EMA/EMI for Psychiatrically Hospitalized Emerging Adults Who Drink to Cope

Phase 2

NCT Number
NCT05074030

PI: Ana M. Abrantes, Ph.D.

Date of last revision: 2/27/25

BUTLER HOSPITAL
INSTITUTIONAL REVIEW BOARD
PROTOCOL

1.) Project

Title of Project: Project CHOICE: Developing a Personalized-Feedback EMA/EMI Intervention for Emerging Adults Leaving Psychiatric Partial Hospitalization

Short Title of Project: Project CHOICE

Principal Investigator (PI): Ana Abrantes, Ph.D.

2.) Description of Study

A. Specific Aims

Anxiety and depression predict problematic patterns of alcohol use, particularly among emerging adults (EA) who drink to cope with negative affect (NA) [1–3], which in turn exacerbates mental health symptomatology. Individuals who drink to cope experience higher rates of depression, anxiety, use-related consequences, and suicide risk[4]. As such, the coping motive may be an indicator of comorbid problematic alcohol use [4] and a target for treatment. Given the relationship between mental health and alcohol problems, there is a need to address comorbidity among EAs with anxiety and/or depression. Thus, it is important to develop interventions that are effective in reducing both coping motives and NA, which, in combination, drive alcohol use.

Previous cross-sectional between-subject studies have found a relationship between NA, coping motives, and alcohol use. We will evaluate changes in variables of interest over time in each condition, and will compare changes between the two conditions. To evaluate within-subject relationships, we are evaluating changes in a state-of-the-art method: Ecological Momentary Assessment (EMA) and Ecological Momentary Intervention (EMI). Given that alcohol interventions are most effective during times of high risk for use, this study will assess risk in real time through EMA and deliver interventional content through EMI [5–10]. We have developed and tested such a coping motive-specific personalized feedback intervention (Pilot PFICope+EMI) for EA with affective disorders in psychiatric hospitalization care that integrated EMA of mood, alcohol use, and intent to drink with EMI coping skills messages over 6 weeks[11]. Pilot results (n=20) showed significant decreases in coping motives and alcohol use [11]. While open pilot findings are promising, the next step is to continue to develop our intervention components and determine preliminary efficacy relative to personalized normative feedback-only in a randomized controlled trial.

The weeks after psychiatric hospitalization are a risky time for problematic alcohol use and recurrence of psychiatric symptoms[12–16]. The delivery of tailored, coping skills-based, real-time messages could have significant impact on problematic drinking and depression/anxiety outcomes by reducing the likelihood that an individual drinks to cope with NA. We propose to adapt and enhance our pilot-tested intervention.

1. To refine PFIcope+EMI.

a. Changes to the intervention and protocol: Based on our experience conducting the previous pilot study, we propose the following 5 modifications to the Coping Motive-Specific Personalized Feedback Intervention + Ecological Momentary Intervention (PFIcope+EMI): increasing compliance rates throughout the course of the study, providing individualized Ecological Momentary Assessment (EMA) prompt times, evaluating the content of EMA coping skills messages, addressing the number of personalized messages that should be provided, and sending messages by intensity level of negative affect.

b. Focus group feedback: In order to obtain participant feedback on the proposed modifications to the PFIcope+EMI intervention, we will conduct a series of 4 focus groups (n=5 per group). Focus group discussion will involve eliciting participant perceptions' of the utility of each of the 5 proposed modifications along with suggestions for further improvement and strengthening of the intervention, input on any additions to the intervention, and ratings of perceived usefulness of coping messages.

2. To test a refined version of the 6-week PFIcope+EMI intervention (EMI) as compared to *personalized normative feedback only group (PNF)* for Emerging Adults (EA) in a partial hospitalization program who drink to cope and binge drink (n=60). The PFIcope+EMI condition (**EMI;** N = 30) includes: 1) an in-person

personalized feedback session to present feedback on problems with drinking to cope, discuss the individual's use of alcohol to cope, and generate coping skills messages to be used in the EMI intervention; 2) EMA to monitor affect, intention to drink, coping skills usage, alcohol use, drinking to cope post-discharge; 3) tailored messages (EMI) delivered within the EMA app based on self-reported EMA data (individualized coping skills messages when Negative Affect (NA) and cravings or intention to drink are reported). The Personalized Normative Feedback condition (PNF; N = 30) will receive a personalized normative feedback report but no EMA or EMI.

a. We will assess participants' alcohol outcomes and psychiatric symptomatology at 6-weeks, 12-weeks, and 6-months to determine outcomes and feasibility/acceptability. We hypothesize:

1. Individuals in PFIcope+EMI arm will report between-subjects reductions in drinking to cope, alcohol use, alcohol-related problems, *and NA* as compared to *PNF.*
2. PFIcope+EMI will be feasible to implement and result in high rates of participant satisfaction.

b. We will explore mechanisms that may underlie the efficacy of the intervention for the PFIcope+EMI group utilizing the daily EMA data. We hypothesize:

1. In response to NA, participants will report an increase in coping skills utilization and decreased intent to drink at the following EMA assessment point.
2. NA reductions and increased coping skills utilization will be related to improvements in alcohol use rates and problems at the following EMA assessment.

We anticipate that this project will lead to the development of a well-specified, personalized, novel, technology-supported, just-in-time intervention for EA with NA who use alcohol to cope that can be tested in a larger multi-site trial. This is the first known EMA/EMI to address comorbid alcohol use problems among EAs receiving psychiatric treatment.

B. <u>Background</u>

Comorbid mental health (i.e., anxiety and depression) and alcohol use issues represent a significant problem, particularly among emerging adults when rates of such disorders are high. Notably, heavy alcohol use exacerbates both anxiety and depression[17,18]. Individuals leaving psychiatric care are at particular risk for substance use and recurrence of psychiatric symptoms, particularly following discharge [12–16] and developing interventions to assist patients and clinicians with this transition should be a high priority. Despite this link between NA and use, alcohol use is typically not targeted or discussed within mental health treatment. Barriers to alcohol-mental health treatment integration may include factors such as lack of knowledge among mental health providers, attractiveness of the therapy to the patient (i.e., lack of motivation to completely abstain from alcohol), and accessibility of the treatment. Additionally, it may be difficult to ascertain which individuals may be in need of an alcohol intervention if they are seeking treatment for another mental health issue. The coping motive (i.e., using alcohol to cope with NA) predicts more negative consequences of use, thus can be utilized as a marker for high-risk use patterns and can be a target for treatment. *However, the majority of studies have found this association in between-subjects analyses. As such, it is important to assess the relationships between mood, coping motive, and drinking outcomes in within-subject analyses as well.* Our previous research has established the effectiveness of a personalized feedback intervention that targets the coping motive (PFIcope) among emerging adults. Additionally, there is evidence that EMA self-monitoring and real-time feedback can be effective at reducing rates of problematic alcohol use. Our previous research has found preliminary evidence for the effects of adding EMA/EMI to the PFIcope intervention in reducing use and problems. However, this intervention was conducted in an open pilot, limiting ability to make causal assumptions. The current proposal is the next step in the augmentation and refinement of this early work, creating a portable, in-the-moment, technology-based EMI intervention designed to pair real-time affective monitoring with individualized coping skills texts for individuals with anxiety and depression who drink to cope (PFIcope+EMI) as compared to *personalized normative feedback only condition (PNF).*

1. **Alcohol use (particularly drinking to cope) is problematic in emerging adults with mental health disorders, and is rarely targeted in psychiatric settings**. The current proposal aims to implement the refined PFIcope+EMI intervention in a population of emerging adults newly-discharged from a psychiatric partial or intensive outpatient hospital program, a high-risk and understudied period, and evaluates alcohol outcomes and mental health-related outcomes compared to a *personalized normative feedback condition.*

2. **No known EMI study (except for our PFIcope+EMI open pilot study) has specifically targeted a reduction in *drinking to cope* with NA, in any population**. EMA/EMI is a promising method to identify and intervene in high-risk situations. EMA studies have been conducted to monitor mood, alcohol use, and motive for drinking over time[19,20], and several EMA/EMI interventions exist for alcohol use and are moderately efficacious[21]. This study aims to improve outcomes by specifically targeting the coping motive.
3. **This treatment development study (PFIcope+EMI) provides personalized, just-in-time coping skills messages.** During risky hours (such as in the afternoon before drinking onset) [21], EMA/EMI allows for monitoring of mood and drinking intent in real-time and can send tailored, individualized coping skills messages as needed to reduce incidence of drinking to cope. This study also allows for self-initiated EMA/EMI, which has not to our knowledge been used in previous studies. Research has shown that self-chosen, personalized messages can be more powerful than ones chosen by others.

C. Experimental Method

C1. Brief Description of Subjects

Phase 1: Focus Groups

Participants (n=20) will be recruited from the Butler Hospital Young Adult Partial Hospitalization (YAPH) Program, or one of the Young Adult Intensive Outpatient programs (IOP). Inclusion Criteria: (a) between 18 and 25 years of age, (b) reported alcohol use at least once a week over the past month with at least one day of binge drinking (as defined as 4+ drinks/episode for men and 3+ drinks/episode for women), (c) self-reported use of coping motive (mean of 2+ on coping with anxiety or coping with depression subscales of MDMQ-R[22], indicating they drink to cope at least "some of the time"), (d) current anxiety and/or depression symptomatology (as assessed CES-D[23] scores above cut-off for high risk for clinical depression and GAD-7[24] scores above cut-off for moderate to severe anxiety), (e) owns a smartphone capable of downloading EMA app.

Phase 2

Participants (n=60) will be recruited from Butler Hospital Partial Hospitalization Programs (PHPs) and Intensive Outpatient Programs (IOPs). Inclusion Criteria: (a) between 18 and 25 years of age, (b) reported alcohol use at least 4x over the past month and at least 1x over the past month of binge drinking (as defined as 4+ drinks/2 hours for men and 3+ drinks/2 hours for women), (c) self-reported use of coping motive (mean of 2+ on coping subscale of MDMQ-R[22], indicating they drink to cope at least "some of the time"), (d) current anxiety and/or depression symptomatology (as assessed CES-D[23] scores above cut-off for high risk for clinical depression and GAD-7[24] scores above cut-off for moderate to severe anxiety), (e) owns a smartphone capable of downloading EMA app. Exclusion criteria : (a) current DSM-5 diagnosis of moderate/severe substance use disorder (other than alcohol, *cannabis,* or nicotine) *as assessed by research staff via SCID*, with use of that substance in the past month, (b) Current and active psychotic symptoms that would interfere with study participation*, as assessed by research staff via SCID*, (c) current suicidal/homicidal ideation.

C2. Study Design

In Phase 2 of the study, there will be two study conditions. In the active condition, termed EMI condition, participants will receive PNF and complete EMA assessments with EMI coping strategies. In the PNF condition, participants will only receive PNF. The goal of this proposed study is to evaluate an EMA+EMI intervention for emerging adults in a psychiatric partial hospitalization program who drink to cope with NA as compared to a personalized feedback only group. This intervention utilizes EMA technology with tailored EMI text messaging (PFIcope+EMI). PFICope+EMI not only aims to reduce drinking to cope, but also alcohol use and NA. This study consists of a 6-week randomized controlled treatment trial to test the PFIcope+EMI intervention as compared to PNF control. We propose to use urn randomization, stratifying on gender, which may predict outcome [25,26]. The intervention will be comprised of (1) an initial orientation session where the intervention is introduced, the participant receives personalized normative information and drinking to cope feedback, and develops personalized coping skills messages to be utilized through the course of the intervention; (2) EMA for monitoring of affect, drinking intention, alcohol use, and coping skills use; (3) EMI-tailored text coping skills messages sent based on EMA responses when participants report NA and intent to drink.

C3. Specific Procedures or Treatments

Phase 1

Participants appearing to meet eligibility, based on IRB-approved medical chart review and self-reported alcohol use, will be provided with a brief study description. Interested persons will be screened for further eligibility. Those who are eligible and interested will then provide verbal consent for the use of e-mail and videoconferencing. This consent will allow us to use videoconferencing to conduct a "virtual focus group" if the participant feels uncomfortable meeting in-person. They will provide informed consent for participation in the focus group and consent to be audio-recorded. The consented participant will then complete a brief questionnaire and participate in open discussion while in the YAPH or IOP (approximately 1 hour) on designated breaks or after the program ends for the day, so as not to take way from scheduled programming. They may also complete the focus group shortly after being discharged from the YAPH or IOP if timing does not allow us to schedule it before they leave. Participants will receive $50 for participation in the focus groups.

Screener. Participants will report on their quantity/frequency of alcohol use, coping motives (coping with anxiety and coping with depression) for alcohol use, and anxiety and depression symptomatology to further determine eligibility for the focus group study.

Questionnaires. Eligible and consented participants will be given a questionnaire packet, including demographics, further investigation of quantity/frequency of alcohol use, a more detailed measure of motives for alcohol use, rating of helpfulness of potential supportive and relapse prevention coping strategies, preferences for number of coping strategies provided per day, preference for intensity ratings of messages which will correspond to levels of negative affect.

Open ended discussion. The open-ended discussion will begin upon completion of the questionnaire packet. Participants will first be oriented to the PFIcope+EMI intervention, including the study components, study design, contents of EMA prompts, and compliance timeline. Participants will provide feedback on the specific changes made to the intervention, timing of the intervention (i.e., length of assessment time (6 weeks)) and follow-up sessions, times of the day in which messages are sent), thoughts regarding the content of the messages, and any other suggested changes to the PFIcope+EMI intervention content and protocol.

Phase 2

Patients' medical records will be reviewed by study staff and in accordance with Institutional Review Board guidelines to assess the inclusion and exclusion criteria detailed above. Given the fact that medical records may not include the information necessary to determine diagnostic eligibility (particularly SUD diagnoses), inclusion and exclusion information will be verified by research staff. Evaluation of eligibility via SCID will be audio recorded. Patients appearing to meet eligibility will be provided with a brief study description. Interested persons will be approached and screened on their 2nd or 3rd PHP/IOP day. Participants appearing to meet eligibility, based on IRB-approved medical chart review and self-reported alcohol use, will be provided with a brief study description. People who express interest will be asked to complete a permission to contact form in order to receive more information about the study. Interested potential participants will complete screening measures through either a paper-and-pencil questionnaire, a link to a REDCap survey, or via phone interview (depending on participant preference). This screening will contain measures of depression, anxiety, and coping motives for alcohol use. Participants who meet preliminary eligibility criteria based on the screening will be asked to give their informed consent and complete a baseline assessment (approx. 1.5 to 2 hours, see Table 2 for measures) while in the PHP/IOP during designated breaks, so as not to take way from scheduled programming. The orientation session will be completed on their last day in the PHP/IOP.

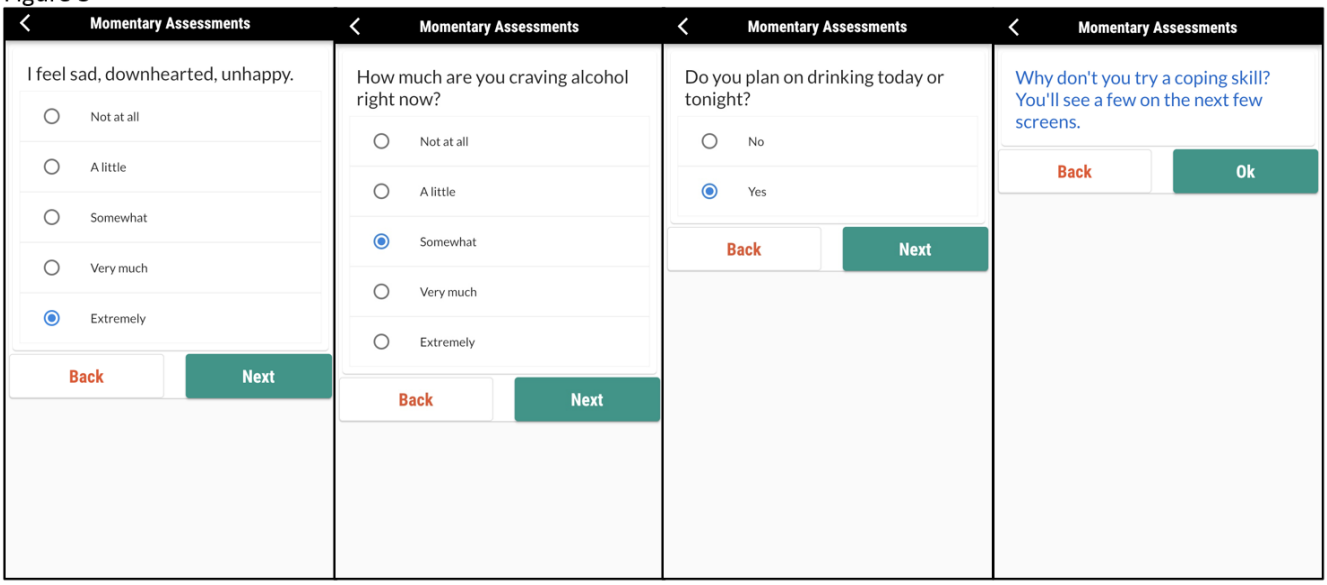
Table 2. Measures	Time Point Assessed	Mode of Administration
Diagnostic & Screening Measures		

Structured Clinical Interview for DSM [27] – SUD, psychosis	B	Interview
Center for Epidemiologic Studies Depression Scale (CES-D)[23]	Phase 1, B, 6W, 12W, 6M	Self-Report
General Anxiety Disorder-7 (GAD-7)[24]	Phase 1, B, 6W, 12W, 6M	Self-Report
Coping Motives for Alcohol Use (coping scales of MDMQ-R)[22]	Phase 1	Self-Report
Feasibility and Acceptability Assessments		
Intervention Feedback Questionnaire	6W	Self-Report
Client Satisfaction Questionnaire (CSQ) [28]	6W	Self-Report
End-of-Treatment Interview (Participant Feedback)	6W	Interview
Systematic Assessment of Treatment-Emergent Events (SAFTEE) [29]	B, 6W	Interview
EMA Response Rate	Continuous through 6W	Self-Report
Primary and Secondary Outcomes		
Modified Drinking Motives Questionnaire-Revised (MDMQ-R) [22]	Phase 1, B, 6W, 12W, 6M	Self-Report
Timeline Follow-Back (TLFB)[30] for Alcohol and Other Substance Use	B, 6W, 12W, 6M	Interview
Alcohol Use Disorder Identification Test (AUDIT)[31]	B	Self-Report (from Chart)
Columbia Suicide Severity Rating Scale (C-SSRS)[32]	B	Self-Report (from Chart)
Alcohol Outcome Expectancies: Comprehensive Effects of Alcohol (CEOA)[33]	B, 6W, 12W, 6M	Self-Report
Brief Young Adult Alcohol Consequences Questionnaire (B-YAACQ)[34]	B, 6W, 12W, 6M	Self-Report
Alcohol Self Concept Scale (ASCS)[35]	B, 6W, 12W, 6M	Self-Report
ASI – with addition of alcohol, cigarettes, nicotine, vaping, cannabis	B, 6W, 12W, 6M	Self-Report
Typical Past Month Alcohol Use	B	Self-Report
Expectations about Descriptive Alcohol Norms	B	Self-Report
Positive and Negative Affect (PANAS)[36]	B, 6W, 12W, 6M	Self-Report
Coping Skills: Brief COPE[37]	B, 6W, 12W, 6M	Self-Report
Daily Sessions, Frequency, Age of Onset, and Quantity of Cannabis Use Inventory (DFAQ-CU)[38]	B, 12W, 6M	Self-Report
Brief Marijuana Consequences Questionnaire (B-MACQ)[39]	B, 6W, 12W, 6M	Self-Report
Difficulties in Emotion Regulation Scale (DERS)[40]	B, 6W, 12W, 6M	Self-Report
Difficulties in Emotion Regulation Scale-Positive (DERS-P)[41]	B, 6W, 12W, 6M	Self-Report
Positive and Negative Urgency Scale Short Form (UPPS-P)[42]	B, 6W, 12W, 6M	Self-Report
Physical Activity Questionnaire[43]	B, 6W, 12W, 6M	Self-Report
Transitions to Adulthood Scale[44]	B, 6W, 12W, 6M	Self-Report
Prodromal Questionnaire (PQ-16)[45]	B, 6W, 12W, 6M	Self-Report
Medication Adherence (MARS-5)[46]	B, 6W, 12W, 6M	Self-Report
Concurrent Treatment	B, 6W, 12W, 6M	Self-Report
Treatment History Interview [47,48]	B, 6W, 12W, 6M	Interview

PFIcope+EMI Treatment Components. Following baseline, the PFIcope+EMI intervention includes:

1. *PFIcope+EMI Orientation Session*. An in-person orientation session will occur with a study staff on the participant's last day in the PHP/IOP. This session will include: a) normative feedback on their alcohol use compared to other emerging adults, b) information about the coping motive for alcohol use and negative outcomes associated with use, c) normative feedback utilizing a Personalized Feedback Report (PFR) regarding the individual's use of alcohol, and negative consequences which will be reviewed using the individual's baseline assessment data, d) information on participants' self-reported use of alcohol to cope and generation of alternate coping strategies which will inform future EMI text coping skills messages (see below), e) installation of the smartphone app on the individual's smartphone, and f) orientation to components and timeline of the intervention, including a discussion of methods of how to increase EMA adherence/compliance (see also C.6.b).

Figure 3



2. *EMA Prompts.* Following their PHP/IOP discharge, participants in the EMI condition will receive EMA prompts for 6 weeks. Prompts will be programmed by research staff who are experienced with EMA programming through **MetricWire,** a HIPAA-compliant web-based platform specifically developed for EMA. Data will be obtained from participants using the free mobile application associated with the program, which is downloaded onto the participant's own smartphone (iOS or Android). EMA prompts will be fixed and time-based, meaning that the app will produce an audible alert once per day in the morning at a time of the participant's self-identified wakeup time (Morning Reports), and 4x per day randomly during the block between 2 hours post-Wakeup Time and participants' self-identified bedtime (Momentary Reports) prompting participants to answer study questions. Participants will also be asked to identify a 2-hour block of time that they are likely to drink, during which they will definitely get a randomized prompt. Thus, participants will be prompted 5 times per day. The exception to this is a once-weekly Weekly Report, which will ask participants questions about medication adherence and questions related to personalization of the EMI for the next week. Questions take no more than 2-5 minutes to complete, lessening burden.

2.a. Current affect (i.e., "RIGHT NOW"), Given the complex nature of NA, several mood states will be included in the EMA prompts. NA will be measured by asking participants to rate how they feel "RIGHT NOW" using three sets of three related emotion words (angry, irritated, annoyed; scared, fearful, afraid; and sad, downhearted, unhappy) on a Likert scale of 0-4. The adjectives chosen and methods are based on previous research [19,49,50], and reflect the variety of NA mood states that can contribute to use. We will also include adjectives of positive affect (glad, happy, joyful), and allow participants to choose an additional emotion word that might serve as a trigger to drinking, to take into account use motivated by other affective states.

2.b. Cravings and current intent to consume alcohol. Participants will be asked about their cravings for alcohol: How much are you craving alcohol right now? (0-4 scale). Intent to consume alcohol will be monitored: "Do you plan on drinking today or tonight?: yes/no". Reports of negative mood and cravings and/or intention to drink will trigger the app to suggest three coping skills from the list generated by the participant at the beginning of the study that they indicated they were willing to try.

2.c. Substance consumption. In Momentary Reports, alcohol consumption will be measured by asking, "In the last 2 hours, did you drink any alcohol? Yes/no." If the individual reports alcohol use, they will be asked to estimate the quantity of standard drinks and to report on their drinking context/environment (drinking location, presence of others, etc.). During the morning report, participants will also be asked about past day total consumption of alcohol and cannabis.

2.d. Motives for use. If alcohol or cannabis was consumed in the previous day as assessed by the Morning Report, we will assess whether their *specific motives* per alcohol and/or cannabis episode aligned with the subscales of the MDMQ-R[22]: e.g., "Did you [drink/use cannabis] to cope with negative feelings?" on a scale from 0 (not at all) to 4 (definitely). Participants will also be asked two additional substance motives questions by being asked to check off additional reasons they may have used alcohol and cannabis in the prior day (e.g.,

to slow down thoughts, to decrease unpleasant thoughts).

2.e. *Alcohol and cannabis co-use.* In the Morning Report, participants will be asked whether they co-used alcohol and cannabis during the previous day (i.e., if they used alcohol and cannabis such that their effects overlapped).

2.f. Any coping skills utilization for NA. In the Morning Report, participants will also be asked about their utilization of coping skills the previous day with the coping skills they were offered that week and answered dichotomously (yes/no). They will be asked to rate how helpful the coping skills were in addressing the difficult emotion on a scale from 0 (not at all helpful) to 4 (extremely helpful). They will also be asked to report any additional coping skills not officially suggested that week in the intervention.

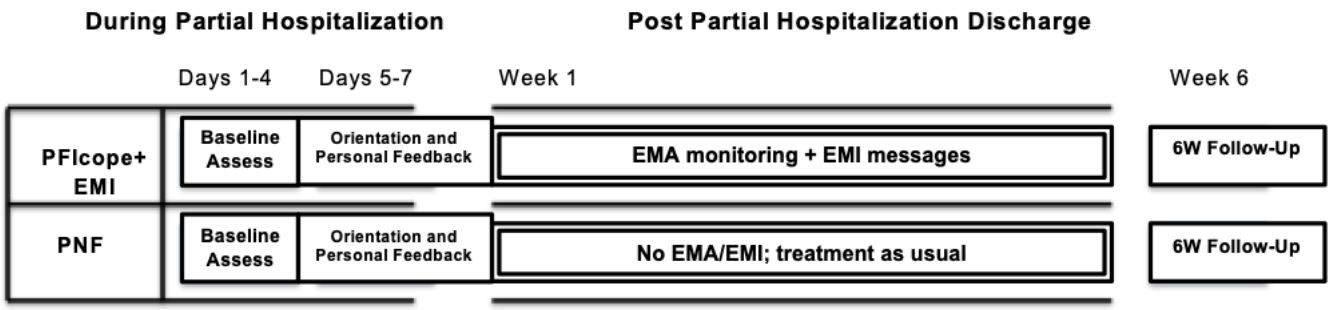
2.g. Medication adherence. In the Weekly Report, participants will be asked if they missed any dosage of medication in the prior week.

2.h. App feedback. In the Weekly Report, participants will be asked to give feedback on the coping skills they are interested in being kept in the "pool" of possible skills to be suggested the following week. Participants will be asked if they need to adjust the time windows of their prompts (wakeup time and bedtime).

3. Self-directed coping skills EMI. In addition to the scheduled EMA prompts, participants in the EMI condition will also have the option of accessing an on-demand list of coping skills they can access at any time they notice they are experiencing negative mood and cravings/intentions to drink. This option may be useful for individuals who can identify their negative mood state and desire to use, and who are aiming to reduce the probability of use. This survey will contain a list of coping skill categories, e.g., "Delay or avoid alcohol use," "Occupy your mind with something else," and then contains lists of coping skills that fall within that category, e.g., "Go get a non-alcoholic drink, such as coffee or tea." *This option will only be provided if a participant chooses to engage in the app of their own accord. The survey will not be given unless a participant chooses.*

4. EMI Messages. EMI messages will be provided on the EMA app based on participants' EMA responses. These messages will be prompted by responses to the 4x daily Momentary Reports (i.e., if the participant reports NA and an intent to consume alcohol during the EMA prompts, coping skills messages will immediately appear on the screen). Coping skills messages will be self-chosen by participants (in the initial orientation and personalized feedback session), with help from study staff, if needed, given that some EA may have difficulty identifying coping strategies. Messages will include coping skills for mental health and substance use that patients identified as being helpful. Although chosen by the participant, we anticipate several message themes[51]: increasing support ("Try calling or texting a friend if you're feeling down or want to drink"), attending a counselor/therapist appointment ("Your therapist has been helpful for you in the past"), identifying irrational thinking patterns ("Watch out for black-and-white thinking: it is a trap that has led you to drink in the past"), and behavioral coping skills for NA or urges to use ("Being physically active helps improve your mood and reduces your cravings"). The purpose of these messages is to remind participants of helpful strategies and reduce the likelihood of drinking in times of NA. See Figure 3 for examples of screenshots of the app.

Figure 4: Study Design



Personalized Normative Feedback (PNF) Components. The purpose of the PNF condition is to determine the unique impact of the EMA/EMI components. Given the efficacy of PNF interventions, it is important to control for this intervention component which is also part of the **PFIcope+EMI Treatment**. Following the baseline assessment, the PNF arm includes an in-person orientation session with study staff. This session will

include orientation to components and timeline of the study. Participants will receive the personalized normative feedback, based on baseline assessment data given to participants, in a Personalized Feedback Report (PFR), which will be reviewed with a study team member. The PNF information will include reports of the participant's use of alcohol, including use relative to United States alcohol use norms, peak blood alcohol concentration, and negative alcohol consequences; in addition, those in the EMI condition will also receive information on their use of drinking to cope. Participants assigned to PNF condition will not receive information about their use of drinking to cope.

Follow-Up Assessment. At the end of the intervention (6 weeks) and the 12-week and 6-month follow-ups, participants in both conditions will complete audio-recorded in-person interviews (see Table 2). In addition to daily EMA data, we will assess self-reported psychiatric symptoms, alcohol use, drinking to cope, and use of coping skills. We will ask participants about psychiatric and/or substance use treatment utilization throughout the study to account for any other intervention received, through the Treatment History Interview[48]. Additionally, we will query treatment feedback through questionnaires and interview about intervention satisfaction. We will monitor EMA adherence, attrition, and potential adverse events throughout the study.

C4. Data Analysis

C.4.a. We believe that a sample size of Aim 1 focus groups (n=5 over 4 focus groups; total n=20) is sufficient to evaluate the refined PFIcope+EMI. In Aim 2, our goal is to determine effects of the intervention, knowing that confidence intervals will likely be large and we may lack power to find statistically-significant differences between conditions. We hope to move to a fully-powered multi-site R01 proposal based on the findings of this study, and so we hope to find preliminary efficacy in reductions in drinking to cope that are associated with reductions in alcohol use and problems [11]. As such, testing the intervention against an active personalized feedback only condition will help determine the incremental intervention impact. A sample size of 60 for the RCT (30 per condition) will allow for examination of group means in variables of interest: (primary outcome = drinking to cope; secondary outcomes = alcohol use, use-related problems, binge drinking, coping skills utilization, NA).

C.4.b. Aim 1 focus groups will provide qualitative and quantitative data. Qualitative data will be transcribed, coded by two trained research staff, and evaluated for themes. For Aim 2, we will present descriptive statistics to summarize the baseline characteristics of the full sample and each intervention arm. Per CONSORT recommendations, tests of significance for between group differences at baseline will not be used to designate covariates. Covariates will include any stratification variables used in the randomization process. A covariate will only be included if there is a rationale explaining why it would be prognostic. Boxplots, histograms, and descriptive statistics will be used to explore the observed distributions and patterns of missing data of outcomes observed during follow-up. Descriptive statistics will be presented for the full sample and for each treatment arm. Preliminary analysis will use boxplots, histograms, and descriptive statistics to explore the distributions of variables of interest. Data will be examined for missingness and handled accordingly [52,53]. Variables will be examined for normality and subsequent analyses will account for skewness or kurtosis utilizing bootstrapping or transformations. Statistical significance will be based on alpha coefficients of .05. Our analyses will emphasize substantive magnitude of effect sizes and confidence interval estimates. Preliminary intent-to-treat analyses will utilize chi-square techniques to examine rates of attrition by condition. We will correct for multiple comparisons using Bonferrori corrections.

C.4.c. Hypothesis a – there will be a reduction in drinking to cope, alcohol use, use-related problems, NA and increase in coping skills utilization. We plan to use fixed-effects panel regression [54]to estimate the effect of intervention. The fixed effects estimator, also called the within subject estimator, differences between subject variability and effectively controls for all time invariant between subject heterogeneity. In this model the effect of treatment is estimated as the treatment by time interaction. Final model specification will be guided by both statistical and graphical analysis. A difference in likelihood ratio chi-square test will be used to statistically compare treatment by linear time, and treatment by unconstrained (each follow-up assessment represented by an indicator variable) time models. Because of the relatively small sample size, this test may fail to reject the null hypothesis that these models provide equally good fit even if the trajectories are distinctly non linear. Therefore, we will also generate line graphs comparing the observed trajectories over time. If the trajectories

are not approximately linear we will estimate the treatment by unconstrained time model. We will examine residual plots to determine if model assumptions are reasonably well approximated. If not, bootstrap resampling will be used to estimate 95% confidence interval estimates. We will utilize 3 measures of drinking to cope: (a) a measure of drinking to cope at BL, 6-weeks, 12-weeks, and 6-months (using coping scales of MDMQR[22]), (b) a daily frequency count of drinking to cope via EMA and TLFB methods where participants rate whether their use was motivated by the coping motive (yes/no, see [55]), and (c) EMA counts of drinking to cope. Secondary outcomes are overall changes in use (TLFB[30]) use-related problems (RAPI[56]), NA (EMA, PANAS), and coping skills utilization (Brief COPE[37]).

C.4.d. Hypothesis b - in response to NA, participants will report an increase in coping skills utilization and decrease in drinking intent at the next EMA assessment point over time. We will use a multi-level mixed modeling approach, which allows for the separation of within- and between-person variability, to analyze the EMA data. NA and coping skills utilization will be within-person centered to determine daily deviation in mood from the individual's typical mood score, thus removing between-person variance. We will specify a random time slope (to allow for variability across participants) and a repeated auto-regressive statement for timepoints. Model A will predict time-varying daily coping skills utilization from the main effect of NA, time, and their interaction; and Model B will predict time-varying daily drinking intent from the main effect of NA, time, and their interaction.

C.4.e. Hypothesis c - reduced negative affect and increased coping skills utilization will be related to improvements in alcohol use outcomes at the next EMA assessment point over time. Again using multi-level mixed modeling approaches for the EMA data, Model C will evaluate NA, time-varying coping skills, and the interaction to predict daily alcohol use; and Model D will evaluate NA, time-varying coping skills, and the interaction to predict daily drinking to cope.

C.4.f. Feasibility and Acceptability. In addition to evaluation of feasibility and acceptability measures in participant questionnaires, we will use responses in recorded qualitative interviews and thematic analysis of qualitative data will be used to aid in evaluation of the intervention. Prior to analysis of qualitative data, written transcripts will be generated –a verbatim interview account. All identifying information will be removed. Researchers will carefully read the transcript to identify any omissions, errors, or misrepresentation of participant emphasis. Dr. Abrantes will analyze and interpret the narrative data. As is typical in qualitative research, we will approach data gathering and interpretation as an "iterative, cyclical process" such that interpretation will begin early in the data collection process so that changes may be made, as necessary, in the sampling strategy and procedures[57]. Analyses will involve the interplay of two interpretive styles: a template organizing style, using an existing framework of codes, combined with an editing organizing style, where themes emerge directly from the text [58]. Following initial line-by-line coding of narrative data using pre-established codes, we will return to the text to identify additional themes. Narrative data files will be analyzed with a widely-used qualitative data software program, *N-Vivo*.

D. Material Inducements

Participants in Phase 1 (focus groups) will earn $50 for participation. Participants in Phase 2 will be compensated up to $820 for full participation. Participants in both conditions will receive $100 each for the baseline, 6-week, 12-week, and 6-month follow-up assessments (up to $400). Participants in the PFIcope+EMI condition will earn $2 for each morning report and $1 for each momentary report completed (up to $252), with a $4 per day bonus if all 5 prompts are completed that day (up to $168). In addition to their baseline and follow-up assessment compensation, those in the PNF condition will receive $200, which is equivalent to what someone in the PFI+EMA condition would be compensated if they had a response rate of about 70% (an expected figure based on previous studies conducted by the research team). In total, participants may receive a maximum of $820 for full participation.

Study Activity	PFIcope + EMI Condition Compensation	PNF Condition Compensation
Baseline, 6-week, 12-week, 6-month assessments	$100/assessment x 4 = $400	$100/assessment x 4 = $400
6 weeks post-Baseline	$2/EMA morning report + $1 x 4/momentary report = $6/day x 42 days = $252	$200
	$4 bonus/day for completing all 5 reports x 42 days = $168 bonus	
Total Possible Compensation	$820	$600

E. Training of Research Personnel

The PI or their designee will train the research staff to administer the study interviews. We will measure fidelity to the interviews by direct observation, review of audio-recordings and data checks. Research staff will meet regularly to review feedback from these reviews and any drift will be addressed.

3) Human Subjects

A. Subject Population

Phase 1: Focus Groups

Participants (n=20) will be recruited from the YAPH or IOP. Inclusion Criteria: (a) between 18 and 25 years of age, (b) reported alcohol use at least once a week over the past month with at least one day of binge drinking (as defined as 4+ drinks/episode for men and 3+ drinks/episode for women), (c) self-reported use of coping motive (mean of 2+ on coping subscale of MDMQ-R[22], indicating they drink to cope at least "some of the time"), (d) current anxiety and/or depression symptomatology (as assessed CES-D[23] scores above cut-off for high risk for clinical depression and GAD-7[24] scores above cut-off for moderate to severe anxiety), (e) owns a smartphone capable of downloading EMA app.

Phase 2

Participants are 60 emerging adults receiving treatment for anxiety and/or depression at the Butler Hospital Partial Hospitalization Programs (PHP) or Intensive Outpatient Programs (IOPs) who use alcohol to cope with negative affect. Inclusion Criteria: (a) between 18 and 25 years of age, (b) reported alcohol use at least once a week over the past month with at least one day of binge drinking (as defined as 4+ drinks/episode for men and 3+ drinks/episode for women)), (c) self-reported use of coping motive (mean of 2+ on coping subscale of MDMQ-R[22], indicating they drink to cope at least "some of the time"), (d) current anxiety and/or depression symptomatology (as assessed CES-D[23] scores above cut-off for high risk for clinical depression and GAD-7[24] scores above cut-off for moderate to severe anxiety), (e) owns a smartphone capable of downloading EMA app. Exclusion criteria : (a) current DSM-5 diagnosis of moderate/severe substance use disorder (other than alcohol, cannabis, or nicotine) as assessed by research staff via SCID, with use of that substance in the past month, (b) Current and active psychotic symptoms that would interfere with study participation, as assessed by research staff via SCID, (c) current suicidal/homicidal ideation.

Participants of all racial and ethnic backgrounds will be eligible. On the basis of the demographic characteristics of patients in the Butler Hospital Young Adult Partial Hospital Program (YAPH), we expect the sample recruited to be at least 12% non-Caucasian. This predominantly non-minority racial representation reflects the adult population of Rhode Island (88% Caucasian). In order to increase the participation of minorities, we will oversample for non-Caucasian participants so that we obtain a final sample that is 20% minority.

B. Recruitment and Consent Procedures

Phase 1: Focus Groups

Participants appearing to meet eligibility, based on IRB-approved medical chart review and self-reported alcohol use, will be provided with a brief study description. Interested persons will be screened for further eligibility. Those who are eligible and interested will then provide verbal consent for the use of e-mail and videoconferencing. This consent will allow us to use videoconferencing to conduct a "virtual focus group" if the participant feels uncomfortable meeting in-person. They will provide informed consent for participation in the focus group and consent to be audio-recorded. The consented participant will then complete a brief questionnaire and participate in open discussion while in the YAPH or IOP (approximately 1 hour) on designated breaks or after the program ends for the day, so as not to take way from scheduled programming. They may also complete the focus group shortly after being discharged from the YAPH or IOP if timing does not allow us to schedule it before they leave. Participants will receive $50 for participation in the focus groups.

Phase 2

Patients' medical records will be reviewed in order to assess the psychiatric and medical inclusion and exclusion criteria detailed above. Interested participants appearing to meet study criteria will be provided brief

information about the study. If the participant is interested in hearing about the study, research staff will give participants a description of the study, and will ask in person for permission to contact the participant by phone/text message (see Permission to Contact form), or may contact participants outside of program times by phone if participants have signed the Permission to Contact – Admission Paperwork Version form. Interested participants will be asked to complete a brief screening battery (either in-person on the unit, over the phone, or if participant desires, sent virtually) to determine preliminary eligibility based on depression and anxiety symptom measures, drinking frequency, and drinking to cope measures. If the participant chooses to complete the screening via a REDCap link, they will be asked to provide verbal consent for the use of e-mail and videoconferencing (see Butler Hospital Verbal Consent for Email and Videoconference form). Patients will also have the option to access a copy of the screening survey directly from flyers posted on the units. The screening survey will collect their contact information, and study staff will review their eligibility based on their screening survey and EMR.

Participants appearing to meet study criteria will be scheduled for a more comprehensive baseline assessment. At the baseline assessment, research staff will carefully explain all aspects of the study, including the experimental nature of the research, the potential risks and benefits, and the expected duration and time commitment of their participation. The patient will be presented with a written informed consent form, will be given the opportunity to ask questions, and will then be asked to sign the consent form if he or she agrees to participate. The consent form will also be signed by the research staff person. Maintaining a high follow-up rate will be essential to the successful completion of this study. We will compensate participants with $100 gift cards at each assessment. Additionally, participants will be compensated for completion of EMA prompts at $2 per morning report, $1 per momentary report, and a $4/day bonus if all prompts are completed for that day, for a maximum of $420 EMA compensation. Participants in the PNF group do not complete EMA prompts and as such will receive $200 for this phase of the study, which will be added to their follow-up assessment compensation ($100 per visit). In total, participants receive a maximum of $600 to $820 for full participation, depending on which condition they are assigned to.

Baseline and follow-up study visits will be conducted in person at Butler Hospital, or if the participant is uncomfortable or unwilling to complete the visits in person, the visits may be completed via phone or videoconference. If the participant chooses to complete the study visit via videoconference, they will be asked to provide verbal consent for the use of e-mail and videoconferencing (see Butler Hospital Verbal Consent for Email and Videoconference form), if they have not already done so during the screening process (see above).

C. Potential Risks

Potential risks include breach of confidentiality, perception of coercion to participate in the study, suicide or homicide, texting, and e-mailing.

D. Protection of the Subject

D1. Measures to Minimize Potential Risks

Breach of confidentiality:

Risks. The risk of loss of privacy is judged to be minimal.

Minimization. Breach of confidentiality is highly unlikely because all data are identified only by numeric code and are stored in locked file cabinets. A master list of names and numbers is kept in a separate location and is used to facilitate the collection of follow-up data. Only senior grant staff will have access to the master list linking names and code numbers. Clinically important assessment data (e.g., suicidal intent) will be made available to clinical staff to more effectively coordinate services. All staff are or will be fully trained in relevant ethical principles and procedures, particularly around confidentiality. All assessment and treatment procedures will be closely supervised by the project's professional staff. Audio-recordings of participant assessments will be uploaded and stored on a secure server in a digital format. A study ID will be used to identify the recordings. Otherwise they are not connected with the primary study database in any way. All audiotapes will be erased upon completion of data analysis.

Daily EMA assessment will be collected via MetricWire, a web-based platform specifically developed for

EMA. This platform also has an associated mobile application (EMA) that enables data collection from participants in their daily lives, from use of their own Apple or Android smartphone device. This is ideal as it increases compliance and reduces burden. There is no cost for participants to use the Metricwire EMA application. The application is free, does not require a data plan, and sends notifications even without internet connection. The EMA system is secure, private, and HIPAA compliant (e.g., no identifying information, data are encrypted prior to being uploaded to cloud-based storage). Data are stored on the participant's mobile device until they choose to upload it from EMA to the cloud server.

Perception of coercion to participate in the study

Risks. Issues related to coercion are unlikely since patients who do not consent to participate in the study will receive the intensive psychiatric treatment provided by the PHP or IOP.

Minimization. All patients will be instructed that their decision as to whether to participate in the study will not influence their current or future standing with Butler Hospital. They will also be informed of their right to withdraw from the study at any time.

Suicide or homicide

Risks. In this type of patient population, the risk of suicide or homicide is always present.

Minimization. All research staff who have direct involvement with patients will be fully trained by the principal investigator in procedures for assessment and intervention in cases where suicidal or homicidal ideation is expressed. In such cases, research staff will also immediately contact the principal investigator or another senior investigator, one of whom will be on-call at all times. Appropriate clinical action will be taken in such circumstances, which may include hospitalization and/or referral to another level of clinical care. These procedures have been in place in our alcohol/depression study, smoking cessation studies, and exercise intervention studies.

Text Messaging

Risks. There are minimal risks associated with text messaging.

Minimization. Participants will be asked for their permission to receive text messages for study-related appointment scheduling and reminders, and reminders to respond to the EMA prompts, if applicable. Text from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages constantly, but it will be checked periodically during regular office hours. Participants will be able to respond to messages from researchers, but will be informed of the limits on this communication. Specifically, participants will be told about the risks associated with sending messages related to their health information via text. It will be made clear that we will only communicate by text to schedule research-related appointments. We will not send text messages to a group of recipients. If the participant shares a mobile phone or messages with others, they will be reminded of the risk of losing privacy surrounding their health information and loss of privacy surrounding their participation in this study. They will be instructed to make sure to protect their phone with a password if they send or receive text messages during participation in this study. Lastly, because we may not check messages daily, participants will be told to not contact us if the matter is urgent and that any medical symptoms should be communicated through telephone or in person.

E-mailing

Risks. There are minimal risks associated with e-mailing.

Minimization. Participants will be asked for permission to send study surveys via secure e-mail from REDCap. Participants will be informed about the risks associated with the use of email. Specifically, participants will be told about the risk that the message could be intercepted by someone other than the participant if others have access to the email account. In turn, others could find out about their research participation which could reveal some private health information such as medical health conditions and psychiatric diagnosis (if applicable). Only the research team will have access to the e-mail communications. We will only

communicate by e-mail to send study surveys. We will not send e-mail messages that contain urgent information or results of medical tests or diagnostic procedures. We will not send messages that direct participants to get medical care.

D2. Measures to Ensure Confidentiality

Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All information will be treated as confidential material and will be available only to research and clinical staff. All information will be kept in locked files. Computer data files will be available only to authorized personnel and no names or obvious identifying information will be stored in computer files. All audio-files will be erased upon completion of data analysis. No subject will be identified in any report of the project.

D3. Data Safety Monitoring Plan

We believe that potential risks to participants in this personalized feedback and ecological momentary assessment intervention trial will be minimal. In this type of patient population, the risk of suicide or homicide is always present. All research staff who have direct involvement with patients will be fully trained by the principal investigators in procedures for assessment and intervention in cases where suicidal or homicidal ideation is expressed. In such cases, research staff will also immediately contact the principal investigator or another senior investigator, one of whom will be on-call at all times. Appropriate clinical action will be taken in such circumstances. In addition, the risks do include the side effects from medication, which will be monitored by the participant's prescribing physician.

The principal investigator, Dr. Abrantes, will take ultimate responsibility for safety monitoring in the study. Dr. Abrantes is a licensed clinical psychologist. They will be in frequent contact with the study staff. All adverse events will be promptly reported to Dr. Abrantes. Additionally, Dr. Heather Schatten, co-investigator, specializes in the identification and treatment of suicidal ideation and behavior. Any incident involving a serious injury, medical hospitalization, or death will be immediately reported to the Butler Hospital IRB and will be presented to the full committee of the Butler Hospital IRB as soon as it is feasible.

In the case an Adverse Effect (AE) or a Serious Adverse Effect (SAE) were to occur, a written report of the AE or SAE will be prepared for submission to the Butler Hospital IRB. Any such AEs or SAEs will be presented to the full committee of the Butler Hospital IRB as soon as it is feasible. The report of such AEs or SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event and whether all enrolled participants should be notified of the event. Finally, as part of the annual progress report, we would provide summary information on all AEs and SAEs that have occurred.

This study will use Care New England's instance of REDCap for the collection, storage, and retrieval of study data in a fully encrypted, HIPAA compliant environment. CNE's REDCap instance is hosted in our HIPAA compliant data center, which has 24/7/365 support. All network data transmissions are also fully encrypted. For more information about REDCap visit http://www.projectredcap.org/. Access to REDCap can be restricted at different levels (e.g., research assistant, PI, and Co-Investigators). Exported data from REDCap will be stored on the Behavioral Medicine and Addiction Research's secure password-protected server.

The EMA app is a HIPAA-compliant platform for the collection of EMA data and secure transmission of those data to a cloud-based central server with dedicated data backup. Nevertheless, our participant identifiers will not be uploaded to the MetricWire, Inc. database and only an anonymized STUDY ID number will be used to track subjects in the MetricWire, Inc. online platform. MetricWire, Inc. protects participant data by temporarily storing participant responses on the device in an encrypted database. Data collected and stored by the MetricWire, Inc. Platform is encrypted while both in transit and at rest. All passwords are suppressed during entry within the MetricWire Researcher Portal, Participant Portal and Mobile Apps. Passwords are encrypted when transmitted across the network using Secure Hypertext Transfer Protocol or HTTPS. All participant generated data are encrypted in transit using encryption keys managed by Metricwire. After successfully logging into the MetricWire mobile app, a unique token is generated for the participant using the

ID, timestamp, a unique randomly generated number and a private key that is only available on the server. The token is returned to the mobile device and every subsequent request or response from the user includes this token as a HTTP Header. When the user submits a response, the server reads and decrypts the token with the private key used to create it, to verify that the response is coming from the correct source (in this case the participant). This also ensures that the data being captured on the mobile device cannot be modified in-transit to the server. Additionally, the data is protected in-transit using HTTPS. This method is commonly used across websites to prevent attacks called "Cross-Site Request Forgery"(CSRF). Information is stored on the phone when it is not being transmitted (i.e., when participant devices do not have sufficient service to transmit). All passwords are stored using a password-based key derivation function called Scrypt, which stores the password in HMAC-SHA256. Data will be obfuscated with non-personally identifiable user IDs and can be accessed by the research team only, not by the app developers. The EMA app on participants' phones will be protected by a PIN that should protect the data on the device in the event that it is lost or stolen.

E. Potential Benefits

By participating in the clinical research project, participants may benefit from the additional intervention that they will receive. In addition, all patients will receive the intensive psychiatric treatment program provided at the PHP or IOP. The risks of suicide or homicide are inherent in this patient population. Our assessment contacts represent potential opportunities to identify and respond to at-risk thinking or behavior patterns which might remain undetected if patients were not in this study.

F. Risk-Benefit Ratio

The risks to participants are judged to be acceptable relative to the anticipated benefits. The risks associated with participation in a mood monitoring and coping skills app-based intervention are minimal. Given this level of risk(s) to the patients and the likelihood that some will benefit from the additional treatment (or from the additional assessment contacts) and the even greater possibility of benefits to the larger population of cannabis-using individuals, the risk/benefits ratio seems favorable.

4) REFERENCES

1. Cooper ML. Motivations for alcohol use among adolescents: Development and validation of a four-factor model. *Psychol Assess*. 1994;6(2):117-128. doi:10.1037/1040-3590.6.2.117
2. Kuntsche E, Knibbe R, Gmel G, Engels R. Who drinks and why? A review of socio-demographic, personality, and contextual issues behind the drinking motives in young people. *Addict Behav*. 2006;31(10). doi:10.1016/j.addbeh.2005.12.028
3. Kuntsche E, Knibbe R, Gmel G, Engels R. Why do young people drink? A review of drinking motives. *Clin Psychol Rev*. 2005;25(7). doi:10.1016/j.cpr.2005.06.002
4. Cooper ML, Kuntsche E, Levitt A, Barber LL. Motivational models of substance use : A review of theory and research on motives for using alcohol, marijuana, and tobacco. In: Sher KJ, ed. *The Oxford Handbook of Substance Use and Substance Use Disorders*. Oxford University Press; 2016:1-117. doi:10.1093/oxfordhb/9780199381678.013.017
5. Cohn AM, Hunter-Reel D, Hagman BT, Mitchell J. Promoting Behavior Change from Alcohol Use Through Mobile Technology: The Future of Ecological Momentary Assessment. *Alcohol Clin Exp Res*. 2011;35(12). doi:10.1111/j.1530-0277.2011.01571.x
6. Riordan BC, Conner TS, Flett JAM, Scarf D. A brief orientation week ecological momentary intervention to reduce university student alcohol consumption. *J Stud Alcohol Drugs*. 2015;76:525-529.
7. Heron KE, Smyth JM. Ecological momentary interventions: Incorporating mobile technology into psychosocial and health behaviour treatments. *Br J Health Psychol*. 2010;15(1). doi:10.1348/135910709X466063
8. Naughton F. Delivering "Just-In-Time" smoking cessation support via mobile phones: Current knowledge and future directions. *Nicotine Tob Res*. 2017;19(3). doi:10.1093/ntr/ntw143
9. Goldstein SP, Evans BC, Flack D, et al. Return of the JITAI: Applying a Just-in-Time Adaptive Intervention Framework to the Development of m-Health Solutions for Addictive Behaviors. *Int J Behav Med*. 2017;24(5). doi:10.1007/s12529-016-9627-y
10. Nahum-Shani I, Smith SN, Spring BJ, et al. Just-in-Time Adaptive Interventions (JITAIs) in Mobile Health: Key Components and Design Principles for Ongoing Health Behavior Support. *Ann Behav Med*. 2016:1-17.

doi:10.1007/s12160-016-9830-8
11. Blevins CE, Marsh EL, Stein MD, Schatten HT, Abrantes AM. Project CHOICE: Choosing Healthy Options in Coping with Emotions, an EMA/EMI Intervention for Alcohol Use. *Under Rev*.
12. Boerema AM, Kleiboer A, Beekman ATF, van Zoonen K, Dijkshoorn H, Cuijpers P. Determinants of help-seeking behavior in depression: A cross-sectional study. *BMC Psychiatry*. 2016;16(1). doi:10.1186/s12888-016-0790-0
13. Chung DT, Ryan CJ, Hadzi-Pavlovic D, Singh SP, Stanton C, Large MM. Suicide rates after discharge from psychiatric facilities: A systematic review and meta-analysis. *JAMA Psychiatry*. 2017;74(7):694-702. doi:10.1001/jamapsychiatry.2017.1044
14. Johansson O, Lundh LG, Bjärehed J. 12-Month Outcome and Predictors of Recurrence in Psychiatric Treatment of Depression: A Retrospective Study. *Psychiatr Q*. 2015;86(3). doi:10.1007/s11126-015-9341-y
15. Kuehner C, Huffziger S. Factors predicting the long-term illness course in a cohort of depressed inpatients. *Eur Arch Psychiatry Clin Neurosci*. 2013;263(5). doi:10.1007/s00406-012-0379-7
16. Olfson M, Wall M, Wang S, et al. Short-Term suicide risk after psychiatric hospital discharge. *JAMA Psychiatry*. 2016;73(11):1119-1126. doi:10.1001/jamapsychiatry.2016.2035
17. Grant BF, Stinson FS, Dawson DA, et al. Prevalence and co-occurrence of substance use disorders and independent mood and anxiety disorders: Results from the national epidemiologic survey on alcohol and related conditions. *Arch Gen Psychiatry*. 2004;61(8). doi:10.1001/archpsyc.61.8.807
18. Substance Abuse and Mental Heath Services Administration. *The National Survey on Drug Use and Health 2015*. Rockville, MD; 2016.
19. Gorka SM, Hedeker D, Piasecki TM, Mermelstein R. Impact of alcohol use motives and internalizing symptoms on mood changes in response to drinking: An ecological momentary assessment investigation. *Drug Alcohol Depend*. 2017;173:31-38. doi:10.1016/j.drugalcdep.2016.12.012
20. Piasecki TM, Cooper ML, Wood PK, Sher KJ, Shiffman S, Heath AC. Dispositional drinking motives: Associations with appraised alcohol effects and alcohol consumption in an ecological momentary assessment investigation. *Psychol Assess*. 2014;26(2). doi:10.1037/a0035153
21. Riordan BC, Flett JAM, Conner TS, Scarf D. Text message interventions for alcohol use: Current research and future directions. In: *Alcohol Consumption: Patterns, Influences and Health Effects*. ; 2016.
22. Grant V V, Stewart SH, O'Connor RM, Blackwell E, Conrod PJ. Psychometric evaluation of the five-factor Modified Drinking Motives Questionnaire--Revised in undergraduates. *Addict Behav*. 2007;32(11):2611-2632. doi:10.1016/j.addbeh.2007.07.004
23. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. *Appl Psychol Meas*. 1977;1(3):385-401. doi:10.1177/014662167700100306
24. Spitzer RL, Kroenke K, Williams JBW, Lo B. A Brief Measure for Assessing Generalized Anxiety Disorder. 2017;166:1092-1097.
25. Wilsnack RW, Wilsnack SC, Kristjanson AF, Vogeltanz-Holm ND, Gmel G. Gender and alcohol consumption: Patterns from the multinational GENACIS project. *Addiction*. 2009;104(9). doi:10.1111/j.1360-0443.2009.02696.x
26. Wilsnack RW, Vogeltanz ND, Wilsnack SC, et al. Gender differences in alcohol consumption and adverse drinking consequences : cross-cultural patterns. 2000;95(April 1997).
27. First MB. Structured Clinical Interview for the DSM (SCID) . In: *The Encyclopedia of Clinical Psychology*. ; 2015. doi:10.1002/9781118625392.wbecp351
28. Attkisson CC. The Client Satisfaction Questionnaire: Psychometric Properties and Correlations with Service Utilization and Psychotherapy Outcome. *Eval Program Plann*. 1983;5:233-237.
29. Levine J, Schooler N. SAFTEE (SYSTEMATIC ASSESSMENT FOR TREATMENT EMERGENT EVENTS). A NEW TECHNIQUE FOR DETECTING SIDE EFFECTS IN CLINICAL TRIALS. *Clin Neuropharmacol*. 1984;7. doi:10.1097/00002826-198406001-00424
30. Sobell LC, Sobell MB. Timeline followback: A technique for assessing self-reported ethanol consumption. In: Allen J, Litten R, eds. *Measuring Alcohol Consumption: Psychosocial and Biological Methods*. Totowa, NJ: Humana Press; 1992:41-72.
31. Babor TF, Higgins-Biddle JC, Saunders JB, Monteiro MG. *The Alcohol Use Disorders Identification Test Guidelines for Use in Primary Care*. 2nd ed. World Health Organization; 2001.
32. Posner K, Brown GK, Stanley B, et al. The Columbia-suicide severity rating scale: Initial validity and internal consistency findings from three multisite studies with adolescents and adults. *Am J Psychiatry*. 2011;168(12). doi:10.1176/appi.ajp.2011.10111704
33. Ham LS, Hope DA. Incorporating social anxiety into a model of college student problematic drinking. *Addict Behav*. 2005;30(1):127-150. doi:10.1016/j.addbeh.2004.04.018

34. Kahler CW, Strong DR, Read JP. Toward efficient and comprehensive measurement of the alcohol problems continuum in college students: The brief Young Adult Alcohol Consequences Questionnaire. *Alcohol Clin Exp Res*. 2005;29(7). doi:10.1097/01.ALC.0000171940.95813.A5
35. Lindgren KP, Neighbors C, Teachman BA, Wiers RW, Westgate E, Greenwald AG. I drink therefore i am: Validating alcohol-related implicit association tests. *Psychol Addict Behav*. 2013;27(1). doi:10.1037/a0027640
36. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: The PANAS scales. *J Pers Soc Psychol*. 1988;54(6):1063-1070. doi:10.1037/0022-3514.54.6.1063
37. Carver CS. You want to Measure Coping But Your Protocol's Too Long: Consider the Brief COPE. *Int J Behav Med*. 1997;4(1):92.
38. Cuttler C, Spradlin A. Measuring cannabis consumption: Psychometric properties of the Daily Sessions, Frequency, Age of Onset, and Quantity of Cannabis Use Inventory (DFAQ-CU). *PLoS One*. 2017;12(5). doi:10.1371/journal.pone.0178194
39. Simons JS, Dvorak RD, Merrill JE, Read JP. Dimensions and severity of marijuana consequences: Development and validation of the Marijuana Consequences Questionnaire (MACQ). *Addict Behav*. 2012;37(5). doi:10.1016/j.addbeh.2012.01.008
40. Gratz KL, Roemer L. Multidimensional Assessment of Emotion Regulation and Dysregulation: Development, Factor Structure, and Initial Validation of the Difficulties in Emotion Regulation Scale. *J Psychopathol Behav Assess*. 2004;26(1):41-54. doi:10.1023/B:JOBA.0000007455.08539.94
41. Weiss NH, Gratz KL, Lavender JM. Factor Structure and Initial Validation of a Multidimensional Measure of Difficulties in the Regulation of Positive Emotions: The DERS-Positive. *Behav Modif*. 2015;39(3):431-453. doi:10.1177/0145445514566504
42. Cyders MA, Littlefield AK, Coffey S, Karyadi KA. Examination of a short English version of the UPPS-P Impulsive Behavior Scale. *Addict Behav*. 2014;39(9). doi:10.1016/j.addbeh.2014.02.013
43. Abrantes AM, Blevins C, Lindsay C, et al. Formative work in the development of a physical activity smartphone app targeted for patients with alcohol use disorders. *Psychol Sport Exerc*. 2019;41:162-171. doi:10.1016/j.psychsport.2018.02.007
44. Arnett JJ. Conceptions of the Transition to Adulthood: Perspectives from Adolescence Through Midlife. *J Adult Dev*. 2001;8(2). doi:10.1023/A:1026450103225
45. Loewy RL, Bearden CE, Johnson JK, Raine A, Cannon TD. The prodromal questionnaire (PQ): Preliminary validation of a self-report screening measure for prodromal and psychotic syndromes. *Schizophr Res*. 2005;77(2-3). doi:10.1016/j.schres.2005.02.009
46. Chan AHY, Horne R, Hankins M, Chisari C. The Medication Adherence Report Scale: A measurement tool for eliciting patients' reports of nonadherence. *Br J Clin Pharmacol*. 2020;86(7). doi:10.1111/bcp.14193
47. Linehan MM, Heard HL, Armstrong HE. Naturalistic follow-up of a behavioral treatment for chronically parasuicidal borderline patients. *Arch Gen Psychiatry*. 1993;50(12):971-974.
48. Linehan MM. *Treatment History Interview*. Seattle, WA.: University of Washington; 1996.
49. Hedeker D, Mermelstein RJ, Berbaum ML, Campbell RT. Modeling mood variation associated with smoking: An application of a heterogeneous mixed-effects model for analysis of ecological momentary assessment (EMA) data. *Addiction*. 2009;104(2). doi:10.1111/j.1360-0443.2008.02435.x
50. Piasecki TM, Hedeker D, Dierker LC, Mermelstein RJ. Progression of Nicotine Dependence, Mood Level, and Mood Variability in Adolescent Smokers. *Psychol Addict Behav*. 2016;30(4). doi:10.1037/adb0000165
51. Marlatt G, Donovan D. *Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviors*. New York: Guilford Press; 2005.
52. Hedeker D, Gibbons RD. Application of Random-Effects Pattern-Mixture Models for Missing Data in Longitudinal Studies. *Psychol Methods*. 1997;2(1). doi:10.1037/1082-989X.2.1.64
53. Little, RJA and Rublin D. Statistical Analysis with Missing Data. *Wiley, New York*. 1987:381. doi:10.1002/9781119013563
54. Allison P. Fixed Effects Regression Models. In: Thousand Oaks, California: Sage Publications; 2009. doi:10.4135/9781412993869
55. Abrantes AM, Blevins CE, Battle CL, Read JP, Gordon AL, Stein MD. Developing a Fitbit-supported lifestyle physical activity intervention for depressed alcohol dependent women. *J Subst Abuse Treat*. 2017;80. doi:10.1016/j.jsat.2017.07.006
56. White HR, LaBouvie EW. Towards the assessment of alcohol problem drinking. *J Stud Alcohol*. 1989;50(1):30-37.
57. Crabtree BF, Miller WL. *Doing Qualitative Research*. Sage Publications; 1999.
58. Addison R. A grounded hermeneutic editing approach. In: Crabtree BF, Miller WL, eds. *Doing Qualitative Research*.

Thousand Oaks, CA: Sage Publications; 1999:145-162.

5) CRITERIA FOR WAIVER OF AUTHORIZATION FOR USE OF PROTECTED HEALTH INFORMATION (PHI)

5A. Does the requested use of PHI involve more than minimal risk to privacy?

☐ **YES** ***[if " YES," project is not eligible for PHI Waiver]*** ☒ **NO** ***[if "NO," address 1-3 below]***

1. **Plan to Protect Patient Identifiers from Improper Use and Disclosure:**
Study materials with identifying information will be kept in locked cabinets or in password-protected electronic files, accessible only to study staff. Screening information will be de-identified for analysis purposes.

2. **Plan to Destroy Identifiers or Justification for Retaining Identifiers:**
At the end of the study and full dissemination of study results, all PHI will be destroyed. No one will be identified in any publications or reports.

3. **Assurances that the PHI will not be Re-used or Disclosed:**
There is no third party to which PHI will be disclosed. PHI will not be re-used for any purposes other than this research study. No one will be identified in any publications or reports from this research.

5B. Could the research be practicably conducted without a waiver? ☐ **YES** ☒ **NO**
5C. Could the research be practicably conducted without access to and use of the PHI? ☐ **YES** ☒ **NO**
5D. PHI is only needed for activities preparatory to research ☐**YES** ☒**NO**

6) DESCRIPTION OF PHI TO BE COLLECTED UNDER WAIVER

1. Demographics (Name, Address, Phone, Date of Birth, Race, Ethnicity, work status, educational level)
2. Current clinical diagnoses
3. Medical Record number
4. Alcohol Use Disorder Identification Test (AUDIT)
5. Columbia Suicide Severity Rating Scale (C-SSRS)

7) ADVERTISEMENTS

A study flyer intended to be posted internally in Butler Hospital on bulletin boards, in areas from which we recruit for Project CHOICE (IOP and PHP program spaces). The flyer will contain a link to a screening and permission to contact form on RedCap. This flyer will not be posted in the community or anywhere outside of Butler Hospital spaces.
The study will also be displayed on Butler Hospital's research website designed by the marketing department. The website page will contain a contact form so that potential participants can express interest in participating.

8) INFORMED CONSENT FORM (ICF), ASSENT OF MINOR & PARENTAL PERMISSION FORM

Indicate number of consent(s): 3
Identify each consent: Phase 1: Focus groups, Phase 2: Main Study Consent form, Verbal Consent for Email and Videoconference

BUTLER HOSPITAL CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

Project CHOICE: Developing a Personalized-Feedback EMA/EMI Intervention for Emerging Adults Leaving Psychiatric Partial Hospitalization

Sponsorship

This study is being paid for by the National Institute on Alcohol and Alcohol Abuse and Internal Funds.

Research Project Summary

You are invited to participate in a study designed to help emerging adults (individuals between the ages of 18-25 years) who are depressed and anxious learn to cope without drinking alcohol. You have been invited to participate because you are currently receiving treatment at one of Butler Hospital's Partial Hospital Programs (PHPs) or Intensive Outpatient Programs (IOPs) and you own a smartphone. Your participation in the study will involve 4 research visits, which will be conducted at our research offices at Butler Hospital or virtually via phone or videoconference. It will require up to 2 hours total to complete each of these visits.

This study will begin with questionnaires about your mental health and substance use, in order to determine whether you are eligible for the study. If you decide to participate, you will complete questionnaires and then participate in an initial orientation session during your time in the PHP or IOP (after daily scheduled activities) where a staff member of the research study will go over all the different parts of the study and give you feedback about your substance use. During the next 6 weeks, after you leave the PHP or IOP program, depending on which part of the study you are in, you may be asked to respond to prompts on a secure app on your phone for 42 days. These prompts will ask you about your mood, substance use, and any coping strategies you have used. You will spend about 5-10 minutes per day responding to prompts. You will be asked to return after 6 weeks, 12 weeks, and 6 months to complete additional questionnaires and interviews. The study will last 6 months. You will be paid for your participation in this study; details can be found below in the Economic Considerations section.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, risks associated with the procedures, possible benefits of participation, and possible alternatives. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form. This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

Description of Procedures

First, you will complete several interviews. If you are eligible, based on those interviews, to continue on in the study, you will be randomly assigned (like the flip of a coin) to one of two programs: 1) Personalized Feedback Intervention plus Ecological Momentary Assessment (PFI+EMA) and 2) Personalized Normative Feedback (PNF). In both conditions, the personalized normative feedback session will be in person during your PHP or IOP admission and will consist of providing you with information about alcohol use. EMA involves using a smartphone app for 6 weeks where you will answer brief questions about how you feel.

Baseline Assessment

If you decide to participate, you will sit down for an interview with one of our research staff to confirm that you are eligible for the study. In this interview, you will be asked questions about your mood and other psychological symptoms, and alcohol and drug use. This confidential interview will take

approximately 1.5 hours and will be audio-recorded (voice taped). These recordings will be reviewed by the researchers for training/supervision purposes, and are completely confidential. You may refuse audio-recording of interviews at any time and still participate in the study. You will also be asked to complete questionnaires, on a laptop computer or tablet device, about your attitudes, mood, alcohol use, and thoughts and feelings relevant to your alcohol use. It is possible that, based on the interview you will not be found eligible to participate in the rest of this study.

Program Conditions

After your baseline assessment, a study clinician will meet with you to go over the 6-week program that you have been assigned to (either PFI+EMA or PNF). We describe each program condition below:

1. **PFI+EMA Program**
   After your baseline assessment, but before you are discharged from the PHP or IOP, a study clinician will meet with you for about an hour to go over the program. You will discuss the structure of the study, and review the information that you provided in the baseline assessment. You will be provided personalized feedback about your responses to questions in the surveys. The study smartphone app will be downloaded to your phone and you will learn how to respond to prompts. This program is an ecological momentary intervention (EMI), which means you will get tailored text messages depending on how you respond to daily questions on the app. Specifically, during the 6-week program (after discharge from the PHP/IOP), the app will notify you at 4 times per day, during waking hours that you designate, to ask you brief questions about your mood, substance use, and coping strategies and, depending on how you are feeling that day, provide encouragement for you to engage in healthy coping. You will also complete a weekly survey that will ask additional questions and help us make personalized changes to your app. Study staff will monitor your use of the app and may contact you through the app system or via text message if you have not opened the app in several days to remind you to use the app. However, you will not be able to communicate with research staff through the app.

2. **PNF Program**
   After your baseline assessment, but before you are discharged from the PHP/IOP, a study clinician will meet with you for about an hour to go over the program. You will discuss the structure of the study, and review the information that you provided in the baseline assessment. You will be provided personalized feedback about your responses to questions in the surveys.

Assessments

You will be asked to come into our research office at Butler Hospital to complete in-person assessments at the 6 week, 12 week, and 6 month time points. If you are not able to attend an in-person assessment, we can conduct these study visits over the phone or videoconference if you would prefer to do so. The assessment will be similar to the assessment you will complete at this baseline assessment and will include questions about your mental health, and alcohol and drug use, as well as your impressions of the program. At the 6-week assessment, researchers will also remove the app from your phone. These assessments allow us to monitor your functioning and mental health symptoms over time. In cases, where we observe significant worsening in your mental health functioning, research staff will check in with you and, if appropriate, refer you to additional treatment resources.

Risks and Inconveniences

You may experience discomfort from some of the interview questions or discussion points during the study visits. You may refuse to answer any questions that make you feel uncomfortable and you can stop participating in the discussion at any time. All information obtained will be confidential. Your responses to the questions will not be linked to any information that can identify you. Your information will be available only to our research staff. We will make every effort to lessen any discomfort you may feel during this process.

Audio Recording:
During the study, we will audio-record interviews. We do this to make sure that study staff are following study procedures in the correct way and also to make sure that we have correctly recorded information that you share with us. We will tell you whenever we plan to use an audio-recorder.

Email
We would like to contact you by e-mail for the purposes of scheduling follow-up assessments or sending you weblinks, which will take you online to a secure database where you can complete various study assessment forms during participation in this research project.

How do e-mail communications with CNE researchers work?
You will receive an e-mail message from our research team sent to you from a secure Care New England-hosted research data system called "REDCap." If the research team is sending you a survey, the message will include a link for you to click. Clicking the link will securely connect you with REDCap, where you will see your study survey. You will respond by clicking on buttons you see on the screen. The e-mail messages you receive will not identify you by name, and the links to surveys you get through REDCap will be associated only with your e-mail address. Your e-mail address and any other information that personally identifies you will be removed from the final research database when the study is over.

Risks related to e-mail communication
You should be aware that there are risks associated with sending your health information via e-mail. There is always a risk that the message could be intercepted or sent to the wrong e-mail address. E-mail messages from research staff may contain health information that identifies you. Information sent by e-mail could allow others to identify you along with your medical health conditions and psychiatric diagnosis (if applicable). Only the research team will have access to your e-mail communications. We will only communicate by e-mail to send you the information listed above. We will not send e-mail messages that contain urgent information or results of medical tests or diagnostic procedures. We will not send messages that direct you to get medical care.

Using this secure e-mail system will help reduce the chance that you will experience loss of confidentiality when using e-mail. If you share a home computer with other family members and do not want them to know you are participating in this study, make sure you provide an e-mail address that only you can access. Your employer or school will have access to any e-mail communications sent or received on a work or school computer. Additionally, when using any public computer you should be careful to protect your username and password, and make sure you log-out before getting up from the computer.

Cautions related to e-mail with researchers
Study participants are required to send any e-mail messages they write to the research team through this secure system. ***E-mails may not be received by researchers on a regular basis. It is possible that a message you send will go unnoticed, or will not be read by the research team for days or weeks. You should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, questions about medications, concerns about effects of study procedures, etc.) should NOT be communicated by e-mail***. These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-455-6219.

Can we contact you via email: ☐Yes _____initial; Email: _____ ☐No _____initial

Texting We would like to contact you by text message for the purposes listed below:
1. To schedule research-related appointments
2. To send reminders about appointments
3. To remind you to respond to the app prompts

How do Text Communications with CNE Researchers Work?

Text messages from the study staff will be sent from a phone that is dedicated for use in this research study. The phone will not be monitored for return messages constantly, but it will be checked periodically during regular office hours. You can respond to messages from researchers by sending them text messages, but there are only certain things you should communicate via text message.

Risks Related to Text Communication

You should be aware that there are risks associated with sending your health information via text. There is always a risk that the message could be intercepted or sent to the wrong number. Text messages from research staff may contain health information that identifies you. Only the research team will have access to your text communications. We will only communicate by text to send you the information listed above. We will not send text messages that contain urgent information. We will not send text messages to a group of recipients. If you share your mobile phone or messages with others, you risk losing privacy surrounding your health information and loss of privacy surrounding your participation in this study. You should make sure to protect your phone with a password if you send or receive text messages during participation in this study.

Cautions related to text messages with researchers

Text messages may not be received by researchers on a regular basis. It is possible that a message you send will go unnoticed, or will not be read by the research team for days or weeks. ***You should use the telephone to contact the research team for any urgent matters. Medical issues (symptoms, side effects, injuries, concerns about effects of study procedures, etc.) should NOT be communicated by text message.*** These should be directed to the research staff by telephone or in person. To discuss medical issues, please contact our office at 401-455-6219.

Can we contact you via text: ☐Yes _____initial; Cell Phone # _____ ☐No _____initial

Risk to Confidentiality and Use of MetricWire EMA App

If you are in the PFI+EMA condition:

Participation involves providing sensitive information (about substance use) that will be stored on a cloud-based platform and managed by a company called MetricWire, Inc.. Your responses to the questions about your mood and substance use will be transmitted to the platform with a coded ID, rather than your name. There is a risk of loss of confidentiality when personal information is being transmitted by a smartphone. The app we use for this study has been tested and has built-in safeguards (consistent with federal regulations) for securely transmitting health information from your smartphone to a cloud-based platform, and then from the cloud via download to the researchers at Butler. Data from this app will be encrypted and cannot be read even if it is intercepted by a third party. In addition, the app on a smartphone will be protected by a PIN (number passcode) that should protect the data on the smartphone in the event that it is lost or stolen. The app management company, MetricWire, Inc., will not have access to your personal information. However, the security of information stored and transferred by a smartphone app may not be the same type or level of security that is used to protect non-research medical records or communications in a regular treatment setting. In the unlikely event that the security features of this app were to be compromised, there is a risk that the confidentiality of your information could not be maintained.

Benefits

We cannot and do not guarantee or promise that you will receive any benefits from this study. The knowledge gained in the study may aid in your mental health or substance use recovery process and may provide future benefits to individuals who have problems by furthering our understanding of the role of mood in substance use.

Economic Considerations

You will receive $100 gift cards at each assessment (baseline, 6 weeks, 12 weeks, and 6 months). If you are in the PFI+EMA condition, you will be compensated for completion of app prompts at $1-2 per completed report, with a $4 per day bonus if you complete all 5 reports per day, for a maximum of $420 app compensation. If you are in the PNF condition, you will not complete app prompts but will receive an additional $200 of compensation. In total, you may receive a maximum of $600 to $820 for full participation, depending on which condition you are assigned to.

Depending on the amount of payment you might receive for your participation in this study, together with payments you might receive in participation in other CNE Research Studies, you might have to provide your name, address, and taxpayer ID or Social Security number to the Butler/CNE Research Accounting Department. In order to receive payment of $300 or more for participation in research, you will have to complete and sign a W-9 form. If you are paid $600 or more in any calendar year for research participation, the IRS will be notified of the total amount you were paid, in accordance with federal regulations. You should ask the researcher for more information if you have questions about this process.

Alternative Treatments/Alternative to Participation

We cannot guarantee that your participation in this study will produce treatment benefits related to your efforts to address alcohol use. Alternative treatments exist to assist you in these continued efforts and are available at other treatment centers and private clinics. These alternatives may include outpatient therapy or attending 12-step meetings.

Financial Disclosure

None.

Voluntary Participation

You are free to decide whether or not to participate in this study, and you are free to withdraw from the study at any time. A decision not to participate or to withdraw from the study will not adversely affect your current or future interactions with Butler Hospital or Care New England. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

Confidentiality

Personal identifiers will be removed from any identifiable private information about you in the final research dataset created by this study. The de-identified information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or from your legally authorized representative).

You will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information you provide to us will be maintained in accordance with state and federal laws. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies and to your treatment team in the PHP/IOP program (only during the time you are enrolled in the program).

Clinically relevant research results, including individual research results, will not be disclosed to you. To keep your information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your name or address) separately from study data (such as questionnaires that you complete). You will not be identified on audio-recordings and they will be stored on a secure server which is password protected and only accessible to research staff. All identifying information will be destroyed 6 years after the completion of the study.

If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can visit this website any time.

This research is covered by a Certificate of Confidentiality. Unless you give special written permission, the researchers and Butler Hospital cannot give out any information about you that could potentially identify you or be used as evidence in a legal case (including any federal, state, or local civil, criminal, administrative, or legislative case).

The only situations where researchers would share your information with others are:

(1) when a specific law (federal, state, or local) requires that potentially harmful things be reported to the authorities (such as reporting child abuse, elder abuse or spread of communicable diseases);
(2) when you have given permission (consent) for the information to be shared in order to help your medical treatment; or
(3) when your information will be used for other scientific research, as allowed by federal regulations protecting research subjects.

Data from this study may be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAA$_{DA}$) at the National Institutes of Health (NIH). NIAAA$_{DA}$ is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers may send deidentified study data about your health and behavior to the NIAAA$_{DA}$. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NIAAA$_{DA}$. The study data provided to NIAAA$_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAA$_{DA}$ data. You will not be contacted directly about the study data you contributed to NIAAA$_{DA}$.

You may decide now or later that you do not want your study data to be added to the NIAAA$_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAA$_{DA}$. If you know now that you do not want your data in the NIAAA$_{DA}$, please tell the study researcher and indicate this on the permission line below. If you decide any time after today that you do not want your data to be added to the NIAAA$_{DA}$, call or email the study staff who conducted this study, and they will tell NIAAA$_{DA}$ to stop sharing your study data. Once your data is part of the NIAAA$_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAA$_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

I agree to share my deidentified data with other researchers through the NIAAA database:

☐Yes _____initial ☐No _____initial

Authorization for use/disclosure of your Identifying Health Information, to Conduct this Research Study

If you sign this document, you give permission to Dr. Abrantes at Butler Hospital to use your health information that identifies you, for the purpose of conducting the research study described above.

Your health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions. The U.S. Food and Drug Administration (FDA) may inspect all study records to ensure that the study is being conducted in accordance with FDA regulations.

Butler Hospital is required by law to protect your health information. Individuals outside of Butler that receive your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we cannot guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in or receive research-related treatment in this study.
- Butler Hospital may not withhold treatment or refuse to treat you, based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your health information for this research study, you must contact the Principal Investigator, Dr. Abrantes, and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, Butler researchers may still use or share health information about you that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to your personal health information related to this research until the study is completed. At the conclusion of the research and at your request, you will have access to your health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital. The designated record set includes medical information or billing records used by doctors or other health care providers at Butler Hospital to make decisions about individuals.
- Your health information will be provided to you or to your physician if it is necessary for your care.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. You should take as much time as you need to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

Authorization:
I have read this form and decided that I _____
(printed name of participant)
will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction.
I have received a copy of this consent form.

_____ _____
Signature of Participant Date

_____ _____
Signature of Principal Investigator Date
~or~

_____ _____
Signature of Person Obtaining Consent Date

Telephone Number of Principal Investigator or Person Obtaining Consent_____

If you have further questions about this project or about research-related injuries, please contact Dr. Ana Abrantes at (401) 455-6440. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at 401-455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE: March 31, 2026

IRBNET ID# 1735988

BUTLER IRB REFERENCE# 2104-001

BY (ADMINISTRATOR): *C. Cordeiro*