STUDY PROTOCOL

Social Behavioral Template

Piloting a novel social support intervention for addiction recovery

Protocol Number

2000035434

Protocol Version

7/23/24

10

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Confidentiality Statement:

Synopsis

Purpose

The purpose of this study is to pilot a novel web-based intervention to help people who engage in hazardous drinking cut down or quit drinking. This intervention will be implemented through Qualtrics, where each night, participants (referred to as “support-receivers”) will access a Qualtrics link containing brief written and video encouragement and information generated by people in addiction recovery communities ("support-providers”). The intervention is designed to help the user maintain motivation to not drink in the short-run, and build connections with addiction recovery communities to sustain their recovery in the long-run.

Objectives

This study will first determine feasibility and acceptability of inviting addiction recovery communities to be support-providers and creating content for this intervention. Second, it will determine feasibility and acceptability of individuals who engage in hazardous drinking using this intervention (aka support-receivers), and determine preliminary efficacy of this intervention on alcohol use and engagement in recovery support services. Third, it will correlate characteristics of content created by support-providers with support-receivers’ ratings of the content to identify which characteristics are well-received by support-receivers, to guide future content creation.

Study Population

The target support-providers are individuals who are involved in addiction recovery community (e.g., support group meeting facilitators, volunteers at recovery community centers) or are allies of the addiction recovery community. The target support-receivers are adults who engage in hazardous drinking and live in Connecticut.

Number of Participants

We will recruit up to 50 support-providers, and up to 30 support-receivers to use the intervention. This sample size is appropriate for a pilot study. We will recruit a subset of these participants (10 support-providers and 10 support-receivers) to participate in a follow-up qualitative interview.

Study Design

This is a study to develop and test an intervention that comprises three parts: 1) We will invite individuals (support-providers) to provide video and written content for the intervention. 2) We will recruit participants who engage in hazardous drinking to be support-receivers and use the online intervention daily for a month; they will also fill in questionnaires about their substance use and engagement with recovery support services at the beginning and end of the study to determine preliminary efficacy. 3) We will then administer qualitative interviews to both support-providers and support-receivers to gain insight into intervention's feasibility and acceptability, and to identify ways to improve the intervention.

Study Duration

It will take support-providers about 30 minutes to complete their portion of this study. Support-receivers will complete questionnaires prior to using the intervention (no longer than 1 hour to complete), then use the intervention for a few minutes each night for one month, and then complete follow-up questionnaires (no longer than 30 minutes to complete) at end of intervention use and one month after the end of intervention use. Both support-providers and support-receivers can take part in an optional qualitative interview after, which will take no more than 30 minutes. Data collection will likely last 1-2 years.

Outcome Variables

We will collect data on recruitment and attrition rates of support-providers and support-receivers to determine feasibility. To determine acceptability, we will collect quantitative data on how often support-receivers engaged with the intervention throughout the month, and qualitative data to obtain participants' views and experiences of the intervention, including barriers and facilitators of use. Preliminary efficacy will be assessed using questionnaire measures of substance use and engagement in recovery support services administered at the start and end of the intervention. We will also characterize the video content created by support-providers and correlate them with support-receivers' ratings of the content, to identify which characteristics are well-received by support-receivers, to guide future content creation.

Locations/Facilities

This entire study will be conducted online. Support-providers will utilize Qualtrics for their portion of the study. Support-receivers will meet with a member of the study team at the beginning via Zoom or phone call, consent via REDCap, and all subsequent activities will occur via Qualtrics. Qualitative interviews will occur over Zoom.

Abbreviations

Abbreviation	Explanation
ARC	Addiction recovery community
AUD	Alcohol use disorder
QI	Qualitative Interviews

Glossary of Terms

Glossary	Explanation
Support-providers (SPs)	These are adults who are from or are allies of the addiction recovery community who will upload videos/content for the intervention.
Support-receivers (SRs)	These are study participants who are adults who currently engage in hazardous drinking, who will use the intervention.
Let's Do Addiction Recovery Together (LDART)	Tentative name for the intervention.

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Protocol Revision History

Version Date	Summary of Substantial Changes
V2 6/30/23	As per IRB feedback, SPs are no longer considered human subjects in this study, and all such references have been removed.
V3 7/14/23	In order to be able to analyze the videos from SPs, SPs will be considered human subjects.
V4 11/27/23	Included study phone as an option for conducting visit 1 remotely, changed a questionnaire to short-form version, rearranged when participants would do which questionnaire, included NCT#.
V5 1/2/24	SPs no longer will be compensated for recording videos. Additional questionnaire added for SR to complete at 3 time points. SRs will be given the option to receive a progress report at the end of the study.
V6 1/23/24	Included measures to screen out scammers posing as potential SR participants, option to provide people who do not meet eligibility criteria with a resource sheet, expanding SR recruitment to CT more broadly
V7 1/25/24	Additional measure added to screen out scammers: potential SR participant will be asked to show some form of ID during the zoom visit to verify their identity. This ID will be visually verified by the study team during the zoom visit and will not be recorded or saved.
V8 1/31/24	Disclaimer to be included during Zoom visit 1 with SRs to state that LDART is not an established form of addiction treatment and if emergencies arise during the study to seek medical care and/or contact 911. Option for SRs to leave comments on videos. Additional analyses to be performed on SP videos and SR rating data.
V9 2/22/24	In-person recruitment method added.
V10 7/23/24	SP compensation increased, SP video collection re-opened.

1 Background

1.1 Background

The impact of addiction on societies worldwide has been devastating and costly[1]. Existing pharmacological[2] and psychological[3,4] interventions can be efficacious, but their efficacy is sometimes negated if deficits in social determinants of health are not concurrently addressed[5-7]. Indeed, studies have found that social support, especially recovery-oriented support networks, is a consistent predictor of addiction recovery[8-12]. This is particularly true during the first few months of recovery, where relapse rates range from 20-85%[13,14]. Connecting individuals in early recovery to resources in the addiction recovery community (ARC), such as support group meetings and recovery community centers, is thus crucial for sustaining addiction recovery[15-17].

Despite its importance, accruing social support can be a difficult process for at least two reasons. First, finding and accessing recovery support services can be challenging due to individual factors (e.g., lack of motivation, anxiety about meeting strangers) and structural factors (e.g., lack of comprehensive lists of recovery resources). Second, because this process is time- and effort-consuming, it requires one to prioritize the long-term benefits of recovery over the short-term benefits of substance use[18,19] -- an ability that is often compromised in individuals with substance use disorders[20]. Thus it is important to keep individuals motivated during this process, for example by having immediate, salient rewards when one reaches their recovery goals. These two barriers can be overcome using a combination of community reinforcement approach[21] and contingency management[22], respectively. Although this is a highly effective treatment approach[23], few clinicians are trained in the former, few treatment centers implement the latter[24], and both require individuals to be already engaged in formal treatment in order to gain access to these specialized treatments.

We propose a novel social support intervention that circumvents all of these barriers, tentatively called *Let's Do Addiction Recovery Together* (*LDART*). Individuals in early recovery will receive a short pre-recorded video every night for a month, contingent on them meeting their recovery goal for the day (e.g., not drinking, attending a support group meeting). These videos, generated by members of the local ARC, have two purposes: 1) to congratulate and motivate the recoveree on their recovery journey (in an acutely rewarding way, not unlike monetary rewards in contingency management); 2) to introduce and "put a face and a voice" to local recovery support services, thereby reducing informational and psychological barriers to engagement. If the daily recovery goal is not met, they will receive written words of encouragement and information on a recovery support service, albeit in a less engaging and rewarding format. Given that many in early recovery feel socially isolated[25], we hypothesize that these videos will be a potent social reward and motivator for reaching one's recovery goals, such as reducing substance use and increasing social support.

1.2 Prior Experience (if applicable)

Both the PI (McCurdy) and faculty advisor (Potenza) have some experience in developing interventions (mHealth apps) and conducting qualitative individuals with adults who engage in addictive behavior. Potenza has also been PI on multiple grants involving clinical trials for addiction treatment.

2 Rationale/Significance

2.1 Rationale and Study Significance

As mentioned above, getting individuals in early recovery from hazardous alcohol use to stay motivated in their recovery can be challenging for a number of reasons, and effective ways of doing this (e.g., contingency management, community reinforcement approach) are often difficult to access. There is thus a need for low cost and easily accessible interventions to keep individuals motivated throughout their recovery. This pilot study will assess feasibility, acceptability, and preliminary efficacy of a novel social support intervention that remotely delivers social reinforcements (vis-à-vis videos of support from the ARC) contingent on reaching individualized recovery goals to individuals in early recovery from alcohol use. The long-term goal of this intervention, if proven to be successful, is to be a freely available resource that can run in an automated manner (with the exception of video inspection to ensure appropriate quality and content), and scaled both spatially (videos can be obtained from people beyond state lines) and temporally (with more videos, this intervention can go on for more than one month, thereby further sustaining recovery).

2.2 Risks

Overall, participation in this study is thought to involve minimal risk. There is some risk that there may be breaches of the SPs' confidentiality, in that SRs may find ways to share or broadcast the videos they receive. However, this is unlikely because i) videos will be uploaded, stored, and viewed via Qualtrics, a HIPAA-compliant platform; ii) the option to download the videos will be disabled; iii) SRs will be provided with explicit instructions to not share these videos with others; iv) SRs will be advised to watch these videos from a private space with no one else around; v) most individuals in the ARC are open and explicit about their involvement in such communities, so in the unlikely event that these videos are shared, no confidential information will likely be released; vi) Their videos, when integrated into the intervention, will only be accessible with a valid participant ID and link, which will prevent others from viewing the videos; vii) SPs will be briefed on these potential risks and can make an informed decision about participating.

There may be breaches of SRs' confidentiality. However, this is unlikely as all information they provide will be de-identified (they will access their videos using their subject ID) and through Qualtrics, which is a secure platform. It is possible that they may experience distress when watching these videos, however, these videos will be pre-screened by the study team for quality control. SRs may experience distress when filling in questionnaires and taking part in qualitative interviews. However, these questionnaires contain minimally (if at all) distressing topics, and the topic of qualitative interviews will be entirely on the intervention, so this is an unlikely risk. Additionally, to mitigate this concern, they will be informed that they can skip any questions for any reason, and there will be the option to "prefer not to answer" on every questionnaire question.

2.3 Anticipated Benefits

We anticipate that participation in this study will be beneficial to both SRs and SPs. Participating in a study to develop an intervention that may improve treatment outcomes for others with alcohol use issues may be considered a benefit. For SPs, being able to give back and help others in recovery is a common desire, and this will be a way for them to easily and directly to do. For SRs, They will receive supportive and motivating videos and/or information about recovery support services each night for a month, which may keep them motivated in their recovery as well as decrease barriers to these recovery services.

This study also would provide the first crucial piece of evidence that such an intervention may be helpful for individuals who engage in hazardous alcohol use. This may form the basis of a useful adjunct to addiction treatment.

3 Study Purpose and Objectives

3.1 Purpose

This pilot study will assess feasibility, acceptability, and preliminary efficacy of a novel social support intervention (LDART) that remotely delivers social reinforcements contingent on reaching individualized recovery goals to individuals in early recovery from hazardous alcohol use. The long-term goal of this intervention, if proven to be successful, is to be a freely available resource that can run in a mostly-automated manner, and scaled both spatially and temporally, that may improve alcohol use and quality of life outcomes for individuals who engage in hazardous drinking.

3.2 Hypothesis

H1: Collecting videos of support from the addiction recovery community will be feasible and acceptable.

H2: Recruitment and retention of SRs will be feasible, and SRs will find the intervention to be acceptable.

H3: There will be a reduction in alcohol use and an increase in engagement with recovery support services by SRs post-intervention relative to pre-intervention.

3.3 Objectives

The primary objectives of this study are to determine whether LDART is feasible, acceptable, and efficacious in reducing alcohol use and increasing engagement with recovery support services in adults who engage in hazardous alcohol use.

The secondary objectives are to determine whether video collection is feasible, to identify ways to improve this intervention, and to identify components of the videos recorded by SPs that were well-received by SRs.

4 Study Design

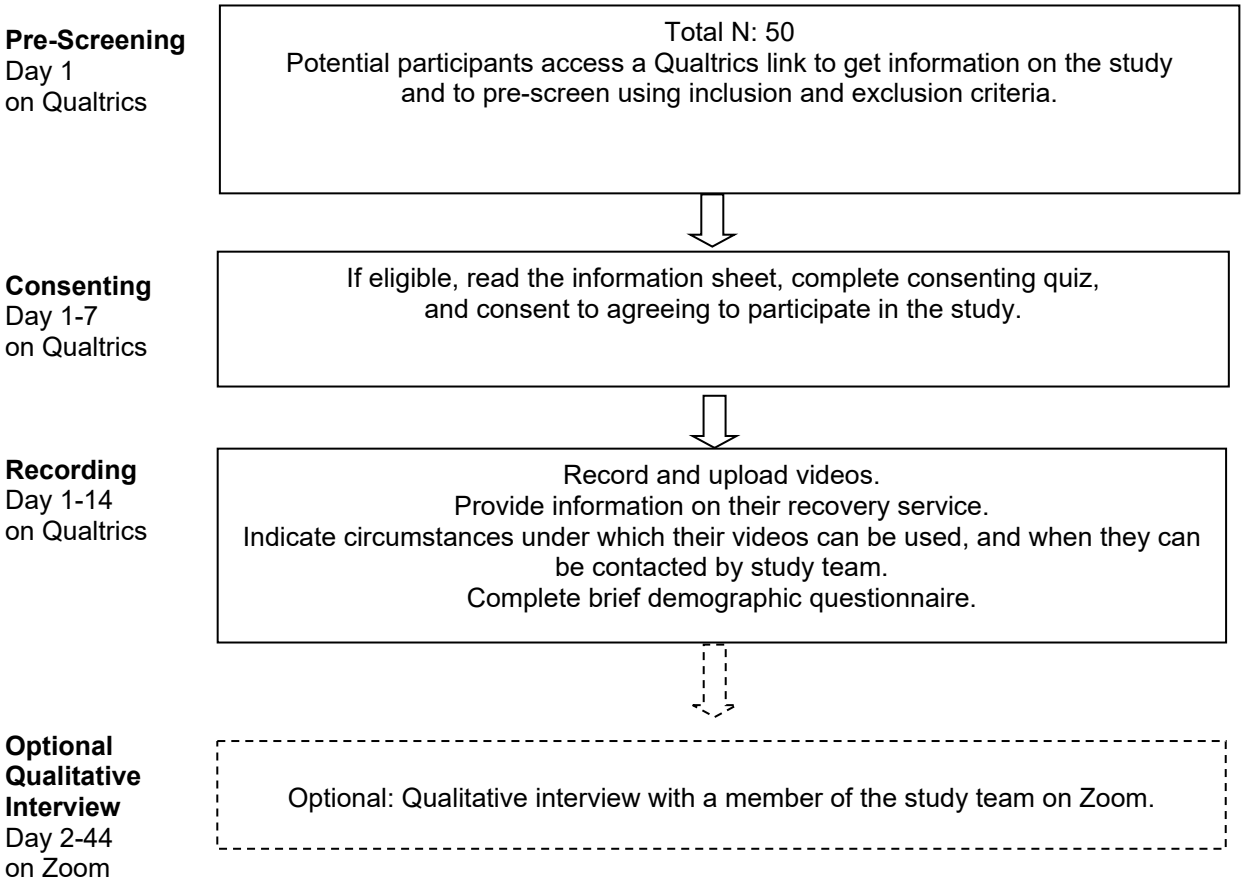
Video collection (SPs): We will recruit up to 50 adults who are involved in or are allies of the addiction recovery community to participate in this study as SPs. This entire process will occur on their own (i.e., without a member of the study team present), but they can email the study team if any questions arise, particularly during the consenting process. Everything they need to do will be on the Qualtrics platform. First, they will be provided information on the study and screened for eligibility. They will then read the information sheet as part of the consenting process and complete a consent quiz. If they agree to participate, they will check a box in Qualtrics indicating so; a copy of the information sheet will be emailed to them. They will also indicate what they consent to regarding how their videos can be used by the study team (e.g., only in this study or in subsequent studies as well, whether they can be shared on the study Twitter page or shown at conferences), and how long they are stored. They will then be guided to record two short videos to motivate people in recovery. The message in this video will be generic (i.e., no SR PHI), as they will have no knowledge of the specific SRs who will view the message. This Qualtrics link will be optimized to work on smartphones, to make it easier to record and upload videos directly from their phone. SPs will be asked to optionally provide their first name, and information on the recovery work they do (e.g., facilitate a support group meeting on Wednesdays at 6pm) and how to access it (e.g., provide the zoom link or physical address of the recovery community center). They will fill in a brief demographic questionnaire which will not be shared with SRs. Finally, they will be asked under what circumstances the study team can contact them (e.g., in the event that their video is selected for use in the intervention, for which they will receive a $40 gift card, and/or in the event that their video is voted as one of the best-rated, so that the team can send them an additional $100 gift card as a prize if they were in the top 3 or $80 if they were 4th or 5th most highly rated.) After our target goal of number of SP videos is collected, we will state on the video-uploading website that we will no longer have financial compensation for uploading videos, but people are still welcome to do so if they desire. For the second round of video-collection, SPs will be compensated with a $50 gift card if their videos is selected for use in the second iteration of LDART.

Pilot intervention (SRs): We will recruit up to 30 adults who engaged in past-year hazardous alcohol use, engaged in heavy alcohol use in the past month, and have some interest in cutting down or quitting drinking, to be SRs in this study. They will be pre-screened by completing a Qualtrics link or a physical copy of the screening document (*SR Study Materials*). If eligible, they will select a day and time for Visit 1. They will also receive an email with more information about the study (*SR Study Materials*). Visit 1 will occur remotely via Zoom or phone call with a member of the study team, and will entail going over the consent document (*SR compound consent*), getting informed consent via REDCap, and filling in some questionnaires about their demographics, substance use, and recovery capital (*SR questionnaires*). This visit should last no longer than an hour, and participants will be compensated $30 for their time.

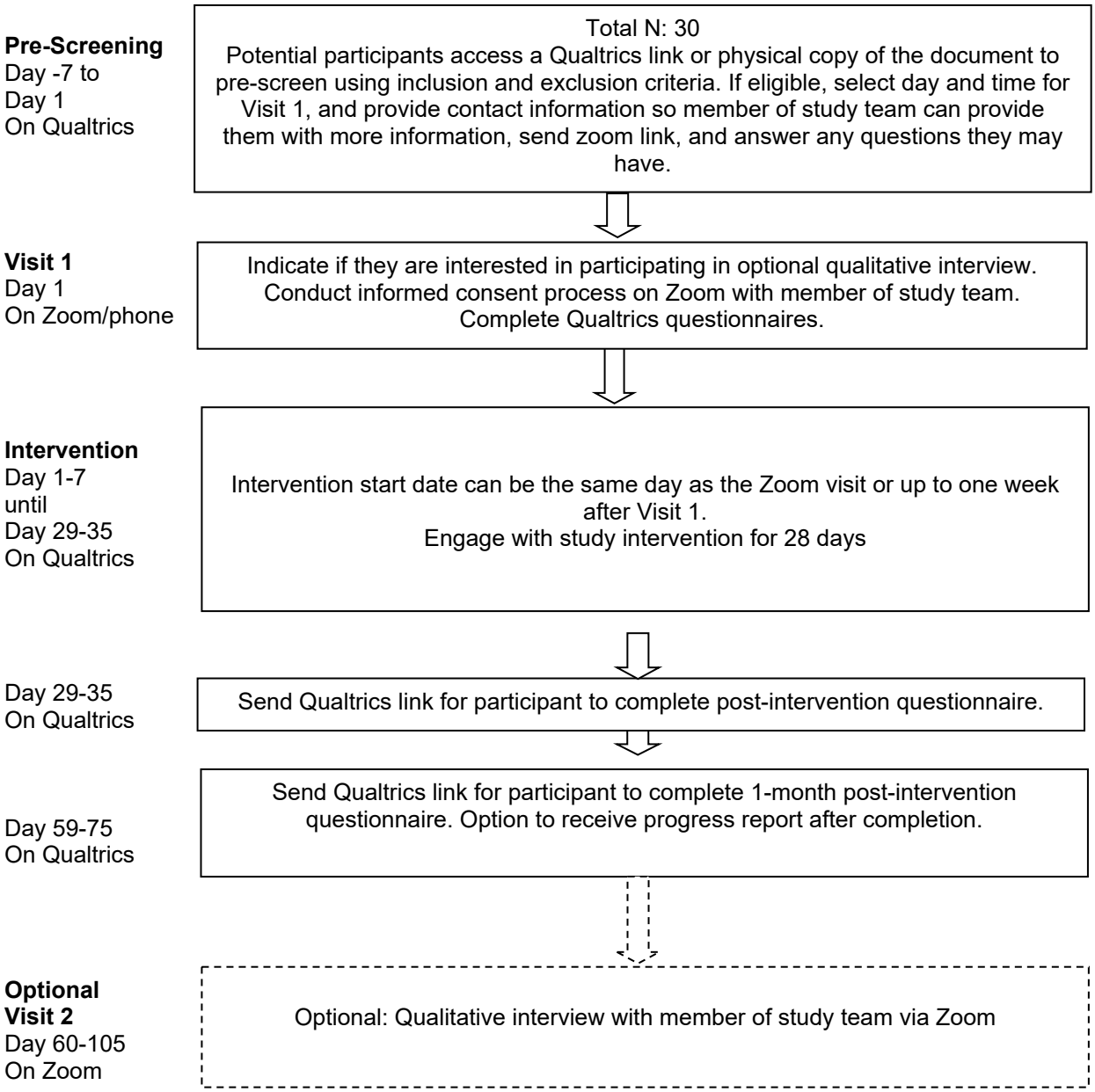
SRs will then receive a reminder email on the day they decide to begin the intervention (*SR Day 0 email; Intervention Materials*), and will receive their first Qualtrics link via email on the night they decide to start participating in the intervention (*Intervention Materials*), each night for a month (*Intervention Materials*). In these links, they will answer whether they met their recovery goal for the day. If they answer yes, a celebratory message from a SP will be shown; if no, an encouraging message from the SP will be shown. Participants will rate on a scale of 0-5 how motivating and supportive they found the message to be with the option of leaving written feedback on the video. Information provided by the SP about the details of the recovery support service they're affiliated with will also be displayed. SRs will then select their recovery goal for the next day (e.g., stay sober, go to a support group meeting). This entire process should take less than 5 minutes to complete each night. They will be compensated a maximum of $30 during this month, depending on how frequently they engage with the intervention; this will be paid as a lump sum at the end of the intervention. On the last day of the intervention, they will complete a few additional questionnaires on the Qualtrics link (*Intervention Materials*). This should take less than 30 minutes to complete, and they will be compensated $30 for their time. They will also be emailed a Qualtrics link with questionnaires one month after the completion of the intervention (*SR questionnaires*), which should take about 30 minutes to complete, and they will be compensated $30. In the last questionnaire, SRs will be asked whether they would like to receive a progress report of their time during the study (*SR progress report*).

Gather feedback (SRs and SPs): Participants who indicate that they can be contacted regarding an optional 30-minute qualitative interview will be emailed after they upload their video (for SPs), and after they complete their 1-month post-intervention questionnaire (for SRs). Participants who consent to being contacted and do not complete their portion of their study may also be contacted, to better understand barriers to completion. This interview will revolve around feedback on, feasibility and acceptability of the intervention, how to improve it, and possible names for the intervention (*QI discussion guide*) for $20.

SP Flow Diagram



Support-Receiver Flow Diagram



4.1 Study Duration

It will take SPs about 30 minutes to complete their portion of this study, which can be done in one sitting or spread out over time. They can additionally take part in a qualitative interview that will take 30 minutes to complete.

SRs can complete the pre-screening in less than 10 minutes. Visit 1 occurs via Zoom or phone call and should be less than an hour. For 28 days (at a start date of their choosing), they will use the intervention for about 5 minutes a day. At the end of the intervention, there will be a questionnaire that should take 30 minutes to complete. And one-month post-intervention, there will be another questionnaire that should take 30 minutes to complete. Optionally, they can take part in a QI that will last about half an hour. So maximum total time for SRs is about 5.5 hours.

Data collection and analysis will likely last 1-2 years.

4.2 Outcome Variables/Endpoints

4.2.1 Primary Outcome Variables/Endpoints

We will collect data on recruitment and attrition rates of SPs and SRs to determine feasibility. To determine acceptability, we will collect quantitative data on how often SR engaged with the intervention throughout the month. Preliminary efficacy will be assessed using questionnaire measures of substance use (Timeline Follow Back) and recovery capital (hours spent engaged in recovery support services, Assessment of Recovery Capital questionnaire) administered at the start and end of the intervention.

4.2.2 Secondary and Exploratory Outcome Variables/Endpoints (if applicable)

Qualitative data with SPs and SRs after the intervention will identify barriers and facilitators to this intervention, and how to optimize it. Content analysis of SP videos will identify themes that they believe to be important in communicating to people in recovery. We will characterize the video content created by support-providers (e.g., speech rate, eye contact with camera) and correlate them with support-receivers' ratings of the content, to identify which characteristics are well-received by support-receivers, to guide future content creation.

5 Study Participants

5.1 Study Population

The target SPs are individuals who are involved in the addiction recovery community (e.g., support group meeting facilitators, volunteers at recovery community centers) or allies of the addiction recovery community. Target SRs are adults who engage in past-year hazardous drinking (as defined as an AUDIT score ≥8), have had at least one heavy drinking day in the past month, and reside in Connecticut.

5.2 Number of Participants

We will recruit up to 50 SPs to create content for the intervention, and 30 SRs to use the intervention. This sample size is appropriate for a pilot study. We will recruit a subset of these participants (20 SRs) to participate in a follow-up qualitative interview.

5.3 Eligibility Criteria

In order to be eligible for inclusion to be a SP, an individual must meet all of the following criteria:

- 18 years of age or older
- Is fluent in English and has a 6th grade reading level or higher
- Either volunteers/works for a recovery support service that is freely available to people with addiction (e.g., support groups, recovery community centers) or is an ally/supporter of people in recovery.
- Has access to a smartphone camera / webcam and microphone
- Is willing to consent to creating a video recording of themselves that will be seen by others.

In order to be eligible for inclusion to be a SR, an individual must meet all of the following criteria:

- 18 years of age or older
- Is fluent in English and has a 6th grade reading level or higher
- AUDIT score of ≥8
- Has had at least one heavy drinking day in the past month
- Has some desire to cut down or quit their alcohol use
- Has a smartphone or computer with access to internet
- Have a geoIP address which indicates being on the East Coast of USA

Any individual who meets any of the following criteria will be excluded from participation in this study:

- Has vulnerable population status (e.g., pregnant people, prisoners)
- Is at the time of study participation receiving in-patient psychiatric treatment involving hospitalization

5.4 Recruitment Procedures

SPs will be recruited using word-of-mouth and physical and digital (i.e., PDF sent via email) flyers at organizations in Connecticut related to addiction recovery (e.g., Connecticut Community for Addiction Recovery, SMART Recovery, Recovery Dharma). Flyers may also be shared via the study twitter page (@TeamLDART). SRs will be recruited via those methods, and using physical flyers in the general New Haven community (e.g., liquor stores, convenience stores) and emails from YCCI to their recruitment database. The flyers are included under *Recruitment Materials*. There will be separate flyers for recruiting SPs and SRs, with QR codes and links that connect to corresponding Qualtrics pre-screening forms. GeoIP addresses will be collected in Qualtrics eligibility screen survey to verify that potential SR participants are indeed in the Connecticut area, to prevent scammers from enrolling in the study. Potential participants will be informed on the first page of the Qualtrics eligibility screen that their GeoIP address will be collected by completing the survey. Participants who are not eligible for the study will be offered to be emailed a PDF of community resources (please see document *List of Addiction Recovery Organizations*) if desired. In-person recruitment may occur at community events (e.g., health fairs) where information sheets on recovery organizations may be given out, and a physical copy of the eligibility screen is given to potential participants. This completed paperwork will be kept by the study PI to ensure their confidentiality. This information will be transcribed by the study team into the Qualtrics eligibility screener and the physical copies will be shredded right after.

Recruitment for follow-up qualitative interviews will utilize participants who were either SPs or SRs and indicated that they would like to be contacted for the interview.

5.5 Consent/Assent Procedures/HIPAA Authorization

All participants will be competent adults who willingly provide their agreement to participate prior to research participation during the informed consent process.

SPs: If a participant is eligible, they will access the Qualtrics link containing the consent document (*SP information sheet*). The consent process will occur on their own (i.e., without a member of the study team present). They can take as much time as they want to read and review the document, to consult with others regarding the decision to participate, and to contact the study team if they have questions. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, even after consenting to participate. They may also rescind their consent regarding how their video is used at any time, and be provided with instructions on how to do so. Participants will also be provided with contact information for the study PIs and the IRB in the event they have additional concerns. Participants will then complete a consent quiz (*SP information sheet*) to ensure informed consent. If they answer all questions correctly and agree to the terms, they will check a box indicating that they agree to participate. They will input their email address to receive a copy of the consent document.

SR pilot intervention: Visit 1 will occur in a password-protected Zoom room or on the phone with a member of the study team. Participants will be advised to have this zoom meeting in a private room. Participants will be asked to show some form of identification (e.g., driver's license) to verify their identity and/or some other proof that they are based in Connecticut (to protect against scammers). This PHI will not be recorded or stored. Each participant will be sent a link to the REDCap consent form (*SR compound consent*). A member of the study team will explain the research study to the participant, read the IRB-approved consenting document containing details on the study intervention, procedures and risks, and answer any questions that may arise. The participant will have the opportunity to carefully review the consent form and ask questions prior to consenting. The participant will have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, even after consenting to participate. They may also choose not to answer any question for any reason. Participants will also be provided with contact information for the study PIs and the IRB in the event they have additional concerns. Participants will then be asked to summarize their understanding of the study and its risks, and the study team member will ensure that they sufficiently understand the study. If the participant agrees to participate, they will electronically sign the consent form on REDCap, and receive an electronic copy of the consent document for their records via email. The study intervention will not be administered prior to receiving informed consent.

Follow-up qualitative interviews: The consenting process will occur over Zoom with a member of the study team.

6 Study Methods/Procedures

6.1 Study Procedures

SP protocol: After consent is complete, they will click on a Qualtrics link (*SP video-recording link*) to record two short videos to motivate someone to keep reaching their daily recovery goal. This Qualtrics link will work on smartphones such that the SP can record and upload videos directly from their smartphone. If used on a computer, the SP will have to record the video using software such as Photo Booth on Mac or Windows Camera on PC, and then upload the video as a file to Qualtrics. SPs will also be asked to optionally provide information on the recovery work they do (e.g., facilitate a support group meeting on Wednesdays at 6pm) and how to access it (e.g., provide the zoom link or physical address of the recovery community center), and a brief demographic questionnaire. Finally, they will be asked under what circumstances the study team can contact them.

SR pilot intervention: Upon completion of the pre-screening form, a zoom meeting or phone call will be scheduled with a member of the study team for Visit 1. Participants will first be asked the same questions that they filled in in the eligibility screen to see if their answers match up. This is to verify the authenticity of the potential participant. This visit will first introduce the study intervention to the participant, with the disclaimer that the intervention is not an established form of treatment and that if emergencies arise while participating in the study, to seek treatment or call 911. Then, a member of the study team will go over the consent document if they are interested in participating. getting informed consent via REDCap, and filling in questionnaires about their demographics, substance use, and recovery capital (*SR Questionnaires*). Their preference for what time to receive emails/text reminders to log onto LDART each night will be recorded. The visit should last no longer than an hour, and participants will be compensated with a $30 electronic gift card for their time. SRs will then receive an email to a Qualtrics link on the night they want to begin the intervention (*SR Day 0, Intervention Materials*). On the days immediately before and after using the intervention (i.e., Day 1 and Day 28), participants will complete the Timeline Follow Back for alcohol use and recovery services, which is built into the Qualtrics intervention. Each night for a month, they will open the Qualtrics link to answer to indicate whether they met their recovery goal for the day. If they answer yes, a celebratory message from a SP will be shown; if no, an encouraging message from a SP will be shown. Video messages will be shown on some nights and written ones (i.e., transcription of the video) on others. Participants will rate how motivating and supportive they found the message to be with the option of leaving written feedback on the video. Information provided by the SP about the details of their recovery support service will also be displayed. They will then select their recovery goal for the next day (e.g., stay sober, go to a support group meeting). This entire process should take less than 5 minutes to complete each night. They will be compensated a maximum of $30 during this time, depending on how frequently they engage with the intervention; this will be paid as a lump sum at the end of the intervention.

On the last day of the intervention, they will complete a few additional questionnaires on the Qualtrics link (e.g., acceptability assessments of the intervention; *SR Day 28, Intervention Materials*). This should take less than 30 minutes, and they will be compensated $30 for their time. They will also be emailed a Qualtrics link with a subset of questionnaires they filled in at the beginning one month after the completion of the intervention, which should take about 30 minutes to complete, and they will be compensated $30 for their time. In the last questionnaire, SRs will be asked whether they would like to receive a progress report of their time during the study (*SR progress report*). This will include a summary of their time using LDART (e.g., number of goals achieved, types of goals achieved), and information on their drinking, recovery support, and quality of life (all data obtained from their questionnaires). If participants who choose to receive it, we will email them the PDF.

Qualitative Interviews: After uploading their videos (SPs) or after completing the one-month post-intervention questionnaires (SRs), they may be invited to participate in the QI, which will be a zoom meeting with a member of the study team that will last about half an hour. Questions will revolve around feasibility and acceptability of the intervention, how to improve it, and possible names for the intervention (*QI discussion guid*e). Participants will be compensated $20 for their time.

Support-Provider "Visit" Schedule Table

	Pre-screening Day 1	Day 1-7	Day 1-14	Day 2-44
Qualtrics: determine eligibility	✓			
Qualtrics: read information sheet, complete consent quiz, indicate consent		✓		
Qualtrics: record video, provide information on recovery services, complete demographic questionnaire, indicate when/where videos can be used.			✓	
Zoom: qualitative interview (optional)				✓

	Pre-screening Day -14-1	**Zoom Visit 1** Day 1	**Intervention** Day 1-7 until Day 29-35	**Post-intervention** Day 29-35	**1 month post-intervention** Day 59-75	**Optional Zoom Visit 2** Day 60-105
Qualtrics: Determine Eligibility - AUDIT (alcohol use severity) - Other inclusion/exclusion criteria	✓					
Informed Consent		✓				
Baseline questionnaires - Demographics - AUDIT - DAST - SOCRATES - MSPSS - MHO attendance history		✓				
Time-insensitive assessment questionnaires - WHOQOL-BREF - Assessment of Recovery Capital - General self-efficacy scale		✓		✓	✓	
Intervention			✓			
Assessment questionnaires - Timeline follow-back: alcohol use - Timeline follow-back: recovery services			✓ ✓ (on day 1 and 28)		✓	
Acceptability assessments				✓		
Qualitative interview (optional)						✓

6.1.1 Data Collection

Video recordings and information on recovery services from SPs will be collected and stored on Qualtrics, which is a secure site. The majority of data from SRs will be collected via standard and validated questionnaires sent to the participant via Qualtrics. Participants will input their unique ID number when filling in all questionnaires, so all questionnaire data will be de-identified. Qualtrics links for SRs with videos made by support-providers will only be accessible with a valid participant ID and link, which will prevent others from viewing the video.

QIs will be semi-structured using the discussion guide (included in *Supporting Documents*), and recordings of the meeting will be collected using the embedded function in Zoom. Audio transcripts of the QIs will be de-identified (i.e., no names will appear in the transcript, only ID numbers).

6.2 Method of Assignment/Randomization (if applicable)

N/A

6.3 Adverse Events Definition and Reporting

An adverse event (AE) means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. There are no expected AEs for this study. The PIs will apprise study personnel of all AEs that occur during the conduct of this research project via email as they are reviewed by the PIs. The protocol's research monitor(s), the Yale School of Medicine Office of Student Research, and regulatory and decision-making bodies will be informed of AEs such as a participant threatening harm to themselves or others within 5 days of the event becoming known to the PIs. An AE or suspected adverse reaction is considered "severe" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Participants who experience a significant psychiatric or medical problem requiring overnight hospitalization at an acute care facility will also be considered as having experienced a severe AE (SAE). All SAEs will result in the completion of an SAE Form that will be submitted to the Yale IRB within 5 days, and events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related require prompt reporting. The procedures for SAE reporting include written documentation related to the adverse event and specific forms detailing the event.

6.4 Reaction Management

It is possible that SRs may experience distress when watching these videos. However, these videos will be pre-screened by the study team for quality control. SRs may experience distress when filling in questionnaires and taking part in qualitative interviews. However, these questionnaires contain minimally (if at all) distressing topics, and the topic of qualitative interviews will be entirely on the intervention, so this is an unlikely risk. Additionally, to mitigate this concern, they will be informed that they can skip any questions for any reason, and there will be the option to "prefer not to answer" on every questionnaire question. If participants experience severe emotional distress as a result of their participation in this research, the study team will refer them to mental health resources where appropriate.

6.5 Withdrawal Procedures

Participants may withdraw from the study at any time. If they request to have their data not used in the analysis, their data will be destroyed. If not, their data will be kept in de-identified form. SPs may withdraw their consent to use their videos at any time, and their videos will be deleted and no longer used as part of the intervention.

6.6 Locations/Facilities

The entire study will be conducted via Zoom, Qualtrics and REDCap.

7 Statistical Design

7.1 Sample Size Considerations

Sample size for the intervention was inferred from other pilot studies of behavioral interventions. Sample size for qualitative interviews was derived from prior qualitative work conducted by members of the research team.

7.2 Planned Analyses

Intervention: Standard statistical analyses will be used to determine preliminary efficacy (e.g., random effects regression models) of continuously measured primary (percentage of days abstinent) and secondary (percentage of heavy drinking days) outcomes, measured at three time points (prior to intervention, post-intervention, and one-month post-intervention).

Video ratings done by SRs will be correlated with features of the SP videos to determine what components of the videos are associated with the video having motivational and supportive properties. We will only analyze videos in which SPs consent to their videos being used “in research publications where the content of their videos and information is analyzed”.

Some examples of video features include the content of the video (e.g., higher proportion of sentences conveying esteem social support), audio (e.g., higher voice pitch variability), and visual (e.g., percent time making eye contact with the camera). To quantify content, videos will be manually transcribed by the PI to extract textual data. This transcript will be de-identified by removing all names of people and recovery organizations. Some examples of types of qualitative analyses that will be performed include content analysis on the textual data using the Social Support Behavior Code (Cutrona & Suhr, 1992) as a coding scheme, where sentences will be labeled as information, network, esteem, and/or emotional support. A text analysis application called Linguistic Inquiry and Word Count (LIWC, Boyd et al., 2022) will also be utilized to characterize the text based on various psychosocial constructs. For example, the word “cried” is classified in the affect category amongst others. Use of self-disclosure or stigmatizing language will be coded in binary (absent/present).

Audio data will be extracted from videos using software such as Adobe Premiere Pro. Quantitative analyses on audio data include using speech analysis software like Praat (Boersma, 2001) to extract audio features such as speech rate (a measure of how quickly the person in the video speaks), variability in waveform amplitude (as a measure of variability of how loudly one speaks) and variability in fundamental frequency (as a measure of how monotonous or prosidic the voice is). Examples of analyses of visual data include manual coding of percent time the person in the video spends looking at the camera versus visibly reading off a script, spontaneous blink rate (as a proxy of dopaminergic tone and arousal), and use of software such as OpenFace (Baltrusaitis et al., 2016) to quantify facial action units such as frequency of raising eyebrows and smiling. We may also use other software to quantify the colorfulness of the video and may qualitatively describe the background location where the video is set (e.g., fake zoom background, person’s living room).

For most of the analyses described, at least two members of the study team will serve as coders/raters, and inter-rater reliability will be determined to ensure consistency. After these analyses have been completed, descriptive statistics will be used to summarize the characteristics. Statistical analyses will also be used to determine whether video characteristics differ as a function of demographics of the people in the videos. (For example, are men more likely to have monotonous speech patterns than women?) Then, after the rating data from are collected, correlational analyses will be performed to identify associations between content/audio/visual video variables and rating scores. Qualitative analyses of comments left by SRs about videos may also be incorporated to inform what SRs like and dislike about the videos.

QI: All participants’ data will be analyzed unless otherwise specified by the participant. Data collected from QIs of support-providers will be analyzed separately from QIs of support-receivers.

7.2.1 Secondary Objective Analyses (if applicable)

N/A

7.2.2 Analysis of Subject Characteristics (if applicable)

N/A

7.2.3 Interim Analysis (if applicable)

We do not intend to have an interim analysis. Instead, we propose to monitor screening data, baseline demographics, retention data, serious adverse events data, and any other data that will help in the assessment of the study. Based on these data, we can determine if changes in recruitment or study termination are necessary.

7.3 Data Relevance

The quantitative and qualitative data collected in this study will provide the first pieces of evidence of LDART's feasibility, acceptability, and preliminary efficacy, which will determine how to improve upon the intervention.

7.4 Data Coding

QI: Two coders on the study team will develop code books independently, drawing from themes observed in the transcripts. The two coders will then merge their code books, resolving any discrepancies by mutual agreement and with input from other researchers.

For most qualitative (e.g., describe the background scene in the video) and quantitative analyses (e.g., how often does SP look directly at the camera?) of SP videos, we will have two coders on the study team rate these variables independently, and discrepancies will be resolved by mutual agreement and input from other members of the study team.

7.5 Data Analysis Tools

Statistical analyses will be performed using software such as MPlus, SPSS and Prism. Video quantification will be performed using software such as NVivo, Praat, and OpenFace. All QI analyses will be done in NVivo.

7.6 Data Monitoring

The PIs (Dr. McCurdy and Potenza) are responsible for monitoring the data, ensuring protocol compliance, and conducting safety reviews. Data pertaining to recruitment, retention, follow-up rates, completeness, and availability of primary outcome data will be discussed at least monthly.

7.7 Handling of Missing Data

Intervention: In cases where significant amounts of missing data occur (>5%), multiple imputation in SPSS will be conducted. QIs: QIs will continue until there are data for each of the questions in the discussion guide. If no one interviewed has personal experience with a particular topic, that will be noted in the results.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality and privacy are strictly held in confidence by the participating investigators, their staff, and the sponsor(s)/funding agency. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. HIPAA guidelines for data collection, management and monitoring will be followed in this study. All personnel involved in this study have already been certified by the Yale Human Investigation Committee as having completed training in the protection of the rights of human subjects who participate in research. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. All research activities will be conducted in as private a setting as possible (via Zoom, in a private physical space). Representatives of the Institutional Review Board (IRB), regulatory agencies or study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.

Video recordings of SPs will be stored and shared with SRs also via Qualtrics, a HIPAA-approved platform. Audio and video recordings of participants during QIs will be recorded using Zoom. The files will be saved on a secure USB hard drive and Yale Secure Box. Audio files will be transcribed and stored in de-identified form. Video files may be retained for nonverbal analyses, and deleted within 5 years after data collection is complete.

The study participant's contact information will be securely stored at each study site for internal use during the study (stored in Qualtrics and Yale Secure Box folder). At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, institutional policies, regulatory, or sponsor/funding agency requirements. Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on study computers. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived on Yale secure systems.

8.2 Data Quality Assurance

The entire study will be conducted by the same study PI (McCurdy) to ensure consistency. The study PI will consult with and be mentored by the other PI (Potenza) who has extensive experience with conducting clinical trials and interventions for addiction. The QIs will be transcribed verbatim by a professional transcription service. Trained research staff will serve as secondary transcriptionists and will review all audio recordings and transcripts and make corrections as needed.

8.3 Data or Specimen Storage/Security

Data will be stored on password-protected, Yale-managed computers and secure online storage spaces e.g., Yale Secure Box and Qualtrics. Data will be de-identified with unique codes and a key in a document separate from the data. Specifically, confidentiality of sensitive or health-related information collected via surveys will be accomplished by assigning unique numeric identifiers to each subject, and exclusively using these numbers on all electronic data records which contain sensitive information. For example, demographic data in Qualtrics will be labeled using participants' unique numeric identifier (assigned to them at the time of enrollment) to keep their identifying information and their survey responses separate. Transcripts of QIs will not include names of participants but rather their numeric identifiers. Analysis of PHI (e.g., full-face SP videos) will occur on password-protected Yale-issued work computers.

APPROVED BY THE YALE UNIVERSITY IRB 8/9/2024

8.4 Study Records

The study PI (McCurdy) will be responsible for maintaining all study documentation (protocols, consent forms, surveys, etc). These files will only be accessible to other members of the study team, via Secure Box.

8.5 Access to Source

Only members of the research team will have access to the data, recordings, and related transcripts.

8.6 Retention of Records

Records will be maintained for 5 years after study completion.

8.7 Data and Safety Monitoring Plan

The principal investigators (PIs) are responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews quarterly. During the review process, the PIs will evaluate whether the study should continue unchanged, require modification/amendment, or terminate enrollment. The PIs and the IRB have the authority to stop or suspend the study or require modifications.

This protocol presents minimal risks to the subjects. Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated, or anticipated but occurring with a greater frequency than expected, and possible/probably/definitely related) or UPIRSOs that may require a temporary or permanent interruption of study activities will be reported immediately (if possible, followed by a written report within 5 calendar days of the PIs becoming aware of the event to the IRB and any appropriate funding and regulatory agencies. The PIs will apprise study personnel of all UPIRSOs and AEs that occur during the conduct of this research project via email as they are reviewed by the PIs. The protocol's research monitor(s), the Yale School of Medicine Office of Student Research, and regulatory and decision-making bodies will be informed of AEs such as a participant threatening harm to themselves or others within 5 days of the event becoming known to the PIs.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required. Study closure will be submitted to the IRB after all research activities have been completed. Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

9.2 Research Personnel Training

The study PI (McCurdy) has expertise in working with individuals with addiction and individuals in the ARC in a research and volunteer setting and conducting qualitative interviews. She is mentored by a PI (Potenza) who has extensive experience in running clinical trials for addiction treatment and various other relevant expertise.

9.3 Study Monitoring

The PIs will monitor the study, and the PIs will meet fortnightly to discuss study progress.

9.4 Unanticipated Problems and Protocol Deviations

A protocol deviation is any noncompliance with the protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to identify and report deviations within 5 working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB via IRES.

The UP report will include the following information:

Protocol identifying information: protocol title and number, PI's name, and the IRB project number;

- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs will be reported to the IRB within 5 days of the investigator becoming aware of the event.

9.5 Study Discontinuation

The study may be discontinued if there are unexpected circumstances, for example in which multiple researchers are unable to continue the project (e.g., due to health emergencies).

9.6 Study Completion

The study is expected to be completed in approximately two years, around September 2025. The IRB will be notified of study completion via Yale’s IRES website.

9.7 Conflict of Interest Management Plan

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest. All investigators will follow the applicable conflict of interest policies.

9.8 Funding Source

This work is funded by Division 50 (Society of Addiction Psychology) of the American Psychological Association.

9.9 Publication Plan

The PIs are responsible for publishing the results of this study.

10 Appendices

Appendix #	Title	Section	Topic
1	Literature cited for Background	1.1	References

Appendix 1

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