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The Healthy Pregnancies Project: Study Protocol and Baseline Characteristics for a Cluster-Randomized Controlled Trial of a Community Intervention to Reduce Tobacco Use among Alaska Native Pregnant Women

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Abstract

Background.—Tobacco use prevalence is high among pregnant Alaska Native (AN) women but few interventions have been evaluated for this group. The Healthy Pregnancies Project aims to evaluate a multicomponent intervention for reducing tobacco use during pregnancy and the

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CONFLICT OF INTEREST

The authors have no conflicts to disclose.

postpartum period among AN women. This report describes the study protocol and participant baseline characteristics.

Design.—Cluster-randomized controlled trial with village as the unit of assignment. Sixteen villages in rural southwest Alaska were stratified on village size and randomized to a multicomponent intervention (n=8 villages) or usual care (n=8 villages).

Methods.—Pregnant AN women from the study villages were enrolled. All participants receive the usual care provided to pregnant women in this region. Participants from intervention villages additionally receive individual phone counseling on healthy pregnancies plus a social marketing campaign targeting the entire community delivered by local AN "Native Sisters." Baseline measurements for all enrolled pregnant women have been completed. Follow-up assessments are ongoing at delivery, and at 2 and 6 months postpartum. The primary outcome is biochemically verified tobacco use status at 6 months postpartum.

Results.—Recruitment was feasible with 73% of eligible women screened enrolled. The program reached more than half (56%) of AN pregnant women from the study villages during the recruitment period. Participants are N=352 pregnant AN women, 188 enrolled from intervention villages and 164 from control villages. At baseline, participants' mean (SD) age was 25.8 (5.0) years, they were at 26.8 (9.8) weeks gestation, and 66.5% were current tobacco users.

Discussion.—Processes and products from this project may have relevance to other Native American populations aiming to focus on healthy pregnancies in their communities.

Keywords

Tobacco; Intervention; Pregnancy; Alaska Native; Women; Community

1. Introduction

Tobacco use during pregnancy is an important public health issue worldwide [1–3]. The adverse effects of cigarette smoking during pregnancy and after delivery on maternal, fetal, and infant health are well documented [4]. Studies also report adverse health risks of prenatal smokeless tobacco (ST) use including increased risk for preterm birth, stillbirth, and low-birth weight [5]. The prevalence of cigarette smoking during pregnancy in the United States (U.S.) is 11%, with the highest prevalence (26%) reported among American Indian and Alaska Native (AI/AN) women [6]. Less than 1% of women worldwide use ST during pregnancy, but its use is higher among Indigenous women [7]. Among pregnant AN women from the Yukon-Kuskokwim (Y-K) Delta region of rural southwest Alaska, 26% reported cigarette smoking and 42% reported ST use [8,9].

A common form of ST used in the Y-K Delta region is Iqmik, a mixture of tobacco leaves and tree fungus ash [10]. The addition of ash raises the pH of the tobacco thereby increasing the amount of free (un-ionized) nicotine available for absorption [10] as well as the available levels of carcinogens [11,12]. Maternal and neonatal serum cotinine concentrations were found to be significantly higher for mothers who used Iqmik than for those using other forms of tobacco or non-users [13]. Qualitative work indicated that Iqmik is perceived as safer to use during pregnancy than cigarette smoking, and there is a low level of knowledge

about adverse health effects of ST use [14]. Studies conducted in this region documented there is no ceremonial use for Iqmik or other tobacco products [14].

A 2017 Cochrane review [15] included 77 trials involving 29,000 pregnant smokers and found that counseling interventions (e.g., motivational interviewing) were more effective than usual care. Only one of the published trials focused on pregnant AI/AN women [16], a pilot randomized controlled trial, conducted in the Y-K Delta region. That study found that an individual, clinic-based, culturally adapted 5*A's* counseling intervention had low reach and was not effective in promoting tobacco cessation.

These findings led us to consider an intervention incorporating both individually targeted and community level components focused on changing social norms about tobacco use in pregnancy. In addition, the intervention is delivered by local AN "Native Sisters," an approach found to be effective for cancer prevention and control efforts among AI/AN women [17,18]. In longitudinal studies, strong perceived anti-tobacco norms are predictive of smoking cessation at the population level [19] and community-based interventions designed to influence social norms are effective for reducing smoking prevalence [20]. Formative work using mixed methods, previously described [21], was used to develop the messaging for the community-wide social media campaign as well as individual counseling components with pregnant women. Both tobacco users and non-users are targeted by the intervention to prevent tobacco use during pregnancy and postpartum [22].

This paper describes the study protocol and participant baseline characteristics for a cluster-randomized controlled trial evaluating the intervention compared with usual care for reducing tobacco use during pregnancy and postpartum. The trial is innovative for the population targeted as well as the multilevel intervention channels.

2. Methods

The design of the trial is in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement and the trial is registered with the Clinical Trials Registry (NCT02083081). Institutional Review Board (IRB) approval was obtained from the Mayo Clinic and Alaska Area IRBs. The study was approved by the Yukon-Kuskokwim Delta Health Corporation (YKHC) Human Studies Committee and Board of Directors.

2.1 Study setting

The Y-K Delta region is located approximately 400 air miles from Anchorage, with a population of about 26,000. The region is comprised of 58 federally recognized tribes from 47 village locations ranging from 28 to 1,133 persons. Bethel (population 6,000) is the hub for the 47 village locations. Residents are primarily of Yup'ik, Cup'ik, or Athabascan ethnicity. The population is of low socio-economic status and most maintain a subsistence lifestyle [23]. Few roads connect any of the villages; residents travel by boat, all-terrain vehicle, snow machine, or small plane. A typical village has a Tribal Council, K-12 school, post office, store, and church. In addition, YKHC supports 44 village-built clinics staffed with Health Aides for the community who are front line providers of health care to regional

residents [24]. Health Aides are selected by and work in their home communities, providing acute, chronic, emergency, dental, behavioral health and preventative health care [24].

The Y-K Delta Regional Hospital (YKDRH), owned and operated by the YKHC, is located in Bethel and provides health care for regional residents. Prenatal care visits are scheduled here as well as at village clinics, at one of the five Sub Regional Clinics, and at the Alaska Native Medical Center in Anchorage. Ninety-six percent of women receive prenatal care beginning at 8 weeks gestation, including a visit at week 36 gestation. Around this time, women stay at the Bethel Pre-Maternal Home or in Anchorage until delivery. There is an average of more than 600 births each year to Y-K Delta women. Consistent with the cultural value emphasizing the health and welfare of children as paramount, YKHC leaders and providers, as well as a community needs assessment, prioritized research that is focused on interventions to reduce tobacco use during pregnancy [14]. The design and focus of the project came from discussions and interactions during a 3-year period with leadership, providers, and local community members.

2.2 Research team

The study extends a long-standing tobacco control research partnership between researchers at Mayo Clinic in Minnesota and local researchers at the YKHC in Alaska. This partnership is made stronger with collective expertise in behavioral tobacco treatment, mixed methods, clinical trials, culturally informed interventions, and outreach in the local community. New collaborations were formed when designing the project with researchers from other institutions having expertise in: community-based interventions, health communications and cultural messaging, motivational interviewing, and lay health advisor approaches to cancer prevention in AI/AN communities.

The study staff includes a local, YKHC employee as the research coordinator. During the course of the project, there has been turn over in this position, with both AN and non-Native women serving in this role, who have a bachelor’s or R.N. degree. The coordinator works closely with provider staff in the YKDRH Women’s Health Department.

Throughout the course of the project, 5 local AN women “Native Sisters” were hired by YKHC to conduct the intervention. Potential Native Sisters were identified by local Tribal Councils and YKHC staff, with assistance from our Community Advisory Committee (see below). The Native Sisters are Elder (older than 55 years of age) or a younger woman who is in good standing in the community, have not used tobacco in the previous 6 months, and have bilingual (English/Yup’ik) communication skills. To enhance their credibility, potential individuals were hired only if their beliefs about tobacco use during pregnancy were consistent with the project goals as assessed by YKHC staff. There was an attempt to hire Native Sisters to implement the intervention in their home villages, but this was not always practical. Thus, a Native Sister from one intervention village may conduct the intervention calls and community intervention for other villages. In addition, one Native Sister from Bethel was hired to conduct the intervention in villages without a Native Sister. The research staff is also trained to serve as back-up interventionists as needed.

2.3 Community Advisory Committee (CAC)

The project is guided by a study-specific CAC comprised of health care professionals, community partners, and local community members. Members provide guidance on study design, recruitment methods and materials, and dissemination strategies through email and in-person meetings held in Bethel. At each meeting, lunch is provided and members are offered an honorarium.

2.4 Study aims

Our study aims are to: (1) Evaluate the efficacy of the intervention compared with usual care (control condition) on the biochemically confirmed, 7-day, point prevalence tobacco use rate at delivery and at 6 months postpartum; and (2) Examine the effect of the intervention on a parsimonious set of SCT-based mediators of change: self-efficacy, perceived norms about tobacco use, and perceived support for non-tobacco use. The primary endpoint is biochemically confirmed tobacco abstinence at 6 months postpartum. Secondary endpoints are biochemically confirmed tobacco abstinence at delivery and self-reported abstinence at 2 months postpartum, along with changes in proposed theory-based mediators of intervention efficacy. We hypothesize that compared with the control condition the intervention will be associated with significantly lower rates of tobacco use at 6 months postpartum. In addition, we expect that intervention effects on tobacco use will be mediated by perceived self-efficacy and anti-tobacco norms.

2.5 Study design

The study design is a cluster-randomized, controlled trial with village as the unit of assignment. Sixteen villages were stratified based on population size (e.g., <600, >600) and randomly assigned by the study statistician to receive the intervention (8 villages) or the control condition (8 villages). When providing consent, participants were informed of their village study assignment. Baseline measurements have been completed by all enrolled pregnant women. Follow-up assessments are ongoing at week 36 gestation/delivery, and at 2 and 6 months postpartum.

2.6 Sample size calculation

Sample size calculations were based on the primary endpoint of tobacco use at 6 months postpartum. From a previous study [22] of 400 AN women who reported tobacco use during the 3 months prior to pregnancy, 83% reported tobacco use during the prenatal period and 69% at 6 weeks postpartum. Among the 17% of women who quit tobacco use during pregnancy, the relapse rate was 63% at 6 weeks postpartum. Of the 432 women reporting no tobacco use in the 3 months before pregnancy, 75% reported tobacco use during the prenatal period, and 70% at 6 weeks postpartum. Alaska Pregnancy Risk Assessment Monitoring System (PRAMS) data [25] indicate similar cessation rates during pregnancy (20%) and rates of postpartum relapse (57%) in the southwest region. During the time frames these estimates were obtained, women received the same usual care as in the current project. Therefore, we did not expect our usual care condition to impact tobacco use beyond the natural history of tobacco use in pregnancy. The Clinical Practice Guideline [26] meta-analysis found that behavioral/psychosocial interventions for pregnant smokers were

associated with an abstinence rate of 13% in late pregnancy vs. 7% for control conditions (OR=1.8, 95% CI 1.5–2.3). We did not have guidance from the literature on the possible impact of interventions for baseline non-tobacco users but would expect greater impact in this group compared to those already using tobacco. Accordingly, we estimated the tobacco use rate at 6 months postpartum to be 70% in the control villages and 55% in the intervention villages (estimated odds ratio 1.91) and at delivery to be 80% versus 65% with an odds ratio of 2.15. A difference of 15% would be of clinical significance in terms of the potential to impact the current standard of care at the YKDRH.

Estimates of intra-class correlations (ICC) within communities were quite modest, e.g., ranging from 0.002 to 0.012 for a variety of survey variables included in the Minnesota Heart Health Program [27]. For the proportion currently smoking, the estimated ICC was 0.003 [27]. We conservatively estimated an ICC at the higher end of the range (0.01).

We estimated enrolling an average of 22 pregnant women per village, accounting for an estimated rate of attrition of 10% based on prior studies [13,16,28] due to miscarriage, abortion, or fetal demise, to achieve a final analysis sample of at least 320 women. For the estimated outcomes with 16 villages total, average village participant size of 20 (total sample size = 320), and with an ICC of 0.01, we would have >80% power to detect the hypothesized differences between conditions at 6 months postpartum.

2.7 Recruitment and eligibility

Recruitment of all study participants has been completed. A study logo that consisted of baby in womb and the text "*Healthy Pregnancies*" was created by our media partner, Northwest Strategies. The logo was placed on all recruitment materials, and was used on any subsequent communications from the research staff. All recruitment materials described the project as a "Healthy Pregnancies Study."

After villages were randomized, initial recruitment procedures were developed through several face-to-face and videoconference meetings with YKHC leadership and Health Aide staff. At the time of a positive pregnancy test or at any visit encounter with a pregnant woman, the Health Aide or YKHC research staff member briefly stated that there is a healthy pregnancy study being done in the village and provided the woman with a 1-page flyer with study information and a toll-free number. Next, the Health Aide or YKHC research staff member asked the woman if she was interested in learning more about the study. If the woman indicated interest, the staff member took the woman's name and contact information and informed the woman that the research coordinator would contact her to provide more details about the project. Each study village clinic designated a staff member who sent the names and contact information of only the women who indicated they wanted to receive more information about the study to the research coordinator by electronic mail or phone on a weekly basis. Health Aides sometimes assisted with recruitment by helping the participant mail or fax her consent form to the research coordinator. To foster implementation of these procedures, research staff initially traveled to all 16 villages to meet with Health Aides and other clinic staff, followed by regular phone calls to the clinic. These methods resulted in recruitment of some participants but were not generally feasible for

clinic staff given other work responsibilities. Health Aides and other village clinic staff had no other role in the research.

Some women contacted the Native Sisters to learn more about the study. The Native Sisters shared the woman's name and phone number with the research coordinator who then contacted the woman to describe the study and enroll her if she was interested.

A highly successful point of recruitment was at a prenatal care visit in Bethel conducted by the research coordinator. Provider staff who care for prenatal patients were informed about the study and asked to hand out a study flyer to any pregnant women. Posters with study information were also displayed at the Women's Health Department and at the Centering Pregnancy Offices along with the Pre-Maternal Home and several places on the YKHC campus. Flyers for the Bethel-based providers and posters displayed in Bethel had the names of all 16 participating villages so that only women from these villages were encouraged to call for information.

Another successful method implemented by the research coordinator utilized information from the YKHC electronic medical record (EMR) system. An electronic report within the YKHC EMR collated the future appointment dates of pregnant women from the 16 villages who had been seen at least once for a current pregnancy. This report included information about the pregnant patient's: name, address, phone number, date of birth, current weeks at gestation, the location and date of her last pregnancy-related medical appointment, as well as the location and date of her next scheduled pregnancy-based appointment.. Potential participants were approached by the research coordinator face-to-face or referred to the study from health care staff from ambulatory and ultrasound clinics.

Research staff conducted a brief screening to assess the study eligibility criteria: (1) AN woman, (2) 18 years of age or older, (3) currently pregnant and < 36 weeks at gestation, (4) provided written informed consent, and (5) had access to a working telephone. We enrolled women up to week 36 gestation to maximize intervention reach and because our primary endpoint was at 6 months postpartum. Adolescents were excluded because different individual-based interventions and age-appropriate assessments may be needed for this group given their differing developmental and cognitive abilities. Only about 7% of pregnancies in the region are among girls <17 years of age. About 95% of Y-K Delta residents have access to a telephone in their home making this approach feasible [28]. Both tobacco users and non-users were eligible.

All participants provided written informed consent. Participants completed the consent form in-person in Bethel, or the consent form was mailed to the potential participant with a postage-paid return envelope or faxed to the village health clinic. The consent form was written at an eighth grade reading and was read to and reviewed with the woman by research staff in person or by phone. The potential participant was given time to ask questions and decide whether or not she wished to participate. After providing written informed consent, the woman was enrolled.

2.8 Interventions

Interventions for enrolled pregnant women are ongoing.

Usual Care Delivered to Participants in Both Study Groups.—As part of usual care in this region, all pregnant women (tobacco users and non-users) receive written materials on the risks of tobacco use during pregnancy provided by Health Aides and/or prenatal care providers. In addition, Health Aides and prenatal care providers provide minimum cessation counseling methods (Ask, Advise) recommended for pregnant tobacco users [26]. The state of Alaska advertises the state quitline and other cessation resources on an ongoing basis throughout the Y-K Delta region through radio, posters, newsletters, and flyers.

Control Villages.—No additional study treatment is provided in addition to the usual care to pregnant women enrolled in control villages.

Intervention Villages.—In addition to the usual care, the intervention villages receive a community-wide social marketing campaign and, for enrolled pregnant women, individual phone counseling delivered by Native Sisters. The intervention builds on effective community- and individual-based approaches for tobacco cessation [26,29], efficacious lay health advisor approaches for cancer prevention among AI/AN women [17,18] and the strengths and values of Yup'ik culture. The theoretical basis for the intervention is social cognitive theory (SCT), which posits that personal change is influenced by both individual- and community-level factors [30]. In particular, self-efficacy has been postulated to be the most influential cognitive mechanism mediating behavioral change [30] and enhanced self-efficacy is associated with non-tobacco use in late pregnancy [31,32]. Intervention strategies designed to influence self- and collective efficacy[33], and perceived norms, include social support and role modeling provided by the Native Sisters. In addition, health communications media can influence knowledge and perceptions that change social norms and prompt action, and can model desired behaviors [34,35]. As acceptance spreads, new norms gain further support through the process of social diffusion within families or other groups [36–38].

Development of the social marketing campaign was previously described [21]. Briefly, we used a social marketing planning framework consistent with National Cancer Institute guidelines for developing health communication programs, addressing key components of message construction. Two rounds of assessments were used to obtain feedback from community members to develop and pre-test the campaign messages. Because the campaign targets the entire community, our audience segments were Elders, family members, and pregnant women; both tobacco users and non-users were included. The first round used qualitative individual interviews (n=60) and the second round comprised quantitative survey interviews (n=52). We used two frameworks for addressing the influence of culture in designing health messages, the cultural variance framework [39], and the surface/deep structure framework [40]. Findings highlighted the need to address not only tobacco use but additional healthy pregnancy targets, primarily stress reduction. Participants reported that that alleviating stress was the main reason for using Iqmik and other tobacco products during

pregnancy [21]. Most participants preferred a factual-based messaging approach for reducing tobacco use in pregnancy with no differences by audience segment.

Campaign media developed were a digital stories DVD created by nDigiDreams, Inc., posters, promotional items (e.g., baby bibs), and mailed postcards describing the Native Sisters intervention. Consistent with prior community-based studies [41], the social marketing campaign will last about 2 years in each intervention village. The Native Sisters are responsible for distributing all media to community members, e.g., handing out the digital stories DVDs and promotional items, and displaying posters. From our qualitative work we determined that 1:1 conversations with community members were preferred interpersonal channels of communication and outreach by the Native Sisters.

Peer counseling telephone sessions delivered by the Native Sisters comprise the individually targeted components of the intervention. Native Sisters attempt to contact all enrolled women for counseling sessions lasting between 10–60 minutes each during pregnancy (weeks 1, 2, & 4 post-enrollment) and postpartum (weeks 2, 4, & 6 after delivery). We chose 6 sessions total based on evidence of a dose response relationship between number of sessions and successful tobacco use outcomes [26]. The research coordinator provides the woman with the campaign media including the digital stories DVD and brochures prior to the first session with the Native Sister.

The content of the 6 sessions closely aligns with the campaign messages and addresses social norms about tobacco use. The sessions: (1) include evidence-based techniques such as providing support, problem-solving, and reinforcement to pregnant women; (2) emphasize the importance of positive cultural and community activities (e.g., berry picking) for coping with withdrawal/stress or preventing tobacco use; and (3) cover other health topics in pregnancy and postpartum(e.g., prenatal care, reducing stress). The Native Sisters encourage participant enrollment in the YKHC clinical Tobacco Prevention and Cessation Program that includes offering a variety of counseling, nicotine replacement therapy (NRT) and other tobacco cessation medications. The Native Sisters use an intervention manual that has a script/talking points for each peer counseling session. Messages and strategies included in the manual were developed from our qualitative work and geared toward both cessation and prevention of tobacco use. The original manual was developed, refined, and then streamlined using an iterative process with feedback from the Native Sisters during the course of the project.

A process evaluation checklist titled “Native Sister Event Totals” was developed for the Native Sisters to document delivery of specific community and individual-level intervention components based on existing measures. Using a checklist, each Native Sister is asked to record distribution of media such as the number of DVDs and brochures provided; and presentations/outreach activities and number of people in attendance. Individual-level components documented include number of sessions completed (of 6 total) and duration.

Extensive 2-day training held in Bethel was provided to the Native Sisters by the research team. The training included an overview of the conceptual framework, roles and responsibilities, specific strategies for implementing and promoting the campaign, reviewing

and personalizing scripts from the counseling manual, and overview and practice with the process evaluation tool. Simulations and role-plays and a discussion of commonly asked questions were provided. A basic overview of tobacco use prevalence, maternal/infant health risks of tobacco use, and treatment referral options were also covered. Using a peer protocol developed for several prior NIH studies, the Native Sisters were trained on lay motivational interviewing communication skills. They were taught how to ask effective open-ended questions and basic reflective listening skills, and were certified based on successful completion of mock test sessions. Two refresher trainings were provided by the research team. Native Sisters also received training and ongoing support by YKHC Behavioral Health Program Calricaraq staff. This preventative services program focuses on strengthening families and cultural values in the region. The Native Sisters were taught to incorporate traditional cultural practices/values and pre-contact Ancestral teachings into the delivery of their intervention such as Yup'ik ways of being healthy.

2.9 Assessments

Baseline assessments from all enrolled participants have been completed. Research staff administered a baseline interview by phone or in-person that included assessment of socio-demographic and tobacco use characteristics, and theory-based mediators (e.g., social norms) (see Table 1). Participants received a $25 recognition card as a thank you for completing the baseline assessment.

The follow-up assessments are underway. Efforts are made to obtain follow-up assessments from all participants by research staff members not involved in the delivery of the intervention. Assessments occur near the time of delivery, and at 2 and 6 months postpartum. The delivery assessment is attempted in-person at the Bethel Pre-Maternal Home at about week 36 gestation or by phone shortly before or after delivery. All other follow-up assessments, as well as those for women whose in-person assessment is missed (e.g., due to pregnancy complications, triage to Anchorage for delivery, or lack of time at the visit), are conducted by phone. In the original protocol, an assessment was planned at week 12 post-enrollment, but this was not feasible because many women enrolled after week 24 gestation, which coincides with the delivery assessment. Thus, to reduce participant burden, we combine the week 12 questions with the delivery assessment and give participants a $50 recognition card for appreciation of their time in completing this more extended assessment. Participants also receive a $25 recognition card for completing each of the 2- and 6-month postpartum assessments.

At all assessments, self-reported use of any tobacco (past 7 days) is assessed [26]. At baseline, delivery, and 6 months postpartum, a saliva specimen is collected for analysis of cotinine in person or by mailing a kit to the participant. Biochemical confirmation of self-reported tobacco abstinence during pregnancy is recommended [42] and cotinine is the recommended biomarker [55]. The sample is analyzed either at the point of contact using a NicAlert test strip or is mailed to Mayo Clinic, Rochester, MN laboratories for analysis. There is precedence for obtaining saliva samples by mail to confirm tobacco use status in previous trials [56,57]. We assess NRT use at follow-up since use would elevate cotinine levels. At delivery and at 6 months postpartum, point-prevalence tobacco abstinence is

defined as no reported use of tobacco during the previous 7 days, biochemically confirmed with a salivary cotinine concentration of ≤20 ng/ml [55,58], or if cotinine is elevated the participant reports NRT use during the past 7 days.

For intervention villages, as part of the program evaluation, the pregnant woman's reported exposure to the social marketing campaign is assessed using scales adapted from prior research [59–62]. Both prompted and unpromoted recall of campaign messagesrecall and use of campaign media (e.g., brochures, digital stories DVD, posters) and promotional items are assessed, along with if these were discussed and shared with others. An intervention exposure index will be created based on item responses to permit exploration of dose response effects [61].

2.10 Quality assurance

We use the same coordination and communication procedures successfully utilized in our previous work, including regular study team meetings held via teleconference. Research staff monitor quality control of the data and study procedures through review of all completed participant forms and the biostatistician performs monthly Research Electronic Data Capture (REDCap) database checks. RedCap is a secure web application for building and managing online databases.

2.11 Data analysis plan

Completed Recruitment and Baseline Analyses.—Recruitment data were summarized, including the total number of potential participants screened from each village, the number excluded for each of the specific inclusion/exclusion criteria, and the number of eligible women who agreed to participate. To assess reach of the program in each village, we calculated the proportion of subjects enrolled to total eligible subjects screened. The recruitment rates between control and intervention villages were compared using the chi-square test. As another measure of program reach, research staff obtained de-identified data from the YKDRH on the total number of AN women aged 18 years and older from the study villages with > 1 positive pregnancy test during the recruitment period. Baseline demographics were summarized and compared between intervention and control villages using the chi-square test for categorical variables and the Kruskal-Wallis test for continuous variables.

Planned Analyses.—We will summarize the biochemically confirmed 7-day point prevalence tobacco use rate at 6 months postpartum for each study group (point estimate and 95% CI) among all participants (intent-to-treat analysis) and then per-protocol (i.e., excluding women lost to follow-up) and compared between conditions using generalized estimating equations (GEE) [63] with a logit link function to account for clustering of outcomes within village (ICC) (Aim 1). Participants lost to follow-up or who do not provide biochemical confirmation will be classified as using tobacco. The analysis will be supplemented with multiple imputation methods [64–66] to classify lost to follow-up as tobacco users or non-users. GEE will also be used to examine condition differences on the point prevalence tobacco use rates at delivery and 2 months postpartum. Because only 14 df would be available for the test of the intervention, we will employ a small sample correction

to the standard GEE [67]. For these analyses, the stratification factor (village size) will be adjusted for in the analysis. Based on the biochemically confirmed tobacco use status at baseline, in an exploratory fashion we will examine potential treatment effects separately among baseline non-tobacco users and tobacco users respectively using GEE. Within intervention villages only, exposure dose will be tested as a predictor of tobacco use at delivery, and at 2 and 6 months postpartum using GEE. A similar analysis will be performed using the intervention implementation index to examine potential dose response effects. Potential village differences on intervention exposure or implementation will be summarized graphically and compared using GEE. The percentage of enrolled participants completing the 6 month follow-up (retention) will be compared between intervention and control villages using GEE.

We will follow procedures suggested by MacKinnon [68,69] to assess mediation (Aim 2), fitting 3 GEE models to the data. We will first estimate the intervention effect separately for the dependent variable (with regression adjustment for covariates); that model will provide an estimate of the total effect of the intervention, which MacKinnon labels C. Next, we will estimate the intervention effect for each mediator (with regression adjustment for covariates); that model will provide an estimate of the effect of the intervention on the mediator, which MacKinnon labels A. Finally, we will estimate the mediated intervention effect for the dependent variable by adjusting for the mediator (and covariates); that model will provide an estimate of the unmediated (i.e., direct) intervention effect, which MacKinnon labels C', and the intervention-adjusted effect of the mediator on the dependent variable, which MacKinnon labels B.

Treatment condition differences on changes in other variables targeted such as perceived stress and second-hand smoke exposure (see Table 1) will be examined using GEE with a logit (binomial outcome) or identity (continuous outcome) links as appropriate.

2.12 Dissemination plan

To communicate the study to the local community, a story was submitted to the regional newspaper and locally-owned radio stations (KYKD, KYUK). The CAC will guide all dissemination activities.. The first level of dissemination will be to the YKHC Human Studies Committee and Board. After receiving approvals, the second level of dissemination will be to the local community by submitting a story to local newspapers, locally-owned radio stations, and the YKHC employee website. A booklet or brochure and a PowerPoint presentation with key project findings will be developed and approved by the YKHC. Presentations will be given to community members at local gatherings in Bethel and to YKDRH providers. The YKHC staff will also travel to all study villages and meet with Tribal Councils to share results as feasible.

Third, we plan to mail out to participants a 2-page project newsletter at 2 time points. One newsletter was recently mailed to share that study enrollment is completed along with describing select aggregated characteristics of those who enrolled. The second mailing is planned at the conclusion of the study to share the results with participants.

As the fourth level of dissemination, we will communicate the findings state-wide with our partners at the Alaska Native Tribal Health Consortium (ANTHC). The YKHC PR department will contract with businesses of their choice to develop three 30-second DVD video spots to be used in waiting areas of prenatal clinics in the Y-K Delta Region and the 15 health care regions served by the ANTHC. Information will also be included in ANTHC newsletters. The investigators and community partners will jointly present at the Alaska Native Health Research Conference held biannually with the audience comprising community members and researchers. If the intervention is successful, tangible products such as intervention manuals and the digital stories DVD will be available for distribution.

Utilizing these various venues for communication and dissemination of the project findings will maximize dissemination of the knowledge gained in this project. There should be lessons learned that will generalize to underserved populations as well as differences that may limit generalizability.

3. Results

3.1 Recruitment feasibility and program reach

Participant enrollment and baseline data collection occurred between January, 2016, and April, 2018; data were analyzed in 2018. About 925 women were potentially eligible based on lists of women scheduled for prenatal appointments, and/or women initially leaving a phone message to express interest in the study. 646 women were successfully contacted and screened for eligibility (278 from control villages, 368 from intervention villages), of which 484 were eligible (208 from control villages, 276 from intervention villages). Reasons for ineligibility were not residing in a study village, age at gestation > week 36 at the time of expressing initial interest, already enrolled in the study during a prior pregnancy, younger than 18 years of age, no phone, or no time to participate.

Of the 484 women screened who were eligible, 73% (352/484) were enrolled. From control villages 79% (164/208) of eligible women enrolled and from intervention villages 68% (188/276) of eligible women enrolled, p= 0.009. The mean number ± SD of participants enrolled from control villages was 20.5 ± 6.6 (range 10–28) and from intervention villages was 23.5 ± 11.7 (range 2–42).

During the recruitment period there were a total of 637 AN adult women from the 16 study villages with at least one positive pregnancy test. Therefore, the program reached more than half (56%, 352/637) of AN pregnant women during the recruitment period.

3.2 Participant baseline characteristics

Table 2 on the following page presents baseline socio-demographic and tobacco use characteristics of the 352 participants. Participants were on average 25.8 ± 5.0 years of age (range 18–46), primarily of Yup’ik ethnicity (98%), and married or living with a partner (83%). Only 15.6% had education beyond high school and 44% were employed/working. Nearly all participants spoke (95%) and read in English; 60% also spoke in Yup’ik and 51% also read/wrote in Yupik. Participants were on average at 26.8 ± 9.8 weeks gestation (range 6–40). Only 22% reported this pregnancy as their first. Current tobacco use was reported by

66.5% and the main tobacco product used was Iqmik (77%). Tobacco users reported on average medium levels of readiness to quit (Contemplation Ladder score= 5.0 ± 2.6 of possible score of 10).

Significant differences were found between intervention and control villages for language spoken (p=0.002), language written (p=0.003), and main type of tobacco used among tobacco users (p=0.006). Control participants were more likely than intervention participants to speak (69% vs. 53%) and read/write (59% vs. 43%) in Yup'ik and more likely to report Iqmik use (86% vs. 68%). Study groups were similar on all other participant socio-demographic and tobacco use characteristics (Table 2). Those that were different will be included as covariates in subsequent outcome analyses.

4. Discussion

The proposed research addresses a substantial gap in the tobacco treatment field. The Healthy Pregnancies Project is the first large randomized controlled trial of an intervention to reduce tobacco use during pregnancy and postpartum among AI/AN women. To promote sustainable impact on tobacco use during pregnancy and postpartum, the intervention is consistent with a social ecological approach [70], with individual, community, and interpersonal levels targeted through the Native Sisters [71]. Study strengths are the longstanding partnership, input from the CAC and other local community members on trial implementation, and the multi-level nature of the intervention targeting both individual pregnant women and the community. Results from this study enrollment and baseline phase indicate that participant recruitment was feasible with program reach to more than half of AN pregnant women residing in the study villages.

Recruitment of the targeted sample was feasible using a variety of approaches, with recruitment by the research coordinator at prenatal care visits and at the Pre-Maternal Home in Bethel being most successful. Encouragingly, the proportion of women screened and eligible who enrolled in the trial was high (73%). The enrollment rate was greater for control than intervention villages; in contrast, in many cluster-randomized trials, recruitment within control conditions can be challenging [67,72]. This may be due to women wanting to be part of a project promoting healthy pregnancies regardless of whether they received the intervention, or reduced burden of study requirements for control participants. All pregnant women were eligible regardless of their tobacco use status, which could have enhanced the overall participation, similar to a previous biomarker study conducted with AN women in an urban region of Alaska [73]. One village enrolled only 2 women. In this village, most women choose to receive prenatal care in Anchorage, which limited our ability to reach potential participants. Nonetheless, the program reached 56% of pregnant AN women residing in the study villages, which along with intervention efficacy from planned analyses, may contribute to the overall impact of the program. Unlike a past pilot study, the trial was successful in enrolling women at a range of gestational age [16].

The baseline data add to the literature on socio-demographic and tobacco use characteristics of AN women enrolled in a clinical trial focused on healthy pregnancies. There were some baseline variables that differed between study groups (i.e., control villages more likely than

intervention villages to use Iqmik and to speak and read/write in the Yup'ik language) that will be included as covariates in subsequent outcome analyses. One possible reason for the language differences is that many intervention villages are located along the Yukon River where during the time of colonization and contact with missionaries, residents were not allowed to speak their local language. In contrast, many control villages are located along the Kuskokwim River where residents were allowed to speak their Native language at the point of contact (Personal Communication, Rose Dominick, local expert).

4.1 Study limitations

We recognize that some aspects of the study population may limit generalizability to other pregnant AI/AN women, such as the use of Iqmik and restricted geographic location. However, there is a need for evidence-based interventions to be tested in randomized clinical trials among pregnant AI/AN women to advance the science and reduce health disparities in these communities. Moreover, the use of non-cigarette forms of tobacco including homemade forms of ST is prevalent or gaining in popularity in many parts of the world among girls and women of reproductive age [7,74]. Therefore, with some modifications, the digital stories and other intervention materials could have broader dissemination potential to other AI/AN communities and in populations with a high prevalence of prenatal tobacco use. Another limitation is that from the study design we will not be able to assess the relative contribution of each component to intervention efficacy.

4.2 Conclusion

The Healthy Pregnancies Project evaluates a multicomponent intervention developed with feedback from the community to reduce tobacco use during pregnancy and the postpartum period. Processes and products from this project may have relevance to other AI/AN populations aiming to focus on healthy pregnancies in their communities, In addition, with some adaptations, the intervention approach may have applicability to address other Native health issues.

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ABBREVIATIONS

AI	American Indian
AN	Alaska Native

ANTHC	Alaska Native Tribal Health Consortium
CAC	Community Advisory Committee
EMR	Electronic Heath Record
GEE	Generalized Estimating Equation
ICC	Intra-Class Correlations
IRB	Institutional Review Board
NRT	Nicotine Replacement Therapy
SCT	Social Cognitive Theory
ST	Smokeless Tobacco
Y-K	Yukon-Kuskokwim
YKDRH	Y-K Delta Regional Hospital
YKHC	Yukon-Kuskokwim Delta Health Corporation

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Table 1.

Measures and Schedule of Assessments

		Time Point			
DATA COLLECTED	**# items**	**Baseline**	**Delivery**	**2 months postpartum**	**6 months postpartum**
Socio-demographics [14]	9	X			
Self-reported tobacco use [26,42]	1	X	X	X	X
Saliva specimen for analysis of cotinine	--	X	X		X
Tobacco users only: FCND/FTQ-ST (nicotine dependence) [43,44]	6/8	X			
Tobacco users only: Contemplation Ladder [45]	1	X	X		X
Program evaluation [16]	11		X	X	X
Nicotine replacement therapy/smoking cessation treatment use	3		X	X	X
Theory-Based Variables (Mediators) Self-efficacy to be tobacco-free [46]	1	X	X		X
Social norms about tobacco use [19]	5	X	X		X
Social support for non-tobacco use [47]	1	X	X		X
Other Variables Targeted Secondhand smoke exposure [48,49]	4	X	X		X
Treatment Self-regulation Questionnaire (TSRQ) (intrinsic motivation scale) [50]	6	X	X		X
Yupik Wellness Questionnaire (i.e., positive cultural activities) [51]	22	X	X		X
Perceived Stress Scale [52]	4	X	X		X
CES-D Depression Scale [53]	20	X	X		X
Prenatal care utilization [54]	2	X	X		X

Table 2.

Participant Baseline Socio-Demographic and Tobacco Use Characteristics in a Randomized Controlled Trial of a Community Intervention for Reducing Tobacco Use among Alaska Native Pregnant (N=352)

Characteristic	*Overall N=352*[*]	*Intervention N=188*[*]	*Control N=164*[*]	*P*[++]
Study Group				
Intervention	188 (53.4)			
Control	164 (46.6)			
Socio-Demographics				0.76
Age, mean (SD)	25.8 (5.0)	25.9 (5.0)	25.8 (5.0)	
Range	18–46	18–43	18–46	
Ethnicity				
Yupik	344 (97.7)	184 (96.8)	160 (97.6)	0.85
Cupik	8 (2.3)	6 (3.2)	2 (1.2)	0.22
Aleut	2 (0.6)	1 (0.5)	1 (0.6)	0.92
Inupiat	2 (0.6)	2 (1.1)	0 (0)	0.19
Athabaskan	4 (1.1)	4 (2.1)	0 (0)	0.06
Other (American Indian/White)	10 (2.8)	5 (2.7)	5 (3.0)	0.83
Education				0.38
Less than high school	86 (24.8)	43 (23.2)	43 (26.5)	
High school/GED degree	207 (59.7)	117 (63.2)	90 (55.6)	
Some college	50 (14.4)	24 (13.0)	26 (16.0)	
College degree	4 (1.2)	1 (0.5)	3 (1.9)	
Marital status				0.92
Married or living with partner	284 (82.8)	152 (82.6)	132 (83.0)	
Single	59 (17.2)	32 (17.4)	27 (17.0)	
Language spoken				
Yupik	212 (60.2)	99 (52.7)	113 (68.9)	0.002
Cupik	3 (0.9)	2 (1.1)	1 (0.6)	0.64
Athabaskan	0 (0)	0 (0)	0 (0)	-
English	333 (94.6)	177 (94.1)	156 (95.1)	0.69
Language read/write				
Yupik	178 (50.6)	81 (43.1)	97 (59.1)	0.003
Cupik	3 (0.9)	2 (1.1)	1 (0.6)	0.64
Athabaskan	0 (0)	0 (0)	0 (0)	-
English	345 (98.0)	183 (97.3)	162 (98.8)	0.33
Employed/working				0.35
Yes	143 (44.3)	79 (46.7)	64 (41.6)	
No	180 (55.7)	90 (53.3)	90 (58.4)	
Follows traditional Native way of life				0.23

Characteristic	*Overall N=352*[*]	*Intervention N=188*[*]	*Control N=164*[*]	*P*[++]
Not at all	9 (2.6)	5 (2.7)	4 (2.5)	
Some	190 (54.8)	109 (58.9)	81 (50.0)	
A lot	148 (42.7)	71 (38.4)	77 (47.5)	
Follows White American (Kass'aq) way of life				0.44
Not at all	21 (6.1)	14 (7.7)	7 (4.4)	
Some	204 (59.6)	106 (57.9)	98 (61.6)	
A lot	117 (34.2)	63 (34.4)	54 (34.0)	
Gestational age, weeks				
mean (SD)	26.8 (9.8)	27.3 (9.5)	26.2 (10.1)	0.45
range	6-40	6-40	7-39	
First pregnancy				0.87
Yes	77 (22.1)	42 (22.5)	35 (21.7)	
No	271 (77.9)	145 (77.5)	126 (78.3)	
No. Children (biological or adopted)				0.93
N	344	184	160	
mean (SD)	2.1 (1.8)	2.1 (1.9)	2.1 (1.7)	
range	0-9	0-9	0-7	
Planning to breastfeed				0.46
Yes	230 (66.1)	125 (66.8)	105 (65.2)	
No	38 (10.9)	23 (12.3)	15 (9.3)	
Unsure	80 (23.0)	39 (20.9)	41 (25.5)	
Seen for prenatal care visit				0.16
Yes	323 (93.4)	175 (95.1)	148 (91.4)	
No	23 (6.6)	9 (4.9)	14 (8.6)	
Tobacco Use				
Used tobacco before learning of pregnancy				0.37
Yes	284 (85.0)	151 (83.4)	133 (86.9)	
No	50 (15.0)	30 (16.6)	20 (13.1)	
Current tobacco use (past 7 days)				0.37
Yes	234 (66.5)	120 (63.8)	114 (69.5)	
No	118 (33.5)	68 (36.2)	50 (30.5)	
Main type of tobacco used (among current users)				0.006
Iqmik	179 (76.8)	82 (68.3)	97 (85.8)	
Copenhagen/other chew	11 (4.7)	7 (5.8)	4 (3.5)	
Cigarettes	43 (18.5)	31 (25.8)	12 (10.6)	
E-cigarettes	0 (0)	0 (0)	0 (0)	
FTCD score[a] (among smokers)				0.59

Characteristic	*Overall N=352*[*]	*Intervention N=188*[*]	*Control N=164*[*]	*P*[++]
N mean (SD) range 1st cigarette smoked within 30 min. of wakening (FTCD)	46 1.1 (1.4) 0-5	33 1.0 (1.3) 0-5	13 1.4 (1.7) 0-5	 0.084
	10 (21.7)	5 (15.2)	5 (38.5)	
FTQ-ST score[b] (among ST users)				0.19
N	191	93	98	
mean (SD)	1.8 (1.6)	2.0 (1.7)	1.7 (1.6)	
range	0-8	0-6	0-8	
1st chew within 30 min. of wakening (FTQ-ST)	46 (24.5)	22 (24.2)	24 (24.7)	0.93
No. times tried to quit tobacco				0.25
None	69 (29.5)	35 (28.5)	34 (30.6)	
1	38 (16.2)	17 (13.8)	21 (18.9)	
2-5	100 (42.7)	58 (47.2)	42 (37.8)	
6-10	12 (5.1)	8 (6.5)	4 (3.6)	
more than 10	15 (6.4)	5 (4.1)	10 (9.0)	
Contemplation Ladder score				0.24
mean (SD)	5.0 (2.6)	5.3 (2.7)	4.8 (2.5)	
range	0-10	0-10	0-9	
0-3 (low readiness), %	53 (24.0)	29 (25.0)	24 (22.9)	
4-6 (medium readiness), %	87 (39.4)	40 (34.5)	47 (44.8)	
7-10 (high readiness), %	81 (36.7)	47 (40.5)	34 (32.4)	
Self-efficacy to quit or stay tobacco-free				0.65
N	326	170	156	
mean (SD)	6.7 (3.0)	6.8 (2.9)	6.6 (3.1)	
range	0-10	0-10	0-10	

Values are n (%) unless indicated

[*] Percentages are based on non-missing data. Some percentages do not add to 100 due to rounding. In some cases (e.g., language spoken, tobacco use among spouse/partner) response categories are not mutual thus percentages may add to > 100%.

[++] Chi-square or Kruskal-Wallis test as appropriate

[a] Fagerström Test for Cigarette Dependence, assessed among participants who reported any cigarette smoking even if not primary tobacco product used. Higher scores are associated with greater severity of dependence.

[b] Fagerström Test for Nicotine Dependence- Smokeless Tobacco, assessed among participants who reported any Iqmik/commercial chew even if not primary tobacco product used. Higher scores are associated with greater severity of dependence.