Contemporary Clinical Trials Communications 10 (2018) 29–35

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

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

Conducting a randomized trial in rural and urban safety-net health centers: Added value of community-based participatory research

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ARTICLE INFO

Keywords:
Colorectal cancer screening
Community-based participatory research
Health disparities
Medically underserved populations
Dissemination and implementation
Randomized trial

ABSTRACT

Background: Colorectal cancer (CRC) is the second most common cancer in the US. Despite evidence that screening reduces CRC incidence and mortality, screening rates are sub-optimal with disparities by race/ethnicity, income, and geography. Rural-urban differences in CRC screening are understudied even though approximately one-fifth of the US population lives in rural areas. This focus on urban populations limits the generalizability and dissemination potential of screening interventions.

Methods: Using community-based participatory research (CBPR) principles, we designed a cluster-randomized trial, adaptable to a range of settings, including rural and urban health centers. We enrolled 483 participants across 11 health centers representing 2 separate networks. Both networks serve medically-underserved communities; however one is primarily rural and one primarily urban.

Results: Our goal in this analysis is to describe baseline characteristics of participants and examine setting-level differences. CBPR was a critical for recruiting networks to the trial. Patient respondents were predominately female (61.3%), African-American (66.5%), and earned < $1200 per month (87.1%). The rural network sample was older; more likely to be female, white, disabled or retired, and have a higher income, but fewer years of education.

Conclusions: Variation in the samples partly reflects the CBPR process and partly reflects inherent differences in the communities. This confirmed the importance of using CBPR when planning for eventual dissemination, as it enhanced our ability to work within diverse settings. These baseline findings indicate that using a uniform approach to implementing a trial or intervention across diverse settings might not be effective or efficient.

1. Introduction

Colorectal cancer (CRC) is the second most common cancer and the second leading cause of cancer-related death in the United States [1]. Routine screening and resultant early detection through a range of strategies (colonoscopy, fecal testing, etc.) [2] are both effective and cost-effective in reducing CRC incidence and mortality and improving survival. Five-year survival for localized CRC is around 90%, but is lower with later-stage detection [3]. CRC incidence and mortality rates have declined over the last few decades yet screening rates remain relatively low and improvement is needed. Only 59% of adults are up-to-date for CRC screening, well below the Healthy People 2020 target of 70.5% [3,4]. There are disparities in CRC screening, mortality, and survival by race, ethnicity, and socioeconomic factors such as income and insurance [5–15].

Much of what we know about CRC screening comes from research in urban areas [5,11]. While fewer studies have focused on rural areas, data suggest that some rural residents face CRC disparities, including higher CRC mortality than urban residents [16–21]. Recent studies have shown that compared to urban residents, rural residents are less likely to have ever been screened for CRC [22] or to be up-to-date with screening guidelines [23]. However, few interventions have been designed for, evaluated in, or disseminated to rural settings. Rural residents and communities are particularly under-represented in research studies on CRC screening interventions. This may contribute to rural-urban CRC disparities [24].

To address the under-representation of CRC screening research and known screening disparities in rural settings, we designed an intervention trial to promote CRC screening in rural and urban federally qualified health centers (FQHCs). This trial was carried out as part of

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https://doi.org/10.1016/j.conctc.2018.02.005
Received 31 July 2017; Received in revised form 15 February 2018; Accepted 27 February 2018
Available online 06 March 2018

the Program for the Elimination of Cancer Disparities (PECAD), an NCI-funded Community Networks Program Center. We planned this as a practical clinical trial [25,26] that was grounded in CBPR [27]. CBPR is a collaborative research approach that allows for participation in all aspects of research by the community affected by the health issue being studied [28]. CBPR may be particularly useful when implementing evidence-based interventions to new settings. Essentially, our community partners were involved in determining every aspect of the study, including study design and planning, recruitment and data collection, as well as intervention selection and adaptation. The inherent differences across settings, particularly rural-urban differences, can make standardizing trial protocols and interventions challenging, but embracing these differences and enabling participation from both rural and urban settings may support successful recruitment, increase the likelihood of intervention success and sustainability, enhance generalizability of findings, and increase the potential for dissemination.

Our goal in this analysis is to describe baseline characteristics of networks and participants to quantify differences between the networks, including the differences in the CBPR related procedural and process factors and how those affected the conduct of the trial. Understanding site differences will allow us to adapt interventions to enable implementation and maximize dissemination. It also will help us adapt future trial procedures to be adaptable to heterogeneous settings.

2. Methods

2.1. Study design

This was a cluster randomized controlled study designed to increase the rate of CRC screening among patients at urban and rural FQHCs. As part of the CBPR approach, PECaD's colon cancer community partnership and the Disparities Elimination Advisory committee (DEAC), which both include community, clinical, and university representation, provided guidance in study design and planning. Health center administrations and primary care providers were involved in planning and implementing the study, including shaping strategies for recruitment and data collection at their sites, and selecting intervention strategies from a “menu” of evidence-based options. These strategies were then tailored to fit each intervention health center, based on discussions with center leaders and local health care providers regarding the logistics and feasibility of each intervention. All procedures and materials were approved by the University's Institutional Review Board and by the administration of each participating health network.

2.2. Study population and recruitment

Health centers (n = 11) were recruited on a rolling basis among FQHCs in metropolitan St. Louis and rural southeastern Missouri. To be included, health centers had to be willing to be randomized to the intervention or control group and to allow the research team access to managers/directors, patients, and providers. To evaluate the intervention, we recruited patients for a self-report baseline survey, with follow-up at 6- and 12-months post-baseline. Participants were eligible if they were English or Spanish-speaking, and age 49 or older. No other inclusion criteria were applied.

While geography (rural versus urban) was a primary defining difference between the two health networks, it was not the sole differentiating factor. To best acknowledge the multiple differences between networks, rather than reducing the networks to a single geographical difference, we chose to refrain from identifying them as “rural” and “urban” and instead label them as network A and network B.

Network A, in the rural area, had sites located an average of four hours from the study headquarters at the university. The administration requested that participants be recruited by mail, indicating that with small waiting areas and fewer patients per day, in-person recruitment would be inefficient and could create challenges for center staff. Through a Memorandum of Understanding, Information Technology specialists generated an automated query that selected patients seen at the health centers in the last 36 months who were English or Spanish speaking, had contact information listed, and were 49 years or older at the time of the query. This list was used to mail an IRB-approved study information sheet, survey invitation, and the option to complete the survey by mail, online, or by telephone.

Network B, in the urban area, had health centers close to the university offices (all practice sites were < 6 miles away). The administration required that the study team recruit participants in-person from the health centers' lobbies. As instructed by the health center administration, research staff set up a table in the main waiting areas, and provided pamphlets and verbal information about the study to patients who indicated interest.

The resulting study population consisted of a total of 490 consented participants across 11 sites. Of those participants, 7 were excluded from the analysis (4 duplicate enrollments, 2 ineligible at baseline due to age, and 1 incomplete enrollment), leaving 483 participants for this baseline analysis. All participants received a $20 gift card for completing the baseline survey.

2.3. Participant survey

Survey items were drawn from pre-existing measures and items used in our prior studies. Where possible, standard measures from national surveys (e.g., HINTS, NHIS, BRFSS, and CAHPS Health Plan Survey) were used, with some modifications to fit the study and improve comprehension. The surveys were pretested internally for length, comprehension, and skip patterns.

2.3.1. Demographics

Relevant demographic measures included gender, month and year of birth (and age), race/ethnicity, monthly income, employment status, and years of education.

2.3.2. Health insurance and utilization

Participants were asked whether they had health insurance and type of insurance; whether they had a usual source of care; and number of visits to a doctor's office, emergency room, or urgent care in the last 12 months. We also asked whether they had delayed or not gotten care because of cost, lack of transportation, or because of the way they thought they would be treated.

2.3.3. CRC screening

Screenings for CRC with fecal occult blood test/fecal immunochemical test (FOBT/FIT), sigmoidoscopy, and colonoscopy were assessed with measures based on Vernon et al. [29]. Participants were asked if they had ever had each test, when they completed their most recent test, if they knew when they were due for their next test, and, for FOBT and sigmoidoscopy, how many tests they had in the past five years.

Based on feedback from network A, we modified the survey slightly for participants from their sites. Specifically, staff at network A indicated that recruitment would be better for a self-administered multimodal survey than for one that required completion by phone. They also requested a shorter survey with a lower reading level. Truncated versions of the survey were created for network A to reduce the reading level and to allow for self-administration by mail or internet. However, key measures analyzed here were asked the same of participants at each site.

2.4. Data analysis

Descriptive statistics from the baseline survey were calculated through SPSS. Bivariate associations were tested to determine differences in patient populations between the different health networks,