The Weaving Healthy Families Program

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Study aim, background, and design

Alcohol and other drug (AOD) abuse and violence in families are co-occurring risk factors [1-3] *for cardiovascular disease (CVD), diabetes, and other chronic diseases* [4, 5]*–all health disparities of Louisiana residents*. These factors also drive health disparities and mortality among Native Americans (NA).[6-10] Since data on social, physical, and mental health disparities have been recorded, NAs tend to experience the most severe health disparities of any U.S. ethnic minority.[1,11-14] According to the 2015 National Health Interview Survey, NAs tend to experience poorer physical health than all other racial groups.[15] In fact, the number of both physically and mentally unhealthy days experienced by NAs approached twice that of non-Hispanic Whites (1.8 and 1.7 times, respectively).[16] *Despite the fact that there are 4 federally recognized and 10 state-recognized NA tribes in Louisiana who experience severe health disparities, they are among the most invisible and understudied regional groups*. Alcohol misuse is one of the largest contributing factors to increased mortality among NAs.[6,7] *AOD* misuse *is associated with suicide, intimate partner violence (IPV), unintentional injuries, CVD, cancer, and diabetes*[5]*,* the latter four being the top causes of death among NAs who experience health disparities across all of these problems.[17] In fact, the rate of unintentional injuries is 2.5 times higher and the rate of diabetes is 3 times higher for NAs than for the general U.S. populations.[17] Alarmingly, violence affects more than four in five NA women (84.3%) and men (81.6%) in their lifetime, with over one-third of NA women (39.8%) and men (34.6%) experiencing violence in the past year.[18] Rates of intimate partner violence (IPV) are 1.7 times higher for women,[18] and rates of child maltreatment are 1.5 times higher for NAs compared with whites.[3] Family approaches to AOD abuse have effect sizes between 2-9 times higher than child-only approaches.[19] Nonetheless, *there have been few NA culturally based and family-focused interventions that enhance diet and well-being (i.e., physical and mental health) and that prevent and reduce AOD abuse and violence in families.*[20-22] Given *the gap* in culturally relevant programs to prevent AOD abuse and violence in families, there is a *critical need* to create interventions that address AOD abuse and violent behavior while promoting health and well-being. Programs that fail to integrate culturally relevant components and the co-occurring problems of AOD abuse and violence ignore the driving forces for NA health disparities and may actually cause harm.[20-22]

The *long-term goal* of this research is to promote health and well-being while reducing AOD abuse and violence in NA families by developing culturally relevant interventions. The *overall objective* is to identify culturally specific protective factors related to diet and well-being to begin to develop the culturally adapted intervention through community-based infrastructures. As stated by the National Institutes of Health (NIH), “Mobile health (mHealth) provides unprecedented opportunities to measure dynamic changes in health state and the key physical, biological, behavioral, social, and environmental factors that contribute to health and disease risk”.[23] This intervention will include a mhealth component developed in collaboration with Tribal members and a community advisory board (CAB) as part of the community based participatory research methodology (CBPR) Our *central hypothesis* is that Tribal members’ perspectives on healthy foods and traditional Tribal diets will inform the nutritional aspects of the intervention, in a culturally relevant way. This project builds upon the principle investigator’s (PI) *9 years of preliminary research with NA tribes in Louisiana and Mississippi*. *The proposed research provides the integral work to develop the first intervention with a mhealth component that reduces AOD abuse and violence in families while promoting resilience, health, and well-being.*

Aim/Phase 1: Identify culturally specific protective factors related to diet (i.e., physical, psychological, social, and spiritual domains). Using ethnographic interviews with key informants and Tribal community members, our *working hypothesis* is that such informants will provide the culturally specific information related to diet and well-being needed to inform the culturally adapted intervention and the mhealth component.

Aim/Phase 2: Create a culturally adapted, family-focused intervention that promotes resilience, health, and well-being to reduce AOD abuse and violence. We will employ CBPR and Whitbeck's (2006) cultural adaptation process to develop the intervention and the mhealth component, infusing: preliminary research, an intervention, and a cultural overlay.

Aim/Phase 3 Test a model of community sustainability by training CHRs to implement the intervention. We will use the CFIR to test our *working hypothesis* that Community Health Representatives (CHRs) can be trained effectively to implement the intervention, a model for sustainable health.

Aim/Phase 4a Pilot test the effectiveness of the intervention on AOD and violence reduction and resilience enhancement. Using a pre-test/post-test design, we will test our *working hypothesis* that the intervention will reduce participant AOD misuse and violence, postpone youth AOD use, and enhance resilience and well-being.

Aim/Phase 4b Pilot test the effectiveness of the intervention on AOD and violence reduction and resilience enhancement. Using a longitudinal design, we will test our *working hypothesis* that the intervention will reduce participant AOD misuse and violence, postpone youth AOD use, and enhance resilience and well-being.

All qualitative data collected for this study will be analyzed using pragmatic horizon analysis, the analysis for the ethnographic method that has been used in all preliminary research by the PI, which will be infused into the adapted intervention and mhealth component. The method and analysis is the exact same that has been approved in the past study (closed for enrollment, open for data analysis only): 527491-OTH, "Bolstering Resilience Among American Indian/Alaska Native (AI/AN) Families"

1. Subject Population

No children or vulnerable populations will be recruited for Aim 1 or Aim 2. All will be adults.

Aim/Phase 1: Qualitative sampling is primarily based on *purposeful sampling,* by determining who is best able to answer research questions, and at what point the data reaches *saturation*, when no new meaningful information is attained. [98] Given the extensive qualitative data collected in preliminary research, key informant and community interviews with 10-20 MBCI participants and 10-20 Montana participants will be sufficient. The inclusion criteria will be adult community members and professionals with expertise in the health practices of the MBCI and similar Southeastern tribes along with tribes in Montana will be recruited for such expertise. For recruitment, The PI has developed relationships with MBCI and Montana tribes for over 9 years and will use her community knowledge and cultural liaisons to recruit the 10-20 participants from each community. Because she has conducted research with over 300 MBCI participants in the past and has longstanding relationships with Montana tribes (over 10 years), no additional recruitment activities will be needed beyond such contacts and word-of-mouth.

Aim 2/Phase: Following Newman et al.'s best practices for CABs in CBPR,[108] the inclusion criteria for CAB members will be (a) familiarity and knowledge of mental health and substance abuse services; and/or (b) culturally specific knowledge of MBCI and Montana tribal traditions and practices. The makeup of the CAB will include members from the following core constituencies: (a) Behavioral health,

(b) Choctaw Health Services program, (c) the Department of Family and Community services, (d) Family violence services, (e) a member of a school and/or after-school program, (f) an elder and expert on cultural knowledge and traditions, (g) Montana Urban Indian Health Center, and (h) health and nutrition professionals. We will also include members from the different MBCI and Montana communities who work in relevant fields. CAB members will review and sign a document describing the expectations and roles of a CAB member prior to solidifying their commitment in the summer of 2018.[108] Based on research recommendations focusing on CAB make-up and group processes and dynamics, 6-15 CAB members will participate.[108] *Prior to the start of this grant, potential CAB members will attend the original White Bison 3-day training as part of the screening and training process, for exposure to the intervention and the overlay components and to assess their interest and commitment.* The CAB meetings will be co-facilitated by the PI and a Tribal member.[108] Participants who have expressed interest based on past research and who are attending the White Bison Training session July 25th-27th, 2018 will make-up the CAB; because this number is over 20 people, and the number for the CAB will be 6-15. No additional recruitment efforts will be needed.

Aim 3/Phase: Up to 50 CHRs will primarily be composed of MBCI, Montana tribal members, or non-tribal professionals working in relevant health settings (e.g., behavioral health, social services, and children and families). CHRs will be 18 years of age or older and have experience and/or interest in working with MBCI/Montana tribal children and families on social issues. Lead CHRs have a formal higher education, including either a substance abuse counselor certification and/or an associate's degree, bachelor's degree, or master's level education in social work, psychology, health, child development, mental health, or other human services related field. Persons without a formal higher education but who have extensive experience working with children and families are also eligible as Lead CHRs.

Aim 4A-B/Phase: Up to 200 targeted MBCI and Montana families will include at least one child and at least one parent/caregiver who is a member of the MBCI or Montana tribe. All parents/caregivers/family members. The research will include children, who are a vulnerable population. Their involvement is necessary, given this family-focused intervention is targeted toward improving the outcomes of children and their family members. This resilience-focused program capitalizes on strengths, is psychoeducational, and positively focused, and therefore, is not involving greater than minimal risk. Any risk is offset by the evidence that this program will improve child and family functioning, as documented by preliminary research of this intervention with other communities. Assent will be gained where possible (ages 12 and above). This research is expected to glean important information on improving the well-being of children and families while reducing problems and use of AOD abuse, and violence or conflict within families.

Assignment to study group

CAB and CHR Assignment: CAB and CHR members will be assigned to respective study groups based on inclusion/eligibility criteria. If they qualify for both CAB and CHR involvement, they will are eligible to participate on both based on their background and time availability.

Family Assignment: Participants will be assigned to clusters of 5-15 families based on the community in which they reside.

2. Procedure

Aims/Phases 1-3: Carspecken's (1996) five stage methodology, which was used in all referenced and approved preliminary research includes validity requirements for each stage of the research process, and is a highly rigorous approach (See Table 1). [97] The data collection and analysis processes are combined in an iterative process, and are thus integrated into this section.

Table 1. Validity Requirements by Stage of Research

Validity Requirements		Stage				
		1	2	3	4	5
1.	**Member Checks**	x	x	x	x	x
2.	**Peer Debriefing**	x	x	x	x	x
3.	**Multiple Recording Devices**	x				
4.	**Prolonged Engagement**	x	x			
5.	**Low Inference Vocabulary**	x				
6.	**Flexible Observation Schedule**	x				
7.	**Negative Case Analysis**		x			
8.	**Expert Checking Coding**		x			
9.	**Checking Findings with Data**		x			
10.	**Use Data Analysis Software NVivo (Audit Trail)**		x			
11.	**Consistency Checks**			x		
12.	**Encourage Explanation By Participants**			x		
13.	**Interview Repeated Times**			x		
14.	**Adhere to Method in Stages 1-3**				x	x
15.	**Close Match Between Reconstruction and Participant Responses**				x	x
16.	**Match of Results and Existing Research**				x	x

Stage 1: Compiling the primary record. The first stage of data collection is the stage of observing and gathering information before engaging in any in-depth dialogue with the sample population. This stage has been completed through the 9 years of preliminary research with the tribe[24,48,81]. A strong foundation of information on the MBCI an Montana tribal dietary and lifestyle practices has been documented through this research. This information, along with consultation with Tribal members and mentors will be used to triangulate the information gathered from community members.

Stage 2: Completing preliminary reconstructive analysis. The analysis for all data conducted in critical ethnographies follows preliminary reconstructive analysis. Paying particular attention to Aims 1 and 2, preliminary reconstructive analysis for all data includes initial meaning construction and pragmatic horizon analysis. During initial meaning construction, data transcriptions are read and listened to two to four times to understand meaning holistically. Next, potential meanings are noted with low-level coding. A hierarchical scheme of codes and sub-codes are then created. Finally, sections are purposively selected for in-depth reconstructive analysis, which involves pragmatic horizon analysis, enabling the identification of explicit and implicit meaning of data and includes horizontal analysis and vertical analysis (for an in-depth description of this analysis, see Burnette, 2014).

Stage 3: Generating dialogic data: Qualitative interviews. Dialogic data generation involves in-depth individual interviews with key informants and MBCI and Montana tribal community members with

knowledge of such communities' foods and dietary practices. [97] Participants will receive $50 for their participation in individual interviews. Interviews will follow the semi-structured guide to ascertain answers to research questions (derived from research aims). Audio-recorded interviews lasting 1-2 hours will then be transcribed by a professional transcription company. A copy of the interview will be offered for participants to keep for themselves and for member checking (i.e., to make sure transcriptions and interpretations of the data are accurate). Because of low educational attainment due to discrimination in the Jim Crow Deep South, particularly for elders who will be part of the key informants and participants, wording is aimed for comprehension at the 5th grade level for heightened accessibility.

Stage 4 and 5: Determining system relations and system relations as explanations of findings. In Stage 4, results are compared across related sites to uncover universal and distinct themes, deepening the understanding of factors affecting mental health. Based on the totality of results, similarities and differences among contextual factors and results will be examined. Research results and analysis from participants will be compared with preliminary research and extant literature written about the dietary practices of the other tribes. Finally, Stage 5 involves explaining findings from Stages 1-4 with incorporation of broad system features, such as cultural context, class, race, gender, and political structures. Identified themes will inform Aim 2 (the intervention adaptation) and the mhealth application.

Expected Outcomes. Given that the methodology was successfully used with the focal tribe for all of the preliminary research, the outcome for this aim will be culturally relevant diet and health information that can inform intervention development and the mhealth component. Because information is derived from community members, it will be culturally grounded and relevant to the community at hand. This process can be used to adapt other interventions for Southeastern tribes and those cross-nationally.

Participation in aim 1 will take each participant 1-2 hours and will occur at a time and place that is convenient for them, either in a private conference room, the participants office, or at the participants home.

Approach for Aim 2: Create a culturally adapted, family-focused intervention that promotes resilience, health, and well-being to reduce AOD abuse and violence: The *objective* of Aim 2 is to culturally adapt an intervention to create a shortened, feasible, and culturally based intervention. Our *working hypothesis* is that the creation of an effective intervention will reduce AOD misuse and violence, while promoting resilience and well-being. Our *approach* employs CBPR with a 6-15-person CAB for the cultural adaptation process. The *rationale* for this aim is that culturally based knowledge must be integrated into extant interventions to ensure cultural relevance, effectiveness, and adoption within NA communities, particularly given that non-culturally based interventions may be ineffective and harmful.[20-22]

Preliminary data in support of Aim. For cultural adaptation, we follow Whitbeck's (2006) Five-Stage process.[99] Stages 1-4 have been completed through preliminary research. According to Whitbeck, *Stage 1* attains a familiarity with key risk and protective factors identified in the mainstream research, whereas *Stage 2* identifies culturally specific risk and protective factors associated with AOD abuse, health disparities, and violence. *Stage 3* translates culturally specific risk and protective factors to a cultural context. *Stage 4* develops measures of risk and protective factors specific to one's culture. *Stage 5*, the focus of this project, uses information in stages 1-4 to develop (and in the future evaluate) a culturally specific, family-focused, and resilience-based intervention for substance abuse and violence

developed through CBPR. This research has been characterized by what have been identified as the *key components of CBPR,* which are highlighted in bold below. [106,107] The first key characteristic, *partnership with community members, organizations, and academic researchers*[106,107] was achieved through the PI's long-standing partnership with the Tribal Council, and through Tribal resolutions, which have proved the proposed and all preliminary research. A second key characteristic, the *identification of community needs, priorities and assets*, also began at the genesis of the PI's work with the MBCI and Montana tribes.[106,107]

As aforementioned, the core themes of preliminary research identified the insidious link of alcohol abuse, family violence, and the importance of family-focused approaches in prevention research, leading to the next study, which focused on the identification of culturally specific risk and protective factors across cultural, community, family, relational, and individual levels. This research has incorporated the key characteristic of *multidirectional exchange of learning and information* between the PI and cultural insiders, including having hired *three Tribal research assistants and engaging in regular dialogues and collaborative data analysis.*[106,107] *Moreover, openness, trust, and power-sharing* have been demonstrated with all resolutions and collaborations with key insiders and the research team. A key component of *extensive follow-up has been completed and is ongoing*, through reporting to the Tribal chief, council, and every participant who could be reached in the preliminary research. Finally, this project has the *potential to increase individual and community capacity* through the training of tribal members in research methods.

The Celebrating Families! Intervention was chosen given that it (a) incorporated the core risk and protective factors identified in preliminary research and (b) integrates both AOD misuse and family violence with a resilience focus. Each 2.5-hour session in this curriculum begins with a family dinner (which will include traditional healthy tribal foods) to promote protective rituals and routines and ends with 30 minutes of connecting with families. This program directly addresses AOD abuse (sessions 7-9) and family violence (sessions 6 and 13) and integrates AOD abuse, violence, nutrition and health, as well as resilience throughout the curriculum.

Table 1. Table of original and adapted sessions

Original Sessions	Revised Session #	Variables by Session
1. Introduction	1.	Historical Oppression, Health, Spiritual health, discrimination
2. Healthy Living circle		
3. Nutrition	Infused in family meal	
4. Communication	2.	Parenting
5. Feelings and Defenses	3.	Emotional regulation, Mental health, Well-being
6. Anger Management		
7. Facts ATOD	4. ATOD	ATOD
8. ATOD		
9. ATOD and the family	5. ATOD	
10. Resilience	6.	Resilience, Dysfunctional Attitudes
11. Resilience	7.	
12. Healthy Boundaries	8.	Violence, Social Support, Adverse childhood experiences
13. Healthy Relationships		
14. Learning	Remove	
15. Resilience	9.	Resilience
16. Celebration	10.	Ethnic identity

Data Collection and Measures.

Recruitment of CAB members. As mentioned, the CAB of 6-15 members will be formed for each community (Mississippi and Montana) following White Bison Training. The CAB serves to gauge community perceptions, preferences, and priorities in the development of research and intervention programs[108]. CAB members will receive $100 for each adapted session (16 sessions total) and $50 (quarterly meetings should future research fund it) for each follow-up meeting. Following Newman et al.'s best practices for CABs in CBPR,[108] the inclusion criteria for CAB members will be (a) familiarity and knowledge of mental health and substance abuse services.

The Process of Cultural Adaptation.

Because it is not feasible for NA families with multiple responsibilities and activities to complete the 16-week curriculum, the Celebrating Families! Curriculum will be shortened from 16 weeks. The CAB and the evaluation of the intervention and its implementation will inform the final number of sessions. Table 1 displays how the sessions may be condensed; however this is contingent on the CAB's discretion and the full 16 may be retained if they

so wish. Table 2 also displays the primary content for each session from the intervention, the cultural overlay content, and preliminary research content. The adapted curriculum will follow these already developed guidelines. During the adaptation process, preliminary research, the Celebrating Families! Program and the cultural overlay components relevant for each session will be presented to the CAB for cultural adaptation and integration. Notes and recordings of CAB adaptation session will be kept for future reference and to implement changes. The timing of the adaptation process will be coordinated based on the availability and schedules of the CAB. After the intervention has been adapted, the CAB will meet at least quarterly throughout the research project. This schedule will be adjusted according to project needs. Likewise, specific CAB members may meet separately in special committees to discuss their areas of specific expertise, such as AOD misuses, violence in families, and cultural traditions. A finalized, adapted curriculum and training will be solidified. The development of the mhealth component will occur in collaboration with the Tribal members to follow the CBPR principles of reciprocal exchange of information and preferences its directions. The CAB will explore and consider the 14 types of mhealth services identified by the WHO, including, (a) health call centers; (b) emergency toll-free telephone services; (c) managing emergencies and disasters; (d) mobile telemedicine; (e) appointment reminders; (f) community mobilization and health promotion; (g) treatment compliance; (h) mobile patient records; (i) information access; (j) patient monitoring; (k) health surveys and data collection; (l) surveillance, (m) health awareness raising; and (n) decision support systems.[44] *It is anticipated that the focal areas for this project will include appointment reminders, community mobilization and health promotion, information access; health surveys and data collection, and health awareness raising.*

Participation in the CAB will take from 16-50 hours, depending on how long it takes to adapt each of the 16 sessions. A schedule for adapting session will be jointly agreed upon on by all CAB members based on the time that works for their schedule. The time for adapting each session is expected to be 1-4 hours.

Data Collection and Measures for Aim 3. *Following the lessons learned from the PI's extensive experience with the MBCI in collecting data all data from Aim 2 and 3 will be collected in the following ways*. Arrangements to collect data will be made with the participant(s) to meet in a private conference room or at a community site. If this option is not available, data will be collected (a) by phone by the data collection staff; (b) by email/electronically; or if none of the alternatives are possible, (c) by mail. This method is congruent with culturally-sensitive, ethical, and rigorous methods as described in the toolkit the PI developed with the focal Tribe. The method of data collection will be recorded and accounted for in the data analysis.

CHR Recruitment. During preliminary research a list of potential CHRs was compiled. The PI and CAB will use existing social networks and referrals identifying CHRs from across tribal communities. CHRs include professionals working in relevant health settings (e.g., behavioral health, social services, and children and families). Following the Celebrating Families! Group administration guide,[50] 1-2 CHR coordinators will oversee all CHRs, managing scheduling and ensuring fidelity and adherence to the program curriculum. A separate Tribal staff member will support the CHR coordinator and assist with data collection.

Inclusion Criteria for CHRs. The inclusion criteria for all CHRs are that they are 18 years of age or older, have at least a high school degree, and have experience working with MBCI children and families. *During screening, anyone with active addiction or violence issues will be excluded in the interview process; these screening measures are already outlined in the implementation manual.* We will recruit CHRs with backgrounds as AOD abuse counselors and degrees in social work, psychology, or related field. CHRs will be compensated at $100 per session (approximately four hours at $25/hour). "Lead CHRs", will include CAB members or other veteran CHRs—with experience running the

curriculum and higher education or experience in behavioral health—will receive $150 session based on their experience, time for planning, and leadership in session facilitation. At least one licensed professional will be at each session.

Training and Data Collection for CHRs. Following the lessons learned from the PI's extensive experience with the MBCI in collecting data,[32] *the CHRs, CAB, and staff will receive specialized confidentiality training developed by the PI and based on preliminary research with the MBCI.* Two, three-day trainings will prepare new CHRs to facilitate the intervention. First, they will receive White Bison's training of the Celebrating Families! program, which will introduce them to the conceptual framework and core components of the program. Next, the PI, CHR coordinator, and CAB will facilitate the 2nd three-day training, which will focus on the modified program, group facilitation skills, and experiential activities. *This training is outlined in the revised implementation manual.* A pilot run of this training was already facilitated in the adaption process with the CAB. This training includes role plays and mock sessions for each component. Moreover, the PI will facilitate bi-annual training refresher courses for CHRs to promote intervention fidelity and integrity.[133] Finally, new CHRs will be paired with more veteran CHRs for experiential training and mentorship before working more independently. *The PI and CHR coordinator will conduct weekly unannounced fidelity checks for each cluster to maintain intervention integrity, and fidelity across sessions.*[133]

Qualitative Measures. Due to the PI's prior success using ethnography with the focal Tribe,[90,96] *including qualitative interviews, observational methods, and survey research*, the critical ethnographic approach will be used to frame these multiple forms of data. Based on other research using the CFIR, in collaboration with the CAB, CFIR semi-structured interviews representing multiple constructs was created (**See Appendix E**) and the CAB will ensure cultural appropriateness, and we will make any changes as necessary.[103-105] Data will include notes from meetings, field notes collected by research team members, and interviews with CHRs and CAB members. All CHRs will have at least one qualitative interview during the implementation process after they facilitate at least one full session, so they can speak from experience. Qualitative interviews will take place in the last six months of the implementation process. CHRs that drop out will be invited to do an exit interview. Beyond this, quantitative measures are collected for Aim 4b at BLSN, 12-MF, and 27-MF. Table 4. Quantitative surveys for CHRs are: ICBS= Implementation Citizenship Behavior Scale; Intervention AS-36= Evidence-based Practice Attitude Scale-36; and the PSI=Program Sustainability Index.

Process Outcomes/Intervention Fidelity. Several evaluation instruments will be collected throughout the active intervention phase. *The Celebrating Families! Curriculum includes an extensive array of evaluation instruments that have been used to evaluate the program in other research and will be used in this research*. These instruments fall into two broad categories: (a) basic pre- and post-program assessments that evaluate how well parents/caregivers retain curriculum information, and (b) evaluation forms, which include parent/caregiver satisfaction with the curriculum, developmentally-appropriate satisfaction forms, and group leader and site coordinator notes on the curriculum. These instruments will be completed with baseline and follow-up measures as described below in Aim 3. The same instruments will also be utilized with the CHRs, who will also evaluate each individual's participation and their ability to complete core components of the curriculum, such as the ability to ask for help, resolve conflict without violence, express affection, etc. Assessment data will be recorded via the HIPPA Compliant, REDCap computer-based survey after the respective sessions with the assistance data collection staff. REDCap has an offline option if connecting to the Internet is difficult. The number of complete sessions attended will be recorded. During the interventions, the CHR coordinator/assistant and/or the PI will conduct unannounced, weekly site visits to assess the extent to which CHRs are following the intervention with fidelity. Basic information, such as whether the core component was completed, and the quality of key components will be collected and rated by the external reviewer.

Analysis of Qualitative CFIR Data. *Analysis will follow thematic analysis, described in Aim 1.*

Statistical Analysis for Aim 3. Data collected from the pre- and post-test training will be entered into our REDCap data system. Data will be imported into SPSS or SAS, managed by the data manager who will conduct extensive consistency checks across all levels of the data and analyzed for changes in the CHR's knowledge/skills over time using the evaluation instruments developed in Aim 1. Mean training outcome scores will be compared between pre- and post-test using t-tests or the Mann-Whitney U test for continuous variables and a Chi-square or Fisher's Exact test for categorical outcomes.

Sampling for Aim 4.

Family Recruitment. The PI, CAB, CHR coordinator, and other tribal partners have had a decade of success in achieving recruitment aims of over 1,000 tribal participants in past research. We will continue this success with recruitment strategies including posting advertisements on the MBCI website, Facebook page, and in the community newsletter, a free hard-copy newsletter widely read by MBCI members. Likewise, community-based recruitment will entail distributing fliers to each of the community recreation buildings in the communities and schools. *The CAB members will each be responsible for assistance with recruitment across communities.* Enrolled members of the family (i.e., participants) will each receive $50 for each data collection session. *Inclusion criteria for families* includes: written consent for adults and assent for children ages 12-17, *families that have at least one parent/caregiver who is a member of the MBCI and at least one child, aged 12-18 living in the household* (data will be collected on developmental and behavioral outcomes and parenting among younger children, but our focus is on outcomes among youth (age 12-18) and adults). Interested families will contact the PI, the CAB, a research team member, or a CHR. The PI or data collection specialist will screen for inclusion criteria over the phone. All household members, males and females, will be actively recruited. The number of families are proportionate to each MBCI community. To promote safety, *anyone with a current protective order or current intimate partner violence (IPV) record will be excluded.*

Data Collection for Aim 4. Pre-test and post-test data (During or before first session and at last session) will be collected at enrollment on all participating families. Data will be obtained from the adults (**See Appendix C)** and children (**Aged 12 and above See Appendix D**). Data will be collected using the REDCap computer-based system on tablets. Based on the PI's extensive background with data collection, survey data will be collected as described in Aim 2. The staff collecting data will undergo training; inter-rater agreement will be estimated to ensure standardization.

Process Outcomes/Intervention Fidelity. As discussed above in Aim 2, several evaluation instruments will be collected at pre-test and post-test that are part of the Celebrating Families! curriculum, including basic pre- and post-program assessments that evaluate how well parents/caregivers retain curriculum information, and evaluation forms, which include parent/caregiver satisfaction with the curriculum, developmentally-appropriate satisfaction forms, and CHR and CHR coordinator notes on the curriculum. These instruments will be completed the in the first session and last session of the intervention which assess core components of the curriculum, such as the ability to ask for help, resolve conflict without violence, and express affection, among others. Participant data and the number of sessions completed will be recorded via the staff data collector using REDCap.

Table 3. **Measures for Aim 1**			
PRIMARY MEASURES: Collected at BSLN, PRE, POST, 6, 9, & 12 MO.			
Variable(s)	Population (A=Adult/Y= Youth)	Name of Measure	Reliability from Pilot Study(s)
ATOD Abuse	A	AUDIT	.87
		DAST-10	.90
	Y (12-18)	AADIS	.94*.
		CRAFFT 2.0	.79*.
Violence	A	CTS-2	.98
Family Environment	A/Y (5-18)	FES-SF	.67-.78*.
Parenting	A/Y (6-18)	APQ-SF	.82
Resilience	A/Y (10-18)	FRI	.88
		CD-RISC	.94
Dysfunctional Attitudes	A/Y (8-18)	DAS-SF, DAS-C	.93*.
Transcendence	A/Y (10-18)	SWLS	.90
Emotional Regulation	A/Y (10-18)	DERS-18	.91*
Nutrition/Health	A/Y (10-18)	BRFSS	**
SECONDARY MEASURES Collected at BSLN, PRE, POST, & 12 MO.			
ATOD	A/Y (12-18)	CSAP	**
Parenting	A	PSDQ-SF	.73-.85*.
General Health	A	SRHP	.96/.96
	Y (8-18)	Kidscreen-27	>.70
Anxiety	A	GAD-7	.93
	A/Y (8-18)	SCARED	.93*
Depression	A	PHQ-9	.92
	A/Y (7-14)	DAS-SF	.87*
PTSD	A	PC-PTSD	.88
Suicide	A	C-SSRS	.73-.95*
Spiritual health	A	SHALOM	.95/.96
Community Resilience	A/Y (5-18)	RRC-ARM/CYRM	.82
	A/Y (12-18)	Communal Mastery	.74*
Social Support	A/Y (10-18)	SSSU	.75/.89
	A/Y (10-18)	SSI	.75
Ethnic identity	A/Y (10-18)	IGI	.853
TERTIARY MEASURES Collected at BSLN AND 12 MO.			
Historical Oppression	A/Y (10-18)	HOS	.97
Historical Loss	A/Y (10-18)	HLS	.95
Discrimination	A/Y (10-18)	EDS	.84
Adverse Experiences	A/Y (10-18)	ACE	.79
Child Well-being	Y (6-18)	CBCL	.92

Impact Outcomes. *We directly assess our working hypothesis that the intervention will reduce parental AOD abuse (AUDIT and DAST) and violence (CTS-2), postpone youth AOD use (AADIS and CRAFFT 2.0), and enhance family members' resilience (CD-RISC, FRI, APQ-SF, FES-SF) and wellness (BRFSS, SWSL, DERS-18, DAS-SF/DAS-C).* Table 3 displays Primary, Secondary, and Tertiary Measures along with names, psychometrics, and associated citations. All measures have been vetted by the CAB and selected through in-depth analysis of the measures' sensitivity to change,[113] relevance to target variables, length, and cultural appropriateness. The majority of measures were also *used to evaluate the original EBP for comparability.*[10] *The time it took to complete all measures in one sitting during pilot data collection ranged from 45-60 minutes for adults, and 30-60 minutes for youth*. Thus, despite all measures being listed below, many are quite short and were vetted in prior research, and some of the original measures have been dropped to reduce participant burden even more. *We reduce participant burden even further than in the pilot data for the proposed research by alternating which measures are collected at different data collection points (See Table 3). We do so in the following ways*: Primary measures will be collected at baseline (BSLN), at the pre-test (PRE) immediately before the active intervention (if these fall at the same time, only one data collection will take place), post-test (POST) directly after the intervention, six-month-follow-up (MF), nine-MF, and 12-MF (See Table 3). Secondary measures will be evaluated as key

Table 3 Abbreviation Key. With exception of the reliability (Cronbach's alpha) for those measures with an asterisk (*), ALL measures have been piloted at least 1 time in pilot study(s), with the remaining instruments being piloted in August of 2019. Populations A=Adults, Y=Youth. The appropriate ages for youth measures are indicated. Abbreviations for secondary and tertiary measures are as follows in the order listed. **AUDIT**= Alcohol Use Disorders Identification Test;[156] **DAST**= Drug Abuse Screening Test[157] **AADIS**= Adolescent Alcohol and Drug Involvement Scale; [158,159] **CRAFFT=C**ar, **R**elax, **A**lone, **F**orget, **F**riends, **T**rouble; [160] **CTS-2**=Conflict Tactics Scale 2.[161,162] **FES**=Family Environment Scale-Short Form; [163,164] **APQ-9**=Alabama Parenting Questionnaire;[165] **FRI**=Family Resilience Scale; [49] **CD-RISC**=Conner-Davidson Resilience Scale; [166,167] RRC-ARM/CRYM= Resilience Research Centre Adult Resilience Measure/Child and Youth Resilience Measure (CYRM);[168-170] **DAS-SF/DAS-C**= Dysfunctional Attitudes Scale-Short Form/Child;[171,172] **SWLS**=Satisfaction with Life Scale; [173] **DERS-18=** Difficulties in Emotional Regulation Scale; [171,172] **BRFSS**=Behavioral Risk Factor Suveillance System (modules on chronic health, diet, and exercise);[174,175] **CSAP** = Center for Substance Abuse Prevention (Minority Initiative) [176,177]; **PSDQ-SF**=Parenting Styles and Dimensions Questionnaire-Short Form[178,179]; **SRHP**=Self-Rated Health Practices;[180] **Kiscreen-27**[181,182]; **GAD-7**=Generalized Anxiety Disorder[183]; **SCARED**=Screen for Child Anxiety Related Emotional Disorders[184,185]; **PHQ-9**= Patient Health Questionnaire[186]; **PC-PTSD**=Primary Care PTSD Screen[187,188]; **C-SSRS**=Columbia-Suicide Severity Rating Scale[189,190]; **SHALOM**= Spiritual Health and Life-Orientation Measure[191]; **RRC-ARM/CYRMA** =Resilience Research Centre – Adult Resilience Measure/Child and Youth Resilience Measure[170,192]; Communal Mastery[193-195]; **SSSU**=Social Support and Social Undermining[196]; **SSI**=Social Support Index[49,197]; **IGI**=In-Group Identification[198]; **HOS**=Historical Oppression Scale[37]; **HLS**=Historical Loss Scale[199]; **EDS**=Everyday Discrimination Scale[200]; **ACE**=Adverse Childhood Experiences[37,201-204]; and **CBCL**=Child Behavioral Checklist.[205]

moderators and mediators, along with sex. The curriculum has assessments for each session built in as well to test the learning of the individual session during the active intervention phase. Beyond this, the larger array of survey items will be collected at BSLN, PRE, POST, and 12-MF. Tertiary measures, which are not thought to be as sensitive to change, will be collected at BLSN and at 12-MF. *Process evaluation measures are discussed in Aim 2.* Outcome data will be collected on all family members, with the primary target being adult caregivers and youth. Collateral reports (parents reporting on youth) will also be collected for these primary outcomes. *With exception of those asterisked (*), all outcome measures have been piloted 1-2 times*, indicating their appropriate use with this community. The reliability psychometrics for each measure used in pilot research is depicted in Table 3; if information from pilot is not yet available, available psychometrics are presented for available research. *All measures have been used with NAs, the vast majority were used to evaluate the original EBP, and many were developed specifically for NA use.*[37,49,134,135] Moreover, the scales included in this research significantly predicted key outcomes of preliminary research.[34]

Statistical Analysis for Aim 3-4. Overall, the analysis will involve (1) descriptive statistics, (2) process data analysis, (3) unadjusted bivariate estimates and tests of associations between variables, and (4) modeling techniques, including multilevel/hierarchical or longitudinal modeling. Data reduction techniques will include applying established scales as well as constructing composite measures. These techniques will include examinations of variation, factor analyses, and internal consistency evaluation. All analyses will be initially performed using SPSS or SAS software. Several procedures will be used to minimize the prevalence of missing data, including screening for inconsistencies, checking the magnitude of missing data, and making necessary adjustments. If the extent of missing data is small, listwise deletion will be used. If a variable of interest has more extensive missing data, multiple imputation or Heckman selection modeling may be used.

3. Risks

Although there are no known risk and participants will not be asked personal questions, the topics of the curriculum focuses on health, addiction, culture and healthy relationships. Talking about such topics may cause unforeseen discomfort. Although personal information is not part of this research, to protect against unforeseen risk, any identifying contact information will be only available to the PI and research personnel and kept in a separate, password protected data file. Participants will be given a separate code names, which will be used for all data analysis keeping contact information separate from the data. Data will be kept on password protected computer of the PI and all hard copy data will be kept in the PI's locked cabinet in a locked office. Only the research team will have access to the data. To protect against the risk of inconvenience, study activities will be arranged to occur at a time and place convenient to the subjects. The raw will be kept for the duration of the study then destroyed.

Although personal information is not part of the research topic, the CAB will include group discussions, which contain an added risk of loss of privacy. The PI will discuss the need for keeping the proceedings confidential with the group at the beginning, throughout the process, and again at the end. The importance of confidentiality for group cohesion will be reiterated throughout the data collection process.

There are no known physical or financial risks to study participants. However, there may be psychological risks, as the participants will be answering questions about sensitive issues, such as alcohol and drug use, conflict or violence, and mental health issues. In disclosing information

about illegal drug use, for example, there could be some risk of legal ramifications if their personal identifiable information was linked with their responses to questions on drug use. Likewise, if study participants report child abuse or a danger to themselves or others, because all people are considered mandatory reporters in the state of Mississippi, this information will be reported to the Department of Human Services and/or law enforcement. Moreover, questions about harm will not be part of survey items for minors.

4. Benefits

There will be no direct benefits to subjects for participating in this research, but the knowledge gained from the study may benefit society in general. Participants will gain understanding and contribute to community and program development. Participants will become educated about important aspects to well-being, such as health, substance use, healthy relationships, and resilience. This could add to self-esteem and competency.

Research participants may benefit from study involvement by participating in the prevention plan, by experiencing reduced alcohol misuse, family violence or conflict, and improved health and wellness. Anticipated benefits outweigh the risks in that this program may prevent major life stressors experienced by many Native American (NA) people, especially alcohol abuse and family violence. Families may experience greater wellness, positive parenting, and supportive bonds, which make the relative risks to this research worth taking.

5. Remuneration

Cash payments using ClinCard or other gift card. Renumeration for participant interviews will total $50 on a gift card, and will be provided immediately following the interview, which will be complete by 12 months after their active intervention phase. Interview times will be set up depending on the schedule of participants. Renumeration for Aim 2-4 will use the ClinCard. The payment on the ClinCard will be deposited immediately following the adaptation of each of the 16 sessions or after the quarterly meetings for the CAB (Aim 2) and immediately following the survey completions and/or interview completion. As aforementioned in "data collection and measures, renumeration for Aim 2 will total $100 for each adapted session (commensurate with what participants would get paid for their time for the 2-4 hours it would take to adapt each session) and $50 for follow up meetings (2-3 hours long). Adaptation of sessions will be scheduled on a mutually agreed upon time with the CAB. Total adaptation of sessions are expected to be complete by July 30th, 2019.

Renumeration for Aims 3 and 4a will total $50 on a gift card for each data collection period (for CHRs and for the families), and will be provided immediately following the interview, which will be complete by December of 2021. Interview times will be set up depending on the schedule of participants.

Renumeration for Aim 4b will total $50 on a clincard for each data collection period (for CHRs and for the families), and will be provided immediately following the interview, which will be complete by December of 2022. Interview times will be set up depending on the schedule of participants.

6. Academic or Extra Credit

NA

7. Costs

There will be no costs to the subject for participating in this research study.

8. Alternatives

Participation is voluntary; subjects do not have to participate in the research.

9. Consent process and documentation

Written signed consent will be achieved for all parts of this study, and will include a verbal description of the PI with each potential participant about study activities, length of time, risks, renumeration, confidentiality, and the voluntary nature of the study activities. Such consent will be achieved prior to study activities beginning, and potential participants will be able to take as much time as the need to decide whether to participate during the data collection process.

10. Qualifications of the investigators

Significant research accomplishments have placed me in an opportune position as PI of this project. My research portfolio documents the crucial combination of high productivity and success in attaining and managing external and internal grants, publishing extensively in high quality peer-reviewed journals, extensive engagement and effectiveness in community-based research, and continued community support with the Montana tribes, United Houma Nation (UHN) and the Mississippi Band of Choctaw Indians (MBCI). Since beginning my career at Tulane University School of Social Work as assistant professor four years ago, I have been highly active in research, publishing over 30 peer-reviewed articles and having presented at over 40 peer-reviewed conferences. A major gap in research with NAs is a culturally relevant theoretical framework to adequately explain, predict, and address chronic health disparities. Thus, a main focus has been to develop an ecological theoretical Framework of Historical Oppression, Resilience, & Transcendence, which can be used to organize, predict, explain, and understand culturally specific and localized risk and protective factors across individual, couple, family, cultural, community, and societal levels, as well as those translatable across communities. This framework has recently been featured in the premiere journal, Social Work, and was co-authored with co-investigator Charles Figley. Not only has this framework been published in multiple peer-reviewed journals and conference presentations, it has been disseminated through presentations and publications through the National Council on American Indians and the National Indian Health Board in Washington relating to the topics of historical oppression, trauma, and resilience.

Moreover, I have received the NIH Career Development Award, Building Interdisciplinary Careers in Women's Health (BIRCWH) focusing on women's cardiovascular health among NAs. I also have received the NIH Loan Repayment Program award for health disparities research and recently served as a Substance Abuse and Mental Health Services Administration (SAMHSA) Grant Reviewer for Indigenous-Project LAUNCH (SM-17-004), which is focused on projects promoting wellness of young children from birth to eight years within tribes. I also have

served on the editorial board for Research on Social Work Practice for the past three years—the premiere social work journal for randomized control trials and other forms of intervention research.

Likewise, I have worked with the Montana partners, the UHN and the MBCI for over nine years and completed the preliminary research that has provided a solid foundation for the proposed research. In fact, the first four phases of the cultural adaptation have been completed, and strong community support has consistently been documented through the approval of multiple project resolutions, high recruitment for study participation, and support from tribal agencies and community members. This preliminary research has been supported by highly competitive external grants (i.e., The Silberman Faculty Grant and the Fahs-Beck Faculty Grant) and seven grants/fellowships through Tulane University. Through preliminary research, I have managed multiple grants, which has included managing all budgetary duties, participant compensation, hiring and overseeing multiple tribal and nontribal consultants and research assistants, and facilitating collaborative data collection and data analysis teams while completing data collection and analysis with multiple tribes in a timely and targeted way. Thus far, I hired, trained, and worked with six tribal research assistants and three Tulane Graduate students, helping to fill a glaring gap in highly trained tribal and non-tribal ally researchers to conduct culturally sensitive research to reduce NA health disparities. This support, particularly for NA scholars, is an urgent need and longstanding goal. This track record of success specifically with the tribes documents a long-standing ability to work effectively in complex and community-engaged and reciprocal research.

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