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# A randomized controlled trial of a faith-placed, lay health advisor delivered smoking cessation intervention for rural residents

Nancy E. Schoenberg [a,*], Christina R. Studts [b], Brent J. Shelton [c], Meng Liu [d], Richard Clayton [b], Jordan Baeker Bispo [e], Nell Fields [f], Mark Dignan [e], Thomas Cooper [g]

[a] Department of Behavioral Science, University of Kentucky, United States
[b] Department of Health Behavior, University of Kentucky, United States
[c] Division of Cancer Biostatistics, Department of Biostatistics, University of Kentucky, United States
[d] Department of Biostatistics, University of Kentucky, United States
[e] Prevention Research Center, University of Kentucky, United States
[f] Faith Moves Mountains, Whitesburg, Kentucky, United States
[g] College of Dentistry, University of Kentucky, United States

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ABSTRACT

*Introduction.* Rural US residents smoke at higher rates than urban or suburban residents. We report results from a community-based smoking cessation intervention in Appalachian Kentucky.

*Study design.* Single-blind, group-randomized trial with outcome measurements at baseline, 17 weeks and 43 weeks.

*Setting/participants.* This faith-placed CBPR project was located in six counties of rural Appalachian Kentucky. A total of 590 individual participants clustered in 28 churches were enrolled in the study.

*Intervention.* Local lay health advisors delivered the 12-week Cooper/Clayton Method to Stop Smoking program, leveraging sociocultural factors to improve the cultural salience of the program for Appalachian smokers. Participants met with an interventionist for one 90 min group session once per week incorporating didactic information, group discussion, and nicotine replacement therapy.

*Main outcome measures.* The primary outcome was self-reported smoking status. Secondary outcomes included Fagerström nicotine dependence, self-efficacy, and decisional balance.

*Results.* With post-intervention data from 92% of participants, those in intervention group churches ($N = 383$) had 13.6 times higher odds of reporting quitting smoking one month post-intervention than participants in attention control group churches ($N = 154$, $p < 0.0001$). In addition, although only 3.2% of attention control group participants reported quitting during the control period, 15.4% of attention control participants reported quitting smoking after receiving the intervention. A significant dose effect of the 12-session Cooper/Clayton Method was detected: for each additional session completed, the odds of quitting smoking increased by 26%.

*Conclusions.* The Cooper/Clayton Method, delivered in rural Appalachian churches by lay health advisors, has strong potential to reduce smoking rates and improve individuals' health.



## 1. Introduction

### 1.1. Tobacco use: health risks and the Appalachian context

Tobacco use, particularly cigarette smoking, is the leading cause of preventable death in the United States (U.S.), contributing to more than 440,000 premature deaths annually, 8.6 million people living with a serious smoking-related illness, and over $96 billion in annual medical expenses (World Health Organization, 2006; Centers for Disease Control and Prevention, 2010a). One-third of all cancer deaths and significant proportions of CVD, stroke, diabetes, and many other chronic conditions are linked to tobacco use (U.S. Department of Health and Human Services, 2004).

Kentucky ranks second in the nation for cigarette smoking, with 25% of the adult population—over 822,000 individuals—self-identifying as smokers. As shown in Fig. S1, smoking is particularly burdensome in the Appalachian region of the state, with nearly double the U.S. prevalence (30.9% versus 18.5% among men, and 27.3% versus 15.8% for women, respectively) (Centers for Disease Control and Prevention, 2010a, 2010b). Related, lung cancer incidence and mortality rates are 43% and 60% higher in Appalachian Kentucky than in the rest of the nation. Kentucky's 54 central Appalachian counties lead the U.S. in

* Corresponding author at: Marion Pearsall Professor of Behavioral Science, University of Kentucky, Lexington, KY 40536-0086, United States.
*E-mail address:* nesch@uky.edu (N.E. Schoenberg).

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mortality from other smoking-associated cancers [e.g., colorectal cancer, diabetes, and cardiovascular disease (CVD)] (Halverson and Bischak, 2008; Centers for Disease Control and Prevention, n.d.; Mudd-Martin et al., 2014).

### 1.2. Community-based smoking cessation interventions

Over the past 30 years, community-based smoking cessation programs have been implemented and evaluated in both urban (Burton et al., 2004; Stillman et al., 1993) and rural (Brownson et al., 1996; Hancock et al., 2001; Nafziger et al., 2001) US settings with diverse populations. Community-based participatory research (CBPR) efforts in smoking cessation typically target ethnic and racial minorities, (Andrews et al., 2007; Daley et al., 2010; McDonnell et al., 2011; Wu et al., 2009) youth, (Horn et al., 2006; Woodruff et al., 2007) and other marginalized populations experiencing health disparities (Matthews et al., 2013). Smoking cessation studies seldom use CBPR (Nafziger et al., 2001; Schorling et al., 1997). Those that have used CBPR generally have yielded modest positive outcomes. In one recent pilot CBPR project, quit rates were at least twice as high for intervention participants (Andrews et al., 2007; Wu et al., 2009). Two large RCTs of community-level approaches to smoking cessation and prevention, neither of which used CBPR, demonstrated moderate success among some population subgroups, but failed to produce significant community-level quit rates (Hancock et al., 2001; Secker-Walker et al., 2008; The COMMIT Research Group, 1995a, 1995b). Although numerous community-based smoking cessation interventions have been evaluated, the heterogeneity of research quality and rigor, study design, process variables, and outcomes recorded has impeded meaningful meta-analysis of the literature (Secker-Walker et al., 2008). In this article, we report results from a CBPR group-randomized trial designed to test the efficacy of a community-based smoking cessation intervention in Appalachian Kentucky.

## 2. Methods

### 2.1. Setting and overview

This faith-placed CBPR project was located in six counties of rural Appalachian Kentucky from 2009 to 2013. Despite the risk factors and health disparities in this region, central Appalachia is rich in local resources that can be leveraged to improve health, including strong social ties, commitment to remain in place, a history of social activism and mutual aid, involvement with local institutions like churches, and traditions like storytelling that can convey important sociocultural messages.

A decade of CBPR in this region informed the project's focus on local practices and institutions to address health inequities. “Faith Moves Mountains” (FMM) was initiated in 2008 to develop, implement, and evaluate three community-based interventions targeting smoking cessation, energy balance, and cancer screening (Schoenberg et al., 2009). Qualitative formative work revealed community preferences for health promotion interventions to be delivered in local churches. Partnering with 28 diverse, rural Appalachian churches that facilitated recruitment and allowed the integration of culturally salient elements into existing interventions. Such elements included an emphasis on group discussions and social support, the inclusion of scripture, and the traditions of storytelling and witnessing (Schoenberg et al., 2012). Churches and participants were recruited from six Appalachian counties in Kentucky.

### 2.2. Theoretical bases

The intervention was informed by Social Cognitive Theory (SCT) and the socioecological model (Glanz et al., 1997). Social Cognitive Theory (SCT) (Glanz et al., 1997; Bandura, 1986) posits that both internal and external factors (such as self-efficacy, lack of knowledge about how to quit smoking, or availability of smoking cessation classes) influence one's willingness and ability to change an unhealthy behavior. The socioecological model emphasizes contributing factors beyond the individual level, extending consideration to multiple levels of influence including the social environment and social support (McLeroy et al., 1988). Consistent with a socioecologically-imbued SCT and extensive community feedback, the program was placed in churches using lay health advisors as interventionists.

### 2.3. Church and participant recruitment, enrollment, randomization, and staff

All study procedures were approved by the University of Kentucky Institutional Review Board. In this group-randomized trial, churches were the unit of randomization. No complete sampling frame of churches in this region exists; thus, a snowball sampling approach was used to recruit churches. Church representatives (typically the pastor or minister) from diverse congregations were contacted by the local project directors and personally invited to participate in this study. Of the 29 churches invited to participate, 28 agreed to enroll in the project; the declining church suggested that its congregation lacked smokers. Consistent with the central Appalachian region, most congregations were relatively small (50–100 members) and were Baptist (32%), Pentecostal (21%), or non-denominational (18%). Other denominations included Mainline Protestant, Church of God, and Roman Catholic. Since the study design was a cluster-randomized trial, the sample size focused on the group allocation rather than the individual. We aimed to have at least 30 participants in each church, anticipating a substantial attrition rate.

The 28 participating churches were randomly assigned by the study biostatistician to either the intervention ($N = 15$) or the attention control ($N = 13$) group using a computer-generated random number sequence, stratified by congregation sizes (i.e., less than 50 members, 50–100 members, and 100 plus members). Table S1 shows the distribution of the churches by size and denomination.

Within each church, local project staff recruited participants by offering an information session, generally after church services or another church event. Interested individuals were screened for eligibility (age 21 and older, being a current cigarette smoker, speaking English, and residing in Appalachian Kentucky with no plans to move out of the area in the next 9 months). Participants were not required to be church members, but did have to be willing to affiliate with a congregation for the duration of the program. Trained study staff completed the informed consent process and administered the baseline questionnaire to willing and eligible participants. These documents were administered orally, if desired by the participant, to reduce concerns about literacy. Participants received $25 for each questionnaire they completed. A total of 585 individual participants clustered in 28 churches were enrolled in the study.

We employed 6 local lay health advisors (LHAs). The LHAs were identified by the local FMM staff based on their willingness to attend training sessions and periodic retraining; personality traits including integrity, honesty and trustworthiness; commitment to their fellow community members; ability to work with diverse participants; and willingness to travel, be persistent, and communicate effectively with both staff and community members. Most LHAs had worked in previous intervention studies conducted by the investigators in these communities. The LHAs ranged in age from early 20s to late 60s, were both male and female, represented several counties, ranged in educational attainment from having a GED to having completed college, and generally had low to moderate incomes. During the course of a three-day training session, the LHAs were trained and certified in the delivery of human subject's protection and the Cooper/Clayton Method by the developers of the intervention. They also received training in Motivational Interviewing by an external and certified consultant. The LHAs were given continuous feedback throughout intervention delivery by the FMM project directors. In addition, formative community input had