Study Protocol

# Native-Changing High-risk Alcohol Use and Increasing Contraception Effectiveness Study

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## Ethics and community engagement

The study protocol was approved by the Institutional Review Board of Washington State University, the tribe involved in this study, and the regional Indian Health Service Institutional Review Board. All participants completed informed consent prior to enrolling in the study. The tribe is not identified to ensure anonymity. Members of the Data Safety Monitoring Board regularly provided recommendations. The study also had an active Community Action Board, which included local elders, community leaders and Indian Health Service providers who advised and assisted the study.

## Sample size, setting, and recruitment

In calculating the study power and sample size, we assumed approximately 15% attrition over follow-up. Based on a type-1 error rate of 5% and a risk of AEP of 70% in the control arm of the trial, we had 80% power to detect a 16% difference in the outcome probability between the two arms if 350 women were enrolled. This difference is consistent with an approximately 30% to 80% reduction in AEP risk among intervention participants in a previous study (Hanson et al., 2017).

Recruitment occurred from April 2019 to April 2023, stopping once the grant funding neared its end while also considering the time needed for follow-up data collection. Participants were recruited at a reservation site and an urban site with a relatively large AI/AN population. Participants were recruited through advertisements on social media and local newspaper and radio announcements. Recruitment also occurred in community settings, including women, infants, and children program offices, health fairs, powwows, the local community college, and word of mouth. Prior to the COVID-19 pandemic, the study's community-based staff set up booths or used dedicated areas in such facilities to display recruitment materials and describe the study's goals, risks, benefits, and eligibility requirements.

## Eligibility

Interested women completed an eligibility questionnaire; all enrollment, randomization, and data collection, including eligibility, was led by the study's community-based staff. Eligibility criteria were age between 18 and 44; self-identification as AI/AN; living in one of eight counties that encompass both the reservation and urban site; and not residing in a household with someone already enrolled in the trial. Other criteria required an ability to get pregnant (not diagnosed as infertile); being sexually active with a male partner in the past 3 months; currently not using effective contraception defined by standard methods (Centers for Disease Control and Prevention, 2023); and either heavy (eight or more standard drinks in a week) or binge drinking (four or more standard drinks in a single day) in the past 3 months.

## Intervention and control group

After establishing eligibility, participants completed baseline data collection within approximately 1 week, either in-person (pre-COVID-19 pandemic) or by telephone or video call (during the COVID-19 pandemic). Participants were then randomized 1:1 to the Native CHOICES intervention or the waitlist control condition. Randomization occurred through a randomization card process using

sealed sequentially numbered envelopes. The control group completed the six-week, three-month, and six-month interview with no other study interactions. After 6 months, individuals in the control group were given the opportunity to enroll in Native CHOICES.

Native CHOICES

The intent of the intervention was to reduce risk for AEP by decreasing or eliminating risky drinking among women who could become pregnant but were not, preventing unintended pregnancies through effective contraceptive use among risky drinkers, or both. The Native CHOICES intervention consisted of two MI sessions delivered over 4–6 weeks, with an elective contraception counseling session at a local clinic. These MI sessions included education on FASD; discussing drink size based on the type of alcohol consumed; and reviewing information on using effective contraception. Activities included a decisional balance exercise (e.g., "good" and "not so good things" about current alcohol and contraception behaviors); readiness rulers to assess how ready and sure participants were to change behaviors; and temptation/confidence exercises to determine certain situations that might put participants more at risk for risky drinking and unintended pregnancies. Goal setting and reviewing goals were completed at the end of both sessions. As with previous CHOICES interventions, all aspects of the intervention were optional but focused on increasing participants' commitment to change using MI, which is a client-centered counseling approach intended to minimize resistance to change. Although both behaviors leading to risk for AEP were targeted, Native CHOICES interventionists could emphasize the behavior a participant chose to focus on in alignment with guidance provided in the original CHOICES protocol (Floyd et al., 2007).

Native CHOICES was facilitated by a trained interventionist, who was a tribal member trained on the intervention and principles of MI. This training was facilitated by the first author, who was trained by the original creators of the CHOICES intervention and has worked in this field for 20 years. Trainings were held in-person and virtually over the course of approximately 3 months, where interventionists learned about FASD, AEP, and Native CHOICES prior to completing education and activities related to MI. The interventionists practiced their MI skills with coworkers and reported back on their experiences during weekly 1-hour staff debriefing sessions.

Measures

Baseline and follow-up data were collected at 6 weeks, 3 months, and 6 months postbaseline either in-person or by telephone or video call determined in part by policies during the pandemic. Data collection was conducted in-person (when COVID-19 conditions permitted) at baseline and 6 months postbaseline, and by telephone or video call at 6 weeks and 3 months postbaseline or when in-person data collection was not possible. All participants were compensated $30 for completing questionnaires at baseline and at six months and $20 for completing data collection at 6 weeks and 3 months. To retain participants, telephone and text reminders were made 2 weeks, 1 week, and 1 day before each scheduled follow-up visit.

At baseline, in addition to self-reported eligibility items, participants were asked about their education, household income, marital status, current residence, and current smoking status. Depression was assessed using the Center for Epidemiological Studies Depression Scale, 10-item version (CES-D-10) that asks respondents to rate how often over the past week they experienced

symptoms associated with depression (Björgvinsson et al., 2013; Radloff, 1977). Scores range from 0 to 30, with higher scores representing a more depressed mood. A score equal to or greater than 10 on the CES-D-10 suggests depression. The Alcohol Use Disorders Identification Test (AUDIT), a 10-item screening tool that assesses alcohol consumption and alcohol-related problems, was used to identify potentially hazardous drinking patterns or active alcohol use disorders (Saunders, n.d.). Scores range from 0 to 40, where 0 indicates abstinence from alcohol and no previous alcohol issues; 1–7 suggests low-risk consumption; 8–14 suggests hazardous or harmful alcohol consumption; and 15 or more indicates the likelihood of alcohol dependence. Participants were also asked about current treatment for substance use or involvement in a support group or 12-step meetings for substance use, activities that could influence risk of AEP.

To evaluate AEP risk, we used questions about binge and heavy drinking adapted from the original CHOICES intervention (Floyd et al., 2007; Project CHOICES Research Group, 2003). Participants were asked about their alcohol consumption in the preceding 2 weeks: whether they had consumed four or more standard drinks on any single day (binge drinking), and if so, on how many days within that period, as well as whether they had consumed eight or more standard drinks within either of those weeks (heavy drinking). If respondents answered negatively for the previous 2 weeks, they were prompted to recall whether binge or heavy drinking had occurred over the last 3 months. Additionally, they were queried about their sexual activity over the preceding 3 months, along with the birth control methods used (e.g., hormonal contraceptives, IUDs, implants, or barrier methods). Women who reported not using any form of contraception during each sexual encounter were exempted from further contraception-related questions, while those who reported using at least one method were asked follow-up questions designed by the Centers for Disease Control and Prevention to assess the effectiveness of contraception use (Centers for Disease Control and Prevention, 2023).

References

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