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All Nations Breath of Life:

A Randomized Trial of Smoking Cessation for American Indians

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Abstract

Introduction—American Indians have the highest cigarette smoking prevalence of any racial/ethnic group in the U.S. There is currently no effective empirically-based smoking-cessation program for American Indians. The purpose of this study was to determine if a culturally tailored smoking-cessation program, All Nations Breath of Life (ANBL), is more effective than a non-tailored cessation program among American Indian smokers.

Design—A multisite RCT was conducted from September 2009 to July 2014; analysis was conducted in 2015.

Setting/Participants—Participants were rural or reservation-based American Indian smokers aged 18 years.

Intervention—Smokers were group randomized to either the culturally tailored ANBL or non-tailored current best practices (CBP) for a total enrolled sample size of 463 (ANBL, $n=243$; CBP, $n=220$).

Main Outcome Measures—The primary outcome of interest was salivary cotinine-verified 7-day point prevalence smoking abstinence at 6 months. Results for both responder-only and intent-to-treat analyses for self-reported and cotinine-verified abstinence are presented.

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Results—Intention-to-treat, imputing all non-responses as smokers, the self-reported point prevalence abstinence rates at 12 weeks were 27.9% in the ANBL arm and 17.4% in the CBP arm ($p=0.028$). There was a statistically significant difference in self-reported 6-month intent-to-treat point prevalence abstinence rates between ANBL (20.1%) and CBP (12.0%) arms ($p=0.029$). None of the cotinine-verified results were statistically significant.

Conclusions—The culturally tailored smoking-cessation program ANBL may or may not be an effective program in promoting cessation at 12 weeks and 6 months. Participants in the culturally tailored ANBL program were approximately twice as likely to quit smoking at 6 months compared with the CBP program, using self-reported abstinence.

Introduction

American Indians have the highest cigarette smoking prevalence of any racial/ethnic group in the U.S., with data from the recent literature varying between 30% and 34%, followed most closely by African Americans (18.1%–24.3%) and whites (19.7%–23.6%).^{1–4} Prevalence among American Indians varies by geographic region, with the lowest in the Southwest (15%–19%) and highest in the Northern Plains (42%).⁵ Potential reasons for the high smoking prevalence include traditional use of tobacco, socioeconomic disparities, discrimination, and historic trauma.⁴ Furthermore, the influence of comorbid psychiatric disorders among American Indian smokers has also been associated with nicotine dependence.⁴ Unfortunately, there are very few culturally tailored cessation programs for American Indian smokers, and even fewer have demonstrated efficacy or effectiveness.^{6,7}

Cancer is the leading cause of premature death among American Indian and Alaska Native populations.⁸ Although the overall cancer death rates declined significantly for white men and women since 1990, rates increased significantly for all American Indian men and women.⁸ Recent data show that the trends in overall cancer mortality were strongly influenced by death rates from lung cancer, which showed little change in American Indian populations compared with whites.⁹ Furthermore, the disparity in overall death rates between American Indians and non-Hispanic white populations in the U.S. remains high for most causes of death.¹⁰

Although smoking prevalence in the non-minority white population has declined over the past several decades, the same improvement has not been observed among American Indians. The factors influencing American Indians' higher rate of recreational cigarette smoking are multifaceted, including cultural issues^{11–13} as well as lack of effective culturally tailored programs.¹⁴

American Indians have been the most under-represented population in all biomedical research, including smoking-cessation studies.^{14–17} Very few smoking-cessation intervention studies have been conducted with American Indian populations, and those interventions that have been formally evaluated have shown limited or no efficacy.^{7,18–21} This study is the largest RCT of a culturally tailored smoking-cessation program for American Indians. The goal of the current study was to evaluate the impact of a culturally tailored smoking-cessation intervention (All Nations Breath of Life [ANBL]) compared with a non-tailored (current best practices [CBP]) program.

Methods

Trial Design

The ANBL intervention was developed using the principles of community-based participatory research, including:

1. tailoring to meet the needs of individuals and communities; and
2. providing the opportunity for community members to participate in development, implementation, and evaluation.

All study procedures were approved and monitored by the human subjects committees at the University of Kansas Medical Center, University of Oklahoma Health Science Center, Oklahoma City Area Indian Health Service IRB, and each respective participating tribal IRB or Tribal Councils from five states across six geographic sites.

Study design, methods, and recruitment procedures have been described in detail elsewhere.²² Participant groups were randomized by site to either the culturally tailored ANBL smoking-cessation program or non-tailored CBP. ANBL is based on the idea that tobacco is a sacred plant and, as such, must be respected rather than abused through recreational smoking.

Participants

Participants were recruited from Southern and Northern Plains regions, from reservation communities and in rural locations including tribal trust land. Eligible participants self-identified as American Indian or Alaska Native, aged ≥ 18 years, had a home address and telephone number, were willing to participate in all study components, smoked ≥ 100 cigarettes in their lifetime, smoked cigarettes in the past 30 days, and were interested in quitting (willing to set a quit date within 2 weeks). Exclusion criteria included intention to leave the state within the next 2 years, being pregnant, breastfeeding, or planning to become pregnant in next 4 months, and being medically ineligible after screening. Participants were recruited beginning in April 2011, the final participant had their 6-month follow-up in July 2014, and analysis was conducted in 2015.

Interventions

All participants, regardless of intervention assignment, were given a choice of pharmacotherapy (varenicline, bupropion, or nicotine gum, patch, or lozenge) at baseline, provided at no cost to the participant. Participants could also choose to participate in all intervention components without pharmacotherapy. Everyone who chose any form of pharmacotherapy received instructions on how to use the specific pharmacotherapy and was medically screened for approval and followed by a physician as needed. The interventions were administered at the program start date, which was the same between both arms, at the initial individual in-person meeting.

The ANBL intervention involved:

1. an individual in-person session at beginning;

2. in-person group sessions (nine sessions over 6 months; length of each session, 60–90 minutes) led by an American Indian facilitator;
3. brief individual telephone counseling (four calls; length of each call, 15–20 minutes) using motivational interviewing between group sessions;
4. a culturally tailored educational curriculum (topics included cigarette smoking and Native people, traditional use of tobacco, American Indian flute music and meditation techniques, reservation-based aerobic exercise techniques, healthy eating at powwows, and family/social support;
5. free pharmacotherapy or nicotine-replacement therapy (NRT); and
6. participant incentives (traditional use DVD, American Indian flute music CD, Rez-Robics DVD, water bottles, pedometers, healthy snacks, quit kit, t-shirt, pen, and bracelet).

For each site, investigators recruited and trained an American Indian group facilitator. Detailed description of ANBL components has been published previously.²²

The CBP arm involved:

1. an individual in-person session at beginning;
2. individual sessions (nine total over 6 months) led by a non–American Indian facilitator (seven individual telephone and two individual in person);
3. brief telephone reminder calls (four calls; length of each call was 5–10 minutes to discuss personal issues or problems and reminder of next session);
4. non-tailored curriculum, focused on a health education–based individual program;
5. free pharmacotherapy or NRT; and
6. participant incentives, all of which were not tailored.²²

For each site, investigators recruited and trained a non–American Indian facilitator.

A major difference between the two arms was that the authors did not exactly match for type or amount of program attention given to each participant (i.e., group versus individual and contact time for each session). Therefore, this study was not able to disentangle the effects of specific components of ANBL. All participants across both arms of the study received the same amount of gift card incentives as well as weekly incentive items.

Measures

Demographic information included gender, age, education, smoking status of partner/spouse, and BMI.

Baseline smoking-related variables included age of smoking initiation, number of days smoked in the past 30 days, cigarettes smoked per day, cigarettes smoked yesterday, use of

traditional tobacco, number of quit attempts in the past 6 months, and smoking restrictions in the home. Nicotine dependence was assessed using the six-item Fagerström Test of Nicotine Dependence²³ and the 30-item Wisconsin Inventory of Smoking Dependence Motives.^{24,25}

The four-item Perceived Stress Scale²⁶ was used to assess self-reported stress experience in the past month with a total score ranging from 0 to 16, with higher scores indicating greater overall stress. The two-item Patient Health Questionnaire²⁷ was used as an assessment for brief depression screener, with scores ranging from 0 to 6. The cut point of 3 was used, following recommendations from the results of the validation study.²⁷ The Interpersonal Support Evaluation List-12 was used to measure the level of social support.²⁸

At baseline, both exhaled carbon monoxide (measured in ppm) and salivary cotinine (measured in ng/mL) were collected. Saliva samples were collected at baseline, 12 weeks and 6 months among participants who self-reported smoking abstinence for the purpose of providing biochemical verification of cessation. Salivary cotinine analysis was conducted using a standard gas chromatography technique.²⁹

Owing to slower than anticipated recruitment and enrollment, the authors received permission from the National Cancer Institute to adjust the primary outcome from 12 months post-baseline to 6 months. The primary outcome of the study was salivary cotinine-verified 7-day point prevalence smoking abstinence at 6 months (*Have you smoked at least part of a cigarette in the last 7 days?*) using both responders-only and intent-to-treat analyses. The secondary outcome was reduction in cigarettes smoked per day among those who did not report quitting.

Sample Size

Based on a pilot study of ANBL, a 30% cessation rate in the ANBL group and 15% cessation rate in the CBP group was used to calculate the sample size for the study.³⁰ A two-sample test for the difference in proportions using unpooled normal approximation adjusted for variance inflation due to intracluster correlation was used.³¹ Furthermore, along with the above assumptions, cluster size of five people, and a very conservative estimated intracluster correlation coefficient of 0.1 (the actual calculated coefficient from this study was 0.114 for self-reported cessation at 6 months) due to lack of relevant data (hence, an inflation factor of 1.4), 27 clusters in each arm were needed to have 80% power to conclude the cessation rate of smokers who receive the ANBL intervention was higher than that of those who receive the non-tailored CBP intervention at a 5% significance level. Considering an attrition rate of 30%, a total of eight people were recruited for each cluster, resulting in a total of $56 \times 8 = 448$ total smokers as the final sample size. Cluster randomization was used because ANBL is a group-based, culturally tailored, smoking-cessation program. Given significant attrition of participants between randomization and study enrollment at the initial baseline visit, the time period was extended to increase recruitment for a total of 78 clusters consisting of 624 total randomized participants. Figure 1 presents the total number of American Indian smokers who completed screening and were randomized, number enrolled at baseline, and participant follow-up through 6 months. Although 624 total participants were randomized (320 to ANBL and 304 to CBP), 161 participants did not enroll in the study (77 from ANBL

and 84 from CBP), resulting in the final enrolled sample size of 463 (243 for ANBL and 220 for CBP). The demographic and smoking-related characteristics of participants who did not enroll were similar to those who did enroll across both arms of the study; there were no statistically significant differences between those who enrolled and those who did not enroll across treatment arms.

Randomization was performed at each site after recruitment, baseline telephone assessment, and determination of eligibility. Participants formed temporal clusters in recruiting order (i.e., the first eight participants formed Cluster 1, the second eight participants formed Cluster 2, and so on), and then pairs of clusters were assigned to the study arms using randomized permuted blocks based on a computer-generated random numbers list to guarantee the balance between arms at each site. Thus, the main purpose was to assure balance with respect to the numbers of participants assigned to each arm of the trial.

Statistical Analysis

Baseline characteristics were summarized for ANBL and CBP arms using descriptive statistics, percentages and frequencies for categorical variables, and means and SDs for quantitative variables. To account for intracluster correlation and adjust individual-level covariates, the generalized estimation equations method assuming exchangeable correlation structure^{32,33} was used for hypothesis testing in comparing the intervention effect for both the primary and secondary aims using SAS PROC GENMOD. Individual-level covariates (were known risk factors from literature and) included age, gender, education, depression, traditional tobacco use, and time to first cigarette. For 7-day point prevalence abstinence rates at 12 weeks and 6 months, comparisons were conducted using:

1. the available participants who provided self-reported smoking status or provided saliva (responders only); and also
2. all participants by imputing the non-responders as smokers (intent-to-treat analysis). In the responder-only analysis, the missing values in covariates were imputed ten times using multivariate imputation by chained equations. Each imputed data set was analyzed by the same model described in the last paragraph, and the results were combined by Rubin's rule.³⁴ The agreement between self-reported and cotinine-verified smoking status was assessed by kappa statistic and the corresponding 95% CI.

All tests of statistical significance were two-sided and all p -values <0.05 were considered statistically significant. Comparison for the primary outcome was performed using a one-sided test and the results were consistent with the two-sided p -values. All analyses were conducted using SAS, version 9.4.

Results

All baseline analyses were based on the total number of enrolled participants (Figure 1). Table 1 presents the baseline characteristics of all participants in both ANBL and CBP arms of the study. Characteristics were similar at baseline for demographic, psychosocial, and

smoking-related variables across both arms. At baseline, the mean age of participants was 44.3 years and 75% were female. Participants reported smoking an average of 15.4 cigarettes per day for approximately 16 years, had a mean Fagerström Test of Nicotine Dependence score of 4.15 (SD=2.444), smoked within 30 minutes of waking (68.5%), had a mean exhaled carbon monoxide of 16.0 ppm, and a mean salivary cotinine of 309 ng/mL. Approximately 31% of the participants reported using tobacco for traditional purposes, such as ceremonial, spiritual, prayer, and others. All participants, regardless of randomization assignment (ANBL or CBP), were given the choice of pharmacotherapy, NRT, or support sessions only, with 17% choosing no pharmacotherapy or NRT, 5% choosing bupropion, 3% choosing bupropion plus NRT, 40% choosing NRT, and 35% choosing varenicline. This was not statistically different between groups at baseline.

Self-reported and biochemically confirmed point prevalence abstinence by responder-only and intent-to-treat results are shown in Table 2. Saliva samples were provided by only 57% of the self-reported quitters at 12 weeks and 63% of the self-reported quitters at 6 months. As a result, the cotinine-verified abstinence rates were underpowered.

For responders only, the self-reported point prevalence abstinence was 49.0% for ANBL versus 30.9% for CBP at 12 weeks (OR=2.16, 95% CI=1.16, 4.04, $p=0.015$) and 35.9% for ANBL versus 28.3% for CBP at 6 months (OR=1.67, 95% CI=0.82, 3.41, $p=0.160$). The corresponding cotinine-verified point prevalence abstinence was 20.3% for ANBL versus 15.8% for CBP at 12 weeks (OR=1.59, 95% CI=0.73, 3.45, $p=0.24$) and 19.8% for ANBL versus 16.6% for CBP at 6 months (OR=1.80, 95% CI=0.74, 4.41, $p=0.20$).

For intent-to-treat point prevalence abstinence, imputing those lost to follow-up as smokers, the self-reported point prevalence abstinence was statistically significant (12 weeks: 27.9% ANBL vs 17.4% CPB, OR=1.87, 95% CI=1.07, 3.26, $p=0.028$; 6 months: 20.1% ANBL vs 12.0% CPB, OR=1.91, 95% CI=1.07, 3.42, $p=0.029$). The corresponding intent-to-treat point prevalence for cotinine-verified abstinence was not statistically different [12 weeks: 11.2% ANBL vs 8.8% CPB, OR=1.31, 95% CI=0.64, 2.73, $p=0.46$; 6 months: 10.8% ANBL vs 6.9% CPB, OR=1.65, 95% CI=0.80, 3.43, $p=0.18$).

Owing to significant loss to follow-up at 6 months and lower than expected number of participants providing saliva, the cotinine-verified abstinence rates were underpowered. Overall, based on the 104 participants who provided saliva at 12 weeks and 73 participants who provided saliva at 6 months, the kappa statistics for self-report versus cotinine were 0.74 (95% CI=0.61, 0.86) and 0.83 (95% CI=0.70, 0.96), respectively.

Among participants who did not report quitting, the 12-week median (interquartile range) reduction in number of cigarettes smoked per day was 9 (2, 15) in the ANBL arm and 9 (3, 15) in the CBP arm, which was not statistically different ($p=0.39$).

Retention rates across both arms were similar from Week 1 through Week 12; however, participants in the ANBL arm had higher retention at 6 months compared to CBP (57.6% and 43.6%, respectively, $p=0.048$, adjusting for intracluster correlation). The group-based ANBL intervention led to higher long-term retention of participants compared with the individual-based CBP arm of the study.

There were minimal adverse events reported by participants in both arms of the study. There were a total of seven participants in the ANBL arm who reported the following adverse events: varenicline—sleep disturbance (one), depression (two), upset stomach (one); nicotine patch—constipation (one); bupropion—aggressiveness and irritability (one); bupropion and nicotine patch—skin reactions (one). A total of eight participants in the CBP arm reported the following adverse events: varenicline—depression (two), nausea (one), elevated blood pressure (one), sleep disturbance (one); nicotine gum—chest pain (one); nicotine patch—chest pressure (one). There were two deaths throughout the study period; however, both were unrelated to study medication or intervention components.

Discussion

This study is the largest multisite RCT for smoking cessation among American Indians. This study tested the efficacy of a culturally tailored smoking-cessation program developed using a community-based participatory research approach. There were statistically significant differences between the tailored ANBL intervention and the non-tailored CBP for self-reported abstinence rates at 6 months for intent-to-treat results. Participants in the ANBL arm were approximately twice as likely to be quit at both 12 weeks and 6 months compared with the non-tailored CBP arm according to intention-to-treat results for self-reports.

This study also found that among participants who had not quit at 12 weeks, all smokers across both arms of the study were able to reduce their consumption by 60% over this time period. Smokers were encouraged to continue in the program even after a relapse and counseled that reducing the number of cigarettes smoked per day would also enhance the probability of successful quitting in the future. Recent studies show that a significant percentage of smokers would consider using a medication to facilitate smoking reduction and those smokers not willing to quit within a month were able to successfully quit using the “reduce to quit” approach.^{35,36} Similar approaches may be appropriate for the American Indian smoking population, given that they may not be ready to quit at their particular clinic visit with their healthcare provider.

Although this study experienced retention issues at 6 months, participants in the ANBL arm had significantly higher retention than those in the CBP arm, despite the fact that the CBP arm primarily consisted of individual-based telephone sessions and the ANBL arm was in person and group based. Higher retention in the ANBL arm may have been due to a greater sense of belonging, group cohesiveness, and added social support. These results align with previous studies supporting the group-based format of the intervention, which was preferred by American Indian smokers in the region.^{14,37} Future intervention studies need to examine additional effective approaches to maintaining higher retention through the end of the study period.

Previous studies of cessation aid uptake have shown lower use among American Indians compared with other racial/ethnic groups.³⁸ Participants in this study demonstrated that a significant number of American Indian smokers chose pharmacotherapy or NRT in combination with the group sessions (ANBL) or individual counseling (CBP), approximately 80%. Differences between this study and prior population-based surveys may

be related to the cost of either NRT or pharmacotherapy because it was provided free to everyone in this study. These findings support an increase in funding to provide smoking-cessation medications to the American Indian population.

Limitations

This study has several limitations, including significant loss to follow-up and lower than expected salivary collection rates, which led to reduced power to detect differences in salivary cotinine–verified cessation rates across both arms of the study. Lower long-term retention of participants was due to various factors including but not limited to change of contact information, inability to contact participants, lack of transportation, and stressors in personal and work life leading to drop out.^{14,39,40} Another limitation was the higher than expected drop off from randomization to enrollment, approximately 26%, which may have been due to the time lapse between screening and intervention, leading to loss of interest in the program. However, the smoking and demographic characteristics between those who enrolled and did not enroll after randomization were not statistically different. This study was focused on two regions of the U.S., and given the difference in smoking prevalence in other parts of the country, the generalizability of the findings may also be limited. Similarly, as the majority of the participants were women, the public health significance of these findings for American Indian men may be limited. However, this presents opportunities for household or family interventions focusing on the women in the home to reduce overall smoking.

Another limitation is the inability to determine which specific components of ANBL contribute to the increased abstinence rates, as well as lack of blinding. The informed consent forms clearly indicated to each participant that they would be randomized to either a culturally tailored or non-tailored program, so the cultural nature of the ANBL could have led to higher self-reporting of quitting among participants in the ANBL arm. In the current design, there were differences by type or amount of program attention given to each participant. Therefore, disentangling the effects of specific components of ANBL was not possible; however, because ANBL was created to be a culturally tailored program with optimal components, if it did not produce higher cessation rates, the question of which component worked would not matter. In addition, given the overwhelming smoking burden in this community, the priority was to test the efficacy of ANBL so that it can be disseminated across different tribes to reduce smoking prevalence.

Future studies of ANBL need to be conducted to separate out the independent contributions of the culturally tailored components to determine future modifications of the program. Despite these limitations, this study provides evidence that large-scale intervention studies are possible in this underserved population and that additional methods need to be identified to decrease the longer-term attrition.

This study also had many strengths, including a high level of engagement and participation from American Indian smokers, representing several different tribes from various regions. This study successfully recruited and randomized more than 600 American Indians and enrolled 463 American Indian smokers. Given the limited number of smoking-cessation interventions previously conducted in this underserved population, this study demonstrates

the high feasibility of recruiting American Indians into a smoking-cessation study and collection of biochemical samples; specifically, saliva for verification of cessation is also feasible.

This study also demonstrated successful collaboration with tribes throughout the Southern and Northern Plains regions of the country, with no refusals from any participating tribes or communities. Active participation and engagement by American Indian team members was a successful recruitment strategy to conduct the study in these reservation and tribal trust land communities.

Conclusions

Currently, there are limited evidence-based culturally tailored smoking-cessation programs for American Indians and results from this study demonstrate the potential effectiveness of ANBL for smoking abstinence, as well as reduction in consumption. ANBL is a culturally tailored smoking-cessation program for American Indians and has promise in increasing smoking abstinence. Furthermore, this study was able to demonstrate successful recruitment, engagement, and retention of American Indian smokers into an RCT of smoking cessation. Therefore, these findings support the need to fund additional studies in this underserved population to build upon these findings to enhance and maintain long-term smoking abstinence.

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Figure 1.
Participant enrollment, allocation, follow-up and analysis.
ANBL, All Nations Breath of Life; CBP, Current Best Practices

Table 1

Baseline Characteristics of Enrolled Study Participants

Characteristic	ANBL group (N=243)	No. of participants with available data	CBP group (N=220)	No. of participants with available data
	N (%) ^{a,b}		N (%) ^{a,b}	
Demographic variables				
Age (years), mean (SD)	45.43 (12.98)	226	43.12 (13.22)	215
Females	167 (72.6)	230	168 (77.4)	217
Partner/spouse is current smoker	75 (33.0)	227	72 (32.9)	219
Education >high school	195 (85.2)	229	192 (87.7)	219
Weight, mean (SD), lb	188.89 (46.81)	211	196.63 (51.52)	205
BMI, mean (SD), kg/m ²	32.72 (11.72)	210	32.35 (8.80)	204
Psychosocial variables				
Stress (PSS-4) score, mean (SD)	6.25 (3.09)	227	5.89 (3.33)	218
Depression: PHQ-2 (% >3)	54 (24.9)	217	48 (22.4)	214
Social support: ISEL -12, mean (SD)	37.95 (6.96)	227	39.69(6.56)	217
Smoking-related variables				
Age started smoking regularly, mean (SD)	16.39 (6.02)	229	17.09 (5.79)	217
Days smoked in past 30 days, mean (SD)	27.18 (6.99)	213	27.50 (6.31)	210
Cigarettes per day, mean (SD)	15.03 (10.23)	230	15.87 (11.08)	219
Cigarettes smoked yesterday, mean (SD)	12.61 (9.22)	230	13.16 (10.19)	219
Number of Years Smoked, mean (SD)	17.2 (14.8)	225	15.6 (13.4)	214
Traditional tobacco usage, No. (%)	69 (30.8)	224	67 (31.5)	213
Salivary cotinine, mean (SD), ng/mL	304.3 (202.5)	153	314.6 (208.3)	151
Exhaled carbon monoxide, mean (SD), ppm	16.00 (11.36)	168	15.95 (9.58)	192
FTND score, mean (SD)	4.09 (2.47)	231	4.21 (2.41)	219
WISDM-30 score, mean (SD)	35.98 (12.04)	227	35.70 (11.64)	218
Time to first cigarette, <30 mins, No. (%)	158 (69.0)	229	147 (68.1)	216
24-hr Quit attempts in past 6 months, mean (SD)	1.80 (5.23)	217	1.44 (3.51)	216
Smoke-free household, No. (%)	71 (31.3)	227	66 (30.3)	218
Pharmacotherapy dispensed				
Support sessions only	45(18.5)		33(15.0)	
Support sessions and Bupropion	13(5.3)		10(4.5)	
Support sessions, Bupropion and NRT	5(2.1)		8(3.6)	
Support sessions and NRT	102(42.0)		83(37.7)	
Support sessions and Varenicline	78(32.1)		86(39.1)	

^aUnless specified otherwise^bDenominator changes due to missing values.

ANBL, All Nations Breath of Life; CBP, Current Best Practices; PSS-4, assessed self-appraised global stress: possible total score ranges from 0 to 16; PHQ-2, cutoff score is >3 on total depression score, indicates likely depression; ISEL-12, Interpersonal Support Evaluation List – higher scores

indicate greater levels of social support; FTND, assessed nicotine dependence: possible total score ranges from 0 to 10; WISDM-30, assessed nicotine dependence using a multidimensional scale: possible total score ranges from 10 to 70; NRT, Nicotine Replacement Therapy

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Table 2Self-Reported and Cotinine Verified 7-Day Point Prevalence Abstinence Rates^{a,b}

Self-reported smoking abstinence	ANBL	CBP		
	N/Total (%)	N/Total (%)	OR (95% CI)	p-value
Responder only				
Quit at Week 12	68/140 (49.0)	37/124 (30.9)	2.16 (1.16, 4.04) ^c	0.015
Quit at Month 6	49/137 (35.9)	26/96 (28.3)	1.67 (0.82, 3.41) ^d	0.160
Intent-to-treat				
Quit at Week 12	68/243 (27.9)	37/220 (17.4)	1.87 (1.07, 3.26)	0.028
Quit at Month 6	49/243 (20.1)	26/220 (12.0)	1.91 (1.07, 3.42)	0.029
Cotinine verified smoking abstinence				
Responder only^e				
Quit at Week 12	27/140 (20.3%)	19/124 (15.8%)	1.59 (0.73, 3.45) ^f	0.24
Quit at Month 6	26/137 (19.8%)	15/96 (16.6%)	1.80 (0.74, 4.41) ^g	0.20
Intent-to-treat				
Quit at Week 12	27/243 (11.2%)	19/220 (8.8%)	1.31 (0.64, 2.73)	0.46
Quit at Month 6	26/243 (10.8%)	15/220 (6.9%)	1.65 (0.80, 3.43)	0.18

Note: Boldface indicates statistical significance ($p < 0.05$).

^aProportions and ORs estimated by GEE taking into account intra-cluster correlations. When age, gender, education, depression, tradition tobacco use, and time to first cigarette were included as covariates: ^{c,f}N=231, ^{d,g}N=202.

^bDenominator changes due to missing values.

^eNot all responders provided saliva. Those not providing saliva were categorized as smokers. ANBL, All Nations Breath of Life; CBP, Current Best Practices; GEE, Generalized Estimation Equations