



# Encompassing Cultural Contexts Within Scientific Research Methodologies in the Development of Health Promotion Interventions

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## Abstract

American Indians/Alaska Natives/Native Hawaiians (AI/AN/NHs) disproportionately experience higher rates of various health conditions. Developing culturally centered interventions targeting health conditions is a strategy to decrease the burden of health conditions among this population. This study analyzes characteristics from 21 studies currently funded under the Interventions for Health Promotion and Disease Prevention in Native American (NA) Populations program among investigators currently funded under this grant mechanism. Four broad challenges were revealed as critical to address when scientifically establishing culturally centered interventions for Native populations. These challenges were (a) their ability to harness culture-centered knowledge and perspectives from communities; (b) their utilization of Indigenous-based theories and knowledge systems with Western-based intervention paradigms and theories; (c) their use of Western-based methodologies; and (d) their cultural adaptation, if based on an evidence-based treatment. Findings revealed that qualitative methodologies and community-based participatory research (CBPR) approaches were very commonly used to finalize the development of interventions. Various Indigenous-based theories and knowledge systems and Western-based theories were used in the methodologies employed. Cultural adaptations were made that often used formative mixed qualitative and quantitative methods. Illustrative examples of strategies used and suggestions for future research are provided. Findings underscored the importance of CBPR methods to improve the efficacy of interventions for AI/AN/NH communities by integrating Indigenous-based theories and knowledge systems with Western science approaches to improve health.

**Keywords** American Indians · Alaska Natives · Native Americans · Native Hawaiians · Culture · Interventions

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## Acknowledging the Medicine (Introduction)

Native communities residing in the USA (American Indians/Alaska Natives/Native Hawaiians [AI/AN/NHs]) experience disproportionately higher rates of physical and psychiatric morbidity and substance abuse prevalence and live shorter and more challenging lives than other Americans. Approximately 75% of AI adults are overweight or obese (Centers for Disease Control and Prevention [CDC] 2017). AIs and NHs are two to three times more likely to have diabetes than non-Hispanic Whites (Grandinetti et al. 2007). In addition, the prevalence of heart disease is 20% higher among AIs compared to all other ethnic/racial groups in the USA (Barnes et al. 2010) and is 68% higher among NHs compared to other Hawaii ethnic groups (Johnson et al. 2004). Furthermore, NHs develop a chronic disease and die, on average, a decade earlier than people of other ethnic groups (Johnson et al. 2004; Nakagawa et al. 2013; Nakagawa et al. 2015). AI/AN/NHs also experience significantly higher rates of cigarette smoking, alcohol and illicit drug use, suicide rates, and traumatic exposure (Beals et al. 2013; Herne et al. 2014; Kaholokula et al. 2006; Manson et al. 2005; Martell et al. 2016; Substance Abuse and Mental Health Services Administration [SAMHSA] 2010; Yuen et al. 2000). These health disparities have been postulated to stem from various historical traumas experienced by this population, such as forced relocation from Native lands and placement into boarding schools (Evans-Campbell 2008). As a result, these stark public health realities create an urgent necessity to mitigate and reduce the gap between Native health and the health of other groups within the USA. A potential strategy is to develop culturally congruent interventions for health promotion in Native communities and to “decolonize” health care, or in other words, recognize and support Indigenous liberation by resisting the restraints existing within Western science.

Harnessing culture-centered knowledge and perspectives from communities to aid in intervention development is critical in creating programs that are sustainable within Indigenous communities. The recognition of community agency and the co-creation and local adaptation of interventions based on local cultural knowledge, practices, and aspirations can improve their ultimate efficacy and sustainability. There is a continuum of incorporating culture into interventions, ranging from more superficial cultural tailoring or adaptations (e.g., inserting Native terms and concepts to currently available Western approaches) to culture-centeredness (e.g., where the focus is on community influence and power to create or co-create specific interventions that incorporate core knowledge systems important to them, based on their histories, languages, values, and healing traditions; Dutta 2007). Other researchers have compared and contrasted the cultural adaptation approach to the cultural grounded approach, which is similar to culture-centeredness (Okamoto et al. 2014; Resnicow et al. 2000). Okamoto et al. (2014), for example, noted that studies

using culturally adapted approaches have yielded mixed results, and thus, they strongly advocate for a culturally grounded approach for Native populations, where the cultural context is at the core of the intervention.

Similar to the notion of cultural grounding, culture-centeredness seeks to draw from cultural strengths, building from people’s agency, power, and language to direct health changes in their communities (Belone et al. 2016, 2017; Dutta 2007; Wallerstein et al. 2018). Culture-centeredness also embraces interventions that are based on Indigenous history, language, values, and healing traditions as ways for people to heal from historical traumas. Harnessing community-based knowledge in the development of culturally centered interventions has the potential to help Indigenous communities both decolonize and reclaim their cultural beliefs, practices, and aspirations that promote health and well-being.

Utilization of Indigenous-based theories and knowledge systems within Western-based intervention paradigms poses unique challenges in the development of culturally centered interventions for Indigenous populations. Nonetheless, research has demonstrated that it is possible to integrate Western-based notions and methods of behavior change with Indigenous holistic health belief systems (Baldwin et al. 2009; Kaholokula et al. 2017). However, even with a trend toward more community-driven prevention strategies and the focus on greater cultural centeredness, many of the approaches used to guide development of prevention programs continue to be based on Western and individualistic paradigms (Kagawa-Singer et al. 2015; Walsh 2014).

Recent influential publications incorporate a broad view of culture as reflecting the real-world context of Indigenous populations (Kagawa-Singer 2012). A recent Office of Behavior and Social Services Research (OBSSR)-funded consensus report calls for a complete “Cultural Framework for Health Research” that recognizes the multidimensionality of culture and the importance of viewing communities within their historical, social, and political contexts (Kagawa-Singer et al. 2015). This comprehensive report also challenges researchers to recognize their socialization into the dominant academic scientific perspective, with its bias that Western science approaches are sufficient. It calls for recognizing that communities and research participants have equally valid understandings and knowledge to contribute. We therefore can create better science and rebalance power between academics and communities through the integration of decolonizing approaches that honor Indigenous and cultural knowledge as key to the research process (Denzin et al. 2008).

There are inherent challenges in infusing scientific methodologies with Indigenous healing practices, as the latter is based on broader systems of knowledge that are more challenging to reconcile within the current established procedures of scientific research (Gone 2016). Although utilization of AI/AN/NH traditional practices has been advocated by many AI/

AN/NH community members and leaders (Dickerson et al. 2012; Native American Health Center 2012), their recognition as a viable and beneficial treatment option among the scientific establishment has been minimal.

To our knowledge, no prior work has described the challenges and issues associated with utilization of Western-based scientific methodologies in the development of culturally centered interventions for this population across a nationally representative group of National Institutes of Health (NIH)-funded studies. This paper seeks to fulfill this gap in the literature utilizing a culturally appropriate framework that includes headings reflecting the process of acknowledging, harnessing, gathering, and honoring the “Medicine” or ways of healing.

## Harnessing the Medicine (Methods)

### Protocol and Approach

This paper was initiated from monthly telephone meetings held among all funded investigators of the Intervention Research to Improve Native American Health (IRINAH) network organized by the NIH from 2015 to 2017. IRINAH comprises the Principal Investigators of projects supported under NIH PAR-17-496 grants (U.S. Department of Health and Human Services [DHHS] 2016) in order to build collaborative relationships and to assist each other in addressing relevant issues in our studies. Funding for the IRINAH grants was as a result of NIH staff recognizing the need for stronger prevention efforts and published research that addresses health concerns affecting AI/AN/NH communities (Crump et al. 2017). Monthly collaborative investigator calls were conducted to foster networking and relationships and the sharing of lessons learned following the implementation of the studies.

### Review Selection

An emergent, qualitative analysis of studies currently funded under the IRINAH program was conducted. Analyses of these studies, which were deemed feasible as part of the IRINAH initiative, will provide the NIH with important information that can be useful in the design of future grant programs addressing AI/AN/NHs, and was an alternative to conducting a larger review of similar studies. The studies were reviewed by all authors utilizing a summary report provided by each of the 21 research teams. These data included the target health condition and Native population, specific aims, and research design and methods. Research proposals and summaries were provided by PIs of the studies analyzed, which included the co-authors of this paper. Studies were reviewed by authors of this manuscript for patterns and themes within and across the studies based on their target health condition and population. Over a series of teleconferences, all authors then discussed the

overarching themes until reaching consensus. In order to minimize bias, strict adherence to the analyses protocol was followed; in addition, several discussions on the interpretation of the results occurred.

## Gathering the Medicine (Results)

### General Study Characteristics

A total of 21 studies funded under the “Interventions for Health Promotion and Disease Prevention in Native American (NA) Populations” program were analyzed (see Appendix 1). Seven of the studies analyzed are led by the eight authors in this paper. Eight NIH Institutes granted funding to these projects. Thirteen (32.5%) of the 40 Principal/Co-Principal Investigators are of AI/AN/NH descent. As shown in Table 1, a wide diversity of health areas are being addressed. Seven studies address substance use issues (33.3%). Most of the studies are being conducted exclusively in rural/tribal communities (14/21, 71.4%). With regard to type of intervention, eight studies developed and analyzed culturally adapted evidence-based treatment (EBT) interventions.

### Challenges Identified

Four broad challenges when scientifically establishing effective interventions for Native populations were revealed. These challenges were (a) their ability to harness culture-centered knowledge and perspectives from communities; (b) their utilization of Indigenous-based theories and knowledge systems within Western-based intervention paradigms and theories; (c) their use of Western-based methodologies and theories; and (d) their cultural adaptation, if based on an EBT.

### Ability to Harness Culture-Centered Knowledge and Perspectives from Communities

Examples of three of the strategies employed as it relates to harnessing culturally centered knowledge and perspectives from communities in intervention development are provided in Table 2. The majority of these studies utilized qualitative methodologies in order to develop and refine interventions and to ensure cultural appropriateness and community buy-in. Tribal and AI/AN community partners were key contributors across research projects. AI/AN community partnership committees, community elders/cultural practitioners, Native research consultants, tribal community advisory groups, and tribal research teams were involved in research activities. Community-based recruitment strategies were employed with regard to recruitment of participants across research projects, including the use of community advisory boards, tribal research teams, community planning groups, and a community action project.

**Table 1** General characteristics of studies funded under the “Interventions for Health Promotion and Disease Prevention in Native American Populations” Program ( $n = 21$ )

Health area addressed	# (%)
Medical health and diet issues	5 (23.8)
Substance use issues	7 (33.3)
Tobacco prevention	2 (9.5)
Mental health issues	1 (4.8)
Best burn practices and respiratory health	1 (4.8)
Caregiver sensitivity and responsiveness	1 (4.8)
Various combinations of health conditions	4 (19.0)
Research setting	
Rural/tribal communities	15 (71.4)
Urban communities	1 (4.8)
Rural/tribal and urban/suburban communities	3 (14.3)
Tribal colleges	2 (9.5)
Type of intervention	
Cultural adaptations of currently available EBTs	8 (38.1)
Development of new interventions incorporating traditional practices	6 (28.5)
Development of colorectal cancer screening interventions	1 (4.8)
Social marketing campaigns	2 (9.5)
Computerized interventions, telemedicine, for multiple risk behaviors	1 (4.8)
Integration of EBTs with traditional practices/knowledge	3 (14.3)

### Utilization of Indigenous-Based Theories (Knowledge) Within Western-Based Intervention Paradigms and Theories

Various Indigenous-based theoretical constructs and theories were utilized across studies. Studies developing interventions incorporating specific traditional practices are provided in Table 3. Wallerstein and Belone (R01-DA07174-01) utilized core Indigenous theory (Cajete 1994; Pankratz et al. 2006), showcasing how culture, language, and community are central to learning in their Family Listening/Circle Program (FL/CP), a culturally centered and evidence-based prevention program that has demonstrated promising preliminary data relating to substance use risk factors for elementary-school children.

Across studies, the most commonly utilized cultural-based measures sought to assess AI/AN/NH cultural identity, social connectedness, and spirituality. Additional cultural-based scales utilized among IRINAH-funded studies included Native Reliance (Lowe et al. 2009, 2016), health impact assessment tool (HIA) (which utilized an iterative process based on discussions in English and the Choctaw language) (HIP, n.d.), a 5-item version of the Oppression Questionnaire (Victoroff 2005), Awareness of Connectedness Scale (Mohatt et al. 2011), and Historical Losses Scale (Whitbeck et al. 2004). Measures of

**Table 2** Harnessing culturally centered knowledge and perspectives from communities in intervention development: examples of strategies utilized

Intervention: Intertribal Talking Circle, a substance abuse prevention intervention targeting AI youth; PI(s): Lowe/Baldwin
Strategies employed: Utilized a Community Partnership Committee(CPC) of 5–6 tribal community representatives (tribal leaders/elders, school personnel, teachers, parents, and students). The CPC will engage in the following activities: (a) review and revise the intervention manual attending to the particular tribal language, community needs and culturally appropriate content, (b) familiarize themselves with and provide input regarding the Native Reliance Questionnaire and other instruments.
Intervention: Caring Contacts, a suicide prevention intervention, PI(s): Comtois/Nelson
Strategies employed: Community leaders and elders will be invited to contribute content and to provide feedback on text messages used in a cultural adaptation of a suicide prevention intervention targeting young AI/AN adults. Candidate text messages will be reviewed by the CAB and by focus groups with tribal members to ensure that they are meaningful, acceptable, and relevant to the community.
Intervention: Motivational Interviewing and Culture for Urban Native American Youth (MICUNAY), PI(s): D’Amico/Dickerson
Strategies employed: Community-based knowledge will be acquired through utilization of Sacred Path Indigenous Wellness Center, Community Advisory Boards, and focus groups with AI/AN youth, parents, and providers who serve the AI/AN community in order to ensure cultural sensitivity and appropriateness of the MICUNAY intervention.

several other critical constructs included the Alaska Native Wellness measure (Wolsko et al. 2006), traditional use of tobacco, boarding school attendance, perceptions of the boarding school experience, engagement in traditional Native activities, social connectedness using the Interpersonal Needs Questionnaire (Van Orden et al. 2008, 2012), and Reflective Processes (adapted from the adult Yup’ik Protective Factors scale; Allen et al. 2012). Whitesell (1R01-DA035111-01) is utilizing various items from Kaufman et al. (2014) to measure cultural knowledge and values. Whitbeck (R01-DA037177-01A1) is planning on using measures of Indigenous family influences and cultural processes. Mishra (1R01-CA192967) plans on utilizing items from prior studies to measure the following constructs: social norms and support; socioecological level variables, such as social norms and health access; cultural influences on colorectal cancer screening; and social network assessment (Philip et al. 2016). Walters et al. (2018) provides a more thorough overview of Indigenous-based theoretical constructs and theories utilized in the development of culture-centered interventions from the ground up (refer to Walters et al. 2018, in this Special Edition Journal).

### Use of Western-Based Methodologies and Theories

Various Western-based theoretical approaches were utilized in the development of interventions throughout IRINAH studies. Gittelsohn (5R01-HL122150-02) is utilizing Social



**Table 3** Utilization of Indigenous-based theories (Knowledge) within Western-based intervention paradigms. Examples of strategies utilized

<p>Intervention: Qungasvik (Toolbox): Alcohol and suicide risk prevention for Yup'ik Alaska Native youth. PI(s): Allen/Rasmus</p> <p>Strategies employed: Indigenous knowledge was utilized in a community-driven and culturally based intervention process guided by a local Indigenous theory of change. The intervention manual implements a flexible, mutable, and syncretic Yup'ik process of local adaptation of cultural activities reflecting both aboriginal as well as post-colonial attributes. The function of these intervention activities involves delivery of protective factors from alcohol misuse and suicide risk to youth.</p>
<p>Intervention: <i>Kā-HOLO Project</i>, an intervention utilizing hula, the Indigenous dance form of Native Hawaiians. PI: Kaholokula</p> <p>Strategies employed: Indigenous knowledge was utilized by employing hula, a long-held traditional practice utilized in Native Hawaiian communities, to address hypertension. Hula is grounded in Indigenous knowledge and values expressed through components of chants/music and dancing, and education with regard to the cultural meaning of each hula dance.</p>
<p>Intervention: A wood stove intervention, PI(s): Belcourt/Noonan/Ward</p> <p>Strategies employed: Indigenous knowledge was utilized by identifying stories identified by community members regarding the historical and cultural role fire and wood stove use has had within the partnering Indigenous communities. As a result, three short films were utilized, including both culturally adapted films and original films that were created by Native community members using traditional ecological knowledge shared by cultural leaders.</p>

Cognitive Theory (Bandura 1986) and the Social Ecological Model (Bronfenbrenner 1986) to guide intervention development by helping to conceptualize the individual as situated within broad family, institutional, community, and political networks that influence their perceptions, behavior, and ultimately, their health status. Booth/Buchwald/Oxford (1R01-NR014153-01) are utilizing Bowlby's Attachment Theory (Bowlby 1969) to guide intervention development in understanding the experience and reactions of infants and children exposed to stress, adverse events, and trauma. To understand the factors affecting tobacco use among AIs, Choi (1R01-CA174481-01) utilizes Critical Medical Anthropology (CMA; Singer and Baer 1995) as an overarching organizing perspective. CMA calls for the integrated study of the political-economic framework and cultural meaning of tobacco. Choi added Kleinman's idea of patient/provider explanatory models (Kleinman et al. 1978) and the Protection Motivation Theory (PMT; Rogers 1975) to guide his web-based smoking cessation program at the intermediate, micro-social, and individual levels. Choi will also address the individual behavior of cessation by incorporating ideas from PMT into his curriculum. PMT includes ideas from the Health Belief Model (Rosenstock 1974) and the constructs of self-efficacy, fear arousal, appraisal, and coping.

Standard randomized control trial (RCT) methodologies were employed in 17 of the 21 (81.0%) of studies. However, some non-RCT approaches were employed. For example,

Wallerstein and Belone (1R01-DA037174-01), using Paulo Freire's empowerment theory from the Global South, are conducting a quasi-experimental comparative longitudinal design within and across three tribal communities by a comparison of the intervention group with the usual and customary comparison group, an advantage not possible with single-group over-time design. Also, utilization of a stratified-group randomized study design was employed by Gittelsohn (5R01-HL122150-02). Three AI communities were selected to serve as an intervention group and three were selected as the comparison (delayed intervention) group since the interventions involved community-based interventions. Whitesell (1R01-DA035111-01) provided one of four components of the intervention "Thiwahe Gluwas'akapi" to participants in order to observe how well each component works in order to create the best intervention "package" at the end. One IRINAH study (Lowe and Baldwin [1R01-DA035143-01A1]) has strengthened youth capacity by having the youth who initially received the intervention help implement the program for the youth in the lagged intervention group. Another study (Belone and Wallerstein [1R01-DA037174-01]) interviews tribal program leaders to assess the level of diffusion of intervention components in order to identify widespread community benefit.

### Cultural Adaptation if Based on an Evidence-Based Treatment (EBT)

Several studies culturally adapted EBTs for Indigenous populations, most often using formative mixed qualitative and quantitative methods. The studies reviewed are not using designs to test whether culturally adapted interventions are more effective than non-adapted interventions. The rationale for cultural adaptation came from initial community needs assessments or other formative/relationship building work indicating that approaches specific to the culture were most relevant and potentially effective. For instance, in the delivery of "5 A's intervention for pregnant smokers," a community-based intervention for tobacco cessation, Patten's study (1R01-CA164533-01A10) uses a "Native Sister," in contrast to research staff to deliver the intervention, which is culturally relevant but brings challenges with respect to ensuring successful implementation and fidelity of the intervention. Patten also modifies content to include digital stories and to promote Native cultural activities to cope with nicotine withdrawal and stress. Social marketing campaign messages and delivery channels were developed through focus groups and individual interviews of pregnant women, family members, and elders. To guide adaptation and implementation of "Brief Alcohol Screening and Intervention for College Students (BASICS)," a Tier 1, evidence-based alcohol intervention from mainstream colleges, Duran (1R01-AA022068-01) is utilizing a qualitative exploration of key themes emerging from Tribal

College students, faculty, and staff to guide adaptation and implementation of the intervention. Booth-LaForce, Buchwald, and Oxford (1R01-NR014153-01) will use a descriptive, qualitative method to adapt the Promoting First Relationships (PFR) intervention. Focus groups will be conducted among elders, caregivers, healthcare, and agency staff to assist in the adaptation of the intervention. Investigators will then discuss and summarize key points with regard to adapting the intervention.

## Honoring the Medicine (Discussion)

Our analysis provides a unique perspective with regard to how researchers currently funded under the “Interventions of Health Promotion and Disease Prevention in Native American (NA) populations” grant mechanism are addressing key challenges to working with AI/AN/NH communities. Our findings highlight the necessity of employing a community-based participatory approach and having partnerships in place between researchers and AI/AN/NH communities to help ensure culture-centered interventions are developed in a culturally appropriate manner. It is clear that community member involvement, from initiation, to planning, to implementation, and evaluation strategies, is a critical aspect of working with tribal communities. A new conceptual CBPR model showcases the value of understanding cultural context as the basis for creating equitable partnering processes (Wallerstein et al. 2018). Effective community involvement can also produce intervention sustainability, build community capacity, and promote culture-centered interventions and transferability of study findings (Belone et al. 2017). Ultimately, obtaining community buy-in and participation in developing/adapting interventions will be more likely to result in a decrease in health disparities by improving interventions and enhancing positive outcomes of health and well-being. Further, federal support addressing health disparities research is needed in order to keep these efforts going and to more fully realize the potential of developing culture-centered interventions.

In the IRINAH network, several teams are using Western-based theories/frameworks. This finding is somewhat surprising due to the specific call of this grant announcement targeting NA communities. Researchers may have been obligated to utilize these theories partially due to the expectation of their use by NIH reviewers. Some Western-based theories, however, may resonate for AI/AN/NH communities or can become hybrid models by incorporating Indigenous constructs and theories. The Western theories/models that may be more relevant are multilevel, collective, or family-based approaches. Several IRINAH projects are also applying Indigenous ways of knowing and theoretical constructs that might be considered more culturally based, such as collectivism, belonging, balance, respect, spirituality, harmony, and

holism. Despite these advances, more research is necessary to assess how the theories/frameworks and constructs used by IRINAH investigators are operationalized across studies and how they are effectively integrated into prevention programs in AI/AN/NH communities (Walsh 2014). Ideal theoretical frameworks for future AI/AN/NH prevention programs might embrace adaptability and cultural tailoring; cultural beliefs, spirituality, resiliency, and traditional practices; and individual, familial, and community factors, while also addressing contextual factors. These contextual factors include historical events and societal risks, such as historical trauma, colonization, racism, and present-day social economic conditions, as well as contextual factors of resilience, including cultural pride and identity, determination, social cohesion, and collective efficacy (Kirmayer et al. 2009, 2011).

Utilization of cultural-based measures analyzing culturally specific constructs, such as cultural identity and spirituality, may assist toward capturing how culturally centered interventions can alleviate AI/AN/NH’s suffering from a variety of health problems. Established guidelines with regard to the development and utilization of assessments analyzing these constructs among AI/AN/NHs are needed. Such efforts can help to advance science by promoting more effective ways to identify common challenges as well as effective CBPR practices.

While the vast majority of funded research studies analyzed in this report utilized some version of a RCT research design, the IRINAH investigators strongly challenge the notion that a RCT is always the best way to test an intervention in the context of AI/AN communities. The advantage of using RCTs are that they fit the traditional scientific “gold standard” of testing efficacy and effectiveness across populations and are highly acceptable to scientific review bodies. However, there are multiple disadvantages to the use of RCTs in AI/AN/NH populations, where they may be perceived as unacceptable and unfair. Randomization may not appear to make sense if the investigators have longer and more established relationships with some communities over others, and therefore may be more “ready” for the intervention. Ethical and social justice concerns often arise through the use of RCTs in this population, as the control-group communities or individuals are seen as receiving a lesser intervention, or none at all. Other challenges include possible cross-contamination in small, close-knit communities, recruiting sufficient numbers in each condition in small communities, the desire to provide fair access to the program to the whole population, and the concern that Western research protocols do not prioritize the importance of providing benefits to the entire community. In fact, for tribal members on the research team, to deny other tribal members the more effective, or even what is perceived to be the more effective intervention, can result in an ethical and cultural, and often stressful, struggle for both academic and community investigators.

Multiple strategies have sought to address the disadvantages of utilizing RCTs among AI/AN/NH communities, though these, too, face challenges. For example, some RCT designs have randomized schools versus randomizing individuals to reduce cross-contamination. NIH reviewers have leveled critiques at these designs because they perceive the units of analysis are too few, even though many tribal communities have only two schools to include in the design. Another strategy (used by several of the IRINAH studies) includes working with multiple tribal communities in order to aggregate data for larger numbers. Randomization of community may be necessary for complex multilevel community-based trials. However, the complexity of this design can also add burdens of increased staff and resource needs, as well as needing to go through independent, and often lengthy, approval processes within each tribe.

It is important to note that other potentially more culturally appropriate designs have been observed. For example, traditionally, designs that have been effective in addressing fair access to interventions can include delayed interventions as comparison groups. Yet, these too may produce more mistrust if community members do not understand the wait or the reasons behind this wait. It is critically important to work through design issues with tribal community advisory boards or tribal research teams. RCTs might be considered the gold standard, but they are often not able to provide the longevity of follow-up or be adaptive enough to respond to changing conditions (Frieden 2017). Other designs are emerging as important alternatives, such as pragmatic adaptive trials; matching interventions with risk; or mixed methodologies that also incorporate qualitative data collection into all kinds of designs, including RCTs, quasi-experimental, single pre-post, or multiple case studies to triangulate understandings about the pathways to change and how cultural perspectives contribute to intervention effectiveness (Frieden 2017). Rather than rely only on comparisons, alternative secondary aims can seek to build capacity in tribal programs for sustainability and diffusion. We recommend, for any research project, that these advantages and disadvantages are well discussed with tribal partners before any decisions are made on the range of available options. Specifically, what forms of non-RCT study designs will work in NA communities and still be acceptable to Western science? The studies reviewed here do not address such questions, but the IRINAH-developed interventions could be incorporated into future studies to examine these issues. The methods used to culturally adapt and re-center EBTs included the use of focus groups, discussions with community advisory boards, key informant interviews, consultation with cultural leaders, and community review and decision-making related to intervention development and methods. Formalizing the process of adaptation helps to ensure that the integrity of the intervention is kept intact, while maximizing its deliverability to the target population (Barrera

and Castro 2006; Lau 2006). Western science has been criticized for assuming that recommended evidence-based interventions (e.g., CDC 2015) “should work for all,” even if subpopulations were not adequately included in the clinical trials. However, there is evidence based on meta-analyses studies by Benish et al. (2011) and Smith et al. (2011) that culturally adapted behavioral interventions may be more effective than their unadapted original version for addressing primary outcomes.

Furthermore, cultural adaptations may be required not just for AI/AN/NHs in a general sense, but also more specifically for AI/AN/NH subpopulations, such as those residing in urban areas, small rural or island communities, or communities where cultural resources are limited. On the other hand, there are few data on the potential impact of culturally designed versus non-adapted (i.e., general audience) interventions (Belone et al. 2016, 2017; Kaholokula et al. 2017). Most of the studies reviewed here are outside the scope of addressing such questions but the IRINAH-developed interventions could be tested in future trials examining this issue. In addition, the extent to which adaptations need to be made to specific tribal groups or subpopulations is not clear, which decreases potential scalability and dissemination of interventions, or if broad adaptations could be made that have relevance to several communities (Institute of Medicine 2012, 2013).

Some interventions identified in this review are utilizing AI/AN/NH traditional practices. Although various reports have advocated for their utilization in the development of new treatments that could address the unique needs of this population, further NIH-funded studies analyzing their potential effectiveness are needed in order to aid in wider dissemination and reimbursement of services by major insurance companies and Medicare/Medicaid.

With regard to study limitations, some authors on this paper are principal investigators of the studies analyzed, which may cause bias. Thus, this study may not be as objective as it would be if non-involved researchers conducted it.

Strategies employed by recently funded researchers under the “Interventions of Health Promotion and Disease Prevention in Native American (NA) Populations” program demonstrate how barriers historically facing researchers can be overcome through utilization of qualitative methodologies and through the blending of both Indigenous-based and Western-based theories and methodologies. Also, recognizing that investigators conducting research among AI/AN/NHs may feel forced into using conventional research designs, including RCTs and various Western-based theoretical constructs, to increase their funding chances deserves further attention. Nonetheless, research strategies found in this study demonstrate how culture-centered interventions, guided by both scientific and Indigenous-based principles, can result in the development of potentially beneficial interventions that can help to decrease health disparities that are known to exist



within this population. Collectively, the funded IRINAH projects demonstrate the importance, relevance, and viability of Indigenous-based theories and knowledge systems in achieving health equity for AI/AN/NH communities.

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## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that we have no conflicts of interest.

**Ethical Approval** This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** Because this article is a review of research projects, informed consent is not applicable.

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