Study Protocol and Analysis Plan

A Novel Worksite Smoking Cessation Intervention for Hispanic Construction Workers

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1) Protocol Title

A Novel Worksite Smoking Cessation Intervention for Hispanic Construction Workers

2) Objectives*

The objective of this study is to develop a brief, culturally sensitive face-to-face smoking cessation intervention for Hispanic construction workers and conduct a pilot two-arm, cluster-randomized clinical trial (RCT) to test the developed intervention for acceptability and potential efficacy- A two-arm, cluster-randomized controlled trial will be conducted with at least 14 construction sites (dependent on how many smokers can be recruited from each site), selected from one Construction Company in south Florida. Cluster randomization is used with construction site chosen as the unit of allocation because it is most practical in this setting and minimizes the risk of spillover effects from the intervention to the control group. Computer-generated random selection will be used to randomize construction sites. Then, construction sites will be randomly assigned to the intervention (enhanced care) or the control group (usual care), and study participants working in these sites will receive treatment accordingly. In conjunction with the site safety manger, we will recruit at least 126 adult Hispanic construction workers who smoke ≥5 cigarettes/day. Participants in the enhanced care will receive one culturally adapted brief face-to-face behavioral counseling session developed in phase 1 and delivered during breaks, two brief follow-up phone counseling calls, fax referral to the Florida quitline (QL), and provision of up to 8 weeks of free NRT. Participants in the usual care will receive fax referral to the Florida QL, and provision of up to 8 weeks of free NRT. *Main outcomes* include: 1) estimating yield (number of workers available divided by number eligible; and number eligible divided by number randomized), 2) facilitators and barriers to delivering the intervention in the proposed setting, 3) willingness of participants to be randomized and acceptability of the intervention, 4) follow-up rates, response rates to questionnaires, adherence/compliance rates, and the time needed to collect and analyze data, 5) QL enrollment rates, and 6) exploring the willingness of the target population in involving in the research design and conduct. *Potential efficacy* outcomes include the difference in prolonged abstinence, and point-prevalence abstinence rates at 6-month follow up confirmed by saliva cotinine < 15ng/ml.

This study will be the first to develop and evaluate a novel, low cost recruitment and intervention strategy in a hard-to-reach and underserved population of Hispanic male construction workers. Our data will inform a larger study of the effectiveness of cessation approaches that have great potential for translation and dissemination to minority construction workers throughout the US.

3) Background*

According to the US Surgeon General's report, cigarette smoking causes more death and disability among American workers than their workplace environment (e.g., workplace injuries). Construction workers have the highest rate of smoking among all occupations, and are frequently exposed to a wide range of workplace

hazards (e.g. toxins), which interact with smoking to increase their health risks. Minority construction workers, in particular, have higher smoking and lower cessation rates compared to other groups, and they generally show lower access and participation in cessation and health promotion services. The number of Hispanic workers employed in the construction industry in the US has tripled in the past decade to 2.6 million (23% of all construction workers). Given that construction trades remain overwhelmingly male dominated, male Hispanic workers constitute a large and increasing group in need for smoking cessation and health promotion.

High mobility and turnover rates among construction workers are major challenges to delivering smoking cessation interventions. An additional challenge is that cessation interventions have yet to be tailored culturally or to the often difficult work/life circumstances of minority construction workers, although culturally sensitive smoking cessation interventions are more effective in minority groups. Therefore, novel methods are needed to reach and intervene with this at-risk population. A novel approach that was recently piloted by our team, is to partner with the lunch truck that routinely visits construction sites to deliver brief, effective interventions. Further development and evaluation of this promising approach is warranted, and should meaningfully involve the target population in these efforts to optimize its cultural relevancy and potential for success and dissemination.

Our approach is guided by recent developments in how to address smoking cessation in *underserved smokers,* defined as: 1) having high smoking rate and disproportionate tobacco-related health burden, 2) lacking access to effective treatment and/or barriers to treatment, and 3) being underrepresented in cessation clinical trials. This framework stresses the need for innovative approaches for *underserved smokers* based on cultural adaptation of evidence-based treatments. Guided by this framework, we have assembled a team with years of experience in smoking cessation development and work with minority construction workers in order to develop and pilot test a culturally sensitive smoking cessation intervention for Hispanic construction workers.

4) Inclusion and Exclusion Criteria*

- Inclusion criteria: 1) Hispanic male, 2) 18 years and older, 3) current smoker, 4) have access to a telephone, 5) have no plans to move in the next six months, 6) interested in making a serious quit attempt in the next 30 days, and 7) have no contraindication to NRT.
- Exclusion criteria: 1) Inability to understand consent procedures, 2) non-Hispanic, 3) female, 4) under 18 years of age, 5) non-smoker, 6) not interested in making a serious quit attempt in the next 30 days, 7) no access to a telephone, and 8) have a contraindication to NRT.

5) Procedures Involved*

Design- This study is a two-arm cluster RCT designed to evaluate the main outcomes and potential efficacy of the brief behavioral intervention developed in Phase 1 plus NRT, compared to referral to the State Quitline (QL). At least 14 construction sites will be randomly assigned into two groups: Enhanced Care (treatment group), and Usual Care (control group). Participants in the "Enhanced Care" intervention arm will receive a single face-to-face behavioral counseling session delivered at the lunch truck, two brief follow-up phone counseling calls, fax referral to the Florida tobacco quitline (QL), and provision of up to 8 weeks of free NRT (up to 6 weeks provided by the study and 2 weeks provided by the QL). The comparison group, called "Usual Care," will receive fax referral to the Florida QL and provision of up to 8 weeks of free NRT (up to 6 weeks provided by the study and 2 weeks provided by the QL). Participants in both groups will receive two follow-up phone assessments at 3-, and 6-months of enrolment. Information about number and time of total contact in both groups will be collected at 3- and 6-month follow-ups.

Recruitment, Study Participants, and Procedures- Our target sample size is up to 150 Hispanic smokers. We will coordinate with the safety managers of the participating construction sites to identify smokers who are interested in quitting smoking and arrange a visit to meet these workers. On day 1, two bilingual PH graduate assistants will approach these workers during their break to explain the study, complete the screening, and then obtain the consent form from those who are eligible. To participate in the study participant should be Hispanic male construction workers on site who are ≥ 18 year old and have smoked ≥ 5 cigarettes/day in the past year. Additionally, potential participants need to be available on site in the following two days, have access to telephone, have no plans to move in the next six months, and be interested in making a serious quit attempt in the next 30 days, and have no contraindication to NRT. Exhaled carbon monoxide levels and saliva cotinine will be tested among eligible participants to verify the self-reported smoking status. Individuals who decline to participate or who are ineligible (e.g., non-Hispanics, women) will be referred to the QL and provided with brochures that include information about the QL contact number and services. They will also be given a flyer about the UM Quitville smoking cessation study for which they may be eligible (only for English speakers). Those who are potentially eligible and interested in participating in the study will sign a consent form, then undergo a baseline screening to confirm eligibility and to collect information about: demographics, job characteristics, acculturation,[41] smoking history, nicotine dependence,[42] stages of change,[43] quit ladder,[44] smoking self-efficacy,[45] depression,[46] social support,[47] exposure to secondhand smoke, and quality of life. All questionnaires, informed consent, and educational materials will be available in English and Spanish and will be administrated by the bilingual graduate assistants. After completing the baseline assessment, a second visit in the following day will be scheduled to provide the intervention. If time does not permit to complete the entire baseline assessment, the exhaled carbon monoxide and saliva cotinine test, demographics and smoking behavior questions will be administered on-site and the remainder will be given to the

participant to be completed. Participants will receive a text-message reminder about the second visit at the evening. If time permits on the first day of recruitment to deliver the intervention, all aspects will be completed on that day rather than on day 2. Dr. Asfar, who has years of experience in training and supervising cessation trials,[37,38,48] will be responsible for the training of PH graduate students in recruitment and conduct of the cessation trial such as 1) human subjects protection, 2) consequences of smoking, 3) motivational strategies, 4) pharmacotherapies used in smoking cessation, and 5) the study's protocol. Photographs and/or video may be taken during the sessions to be used for progress reports and presentations.

Participants in the **Usual Care** will receive up to six week supply of NRT, brochures about the QL services, and will be referred to the QL using the "fax referral form". Participants will be informed that the QL is free, and the QL counselor will work with them to devise a specific plan to quit smoking and will arrange the delivery of free 2-week NRT for their quit attempt. Participants will have access to free NRT for a total of eight weeks (2-week supply from the QL, and 6-week supply from the study).

Participants in the **Enhanced Care** will receive in addition to the above, a brief one face-to-face behavioral counseling session delivered at the "lunch truck", and two brief follow-up phone calls. The face-to-face session will be an evidence-based intervention that is culturally adapted based on focus groups,[17] and expected to feature three key processes: 1) preparing to quit, 2) the quitting process, and 3) relapse prevention and proper use of NRT.[34] Additionally, participants will be given a "Patient Card" that summarizes "take home" messages for the most important points of each of the three phases. During the preparation-to-quit discussion, we will focus on reducing the number of cigarettes, stimulus control, and other quit preparation strategies (e.g., disposal of cigarettes before the quit date). We will also emphasize the importance of a quit date and discuss when a good quit date would be.[34] During the quitting discussion, we will emphasize proper use of NRT, reinforce the use of NRT, and what to expect during the first few days of being a nonsmoker and how to cope. Finally, during the relapse prevention discussion, we will discuss the 5A's for preventing relapse (Avoid high temptation situations, Alter those situations you can't avoid, use Alternatives, Anticipate high risk situations, and become Active).[34] The first phone call will occur one day before the quit date to remind participants about their quit date and provide more support, and the second will occur two weeks after quit date to review progress and skills to prevent relapse

Nicotine Replacement Therapy (NRT)- Participants in both trial arms will receive a free supply of NRT to enhance their chances of quitting. Participants in the QL referral group will receive up to 8 (up to 6 weeks provided by the study and 2 weeks provided by the QL). Participants in the brief intervention group will receive a free up to 8 weeks supply of NRT after enrollment (up to 6 weeks provided by the study and 2 weeks provided by the QL- type will depend on participants'' preference elicited at focus groups). Participants will be provided information on the side effects of NRT and will receive detailed instructions regarding proper use. In addition, potential participants will be screened for NRT contraindications. Individuals will be

disqualified from the study if they report a history of hypersensitivity to nicotine, recent (past month) myocardial infarction, or any history of serious arrhythmias or unstable angina pectoris, consistent with Clinical Practice Guidelines. In addition, individuals will not be eligible if they have a generalized chronic dermatological disorder (e.g, psoriasis), a contraindication for patch use, unless they are able to use nicotine gum. If there are no contraindications, participants will be given their preferred form and will be provided information on the side effects and proper use. Concomitant smoking and NRT use, as well as use of additional prescription and/or OTC NRT or cessation drugs (e.g., bupropion) will be tested at recruitment, and 3- and 6- month follow ups.

Follow-up and Retention- Participants in both arms will receive two follow-up phone calls at 3 and 6 months after enrollment to assess their smoking status. Those who report quitting smoking at 6 months will be visited at a mutually agreed-upon location to obtain a saliva sample to validate their smoking cessation status using saliva cotinine< 15 ng/ml.[50,51] Saliva samples will be collected using NicAlert™ kits and analyzed by automated gas liquid chromatography using nitrogen-phosphorus detection and structural analogues of cotinine as internal standards.[52] To increase completion of the 6-month follow-ups, for those participants that we are unable to meet in person we will mail the NicAlert™ kits with instructions on how to complete and mail back to us.

To maintain active participation for the entire length of the study, extensive retention measures will be taken. These include collecting detailed contact information for relatives/friends, who would know the participant's whereabouts, contacting participants with personalized letters/cards, sending out study-relevant information at 3-month, and individual case management. Participants who complete all portions of the intervention will be given a $50 incentive. Twenty dollars will be provided after completing the first treatment session, and $30 at the 6-month follow-up assessment.

Protocol for Retention - After the participant received the intervention for their assigned group, the follow-up phone calls will vary in number. In the Enhanced care, the participant will receive 4 phone calls in total. The first will be the day before the quit date and the second will be 2 weeks after the quit date to provide them with additional support. The last two phone calls will be a 3 and 6 month follow-up phone call to review their status. The Usual care will only receive 2 phone calls after their intervention. These phone calls will be placed 3 months and 6 months after their quit date to review their smoking status. If the participants fail to be contacted at any of their scheduled dates, we will proceed as follows:

Every participant will receive up to 10 phone calls to their preferred phone number. Throughout these 10 calls, voicemails will be left to remind the participant that we are trying to get in contact with them. Within the 10 phone calls, 2 text messages will be sent. One text after 5 calls and the second text after the 10 phone calls. In the text, we will encourage participant to call us back to get

more support regardless of their smoking status. After we have completed the 2 text messages, the voicemails and the 10 phone calls, we will send a "thinking of you" letter to their house indicating that we are still interested in speaking to them to assess their progress and provide additional support at any step they may be in the process. We will stress that we are here to help them and to increase their chances of quitting smoking in the future. We will also remind them that they must keep in contact with us until the 6 month follow up to receive the additional $30. After 2 weeks of not hearing back from the date of the card being sent, we will begin to contact their references that were written down in the baseline survey.

Sample Size: Major goals of this pilot study are to explore acceptability of our intervention. These data also will help us to estimate the intervention's effect size to help determine sample size needs for a future full-scale RCT. We will follow the general rule of thumb and recruit at least 126 participants (63 per group) to estimate the parameters. We will use a two-group comparison of proportions at the two-tailed alpha level and assume that the intra-cluster correlation will be low (0.01). This sample size will allow us to detect a 22% difference between the two groups (a moderate effect size of 0.46) at the two-tailed 0.05 alpha with 80% power. Expecting 20% attrition rate this will leave us with a sample of 51 subjects per group. We will, however, include all randomized participants in assessment of endpoints. We realize limitations of using pilot data to power subsequent studies, related to the inherent imprecision of estimates with small sample sizes. It is important to note, though, that our sample size is large enough to estimate the effect with a reasonably tight confidence interval, and we will not rely exclusively on this effect to estimate power, but will also make use of the extant literature.

6) Data and Specimen Banking*

The following self-reported measures will be obtained specifically for research purposes. These data will be stored in stored on a password-protected computer accessed only by approved study personnel.

i. Demographic Data and Work Characteristics: This will include: Age, ethnicity, native borne, non native born, acculturation, income, education, health insurance status, and job activities.

ii. Fagerstrom Test for Nicotine Dependence (FTND): All participants will be given the FTND to assess nicotine dependence. This instrument has been widely tested and used in smoking studies.

iii. Tobacco Use History: This will include: age when the participant began smoking, number of years as a smoker, the number of cigarettes smoked per day, whether the participant had made a quit attempt in the last year, the number of past year quit attempts, and the number of last year successful quit attempts (defined as being quit for at least one month).

iv. Depressive Symptomatology: will be assessed with the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977; Thomas et al., 2001).

v. Additional measures such as: social support, smoking self-efficacy, nicotine dependence FTND, stages of change, quit ladder, exposure to secondhand smoke, and Hatsukami withdrawal scale will be also collected.

vi. Medication Side Effects, Adverse Events and Participant Adherence: These will all be monitored on study participants throughout the study. These will be reported to the study's PI and co-investigators for appropriate follow-up.

vii. Concomitant Medication Use or Behavior Therapy During Follow-up Visits: The use of additional gum, patch, nicotine nasal spray, inhaler or lozenge, or antidepressants prescribed for smoking cessation will be monitored as they can affect cessation rates. Participation, in additional behavioral cessation programs, will also be carefully tracked for this reason.

viii. Saliva cotinine: For participants claiming via self-report that they have quit smoking at 6-month follow up, we will obtain biomedical validation using salivary cotinine. The saliva cotinine test is noninvasive with virtually no risks. This involves providing saliva. Participants will be visited at a mutually agreed-upon location to obtain a saliva sample. This procedure will be explained during administration of consent as well as in detail, during the 6- month follow up phone interview. Note that in the event that participants (a) report they are not smoking, but (b) refuse to provide a saliva sample, they will be considered smokers. A monetary incentive of $30 will be given to participants at 6-month follow-up after completing of the test.

7) Data Management*

Outcome Measures- This pilot study aims to explore the acceptability potential and efficacy of the developed intervention compared to QL. *Main outcomes* include: 1) estimating yield (number of workers available divided by number eligible; and number eligible divided by number randomized), 2) facilitators and barriers to delivering the intervention in the proposed setting, 3) willingness of participants to be randomized and acceptability of the intervention, 4) follow-up rates and response rates to questionnaires, adherence/compliance rates, and the time needed to collect and analyze data, and 5) exploring the "willingness" of the target population to be involved in the research design and conduct.[60-62] *Potential efficacy outcomes* will focus on comparing prolonged abstinence (defined as no smoking, not even a puff, after a grace period of two weeks after quit date), and point-prevalent abstinence (defined as self-report of not smoking in the past 7-days; not even a puff) confirmed

by saliva cotinine level of <15ng/ml at 6-month between the two study arms. For individuals who do not quit entirely, the decrease in smoking (i.e., cigarettes/day) will be assessed.[63,64] Relapse is defined as smoking at least once/week on two consecutive weeks.[65] Secondary outcome measures will focus on differences in stage of change/readiness to quit,[66] and treatment adherence according to intervention assignment.[37]

All participant data will be coded with an identification number and only approved personnel will have access to the key linking identification numbers with participant names. Data will be stored and managed in REDCap and accessed only by approved study personnel. Paper interview instruments will be stored in a locked filing cabinet.

Quality Assurance- Our research team is well versed in quality assurance processes for intervention studies.[44,45,59] Following the strategy suggested by Sechrest,[69] evaluation of any treatment program should involve satisfactory answers to three questions: 1) was the intervention both standardized and delivered as intended to the participant? 2) if so, did the participants receive it? and 3) if so, was the intervention efficacious in changing behavior? Sechrest's 3rd question involves the evaluation of outcomes, which is outlined in the Data Analysis section below. However, Sechrest's 1st and 2nd questions address treatment implementation issues. To ensure standardization of intervention content and delivery, we will use standardized treatment manuals/procedures developed particularly for this study. Participants will respond to a brief questionnaire at baseline and the 3- and 6- month follow-up to assess whether key points were learned, including the techniques and information discussed in the intervention sessions. Standard procedures will be used for instrument development, protocol and forms, and data management (e.g. entry, reconciliation, updating, and data security and confidentiality). Additionally, we will audiotape a random sample of 10% of counseling sessions for review and feedback. Participants will be asked for permission to audiotape these selected sessions as part of the consent process.

Data Analysis

The analyses of the outcomes were mainly descriptive. Chi-square tests and between-group t-tests were used to compare between-group differences in baseline characteristics, and indices of treatment implementation, adherence, and retention. Intra-class correlation coefficients were used to adjust for clustering within sites.[55] This adjustment accounted for within-site clustering of workers characteristics at each of the 17 participating sites in the trial. Chi-square tests were used to compare cessation rates in the two arms. Analyses were performed on an intention-to-treat basis, with individuals with missing outcome data or self-reported abstinence not confirmed by eCO at 6-month follow-up classified as not quit. Logistic regression analyses were conducted to assess baseline predictors of prolonged abstinence at 6-months.

8) Risks to Subjects*

Potential risks and adverse effects of the study medication will be explained to each participant when informed consent is obtained. Each participant will be instructed to

keep a record and notify the center of any potential adverse effects, illnesses, or hospitalizations. Potential risks to study participants may include:

i. Randomization: Although it is expected that both the study treatments will be beneficial, it is possible that the treatment a participant is assigned to may later be shown to be less effective.

ii. Nicotine Withdrawal: Smoking cessation is associated with a variety of nicotine withdrawal symptoms including: depressed mood, difficulty sleeping, irritability, anxiety, difficulty concentrating, restlessness, and increased appetite or weight gain. These symptoms are typically not severe and dissipate within a few weeks of cessation, with the exception of weight gain, which may persist for up to one year.

iii. NRT Use: type of NRT will depend on participants'' preference elicited at phase 1 (focus groups).

Nicotine Patch Use: Although most persons do not experience any major adverse effects from the nicotine patch, it is possible that a participant could experience any of the following side effects. All participants will be questioned or evaluated for these specific side effects at each session.

a. Skin erythema, pruritus, edema, burning, and rash at the application site of the patch
b. Dizziness, dry mouth
c. Arthralgia, myalgia, back pain
d. Abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, vomiting
e. Impaired concentration, depression, headache, insomnia, abnormal dreams, nervousness
f. Cough, sinusitis
g. Allergy to nicotine
h. Cardiovascular side effects (cardiac arrhythmia, tachycardia, vasospasm, elevated blood pressure)

Nicotine Gum Use: Although most persons do not experience any major adverse effects from the nicotine gum, it is possible that a participant could experience any of the following side effects. All participants will be questioned or evaluated for these specific side effects at each follow-up visit.

a. Mouth soreness. Very rare; probability of occurrence is low and risk is low.
b. Hiccups. This typically occurs through improper use of the gum. If participants report this, we work on how they are using the gum. Probability is common in those who misuse the gum; risk is low
c. Dyspepsia. Probability and risk is low.
d. Jaw ache. Probability and risk is low.

Although these adverse events have been reported in those who use NRT, they have been infrequent and are less likely to be observed in persons who are regular cigarette smokers. In addition, many of these same symptoms are reported by persons who quit smoking without NRT, and have been attributed to nicotine withdrawal from smoking cessation.

9) Potential Benefits to Subjects*

Participants will benefit by being involved in a no-cost program that may help them to quit smoking, reducing their risk for a variety of health conditions. Given the substantial potential benefits and the minimal risks for participants involved in this project, it is felt that the benefits significantly outweigh the possible risks.

10) Recruitment Methods

Two bilingual (English, Spanish) public health graduate students will approach construction workers either at their morning or noon food break at multiple construction sites in South Florida in partnership with the lunch truck service. Using a verbal consent script, potential participants will be asked if they are interested in participating in our study. If they agree, they will asked a series of questions to determine whether they are eligible (Hispanic male construction workers who are ≥ 18 year old and have smoked ≥ 5 cigarettes/day in the past year). Additionally, potential participants need to have access to telephone, have no plans to move in the next six months, and be interested in making a serious quit attempt in the next 30 days. Individuals who decline to participate will still be encouraged to quit smoking, and given a list of available cessation resources. Those willing to participate but who are ineligible (e.g., non-Hispanics, women) will be referred to the QL and provided with brochures that include information about the QL contact number and services. Those who are potentially eligible and interested in participating in the study will be consented, then undergo a baseline screening to confirm eligibility and to collect information. All questionnaires, informed consent, and educational materials will be available in English and Spanish and will be administrated by the bilingual graduate assistants.

11) Local Number of Subjects

We seek to enroll up to 150 participants who are eligible according to the inclusion criteria.

To avoid intervention contamination within participating construction worksites, the RCT design will be a two-group cluster randomized design with seven sites per group. Our resources for this R21 allow seven subjects per group. We assume that the intra-cluster correlation will be low (0.01). We will use a two-group comparison of proportions at the two-tailed alpha level. Assuming that 10%-15% of the control group and 25% of the intervention group respond to the intervention, we will have 23% power to detect a 10% difference and 50% power to detect a 15% difference. To achieve 80% power

for a 10% and 15% difference under the same assumptions would require sample sizes of 64 and 16 subjects per site, respectively.

12) Confidentiality

Participant names will be replaced with ID numbers and a key linking the two will be kept separate from other data and accessed only by Drs. Lee and Asfar. Survey data will be stored on Dropbox and accessible only by approved study personnel. Survey data from the RCT will stored and managed in REDCap. These data will be stored for the duration of the study protocol and until all data analysis is complete and manuscripts have been published.

13) Provisions to Protect the Privacy Interests of Subjects

Participants will interact with only a limited number of approved study personnel and will be assured that their personal information will be kept private, will be used only for research purposes, and will not be accessible to non-study personnel.

14) Consent Process

Verbal consent will first be obtained after potential participants are screened on site. Those who verbally consent will then sign a written consent before the intervention begins. Because we are recruiting Hispanic participants the consent documents will be available in both English and Spanish.

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