

## Brief Report

# Characteristics of Rural Appalachian Women who Enroll in a Tobacco Dependence Treatment Clinical Trial

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## Abstract

**Introduction:** Clinical trials are needed to inform evidence-based smoking cessation approaches in rural and Appalachian women, but trial enrollment in these groups is sparse. Little is known about factors associated with enrollment of Appalachian women in tobacco dependence treatment randomized clinical trials (RCT). We report a comparison of Appalachian women enrolling in a tobacco dependence treatment RCT to those declining and identify correlates to enrollment.

**Methods:** Smokers identified during a cervical health-related survey among Ohio Appalachian women were invited to enroll in a tobacco dependence treatment RCT incorporating behavioral counseling and nicotine replacement. Women who agreed to enroll were compared to women who declined in terms of sociodemographic, health- and smoking-related measures.

**Results:** The mean age of women sampled was 35.1 years. Women reported daily consumption of 1–10 (39%), 11–20 (46%), or >20 (16%) cigarettes. In a multivariable logistic regression model adjusting for age and nicotine dependence, pros of smoking most outweighing cons (odds ratio [OR] = 0.11, 95% confidence intervals [CI] = 0.03, 0.39), ≥3 prior quit attempts versus 1 attempt (OR = 0.18, 95% CI = 0.06, 0.59), and not having health insurance (OR = 0.29, 95% CI = 0.12, 0.77) were associated with decreased odds of RCT enrollment.

**Conclusions:** Rural Appalachian women who enrolled in a tobacco dependence treatment RCT differed significantly in motivational and cognitive attitudes toward smoking, insurance status, and number of prior quit attempts, as compared to those who did not enroll. Techniques that foster motivation to quit smoking as a means of boosting RCT enrollment are discussed.

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## Introduction

Appalachian residents have a higher prevalence of tobacco use compared to the U.S. population (State of Ohio, Department of Insurance, Department of Job and Family Services, Department of Health, and Department of Mental Health, 2009; Zhang et al., 2008). Rural and Appalachian smokers experience substantial barriers to cessation services, as well as attitudes and beliefs that interfere with utilization of cessation resources (Ahijevych et al., 2003; Hutcheson et al., 2008; Stevens, Colwell, and Hutchison, 2003; Wewers et al., 2000). Little evidence exists to guide tailored interventions to encourage smoking cessation in rural settings, and the U.S. Public Health Service has called for renewed emphasis on trials of new techniques and treatment delivery strategies among populations of high smoking prevalence (Fiore et al., 2008). However, clinical trials conducted in rural Appalachian communities have suffered from poor rates of enrollment (Paskett et al., 2002).

Potential barriers to trial participation identified by rural survey respondents include transportation issues, work-related issues, and aversion to outsiders (Morgan, Fahs, and Klesh, 2005). In general, studies of tobacco dependence treatment trials have identified factors such as heavier smoking, greater nicotine dependence, older age, employment, and higher levels of education that are positively associated with participation (Ahluwalia et al., 2002; Dahm et al., 2009; Fortmann and Killen, 1994; Gariti et al., 2008; Ruggiero, Webster, Peipert, and Wood, 2003; Schnoll et al., 2004). Associations have not been consistent between groups, and no prior studies have focused on rural Appalachian women. It is difficult to use these studies to hypothesize which factors may be associated with enrollment of rural Appalachian women in tobacco dependence treatment trials.

In this study, we investigated correlates of enrollment in a tobacco dependence treatment randomized clinical trial (RCT) offered to rural Appalachian female smokers. These women were identified as current smokers during a study about cervical health in Appalachian women. Our findings may be used to develop hypotheses of factors associated with tobacco dependence treatment trial enrollment among this understudied group. Better understanding of these factors may lead to increased enrollment of rural and Appalachian women in tobacco dependence treatment trials, expanding the representativeness of future trials.

## Methods

Data were collected during face-to-face baseline surveys for the CARE Project (P50 CA105632), a study of cervical cancer disparities in Ohio Appalachia (Paskett et al., 2010). Clinics in 16 Ohio Appalachian counties were invited to participate if they performed more than 200 cervical cancer screenings per month and served a population of diverse socioeconomic status; 14 (63.6%) of 22 invited clinics participated. Eligibility criteria for survey respondents included female, aged 18 or older, English-speaking resident of the county, nonpregnant, intact uterus, no history of invasive cervical cancer, and had visited the clinic in the past 2 years. Among 4585 women randomly sampled from study clinics, 2903 were potentially eligible by chart review and 801 were contacted and fully eligible to be interviewed. Interviews were conducted at women's homes: 570 women completed interviews and one woman partially completed an interview. Interviews identified 297 never smokers, 117 former smokers, and 156 current smokers reporting daily tobacco use. Current smokers were invited to participate in a tobacco dependence treatment RCT (Wewers, Ferketich, Harness, and Paskett, 2009), and these women are the focus of our report.

Interviewers explained to survey respondents that RCT participants would be randomized to receive either (a) eight free behavioral counseling sessions by a lay health advisor at a time and place chosen by the participant and free nicotine replacement therapy or (b) a "You Can Quit Smoking: Consumer Guide" (Fiore et al., 2000) by mail with a letter from the clinic physician encouraging her to make an appointment to discuss tobacco dependence treatment. Interviews were conducted at the invitation timepoint and 3, 6, and 12 months post-randomization. Women received a gift card for completing each interview.

Sociodemographic measures analyzed included age, education, marital status, employment, insurance status, and poverty income ratio, which is the ratio of the midpoint of observed family income to the poverty threshold of a family of the same size in that calendar year (U.S. Census Bureau, Housing and Household Economic Statistics Division 2009). Health-related measures included alcohol consumption, perceived stress using the Perceived Stress Scale (Cohen, Kamarck, and Mermelstein, 1983), and depressive symptoms using the Center for Epidemiologic Studies Depression Scale (Devins et al., 1988; Myers and Weissman, 1980; Radloff, 1977). Smoking-related measures included daily cigarette consumption, prior quit attempts, nicotine dependence using the Fagerström Test of Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, and Fagerstrom, 1991; Pomerleau, Carton, Lutzke, Flessland, and Pomerleau, 1994), and decisional balance using the Decisional

Balance Scale (Velicer, DiClemente, Prochaska, and Brandenburg, 1985). The outcome variable of interest was categorized as whether or an invited woman enrolled in the offered RCT.

Statistical analysis was performed using SAS, v. 9.2, copyright 2008 SAS Institute Inc., Cary, NC and STATA, version 9.2, copyright 2005 StataCorp LP., College Station, TX. Univariate associations were modeled using logistic regression. The "linear in the logit" assumption that the natural log of the odds of study enrollment is a linear function of continuous covariates was tested using the STATA `fracpoly` command. Univariate associations with  $p < .2$  were included in setwise forward selection of a multivariable logistic model. Variables were grouped in three sets—sociodemographic, health-related, and smoking-related variables—and were identified as significant variables if their addition to the model significantly improved model fit ( $\alpha = 0.05$ ). The final main effects model was assessed for confounding; biologically plausible 2-way interactions; goodness of fit using the Hosmer–Lemeshow test; and discrimination using a Receiver Operating Characteristic curve (Hosmer and Lemeshow, 2000).

## Results

Of 156 women invited to enroll in the offered tobacco dependence treatment RCT, 56 (35.9%) enrolled and 100 (64.1%) declined (Table 1). Age, insurance status, alcohol consumption, decisional balance score, and prior quit attempts qualified for consideration in setwise model selection ( $p < .2$ ). The continuous decisional balance variable failed the linear in the logit assumption, so a categorical variable using score quartiles was substituted. Age, insurance status, decisional balance, and prior quit attempts each significantly improved model fit during setwise model selection ( $p < .05$ ); however, addition of alcohol consumption to a model containing age and insurance status did not significantly improve fit ( $p = .18$ ). FTND score was included in the multivariable model as a confounder of the association between prior quit attempts and enrollment: the unadjusted odds ratio (OR) and the FTND-adjusted OR for prior quit attempts differed by 24%.

The final multivariable logistic model showed that RCT enrollment was significantly associated with decisional balance, insurance status, and prior quit attempts after adjusting for age and nicotine dependence (Table 2). The final model had good fit ( $p = .092$ ) and discrimination ( $c = 0.77$ ), with no biologically plausible interactions identified at the  $\alpha = 0.1$  significance level. After adjusting for other final model covariates, women who scored in the highest quartile on the Decisional Balance Scale had much lower odds of RCT enrollment compared to women who scored in the lowest quartile (OR = 0.11; 95% confidence intervals [CI] = 0.03, 0.39), uninsured women had lower odds of enrollment compared to women with any health insurance (OR = 0.29; 95% CI = 0.12, 0.77), and women with more than three prior quit attempts had lower odds of enrollment compared to women with one prior quit attempt (OR = 0.18; 95% CI = 0.06, 0.59).

## Conclusions

In our comparison of rural Appalachian women who enrolled in a tobacco dependence treatment RCT to those who declined

Table 1. Sample Characteristics

Variable	Declined ( <i>n</i> = 100)	Enrolled ( <i>n</i> = 56)	Total ( <i>n</i> = 156)	<i>p</i> value
Age ( <i>n</i> = 156)				0.055
<i>M</i> ± <i>SD</i> (years)	36.4 ± 11.6	32.7 ± 11.2	35.1 ± 11.5	
Range	19–65	19–62	19–65	
Education ( <i>n</i> = 156)				0.607
>High school	42 (42.0%)	24 (42.9%)	66 (42.3%)	
High school/GED <sup>a</sup>	47 (47.0%)	23 (41.1%)	70 (44.9%)	
<High school	11 (11.0%)	9 (16.1%)	20 (12.8%)	
Marital status ( <i>n</i> = 156)				0.257
Married/member of couple	60 (60.0%)	27 (48.2%)	87 (55.8%)	
Divorced/widowed/separated	22 (22.0%)	13 (23.2%)	35 (22.4%)	
Never married	18 (18.0%)	16 (28.6%)	34 (21.8%)	
Employment ( <i>n</i> = 156)				0.872
Employed	63 (63.0%)	34 (60.7%)	97 (62.2%)	
Unemployed/disabled	18 (18.0%)	12 (21.4%)	30 (19.2%)	
Other	19 (19.0%)	10 (17.9%)	29 (18.6%)	
Insurance status ( <i>n</i> = 156)				0.075
Insured	71 (71.0%)	47 (83.9%)	118 (75.6%)	
Uninsured	29 (29.0%)	9 (16.1%)	38 (24.4%)	
Poverty income ratio ( <i>n</i> = 151)				0.698
≥3.00	18 (18.6%)	8 (14.8%)	26 (17.2%)	
2.00–2.99	11 (11.3%)	5 (9.3%)	16 (10.6%)	
1.00–1.99	36 (37.1%)	18 (33.3%)	54 (35.8%)	
<1.00	32 (33.0%)	23 (42.6%)	55 (36.4%)	
Alcohol consumption ( <i>n</i> = 156)				0.052
No drinks in past month	52 (52.0%)	20 (35.7%)	72 (46.2%)	
Any drinks in past month	48 (48.0%)	36 (64.3%)	84 (53.9%)	
Perceived stress score <sup>b</sup> ( <i>n</i> = 156)				0.833
<i>M</i> ± <i>SD</i> (score)	20.6 ± 8.5	20.3 ± 7.7	20.5 ± 8.2	
Range	3–39	7–37	3–39	
CES depression score <sup>c</sup> ( <i>n</i> = 156)				0.566
Score < 16	53 (53.0%)	27 (48.2%)	80 (51.3%)	
Score ≥ 16	47 (47.0%)	29 (51.8%)	76 (48.7%)	
Cigarette consumption ( <i>n</i> = 155)				0.474
1–10 cigarettes/day	37 (37.4%)	23 (41.1%)	60 (38.7%)	
11–20 cigarettes/day	44 (44.4%)	27 (48.2%)	71 (45.8%)	
>20 cigarettes/day	18 (18.2%)	6 (10.7%)	24 (15.5%)	
Prior quit attempts ( <i>n</i> = 156)				0.007
No prior attempts	22 (22.0%)	6 (10.7%)	28 (18.0%)	
1 Prior attempt	19 (19.0%)	20 (35.7%)	39 (25.0%)	
2 Prior attempts	27 (27.0%)	22 (39.3%)	49 (31.4%)	
≥3 Prior attempts	32 (32.0%)	8 (14.3%)	40 (25.6%)	
Decisional Balance Score <sup>d</sup> ( <i>n</i> = 156)				0.013
Quartile 1: –27.34 to –9.65	21 (21.0%)	18 (32.1%)	39 (25.0%)	
Quartile 2: –9.64 to –1.99	26 (26.0%)	13 (23.2%)	39 (25.0%)	
Quartile 3: –1.98 to 8.24	20 (20.0%)	19 (33.9%)	39 (25.0%)	
Quartile 4: 8.25 to 42.71	33 (33.0%)	6 (10.7%)	39 (25.0%)	
Nicotine dependence score <sup>e</sup> ( <i>n</i> = 142)				0.464
<i>M</i> ± <i>SD</i> (score)	3.7 ± 2.5	3.4 ± 2.2	3.6 ± 2.4	
Range	0–9	0–8	0–9	

Note. Sample characteristics are reported by enrollment status. Frequencies and percent distributions are shown for categorical variables. *M*, *SD*, and ranges are shown for continuous variables. Univariate associations between each characteristic and enrollment were analyzed using logistic regression; *p* values for these associations are reported.

<sup>a</sup>General Educational Development.

<sup>b</sup>Measured with Perceived Stress Scale. Higher scores indicate greater perceived stress (range 0–40).

<sup>c</sup>Measured with Center for Epidemiologic Studies Depression Scale. Scores of 16 or greater suggest a depressive case.

<sup>d</sup>Measured with Decisional Balance Scale. Higher scores indicate greater importance of pros of smoking relative to cons of smoking.

<sup>e</sup>Measured with Fagerström Test for Nicotine Dependence. Higher scores suggest greater nicotine dependence (range 0–10).

**Table 2. Characteristics Associated with Tobacco Dependence RCT Enrollment**

Variable	OR	95% CI	p value
Age ( <i>n</i> = 156)	0.97	0.94, 1.01	0.174
Insurance status ( <i>n</i> = 156)			0.013
Insured	1.00		
Uninsured	0.29	0.12, 0.77	
Prior quit attempts ( <i>n</i> = 156)			0.027
No prior attempts	0.32	0.09, 1.12	
1 Prior attempt	1.00		
2 Prior attempts	0.59	0.22, 1.60	
≥3 Prior attempts	0.18	0.06, 0.59	
Decisional Balance Score <sup>a</sup> ( <i>n</i> = 156)			0.002
Quartile 1: -27.34 to -9.65	1.00		
Quartile 2: -9.64 to -1.99	0.35	0.12, 1.05	
Quartile 3: -1.98 to 8.24	0.81	0.28, 2.28	
Quartile 4: 8.25 to 42.71	0.11	0.03, 0.39	
Nicotine Dependence Score <sup>b</sup> ( <i>n</i> = 142)	1.03	0.87, 1.22	0.718

Note. Characteristics associated with enrollment were identified using setwise forward selection. Eligible characteristics were evaluated using multivariable logistic regression. Odds ratios (ORs), 95% confidence intervals (CI), and *p* values are reported.

<sup>a</sup>Measured with Decisional Balance Scale. Higher scores indicate greater importance of pros of smoking relative to cons of smoking.

<sup>b</sup>Measured with Fagerström Test for Nicotine Dependence. Higher scores suggest greater nicotine dependence (range 0–10).

enrollment, we found that women with the most positive decisional balance scores—those for whom the pros of smoking were greatest relative to the cons of smoking—had dramatically lower odds of enrollment than women with the most negative score, after adjusting for other final model variables. This finding suggests that modifying motivational and cognitive attitudes toward smoking may be a means of influencing interest in tobacco dependence trials among rural women.

Trial recruiters may target specific themes from the Decisional Balance Scale to increase receptiveness of rural women to tobacco dependence treatment trials, such as emphasizing the health effects of smoking on potential participants and their families, addressing apprehension of negative consequences of quitting, or using motivational interviewing to strengthen motivation for change (Hutcheson et al., 2008; McCaul et al., 2006; Miller and Rollnick, 2009). Further research is needed to develop brief interventions implemented by trial recruiters to modify attitudes toward smoking among rural women and thus increase tobacco dependence treatment trial enrollment.

We found that women with private insurance, Medicare, or Medicaid had significantly higher odds of RCT enrollment than uninsured women. Insurance status is unlikely to represent a proxy effect of socioeconomic status, given that this isolated difference was observed in the absence of significant differences among other socioeconomic indicators. Uninsured women face financial barriers to participation in many trials. While we attempted to minimize these barriers to enrollment, women randomized to the clinic letter condition faced potential costs for clinic visits and treatment services; these concerns may have disproportionately discouraged uninsured women from RCT enroll-

ment. While further research is needed in this area, future trials may improve enrollment of rural uninsured women by minimizing or eliminating potential costs associated with participation.

Our study found that interest in enrolling in a tobacco dependence treatment trial initially increased and then subsequently diminished with increasing prior quit attempts. Nicotine dependence substantially confounded this association but did not independently influence enrollment. Our findings suggest a complex relationship between nicotine dependence, prior quit attempts, and tobacco dependence treatment trial enrollment. Those with no prior quit attempts may represent a group that is uninterested in smoking cessation and therefore unmotivated to enroll in a tobacco dependence treatment RCT. Those with one or two quit attempts may be interested in quitting and thus are motivated toward enrollment. However, those with greater quit attempts may have lower self-efficacy for cessation, discouraging them from enrolling in the offered RCT. If so, recruiters who boost cessation self-efficacy may increase motivation toward RCT enrollment among those with greater prior quit attempts. Increased enrollment of this underrepresented group would augment both total trial enrollment and the applicability of trial findings to those with multiple prior quit attempts.

The generalizability of our findings to rural and Appalachian populations is limited by the sample population studied. All women were selected from a larger study of cervical cancer risk factors among Appalachian women. There is potential for nonresponse bias, since the estimated response rate was 28%; however, among those successfully contacted and determined to be fully eligible, the participation rate was 71%. Comparison of interviewed women with population-based surveys of Ohio Appalachian adult women (unpublished data) found that survey respondents were of younger age, had high levels of education, and were more likely to be employed; yet, a greater proportion of survey respondents had incomes below the federal poverty line than in the general population. Survey respondents were similar to the general population with respect to marital status, race, and smoking status.

Our offered RCT attempted to mitigate barriers to enrollment experienced by rural and Appalachian women, but barriers to enrollment likely persisted and may have had an important influence that was not directly evaluated in our study. These include skepticism of pharmacotherapy or counseling efficacy, cost and transportation associated with clinic visits in the clinic letter condition, and poor self-efficacy for cessation. While participants chose the time and place of therapies and interviews, the necessary time commitment may have deterred enrollment. Lastly, women were not aware that they would be invited to a tobacco dependence treatment RCT when they consented to a baseline interview about cervical health. Women may have been more receptive to the offered RCT if they were informed before the interview and had more time to weigh their decision.

Future tobacco dependence treatment trials must include a wide range of smokers from different backgrounds to increase the external validity of their findings. We have identified significant differences between those enrolling and those declining enrollment in a tobacco dependence treatment RCT. We propose potential explanations for these findings and suggest potential interventions that may boost enrollment among rural and Appalachian women. Future efforts to develop interventions

based on our findings may be used to increase enrollment among rural and Appalachian women and improve the representativeness of future tobacco dependence treatment trials in underserved smokers.

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### Declaration of Interests

None declared.

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