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Original investigation

Effectiveness of Two Community Health Worker Models of Tobacco Dependence Treatment Among Community Residents of Ohio Appalachia

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Abstract

Introduction: Community health workers (CHW) may be effective in the delivery of tobacco dependence treatment with underserved groups. This study evaluated two evidence-based CHW models of treatment. It was hypothesized that smokers assigned to a CHW face-to-face condition would have higher abstinence at 12-month posttreatment than smokers enrolled in CHW referral to a state-sponsored quitline condition. Intrapersonal and treatment-related factors associated with abstinence at 12 months were determined.

Methods: A group-randomized trial was conducted with residents of 12 Ohio Appalachian counties with counties (n = 6) randomized to either a CHW face-to-face (F2F) or CHW quitline (QL) condition. Both conditions included behavioral counseling and free nicotine replacement therapy for 8 weeks. Follow-up data were collected at 3-, 6-, and 12-month posttreatment. Biochemically validated abstinence at 12 months served as the primary outcome.

Results: Seven hundred and seven participants were enrolled (n = 353 CHWF2F; n = 354 CHWQL). Baseline sample characteristics did not differ by condition. Using an intent-to-treat analysis (85.4% retention at 12 months), 13.3% of CHWF2F participants were abstinent at 12 months, compared to 10.7% of CHWQL members (OR = 1.28; 95% confidence interval [CI] = 0.810, 2.014; p = .292). No differences in abstinence were noted at 3 or 6 months by condition. Age, marital status, and baseline levels of cigarette consumption, depressive symptoms, and self-efficacy for quitting in positive settings were associated with abstinence, as was counseling dose during treatment.

Conclusions: This research adds to the body of science evaluating the effectiveness of CHW models of tobacco dependence treatment. Both approaches may offer promise in low-resource settings and underserved regions.

Implications: This 12-county community-based group–randomized trial in Ohio Appalachia adds to the body of science evaluating the effectiveness of CHW models of tobacco dependence treatment.

Both CHW approaches may offer promise in low-resource settings and underserved regions. These findings are useful to national, state, and local tobacco control agencies, as they expand delivery of preventive health care services postadoption of the Affordable Care Act in the United States.

Introduction

Appalachian Americans have a high prevalence of tobacco consumption,[1] higher rates of tobacco-attributable cancers, and lower rates of cancer survival.[2] In this underserved region, prevention-related services, such as tobacco dependence treatment, are often absent and community-based treatment for smoking cessation is lacking.[3] This is unfortunate since Appalachian smokers have difficulty in quitting, as evidenced by poor cessation-related outcomes.[4] To address this gap in treatment services, state and national telephone quitlines are utilized as a resource for those interested in stopping smoking.[5] In this approach, professional counselors, often located out-of-state, provide individual proactive and reactive telephone counseling and nicotine replacement therapy (NRT) through a personal quit plan. A meta-analysis examining this type of treatment noted that telephone counseling significantly increases quit rates compared to minimal or self-help interventions.[6]

An alternative approach that also offers assistance in low-resource regions is the community health worker (CHW) model. Use of CHWs in behavior change is based on Rogers' innovation diffusion theory where diffusion of an innovation, or behavior change is communicated to an individual through another community member.[7] The process involves awareness of the innovation, or knowledge; a favorable attitude toward the innovation, or persuasion; and engagement in activities that lead to adoption of behavior change, or decision and implementation. Certain members of the social system, in this case a community, play important roles in the innovation. They include opinion leaders who have influence, and change agents who positively impact the decisions to change behavior. CHWs, or lay group members, are effective change agents since they can convincingly communicate messages to others. CHWs are members of the community and share similar attitudes, beliefs and values. They are perceived as credible and genuinely interested in the welfare of community members.[7] The use of CHWs has been an effective method for promoting various lifestyle health behavior changes.[8] CHWs can be trained by system-based health care providers to deliver educational and counseling-related services, especially with underserved groups.[9]

With regard to smoking cessation, Lando,[10] the first to compare a professional counselor and a lay health worker, observed that effectiveness was not diminished in a CHW model. Others have noted that CHWs represent an effective method for mobilizing participation in health promotion programs among hard-to-reach urban smokers.[11] CHWs have been trained to serve as tobacco counselors and successfully intervene with smoking mothers seen in pediatric clinics,[12] women residing in public housing,[13] adolescents who smoke,[14] Spanish-speaking communities in the role of "promotores,"[15,16] and among childhood cancer survivors.[17]

As applied to the Appalachian region of Ohio, a clinic-based model of tobacco dependence treatment indicated that cotinine-validated quit rates were significantly higher at 3 and 6 months among women smokers exposed to a CHW-delivered intervention that was managed by a clinic nurse, as compared to control group women smokers who received a personalized letter and self-help materials from the clinic physician.[18] However, the effectiveness in CHW models in community-based trials has yet to be adequately tested in large-scale investigations.

An innovative model, based on Rogers' theory and relevant to underserved rural communities, relies on the credibility of a county-based US Department of Agriculture extension agent as an opinion leader who can assist with recruitment and combines the expertise of a local public health department nurse with a local CHW who delivers face-to-face treatment over an extended period of time. It is plausible that this approach to tobacco dependence treatment is more effective than a one-time encounter with a local CHW who encourages participation in a national or state-sponsored quitline resource. It is also important to examine whether individual characteristics of smokers are associated with abstinence in both CHW models. Given the association between persistent tobacco use and factors such as low socioeconomic status, nicotine dependence, stress, and affective state,[19] tobacco control agencies responsible for treatment delivery may tailor CHW services to meet the needs of community residents at risk for relapse. Finally, there is compelling evidence that the dose of the intervention is related to successful quitting.[20] As such, an examination of dose–response within the two CHW models of treatment is warranted.

The purposes of this study were twofold. First, the effectiveness of CHW face-to-face treatment in promoting long-term abstinence from tobacco among adult Appalachian tobacco users was evaluated. It was hypothesized that CHW face-to-face participants (CHWF2F condition) would have a tobacco abstinence rate at least 10 percentage points greater than participants enrolled in CHW referral to state-sponsored quitline treatment (CHWQL condition) at end-of-treatment (3 months) and 6- and 12-month posttreatment. Second, since the two conditions varied in the delivery of treatment content, an examination of intrapersonal (ie, sociodemographic, affective, and tobacco-related variables) and treatment factors (ie, dose) associated with abstinence at 12 months was performed, controlling for treatment condition. This examination may be useful in future tailoring of tobacco control programs for smokers in low-resource regions.

Methods

Research Design

A group-randomized trial was conducted with smokers recruited from Ohio Appalachian counties ($n = 12$). Counties were randomized to one of two study conditions, CHWF2F treatment or CHWQL treatment, resulting in six counties per condition. The 12 counties were chosen from the 32 total Ohio Appalachian counties based on highest smoking prevalence (range = 30%–42%).[21] Data were collected at baseline and 3, 6, and 12 months following treatment. The study, approved by the University's Institutional Review Board, was conducted in three waves, with one-third of the CHWF2F and one-third of the CHWQL counties included in each wave. Counties were arbitrarily assigned to waves to maximize geographic separation among CHWF2F and CHWQL counties during each wave.

Sample Size Estimation

To test the primary hypothesis, the detectable difference in abstinence rates by condition was calculated as a function of number of counties and average number of smokers per county.[22] An intraclass correlation

of 0.005 was chosen, based on reports of quitting among adults in community-based cessation studies.[23,24] With six counties per condition and 59 smokers per county at baseline, with retention of 50 smokers at 12 months (n = 600), the study had 85% power to detect at least a 10 percentage point difference (15% vs. 5%) in quitting rates at 12 months, using a two-sided Type I error rate of 5%.

Eligibility Criteria

Eligibility criteria included (1) male or female, 18 years and older; (2) current self-reported tobacco use on a daily basis; (3) resident of one of 12 participating counties; (4) the absence of clinical condition contraindicating use of NRT, including severe arrhythmias, severe angina, or myocardial infarction within the previous 4 weeks; (5) if female, nonpregnant, as confirmed by urine human chorionic gonadotropin test; (6) willing to participate in study protocol; and (7) informed written consent.

Study Personnel

All research team members were paid to participate in the implementation of the study. Included as personnel in each of the 12 counties were an extension agent, an interviewer, and CHW. An extension agent is a member of a statewide Cooperative State Research, Education and Extension Service[25] whose mission is to promote county-specific agricultural, environmental, economic, human health, and well-being initiatives and is partially supported by the US Department of Agriculture. Job postings for interviewers and CHWs were placed through the university's human resources Web site. Local interviewers were hired to collect baseline and outcome data. In both conditions, a county-specific lay resident was hired as a CHW to implement the protocol. Residents with a health- or counseling-related background were not considered for the CHW position. In CHWF2F counties, a percentage of a county public health department clinic nurse's salary was paid by project funds to supervise the delivery of the CHWF2F intervention.

All research team members participated in condition-specific face-to-face training to conduct the protocol, as documented in a detailed condition-specific manual. Additionally, prior to implementation of the protocol, in CHWF2F counties, each CHW and county nurse completed a 40-hour tobacco treatment specialist training course conducted by the Ohio Department of Health.

Procedure

Recruitment was accomplished by the county CHW and a county extension agent that facilitated CHW entry to county sites. In order to recruit a diverse study sample, recruitment occurred face-to-face at venues and events that were geographically and socioeconomically distributed. Advertisements were aired on the radio, placed in local county newspapers, and distributed at retail outlets. Potential participants were screened onsite or directed to contact the county CHW via phone for screening. County residents who met eligibility criteria were subsequently contacted by a trained county interviewer who explained the purposes and requirements of the study and obtained informed consent. Next, the interviewer administered a face-to-face questionnaire and participants were paid $25 for completion of the questionnaire. Participants were then informed that a county CHW would contact them to schedule a treatment visit. Extension agents, nurses, interviewers, and CHWs were blinded to the primary hypothesis of the study; they were only aware of the study in those counties assigned to their condition (CHWF2F or CHWQL).

Study Conditions

Community Health Worker Face-to-Face (CHWF2F)

The team included a CHW and a registered nurse employed in the county public health department clinic. Treatment consisted of seven face-to-face visits delivered over a 10-week period. Participants met weekly with the CHW during weeks 1–4 and again at weeks 6, 8, and 10. Each visit, intended to last an average of 30 minutes, was delivered in a mutually agreed on convenient location (eg, participant's home, county Extension office, county library). All participants were encouraged to set visit 3 as a "quit date" and received cognitive-behavioral counseling and NRT throughout the intervention, as recommended by the USPHS *Treating Tobacco Use and Dependence Guideline*.[20] Beginning on quit day and lasting for 8 weeks, each participant was instructed to apply a new 21-mg nicotine patch at the start of each day. A supply of free patches was distributed by the CHW at each visit and all unused patches were returned to the CHW at the subsequent visit. At 48 hours after visit 3, the CHW contacted participants by phone to assess progress and encourage continuation of NRT. The CHW also met separately with the county public health department clinic nurse on a weekly basis to discuss each participant's progress.

Community Health Worker Quitline (CHWQL)

On completion of the baseline interview, the county CHW contacted the participant to schedule a one-time visit at a place convenient to the participant. At this visit, intended to last an average of 30 minutes, each participant was given print information describing the Ohio Tobacco QUIT LINE (1-800-QUIT-NOW). The CHW strongly encouraged the participant to call for proactive telephone counseling and free NRT. Quitline services were provided by trained counselors from National Jewish Health[26] and included up to five proactive telephone counseling sessions, unlimited reactive calls from the participant, and up to two mailings of a 4-week supply of free 21-mg nicotine patches. To receive the second 4-week supply of free NRT, each participant was required to have completed at least two proactive counseling calls.

In both conditions, a research manager observed the CHW's interactions with selected participants to insure protocol fidelity. This was accomplished by determining whether the protocol was delivered according to the condition-specific protocol manual. In rare instances where protocol fidelity was violated, the CHW was alerted and retrained. In addition, for quality control purposes, 10% of study participants were randomly selected and contacted by phone by a research team member to confirm the CHW's documentation of date, length, and content of visits.

Measures

Intrapersonal Factors

All intrapersonal factors were measured at baseline. First, sociodemographic characteristics (ie, age, gender, race, education, marital status, number of household residents, employment status, health insurance status, income), current tobacco consumption (ie, number of cigarettes smoked per day), and number of past year quit attempts were assessed. The Perceived Stress Scale,[27] a four-item instrument that measured the frequency of stress-related affective symptoms during the past month, was administered. Respondents reported frequency on a 5-point Likert scale ranging from "never" to "very often"; the instrument has established reliability and validity.[27] Symptoms in the past week associated with depression were assessed by the Center for Epidemiologic Studies Depression Scale (CES-D) Short Form,[28] a 10-item instrument that is scored on a 4-point

scale from 0 to 3. Scores range from 0 to 30 with higher scores indicating more depressive symptoms. A score of ≥10 is considered a reliable and valid cutpoint for depressive symptoms.[28] Two instruments assessed nicotine dependence, including the Fagerström Test of Nicotine Dependence (FTND)[29] and the Heaviness of Smoking Index (HSI).[30] The FTND is a six-item scale that measures perceived nicotine dependence; the total score ranges from 0 to 10. The HSI is a two-item scale that quantifies time to first cigarette of the day and daily consumption. For the FTND and HSI, higher scores indicate higher dependence. Both scales are considered standard measures of dependence and demonstrate acceptable reliability and validity.[29,30] The Decisional Balance Scale Short Form[31] included two reliable and valid subscales; a three-item "pro" subscale evaluating aspects of tobacco use viewed as positive and a three-item "con" subscale that evaluated negative aspects of use. Responses ranged from 1 (not important) to 5 (extremely important). A Decisional Balance Score was calculated by subtracting the con score from the pro score, with higher scores indicating more favorable views of tobacco use. The Smoking: Self-Efficacy/Temptation Scale Short Form[32] contained three subscales (Positive/Social; Negative/Affective; and Habit/Addictive) that measured how tempted a participant was to smoke in each type of situation. Responses were recorded on a 5-point scale (1 = not tempted at all to 5 = extremely tempted). The instrument has demonstrated excellent reliability and validity.[32]

Outcome Measures

Follow-up interviews were conducted at 3-, 6-, and 12-month posttreatment. Biochemically validated point prevalence abstinence[33] from tobacco at 12 months served as the primary outcome. Abstinence estimates were also calculated at end-of-treatment (3 months) and 6 months. Participants were classified as biochemically abstinent if they self-reported no use of tobacco during the past week and either the saliva cotinine concentration was <15 ng/mL or the expired air carbon monoxide level was <8 parts per million.[34] Prolonged abstinence and number of quit attempts during the protocol and posttreatment were assessed as secondary outcome variables. Prolonged abstinence was defined as self-report of no tobacco use and biochemically validated abstinence at 3, 6, and 12 months, after a 2-week postquit-date grace period.[33] A quit attempt was described as not smoking for at least 24 hours in a serious attempt to stop smoking.[35] Each participant was reimbursed $10 at 3 and 6 months and $25 at 12 months for completing the follow-up interview.

Treatment Factors

At 3-month posttreatment, the dose of the intervention was calculated separately for each condition, based on number of counseling visits completed and amount of NRT administered. For the CHWF2F condition, the number of face-to-face in-person visits (0–7) were counted and the duration of NRT use ranged from <2 to ≥8 weeks. In the CHWQL condition, the number of counseling calls were recorded (0 to ≥5); the number of weeks of NRT supplied were categorized as 0, 2–4, or >4 weeks, according to the mailed distribution policy of the state quitline. Treatment factor information for CHWQL participants was provided on a quarterly basis from National Jewish Health,[26] as part of a contractual research agreement.

Statistical Analyses

Descriptive statistics were used to analyze baseline categorical and continuous level sample characteristics.[36] An intent-to-treat analysis was used to test the primary hypothesis comparing abstinence rates by condition at 12 months. Participants who refused to complete follow-up interviews or did not provide a biological sample (ie, saliva or expired air) after self-reporting abstinence were categorized as smokers. A logistic mixed-effects regression model was used for the primary analysis with biochemically validated abstinence as the response variable, condition as the predictor, and county as a random effect. To characterize other variables that were predictors of 12-month abstinence, a model-building approach was utilized.[37] Intrapersonal or treatment-related variables that were significant at the 0.1 level in unadjusted models were included in the larger model. A backward selection approach was used until only variables that were significant at 0.05 level remained. The approach was repeated three times, first using the entire sample and then for the CHWF2F and CHWQL conditions separately.

Results

The study was implemented in three waves from November 2010 through October 2014. Eight hundred and eighty-five people were screened for participation, with 853 (96.4%) determined to be eligible. Of those eligible, 82.9% enrolled. There was no difference in participation rate by condition. The final sample included 707 participants (n = 353 in the CHWF2F condition and n = 354 in the CHWQL condition). Table 1 summarizes the baseline characteristics of participants.

Baseline Characteristics

Sociodemographic Variables

Participants in both conditions were similar, with the majority of participants categorized as white, female, and aged 25–54 years. Approximately one-half of the sample had greater than a high school/General Educational Development (GED) degree and about 50% were employed full time or part-time; most (~70%) had health insurance. However, one-third of participants were classified as below the federal poverty level.

Affective Variables

Over two-thirds of participants reported a CES-D score (short form) ≥ 10, which represents the cutpoint for the presence of depressive symptomatology. Mean Perceived Stress Scale scores were alike in both conditions.

Tobacco-Related Variables

Participants in both conditions reported smoking about one pack of cigarettes per day, on average. The mean FTND and HSI scores were 5.2 and 3.5, respectively, and on average, participants reported less than two serious quit attempts in the past year. Quitting self-efficacy mean scores were similar by condition.

Outcomes

Abstinence

A total of 85.4% of participants were available for follow-up assessment at 12 months. Retention percentages were similar by condition (85.6% vs. 85.3% for CHWF2F and CHWQL participants, respectively). Table 2 displays 7-day point prevalence abstinence

Table 1. Baseline Characteristics of the Sample by Treatment Group

Characteristic	CHW face-to-face (n = 353)	CHW quitline (n = 354)
	N (%)	*N* (%)
Age (n = 707)		
18–24	16 (4.5)	19 (5.4)
25–54	222 (62.9)	233 (65.8)
≥55	115 (32.6)	102 (28.8)
% Male (n = 707)	121 (34.3)	107 (30.2)
% White (n = 703)	340 (96.3)	332 (93.8)
Highest educational attainment (n = 701)		
<HS degree	47 (13.3)	37 (10.5)
HS degree	106 (30.0)	92 (26.0)
GED degree	20 (5.6)	30 (8.5)
>HS/GED degree	177 (50.1)	192 (54.2)
Marital status (n = 707)		
Single	62 (17.6)	72 (20.3)
Married/living together	187 (53.0)	157 (44.4)
Separated/divorced	84 (23.8)	107 (30.4)
Widowed/other	20 (5.7)	18 (5.1)
Number of people in household (n = 707)		
1	70 (19.8)	60 (17.0)
2	135 (38.2)	127 (35.9)
3	71 (20.1)	77 (21.8)
≥4	77 (21.8)	90 (25.4)
% Employed full/part-time (n = 706)	165 (46.7)	177 (50.0)
% With health insurance (n = 706)	250 (70.8)	254 (71.8)
% Below federal poverty line (100%) (n = 698)	128 (36.3)	120 (33.9)
% CES-D score ≥ 10 (short form)	244 (69.1)	236 (66.7)
	Mean (*SD*)	Mean (*SD*)
Cigarettes smoked per day	22.3 (11.7)	20.9 (9.2)
Fagerström Score	5.2 (2.2)	5.2 (2.2)
Heaviness of Smoking Index	3.5 (1.5)	3.5 (1.4)
Decisional Balance Score	−0.27 (2.8)	−0.32 (3.0)
Past Year Serious Quit Attempts	1.7 (3.4)	1.2 (2.0)
Perceived Stress Scale Score	8.8 (3.7)	9.1 (3.3)
Quitting Self-Efficacy/Temptation Subscale Score		
Positive/Social	10.6 (2.7)	10.8 (2.6)
Negative/Affective	12.6 (2.3)	12.8 (2.1)
Habit/Addictive	10.2 (2.4)	10.2 (2.3)

CES-D = Center for Epidemiologic Studies Depression Scale; CHW = community health workers; GED = General Educational Development; HS = high school.

Table 2. Group Abstinence Percentages at 3-, 6-, and 12-Month Posttreatment by Self-report and Biochemical Validation

7-d point prevalence abstinence	Self-report		Biochemically validation	
	CHW face-to-face (n = 354)	CHW quitline (n = 353)	CHW face-to-face (n = 354)	CHW quitline (n = 353)
3 mo	20.7	14.4	12.2	8.5
6 mo	16.7	10.5	11.3	8.5
12 mo	15.0	12.7	13.3	10.7

CHW = community health workers.

by self-report and biochemical validation for both conditions, with individuals missing follow-up classified as not abstinent. Self-reports of abstinence were higher than biochemically validated estimates in both conditions and at all follow-up intervals. At 12-month follow-up, 13.3% of CHWF2F group participants were biochemically validated to be abstinent, as compared to 10.7% of CHWQL group members (*OR* = 1.28; 95% CI = 0.810, 2.014; p = .292). Similarly, no statistically significant differences in self-reported or biochemically validated abstinence were noted by condition at 3 or 6 months follow-up. Prolonged abstinence was approximately twice as high for CHWF2F participants (7.9%, 5.7%, and 5.4% at 3, 6, and 12 months) compared to 4.5%, 2.5%, and 2.5% at 3, 6, and 12 months for CHWQL condition member, but these differences were also not statistically significant (data not shown).

Quit Attempts

At 3-month posttreatment, 95.7% of CHWF2F participants reported at least one quit attempt, as compared to 81.4% of CHWQL

participants. This difference was statistically significant (p = .0001). The median number of self-reported posttreatment quit attempts for those still smoking at 12 months was 3 (25th percentile = 1; 75th percentile = 5) and 2 (25th percentile = 1; 75th percentile = 4) for CHWF2F and CHWQL participants, respectively (p = .105).

Intrapersonal Factors

As presented in Table 3, three logistic regression model analyses were conducted. With participants from both treatment conditions included in the analyses, and controlling for treatment condition, those with higher daily cigarette consumption at baseline were less likely to be abstinent at 12 months. Specifically, for each additional cigarette consumed, participants were, on average, 6% less likely to be abstinent at 12-month posttreatment (adjusted odds ratio [*AOR*] = 0.94; 95% CI = 0.91, 0.97; p < .001). In addition, each one-unit increase in CES-D score at baseline was associated with 6% lower odds of quitting (*AOR* = 0.94; 95% CI = 0.90, 0.99; p = .022).

Among CHWF2F participants only, older age and daily cigarette consumption at baseline were significantly associated with abstinence at 12-month posttreatment. For each additional year in age, participants were 4% more likely to quit (*AOR* = 1.04; 95% CI = 1.01, 1.06; p = .003), and for each additional cigarette smoked at baseline, participants were 8% less likely to be abstinent at 12-month posttreatment (*AOR* = 0.92; 95% CI = 0.88, 0.96; p < .001).

Among CHWQL participants only, having depressive symptoms at baseline (ie, CES-D ≥ 10) was associated with failure to quit. Those classified above the cutpoint for depressive symptoms were about 56% less likely to be abstinent at 12 months (*AOR* = 0.44; 95% CI = 0.22, 0.89; p = .023) compared to those below the cutpoint. Marital status was also associated with abstinence at 12 months (p = .019); those who were married or living together were more likely to be abstinent at 12 months (*AOR* = 1.45; 95% CI = 0.60, 3.47) compared to those who were single, while those who were separated/divorced were less likely to be abstinent at 12 months (*AOR* = 0.34; 95% CI = 0.11, 1.10). A third variable was associated with failure to quit among CHWQL participants. Those who reported lower self-efficacy for quitting in positive settings (eg, socializing with friends) at baseline were 16% less likely to quit for each additional one-unit increase in subscale score (*AOR* = 0.84; 95% CI = 0.73, 0.96; p = .011).

Treatment Factors

Dose (ie, counseling visits and NRT) and abstinence at 12-month posttreatment is summarized in Table 4. Among CHWF2F participants, those who completed all seven face-to-face visits had the highest rate of abstinence (17%) at 12 months; almost one-fifth who used NRT for 4–6 weeks were abstinent. In contrast, only 6% of CHWF2F participants who completed 0–4 visits were abstinent and 4% of those who used NRT for <2 weeks were biochemically validated as abstinent at 12 months. With regard to CHWQL participants, 23% who completed five or more calls were abstinent, while those who completed fewer calls had abstinence rates of ≤8%. The relationship between use of NRT and abstinence at 12 months was less apparent. Those who received no NRT had abstinence rates of 11%, while those who received a 2- to 4-week and >4-week supply had abstinence rates of 9% and 12%, respectively.

Discussion

This study examined the effectiveness of a large-scale trial that utilized CHWs to deliver tobacco dependence treatment to Ohio Appalachian adults interested in quitting smoking. The 12-county group–randomized trial design successfully recruited participants who were similar with regard to sociodemographic and tobacco-related characteristics. Seven hundred and seven participants were enrolled to attain a highly powered sample size. Participant attrition was minimal throughout the 12-month follow-up; incentives, such as free NRT and modest gift cards (ie, $70 total), as well as reliance on local county research staff, may have contributed to these notable recruitment and 12-month retention rates.

The protocol for both conditions was based on USPHS clinical practice guidelines[20]; the CHWF2F condition was more intensive and involved additional protocol supervision by a county public health department clinic nurse. On the other hand, the CHWQL condition used fewer county resources, as treatment was delivered through a state-sponsored quitline. Despite these distinctions, a significant difference in point prevalence and prolonged abstinence was not detected between conditions at 3, 6, or 12 months. A significantly greater proportion of CHWF2F participants reported at least one quit attempt and their abstinence rates approached the hypothesized estimate. However, the CHWQL 12-month abstinence estimate of 10.7% was

Table 3. Adjusted Odds Ratios and 95% CI From Logistic Regression Models for the Primary Outcome, Biochemically Validated Abstinence at 12-Month Postintervention

Variable	Adjusted odds ratio (95% CI)	p
Model with both treatment groups included (n = 707)		
Treatment	1.35 (0.85, 2.15)	.210
Cigarette consumption per day: one-unit increase	0.94 (0.91, 0.97)	<.001
Depression score (short form): one-unit increase	0.94 (0.90, 0.99)	.022
Model with CHW face-to-face treatment group only (n = 353)		
Age: 1-y increase	1.04 (1.01, 1.06)	.003
Cigarette consumption per day: one-unit increase	0.92 (0.88, 0.96)	<.001
Model with CHW quitline treatment group only (n = 354)		
Depression CES-D score ≥ 10 (short form)	0.44 (0.22, 0.89)	.023
Marital status		.019
Single	1.00 (ref.)	
Married/living together	1.45 (0.60, 3.47)	
Separated/divorced	0.34 (0.11, 1.10)	
Self-efficacy (positive score): one-unit increase	0.84 (0.73, 0.96)	.011

CES-D = Center for Epidemiologic Studies Depression Scale; CHW = community health workers; CI = confidence interval.

Table 4. Dose of Counseling/NRT and 12-Month Abstinence, According to Face-to Face and Quitline Treatment Groups

Dose	*N* (% of total)	% Abstinent at 12 mo
Face-to-face in-person visits (*N*)		
0–4	54 (16)	6
5	30 (9)	10
6	64 (18)	13
7	205 (58)	17
Face-to-face NRT duration		
<2 wk	51 (14)	4
2–4 wk	38 (11)	13
4–6 wk	54 (15)	19
6–8 wk	92 (26)	14
≥8 wk	118 (33)	14
Quitline counseling calls (*N*)		
No calls	68 (22)	5
1–2	124 (35)	8
3–4	74 (21)	7
≥5	88 (25)	23
Quitline weeks of NRT given		
0	114 (32)	11
2–4	119 (34)	9
>4	121 (34)	12

NRT = nicotine replacement therapy.

higher than expected. This finding is encouraging and consistent with recent meta-analytic results for quitline interventions.[6] It should be noted that a 5% abstinence estimate had been postulated for the CHWQL condition since previous studies had recruited smokers after an initial proactive quitline call was made. Conversely, this study recruited smokers first at community sites and then tested whether a CHW could successfully prompt a smoker to call a quitline where treatment was offered. Second, participants in this study were categorized as abstinent based on self-report and biochemical validation, rather than self-report only, as had been considered sufficient in the meta-analysis.[6] For these reasons, a conservative estimate of abstinence in the CHWQL condition was used to test the study hypothesis.

Abstinence estimates remained relatively stable over the course of 12-month follow-up; as such, it is unclear whether extending treatment past 8 weeks would have influenced 12-month outcomes. Also, these results may be partially explained by intrapersonal and treatment factors that were associated with abstinence. The baseline level of depressive symptoms noted in this sample was startling and higher than the 50% prevalence noted in an earlier clinic-based CHW-delivered intervention among female Ohio Appalachian smokers.[18] Further, logistic regression analyses indicated that CHWQL participants categorized with a high level of depressive symptoms had significantly lower odds of quitting, as compared to those without symptoms. Interestingly, this finding was not apparent for those assigned to the CHWF2F condition. Although not directly measured, it is possible that participants engaged in weekly face-to-face counseling visits also received CHW support that lessened depressive symptoms. Of note, married or partnered participants in the CHWQL condition were more successful, suggesting that partners provided a certain degree of support. In addition, CHWQL participants who initially reported lower self-efficacy for quitting in positive situations were less likely to succeed at 12 months. Again, while not assessed in this study, it could be that long-distance counseling via the quitline fails to sufficiently address a participant's temptation to smoke in positive situations. Conversely, face-to-face counseling from a CHW who is sensitive to local prosmoking norms and able to appreciate cultural pressures in social situations may provide more assistance. These elements of CHWF2F treatment are consistent with Rogers' Diffusion of Innovation theoretical constructs where local change agents are viewed as instrumental to the adoption of new behaviors.[7] In the CHWQL condition, CHWs promoted referral to a quitline but were not directly involved in smoking behavior change by the participant. These findings may provide tobacco control agencies with additional information about treatment factors as CHW interventions are designed.

The USPHS clinical practice guideline for treating tobacco dependence recommends both behavioral counseling and pharmacotherapy.[20] Results from this study indicated that counseling dose, measured by number of visits in the CHWF2F condition and number of phone calls in the CHWQL condition, was associated with abstinence. The relationship between adherence to pharmacotherapy and abstinence was not straightforward. Findings from this research suggest that counseling is critical, while NRT may not be needed by all participants. Because of differences in the timing and delivery of nicotine patches by condition, this finding should be interpreted with caution. CHWF2F participants received patches from the CHW on a weekly/biweekly basis; CHWQL participants received two 4-week mailings. Additional analyses are planned to determine if process-related factors associated with counseling influenced outcomes (eg, participant responsiveness to counseling visit/call; unlimited vs. limited cell phone minutes contract).

The contribution of other relevant social and contextual factors to persistent smoking, even among those motivated to quit, must be acknowledged. It has been argued that social contextual variables that include interpersonal, organizational, neighborhood, and community-level factors have been inadequately addressed in traditional tobacco control programs.[38–40] Lack of attention to these factors may partially explain the increasing class-based disparity in smoking behavior.[19] Studies that examine these factors in concert with determining the efficacy of tobacco dependence treatment approaches could assist to better understand the challenges associated with achieving permanent abstinence.

As the Affordable Care Act facilitates access to health insurance for underserved US residents, innovative CHW models may be needed to address the increasing demand for preventive services. Tobacco dependence treatment represents a critically needed preventive service, especially among selected groups. For example, Medicaid expansion provides an opportunity to test CHW models of tobacco dependence treatment among Medicaid enrollees with smoking prevalence estimates double that of the general population.[1] Incorporating a chronic disease management approach to tobacco dependence treatment is suggested by the USPHS *Treating Tobacco Use and Dependence Guideline*[20] and utilization of trained and appropriately supervised CHWs may be of benefit. However, as Kangovi et al.[41] and others[42] have noted, CHW models must address key barriers to implementation. These barriers include insufficient integration with health care providers, fragmented and disease-specific interventions, lack of clear protocols, high turnover and variable performance, and a history of low-quality evidence. As applied to tobacco dependence treatment, strategies to reduce these barriers might include integration of CHW models within a public health clinic that included rigorous selection of CHWs, intensive training, and detailed protocols.

The strengths of this study included its longitudinal design that was sufficiently powered, biochemical validation of abstinence, and

excellent participant retention. Both conditions were associated with low rates of CHW turnover, and their performance was closely monitored by research staff. Unfortunately, a three-group design that added a usual condition (self-help materials with quitline information only) was not feasible, due to budgetary limitations.

In conclusion, this research adds to the body of science evaluating the effectiveness of CHW models of tobacco dependence treatment. While the two conditions offered different evidence-based treatment delivery formats, both approaches may offer promise in low-resource settings and underserved regions. As a logical next step, a cost-effectiveness analysis of these two formats should be conducted to assist future planning and programing by local and state tobacco control agencies.

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Declaration of Interests

None declared.

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