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Protocol and Statistical Analysis Plan

Project Title: Preventing Alcohol Exposed Pregnancy among Urban Native Young Women: Mobile CHOICES
Principal Investigator: Carol E. Kaufman and Michelle Sarche (MPI)
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I. Hypotheses and Specific Aims:

Fetal Alcohol Spectrum Disorders (FASD) result in neurodevelopmental deficits and lifelong disability; they are a leading cause of preventable birth defects in the U.S.[1,2] According to the CDC, any sexually active woman of reproductive age who drinks alcohol and does not use effective contraception is at risk for an alcohol exposed pregnancy (AEP) that could cause FASD.[2] By this definition, American Indian and Alaska Native (AIAN) young women are especially vulnerable. AIAN girls initiate alcohol use earlier than their non-AIAN peers;[3-6] they are also more likely to have used alcohol in their lifetimes, in the last 30 days, and on a daily basis.[7] Concomitantly, compared to all other race groups, high school-aged AIAN girls report the highest levels of ever having had sex (69%), and having had sex in the last 3 months (50%). Across all AIAN youth, 32% reported using alcohol or drugs before last sex, the highest rate across all race groups, and 80% reported not using effective contraception at last sex.[8,9] Unsurprisingly, the birth rate for AIAN women ages 15-19 is 27 per 1000—the third highest rate after non-Hispanic Blacks and Hispanics.[10] One study estimates that 25% of these teen births are substance involved, with the most common substance, alcohol, accounting for more than half of these.[11] While an estimated 72% of AIAN young women live in urban areas,[12] research relevant to AEP is largely based on reservation samples.[13-15] With rare exceptions,[16-20] the research base for urban AIAN youth and young adults remains thin. Urban AIANs tend to live not in concentrated neighborhoods but rather dispersed across the urban landscape; thus, common community-based recruitment and intervention strategies are expensive or rarely applicable for research engagement of urban AIANs.[21] Consequently, urban AIAN needs are often ignored in research aimed at developing, implementing, and evaluating culturally appropriate services. Recent research indicates that mobile health (mHealth) interventions are promising for delivering effective interventions to hard-to-reach populations.[22-24] The goal of this project is thus to expand reach and services to urban AIAN young women through mHealth technology to prevent AEP and FASD.

The proposed project builds directly on the work of an earlier NIAAA-funded project (R21AA17596; Sarche, PI {Ojibwe, MPI on this project}). Using intensive community-based participatory research (CBPR) methods,[25,26] tribal community and AEP prevention experts guided the adaptation of CHOICES (**C**hanging **H**igh-risk alcoh**O**l use and **I**ncreasing **C**ontraception **E**ffectiveness **S**tudy),[27] an evidence-based brief AEP intervention supported by the CDC, for use with young American Indian women age 16-20. CHOICES relies on motivational interviewing (MI) to increase contraceptive use and decrease drinking among adult women at risk for an AEP.[27] The adapted version, American Indian Youth CHOICES (AIY-C) preserves the brief MI format and focus on AEP prevention through increased contraceptive use and decreased drinking. AIY-C diverges from CHOICES in its cultural content, its universal approach, and its youthful age range. AIY-C supports all young AIAN women in making current (for sexually active or drinking youth) or future (among abstinent youth) healthy choices about contraception and drinking. AIY-C contains features that make it highly amenable to mHealth approaches, including a framework for integrating diverse cultural teachings, few modules of short duration, and concrete opportunities for goal-setting and achievement. This proposed project is innovative in its plan to recruit AIAN young women from major urban areas in the US through social media and to deliver AIY-C via mobile devices—both of which are increasingly ubiquitous among AIAN young adults.[28,29] While social media recruitment and mHealth interventions are not new,

including for adult AEP prevention,[30-33] only very recently have they been used with AIAN populations.[34-36] Appropriate partnership with urban AIAN organizations is foundational to the project's success.[37] We have engaged strong collaborators to guide us through social media recruitment strategies, mHealth intervention translation and implementation, and evaluation processes in urban AIAN settings. Engaging with cultural and intervention expert guidance, we propose the following specific aims:

SA1: **Develop social-media-based recruitment strategies** for urban AIAN young women; we will pilot and refine these strategies.

SA2: **Translate AIY-C for mHealth delivery** through an iterative and theoretically driven process, integrating urban AIAN young women's input to enhance cultural and health engagement content and responsiveness; we will pilot and refine the translated mHealth AIY-C intervention.

SA3: Recruit 700 (final N=525) urban AIAN young women using the refined social media strategies, and conduct an RCT to **rigorously evaluate the effectiveness of the mHealth translation of AIY-C** for preventing AEP and FASD.

SAs 1 and 2 were conducted under a separate COMIRB protocol (#18-0574) as preparatory to research efforts. For this protocol, we focus only on SA 3.

II. Background and Significance:

In the US, an estimated 1 in 8 pregnancies are exposed to alcohol.[38] In any given month, 2 million women, about 1 in 30, are at risk of AEP that could result in FASD.[39] FASD include FAS, partial FAS, alcohol-related birth defects, and alcohol-related neurodevelopmental disorders.[40] Children born with FASD suffer cognitive, physical, and social-emotional consequences throughout life; social and financial costs are enormous to individuals and society[41-46] Rates of drinking among pregnant AIAN women exceed those of other groups,[47-49] with rates of 30%[15]-43%[50] in some samples. Prevalence estimates for FASD in AIAN communities are limited and often dated but exceed other groups by at least 2 or more times.[48,51,52]

Given these data as well as a strong commitment to the health of future generations, tribal communities prioritize youth AEP prevention.[11,53,54] AIAN youth are at-risk for initiating alcohol use at younger ages relative to their non-AIAN peers[9] while patterns of use among AIAN youth who drink are more likely to put their own health and that of an unborn child at risk. High school AIAN girls are more likely to have drunk alcohol prior to age 13, currently drink, and drink 5+ drinks at a time compared to those in all other race groups.[8] AEP data for AIANs are limited due to insufficient sample sizes in large national studies;[55] however, the rates cited here confer risk for AEP when coupled with the early and unprotected sexual activity documented for AIAN youth.[9,53,56] While over 70% of AIANs live in urban areas, little research exists on patterns of AEP among urban AIAN young women in particular. What does exist indicates that they may be at the same or greater risk for alcohol use and sexual risk compared to their non-AIAN counterparts.[9,17,57]

In part, the lack of research reflects the research challenges of a small population overall (<2% of the US population), widely dispersed across urban centers (i.e., few AIAN neighborhoods exist in most urban settings). New recruitment and intervention implementation strategies to reach this population are critical. While social media recruitment is not new,[87-89] it has rarely been used among AIAN participants;[34] yet, this approach may hold substantial promise. Moreover, the potential for mobile health (mHealth) - delivered youth interventions, including AIANs, is growing. The Pew Research Center estimates that, in 2015, 86% of adults aged 18-29 owned a smart phone and 50% owned a tablet,[90] while almost 76% of teens aged 15-17 owned smart phones and 56% owned a tablet.[91] While the "technology divide" still exists, it is fast disappearing among teens and, perhaps, among AIAN populations in particular. A survey of adults from 128 tribal communities found AIANs were more connected to the internet than the general population, perhaps because mobile technology and the access it provides to email, texting, social media, and websites can virtually diminish large distances or isolation.[29,92]

We have selected one intervention that has had demonstrated impact in preventing AEP, CHOICES (**C**hanging **H**igh-risk alcoh**O**l use and **I**ncreasing **C**ontraception **E**ffectiveness **S**tudy),[27] an evidence-based brief AEP intervention supported by the CDC to implement with urban AIAN young women. In earlier work, Dr. Sarche (MPI; Ojibwa), using intensive community-based participatory research (CBPR) methods,[25,26] along with tribal community and AEP prevention experts, guided the adaptation of CHOICES for use with young American Indian women age 16-20 (American Indian Youth-CHOICES, or AIY-C). Based on this work (R21AA17596; Sarche, PI) and our formative work, we developed an mHealth version for smart phone use that we have named **Native WYSE (women young strong empowered) making CHOICES (NWC)**. In this way, in tandem with social media and other recruitment, we will offer a culturally tailored intervention that this population can access at their convenience.

To assess the effectiveness of NWC to encourage urban AIAN young women to make and sustain healthy decisions related to alcohol use and sexual risk taking, we will conduct a randomized controlled trial.

III. Preliminary Studies/Progress Report:

Adapted AIY-C intervention content**.** AIY-C integrates tribal values with guidance about young women's sexual health along with core messages about alcohol use and effective contraception from the original CHOICES curriculum. Given its applicability and relevance for all young women regardless of alcohol use or sexual activity, AIY-C adds messages to support young women who may choose to abstain from sex. Given AIY-C's focus on young women, messages about alcohol convey that no safe level of drinking exists for those under 21. In Table 3 we outline the AIY-C components (CHOICES core components) and their cultural, developmental, and universal adaptations that the CBPR methodology produced. We worked closely with our advisory board of cultural and scientific experts to translate AIY-C to an mHealth format.

Table 3. AIY-C Selected components and adaptations

	AIY-C Components	Cultural/ Developmental/Universal Adaptations
Session 1	**Introduction**: What is it? How does it work? How does it help?	Relevance for young Native women, simplified language, scope of intervention broadened
	Reflection on 7 Teachings of Anishinaabe: Love, honesty, respect, kindness, humility, bravery, wisdom	AIY-C specific cultural teachings emphasizing wellness and balance; reflections on presence/absence/relevance of teachings
	Reflection on Medicine Wheel: Spiritual (North); Emotional (South), Physical (East), Mental (West)	AIY-C cultural heuristic emphasizing spiritual wholeness and balance; participants asked to reflect on alcohol's impact in key spiritual realms.
	Important Facts for Young Women: Safer sex, birth control, and pregnancy	Simplified language, universal language about sex, condom use, safer sex practices, STD risks
	Daily Journaling: Instructions.	Online for security. added questions: offered drink/sex, safer sex practices, thoughts/feelings
Session 2	**Personal Feedback**: Alcohol risk, cost, and calories	Review of offers to drink, alcohol risk assessment based on any drinking
	Personal Feedback: Birth control & safer sex, pregnancy, AEP, and STD Risk	Review of offers to have sex, STD risk assessment
	Personal Goals: Alcohol	Continuing NOT to drink as goal for those who do not drink; cultural supports for goal attainment
	Change Ruler: Birth control & Safer sex	Added safer sex practices
	Personal Goals: Birth control & Safer sex	*Continue NOT to have sex* a goal for not sexually active, safer sex goals, cultural supports for goals
Optional: Contraceptive Visit with Healthcare Provider (recommended after session 2)		
Session 3	**Birth Control Visit Review**, if applicable	Core CHOICES exercise
	Discuss changes in alcohol use, birth control use, and safer sex practices	Continuing not to drink/have sex as goals; safer sex practices
	Review goals and change plans	Continuing not to drink/have sex as goals; safer sex practices
Session 4	**Discuss changes** in alcohol use, birth control use, and safer sex practices	Continuing not to drink/have sex as goals; safer sex practices
	Final Goals: Birth Control & Safer Sex	Continuing NOT to have sex as goal for those not sexually active, safer sex goals, cultural supports for goal attainment
	My AIY-C Story Review	Core CHOICES exercise

Formative research (accomplished under protocol #18-0574)

In-depth interviews. We conducted 32 in-depth interviews (IDIs) to inform both methodology and content in

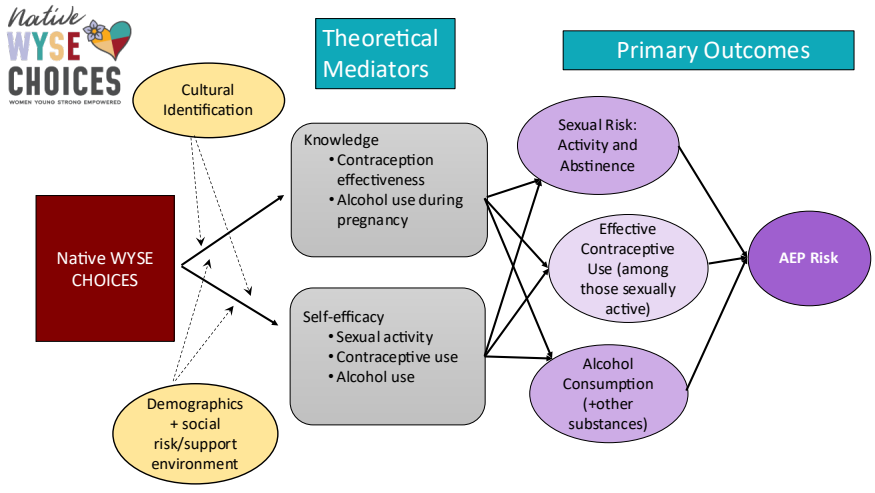
our mobile health adaptation of NWC. We recruited AIAN young women nationally through carefully designed social media advertisements. We conducted three iterative rounds of IDIs to hone ideas and preferences on platform use, types of technology engagement, and content on alcohol, contraception, and culture. Findings from these IDIs were critical to ensuring relevance and acceptance of our intervention for young Native women. The data revealed that an intervention that addresses alcohol and contraceptive use rather than as AEP prevention was preferred. Participants suggested that cultural symbols such as medicine wheel, Sun and Moon and Sacred Mountains should be considered when conveying information about AEP. Participants also mentioned traditional ceremonies and the arts could be used to highlight the message of wellbeing and health. Most participants indicated that they would be able to relate to most of the alcohol mentioned in the CHOICES curriculum, excluding wine. In regards to conveying information about alcohol and contraceptive use most of the participants stated they preferred the quizzes with visuals over the ones without since those were more engaging. All participants felt the online journaling would be received well and recommended its use.

NWC mobile app. Findings from our IDIs informed the content to include in our mobile app. The app contains six sessions; these sessions include content on alcohol use, birth control and safer sex, and facts of AEP and FASD. The app also includes culturally relevant imagery such as the medicine wheel and connections across generation. Motivational interview elements of tone, assessment of personal risk, decisional balance exercises, and goal setting are also included. Participant knowledge of alcohol and birth control methods, including condoms, is assessed through the app. See Appendix A for a selection of images from the App.

IV. Research Methods

We propose using an RCT with a baseline sample n=700 urban AIAN young women aged 16 to 20 to evaluate NWC for its effectiveness in AEP prevention.

Figure 1. NWC Conceptual Model



Outcome Measure(s): Figure 1 depicts the measures used the assess the impact of NWC. These measures include demographics, such as age, education level, and income, measures of social risk; environmental support; and cultural identity. Theoretical mediators include knowledge of effective contraception and alcohol use during pregnancy and self-efficacy related to sexual activity and contraceptive and alcohol use. Our primary outcomes include sexual activity, abstinence, effective contraceptive use, and alcohol and other substance consumption—AEP protective and risk factors. With the pandemic, we have also added measures on experiences with COVID-19 to capture appropriate context.

B. Description of Population to be Enrolled:

Our population of focus will be AIAN women, ages 16-20, who live in urban areas (50,000 people or more), and who are not pregnant or breastfeeding at the time of enrollment. Currently, we are awaiting approval from the Southcentral Foundation of Alaska, a research review IRB for Alaska Native healthcare in

Anchorage (the only urban area in Alaska with population > 50,000). Until we receive this approval, we will exclude residents from Alaska.

C. Study Design and Research Methods

Screening
We will screen each participant for eligibility before enrolling them into the study. The questions are administered by Qualtrics (accessed by URL from a recruitment flyer or social media post). These questions include items not on the recruitment advertisements as a way to screen out frauds - those who try to game the screening criteria to collect compensation. Each potential participant will provide answers to the following questions within the Qualtrics screening survey:
1. What is your assigned sex at birth?
(if "other": What gender do you identify as?)
2. How old are you in years?
3. What is your race/ethnicity? Please select all that apply.
4. Are you currently pregnant?
5. Are you currently breastfeeding?
6. Do you currently live on an American Indian reservation or in an Alaska Native village?
7. What city do you live in?
9. In what state do you currently reside?
To be eligible for Native WYSE CHOICES, they must be: Biologically female, 16-20 years old, American Indian or Alaska Native (may identify with other races), not pregnant or breastfeeding, not living on a reservation, and living in an urban area (population >= 50,000). Because we do not yet have approval from the Native Alaska organization with oversight in Anchorage (the only Alaskan city to meet population size requirements), we will exclude Alaskan residents. Once a participant meets all eligibility criteria in the first part of the screener questions, they will be asked to enter their first name, cell phone number, email address, a second email address (optional) and birth month and year. The completed eligibility data are reviewed by a team member who will also check city population size. If all appropriate eligibility data are selected and the city named has a population of 50,000 or more, the participant is identified as "tentatively eligible." At this point, a member of the research team will reach out up to 4 times to confirm eligibility through a phone call or a text (for those youth uncomfortable with a phone call) by asking the respondent to confirm their name, birth month and year, city and state, and email address. This confirmation is short but provides an important opportunity to screen out frauds.

Obtaining informed consent**.** Preliminary conversations with our university IRB have confirmed that, like our other projects, this project will also likely qualify for a waiver of parental consent for minors, based on minor participants' ages (16-17) and the sensitive nature of the topic wherein participants may incur risk if participation is disclosed to a parent. Participants will be asked to consent to project participation as adults. During the consent process, participants can contact the project team with any questions or concerns. The consent process will describe the 2 arms of the study and let them know that after they complete the baseline survey, their assignment to a particular arm will be random. After reading the consent, participants will be asked follow-up questions to verify comprehension.

Consent
Once the identity is confirmed, the respondent will be sent a unique link (exclusive to that participant) to the consent. Once they have read the consent (which they can scroll up or down for review) they will be asked to electronically sign the form in a signature box if they consent. The participant can take as long as they would like to review the consent or discuss with others. They are able to click on the consent link at a later time if they want to think about their participation. If they consent, we will ask them to write or type their name indicating they agree to an electronic signature and that they consent. We include as a part of the consent that they can take a screenshot or video screen recording of the signed consent form for their

records, or they can request a copy be sent to them by email or USPS. We will ask them for a mailing address (optional, unless they request a USPS-delivered signed consent), and social media handles. These latter contact data are helpful as backup for multiple options to contact participants over the course of the 12 month study should cell number and email no longer work. If they do not consent, they will not be able to participate in the study.
The contact information and consenting signature will be stored in a secured database separate from survey data, and accessible only by project staff.

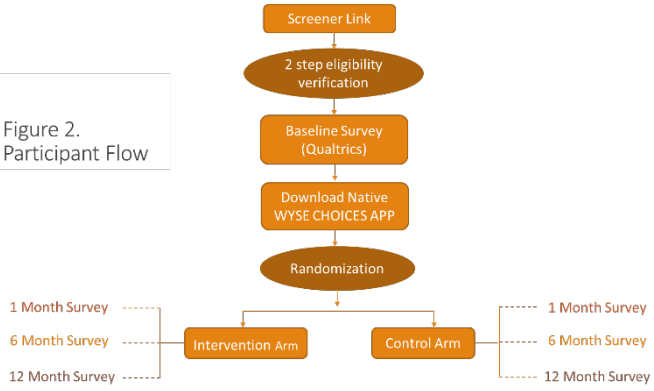


Figure 2. Participant Flow

Assignment methods**.** Once recruited and consented, eligible AIAN young women will complete the baseline survey, and asked to download the NWC app. Once they have done this, the app will immediately electronically randomize the participant to either NWC or the comparison condition. That is, the two interventions are accessed through the same app – once the participant registers to download the app, she will be randomly assigned one arm or the other. Figure 2 shows participant flow through the proposed project.

Progression of NWC**.** Because of the electronic mode of administration, participants can progress through each session at their own pace. We will provide electronic reminders if timely progression of the app has not been demonstrated.

Counterfactual intervention. We will provide young women in the comparison arm an engaging online intervention which is independent of our outcomes of interest. The focus will be on life skills including social media safety, budgeting, resume building, and career development.

Participant tracking methods**.** Participant tracking involves two sets of processes. The first is through screening and enrollment and then survey completion. The second centers on downloading the app and progression through the other surveys in a timely way. 1) On the screening survey, once participants are considered eligible, they will be required to provide their name, phone number, birth month and year, email address, and a second email address (optional). A second email is useful to keep in contact participants in case a primary email is closed. Once a participant has been determined eligible and has read and signed the consent form, we also request mailing address and social media handles, again, useful contact information to track participants over time since at this young age, contact information can change frequently. 2) During the registration process for the app, participants use an email address to register (the registration email is the link to the survey data, to track which participants downloaded and engaged in the app). Through the intervention stage, progress in NWC will be tracked electronically. We will send reminders to young women who have not completed a survey in a timely way (we allow 2 weeks). We will follow up with personal texts, emails, phone calls, or private social media contacts provided, up to 4 times, as necessary.

Fidelity. Since intervention content will be administered electronically, we anticipate full fidelity. We expect full adherence, and we will be able to monitor closely progress towards this goal. However, we will track occurrences of technological challenges (e.g., lost devices, or navigational issues), or other unanticipated events with respect to the intervention content delivery.

Post-intervention follow-up retention plans**.** After the intervention, when surveys are months apart and risk of attrition is high, we have integrated additional retention plans. Every two months, we will offer a small

incentive (e.g., $10 gift card) to participants who confirm their contact information.

Throughout the project, we will use electronic data to monitor study participation. As data are accrued across the rolling sample, we will use electronic data to monitor sample intake, responses rates, and baseline equivalency.

RCT timing**.** Recruitment will begin PY3 (see "Timeline," below). We anticipate a rolling recruitment across 2 years. This roll-out will allow sampling strategy adjustment as needed.

Procedures/modes of data collection. Once IRB approvals are obtained, we will begin implementation. We will use the University's Qualtrics survey system, a HIPAA-compliant and secured software for research which can be optimized for smartphones or other devices. As noted above, eligible participants who provide consent will be sent a unique URL to complete a baseline survey. Through the tracking software, we will issue additional URLs for follow-up surveys at the appropriate time. Participants will be compensated $25 for baseline and the first post-intervention survey, increasing to $35, $40, and $50, respectively, for each of the 3 follow-up surveys. Participants will not be re-consented at each survey point; still, at each survey, participants will be reminded that participation is voluntary, and they can decline participation at any time.

Intervention and survey progression. After the baseline survey, participants will be asked to download the app using their email and a password, so we can track their registration and ultimately link app use with survey data (e.g., to check number of sessions responded engaged in). We will incentivize the app download with a small e-gift card ($10). Once registered, the app will randomize participants and they can immediately begin their first intervention sessions (NWC or counterfactual). Once participants have progressed through their respective programs, each will be given an additional small e-gift card ($10), and, 2 months later, a URL for the first posttest. Similarly, at 6 and 12 months after program completion, each will be sent URLs to complete a survey.

We will regularly monitor electronic reports of progress through the intervention (for NWC), and survey completion progress for follow-up (both arms). Survey data will be routinely checked by the Data Management team for any problems, inconsistencies, or missing data. They will routinely summarize response rates for each survey, and by arm. If response rates are low, or unbalanced by arm, Drs. Kaufman and Sarche will identify possible causes, their solutions, and quickly implement changes to rectify deficiencies.

D. Recruitment

The primary method of recruitment will be through multiple social media platforms. Specific recruitment activities will vary across the platforms, but will typically include posts to promote the program and study. We will also use seed recruitment, and encourage AIAN young women participants to invite their peers and family members to sign up for the program (i.e., chain referral, up to 3).

We will ask the participants enrolled in the study to follow our page on Instagram, share our recruitment post on their Instagram page and tag us in that post. This strategy will amplify our recruitment post among their followers (who may be similarly eligible) and encourage participation in our study (as the recruitment post will have come from a trusted source). This is completely voluntary and the recruitment post does not require participants to disclose any personal health information.

We will also recruit by posting flyers and information throughout locations including AIAN-serving youth facilities and college centers (if pandemic conditions allow for this). We also will disseminate recruitment flyers via listservs and email networks. Finally, if pandemic conditions allow, we will attend community events (e.g., powwows, health fairs), to invite potentially eligible women to enroll by giving them a

recruitment flyer with a link to the screener. Recruitment will continue until we have 700 participants enrolled.

E. Description, Risks and Justification of Procedures and Data Collection Tools:
Description Risks and justification:
As with any electronically based system, our electronic data could be hacked. Thus, potentially compromising confidentiality and privacy. However, we have a strong system in place to guard against such possibilities, including the use of University-sanctioned electronic data collection systems. Further, any data stored on university servers (in locked rooms) will be accessible only by password and usernames, and only by research staff. The justification for using this system is immense. It offers an innovative way to increase research participation by a vastly under-represented population, while also providing services that are culturally tailored to individuals who may not otherwise have access to such services.

F. Potential Scientific Problems:
The innovative aspects of this project necessitate some uncertainty. The proposed social media recruitment and mHealth intervention strategy for AEP have not been used with urban AIAN young women before, although similar approaches have been successful with other populations nationally and appear promising for adult AIAN women. We do not yet fully know the parameters for targeted recruitment of AIANs in urban areas or their engagement with electronically administered interventions, but this study will provide an important opportunity to understand them. Other more common caveats also apply. All measures will be self-reported without independent verification. Although we will strive for broad national representation and cultural diversity of AIAN young women, we cannot guarantee that. Our project is technologically based. While this provides great reach and accessibility, we do not yet know if the loss of direct human guidance will critically hamper outcomes for this population. We also know that not all urban AIAN young women have access to technology.

G. Data Analysis Plan:
All intervention effectiveness analyses will be based on an intention-to-treat approach. For continuous outcomes (frequency/quantity indices of alcohol) and mediational outcomes (alcohol and contraceptive self-efficacy), we will estimate a series of latent growth curve models (LGCM) in Mplus to assess the effect of intervention exposure on the trajectories of those outcomes over the study period.[165] The “normative” trajectory of an outcome is estimated for the comparison group before estimating the same trajectory among those exposed to the intervention. The third step estimates the degree to which the normative growth trajectory is altered by intervention exposure. On the fourth and final step, the interaction between intervention exposure and pre-intervention status on the outcome is tested. This permits an assessment of the differential effectiveness of the intervention as a function of baseline levels of the outcome variable.

For dichotomous outcomes, Latent Markov Models (LMM) will be used to evaluate transitions between behavioral states (e.g., sexually active to abstinent) throughout follow-up.[166,167] Intervention status is modeled as a time-invariant covariate; its effect on the transition probabilities is estimated freely. Effectiveness is indicated if those in the intervention have significantly lower probabilities than the controls of transitioning out of the abstinence state and significantly higher probabilities of transitioning out of the sexually active state. LMM may also reveal that early sexual experience among control group participants predicts sexual activity across the course of the study but that this relationship is interrupted among intervention participants. Other moderators of intervention effectiveness will also be explored (e.g., enculturation).

H. Summarize Knowledge to be Gained:
If successful, the overall study will generate evidence of NWC effectiveness for AEP prevention by demonstrating: 1) increased effective contraceptive use or sexual abstinence among urban AIAN young

women; 2) decreased or eliminated alcohol use in urban AIAN young women who drink; and 3) maintained abstinence (sexual or alcohol) among those who have this as their goal. If successful, the project will also provide vital information about the feasibility of mHealth interventions for reaching urban AIAN young women or other urban AIAN populations who might otherwise not access health information or interventions

I. Supplement Award

At the end of July, 2021, we were awarded NIAA supplemental funds to the current grant to conduct qualitative interviews with participants enrolling in our ongoing social/behavioral RCT. The supplement funds us to conduct phone or video (i.e., Zoom or similar) interviews with a sub-sample of enrolled participants about the impact of COVID on behaviors related to alcohol exposed pregnancies. We will not be conducting the interviews at this time; instead, with this consent change requested in this amendment, we aim to grow the pool of potential respondents immediately.

J. Background and Specific Aim

The devastating impact of COVID-19 on American Indian and Alaska Native (AIAN) communities has been well-documented,[168-170] with substantial focus on reservation or other tribal land-based communities, often rural and remote.[171,172] However, more than 72% of AIANs reside in urban settings,[173] a majority of the racial group, but a small fraction – often less than 1% - of most urban communities. Many urban AIANs are tightly connected to tribal communities and cultural practices,[174] commonly traveling between urban areas and tribal reservation communities to participate in family events or important cultural celebrations and ceremonies. However, urban AIANs are likely to experience different cultural, social, and economic impacts of the pandemic compared to AIANs living in tribal reservation settings[175]– and those differences may be critical to alcohol-exposed pregnancy (AEP) risk. Early pandemic-related data in the general population indicate increased alcohol use by youth[176,177] and decreased access to effective contraception among women.[178] This combination is likely to increase AEP risk, and for urban AIAN young women – often with limited local resources – that risk may be especially elevated. Yet, as research moves quickly to monitor pandemic-related risk among the most vulnerable, this small demographic is rarely considered.[179] We know little about the impact of COVID-19, the changes in alcohol use, sexual activity, or contraceptive use to assess AEP risk among young urban Native women. Similarly, we know little about the ways in which they find resilience and strength in their communities to overcome pandemic hardships or to engage in the promise of vaccines.

We will conduct in-depth interviews with participants purposively selected based on baseline survey responses. To maximize insights in the diversity of experience of the pandemic and gain timely, in-the-moment, insights, we will recruit and interview young women from our RCT sample (n=32) over 2 years. We will also interview selected participants (n=8) at regular intervals over 2 years to capture their experiences longitudinally as circumstances of the pandemic shift. With this qualitative design – i.e. cross-sectional insights complemented by a longitudinal view of urban AIAN young women's journey through the changing circumstances – we will be able to integrate our statistical findings within an agile interpretive frame. Across two years of data collection and analysis, we propose the following supplemental aims to the parent grant:

Supp SA: Contextualize patterns of drinking, sexual activity, and contraceptive use among urban AIAN young women during the evolving pandemic through cross-sectional and longitudinal in-depth interviews.

Completion of the supplemental aim will provide critical insights to inform policies and interventions to address AEP risk in this vulnerable yet resilient population under evolving pandemic conditions – including an unfolding recovery from the pandemic. Incorporating this work into a randomized trial will amplify evidence of vulnerability and resilience, and provide context for the efficacy of the culturally tailored intervention we are testing. As repercussions of the pandemic persist, we will need more than just behavioral assessments; appropriate strategies to prevent AEP will require contextual and pandemic-specific parameters.

K. Supplement Study Design and Research Methods

We will conduct both longitudinal and cross-sectional In-Depth Interviews (IDIs) to capture the depth and breadth of urban AIAN young women's behavior, experience and perceptions during the next phases of the pandemic. Longitudinal IDIs will be conducted with the same 8 participants every 6 months over a 24-month period (i.e. 4 interviews per participant) to allow for an in-depth exploration of pandemic response and recovery and implications for AEP risk. While these longitudinal IDIs will provide a depth of understanding, cross-sectional interviews with different participants each time will increase the breadth of understanding. Cross-sectional IDIs will therefore be conducted with 8 different participants every 6 months over a 24-month period for a total of 32 unique interviews (i.e. 8 interviews per period).

IDI participants will be invited to reflect on questions about the family, peer, and/or partner influence on, as well as the broader environmental context of, their drinking, sexual activity and contraceptive access and use. Participants will be asked how they perceived changes in their personal choices in these areas over the course of the pandemic, including pandemic conditions at the time of the interview. In addition, participants will also be asked about their community's and their own pandemic-related safety practices (mask wearing, social distancing, vaccination interest), and how the pandemic has shaped their employment and educational opportunities or aspirations. Finally, participants will be invited to talk about resources, including cultural ones, that were instrumental in supporting them through the pandemic.

The IDIs will last approximately 1 hour. All the interviews will be conducted over phone or video (over Zoom) depending on the technological bandwidth of participants and will be recorded.
The recording will be safely stored in the University's password protected server. Only Native WYSE CHOICES project staff will have access to the audio file. The audio recordings will be destroyed on a timeline in accordance with NIH policy on data destruction.

L. Supplement Recruitment

IDI participants will be sampled purposively from our pool of existing RCT participants. Through this amendment our consent form will allow participants to endorse interest in an IDI; for those endorsing interest, we will invite participants based on their baseline answers to questions on drinking, sexual activity and contraceptive use, but also other experiences in the pandemic – for example, housing, work, or educational experience, vaccine beliefs and experiences, or personal experience of the disease.

Our project staff will send out a Qualtrics survey asking interested participants if they would like to participate in the IDIs. Participants will be randomly selected and will be given an option to either participate in cross-sectional or longitudinal IDIs. This process will continue until we meet the threshold of 8 participants for each format of IDIs. Once this process is completed, our project staff will set up time for the IDIs. Participants will have an option for conducting interviews over telephone or over zoom depending on their technological bandwidth. The IDIs will be audio recorded. At the end of the interview, participants in the longitudinal interviews will be asked to set up a time/date for the next interview. Cross-sectional IDI participants will be thanked for their participation. Additionally, we will resume the same recruitment process for cross-sectional IDIs every 6 months for next 24 months. Participants will receive $40 in amazon gift card at the completion of each interview.

M. Supplement Data Analysis
IDI recordings will be deidentified, transcribed, and analyzed using NVivo. Two coders familiar with the study will code the data to maintain reliability and methodological coherence of the qualitative data. We will use a combination of inductive and deductive coding approaches. The primary coder will begin by carefully analyzing the transcripts through the process of inductive or open coding. This process allows the primary coder to code data, categorize the codes, and reorganize the categories thematically. Next, the secondary coder will code the transcripts utilizing the major themes. In addition, the secondary coder will also look for additional emergent themes. To ensure the reliability of the findings of the study, both coders will discuss emergent themes with the study lead. Kappa scores for each theme will be calculated to assess interrater reliability.

N. Supplement Description, Risks and Justification of Procedures and Data Collection Tools:
Description Risks and justification:
As with any electronically based system, our electronic data could be hacked. Thus, potentially compromising confidentiality and privacy. However, we have a strong system in place to guard against such possibilities, including the use of University-sanctioned electronic data collection systems. Further, any data stored on university servers (in locked rooms) will be accessible only by password and usernames, and only by research staff. The justification for using this system is immense. It offers an innovative way to increase research participation by a vastly under-represented population, while also providing services that are culturally tailored to individuals who may not otherwise have access to such services.

O. Supplement Potential Scientific Problem
For the IDIs, we are drawing participants from the existing pool of RCT participants. While the IDIs focus on participants who are at-risk for AEP, the RCT includes participants who are not at-risk for AEP. Therefore, it is possible to not have a sufficient number of participants who are at-risk for AEP in our pool of RCT participants limiting our chance of adequately recruiting enough participants for the IDIs.

P. Supplement Summarize Knowledge to be Gained:
If successful, the supplement will provide us with a greater contextual understanding around patterns of drinking, sexual activity and contraceptive use among urban AIAN young women during the evolving COVID-19 pandemic.

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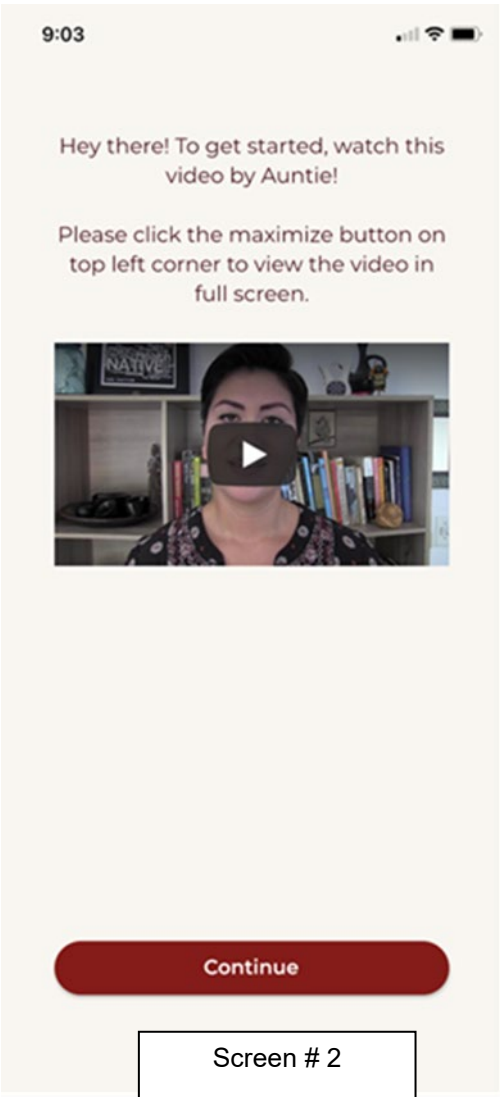
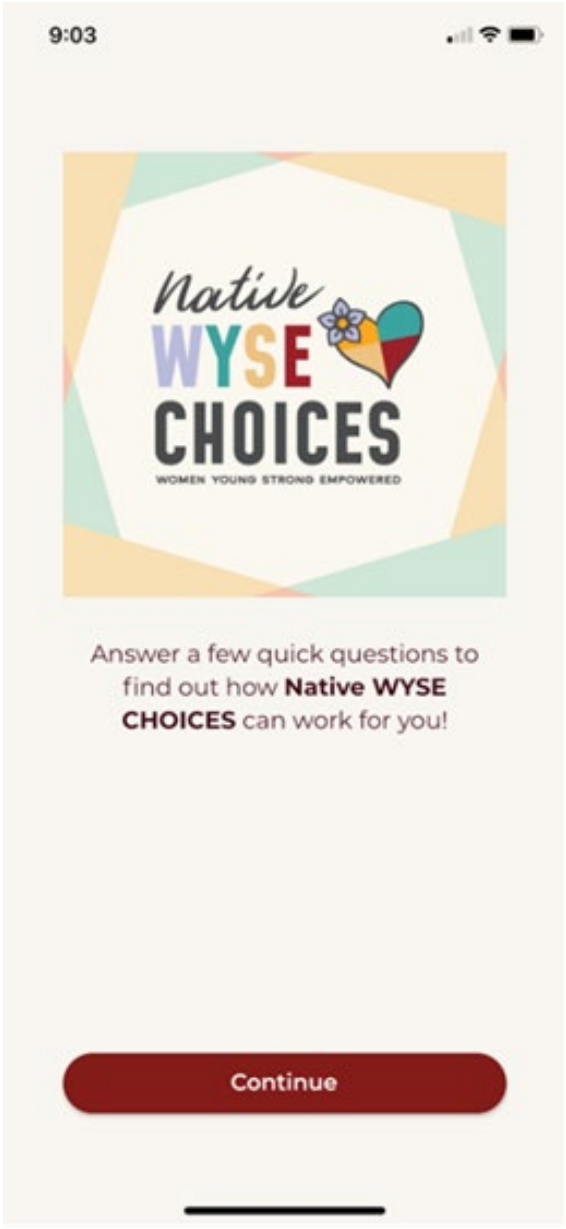
Appendix A: Screenshots of the Native WYSE CHOICES app, Welcome Session (intervention arm)

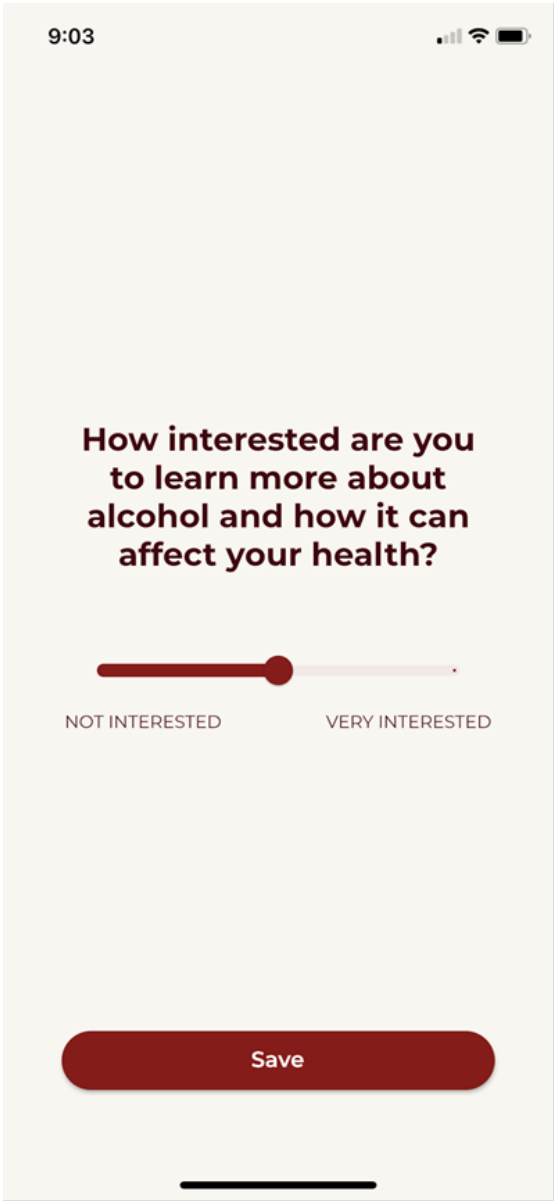
Screen # 1



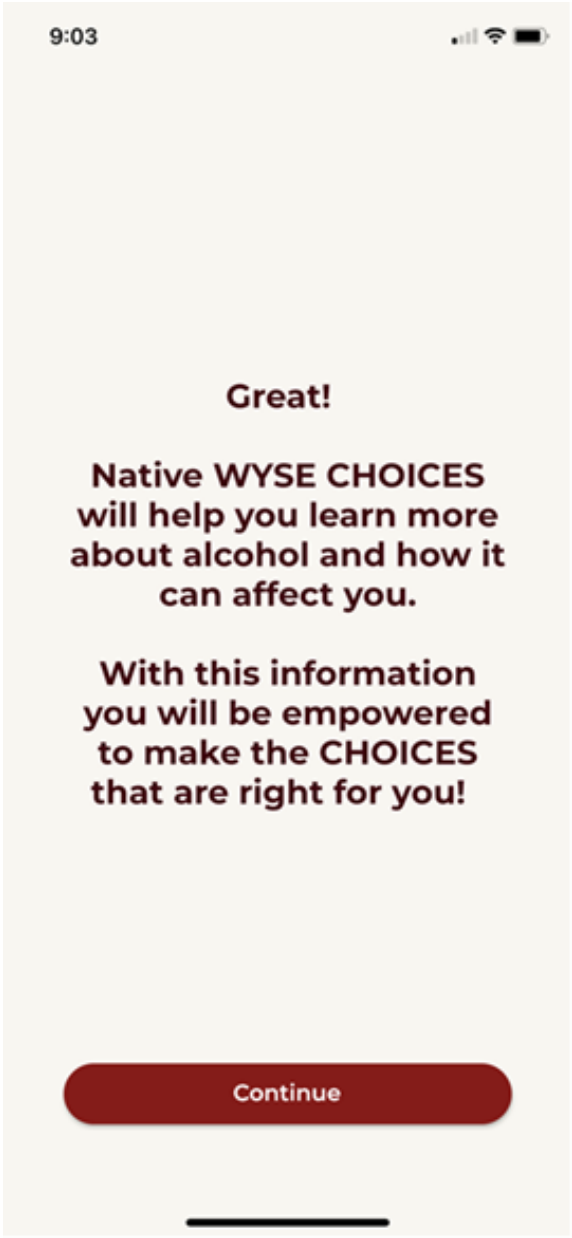
Screen # 2



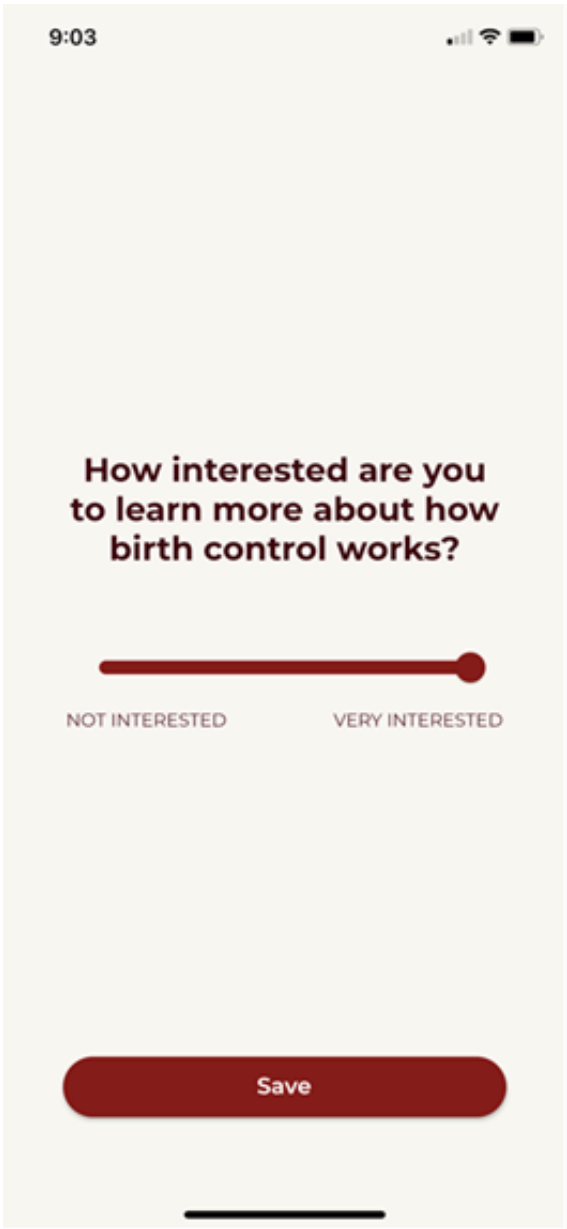
Screen # 3



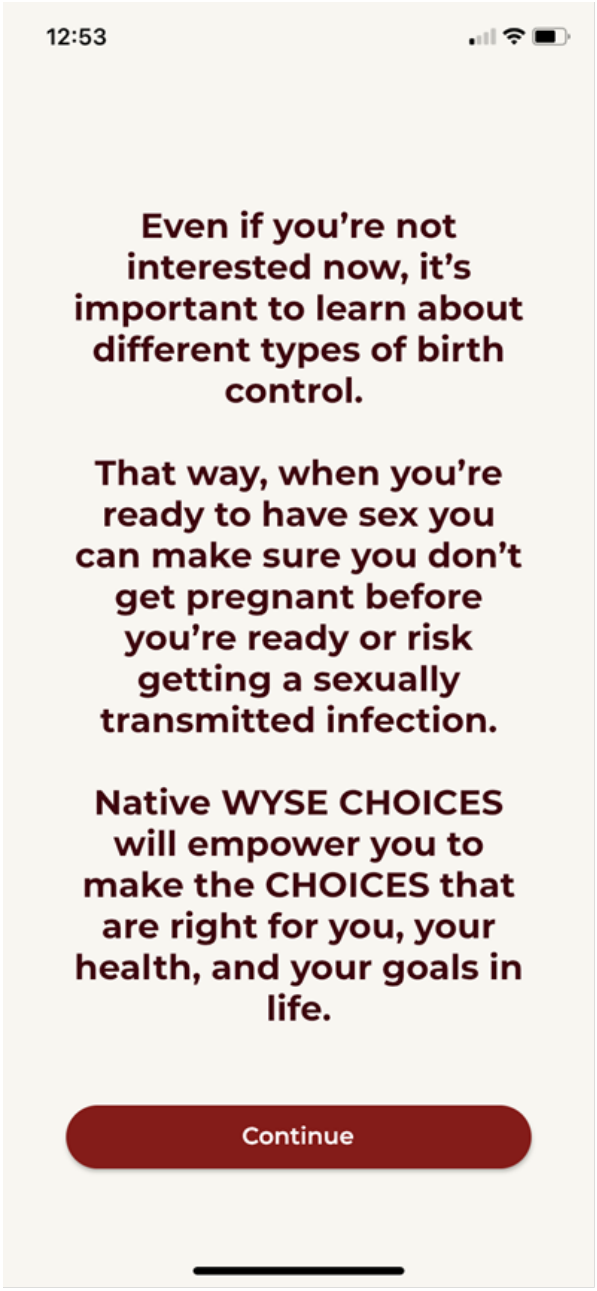
Screen # 4



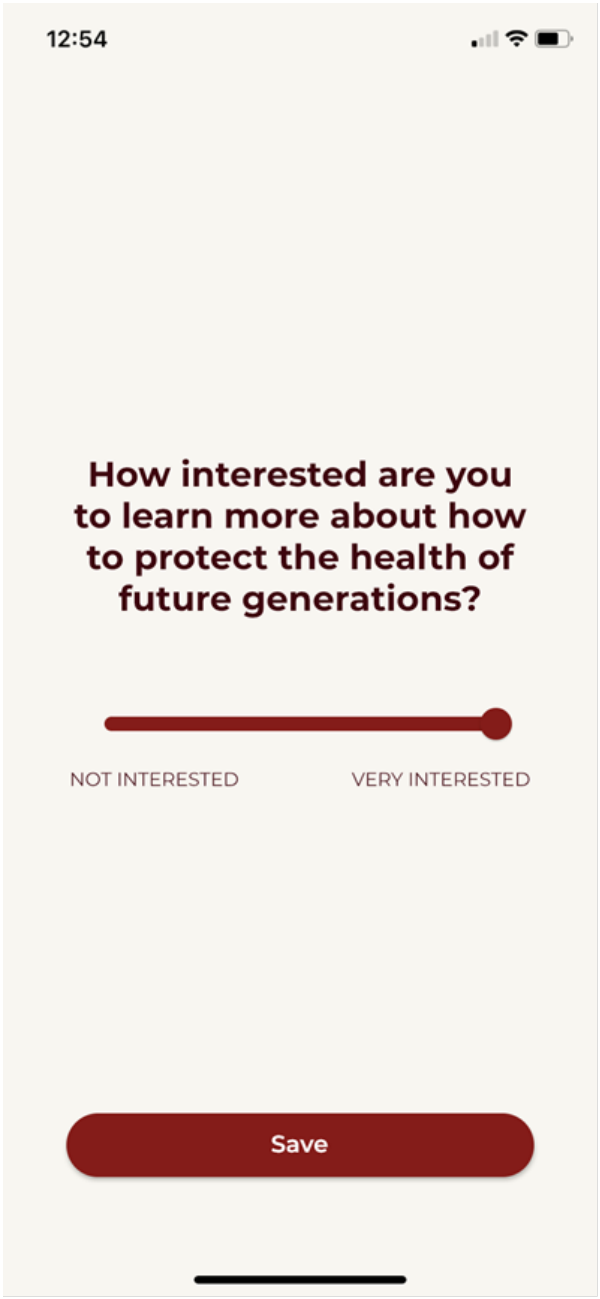
Screen # 5



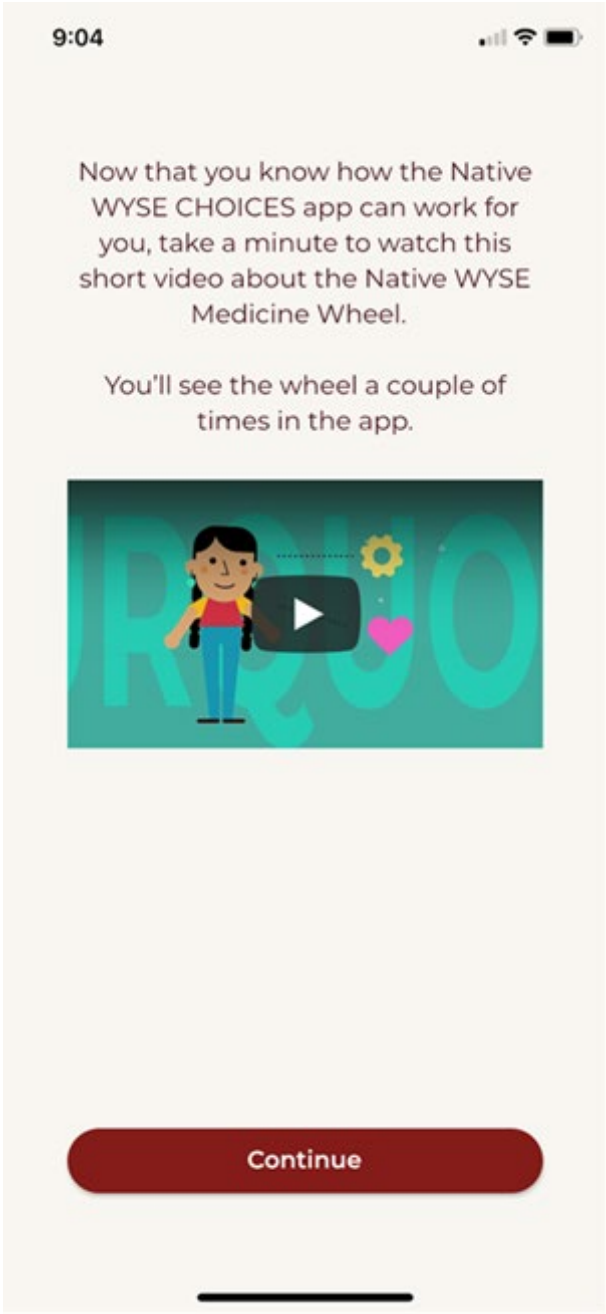
Screen # 6



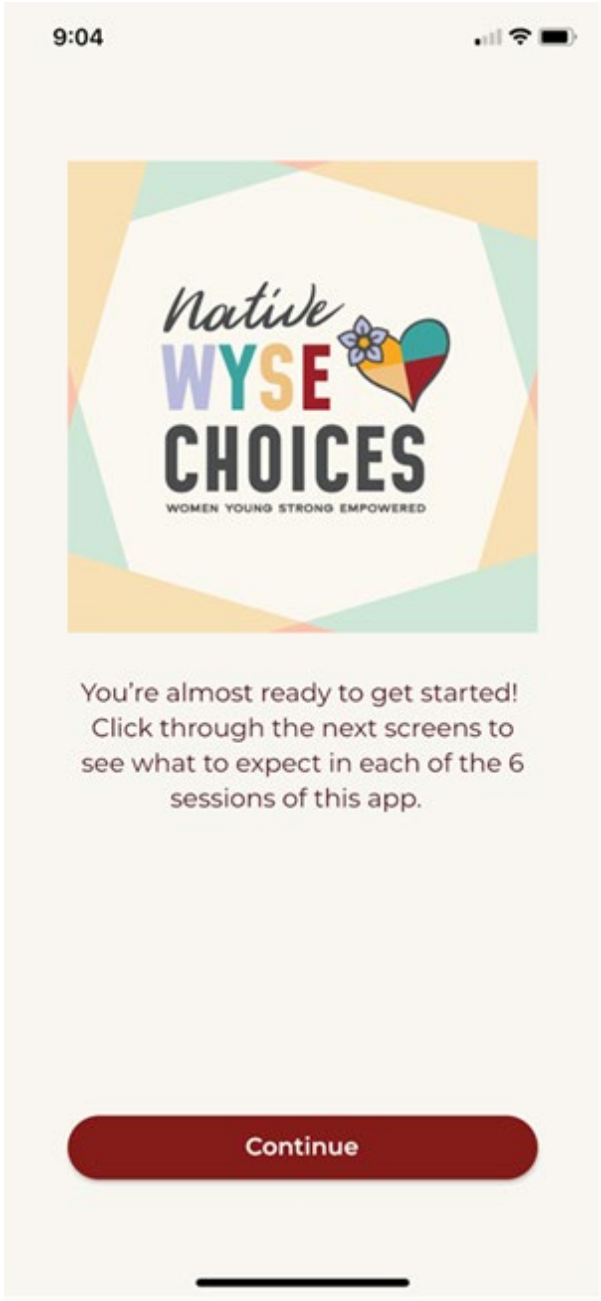
Screen # 7



Screen # 8



Screen # 9



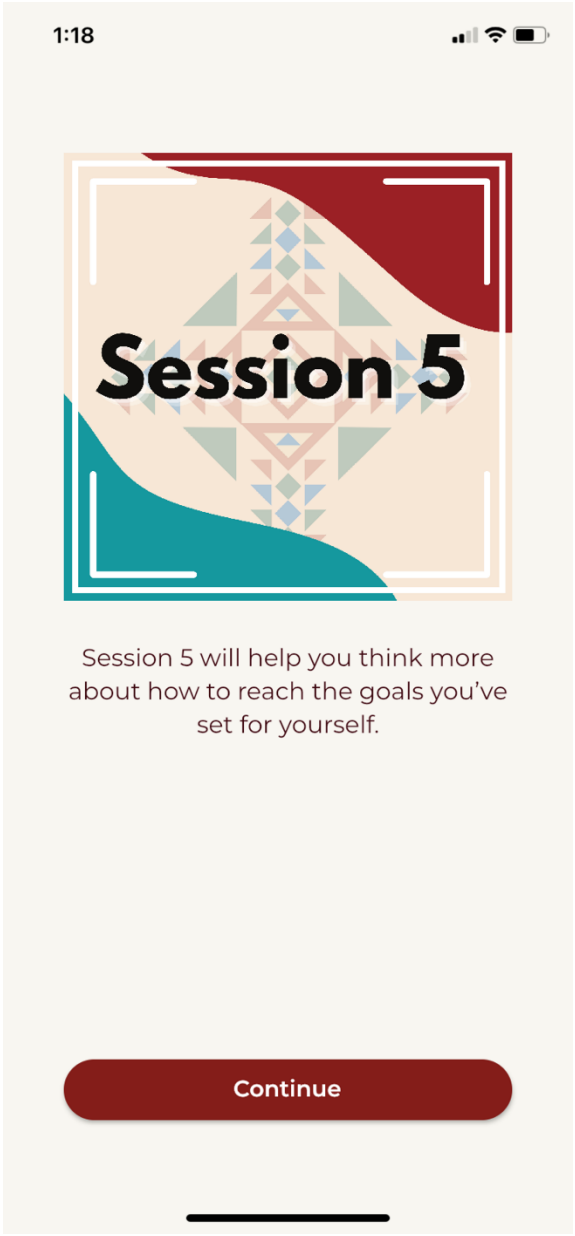
Screen # 10

Screen # 11

Screen # 12

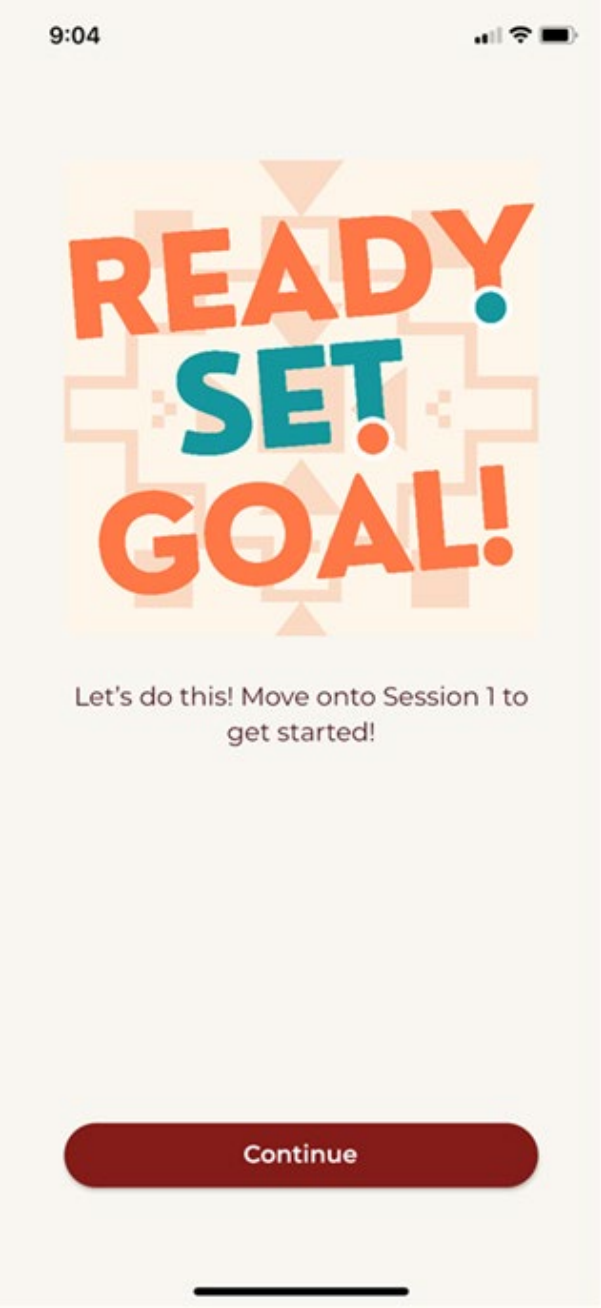
Screen # 13

Screen # 14



Screen # 15

Screen # 16


9:04
READY
SET
GOAL!
Let's do this! Move onto Session 1 to get started!
Continue

Screen # 17