RESET CHALLENGE PROTOCOL

Title of Project: Feasibility and Preliminary Efficacy of the 30-Day Reset Challenge

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Abstract

Alcohol is a modifiable risk factor for gastrointestinal (GI) and breast cancers, with heavy, binge, and daily drinking increasing cancer risk. In 2021, the U.S. reported 340,050 GI cancer cases (3,467 in Oklahoma) and 272,454 breast cancer cases in women (2,547 in Oklahoma). To reduce these cancers, accessible, effective, and scalable alcohol interventions are needed. Mobile Health (mHealth) platforms are well suited for this purpose, as they can screen for high-risk drinking and deliver on-demand, evidence-based interventions directly to at-risk individuals. Building on the success of the 'Dry January' community intervention, the current study will develop and test a 30-day mHealth Reset Challenge. This single-arm trial will recruit 150 adults with high-risk drinking in Oklahoma and pursue three aims. Aim 1 is to evaluate the feasibility and preliminary efficacy of the Reset Challenge. Aim 2 is to evaluate whether improving self-efficacy is associated with a higher likelihood of achieving 30-day abstinence. Exploratory Aim 3 is to examine the feasibility of using an alcohol sensor as an objective outcome measure in a subsample (n=30). To date, Dry January community interventions have only minimally investigated treatment mechanisms, and their outcomes have been assessed solely through self-reported alcohol use. Findings from the current study will determine the feasibility and preliminary efficacy of the Reset Challenge and clarify the potential role of self-efficacy as a critical predictor for successful abstinence. This work will provide foundational data for future large-scale R01 trials aimed at reducing high-risk drinking, and ultimately lowering alcohol-related cancer in the U.S.

A. Specific Aims

- **Aim 1:** To determine the feasibility and preliminary efficacy of the Reset Challenge, we will administer the Daily Drinking Questionnaire13 to screen high-risk drinking among individuals aged 18+. Eligible participants will be immediately invited to enroll in the Reset Challenge.
- **Aim 2:** To examine the role of self-efficacy in successful abstinence, daily surveys will assess abstinence self-efficacy and alcohol use throughout the challenge. Free-text qualitative responses will examine how participants describe changes in self-efficacy and identify self-regulatory strategies supporting abstinence to inform intervention refinement.
- **Aim 3 (Exploratory):** To test the feasibility of using an alcohol sensor as an objectively outcome measure, a subsample (n = 30) will wear the sensor two weeks before and throughout the challenge.
- This study will evaluate the feasibility and preliminary efficacy of the Reset Challenge to reduce high-risk drinking, and ultimately to reduce alcohol-related cancers. It will lay the groundwork for developing an effective and scalable prevention mHealth app to reduce high-risk drinking. Successful outcome will provide robust preliminary data for R01 grants to NIAAA and NCI (PAR-25-221, PAR-26-001).

B. Background and Significance

Alcohol is widely used in the US (48%, 134.7 million)[2] and in Oklahoma (45% of adults).[3] High-risk drinking patterns, including heavy, binge, and daily drinking, increase the risk of gastrointestinal (GI)[2,3] and breast cancer.[4,5] Several GI cancers (i.e., colorectal, esophageal, hepatobiliary track, and oropharyngeal cancers) occur at higher rates in Oklahoma than the national average.[6] To reduce these cancers, we need an effective intervention tool for high-risk drinking in Oklahoma and across the US.

mHealth is promising for providing an on-demand, low-burden, scalable solution that can facilitate self-directed motivation by allowing high-risk drinkers to instantly engage in evidence-based interventions. One such intervention is a 30-day abstinence challenge (modeled after Dry January). Studies find that 60% of participants abstained from alcohol during similar abstinence challenges,[7-9] and participants reduced their weekly drinking (d = -0.53, a moderate effect) and the number of drinks per episode (d = -0.25, a small effect) six months after the challenge.[10] Building on the success of the 'Dry January' approach, the current study will develop a 30-day mHealth-based alcohol Reset Challenge ('Reset Challenge') to address high-risk drinking.

C. Preliminary Studies/Progress Report

Our pilot research demonstrated that a 30-day abstinence challenge can be safely implemented among heavy drinkers with chronic pain.[1] The protocol was flexible, allowing participants to select their own start date, use their preferred coping strategies (e.g., avoiding drinking-related social occasions or choosing non-alcoholic beverages), and seek medical treatments as needed. Consistent with findings from Dry January studies,[7-9] 68% of participants abstained from alcohol during the challenge.[1] Importantly, nearly all participants (94%) reported health benefits, including reductions in withdrawal symptoms (d = -0.79) and sleep problems (d = -0.63).[1] Participants also reported increased abstinence self-efficacy (d = 0.56).[1] As self-efficacy is a determinant of behavior changes in the social cognitive theory,[11] increased self-efficacy may represent a key mechanism underlying treatment success.

D. Research Design and Methods (What, When, How, Where)

1. This single-site, single-arm, online study will recruit 150 participants with high-risk drinking within one year. High-risk drinking includes heavy drinking, defined as ≥8 (women) or ≥15 (men) drinks/week[12]; binge drinking, defined as ≥ 4 (women) or 5 (men) drinks within 2 hours[12]; and daily drinking, defined as ≥ 1 drink/day.
2. Interested participants will first complete the prescreening survey and then, potentially eligible participants will schedule a Zoom interview with a research coordinator to confirm their eligibility and go through the informed consent process.
3. Those who are eligible and e-signed the informed consent via REDCap will select a start date and complete daily alcohol-use surveys for 2 weeks before and throughout the 30-day challenge (Table 1). During the challenge, daily prompts will assess drinking plans, coping, craving, and self-efficacy. Follow-up surveys at 1, 2, and 3 months will track sustained changes in alcohol use. We will use REDCap platform to collect the self-reported outcomes.
4. There will be no randomization and blinding as this is the single-arm, feasibility study.
5. If a participant decides to withdrew during the study period and the study prematurely ends, the participant continue working with their treating physicians, seek out treatments, and resume their typical lifestyle. The study provides mental health resources before, during, and after the study ends.
6. Individual research results will not be disclosed to participants. Because this study relies on self-reported outcomes related to drinking, participants will already know whether they succeeded or not in abstaining, and the primary goal is to evaluate the effects of the Reset Challenge at the group level. However, depression symptoms will be monitored closely; if a participant reports severe

Table 1. Timeline (N = 150)

Pre-Challenge	Challenge	Post-Challenge
D-14	D01 ~ D30	Month 1, 2, & 3
Baseline Survey		Monthly Follow-up
Daily Survey ---------->		
		Qualitative Survey
Alcohol sensor (n = 30) ------->		

depressive symptoms, we will notify them and encourage them to seek appropriate treatment.
7. Identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

E. Inclusion / Exclusion Criteria

1. Inclusion criteria:
    a) Age of ≥ 18 years,
    b) Oklahoma residents
    c) Current high-risk alcohol use (daily, binge, and heavy drinking) in the past 30 days.
    d) Access to a computer, smartphone, or tablet.
2. Exclusion criteria:
    a) Lack of proficiency in English,
    b) Pregnancy
    c) Life-threatening illness (e.g., newly diagnosed or untreated cancer),
    d) Severe mental health concerns (e.g., severe depression, suicide ideation, cognitive impairments)
    e) Current participation in alcohol treatments.
    f) History of severe withdrawal symptoms (e.g., tremors, seizures, hallucinations, delirium tremens).
3. Early termination criteria: Participant death determined to be related to study participation.

F. Gender/Minority/Pediatric Inclusion for Research

Only adults aged 18 years and older will be enrolled. This age restriction is justified because the intervention has been safely tested and implemented only among community-dwelling adults, and there is insufficient evidence to support its use in minors. Women and individuals from minority groups will be fully included, and recruitment efforts will aim to ensure representation consistent with local community demographics. However, pregnant women will be excluded for safety reasons. No other population groups are excluded.

G. Recruitment and Enrollment

1. **A. Plans for Recruitment**: Participants will be recruited through community-facing advertisements and online outreach. Recruitment materials will include flyers and digital advertisements posted on platforms such as Facebook, Instagram, and YouTube. These materials will direct potential participants to a secure REDCap prescreening survey, where initial eligibility will be assessed. Because this is a fully remote study, all recruitment methods are designed to reach community-dwelling adults across Oklahoma. **B. Multicenter considerations**: This is a single-site study. All recruitment methods (flyers, online advertisements, and REDCap prescreening) are under the control of the local study team. No call centers, external recruitment vendors, or national advertisements will be used.

2. **Consent Procedures**: All study procedures will be conducted remotely. Individuals who appear eligible based on the REDCap prescreening survey will be contacted by study staff to schedule a Zoom session. During this session, study personnel will:
    - Confirm eligibility
    - Review the consent form in detail
    - Answer any questions
    - Document informed consent electronically

Electronic consent will be obtained using REDCap's secure e-consent framework. This approach is appropriate and justified because the study is fully remote, involves minimal risk, and eliminates barriers associated with in-person visits or mailing physical consent documents.

3. Notably, a waiver of signed consent will be obtained for Prescreening survey.
4. Consent will be obtained during a scheduled Zoom videoconference session. Participants may join the session from their own home or another private location of their choosing. No consenting will occur in clinical settings, inpatient units, emergency departments, or other medical environments.
5. Non-English-speaking participants will not be enrolled in this study. All study materials—including recruitment materials, the consent form, and all assessments—are available only in English. The intervention content has not yet been validated in languages other than English, and resources for translation, cultural adaptation, and interpreter support are not available for this protocol.
6. Several steps will be taken to minimize the possibility of coercion:
   - Participants will receive the consent form in advance (via secure electronic link) and will be encouraged to review it at their own pace before the consent meeting.
   - During the Zoom consent session, ample time will be provided for questions, and participants will be reminded that participation is voluntary and can be discontinued at any time.
   - No participants with pre-existing treatment relationships with the study investigators (e.g., private patients, clinical supervisees) will be recruited.
   - Study staff will avoid recruiting employees, students, or individuals in dependent relationships with the investigators.
   - Compensation will be modest and structured to avoid undue influence.

H. Patient reported outcome measures and the timeline

This study will administer **validated self-report measures** as listed in the table below.
Questionnaires

	Baseline	Daily Survey	Monthly Follow-up
Demographics, Drinking history (Self and Family), Medication, DAST-10[13,14]	X		
[Daily Survey]			
Confidence in abstinence (0-10),[15] craving (0-10),[16,17] coping, alcohol use	X	X	X
Goal Adjustment Difficulty		X	X
Significant changes in health (weekly)		X	
[Drinking-related variable]			
DMQ,[18] DSM-5 AUD symptom checklist[45]	X		
AASE,[19] DRSE,[20] PACS,[21] SAWS,[22] AUDIT,[23,24]	X		X
[Life stress, Coping, Personality Traits]			
PSS,[25] GSE,[26] BSCS,[27] ERQ,[28]	X		X
[Physical and Psychological Health Outcomes]			
PROMIS-Depression, Anxiety, Anger,[29,30] Sleep Disturbance,[31] Fatigue,[32] and Cognitive Function	X		X

Note: DAST-10: Drug Abuse Screening Test; DMQ-A: Drinking Motives Questionnaire for adults; AASE: Alcohol Abstinence Self-Efficacy; DREQ: Drinking Refusal Self-Efficacy; PACS: Penn Alcohol Craving Scale; SAWS: Short Alcohol Withdrawal Scale; AUDIT: Alcohol Use Disorder Identification Test; PSS: Perceived Stress Scale; GSE: General Self-Efficacy; BIS: Barratt Impulsiveness Scale; ERQ: Emotion Regulation Questionnaire

I. Risks and Benefits

Adverse events	Frequency (%)
1. Alcohol withdrawal symptoms in the first week of challenge	5 (14.7)
2. Increased other substance use	4 (11.8)
3. Consuming more food or sweets	3 (8.8)
4. Increased craving during the challenge	3 (8.8)
5. Difficulty falling asleep	2 (5.9)
6. Increased physical pain	2 (5.9)
7. Increased online shopping	1 (2.9)
8. Weight gain	1 (2.9)
9. Increased anxiety during the challenge	1 (2.9)

Note: Sum is >100% because some participants endorsed more than one event.

Table 1. Reported Adverse Events for the 30-day challenge among heavy drinkers with chronic pain.[1]

1. The 30-day Reset Challenge is a community-based behavioral intervention with no restrictions on participants' access to medical or behavioral health treatment. While the intervention is considered low risk, several potential risks should be noted:

a. Physical Risks:

Participants who significantly reduce or stop drinking during the first week of the Reset Challenge may experience alcohol withdrawal symptoms, including anxiety, sweating, insomnia, irritability, or gastrointestinal discomfort. Severe withdrawal symptoms are possible but unlikely given the community-based nature of the intervention. Participants may choose to drink alcohol or use appropriate medications to manage withdrawal symptoms if needed. Prior to starting the challenge, participants will be encouraged to discuss withdrawal symptom management with their primary care providers. Any severe or concerning symptoms, however, may require prompt medical evaluation or treatment.

b. Psychological/Mental Health Risks:

Participants may experience temporary stress, emotional discomfort, or increased cravings while attempting to modify their drinking behaviors. Discussing alcohol use may produce feelings of guilt or distress for some individuals. We will monitor depression and anxiety symptoms and encourage participants to seek appropriate mental health care and attend a support group as needed.

c. Social Risks:

Disclosure of study participation or alcohol use to others may cause discomfort or stigma. Participants control when and with whom they share personal information.

d. Financial Risks:

There are no anticipated direct financial risks; participation costs are minimal because all procedures are remote.

e. Confidentiality Risks:
Loss of confidentiality is a potential risk for any study involving sensitive behavioral health information. However, strict data security procedures will be used to minimize this risk.

2. **Protection of Privacy and Confidentiality**
Several measures will be implemented to protect participant privacy and minimize risks

List of perceived benefits (N = 34).

Benefits	Frequency (%)	
Physical health	**26**	**(76.5)**
1 Better sleep	17	(50.0)
2 More energy/less fatigue	11	(32.4)
3 Weight loss	6	(17.6)
4 Overall better health	4	(11.8)
5 Lower blood pressure	4	(11.8)
6 Improved GI symptoms (e.g., acid reflux, nausea)	3	(8.8)
7 Less physical pain	2	(5.9)
8 Less leg cramps at night	1	(2.9)
9 Less severe hot flashes	1	(2.9)
10 Less facial puffiness in the morning	1	(2.9)
Mental health	**19**	**(55.9)**
1 Better cognitive function (e.g., focus, memory)	7	(20.6)
2 Less anxiety symptoms	7	(20.6)
3 Better mood	5	(14.7)
4 Increased general self-efficacy	5	(14.7)
5 More present focused	4	(11.8)
6 More patience/not easily frustrated	2	(5.9)
Alcohol-related	**13**	**(38.2)**
1 Increased self-efficacy about alcohol use/abstinence	9	(26.5)
2 Reduced craving/desire for alcohol	6	(17.6)
3 No hangover/withdrawal symptoms	2	(5.9)
Other	**13**	**(38.2)**
1 Improved productivity/efficiency at work	5	(14.7)
2 Make better choices in life	4	(11.8)
3 More active/exercise	3	(8.8)
4 Save money	2	(5.9)
5 Better food taste	1	(2.9)
6 Improved relationship with a partner	1	(2.9)

Note: Some participants reported more than one benefit. GI: gastrointestinal.

Table 2. Perceived benefits of the 30-day abstinence challenge.[1]

related to the handling of Protected Health Information (PHI):

a) All study data will be collected and stored in secure, password-protected REDCap databases on institutional servers.
b) Access to identifiable information will be restricted to authorized study personnel only.
c) No study data will be stored on personal devices.
d) Electronic communications with participants (e.g., Zoom, email) will use secure, encrypted platforms.
e) Identifiers will be removed from analytic datasets whenever possible.
f) A **Certificate of Confidentiality** will be obtained to provide additional legal protection against forced disclosure of sensitive information.
g) Physical records, if any, containing PHI will be stored in locked cabinets accessible only to study staff.

These procedures collectively minimize the risk of unauthorized access, loss, or disclosure of participant information.

3. **A. Benefits to Participants:**
Participants may experience reductions in alcohol use, improved physical and mental well-being, and increased motivation to engage in healthier behaviors. Based on prior studies of the Reset Challenge, most participants (85.3%) report perceived benefits in one or more of physical, mental, alcohol-related, and other domains (Table 2).

B. Benefits to Others and Society:
This study may provide valuable insights into brief, community-based interventions for high-risk alcohol use. Findings could inform scalable public health strategies, guide future behavioral interventions, and expand access to low-burden programs for adults who wish to reduce alcohol use but are not seeking specialty alcohol treatment. By evaluating the effects of the Reset Challenge, this research may ultimately benefit broader communities by promoting evidence-based approaches to alcohol reduction and the prevention of alcohol-related cancers.

4. The risks associated with participation in the 30-day Reset Challenge are expected to be minimal to moderate and are primarily related to temporary withdrawal symptoms, emotional discomfort, or psychological stress while attempting to reduce alcohol use. These risks are mitigated through careful monitoring of participants' physical and mental health, encouragement to seek medical or behavioral health care as needed, and robust confidentiality protections, including a Certificate of Confidentiality. The potential benefits such as reduced alcohol use, improved physical and mental well-being, and contributions to evidence-based, community-level alcohol reduction strategies are meaningful for both participants and broader communities. Given the low likelihood of severe adverse effects and the significant potential benefits to participants and society, the risks are reasonable in relation to the anticipated benefits.

B. Statistical Methods

1. **Aim 1** is to determine feasibility and preliminary efficacy of the Reset Challenge. Feasibility criteria includes: 1) enrolling 50% or more of eligible participants, 2) successfully recruiting 150 participants in 1 year, and 3) maintaining a dropout rate < 20% over the 3-month study period. Preliminary efficacy criteria include: 1) at least 60% of participants will abstain from alcohol during the challenge and 2) a reduction in weekly alcohol use during the challenge compared with baseline, with 3) effects maintained up to 3 months. Analysis plan: To evaluate changes in alcohol use over time, a **linear mixed-effects model (LMM)** will be employed. This model is well-suited for repeated measures data and can accommodate missing data due to dropout, providing unbiased estimates under the assumption of missing at random. The LMM will:
    - Examine whether weekly drinking during the challenge is significantly lower than baseline.
    - Assess whether reductions are maintained at the 3-month follow-up.
    - Estimate trends in weekly drinking during baseline, changes in level and slope during the challenge, and slope during the post-challenge period.

Sample size calculation: Assuming a small effect size (Cohen's d = 0.30), two-sided hypothesis testing, $\alpha = 0.05$, and 90% power, 117 participants are required to detect significant changes in alcohol use. To account for an anticipated dropout rate of ≤ 20%, we plan to recruit 150 participants who are heavy, binge, or daily drinkers. This sample size will provide adequate power to detect meaningful changes in alcohol use and evaluate feasibility outcomes.

2. **Aim 2** is to examine the role of self-efficacy in successful abstinence. Analysis plan: To evaluate whether self-efficacy predicts successful 30-day abstinence, a **multilevel logistic model (MLM)** will be used. This model accounts for the nested structure of the data, with repeated daily observations nested within participants. Specifically, the MLM will examine whether a) Individual differences in baseline self-efficacy (intercept) and Rate of change in self-efficacy during the challenge (slope) predict the likelihood of achieving 30-day abstinence. This approach allows us to assess both between-person effects (overall levels of self-efficacy) and within-person effects (changes in self-efficacy over time) while accounting for correlations among repeated measures. Multilevel logistic models handle missing data using maximum likelihood, allowing all available observations to contribute to estimation and producing unbiased parameter estimates under the Missing at Random assumption.
   Sample size calculation: Each participant will provide up to 44 daily observations (baseline and 30-day challenge period, plus follow-up assessments). With 150 participants (as determined for Aim 1), we will have sufficient power (90%) to detect small effects, corresponding to odds ratios of 1.3–1.5, while accounting for within-person correlation (r = 0.3). This sample size is considered adequate for multilevel modeling with repeated measures and small effect sizes.
   Qualitative analysis plan: Free-text responses from participants will be analyzed to explore self-regulation strategies and their relationship to outcomes. Participants will be categorized into three naturally occurring outcome groups: a) Abstinence, b) Reduced drinking, c) Unchanged or increased drinking. Then, we will conduct the text analysis procedures such as 1) Preprocessing: Tokenization, stop-word removal, and stemming, 2) Analyses: Word frequency, co-occurrence, and clustering using R-based text mining, and 3) Theme Extraction: Latent Dirichlet Allocation (LDA) to identify underlying themes. Emergent themes will be mapped to outcome groups to examine whether self-efficacy and self-regulation strategies are associated with successful abstinence or reduced drinking. This mixed-methods approach combines quantitative and qualitative data to provide a comprehensive understanding of the role of self-efficacy in influencing outcomes in the Reset Challenge.

3. **Aim 3** is to examine the feasibility of using an alcohol sensor as an objective outcome measure. Feasibility will be defined as at least 80% of participants wearing it at least 80% of the time (134 hours per week), including during drinking occasions. Analysis plan: A) Adherence rates will be calculated for each participant as the proportion of hours worn relative to the total possible hours (hours worn ÷ total hours). These rates will be summarized descriptively using means, standard deviations, and proportions meeting the feasibility threshold. If 80% (n = 24) meet the adherence threshold, the corresponding 95% confidence interval would be approximately 63% to 90%, calculated using the Wilson binomial method. B) Concordance Analysis: The relationship between sensor-detected drinking episodes and

self-reported alcohol use will be examined to assess the accuracy and reliability of the sensor as an objective outcome measure. Concordance will be evaluated using measures such as sensitivity, specificity, and agreement statistics (e.g., Cohen's kappa). This aim will provide critical information on the practicality of using alcohol sensors in a community-based intervention, including adherence patterns and agreement with self-reported drinking, to inform future larger-scale studies.

C. Data and Safety Monitoring Plan

This study is classified as **minimal risk**. The primary measures to ensure participant safety include monitoring **privacy and confidentiality**, as outlined in the Privacy and Confidentiality section.

1. ***Monitoring of Participant Safety:***
    a. Participants will meet with a research coordinator to discuss a withdrawal symptom management plan before starting the challenge. There will be no restrictions on receiving medical or psychological treatments. Participants will be encouraged to consult with their treating physician before and during the challenge, may resume their usual methods for managing withdrawal, including drinking alcohol if needed, and may engage in alcohol treatments at any time.
    b. Participants' depression and anxiety symptoms will be monitored through self-reported assessments.
    c. Participants experiencing severe symptoms, including suicidal ideation, will be promptly notified and encouraged to seek appropriate mental health care.
    d. **Collection of Safety Data:** Safety data will be collected primarily through daily surveys completed by participants during the challenge and monthly survey after the challenge via REDCap. These surveys will include items assessing withdrawal symptoms and mental health indicators such as depression and anxiety. Any flagged risks—such as severe withdrawal symptoms or high depression scores—will be automatically notified to the research coordinator and the PI, Dr. You, for follow-up. Additional safety information may be collected through telephone or Zoom calls as needed to assess participant well-being. Participants will also be provided mental health resources at the time of enrollment and throughout the study period.
    e. **Frequency of Data Collection:** Safety data collection begins on day 1 of the Reset Challenge and continues daily throughout the 30-day challenge and the 3-month follow-up period. Participants will complete daily surveys during the challenge and monthly surveys during follow-up to monitor ongoing safety concerns.
    f. **Review of Cumulative Data:** Cumulative safety data will be reviewed **weekly** during the weekly research team meeting.
    g. **Conditions for Intervention and Intervention Plan:** The research team will intervene if a participant reports **severe depression, suicidal ideation, or other indications of imminent harm** to self or others. Intervention includes: a) Immediate telephone ontact by the research coordinator and PI. b) Encouragement to seek **urgent mental health care** or contact emergency services. c) Providing referrals to local mental health providers or crisis services.
    h. **Conditions Triggering Immediate Suspension of Research**: The research may be **immediately suspended** if any of the following occur: a) Evidence that participation is causing serious physical harm or life-threatening withdrawal events. b) Unanticipated adverse events that indicate participants are at high risk of harm

despite intervention. c) Systemic issues with survey or monitoring procedures that prevent timely identification and response to safety concerns.

2. For clinical studies, describe the Data and Safety Monitoring Plan (DSMP)
    a) All adverse events will be documented and reported according to institutional and federal requirements. For this study, all AEs, including serious adverse events (SAEs), will be reported to the IRB per OUHSC policy and timeline.
    b) **Adverse event (AE) grading**:
        - Mild: Transient symptoms requiring no intervention.
        - Moderate: Symptoms requiring minimal intervention or monitoring.
        - Severe: Symptoms causing significant discomfort, functional limitation, or requiring medical evaluation.
        - Serious: Life-threatening events, hospitalization, or death.
    c) **Plan for unanticipated AE reporting**: Any unanticipated AEs or SAEs identified through daily surveys, follow-up calls, or participant contact will be reported immediately to the PI (Dr. You) and the research coordinator. The IRB will be notified according to institutional policy for unanticipated problems involving risks to participants or others.
    d) **Plan for annual reporting of AEs:** A cumulative summary of all AEs and SAEs will be submitted annually to the IRB as part of the continuing review process. This summary will include frequency, severity, and relationship to study participation.
    e) Interim efficacy analysis where appropriate: Given the preliminary and minimal-risk nature of this study, formal interim efficacy analyses are not planned. Descriptive trends in alcohol use, adherence, and safety outcomes will be monitored throughout the study to ensure no unanticipated harm occurs.
    f) **Summary:** This DSMP ensures that participant safety is continuously monitored, that AEs are promptly addressed, and that reporting is in compliance with institutional and federal regulations. The plan is proportionate to the minimal-risk nature of the study while maintaining rigorous oversight.

3. A formal Data and Safety Monitoring Board (DSMB) will **not** be used for this minimal-risk study. Instead, the **study team will review all safety data on a weekly basis**. This includes daily survey responses on alcohol use, withdrawal symptoms, and mental health indicators (e.g., depression and anxiety).
    a. **Safety Review Procedures:**
    - Weekly review meetings will be conducted by the PI (Dr. You) and the research coordinator to assess participant safety and adherence.
    - Any adverse events, severe withdrawal symptoms, or mental health concerns will be identified and addressed promptly, including contacting participants and referring them to medical or behavioral health services as needed.
    - Trends in safety data across participants will also be evaluated to ensure early detection of any emerging risks.

Because this is a minimal-risk, community-based intervention and not a Phase III, NIH, cooperative group, or drug-sponsored study, no external DSMB or sponsor oversight is required. The weekly internal review by the study team provides sufficient oversight to protect participant safety.

D. Data Sharing

1. **Data Sharing with Outside Entities**. This study does **not plan to share identifiable participant data** with outside entities. However, de-identified or coded datasets may be shared for **research purposes** if requested by collaborating investigators or for future secondary analyses.
2. **Process for Data Transfer.** If data sharing is required, de-identified datasets will be transferred securely via encrypted institutional servers or secure file-sharing platforms approved by OUHSC IT and the Office of Research Administration.
3. **Data Type:** Only **de-identified or coded data** will be shared. No direct identifiers (e.g., name, date of birth, address) will be included. If identifiable data were ever needed, a clear justification would be required and additional IRB approval obtained.
4. **Use of Data.** Shared data will be used solely for **research purposes**, including replication of analyses, secondary analyses, or methodological development. Data will not be used for commercial purposes.
5. **Agreements:** All data sharing arrangements will be formalized through a **Data Use Agreement (DUA)** or equivalent, processed through the **Office of Research Administration**. No data will be transferred without an approved agreement in place.

E. Confidentiality

Research records will be maintained to protect participant privacy and to allow inspection by government agencies, the sponsor, the University, and other applicable entities.

a) Storage of Data:

- **Electronic data** (survey responses, daily reports, self-reported outcomes) will be stored in **secure, password-protected REDCap databases** on OUHSC institutional servers.
- **Paper study documents** (signed consent forms, HIPAA authorization forms) will be stored in **locked cabinets** in a secure research office accessible only to authorized study personnel.

2. **Duration of Storage:**
   a) All study records will be retained for a minimum of **7 years** following the completion of the study, in accordance with institutional policy and applicable regulations.
3. **Access by Departments or External Entities:**
   a) Access to study data is **limited to authorized study personnel**.
   b) No external entities will have access to identifiable data unless a formal **Data Use Agreement (DUA)** is executed and approved by the Office of Research Administration.
4. **Transport of Data:**
   a) Electronic data may be accessed remotely via **secure, encrypted connections**; no data will be stored on personal devices.
   b) Any data transfer (e.g., for collaboration or secondary analyses) will occur through **encrypted institutional servers** or secure file-sharing platforms.
   c) Paper records, if transported for audit or review, will be **locked and physically secured during transport**.
5. **State of the Data:**
   a) Data will remain **identifiable** during active study conduct to allow for participant

follow-up and safety monitoring.

b) After study completion and de-identification procedures, datasets may be **coded or de-identified** for future analyses or data sharing.

6. **Other Considerations:**
   a) All research software and mobile devices used in this study comply with **University IT Security requirements**.
   b) Use of the Cloud and external data storage (if applicable) meets **University data security policies** for research data.

7. Literature Cited

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Appendix A Questionnaire
[Prescreening Survey]

1. Are you at least 18 years old? Yes/No
2. Tell us your sex/gender
    a. Male
    b. Female
    c. Non-binary
    d. Decline to answer
3. (if female) Are you pregnant? Yes/No
4. Do you drink alcohol? Yes/No
5. Are currently in any alcohol treatment? (Medication or psychological treatment) Yes/No
6. Are you currently seeking treatment for alcohol treatment? Yes/No
7. How many years have you been drinking alcohol (best guess) _____ years
8. Have you tried to quit drinking before? Yes/No
9. How many times have you tried to quit drinking for any reasons? (best guess)
   0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and more than 10 times
10. When you answer how much you drink in the following questions, use this chart.

ONE STANDARD DRINK IS EQUAL TO:

Standard American BEER (3-5% alcohol) — 12 oz. Can, Bottle or Glass

Microbrew or European BEER (8%-12% alcohol) — 1/2 of a 12 oz. Can or Bottle

WINE (12 – 17% alcohol) — 4 oz. Glass

WINE Cooler — 10 oz. Bottle

HARD LIQUOR (80-proof, 40% alcohol) — 1-1/2 oz. or One Standard Shot

HARD LIQUOR (100-proof, 50% alcohol) — 1 oz.

WINE: 1 Bottle

25 oz. (12 – 17% alcohol) = 5 standard drinks
40 oz. (12 – 17% alcohol) = 8 standard drinks

HARD LIQUOR: 1 Bottle

12 oz. = 8 standard drinks
25 oz. = 17 standard drinks
40 oz. = 27 standard drinks

11. (if yes to Q4) For each day of a typical drinking week in the past 30 days: 1) Estimate the number of standard drinks consumed, and 2) Estimate the number of hours spent drinking. A standard drink is defined as 12 oz beer, 5 oz wine, or 1.5 oz liquor. (Enter 0 if you don't typically drink alcohol on any of the day)
    Monday: Drinks _____ Hours Drinking _____
    Tuesday: Drinks _____ Hours Drinking _____
    Wednesday: Drinks _____ Hours Drinking _____
    Thursday: Drinks _____ Hours Drinking _____
    Friday: Drinks _____ Hours Drinking _____
    Saturday: Drinks _____ Hours Drinking _____
    Sunday: Drinks _____ Hours Drinking _____

12. (if yes to Q4) In the past 30 days, approximately how many standard alcoholic drinks did you typically consume in a week? _____drinks/week
13. (if yes to Q4) Have you ever been in treatment for an alcohol problem? Never/Currently/In the past
14. (if yes to Q4) Are you currently seeking treatment for alcohol treatment? Yes/No
15. (if yes to Q4) How many years have you been drinking alcohol? _____ years
16. (if yes to Q4) Have you ever tried to quit drinking? Yes/No If Yes, how many times?
17. (if yes to Q4) When you tried to quit, did you experience severe alcohol withdrawal symptoms requiring medical attention or hospitalization? Yes/No
18. Please respond to each question or statement by marking one box per row.

In the past 7 days …	Never	Rarely	Sometimes	Often	Always
I felt worthless	1	2	3	4	5
I felt helpless	1	2	3	4	5
I felt depressed	1	2	3	4	5
I felt hopeless	1	2	3	4	5

Note: Total score of 17 or higher (> 70T) would indicate severe depression symptoms and those with < 17 will be eligible.

19. (if eligible) 30-Day Reset Challenge Invitation. We are conducting a study called the 30-Day Reset Challenge, which asks participants to challenge themselves not to drink alcohol for 30 days. The goal is to help adults understand their drinking habits, develop your own self-regulation strategies, and see the potential health benefits of reducing alcohol use. Are you interested in participating in the 30-Day Reset Challenge? Yes/No
20. (If Yes) Would you like to schedule a Zoom interview to discuss your eligibility and next steps?
    a. Yes, please schedule a Zoom interview
    b. No, not at this time
21. (If want to schedule a zoom interview), Tell us your name
22. Tell us your email address
23. Tell us your phone number
24. Can we leave a message on your phone? Yes/No
25. Are you interested in receiving information about future research opportunities? If you select Yes, we may contact you by email about new studies you may be eligible for. Yes/No

-Closing Message-
Thank you for completing the survey.
If you are in crisis, call or text 988 to get connected with a trained professional.
https://oklahoma.gov/odmhsas/treatment/comprehensive-crisis-response.html

If you need behavioral health treatments for mental health and substance use issues, please visit the following website:

a) Find Certified Community Behavioral Health Clinics, Call 405-248-9341 >>
https://oklahoma.gov/odmhsas/treatment/ccbhc.html

b) OU Health – Autumn Life Behavioral Center, Call 855-625-1680
https://www.ouhealth.com/health-services/mental-behavioral-health/

c) NAMI Oklahoma (800) 583-1264
https://namioklahoma.org/

d) SAMSHA's National Helpline: 1-800-662-HELP(4357) | TTY:1-800-487-4889
https://www.samhsa.gov/find-help/national-helpline

e) National Suicide Prevention Lifeline: 1-800-273-TALK (8225) | TTY: 1-800-799-4889
https://suicidepreventionlifeline.org/

[Zoom Screening]
Thank you for speaking with me today. The purpose of this screening interview is to determine whether you meet the criteria to take part in our 30-day Reset Challenge research study. The screening will take about 10 minutes. There is no compensation for completing this screening interview and there are no direct benefits to you but if you are eligible, you may participate in the main study, Reset Challenge and your time will be compensated.

Before we begin, may I ask you some eligibility questions?

(If yes, continue.) Great. Participation in this screening is completely voluntary. You can choose to answer or not answer any question, and you may stop the screening at any time without any penalty. Your decision about whether to participate will not affect your medical care in any way.

Is it okay if we continue?

(If yes, continue.) The risks of participating in this screening interview are very small. The questions are not designed to ask for sensitive personal information, but some people may feel uncomfortable answering certain items. If at any time during or after this interview you do not want us to collect your information, please let us know, and we will not retain any of your personal information.

We will keep your information confidential to the extent allowed by law, but there is a small risk that people outside the research team could gain access to this information. We obtained a Certificate of Confidentiality from the National Institutes of Health, which helps protect identifiable research information from forced disclosure. This means we cannot be required to release your information in legal proceedings, except in limited circumstances such as concerns about harm to yourself or others.

If you have any questions, concerns, or complaints about this research study, its procedures, risks, or benefits, please contact the Protocol Director, Dr. Sophia You, at dokyoung-you@ou.edu or 918-660-3923. For questions about your rights as a participant, contact the Human Research Participant Program at (405) 271-2045.

Do you have any questions before I ask you questions?
(If no questions, continue)

1. Do you feel comfortable reading, writing, and speaking English well enough to complete surveys and understand study instructions? Yes/No (to be eligible, Yes)
2. Do you have regular access to a computer, smartphone, or tablet that you can use for the study? Yes/No (to be eligible, Yes)
3. Tell me your age _____ years (to be eligible, 18 years or older)
4. Do you drink alcohol? Yes/No (to be eligible, Yes)
5. In the past 30 days, how many drinks do you usually have in a typical week? (to be eligible at least one drink daily, binge: 4 (female) or 5 (male) drinks within 2 hours in one drinking episode, or heavy drinking 8 (female) or 15 (male) drinks in a week)
6. How many years have you been drinking alcohol? _____ years
7. Are you currently in an alcohol treatment? Yes/No (to be eligible, No)
8. Are you currently seeking alcohol treatment? Yes/No (to be eligible, No)

9. Have you tried to quit or cut down on alcohol? Yes/No
10. (If yes) what withdrawal symptoms did you experience when you tried to stop or reduce drinking? _____ (to be eligible, participants must **not** have serious withdrawal symptoms—such as severe tremors, hallucinations, seizures, or confusion—that would require hospitalization or medical treatment.)
11. (For females only) Are you currently pregnant or planning to become pregnant in the next few months? Yes/No or NA (To be eligible, the answer must be "No" or "N/A.")
12. I'd like to ask a few general questions to make sure this study is safe for you. Please answer as honestly as you feel comfortable. Some health conditions or recent experiences may make participation unsafe, such as severe depression, serious thinking or memory problems, or life-threatening medical conditions. Do you currently have any health concerns like these that might make it unsafe for you to participate? Yes/No
13. (If Yes) Thank you for letting me know. To help us understand your situation better, could you briefly describe which type of health concern you are experiencing? For example, is it related to depression, memory or thinking problems, or a serious medical condition? _____ [NOT eligible if life-threatening illness such as newly diagnosed or untreated cancer and severe mental health concerns such as severe depression, suicide ideation, cognitive impairments]
14. Last question: Please provide proof of your home address, including your ZIP code, to verify Oklahoma residency. Acceptable documents include a driver's license, passport, utility bill, or similar official document. Please hold the document up to the camera while I record your full address. We may use this address to mail an alcohol sensor for a sub-study. _____
15. You are eligible for this study, would you be interested in participating in Reset Challenge study? If you decide to participate, we will email you the full informed consent form. The consent form explains the study in detail, including what participation involves, any potential risks or benefits, and your rights as a participant. You will have the opportunity to read it carefully and ask any questions before deciding whether to join. Yes/No
16. Please provide your email address so we can send you the informed consent form:

    _____

-------After consent---------

[Baseline Surveys]

1. Tell your age in years _____Years old
2. What is your sex/gender?
    a. male
    b. female
    c. non-binary
    d. decline to answer
3. Which of the following groups do you most strongly consider yourself to be a member of? (check all that apply)
    a. Hispanic or Latino
    b. White, Non-Hispanic
    c. Black or African American, Non-Hispanic
    d. American Indian/Alaska Native
    e. Native Hawaiian or Other Pacific Islander
    f. Asian
    g. More than one race
    h. Other
    i. Prefer not to answer
4. At what age did you start drinking?
5. At what age did you start drinking regularly?
6. How many years have you been drinking at the current level?
7. Has anyone in your immediate family (parents, siblings) had problems with alcohol use? Yes / No / Not sure
    a. If yes, please indicate relationship(s)
8. Please answer "Yes" or "No" for each statement about your alcohol use in the past year.

	Yes	No
I often drank more alcohol than I intended or for longer than I planned.		
I wanted to cut down or stop drinking but couldn't.		
I spent a lot of time drinking, thinking about drinking, or recovering from drinking.		
I had strong cravings or urges to drink.		
My drinking made it hard to do my job, school, or home responsibilities.		
I continued drinking even though it caused problems with family or friends.		
I gave up or reduced important social, work, or recreational activities because of drinking.		
I drank in situations that were physically dangerous (e.g., driving).		
I kept drinking even though I knew it was causing or worsening physical or mental health problems.		
I needed more alcohol than before to get the same effect (tolerance).		
I experienced withdrawal symptoms when I stopped or reduced drinking, or drank to avoid withdrawal (e.g., shaking, sweating, nausea, anxiety).		

For DSM-5 total score interpretation: 2-3 Mild, 4-5 Moderate, > 5 Severe

9. Do you take any prescription medications? Yes/No
10. Please list all medications you are currently taking:
    a. Medication 1
    b. Medication 2

c. Medication 3

11. Do you have ongoing body pain? Yes No
12. (If Yes for pain) How long have you had body pain _____(in years)
13. (If Yes for pain) What are your pain conditions?
    a. Back pain
    b. Neck pain
    c. Headache/Migraine
    d. Shoulder pain
    e. Widespread body pain or fibromyalgia
    f. Joint pain
    g. Others (describe:)
14. Listed below are 16 reasons people might be inclined to drink alcoholic beverages. Using the four-point scale below, decide how frequently your own drinking is motivated by each of the reasons listed.

I drink…	Never/Almost Never	Sometimes	Often	Almost always/always
1. As a way to celebrate.	1	2	3	4
2. To relax.				
3. Because I like the feeling.				
4. Because it is what most of my friends do when we get together.				
5. To forget my worries.				
6. Because it's exciting.				
7. To be sociable.				
8. To feel more self-confident or sure of myself.				
9. To get high.				
10. Because it is customary on special occasions.				
11. Because it helps when I feel depressed or nervous.				
12. Because it's fun.				
13. Because it makes a social gathering more enjoyable.				
14. To cheer up when I am in a bad mood.				
15. Because it makes me feel good.				
16. To mange pain				

15. Listed below are a number of situations that lead some people to use alcohol. We would like to know how confident you are that you would not drink alcohol in each situation during the past week.

Situation	Confident Not to Drink Alcohol				
	Not at all	Not very	Moderately	Very	Extremely
1. When I am in agony because of stopping or withdrawing from alcohol use.	1	2	3	4	5
2. When I have a headache.					
3. When I am feeling depressed.					

4. When I am on vacation and want to relax.					
5. When I am concerned about someone.					
6. When I am worried.					
7. When I have the urge to try just one drink to see what happens.					
8. When I am being offered a drink in a social situation					
9. When I dream about taking a drink.					
10. When I want to test my will power over drinking.					
11. When I am feeling a physical need or craving for alcohol.					
12. When I am physically tired.					
13. When I am experiencing some physical pain or injury.					
14. When I feel like blowing up because of frustration.					
15. When I see others drinking at a bar or a party.					
16. When I sense everything is going wrong for me.					
17. When people I used to drink with encourage me to drink.					
18. When I am feeling angry inside.					
19. When I experience an urge or impulse to take a drink that catches me unprepared.					
20. When I am excited or celebrating with others.					

16. The following questions ask about how confident you feel in handling difficult situations or challenges in your daily life. Please read each statement and select the response that best describes how true it is for you. There are no right or wrong answers. We are interested in your personal beliefs, not what you think you "should" say.

	Not at all true	Hardly true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough				
2. If someone opposes me, I can find the means and ways to get what I want.				
3. It is easy for me to stick to my aims and accomplish my goals.				
4. I am confident that I could deal efficiently with unexpected events.				

5. Thanks to my resourcefulness, I know how to handle unforeseen situations.				
6. I can solve most problems if I invest the necessary effort.				
7. I can remain calm when facing difficulties because I can rely on my coping abilities.				
8. When I am confronted with a problem, I can usually find several solutions.				
9. If I am in trouble, I can usually think of a solution				
10. I can usually handle whatever comes my way.				

17. The following statements are about how you view yourself. Please indicate to what extent the statements apply to you. Tick the answer of your choice.
    I (not at all like me) to 5 (very much like me)

1. I am good at resisting temptation.	1	2	3	4	5
2. I have a hard time breaking bad habits.	1	2	3	4	5
3. I am lazy.	1	2	3	4	5
4. I say inappropriate things.	1	2	3	4	5
5. I do certain things that are bad for me, if they are fun.	1	2	3	4	5
6. I refuse things that are bad for me.	1	2	3	4	5
7. I wish I had more self-discipline.	1	2	3	4	5
8. People would say that 1 have iron self-discipline.	1	2	3	4	5
9. Pleasure and fun sometimes keep me from getting work done.	1	2	3	4	5
10. I have trouble concentrating.	1	2	3	4	5
11. I am able to work effectively toward long-term goals.	1	2	3	4	5
12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	1	2	3	4	5
13. I often act without thinking through all the alternatives.	1	2	3	4	5

18. Please read the each item carefully and circle the number that best describes your craving <u>during the past week</u>

During the past week	0 Never (0 times) 1 Rarely (1 to 2 times) 2 Occasionally (3-4 times) 3 Sometimes (5 – 10 times/week or 1 to 2 times/day) 4 Often (11 to 20 times/week or 2 to 3 times/day) 5 Most of the time (20 to 40 times/week or 3 to 6 times/day) 6 Nearly all the time (more than 40 times/week or more than 6 times/day)

How often have you thought about drinking or about how good a drink would make you feel?	0	1	2	3	4	5	6
At its most severe point, how strong was your craving during the past week	0	1	2	3	4	5	6
How much time have you spend thinking about drinking or about how good a drink would make you feel	0	1	2	3	4	5	6
How difficult would it have been to resist taking a drink if you have known a bottle were in your house?	0	1	2	3	4	5	6
Keeping in mind your responses to the previous questions, please rate your overall average alcohol craving for the past week.	0. Never thought about drinking and never had the urge to drink 1. Rarely thought about drinking and rarely had the urge to drink 2. Occasionally thought about drinking and occasionally had the urge to drink 3. Sometimes thought about drinking and sometimes had the urge to drink 4. Often thought about drinking and often had the urge to drink 5. Thought about drinking most of the time and had the urge to drink most of the time 6. Thought about drinking nearly all of the time and had the urge to drink nearly all the time.						

19. Please answer the following questions about your alcohol use. Select the response that is most correct for you in relation to your alcohol use over the last 3 month.

	0	1	2	3	4
How often do you have a drink containing alcohol?	Never	Monthly or less	2-4times a month	2-3 times a week	4 or more times a week
How many standard drinks containing alcohol do you have on a typical day when drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
How often do you have six or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
During the past year, how often have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
During the past year, how often have you needed a drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily

During the past year, how often have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
During the past year, how often have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
Have you or someone else been injured as a result of your drinking?	Never		Yes, but not in the past year		Yes, during the past year
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested you cut down?	Never		Yes, but not in the past year		Yes, during the past year

Interpretation (last year): 0-3: Low risk, 4-9: risky, 10-13: Harmful, 14+ Severe

20. The following questions concern information about your possible involvement with drugs not including alcoholic beverages during the past 12 months. Drug abuse" refers to (1) the use of prescribed or over-the-counter drugs in excess of the directions, and (2) any nonmedical use of drugs. The various classes of drugs may include cannabis (marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g. Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., LSD) or narcotics (e.g., heroin). Remember that the questions do not include alcoholic beverages. Please answer every question. If you have difficulty with a statement, then choose the response that is mostly right.

In the past 12 months…	Yes	No
Have you used drugs other than those required for medical reasons?		
Do you abuse more than one drug at a time?		
Are you unable to stop abusing drugs when you want to?		
Have you ever had blackouts or flashbacks as a result of drug use?		
Do you ever feel bad or guilty about your drug use?		
Does your spouse (or parents) ever complain about your involvement with drugs?		
Have you neglected your family because of your use of drugs?		
Have you engaged in illegal activities in order to obtain drugs?		
Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?		
Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)?		

For interpretation: 0 No problem, 1-2 Low, 3-5 Moderate, 6-8 Substantial, 9-10 Severe

21. The questions in this scale ask you about your feelings and thoughts <u>during the last week</u>. In each case, you will be asked to indicate by selecting how often you felt or thought a certain way.

How often have you been upset because of something that happened unexpectedly?	Never	Almost never	Sometimes	Fairly often	Very often
How often have you felt that you were unable to control the important things in your life?					
How often have you felt nervous and "stressed"?					

How often have you felt confident about your ability to handle your personal problems?					
How often have you felt that things were going your way?					
How often have you found that you could not cope with all the things that you had to do?					
How often have you been able to control irritations in your life?					
How often have you felt that you were on top of things?					
How often have you been angered because of things that were outside of your control?					
How often have you felt difficulties were piling up so high that you could not overcome them?					

22. We would like to ask you some questions about your emotional life, in particular, how you control (that is, regulate and manage) your emotions. The questions below involve two distinct aspects of your emotional life. One is your emotional experience , or what you feel like inside. The other is your emotional expression , or how you show your emotions in the way you talk, gesture, or behave. Although some of the following questions may seem similar to one another, they differ in important ways. For each item, please answer using the following scale:

	1 Strongly disagree	2	3	4 Neutral	5	6	7 Strongly agree
When I want to feel more positive emotion (such as joy or amusement), I change what I'm thinking about.							
I keep my emotions to myself.							
When I want to feel less negative emotion (such as sadness or anger), I change what I'm thinking about.							
When I am feeling positive emotions, I am careful not to express them.							
When I'm faced with a stressful situation, I make myself think about it in a way that helps me stay calm.							
I control my emotions by not expressing them.							
When I want to feel more positive emotion, I change the way I'm thinking about the situation.							
I control my emotions by changing the way I think about the situation I'm in.							
When I am feeling negative emotions, I make sure not to express them.							

When I want to feel less negative emotion, I change the way I'm thinking about the situation.							

Scoring (no reversals) Reappraisal Items: 1, 3, 5, 7, 8, 10; Suppression Items: 2, 4, 6, 9.

23. PROMIS-Depression, Anxiety, and Anger

Please respond to each question or statement by marking one box per row.

In the past 7 days		Never	Rarely	Sometimes	Often	Always
EDDEP04	I felt worthless	1	2	3	4	5
EDDEP06	I felt helpless	1	2	3	4	5
EDDEP29	I felt depressed	1	2	3	4	5
EDDEP41	I felt hopeless	1	2	3	4	5
EDANX01	I felt fearful	1	2	3	4	5
EDANX40	I found it hard to focus on anything other than my anxiety	1	2	3	4	5
EDANX41	My worries overwhelmed me	1	2	3	4	5
EDANX53	I felt uneasy	1	2	3	4	5
EDANG03	I was irritated more than people knew	1	2	3	4	5
EDANG09	I felt angry	1	2	3	4	5
EDANG15	I felt like I was ready to explode	1	2	3	4	5
EDANG30	I was grouchy	1	2	3	4	5
EDANG35	I felt annoyed	1	2	3	4	5

24. PROMIS-Sleep Disturbance

In the past 7 days		Very poor	Poor	Fair	Good	Very good
Sleep109	My sleep quality was	5	4	3	2	1
In the past 7 days		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep116	My sleep was refreshing	5	4	3	2	1
Sleep20	I had a problem with my sleep	1	2	3	4	5
Sleep44	I had difficulty falling asleep	1	2	3	4	5
Sleep108	My sleep was restless	1	2	3	4	5
Sleep72	I tried hard to get to sleep	1	2	3	4	5
Sleep67	I worried about not being able to fall asleep	1	2	3	4	5
Sleep115	I was satisfied with my sleep	5	4	3	2	1

25. PROMIS-Fatigue

In the past 7 days	Not at all	A little bit	Somewhat	Quite a bit	Very much

HI7	I feel fatigued	1	2	3	4	5
AN3	I have trouble starting things because I am tired	1	2	3	4	5
FATEXP41	How run-down did you feel on average?	1	2	3	4	5
FATEXP40	How fatigued were you on average?	1	2	3	4	5

PROMIS-Cognitive Function

In the past 7 days		Never	Rarely (Once)	Sometimes (Two or three times)	Often (About once a day)	Very often (Several times a day)
PC2r	My thinking has been slow	5	4	3	2	1
PC35r	It has seemed like my brain was not working as well as usual	5	4	3	2	1
PC36r	I have had to work harder than usual to keep track of what I was doing	5	4	3	2	1
PC42r	I have had trouble shifting back and forth between different activities that require thinking	5	4	3	2	1

25. Please mark in the boxes to show how you have been feeling about all of the following conditions in the last 24 hours

	0	1	2	3
Anxious	None	Mild	Moderate	Severe
Feeling confused				
Restless				
Miserable				
Problems with memory				
Tremor (shakes)				
Nausea				
Heart pounding				
Sleep disturbance				
Sweating				

Daily Survey (web or app version)

1. Did you drink alcohol in the past 24 hours? Yes/No
2. **On a scale of 0 to 10, how confident did you feel about not drinking for the past 24 hours?**

0	1	2	3	4	5	6	7	8	9	10
not at all confident					Somewhat confident					Extremely confident

3. **How much have you craved your alcohol for the past 24 hours?**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Extremely

4. **How tense and anxious have you been over the past 24 hours?**

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very much

5. How depressed and discouraged have you been over the past 24 hours?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Very much

6. Please rate average pain intensity in the last 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Worst Pain imaginable

7. On a scale of 0 to 10, how confident do you feel about not drinking for the next 24 hours?

0	1	2	3	4	5	6	7	8	9	10
not at all confident					Somewhat confident					Extremely confident

8. Did you need to change how you approached your goal of staying alcohol-free today? (Yes/No)
Only those who answer 'Yes' to the following item will respond to the three items below:

9. *If **yes**, they will complete the following measure:*
Please respond to the following statements about your experiences today with your goal to be alcohol-free.
1 (*Strongly disagree*), 2 (*Disagree*), 3 (*Slightly disagree*), 4 (*Slightly agree*), 5 (*Agree*), 6 (*Strongly agree*)

a. Today, I found it difficult to change how I approach my goal of staying alcohol-free.
b. I struggled to rethink or adapt how I pursued my goal of staying alcohol-free today.
c. It was hard for me to accept that I might need to adjust my approach to staying alcohol-free today.

10. In the past 7 days, have you experienced any significant **positive or negative** health-related changes?

a. Positive change
b. negative change
c. No change

11. *If yes to a or b:* Please briefly describe your health-related change you experienced:_____