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Clinical trials and American Indians/Alaska Natives with substance use disorders: identifying potential strategies for a new cultural-based intervention

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Abstract

Purpose – The purpose of this paper is to address a significant public mental health disparity affecting American Indians/Alaska Natives (AI/ANs): the shortage of clinical trials research analyzing the benefits of AI/AN traditional-based treatments, e.g. drumming.

Design/methodology/approach – A total of four focus groups were conducted among outpatient and inpatient AI/AN substance abuse patients and providers serving AI/ANs. The purpose of these focus groups was to obtain insights relating to the recent challenges of conducting a clinical trial within the outpatient treatment setting seeking to analyze the benefits of a new substance abuse treatment intervention utilizing drumming for AI/ANs [Drum-assisted Recovery Therapy for Native Americans (DARTNA)] and to obtain recommendations to successfully conduct a similar study within an inpatient treatment setting.

Findings – The most prevalent barriers to conducting a clinical trial within an outpatient setting were transportation and child care issues. Recommendations were obtained with regard to optimizing recruitment and retention for a future study within an inpatient setting.

Originality/value – This research offers the field rare information that helps toward identifying strategies to successfully conduct clinical trials investigating the benefits of culturally-appropriate treatments for AI/ANs with substance use disorders.

Keywords American Indians, Alaska Natives, Substance abuse, Mental health, Public health, Drumming, Traditional treatment

Paper type Case study

Introduction

American Indians/Alaska Natives (AI/ANs) have higher rates of past-month binge alcohol use and illicit drug use than the national average for adults in the USA [30.6 vs 24.5 percent and 11.2 vs 7.9 percent, respectively; Substance Abuse and Mental Health Services Administration (SAMHSA), 2010]. However, despite this knowledge, AI/ANs have historically been grossly under-represented in clinical trial research across the substance abuse continuum (Burlew *et al.*, 2011; Greenfield and Venner, 2012). This is important to recognize since clinical trials, which are considered the “gold standard” of research, assist in establishing the efficacy of treatments (Chambless and Ollendick, 2001).

Traditional-based practices (i.e. AI/AN drumming, sweat lodge ceremonies) have been strongly advocated by AI/AN communities [Dickerson *et al.*, 2012a; Native American Health Center (NAHC), 2012]. Furthermore, the role of indigenous culture among AI/ANs can assist in enhancing protective factors through a sense of cultural identity, feeling of commitment, and

purpose (Wexler, 2013). However, provision of traditional-based substance abuse treatments within the clinical setting is often limited. Drum-Assisted Recovery Therapy for Native Americans (DARTNA) is a culturally relevant therapeutic drum behavior therapy for AI/ANs with substance use disorders (Dickerson *et al.*, 2012b). This 12-week treatment approach incorporates drumming, talking circles, the 12-steps of Alcoholics Anonymous, and the *12 Steps and Medicine Wheel* program developed by White Bison Inc. (2007). Our initial series of developmental research activities resulted in finalizing and pretesting DARTNA. In an open-trial pretest of DARTNA conducted among ten AI/ANs with histories of substance use disorders, significant improvements in medical and psychiatric status, spirituality, and physical/functioning levels were demonstrated (Dickerson *et al.*, 2014). However, a subsequent randomized, controlled trial pilot study was terminated early due to time constraints and challenges with recruitment and retention within an outpatient urban AI/AN treatment setting.

Methods

Design

In total, four focus groups were conducted during April and May of 2013 to examine why recruitment and retention were difficult in the pilot DARTNA clinical trial and to provide insights into how to successfully conduct a similar trial in an inpatient treatment setting. The four focus groups were conducted among outpatient and inpatient substance abuse AI/AN patients with histories of substance use disorders, and outpatient and inpatient substance abuse treatment providers serving AI/ANs. The two outpatient focus groups were conducted in Los Angeles County at a comprehensive outpatient clinic serving AI/ANs. The two inpatient focus groups were conducted at an inpatient substance abuse center serving AI/ANs, also in Los Angeles County.

All participants were recruited via flyers in three clinics serving AI/AN patients and in one large AI/AN community center in Los Angeles. Inclusion criteria for providers included being a certified alcohol and drug counselor, social worker, counselor, psychologist, or physician with at least one year of experience providing substance abuse services to AI/ANs. Inclusion criteria for the AI/AN patients consisted of meeting *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR; American Psychiatric Association (APA), 2000) criteria for current or past alcohol or drug abuse or dependence, self-identifying as AI/AN, being at least 18 years old, and reporting no psychiatric conditions that would preclude focus group participation.

Participants

Females constituted the majority of outpatient patients and outpatient providers (six of seven or 85.7 percent, and 6/8 or 75.0 percent, respectively). However, there were no inpatient female patients (0/7, 0 percent), and females constituted less than half of inpatient providers (2/5, 40 percent). With regard to ethnicity, all outpatient and inpatient patients were AI/AN (7/7 and 7/7, respectively). Among outpatient providers, 5/8 (62.5 percent) were AI/AN, and among inpatient providers, 5/5 (100.0 percent) were AI/AN. With regard to education level, none of the AI/AN inpatient or outpatient patients had a bachelor's degree (both 0/7, 0 percent). In total, three of eight (37.5 percent) of the outpatient providers and 3/5 (60.0 percent) of the inpatient providers had at least a bachelor's degree. The average age was 37.6 years among outpatients, 31.7 years among inpatients, 46.9 years among outpatient providers, and 49.4 years among inpatient providers.

Data collection

All focus groups were moderated by the first author of this paper. For the outpatient patients and providers, questions were asked to elicit information relating to the challenges of the recent DARTNA pilot clinical trial, which was conducted in an urban outpatient setting. For the inpatient patient and provider focus groups, questions were asked to obtain information on how a future DARTNA clinical trial could be successfully conducted within an inpatient setting. The focus groups were audio recorded and later transcribed. The study protocol was reviewed and approved by the University of California, Los Angeles (UCLA), Institutional Review Board.

Data analysis

The transcripts were reviewed by the first author of this manuscript and one of his assistants for completeness and accuracy. Notes were taken during the focus groups, and the transcripts were reviewed for categories, patterns, and themes within and across the groups. A code list was developed that was guided by the focus group topics (e.g. recruitment, retention, clinical trials, research). The first author and his assistant then discussed the overarching themes until reaching consensus.

Results

Outpatient patients and providers

The most reported challenge that patient participants reported for the pilot DARTNA clinical trial was a lack of transportation to attend the therapy sessions. The second most reported challenge was obtaining childcare in order to attend. Barriers expressed by outpatient substance abuse providers included the stigma of substance abuse and mental illness, and confidentiality concerns. Another barrier to research participation that was identified by patients was past unethical research conducted among AI/ANs. For example, one patient stated, "Oh my God, here we go again [...]. They're going to use us, abuse us, and throw us back into the gutter."

Various recruitment strategies were recommended by outpatient patients. They recommended emphasizing DARTNA as a tribally adaptable program that can accommodate the needs of a variety of AI/AN tribal groups. Also, for recruitment, outpatient patients recommended emphasizing the opportunity to learn about their own cultural histories and to learn how to stay alcohol- and drug-free in an AI/AN traditional manner. It was also suggested that hosting guest drumming groups, including DARTNA alumni drumming groups and guest elder speakers, could enhance recruitment and retention in a future study.

Patients expressed a preference for cash compensation rather than gift cards, stating that cash could be more helpful for specific needs. In addition to cash, other compensation ideas included serving coffee and food, having traditional medicines available, providing donations for basic needs, and providing an AI/AN drum.

Inpatient patients and providers

Neither of the inpatient focus groups foresaw significant challenges with recruiting or retaining AI/ANs within an inpatient setting. As one inpatient provider stated, the AI/AN inpatient environment would be culturally appropriate and supportive. However, strategies to overcome research barriers were identified among inpatient focus groups. For example, one inpatient substance abuse provider suggested offering individuals selected to the DARTNA comparison group (i.e. education group) an opportunity to participate in DARTNA at a later time. Another inpatient provider suggested emphasizing to eligible research participants of their potential of ultimately helping other AI/ANs with addiction problems through their participation in a study that seeks to validate a potentially beneficial substance abuse treatment for AI/ANs. This discussion was identified as assisting toward decreasing the stigma of research and educating AI/ANs with regard to the potential benefits of research.

Discussion

Results from these focus groups provide rare feedback relating to barriers to conducting a substance abuse clinical trial (in this case, DARTNA) in an outpatient clinical setting as well as strategies to assist in the preparation for a future clinical trial within an inpatient treatment setting. The most commonly cited barriers to conducting this clinical trial within an outpatient setting were transportation and child care issues. The prospective inpatient substance abuse treatment setting was noted as having the advantage of not needing to address transportation and childcare issues, in addition to occurring in a supportive and culturally appropriate environment.

Utilizing a Community-Based Participatory Research (CBPR) approach to conducting studies among AI/ANs, such as was done in this qualitative study, has been recommended as it fosters

community involvement with AI/ANs (Burlew *et al.*, 2011) in addition to optimizing feasibility. By actively engaging with the AI/AN community and convening a community advisory board (CAB), we gained community trust and were alerted to potential barriers to recruitment and retention in a full trial, thereby creating greater reciprocity between substance abuse researchers and the AI/AN community. For example, the researchers benefited from community-based knowledge in terms of recruitment, how to best assess participants, and how to interpret the findings. In turn, the community and community partners benefited from research through participation in a transparent research process. To facilitate this process, regularly scheduling meetings with the community and CAB to provide updates on the progress of study implementation and results is recommended.

In conclusion, results from this study provide useful qualitative data as it relates to conducting a treatment clinical trial (DARTNA) for AI/ANs with substance use disorders.

By recognizing the potential barriers to substance abuse clinical trials both within outpatient and inpatient treatment settings and utilizing a CBPR approach, there is potential for identifying culturally-appropriate substance abuse treatments that may be beneficial for AI/ANs.

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