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

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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.

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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

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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

previously suggested that given the challenges of quitting smoking and the high degree of ambivalence about tobacco use in the region, extra attention must be provided to support the struggles of life-long smokers. We employed and trained interviewers, distinct from lay health advisors, to assess outcomes, thereby likely limiting potential positive self-reporting bias.

2.4. Measures

Consistent with our theoretical underpinnings, study measures included a selection of SCT and socioecological constructs. Specifically, participants completed the MOS social support scale (19 Likert-type items, higher scores indicated higher levels of social support); (Sherbourne and Stewart, 1991) the Fagerström nicotine dependence scale (6-item scale yielding both continuous and categorical levels of nicotine dependence); (Buckley et al., 2005) adapted measures of smoking cessation self-efficacy (10 Likert-type items, higher scores indicated higher levels of self-efficacy); (Velicer et al., 1995) and smoking cessation decisional balance (5 Likert-type items measuring perceived benefits, 5 Likert-type items measuring perceived barriers, higher scores indicated higher levels of each) (Prochaska and DiClemente, 1983). Data from the formative phase focus groups (Schoenberg et al., 2014) guided the development of a 10-item index of barriers to smoking cessation. Standard sociodemographic and health data were also collected, including race, age, education and income levels, insurance coverage, household composition, and a comprehensive series of questions on health status. To measure smoking cessation, we used self-reported smoking status, the most commonly employed assessment measure at the time of project initiation and still common today. {Ybarra, 2013 #5134} Cessation was measured as seven-day point prevalence for abstinence. {Williams, 2005 #5135} All instruments were pilot tested with eight local residents to ensure relevance and comprehension.

2.5. Study design

Fig. S2 depicts the flow of this single blinded, two-arm group-randomized trial with an attention control group, through the assessment of the primary outcome at posttest 1. In the intervention arm, data were collected during three assessment periods: upon enrollment (baseline); at 17 weeks after baseline, which was approximately one month after intervention completion (posttest 1); and at 43 weeks after baseline, which was just over six months after intervention completion (exit interview). Participants in the attention control group were administered assessments upon enrollment (baseline); at 17 weeks after baseline (posttest 1); and at 43 weeks after posttest 1, which was 60 weeks after baseline and the same length of time after intervention completion as was scheduled for the intervention group. The intervention group received the smoking cessation program shortly after enrollment, while the attention control group received an attention-control lunch program on stress management between one and three weeks after baseline and initiated the smoking cessation program within one month following posttest 1.

2.6. Smoking cessation intervention

The Cooper/Clayton Method to Stop Smoking is a 12-week behavioral smoking cessation program targeting participants who are dependent on nicotine. Participants met with an interventionist for one 90 min group session once per week for 12 weeks. The manualized intervention curriculum incorporated in-session didactic information via DVDs delivered in each session by the developers, group discussion and processing, and scheduled nicotine replacement therapy (NRT). Following the introductory session, the participants completed a weekly self-monitoring log between sessions to record every cigarette smoked in 30 min segments. Log results were used to recommend dosing of

Nicoderm CQ® patches, initiated after the introductory session and used throughout the remainder of the program. All participants were offered NRT free of charge, but receipt of NRT was for one week only and required program attendance.

The first 6 sessions of the Cooper/Clayton Method focused on biological aspects of nicotine dependence. The final 6 sessions addressed issues related to relapse prevention (i.e., coping with stress, depression, anger, and other triggers for relapse; exercise and food intake). During each weekly group session, participants shared their successes as well as strategies used to overcome any struggles encountered during the previous week. The LHAs were trained to be positive and encouraging. Report of a lapse was addressed with the question, “How many cigarettes were you smoking when you entered the program?” Generally, the relapse level was lower than the starting point, eliciting encouragement from the LHAs. Between the first and second sessions, the LHAs conducted one individualized MI session with each participant to promote adherence to the program, including development of individualized action plans.

The sessions took place in community settings, mainly churches. In the formative work preceding this project, churches were viewed as positive locations, perceived as trustworthy, centrally located, convenient, and more personal and warm than health or medical settings. Moreover, given our past successful health-promotion partnerships with faith communities in the region, we anticipated being able to reach diverse community members. Churches provided space, amenities like beverages and snacks, and input from ministers on spiritual guidance that might bolster cessation efforts. These spiritual references were part of the LHAs' opening and closing segments of the session. In qualitative post-intervention interviews, many participants articulated that the inclusion of scriptural references and location in the church bolstered their commitment to cessation efforts.

2.7. Statistical analysis

Four major research questions were addressed in the analyses. First, intervention efficacy was assessed by comparing the primary outcome of the proportion of individuals smoking at posttest 1 between the intervention and attention control group churches, using individual-level marginal modeling with generalized estimating equations (GEEs). Second, potential differences between intervention and attention control groups were examined for the secondary outcomes of Fagerström nicotine dependence, stage of change, self-efficacy, and decisional balance, also using GEE for continuous outcomes. Third, to evaluate the effect of the intervention within the attention control group churches, McNemar's test for paired proportions adjusted for the group-randomized design (Obuchowski, 1998; Lieber, 1998) was conducted with participants in attention control group churches only. This analysis compared the proportions of attention control participants smoking at posttest 1 and at exit interview (i.e., pre- and post-intervention). Fourth, the potential dose effect of session attendance was assessed, controlling for study arm. Five participants were excluded after randomization and baseline because they reported already having stopped smoking. Of the 585 remaining participants, 48 (8%) did not provide posttest 1 data, and their smoking status was coded as missing. All analyses were conducted using SAS version 9.3.

3. Results

3.1. Sample characteristics

Table 1 shows baseline participant characteristics for the entire sample (N = 585) and indicates initial equivalence between individuals in intervention versus attention control churches. Reflecting the demographics of the region, most participants were white (95.4%) and of lower socioeconomic status (SES), with 70% having a high school education/GED or less; over two-thirds with incomes below \$30,000; and

fewer than one in three currently employed. Nearly one-third of the participants reported lacking health insurance. Regarding health status, only 22% reported their health as excellent or very good, while 37.4% and 18.3% classified their health as fair or poor, respectively.

As shown in Table 2, no statistically significant differences were detected at baseline between participants in the intervention versus attention control group churches regarding scores on the Fagerström scale of nicotine dependence. Most participants were categorized as dependent on nicotine. There were also no statistically significant differences between participants in the intervention and attention control churches in self-efficacy, decisional balance, and barriers to smoking cessation.

Because the randomization scheme involved churches rather than individuals, it is important to examine potential differences between intervention (N = 15) and attention control (N = 13) congregations. As shown in Table S1, several minor imbalances existed between the two groups. For the intervention group, approximately half of the churches were considered small (<50 members), with the remaining churches medium-sized (50–100 members) or larger (>100 members). The attention control group was nearly evenly divided among these three sizes. The use of GEE with unequal cluster sizes likely preserves power despite minor imbalances (Eldridge et al., 2006). Flow of participants through the study is depicted in Fig. 1.

Table 1
Baseline sample characteristics.

	Intervention N = 422	Attention control N = 163	Overall N = 585
Age (in yrs.: mean, sd)	44.8 (13.3)	45.0 (14.3)	44.8 (13.5)
	n (%)	n (%)	n (%)
Race			
White	401 (95.0%)	157 (96.3%)	558 (95.4%)
Non-white	21 (5.0%)	6 (3.7%)	27 (4.6%)
Gender			
Female	279 (66.1%)	104 (63.8%)	383 (65.5%)
Male	142 (33.7%)	59 (36.2%)	201 (34.3%)
Missing	1 (0.2%)	0	1 (0.2%)
Marital status			
Married/partnered	238 (56.4%)	73 (44.8%)	311 (53.2%)
Separated/divorced/widowed	146 (34.6%)	63 (38.7%)	209 (35.7%)
Never married/other	38 (9.0%)	27 (16.6%)	65 (11.1%)
Education			
Less than high school	123 (29.2%)	50 (30.7%)	173 (29.6%)
High school grad/GED	168 (39.8%)	68 (41.7%)	236 (40.3%)
Some college	100 (23.7%)	37 (22.7%)	137 (23.4%)
College graduate or more	28 (6.6%)	5 (3.1%)	33 (5.6%)
Missing	3 (0.7%)	3 (1.8%)	6 (1%)
Income			
Below \$30,000	284 (67.3%)	113 (69.3%)	397 (67.9%)
\$30,001–\$50,000	42 (10.0%)	17 (10.4%)	59 (10.1%)
Above \$50,000	23 (5.5%)	9 (5.5%)	32 (5.5%)
Don't know/prefer not to say	71 (16.8%)	24 (14.7%)	95 (16.2%)
Missing	2 (0.5%)	0	2 (0.3%)
Insurance			
Some insurance (private, company sponsored, Medicare, veteran benefits and others)	214 (50.7%)	76 (46.6%)	290 (49.6%)
Medicaid	64 (15.2%)	37 (22.7%)	101 (17.3%)
None	142 (33.7%)	49 (30.1%)	191 (32.7%)
Missing	2 (0.5%)	1 (0.6%)	3 (0.5%)
Perceived health condition			
Excellent	6 (1.4%)	3 (1.8%)	9 (1.5%)
Very good	39 (9.2%)	18 (11.0%)	57 (9.7%)
Good	125 (29.6%)	67 (41.1%)	192 (32.8%)
Fair	172 (40.8%)	47 (28.8%)	219 (37.4%)
Poor	79 (18.7%)	28 (17.2%)	107 (18.3%)
Missing	1 (0.2%)	0	1 (0.2%)
Currently work			
Yes	123 (29.1%)	52 (31.9%)	175 (29.9%)
No	299 (70.9%)	111 (68.1%)	410 (70.1%)

3.2. Primary outcome: smoking status at posttest

Table 3a highlights the primary outcome, smoking status at posttest 1, collected from 92% of enrolled participants (N = 537). Of participants enrolled in intervention group churches, 28.2% had stopped smoking by 16 weeks after baseline, compared to 3.1% of those enrolled in the attention control group churches. As shown in Table 3b, adjusting for church size and number of enrollees from each church, the odds of stopping smoking were 13.6 times higher among participants in intervention group churches. This effect size increases when sociodemographic and theoretical baseline covariates of interest are included (i.e., education level, income level, insurance status, age, perceived health status, Fagerström nicotine dependence score, stage of change, self-efficacy, and decisional balance).

3.3. Secondary outcomes: Fagerström and psychosocial scales

Table 4 summarizes the effects of the intervention on secondary outcomes at posttest 1. Secondary outcomes included the Fagerström nicotine dependence score, self-efficacy, and decisional balance (perceived benefits and perceived barriers). Participation in the intervention was significantly ($p < .05$) associated with all of these outcomes, with the exception of perceived benefits of quitting smoking. Specifically, compared to those in attention control group churches, at posttest 1 participants in intervention group churches had lower levels of nicotine dependence, greater movement in stage, a stronger sense of self-efficacy, and fewer perceived barriers to stopping smoking.

3.4. Smoking cessation within attention control group churches only

Of the 145 participants in attention control group churches who had smoking status data at posttest 1 and the exit interview (conducted approximately 6 months after intervention completion), 23 (15.8%) reported that they had stopped smoking post-intervention, compared to 5 (3.2%) who reported having quit at posttest 1, before receiving the intervention. However, McNemar's test (adjusting for group-randomization) of paired proportions revealed that this difference was not statistically significant, χ^2 (1df, N = 145) = 3.19, $p = 0.07$.

3.5. Dose effect of the intervention

The average number of sessions attended (out of 12 possible) was similar for participants in the intervention group churches (mean = 6.7) and attention control group churches (mean = 6). Logistic regression analyses controlling for intervention versus attention control group status revealed that independent of group assignment, for each additional session attended, the odds of smoking cessation reported at the exit interview (i.e., 6 months post-intervention) increased by 26%. For example, a participant who attended 6 sessions had 26% higher odds of becoming a nonsmoker than a participant who attended 5 sessions ($p < .001$). Given that most smoking cessation interventions limit the measurement of programmatic adherence exclusively to participants' self-report on NRT use, these exposure results are particularly noteworthy (Kotz et al., 2014).

Table 2
Age, Fagerström score and means (standard deviations) for psychosocial scales by group at baseline.

	Intervention N = 422	Attention control N = 163	Overall N = 585
Age	44.8 (13.3)	45.0 (14.3)	44.9 (13.6)
Fagerström	6.5 (2.2)	6.5 (2.1)	6.5 (2.1)
Self-efficacy	24.6 (10.8)	23.5 (10.3)	24.3 (10.7)
Perceived benefits	18.1 (4.6)	17.1 (4.4)	17.8 (4.6)
Perceived barriers	13.8 (5.0)	14.0 (4.4)	13.9 (4.8)
Barrier score	20.4 (4.8)	19.9 (4.6)	20.3 (4.8)

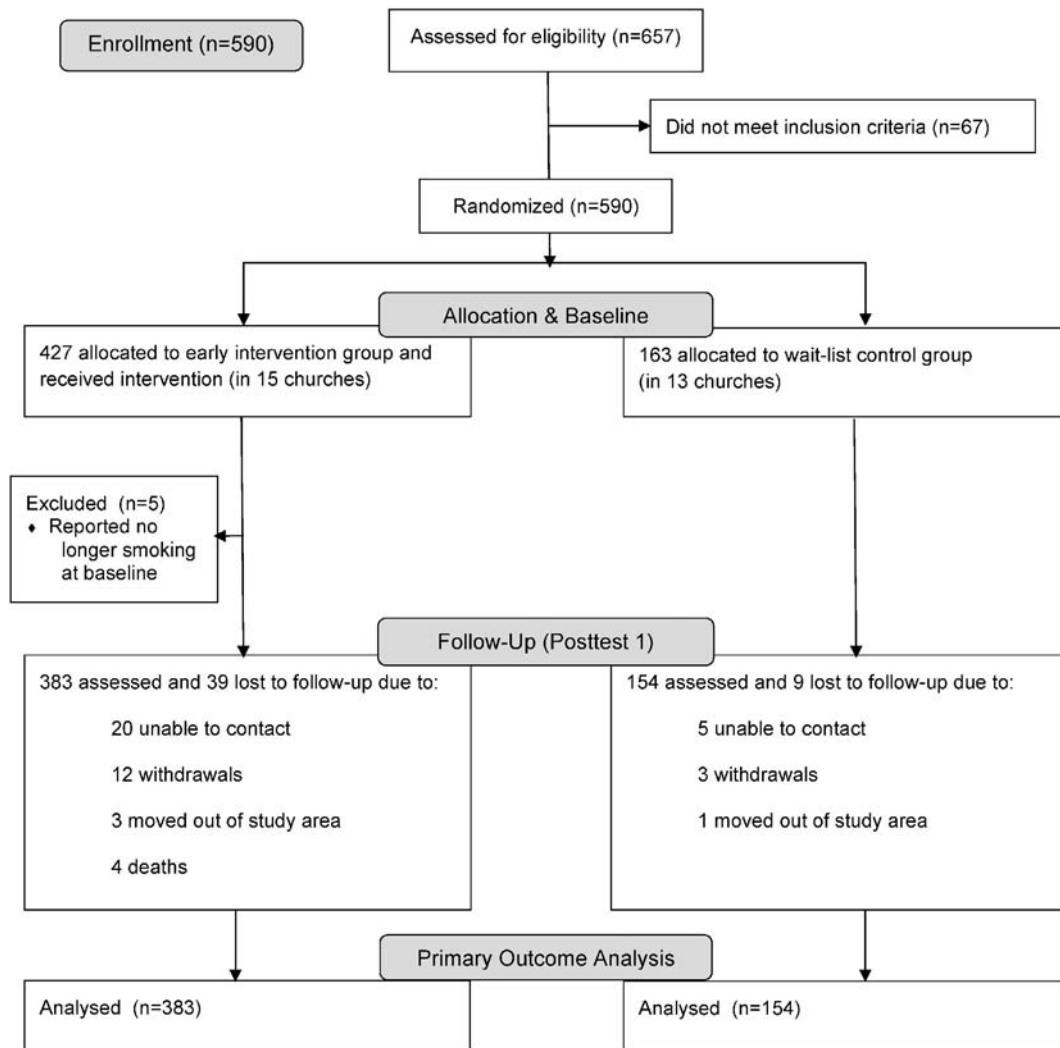


Fig. 1. Study Flow: Kentucky, USA, 2009–2013.

4. Discussion

The 585 participants in this group-randomized trial were residents of 6 persistently poor, rural and isolated Appalachian counties, likely predisposing them to even greater challenges than those facing other nicotine dependent populations. Health and health care resources are less available to health disparity populations, making it challenging to access and utilize existing health care resources. Further, the high prevalence of smoking in this extremely close knit rural region (Schoenberg et al., 2016) constitutes a significant barrier to smoking cessation.

This CBPR project used a single blind, group-randomized trial design, assigning churches to intervention and attention control conditions. One month after the intervention was completed, participants in intervention group churches had dramatically higher odds of quitting smoking (OR = 13.6) compared to those in attention control group churches. Among only those participants in attention control group churches, the proportion reporting smoking cessation increased from 3.1% at posttest 1 (before the attention control group churches received the intervention) to 15.4% at exit interview (6 months after the intervention ended), though this increase was not statistically significant.

Controlling for intervention versus attention control group status, a significant dose effect was detected among all participants: for each additional intervention session completed, the odds of quitting increased by 26%, a finding rarely reported. One factor that might contribute to this dose effect is the distribution of free nicotine replacement

therapy during the sessions. The characteristics of participants themselves may also shape the dose effect; it is possible that those participants who attended more sessions may have been more committed to quitting or may have had more resources (transportation, social support, free time) than participants who attended fewer sessions (Kotz et al., 2014; Raupach et al., 2013).

Several features of this intervention may have resonated with the target population. First, the Cooper/Clayton Method is a comprehensive intervention, allowing participants to address the spectrum of challenges with smoking cessation, from physiologic urges to psychological discomfort to behavior maintenance. Additionally, given the emphasis on social connectedness in this population, the group format and socially supportive orientation of the intervention may have been helpful. The faith-placed nature of the program may have engendered trust in the program and setting. The distribution of free NRT to a low income, underinsured, under-employed population likely increased its access to a proven cessation treatment, as did the delivery of the Cooper/Clayton Method intervention by local LHAs. Moreover, the training and certification of LHAs by the program developers likely promoted fidelity to the intervention.

4.1. Limitations

As in many community-engaged research endeavors, several limitations of this study deserve mention. First, smoking status, the primary

Table 3
Primary outcome: smoking cessation at post-test1.

a					
Primary outcome:	Intervention (N = 422)		Attention control (N = 163)		
Stopped smoking	119 (28.2%)		5 (3.1%)		
Smoking	264 (62.6%)		149 (91.4%)		
Missing	39 (9.2%)		9 (5.5%)		
b					
Covariates	Multivariate model 1*		Multivariate model 2		
	Adjusted odds ratio [95% CI]	p	Adjusted odds ratio (95% CI)	p	
Age (10 years increase)			1.34 [1.17, 1.55]	<.001	
Gender					
Male			Reference	–	
Female			0.99 [0.65, 1.52]	.970	
Marriage					
Married/partnered			Reference	–	
Separated/divorced/widowed			0.64 [0.41, 0.98]	.041	
Never married/other			0.76 [0.19, 3.10]	.706	
Education					
Less than high school			Reference	–	
High school grad/GED			1.27 [0.79, 2.05]	.321	
Some college			1.44 [0.91, 2.27]	.116	
College graduate or more			1.16 [0.48, 2.81]	.734	
Income					
Below \$30,000			Reference	–	
\$30,001–\$50,000			1.29 [0.61, 2.74]	.505	
Above \$50,000			2.28 [0.52, 9.98]	.273	
Don't know/prefer not to say			0.94 [0.51, 1.75]	.854	
Insurance					
None			Reference	–	
Some insurance (private, company sponsored, medicare, veteran benefits and others)			1.36 [0.95, 1.93]	.090	
Medicaid			1.07 [0.48, 2.41]	.861	
Perceived health condition					
Good and above			1.25 [0.75, 2.08]	.396	
Fair and poor			Reference	–	
Current working					
Yes			0.73 [0.36, 1.47]	.378	
No			Reference	–	
Intervention effect					
Intervention	13.62 [6.99, 25.55]	<.001	15.47 [6.65, 35.97]	<.001	
Attention control	Reference	–	Reference	–	
Church membership size					
<50	Reference	–			
50–100	1.65 [0.82, 3.29]	.158	1.45 [0.66, 3.15]	0.3548	
>100	1.39 [0.80, 2.43]	.245	0.48 [0.70, 2.71]	0.3475	
Number of participant (10 increased participants)	0.88 [0.58, 1.34]	.559	0.91 [0.59, 1.41]	0.6744	

*Terms in the model 1 include group (intervention vs. attention control), church membership size (0–50, 51–100, 100+), and number of participants in that church.

*Terms in the model 2 include Age (10 years increase), Gender (Female vs. Male), Marriage (Married, Separated, Never married), Education (Less than High School, High School, Some College, College Graduate), Income (Below \$30,000, \$30,000–\$50,000, Above \$50,000, Unknown), Insurance (None, Some insurance, Medicaid), Perceived Health Condition (Good or above, Fair and Poor), Current working status (Yes, No), group (intervention vs. attention control), church membership size (0–50, 51–100, 100+), and number of participants in that church.

*Boldface indicates statistical significance.

outcome variable, was self-reported and not biochemically verified. Self-report was commonly employed at the initiation of the project, and was consistent with the approach we proposed in our NIH-sponsored proposal. Furthermore, as suggested by the Behavioral Change Consortium (BCC), while biochemical validation is encouraged in populations with distinct social demands (pregnant women, adolescents, patients with smoking-related illnesses), our general population may not warrant such an approach. {Williams, 2005 #5135} Consistent with the BCC, we maintain that the population has a low misrepresentation rate, given the study setting—in small rural churches and counties where “everyone knows what everyone else is doing”—it is likely that participants self-reported smoking status accurately. Additionally, in a region where over one third of adults smoke, {Foundation for a Health Kentucky, 2015 #5136} continuing to smoke may be less stigmatized than in most US locations.

Second, in spite of a relatively large overall sample (N = 585) and roughly equal number of churches in the intervention (N = 15) and attention control (N = 13) groups, the number of individual participants in the two groups was unequal. While our analytic procedures took into account unequal cluster sizes, and while we employed individual-level marginal modeling with GEE, the unequal number of participants in intervention versus attention control group churches illustrates one of the challenges of conducting community-engaged research with local staff in underserved settings. In addition, five participants who were originally enrolled were subsequently excluded because they reported having already stopped smoking at the baseline assessment. We treated the 8% of participants who did not provide post-test 1 data as missing rather than imputing values of the primary outcome variable, so a pure intent-to-treat analysis was not used. Finally, the results observed in our rural Appalachian Kentucky population

Table 4
Secondary outcomes (differences at posttest1).

Score variables	Intervention mean (SD)	Attention control mean (SD)	Overall mean (SD)
Fagerström	N = 267	N = 148	N = 415
Baseline	6.8 (2.08)	6.5 (2.04)	6.7 (2.07)
Posttest 1	4.8 (2.38)	6.1 (2.18)	5.3 (2.39)
p* = 0.001			
Self-efficacy	N = 379	N = 150	N = 529
Baseline	24.5 (10.51)	23.6 (10.30)	24.2 (10.45)
Posttest 1	28.7 (13.35)	22.1 (10.14)	26.8 (12.86)
p* = 0.003			
Perceived benefits	N = 382	N = 155	N = 537
Baseline	18.1 (4.66)	17.1 (4.40)	17.8 (4.61)
Posttest 1	18.1 (4.42)	17.4 (4.39)	17.9 (4.42)
p* = 0.002			
Perceived barriers	N = 377	N = 154	N = 531
Baseline	13.8 (4.97)	14.0 (4.37)	13.8 (4.80)
Posttest 1	13.5 (5.18)	15.0 (4.76)	13.9 (5.11)
p* = 0.016			
Barrier score	N = 379	N = 152	N = 531
Baseline	20.6 (4.79)	19.9 (4.63)	20.4 (4.75)
Posttest 1	22.9 (5.65)	20.9 (3.98)	22.4 (5.31)
p* = 0.005			

Boldface indicates statistical significance.

* p-Value is for posttest 1 differences between intervention and attention control adjusted for baseline score and church size at randomization.

may not be generalizable to other populations; however, we conclude that if this program offers promise among this low resourced, highly nicotine-dependent population, other groups may demonstrate even greater success.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.pmedr.2016.03.006>.

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Transparency document

The Transparency document associated with this article can be found, in the online version.

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