BabySTEPs: Supportive Texts to Empower Parents

NCT04719390

Study Protocol and Statistical Analysis Plan

Document Approved: July 2023

Please Note: This protocol pertains to Aim 3: Pilot Micro-Randomized Trial, as detailed below.

STUDY PURPOSE AND AIMS

The purpose of this study is to develop and pilot test a theory-driven, adaptive text messaging intervention (TMI) for heavy episodic drinking (HED) in postpartum women. HED is prevalent among women of childbearing age, with 35% of women ages 18-25 and 28% of women ages 26-44 reporting past month binge drinking. The postpartum period is a time of high risk for relapse, as more than half of women who reduce their drinking during pregnancy return to pre-pregnancy levels within the first 3 months postpartum. Postpartum HED is associated with poor mother-baby bonding, increased risk for child abuse and neglect, and poor long-term child outcomes. The majority of adults who engage in HED do not seek treatment. Postpartum women may be especially unlikely to seek formal treatment due to stigma, fears of child removal, and barriers to accessing treatment. Text messaging is a promising strategy for reaching non-treatment-seeking risky drinkers, with research supporting the impact of motivational and behavioral TMIs on reducing drinking. This approach may be particularly suitable for postpartum women, as it is convenient and anonymous. The TMI literature suggests that to maximize efficacy, TMIs should be theory-driven, incorporate evidence-based interventions, and adapt in the moment to fluctuating levels of risk factors. Few existing TMIs for HED meet these criteria, and there is no existing TMI for HED that is specifically designed for postpartum women. To fill this important gap, the proposed TMI will be based on relapse prevention theory, an empirically supported framework for treatment of alcohol use that targets coping skills and motivation to avoid drinking in the presence of context-specific triggers. Triggers specific to the postpartum context include poor sleep and baby irritability, which increase vulnerability to three established risk factors for HED: stress, negative mood, and lowered self-efficacy. Consistent with relapse prevention theory, the proposed TMI will include evidence-based cognitive-behavioral and motivational interviewing intervention messages aimed at strengthening adaptive coping skills and bolstering motivation to resist the urge to drink in the presence of poor sleep and baby irritability leading to higher stress and negative mood and lower self-efficacy.

The study has three primary aims:

Aim 1: Test and refine the proposed theoretical model via Ecological Momentary Assessment (EMA). This aim will refine the theoretical model underlying the TMI that specifies the impact of the proposed intervention components on the theoretical risk factors for postpartum RD, as well as decision rules for adaptive tailoring. Aim 1 work will include cellphone-based data collection using EMA with 30 women for 14 days to determine patterns and fluctuations of stress, negative mood, and self-efficacy in response to perceived sleep quality and baby irritability, and their impact on motivation, coping, and drinks per day.

Aim 2: Develop the components of an adaptive TMI aimed at reducing postpartum risky drinking. This aim will develop content and decision rules for adaptive tailoring that are consistent with Aim 1 results. TMI components will be based on evidence-based motivational and behavioral interventions for alcohol use and will be adaptively tailored to individual fluctuations in stress, negative mood, and self-efficacy. Components will be refined via iterative cycles of user feedback collected via focus groups with 30 women.

Aim 3: Conduct a pilot micro-randomized trial (MRT) to assess feasibility of design and methods in preparation for a future fully powered optimization trial. We will conduct a pilot MRT with 50 postpartum women with the primary goal of demonstrating feasibility and acceptability of MRT methods and the secondary goal of providing proof-of-concept data on the comparative impact of maternal-focused and drinking-focused messages on proximal (motivation, self-efficacy, and self-regulation) and distal (daily drinking) outcomes.

To achieve these aims, the study will apply the Multiphase Optimization Strategy (MOST) framework. Study activities comprise the Preparation Phase of MOST, and will proceed in three phases to achieve the three study aims. Phase 1 (Aim 1) (10 months) will include EMA with 30 women for 14 days aimed at refining the conceptual model and evaluating EMA feasibility. Phase 2 (Aim 2) (10 months) will develop TMI components, including message content and decision rules to guide adaptive tailoring of the TMI via an

iterative user-centered design process with 30 women. Phase 3 (Aim 3) (11 months) will consist of a pilot MRT with 50 women to examine feasibility of the MRT design and preliminary effects of the TMI components on the proximal and distal outcomes.

PARTICIPANTS AND RECRUITMENT

Participants

We will recruit 50 participants via social media. To be eligible for study enrollment, participants must meet the following criteria: (1) adult women ages 18-45 years who gave birth to an infant within the past 4 weeks that will remain in their care; (2) English-speaking; (3) own a smartphone with internet access; (4) report a score of 2 or higher on the T-ACE alcohol risk screener OR having 8 or more standard drinks in a week in the 12 months prior to becoming pregnant OR drinking 4 or more drinks at one time once a month or more in the 12 months prior to becoming pregnant.

Recruitment

We will advertise the study on several social media sites, including Facebook, Instagram, Reddit, NextDoor, BabyCenter, and TikTok. If an individual clicks on a study ad on one of the social media sites, they will be directed to the study website, where they can learn more about the study, and complete eligibility screening and informed consent either online or via phone with the study RA. Facebook is the social network with the highest number of users among adults and well-suited for recruiting study participants. Recruitment of participants for medical research via Facebook has been shown to produce samples similar to traditional recruitment methods and is an efficient recruitment strategy for addiction research, yielding research samples with high severity of SUDs. Research also supports the use of Reddit, NextDoor, and BabyCenter for recruitment of similar populations. Our Co-I Dr. Thrul is experienced in using online recruitment techniques, including Facebook and Instagram and Reddit, to recruit hundreds of participants for substance use studies.

In addition to the click-to-website ads, we will use two other types of advertising on Facebook only, that will allow interested individuals the opportunity to connect directly with the study team to get more information on the study. In Facebook lead ads, clicking on the ad will immediately open a form in which an individual can enter their first name and cell phone number to allow the study RA to contact them directly. Additionally, we will employ ads that link directly to Facebook Messenger, so that when an individual clicks on the ad, it immediately opens up Facebook Messenger, so that the person can send a message to the study team to indicate their interest in learning more.

Retention Strategies

To maximize retention of participants in the Aim 3 MRT, we will employ strategies that have been used in other EMA studies, including those conducted by co-I Thrul. These strategies include participant training prior to beginning the TMI, which will ensure that participants are fully informed of the nature of the program and the level of responsivity that is required, personal contact with study personnel via phone prior to enrollment and upon completion of the TMI, tailored feedback on EMA completion rates sent via text or email (depending on participant preference) at the end of every week of the 4-week TMI period, and bonus incentives for compliance. In addition, we will monitor compliance with EMA every 3 days during the Aim 1 EMA data collection and the 4-week pilot MRT, and for those clients who do not respond to any EMA surveys in a 3-day period, the RA will send reminder text messages.

Eligibility Screening

Participants will complete eligibility screening online via a secure Qualtrics survey that contains the eligibility screen.

Technology Platforms for Data Tracking, EMA and TMI Implementation

We will use Partnership to End Addiction's JITAI Master Platform for tracking participants through the study. For EMA and MRT data collection, we will use MetricWire's data collection app, Catalyst. Developed by MetricWire Inc., the MetricWire EMA system will collect the study's EMA survey data through the Catalyst EMA study app. Catalyst is secure and HIPAA compliant and does not have any associated conflicts of interest. Participants will install the Catalyst app on their own smartphones. Data on the participant's smartphone are

synced (encrypted in-transit) to the server and wiped from the mobile device when a connection is available. When the participant's device is not connected to the internet, data are stored (encrypted) on the device. When offline, the app/server periodically checks for a connection in the background and performs the sync/wipe of any response data. This allows triggers and data collection to occur offline while minimizing the amount of time data are stored on the device.

All participant generated data are stored in production information systems in hosted (cloud) environments and are not permitted to be stored on locally managed electronic devices such as MetricWire workstations.

User Identification
• All critical Information systems require a unique and valid User Login ID and password for each individual user.
• Shared accounts for critical Information Systems are prohibited.
• All critical Information systems require Two-Factor Authentication (2FA) to prevent account Sharing.

Encryption And Decryption
• MetricWire critical Information systems use symmetric AES-256-CBC for data encryption at the database level, with a random, unique initialization vector for each operation.
• Authentication is performed using HMAC-SHA-256 and HMAC-SHA-512.
• Encryption Keys are stored on a NIST FIPS 140-2 Certified Key Management Server
• All participant generated data are encrypted in transit using 4096-bit RSA keys

• Data are encrypted end to end through the entire application.
• Encryption keys and machines that generate keys are managed by MetricWire, protected from unauthorized access and encryption keys are regenerated after 365 days.
• MetricWire monitors the transmission activity of critical information systems automatically
• Information system owners review logs on a weekly basis and in accordance with quarterly risk assessments.

The MetricWire system will not store any PII. We will assign participant IDs as login information for study participants instead of their names, email addresses, or other contact information.

Once study data collection is completed, all data will be downloaded from the MetricWire backend server, stored on Partnership's secure server, and deleted from the MetricWire server. Data download from the MetricWire backend server will be done via an encrypted HTTPS protocol.
Only the research team at Partnership to End Addiction will have access to the participant data.

PILOT MICRO-RANDOMIZED TRIAL (MRT)

Purpose of Pilot MRT

The goals of the Aim 3 pilot MRT are to (1) evaluate feasibility and acceptability of MRT methods and messages, and (2) collect proof-of-concept data on the comparative impact of maternal-focused and drinking-focused messages on proximal (motivation, self-efficacy, and self-regulation) and distal (alcohol use) outcomes. An MRT design is recommended for optimizing text messaging interventions because it provides an empirical basis for decisions about delivery of intervention components[1]. In an MRT, participants are re-randomized at each decision point, allowing for the examination of causal time-varying effects of intervention components on proximal outcomes with a smaller number of participants, thus maximizing efficiency[2]. The proposed study will pilot the MRT design to test the TMI for postpartum HED. Results will include feasibility and acceptability and preliminary main effects estimates to inform a fully-powered MRT in a future study.

Sample and Power

MRT participants will include 50 postpartum women who meet study eligibility criteria recruited following procedures described above (see Participants and Recruitment). In line with published recommendations for

Stage I intervention development research[3,4,5] the primary goal of the pilot MRT is to assess feasibility and to generate provisional evidence of efficacy to inform planning a fully powered MRT, which will be conducted in a future study. Thus, our sample size of 50 was selected to balance recruitment feasibility with the goal of obtaining sufficient data to generate provisional evidence of main effects of intervention components[5], and is consistent with other studies using MRT in the early stages of intervention development[6]. Given the small sample, we will interpret results based on effect size rather than statistical significance. Stage I studies are not required to demonstrate adequate power to detect significant effects[3]; thus, a formal power analysis was not conducted.

Procedures

Study participants will be recruited via social media, as described above (Participants and Recruitment). After signing informed consent, participants will proceed through the following steps.

Step 1: Baseline Assessment. Participants who sign informed consent will be asked to complete a Baseline Assessment via Qualtrics. Participants will be sent a secure link to the Qualtrics survey via text or email. The Baseline will take approximately 30 minutes to complete and will include questions about demographics, parenting, mental health, stress and coping, motivation, and drinking and other substance use.

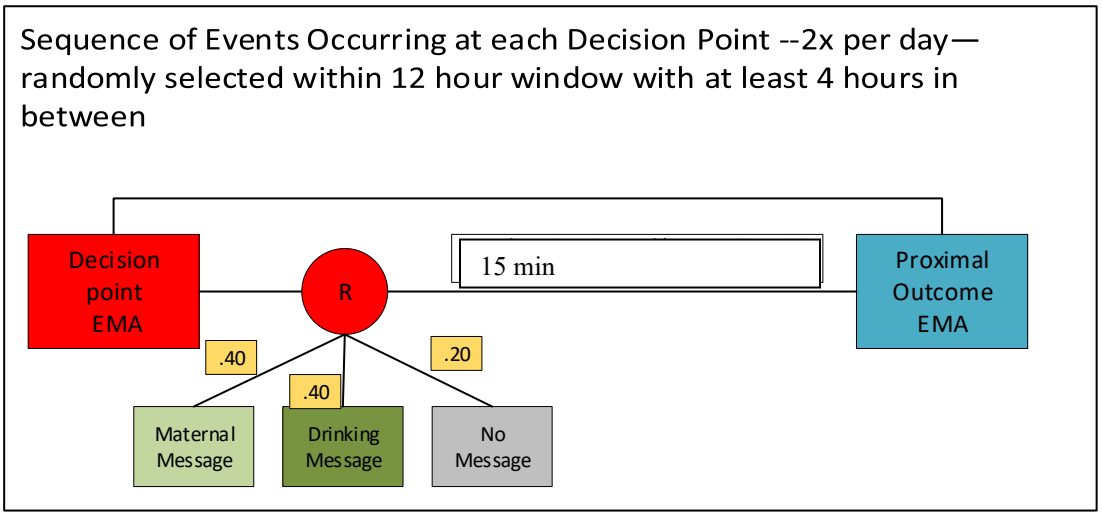
Step 2: Catalyst Training. Following completion of the Baseline, participants will participate in a one-on-one 15-minute training session with the RA via Zoom to provide training on how to download and use the Catalyst app. In order to avoid fraudulent participants, participants will be asked to turn on their camera for 1 minute of the training, after which they will be allowed to turn off their cameras for the remainder of the training if that makes them more comfortable. Participants who complete both the baseline survey and the Catalyst training session will receive a $25 Amazon gift card upon completion of the Catalyst training session.

Step 3: 28-day MRT. After completing the training, the TMI sequence of EMAs and TMI text messages will begin as described below and will last for 28 days.

TMI Sequence and Randomization

Upon completion of the Catalyst training, the TMI sequence of EMAs and TMI component delivery will begin (see Figure 2).

Figure 2. TMI Sequence



There will be two decision points per day. Decision points will be randomly selected within a 12 hour window starting at the participant's pre-selected start time. There will be at least 4 hours between the two decision points. At each decision point, participants will receive the "decision point EMA." Upon completion of the decision point EMA, participants will be randomized to one of three options: (1) a maternal-focused message (.40 probability); (2) a drinking-focused message (.40 probability); or (3) no message (.20 probability). Fifteen minutes after randomization, participants will receive the "proximal outcome EMA." This sequence will repeat 2 times per day, at each decision point. Participants will also be sent a "morning survey" each morning within 30 minutes of their selected start time that will ask questions about the prior day. After each survey prompt, the survey will be

available for up to 60 minutes, with 2 reminder prompts sent (every 20 minutes). Surveys that are not completed within the 60 minute window will expire.

Additionally, an optional "nighttime sequence" will become available nightly at 10 PM. The nighttime sequence will be optional with no prompt sent to avoid disturbing participants during the night. The reason for the nighttime sequence is to enable data collection and message receipt during the night when participants may be awake with their baby, which may be times of high risk for new mothers.

The questions asked in each survey are shown in Tables 4-6 below. Completion of the morning survey should take approximately 2 minutes. Completion of each EMA survey should take approximately 1 minute.

We will use the following procedures to encourage and monitor compliance: (1) one-on-one training prior to the start of data collection; (2) availability of technical support; (3) daily reminders to complete surveys; (4) bonus incentives; (5) outreach to participants who did not complete any EMA surveys 3 days in a row. If 3 days pass without any EMA responses, participants will receive an automated text message reminding them to complete the surveys. The reminder message will be sent once per day for 5 days. If there is still no response, the participant will be considered dropped from the study.

In order to ensure participants are adequately supported during the study, we will provide information on how to obtain additional support for drinking (support hotlines). This information will be available within the Catalyst app at all times for participants to access if needed; (3) provide all participants with a list of local resources at the outset of the study.

MRT Measures

Baseline Assessment:

Construct	Measure
Demographics	Questions developed for study
Drinking Self-efficacy	Drinking Refusal Self-Efficacy Questionnaire-Revised[7]
Alcohol and Drug Use history	NIDA modified ASSIST[8] NIAAA Recommended Alcohol Questions[9]
Alcohol and Drug Use	Timeline Follow Back[10]
Motivation/Readiness for Change	Maternal Motivation Scale[11]
Postpartum Depression	Beck Depression Inventory[12]
Maternal Self-efficacy	Karitane Parenting Confidence Scale[13]
Trauma History	ACE 10 item Questionnaire[14]
Maternal Attachment	Infant Bonding Scale[15]
Fatigue	Fatigue Assessment Scale[16]
Stress	Perceived Stress Scale-4[17]
Drinking Motives	Drinking Motives Revised Questionnaire[18]
Coping self-efficacy	Coping Self-Efficacy Scale[19]
Social Support	SSQ6[20]
Digital Literacy	Media and Technology Usage and Attitudes Scale[21]

Feasibility and Acceptability. Feasibility and Acceptability Outcomes:

Drawing from other EMA feasibility studies[22-27], feasibility outcomes will include the percent of EMA surveys completed each day, each week, and at the end of the 14-day period; the percentage of each EMA measure completed; and the percentage of respondents who completed 50% and 80% of EMA surveys[22,23]. Acceptability measures will be collected via a short text-based survey at the end of the 14-day EMA period and will include assessment of technical challenges, burden, emotional response, and overall satisfaction, using Likert-scale items from other EMA studies [24-27].

Morning Survey Measures:

[Sent daily at participant-selected wakeup time.]

Construct	Items
EMA Burden/ Acceptability questions [include	Retrospective questions 1=not at all, 7= very much Burden: 1. Answering to the questions disrupted my everyday life

in final daily diary at end of study]	2. The questionnaires on the phone stopped me from doing my usual activities 3. I found it embarrassing when the alarm sounded around other people 4. I enjoyed using the app 5. I found it stressful to use the app 6. Did your motivation to respond to the notifications decrease during the weeks? 7. How tiring was it to take part in this study? 8. Did the questionnaire become boring during the day? 9. Did you get irritation while filling in the questionnaire? Ease of use 1. The questionnaires on the phone were easy to complete/ 2. At times I had to rush to complete the questionnaire on the phone on time 3. I found it easy to remember to carry the phone with me during the time of the study
How much time did you spend with your baby yesterday?	1. Most or all of the day 2. About half of the day 3. Less than half of the day 4. Evening and night only 5. None 6. Other a. For "how much time did you spend with your baby yesterday" you selected other. Please write in your response below.
Prior night sleep[28]	1. How well did your baby sleep last night (0 = poor to 7 = excellent) 2. How well did you sleep last night [0 = poor to 7 = excellent]
Mastery-Parenting[29]	1. Yesterday, I was good at feeding my baby a. Strongly disagree b. Disagree c. Agree d. Strongly agree 2. Yesterday, I was good at soothing my baby when they became upset a. Strongly disagree b. Disagree c. Agree d. Strongly agree 3. Yesterday, I was good at reading my baby's cues a. Strongly disagree b. Disagree c. Agree d. Strongly agree 4. Yesterday, my baby responded well to me a. Strongly disagree b. Disagree c. Agree d. Strongly agree
Baby fussiness[30]	1. Yesterday, how easy or difficult was it for you to calm or soothe your baby when they were upset? [1 to 7: 1 = very easy; 7 = difficult]. 2. Yesterday, how much did your baby cry and fuss in general? [1 to 7: 1 = very little/much less than the average baby; 7 = a lot/much more than the average baby]
Social support[31]	How often was support available to you when you needed it yesterday? a. None of the time b. Little of the time c. Some of the time d. Most of the time
Drinking	1. Did you consume any alcohol yesterday? Yes/no 2. If yes, how many drinks did you consume? 3. If yes, select all time periods when you drank yesterday [morning, lunchtime, afternoon, evening, during the night]
Alcohol motivations[18]	If you drank yesterday, why did you drink: 1. Because it makes social gatherings more fun 2. To forget about your problems 3. Because it gives you a pleasant feeling 4. To be liked
Mastery-Drinking	1. How strong was your urge to drink yesterday? 1= very low, 7=very high

	Look at this in relation to actual drinking. 2. To what extent did you feel that you overcame your urge to drink yesterday? 1=not at all, 7= to a very great extent
Drinking cues[32]	1. Was alcohol available to you yesterday (yes/no) 2. Were other people in your household drinking yesterday (yes/no)
Discrimination	1. At any time yesterday did you feel that you were treated unfairly? (yes/no) 2. What was the main reason(s) for the unfair treatment that you experienced yesterday? (check all that apply) a. Your age b. Your gender c. Your race d. Your ethnicity or nationality e. Your religion f. Your height or weight g. Some other aspect of your appearance h. A physical disability i. Your sexual orientation j. Your drinking k. Your smoking l. Your other substance use m. Being poor n. Being a mother o. Other i. For "What was the main reason(s) for the unfair treatment that you experienced yesterday?" you selected other. Please write your response below: 3. Who treated you unfairly yesterday? (check all that apply) a. Family member b. Partner c. Stranger d. Acquaintance e. Employer f. Health care provider g. Other social service provider h. Other ____ i. For "Who treated you unfairly yesterday?" you selected other. Please write in your response below:

Decision Point/Daily EMA
[sent 2x daily]

Construct	Items
	1. Were you with your baby since the last survey you completed? Yes/no [IF NO: Skip Baby Fussiness] 2. Will you be with your baby in the next hour? Yes/no [IF NO: Skip Maternal SE]
Maternal SE	How confident are you that you will be able to meet your baby's needs (such as needs to be fed, changed, soothed, or entertained) over the next hour? [Not at all confident to extremely confident 1-7]
Drinking SE[33]	How confident are you that you can avoid drinking for the next hour? [1 = not at all confident to 7 = extremely confident]
Stress[34]	Rate your overall stress level right now 1-7, very low to very high.
Mood	1. What is your overall feeling right now [very unpleasant to very pleasant 1-7] 2. What is your overall energy level right now [very low to very high 1-7] 3. What is your anxiety level right now [very low to very high 1-7]
Fatigue[16]	1. How physically exhausted are you right now? 2. How mentally exhausted are you right now? [not at all to extremely 1 -7]
Baby Fussiness[35]	1. Since your last assessment, how many times did your baby fuss, cry, or seem upset? [0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more times] 2. How many of these times were you able to successfully soothe your baby? [all of them, most of them, some of them, a few of them, none of them]
Intent to Drink[33]	How committed are you to not drink in the next hour? [1 = not at all to 7 = extremely]
Urge to Drink	How strong is your urge to drink right now? 1= very low, 7=very high

Drinking	4. Did you consume any alcohol in the past hour? Yes/no 5. If yes, how many drinks did you consume?

Proximal Outcome EMA

Construct	Items
Maternal SE	How confident are you that you will be able to meet your baby's needs (such as needs to be fed, changed, soothed, or entertained) over the next hour? [Not at all confident to extremely confident 1-7]
Drinking SE[33]	How confident are you that you can avoid drinking for the next hour? [1 = not at all confident to 7 = extremely confident]
Intent to Drink[33]	How committed are you to not drink in the next hour? [1 = not at all to 7 = extremely]
Urge to Drink	How strong is your urge to drink right now? 1= very low, 7=very high
Drinking	6. Did you consume any alcohol since the last survey you received? Yes/no 7. If yes, how many drinks did you consume?
Stress coping	1. Since the last survey you completed, did you use any strategies to cope with negative feelings or stress? a. I didn't experience negative feelings or stress since the last survey b. I drank alcohol c. I changed my thinking d. I changed my current situation to cope with negative feelings or stress e. I found something else to do f. I sought advice or support g. I came up with a plan to cope with negative feelings or stress h. I set a goal or kept track of my progress towards my goal i. I directly communicated my needs to others j. I tried to relax k. I took medication l. I pushed negative feelings or stress away m. I used another strategy n. I didn't use any strategies to cope with negative feelings or stress 2. In the previous question you indicated that you took medication to cope with negative feelings or stress. Was this medication intended for the purpose of managing negative feelings or stress/for the purpose of managing alcohol cravings? a. Yes b. No 3. Was this medication prescribed to you by your healthcare provider? a. Yes b. no 8. You selected "I used another strategy to cope with stress". Please describe what you did below:
Drink Coping	1. Since the last survey you completed, did you use any strategies to manage the urge to drink alcohol? a. I didn't experience an urge to drink alcohol since the last survey b. I changed my thinking c. I changed my current situation to cope with negative feelings or stress d. I found something else to do e. I sought advice or support f. I came up with a plan to cope with negative feelings or stress g. I set a goal or kept track of my progress towards my goal h. I directly communicated my needs to others i. I tried to relax j. I made an effort to stay safe and avoid risks while drinking alcohol k. I took medication l. I pushed negative feelings or stress away m. I used another strategy n. I didn't use any strategies to cope with negative feelings or stress 2. In the previous question you indicated that you took medication to cope with the urge to drink alcohol. Was this medication intended for the purpose of managing negative feelings or stress/for the purpose of managing alcohol cravings? a. Yes

	b. No 3. Was this medication prescribed to you by your healthcare provider? a. Yes b. No You selected "I used another strategy to cope with the urge to drink alcohol". Please describe what you did below:

MRT Data Analysis

Given that this is a pilot MRT and not powered to detect statistically significant effects, our primary focus in interpretation of findings is to assess feasibility of this design for a future fully-powered optimization trial. Feasibility analysis will include: (1) Recruitment Feasibility: We will evaluate length of time to recruit 50 MRT participants and demographic and clinical characteristics of those who enroll vs. those who decline enrollment; (2) Engagement Feasibility: We will examine paradata collected automatically by the TMI platform, including number of EMAs responded to, number of messages viewed, and number of days of engagement; (3) Retention Feasibility: We will track retention rates and predictors of retention using logistic regression analyses. We will follow the general recommendations of Klasnja and colleagues for analysis of MRT data to inform JITAI[36] optimization. Multilevel mixed effects models will be the primary analytic approach, and will account for nesting of observations within participant[37]. To test main effects of TMI components on the proximal outcomes, we will first examine models that include only the intercept and a term for the TMI component. The coefficient associated with TMI component represents the mean difference in proximal outcome between person times when the component is delivered and person times when it is not delivered, averaged across the study period. We will compute the standardized effect size for all main effects following the recommendations of Luers et al[1].

PARTICIPANT INCENTIVES

Study participants will receive incentives to participate in the study. Incentives will be received in the form of gift cards to Amazon. Incentives will be provided for completion of the Aim 3 baseline assessment and Catalyst training, and the Aim 3 follow-up survey and qualitative interview. Reimbursement for the Aim 3 baseline assessment and Catalyst training will be provided upon completion of the Catalyst training. Reimbursement for the Aim 3 EMAs (as part of the MRT) will be provided at the end of the four-week testing period of the TMI, and reimbursement for the follow-up survey and qualitative interview will be provided upon completion of each survey. Gift cards will be provided via email or text. Participants who withdraw from the study prematurely will receive reimbursement for all study components they completed. Participants will receive $25 for completing the baseline and training, $25 for the follow-up, and $25 for the qualitative survey. Participants will receive $0.50 for each EMA survey they complete, plus a $20 bonus for completing 50% of surveys and a $30 bonus for completing 80% of surveys.The bonus incentives for completing 50% and 80% of required EMA surveys are used routinely in EMA studies to boost compliance, and have been used in EMA studies with postpartum women (for example: [38]), and are not thought to be coercive given the relative low amount of money provided. Johannes Thrul (study Co-I) has used these methods in prior studies of young adult smokers, with bonus incentive rates up to $60 (see [22,32,39]. Due to an increase in fraudulent participants, we have added language to the consent form that states that participants who are determined to have entered the study fraudulently will not be compensated and will be unenrolled from the study.

RISKS AND BENEFITS

Potential Risks for Participants

This study presents no greater than minimal risk to participants. Potential risks for study participants include risks associated with assessment questions, general risks associated with confidentiality, mandated reporting of child abuse and neglect, and specific risks associated with the use of cell phones to deliver an intervention for risky drinking. Each of these risks is described in the following sections.

Assessment Risks. There is some risk that participants will feel uncomfortable answering questions about drinking and other sensitive topics in the EMA as well as the baseline and follow-up assessments. No side effects have been noted in the literature in association with any of the assessment tools used in this study, although, as with many assessment batteries, some people may experience mild fatigue or momentary concern about their ability to do well. It is unlikely that participants will experience more than minor discomfort. Our past experience with many of the assessment tools to be used in this study indicates that these measures are largely acceptable to participants.

General Confidentiality Risks. Every effort will be made to keep all materials confidential and to protect the identities of participants. While we cannot guarantee absolute confidentiality, we believe that the risk of a confidentiality breach is extremely low for this study. Confidentiality breach may occur related to the data collected if an unauthorized person gains access to the data files and/or a participant's identity is discovered. We will take the following precautions to minimize these risks as much as possible: No identifying information will appear on any data collection survey; all data will be coded by participant ID. All study data will be stored in databases on Partnership to End Addiction's secure server, where all participant records will be coded and filed numerically according to a unique project identification number, with no names attached to the database. A master table linking participants to project ID codes will be kept in a separate secure file, with access restricted only to those members of the research team who require client contact information for the purposes of tracking and follow-up. For extra security, this file will be password-protected. Follow-up contacts will be made by project staff under explicit guidelines that preserve confidentiality when telephoning or emailing information to participants. Only the PI and RAs who recruit or follow the participants will have access to identifying information. Recordings of focus groups will be audio-only. These recordings will be stored on Partnership's secure server, labeled only by Study ID. However, it is possible that due to the small sample size, an individual's voice may be recognizable on the recording. Recordings will only be listened to by authorized study staff who will be required to keep all aspects of the recording confidential. An additional confidentiality risk is possible within the focus groups. It is possible that a focus group participant may break the confidentiality of the group. We will make every effort to prevent this from happening by respectfully requesting that all focus group participants keep the information discussed private.

Mandated Reporting. There is some risk in this study that investigators may become aware of child abuse or neglect that would necessitate a report to child protective services. Given that the study is being conducted remotely, it is extremely unlikely that information requiring reporting would come to the attention of study staff. However, if study staff becomes aware that a child is in danger of abuse or neglect, a report to CPS would be required. The two ways study staff would become aware of harm to a child are (1) if a participant directly informs staff during a phone contact or focus group, or (2) staff witnesses a child being harmed during an online focus group in which a participant has her camera on. In either of these unlikely scenarios, we will make every effort to inform the family first before making a report to CPS. All project staff at Partnership to End Addiction are required to complete web-based training courses on identifying and reporting child abuse and neglect. These procedures have been followed in our two prior studies of pregnant and postpartum women in New Jersey home visiting programs.

Risks Associated with Cell Phone Based EMA and Intervention Delivery. There is some risk of a breach of confidentiality concerning risky drinking behavior. It is possible that since participants will be receiving messages on their personal cell phones, another person may view a message specific to changing alcohol use from an unguarded phone. Messaging also holds the potential to trigger individuals who may use avoidant tactics to reduce alcohol use. In a prior study done by the Co-I (Muench) that was focused on developing a TMI for problem drinking, 12% reported being a little bit triggered by the messages, but only one person reported being extremely triggered by the messages. In that study, being triggered by messages had no impact on drinking outcomes and was not significantly negatively correlated with messages helping to reduce cravings. This suggests that a small number of people may be triggered by the messages, but they are able to control resulting cravings without drinking. Additionally, while unlikely, it is possible that there may be a breach of confidentiality if a participant's cell phone number is obtained through the computerized database. There is a risk that a participant may receive a text message while driving, or in another situation in which reading or responding to a text message would be dangerous. To minimize the risk of participants reading or responding to text messages while driving or in otherwise dangerous situations, we will include in the baseline EMA and TMI training session information about risks associated with texting while driving and other situations in which texting would be dangerous. We will also develop a Training Guide for participants that will include information on the dangers of texting while driving. In every contact that study personnel has with participants (scheduling assessments, conducting baseline and follow-up assessments, troubleshooting EMA), we will ensure that participants are reminded that they should not read or respond to any text message while driving or in any other situation in which it would be dangerous to do so. Two additional risks associated with cell phone based intervention delivery include data use overage and text message security. Participants who do not have an unlimited text messaging plan may be charged for the text messages they send and receive in the study. As with any mobile phone, there is a risk that messages might be read by other people. We will ensure that

participants are fully aware of these risks before deciding whether to enroll in the study. There is also always the risk of technical difficulties resulting in failure to receive or send messages.

Risks to Infants. If study participants are engaging in hazardous drinking and/or breastfeeding while drinking, their infant children may be at risk. To mitigate this risk, we will take the following steps, based on prior text-messaging research studies with high-risk populations. First, we will use the baseline training session to educate study participants on the risks associated with drinking and breastfeeding. The TMI will also include messages providing psychoeducation regarding the risks of drinking while breastfeeding.. At the beginning of the study, we will provide participants with a list of local treatment providers and support groups that they can access if they choose to. Drinking while breastfeeding is not reportable as child abuse.

Potential Study Benefits

Study participants may or may not benefit directly from participating in this study. It is possible that some participants may benefit from the supportive text messages they will receive because they may find the messages to be supportive and helpful. The primary benefit of the study will be in terms of the knowledge gained and the potential for improving reach to postpartum women who struggle with alcohol, an important and currently underserved group. The knowledge gained as a result of this study will be invaluable to future efforts to provide interventions directly to postpartum women to address risky drinking and other negative health behaviors. Postpartum women are a currently underserved population at high risk for negative consequences of drinking and are unlikely to be reached by the formal service system. Text messaging represents a potential low cost and low burden approach for reaching this population, with potential large impact in terms of reach and scalability. The risks to study participants are reasonable in relation to anticipated benefits. Procedures have been developed and will be in place throughout the study to minimize these risks to the greatest degree possible. These procedures have been successful in preventing risk in past studies using similar procedures.

PROTECTIONS AGAINST RISK

General Protections Against Study Risks

If the baseline assessment indicates very severe substance use or psychiatric problems that would not be adequately served by the TMI provided as part of the proposed study, the participant will be referred to local inpatient or outpatient treatment providers or to another appropriate care facility. We will develop an information sheet with information on local treatment providers and support groups and provide this to participants at the beginning of the study, and again at the baseline assessment if the baseline assessment reveals substance use or psychiatric problems at the level that would not be adequately served by the TMI provided in the study. Risks to infants, such as risks associated with drinking while breastfeeding, will be addressed through provision of psychoeducational information to participants during the baseline training session, as well as regularly throughout the intervention period via text message.

The issues surrounding confidentiality are of supreme importance and sensitivity because highly personal clinical information will be obtained from participants. Participants will sign a statement that attests to their understanding that the information they provide will be held as confidential to the extent permitted by law. Consent forms will clearly state the right to refuse participation or to withdraw at any time.

In order to address any concerns regarding coercion, clients will be informed that they are free to choose not to participate and may withdraw at any time (this is included in the consent form). In addition, the reimbursement rates of $25 per interview and $0.50 per EMA are moderate amounts that are appropriate for the time investment and not considered coercive. Individuals who are hesitant to consent or express the desire to withdraw will not be offered additional financial incentives to continue.

Protection Against Risks Associated with Cell Phone Based EMA and Intervention Delivery

All text messaging for the purposes of participant tracking will occur though Partnership to End Addiction's JITAI Master Platform, which has been used in studies by Columbia University, NYU, Northwell Health and the American Cancer Society, and all EMA data collection will occur through Metricwire's Catalyst app.

Partnership's Platform: The Platform uses an Internet Information Server (IIS) structure to authenticate and assign the proper groupings to the logins. At no point does the program ask clients for their name or contact information, other than phone number and email. The Platform Data Services and Web Application are

hosted in Amazon Web Services (AWS) in AWS HIPAA-compliant services. Industry-standard application architecture guidelines and principles are best practices including features such as: Route53-highly available and scalable cloud Domain Name System (DNS) web service, Elastic Beanstalk, Multi-AZ Remote Database Service, Guard duty – continuous security monitoring service that analyzes and processes the following data sources: VPC Flow Logs, AWS CloudTrail event logs, and DNS logs, and Inspector service that enables you to analyze the behavior of your AWS resources and helps you identify potential security issues. In addition, the platform includes best practices in HIPAA-compliant authentication and security (e.g., password restrictions, 2-factor authentication, role based security, and audit logging and reporting).

Participants will be informed of the risks of using their cell phone for research purposes, and informed that it is their responsibility to secure their phone at all times. They will be told that they can delete text messages after reading (and responding when necessary). They will also be reminded that while our databases are secure, all email and SMS communication is as secure as any other email or SMS message they may receive. We will reinforce this risk during recruitment and the consent process, and during the baseline training session.

When a participant enters his/her phone number in the Platform, a unique data identifier will be created automatically. A separate database reference system will be created. All electronic files (e.g., database, spreadsheet, etc) containing identifiable participant information are password protected and restricted only to key study personnel who need access to this information for the purposes of tracking participants through the study. All computers hosting such files have a BIOS password to prevent access by unauthorized users. Research staff will have a secure login to access study data.

Metricwire: We will take precautions to ensure that participants are aware of steps they can take to protect their privacy and include a number of built-in features to protect privacy while using the Catalyst app. Specifically, we will include the following features in EMA and TMI to protect participant security and privacy when using the smartphone app:

(1) Participants will be provided information about ways to protect their privacy when using their smartphone. We will send a message that contains a link to a webpage with information about security steps participants can take to protect their privacy (http://www.techlicious.com/tip/9-ways-to-secure-your-smartphone/). Steps may include setting a password to protect from others accessing their device and not using the app while connected to an unsecured wireless network. We will encourage participants to secure their entire smartphone with the built-in “screen lock.” This can use a variety of identification mechanisms (password, face recognition, or fingerprint) that the participant determines is most convenient. Generally, we will encourage participants to use the lock/password features, but we will not require it because it may act as a barrier to using the app (e.g., if participants forget their password or find it frustrating to enter their password each time they want to open the app).

(2) We will not retain data on participants’ smartphones. Rather, data will be stored on the Metric Wire secure server, which is backed up on a continual basis. Data will be downloaded daily by the study team and stored on Partnership’s secure server. Data on participants’ smartphones will be deleted within several minutes after the information is captured to the server database.

(3) All data will be transmitted directly between participants’ devices and the server. Transmissions will be encrypted and will not contain any personally identifiable meta-data.

(4) At the beginning of the study, we will require all participants to “register” their phone (i.e., verify their credentials) to download the app and sync with the protected server. This will be a one-time event, but will ensure that only participants who pass the inclusion criteria and enroll in the study have access to the app.

(5) Participants do not have the ability to see their data once it is submitted to the Metricwire secure server. For participant generated data, the EMA application interface functions in one direction only. This helps ensure that the participants’ submitted data remains secure even if the device is lost of stolen. In addition, Metricwire has the capability to prevent the participants’ version of the EMA application from connecting to the secure server in the event the phone is lost or stolen.

All data collected using the Metricwire app is property of Partnership to end Addiction, and the agreement with the vendor explicitly specifies this.

CONFIDENTIALITY

Regarding assessment data and other records, Partnership to End Addiction study investigators have an established set of procedures designed to ensure the confidentiality of study data. All staff at Partnership who participate in research with human subjects is required to complete CITI online training on the protection of human subjects, including confidentiality. Additionally, research staff will be trained on and strictly monitored for adherence to federal guidelines for maintaining the privacy and confidentiality of participants throughout the study. All assessment data will be collected via a computer administration platform. No identifying information will appear on any data collection survey; all data will be coded by participant ID. All study data will be stored in databases on Partnership to End Addiction's secure server, where all participant records will be coded and filed numerically according to a unique project identification number, with no names attached to the database. All study databases will be stored in a secure folder on Partnership's network, with access restricted only to the members of the research team. A master table linking participants to project ID codes will be kept in a separate secure file, with access restricted only to those members of the research team who require client contact information for the purposes of tracking and follow-up. For extra security, this file will be password-protected. Follow-up contacts will be made by project staff under explicit guidelines that preserve confidentiality when telephoning or emailing information to participants. Only the PI and RAs who recruit or follow the participants will have access to identifying information.

We will obtain a Certificate of Confidentiality (COC) from NIH to provide an extra layer of protection to all data collected in conjunction with the proposed study. NIH routinely issues COCs to protect research information provided by study participants from compulsory legal demands such as subpoenas for identifying information. The COC can be used to avoid forced disclosures of information collected in the context of a research study and would thus protect against court subpoena of research data.

PROCEDURES FOR OBTAINING INFORMED CONSENT

Informed consent will be obtained online, via a secure Qualtrics form. Participants can complete informed consent either fully online, or via phone with the study RA. Procedures for both options are described below.

Informed Consent by Phone with Study RA: Study participants will be recruited from Central Intake or social media (Facebook, Instagram, Reddit, NextDoor, BabyCenter) during the last trimester of pregnancy. For clients recruited from Central Intake, Central Intake (CI) providers will briefly introduce the study to potentially eligible clients using a script provided by the study team. If a client is interested, the CI provider will ask for permission to provide her contact information and due date to the study team. Within two weeks of the due date, the RA will contact interested clients by phone to screen for eligibility, describe the study, and obtain informed consent. Eligibility screening will include administration of the T-ACE alcohol risk screener with supplementary questions. At the end of eligibility screening, if the participant is eligible, the RA will ask the participant if they are interested in enrolling in the study. If the answer is yes, the RA will send the participant a link to the secure Qualtrics informed consent form via email or text (whatever the participant prefers). The RA will allow them a few minutes to read it, and then review the main points in each section and answer any questions the participant has. The confidentiality that surrounds research studies will be discussed with clients, explaining that confidentiality is assured to the extent permitted by law. This means that the information they provide is confidential, except for the case of potential abuse of a child, or danger to their lives or the lives of others. Given the remote nature of the study, it is extremely unlikely that study staff would become aware of any information that would necessitate breaking confidentiality, such as child abuse or danger to themselves or others. The only way we would become aware of child abuse or neglect is if (1) a participant tells us directly during a phone contact or focus group, or (2) we witness a child being harmed during a zoom focus group in which a participant has their video camera on. Reports of drinking behaviors do not automatically rise to the level of child abuse reporting. Participants will also be informed about the protections afforded by the Certificate of Confidentiality. Participants will be informed that information collected from the EMA, TMI, focus groups, and baseline follow-up assessments will be used only for research purposes and reported in aggregate form (i.e., the confidentiality of individuals will be maintained). Following review of the consent form, the RA will ask if the participant has any questions. If the participant would like to provide consent to enroll in the study, the RA will ask them to complete the questions in the Qualtrics form that assess understanding of the consent form and then click the box labeled "I consent to enroll in the study" to enroll. Participants who are recruited

from social media will also be provided the option to connect with the study RA via phone to complete eligibility screening and informed consent. For participants who select this option, the steps detailed above will be followed.

Informed Consent Online: Participants who click on a social media ad will be directed to the study website, where they will view information about the study and will be prompted to click on a link to complete eligibility screening. Clicking on the link will take them to a secure Qualtrics survey that contains the eligibility screening questions. After answering the questions, eligible participants will be presented with an electronic consent form, in a secure Qualtrics form. The form will provide the name of the PI (Dr. Dauber) and her contact information and inform respondents that she, as the PI, has IRB approval to conduct the study. The consent form will contain a thorough description of the research project, including the procedures involved, the risks and benefits, compensation, the right to non-participation, and the Research Subject's Bill of Rights. All information described above regarding confidentiality and mandated reporting will be included in the consent form. At the beginning of the consent Qualtrics form, there will be a link to a video that participants must view in order to complete the consent process. In the video, the study RA will review the consent form the same way they do with participants who complete the consent process via phone. To assess understanding of the information provided in the informed consent, eligible participants will be asked a series of multiple-choice questions regarding the informed consent before being able to proceed with the study. Answers will be collected and any wrong answer will result in the potential participant being prompted to review the full consent document before attempting the consent questions again. Potential participants will not be enrolled in the study if they answer the questions incorrectly four times. After completing the questions correctly, participants will be asked to check a box to indicate whether they would like to enroll in the study. Participants who enroll will be prompted to enter their first name and cell phone number into the secure Qualtrics form to allow the study RA to contact them for the Baseline Assessment and EMA training. At any time during the online consent process, participants will have the option to text "BABY" to the study number to contact the study RA to ask questions and/or to complete the consent process via phone.

DATA SHARING

As an NIAAA-funded study, this study is bound by the requirement that all NIAAA-funded human subjects research studies participate in the NIAAA Data Archive. The purpose of the Data Archive is to promote data sharing across the scientific community. NIAAA requires that certain language be included in the informed consent forms to allow participants to make an informed decision about whether they agree to include their data in the Data Archive. Participants who do not agree to have their data included in the Data Archive can still participate in the study. Participants who initially agree to have their data included have the right to change their minds at any time during the study, as stipulated in the consent form. However, once a participant's data is part of the $NIAAA_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that the participant changed their mind.

Participant information that is entered into the Data Archive is coded according to a "Global Unique Identifier" or "GUID." According to the NIAAA Data Archive, the GUID is a subject ID that allows for the linking of data from a unique individual across multiple studies, but does not expose any personally identifying information. The GUID is generated based on the following information: full name at birth, sex, date of birth, city of birth. All of this information is collected by the research team, who uses the NIAAA GUID Tool to create the GUID. The participant's study data is then submitted to the Data Archive along with the GUID. No identifying information about any study participant is submitted to the Data Archive at any time.

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