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A cluster randomized pilot trial of a tailored worksite smoking cessation intervention targeting Hispanic/Latino construction workers: Intervention development and research design

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ABSTRACT

Construction workers have the highest smoking rate among all occupations (39%). Hispanic/Latino workers constitute a large and increasing group in the US construction industry (over 2.6 million; 23% of all workers). These minority workers have lower cessation rates compared to other groups due to their limited access to cessation services, and lack of smoking cessation interventions adapted to their culture and work/life circumstances. Formative research was conducted to create an intervention targeting Hispanic/Latino construction workers. This paper describes the intervention development and the design, methods, and data analysis plans for an ongoing cluster pilot two-arm randomized controlled trial comparing an Enhanced Care worksite cessation program to Standard Care. Fourteen construction sites will be randomized to either Enhanced Care or Standard Care and 126 participants (63/arm) will be recruited. In both arms, recruitment and intervention delivery occur around "food trucks" that regularly visit the construction sites. Participants at Enhanced Care sites will receive the developed intervention consisting of a single face-to-face group counseling session, 2 phone calls, and a fax referral to Florida tobacco quitline (QL). Participants at Standard Care sites will receive a fax referral to the QL. Both groups will receive eight weeks of nicotine replacement treatment and two follow-up assessments at three and six months. Feasibility outcomes are estimated recruitment yield, barriers to delivering the intervention onsite, and rates of adherence/compliance to the intervention, follow-ups, and QL enrollment. Efficacy outcomes are point-prevalence and prolonged abstinence rates at six month follow-up confirmed by saliva cotinine < 15 ng/ml.

1. Introduction

Cigarette smoking causes more death and disability among American workers than their workplace environment (e.g., injuries) [1]. Smoking prevalence among US construction workers (39%) is twice the national average [2]. Construction workers are frequently exposed to a wide range of workplace hazards, including exposure to toxins (e.g., carbon monoxide, air pollutants, fibers), many of which interact with smoking to increase workers' risk for lung cancer and chronic lung disease [3–6]. Construction trades remain overwhelmingly male dominated (2.3% women) [7,8]. Therefore, male construction workers are a high-risk group for smoking-related health problems and should be a prime focus for smoking cessation efforts.

Hispanics/Latinos are one of the fastest growing and largest minority groups in the US [9]. Further, the number of Hispanic/Latino workers employed in the construction sector in the US has tripled over a 10-year period to reach 2.6 million workers in 2014, representing nearly a third of the construction workforce [10]. Despite the fact that Hispanic/Latino construction workers are at high risk for tobacco-related morbidity and mortality, cessation efforts among them are

Abbreviations: QL, quit line; NRT, nicotine replacement treatment; RCT, Randomized clinical trial

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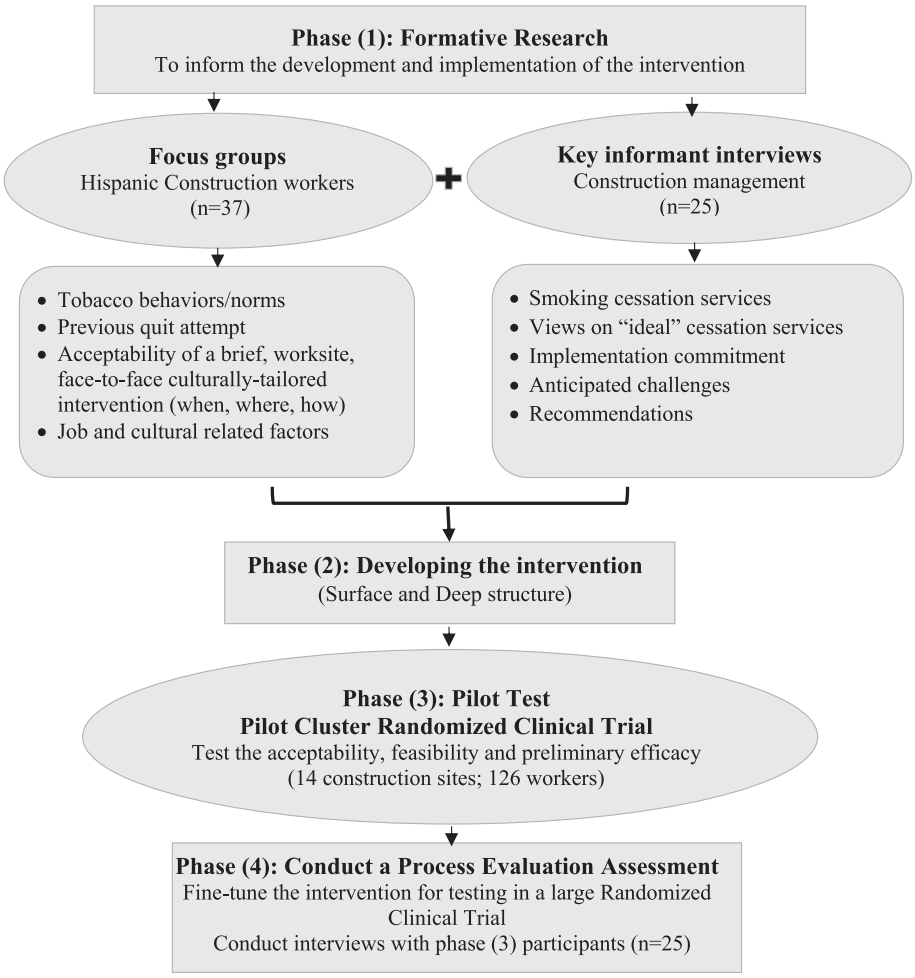

Fig. 1. Study design.

hindered by their limited access to cessation and health promotion services [11,12]. A unique approach to reach out to this population with smoking cessation is through the use of the worksite as an intervention setting [13,14]. Potential benefits of such settings include attracting workers who are less likely to seek advice [15], and the provision of a convenient service that will not require extra efforts to access (e.g. appointment, travel) [13]. Another unique approach developed and tested by our team is to partner with the "food truck" for intervention delivery [16–18]. Food trucks visit construction sites several times a day and can thus provide an optimal opportunity to deliver health promotion services [11,19]. Our pilot study demonstrated the feasibility and success of recruiting around the "food truck" visits as a means to reach this population with health promotion efforts [11].

Despite advances in health promotion programs, promising smoking cessation interventions that are tailored to the culture and work nuances of Hispanic/Latino construction workers are still lacking [20–22]. To date, only a few smoking cessation intervention studies have targeted construction workers [22,23], and none of these were tailored to Hispanic/Latino workers [12]. This project aims to: 1) develop a culturally sensitive smoking cessation intervention for Hispanic/Latino construction workers, built around formative research; 2) test the intervention for feasibility and potential efficacy in a pilot cluster randomized clinical trial (RCT); and 3) conduct a post-intervention evaluation to fine-tune the intervention before wider testing and dissemination [24]. The current report will describe the intervention development and the design, methods, and data analysis plans for its testing in an ongoing pilot cluster RCT.

2. Methods/design

Recently, a novel framework has been recommended to improve cessation services for underserved smokers who are defined as: having a high smoking rate and disproportionate tobacco-related health burden, lacking access to effective treatment; and being understudied in cessation trials [25]. This framework stresses the need for innovative cessation strategies among underserved smokers based on adaption of evidence-based treatments to accommodate the cultural, values, attitudes, and behaviors of the target population [25,26]. Based on this framework, four phases of cultural adaptation are proposed (Fig. 1). Phase (1) involves collecting qualitative data from the target population to help guide changes in the intervention in terms of surface and deep structure. Surface structure refers to matching the intervention content and materials to the social and behavioral characteristics of the target population (e.g., language, location, delivery channel), and deep structure refers to incorporating the core cultural values of the target group to increase saliency of the program impact (e.g., involve family members, get personal, show respect) [27]. Phase (2) involves the adaptation and modifications of the intervention (content, modality, intensity, delivery). Phase (3) involves pilot testing the culturally adapted intervention for feasibility and initial efficacy. Phase (4) involves measurement of a variety of outcomes in addition to treatment response to fine-tune the intervention for large scale testing. Guided by this framework, this section is divided according to the stages of the study into 4 Phases: Formative Research, Developing the Intervention, Pilot Cluster RCT, and Process Evaluation (Fig. 1).