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Strategies for Pacific Empowerment and Alcohol Reduction for Native Hawaiian/Pacific Islander Young Adults: Study Protocol for a Community Randomized Controlled Trial

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Keywords: Native Hawaiian/Pacific Islander young adults, alcohol use disorder prevention, culturally grounded intervention, randomized controlled trial

Posted Date: November 5th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10295786/v1

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Additional Declarations: No competing interests reported.

Abstract

Background

Native Hawaiian/Pacific Islander (NH/PI) young adults endure severe disparities in alcohol use disorder (AUD) and alcohol-related harms, yet NH/PI are almost entirely absent from alcohol trials research. *SPEAR* (Strategies for Pacific Empowerment and Alcohol Reduction) is a culturally grounded, five-session group intervention designed to reduce these disparities by targeting five empirically-identified risk and protective mechanisms for NH/PI young adult AUDs: alcohol knowledge and attitudes, cultural drinking norms, alcohol refusal skills, stress coping, and distress communication.

Methods/Design

This protocol describes a two-arm randomized controlled trial evaluating *SPEAR* versus an active control matched on format, setting, attention, and peer contact without alcohol content. The trial will recruit 200 NH/PI young adults (100 per arm) aged 18 to 30 years with elevated AUD risk. Eligibility criteria include self-reported NH/PI heritage, past-month alcohol use, and screened AUD risk. The primary outcome is frequency of heavy episodic drinking days (Daily Drinking Questionnaire) assessed at pretest, immediate posttest, and 3- and 6-month follow-up. Analyses will follow intention-to-treat principles using generalized linear mixed models for repeated measures. Eligibility criteria include self-reported NH/PI heritage, past-month alcohol use, and screened AUD risk.

Discussion

This trial will provide the first efficacy evidence for a culturally grounded AUD prevention intervention for NH/PI young adults. If efficacious, *SPEAR* could address a substantial gap in health disparities and prevention science by providing a scalable AUD prevention approach for at-risk NH/PI communities.

Trial Registration

ClinicalTrials.gov Identifier: NCT06337721; Registered 03-29-2024

Background

Native Hawaiians/Pacific Islanders (NH/PI) are a federally designated U.S. racial group that bears an extreme burden of alcohol-related disparities including hazardous alcohol use, alcohol use disorders (AUD), and alcohol-related harms (1–3). In NH/PI communities in the U.S., young adults aged 18–30 years are at particularly high risk for hazardous alcohol use and harm, with nearly half of NH/PI young adults screening positive for AUD risk and approximately 40% experiencing alcohol-related harms involving health, social, work, or home functioning (1). These rates far exceed national averages and mirror patterns documented in countries with large NH/PI populations such as New Zealand and Australia (4–8).

Young adulthood is the developmental period of peak risk for hazardous alcohol use and AUDs, driven by reduced informal social controls, increased access to alcohol, and emergent stressors such as financial and family obligations (9–12). For NH/PI young adults, community reports and formative research indicate that this heightened risk is further shaped by social and cultural forces specific to NH/PI contexts that include: permissive cultural drinking norms within family and peer networks, cultural obligations that create pressure to drink at social gatherings, limited skills training for refusing alcohol in high-pressure social situations, alcohol use as a primary coping strategy for stress, and difficulty seeking social support as an alternative to drinking (13). Unfortunately, despite their heavy alcohol burden, NH/PI young adults have been poorly represented in alcohol prevention trials research, and as a result, AUD prevention interventions for this population remain underdeveloped—a glaring clinical and research gap the proposed randomized controlled trial (RCT) will address.

Prevention science suggests that designing an effective AUD prevention intervention for NH/PI young adults calls for risk- and protective-focused approaches that directly target the malleable risk and protective factors that drive the population's alcohol/substance use (14, 15). Similarly, prior alcohol/substance use research has demonstrated that a culturally grounded approach is desirable for intervening on NH/PIs and other racial/ethnic minorities' AUD risk and protective factors by strengthening effective outreach and engagement, and improving intervention feasibility, acceptability, and effectiveness (16–18). Culturally grounded interventions have previously been referred to as "deep-structure" adaptations (rather than surface-level translations) of existing evidence-based intervention strategies that are infused with, and originate from, the cultural worldviews and practices of the target population (16). More specifically, culturally grounded interventions are built upon the distinct worldviews, beliefs, and practices of the target prevention population, with a recent systematic review suggesting increased scientific interest in supporting the development and evaluation of these interventions with NH/PIs (19). Although culturally grounded approaches may carry higher costs both in development and testing, they are ideally suited to address alcohol disparities in underserved populations such as NH/PIs who have substantial unmet treatment need, limited existing adaptation research to draw upon, and a documented pattern of poor response to non-adapted interventions (16).

Grounded in a prevention science and culturally grounded approach, this team developed the culturally grounded manualized AUD prevention intervention *SPEAR* (*Strategies for Pacific Empowerment and Alcohol Reduction*) via funding from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). Specifically, the intervention was designed through NIAAA work in which NH/PI young adults and providers selected and shaped evidence-based AUD prevention components/strategies for cultural fit and relevance using deliberative citizens' panels processes (20). This process consists of engaging NH/PI young adults and stakeholders in informed deliberation and decision-making to allow for the integration of evidence-based AUD prevention strategies (e.g., expectancy challenge, drinking norms education, drink refusal skills training, communication skills training) (21–29) with NH/PI cultural practices and formats (e.g., group dialogue, cultural art, narrative story-telling, spirituality) to reduce AUDs and alcohol-related harms among at-risk NH/PI young adults.

Objectives/Hypotheses

This paper presents the protocol for the *SPEAR* RCT (ClinicalTrials.gov Identifier: NCT06337721). The primary objective of the RCT is to test the hypothesis that *SPEAR* will produce significantly greater reductions in heavy episodic drinking (HED) versus active control among NH/PI young adult participants with elevated AUD risk. By testing SPEAR in two communities that differ in urbanicity, region, and pre- and post-migration history yet share common AUD risk and protective profiles, findings will support the generalizability of *SPEAR* across diverse NH/PI young adults.

Methods/Design

Overview

This paper describes a multi-site, parallel-group superiority RCT with 1:1 allocation, comparing *SPEAR* with an active supportive-discussion control—matched on format, setting, attention, and peer contact without alcohol content. The trial uses a pretest–posttest design with follow-up assessments at 3- and 6-months post-intervention. The analytic framework is superiority-oriented to determine whether *SPEAR* produces greater reductions in hazardous drinking versus the active control. The protocol follows Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (30).

Participants and Study Setting

A total of 200 NH/PI young adults with AUD risk (score of AUDIT-C ≥ 4 for men and ≥ 3 for women) will be randomized to the SPEAR (n = 100) or active control (n = 100) arm. The trial will be conducted at community partner sites (e.g., churches, community centers) embedded within NH/PI communities in California and Arkansas. These two communities were selected because they: (1) are among the largest urban and largest rural NH/PI communities in the continental United States, and (2) contain large numbers of NH/PIs of Polynesian and Micronesian heritage. Collectively, Polynesian and Micronesian NH/PIs compose nearly 90% of NH/PIs in the United States (31), supporting the generalizability of intervention trial findings.

Eligibility Criteria

Inclusion criteria include: (1) 18–30 years-old; (2) self-identify as full or part NH/PI heritage; (3) English reading and writing fluency; (4) current drinking (at least one drinking day in the past 30 days); and (5) screen positive for elevated AUD risk (determined via Alcohol Use Disorders Identification Test-Consumption [AUDIT-C (32)] scores of ≥ 4 for men and ≥ 3 for women). Participants who use other substances such as cannabis or tobacco will be eligible for study inclusion to bolster ecological validity, as polysubstance use commonly co-occurs with alcohol use among young adults. Exclusion criterion is current engagement in formal alcohol treatment, which might confound intervention effects.

Recruitment, Consent, and Assignment

The recruitment strategy is multifaceted and community-based. Staff will approach potential participants in community settings, distribute flyers online and in person, as well as use remote listserv and social media outreach, and encourage peer sharing of study materials. A brief 5-minute screening survey will be administered either on an iPad in the field or online through Kobo Toolbox, with a small incentive for screening completion. Contact information will be stored in a protected master file for eligibility review and follow-up contact by study staff. Individuals meeting eligibility criteria will be contacted by text and telephone to review trial procedures, including randomization and incentives, and to establish participation.

Once eligible individuals agree to participate, they will be randomly allocated 1:1 to *SPEAR* or the active control. The randomization sequence will be generated using a computer-based random number generator by the study principal investigator, who will maintain the randomization sequence in a secure system separate from the intervention staff. Allocation will occur only after the baseline assessment is complete to prevent assignment from influencing eligibility screening or baseline assessment. Participants will be informed of their assigned condition after randomization and scheduled for the corresponding intervention activities. To minimize contamination risk, participants will be instructed not to discuss intervention content with anyone outside their immediate family such as their peers or other similar age individuals.

Blinding

As *SPEAR* is a group-delivered behavioral intervention, participants and facilitators cannot be blinded to intervention allocation. However, research staff conducting follow-up assessments will be blinded to participants' allocation whenever feasible.

Facilitator Training and Fidelity

Lay NH/PI facilitators will complete a multi-day training for *SPEAR* and the active control, led by the study principal investigator. The *SPEAR* training will combine didactic instruction, role-play, and a criterion delivery: each provider must deliver a full *SPEAR* session rated against a structured fidelity checklist before independent delivery. The active control training will also involve facilitating a full control session rated against a checklist.

During the RCT, research staff will rate a random sample of audio recordings from *SPEAR* and control sessions against arm-specific checklists. For example, control arm coding will specifically flag alcohol content or structured skills training as fidelity violations. Providers will receive regular group supervision and individual corrective feedback as needed by the principal investigator and research team members.

Intervention and Control

SPEAR. *SPEAR* is a five-session, manualized group intervention delivered in closed-enrollment groups of mixed sex and age (18–30 years) by trained lay NH/PI peer providers at community partner sites (see Table 1 for intervention and control content). Sessions are 75 minutes in length and are designed to target the culturally grounded intervention mechanisms identified in prior NH/PI young adult formative work. These mechanisms of change each map to a risk or protective factor identified from our prior research and consists of: (1) shaping alcohol-related knowledge and attitudes; (2) shaping safer drinking norms; (3) building alcohol refusal skills; (4) increasing stress-coping skills; and (5) increasing skills for communicating distress to obtain social support in lieu of alcohol-based coping and misuse (13).

The format for each session combines didactic content (lecture plus handout), a culturally grounded activity or narrative film, and facilitated group discussion connecting the content to participants' alcohol perspectives and own drinking. To convey core intervention content in a culturally grounded, community-chosen fashion, three professionally filmed short narrative films (7 minutes long) were created for *SPEAR*.

Creating and utilizing narrative films that simultaneously utilize oral, visual, and narrative (story-telling) mediums to convey *SPEAR* content is an innovative, empirically-based component of *SPEAR* as narratives (stories) have been demonstrated to generate greater, more durable impact on people's health knowledge, attitudes, and behaviors than standard public health/health behavior change approaches (e.g., lecture, public service announcements) (33–37). Driving its implementation in *SPEAR*, NH/PI young adults overwhelmingly chose narrative films as a preferred intervention approach during *SPEAR* development—closely aligning with NH/PI culture, which are oral societies that prefer oral, visual, and narrative learning (38, 39), conveying important cultural information through narratives for centuries (40–42). The three films depict NH/PI characters modeling relevant behaviors for preventing AUDs and alcohol-related harms (alcohol education, assertive drink refusal, and communicating distress) and are embedded across the five sessions.

The five sessions consist of: (1) orientation to the intervention and presentation of alcohol education content (21, 43), followed by discussion of alcohol's role in NH/PI culture and participants' lives; (2) viewing of the first narrative film, *Straight Talk*, followed by presentation of alcohol education content coupled with a drinking norms exercise (24) and compressed expectancy challenge exercise (25, 44); (3) presentation of assertive drink refusal techniques (17, 45, 46), modeled in the second narrative film, *Party Time*, followed by structured role-play with facilitator feedback; (4) presentation of stress coping skills (mindfulness techniques and NH/PI spirituality-based coping) (26, 47, 48) as alternatives to drinking to cope; and (5) modeling of strategies for approaching family or friends to communicate distress and obtain social support (49–51) via the third narrative film, *Reaching Out*, followed by role-play practicing of these strategies. The full SPEAR facilitator manual, handouts, and videos will be made available to trial sites.

Active Control. Control participants will attend two 75-minute, non-directive supportive discussion group sessions, delivered in the same community settings, group sizes, and format as *SPEAR*, and led by the

same *SPEAR* facilitators. The sessions (titled "*Life, Community, and Young Adulthood*" and "*Wellness, Balance, and Resources*") use a facilitated, non-directive discussion format covering NH/PI-relevant young adult life topics—school/work stress, family and community expectations, cultural identity, and personal strengths and goals—without alcohol content, structured skills training, or active therapeutic technique (e.g., cognitive-behavioral, motivational interviewing, or mindfulness exercises). This design intentionally controls for nonspecific factors common to both arms (NH/PI peer provider contact, group format, group site, facilitator attention) while excluding *SPEAR*'s active ingredients, supporting a clean test of *SPEAR*'s treatment efficacy. Excluding alcohol content from the control condition was a specific design requirement of this study's NH/PI community partners. See Table 1 for an overview of *SPEAR* and active control session structure and content.

Table 1
SPEAR and Active Control Session Structure and Content Overview

Session	Title	Mechanism	Key Content
SPEAR			
1	*Getting to Know Each Other*	Building Group Rapport and Engagement Shape Alcohol Knowledge and Attitudes	• Cultural NH/PI *tapa cloth* icebreaker • Group rapport-building • Discussion of alcohol's role in NH/PI culture and participants' lives • Standard drink concept
2	*Alcohol Facts, Responsible Behaviors, and Expectancies*	Shape Alcohol Knowledge and Attitudes Drinking Norm Re-education Alcohol Expectancies	• Film 1: *Straight Talk* (alcohol education) • Alcohol education content • Injunctive drinking norms exercise (approval/harm) • Compressed expectancy challenge exercise
3	*Alcohol Refusal Skills*	Increase Alcohol Refusal Skills	• Film 2: *Party Time* (drink refusal modeling) • Assertive drink refusal techniques (Refuse-Explain-Leave) • Structured role-play with facilitator feedback
4	*Managing Stress without Drinking Heavy*	Increase Stress Coping Skills as Alternatives to Drinking	• Mindfulness coping techniques • NH/PI spirituality-based coping
5	*Communicating Distress*	Increase Distress Communication Skills as Alternatives to Drinking	• Film 3: *Reaching Out* (communicating distress); • Role-play of approaching family/friends to seek social support; • Graduation/award ceremony
Active Control			
1	*Life, Community, and Young Adulthood*	None (nonspecific-factors comparator)	• Non-directive discussion of young-adult life stage, family/community expectations, identity, and strengths • No alcohol content

Session	Title	Mechanism	Key Content
SPEAR			
2	*Wellness, Balance, and Resources*	None (nonspecific-factors comparator)	• Non-directive discussion of daily balance, adult responsibilities, and community resources • No alcohol content

All *SPEAR* sessions and control sessions are 75 minutes in duration.

Outcomes

The primary RCT outcome is frequency of heavy episodic drinking (HED) days, defined as 5 + drinks per occasion for men and 4 + for women, assessed via the Daily Drinking Questionnaire (DDQ) (52) over the past 30 days. The 3-month posttest assessment will serve as the primary efficacy endpoint and the 6-month assessment serves as a secondary endpoint for evaluating durability of effect.

Secondary outcomes include 7-day alcohol consumption (DDQ) (52); alcohol-related consequences (Brief Young Adult Alcohol Consequences Questionnaire) (53), and alcohol knowledge, attitudes, and behaviors (a 25-item composite assessing standard drink knowledge, blood alcohol concentration, alcohol's physical effects, poisoning signs, and personal drinking-acceptability attitudes) (54, 55).

Participant Timeline

Table 2 presents the SPIRIT schedule of enrollment, interventions, and assessments while the SPIRIT checklist of items to address in a randomized trial protocol is presented as a supplemental file. Eligibility screening and informed consent occur prior to randomization; the pretest survey is administered immediately before the first intervention session. *SPEAR* is delivered across five sessions and the active control across two sessions. The posttest survey is administered immediately after each arm's final session, and follow-up surveys are administered at 3- and 6-months post-intervention by online Qualtrics survey or telephone. All outcome measures are collected at all four assessment points.

Table 2
SPIRIT Schedule of Enrollment, Interventions, and Assessments

Study Procedure	Enrollment	Sessions	Posttest	3-Month	6-Month
Eligibility screen	✓				
Informed consent	✓				
Baseline survey	✓				
Randomization	✓				
SPEAR		✓			
Active control		✓			
Attendance log		✓			
Heavy episodic drinking	✓		✓	✓	✓
7-day alcohol consumption	✓		✓	✓	✓
Alcohol consequences	✓		✓	✓	✓
Alcohol knowledge, behavior, and attitudes	✓		✓	✓	✓

Retention and Attrition

Retention strategies include pre-session reminder calls or texts, transportation assistance when needed, per-session and per-assessment incentives, and proactive contact and advance reminders before follow-up surveys (e.g., text, email, and outreach to a participant's designated close contact after repeated non-response). Participants will receive incentives for screening, session attendance, and follow-up assessment completion. For the RCT, participants will receive $20 per *SPEAR* or active control session, $30 for the immediate posttest survey, $30 for the 3-month follow-up survey, and $50 for the 6-month follow-up survey. If a participant cannot be reached after five attempts, staff will contact the participant's nominated close contact to update contact information or status. Participants who cannot be reached after five phone calls will be deemed to be missing at that data collection time point. The research team will attempt to contact participants again at the next data collection time point, following the same procedure, unless the participant actively withdraws.

Sample Size

The trial is powered to detect a medium effect size (Cohen's d = 0.39) in HED frequency at the 3-month primary endpoint, consistent with effect sizes obtained in prior young adult alcohol prevention trials targeting similar behavioral mechanisms (e.g., AlcoholEdu, BASICS) (56, 57). Using the SIMR package in R (58) with a two-tailed α of .05 and a minimum 80% retention rate at 3 months, a sample of 200 participants (100 per arm) will exceed 80% power.

Data Collection and Management

Trained research staff will administer all study measures. Baseline and immediate-posttest surveys are administered in person at the intervention site. Follow-up surveys at 3- and 6-months will be administered via Qualtrics or telephone. Attendance at every session is recorded via sign-in logs for both arms. For participants who discontinue the intervention or are lost to follow-up, all available outcome data up to the point of dropout will be retained, and reasons for non-completion or non-retention will be recorded.

Participant data will be linked to unique identification numbers rather than direct identifiers. Master identifier lists will be stored on a password-protected, access-restricted system separate from the data. Hard-copy consent forms and paper measures will be stored in locked files. Audio recordings from group sessions will stored on encrypted systems. Survey data will be de-identified prior to aggregate analysis.

Statistical Analysis

Analyses will follow the intent-to-treat principle that includes all *SPEAR* and active control trial participants regardless of intervention completion. The analysis will use generalized linear mixed models (GLMM) implemented via SAS PROC GLIMMIX to test *SPEAR* versus control arm differences in primary outcomes across all four time points (pretest, posttest, 3-month, 6-month), modeled as a categorical time factor. Models will include fixed effects for condition, time, and condition-by-time interactions, with time treated categorically across baseline, posttest, 3-month follow-up, and 6-month follow-up. Participant-level random effects will account for within-person correlation over time. Because the primary outcome is a count of HED days, models will use an appropriate count distribution and link function after evaluating the outcome distribution, overdispersion, and excess zeros. Missing data will be addressed via multiple imputation under a missing-at-random assumption, with the selection and assumptions guided by sensitivity analyses under alternative missing data mechanisms (59). No interim efficacy analyses or formal stopping rules are planned; all primary analyses will be conducted after completion of 6-month follow-up.

Harms Monitoring

Anticipated risks and harms from the study and intervention are minimal and include potential discomfort when discussing personal drinking or stressful situations consistent with levels experienced during routine health conversations. Trained research staff and facilitators will monitor participants for acute distress. If a participant discloses suicidality, severe distress, or aggression, staff will initiate a standardized safety protocol of: private check-in, provision of crisis and behavioral health referrals, and if indicated, emergency services, with rapid notification of the principal investigator. Adverse events and severe adverse events will be assessed during intervention contacts and may also be reported by participants or facilitators at any point during the trial. The principal investigator will review all adverse events within five business days. This includes reviewing participant safety, determining appropriate

follow-up, and stopping study participation if needed. These events will be tracked, graded, and reported to the IRB and the funding agency per standard procedures.

Ethics and Dissemination

This trial involves human participants, and received approval by the University of California, Riverside Institutional Review Board (UCR IRB). Findings will be disseminated to: (1) NH/PI communities through public reports and presentations to the community partners and other interested community stakeholders; and (2) the scientific community through scientific conference presentations and peer-reviewed manuscripts. De-identified datasets will also be posted and released through Mendeley Data following completion of primary outcome analyses, consistent with participant consent, IRB approvals, and NIH data sharing requirements.

Data Safety Monitoring

The RCT will be overseen by the principal investigator and an independent Data and Safety Monitoring Board (DSMB), which will provide independent oversight of participant safety and trial integrity. The DSMB will include three independent members with expertise in clinical trials, biostatistics, or community-based research. All DSMB members are independent of the sponsor, the funder, and the trial investigators and have no financial or scientific conflicts of interest with the study. The DSMB will meet two times per year during the trial to evaluate participant safety, adverse events, recruitment and retention, protocol adherence, data quality, and overall study progress.

The DSMB will provide written recommendations regarding trial continuation, modification, or termination. Serious adverse events or urgent safety concerns will be reported to the DSMB in real time, and DSMB recommendations will be submitted to the UCR IRB and the funder as required.

Intervention Discontinuation and Concomitant Care

Participants may discontinue intervention attendance or withdraw from the study at any time without penalty. Participants who discontinue attending *SPEAR* or active control sessions will remain eligible to complete follow-up assessments unless they withdraw consent for further participation. Participants who disclose severe alcohol-related concerns, acute distress, suicidality, or other behavioral health needs will receive appropriate referral information and, when indicated, safety procedures will be initiated. The trial does not restrict participants from seeking outside care and does not provide formal alcohol treatment as part of either study arm. Initiation of formal alcohol treatment or other behavioral health services after randomization will not require study withdrawal, but will be documented and considered in interpretation of trial outcomes. No special post-trial arrangements for compensation or long-term clinical care are planned beyond standard referral to existing community and clinical services.

Discussion

This study will provide critical data on the efficacy of *SPEAR*, a novel culturally grounded AUD prevention intervention for NH/PI young adults developed in collaboration with NH/PI stakeholders, experts, and

communities. If efficacious, *SPEAR* would reduce AUD risks and associated harms for NH/PI young adults, who despite documented AUD rates vastly exceeding the U.S. national average have been almost entirely absent from alcohol prevention research and trials. *SPEAR* was designed to address this gap by integrating evidence-based AUD prevention strategies with NH/PI cultural practices, learning formats, and preferred delivery structures. Because *SPEAR* was built to target community-identified risk and protective mechanisms and is being tested concurrently in two NH/PI subgroups (Polynesian and Micronesian) that differ in migration history, geography, and urbanicity but share common AUD risk and protective profiles, a positive trial result would help support both *SPEAR's* efficacy and generalizability across diverse NH/PI young adult populations. This was an important consideration for the research team and our community partners given NH/PIs' substantial subgroup ethnic, linguistic, and contextual diversity (31, 60, 61).

Beyond this community-driven consideration, several design features strengthen the study. First, *SPEAR* is based on NIAAA-funded community-based participatory research that engaged NH/PI young adults and stakeholders in its culturally grounded design rather than a top-down surface-level cultural adaptation. Adopting this empirically driven and culturally grounded approach has been shown to lead to feasible, acceptable, and efficacious interventions for NH/PI populations in prior prevention research (62, 63). Second, the trial includes an active control matched for attention and dose rather than a minimal treatment comparison. Third, our use of lay NH/PI peer providers supports ecological validity and future implementation potential if the intervention proves effective within NH/PI communities.

Concurrently, the study faces several challenges. Recruitment may be affected by low perceived need for alcohol-related services among NH/PI young adults with elevated AUD risk. To address this, *SPEAR* was deliberately designed as a broader young-adult life-skills and wellness intervention (incorporating stress coping, communication, and culturally syntonic content) rather than a narrow alcohol-focused program, with NH/PI young adults in our prior *SPEAR* design research expressing strong enthusiasm for this approach. Additionally, the trial addresses this by utilizing community-based outreach, peer referral, flexible screening, use of trusted and accessible community locations, and incentives. Contamination is also possible because NH/PI communities are socially interconnected; this study reduces this concern through participant instructions about sharing intervention content. Blinding is limited by the behavioral nature of the intervention, but the use of standardized self-report assessments including remote assessments at follow-up, pre-specified analyses, and fidelity monitoring reduce bias.

In sum, if *SPEAR* reduces HED and related alcohol outcomes, it would provide one of the first empirically tested AUD prevention models designed specifically for NH/PIs—who bear elevated risk for alcohol, substance use/misuse, and mental disorders but do not use existing treatment services (1, 2, 64). In this way, this study would address a persistent health disparity affecting NH/PIs while advancing prevention science with Indigenous-colonized populations that have often been excluded from intervention trials. Lastly, it would provide an empirically sound model for conducting culturally grounded AUD prevention outside specialty clinical environments, and the foundation for a follow-up dissemination and

implementation study to evaluate *SPEAR*'s adoption, fidelity, and impact across an extended range of NH/PI communities in the U.S. and U.S.-affiliated Pacific territories.

Protocol Version and Trial Status

This protocol describes the *SPEAR* RCT registered at ClinicalTrials.gov: NCT06337721 (registered March 29, 2024). The current manuscript is based on protocol version 2.0, June 1, 2026. The University of California, Riverside serves as the lead institution and coordinating center for the trial. Trial recruitment began on July 1, 2026. Anticipated enrollment completion date is June 30, 2028. This protocol was developed in accordance with the SPIRIT 2025 guideline and the full protocol, statistical analysis plan, and SPIRIT checklist will be made available upon request.

Protocol Amendments

Substantive protocol amendments will be submitted to the University of California, Riverside Institutional Review Board for approval. Approved protocol changes will be communicated to participating study staff, community partners, and other relevant investigators before implementation. When applicable, trial registration information will be updated on ClinicalTrials.gov to reflect major protocol modifications.

Community and Public Involvement

SPEAR was developed through a community-engaged intervention design process involving NH/PI young adults, informal NH/PI providers (e.g., clergy, elders), community advisors, and cultural experts. Formative work used deliberative citizens' panels (20) and advisory input to: (1) identify alcohol-related risk and protective mechanisms relevant to NH/PI young adults (13), and (2) shape intervention content, format, and delivery strategies for cultural acceptability and fit (20). Community input informed *SPEAR*'s emphasis on group discussion, narrative storytelling, cultural values, spirituality, stress coping, refusal skills, and communication with family and peers. Community partners also informed the design of the active control condition, including the decision to exclude alcohol-specific content while retaining culturally relevant discussion topics, peer contact, and group format. Trial findings will be disseminated back to NH/PI communities through public reports, community presentations, and other accessible formats in addition to peer-reviewed publications and scientific conference presentations.

Abbreviations

ASSIST: Alcohol, Smoking and Substance Involvement Screening Test

AUD: Alcohol use disorder

AUDIT-C: Alcohol Use Disorders Identification Test - Consumption

BASICS: Brief Alcohol Screening and Intervention for College Students

B-YAACQ: Brief Young Adult Alcohol Consequences Questionnaire

DDQ: Daily Drinking Questionnaire

GAD: Generalized anxiety disorder

GAD-7: Generalized Anxiety Disorder 7-item scale

GLMM: Generalized linear mixed model

HED: Heavy episodic drinking

IRB: Institutional Review Board

MDD: Major depressive disorder

NIAAA: National Institute on Alcohol Abuse and Alcoholism

NIH: National Institutes of Health

NH/PI: Native Hawaiian/Pacific Islander

PHQ-9: Patient Health Questionnaire 9-item scale

RCT: Randomized controlled trial

SPEAR: Strategies for Pacific Empowerment and Alcohol Reduction

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

Declarations

Ethics Approval and Consent

The Institutional Review Board at the University of California, Riverside (UCR) approved this study and serves as the single IRB of record (sIRB) for all participating sites under formal reliance agreements (Approval: 30051; Approval Date: March 7, 2024). UCR's IRB is registered with the U.S. Department of Health and Human Services Office for Human Research Protections. Informed consent will be obtained from all participants prior to any study procedures.

Consent for Publication

Not applicable. This protocol contains no individual participant data, images, or identifying details.

Availability of Data and Materials

The *SPEAR* facilitator manual, session handouts, narrative films, and fidelity checklists will be made available to trial sites. De-identified trial data will be deposited in Mendeley Data following completion of primary outcome analyses, subject to participant consent and applicable data use agreements. Access to the final trial dataset will be limited to the principal investigator, study biostatistician, and approved study team members responsible for data analysis. De-identified data may be made available upon reasonable request after publication and in accordance with IRB approvals, participant consent, NIH data sharing requirements, and any applicable community or institutional agreements. These data sharing procedures are intended to promote transparent, reproducible research in line with SPIRIT 2025 recommendations for open science.

Competing Interests

The authors declare no competing interests.

Funders and Sponsor

This work is supported by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), grant number R01AA030786. The funder had no role in study design and will have no role in data collection, analysis, interpretation, or the decision to submit results for publication. The trial sponsor is the UCR. The trial sponsor holds legal and ethical responsibility for the trial and oversight of trial conduct through the UCR IRB, but exercises no authority over scientific decisions, analysis, interpretation, or publication.

Authors' Contributions

AS serves as the principal investigator. He conceived the study with all study authors and led the intervention and protocol development. LW, EG, and DI contributed to study design and intervention refinement. EK is the trial biostatistician and led the statistical analysis plan. HM provided senior methodological and clinical-trials guidance. NA provided cultural and community-engagement expertise. All authors reviewed the manuscript.

Acknowledgments

The authors thank the community advisory councils, lay peer providers, and citizens' panel and pilot participants.

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