

STUDY PROTOCOL

**Web-based Addiction Treatment: Cultural Adaptation with American Indians
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ABSTRACT

American Indian/Alaska Native (AI/AN) communities face long-standing disparities across numerous health indicators including higher rates of substance use disorders (SUD), a particularly damaging problem which impacts not only physical and mental health, but also community capacity and cultural connectedness. To address these disparities and the ongoing problem of access to appropriate treatment services, culturally relevant, evidence-based interventions must be developed and successfully disseminated. Urban AI/AN (i.e., those who live off Tribal land in urban centers) have more severe substance use problems and encounter unique barriers to treatment. For example, the majority of Indian-managed substance abuse treatment facilities are located in rural areas (60%), yet 78% of AI/AN reside in urban areas. Given these disparities in disease and treatment access, a web-delivered culturally congruent intervention could be a means of improving treatment outcomes among urban AI/AN. Web-based interventions can address challenges to adoption and implementation, enhance accessibility to and intensity of treatment, and improve outcomes. The investigative team completed a mixed methods acceptability study of an efficacious web-based version of the Community Reinforcement Approach (CRA) (plus contingency management [CM]) called the Therapeutic Education System (TES) (Bickel et al., 2008; Campbell et al., 2014) with urban AI/AN from programs in NIDA's Clinical Trials Network (CTN). Results showed high acceptability for core TES content delivered via computer but also that cultural adaptation would be highly desirable. Research supports culturally-informed interventions for AI/AN. Although urban AI/AN are diverse with regard to tribal affiliation (i.e., language, history cultural activities), many similarities and consistencies in culture, values, and traditions exist. A cultural adaptation of TES for urban AI/AN (TES-NAV) was recently completed with supplemental CTN support. Building upon this developmental work, the goal of the current proposal is to evaluate the preliminary efficacy of TES-NAV to determine whether a future large-scale effectiveness trial is warranted. Specifically, a randomized controlled trial among urban AI/AN (N=80) attending outpatient addiction treatment services will be conducted to (1) estimate preliminary effect size of 12 weeks of TES-NAV on SUD outcomes; (2) explore relevant moderators of TES-NAV outcomes and potential mechanisms of action; and (3) assess cultural factors that may correspond to variation in outcome. A three-month post treatment follow-up will further inform the promise of TES-NAV and key implementation drivers. This work follows the tenets of the Community Based Participatory Research approach and is guided by a long-standing collaborative board. In the final months of the project, the board, other stakeholders and the investigative team will interpret findings and develop the design, methods, and procedures for a R01 application. Aligning with national public health initiatives and NIDA strategic priorities, this proposal targets longstanding SUD health disparities among AI/AN communities, would be among only a handful of controlled trials of any intervention for SUD with urban AI/ANs, and the first of a highly efficacious, culturally adapted, web-delivered treatment.

Background, Significance and Rationale

Research to reduce health disparities and substance use disorders among American Indians/Alaska Natives (AI/AN) is a critical and noted national health priority. AI/AN face disproportionate health disparities compared to other racial/ethnic groups in the United States (1,47) including higher rates of substance use disorders; 16% of AI/AN meet criteria for a substance use disorder compared to 10% in the general population (5,10,35,48-50). Substance use disorders are particularly damaging, impacting not only physical and mental health, but also community capacity and cultural connectedness (10-13). Substance abuse has been linked to poorer health outcomes among AI/AN compared to other American racial subgroups (10,42- 52).

Although numerous factors contribute to persistent health disparities, limited access to adequate care and resource poor systems of care that fail to offer culturally appropriate or science-based services for AI/AN clients are major barriers of concern (10,51-52,55). Treatment for AI/AN with substance use disorders is often limited to the Indian Health Service (IHS), an under-funded program with per capita health expenditures lower than Medicare, Medicaid, federal employees, and the Veteran's Administration (56,57). Service access is also complicated for AI/AN who don't qualify for federal Indian health aid provided by IHS because they are members of one of the 109 tribes no longer recognized by the U.S. government, are not enrolled tribal members, or are unsure of how to engage with their communities (58). Members of the 562 federally recognized tribes are entitled to IHS care, but are often required to travel to rural reservation locations that are especially difficult for urban AI/AN to reach (58-59). To date, the majority of treatment programs operated by the IHS (63%) and Tribal entities (73%) are located in rural areas, leaving a significant gap in services for urban dwelling AI/AN clients, who comprise 78% of the AI/AN population (10). Further, states with large AI/AN populations (e.g., North and South Dakota) often have a single treatment program serving a huge geographic area, making travel for weekly visits to get care prohibitive.

Urban AI/AN (identified as individuals who live away from tribal lands, have diverse tribal affiliation, and variation in ties to their tribal culture [18,60]) present a growing, evolving, and shifting demographic. Many urban AI/AN face difficulties navigating the health care system, based in part on unique histories of migration and mobility, enculturation (i.e., extent of ties to one's cultural norms/values), and variable levels of tribal affiliation (60,61). Although research on urban AI/AN is limited, data suggest that these individuals may experience more severe substance-related health disparities (17). In response, the Urban Indian Health Commission issued a recommendation that public and private sector efforts to improve health care for AI/AN populations recognize and respond to the growing number of AI/AN living in cities and urban areas (58). Thus, availability of and ready access to culturally appropriate and effective addiction treatment for urban AI/AN is of particular concern.

Previous research has shown that evidence-based treatments (EBTs) improve patient outcomes, including engagement, retention, and health status (62-68); however, there is a woeful lack of research on specific treatments designed for AI/AN or adaptation of existing EBTs for AI/AN (47,69-71). In the past decade, two published literature reviews questioned the quality of behavioral health for AI/AN clients while noting the lack of information about the availability and use of empirically supported treatments (72-73). Further, methodological challenges, such as small sample sizes and dispersed populations, and lack of AI/AN representation in federally-funded research serve to limit development of culturally relevant EBTs. Tribal values of generosity and respect also might not allow for certain clinical trial designs which delay or deny services (76), and AI/AN clients and staff often distrust traditional research processes given experiences of historical abuse and oppression (5,37,70,77-78). Thus, research continues to document a significant shortage of culturally relevant EBTs for AI/AN clients (35,46,79-80).

Technology-based interventions hold the promise of minimizing barriers to culturally appropriate EBTs for urban AI/AN with substance use disorders (81-82). Web-delivered interventions may: a) increase access to efficacious practices (27,81); b) enhance consistency and fidelity of delivery of such practices without increasing demands on staff time (84); c) allow for flexibility and individualized learning (85); and d) provide a more private venue appropriate for sensitive topics (86). Web-delivered tools also improve access to care by leveraging technology's 24/7 availability outside of standard treatment hours to vastly improve service delivery times, locations, and support – a critical need for urban AI/AN clients (21,87-88). Research supports the use of computerized cognitive behavioral therapies (19,83,89), web-based delivery of the community reinforcement approach (1), and motivational interviewing to treat substance use disorders (90). The use of these interventions may be especially helpful in broadening the availability of EBTs to AI/AN.

Treatments developed specifically for cultural or ethnic groups and those adapted to be more culturally congruent have been shown to produce better outcomes (91). Cultural adaptation is especially important in implementation of EBTs to treat substance abuse (11,92-94). Specifically, AI/AN populations utilize coping processes unique to their culture (95-97) and benefit from treatments that reflect their experience and heritage (11,38-45). AI/AN disparities in substance use disorders have been attributed to a lack of connection to tradition, a history of oppression, and cultural eradication (98-99). Thus, adaptation of EBTs to integrate culturally relevant factors and better represent AI/AN values and traditions is a necessary component of effective treatment (100).

This study targets barriers of treatment accessibility and use of culturally-specific EBTs among urban AI/AN by conducting a randomized controlled pilot study of an adapted version of the web-delivered Therapeutic Education System (TES Native Version or TES-NAV) among 80 urban AI/AN seeking outpatient substance abuse treatment. TES is an effective, web-based version of the Community Reinforcement Approach plus contingency management (27-28,30). It is self-directed and employs interactive instruction to convey skills and knowledge that support abstinence. Prize-based contingency management is included within the program to increase initial engagement and promote abstinence. TES is delivered via the internet, allowing users to access the program from any location with a computer/smart phone and internet access. Our team completed an acceptability study of TES (32) with 40 urban AI/AN, demonstrating approval of core content deployed using computer-assisted technology. Qualitative results suggested adaptation consisting of cultural tailoring and infusion of relevant context and accurate representations of AI/AN would improve congruence and relevance. With support from NIDA's Clinical Trials Network (CTN), the research team recently completed adaptation of TES with urban AI/AN.

This study uses rigorous and innovative scientific methods, as well as a technology-driven advancement in service that expands access and engages an underserved population in state-of-the art evidence-based care. The paucity of randomized trials EBTs among AI/AN make the current proposal both unique and essential to addressing long-standing health disparities and advancing substance use disorder treatment research among AI/AN. The study utilizes both a science-based treatment development process (i.e., stage model) and a Community-Based Participatory Research approach (CBPR). This culturally appropriate methodology combines the development of sustained, collaborative partnerships with AI/AN stakeholders within a rigorous scientific process. Further, the study is the first to test an adapted web-delivered addiction treatment intervention with urban AI/AN. Given the ongoing demographic shift with an increasing population of urban AI/AN (and fluidity of residence on and off tribal lands), testing culturally relevant EBTs with urban AI/ANs is both innovative, scientifically sound and important for developing effective health services for this population.

Specific Aims and Hypotheses

Specific Aim 1: Conduct a randomized controlled pilot study with urban AI/AN to estimate the effect of TES-NAV+TAU (n=40) compared to TAU (n=40) on the primary outcome of number of consecutive weeks of drug/alcohol abstinence and relevant secondary outcomes: a) abstinence in last 4 weeks of treatment; b) post-treatment abstinence (proportion days abstinent at 3-month follow-up); c) retention (time to drop-out); d) coping skills; e) social functioning; and f) HIV risk behavior.

Primary Outcome Hypothesis: TES-NAV+TAU will promote greater number of consecutive weeks of drug and alcohol use abstinence compared to the TAU arm during the 12 weeks of treatment.

Secondary Outcomes Hypotheses: The effect of randomization to the TES-NAV+TAU arm is hypothesized to (a) increase the proportion abstinent in the last 4 weeks of treatment; (b) increase the proportion of days abstinent three months post treatment; (c) increase treatment retention; (d) improve coping skills; (e) improve social functioning; and (f) increase proportion of consistent condom users will be estimated.

Specific Aim 2: Estimate putative moderator (e.g., baseline substance use severity, demographic characteristics) and mediator (e.g., coping, social connectedness) mechanisms of action.

Specific Aim 3: Describe cultural factors (enculturation, cultural/ethnic identity, Tribal affiliation) that may correspond to variation in clinical outcomes (i.e., longest consecutive weeks of abstinence) and acceptability; qualitative interview data will be collected to further contextualize quantitative findings.

Description of subject population

Subjects will be adults (18 and older), who self-identify as American Indian or Alaska Native, and are seeking treatment for a substance use disorder (alcohol or drug) at the participating recruitment site (Native American Rehabilitation Association of the Northwest [NARA] located in Portland, OR).

Only clients who identify as AI/AN will be eligible to participate (100% AI/AN). There are no exclusion criteria based on sex or gender. Given the current demographic data available from the participating recruitment site, we expect approximately half of the sample to be female.

NARA serves approximately 400 clients per year, 52% are female. Among clients entering treatment, 33% presented with a primary stimulant use disorder, 29% with a primary alcohol use disorder, 28% with co-occurring stimulant and alcohol use disorders, and 10% with opiate use disorder. The demographics of NARA's Outpatient Treatment Center will allow for recruitment of a diverse sample of urban AI/AN participants with regards to tribal affiliation and primary substance of abuse. Further, there are sufficient numbers to recruit and enroll approximately four participants per month to achieve a study sample of N=80 over 21 months.

Recruitment Procedures

All recruitment activities will take place within the participating treatment site (NARA), an outpatient substance use disorder treatment program located in Portland, OR. NARA's Outpatient Treatment Center offers a standard mix of alcohol and drug education groups, relapse prevention skills training, and process group therapy as well as mental health counseling for survivors of trauma using group therapy practices such as Seeking Safety. NARA also incorporates optional Native American cultural activities such as traditional drumming circles, Red Road to Sobriety groups, and local powwow participation. The typical course of treatment is approximately 4 months (6-9 groups/week and weekly or bi-weekly individual sessions).

Potential participants will be informed of the study at NARA treatment entry (or within the first 30 days of treatment). A variety of strategies may be employed to ensure that all new intakes are informed about the opportunity to participate in the study. For example, NARA intake workers may introduce the patient to a study Research Assistant so they can learn about the opportunity to participate or arrange a follow-up time to do so. Alternatively, all new intakes can be provided a flyer providing a brief description of the trial and a permission to contact form which they can sign to indicate they would like to learn more about the trial. They can provide their contact information and a Research Assistant will then contact them (assuming the patient and Research Assistant are unable to speak at the patient's time of intake). Note that by completing the permission to contact form, patients are not consenting to participate in the trial but are giving permission for research staff to contact them (either in-person at NARA or via phone to inform them about more details of the study). NARA staff will also be informed about the study so that they can address questions about/interest in the study by patients.

IRB-approved study flyers and posters may be posted within NARA about how to contact research staff to learn more about the opportunity to participate in the study.

Inclusion / Exclusion Criteria

Inclusion Criteria	Method to Ascertain
18 years of age or older	Screener; Demographics Form
Self-identify as American Indian or Alaska Native	Screener; Demographics Form
Self-report a substance use problem (drug or alcohol); having a substance use disorder is not an inclusion criteria, but it will be assessed	Screener; DSM-V Checklist
Report at least one day of drug or alcohol use in the last 30 days (before baseline) or, if released from an inpatient facility (e.g., jail, inpatient treatment, detox) within the last 30 days, report at least one day of drug or alcohol use in the last 60 days (before baseline).	Baseline' TLFB
Exclusion Criteria	
Planned treatment episode of less than 3 months	Screener
Insufficient ability to provide informed consent to participate or lack sufficient ability to use English to participate in the consent process, intervention, or research assessments	Informed consent interview and consent quiz

Consent Process

During the initial study contact, trained research staff will conduct a (approximately) 5-10-minute brief screening interview to assess if participants meet eligibility criteria for the study and do not meet exclusionary criteria for the study. The screener can be conducted in person or over the phone. Research staff will provide a brief description of the study (information sheet) and obtain verbal consent for the brief screening interview. Verbal consent is requested given the minimal risks to participants. Only information necessary to assess individuals' eligibility will be obtained at this initial screening (e.g., where they heard about the study, sex, age in years, date of most recent substance use, treatment duration, and primary substance). Further, the only record linking the potential participant and the research would be the consent document. Thus, a verbal consent process (waiver of consent documentation) reduces the potential harm resulting from a breach of confidentiality. A copy of the information sheet will be provided at participants' discretion. If a participant is eligible and interested in joining the study, s/he will be asked to complete the study Informed Consent procedures.

Informed consent procedures should be conducted within 30 days of the date that participants enter NARA for a new treatment episode. Every effort will be made to conduct consent procedures as soon as possible after a patient enters NARA; however, a 30-day window allows for a broader array of eligible patients to be considered for study participation. The trained research assistant/study coordinator will review and discuss the Informed Consent and administer the Consent Comprehension Quiz.

A waiver of documentation of consent is requested for the screener only. The screener collects only information to determine basic eligibility (see attached screener questions). If the potential participant is eligible and interested in participating following the screener, a baseline assessment visit will be scheduled and name/contact information collected for the purpose of giving the participant a reminder message. Collecting a consent signature and printed name would increase the risk to subject confidentiality because if the participant is not eligible or not interested in participating after completion of the screener no name is needed.

Study Procedures

Baseline Assessment

After signing Informed Consent, participants will be asked to complete the baseline assessments with a research staff person and provide a urine sample. We expect that participants will complete Informed Consent and baseline assessment in the same day. Baseline assessment will take approximately 2 hours. If s/he does not finish the baseline assessments in one day, s/he will be asked to return as soon as possible (and preferably the following day but within the eligibility window of 30 days post treatment intake). In this case, another urine sample will be collected at the subsequent visit and the day that the intake is completed will be counted as the study intake day.

Randomization

After completing the baseline assessment, participants will be randomly assigned to either (1) treatment-as-usual (TAU) or (2) TAU + TES-NAV. Randomization will be used to provide balance with respect to measured and unmeasured patient characteristics across the treatment arms. Randomization will be stratified by drug-positive/negative at baseline (alcohol or drug) and sex. Short periods of abstinence at treatment entry is common and have been found to be a strong predictor of outcome (30,132-133) suggesting the importance of balancing on this variable and including it as a covariate in the primary outcome analysis (134). Results from a prior TES effectiveness study indicated that sex may be a predictor of outcome (30). The randomization sequence will be unknown to research staff, but treatment arm assignment will not be masked. The randomization schedules will consist of balanced blocks within strata to ensure relative equality of assignment across treatment arms. The study statistician will manage and monitor randomization schema. Research staff, including PIs, will not be privy to randomization schema or balance.

Assessment Visits

All participants will be asked to complete a 12-week treatment phase.

Treatment Phase: Participants in both treatment arms will be asked to meet twice per week with the research staff and provide a urine sample at each visit; at one of the two weekly visits, participants will also be asked to complete the TLFB. In addition to brief weekly visits, participants will be asked to complete longer assessments

at week 6 and week 12 (approximately 1 hour), similar in content to the baseline assessment. (See Measurement Table)

Follow Up: Participants will be asked to return to the treatment program to complete a follow up assessment at week 24 (approximately 90 minutes). This assessment is similar in content to the baseline assessment, including collection of a urine specimen. (See Measurement Table)

In addition, at the week 24 follow-up visit, a subgroup of participants will be randomly selected to participate in an additional interview to ask about their experiences in the study. This interview will last about 30 minutes. This interview will be digitally audio recorded to accurately capture responses to questions for the purpose of analysis. The recordings will be transcribed (that is, what was said in the recordings is written as text). Once transcribed the audio recordings will be destroyed (within no more than 3 years). Any words said during the interview may be used, anonymously, in the presentation of research.

The digital recordings of interviews will be sent to a professional transcription service and will not contain personal health information. Interviews will be identified only by a numerical code. The recordings will be uploaded via a secure website. The transcription service will return a copy of the transcribed interview in approximately 10 days. Digital recordings will be kept by the transcription service until project completion and invoice payment and then destroyed.

The NYSPI study site will maintain the digital recordings through the end of the study and then they will be destroyed. The transcribed interviews will be maintained for a minimum of 7 years.

Study Interventions

Treatment-as-usual TAU: All participants will receive standard outpatient alcohol and drug use treatment at the study site (NARA) during the 12 week treatment phase of the study, regardless of randomization arm. The nature of TAU provided to participants will be documented using a TAU Tracking Form (e.g., duration and frequency of group and individual sessions; inclusion of HIV prevention content; provision of pharmacotherapy for substance use disorders, medical disorders or psychiatric disorders). NARA's Outpatient Treatment Center offers a standard mix of education groups, relapse prevention skills training, and process group therapy, as well as mental health counseling for survivors of trauma using group therapy practices such as Seeking Safety (6-9 groups/week and weekly/bi-weekly individual sessions). NARA incorporates optional AI/AN cultural activities such as traditional drumming, local powwow participation, and the Red Road recovery groups. The recommended duration of outpatient treatment at NARA is 4 months, similar to outpatient treatment programs in general. Participants will be enrolled into the study within their first month of TAU, thus the study treatment phase will overlap completely with TAU. Once the 12 week treatment phase of the study is complete, all participants will continue with standard care as usual at NARA.

TES-NAV (psychosocial intervention + contingency management): Participants randomized to TAU + TES-NAV arm will receive TES-NAV in addition to TAU. Participants will be asked to complete 4 TES-NAV modules (or topics) per week during the 12-week treatment phase. Each module requires approximately 20 minutes to complete. Participants will be provided with access to TES-NAV on their mobile smart phone (as available), as well as on tablets at the treatment program. TES-NAV has a back-end system that tracks participant activity.

Participants need not have prior experience to use TES-NAV. The program is self-directed and includes training that instructs the user how to navigate the program by providing an overview of goals, organization, how to respond to questions, etc. After the training, users will have access to 26 TES-NAV modules. Once they've completed all modules they will be able to repeat modules that are most relevant or for which they'd like additional practice. Content focuses on relapse prevention skills, social functioning, and HIV and other sexually transmitted infection prevention (see attached Table for a list of modules). TES-NAV includes an electronic reporting system (with appropriate password protection and an encrypted Internet connection via Secure Sockets Layer (SSL), the de facto standard for securing communications on the Web) summarizing patients' activity.

Participants randomized to receive TES-NAV will also be able to earn incentives contingent upon objective evidence of alcohol and drug abstinence (urine drug and EtG screens) and completion of modules in

accordance with an intermittent schedule of reinforcement shown to be efficacious in prior studies - a “fishbowl” prize system (140). Participants can earn draws in the following ways: (1) providing drug- or EtG-negative samples (collected twice per week) for their primary substance. Each negative sample results in a draw from the computerized ‘prize bowl’, which allows for automation of prize calculation and tracking. The number of draws will increase by 1 for each week in which the submitted samples are negative (and will reset to 1 after an unexcused absence or submission of a positive sample). (2) To offset low rates of reinforcement early in the study, when number of draws is low, a large prize will be awarded when the participant first achieves 2 consecutive weeks of abstinence from their primary substance. (3) Participants will earn 2 bonus draws each time they are negative for all substances (alcohol and drugs) to promote abstinence from all substances. (4) Participants will be provided with a single draw for each module completed (up to 4 per week).

Half of the draws in the prize bowl will be non-winning and read “good job”. The other “winning” half of draws will be structured such that 41.8% of draws will be for ‘small’ prizes worth about \$1 (e.g., make-up, socks, restaurant gift cards), 8% will be for large prizes worth about \$20 (e.g., watches, clothing), and 0.2% will be for jumbo prizes worth up to \$100 (e.g., iPod, head phones). The maximum dollar amount in prizes that can be earned is approximately \$625; however, based on prior trials the amount will likely be 40-50% of possible earnings. Intermittent prize-based, “fishbowl” schedules of reinforcement have been shown to be of comparable efficacy to fixed, voucher-based escalating reinforcement schedules (141), have repeatedly been demonstrated to be effective, cost-effective and feasible to implement in a wide variety of outpatient programs (142-143), and have been shown to create a positive culture within programs (144). Prizes will be stored in a locked cabinet, on display to participants. Research staff will be responsible for ensuring that the prize cabinet is well-stocked and will have flexibility regarding the types of prizes offered.

Clinician Involvement

NARA clinicians will provide TAU to participants in both treatment arms to reflect real-world integration of TES-NAV. To limit cross contamination and training burden, clinicians will not receive specific training on TES-NAV, but will be informed of the nature of the study and the general therapeutic content of TES-NAV (i.e., Community Reinforcement Approach and contingency management). The risk for cross treatment contamination is minimal because the experimental arm is comprised of a web-delivered intervention whereby participants complete the intervention on their own and often offsite. Treatment program clinicians will be asked to participate in a one-hour focus group post-study (Year 3, Month 9) to receive preliminary outcomes, share feedback on client experiences, implementation of TES-NAV, and make recommendations regarding design and methods of a larger trial.

Study Retention

All participants will be tracked and asked to complete study research visits regardless of whether they are currently engaged in care. High follow-up rates are important to minimize missing data in the key outcome analyses, and the methods to be employed here were developed and refined in our previous multi-site effectiveness trial of TES, where 90% follow-up rates were achieved 12, 24, and 36 weeks after randomization (24). A “tool box” of strategies will be engaged to ensure the highest possible participant assessment completion rates: 1) Comprehensive contact information from all participants at enrollment to include cell (text), e-mail and social media contacts (e.g., Facebook); contact information of friends/family, and social security and driver’s license numbers for use in standard search engines. Contact information will be updated at each study visit; 2) Voicemail, text, and email reminders; 3) Reminder letters mailed within two weeks of main study visits (certified mail/fed-ex may be used to confirm delivery); 4) Home visits and other off-site visits, following detailed safety and confidentiality guidelines, to attempt contact, as well as telephone visits when necessary. Follow-up procedures are detailed in the study consent.

End of Study Treatment

Following the 12 week treatment phase, participants will continue in treatment-as-usual as normal. For participants no longer in treatment-as-usual at any of the research study visits, research staff will be prepared to offer referrals to other treatment or services, as needed. A referral list, to be kept up to date and vetted, will be developed and available for this purpose.

Criteria for Early Discontinuation

Although the risks expected from this study are minimal, the population studied in this trial can be high risk given the nature of their substance use disorders and other mental and physical health challenges. Risks of clinical deterioration and psychological/psychiatric distress must be anticipated. Participants will be discontinued from the treatment phase of the study if they are discharged from the participating treatment program (NARA), however they will still be asked to complete research study visits (as appropriate). Participants will be discontinued from the study if the principal investigators and/or NARA staff determine it is in the best of interest of the participant.

Urine Drug Screen Procedures

Urine samples will be collected at baseline, twice weekly during the 12-week treatment phase, and at the 3-month follow-up interview to screen for recent alcohol and drug use and for contingency management purposes. Urine will be tested for 10 drugs using a dipcard screen (cocaine, opiates, MDMA, amphetamines, cannabinoids, methamphetamines, benzodiazepines, oxycodone, methadone, and barbiturates) and for ethyl glucuronide (EtG). EtG is a biomarker assessing alcohol use (direct metabolite) and can be measured using a rapid dipcard test. A cut-off of <300 ng/mL is sufficient to capture drinking up to 5 days prior and is not associated with inadvertent alcohol exposure (157). We will use commercially available tests.

Assessment Instruments

Participant Characteristics (PC) is used to collect information on demographic and other psychosocial characteristics, including: age, sex, gender, sexual orientation, race/ethnicity, time spent living on a reservation, education, employment status, monthly income, dependent children, insurance status, criminal justice status, chronic medical problems, use of medical cannabis, and internet access.

Timeline Follow-Back (TLFB) (135) assesses self-reported alcohol and other drug use (frequency, quantity) using calendars and memory aids to enhance recall. The TLFB has good psychometric properties, including test-retest reliability with multiple populations, and content, criterion, and construct validity across multiple related measures (136). Two additional questions will assess intensity and number of days of craving.

TAU Tracking Form (TTF). This form is completed by research staff on a weekly basis during the 12-week treatment phase to capture services received in TAU, including modality, frequency, and number of minutes.

Coping Strategies Scale (CSS) (137) is a 23-item, self-report measure (originally adapted from the Processes of Change) (138) assessing change processes, coping skills, and problem-solving related to urges to use substances. It has good reliability across samples ($\alpha=.83$ to $.87$).

WHO Quality of Life-BREF (QoL) (139). The WHO QoL scale assess one's overall perception of quality of life as well as health, psychological health, and social life.

HIV Risk Taking Behavior Scale (HRBS) (140) is a brief 11 item measure assessing drug and sexual risk behaviors for HIV and other STIs and shown to be a valid and reliable measure for evaluating risk reduction interventions. Questions assessing condom use intention (availability, likelihood, insistence) and, for female participants, pregnancy control methods, are also included.

American Indian Enculturation Scale (AIES) (142) is a 17 item, 7-point scale, self-report measure assessing involvement/adherence with traditional behavioral and spiritual activities with excellent reliability ($\alpha=.91$), convergent and discriminant validity among AI/AN clinical samples (143-145). The Cultural Affinity subscale (5 items) from the Native American Enculturation Scale (141) will be included.

The Multi-Group Ethnic Identity Measure (MEIM) (146) is a 15 item, 4-point scale, self-report measure assessing affirmation and belonging to one's AI/AN ethnic group or heritage ($\alpha=.80$ or higher).

Historical Loss Scale (HLS) (120) is a 12-item, 6-point scale, self-report measure assessing type of loss (e.g., language, land) and frequency of loss for AI/AN with excellent reliability ($\alpha=.94$).

Social Connectedness Scale (SCS) (147-148) is a 20 item, 6-point scale, self-report assessing psychological belonging or interpersonal closeness with good reliability among a diverse sample ($\alpha=.91$).

Non-study Service Utilization (NSU) is a modified version of the Treatment Services Review (149) and collects services not part of TAU (e.g., medical, detox, addiction medications, psychiatric). Validity of self-reported service use has been demonstrated (150-153).

DSM-5 Checklist (DSM) (154) is a semi-structured interview that provides current diagnosis for alcohol and other substance use disorders and level of severity based on DSM-5 diagnostic criteria.

Patient Health Questionnaire (PHQ) (155) was developed for use in primary health settings and screens for DSM psychiatric diagnosis of major depression and generalized anxiety. The PHQ has acceptable reliability with mental health professional diagnoses among American Indians (156). The 20 item (+ assessment of PTSD

Criterion A, traumatic event) PTSD Checklist-5 (PCL-5) will be used to screen for Posttraumatic Stress Disorder (PTSD) (157).

Kessler 10 (K10) (158) is a brief, 10-item self-report measure of general psychiatric distress. It has good reliability and is used in World Health Organization mental health surveys in 30 countries.

Fagerstrom Test for Nicotine Dependence (FTN) (164) is a 6-item ordinal measure of nicotine dependence related to cigarette smoking, including quantity of cigarette consumption, severity, and compulsion to use. An additional question assesses the use of medication to help stop smoking.

Momentary Self-regulation Questionnaire (MSQ) (165) is a 12-item measure (5-item Likert-type scale) to assess self-regulation. This measure was specifically developed and validated for use with technology-based interventions.

TES-NAV Acceptability/Feedback Form (TAF) is a 7-item self-report measure comprised of indicators of TES-NAV acceptability on 10-point scales: interesting, useful, new information, easily understood, satisfaction, relevance, cultural congruence and fit.

Qualitative Interviews will be conducted with TES-NAV clients (n=20) at the follow-up visit to elicit personal accounts of their experience using the program, acceptability of the program, examples of how the intervention was culturally relevant or not, and suggestions for improvement. These interviews are critical to understanding the feasibility of a larger trial.

Treatment to be provided at the end of the study

All participants will receive TAU at the participating treatment site (NARA). No additional treatment will be provided following participation in the research study.

Clinical treatment alternatives

TAU (treatment-as-usual) will be offered at the participating treatment site which the participant is attending. The participant must be enrolled in the treatment program to be eligible to participate in the research study. Outpatient psychosocial treatment is the standard of care for substance use disorder treatment in the community.

Risks / Stress / Discomfort

In general, risks associated with research comprised of behavioral interventions are minimal. The research assessments may lead to some psychological discomfort as participants discuss sensitive areas related to high risk drug or sexual behaviors. They may feel uncomfortable answering such questions and/or become distressed when faced with reviewing their involvement in high risk behaviors. TES-NAV should not induce any more discomfort than other treatments offered as part of outpatient substance use disorder treatment.

TES-NAV may be completed on (1) personal smartphones, or (2) tablets at the treatment program. There are no additional risks associated with completing TES-NAV on tablets at the treatment program, as no PHI is entered and the research staff will control access to the tablets.

If a participant decides to complete the intervention on a personal smartphone, there will be evidence of the TES-NAV application ("App") on the phone which someone else could potentially see if they had access to the personal electronic device. For smartphones with iOS, the participant will need to use their log-in for the "App Store" to download TES-NAV. For Android smartphones, the hosting service will have an Internet Protocol address (numerical label assigned to each device that accesses the internet) but this is not traceable to a smartphone or to the participant directly.

Procedures for minimizing risks

The written consent form will indicate the potential risks of participating in the study, including the visibility of the TES-NAV App on their phone and risk associated with each type of smartphone operating system. Participants will be advised that they do not have to answer research study questions with which they do not feel comfortable. The consent form will also indicate that participants are free to discontinue the study at anytime for any reason with no explanation. If participants become overly distressed, they will be directed to clinical staff working at their treatment program. In addition, study research staff will elicit participant reporting of any adverse events (including increased substance use) at all study assessment visits. Adverse events assessment will initiate with participant consent and follow-up will continue through 30 days after the final study

visit. A study investigator will review all reportable adverse events for seriousness, severity, and relatedness weekly.

Protection of Confidentiality

Procedures to assure confidentiality will be strictly observed. All participant personal information will be kept confidential and will not be released without written permission, except as required by law. Records will only be available to research staff, and Federal, State and Institutional personnel (who may review records as part of the routine audits). All information that is entered into the electronic databases is kept secure in accordance with federal guidelines and can only be accessed by research staff.

To maintain participant confidentiality, all data will be 1) kept in confidential locked files or on encrypted computer servers; 2) identified by participant number only; and 3) kept separately from identifying information on consent forms and locator forms. A list referencing study identification number to name will be kept under lock and key in a separate, location in the Site PI's office. No identifying information will be disclosed in reports, publications or presentations. The consent form will specifically state the types of information that are required to be reported and the fact that the information will be reported as required.

These include suspected or known sexual or physical abuse of a child or elder, or threatened violence to self and others.

Per Section 2012 of the 21st Century Cures Act as implemented in the 2017 NIH Certificates of Confidentiality Policy, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality (CoC). A federal CoC protects participants against disclosure of any sensitive information or illicit behavior (e.g., drug use).

Compensation

All participants will receive the following compensation: \$5 for screening, \$30 for baseline assessment, \$20 for assessment at week 6, \$20 for assessment at week 12, and \$30 for assessment 3 months post treatment (week 24). Participants randomly selected to complete a post-treatment qualitative interview will receive an additional \$25. All participants will receive \$2/week for urine drug and EtG screening during the 12-week treatment phase (total of \$24). Participant compensation is designed to encourage protocol participation and these incentives are provided to all participants. Thus, the maximum compensation a participant could receive for research visit procedures is \$154. To avoid competing with the potential treatment effect of the contingency management component, compensation for providing urine samples will be given to all participants at week 6 and week 12.

Contingency management (procedures described earlier in the study procedures section) is designed to reinforce abstinence, and those incentives are part of the TES-NAV intervention procedures and only provided to participants randomized to the TAU + TES-NAV arm. Participants in TES-NAV will be able to earn draws for prizes using an electronic "fishbowl" in the TES-NAV system for the following behaviors:

(1) urine tests negative for primary substance (number of draws will increase by 1 each week in which all submitted samples are free of the primary substance and will reset to 1 after submission of a sample positive for the primary substance); urine tests negative for all substances (2 bonus draws), and completion of modules (up to 4 per week). To offset low rates of reinforcement early in the study, a large prize will be awarded when the participant first achieves 2 consecutive weeks of abstinence from their primary substance. About half of the draws will be non-winning and will read "good job". The other "winning" half of draws will be structured such that 41.8% of draws will be for 'small' prizes worth about \$1, 8% will be for large prizes worth about \$20, and 0.2% will be for a jumbo prize worth up to \$100. The maximum dollar amount of prizes that could be earned if all possible draws are met is \$625 (this will not be in the form of cash but prizes). Based on prior studies, however, most participants will earn approximately \$280-400.

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