

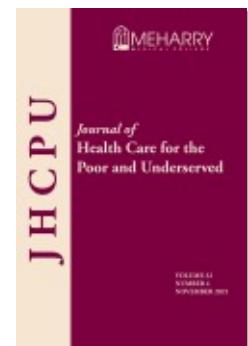


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## **Pilot Testing All Nations Snuff Out Smokeless (ANSOS): A Culturally Tailored Smokeless Tobacco Cessation Program for American Indians**

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*Abstract:* American Indians have the highest rates of smokeless tobacco (SLT) use of any racial/ethnic group in the United States, yet no proven effective cessation programs exist for them. Because tobacco is a sacred plant to many American Indians, cessation programs must not portray it in a completely negative manner. Based on our successful All Nations Breath of Life smoking cessation program, we developed and pilot-tested the All Nations Snuff Out Smokeless (ANSOS) program. Of 48 participants who began the program, 33 completed to six months (68.8% retention rate). Among participants who completed the program, 11 (34%) self-reported abstinence. When those lost to follow-up are considered current users, the cessation rate is 22.9%. An additional 14 individuals reported decreasing use (29.2% of all participants), with an average of 3.4 days per week decrease. All Nations Snuff Out Smokeless shows promise as a culturally appropriate SLT cessation program and is ready for efficacy testing.

*Key words:* American Indians, smokeless tobacco cessation, cultural tailoring, community-based participatory research.

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American Indians have the highest rates of smokeless tobacco use (e.g., chewing tobacco or snuff) of any racial or ethnic group in the United States. Prevalence varies by tribe and region, but overall, in 2016, 8.4% of American Indian adults were current users compared with 3.4% of non-American Indian adults. Prevalence was highest among younger individuals (10.1% for age 18–25, 9.1% for age 26–34 versus 5.7% and 4.6% among non-American Indians in the same age groups).<sup>1</sup> Our own work shows an even higher prevalence of 19% among tribal college students,<sup>2</sup> compared with approximately 7% among male college students of all races combined and less than 1% of female college students.<sup>3</sup> Data from Monitoring the Future show that heightened prevalence among American Indians is found in even younger age groups, with the highest prevalence among high school seniors also in American Indian students (males 41.1%, females 39.4%), indicating a possible increase in smokeless tobacco use.<sup>4</sup> The National Youth Monitoring Survey found tobacco use of 16% among American Indians in grades six through 12.<sup>5</sup> In South Dakota high schools, where use is among the highest in the country, more than 56% of American Indian youth reported ever trying smokeless tobacco, and 28% were current users.<sup>6</sup>

Despite the high prevalence of smokeless tobacco use among American Indians, few programs have been designed to specifically address it. “Enough Snuff” is a self-help cessation program designed for anyone who wishes to quit that has been found most effective when coupled with phone counseling and a video.<sup>7</sup> There is a version called “Enough Snuff: A guide to quitting smokeless tobacco for American Indians” that is labeled as culturally tailored, but no information on effectiveness is available.<sup>8</sup> Our own All Nations Breath of Life is a culturally tailored, in-person, group-based smoking cessation program that also includes individual counseling, choice of pharmacotherapy, educational materials, and incentives; it was developed and tested using community-based participatory research over a decade.<sup>9,10</sup> All Nations Breath of Life has shown efficacy in a cluster randomized trial among reservation communities<sup>11</sup> and feasibility for real-world implementation in urban communities.<sup>12</sup> The culturally tailored program produced a 20.1% cessation rate compared with 12.0% in a non-tailored Current Best Practices comparison arm among reservation communities.<sup>11</sup> An urban single arm implementation feasibility study produced similar cessation to the randomized study at 22.1%.<sup>12</sup>

Treatments that work for smoking do not always work for smokeless tobacco because nicotine content is higher in smokeless tobacco than cigarettes (133.0 mg in one dose of chewing tobacco vs. 8.4 mg in a single dose of a cigarette), nicotine is more rapidly absorbed from cigarettes into the lungs and brain with subsequent release of dopamine that provides satisfaction for craving (7 seconds for cigarettes, up to 30 minutes for smokeless tobacco), and the fact that when a cigarette is extinguished, nicotine delivery ceases, while it continues for an hour after smokeless tobacco use.<sup>13</sup> Therefore, smokeless tobacco cessation programs must be somewhat different from cigarette smoking cessation programs. We have taken the successful All Nations Breath of Life and modified it, with the help of community partners and advisors, to create All Nations Snuff Out Smokeless (ANSOS).<sup>14,15</sup> Here, we report results of our initial pilot testing of the ANSOS program.

## Methods

Development of ANSOS began in 2014 with a series of focus groups with American Indian smokeless tobacco users.<sup>15</sup> The project has used community-based participatory research methods since the beginning and, therefore, went through multiple iterations with community input during development. A full explanation of our development process is available elsewhere.<sup>14</sup> All Nations Snuff Out Smokeless is based in a critical medical anthropology framework that includes elements from four levels of analysis, including the macro-social, intermediate social, micro-social, and individual levels.<sup>16</sup> American Indian relationships with the federal government and Western medical practitioners through the Indian Health Service, including both historical issues and contemporary, provide a macro-level context in which smokeless tobacco use and treatment takes place. Traditional worldviews are also a part of the macro-level context in which cessation must occur. The intermediate level includes cessation programs and support available in different communities, as well as traditional tobacco practices within individual communities. The micro-level environment includes interactions with cessation counselors or cessation groups, as well as support networks available to smokeless tobacco users within a community. Finally, the individual level includes a particular smokeless tobacco user's beliefs and available supports, as well as their own behavior change. We incorporate aspects of Protection Motivation Theory<sup>17</sup> to understand individual behavior change. In this behavioral model, the individual weighs the rewards of smokeless tobacco use versus perceived susceptibility to problematic health outcomes associated with it. These aspects, taken from the Health Belief Model,<sup>18</sup> are enhanced through the construct of self-efficacy, which is very important for smokeless tobacco users trying to quit. The individual behavior of smokeless tobacco use is influenced by the other levels of analysis. The ANSOS educational curriculum was developed based on these theoretical and behavioral constructs.

All Nations Snuff Out Smokeless was pilot-tested with 48 American Indian smokeless tobacco users in the Plains region of the United States, including both urban and reservation communities. All study activities and materials were approved through the University of Kansas Human Subjects Committee prior to use, as well as appropriate tribal review boards. The program consisted of group support sessions, individual telephone counseling, a culturally tailored educational curriculum, and participant incentives designed to help with quitting. Each of these components is described below. We discussed providing pharmacotherapy to participants with community members throughout development of ANSOS. Community members were not interested in receiving pharmacotherapy as a part of the intervention; therefore, we did not include it as a part of the program. Participants were told they could take any form of pharmacotherapy they wished on their own during the program and we would track their use. No participants chose to take pharmacotherapy.

**Group support sessions.** The primary component of ANSOS was a series of nine group-based support sessions, provided over a six-month period. We discussed who would lead the sessions at length, particularly whether they needed to be trained counselors or have certain educational degrees. We decided the most important factor for group leaders was their community ties, similar to our previous smoking cessation

program, All Nations Breath of Life.<sup>12</sup> Similar to All Nations Breath of Life, we did not limit our leaders to individuals with counseling degrees or experience, but instead trained American Indian community members in group support and counseling skills to become facilitators for the groups. The group members provided the majority of support and advice, with help from the facilitator and curriculum. Group sessions began with team-building and personal discussion among members about their lives, both things related directly to smokeless tobacco use and other things that helped or hindered quit attempts. See Figure 1 for session topics and flow of sessions.

**Individual telephone counseling.** Community members requested individual counseling, particularly for people who were uncomfortable talking about certain things in our mixed-gender and -age groups. We included telephone calls in ANSOS for this purpose. Between groups, facilitators called participants to see how they were doing, discuss personal issues, and to remind them of the next group. Telephone sessions were provided between each group session for the first 12 weeks of the program, then monthly until the month 6 final group (see Figure 1).

**Educational curriculum.** The ANSOS curriculum covered typical topics used in the majority of smokeless tobacco cessation programs, as well as culturally specific topics. Throughout development, community members stressed cultural issues must be ingrained in the program, not given “lip service” through pictures of American Indians on otherwise “white” materials. Typical smokeless tobacco cessation topics covered included: preparing to quit, coping with withdrawal, facts about smokeless tobacco, stress reduction, social support, and staying quit. Each of these topics was modified to include culturally-specific information, such as facts that were specific to American Indians and stress reduction using traditional and nontraditional activities. In addition, certain topics were added, such as the differences in reasons for use of smokeless tobacco among American Indians compared with other populations, cultural support networks, historical trauma as it relates to addiction, mistrust of the medical system based on historical abuses, and the use of tobacco for traditional purposes. Learning objectives for each session were determined with input from tobacco experts, community advisory board members and American Indian team members and focused on behavioral changes that participants needed to make to quit and knowledge focused on the constructs within our theoretical framework.

**Participant incentives.** Incentives were identified by community advisory board members and American Indian research team members and included such things as quit kits (hard candy, toothpicks, etc.), stress balls, and traditional aerobic dance videos, etc. At baseline and 6 months, participants received \$20 gift cards for completion of surveys and \$10 gift cards for collection of saliva for cotinine testing for verification of smokeless tobacco use status. Thus, participants could receive \$30 each at baseline and 6 months. To increase participation in group sessions we provided an additional \$20 gift card for those participants who completed 5 or more of the group sessions.

**Recruitment.** Participants were recruited through word-of-mouth, social media, and attendance at community events, such as powwows, other cultural activities, and health fairs between February 2016 and January 2017. Members of the research team, primarily American Indian members of the team, described the program to participants either in-person or via telephone after an individual contacted us through social

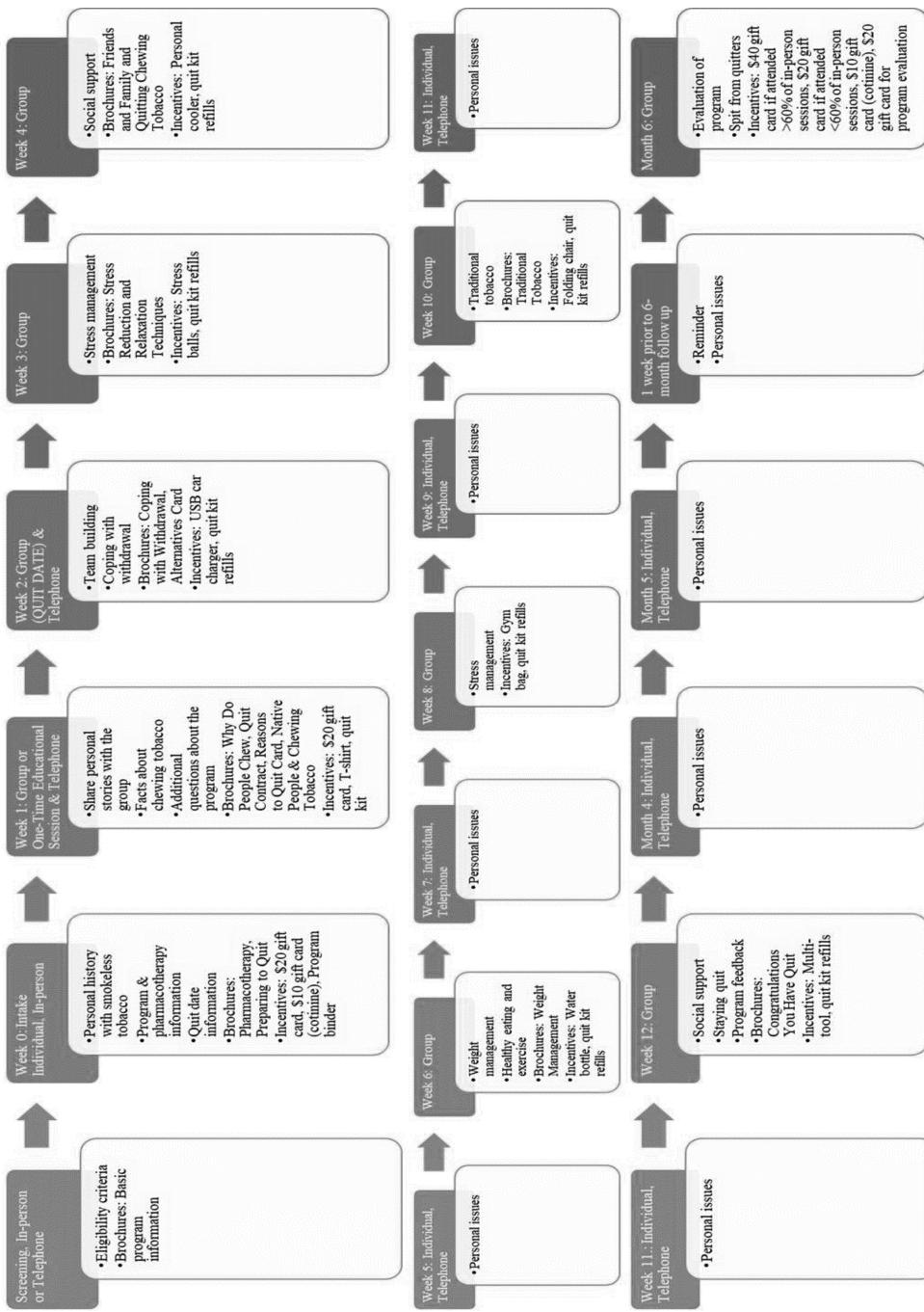


Figure 1. Progress of group and individual sessions.

media. If a participant showed interest, he or she was asked to meet with the facilitator for the program to go over the study in more detail and to provide informed consent. Participants were then grouped together into groups of four to 10 based on meeting location and time preferences.

**Measures and Data Collection.** Participants were asked to fill out surveys via the REDCap™ on-line database system at baseline, during group sessions, and at the six-month endpoint. If Internet service was unavailable, paper copies of the surveys were used. Participants were asked to answer questions related to demographic information, smokeless tobacco and other tobacco product use, nicotine dependence, self-efficacy, motivation and confidence to quit, social environment, and depression and anxiety at baseline and six months. Surveys at other group sessions focused on smokeless tobacco use and motivation and confidence to quit, as well as a simple depression screener. Measures are described below.

**Demographics.** Participants were asked about age, biological sex, marital status, educational level, occupation, health insurance coverage, tribal affiliation, and where they grew up (e.g., reservation versus urban area).

**Smokeless tobacco and other tobacco use.** The primary endpoint was salivary cotinine verified point prevalence abstinence, defined as no smokeless tobacco for the previous 30 days, at six months post-baseline.<sup>19</sup> Saliva was collected and labeled during group sessions by program facilitators. Cotinine was selected because of sensitivity and specificity; we used the recommended cut-point of 15ng/ml to differentiate users from nonusers.<sup>20-23</sup> Participants who could not be located were labeled current users for the most rigorous analysis. We also obtained self-reported smokeless tobacco status. At baseline, participants were asked about their tobacco history (i.e., number of years of smokeless tobacco use and age at initiation, amount of smokeless tobacco per day, number of years of traditional use, other recreational tobacco use, and number of lifetime quit attempts). We also asked about types of traditional use using questions developed by our American Indian team members previously.

**Nicotine dependence.** We used the Severson Smokeless Tobacco Dependency Scale (SSTDs)<sup>7</sup> to measure nicotine dependence at baseline and endpoint. This scale has been found to be more effective<sup>24</sup> than the Fagerstrom Tolerance Questionnaire for Smokeless Tobacco<sup>25</sup> or the Glover-Nilsson Smokeless Tobacco Scale.<sup>26</sup> At baseline, we also used the Fagerstrom Tolerance Questionnaire for Smokeless Tobacco and the Glover-Nilsson Smokeless Tobacco Scale to allow comparison among the scales with American Indian smokeless tobacco users.

**Motivation and confidence.** Motivation and confidence to quit were assessed by asking, "On a scale of 0 to 10, how important is it to you to quit smokeless tobacco or stay quit in the next week? 0=not important and 10=extremely important," and "On a scale of 0 to 10, how confident are you that you can quit smokeless tobacco or stay quit in the next week? 0=not confident and 10=extremely confident."

**Statistical analysis.** Categorical variables were summarized with percentages and continuous variables were summarized by means and medians. Data management and statistical analyses were performed using SAS software (version 9.4) (Copyright (c) 2002-2012 by SAS Institute Inc., Cary, NC, USA. All Rights Reserved).

## Results

A total of 48 participants began the program; 33 completed to six months, giving us a 68.8% retention rate. The majority of participants (81%) were men and the average age was 39. The majority of participants were American Indian alone, not in combination with another race (60%), grew up on reservations (60%), were married (58%), and had children (73%). Participants were nearly all employed (89%) and 61% had at least a college education. Use of smokeless tobacco began on average at age 17, though the age at first use ranged from eight to 45. Though 80% of participants preferred smokeless tobacco over other forms of tobacco, 33% used other forms of tobacco in addition to smokeless tobacco. Only 50% of participants had made a 24-hour quit attempt in the last 12 months, though some participants had successful quit attempts in the past of up to 15 years. Fifty-one percent of participants were seriously thinking about quitting in the next 30 days or six months. Full demographic information is provided in Table 1.

The primary outcome was salivary cotinine verified 30-day point prevalence abstinence at six months post-baseline. Secondarily, we obtained self-reported quit status and reductions in smokeless tobacco use, as well as motivation and confidence to quit smoking status, and use of traditional tobacco. Eleven participants (34% of participants who completed the program) self-reported no smokeless tobacco use in the previous 30 days. If we assume those lost to follow-up as current smokeless tobacco users, the quit rate for the program was 22.9%. Of the 11, nine provided viable saliva samples. The other two samples did not contain enough saliva for analysis. Of the nine saliva samples, six were verified as non-users of any tobacco products, leaving us with a 12.5% quit rate using the most rigorous of analyses. Of the three saliva samples that showed tobacco use, two participants self-reported that they had smoked cigarettes in the past 30 days and the third participant self-reported complete abstinence. Of the participants who reported still using smokeless tobacco, 14 had reduced their amount of use per day (42.4% of the people for whom we have endpoint data or 29.2% of participants who began the program), with a mean reduction of 3.4 days per week. There was a corresponding drop in the average smokeless tobacco dependency score ( $7.79 \pm 3.41$  on the short version of the Severson Smokeless Tobacco Dependence Scale, dropping to  $6.67 \pm 3.77$ ), but it was not significant. Participant tobacco characteristics at baseline, week 12 (end of treatment) and month six are provided in Table 2.

Though participants were told that ceasing or reducing cigarette smoking was not the primary aim of the study, recreational cigarette smokers were encouraged to quit smoking as well. Based on self-report data, smokers were also able to quit while participating in ANSOS and trying to quit using smokeless tobacco (12 participants, 31%, at baseline versus 5 participants, 18%, at endpoint). Use of traditional tobacco also decreased from 28 participants (60%) at baseline to nine participants (32%) at endpoint. Participants were not instructed to quit use of traditional tobacco for prayer or ceremonial purposes.

**Table 1.****PARTICIPANT DEMOGRAPHIC INFORMATION**

		ANSOS Participants N (%)
Gender	Male	39 (81)
	Female	9 (19)
Age (mean, $\pm$ std, range)		39 $\pm$ 12.23 (22–66)
Race/Ethnicity	American Indian alone	28 (60)
	American Indian in combination with another	19 (40)
Where participant grew up	Reservation or tribal trust land	29 (60)
	Rural area	6 (13)
	Urban/suburban/Military area	9 (19)
	Multiple places	4 (8)
Current Living Situation	Married/Living with partner	28 (58)
	Other	20 (42)
Children in the home	Yes	35 (73)
	No	13 (27)
Highest grade of school completed	High school or less	18 (39)
	Some college, 2-year degree, or other post-secondary certification, 4-year college or graduate degree	28 (61)
Current college student	Yes	7 (15)
	No	41 (85)
Athletic participation	Yes	18 (41)
	No	26 (59)
Current employment	Yes	41 (89)
	No	5 (11)
Age at first use of SLT (mean, $\pm$ std, range)		17 $\pm$ 5.92 (8–45)
Tobacco use	SLT only	32 (67)
	SLT and cigarettes	6 (12)
	SLT and some other product(s)	10 (21)
	SLT preferred	36 (80)
Preferred tobacco use	Cigarettes preferred	7 (16)
	Some other product(s) preferred	2 (4)
Number of 24-hour quit attempts in last 12 months	0	23 (50)
	1–2	14 (31)
	3–9	8 (17)
	10 or more	1 (2)
Longest amount of time quit from SLT in days (mean, $\pm$ std, range)		358 $\pm$ 1194.93 (0–5475)
Seriously thinking about quitting SLT	Yes, within the next 30 days	11 (25.5)
	Yes, within the next 6 months	11 (25.5)
	Yes, within the next year	9 (21)
	Not sure/No	12 (28)

**Table 2.****PARTICIPANT TOBACCO CHARACTERISTICS AT BASELINE, 12 WEEKS, AND 6 MONTHS**

	<b>Baseline</b> N (%)	<b>12 Weeks</b> N (%)	<b>6 Months</b> N (%)	
Days per week using smokeless tobacco	0 1 2 3 4 5 6 7	0 (0) 1 (2) 2 (4) 3 (7) 5 (11) 8 (17) 2 (4) 26 (55)	9 (45) 1 (5) 0 (0) 0 (0) 1 (5) 1 (5) 1 (5) 7 (35)	11 (34) 2 (6) 3 (9) 2 (6) 4 (12) 4 (12) 0 (0) 7 (21)
Motivation to quit (mean, $\pm$ std, range)		6.58 $\pm$ 2.43 (1-10)	5.55 $\pm$ 3.27 (1-10)	6.18 $\pm$ 2.22 (3-10)
Confidence in ability to quit (mean, $\pm$ std, range)		6.67 $\pm$ 2.65 (1-10)	5.82 $\pm$ 3.46 (1-10)	5.77 $\pm$ 2.52 (2-10)
Current smoker	Yes No	12 (31) 27 (69)	1 (5) 19 (95)	5 (18) 23 (82)
Current user of other tobacco products	Yes No	10 (21) 38 (79)	N/A N/A	N/A N/A
Traditional tobacco use	Yes No	28 (60) 19 (40)	3 (15) 17 (85)	9 (32) 19 (68)
Spouse uses smokeless tobacco	Yes No	4 (8) 44 (92)	N/A N/A	5 (19) 22 (81)
Spouse smokes	Yes No	7 (15) 41 (85)	N/A N/A	4 (14) 25 (86)
Severson Smokeless Tobacco Dependence Scale-Short Score (mean, $\pm$ std, range)		7.79 $\pm$ 3.41 (2-15)	7.45 $\pm$ 5.05 (1-16)	6.67 $\pm$ 3.77 (0-15)
Glover-Nilsson Smokeless Tobacco Behavioral Questionnaire Score (mean, $\pm$ std, range)		15.13 $\pm$ 6.45 (3-31)	N/A	N/A
Fagerstrom Tolerance Questionnaire for Smokeless Tobacco (mean, $\pm$ std, range)		10.06 $\pm$ 3.23 (4-16)	N/A	N/A

**Discussion**

The ANSOS program shows promise as a culturally tailored smokeless tobacco program for American Indian smokeless tobacco users. Smokeless tobacco cessation among American Indians is largely an unknown area of study. The pilot test of ANSOS showed similar quit rates to our culturally tailored smoking cessation program, All Nations Breath of Life (22.9% in ANSOS, assuming those lost to follow-up as current users, versus 20.1% and 22.1% in two trials of All Nations Breath of Life). Though the cotinine verified quit rate for ANSOS in this pilot was 12.5%, the small sample size of self-reported successful participants (N=11), makes it an unreliable number. Two of

the 11 samples were too small for analysis and an additional two were self-reported smokers at the time of collection. Only one participant who self-reported abstinence came back as a current user when saliva was analyzed for cotinine level. In a larger study, we would be better able to discern a true cotinine verified quit rate. Additionally, had we not allowed polytobacco users (individuals who both used smokeless tobacco and cigarettes) to participate, our cotinine verified quit rate would have been more reliable. Allowance of polytobacco users was made at community request for inclusivity. A more detailed quantitative analysis of salivary cotinine in a larger sample may be able to discern differences in cotinine levels among smokeless tobacco users and cigarette smokers.

Many participants who were also smokers were able to stop using both smokeless tobacco and cigarettes. This was not mandated for participation in the study but was encouraged. Further study is needed to determine if a hybrid program that includes aspects of both All Nations Breath of Life and ANSOS could prove successful for American Indian tobacco users of all types, including polytobacco users. It may be possible to establish one program for all American Indian tobacco users rather than programs specific to different types of tobacco. This could prove cost-effective and appropriate for communities with high rates of smokeless tobacco use and cigarette smoking, among which are many American Indian communities.

Many of our participants ceased use of traditional tobacco as well, which was not encouraged in ANSOS. In fact, ANSOS was developed to respect sacred tobacco by honoring it through traditional or ceremonial use rather than recreational use,<sup>14</sup> as All Nations Breath of Life was.<sup>9</sup> Our previous research shows that smokers are more likely to remain quit if they continue use of traditional tobacco, but not including smoking for prayer or ceremony.<sup>27</sup> Much traditional use does not include smoking, but rather gift-giving or burning in another form and not smoking.<sup>28</sup> Further study is needed to understand the complex relationship between traditional tobacco and recreational use through smoking or smokeless tobacco.

This small pilot study was conducted in a limited geographic area in the Plains. However, it included both reservation and urban locations, as well as cessation groups that included only one tribe or multiple tribes represented, thus showing feasibility of the program in different types of locations. It is now ready for full-scale testing in a randomized trial.

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