

## A culturally-tailored behavioral intervention trial for alcohol use disorders in three American Indian communities: Rationale, design, and methods



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### ABSTRACT

**Background:** Disproportionately high rates of alcohol use disorders are present in many American Indian/Alaska Native (AI/AN) communities, yet little information exists regarding the effectiveness of alcohol treatments in AI/AN populations. Contingency management is an intervention for illicit drug use in which tangible reinforcers (rewards) are provided when patients demonstrate abstinence as assessed by urine drug tests. Contingency management has not been widely studied as an intervention for alcohol problems because until recently, no alcohol biomarker has been available to adequately verify abstinence.

**Aims:** The HONOR Study is designed to determine whether a culturally-tailored contingency management intervention is an effective intervention for AI/AN adults who suffer from alcohol use disorders.

**Methods:** Participants include 400 AI/AN alcohol-dependent adults residing in one rural reservation, one urban community, as well as a third site to be decided, in the Western U.S. Participants complete a 4-week lead-in phase prior to randomization, then 12 weeks of either a contingency management intervention for alcohol abstinence, or a control condition where participants receive reinforcers for attending study visits regardless of alcohol use. Participants are then followed for 3-more months post-intervention. The primary study outcome is urinary ethyl glucuronide-confirmed alcohol abstinence; secondary outcomes include self-reported alcohol and drug use, HIV risk behaviors, and self-reported cigarette smoking.

**Discussion:** This will be the largest randomized, controlled trial of any alcohol for AI/ANs and the largest contingency management study targeting alcohol use disorders, thus providing important information to AI/AN communities and the alcohol treatment field in general.

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### 1. Introduction

For complex reasons the need for alcohol treatment is great in many American Indian and Alaska Native (AI/AN) communities. Previous studies have observed higher rates of alcohol use disorders (AUD) in AI/AN communities than in the mainstream U.S. population (10.7% vs. 7.6%) [1]. In another study, nearly twice as many AI/AN adults reported needing alcohol treatment, when compared to others in the U.S. [3] Alarmingly, only 13% of AI/ANs who needed AUD treatment received it in the last year [3]. When AI/AN adults do receive treatment, their completion rate is lower than that of the general population [2–4]. As a result

of these disparities, the alcohol mortality rate AI/ANs experience is approximately twice that of other Americans [5]. AI/AN communities are seeking culturally acceptable, feasible, and cost-effective strategies to combat AUDs.

Despite this need, little information exists about the effectiveness of AUD interventions for AI/AN populations. Observational studies support use of “Western” and AI/AN cultural-based AUD interventions in Native communities [6–9]. Surprisingly, there are only three published randomized, controlled trials of AUD interventions in AI/AN adults [10–12]. Two observed reductions in alcohol use associated with pharmacological (naltrexone) [10] and behavioral (motivational interviewing) [11] interventions; while another found no impact on drinking when AI/AN women participated in an online intervention focused on preventing prenatal alcohol exposure [12]. While two of

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these studies observed reductions in drinking; one was not focused exclusively on AI/ANs and therefore, lacked the statistical power to determine intervention effectiveness for AI/ANs, and the other only included individuals involved in the criminal justice system [11]. Further research is needed to identify effective AUD interventions for AI/AN communities.

Contingency Management (CM) is an addiction intervention where participants receive reinforcers such as vouchers or prizes for providing objective evidence of drug abstinence [13,14]. CM is an effective intervention for illicit drugs, and relative to other psychosocial interventions, CM is the most successful at initiating abstinence [14–16,18–25]. In previous studies CM has demonstrated cost-effectiveness, feasibility, and a long term reductions in substance use that are comparable to cognitive behavioral therapies [15–17]. Though untested in AI/ANs, CM is an effective intervention for illicit drug use in other minority racial and ethnic groups [18–21].

Feasible CM interventions require a biomarker that can detect substance use in the preceding three days. Previous research on CM for AUDs has been limited by lack of such a biomarker. Ethyl glucuronide (EtG) is an alcohol metabolite [22–31] that can be detected in urine for up to five days after drinking and can be evaluated in a clinical setting using a benchtop analyzer [29,32–35]. Our work supports the efficacy and feasibility of an EtG-based CM intervention [36].

### 1.1. Study aims

In collaboration with three communities, we are conducting the Honoring Our Native Ongoing Recovery (HONOR) study, funded by the National Institutes of Health (R01AA022070), to: 1) determine whether participants randomized to a culturally-tailored CM intervention are more likely to achieve alcohol abstinence, as assessed by EtG urine tests, compared with those assigned to a control group; 2) quantify group differences for other addiction and health outcomes; and 3) identify demographic, clinical and cultural factors that modify the effect of CM on alcohol abstinence.

## 2. Methods

### 2.1. Design

The HONOR Study involves two phases: 1) a qualitative phase focused on identifying cultural adaptations to the CM intervention and 2) an RCT of the adapted CM intervention (Fig. 1). One or more focus groups will be conducted at each of the three study sites to improve the cultural acceptability of the study recruitment and intervention

procedures. Up to 20 alcohol treatment providers, individuals with alcohol dependence, and their family members will be recruited from each community to participate in focus groups. Focus group data will be used to modify study recruitment and intervention materials, including the CM reinforcers. After focus groups are completed, 400 AI/AN alcohol dependent adults will be recruited and will complete a four-week lead-in assessment period designed to increase engagement and reduce post-randomization dropout (weeks 1–4). Those who complete the lead-in phase will be randomized to receive 12 weeks (weeks 5–16) of either treatment-as-usual with contingency management (CM group) or treatment-as-usual with reinforcers that are not contingent on alcohol abstinence (Non-contingent [NC] or control group). All randomized participants will be followed for an additional three months to assess post-intervention outcomes (weeks 17–28).

### 2.2. Setting

The study will take place at an Urban Indian healthcare clinic in the Northwest, one rural reservation located on the Northern Plains, and a to-be-determined third study site pending approval. To protect their confidentiality, specific names of these sites are not provided. The Urban Indian healthcare clinic provides primary care, disease prevention, mental healthcare, and addiction treatment to AI/AN adults and youth in a city surrounded by a number of rural reservations. The site also hosts numerous cultural events and engages in community outreach, with a focus on health promotion and disease prevention. The agency does not offer intensive outpatient addiction treatment to adults; patients are instead referred to outpatient addiction providers throughout the community.

The Northern Plains site is home to approximately 11,000 tribal members from two AI tribes. Addiction treatment services are offered at two locations on the reservation and both utilize a culturally informed intensive outpatient addiction treatment model. Individuals with addictions at this site also have access to mental and physical health care through Indian Health Services.

Importantly, alcohol possession and consumption are illegal in the reservation participating in this study.

### 2.3. Participants

We will recruit 400 alcohol-dependent AI/AN individuals through advertisements in outpatient addiction clinics, primary care clinics, social service agencies, and places where adults with alcohol problems are likely to frequent, as well as through radio, newspaper, and online

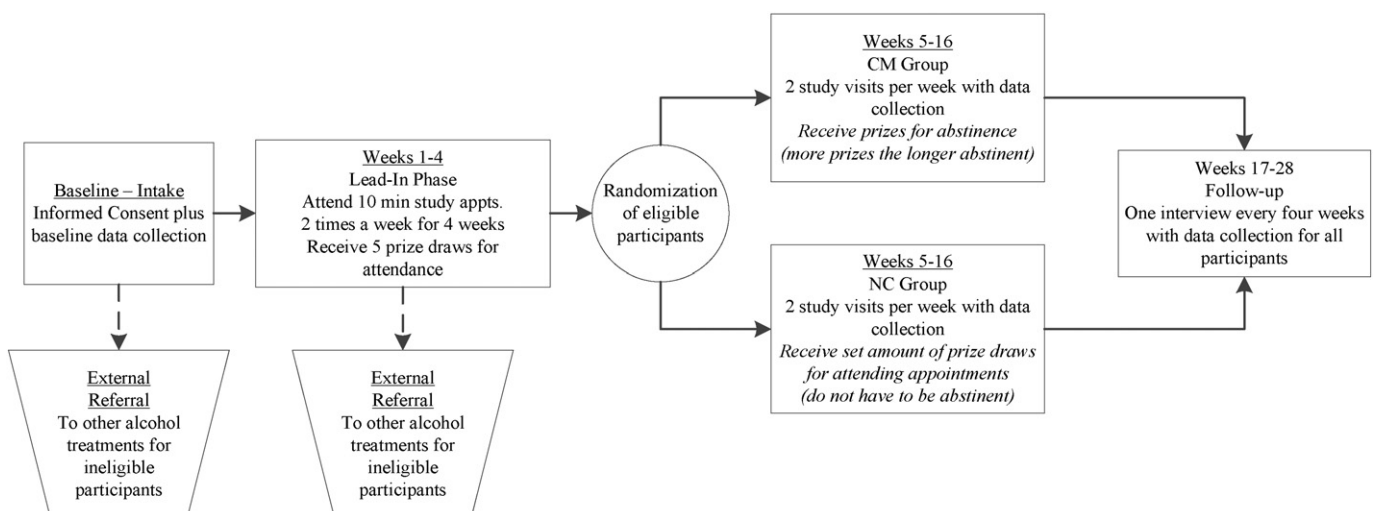


Fig. 1. Overview of HONOR Study procedures.

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