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Conference Report

The Oglala Sioux Tribe CHOICES Program: Modifying an Existing Alcohol-Exposed Pregnancy Intervention for Use in an American Indian Community

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Abstract: Alcohol-exposed pregnancies are a health issue for many American Indian communities. The goal of this manuscript is to outline how an existing alcohol-exposed pregnancy prevention program with non-pregnant women (Project CHOICES) was modified to fit the needs and norms of an American Indian community. The Oglala Sioux Tribe CHOICES Program was developed and implemented using community feedback through initial meetings, reviewing materials, gathering input into recruitment and intervention logistics, and conducting interviews to evaluate the program. The intervention was implemented and has been enrolling non-pregnant American Indian women for the past several years. While data collection is ongoing, it has shown preliminary success in changing behaviors and in impacting how the community views the prevention of alcohol-exposed pregnancies. Overall, this study highlights the potential to expand this prevention program to other sites and with other populations, such as adolescents. By the end of this article, readers will comprehend the steps necessary to replicate such a program at other tribal and rural sites.

Keywords: alcohol-exposed pregnancy; American Indians; alcohol; birth control; program development

1. Introduction

Fetal Alcohol Spectrum Disorders (FASD) is the continuum of lifelong outcomes in those born prenatally exposed to alcohol and includes a diagnosis of fetal alcohol syndrome (FAS) [1]. FAS, the most physically recognizable outcome, is characterized as having facial abnormalities (*i.e.*, palpebral fissures, thin vermilion, smooth philtrum); evidence of growth retardation; and evidence of delayed brain growth [2–4]. In addition to physical features, prenatal exposure to alcohol is linked to conduct disorders (*i.e.*, delinquency and aggressiveness), mental illness (*i.e.*, depression, anxiety disorders), and psychosocial functioning [5–7].

FASD is especially concerning for American Indian communities, although it is by no means unique among this population [8]. In a previous study, Indian Health Service (IHS) reported that up to 56% of pregnant American Indian patients reported drinking alcohol during pregnancy [9,10], while a recent national study found that 7.6% of pregnant women drank any amount of alcohol and 1.4% binge drank, compared to a national study from ten years ago where 2% and 5% of women reported binge drinking during pregnancy and 10–13% of pregnant women consumed moderate amounts of alcohol [11,12]. Rates of FAS among Northern Plains American Indians range as high

as 9 per 1,000 births [13], although there have been few recent studies on the surveillance of FAS or FASD in American Indian communities. Among the general population, a recent study utilizing active case ascertainment to examine FASD among first grade children in an Upper Midwest city found the rate of FAS in this community to be 5.9 to 10.2 per 1000 children [8].

Traditionally, interventions to prevent FASD have focused on pregnant women, although recent research concludes that prevention of FASD must begin preconceptionally, or before a woman even becomes pregnant, by either reducing alcohol consumption in women at-risk or planning pregnancy, or preventing pregnancy in women drinking at risky levels [14]. Studies have shown between 10% and 26% of sexually active women are at-risk for AEP [15], and in many American Indian tribal communities, rates are higher. For example, a previous project with three Northern Plains tribes found among a population of women drinking at risky levels, nearly 30% were not using birth control to protect against pregnancy [16], meaning they were at risk for AEP. Another study from the South Dakota Tribal Pregnancy Risk Assessment Monitoring System found that 43% of American Indian women surveyed were binge drinking in the three months prior to pregnancy [17]. Among this same sample, 65% who were sexually active (but *not* trying to get pregnant) were not using any birth control at conception.

One AEP prevention program currently underway with non-pregnant American Indian women is the Oglala Sioux Tribe (OST) Changing High-risk alcohol use and Increasing Contraception Effectiveness Study (CHOICES) program. This is based on the original Project CHOICES curriculum focused on reducing risk for AEP through alcohol reduction and pregnancy prevention using an in-person brief intervention and motivational interviewing sessions with non-pregnant women at-risk for AEP [15,18–22]. Motivational interviewing is a counseling style that “guides the individual to explore and resolve ambivalence about changing [behavior], highlighting and increasing perceived discrepancy between current behaviors and overall goals and values” [19]. The original Project CHOICES participants received four face-to-face motivational intervention sessions, plus a separate contraception counseling session. The focus of the intervention was on self-guided change, where the participants themselves set behavior goals and worked with the interventionists to assess readiness to change. The original CHOICES intervention significantly decreased the risk of an AEP in the intervention group [18].

The CHOICES theoretical model was previously implemented with OST and two other tribes through a five-year project that utilized a telephone-based enrollment and participation [23], personalized feedback, and a workbook based on self-guided change constructs. Follow-up phone calls were conducted every three months for one year. A total of 230 AI women were included in the analysis. Baseline drinking among the participants averaged 7.0 drinks per occasion, and 30% of those who were sexually active used no contraception during sex. Data analyses indicated that participants had significant decreases in alcohol consumption, and there was a significant increase in those using protection from baseline to the three month follow-up. However, there was a fairly high loss to follow-up rate [16], and it was felt that a face-to-face intervention over a shorter time period might yield more participation [19].

Therefore, OST took data from this study to develop its current OST CHOICES Program, beginning by modifying CHOICES materials and piloting the CHOICES intervention at tribal clinics. The goal of this manuscript is to outline how an existing AEP prevention program (CHOICES) was modified to fit the needs and norms of an American Indian community. We also present preliminary data on the success of the OST CHOICES Program in lowering risk for AEP with non-pregnant American Indian women.

2. Methods

The OST CHOICES Program began in September, 2010 by working with three clinics, two located on the reservation and a third that serves American Indian women in an urban setting. There were two major stages to this program that will be reported here: first, an evaluation of the feasibility

and acceptability of the CHOICES intervention with a tribal community, and second, the actual implementation of the program, highlighted through preliminary data analysis.

To begin the first stage, initial meetings were held with clinic staff at the sites to introduce the project and to discuss questions and concerns. The initial questions involved clearly defining the benefits of this project for the patients and the tribe. The clinics felt the intervention should be conducted by someone already working within the clinics or a tribal member who the women would be comfortable interacting. These types of meetings were held regularly to get input on the development and implementation of the CHOICES curriculum.

In addition, project staff met with the clinic directors and staff to review the CHOICES materials in an informal group setting where OST CHOICES staff went through all the materials with the CEOs of the clinics involved, nursing/midwife staff, clinical directors, and an administrative officer at one of the clinics. The focus of these meetings was to suggest alterations to make the CHOICES materials more locally appropriate. For example, the clinics wanted local images added to the intervention materials, an acceptable readability, and to make information local (*i.e.*, local statistics on how many pregnancies are unplanned). Similarly, information in the materials had to be changed to fit with the most common types of alcohol consumed in the communities, and certain types of birth control information had to be taken out, as the clinics did not offer certain methods of contraception.

Next, the implementation of CHOICES into tribal clinics involved gathering input into recruitment and intervention logistics. Clinic staff was actively involved in figuring out recruitment strategies. For instance, one of the sites utilized a CHOICES brochure and “word of mouth” to encourage recruitment. At another site, recruitment occurred via flyers and newspaper ads, as well as receiving referrals from the clinic’s midwife. At one of the sites, there was an interest in CHOICES but staff was unable to implement the curriculum because of a shortage in providers at the time. However, this site was still involved in CHOICES by referring women to the other CHOICES sites. It was also the clinics that identified who would be best to conduct the intervention. For example, a nurse practitioner showed interest in being the interventionist at one site, while a behavioral health specialist was involved at another site.

Finally, in order to better evaluate the efficacy and sustainability of the CHOICES program at the sites, the evaluation team conducted qualitative interviews with the CHOICES interventionists at the two initial CHOICES sites, as well as with a clinic manager at one of the sites. Open-ended questions were utilized to ask these key staff about their thoughts on preventing AEP with non-pregnant women; suggestions for improving the CHOICES; barriers and successes in implementing the intervention; success stories with the CHOICES participants; and how they envision sustaining the CHOICES program in the long-term.

We then moved to the second stage of implementation. Based on this extensive process of gathering community and clinic input, the OST CHOICES intervention was implemented and has been enrolling participants since 2012. At one site, American Indian women in the OST CHOICES program see the interventionist for four motivational interviewing sessions, while at two others they receive two sessions, per the preference of the site and stakeholder input. At the CHOICES sessions, participants set goals for their drinking and contraception behavior. They also complete daily diaries that track their drinking, sexual activity, and contraception use, and work with the interventionist to define their readiness to change these behaviors. After the sessions and the separate birth control session, the CHOICES interventionist follows up with women at three and six months to evaluate if they sustain behavior changes related to AEP.

3. Results

3.1. OST CHOICES Feasibility and Acceptability

The first two years of the project (2010–2012) were dedicated to adapting the CHOICES materials for AI women and evaluating the feasibility of the CHOICES components with this population.

Overall, the staff at the three tribal clinics involved in this first stage were extremely enthusiastic about the program and the potential for reducing AEP, and there was a willingness to implement the CHOICES curriculum within the clinic protocol. Input was gathered on modifying the CHOICES curriculum to make it appropriate for the tribal partners, including adding culturally appropriate images, checking the materials for readability, ensuring that data (such as rates of unplanned pregnancy) were local rather than national data, and determining the relevance of the information, such as what birth control options are available locally and the types of drinks that women drink.

While the OST CHOICES Program began in September, 2012, it began slowly because of various implementation issues. One of the sites dropped out of participation and declined to enroll women because of a staff shortage, meaning that although they were interested in the OST CHOICES Program, they were unable to dedicate any staff time to enrolling participants into the program. Another site began enrolling women but the interventionist soon left the program and no follow-ups were conducted. Staff turnover was a concern, although that challenge is now overcome because both authors of this manuscript, who are key staff with the OST CHOICES Program, attended a national CHOICES “training of trainers” and are now able to train any new staff.

However, the results of the qualitative interviews with two of the OST CHOICES interventionists and other relevant clinic staff point to the positive outcomes of the intervention in this feasibility/acceptability stage. These interviews revealed that the focus on preventing AEP with women that aren’t currently pregnant is an ideal prevention route. Most of the women enrolled appear to like the birth control part of this effort. The interventionists also feel that the approach is non-judgmental, which resonates with the women they see. The largest success stories include young women with multiple children who begin using birth control, in particular long-term birth control methods. When asked about sustaining the CHOICES intervention, one suggestion was to make CHOICES an official Indian Health Service program so that all American Indian women would be screened for alcohol consumption and pregnancy risk and would automatically be referred to the local CHOICES interventionist to enroll.

3.2. OST CHOICES Implementation

Based on the positive input from the OST CHOICES interventionists, two additional sites were added in 2013 with the advent of further funding for CHOICES for a total of three clinic sites, and their data is included here. While enrollment and follow-up is ongoing, as of June 18 2015, 117 women have been enrolled at these three sites for the individual CHOICES sessions (see Figure 1). All participants were at-risk for an AEP because they were binge drinking and were sexually active and not using effective birth control. Note that “waiting for [3- or 6-month] follow-up” in Figure 1 indicates that the participant has not completed the follow-up because they have not reached that time point yet.

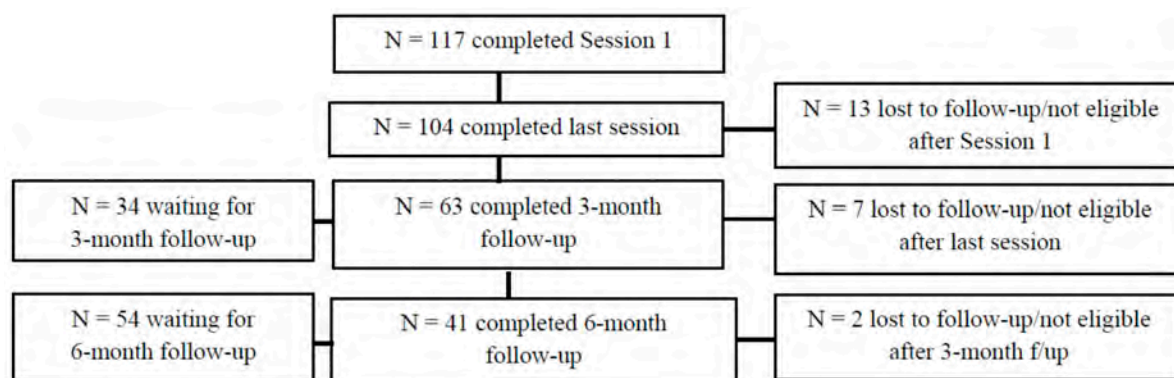


Figure 1. OST CHOICES program: individual session data.

As stated earlier, during these CHOICES sessions, MI techniques are used along with various activities, including decisional balance exercises, goal setting, and behavioral change plans. One component of the OST CHOICES intervention includes asking the participant to identify a person that can help in reaching behavioral goals and ways they can help. See Table 1 for examples. In addition, participants were asked to complete “decisional balance” exercises to reflect about the good and not so good things about their drinking alcohol and use of birth control. Table 2 includes just a few responses from the participants enrolled in OST CHOICES.

Finally, participants were asked to set goals for their drinking and birth control use and reflect on why they chose their particular goal. Women said powerful things about their alcohol goals, such as, “To start building confidence in myself”; “I’m still young and I just drink all the time” and “Because I want to be here for my children living an alcohol/dry free life.” To change their drinking, they noted steps they needed to take, including keeping the empty bottles or tabs by them to see how much they’ve been drinking, being around friends and family who don’t drink and avoiding friends that do, and keeping busy with work and school. Participants also discussed cultural elements such as praying, going to sweats, smudging, and engaging in ceremonies to get healthy. Regarding using birth control, they said powerful things about using birth control, such as, “Because I believe I am a risky drinker and I don’t want any more children”; “My life as a young adult can be at stake. My life is at stake. I’m not ready” and “Because I do not want STDs or a baby with FAS”. At the final assessment, when asked to make a final goal statement about alcohol use, participants made goals to not binge drink, to socialize with friends and family that do not drink, attend alcohol treatment, AA, or other support meetings, and to look at their children as motivators in avoiding drinking. One participant said, “I plan to not give up on myself.” See Table 3 for some final thoughts from OST CHOICES participants on the intervention.

Table 1. Identified social support person and impact on behaviors.

Individual	How/Why They Impact Drinking	How/Why They Impact Birth Control
Mother	Keeps woman focused on other things and supports. She doesn’t drink/doesn’t like drinking and gets mad.	Reminds her to avoid unplanned pregnancy Will drive her to appointments.
Older female relatives/ female elder	Dislikes drinking and worries about woman. Talks about consequences and keeps her focused.	Reminds her about birth control. Supports woman no matter what.
Young female relative (sister, cousin)	Don’t drink as much or at all (against drinking). Provide encouragement and confidence to be sober.	Reminds of difficulty of having children. Go with/remind about birth control appointment.
Boyfriend/male partners	He doesn’t drink/don’t buy alcohol for participant. Positive support and supports alternative activities.	Go with to appointment for support. Talk about birth control options.

While enrollment and follow-up is ongoing, as of June 18, 2015, 117 women have been enrolled at these three sites for the individual CHOICES sessions (see Figure 1). Because women were self-selected, none refused to participate. All participants screened positive and were at-risk for an AEP because they were drinking at risky levels, were sexually active, and were not using effective birth control. We lost a total of 22 participants (18.8%) from baseline to the last follow-up session (of note, there are no significant differences in those that were lost to follow-up *versus* those that were not), and some participants have not yet received their follow-up sessions. Of the 63 women reached for the 3-month follow-up, 42 (66.7%) were at reduced risk for an AEP because of their use of

birth control (60.9% of the total who completed follow-up), reduced alcohol consumption (4.4%), or changes in both behaviors (34.7%). At the 6-month follow-up, of the 41 reached, 31 (75.6%) were at reduced risk for AEP either because they began utilizing birth control (67.7%) or both began using birth control and reduced alcohol consumption (32.3%). The team is encouraged by the results, as preliminary data analyses indicate that the intervention successfully reduced risk for AEP in the majority of participants.

Table 2. Decisional balance exercise responses.

Behavior	Good Things	Not So Good Things
Alcohol	Forget problems; don't feel the pain, in a better mood. Have a good time. To celebrate. Be with friends and make new friends. Happier, more outspoken and outgoing.	Cost/no money. Family is sober and dislikes her drinking. Going to jail, other problems with the law, like DUIs. Problems are still there. Can ruin friendships. Hangovers/feeling sick and tired the next day. Fighting or getting hurt while drinking. Dirty house. Not taking care of kids/being away from children for days. Smoking cigarettes/weed when drinking. Missing work. Blacking out/not remembering things. Unprotected sex/embarrassed about a sexual encounter. Being sad/remembering people who passed away. Losing cell phone and other things while drinking. Causes health issues. Sad and lonely when she sobers up.
Birth control	Fixes abnormal menstrual periods. Prevents STDs. Birth control free at IHS. Pregnancy prevention.	Weight gain. Irregular periods or bleeding between periods. Have to use method all the time (pill, condoms). Men don't always have condoms with them. Condom could break/safety of condoms. Remembering to take the pill. Sometimes birth control isn't available or can't afford birth control. Fighting with boyfriend about birth control.

Table 3. Opinions of OST CHOICES participants on the intervention.

"To control my habit and to be realistic about goal setting, to be more careful about my sexual activities to practice safe sex. Alcohol is a bad habit for me and I need to slow down because I am always the one hurting myself and it enables me to be active with my daughter. So cut back and believe in myself that I can do this and accomplish my goals, maybe in time I will be alcohol-free."
"That my alcohol use affects a lot of different aspects of my life. It affects my health, my financial stability, my family. I've learned that if I cut back on my drinking, I could do more positive things with my children, I could save a lot more money if I didn't drink (so much). I don't have to worry about things I may have done while drunk and impaired, I've learned that I can control my own actions and alcoholism if I really wanted to."
"I've learned so much from CHOICES, the awareness of alcohol and unsafe sex and just getting the education of both is reality. It has taught me to talk to my nieces, cousins, daughter that it's really important. CHOICES is the best education and prevention of also STD's, drinking too much. I've learned a lot."
"I am thankful for CHOICES because they taught me a lot about drinking and the effects it had on my child. Thanks to the program I am now going to AA classes and I now have a better view on the effect of alcohol on a baby."

4. Discussion

The OST CHOICES Program was modified from the original CHOICES program through extensive community and clinic input, highlighting that CHOICES is feasible within a tribal clinic setting, keeping in mind that formative work is necessary to make the program's materials culturally and geographically appropriate. The intervention has been enrolling non-pregnant American Indian women for the past several years and has shown preliminary success in changing behaviors and in impacting how women as well as practitioners view prevention of AEP. Our study also showed that the CHOICES intervention was an acceptable and even welcomed intervention by this particular tribal community in order to prevent AEP, and its success shows that it can be implemented with other interested populations. In fact, there is interest from other tribes in seeing the CHOICES curriculum developed and implemented in their communities. Two staff members from the CHOICES team were trained to provide the CHOICES curriculum training (*i.e.*, training of trainers), meaning that the expansion of CHOICES to other tribal sites and clinics should be fairly economical and straightforward. In addition, while the process to modify and implement the CHOICES curriculum within this community was fairly methodical and relatively time consuming, the implementation in other communities need not be. The CHOICES curriculum is free and available online, therefore communities need only make community-based modifications as they see fit, if at all.

Overall, the OST CHOICES Program is unique because it is a *tribally-run program* that has worked in collaboration with a research center for the past several years. Using a community-based participatory research (CBPR) approach, we have balanced research and programmatic action for the mutual benefit of our partners and the women we work with. Similar to a previous study by Masis and May (1991), American Indian women at-risk for an AEP can lower their risk by either reducing alcohol consumption or preventing pregnancy, or as is often the case, by doing both [24]. The OST CHOICES Program is also unique from previous studies focused on preventing FASD because it targets non-pregnant but at-risk women, highlighting the importance of primary prevention efforts, especially by increasing utilization of birth control, in the reduction of AEP risk. This type of work and intervention is also significant because it focuses on a demographic (American Indians) that are often left out of programmatic research because of its relatively small population.

What makes the evidence-based CHOICES intervention distinctive in the prevention of AEP is that it targets more than one risky behavior related to AEP, reducing risk for AEP either by increasing a woman's use of contraception or by decreasing alcohol consumption. The women in our study typically focused their behavioral efforts on obtaining and utilizing an effective form of birth control rather than decreasing alcohol consumption or addressing both contraception and drinking. Although our OST CHOICES data is preliminary, our initial analysis indicates that the AI women in our program are more willing to begin utilizing contraception to prevent pregnancy rather than reducing alcohol consumption. This compares to the original CHOICES study, which included a randomized controlled trial, where participants were more equally distributed in their ways of reducing risk for AEP [18]. Specifically, at the three month follow-up, 33.8% of CHOICES participants reduced AEP risk by utilizing contraception, 27.6% reduced drinking, and 38.6% of women used both effective birth control and reduced drinking. At the 9-month follow-up, over 47% of participants were both using birth control and had reduced drinking.

While the OST CHOICES Program was successfully implemented and enrollment and data collection is ongoing, our team saw a critical need to expand the program to include components the community deems important. First, we conducted a validity/reliability study to further our efforts on the expansion of the CHOICES intervention with American Indian women [25]. Second, we conducted a needs assessment in 2013 that identified several ways to expand OST CHOICES, including a desire to include interpersonal social support in the intervention [26]. To meet this community need, we are in the process of piloting the CHOICES intervention in a group setting, a methodology that utilizes cultural norms of group communication and provides support through group interaction [27]. Through our community engagement, we also identified a need to work with

adolescents and young American Indian women to expand the population we work with, and we have applied for funding to expand to that group [28]. With this important community input and with extensive opportunities for expansion, the OST CHOICES Program will only grow in the coming years and expand to serve additional women in the movement to prevent AEP.

Limitations

There are a few limitations to this study. First, the development, implementation, and evaluation of preliminary results are confined to one American Indian tribe and one urban community; therefore, the results cannot be generalized to all American Indians/Alaska Natives. In addition, we have a relatively small sample size, although data is ongoing. Also, as with many intervention projects that include follow-up, we did have participant turnover for a variety of reasons (*i.e.*, women no longer interested in participating or their contact information has changed), and our staff continues to work diligently to contact participants via both telephone and letter. Finally, our project has faced staff turnover and a clinic dropping-out of data collection, which although created difficulty in the short-term, added to understanding the feasibility of CHOICES within a tribal community. We were able to add a new site and train additional interventionists to overcome these set-backs. As stated earlier, two of our staff members attended a CHOICES “training of trainers” so that we are able to train new staff in-house, meaning that staff turnover can be quickly addressed. Our staff learned a great deal in developing and implementing the OST CHOICES Program and those lessons learned should assist in sustaining the program long-term.

5. Conclusions

Overall, the methods and results of this study highlight the potential to expand an AEP prevention program to other sites. Garnering community input and appropriately modifying materials has led to a successful AEP intervention within an American Indian community. Ideally, those involved in future CHOICES implementation efforts can utilize the methods and results discussed above to implement and sustain this important AEP prevention program.

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Establishing Survey Validity and Reliability for American Indians Through “Think Aloud” and Test–Retest Methods

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Abstract

The purpose of this study was to use a mixed-methods approach to determine the validity and reliability of measurements used within an alcohol-exposed pregnancy prevention program for American Indian women. To develop validity, content experts provided input into the survey measures, and a “think aloud” methodology was conducted with 23 American Indian women. After revising the measurements based on this input, a test–retest was conducted with 79 American Indian women who were randomized to complete either the original measurements or the new, modified measurements. The test–retest revealed that some of the questions performed better for the modified version, whereas others appeared to be more reliable for the original version. The mixed-methods approach was a useful methodology for gathering feedback on survey measurements from American Indian participants and in indicating specific survey questions that needed to be modified for this population.

Keywords

aboriginal people, North America; alcohol / alcoholism; contraception; reliability; validity; qualitative

The negative health risks associated with alcohol consumption during pregnancy represent a leading preventable cause of disabilities in the United States, including fetal alcohol syndrome (FAS; Bailey & Sokol, 2008). Even moderate alcohol use during pregnancy has been associated with adverse effects, including an increased risk of low birth weight and pre-term delivery, and represents a major public health concern (Chen, 2012; Kesmodel, Wisborg, Olsen, Henriksen, & Secher, 2002). In addition, approximately half of pregnancies in the United States are unintended, some of which occur in women using contraception, thus delaying pregnancy recognition (Trussell, 2011). Women who experience an unplanned pregnancy are at an increased risk of adverse maternal behaviors (Finer & Zolna, 2011). Although many women stop drinking when they find out they are pregnant, an estimated 130,000 pregnancies in the United States are exposed to high levels of alcohol each year (Lupton, Burd, & Harwood, 2004).

Overall, between 10% and 26% of women are at risk for alcohol-exposed pregnancy (AEP; Project CHOICES Research Group, 2002). This risk is even higher in many American Indian tribal communities (Hanson, Miller, Winberg, & Elliott, 2013). A previous project indicated that the number of drinks consumed in an average week

by non-pregnant American Indian women was nearly 18, and 30% were sexually active but not using any birth control to protect against pregnancy (Hanson et al., 2013). One American Indian tribe in the Northern Plains, de-identified for privacy reasons, conducted an adapted program, Project CHOICES (Changing High-risk alcohol use and Increasing Contraception Effectiveness Study), that focuses on the prevention of AEP in non-pregnant American Indian women. The tribe’s CHOICES Program is centered on reducing the risk for AEP through alcohol reduction and/or pregnancy prevention using in-person motivational interventions (Floyd, Ebrahim, & Boyle, 1999; Floyd et al., 2007; Ingersoll, Floyd, Sobell, Velasquez, & Project CHOICES Research Group, 2003;

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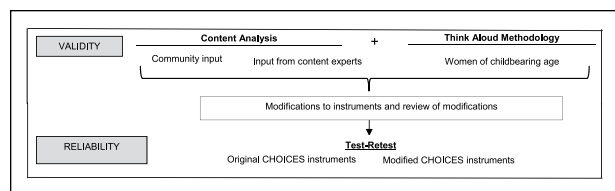


Figure 1. Validity and reliability methods.

Note. CHOICES = Changing High-risk alcohol use and Increasing Contraception Effectiveness Study.

Project CHOICES Research Group, 2002; Sobell et al., 2003).

Unfortunately, there is a lack of established validity and reliability of the CHOICES measures with American Indian women. In fact, the tribe's CHOICES Program is one of the first of its kind with American Indian women, which is laudable in terms of inclusion of a high-risk population but also concerning in that some of the measurements might not include linguistic (i.e., readability or clarity) or cultural norms for this population. While the CHOICES measurements have been previously validated with a variety of populations (Floyd et al., 2007; Ingersoll et al., 2003), there is still a great need for this type of research in American Indian communities. In particular, while this tribe's CHOICES intervention has been successfully implemented with American Indian women, there are still validity concerns. For example, interventionists report some confusion from participants regarding key measurements within the intervention, such as not understanding the meaning behind certain questions, which may affect the responses.

Therefore, the goal of the project was to establish validity (accuracy in measurement) and reliability (reproducibility) of critical measurements of the evidence-based CHOICES protocol for American Indian women. These measures included behavioral health screening measurements, temptation and confidence measurements, and readiness rulers, which are described in greater detail in the "Method" section. Using a mixed-methods approach, this reliability and validity project enriches an innovative existing program on AEP prevention with non-pregnant American Indian women and also adds to the reliability and validity literature on American Indian health behavior.

Method

Before beginning data collection, the project was reviewed and approved by the tribe's research review board, as well as by the principal investigator's internal institutional review board. All participants in the "think aloud" and test-retest signed informed consent documents before beginning their participation in this study.

We did not seek informed consent from those involved in the content validity process because the review boards deemed this as "non-research."

The original CHOICES authors cited several critical core theoretical components of the intervention that informed the focus of this validity/reliability study (Floyd et al., 2007). CHOICES is theory-based, drawing on social learning theories that underpin its cognitive-behavioral therapy activities and assessments (Velasquez et al., 2010). First is an initial behavioral (alcohol and contraception) assessment, collected via use of 4 of the 10 AUDIT alcohol screening questions (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001) and questions about vaginal intercourse (yes/no), use of contraception (yes/no), and type of contraception used. Other key measurements include temptation and confidence related to alcohol consumption and birth control utilization, based on the Brief Situational Confidence Questionnaire (Breslin, Sobell, Sobell, & Agrawal, 2000) and the Self-Efficacy for Contraception Scale (Grimley et al., 1996). Third are "readiness to change" questions, which are based on Readiness Rulers (Nieman, Velasquez, Groff, Cheng, & Foxhall, 2005). To determine validity and reliability, we instigated a three-step, mixed-methods approach (see Figure 1), where input from extensive qualitative data collection led to changes in the CHOICES questionnaire, with the original and modified versions both tested for reliability via a test-retest method.

First, to establish *content validity*, or the content representativeness and relevance of the CHOICES measures for American Indian women, we solicited input from community members (including American Indian elders) and from content experts in American Indian health. They were recruited through current contacts, collaborations, and community advisory boards and asked via email about their interest in participating. These individuals were sent paper copies of key CHOICES measures and asked to thoroughly review and note questions, problems, and ideas for changes, and send this information back to the principal investigator via email or regular mail. Each participant received a US\$25 gift card to thank them for their time and was also asked if they were willing to "re-review" the modified CHOICES questionnaire.

Second, we utilized a "think aloud" methodology with American Indian women, collecting information about response reasoning and decision making by having participants verbalize their thoughts when completing the CHOICES measurements (Fonteyn & Fisher, 1995). Uses of the think-aloud method are well documented in the medical research literature (Chase, Reicks, Smith, Henry, & Reimer, 2003; Gardin, 2010; Gillam, Fargo, & Robertson, 2009; Göransson, Ehnfors, Fonteyn, & Ehrenberg, 2008; Holmstrup, Stearns-Bruening, & Rozelle, 2013; Jaspers, Steen, van den Bos, & Geenen,

2004; MacNeela et al., 2010; Van Den Haak, De Jong, & Schellens, 2003). Benefits of the think-aloud method include capturing decision making and critical thinking in context (Gardin, 2010). The think aloud indicates validity by highlighting overarching problems when responding to measurements, and therefore issues with the accuracy of the measurement.

Based on previous literature, the goal was to engage 20 to 30 participants from the tribal community. Eligible participants for the think-aloud methodology were non-pregnant, adult American Indian women. They were recruited by posting flyers at clinics and community centers and sponsoring radio announcements, inviting interested individuals to contact the project assistant. Participants were scheduled for the think-aloud session at a later time point and were sent a reminder appointment card. Participants met with the project assistant at a private office or area. After signing an informed consent, participants were instructed to think aloud as they deliberated answering the CHOICES measures, and were asked to say whatever came into their mind while reading. If participants paused for longer than a few seconds while reading the survey, the project assistant quietly reminded them to “keep thinking aloud” and “please keep talking.” Aside from these reminders, all interactions between the participant and the project assistant were kept to a minimum to not interfere with the participants’ flow of thoughts. If participants seemed hesitant to “think aloud,” they were asked their thoughts at the end of each question. Each participant received a US\$25 gift card. The entire think-aloud session was audiotaped, and thorough notes were taken by the project assistant throughout the interaction.

To analyze the think-aloud data, the team conducted a type of “script analysis” that aims to “provide an overall description of the reasoning processes” and “illustrate what information subjects attended to during problem solving,” and the “rationale for the choices and decisions they made” (Fonteyn, Kuipers, & Grobe, 1993). To complete this, the project assistant listened to each audiotape and made notes on problem areas (i.e., confusion with a question, need for an example) for each question. These notes were given to the principal investigator, who created a spreadsheet that noted changes, problems, and confusion resulting from the content validity and think-aloud methodologies. This spreadsheet was shared on a conference call with a larger group, including the principal investigator, research assistants, and staff from the tribe’s CHOICES Program. As a group, alterations to the CHOICES survey were made based on the content validity and think-aloud suggestions. The group evaluated each individual question to see what possible modifications were suggested, and changes were made based on group consensus. After amendments were made, a

modified version of the CHOICES measurements was shown to community members and content experts who agreed to “re-review” the modified version.

After identifying survey modification needs via qualitative methodology, the team focused on determining reliability of both the original CHOICES survey and the modified version via a *test-retest methodology*. Based on a power analysis, the goal was to recruit at least 20 respondents in each of the groups (Donner, 1987; Fleiss, 1986), and the team aimed to oversample to reach these numbers. To recruit, the project assistant staffed tables at three health care facilities. Women who approached the table were asked to complete an eligibility screen (i.e., adult, non-pregnant American Indian women). Eligible participants were given a subject identifier and randomly assigned to complete either the modified CHOICES measurements or the original survey. Randomization occurred by asking participants to choose a sealed envelope from a box; each envelope stated either “original” or “modified.”

After completing the survey, participants were asked for contact information (phone number and alternate numbers) for future contact for the retest process. The project assistant called each participant 2 weeks after the initial “test” to convey the date and time of the retest. About 75% of the women were able to be contacted using the numbers and information they provided. Many of those who were unable to be reached had disconnected numbers or were not at the number they had listed. The retest involved a similar procedure of setting up a table at the same location; participants were free to come to the site to fill out the survey when it was convenient for them on the designated days in their area. Participants received a US\$10 gift card for completing the “test” and a US\$15 gift card for completing the retest. The survey took 20 to 45 minutes to complete.

Test-retest reliability of the original Project CHOICES questionnaire (OPCQ) and modified Project CHOICES questionnaire (MPCQ) was analyzed using percent agreement, weighted kappa with Cicchetti-Allison weights, Gwet’s AC1 and AC2 (with varying beta values; Gwet, 2001). Gwet’s statistics are thought to be more stable for unusual marginal distributions when the kappa statistics does not perform as expected (Cicchetti & Feinstein, 1990). Test-retest questions were analyzed on their original scale, except for those relating to thinking about behavior for both alcohol and contraception. For these questions, the 10-point scale was reduced to a 5-point scale by collapsing ratings with the closest values (e.g., 1 and 2 were grouped together). Agreement measures were not formally compared between questionnaires, given the small sample sizes and large variances. Qualitative comparisons were made for hypothesis generation. Statistical analysis was performed using SAS software, version 9.3,

SAS Institute Inc., Cary, North Carolina, United States. The AC1AC2 Macro by Blood and Spratt was used to calculate AC1 and AC2 (Blood & Spratt, 2007).

Results

Content Analysis

Feedback on the CHOICES measures was received by 17 native and non-native individuals, including 9 individuals working locally at tribal health centers, tribal non-profit organizations, and research projects occurring on tribal land, as well as 8 research and health professionals from universities and research institutions across the country who have previously worked with American Indians and AEP. Reviewers suggested *wording changes* (i.e., using “feeling down” instead of “depressed” and changing “experience side effects” to “have problems with” in regard to birth control), *giving examples* (for instance, adding pictures of alcoholic beverages to ease answering questions about drinking), *adding additional context to questions* (adding “feeling stressed” to a statement on being “physically tense”), and *emphasizing the role of partners* (for instance, clarifying if birth control questions address partners’ role in discouraging contraception, such as pressure to not use birth control or becoming angry if a woman utilizes birth control). Of those who agreed to re-review the modified measurements, none had additional comments or concerns.

Think Alouds

Twenty-three non-pregnant American Indian women from various communities across the reservation and in a local non-reservation city participated in the think-aloud methodology. The average age of participants was 40.4 (range = 23–66), and all but one of the participants had children. Marital status, education level, and employment status varied among the participants as highlighted in Table 1.

When responding to questions about the number of standard drinks, participants appeared confused on how to respond, especially because *examples of standard drinks* (i.e., a glass of wine) are not a typical drink for women in this area, who tend to drink alcohol-based energy drinks, such as Joose. Therefore, appropriate types and pictures of local drinks were added to clarify the standard drinks questions. When asked about contraception, some were unsure as to the different *types of birth control*, and many also had problems understanding “effective use,” therefore a description and a definition of effective use were added for each method. As well, more description was provided on surgical methods (i.e., hysterectomy) and menopause. Local slang for certain methods was deemed

Table 1. Demographics of “Think Aloud” Participants ($n = 23$).

	<i>n</i>	%
Marital status		
Single, never married	9	39.1
Divorced or separated	8	34.8
Married or living with a partner	6	26.1
Education		
High school diploma or GED	9	39.1
College degree (associates, 4-year, or graduate degree)	8	34.8
Some college	4	17.4
Less than a high school diploma	1	4.3
Master’s degree	1	4.3
Employment		
Employed	10	43.5
Student	6	26.1
Unemployed	4	17.4
Homemaker	2	8.7
Retired	1	4.3

Note. GED = general education development.

necessary, such as using “morning-after pill” as opposed to “emergency contraception.” Also, self-reported questions about drinking and sexual activity behaviors used a *time frame* of “the past three months,” which appeared too specific; therefore, the behavioral time frame was adjusted to “the past few months.”

In the section on “Temptation” (or certain situations that might make an individual to drink at risky levels or *not* use contraception) and “Confidence” (how confident these individuals would be to *not* drink and to use birth control in the same situations), several major thematic challenges stood out. In general, *examples and relatable terminologies* appeared lacking. For example, participants seemed to need examples or additional clarifications on questions regarding “testing control,” “urges,” and “conflict with others” when it came to temptation to drink alcohol, and also were unsure about “side effects” of birth control. Certain words also appeared to be inappropriate for this population, such as “unpleasant feelings,” which respondents felt was confusing and might be misleading; “depression,” which was viewed as too extreme and negative; and “self-efficacy,” which was read as “self-efficiency,” “self-effective,” or skipped completely. Examples and wording changes were provided in these sections. Finally, because the overall formatting of the Temptation/Confidence questions appeared confusing, *precursors* were viewed as necessary to provide a context for each measurement. For example, “How tempted would you be to drink alcohol if . . .” was added before each alcohol temptation statement/question. Table 2 highlights many of these changes using the original

Table 2. Comparison of Original and Modified Temptation/Confidence Alcohol Measurements.

OLD Temptation: Alcohol	NEW Temptation: Alcohol
Unpleasant emotions: If I were depressed in general; if everything were going badly for me.	How tempted would you be to drink alcohol if you were feeling stressed, upset, or down in general?
Physical discomfort: If I were having trouble sleeping; if I felt jumpy and physically tense.	How tempted would you be to drink alcohol if you were having trouble sleeping; if you were in pain or physical discomfort?
Pleasant emotions: If something good happened and I felt like celebrating; if things were going well.	How tempted would you be to drink alcohol if something good happened and you felt like celebrating; if things were going well?
Testing control over my use of alcohol: If I started to believe that alcohol was no longer a problem for me; if I felt confident I could handle a few drinks.	How tempted would you be to continue drinking alcohol if you needed to stop drinking, such as after three to four drinks or if you had to drive home?
Urges and temptations: If I suddenly had an urge to drink; if I were in a situation in which I was in the habit of having a drink.	How tempted would you be to drink alcohol if you were in the habit of having a drink; for example, every Friday night?
Conflict with others: If I had an argument with a friend; if I weren't getting along with others at work.	How tempted would you be to drink alcohol if you had an argument with a friend, partner, or family member; if you weren't getting along with others at work or school?
Social pressure to drink: If someone pressured me to be a good sport and have a drink if I were invited to someone's home and they offered me a drink.	How tempted would you be to drink alcohol if someone pressured you to drink; if you were invited to someone's home and they offered you a drink?
Pleasant times with others: If I wanted to celebrate with a friend; if I were enjoying myself at a party and wanted to feel even better.	How tempted would you be to drink alcohol if you were enjoying yourself at a party; if everyone around you was drinking?
OLD Confidence (Self-Efficacy): Alcohol	NEW Confidence: Alcohol
Unpleasant emotions: If I were depressed in general; if everything were going badly for me.	How sure are you that you would NOT drink alcohol if you were feeling stressed, upset, or down in general?
Physical discomfort: If I were having trouble sleeping; if I felt jumpy and physically tense.	How sure are you that you would NOT drink alcohol if you were having trouble sleeping; if you were in pain or had physical discomfort?
Pleasant emotions: If something good happened and I felt like celebrating; if things were going well.	How sure are you that you would NOT drink alcohol if something good happened and you felt like celebrating; if things were going well?
Testing control over my use of alcohol: If I started to believe that alcohol was no longer a problem for me; if I felt confident I could handle a few drinks.	How sure are you that you would NOT drink alcohol if you needed to stop drinking, such as after three to four drinks or if you had to drive home?
Urges and temptations: If I suddenly had an urge to drink; if I were in a situation in which I was in the habit of having a drink.	How sure are you that you would NOT drink alcohol if you were in a situation in which you were in the habit of having a drink; for example, every Friday night?
Conflict with others: If I had an argument with a friend; if I weren't getting along with others at work.	How sure are you that you would NOT drink alcohol if you had an argument with a friend, partner, or family member; if you weren't getting along with others at work or school?
Social pressure to drink: If someone pressured me to be a good sport and have a drink; if I were invited to someone's home and they offered me a drink.	How sure are you that you would NOT drink alcohol if someone pressured you to drink; if you were invited to someone's home and they offered you a drink?
Pleasant times with others: If I wanted to celebrate with a friend; if I were enjoying myself at a party and wanted to feel even better.	How sure are you that you would NOT drink alcohol if you were enjoying yourself at a party; if everyone around you was drinking?

alcohol Temptation/Confidence measurements and how they were modified.

The last major section of the survey was readiness rulers, where participants were asked to rank on a scale of 1 to 10 how (a) important, (b) sure, and (c) ready they were

to change drinking and birth control behaviors. One area that was modified was in the alcohol readiness ruler section, as "*risky drinking*" was defined in an opening paragraph but not within each ruler. Therefore, the ruler was altered to say, "drink less than four drinks on any one

Table 3. Demographics of “Test–Retest” Participants (*n* = 79).

	<i>n</i>	%
Marital status^a		
Married or partnered	42	53.2
Single, never married	27	34.2
Divorced or separated	8	10.1
Education^b		
High school diploma or GED	30	38.0
Some college	23	29.1
College degree (associates, 4-year, or graduate degree)	12	15.2
Less than a high school diploma	11	13.9
Employment^a		
Employed	31	39.2
Unemployed	21	26.6
Homemaker	14	17.7
Student	7	8.9
Other	4	5.1

Note. GED = general education development.

^aMissing *n* = 2.

^bMissing *n* = 3.

occasion or less than eight drinks per week” for all three (important, sure, and ready) alcohol rulers. The contraception rulers remained the same.

Test–Retests

As stated, based on the input from qualitative means via content experts and the think-aloud methodology, several modifications were made to the existing CHOICES survey as shown in Table 2. For the test–retest to evaluate the reliability of the original versus modified measures, 79 non-pregnant American Indian women were enrolled at one of the three recruitment sites. Of these, 44 were randomly assigned to receive the MPCQ, and 35 completed the OPCQ. The average age of participants was 27.9 (range = 18–44), and the majority (90.6%) of participants had children. Marital status, education level, and employment status varied among the participants as highlighted in Table 3.

At the time of “retest,” which occurred approximately 2 weeks after the initial recruitment, 23 participants completed the MPCQ and 16 completed the OPCQ, for a retest response rate of 52.3% and 45.7%, respectively. Data for alcohol questions are presented in Table 4. Agreement statistics for alcohol questions regarding temptation and confidence appeared slightly better for the MPCQ compared with the OPCQ. Measures of agreement were consistent across the different statistical approaches. For the alcohol questions relating to thinking about behavior (i.e., readiness rulers), reliability was

quite varied for both OPCQ and MPCQ, possibly because of the wide range of values included.

Data for questions regarding contraception are provided in Table 5. The weighted kappa statistic performed poorly in the contraception analysis due to an imbalance in marginal totals (e.g., for some questions only one or two response categories were used). When examining the AC statistics, unlike the alcohol questions, the OPCQ appeared to have slightly higher agreement compared with the MPCQ for both the temptation and confidence questions for the contraception analysis. The contraception readiness rulers had similar agreement measures for both the OPCQ and MPCQ.

Discussion

While the theoretical cores of the CHOICES intervention have been utilized with American Indian women (Canales & Rakowski, 2006; Fahrenwald & Shangreaux, 2006; May et al., 2008), previous use of the CHOICES survey measures with American Indian women is lacking. Therefore, the ultimate aim of this project was to establish the validity and reliability of the CHOICES measures, and therefore to improve this AEP prevention program for American Indian women.

Our team utilized mixed-methods approach, beginning with a content analysis and think-aloud methodology to derive community input into survey measurements. Using the think-aloud qualitative methodology, we found definite “themes”—or problems with specific wording or questions that are similar for the majority of participants. This tells the team that use of a think-aloud methodology in gathering community input on survey measurements can be a fairly uncomplicated process and one that can provide a wealth of input on how the questionnaire and even the overall project can be made community-appropriate. Previous use of the think-aloud methodology has focused primarily on nutrition and diet behaviors (Chase et al., 2003; Henry et al., 2003; Holmstrup et al., 2013; Reicks et al., 2003), as well as with understanding decision-making processes of health care providers (Fonteyn & Fisher, 1995; Göransson et al., 2008; MacNeela et al., 2010) and students (Gardin, 2010; Gillam et al., 2009; Pottier et al., 2010; Van Den Haak et al., 2003), making this particular think-aloud study with American Indian women and AEP prevention unique.

The results from the think aloud were vital in informing how questions are asked of the American Indian women. The think-aloud participant variance in comprehension of survey questions resulted in the revision of some key pieces of the survey to fit the community being served. Repeated reports by participants acknowledged the low literacy rates and lack of comprehension, especially in young women of the community and those in the

Table 4. Agreement Statistics for Alcohol Questions.

Question	Agree (n)	Observation (n)	% Agree	Weighted Kappa	AC1	AC2a	AC2b
Original questionnaire							
Temptation							
Q1	10	16	62.5	.69	.54	.42	.48
Q2	11	16	68.8	.54	.64	.52	.59
Q3	6	16	37.5	.42	.23	.20	.22
Q4	7	15	46.7	.39	.36	.29	.33
Q5	10	16	62.5	.56	.55	.42	.48
Q6	11	16	68.8	.63	.64	.51	.58
Q7	12	16	75.0	.58	.70	.52	.60
Q8	7	16	43.8	.38	.31	.25	.28
Confidence							
Q1	11	16	68.8	.53	.62	.46	.52
Q2	8	16	50.0	.31	.40	.30	.35
Q3	5	16	31.3	.25	.16	.13	.15
Q4	9	16	56.3	.40	.47	.35	.39
Q5	9	16	56.3	.50	.46	.35	.40
Q6	8	15	53.3	.39	.43	.33	.37
Q7	8	16	50.0	.36	.38	.29	.33
Q8	8	16	50.0	.36	.38	.29	.32
Thinking							
Q1	11	16	68.8	.75	.61	.47	.53
Q2	5	16	31.3	.33	.32	.25	.29
Q3	8	16	50.0	.47	.46	.35	.40
Modified questionnaire							
Temptation							
Q1	16	23	69.6	.74	.63	.49	.56
Q2	16	22	72.7	.69	.68	.54	.61
Q3	17	23	73.9	.75	.68	.52	.59
Q4	14	23	60.9	.43	.55	.44	.50
Q5	12	23	52.2	.46	.42	.33	.37
Q6	13	22	59.1	.65	.51	.41	.47
Q7	17	23	73.9	.74	.69	.53	.60
Q8	15	23	65.2	.76	.57	.45	.51
Confidence							
Q1	14	23	60.9	.48	.52	.38	.44
Q2	13	23	56.5	.58	.46	.37	.42
Q3	11	23	47.8	.34	.35	.26	.29
Q4	11	23	47.8	.37	.36	.28	.32
Q5	15	23	65.2	.56	.57	.43	.48
Q6	10	23	43.5	.34	.30	.22	.25
Q7	12	23	52.2	.41	.41	.31	.35
Q8	13	23	56.5	.39	.46	.34	.38
Thinking							
Q1	8	20	40.0	.41	.39	.29	.33
Q2	12	21	57.1	.61	.54	.42	.47
Q3	11	21	52.4	.40	.43	.33	.38

more rural areas. It was clear that future use of surveys with American Indian populations needs to be reviewed by community members *before* implementation to have appropriate language and other visual aids addressed. The

think aloud is a method that can gather community information while evaluating the validity of survey measurements. Examinations of verbal think-aloud protocols can provide useful information about comprehension that is

Table 5. Agreement Statistics for Contraception Questions.

Question	Agree (n)	Observation (n)	% Agree	Weighted Kappa	AC1	AC2a	AC2b
Original questionnaire							
Temptation							
Q1	11	15	73.3	.62	.68	.52	.60
Q2	12	15	80.0	.61	.76	.59	.67
Q3	9	15	60.0	-.01	.56	.45	.51
Q4	13	15	86.7	.15	.86	.68	.77
Q5	14	15	93.3	—	.93	.75	.84
Confidence							
Q1	10	15	66.7	.64	.59	.44	.50
Q2	11	15	73.3	.77	.67	.51	.59
Q3	8	14	57.1	.52	.49	.38	.43
Q4	10	15	66.7	.56	.60	.46	.53
Q5	12	15	80.0	.71	.76	.59	.67
Thinking							
Q1	9	16	56.3	.71	.79	.63	.71
Q2	10	16	62.5	.63	.63	.50	.57
Q3	9	16	56.3	.72	.62	.49	.56
Modified questionnaire							
Temptation							
Q1	13	20	65.0	.34	.60	.48	.55
Q2	13	21	61.9	-.14	.59	.48	.55
Q3	14	21	66.7	.11	.63	.52	.59
Q4	13	21	61.9	.09	.58	.48	.54
Q5	16	21	76.2	.38	.75	.60	.68
Confidence							
Q1	11	21	52.4	.28	.43	.35	.40
Q2	8	21	38.1	.13	.27	.22	.26
Q3	9	21	42.9	.22	.31	.24	.28
Q4	11	21	52.4	.20	.43	.33	.38
Q5	14	21	66.7	.19	.62	.48	.55
Thinking							
Q1	15	20	75.0	.52	.78	.62	.70
Q2	13	21	61.9	.71	.73	.59	.67
Q3	17	21	81.0	.78	.84	.66	.75

not readily available from traditional measures of comprehension performance, such as question and answer and recall tasks (Gillam et al., 2009).

Based on these qualitative efforts, modifications to the original CHOICES measures were made, including refining questions using clarifying statements, giving examples, and rewording certain questions. The test-retest revealed that for the alcohol temptation/confidence questions, the modified questions were more reliable, but for the contraception temptation/confidence measures, the original questions appeared more reliable. One possible reason for this is that alcohol consumption is fairly pervasive in our country and within this community specifically. In addition, many CHOICES participants appear less aware and have less knowledge of contraception and the varying methods to prevent

pregnancy when compared with their awareness and knowledge of alcohol consumption, which may indicate that birth control is less relevant to their daily lives when compared with alcohol.

These findings provide novel evidence that certain CHOICES components should be modified for use with American Indian women to increase the efficacy of the brief intervention protocol. The next step in this process is to work with the tribe's CHOICES sites to determine what survey measurements will be implemented and what measures should remain the same within the current program. Overall, this type of mixed-methods approach is significant as there is a dearth of validity and reliability studies conducted with American Indian communities, particularly in regard to alcohol or contraception behaviors (Abbott, 2011; Leonardson et al., 2005).

Limitations

A potential limitation to the think-aloud methodology is the presence of the project assistant, who might influence verbalizations. However, most participants from previous think-aloud projects indicated that “the investigator’s presence was not influential regarding what they thought, said, or did” (Chase et al., 2003, p. 503). In addition, unlike the think-aloud analysis described in this article, think-aloud data are sometimes analyzed using traditional content analysis, including the use of data transcripts (Göransson et al., 2008). This team utilized recommendations made by other research (Fonteyn et al., 1993), focusing on script analysis as described in the method section, which provided important input into the validity of the CHOICES measures. A final limitation is that the project was conducted with one tribal area, limiting the generalizability of this study. However, this points to the potential to replicate this methodological model with other communities as CHOICES is expanded to other tribes.

Conclusion

The use of the “think alouds” was a unique and novel way to gather input on the existing measures for a prevention program with American Indian women. The use of qualitative methodology is important when working with American Indian participants, as cultural elements are best revealed and understood through open-ended methodologies (Denzin & Lincoln, 2000; Israel et al., 2005). Through the “think aloud” methodology, we were able to better understand overarching problems and response reasoning to the CHOICES questionnaire among American Indian women, and therefore possible issues with the accuracy of the measurements. Without this qualitative piece, the test–retest could not have been conducted, highlighting the important nature of qualitative methodology, especially when working with American Indian communities.

Overall, the findings in this article are significant as they close knowledge gaps to understanding American Indian health and measuring certain health behaviors, specifically to the prevention of AEP with American Indian women. In particular, the article adds to the current literature on the CHOICES intervention, as well as informs validity and reliability studies with American Indian communities. In addition to expanding current knowledge, the results also indicate educational needs regarding AEP, such as clarifying “standard drink” measures and telling researchers the types of alcohol being consumed in such rural communities. For instance, the inexpensive energy-type drinks typically being consumed in this community are those with high alcohol content, equivalent to five to six standard drinks.

In conclusion, the mixed-methods approach utilized within this article highlights the modifications necessary for the CHOICES measurements for this particular community. As stated, the next step is to implement some of these suggested changes into current practice. This type of research is important in highlighting the need to better educate professionals interested in AEP prevention and health disparities research about cultural and linguistic differences that must be taken into account when developing and implementing intervention research. There is a definite need to continue straying from the “one size fits all” mentality by establishing validity and reliability for survey measurements with subpopulations before implementing within health research.

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Authors’ Note

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Minority Health and Health Disparities or the National Institutes of Health (NIH).

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

Jessica D. Hanson , Morgan E. Nelson, Jamie L. Jensen, Amy Willman, Jacque Jacobs-Knight, and Karen Ingersoll

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)

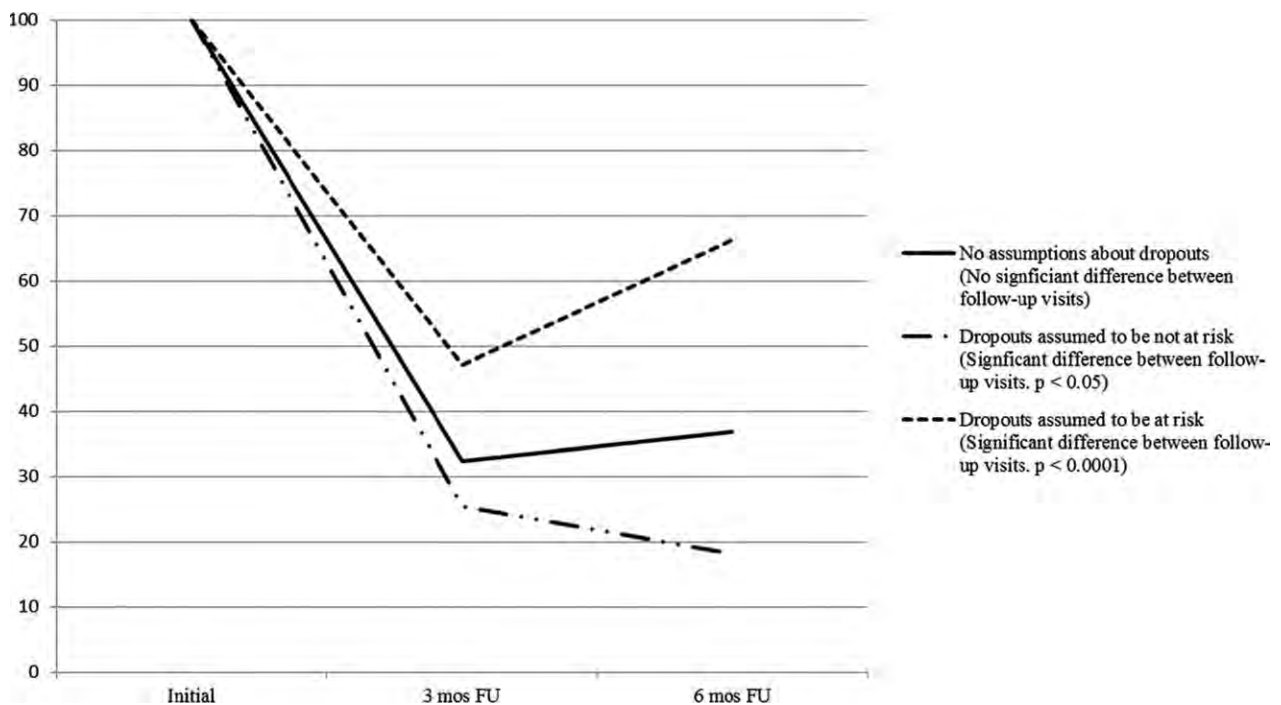


Fig. 1. Proportion at risk for AEP at each follow-up visit.

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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A culturally tailored intervention to reduce risk of alcohol-exposed pregnancies in American Indian communities: Rationale, design, and methods

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ABSTRACT

Introduction: Prenatal exposure to alcohol can cause lifelong physical and cognitive challenges in the form of fetal alcohol syndrome and other fetal alcohol spectrum disorders (FASDs). The prevention of prenatal alcohol exposure is thus a public health priority – and one that should account for the particular needs of subpopulations, including in American Indian/Alaska Native (AI/AN) communities. Prior to conception, alcohol-exposed pregnancy prevention is accomplished by encouraging the reduction or elimination of risky alcohol use and/or promoting effective contraceptive use among risky drinkers who could become pregnant. The current study builds on promising findings about the impact of the Centers for Disease Control and Prevention CHOICES intervention with AI/AN communities by implementing a randomized control trial of Native CHOICES, a cultural adaptation of CHOICES, with AI/AN women in a rural reservation community.

Methods: AI/AN women aged 18–44 who are at-risk for an alcohol-exposed pregnancy are being recruited. Participants are randomized in 1:1 proportion to the intervention and a services-as-usual, waitlist control condition. The Native CHOICES intervention consists of 2 motivational interviewing (MI) sessions, an elective contraception counseling session, and electronic messaging to boost the effects of MI. Data are collected at baseline and at 6 weeks, 3 months, and 6 months post-baseline. Those assigned to the control group are eligible to enroll in Native CHOICES following the completion of the 6 months post-baseline data collection. In addition to testing intervention effectiveness, the study is designed to yield a comprehensive economic evaluation, which will provide important information regarding the financial feasibility and sustainability of Native CHOICES for healthcare systems serving AI/ANs.

1. Introduction

Fetal alcohol syndrome (FAS) and other fetal alcohol spectrum disorders (FASDs) pose a clear and actionable public health concern. They are preventable conditions with enormous costs to individuals and society. National rates of FAS have been difficult to reliably establish due in part to differences in methods and diagnostic criteria across studies

[1]. Factors such as quantity, frequency, and timing of prenatal alcohol exposure as well as maternal age, general health, and various other environmental factors have been linked to the prevalence and severity of FAS and FASDs [2–5].

American Indian/Alaska Native (AI/AN) women may be at higher risk for an alcohol-exposed pregnancy that can result in a child being born with an FASD. A comparative study of drinking patterns found that

Abbreviations: FAS, fetal alcohol syndrome; FASD, fetal alcohol spectrum disorders; AI/AN, American Indian/Alaska Native; AEP, alcohol-exposed pregnancy; CAB, community advisory board; PAC, Program Advisory Board; DSMB, data safety monitoring board; WIC, Women, Infant, and Children; MI, motivational interviewing; AUDIT, Alcohol Use Disorders Identification Test; QALYS, quality-adjusted life years; PeTH, Phosphatidylethanol.

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the percentage of AI women who reported binge drinking was higher compared to non-AI/AN women [6]. In another study, 16.2% of AI/AN women seen at a prenatal clinic in the Great Plains reported drinking alcohol during pregnancy [7], in contrast to a national study where 10.2% of pregnant women from the general population reported drinking [8]. Although AI/AN women are more likely to abstain from alcohol compared to other racial/ethnic groups, those who do drink are more likely to do so in ways that are particularly risky (e.g. binge drinking) [9].

Because damage from alcohol exposure often occurs before pregnancy recognition, alcohol-exposed pregnancy (AEP) risk reduction during the preconceptional period is crucial [10]. Prior to conception, AEP prevention is accomplished by either reducing or eliminating risky alcohol use and/or increasing effective contraceptive use among risky drinkers who could become pregnant. Data from the South Dakota Tribal PRAMS Project found that 55% of AI/AN women from Great Plains Area tribes binge drank in the 3 months prior to pregnancy [11]. Among this same sample, 82% were sexually active, not trying to get pregnant, and not using any birth control at conception – all of which underscore the importance of preconceptional AEP prevention for AI/AN women as a public health priority.

Previous research on AEP prevention among adult AI/AN women has focused on tailored, culturally sensitive interventions that decrease risky drinking and/or increase effective contraception use. In one such intervention, researchers modified the evidence-based Centers for Disease Control and Prevention CHOICES intervention to meet the needs of AI/AN women living in a Great Plains AI reservation community [12,13]. Designed for delivery in 2 or 4 in-person sessions, CHOICES employs motivational interviewing (MI) with women at high risk for an AEP to assess readiness to change and to support goal setting for reducing risky drinking and/or increasing effective contraceptive use [12].

An efficacy study of the culturally- and contextually-adapted CHOICES intervention showed significantly reduced AEP risk among adult AI/AN women [14]. The current study is designed to build on these promising findings while also addressing their methodological limitations by implementing a randomized control trial of the adapted (Native) CHOICES intervention with AI/AN women residing in a rural reservation community. In addition, a comprehensive economic evaluation regarding the financial feasibility and sustainability of Native CHOICES for healthcare systems serving AI/ANs is included.

2. Methods

2.1. Community engagement

This study builds on well-established, trusting relationships between university-based researchers and partners in an American Indian tribal community in the Great Plains of the United States. The partnership involves ongoing conversations, emails, and telephone calls to ensure the ongoing alignment of research activities with the community's culture, needs, and service ecology. Tribal partners were involved in the initial design of the study and remain closely involved in the ongoing implementation (e.g., recruitment, data collection, and intervention delivery), data analysis and dissemination. Community-based research staff are members of the tribal community who represent the community's interests; they participate in bi-weekly conference calls and frequent email correspondence with the rest of the research team to ensure protocol responsiveness to community needs and protocol adherence. The project has an active Community Action Board (CAB), which includes local elders, community leaders, and Indian Health Service providers who offer advice and support to the study and assist in refining the intervention as necessary. The CAB holds bi-annual meetings and actively participates in large team meetings and presentations.

2.1.1. Other review partners

In addition to our community partners and the CAB, we regularly solicit input from 2 major external boards. The first is the Program Advisory Committee (PAC), a group of approximately 5 external professionals who are researchers representing a cross-section of the disciplines relevant to our work (e.g., alcohol use disorders, AI/AN health, and community-based participatory research). The PAC meets yearly to conduct annual program reviews and provide project-specific input, and participates in ad hoc teleconferences, as necessary, between the scheduled meetings. The second external board is the Data Safety Monitoring Board (DSMB), an independent group of experts that meets at least annually or more often if requested, to review unanticipated adverse events, reported deviations in protocol, and other events reported to the project's multiple institutional review boards (e.g., university and tribal). The DSMB also reviews and provides input on study enrollment data and makes recommendations as appropriate regarding ongoing recruitment and retention procedures.

2.2. Participants and recruitment

2.2.1. Power and sample size calculation

This study was designed to have 1:1 allocation to intervention and control groups. In calculating the study power and sample size, we assume approximately 15% attrition over follow-up as we were using national recommendations to improve follow-up and retention of participants. The Strong Heart Study, part of which was conducted in the same community as Native CHOICES, had an attrition rate of only 12% between examinations, which were approximately 3 years apart [15]. Based on a type-1 error rate of 5% and a baseline risk of AEP of 70% in the control arm of the trial, we have 80% power to detect a 16% difference in the outcome probability between the 2 arms if 350 women are enrolled. This implies we have 80% power to detect an intervention that lowers the risk of AEP in the treatment arm to 54% (relative to the 70% in the control arm). This difference is consistent with an approximately 30% to 80% reduction in AEP risk among intervention participants in a previous study [14]. We note that this is a conservative estimate. If the control arm has a higher risk of AEP, such as 80% or 90%, we have power to detect differences in outcome probabilities of 14% or 12%, respectively. Further, our ability to collect repeated information on AEP risk over time will further augment the power of this study.

2.2.2. Eligibility

In addition to meeting inclusion criteria for age (18–44) and race (AI/AN), participants must be able to get pregnant (i.e. must be sexually active with a male partner in the past 90 days or potentially active with a male partner in the next year; must not currently use effective contraception defined by standard methods; cannot be diagnosed as infertile); cannot be pregnant or planning to become pregnant within the next year; must have a diagnosed AUD or must self-report heavy drinking behavior (average ≥ 7 drinks per week) or episodes of binge drinking (≥ 3 drinks on a single occasion) in the past 90 days; and must not be living in a household with someone already enrolled in the trial.

2.2.3. Recruitment

To recruit participants, the study is advertised through Facebook, newspaper ads, radio interviews, and local meetings. Women are also recruited in community settings and events, including Women, Infants, and Children (WIC) program offices, health fairs, powwows, the local community college, and word of mouth. Prior to the COVID pandemic, the project's community-based staff set up booths or used dedicated areas in facilities to display recruitment materials and describe the study's goals, risks, benefits, and eligibility requirements. Interested women complete a brief pre-screening survey, and potentially eligible women are invited to schedule within a week an in-person or telephone visit, following the tribal community's public health guidelines, for enrollment and baseline data collection.

2.3. Intervention

2.3.1. Randomization and control group

Participants are randomized in 1:1 proportion to the intervention and control condition (usual care). Randomization is completed through a randomization card process using sealed sequentially numbered envelopes. At the end of the baseline visit, the study staff enter the participant's randomization assignment group and randomization card number into REDCap, the project's data capture system. Participants assigned to the intervention group are scheduled for their first MI session within 2 weeks of group assignment. The study employs a wait-list control group; those assigned to the control group receive usual care during the 6 months of the study and complete the 6-week, 3-month, and 6-month assessments. After their 6 months of participation, individuals in the control group are given the opportunity to enroll in Native CHOICES.

2.3.2. Intervention description

The Native CHOICES intervention consists of 2 MI sessions and activities delivered over 4–6 weeks, an elective contraception counseling session at a local clinic, and 3 months of electronic messaging to boost the effects of MI and counseling by increasing perceptions of social connection and social support for behavior change. Contraception counseling is typically completed within 2 weeks after the first MI session, so the maximum duration of MI and counseling for each participant is 6 weeks. Participants are not blinded to which arm of the trial they are allocated, a potential limitation of this study. Follow-up data collection is conducted in person at baseline and at 6 months, and by telephone, email, text messaging, or postal mail at 6 weeks and 3 months post-baseline. See Fig. 1.

All participants receive \$30 in the form of a gas or grocery gift card after completing data collection at baseline and at 6-month follow-up. After completing data collection at 6 weeks and 3 months, they receive a \$20 gift card. As an additional measure to retain participants,

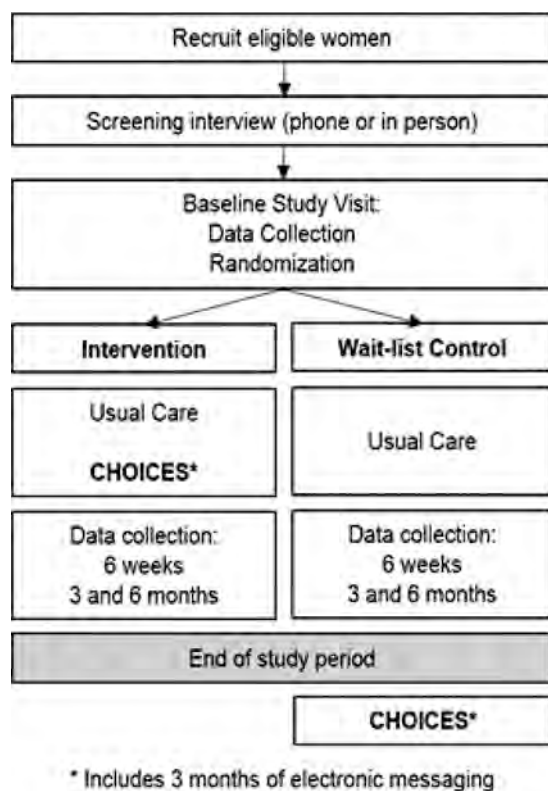


Fig. 1. Study design.

telephone and text reminders are sent 2 weeks, 1 week, and 1 day before each scheduled visit or phone call. For missed data collection interviews or visits, staff contact participants up to 4 times to reschedule within 2 weeks. Those who cannot be reached are mailed a letter communicating the assumption that they have withdrawn from the study.

2.4. Measures

2.4.1. Alcohol use

The Alcohol Use Disorders Identification Test (AUDIT) is used to identify potentially hazardous drinking patterns or active alcohol use disorders [15]. In addition, alcohol consumption and binge/heavy drinking are assessed using the following questions, taken from the original CHOICES intervention: *In the past 2 weeks, was there ever a time that you had 4 or more standard drinks in a single day? If yes, during the past 2 weeks on how many days did you have 4 or more standard drinks in a single day? In the past 2 weeks, was there ever a time that you had 8 or more standard drinks in 1 week? If no to the past 2 weeks, thinking about the last 3 months, was there ever a time that you had 4 or more standard drinks in a single day? If no to the past 2 weeks, thinking about the last 3 months, was there ever a time you had 8 or more standard drinks in 1 week?*

These measures define 'standard drinks' as 0.6 oz of absolute alcohol, documented with assistance from study staff with regard to serving sizes. Heavy drinking is defined using National Institute on Alcohol Abuse and Alcoholism criteria as a binary indicator of ≥ 8 drinks in any 1-week period, or as the total number of "heavy drinking days" on which ≥ 4 drinks were consumed over the past 30 days. Binge drinking is defined >4 drinks per occasion or total number of binge drinking episodes over the past 30 days [16].

2.4.2. Alcohol consumption biomarker

Phosphatidylethanol (PEth) blood assays are used as a biomarker to validate self-reported data on alcohol consumption. PEth levels are measured using high-performance liquid chromatography-tandem mass spectrometry with a limit of detection of 10 ng PEth/mL blood. Sample collection involves a finger prick and placement of a drop of blood on a spot card. Blood spots are air-dried overnight at room temperature, protected from light, stored in sealed Ziploc bags, and then shipped to a lab for analysis. Blood samples are collected from all participants in the intervention and control groups at baseline and 6-month follow-up. At each visit, a random 10% of participants provide blood for 2 cards, which is used for blinded reliability assessments. At the tribal community's request, PEth results are not linked with self-report data until after the study is complete to guard against negative consequences if the PEth assay results contradict self-reported information.

2.4.3. Contraception

A comprehensive self-reported assessment of contraceptive use is administered. Participants are asked if they have had vaginal intercourse over the prior 3 months. Participants are asked which forms of birth control they used over the past 3 months with follow-up questions to determine if contraception was used effectively. Effective contraceptive use is assessed by self-report and defined as current use of hormonal contraceptives, IUDs, implants, or barrier methods. Follow up questions developed by the Centers for Disease Control and Prevention help determine if contraception was used effectively [17].

2.4.4. Other measures

Demographic data include age, education, marital status, household income, previous pregnancies, current pregnancy status, and number of children living in the household. Questions about smoking are also asked using standardized methods, as are questions assessing current, former, or never smoker status and questions assessing for depression using the Center for Epidemiologic Studies Depression (CES-D) scale [18]. Enculturation (the extent to which someone feels involved and a part of their culture) and spirituality are measured by questions from the

American Indian Service Utilization, Psychiatric Epidemiology, Risk and Protective Factors Project [19]. Social connectedness is assessed using the Instrumental Social Support questions from the Social Support and Social Undermining Items instrument detailed by Oetzel et al. [20] and the Social Connectedness Scale – Revised [21]. An adapted version of a brief survey to assess knowledge and beliefs about health risks related to drinking in pregnancy is also administered [22].

2.5. Data analysis

Our primary outcome is reduction in risk of AEP measured as a binary (yes/no) indicator of reduction in risky drinking, increase in use of effective contraception, or both. Alcohol consumption is assessed by self-report at every data collection and will be validated by data from PEth assays at baseline and 6-month follow-up. Effective contraception use is measured based on “perfect use” (correct and consistent use of a reliable method). The primary analysis for this randomized control trial will be to compare, at the end of follow-up, the proportion of women who are at risk of an AEP in the intervention and control arms. The crude difference in proportion and 95% CIs will be used to estimate the effect of treatment. Baseline imbalance in predictors of AEP risk will be explored and logistic regression models will be used to adjust for any variables notably different across participants in intervention and control arms. Regression estimates will be used to estimate marginal effects and 95% CIs.

Subsequent analyses will make use of the repeated measurements of AEP risk. Longitudinal models will be fit to make full use of the repeated data (collected up to 4 time points per participant). Regression models will include indicator of AEP risk as the dependent variable, with intervention versus control group, follow-up time and the interaction between the two variables as predictors. The interaction term will be used to estimate the change in AEP risk over time between the 2 arms of the trial. As above, we will adjust for any variables that are not well balanced by baseline randomization. Because Native CHOICES may be differentially more effective at changing drinking behavior or contraception use, exploratory analyses will consider each component of AEP risk separately.

Although Native CHOICES has implemented protocols to prevent loss to follow-up, such as frequent patient contact by trained interviewers who know the study community, some attrition is inevitable. Loss to follow-up will be systematically evaluated and adjusted for, where necessary. Demographic characteristics will be compared between participants who are and those who are not lost to follow-up over the course of the study. If there are important predictors of loss to follow-up, our primary analyses, outlined above, will be adjusted to account for this, using inverse probability of attrition weights. These weights compute the probability of attrition conditional on relevant predictors of attrition. The resulting probability weights are used in the primary outcome analyses to adjust for possible selection bias due to differential loss to follow-up.

2.5.1. PEth analysis

PEth blood concentrations are measured on a continuous scale (ng/mL). We will use thresholds established in previous empirical research to categorize drinking behavior, but acknowledge that these values have not been validated in AI/ANs. Values ≥ 20 ng/mL will be taken to indicate any drinking over the past 2 weeks [23], values of 45–99 ng/mL to indicate probable heavy or binge drinking, and values ≥ 100 ng/mL to indicate heavy drinking.

2.5.2. Economic evaluation

The study includes an economic evaluation as to the impact of the Native CHOICES intervention. This is of particular importance when considering the high lifetime cost of FASDs. The 2018 per-person economic cost of FASDs has been estimated at \$68,151 per year in the US. This figure is averaged from 21 studies reporting estimated costs ranging

from \$2035 to \$298,975 and include costs such as health care, residential care, productivity losses due to morbidity and premature mortality, productivity losses of caregivers of children with FASD, special education, correction system, and intangible costs. Considering these costs plus the life expectancy of 73 years among American Indians, an individual with FASD has an expected lifetime cost of FASD of just under \$2.1 million dollars, discounted at a real interest rate of 3%.

Our results will provide an estimate for the reduced risk of AEPs among women who participate in Native CHOICES. The estimated overall cost savings will be used in a cost-benefit analysis of the Native CHOICES intervention. In addition, in the first of two primary cost-effectiveness analyses of Native CHOICES, we will use overall cost savings as an outcome to measure the effectiveness of Native CHOICES for lowering community health care costs. As the second outcome in the primary cost-effectiveness analyses, we will evaluate gains in quality-adjusted life years (QALYs). The health-related quality-of-life preference weights required to calculate the change in QALYs will be obtained from the EQ5D, the most widely used preference-based instrument for prospective cost-effectiveness analysis [24,25].

We will also estimate the short-term cost-effectiveness of Native CHOICES for reducing women’s direct healthcare costs and illegal behaviors. Data on within-study healthcare use will be retrieved from study records. Data on use of non-study medical resources (e.g., medication, use of inpatient services, time spent traveling to obtain health care) will be collected from participants’ electronic health records, supplemented with self-reported data. The validity of self-reported data on healthcare use is well-established [26–29]. Costs of Native CHOICES include both those incurred by participants and the cost of implementing the intervention. The costs of participation will be collected at each contact; they include direct costs, such as travel and childcare, and opportunity costs for items like earnings lost for time taken away from work activities. Implementation costs will be assessed using the costs of the study intervention, including labor and administrative costs for MI, record keeping, text messaging, and other activities.

3. Preliminary data and adaptations during COVID-19

From approximately March 1, 2019 (when active recruitment began) to February 27, 2020 (immediately prior to the COVID-19 pandemic and subsequent lock-downs), 176 individuals were screened for inclusion in Native CHOICES and $n = 112$ eligible and enrolled. The average enrolled per month for the first year of the project was 9.6 participants, almost exactly what was needed to complete recruitment in the allocated time. Retention and follow-up with participants was ongoing but appeared to be successful with the majority completing follow-up data collection. Specifically, $n = 79$ had completed their 6-week follow-ups and $n = 13$ had not reached the time point of 6-week follow-up data collection yet. For the 3-month follow-up, $n = 65$ had completed the follow-up and $n = 25$ were not yet due, and for the 6-month follow-up, $n = 56$ had completed their follow-up data collection with another $n = 46$ not yet due.

In-person data collection stopped in March 2020 due to the global pandemic. In response to COVID-19 restrictions, Native CHOICES employed adaptations to continue to operate remotely. All data collection and consenting is now done over the phone or via HIPAA-compliant video calls, and biosample collection is suspended. Participants will receive their intervention materials electronically, by mail, or through contactless pick-up. Additional participant survey questions have been added to try to account for the economic and behavioral impacts of COVID-19 among participants.

4. Discussion

Native CHOICES is driven by three main considerations: 1) the intervention has been shown to be effective in reducing AEP risk in non-Native populations [12], 2) it has already been implemented in one

Northern Plains reservation community, with preliminary data demonstrating its feasibility and acceptability in this setting [14], and 3) its effectiveness among AI/ANs has not yet been established by a randomized controlled trial, and it is scientifically premature to assume that effect sizes in non-Native samples will translate to these unique populations. While the qualitative and quantitative data collected in a nearby Northern Plains community suggest that CHOICES is likely to be beneficial among AI/ANs, these findings are not conclusive and the magnitude of benefit is unknown. The 6-month duration of our follow-up period enables us to recruit a sample size yielding greater statistical power, and the time period is consistent with that used in the previous randomized controlled trial in a non-Native sample [12].

In addition, by adding an electronic health messaging component, Native CHOICES will evaluate a novel adaptation of the original CHOICES intervention. Other advantages include the cost-effectiveness analysis, which will allow tribal policymakers and others to make informed choices about sustainability and implementation. Furthermore, our wait-list control group design enables unbiased estimation of the intervention's effectiveness while satisfying our tribal partner's requirement that all women in the study have an opportunity to participate in the intervention. Moreover, the use of the PETH analysis is a unique way to validate alcohol data and will yield information about the quality of self-reported data in this population. By augmenting self-reported data on alcohol consumption with validation by biomarker assays, we also reduce the risk of misclassification bias in our primary analysis, and, for the first time, examine the accuracy of self-reported alcohol data for AEP research in AI/ANs.

Our long-standing partnership with the tribal community allows for a robust community-engaged project with a strong study design. Often, underserved communities with historically negative experiences with research projects have balked at more 'experimental' types of studies, such as those involving control groups, instead preferring every community member to have the opportunity to participate in an intervention [30]. Our project was responsive to the particular needs of the AI/AN community by including a wait-list control protocol that allows any eligible person to enroll in the intervention at some point. Our wait-list control design meets this need while still adhering to the rigors of solid research design. Future randomized control and clinical studies with tribal communities must acknowledge past research harms and utilize community-based participatory research tenants to ensure that interventions are "culturally centered, a community priority, and perceived by community members to hold real value and promise for improving Native health" [30].

Finally, our relationship with our community partner has allowed us to meet the challenges of the pandemic head on. Although the project was forced to "pivot" to a telephone-based intervention because of the COVID-19 pandemic, the use of trained staff who are members of the tribal community has allowed us to continue our trajectory with only minor disruption.

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