

Recruitment and Retention in Randomized Controlled Trials with Urban American Indian/Alaska Native Adolescents: Challenges and Lessons Learned

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Abstract

Background: Although the majority of American Indians/Alaska Natives (AI/ANs) reside in urban areas, there are very few randomized controlled trials (RCTs) analyzing culturally centered substance use prevention interventions for this population.

Methods: We describe methods employed to recruit and retain urban AI/AN adolescents into a RCT, which was focused on testing the potential benefits of a substance use prevention intervention for this population. We also report challenges encountered in recruitment and retention of participants and strategies employed addressing these challenges. Data collection occurred from August 2014 to October 2017.

Results: We partnered with two community-based organizations in different cities in California. We utilized AI/AN recruiters from communities, placed flyers in community-based organizations, and asked organizations to post flyers on their web and social media sites. We also offered gift cards for participants. Our initial recruitment and retention model was moderately successful; however, we encountered five main challenges: 1) transportation, 2) increasing trust and interest, 3) adding research sites, 4) getting the word out about the project, and 5) getting youth to complete follow-up surveys. Strategies employed to overcome transportation challenges included shortening the number of sessions, offering sessions on both weekends and weekdays, and increasing bus tokens and transportation options. We hired more staff from AI/AN communities, added more research sites from our previously established relationships, and were more pro-active in getting the word out on the project in AI/AN communities. We also utilized more field tracking, and emailed and mailed survey invitations to reach more participants for their follow-up surveys. Because of our efforts, we were nearly able to reach our initial recruitment and retention goals.

Conclusions: By identifying challenges and employing culturally appropriate strategies, we were able to collect valuable data on the potential effectiveness of a substance use prevention intervention for urban AI/AN adolescents. Findings from this study assist toward the development of potentially successful strategies to successfully recruit and retain urban AI/AN adolescents in RCTs.

Background

Approximately 70% of American Indians/Alaska Natives (AI/ANs) reside in urban areas [1]. However, there are few randomized controlled trials (RCTs) with this population that analyze the potential benefits of substance use prevention interventions [2]. RCTs analyzing the potential benefits of substance use prevention interventions among urban AI/AN adolescents are also quite limited, and most RCTs have been conducted on reservations and with older AI/AN participants [3]. In a recent study describing funded studies of prevention interventions for AI/ANs under the National Institutes of Health (NIH) mechanism, Intervention Research to Improve Native American Health (PAR-14-260), only one of thirty-one studies focused on analyzing the benefits of an intervention among urban AI/AN teens using an RCT design [4].

Furthermore, there is little work describing the experiences of conducting RCTs in urban settings with AI/AN adolescents. As a result, there are few well-developed strategies that address recruitment and retention of urban AI/AN adolescents in RCTs.

Inherent challenges exist in conducting RCTs with AI/AN populations as researchers in the past often conducted studies with AI/ANs unjustly and without community input. Community interest was typically not considered, which led to a mistrust of the research process within many AI/AN communities [5]. For example, in one study conducted in an AN village during the 1970s, researchers released findings of high alcohol rates to a major news source prior to discussion with community members [6] resulting in a negative media portrayal of their community. Also, in a study conducted with the Havasupai tribe in 1990, researchers obtained DNA samples to analyze potential genetic clues to the tribe's high rate of diabetes without consent to investigate other aspects of their lives, including theories of the tribe's geographical origins. The researchers then published findings without the tribe's consent suggesting that contrary to the tribe's origin story, its ancestors migrated across the Bering Sea [7, 8]. Furthermore, past "helicopter research" sought to exploit AI/ANs by swooping into AI/AN communities, gathering data, and leaving them without recommending any changes. As a result, researchers took their data and then left AI/AN communities without any resources to implement, disseminate, or sustain promising interventions [8, 9]. Furthermore, most researchers in health promotion research are not AI/AN, which dampens community trust necessary for successfully conducting studies within this population [4, 10, 11, 12].

Another challenge in conducting RCTs with AI/ANs in urban areas is that the population is widely dispersed across large urban environments, making it more difficult to find and recruit participants. Further, this population may find it challenging to connect to AI/AN social networks, clinics and organizations where they may be able to learn about potential research opportunities [13]. Urban AI/ANs also experience high rates of poverty and unemployment [14], which may decrease feasible transportation options necessary for research participation.

Motivational Interviewing and Culture for Urban Native American Youth (MICUNAY)

Our team worked together with several AI/AN communities in the state of California to develop and test Motivational Interviewing and Culture for Urban Native American Youth (MICUNAY), an alcohol and other drug (AOD) use prevention intervention program that integrates motivational interviewing (MI) and AI/AN traditional practices [15, 16]. The foundation of MICUNAY is based on extensive community-based work conducted by Daniel Dickerson and Carrie Johnson [18, 19, 20], Kurt Schweigman [21], Ryan Brown [22, 23, 24], and Elizabeth D'Amico [25, 26, 27, 28]. MICUNAY targets a variety of behaviors, including reducing AOD use and increasing well-being, spirituality and cultural identification. All MICUNAY workshops use a MI approach and different MI strategies, such as discussion of the pros and cons of AOD use and rulers [29]. MICUNAY also utilizes the Northern Plains Medicine Wheel, which is a conceptual, culturally acceptable model [30] routinely utilized in health clinics serving urban AI/ANs in California. The Northern

Plains Medicine Wheel focuses on emotional, mental, physical, and spiritual aspects of well-being and helps to provide participants with a visual representation of session content.

The purpose of this article is to describe how we successfully conducted an RCT in AI/AN urban communities with AI/AN adolescents across the state of California. We discuss how we incorporated feedback from focus groups with the MICUNAY Community Advisory Board (CAB) and the adolescent CAB to address initial challenges in starting up the project, the challenges we encountered over the course of the project in recruitment and retention of participants in the RCT, and the strategies we employed to address these challenges.

Methods

Research Team

The research team was comprised of co-Principal Investigators, Dr. Elizabeth D'Amico from RAND, Dr. Daniel Dickerson from UCLA, Integrated Substance Abuse Programs (ISAP), Dr. Ryan Brown, co-Investigator, from RAND, and the RAND Survey Research Group (SRG). We also collaborated with our community partner, Sacred Path Indigenous Wellness Center (SPIWC), led by Dr. Carrie Johnson. Dr. Dickerson is an Alaska Native (Inupiaq) addiction psychiatrist known for his research on the development and implementation of culturally centered substance use treatment and prevention interventions [15,20]. Dr. D'Amico is recognized for her work developing and implementing MI interventions with vulnerable adolescent populations [31,32,33], and Dr. Brown has conducted field research with marginalized youth populations around the world, including five years of fieldwork among the Eastern Band of the Cherokee Indian [24,28]. The RAND SRG team was led by Ms. Parker, Senior Survey Coordinator, who oversaw research activities. SRG has extensive experience interviewing people of various ethnic backgrounds in diverse settings and collaborating with community-based organizations. SPIWC is a non-profit (501c3) organization that provides consultation and service-related assistance for research entities and organizations conducting research within AI/AN communities led by Dr. Johnson. Dr. Johnson is Wahpeton Dakota, and has worked within the AIAN community for over 20 years. SPIWC helps to ensure that research and services provided are culturally appropriate. SPIWC also employs recruiters and facilitators in different communities to assist with community engagement, which ensures that individuals are familiar with their community and are well respected and trusted.

Research Overview

The NIH mechanism, Intervention Research to Improve Native American Health (PAR-14-260) funded the MICUNAY research study. The purpose of this funding opportunity announcement (FOA) was to develop, adapt, and test the effectiveness of health promotion and disease prevention interventions in Native American populations. This FOA sought intervention approaches that targeted both individual behaviors and intervened at social and institutional levels. This FOA required that researchers employ a community-

based participatory research (CBPR) approach, focusing on intervention development during the first year. Researchers would then conduct the RCT, followed by analysis of the potential benefits of the intervention [34].

As part of the intervention development phase, our project worked with several urban AI/AN communities and organizations to finalize the development of MICUNAY, learn about challenges facing urban AI/AN adolescents, and discuss recruitment and retention strategies for the RCT [15,35]. We conducted focus groups with AI/AN adolescents, providers, parents, and the MICUNAY CABs at several research sites. We had an adult CAB, which consisted of AI/AN leaders in the community, elders and community members, and an adolescent CAB, which consisted of teens who provided feedback throughout the project. Focus groups discussed all project materials and recruitment plans. The project employed Robert Young (Pueblo of Acoma), an AI graphic artist to design various options of project logos. These logos were then vetted by community members to select the final project logo. This assisted with community engagement and initial interest in the project.

Next, we conducted the MICUNAY RCT. We invited youth in two urban areas in northern and southern California between the ages of 14 and 18 to participate in the project (See Overall Demographics on Table 1). All youth who enrolled in the RCT completed a baseline survey. We administered the survey on paper, and youth who completed it received \$25 cash. We held survey sessions at community partner sites when possible. We randomly assigned youth to one of two groups. We asked youth assigned to the control group to attend a Community Wellness Gathering (CWG). We also asked youth assigned to the intervention group to attend both a CWG and the MICUNAY intervention workshops. CWGs consisted of community gatherings with various cultural events aimed toward promoting healthy behaviors and an alcohol/drug free lifestyle. MICUNAY workshops incorporated traditional AI/AN teachings with MI. A group facilitator experienced in working with AI/AN populations led each of the three, two-hour workshops. We offered youth who randomized to the control group the opportunity to attend MICUNAY workshops after data collection was completed. We asked all youth to complete follow-ups at 3- and 6-months. Youth completed follow-up surveys via web or on paper [16].

Initial Recruitment Approach

To ensure community engagement and successful recruitment of youth, we worked with SPIWC to hire AI/AN recruiters and facilitators who were from the communities where we were conducting the research. We asked community partner staff at organizations that serve AI/AN adolescents to place flyers. We also asked them to post the flyer on their web and social media sites. We trained site staff on how to present the project to interested youth, and ask interested youth to complete a Consent to Contact (CtC) form that staff would then fax and send via FedEx to RAND. The CtCs asked for basic contact information to give RAND SRG permission to call the parent/guardian to explain the project and ask for consent.

RAND SRG hired interviewers from outside the community to conduct baseline survey sessions based on our discussions with the community. This was because surveys asked about personal information such as substance use. Based on our discussions and focus groups, it was clear that having people outside the community was important for the survey component so that teens felt comfortable handing in completed surveys, which was more likely if they could hand them in to a stranger, versus someone from their community who may know a family member.

Initial Retention Approach

In order to encourage attendance at baseline survey sessions and the MICUNAY workshops, we initially offered bus tokens or train reimbursement to assist with transportation costs. In addition, the research team gave teens who attended all three MICUNAY sessions a certificate of completion and a MICUNAY hoodie. At CWGs, we conducted raffles for prizes like re-usable water bottles, project t-shirts, and project hoodies, and one \$50 gift card per gathering. We also provided adolescents with a \$50 gift card for completing the 3-month survey and a \$75 gift card for completing the 6-month survey.

Results

Challenges encountered

We encountered five main challenges during initial recruitment: 1) transportation, 2) increasing trust and interest, 3) adding research sites, 4) getting the word out about the project, and 5) getting youth to complete follow-up surveys. In order to address these challenges, we developed several different strategies. We describe each challenge and the strategies we employed in the following paragraphs.

Modified Recruitment and Retention Approaches

Transportation

Initially, we had planned to offer six one-hour MICUNAY workshops. We received feedback from focus groups that transportation to workshop locations could be challenging for youth. For example, one provider stated, "I think in [our community], transportation is a big issue." Based on these discussions, we decreased the number of workshops from six one-hour sessions to three two-hour sessions. One urban AI/AN youth stated, "I think more [sessions] on the weekends than on the weekdays because people would come at 7 o'clock [p.m. during weekdays]." In response to this feedback, and in order to maximize attendance at the MICUNAY workshops, we also held sessions on weekends in addition to weekdays. This allowed teens with conflicts during the week to attend sessions. Reduced weekend traffic also eased

the burden on parents to be able to bring their son or daughter to sessions. To further assist with transportation issues, we also increased the amount of bus tokens and train reimbursements offered. In addition, one urban youth suggested, "Provide rides like we do here. They pick us up and drop us off." After further discussion with our community partner organizations, when sites offered transportation, we provided stipends to assist organizations with costs as necessary. These modifications increased the chances that these urban AI/AN teens could attend MICUNAY sessions.

Increasing trust and interest

Burdened with their own workloads, community partner staff who agreed to help distribute flyers and present the project to teens indicated that it was difficult to take time to explain the project to youth given their day-to-day work requirements. In meeting with our community partners, we quickly learned that we would need to hire dedicated staff from the AI/AN community to help with recruitment and increasing interest and trust in the community. SRG and SPIWC worked together with several AI/AN organizations in each city to identify AI/AN community members and respected individuals in the community to approach potential participants in a culturally appropriate manner in order to increase comfort levels. We emphasized to all the communities our plans of returning to present our findings and obtain feedback on their view of the project and interpretation of findings. We also emphasized that they could use data from our project for future grants to support their organizations as data on urban AI/AN adolescents are very limited.

Adding research sites

Due to lower than expected recruitment early on in the RCT, the project approached a multitude of other community-based organizations and added several new research sites in California. Dickerson and Johnson had several previously established relationships with AI/AN communities and organizations throughout California. Their presence in community meetings and discussions at new research sites helped to garnish trust among community members. These community partners were particularly encouraged that we offered MICUNAY workshops to teens randomized to the control group upon completion of data collection, thus highlighting that our project wanted to ensure that everyone who wanted the intervention was able to receive it. Community partners also appreciated our willingness to share de-identified, aggregate data once analyses were completed. Given our CBPR approach, we were able to partner with organizations in 10 cities across northern, central, and southern California.

Getting the word out about the project

In order to increase recruitment, dedicated staff created a social media presence for the project by maintaining a Facebook page of project related events. We also set up informational events with our

community partners where we would present the project to staff and the communities they served. We always provided food at these events, and we had entertainment when feasible. During these presentations, we would explain to staff that the project would not compete with their current programming, but could help supplement programming and be an additional resource. We also discussed the importance of research on urban AI/AN teens, and how programs could use our aggregate data to help with future funding opportunities. Feedback retrieved from the CAB focus group suggested a wider recruitment approach. For example, one CAB member stated, "I think in terms of recruiting, that's why we focus the different areas that are close to here, just so you have a wider group of kids to select from...so that's why we try to disperse the people to [section of community] and to [section of community] to have a wider pool of kids that would be less duplicated." Applying this feedback, our recruiters attended more community events such as Pow Wows, AI/AN gatherings, and established AI/AN youth and parent groups to help get the word out about the project. The project set up informational tables at these events so recruiters could introduce the project to teens and their families. In order to encourage teens to approach the MICUNAY table, we purchased giveaways, such as colored pencils that changed color when touched, re-usable water bottles with the project logo, and T-shirts. Feedback from our CAB focus group highlighted the importance of incentivizing participants. Thus, we added an incentive of either a \$5 Target gift card or a free movie pass for teens who attended each session. For CWGs, we assisted organizations by paying the presenters they brought in, which allowed them to enhance the cultural programming for their communities.

Getting youth to complete follow-up surveys

When we began fielding the 3-month follow-up survey, we initially experienced a low response rate of survey completion, which was surprising to us given the incentive (\$50) and that the survey could be completed via the web. We therefore began to use both email and mailed survey invitations, increased the number of mailings, added in phone follow-ups, and employed field tracking for the hard-to-reach teens. Through field tracking, we found that by using mobile phone technology, teens were mostly at home and were willing to complete the survey. In talking with teens and families about why they had not completed the survey, many indicated that barriers to completing the survey on the web and via mail were mostly due to lack of internet access and lack of experience with and motivation to use "snail mail."

Recruitment and retention results

Our initial goal when we started the project was to enroll 200 teens. We enrolled 185 youth during the RCT period, which was 92.5% of our goal N of 200. Of these 185 youth, we randomized 115 to receive both the CWG and MICUNAY (MICUNAY group) and 70 the CWG only (CWG group). In terms of retention, 69 of the MICUNAY group (60%) and 44 of the CWG group (63%) attended a CWG within 3 months of the baseline survey, for a total of 113 youth (61%). Of MICUNAY group teens, 66 (57%) attended all three intervention

sessions within 3 months, and 94 youth (92%) attended at least one session within 3 months. Overall, we were able to reach 76% for follow-up surveys at 3 months, and 82% at 6 months [16].

Discussion

This study provides crucial data on understanding and overcoming challenges that exist when conducting RCTs with urban AI/AN adolescents. Although our research team was well prepared to carry out the proposed research activities, we experienced many challenges that affected both recruitment and retention during the RCT. These challenges included transportation, increasing trust and interest, adding research sites, getting the word out about the project, and getting teens to complete follow-up surveys. However, because we worked closely with our community partner, SPIWC, and with the individual urban communities, we were able to develop strategies to address these challenges, which helped us nearly reach our initial recruitment goal. In addition, we had good retention rates at both three- and six-month follow up. Given that few RCTs are conducted with urban AI/AN teens, findings provide important information on how to successfully conduct a RCT among a marginalized population. We hope that our experience can assist toward the development of more formalized strategies to successfully engage vulnerable populations in RCTs.

Use of CBPR methods allowed our research team to garnish trust and interest and fully engage these urban AI/AN communities in California, which was necessary to successfully conduct our study. We accomplished this by involving the community at the start of the project, providing community presentations, training new MICUNAY facilitators within communities, and hiring community workers. We also offered the opportunity for adolescents randomized to the control condition to participate in MICUNAY after their participation in the study, and we scheduled presentations in each community to present the findings from the project.

Given our previous work with these populations, we had established relationships with AI/AN communities that created an opportunity to add more research sites and work effectively in partnership with 10 different urban AI/AN communities. In addition, it was crucial to have research team members of AI/AN descent, which helped increase the trust of the communities in the research process, and led to the development of new relationships.

We further enhanced our recruitment efforts by proactively reaching out to the community for help. Our research team was comprised of very dedicated community members in each city who were part of AI/AN organizational staff and who attended numerous AI/AN community events and meetings to share information on the MICUNAY project. We also assisted these communities by providing funds for gatherings to have different presenters (e.g., beading workshop, hoop dancing, storytelling) for the CWGs, which significantly enhanced the cultural programming that these communities were able to provide to families.

Low initial retention rates were surprising given that follow-up surveys were web-based and incentivized. However, our proactive outreach efforts, including mailing reminders, phone calls, and field tracking

helped reverse this trend and provide a better understanding of how to increase the number of completed surveys.

Although this study provides important information on engaging urban AI/AN populations in RCT research, there are some limitations. First, we conducted this study in California, thus, we cannot generalize results to other urban areas in the U.S. For example, urban areas in other states may not experience the same barriers that we did in California (e.g., some urban areas have excellent public transportation), and they may also have barriers that we did not experience. In addition, our team had two AI/AN investigators who had extensive experience conducting research and working in these community-based settings. Other projects may not have the same level of experience or connections with the community.

In conclusion, findings from this study significantly build on our knowledge about effective recruitment and retention strategies for RCTs focused on analyzing the potential benefits of substance use prevention interventions conducted among urban AI/AN adolescents, thereby helping to address a significant and under-recognized public health issue in the U.S. We hope that our results will contribute to the development and implementation of future RCTs among this population. Findings highlight the importance of developing collaborative and meaningful relationships with urban AI/AN communities, and emphasize that by working closely with community members, it is possible to design a culturally appropriate RCT, thereby increasing success, which can lead to better prevention and intervention programming for this under recognized and vulnerable population.

Abbreviations

AI/ANs: American Indians/Alaska Natives

AOD: Alcohol and other drug

CAB: Community advisory board

CBPR: Community-based participatory research

CWG: Community Wellness Gathering

CtC: Consent to Contact

FOA: Funding opportunity announcement

NIH: National Institutes of Health

MI: Motivational interviewing

MICUNAY: Motivational Interviewing and Culture for Urban Native American Youth

RCT: Randomized Controlled Trial

SPIWC: Sacred Path Indigenous Wellness Center

SRG: Survey research group

UCLA: University of California, Los Angeles

Declarations

Ethics Approval and Consent to Participate

Institutional Review Board (IRB) approval was granted by RAND HSPC (Human Subjects Protection Committee), #2012-0989-CR08. Written consent and assent was obtained from study participants and written consent was obtained from a parent or guardian for participants under 16 years of age.

Consent for Publication

Not applicable

Availability of data and materials

The datasets supporting the conclusions of this article are included within the article.

Competing Interests

The authors declare that they have no competing interests.

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Authors Contributions

All authors contributed to the article's conception. DD and JP led the writing of the manuscript. JP and CJ provided details with regard to challenges encountered in the randomized clinical trial. RB and DD provided and interpreted focus group data analyzed. ED helped conceptualize the themes in the paper. All authors contributed to the interpretation of the findings; and all authors read and approved the final manuscript.

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Tables

Table 1. Demographics of Total Sample (n=185)

Age	n, %
14	51 (28%)
15	38 (21%)
16	45 (24%)
17	31 (17%)
18	19 (10%)
Gender	
Female	105 (57%)
Male	80 (43%)
Race/Ethnicity [^]	
Hispanic/Latino	83 (45%)
AI/AN	150 (81%)
Asian/Asian American/Pacific Islander	8 (4%)
Black/African American	21 (11%)
White/Caucasian	32 (17%)
Other	8 (4%)
Mother's education >=High school graduate	120 (65%)
Father's education >=High school graduate	94 (51%)

[^] Note that all youth had to self-identify as Native American to be part of the project. They then completed a survey asking them to label their race/ethnicity. These numbers and percentages reflect what youth reported on the survey and can overlap if they identified more than one race/ethnicity. Thirty-five youth did not check AI/AN on the survey, although they self-identified verbally as Native American to be in the study.

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