


Impact of the CHOICES Intervention in Preventing Alcohol-Exposed Pregnancies in American Indian Women

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Background: Fetal alcohol spectrum disorders (FASD) comprise a continuum of lifelong outcomes in those born prenatally exposed to alcohol. Although studies have shown no differences in rates by race, FASD is of particular concern for American Indian communities. One tribally run prevention program is the Oglala Sioux Tribe (OST) CHOICES Program, which is modeled after the evidence-based CHOICES program that was focused on preconceptional prevention of alcohol-exposed pregnancy (AEP) by reducing risky drinking in women at risk for pregnancy and/or preventing unintended pregnancy.

Methods: The OST CHOICES Program was made culturally appropriate for American Indian women and implemented with 3 communities, 2 on the reservation and 1 off. Data on drinking, sexual activity, and contraception use were collected at baseline and 3 and 6 months postintervention. Data were analyzed using descriptive statistics, 1-way analysis of variance, and a random intercept generalized estimating equation model.

Results: A total of 193 nonpregnant American Indian women enrolled in the OST CHOICES Program, and all were at risk for AEP because of binge drinking and being at risk for an unintended pregnancy. Fifty-one percent of participants completed both 3- and 6-month follow-ups. Models showed a significant decrease in AEP risk from baseline at both 3- and 6-month follow-ups, indicating the significant impact of the OST CHOICES intervention. Women in the OST CHOICES Program were more likely to reduce their risk for AEP by utilizing contraception, rather than decreasing binge drinking.

Conclusions: Even with minor changes to make the CHOICES intervention culturally and linguistically appropriate and the potential threats to program validity those changes entail, we found a significant impact in reducing AEP risk. This highlights the capacity for the CHOICES intervention to be implemented in a wide variety of settings and populations.

Key Words: FASD Prevention, American Indian Women, Preconception, CHOICES Intervention.

FETAL ALCOHOL SPECTRUM disorders (FASD) comprise a continuum of lifelong outcomes in those born prenatally exposed to alcohol. Fetal alcohol syndrome (FAS), the most physically recognizable outcome, is diagnosed using facial abnormalities (i.e., palpebral fissures, thin vermilion, smooth philtrum); prenatal or postnatal growth deficiencies, including height or weight less than the 10th percentile; evidence of delayed brain growth, such as a head circumference less than the 10th percentile; and neurobehavioral impairments, with or without cognitive impairment (Hoyme et al., 2016). Prenatal exposure to alcohol is also linked to conduct disorders, mental illness, and

problems in psychosocial functioning (Disney et al., 2008; Hellemans et al., 2009; Roebuck et al., 1999). As it is caused by prenatal alcohol exposure, FASD is preventable, and most major medical and health associations recommend complete abstinence of alcohol during pregnancy and when planning pregnancy (American College of Obstetrics and Gynecology, 2013; Centers for Disease Control and Prevention, 2005; International Alliance for Responsible Drinking, 2016; UK Chief Medical Officers, 2016; Williams and Smith, 2015).

Although studies have shown no aggregate differences in rates by race (May et al., 2014), FASD is of particular concern for many American Indian communities. In 1 study, 16.2% of American Indian women seen at an Indian Health Service prenatal clinic reported drinking alcohol during pregnancy (May et al., 2004), in contrast to a national study which found that 10.2% of pregnant women drank (Centers for Disease Control and Prevention, 2015). Rates of FAS among Northern Plains American Indians range as high as 9 per 1,000 births (May et al., 2002), although there have been few recent studies on the surveillance of FAS or FASD in American Indian communities. In comparison, a recent study in a general population of first graders in the Upper Midwest that utilized active case ascertainment found the

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rate of FAS to be 5.9 to 10.2 per 1,000 children (May et al., 2014), which is higher than the national rate cited by the Centers for Disease Control and Prevention (1997, 2002).

Most previous FASD prevention projects within American Indian tribal communities have focused on pregnant women (May et al., 2008) or community education (Ma et al., 1998; May and Hymbaugh, 1989; Plaiser, 1989; Rentner et al., 2012; Shostak and Brown, 1995; Williams and Gloster, 1999) to reinforce the message of completely abstaining from alcohol during pregnancy. In addition, public health officials have concentrated FASD prevention efforts on the preconceptional time period, or before a woman becomes pregnant. Preconceptional prevention of FASD can occur by either encouraging the reduction or elimination of alcohol consumption in women at risk or planning pregnancy; or preventing pregnancy in women drinking at risky levels, or binge drinking, which for non-pregnant women means drinking 4 or more drinks on an occasion, or more than 7 drinks per week (Caetano et al., 2006; Floyd et al., 2008; National Institute on Alcohol Abuse and Alcoholism, 2008). This is because pregnancy, particularly unintended pregnancies, may not be recognized during the early but developmentally critical weeks of pregnancy. Therefore, the “maximum prevention benefit” is to encourage behavior change among women at the greatest risk for an alcohol-exposed pregnancy (AEP) before they become pregnant (Floyd et al., 1999).

Rates of risky behaviors related to AEP vary nationally (Ethen et al., 2009; Project CHOICES Research Group, 2002), as well as with local American Indian communities. For example, a previous project with 3 Northern Plains tribes found among a population of women drinking at bingeing levels, nearly 30% were not using birth control to protect against pregnancy (Hanson et al., 2013), indicating that they were at risk for an AEP. Another study from the South Dakota Tribal Pregnancy Risk Assessment Monitoring System found that 43% of American Indian women from Aberdeen Area tribes were binge drinking in the 3 months prior to pregnancy (Rinki et al., 2009). Among this same sample, 65% were sexually active, were not trying to get pregnant, and yet were not using any birth control.

One AEP prevention program currently under way with nonpregnant American Indian women is the Oglala Sioux Tribe (OST) CHOICES Program. OST, also known as the Pine Ridge Indian Reservation, is one of the largest American Indian reservations in the country. There are 45,364 enrolled members, with approximately 30,000 members living on the reservation (Oglala Lakota Nation, 2014). Although unemployment, poverty, housing shortages, and health disparities abound for the people living in the tribe's communities (Agency for Healthcare Research and Quality, 2014; Haverkamp et al., 2008; Red Cloud Indian School, n.d.; United States Census, 2013; U.S. Department of Health and Human Services, n.d.), the tribe remains engaged in increasing economic activity and addressing public health issues through tribally run prevention programs.

The OST CHOICES Program is based on the Project CHOICES (Changing High-risk alcohol use and Increasing Contraception Effectiveness Study) intervention, an evidence-based program focused on reducing risk for AEP through a decrease in binge drinking and reducing unintended pregnancies (Centers for Disease Control and Prevention, 2003; Floyd et al., 1999, 2007; Project CHOICES Intervention Research Group, 2003; Velasquez et al., 2010). The heart of the intervention is its use of motivational interviewing (MI), which focuses on the woman's own perspectives about changing behaviors, and helping her set goals and develop personalized plans for change (Project CHOICES Intervention Research Group, 2003). The original CHOICES intervention used MI to deliver personalized feedback regarding drinking behaviors and a participant's risk for an unintended pregnancy, and participants set goals regarding drinking and contraception (Project CHOICES Intervention Research Group, 2003). Participants were also encouraged to complete a daily journal for self-monitoring of the 2 target behaviors. The intervention also included an optional medical appointment to discuss birth control options. Now listed in SAMHSA's National Registry of Evidence-based Programs and Practices (NREPP) (Substance Abuse and Mental Health Services Administration, 2014), the CHOICES intervention significantly decreased the risk for an AEP in the intervention group when compared to the control group in a large multisite randomized clinical trial (Floyd et al., 2007).

Developed through community and clinic input (Hanson and Pourier, 2016; Hauge et al., 2015), the tribally run OST CHOICES Program used MI to encourage participants to decrease binge drinking and/or increase birth control, thereby reducing risk for AEP. The purpose of this study was to present data on the impact that the OST CHOICES Program had on risk for AEP among American Indian women from 1 geographic area of the United States and highlight the potential that this intervention has for preventing FASD in tribal nations across the country.

MATERIALS AND METHODS

Recruitment and Eligibility

The OST CHOICES Program enrolled participants at 3 sites, 2 located on the reservation and a third that serves American Indian women in an urban setting approximately 2 hours from the reservation and where 13% of the population is American Indian (United States Census, 2010). Recruitment occurred through referrals from healthcare providers; social media outlets, such as the CHOICES Facebook page; and distributing flyers in local businesses and at health fairs. Many of the program's referrals came through “word-of-mouth,” as we invested in a small incentive (\$5) for every referral made to the OST CHOICES Program. There was no cap on the number of referrals or on the number of \$5 incentives, an individual could make to the OST CHOICES Program. Recruitment efforts occurred both on the reservation and outside the reservation. These recruitment efforts led to a total of 193 American Indian women enrolled into the OST CHOICES Program.

Eligibility was based on race (American Indian), age (18 years old or older), and risk for AEP, which was defined based on previous CHOICES studies. Participants had to exceed low risk drinking limits for women, which included binge drinking (4 or more drinks per occasion) or 8 or more drinks per week (National Institute on Alcohol Abuse and Alcoholism, 2008). As the focus was on pre-conceptional prevention, participants were not pregnant but were at risk for pregnancy. Specifically, behavioral eligibility included being sexually active with a male, fertile (i.e., able to get pregnant, has not experienced menopause, and has not been sterilized), and not using any contraception or using a method incorrectly or inconsistently.

OST CHOICES Intervention

At 1 site, interventionists provided 4 CHOICES sessions, while at 2 others, they provided 2 sessions, per the preference of the site and stakeholder input. The sessions were held approximately 1 to 2 weeks apart. Participants were given gift card incentives for participating in the intervention. Specifically, participants could receive up to \$125 in gift card incentives for participating in all sessions of the intervention and completing the follow-up data collection (see below).

At the OST CHOICES sessions, trained interventionists used MI counseling techniques, such as reflective listening and open questioning. MI techniques were also used to guide the participants through activities designed to build momentum for change, such as considering the pros and cons of change if the individual was ambivalent, identifying change goals for both alcohol and birth control, and articulating change plans for alcohol consumption and birth control. Specific activities are detailed in previous literature (Velasquez et al., 2010). The OST CHOICES Program was modified slightly to incorporate community input, as highlighted in previous publications from this team. These modifications include adding local images and data to the curriculum; revising to lower readability level and changing wording for some of the survey and activity measurements; and changing information in the materials to fit with the most common types of alcohol consumed in the communities and what birth control is available at the local clinics (Hanson and Pourier, 2016; Hauge et al., 2015).

Participants were also asked whether they intended to lower their alcohol consumption (yes/no), and using “readiness rulers” and a scale from 1 to 10, how ready they were to change their drinking, how important it was to them, and how sure they were that they could decrease their drinking to below bingeing levels. With regard to birth control, participants were asked to self-identify any reasons why they had sexual intercourse without using contraception, as well as whether they intended to start using contraception at each sexual encounter (yes/no), and on a scale from 1 to 10, how ready they were to use contraception at each sexual encounter, how important it was to them, and how sure they were that they could use contraception at each sexual encounter. Outside of the intervention itself, participants were asked to complete daily diaries that track their drinking, sexual activity, and contraception use, and to bring these daily diaries to their next CHOICES session(s) to discuss with the interventionist.

Finally, OST CHOICES included referrals to a local healthcare provider for birth control, and participants were encouraged (but not required) to make an appointment after the first session to discuss their birth control options. The interventionists also had a contact list for any necessary referrals for services, including contact information for alcohol treatment services, domestic violence services, and other social service agencies in the event these were needed for OST CHOICES participants.

Follow-Up Data Collection and Analysis

At the end of the last OST CHOICES session, each participant completed a Locator Form, which asked for the participant’s phone

number(s), mailing address, and email address, as well as the names, phone numbers, and email addresses of 2 alternate contacts who the participant identified as a person able to reach them. To contact for follow-up, participants received up to 5 telephone calls using the primary phone number listed. If telephone contact was unsuccessful, a letter was sent to the participants mailing address asking the participant to contact the OST CHOICES interventionist. If these contacts were not viable, we called alternate contacts up to 3 times over an additional 4-week period before considering the participant lost to follow-up.

OST CHOICES participants were contacted at 3 and 6 months postintervention to evaluate risky behaviors related to alcohol consumption, sexual activity, and contraception use. These follow-ups were either conducted via the telephone (preferred) or in-person at the participant’s request. Identical to the baseline eligibility questionnaire, follow-up questions were focused on alcohol use, sexual intercourse episodes, and contraception use. Participants were given a \$25 gift card incentive after each of the 2 follow-up data collection points. Data were collected by the interventionist and later entered into an Access database.

Data were analyzed using descriptive statistics to highlight demographics and behaviors at baseline and follow-up. To explore differences in those who were compliant with the study, 1-way analysis of variance was used to detect differences in drinking behaviors between those who completed at least some follow-up and those who did not. Proc Glimmix (SAS Institute, Cary, NC) was used to run negative binomial models with random intercepts to detect differences in drinking behaviors by age over time.

In addition, a random intercept generalized estimating equation model was used to calculate the proportion of women at risk for an AEP (based on alcohol consumption and risk for unintended pregnancy) at both follow-up points. Participants were categorized into “at risk” for an AEP if their drinking was considered at risk (defined as average drinks in a day greater than 4 or 8 or more drinks in a week) and their contraceptive practices were considered to put them at risk of pregnancy (using no method of protection at anyone point or failure to always use a contraceptive method). Participants were also categorized as “at risk” if they were pregnant at either follow-up point.

The sample size did not allow for nesting by site or a random slope. Site and age were the only covariates considered and neither contributed significantly to the model. As dropout was not assumed to be missing at random, or that the missing data are nonignorable and need to be accounted for in some way, other models were fit to capture the information about missing data. Two statistical approaches for nonrandom dropout were attempted, but lacked sufficient data for use. Instead, 3 models were fit to assess the effect of dropout under different assumptions: a model with no assumptions about dropout, a model with all dropouts assumed to be “at risk,” and a model with all dropouts assumed to be “not at risk.” We suspected that those who drop out are more likely to be at risk after dropout, but there are likely exceptions to that, and therefore, the best model likely lies between the model with no assumptions about dropout and the model with all dropouts assumed to be at risk.

RESULTS

Due to eligibility criteria, all 193 OST CHOICES Program participants were adult and nonpregnant American Indian women. The average maternal age of all participants was 29.0 (± 6.8), with a range of 18 to 46. There were no significant age differences when comparing the 3 sites. No other demographic features were collected.

At baseline, all participants were drinking at binge drinking levels. Participants were found to be drinking a variety of alcohol beverages, including beer, hard liquor, and malt beverages. Of those who responded to a question on *where* they typically drink alcohol, the majority (76.1%) drank at home either alone or with a group of people; only 23.9% stated they drank at a bar or restaurant. As part of the CHOICES “readiness ruler” activity, participants indicated their readiness to decrease their drinking to below binge drinking levels (Table 1). In addition, all participants were at risk for an unintended pregnancy because they were sexually active and not using effective contraception at all or at each sexual encounter, although there also appeared to be a readiness to begin using birth control (Table 1).

Of the total number enrolled in OST CHOICES, $n = 99$ (51.3%) completed both the 3- and 6-month follow-up sessions, and an additional $n = 53$ (27.5%) completed the 3-month follow-up (but not the 6-month follow-up). A total of $n = 41$ (21.2%) completed the OST CHOICES Program but were completely lost to follow-up. A total of $n = 16$ (8%) reported being pregnant when reached for follow-up and were coded as “at risk,” although once participants reported pregnancy, they were not asked any questions about alcohol

consumption. There was 1 significant baseline difference in drinking behaviors between those who completed at least some follow-up and those that did not: The average number of days per week that a participant had a binge drinking episode was significantly lower in those who completed at least some follow-up than those who did not continue to follow-up.

All 3 models described in the Methods section showed a significant decrease in AEP risk from baseline at both 3- and 6-month follow-ups, indicating the significant impact of the OST CHOICES intervention (see Fig. 1) When analyzing behavioral changes from just the 3-month to the 6-month follow-up, there were no differences in proportions between these 2 time points in the model with no assumptions about dropouts, while both imputation models showed significant differences between the 3- and 6-month follow-ups (Fig. 1). The proportion at risk for AEP at the 3-month follow-up ranged from 25.4 to 47.2, depending on the assumption about the dropouts, while the proportion at risk for AEP at the 6-month follow-up ranged from 18.1 to 66.3, again depending on the dropout assumptions. While some women may become at risk again as time goes on, the proportion at risk was still significantly lower at the later follow-up than before the intervention in all the models. There were no significance differences by site, indicating that the intervention worked equally well across sites and whether it offered 2 or 4 sessions. There were also no significant differences when comparing for continuous baseline drinking variables, indicating that the intervention worked well regardless of how much drinking the participant reported at baseline.

Table 1. Readiness Ruler Results

	Important	Sure	Ready
Alcohol	7.5 (± 2.4)	6.9 (± 2.5)	6.3 (± 2.2)
Birth control	8.5 (± 2.4)	8.1 (± 2.5)	7.6 (± 2.5)

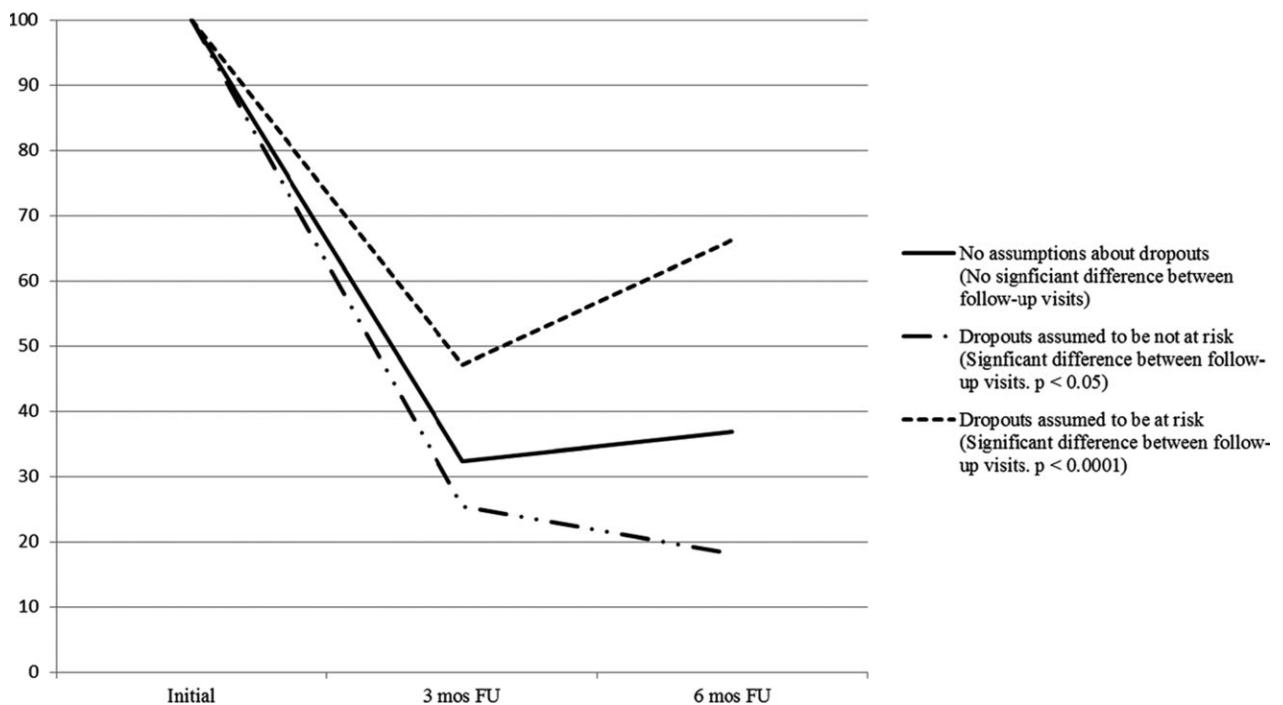


Fig. 1. Proportion at risk for AEP at each follow-up visit.

When analyzing the reduction in AEP risk by behavior, we found that most participants reduced their risk for AEP at both 3 and 6 months postintervention using effective birth control at each sexual intercourse (67.7% at 3 months and 61.5% at 6 months) (see Table 2). At 3 months, the top 3 birth control choices were condoms, the Depo-Provera shot, and IUDs. At the 6-month follow-up, the top 3 birth control choices were birth control pills, the Depo-Provera shot, and IUDs. Of additional note, 25.7 and 23.9% stated they were currently abstaining from sexual intercourse as their method of pregnancy prevention at the 3- and 6-month follow-up, respectively.

Women also reduced risk using birth control *and* lowering their rates of alcohol consumption to below binge drinking levels (defined earlier), with 22.6% of women improving both behaviors at 3 months and 18.5% at 6 months. While fewer participants only reduced drinking to below binge drinking levels, there were changes in mean alcohol consumption over time, with nearly 10% reducing their drinking to below binge levels at 3 months postintervention and 20% reducing to below binge levels at 6 months (Table 2). When analyzing differences in drinking amounts by age over time, older age led to lower “average drinks daily” and smaller “largest number of drinks at one time.” No other significant differences were found.

DISCUSSION

The OST CHOICES Program significantly reduced risk for AEP in preconceptional American Indian women by increasing contraceptive use and somewhat by decreasing drinking to below binge drinking levels. The results of the OST CHOICES Program compare favorably with other CHOICES-based studies with geographically diverse groups of women. A CHOICES study with Hispanic women found that two-thirds (66%) of all Hispanic women had reduced their overall risk of an AEP, primarily by practicing effective birth control (LeTourneau et al., 2016), as we found with American Indian women. Similarly, a study that utilized both in-person and telephone-based adaptations of CHOICES interventions with women at clinics and college campuses in Wisconsin found that risk of AEP was significantly reduced, mostly due to improved contraception with minor reductions in alcohol use (Wilton et al., 2013). Women in 2 urban communities (Baltimore and Denver) who received the 2-session version of CHOICES also lowered their AEP risk at significant rates, and were more likely

than our study to change *both* behaviors, finding similar results to the original CHOICES study (Hutton et al., 2014).

The OST CHOICES Program successfully followed up with participants. The follow-up rate (51.3% completed both follow-ups and an additional 27.5% completed at least 1 follow-up) was consistent with the 71% retention rate found in the original CHOICES study (Floyd et al., 2007), although could be improved in future studies using recommendations for retention with American Indian participants (Redwood et al., 2011). Our retention rate was likely due to the gift cards given to participants for completing the follow-up data collection. Additionally, OST CHOICES interventionists made connections with many of our participants because of their training in the proper use of MI, and also because our interventionists were members of the community who lived healthy, positive lives. Anecdotally, several participants wanted to keep meeting with the OST CHOICES interventionist, “just to talk.” We found 1 significant difference in drinking behaviors: those who completed at least 1 follow-up when compared to those that did not had significantly lower number of days per week that they binge drank. This indicates that while we were successful in reaching many high-risk women, we may be missing data on those women who are at higher risk due to binge drinking more frequently.

Most of our participants reduced their risk for AEP at both 3 and 6 months postintervention using effective birth control at each sexual intercourse, with some reducing risk by changing both drinking and birth control behaviors. This is compared to the original CHOICES study, where 47.3% of women in the intervention group had reduced risk by changing both behaviors, with 32.8% increasing use of birth control only and 19.9% reducing drinking only (Floyd et al., 2007). We acknowledge that the baseline alcohol consumption of our study participants may have been a potential effect modifier. More specifically, our sample was fairly homogenous in terms of level of drinking, as the participants were drinking at high bingeing levels. It is possible that the intervention may have had a different effect on alcohol consumption if they were drinking at lower, more moderate levels.

However, our findings are similar to other CHOICES-related research. A higher rate of participants in our study and other CHOICES-based studies (Ingersoll et al., 2005, 2013; LeTourneau et al., 2016; Wilton et al., 2013) increased effective birth control use, rather than reduced drinking. This consistent recent finding demonstrates that reducing risk for AEP and FASD cannot just occur through a focus on alcohol reduction, as many women improve birth control use to achieve lowered AEP risk. It also indicates that additional research is necessary on how to reduce binge drinking in American Indian women who enroll in CHOICES or a similar prevention program. While we are encouraged by the reduction in overall AEP risk, there is still concern that our participants were drinking at risky levels and/or patterns (i.e., bingeing). Recommendations for future studies include adding booster sessions that specifically address alcohol consumption.

Table 2. Reduction of AEP Risk by Behavior

	3 months (<i>n</i> = 102)	6 months (<i>n</i> = 65)
Reduced risk by lowering binge drinking	10 (9.8)	13 (20.0)
Reduced risk using effective birth control	69 (67.7)	40 (61.5)
Reduced risk using birth control and lowering binge drinking	23 (22.6)	12 (18.5)

Another important finding from our OST CHOICES study is that it worked equally well if it was offered in 2 or 4 sessions, indicating the robustness of the intervention, regardless of the community's or clinic's preference for number of sessions. In addition, our team made relatively minor changes to the CHOICES measures and curriculum by gathering community input as described elsewhere (Hanson and Pourier, 2016; Hauge et al., 2015). Even with these changes to make the CHOICES intervention culturally and linguistically appropriate and the potential threats to program validity those changes entail, we found a significant impact in reducing AEP risk. This highlights the capacity for the CHOICES intervention to be implemented in a wide variety of settings and populations.

There were some limitations to our study. Our participants were typically self-referred, although some were referred from healthcare providers, and the motivation to enter into the OST CHOICES Program may indicate that some women were already initiating behavioral change. Self-referral may mean that the program is not reaching women who are drinking at extremely high levels and/or women at extremely high risk of an AEP. We did not have a comparison or control group, although the main focus of our study was to observe how the curriculum, as adapted for American Indian women, impacted behavior. This sample was mainly women from 1 reservation, although women from a nontribal site enrolled. This study did not collect demographics besides race and age, although a previous study on AEP prevention with American Indian women found that drinking is typically lower in American Indian women who have never been married and who have a high school diploma or greater (Hanson et al., 2013). Finally, the study had a relatively large lost to follow-up rate.

CONCLUSION

It is essential to prevent FASD before conception, and this research and others have shown that the evidence-based CHOICES curriculum is efficacious to reduce risk for AEP. CHOICES can be adapted to different ages and populations and can be made community and culturally appropriate with formative research before implementation (Hanson and Pourier, 2016). Our work with American Indian women highlights a successful implementation of the CHOICES curriculum as a tribal program for a reservation and rural community. Despite concerns that participants' access to contraception could be limited due to long distances to the nearest healthcare setting to receive contraception, as well as issues with privacy, we have shown that birth control can be successfully accessed and utilized with this population.

In addition, we know that many American Indians find that drinking alcohol is normalized. We found this to be true in our sample, where OST CHOICES Program participants were drinking at home, typically in a group where it is likely that large bottles of hard liquor and malt beverages were shared. This highlights how prevention efforts in reservation

or rural communities might be complicated, as eligible participants may have social pressures to continue drinking, and they may also not have positive social networks that can aid in reducing drinking. We believe this indicates the need to address the risk for AEP by either enhancing or creating social support for reduced drinking among American Indian women.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to report.

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