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Effectiveness of a nurse-managed, lay-led tobacco cessation intervention among Ohio Appalachian women

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Abstract

Objectives—The purpose of this study was to evaluate a nurse-managed lay-led tobacco cessation intervention delivered to adult women in Ohio Appalachia.

Methods—A randomized controlled experimental design included intervention participants (n=147) enrolled in a nurse-managed lay-led protocol that incorporated nicotine replacement and behavioral counseling. Control participants (n=155) received a personalized letter from their clinic physician who advised them to quit smoking and requested they schedule a clinic appointment to discuss cessation.

Results—Self-reported and cotinine-validated quit rates were significantly higher among intervention group participants compared to control group participants at 3 and 6 months follow-up ($p<0.02$). At 12 months, self-reported abstinence was 19.1% (intervention group) and 9.0% (control group), with cotinine-validated rates of 12.2% and 7.1%, respectively ($p=0.13$). Prolonged abstinence rates were significantly different between groups at 3, 6, and 12 months ($p<0.02$). Logistic regression analyses indicated adjusted odds of cotinine-validated quitting was associated with cigarette consumption per day (OR=0.94; 95% CI, 0.89–0.99) and CES-D score ≥ 16 (OR=0.39; 95% CI, 0.17–0.90).

Conclusions—A lay-led approach that is managed by a nurse may serve as an effective cessation strategy among this high-risk population. Additional efforts are needed to sustain long term abstinence, even after intensive intervention.

Keywords

smoking cessation; Appalachia; women; SES; cancer prevention

INTRODUCTION

Socioeconomically disadvantaged populations have higher rates of tobacco-attributable morbidity and mortality, such as heart and lung disease and cancer [1,2]. In relation to the entire United States, incidence and mortality rates from cervical cancer are higher in Appalachian regions [3] and tobacco consumption has been established as an independent risk factor for cervical cancer [4]. Appalachians are known to experience increased levels of poverty compared to the general population and have lower levels of education [5]. In addition, tobacco use is more prevalent among Appalachians, especially those who are disadvantaged [5,6]. For example, among Ohio Appalachian women, smoking prevalence has been estimated at greater

than 30% [5]. Evidence-based tobacco cessation approaches have received limited testing in Appalachian smokers [7] and it has been suggested that barriers and access to preventive services operate, as well as lack of information about tobacco prevention and cessation [8–10]. Within health care settings, clinical interventions (i.e. behavioral counseling and nicotine replacement therapy) are recommended as efficacious approaches to tobacco treatment, but have received little attention among underserved groups [7,11].

Creative approaches offer promise in addressing Appalachian health needs. One model that has received some attention in tobacco cessation treatment involves the use of a lay health adviser to deliver the intervention [12–16]. This model is based on innovation diffusion theory and suggests that lay advisers, or educators, are members of the group of interest who share similar values and are viewed as credible and influential [17]. A tobacco cessation intervention that is coordinated by a health clinic, yet delivered by a lay health adviser, may potentially represent an effective approach for promoting long-term tobacco cessation with a subsequent reduction in morbidity and mortality. The purpose of this study was to evaluate the effectiveness of a lay-led tobacco cessation intervention in promoting long-term abstinence from tobacco among women smokers seen in Ohio Appalachian health clinics. This project was part of a larger National Cancer Institute Center for Population Health and Health Disparities P50 Award entitled 'Reducing Cervical Cancer in Appalachia' (P50 CA105632).

METHODS

Research Design

A randomized controlled longitudinal experimental design was implemented in federally-designated Ohio Appalachian counties. Equal numbers of rural and urban counties were selected using probability proportional to the estimated average annual counts of cervical cancer in each county from 1998–2000. All identified primary care and women's health clinics that served a socioeconomically diverse population and reported > 200 Pap smears/month were invited to participate in the study (n=22). A total of 14 county clinics agreed to participate, for a 63.6% participation rate. Abstinence rates between intervention and control group participants were compared to detect a treatment effect at 3, 6 and 12 months post-randomization. The primary research hypothesis that was tested was the following: intervention group participants will have a point-prevalence tobacco abstinence rate at least 15% greater than control group participants at 12 months.

Sample Size Estimation

To detect a 15% difference in abstinence rates between the intervention and control groups (17.5% vs. 2.5%; chi-square test (1 df)), with a power of 80% and alpha of .05 (two-sided), a total of 150 participants per group (total sample size of 300) were needed.

Eligibility Criteria

To be eligible to participate in this study, the patient must have been: 1) Female; 2) 18 years of age and older; 3) A current self-reported user of tobacco on a daily basis; 4) A resident of an Appalachian county; 5) English-speaking; 6) Receiving care in the clinic within the last two years; 7) Free of any clinical condition that contraindicated use of over-the-counter nicotine replacement therapy, including: severe arrhythmias, severe angina, or myocardial infarction within the previous 4 weeks; 8) Non-pregnant, as confirmed by urine human chorionic gonadotropin (HCG) test; 9) Free of prior history of cervical cancer; and 10) Willing to participate in the study and provide signed, informed written consent. Prior to entry into the study, its purpose was explained and informed consent was obtained. The study was approved by the Human Subjects Biomedical Review Committee at The Ohio State University.

Procedure

Each clinic sent a complete list of women who visited the clinic within the past two years to biostatisticians on the project. Next, a biostatistics core staff member sent randomly-selected names of women to a research nurse assigned to each clinic. A medical chart review of each name was then conducted by a trained clinic nurse to identify potentially eligible women who were sent a letter explaining the study and subsequently received a telephone call to reassess eligibility and invite eligible women to participate in the study. Women who agreed were scheduled for a baseline in-home survey by a trained staff interviewer who answered questions, obtained informed consent and administered a urine pregnancy test prior to baseline data collection. The trained interviewer (who did not participate in delivery of the cessation protocol) read each survey item to the participant and recorded a response into a computer assisted personal interview (CAPI) system. Upon completion of the interview, if eligibility was intact, the participant was randomly assigned to the intervention or control group and the tobacco cessation protocol was implemented.

Independent Variable

Intervention Condition—The intervention was based on the U.S. Public Health Service *Treating Tobacco Use and Dependence* Clinical Practice Guideline [7,11]. A trained lay health adviser was assigned by county to implement the 12 week study protocol. Prior to protocol implementation, lay health advisers and clinic nurses completed 40 hours of training conducted by the research project staff. Training content included understanding of nicotine dependence, effective behavioral counseling techniques, relapse prevention approaches, use of nicotine replacement therapy and adverse side effects.

The 12 week intervention protocol included eight face-to-face visits by the lay health adviser (usually in the woman's home) involving behavioral counseling and nicotine replacement therapy. Participants set a quit date for week 3; at that time participants were instructed to apply a free 21 mg nicotine patch daily for eight weeks. Behavioral counseling was provided by the lay health adviser at each visit, which occurred weekly during weeks 1–4 and bi-weekly at weeks 5–12. Each visit lasted 30–40 minutes. Counseling topics included: 1) concept of nicotine dependence; 2) reasons people use tobacco; 3) health effects of tobacco use (e.g. cervical lesions) and health benefits of cessation; 4) positive and negative aspects of tobacco use (pros and cons of tobacco use); 5) self-monitoring of tobacco consumption behaviors; 6) stimulus-control strategies; 7) withdrawal symptomatology; 8) nicotine replacement therapy; 9) mechanisms for coping with triggers to use; and 10) relapse prevention techniques. Throughout administration of nicotine replacement, all unused nicotine patches were collected and recorded at each visit. A new supply of replacement was then distributed, based on the amount of product needed until the next scheduled visit. Implementation of the intervention strategies were documented by the lay health adviser at each visit. A clinic nurse was assigned to manage, or supervise the implementation of the protocol. In this capacity, the nurse met weekly with each lay health adviser, either by phone or face-to-face, to discuss the smoker's progress. Topics for discussion included participant progress with quitting, barriers to cessation, and issues associated with medication adherence and behavioral counseling.

Control Condition—Participants assigned to the control condition received a letter, signed by their personal clinic physician. The letter strongly advised the woman to quit smoking and encouraged her to make an appointment with the physician to discuss tobacco dependence treatment. A self-help educational pamphlet entitled *You Can Quit Smoking Consumer Guide*¹ was enclosed in the letter. The guide included tips for successful quitting and explained

¹U.S. Public Health Service. Agency for Healthcare Research and Quality. You Can Quit Smoking. <http://www.ahrq.gov/consumer/tobacco/card.htm>. 2000.

that nicotine replacement was an effective medication to use during the cessation process. The guide urged the consumer to contact a health care provider for assistance. One week after mailing, a research staff member called the woman to verify receipt of the letter. If the woman did not recall the letter, the process was repeated.

Measures

Baseline survey—A face-to-face survey was conducted by a trained interviewer at enrollment to assess sociodemographic information, tobacco use and health-related factors. All participants were paid \$25 for completion of the baseline survey.

Social and demographic characteristics: Variables included age (18–30, 31–50, and ≥ 51 years), education ($<$ high school (HS), HS/GED, and $>$ HS), race (white versus other), marital status at time of interview (never married, married/member of couple, and divorced/widowed/separated), employment (full-time, part-time, unemployed/disabled, other), occupation (professional as defined by a degree, skilled labor, unskilled labor, other), annual household income and percent of lifetime spent in an Appalachian county.

Life course socioeconomic position (SEP): Previously validated approaches to adult (i.e. current) and childhood socioeconomic status were used to create a four-level life course SEP variable [18–22]. A woman's adult SEP was defined as 'high' if she had $>$ HS education, had private insurance and her poverty income ratio (PIR) was above the sample median of 1.14 (defined by U.S. Census Bureau as ratio of midpoint of observed family income category to official poverty threshold of a family of the same size for the same calendar year). Otherwise, her adult SEP was defined as 'low'. A woman's childhood SEP was defined as 'high' if she lived with both parents at age 14 years and both parents had a high school education. Otherwise, her childhood SEP was defined as 'low'. The four-level life course SEP included the following categories: 1) high childhood/high adult SEP; 2) high childhood/low adult SEP; 3) low childhood/high adult SEP; and 4) low childhood/low adult SEP.

Cumulative disadvantage: A measure of cumulative disadvantage was constructed using scores from measures of childhood and adult SEP described above. The score for childhood SEP (0–3) was summed with participants receiving one point each for: 1) living with one parent only; 2) having a mother with $<$ HS education; and 3) having a father with $<$ HS education. Likewise, the score for the adult SEP was summed with participants receiving one point each for having: 1) $\leq$ median PIR, 2) no private insurance; and 3) $\leq$ HS education. The total cumulative score was taken as the sum of childhood and adult SEP (range 0–6). Scores were then collapsed into four categories classified as 0, 1–2, 3, and 4–6.

Health-related factors: Variables included the Perceived Stress Scale (PSS) [23], the Center for Epidemiologic Studies Depression Scale (CES-D) [24] and amount of alcohol consumption. The PSS is a ten-item self-report instrument that measures a person's evaluation of stressfulness experienced in the past month. The CES-D is a 20-item screening tool that assesses depressive symptoms. Scores ≥ 16 indicate presence of depressive symptoms that warrant further investigation.

Tobacco-related variables: Measures were self-reported daily cigarette consumption, previous quit attempts, decisional balance [25], the Fagerström Test of Nicotine Dependence (FTND) [26] and the Heavy Smoking Index [27]. A saliva sample was obtained for quantification of cotinine concentration.

Outcome variables—Point prevalence abstinence [28] from tobacco use at 12 months post-randomization served as the primary outcome measure; abstinence was also measured at 3 and

6 months post-randomization. Tobacco use status was determined by self-report with concurrent biochemical confirmation by saliva cotinine analysis. Participants who reported no tobacco use within the previous week and had a saliva cotinine level ≤ 14 ng/mL were classified as abstinent [29]. Participants were paid \$25 for information provided at 12 months and \$15 for data obtained at 3 and 6 months. As a secondary outcome, prolonged abstinence was also assessed at 3, 6, and 12 months post-randomization [28]. All outcome measures were collected by a trained interviewer; the lay health adviser did not participate in any outcome assessments.

Saliva was collected using a Sali-Saver® kit. Samples were processed in the clinic, frozen and brought weekly to the laboratory for storage at -85°C until analyses were conducted. Cotinine was extracted from saliva using a gas chromatography/mass spectrometry (GC-MS) technique [29]. Extraction efficiency was assessed by adding an internal standard (ketamine) to all samples. The assay detection limit for cotinine was 7 ng/ml, while the assay calibration curve was sensitive from 10 to 200 ng/ml.

Statistical Analyses: Baseline characteristics of women in the two groups were examined. Next, self-reported and cotinine-validated abstinence rates were estimated at 3, 6 and 12 months post-randomization. An intent-to-treat analysis was used. Women who refused to complete a follow-up interview at each time point were considered to be smokers at that time interval. To evaluate the primary research hypothesis of the study, abstinence rates at 12 months post-randomization were compared between the intervention and control group participants, first using an unadjusted chi-square statistical test. The primary outcome, cotinine-validated abstinence at 12 months, was modeled using a multivariate logistic regression model that controlled for the effects of covariates. The potential confounders that were included in the analysis of covariates were cigarette consumption, because of differences in the distribution of values between the intervention and control groups, and CES-D score, as it has been significantly associated with current smoking in earlier work among this population.²

RESULTS

The first participant was randomized in August 2005 with final 12 month follow-up completed in March 2009. A total of 566 women were determined as eligible to participate in the study. One hundred fifty-two women refused (26.9%) and 112 women were unable to be contacted to schedule their baseline interview (19.8%). A total of 302 women (53.3%) agreed to participate in the study. Of these, 147 and 155 women were randomized to the intervention and control groups, respectively. Table 1 summarizes the baseline characteristics of the two groups.

Sociodemographic characteristics

There were no significant differences between the two groups for sociodemographic characteristics. The sample was relatively young, with the majority $\leq$ age 50. Almost half had greater than a high school degree and most worked full- or part-time, primarily as unskilled laborers. Income-related variables indicated that a sizeable proportion of the sample was socioeconomically disadvantaged. Approximately 50% had a poverty-income ratio (PIR) of < 1 and an annual household income of $< \$20,000$.

About two-thirds of the sample reported a low socioeconomic position in childhood and at present, and over half had a cumulative disadvantage score of ≥ 3 .

²Hade EM, Ferketich AK, Lehman AM, Paskett ED, Wewers ME, Ruffin M, Tatum C, Lemeshow S. Background and design of the Community Awareness, Resources, and Education (CARE) project: Reducing cervical cancer in Appalachia. *Prev Med* (Submitted).

Health-related factors

Health-related factors did not differ between groups at baseline. About 50% of the sample reported a CES-D score of ≥ 16 , which represents the cut-point for the presence of depressive symptomatology [24]. Almost half of the sample consumed no alcohol in the past month, while close to 15% reported consumption of more than one drink/week during the same time frame. Mean Perceived Stress Scale (PSS) scores were mid-range and nearly identical for the two groups.

Tobacco-related variables

At baseline, groups were similar for mean cotinine concentration, Fagerström score, Heavy Smoking Index, decisional balance and proportion who had ever tried to quit smoking in the past. Control group participants consumed more cigarettes per day at baseline, as compared to intervention group participants ($p=0.05$).

Abstinence Rates

A total of 259 (85.8%), 248 (82.1%), and 246 (81.5%) study participants were available for follow-up assessments at 3, 6, and 12-months, respectively. Retention rates differed between groups at 3 months (80.3% intervention vs. 91% control; $p=0.007$) and 6 months (77.6% intervention vs. 86.5% control; $p=0.04$). There was no statistically significant difference in retention by group at 12 months (77.6% intervention vs. 85.2% control; $p=0.08$).

Self-reported and cotinine-validated 7-day point-prevalence abstinence percentages between the intervention and control groups are presented in Table 2. Only those participants who reported abstinence and provided a saliva sample for cotinine analysis were classified as self-reported abstainers. Results indicated that 27.9% of the intervention group reported abstinence at 3 months, compared to 2.6% in the control condition. The pattern in self-reported abstinence continued at the 6 month timepoint, with 21.8% of intervention group participants reporting abstinence, compared to 5.8% of control group participants. At 12 months, the self-reported rates among intervention and control group participants were 19.1% and 9.0%, respectively.

Cotinine-validated point-prevalence rates indicated statistically significant differences in abstinence for the intervention and control group participants at the 3 and 6 months timepoints, again using an intent-to-treat analysis. Among intervention group participants, at 3 and 6 months, 17.7% and 14.3% reported abstinence respectively, compared to 1.9% and 4.5% for control group participants at 3 months ($p<0.02$) and 6 months ($p<0.02$). At 12 months, the cotinine-validated 7-day point prevalence abstinence comparison was no longer significant (12.2% for intervention group and 7.1% for control group; $p=0.13$). The self-reported prolonged abstinence rates for all intervention group participants were 19.1%, 16.3% and 10.2% at 3, 6 and 12 months, respectively. Among control group participants, 1.3% reported prolonged abstinence at 3 months; none reported prolonged abstinence at 6 and 12 months. Cotinine-validated prolonged abstinence rates are also presented in Table 2. Similarities to self-reported prolonged abstinence were apparent between the two groups, with the caveat that cotinine validation did not necessarily confirm prolonged abstinence [28].

Table 3 presents information about the use of additional smoking cessation resources (e.g. quitline, health care provider) by the entire sample during the 12 months following randomization. Approximately 12–21% of intervention group participants continued to seek resources while the percentage of those using any cessation medication dropped from 68.6% at 3 months to 19.3% at 12 months. Among control group participants, the proportion of women using any resource steadily increased over time, from 14.2 to 29.4%, as did the percentage of participants accessing medication (9.9% to 24.4%).

Logistic regression analysis

A multiple logistic regression was performed to determine factors associated with the primary outcome, 7-day point prevalence cotinine-validated abstinence at 12 months, controlling for group assignment. Although participants were nested within clinics, the final model excluded a clinic effect in the analytic plan. In initial analyses, adding clinic as a random effect contributed to model instability, which was attributed to small numbers of participants in some clinics. Because the clinic effect did not alter model coefficients or final results, and since participants were individually randomized to treatment, the final analytic plan did not control for this effect. As seen in Table 4, the adjusted odds of being classified as an abstainer at 12 months post-randomization were significantly lower for those participants who consumed more cigarettes daily (OR=0.94; 95% CI=0.89–0.99) and had a CES-D score ≥ 16 (OR=0.39; 95% CI=0.17–0.90). The model was assessed by the Hosmer and Lemeshow Test [30] and was determined as fit ($\chi^2=3.98$, df=7, $p=0.78$). The area under the Receiver Operating Characteristic (ROC) curve was 0.69. For every one cigarette increase in daily consumption, the odds of abstinence decreased by 6%. Those with depressive symptomatology (CES-D ≥ 16) were 61% less likely to be classified as an abstainer at 12 months.

DISCUSSION

This investigation represents the first trial of tobacco cessation treatment among adult female Appalachians using the recommendations from the U. S. Public Health Service Clinical Practice Guideline [7]. To date, few controlled trials of evidence-based tobacco treatment exist among Appalachian populations. Findings from this study indicated that intensive treatment that included free nicotine replacement therapy and a nurse-managed lay-led counseling was effective in promoting point-prevalence abstinence at three and six months post-enrollment, but was not sufficient to maintain longer term abstinence (i.e. 12 month), as compared to control group participants. Abstinence rates at all time points were lower than the estimated 6-month quit rate of 23.4% observed in recent meta-analytic studies [7]. These results demonstrate the persistent and threatening nature of tobacco dependence in a group of women at high risk for tobacco-attributable disease. Given the increased risk for tobacco use prevalence and morbidity and mortality estimates among residents of the Appalachian region, additional tobacco control efforts are critically needed. It may be necessary to extend pharmacotherapy and counseling beyond current treatment recommendations to sustain cessation and manage relapse-related events.

The sample characteristics of women smokers enrolled in this study were representative of the general population of smokers, with the exception of education [31]. In the current study, the majority of women had more than a high school education. This finding may be indicative of the decision to use a clinic-based recruitment strategy and enroll women who actively sought health care services in the past two years. On the other hand, the women participants shared many other relevant social factors with current U.S. smokers. The sample, while mostly employed, was primarily composed of blue-collar laborers, living on limited incomes, as noted by the reported low PIR. The lifecourse socioeconomic position of most participants indicated that the majority lived a disadvantaged childhood, which is the critical period for adoption of a smoking behavior [32]. Of note, approximately one-half of the sample demonstrated depressive symptomatology, as demonstrated by their CES-D scores. This finding may partially explain the resumption of smoking in an attempt to perhaps manage and self-medicate during depressive episodes. Indeed, increased daily tobacco consumption and depressive symptoms accounted for the decreased likelihood of being categorized as abstinent at 12 months, based on the logistic regression analyses. In future studies, the role of depression should be addressed, especially in clinic-based trials, where the disorder can be appropriately managed by a health care provider. Similarly, the interaction between depression and the social

environment deserves additional examination, as disadvantage and lifecourse SEP, in the context of an Appalachian culture where tobacco use is socially acceptable, may influence long term cessation outcomes.

Interestingly, a significant portion of intervention group participants underreported post-treatment tobacco use, based on biochemical validation. At three months, approximately 1/3 of self-reported intervention group abstainers were subsequently classified as smokers, when cotinine validation was performed. As previously reported, when demand for abstinence is high, misclassification is more likely to occur [28]. Given the close, interpersonal nature of a lay-led intervention, underreporting by the participant (even to a trained interviewer who was not directly involved with the intervention) may operate to a greater extent. Thus, consideration should be given to using biochemical confirmation as an outcome measure of abstinence in these types of community-based cessation approaches. This recommendation is consistent with the Society for Research on Nicotine and Tobacco's position on biochemical verification of tobacco use and cessation [33]. Demand characteristics may also partially explain the significantly higher attrition rates at three and six month follow-up for intervention group participants, as compared to control condition participants.

With regard to control group participants, the initial quit rates were minimal, which was to be expected, given the self-help approach to treatment [7,11] and the format that required the participant to initiate assistance from the clinic provider. However, the increased use of cessation resources and pharmacotherapy over time, accompanied by increased quit rates over the 12 month follow up period, suggest that control condition women were motivated to seek assistance with quitting. For example, at the time this study was conducted, the Ohio Quitline (with access to nicotine replacement therapy at reduced prices) was promoted in a variety of media outlets, including television. Control condition women may have been more inclined to seek resources, as compared to intervention participants who had already been offered pharmacotherapy during the protocol.

Given the increased prevalence of tobacco use in Appalachian counties, which is coupled with the loss of Ohio Master Settlement Funds that, in the past, supported state-wide tobacco treatment for the underserved,³ clinicians must now accelerate efforts to deliver treatment at point of access. Creative tobacco control efforts must be considered if high risk, vulnerable populations such as these are to be reached. The current study represents an important first step in developing and evaluating a lay-led approach to the delivery of evidence-based treatment among a high-risk vulnerable group [7,11].

Finally, experts have warned that the increasing disparity in prevalence of tobacco use between privileged and disadvantaged groups must be acknowledged [7,34–35]. Public health initiatives have yet to significantly influence tobacco use among poor smokers and it has been suggested that unless the overall life circumstances of deprived groups are improved, future health promotion efforts will not succeed [34–35]. Given this perspective, researchers, clinicians and policymakers must continue to broadly develop and test potentially efficacious mechanisms to reduce the present inequality in tobacco use prevalence and cessation.

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³American Legacy Foundation. For now – Ohio dollars stay for Ohio tobacco control. Legacy e-News February 2009. http://www.reviewsite.net/legacy_e-news/feb_2009/article9.html

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Table 1

Baseline characteristics of the sample by treatment group.

Characteristic	Intervention (n=147)	Control (n=155)	p-value
Demographics			
Age (%)			0.34
18–30	44.2	36.8	
31–50	42.9	45.8	
≥ 51	12.9	17.4	
Education (%)			0.55
Less than High School (HS)	16.3	20.7	
HS diploma or GED	32.7	33.5	
> HS diploma	51.0	45.8	
Race (%)			0.44
White	91.2	93.6	
Other	8.8	6.4	
Marital status (%)			0.57
Never married	25.8	27.1	
Married/member of couple	49.0	43.2	
Divorced/widowed/separated	25.2	29.7	
Employment (%)			0.18
Works full-time or part-time	55.1	48.4	
Unemployed/disabled	20.4	29.7	
Other	24.5	21.9	
Occupation (%)			0.77
Professional (needs a degree)	10.2	10.3	
Skilled labor	23.1	18.7	
Unskilled labor	51.0	52.3	
Other	15.7	18.7	
Percent of lifetime in county (n=301) (%)			0.30
0 to ≤ 25%	13.0	17.4	
> 25 to ≤ 50%	13.0	16.1	
> 50 to ≤ 75%	15.1	9.0	
> 75%	58.9	57.4	
Income –Historical and Current			
Parents owned home at age 14 (%)	66.7	65.2	0.78
No adult man in home at age 14 (n=301) (%)	18.5	12.9	0.18
Poverty income ratio (n=276) (%)			0.47
<1	40.6	51.7	
1–1.99	27.1	25.9	
2–2.99	13.5	8.4	
3–3.99	12.8	9.8	
4–4.99	4.5	2.8	
≥ 5	1.5	1.4	
Annual Household Income (n=276) (%)			0.08
< \$20,000	45.1	58.7	
\$20 – 50,000	40.6	29.4	
> 50,000	14.3	11.9	
Life course SEP (n=274) (%)			0.56
Low child, low adult SEP	61.1	62.9	
Low child, high adult SEP	12.2	7.7	
High child, low adult SEP	17.5	19.6	
High child, high adult SEP	9.2	9.8	
Cumulative disadvantage score (n=274) (%)			0.67
0	9.9	11.2	
1–2	32.8	30.8	
3	25.2	20.3	
4–6	32.1	37.7	
Health-Related Factors			
CES-D score ≥ 16 (%)	52.4	49.0	0.56
Alcohol use (%)			0.69
No drinks in past month	46.9	49.7	
Up to 1 drink/week in past month	39.5	34.8	
More than 1 drink/week in past month	13.6	15.5	
Perceived Stress Scale (PSS) score			0.95
Mean ± SD	20.7 ± 7.2	20.8 ± 8.1	
Range	0–36	5–37	
Tobacco-Related Factors			
Cotinine concentration (ng/mL)			0.09
Mean ± SD	228.3 ± 187.5	268.6 ± 208.1	
Range	0–910	0–952	
Fagerström score			0.26

Characteristic	Intervention (n=147)	Control (n=155)	p-value
Mean $\pm$ SD	4.07 $\pm$ 2.46	4.39 $\pm$ 2.39	0.09
Range	0–10	0–10	
Heavy Smoking Index			0.05
Mean $\pm$ SD	2.7 $\pm$ 1.57	3.03 $\pm$ 1.60	
Range	0–6	0–6	0.89
Daily cigarette consumption (number)			
Mean $\pm$ SD	17.2 $\pm$ 9.4	19.4 $\pm$ 10.3	0.50
Range	3–70	3–50	
Decisional balance			0.89
Mean $\pm$ SD	−7.83 $\pm$ 10.08	−7.67 $\pm$ 9.78	
Range	−32–30	−33–26	0.50
Ever tried to quit smoking (%)	83.7	86.5	

Table 2

Intervention and control group abstinence percentages at 3-, 6-, and 12-month post-randomization by self-report and validated by cotinine[†].

	Intervention (n=147)		Control (n=155)	
	Self-report	Cotinine Validated	Self-Report	Cotinine Validated
7-day Point Prevalence				
3 months	27.9	17.7	2.6	1.9
6 months	21.8	14.3	5.8	4.5
12 months	19.1	12.2	9.0	7.1
Prolonged Abstinence				
3 months	19.1	15.7	1.3	1.3
6 months	16.3	12.9	0	0
12 months	10.2	8.8	0	0

[†] All p-values comparing intervention to control groups were < 0.02 except for 12-month cotinine validated 7-day point prevalence abstinence comparison (p = 0.13)

Table 3

Percentage of intervention and control group participants who used additional resources and other cessation medications at 3-, 6-, and 12-month post-randomization.

	Intervention	Control
Any Smoking Cessation Resource		
3 months (n=259)	11.9	14.2
6 months (n=247)	12.3	20.9
12 months (n=193)	20.9	29.4
Any Smoking Cessation Medication		
3 months (n=259)	68.6	9.9
6 months (n=247)	33.6	14.2
12 months (n=245)	19.3	24.4

Table 4

Crude and adjusted odds ratios (OR) and 95% confidence intervals (CI) from logistic regression model for the primary outcome, cotinine-validated abstinence at 12 month post-randomization.

	Unadjusted OR (95% CI) of 7-day point prevalence abstinence at 12 months	Adjusted [†] OR (95% CI) of 7-day point prevalence abstinence at 12 months
Treatment Group		
Control	1.0	1.0
Intervention	1.83 (0.83–4.01)	1.84 (0.89–4.11)
Cigarette consumption per day		0.94 (0.89–0.99)
CES-D score		
< 16		1.0
≥ 16		0.39 (0.17–0.90)

[†] Adjusted for other variables listed