Contemporary Clinical Trials 45 (2015) 404–415

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Fe en Accion/Faith in Action: Design and implementation of a church-based randomized trial to promote physical activity and cancer screening among churchgoing Latinas

Elva M. Arredondo [a,*], Jessica Haughton [a], Guadalupe X. Ayala [a], Donald J. Slymen [a], James F. Sallis [b], Kari Burke [a], Christina Holub [a], Dayana Chanson [a], Lilian G. Perez [a], Rodrigo Valdivia [c], Sherry Ryan [d], John Elder [a]

[a] Graduate School of Public Health, San Diego State University, Institute for Behavioral and Community Health (IBACH), San Diego, CA, USA
[b] Department of Family Medicine and Public Health, University of California, San Diego, Active Living Research, San Diego, CA, USA
[c] Diocese of San Diego, San Diego, CA, USA
[d] School of Public Affairs, San Diego State University, San Diego, CA, USA

ARTICLE INFO

Article history:
Received 18 June 2015
Received in revised form 1 September 2015
Accepted 3 September 2015
Available online 8 September 2015

Keywords:
Faith-based intervention
Health promotion
Minority health
Physical activity
Cancer screening
Hispanics/Latinos

ABSTRACT

Objectives: To describe both conditions of a two-group randomized trial, one that promotes physical activity and one that promotes cancer screening, among churchgoing Latinas. The trial involves *promotoras* (community health workers) targeting multiple levels of the Ecological Model. This trial builds on formative and pilot research findings.
Design: Sixteen churches were randomly assigned to either the physical activity intervention or cancer screening comparison condition (approximately 27 women per church). In both conditions, *promotoras* from each church intervened at the individual- (e.g., beliefs), interpersonal- (e.g., social support), and environmental- (e.g., park features and access to health care) levels to affect change on target behaviors.
Measurements: The study's primary outcome is min/wk of moderate-to-vigorous physical activity (MVPA) at baseline and 12 and 24 months following implementation of intervention activities. We enrolled 436 Latinas (aged 18–65 years) who engaged in less than 250 min/wk of MVPA at baseline as assessed by accelerometer, attended church at least four times per month, lived near their church, and did not have a health condition that could prevent them from participating in physical activity. Participants were asked to complete measures assessing physical activity and cancer screening as well as their correlates at 12- and 24-months.
Summary: Findings from the current study will address gaps in research by showing the long term effectiveness of multi-level faith-based interventions promoting physical activity and cancer screening among Latino communities.

Many chronic diseases impact Latinas at disproportionate rates. Latinos have a higher prevalence of diabetes and obesity than non-Hispanic whites, which puts Latinos at greater risk for developing other health conditions (e.g., cardiovascular health problems and depression). Latina women are twice as likely to be diagnosed with cervical cancer, and 1.5 times more likely to die from cervical cancer compared to non-Hispanic white women. The low engagement in moderate-to-vigorous leisure-time physical activity (MVPA) [1] and screening rates for many cancers like cervical and colorectal [2] contributes to high disease rates and mortality in Latinas. The large size and rapid growth of the Latino population is a compelling rationale to focus on chronic disease prevention, as Latinos will account for most of the U.S. population growth through 2050 [3].

Emerging research suggests that disparities in health behaviors and outcomes are the result of a range of proximal, intermediate, and distal determinants [4]. Proximal determinants involve biologic factors, behaviors, and psychological factors such as mental health status and cognitions. Intermediate determinants consist of social norms and social support, while distal determinants include the social and physical or built environment (e.g., density of grocery stores or parks in a neighborhood). A key tenet of ecological models is that interventions that target multiple levels of influence (e.g., individual, social, and environmental) should be more effective in changing behavior than those that target only one level [4]. There have been a limited number of multi-level interventions focusing on the promotion of physical activity among adults [5–7] and, to our knowledge, only one study used a randomized controlled design [6]. When considering interventions for cancer prevention, a fewer programs have used the ecological approach to inform program development. The relative popularity of multi-level interventions

* Corresponding author.
E-mail address: earredon@mail.sdsu.edu (E.M. Arredondo).

http://dx.doi.org/10.1016/j.cct.2015.09.008
1551-7144/

recognizes the importance of creating socially and physically supportive environments to achieve sustained behavior change.

Numerous health promotion researchers [8–13] and national surveys suggest that churches are ideal settings for Latino-focused health promotion programs because they can have substantial reach into Latino communities. Sixty-eight percent of Latinos identify as Catholic (15% Evangelical Protestant), and close to 42% of Latino Catholics indicate attending church at least weekly [14]. Churches are attractive settings for promoting health because they have infrastructural resources (e.g., meeting spaces) and a system of volunteers that can provide social support for adopting and maintaining new health behavior changes [15]. Health promotion programs that partner closely with churches and increase the capacity of church members to provide mutual support are likely to be sustainable after the research is completed. A systematic literature review of faith-based physical activity interventions underscored the need for implementing faith-based multi-level physical activity programs [16]. This review found that the majority of church-based physical activity interventions increased physical activity. However, almost all of the studies were limited because they assessed physical activity by self-report, were short in duration (intervention of 12 weeks or less), and targeted primarily African American women.

This manuscript describes a two-group randomized controlled trial to assess the effectiveness of a physical activity intervention targeting multiple levels of influence for behaviors among Latinas, *Fe en Acción* (Faith in Action). Sixteen churches were recruited and randomly assigned to either the physical activity intervention or cancer screening comparison condition. Trained bilingual/bicultural (Spanish/English and Mexican-origin) *promotoras* (community health workers) intervened at the individual (e.g., motivational interviewing), social (e.g., informational support), and environmental (e.g., park features and access to health care) levels. Evaluation protocols assessed changes at these levels, including implementation fidelity. The physical activity intervention is innovative in its focus on promoting physical activity in Latino faith-based organizations and its modification of the built environment (e.g., increasing access to safe parks and neighborhoods) [12,17–19]. Churches provide valuable settings in which to promote chronic disease prevention, as they are established institutions that mobilize Latino communities [16,12,18]. Undertaking two interventions simultaneously recognizes the multiple health needs in this community, provides useful services to all participants, and is an efficient method of evaluating multiple interventions.

1. Methods

1.1. Overview of study design and research aims

This two-group randomized controlled trial combines innovative and traditional methods for promoting MVPA and cancer screening (breast, cervical, colorectal, and skin) among Latinas, and is tested simultaneously in a two-group design. Both interventions lasted two years. The study's primary outcome was min/week of accelerometer-assessed MVPA at baseline (M1) and 12 months (M2) and 24 months (M3) following the start of the intervention. We selected cancer screening as a comparison condition given the relevance of this topic to our target community (i.e., low cervical and colorectal cancer screening rates and follow-up). It was hypothesized that over time, participants in the physical activity condition would engage in significantly higher levels of MVPA, compared to participants in the cancer screening condition. We also expected greater changes in individual-, interpersonal-, and environmental-level correlates of physical activity among participants in the physical activity condition compared to those in the cancer screening condition. Conversely, we expected that participants in the cancer screening condition would engage in higher screening rates compared to those in the physical activity intervention. We anticipated greater changes in individual, interpersonal, and environmental correlates of cancer screening in this condition compared to the physical activity condition (Fig. 1).

While recruitment, randomization, *promotora* training, and baseline and 12-month follow-up assessments are all completed, the intervention and final measures remain active through the end of 2015. All study protocols were approved by the Institutional Review Board of San Diego State University. The current trial is registered under NCT01776632.

1.2. Recruitment and eligibility criteria

1.2.1. Recruitment of churches

The Principal Investigator and Project Coordinator discussed the study with the Chancellor of the Roman Catholic Diocese of San Diego, who provided a list of 53 churches offering services in Spanish. A staggered recruitment strategy was used and began for the first wave in January 2011 and was completed for the final wave in March 2013. Project staff approached churches with a minimum of 200 Latino families and at least one Spanish-language mass. Inclusion criteria included agreeing to be randomly assigned to either condition (physical activity or cancer screening) and commitment of space for program activities and participant measurements. The original goal was to only include churches that were at least 3 miles apart. As recruitment progressed it was necessary to include a few churches that were about 1 mile apart. However, the participant criterion that they attend only their nearby church reduced concerns about potential contamination. During enrollment, the pastor from each participating church signed a memorandum of understanding that outlined the pastor's commitment of space for measurement and intervention activities, announcements at mass and other meetings, promotion of the project on church grounds, and assistance in identifying potential candidates for the *promotora* roles. The study recruited 16 Catholic churches in San Diego County and 436 Latinas who attended these churches, an average of 27 participants per church.

1.2.2. Recruitment of participants

Participant recruitment for the first wave began in April 2011 and continued through August 2013 for the final wave of churches. Participants were blinded to condition during recruitment. Women were recruited via fliers, word of mouth, printed announcements in church bulletins, and verbal announcements during Spanish-language masses and other ministry group meetings targeting Latinas (e.g., Bible study, choir, and marriage classes). Recruitment efforts were conducted in Spanish or English. Inclusion criteria were women who self-identified as Latina, were between the ages of 18 and 65, attended the church at least four times a month for any reason, lived within 15 minutes driving distance from the church, had access to reliable transportation to get to the church, identified no barriers to attend activities at the church during the week, planned on attending the church for the next 24 months, did not attend other churches enrolled in the study, and had relatively low levels of physical activity (details described below). Recruitment was limited to those living near and attending only a participating church to enhance exposure to both the classes and the local environmental change components of the intervention. Churchgoers and community members not enrolled in the study could participate in intervention activities as all activities were offered free at the church or local parks and community centers.

Potential participants were excluded if they had a health condition that limited their ability to be physically active (e.g., being pregnant or having a disability). Women were screened and completed the Physical Activity Readiness Questionnaire (PAR-Q) to assess risks for complications resulting from physical activity [20]. The PAR-Q assesses potential heart problems, joint or bone problems, pregnancy, diabetes, and current medication use. Individuals who reported one or more positive responses to the PAR-Q were required to have their physician approve their participation in the program by completing the PARmedX. Table 1 provides the sociodemographic characteristics of our sample.