

STUDY PROTOCOL

Personalized Feedback Intervention to Address Hazardous Drinking and Alcohol-Opioid Interactions Among Adults With Chronic Pain

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1. BACKGROUND AND RATIONALE

Hazardous drinking and chronic pain are two highly prevalent and frequently co-occurring public health conditions. Over 25% of American adults engage in hazardous drinking, defined as a pattern of alcohol consumption that increases the risk of harmful consequences, making it the third leading cause of preventable death in the United States. Chronic pain affects over 100 million American adults and is substantially more prevalent among hazardous drinkers compared to non-problem drinkers.

Approximately 20% of individuals prescribed opioids for pain management report concurrent use of alcohol and opioids, which can produce dangerous and potentially fatal health effects including respiratory depression and liver damage. Despite significant public health impact and well-documented reciprocal relations between pain, hazardous drinking, and prescription opioid use, no interventions had previously been developed to simultaneously address these interrelated conditions.

Brief, single-session, computer-based personalized feedback interventions (PFIs) have demonstrated utility in motivating health behavior change across a variety of conditions. PFIs grounded in motivational principles and social norms theory motivate change by presenting personalized feedback, normative comparisons, and psychoeducation. The current study builds upon prior PFI development work with hazardous drinkers (R34 AA023739) and individuals with comorbid chronic pain and substance use (R21 DA038204) to develop and test a novel integrated intervention targeting the interplay between chronic pain, hazardous drinking, and prescription opioid use.

2. SPECIFIC AIMS

Aim 1. Phase 1A: Develop a brief, single-session, integrated, computer-based pain-alcohol personalized feedback intervention (PA-PFI) designed to: (1) enhance knowledge regarding adverse pain-alcohol-opioid interrelations; (2) increase motivation and intention to reduce hazardous drinking; and (3) reduce positive attitudes and intention regarding concurrent use of alcohol and prescription opioid medications.

Aim 2. Phase 1B: Conduct a randomized controlled trial (RCT) testing the effects of PA-PFI versus Control PFI (C-PFI) on motivation/intention to reduce drinking, attitudes regarding concurrent use of alcohol and prescription opioids, expectancies for pain management via drinking, and knowledge regarding pain-alcohol-opioid interrelations, among hazardous drinkers with chronic pain who are prescribed opioids (N = 174).

Exploratory Aim 3: Explore change in motivation, expectancies, and attitudes/intentions as mediators of 3-month follow-up outcomes.

3. STUDY DESIGN

This study follows a Stage I NIH treatment development model and consists of two sequential phases: Phase 1A (intervention development via focus groups) and Phase 1B (randomized controlled trial). All study procedures for both phases were conducted virtually via Zoom. Participants were recruited nationally through online advertisements.

4. ELIGIBILITY CRITERIA

4.1 Inclusion Criteria

- 21 years of age or older
- Current hazardous drinking pattern (AUDIT-C score ≥ 4 for males, ≥ 3 for females)
- Current chronic pain
- Current use of prescription opioid medications

4.2 Exclusion Criteria

- Current enrollment in alcohol or other substance use treatment
- Not fluent in English
- Current psychiatric distress or thought disorder (assessed via Brief Symptom Inventory; BSI score > 2 on any item)

5. PARTICIPANT RECRUITMENT

5.1 Methodology

Participants for both Phase 1A and Phase 1B were recruited nationally via online methods. Recruitment materials were distributed through online platforms and directed interested individuals to contact the study team. Eligibility was assessed via telephone screening. Upon confirmation of eligibility, participants were scheduled for a virtual study visit conducted via Zoom. Participants provided their email address to receive the electronic consent form, Zoom meeting link, and links to study surveys and intervention components. Phase 1A targeted enrollment of $N = 21$ focus group participants. Phase 1B targeted enrollment of $N = 174$ randomized participants.

5.2 Sample size/power analysis

Based on pilot data and prior published research, moderate effects ($d > .45$) of the PA-PFI on primary post-test and 3-month follow-up outcomes were hypothesized. Power analyses conducted using GPower, RMASS, and simulation studies for indirect effects indicated that a Phase 1B sample of $N = 174$ would yield greater than 80% power to detect effects for primary study aims at $\alpha = .05$.

6. STUDY PROCEDURES

6.1 Phase 1A: Focus Group Procedures

Phase 1A consisted of three iterative focus groups of approximately 7 participants each (total $N = 21$), conducted virtually via Zoom. The purpose of Phase 1A was to develop and iteratively refine the PA-PFI based on qualitative and quantitative feedback from the target population.

Following telephone screening and scheduling, participants were emailed an electronic consent form and a Zoom meeting link on the day of their appointment. Participants were individually brought into a Zoom room with a researcher, who obtained verbal consent. Consent was documented in researcher field notes.

After completing informed consent, participants were provided a link to a baseline survey (approximately 30-40 minutes) and then presented with slides containing example PFI content (approximately 20-30 minutes). Participants then participated in a focus group discussion (approximately 30 minutes) facilitated by two clinical psychology doctoral graduate students.

Focus groups were recorded via the Zoom recording function (video and audio). Qualitative and quantitative data were collected to guide iterative refinement of intervention content after each focus group.

Participants were compensated \$115 total via Amazon electronic gift cards (\$30 baseline, \$30 PFI completion, \$25 post-intervention questionnaire, \$30 focus group feedback).

6.2 Phase 1B: Randomized Controlled Trial Procedures

Phase 1B consisted of a randomized controlled trial comparing the PA-PFI to a Control PFI (C-PFI) among hazardous drinkers with chronic pain who were prescribed opioid medications. All procedures were conducted virtually via Zoom.

Following screening and scheduling, participants were emailed an electronic consent form and a Zoom meeting link. After completing the informed consent process, participants completed baseline measures on a computer (approximately 30-40 minutes). Participants were then randomly assigned to either the PA-PFI or C-PFI condition. Condition-specific computer-based measures were completed, with pre-selected responses dynamically extracted and imputed to personalize the respective PFIs. Participants then completed their assigned PFI (approximately 20-30 minutes) followed immediately by a post-test questionnaire (approximately 20 minutes). The full study visit took approximately 1.5 hours.

A 3-month follow-up online survey (approximately 30 minutes) was completed remotely via secure online survey platform. The follow-up was scheduled at the conclusion of the study visit.

Participants were compensated \$160 total via Amazon electronic gift cards (\$85 for the study session, \$75 for the 3-month follow-up).

7. RANDOMIZATION AND BLINDING

Phase 1B participants were randomly assigned to PA-PFI or C-PFI conditions. The study employed a single-blind parallel-group design (participant-blind). Participants were not aware of the specific content differences between conditions prior to randomization.

8. INTERVENTIONS

8.1 Pain-Alcohol Personalized Feedback Intervention (PA-PFI)

The PA-PFI is a brief, single-session, computer-based intervention developed to simultaneously address hazardous drinking and concurrent alcohol-prescription opioid use in the context of chronic pain. It was developed and refined through iterative focus group feedback in Phase 1A and grounded in the Transtheoretical Model, Health Belief Model, and principles of motivational interviewing.

PA-PFI content includes personalized profiles covering: alcohol consumption (quantity/frequency, drinking pattern, readiness to reduce); prescription opioid use (type, quantity, frequency, compliance); and perceived interrelations between pain and alcohol (expectancies for alcohol analgesia). Feedback components include: normative feedback (age- and sex-specific drinking and medication norms); chronic pain feedback (goals for pain reduction); pain medication use feedback (alcohol-opioid interactions); and pain-alcohol feedback (reciprocal relations, corrective feedback on alcohol analgesia expectancies, risks of

continued drinking in the context of chronic pain). CDC evidence-based strategies to reduce alcohol consumption are also provided.

8.2 Control Personalized Feedback Intervention (C-PFI)

The C-PFI serves as an attention-matched control condition. It is identical to the PA-PFI in terms of length, number of slides, text/graphics, and health behavior focus. However, the C-PFI provides personalized feedback relevant to exercise and nutrition only and does not address drinking reduction or pain-alcohol-opioid interrelations.

9. OUTCOME MEASURES AND ASSESSMENT SCHEDULE

Primary post-test outcomes (Aim 2, Hypotheses H1A-H1D) include: motivation/intention to reduce drinking (Alcohol Ladder), attitudes and intentions regarding concurrent use of alcohol and prescription opioids (AOAI), expectancies for pain-coping/reduction via drinking (EAA), and knowledge regarding pain-alcohol-opioid interrelations (PAOKQ). Primary 3-month follow-up outcomes (H2A-H2B) include: hazardous drinking status (AUDIT) and frequency of concurrent alcohol and prescription opioid use (FCAO).

10. STATISTICAL ANALYSIS PLAN

We first examined the effects of the PFI intervention condition (i.e., Integrated PFI, control PFI) on each post-treatment and 3-month follow-up outcomes via analysis of covariance (ANCOVA), adjusting for the corresponding baseline measure. For each ANCOVA model, we assessed model assumptions, including normality, homoscedasticity, homogeneity of regression slopes, and linearity of the baseline covariate. When the homogeneity of regression slopes assumption was violated, an interaction term between the baseline score and the intervention condition was included in the model. Robust (HC3) standard errors were reported when the assumption of homoscedasticity was not met. Next, simple mediation analyses were conducted to examine the effect of PFI intervention on each 3-month outcome. Indirect effects were considered statistically significant if the bootstrap confidence intervals (CIs) did not include zero.