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Original Investigation

Feasibility of a tobacco cessation intervention for pregnant Alaska Native women

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Abstract

Background: Among Alaska Native women residing in the Yukon-Kuskokwim (Y-K) Delta region of Western Alaska, about 79% smoke cigarettes or use smokeless tobacco during pregnancy. Treatment methods developed and evaluated among Alaska Native pregnant tobacco users do not exist. This pilot study used a randomized two-group design to assess the feasibility and acceptability of a targeted cessation intervention for Alaska Native pregnant women.

Methods: Recruitment occurred over an 8-month period. Enrolled participants were randomly assigned to the control group ($n = 18$; brief face-to-face counseling at the first visit and written materials) or to the intervention group ($n = 17$) consisting of face-to-face counseling at the first visit, four telephone calls, a video highlighting personal stories, and a cessation guide. Interview-based assessments were conducted at baseline and follow-up during pregnancy (≥60 days postrandomization). Feasibility was determined by the recruitment and retention rates.

Results: The participation rate was very low with only 12% of eligible women (35/293) enrolled. Among enrolled participants, the study retention rates were high in both the intervention (71%) and control (94%) groups. The biochemically confirmed abstinence rates at follow-up were 0% and 6% for the intervention and control groups, respectively.

Discussion: The low enrollment rate suggests that the program was not feasible or acceptable. Alternative approaches are needed to improve the reach and efficacy of cessation interventions for Alaska Native women.

Introduction

Tobacco use during pregnancy is a major public health problem in the United States. Estimates of smoking prevalence during pregnancy among U.S. women range from 11% to 22% (Goodwin, Keyes, & Simuro, 2007; L. T. Martin, McNamara, et al., 2008). Among U.S. women who gave birth in 2005, the smoking rates during pregnancy were American Indian and Alaska Native (AI/AN) women (18%), non-Hispanic White (14%), non-Hispanic Black (9%), Hispanic (3%), and Asian women (2%; Substance Abuse and Mental Services Administration [SAMHSA], 2007). Smoking during pregnancy is the leading preventable cause of low infant birth weight and is associated with other maternal and infant adverse perinatal events (Cnattingius, 2004). Less than 1% of U.S. women report smokeless tobacco (ST) use during pregnancy (SAMHSA, 2007). A number of studies report potential adverse health risks of ST use during pregnancy for both the mother and infant including increased risk for preterm birth, stillbirth, and low birth weight (England et al., 2003; Gupta & Subramoney, 2006; Steyn, de Wet, Saloojee, Nel, & Yach, 2006).

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The adverse effects of tobacco use on maternal and infant health outcomes are especially relevant for populations with a high prevalence of tobacco use, such as Alaska Native people. In 2007, in Alaska, the prevalence of current smoking (28% vs. 19%) and ST use (13% vs. 4%) was higher among Alaska Native adults compared with non-Natives (Alaska Department of Health and Human Services, 2008). Using the Alaska Pregnancy Risk Assessment Monitoring System (PRAMS) data, among Alaska women who delivered a live birth in 2003, the prevalence of cigarette smoking, ST, and any tobacco use during pregnancy was 17%, 26%, and 40% for Alaska Native women compared with 0.4%, 15%, and 16%, for White women, respectively (Kim, England, Dietz, Morrow, & Perham-Hester, 2009a). Prenatal ST use was highest for women residing in the southwestern region of Alaska, where nearly 60% of women used ST. Similarly, among Alaska Native women residing in the Yukon-Kuskokwim (Y-K) Delta region of Western Alaska and enrolled in the Women, Infant, and Children (WIC) program between 2001 and 2002, we found that 79% reported tobacco use during pregnancy (Patten, Renner, et al., 2008). This was primarily due to the increase in use of ST from 14% in the 3 months before pregnancy to 60% during pregnancy. Data available from the GPRA (Government Performance and Results Act) indicate that in 2007, there were 898 pregnant women in the Y-K Delta region; 99% (889) were screened for tobacco use. Of these, 77% (689) used tobacco: 50% smoked cigarettes and 50% used ST.

The most common form of ST used by Alaska Native people residing in this region is Iqmik, a mixture of tobacco leaves and fungus ash (Renner et al., 2005). This homemade ST product may result in higher maternal and fetal nicotine exposure than use of other tobacco products (Hurt et al., 2005). The addition of ash raises the pH of the tobacco and increases the amount of free (unionized) nicotine available for absorption (Renner et al., 2005). Nonetheless, our focus group work with pregnant women and other Alaska Native adults suggests that Iqmik is perceived as safer to use during pregnancy than other tobacco products (Renner et al., 2004). One reason why Iqmik is perceived as safer is because it contains "natural" ingredients, for example, ash.

The high prevalence of tobacco use during pregnancy suggests that cessation interventions targeting Alaska Native women are a public health priority (Kim et al., 2009a). Although several decades of research have focused on interventions for pregnant smokers, interventions developed and evaluated among AI/AN pregnant women do not exist (Melvin & Gaffney, 2004; U.S. Department of Health and Human Services, 2001). The updated Clinical Practice Guideline (Fiore et al., 2008) highlighted the need for development of effective interventions and delivery strategies for pregnant tobacco users generally and especially populations that carry a disproportionate burden from tobacco such as Alaska Native women. In addition, no previous work has evaluated interventions for women who use ST during pregnancy. To enhance acceptability and feasibility, the updated Clinical Practice Guideline emphasized that new techniques and treatment delivery strategies may be required to address the needs of AI/AN pregnant tobacco users (Fiore et al.). The current pilot study assessed the feasibility and acceptability of a targeted cessation intervention for pregnant Alaska Native women. Information learned from this study could be useful in developing cessation interventions for pregnant women in other AI/AN communities.

Methods

This study was approved by the Alaska Area Institutional Review Board (IRB), the Yukon-Kuskokwim Health Corporation (YKHC), the Alaska Native Tribal Health Consortium, and the Mayo Clinic IRB.

Study setting

The Y-K Delta region is located in Western Alaska with a total population of 25,000. Bethel (population 5,000) is the hub of the 56 villages comprising this region. The geography and climate of the Y-K Delta region pose severe transportation limitations. There is no road system connecting the villages and people travel by small airplane, boat, or snow machine. Approximately 94% of the population outside of Bethel are of Alaska Native ethnicity (Yup'ik or Cup'ik) and are homogenous with respect to language and culture. Few Alaska Natives are employed and most engage in subsistence living (Alaska Humanities Forum, 2003). About 99% of women receive prenatal care at the Y-K Delta Regional Hospital (YKDRH) in Bethel. In addition to the first prenatal visit at the YKDRH, nearly all women are seen at about Week 36 of gestation. At this time, high-risk pregnancies are triaged to the Alaska Native Medical Center in Anchorage. The remaining women stay at the Bethel prematernal home until delivery. There was an average of 600 Y-K Delta births per year from 2000 to 2007.

The YKDRH clinical cessation program has provided nicotine dependence treatment services to patients and employees of YKHC since 1999. This program provides nicotine dependence treatment and counseling services to all patients of the hospital through referrals from the medical staff. The nicotine dependence treatment consultation consists of an initial face-to-face visit with the patient about 45 min in duration and subsequent telephone follow-up contacts up to 30 min each on the quit date, then at 1, 2, 3, 6, 12, 26, 52 weeks. Additional support calls can be requested by the patient. Depending on the treatment plan, the counselors work with the patient's physician to prescribe tobacco cessation medications, including nicotine replacement therapy (NRT), varenicline, and bupropion SR (Zyban).

As part of normal care, prenatal and WIC providers routinely ask about tobacco use and provide brief advice to quit but cessation interventions are not routinely provided and there is currently no system in place to refer pregnant women to the YKDRH clinical cessation program. GPRA data indicate that in 2007, of the 689 pregnant tobacco users in the region, only 14 (2%) used the YKDRH clinical cessation services.

Procedures

The study was conducted in two phases, consistent with the goals of Stage I tobacco treatment development research (Rounsaville, Carroll, & Onken, 2001). In Phase 1, the intervention was developed, refined, and pretested. Phase 2 consisted of a formative evaluation.

Phase 1: Treatment development

Patient education methods (video, cessation guide, telephone counseling) were adapted from the SCRIPT (Smoking Cessation and Reduction in Pregnancy Treatment) trials (Windsor et al., 1985, 1993, 2000) to be appropriate to the Yupik culture and were

based on a social cognitive theoretical framework (Bandura, 2004). The patient education components emphasized abstinence from all forms of tobacco. Consistent with the United States Public Health Service Guideline (Fiore et al., 2008), the counseling strategies were similar for stopping use of ST or cigarette smoking, for example, implementing a tobacco-free household.

Treatment components

Video. A video was produced that included stories of Alaska Native women who stopped using tobacco during pregnancy. The women served as role models to reinforce self-efficacy and positive outcome expectancies of quitting tobacco for the pregnant woman, her baby, and her family. Two important learning mechanisms among Alaska Native people are role-modeling and storytelling (Pelusi & Krebs, 2005; Stillwater, Echavarria, & Lanier, 1995). Storytelling has been used to preserve traditions of the culture, explain illness and health (Fienup-Riordan, 1994; Fleming, 1992; Tom-Orme, 2000), overcome cultural barriers to health behavior change (Hodge, Fredericks, & Rodriguez, 1996), and serve as social modeling and teaching tools (Kreuter et al., 2007). Prior focus groups with pregnant women and other Alaska Native tobacco users documented that personal stories were a potentially acceptable intervention component (Renner et al., 2004). In a retrospective chart review study of 100 women seen for prenatal care, we learned that 98% reported a television and VCR/DVD player in their home (Patten, Enoch, et al., 2008), suggesting the potential feasibility of a video.

The video was filmed in various villages in the region and at the YKDRH. Pregnant women, their families, YKDRH tobacco cessation program counselors, and providers were interviewed for the video. A 22-min rough cut of the video, "Angelina's Journey," was produced and narrated by a Yupik female elder. The video followed a mother during her pregnancy until she gave birth to her child named Angelina. Family members and prenatal care providers reinforced the mother to quit and remain abstinent. The video highlighted stories from other women who had quit when they learned they were pregnant. Women discussed how they engaged in positive cultural activities to help them quit, for example, berry picking. Family members also discussed the support they provided to the woman, for example, one spouse quit when he learned his wife was pregnant.

Telephone counseling. A draft of the counselor manual was developed based on completed evaluation research (Parker et al., 2007; Windsor et al., 1985, 1993, 2000). This included the content for the face-to-face session at the first prenatal visit and four telephone contacts. Previous work suggested that telephone counseling may be a feasible mode of treatment delivery as 93% of pregnant women reported access to a telephone (Patten, Enoch, et al., 2008).

Cessation guide. A written cessation guide was adapted from the SCRIPT trials (Windsor, 2005) and from culturally appropriate brochures developed and used by the YKDRH clinical cessation program.

Treatment refinement

Feedback was obtained on the patient education methods from two focus groups of pregnant women who used tobacco ($N = 12$) and interviews with seven adult family members (5 males, 2 females). In the first focus group, pregnant women reviewed the telephone counseling protocol and cessation guide. In the second focus group, pregnant women reviewed the video. The family members were interviewed to obtain feedback on the video. The primary change recommended by participants was to add more information to the video and counseling protocol about the potential harmful effects of maternal Iqmik use for the baby.

The counselor manual and cessation guide were revised to address the misconception about the perceived safety of Iqmik. Highlighted were findings from our pilot study (Hurt et al., 2005) showing significantly higher average cotinine concentrations at delivery among Yupik pregnant women who used Iqmik compared with those using other forms of tobacco and nontobacco users. A personal story of a Yupik woman who had chewed Iqmik during her pregnancy because she thought it was safer was added to the video. The video was expanded to 25 min and the final cessation guide was 27 pages.

Intervention pretesting

The intervention and other study procedures were piloted with three pregnant women. Two participants completed the intervention and one completed the counseling at the first visit and only the first telephone session. At the Week 6 assessment, participants rated the intervention as highly acceptable. No changes to the intervention were recommended.

Phase 2: Formative evaluation

The formative evaluation utilized a randomized two-group design with assessments at baseline and during pregnancy.

Participants

Recruitment for the pilot occurred over an 8-month period from 2007 to 2008. Based on the primary aim of feasibility, our targeted sample size was 60 women (Lancaster, Dodd, & Williamson, 2004; Rounsaville et al., 2001). Eligibility included (a) ≥18 years, (b) ≤24 weeks gestation, (c) self-reported smoking or Iqmik/ST use in the last 7 days, (d) planning to quit in the next 30 days, (e) access to a telephone and VCR/DVD player, and (f) willing to participate in all study procedures. Exclusion criteria were (a) planning an abortion, (b) current (past 3 months) participation in pharmacological or behavioral tobacco treatment, and (c) another woman from her household had enrolled.

Prenatal and WIC providers identified women who were ≤24 weeks pregnant and self-reported using tobacco as potentially eligible. Most providers were not from the local community. The provider asked if the woman was interested in learning about participating in a study to help pregnant women quit tobacco. The providers did not track the number of women who were not eligible or not interested in participating. However, feedback obtained from providers indicated the major reason for lack of referral to the study was gestation >24 weeks. If the woman expressed interest, she was referred to the study coordinator at the clinical cessation program located in the same building and in close proximity to the obstetrics/prenatal care and WIC programs. The study coordinator was an Alaska Native female from the local community. When the study coordinator met with the potential participant, she explained that the program was designed to help Alaska Native women quit tobacco and involved counseling and written materials.

Procedures

The assessments and interventions were conducted by the same individual, a trained Yupik female tobacco cessation counselor. A baseline interview lasting 20 min was conducted in-person and privately to obtain baseline demographics and tobacco use information. A saliva sample was collected for analysis of cotinine. A 15-min follow-up, performed in-person or by telephone, including a saliva sample, was scheduled at ≥60 days postrandomization to assess treatment use and acceptability. If the assessment was done by telephone, the study coordinator arranged for the village-based community health aide to collect the saliva sample. Participants received a $25 gift certificate after completion of each assessment.

Interventions

For both study groups, the counselor encouraged and assisted the participant to set a quit date. Participants requesting NRT or another medication from the counselor were referred to the YKDRH clinical cessation program and enrollment in this program was tracked as part of this study. However, the counselor did not encourage use of NRT or utilization of the YKDRH clinical cessation program.

Control group. The intervention provided to control group participants was consistent with the five-component treatment (5 *A*'s) recommended for pregnant smokers by the Clinical Practice Guideline: Ask, Advise, Assess, Assist, and Arrange (Fiore et al., 2008). At the first visit, participants in this condition received a brief (5-min) face-to-face intervention based on the 5 *A*'s and four pregnancy and culturally specific brochures (Fiore et al., 2008).

Intervention group. At the first visit, participants in this condition received the cessation guide and 15–25 min of counseling based on the recommended 5 *A*'s (Fiore et al., 2008). Next, the woman viewed the video in private. The counselor then spent 10–15 min discussing the video, teaching cessation skills, emphasizing the importance of establishing tobacco-free homes and families, and problem solving of potential barriers to enhance the woman's self-efficacy to quit tobacco. The video (DVD or VHS version) was provided to the woman for in-home viewing with family members to elicit their support.

Participants were scheduled for four 10–15 min proactive telephone sessions, at Weeks 1, 2, 4, and 6. At each session, the counselor reviewed the participant's tobacco use and assessed motivation level and self-efficacy to quit. These sessions provided opportunities for the counselor to teach additional cessation skills and reinforce self-efficacy. The woman was encouraged to set a quit date at each contact, if she had not quit.

Treatment fidelity. The counselor was trained on both manual-based interventions using didactics, role-plays, and mock sessions. A "refresher" training session was conducted 3 months after initial training. The counselor timed and completed a checklist indicating topics covered for each session. All sessions were audiotaped and the first author reviewed the audiotapes and provided feedback to the counselor on a weekly basis. Counselor adherence to the respective treatment manuals, defined as the number of manual-based intervention components delivered to the total number intended, was 98% for the control group and 97% for the intervention group.

Measures

Sociodemographics. A baseline interview form, developed in our previous work as a culturally appropriate tool (Renner et al., 2004), documented age, ethnicity, language, marital status, education, number of children, duration of pregnancy, intention to breast-feed, spouse/partner tobacco use status, and home restrictions on tobacco use.

Feasibility measures. Data related to participant recruitment were collected, including the number of eligible subjects screened, the number excluded for each of the specific inclusion and exclusion criteria, and the number of eligible women who agreed to participate. The recruitment rate was calculated as the ratio of the number of enrolled subjects to total eligible subjects. Study retention was based on the proportion of enrolled women who completed the follow-up assessment. To assess treatment compliance, for both study groups, the counselor recorded completion and number of minutes spent for the face-to-face session at the first prenatal visit and for each telephone counseling session for women assigned to the intervention group.

Treatment acceptability measures. At follow-up, we assessed whether participants would recommend the program to a friend/family member with response options: definitely would, probably would, unsure, probably would not, and definitely would not. Participants were asked about the perceived helpfulness of the overall program and the written materials, and for women in the intervention group the video and counseling calls, with response options: very helpful, somewhat helpful, a little helpful, and not at all helpful. All participants were asked the extent of written materials read with response options: none, some, most of it, all of it. In addition, all participants were asked to provide open-ended feedback on the intervention.

Tobacco use status. To enhance disclosure, self-reported tobacco use status was obtained at screening and follow-up using a multiple-choice response format (Fiore et al., 2008). A saliva sample was collected at baseline and follow-up for cotinine analysis (Benowitz et al., 2002). We assessed use of NRT at follow-up because use would elevate the cotinine concentrations. Saliva samples were analyzed by the Mayo Clinic Laboratories in Rochester, MN. At follow-up, participants who self-reported no use of tobacco in the last 7 days confirmed with a cotinine concentration of ≤20 ng/ml (Hughes et al., 2003) were classified as nontobacco users.

Statistical methods

Group comparisons were made using an exact test for categorical variables and the two-sample rank sum test for continuous variables. p values ≤.05 were statistically significant.

Results

Feasibility of recruitment

Figure 1 summarizes participant recruitment, treatment completion, and follow-up information. Prenatal/WIC providers referred a total of 293 eligible pregnant tobacco users to the study coordinator (Figure 1). Of these, 81 (28%) did not keep their appointment and 212 (72%) were screened by the study coordinator. Of those screened, about half (54%, $n = 114$) were not eligible because they reported not using tobacco, 59 (28%)

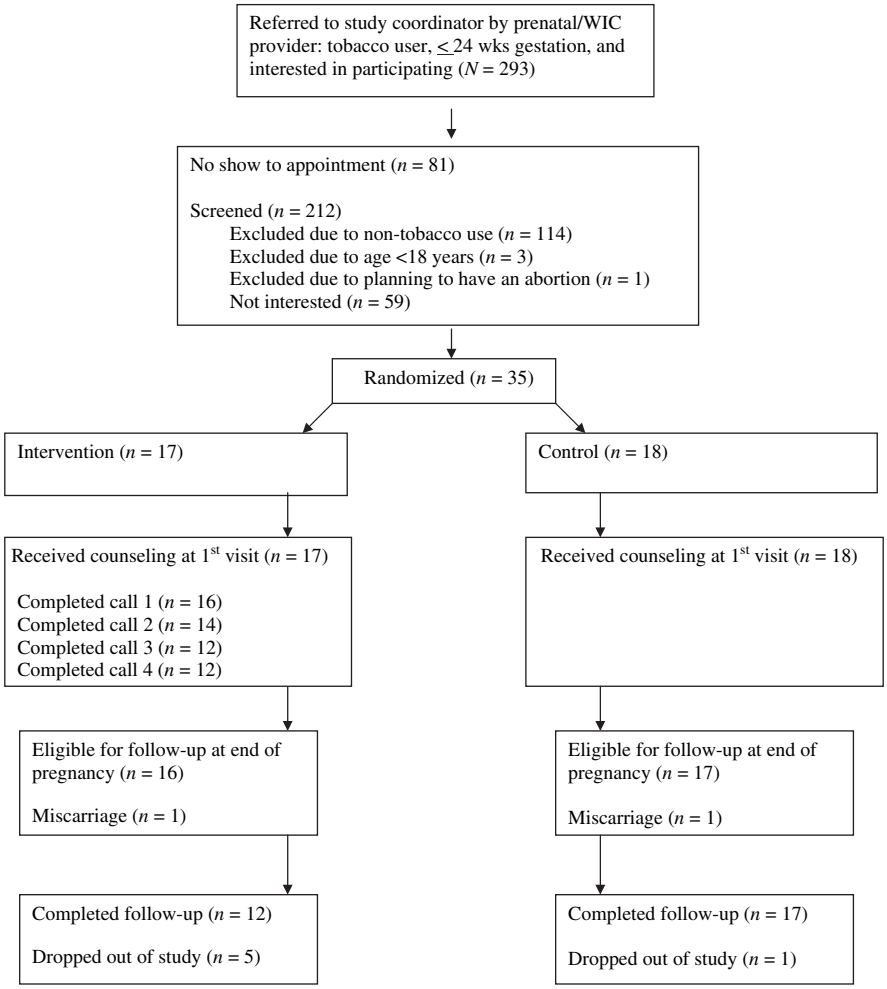

Figure 1. Participant recruitment and follow-up.

were not interested in participating, 4 (2%) were excluded based on other eligibility criteria, and the remaining 35 women (16%) provided consent and were enrolled. Among women screened, the main reasons cited for not participating were not ready to quit and lack of time to complete the counseling at the visit because of the need to catch their scheduled flight back to their village. However, when the study coordinator offered to conduct the counseling by telephone, participation did not increase.

Participants

The 35 participants were stratified by primary type of tobacco used (Iqmik, commercial ST, or cigarettes) and randomly assigned to the control ($n = 18$) or intervention ($n = 17$) condition. Table 1 shows the baseline characteristics and comparability by study condition.

Treatment compliance and acceptability

In addition to Figure 1, Table 2 describes the program outcomes, including study retention, treatment compliance, treatment acceptability, and tobacco abstinence. One participant in each treatment group miscarried during the study and was ineligible for follow-up. For the remaining women, the follow-up assessment occurred on average at 82 days postrandomization for controls and 108 days for intervention participants ($p = .14$). One participant in each treatment group had a premature delivery and completed the follow-up after delivering her baby. Excepting these women, follow-up occurred at a mean of 26.3 ($SD = 7.8$) weeks of pregnancy among control participants and 24.3 ($SD = 6.1$) weeks among intervention participants.

Among enrolled participants, the study retention and treatment compliance rates and treatment acceptability ratings were very good. It was also feasible to obtain a saliva sample from women at follow-up. Three (17%) control and six (35%) intervention participants ($p = .26$) enrolled in the YKDRH clinical cessation program during the study period and received NRT, but were not using NRT at follow-up. Open-ended feedback from the women in both treatment groups indicated that the most commonly recommended change was to provide more "objective" information on the harmful effects of maternal Iqmik use for the baby.

Discussion

The current study addressed an important gap in the field. To our knowledge, no previous study has developed and evaluated

Table 1. Baseline characteristics of Alaska Native pregnant tobacco users enrolled in a pilot randomized clinical trial by treatment condition[a]

Characteristic	Control group ($N = 18$), % (n) or mean ± SD	Intervention group ($N = 17$), % (n) or mean ± SD	p value
Age: years	24.8 ± 5.0	25.4 ± 4.2	.56
Yupik ethnicity	100% (18)	100% (17)	1.0
Fluent in English language	100% (18)	100% (17)	1.0
Fluent in Yupik language	66% (12)	65% (11)	1.0
Married	44% (8)	47% (8)	1.0
Highest level of education			.24
Less than high school	22% (4)	44% (7)	
High school	61% (11)	31% (5)	
Some college/trade school	17% (3)	25% (4)	
No. of adults in home	2.8 ± 2.2	2.8 ± 1.4[b]	.85
No. of children in home ≤17 years	2.6 ± 2.0	2.8 ± 2.0[b]	.69
Gestation, week	14.9 ± 5.5	11.6 ± 4.2[b]	.09
First pregnancy	11% (2)	6% (1)[b]	1.0
No. of children	2.3 ± 1.6	2.4 ± 1.5[b]	1.0
Plans to breastfeed	67% (12)	80% (12)[c]	.46
Current tobacco use: past 7 days			1.0
Iqmik	44% (8)	47% (8)	
Commercial chew	22% (4)	18% (3)	
Cigarette smoking	33% (6)	35% (6)	
Salivary cotinine: ng/ml (range)	187.9 ± 136.3 (49–500)	210.7 ± 97.6[c] (69–435)	.36
Spouse/partner uses tobacco	78% (14)	54% (7)[d]	.25
Smoking ban in the home	89% (16)	88% (14)[b]	1.0
Chewing ban in the home	12% (2)[b]	19% (3)[b]	.66

Note. [a]Because of rounding, not all percentages total 100. Percentages are based on non-missing data.

[b]Data were missing for one participant.

[c]Data were missing for two participants.

[d]Percentage is based on N of 13 (one woman did not report having a spouse/partner and data were missing for three additional women).

an intervention for pregnant American Indian or Alaska Native women. Because the intervention was targeted and developed with feedback from Y-K Delta pregnant women, it may lack generalizability to other AI/AN women. Nonetheless, our findings on recruitment of pregnant women could inform future intervention development efforts in other Native communities. This evaluation was the next step on our successful 8-year partnership with the YKDRH and addressed an important concern among community members and providers (Enoch & Patten, 2004). A major strength of our investigation is that the intervention was developed with input and advice from the community. Other strengths are the use of an experimental design, use of theoretically based, well-defined intervention components to enhance replication, and inclusion of quality control procedures.

A key finding was the very low rate of participation suggesting that the program was not feasible or acceptable to pregnant Alaska Native women. Of the 293 women referred to the study, 87% (254) either actively or passively refused to enroll. Reasons reported by women who were screened and decided not to participate were lack of time and not being ready to quit using tobacco. Among women who did not keep their appointment with the study coordinator, anecdotal feedback indicated that the social stigma of tobacco use during pregnancy was a major enrollment barrier. The clinical cessation program was located in front of a large waiting area within the hospital, which could have deterred some women concerned about the social implications of using tobacco during pregnancy. The method by which women were referred to the study may have also played a role. As part of the prenatal care encounter, women were asked if they were interested in participating in a study to help them quit tobacco after being advised of the risks of tobacco use for the mother and fetus. It is possible that in this context, social desirability influences or perceived pressure to participate from a provider who was not from the local community may have played a role.

The perception that Iqmik is safer to use during pregnancy than other forms of tobacco (Renner et al., 2004) may have also presented a barrier to participation and quitting among enrolled participants. Our focus group work suggested that Alaska Native people are aware of the risks of cigarette smoking during pregnancy but there is a lack of awareness of the harmful effects of Iqmik use (Renner et al., 2004). Accordingly, the proportion of our participants reporting home bans on chewing was much less than for bans on smoking (15% vs. 88%, Table 1). The primary change for future interventions recommended by our participants was to provide more objective information on the risks of Iqmik use for the baby. Among women from this region of Alaska, pregnancy appears to be a high-risk period in which use of Iqmik and other ST increases dramatically compared with

Table 2. Study outcomes by treatment condition[a]

Outcome	Control group ($N = 18$), % (n) or mean ± SD	Intervention group ($N = 17$), % (n) or mean ± SD	p value
Study retention	94% (16)	71% (12)	.09
Minutes of counseling: First visit[b] (range)	12.6 ± 2.0 (10–17)	18.5 ± 4.0 (15–30)	<.001
Minutes of counseling: First call (range)	—	7.4 ± 3.7 (3–20)	
Minutes of counseling: Second call (range)	—	6.9 ± 2.6 (3–13)	
Minutes of counseling: Third call (range)	—	6.0 ± 2.3 (2–11)	
Minutes of counseling: Fourth call (range)	—	7.7 ± 2.5 (2–11)	
Amount materials read[c]			1.0
All	29% (5)	33% (4)	
Most	41% (7)	42% (5)	
Some	24% (4)	25% (3)	
None	6% (1)	0% (0)	
Probably/definitely would recommend program to another pregnant woman[c]	82% (14)	92% (11)	.62
Overall program: Somewhat/very helpful[c]	89% (15)	84% (10)	1.0
Written materials: Somewhat/very helpful[c]	59% (10)	67% (8)	.94
Counseling calls: Somewhat/very helpful[c]	—	75% (9)	–
Video: somewhat/very helpful[c]	—	75% (9)	–
Watched video with spouse/family[c]	—	58% (7)	–
Provided saliva sample[c]	94% (16)	83% (10)	.56
Self-reported tobacco abstinence rate[d]	6% (1)	6% (1)	1.0
Confirmed abstinence during pregnancy[d]	6% (1)	0% (0)	1.0
95% confidence interval	0.2%–28.7%	0%–20.6%	
Quit attempt since study enrollment[d]	94% (16)	69% (11)	.09

Note. [a]Because of rounding, not all percentages total 100. Percentages are based on non-missing data.

[b]All participants in each group completed the counseling at the first visit.

[c]Percentages for each group are based on the number completing the follow-up assessment: 17 for the control group and 12 for the intervention group.

[d]The percentages for each group are based on the number eligible for follow-up: 17 for the control group and 16 for the intervention group.

before pregnancy (Kim, England, Dietz, Morrow, Perham-Hester, 2009b; Patten, Renner, et al., 2008). In one study (Patten, Renner et al.), there were 432 women who did not use any tobacco in the 3 months before pregnancy of which 323 (75%) reported tobacco use during pregnancy. The majority (78%) of these women reported exclusive use of ST during pregnancy. This may be due to cultural reasons that need exploration in future qualitative studies. In particular, assessment of the cultural beliefs surrounding Iqmik use during pregnancy may inform future intervention efforts.

Additional qualitative work could also determine the best timing for enrolling women in cessation services within the context of pregnancy. Our intervention targeted women who were planning a quit attempt. It may be useful to interview women who are not ready to quit to learn what would attract them to a cessation program and what types of objective information on Iqmik (i.e., biomarker feedback on fetal tobacco-specific carcinogen exposure) would motivate them to quit tobacco. In addition, women's preconceptions about research should be explored.

Unfortunately, the low participation rate did not allow for adequate testing of the intervention with respect to tobacco abstinence outcomes. While the abstinence rates were very low, the majority (82%) did report ≥1 quit attempt. The low abstinence rates could be attributed to social and demographic characteristics of our sample previously shown to be associated with continued tobacco use during pregnancy such as low income and high parity (Adams, Melvin, & Raskind-Hood, 2008; J. A. Martin, Kung, et al., 2008), nicotine addiction, extensive social–environmental cues to use tobacco, and/or cultural influences. The control group intervention was consistent with recommended best practices for pregnant women (Fiore et al., 2008). However, a limitation of our study design is that the treatment groups were not equated for counselor contact time. Future evaluation studies should include a control group that is balanced for contact time.

Most pregnant women who used tobacco in this region of Alaska were not reached by our recruitment methods and the intervention did not appear to be successful among women who did enroll. Continued efforts to reduce tobacco use among pregnant women are an essential component of a regional plan to significantly improve maternal and infant health (Enoch & Patten, 2004), but it is clear that alternative approaches are needed. We recommend additional qualitative work to explore options for attracting women to cessation programs and cultural beliefs surrounding tobacco use during pregnancy. To reduce the perceived stigma of tobacco use as an enrollment barrier, future studies could consider lifestyle or multiple risk behavior interventions that address issues faced by pregnant

women such as stress, physical inactivity, depression, and/or child rearing (Katz et al., 2008; Prochaska, Spring, & Nigg, 2008). Research could explore recruitment of women at the time of the pregnancy test that is done by village-based health aides as a means to reach women earlier in their pregnancy. A positive pregnancy test could be an opportune time to offer a healthy lifestyle intervention for women irrespective of their tobacco use. This could help to destigmatize tobacco use to increase enrollment among tobacco users and possibly help to prevent initiation of tobacco use during pregnancy among nonusers. There are also opportunities to utilize elders and other local community members to promote tobacco cessation (Burhansstipanov, Dignan, Wound, Tenney, & Vigil, 2000). In addition, tobacco control efforts targeting the entire community, not just pregnant women, may yield greater reductions during pregnancy.

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Declaration of Interests

None declared.

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