



Original article

Planning for a Group-Randomized Trial With American Indian Youth

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A B S T R A C T

Purpose: To describe lessons learned working with tribal communities in the Northern Plains to plan and implement a group randomized trial of multimedia *Circle of Life* (mCOL), a sexual risk reduction program designed for American Indian (AI) youth.

Methods: Project records including emails, travel reports, and meeting minutes were reviewed and synthesized to describe participatory development of the project.

Results: Several challenges were identified including: discussing sexual health interventions for preteens with communities; developing a culturally appropriate research design; managing costs of conducting research in remote and culturally distinct tribal communities; and building research infrastructure of partner organizations. Opportunities for strengthening research partnerships included transparency, openness to bi-directional learning, planning for change, flexibility, and strategic use of technology.

Conclusions: Findings suggest that meaningful AI community participation in research trials is achievable and a critical step towards generating evidence for interventions in settings where they are most needed. Substantial investments in time, resources, and relationship-building are necessary.

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IMPLICATIONS AND
CONTRIBUTION

Little is known about developing randomized trial research designs with tribal communities. This paper describes our experiences navigating between the worlds of research and tribally based organizations serving American Indian youth to assess a culturally appropriate sexual risk reduction program.

American Indian and Alaska Native (AIAN) youth 15–19 years of age experience high birth rates. Nationally in 2010, AIANs had the third highest teen birth rates (38.7 births per 1,000), after African-Americans (51.5 births) and Hispanics (55.7 births) [1]. However, national statistics mask especially high teen birth rates for AIANs in certain areas of the country, such as North Dakota and

South Dakota, the location of the project. In these states, AIAN teen levels are 96.4 and 99.3 per 1,000, respectively, rates almost five times higher than their White counterparts of the same state [1]. In contrast, birth rates for younger adolescents, 10–14 years of age, are comparable across race groups and substantially lower than those of 15–19 years of age. Clearly, effective prevention messages for AIAN youth should be aimed at this younger group. Yet, to date, no evidence-based intervention exists for this population.

Circle of Life (COL) is a classroom-based curriculum developed for AIAN youth to address sexual risk [2,3]. The original curriculum was an age-appropriate comprehensive HIV prevention program, developed with extensive community review and input from AIAN parents, educators, and health experts across the country. In a school-based group-randomized trial (GRT) with AI seventh and eighth graders of a Northern Plains community, COL was shown to be effective in delaying sexual initiation among the

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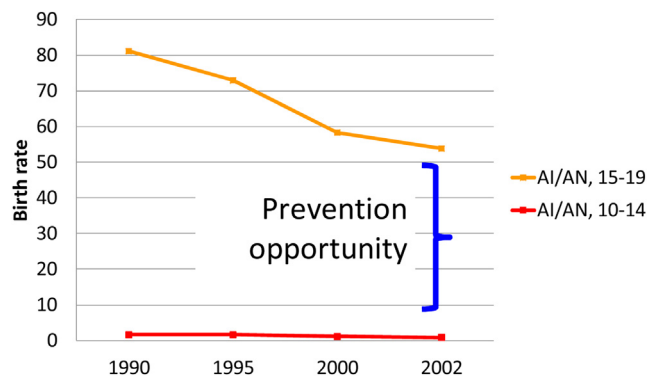


Figure 1. Teen birth rates, American Indian/Alaska Native girls 10- to 14-year-olds and 15- to 19-year-olds (per 1,000) [26].

youngest of this sample—those who received COL at 13 years of age or younger [4].

In 2010, we received funding from the Office of Adolescent Health as a part of the Teen Pregnancy Prevention Program innovative strategies grants to adapt the COL curriculum to an online format appropriate for 10- to 12-year-olds in after-school settings and to test the modified curriculum's effectiveness in a GRT. We partnered with the Office of Minority Health Resource Center and the Indian Health Service to revise COL in a multimedia format (mCOL). The adapted curriculum comprises seven online chapters with supplemental group activities. The new version also contains more information on teen pregnancy prevention and Hepatitis B and C, a growing health concern in AIAN communities. We employed community-based participatory research (CBPR) approaches in this research effort, partnering with Native Boys and Girls Clubs (NBGCs) in tribal communities of the Northern Plains. CBPR is recognized as key to success in research with minorities [5,6]. However, little is known about the interplay of partnership and the implementation of randomized trials in AIAN communities [7]. In randomized trials, researchers strive for a controlled environment; in many AIAN settings, scarce resources, traumatic events, weather, long distances, and distrust of outsiders may combine in various ways to disrupt the research process. Yet, evaluating interventions in challenging settings is vital; youth in such settings are often those most in need of effective programs. In any setting, a successful trial requires planning. The literature is replete with guidance for conventional clinical trials. However, the paucity of community-based trials in tribal settings has resulted in a virtual absence of analogous guidance. Here, focusing on preparations for a randomized trial, we share our experiences in navigating between the worlds of research and tribally based organizations serving AIAN youth to generate evidence of effectiveness for a culturally appropriate sexual risk reduction program.

The Setting

Our partners, the NBGCs, were located in highly disbursed tribal communities spanning an area of more than 6,250 square miles—the combined tribal populations totaled about 100,000 or approximately 16 persons per square mile. To serve youth across such wide expanses, several NBGCs had multiple sites, called “units.” In total, the project worked with 16 different units located in distinct tribal communities. These communities were located in some of the poorest counties of the nation, where educational and

employment opportunities lagged substantially behind the nation's average [8]. They have withstood a long history of damaging federal policies resulting in the loss of land and forced relocation, educational policies emphasizing deculturation, and a prohibition on spiritual expression that extended into the 1970s [9–11]. Despite the difficult history, these tribes took deep pride in their legacy of activism and resilience, marked by a resurgence in traditional teachings, practices, and language [12]. (Due to an agreement with our tribal partners, we do not name specific communities.)

NBGCs in these small, rural communities faced unique challenges. They operated as not-for-profit organizations, legally independent of tribal government. However, the relationship of each NBGC with its respective tribe varied considerably. Some tribes were highly supportive (financially and organizationally), whereas others were uninvolved and separate. To remain viable, each NBGC had to obtain its own funding, but securing stable financial support was often challenging. In contrast to urban Boys and Girls Clubs, which often receive corporate sponsorships or community funding, these rural NBGCs had few, if any, profitable local businesses for sponsorship. Consequently, without tribal support, the NBGCs struggled for funding.

Community Views on Rigorous Research With Young AIAN Adolescents

The design for the project was a longitudinal GRT with young adolescents to evaluate a sexual risk reduction intervention. Many components of the project were potentially problematic for the communities. First, research with AIAN communities has had a turbulent history punctuated by violations in confidentiality, research protocol, and ethics [13,14]. Second, the concept of a control group has been objectionable to many underserved communities, since needs are so great. Excluding half of the participants from services has been simply unacceptable. Finally, while some in the communities were familiar with evaluation, few had experience with randomized trials. The requirements of a highly controlled setting were often incompatible with the practicalities of everyday life in NBGCs of reservation communities.

Acknowledging the sensitive nature of this project, we worked to provide transparency and flexibility in anticipation of community concerns. Several examples illustrate this approach. (1) We had three community-based tribal members on our project team, all with extensive experience conducting research in AIAN Northern Plains communities. These team members were vital to initiating and sustaining community relationships. (2) We established a community advisory board (CAB) of representatives from each community. We held open discussions with the NBGCs, CAB, and respective tribes to present the project design including the risks and benefits afforded to participants and communities by collaboration. As those relationships strengthened, these entities in turn fostered support among community families. (3) Our design was originally a wait-listed design—so all units would receive the intervention but at staggered intervals. However, the CAB preferred a design with an alternative treatment. We thus modified our design to include a science intervention for the comparison group. This program, called After-School Science Plus [15], had no on-line section, but was age appropriate, included approximately the same number of chapters and time commitment as COL, involved simple hands-on activities, and had no content overlap with COL. (4) Random assignment was also a concept not readily accepted. Parents (and NBGC staff) thought it odd that programs would be

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