interviewers will be Latino men fluent in Spanish. Study investigators will require field personnel to inform the project director if any adverse events are reported during survey administration.

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.

Statistics

Corner selection and assignment. Our recent corner needs assessment study mapped 44 corners in the Houston area bounded by the Sam Houston Tollway, covering about 350 square miles. We will base our sampling design on that number and distribution, and, prior to implementation we will survey corner sites to confirm their stability and identify new corners that may have emerged using the methodology of our Phase I pilot study. The Workers Center Outreach Coordinator will be responsible for visiting and mapping the corners. 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. To reach our enrollment goal of a total of 300 LDL, we plan to randomly sample 30 corners from the total number identified and select an average of 10 LDL at each corner to enroll in the study. As corner sizes vary, we may enroll fewer LDL at some corners than at others. The number of corners/clusters sampled will be kept to the sampling design of 10 per group (total of 30) to maximize statistical power.

Sample size. Sample size was estimated using Monte Carlo simulation procedures. For purposes of the simulation, we made the following assumptions: a cluster randomized design, an intervention condition at the cluster (i.e. street corner) level, 20 interventions corners, split equally across the two intervention conditions, 10 control corners, an intraclass correlation coefficient (ICC) of 0.02, an across-time correlation of outcome measures of 0.5 (derived from our pilot data), a nominal alpha of 0.05, desired power of at least 80%, three measurement waves (one pre-test and two post-test), and attrition between baseline and wave 3 of 30%. A group by time interaction serves as the primary indicator of treatment effect, with a minimum desired detectable interaction parameter estimate of 1.5 units (a value also derived from our pilot data) on the workplace hazards scale. Based on these parameters, we require an average of 10 participants from each of the 30 corners, for a total of 300 participants at baseline.

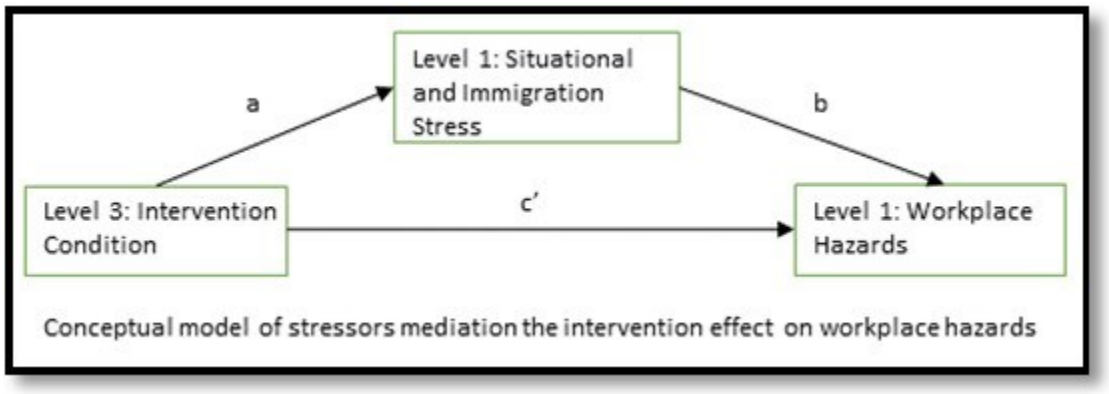
Analyses. **AIM1: Determine the efficacy of VALES+Tú in reducing hazardous exposures at work**. Our primary method of longitudinal data analysis will be growth curve modeling using multilevel models (MLM). MLM is a flexible technique that can accommodate individually-varying times of observation, and time-variant and invariant variables as needed. To develop the MLM, we specify a three-level model, with repeated measures nested within individuals nested within corners, thus accounting for the clustered nature of our study design. Using matrix notation, this model takes the form $\boldsymbol{y = XB + Zu + e}$ for continuous outcomes, where **y** is n x 1 vector of responses**, X** is the n x p design matrix of fixed effects **B, Z** is the n x q design matrix of random effects **u**, and **e** is the n x 1 vector of residual errors. Of primary interest is the two-way interaction between intervention status (intervention or control) and time located in the **X** vector, with random intercepts at the individual and corner levels, both located in the **Z** vector. The **X** vector will also contain important covariates as needed. The two-way interaction will indicate whether the intervention has an effect on workplace hazards during the study period, as compared to controls. Consistent with Aim 1, the two treatment groups (Brief Motivational Intervention and Group Problem Solving) will be compared separately against a common control group. Models will be estimated using maximum likelihood estimation.

To explore the possibility that the effect of the intervention depends on certain other variables (i.e. moderation or effect modification), we will examine whether potential moderators statistically interact with the intervention condition, resulting in differential intervention effects. This is accomplished by adding a third term to the group by time interaction, creating a three-way interaction term. The multilevel model can accommodate moderators at the individual or cluster level (e.g. a cross-level interaction). Consistent with the FOA we are responding to, a moderator of particular interest is Latin American country of origin. Given the composition of the day labor pool in Houston, with a predominant Mexican population, we will examine country of origin as Mexico v. Central America. These methods are applicable for other potential moderators, like individual characteristics (e.g. demographic variables, anxiety, alcohol use) and characteristics of the street corners (e.g. size).

AIM 2 Determine the mediating effect of psychosocial stressors on VALES+Tú primary outcomes. To determine whether situational and immigration stress mediate the relation between the intervention and outcome (i.e. whether these variables "carry" the intervention effect), we will use cross-level

IRB NUMBER: HSC-SPH-18-0337
IRB APPROVAL DATE: 10/15/2021

mediation analysis, which accommodates a situation where the intervention is assigned at the cluster level, but the proposed mediator and the outcome are measured repeatedly over time. A conceptual model of the proposed analysis is shown in the figure below. We will use a version of the widely accepted product of coefficients methods with bias corrected bootstrapped confidence intervals, adapted for longitudinal designs with a randomized intervention assigned at the cluster level. The product of coefficients method has been shown to have greater statistical power than the Baron and Kenny causal steps method. In the three-level operationalization of mediation analysis, two models are specified: 1) A three-level model (street corners, individuals, and repeated measurements) with the mediator as the dependent variable and intervention condition, time and the intervention by time interaction (path *a)* as the predictors; and 2) a separate three-level model with the outcome (e.g. workplace hazards) as the dependent variable, and intervention condition, time, the mediator (treated as a time-varying covariate; path *b*), and the intervention by time interaction as predictors. The product of paths *a* (intervention effect to mediator) and *b* (mediator to outcome) from model 1 and model 2, respectively, is the mediated effect. Bootstrap resampling methods are then used to compute bias-corrected 95% confidence intervals for purposes of significance testing.



Ethics

IRB approval will be sought from CPHS. State whether IRB approval will be sought from CPHS or another IRB (under UT System Reciprocity Agreement).

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.

Data handling and record keeping

Access to source documents will be limited to the Principal Investigator and other Key Personnel. Electronic records will be stored on password protected personal computers and on the University server. Records will be retained in accordance with applicable regulations. Paper records will be stored in locked cabinets.

Participants will be assigned a unique study number. This number will be used to track data and other records. It will be necessary to collect names and contact information (including that for selected

friends and family) so that participants can be reached to schedule their follow-up interviews. This information will be stored in separated files and will be accessed on a need to know basis.

Surveys will be conducted using iPads. When not in use, iPads will be stored in locked cabinets. Completed surveys will be downloaded on a regular basis by the data manager.

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.

ATTACHMENTS

1. Schematic of Study Design
2. Study Schedule
3. Consent Document
4. Case Report Form

COVID-19 Supplemental Study

Background and Rationale

The Vales+ Tu injury prevention study was awarded a supplemental grant from the National Institute on Minority health and Health Disparities (3R01MD012928-03S1). The purpose of the supplemental study is to assess the impact of the COVID-19 pandemic on Latino Day Laborers and their ability to adhere and implement COVID-19 mitigation practices.

LDL are routinely exposed to multiple interrelated stressors associated with both their work and their immigration status such as temporary work, crowded living conditions, and food insecurity. While the stressors are not new, they have been intensified by the COVID-19 pandemic as evidenced by their Latino's high COVID-19 mortality and morbidity rate.

Objectives

The study will address this question: *How do stressors and protective factors experienced in the context of the COVID-19 pandemic influence the mental health of Latino day laborers and impact their ability to adhere to COVID-19 mitigation practices?* To answer this question, our research will be guided by the following aims:

1. Describe Latino day laborers' adherence to COVID-19 mitigation practices and identify the barriers and facilitators associated with their adoption.

    a. Conduct two focus groups stratified by age and corner (i.e. public hiring location) with 16 LDL to characterize barriers and facilitators associated with COVID 19 mitigation practices.

    Administer a survey to 300 Latino day laborers.

2. Using a Structural Modeling approach, determine the impact of social, psychological and economic stressors on LDL mental health and their compliance with COVID-19 mitigation practices.

    a. The Measurement Model: Use Aim 1 survey data to conduct a confirmatory factor analysis to develop good-fitting measures of stressors, protective factors, mental health and adherence to COVID-19 mitigation practices.

    b. The Structural Model: Use structural equation modeling to test hypothesized relationships among and between the latent variables to identify mediators and moderators that will point to plausible intervention strategies to increase compliance with COVID-19 mitigation practices.

Survey Approach

Study Population and sampling. We plan to recruit approximately 300 LDL, a size comparable to our samples in previous studies. We will recruit participants in the field at locations ("corners") where LDL congregate to seek employment. We will recruit from corners identified from our previous studies.

Corner selection. Field team will visit randomly selected corners identified in our parent study. We will follow the same corner selection procedure specified in the parent study to recruit participants. Our total sample size will be 300 participants.

Participant eligibility: Eligible participants will be 18 years of age or older, self-identify as Latino, be at the corner looking for work, and have a previous history of seeking employment at the corner or similar locations. 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.

Survey interview. The interviewers will visit the selected corners and approach LDL about participating in our study. After explaining the purpose of the study and verifying requirements, the interviewer will obtain oral informed consent and administer the Assessment. Responses will be recorded using Qualtrics installed on iPad tablets. The COVID-19 survey will be conducted at least eight weeks after completion of the parent study post-test survey, which is conducted one to two months after the baseline survey.

Given the ongoing COVID-19 pandemic, the field team will continue to adhere to COVID-19 mitigation practices such as mask use and social distancing when interacting with LDL in the field. All field staff are familiar with these practices as they were implemented and tested during implementation of the parent study. Field team members have been trained in, and have experience with, approaching and recruiting potential participants, determining eligibility, obtaining informed consent, and administering surveys. However, they will receive additional training and get familiar with administering the current survey before recruitment starts.

Compensation: Participants who complete the COVID-19 survey will receive a one time incentive payment of $100 in the form of a Visa gift card. We are providing a higher than usual incentive payment due to the fact that the interview will be long (60-75 minutes), and it may prevent some participants from getting hired for the day. Even when they will be encouraged to attend to their job search activities and return to the interview the following day, many day laborers may choose to attend to the interview with the unclear expectation that they will get a job later in the day. The incentive will partly cover the possible loss of partial or full employment for that day. Gift card distribution will be tracked and properly documented.

Survey measures. The survey to be administered to study participants will include an array of measures to answer our proposed aims. Some of the measure include, but are not limited to, COVID-19 Psychosocial factors, COVID-19 mitigation practices, Socio-Economic Stressors, Mental Health Measures, Protective Factors, and COVID-19 vaccination beliefs. Please refer to the COVID-19 survey table of contents for a list of all measures to be collected.

Data Analysis.

The primary goal of AIM 1 is to provide a careful description of the LDL who seek work at the corners during this pandemic. Survey items are based on the priorities identified in Aim 1 and on a more recent literature review of measures of practices and behavioral determinants which reflect the most recent changes in the pandemic.

Initially, we will look for evidence of variability and patterns of missing data, and check for data accuracy and adherence to the assumptions of planned statistical procedures. The primary statistical analyses to

be conducted to satisfy AIM 1 will be descriptive (means, frequencies, correlations) in order to understand how participants vary by time in the US, age, corner type, and other critical factors. We will look at frequency distributions or calculate means and standard deviations for responses to all questions on the questionnaire, and evaluate differences in proportions or means by salient sample characteristics using appropriate statistics. A significance level of 0.05 will be used to identify critical subgroup differences. However, since we are conducting these analyses primarily for description, and we are conducting multiple tests, we realize the limitations of any test of significance and will interpret results accordingly. The descriptive analyses conducted to satisfy AIM 1 will provide a good profile of LDL working during this pandemic and will be used to insure that data meet the requirements for answering the more complex questions of AIM 2.

The goal of Aim 2 is to use a Structural Equation Modeling approach to determine the impact of social, psychological and economic stressors on LDL mental health and their compliance with COVID 19 mitigation practices. We understand the determinants of COVID 19 mitigation practices as a set of conditions, behaviors, cognitions and exposures that lead to health inequalities as proposed by Adler and Ostrove's Pathways to Health framework. This model posits that structural conditions in the lives of individuals facilitate or constrain their access to environmental resources, shape their psychological makeup and influence exposure to pathogens, stress responses and performance of health behaviors. While this model describes distal and proximal influences on health, we are adapting it to address the COVID 19 pandemic as a current event that has multiple and simultaneous influences on the structural, social and psychological stressors experienced by Latino day laborers and on protective factors that influence their mental health and COVID 19 mitigation practices.

We intend to use basic demographic, mental health (stressors, depression, isolation and substance use) data collected during the current injury trial to inform the model of the determinants of COVID mitigation practices.

Hypotheses. The proposed project will identify individual risk and protective factors (stressors related to immigration status; familiarity with COVID-19 and its transmission modes and familiarity with the types of actions that are recommended to minimize exposure to COVID-19). We hypothesize that the added stress of the pandemic, coupled with their pre-existing vulnerabilities (e.g. high levels of stress related to their immigration status) will have a negative impact on LDLs' mental health. This will render them less capable of adhering to CDC's COVID-19 prevention guidelines thus putting them at a higher risk of contracting the virus. We also propose that the protective factors identified above may help mitigate the influence of stressors on mental health during the current pandemic. Using a Structural Equation Modeling approach to explore these relationships will allow us to answer fairly complex questions about the associations of multiple constructs at one time. The results will provide a better understanding of the social and personal assets that can be instrumental and serve as intervention targets for this population in the current pandemic.